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Prepared By: FAS Beijing Staff

Approved By: Adam Branson

Report Highlights:

The People's Republic of China (PRC) continues to advance toward commercial cultivation of domestically developed genetically engineered (GE) corn and soybean crops. Since the last report, the PRC made significant regulatory changes to facilitate the cultivation of GE crops, including publishing the first variety registration list for GE corn and soybeans and an updated draft measure on labeling agricultural GE products. Additionally, the Ministry of Agriculture and Rural Affairs (MARA) issued nine new biosafety certificates and two renewed biosafety certificates for GE crops approved for import as processing materials, clarified the classification criteria and requirements for evaluating gene-edited plants, and approved the country's first ever gene-edited plant for domestic cultivation. The PRC's prohibition on foreign investment in GE seeds and its opaque, unpredictable review processes for foreign products favors domestic biotech developers and undercuts access to GE varieties developed outside China.

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On March 2, 2022, the Supreme People's Court of China issued an opinion clarifying the requirements for criminal trials related to seeds. Entitled "Guiding Opinions on Further Strengthening the Criminal Trial Work Involving Seeds", the opinion covers the application of law to seed-related crimes, and improvement of relevant enforcement mechanisms. This Opinion is latest in a trend of messaging and policies by the PRC to strengthen variety protection and encourage a market environment for the seed industry with intellectual property protections for the seed industry. Please refer to GAIN Report CH2022-0031

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Executive Summary

The People's Republic of China (PRC) continues to advance its agricultural biotechnology development and regulatory framework in preparation for commercial cultivation of domestically developed genetically engineered (GE) food and feed crops, specifically corn and soybeans. However, with the exception of GE cotton and papaya, the PRC has not yet approved any GE food or feed products for domestic commercial cultivation outside of designated pilot areas..

The PRC continues to prohibit foreign agricultural biotechnology developers' foreign direct investment in the biotech sector by placing GE variety breeding and GE seed production on Negative Lists for the nation and its Free Trade Zones. Additionally, the PRC prohibits the cultivation of foreign-developed biotech products in China. Accordingly, the PRC divides its biosafety assessment process between foreign developers who may apply for a biosafety certificate for "Import for Processing Material" and domestic developers who may apply for a biosafety certificate for "cultivation and application."

Since the publication of the [2022 Agricultural Biotechnology Annual](#) report, the PRC has taken meaningful regulatory steps towards commercial cultivation of GE crops and in developing regulatory frameworks for gene-edited products, including the first ever biosafety certificate for a gene-edited event. Major updates include:

- On January 13, 2023, MARA published a finalized revised [Guideline for Safety Assessment of Genetically Modified \(GM\) Plants](#). The Guideline applies to bio-safety certificate application for both domestic cultivation and importation of processing materials. The finalized Guideline makes only minor changes to the draft version, which was published for public comments in July 2022 (see GAIN Report [CH2022-0084](#)). Substantive changes compared with the previous version of the Guideline in effect include:
 - 1) The new Guideline changes the nature of biosafety assessments from being on a "crop variety and event" basis to solely on an "event" basis, bringing it into alignment with the Administrative Measures for the Safety Assessment of Agriculture GMOs as revised in January 2022.
 - 2) In addition to Polymerase chain reaction (PCR) and Southern blotting, sequence determination is added as a method to analyze integration of a/an inserted sequence in plant genomes.
 - 3) Suitable ecological areas for major GM crops are newly listed in the Guideline. It is required that at least one production trial site should be set in each major ecological area for the application of cultivation safety certificate of an event.
- On April 28, 2023, MARA issued [the Rules for Review of Gene-Edited Plants for Agricultural Use \(Trial\)](#) (link in Chinese), which clarifies the classification criteria and requirements for evaluating gene-edited plants. The Guideline released in January 2022 classified gene-edited plants into four categories based on the risk profile of the target trait but did not indicate a process for determining how to classify gene-edited products within each risk category or provide specific types of acceptable data. The Review Rules expand

upon the processes established under the Guideline by providing additional information in three areas: molecular characteristics, environmental safety, and food safety.

The Review Rules also state that evaluations in these three areas can all be carried out in the intermediate test stage. If data from the test stage show that the target trait does not increase the environmental safety risk, the safety certificate can be applied for immediately after passing the evaluation. If the data obtained in the intermediate test stage indicate that the target trait may increase environmental safety risks, environmental release or production tests need to be carried out, and safety certificates can only be applied after passing the safety evaluation. For additional information, please see GAIN Report [MARA Updates Rules for Review of Gene-Edited Plants for Agricultural Use | CH2023-0080](#).

- On October 17, 2023, the PRC National Crop Variety Registration Committee (CNCVRC) published the first-ever variety registration list for genetically modified (GM) corn and soybeans. The list includes 37 GM corn varieties and 14 GM soybean varieties and is open for public comment for 30 days, or until November 15, 2023. Once finalized, listed GM corn and soybean varieties will be eligible for planting in approved areas.
- On October 17, 2023, MARA published on its website a draft revision of the "Administrative Measures on Labeling Agricultural Genetically Modified Organisms (GMOs)" for a 30-day public comment period. Significant updates in the proposed revision include the establishment of a three percent labeling threshold for products listed in Agricultural GMOs Labeling Catalog, changes to the products listed in the catalog, and requirements for "non-GMO" labeling. On November 24, 2023, the PRC notified the same draft revision to the WTO as G/TBT/N/CHN/1775.

Since the publication of the [2022 Agricultural Biotechnology Annual](#) report, the PRC has issued three tranches of new and renewed biosafety certificates. These include:

- On January 13, 2023, MARA issued biosafety certificates for 10 biotech crops approved for import as processing materials (including three new GE cotton events, one new GE rapeseed event, two new GE sugarcane events, two new GE alfalfa events, and two renewed GE cotton events), and 38 certificates for domestic cultivation and production (including two new GE corn events, one new GE soybean event, three new animal vaccines, 29 renewed GE cotton events, and three renewed animal vaccines).
- On April 28, 2023, MARA issued 113 certificates for domestic cultivation and production (including one new GE soybean event and 112 renewed GE cotton events) and the first ever biosafety certificate for a gene-edited soybean event. The approval of China's first ever gene-edited plant for domestic cultivation comes just over a year after MARA issued [Guidelines for Safety Evaluation of Gene-edited Plants for Agricultural Use \(Trial\)](#) which established application procedures and requirements for gene-edited plants.
- On October 17, 2023, MARA issued biosafety certificates for one new biotech canola event approved for import as processing materials, 162 biosafety certificates for renewed GE cotton events for domestic cultivation and production, and 21 new and renewed biosafety certificates for genetically modified microorganisms (GMMs) for animal use. For the first time, MARA issued a separate list of GMMs for animal use, rather than

including them in the same table as GE crop events for domestic cultivation and application.

In addition, on October 7, 2023, the National Health Commission (NHC) announced approval of 2'-fucosyllactose (2'-FL), a purified human milk oligosaccharide (HMO), for use as a food nutrition fortifier, particularly in infant formula. The approval is NHC's first for a GMM-derived food ingredient outside the enzyme category.

The PRC committed to several reforms of its agricultural biotechnology policies and procedures under Chapter 3, Annex 16 of the Phase One Economic and Trade Agreement, which entered into force on February 15, 2020. Some of these commitments, including the 24-month timeline from submission of a formal application for agricultural biotechnology products for feed or further processing to the final decision on approval or disapproval of the product, remain unfulfilled.

The below list contains links to all FAS China agricultural biotechnology related GAIN Reports issued since the publication of the 2022 China Agricultural Biotechnology Annual report:

1. [Agricultural Biotechnology Annual 2022 | CH2022-0112](#)
2. [China Releases Plant Variety Protection Regulations for Comment | CH2022-0127](#)
3. [MARA Issues New and Renewed GE Biosafety Certificates | CH2023-0007](#)
4. [MARA Finalizes GE Safety Assessment | CH2023-0011](#)
5. [NHC Approves New Food Materials and Additives including GMM Derived Enzymes | CH2023-0037](#)
6. [Administrative Measures for Non-major Crops Variety Record Open for Comment | CH2023-0041](#)
7. [Plant Variety Protection Office Clarifies Sexual Propagation Material Submission Requirements | CH2023-0064](#)
8. [MARA Publishes Information to Improve Public Awareness of Essentially Derived Varieties | CH2023-0065](#)
9. [Draft Implementation Opinions for Crop Seed Certification | CH2023-0072](#)
10. [New and Renewed Biosafety Certificates Issued Including First Ever For Gene-Edited Event | CH2023-0078](#)
11. [MARA Updates Rules for Review of Gene-Edited Plants for Agricultural Use | CH2023-0080](#)
12. [Planting Seed 2023 Annual | CH2023-0099](#)
13. [MARA Publishes Q and A on Agricultural Biotechnology | CH2023-0118](#)
14. [PRC Issues Final Implementation Opinions for Crop Seed Certification | CH2023-0127](#)
15. [WTO Notified Measures for Plant Propagation Materials | CH2023-0133](#)
16. [Revised Draft Measures on Labeling Agricultural GMOs Published for Comments | CH2023-0147](#)
17. [MARA Issues New and Renewed Biosafety Certificates | CH2023-0148](#)
18. [Inaugural Genetically Modified Corn and Soybean Variety Registration List Published - Comment Period Opened | CH2023-0149](#)

Chapter 1: Plant Biotechnology

Part A: Production and Trade

a) Research and Product Development

Despite decades of research by PRC biotech developers, China has not commercialized any GE products, with the exception of cotton and papaya. However, local developers have applied for and received biosafety certificates for the cultivation of GE rice, corn, and soybeans in regions across China (see Appendix 3 for a list of biotech crops approved for cultivation). The PRC amended Administrative Measures for Major Crops Variety Registration in January 2022, which added application procedures and requirements for GE variety registration, and introduced the National Registration Standards for Genetically Engineered Soybean Varieties (Trial) and National Registration Standards for Genetically Engineered Corn Varieties (Trial) in June 2022. In October 2023, the first-ever variety registration list for GM corn and soybeans for public comments (see GAIN Report [CH2023-0149](#)). The list includes 37 GM corn varieties and 14 GM soybean varieties.

As a result of these updated regulations, industry sources initially expected GE corn to reach full commercial cultivation in 2023. However, the February 2023 issuance of the PRC's [No. 1 Document](#), a top-level policy document that provides broad guidance for resource allocation and development goals in China's agricultural sector, cast doubt on that possibility. In reference to commercialization of GE crops, the document stated China will "accelerate the pace of industrialization of corn and soybean bio-breeding, orderly expand the pilot areas", suggesting existing pilot programs would be expanded rather than approval of full commercialization.

Chinese developers have pursued various forms of biosafety approvals and other reviews abroad, including voluntary consultations with the U.S. Food and Drug Administration (FDA). In 2018, Huazhong Agricultural University completed its [consultation](#) with FDA on its Huahui No.1 rice product, which received a biosafety certificate from MARA in 2009 (the biosafety certificate was renewed in 2014 and 2021). Additionally, Beijing Da-Bei-Nong Technology Group (DBN), completed a consultation with FDA in July 2021 and October 2021 for two corn events, DBN9936 and DBN9858.

Chinese developers have also received several safety approvals for cultivation in Argentina. On February 27, 2019, DBN received [approval](#) from Argentina to cultivate its herbicide-resistant soybean DBN09004-6. Following the approval, this event obtained a biosafety certificate for food, feed, and processing (import) in China in June 2020, meaning it can be exported to China from Argentina. DBN's pest resistant soybean event DBN8002 received cultivation [approval](#) from Argentina in November 2022 and from China in April 2023. On October 4, 2023, DBN received cultivation [approval](#) from Argentina for its stacked event DBN9004×DBN8002.

The PRC has provided significant support to the development of GE technology and continues to highlight advancements in agricultural biotechnology as key components of national plans focusing on agricultural productivity and food security. For example, since 2008 the National Major Science and Technology Projects of China for Breeding New Biotech Varieties has received a total of 24 billion yuan (about \$3.3 billion¹), approximately half of which came from

¹ The exchange rate used in this report is US\$1=7.2 Yuan

central and local governments and half from private sector investment. Industry contacts report these projects continue under the 14th Five-Year Plan (2021-2025).

In February 2021, MARA issued a [public notice](#) (link in Chinese) containing six articles for the purpose of encouraging the indigenous innovation and regulating the transfer of biological materials. The notice, a guiding document rather than a binding rule, sets the tone for research and transfer of biological materials, and emphasizes the accountability of biosafety certificate bearers. Recently published research articles include:

- In March 2023, National Science Review published [Genetic modification of Gγ subunit AT1 enhances salt-alkali tolerance in main *graminaceous* crops](#). The article by Chinese scientists discusses the discovery of a gene related to crop salt-alkali tolerance. The research indicates the gene, AT1/GS3, has great potential for breeding salt-alkali-resistant crops to grow in salt-alkaline soils.
- On March 8, 2023, a Chinese paper titled [Blocking gene that inhibits root growth may enhance drought resistance in crops](#) was published in the journal *New Phytologist*. The article reports that blocking a negative regulator gene of root development leads to enhanced root growth in plants. The gene, called RRS1 (Robust Root System 1), encodes an R2R3-type MYB family transcription factor that activates the expression of another gene (OsIAA3) that inhibits root growth. Knocking out RRS1 in plants led to longer root length, longer lateral root length, and larger lateral root density. Also, a natural variant of RRS1 that changes the activity of the RSS1 protein had a similarly beneficial effect on roots. According to the author, RRS1 is a new gene resource for improving root systems and cultivating drought-resistant rice varieties through gene-editing or marker-assisted breeding processes.
- On May 8, 2023, the *Plant Biotechnology Journal* published online research of the Institute of Plant Protection of the Chinese Academy of Agricultural Sciences (CAAS) on [Gene-editing technology creates new rice material with enhanced disease resistance](#) (link in Chinese). The researchers identified two new genes related to rice blast susceptibility from rice, and through gene editing of the two genes, combined with the results of disease resistance identification, it was confirmed that the two genes were susceptibility genes. The editing and transformation of the two genes can improve the rice resistance to rice blast and bacterial blight without adverse effects on other major agronomic traits.
- In an August 7, 2023 [study](#), the Agricultural Genomics Institute at Shenzhen (AGIS) cooperated with the China National Rice Research Institute, the Institute of Crop Science of Chinese Academy of Agricultural Sciences and Yangzhou University to produce a complete assembly of the rice reference genome T2T-NIP, which contains 12.5 million base pairs of newly identified sequence, and achieved a complete sequence of this important rice reference genome with 385.7 million base pairs.

b) Commercial Production

MARA's 2016 roadmap for the commercialization of GE crops prioritized non-food use GE crops (such as cotton), then GE crops for indirect food use (such as soybeans and corn), and finally GE food use crops (such as rice and wheat). Since 1997, China has commercialized six GE products (cotton, tomato, sweet pepper, petunia, poplar, and papaya), but only cotton and papaya are in commercial production today.

On August 24, 2023, MARA published a report titled [“Head of the Science and Technology Development Center and the National Agricultural Technology Extension Service Center of MARA Answering reporters' questions on promoting the pilot project of biological breeding Commercialization”](#) (link in Chinese) on its website. According to the report, the PRC launched a pilot project for the commercialization of GE corn and soybeans in 2021, which was carried out in scientific research and experimental fields. In 2022, it expanded the pilot project to farmer fields in Inner Mongolia and Yunnan. In 2023, the pilot project was expanded to 20 counties in 5 provinces including Hebei, Inner Mongolia, Jilin, Sichuan and Yunnan, and GE seed production was arranged in Gansu. The report also praises the performance of the GE crops, noting the traits of insect resistance and herbicide tolerance of GE corn and soybean are “outstanding.” The control effect on *Lepidoptera* pests such as *Spodoptera frugiperda* is over 90 percent, and the weeding effect is over 95 percent. The yield of GE corn and soybean increases by 5.6-11.6 percent.

The area of GE crops under cultivation increased slightly to 3.2 million hectares in 2019, according to the International Service for the Acquisition of Agro-Biotech Applications (ISAAA) report titled [“Biotech Crops Drive Socio-Economic Development and Sustainable Environment in the New Frontier.”](#) (Note: This is the most recent ISAAA report available on China’s GE cultivation area, which was published in 2019). This area only includes GE cotton and papaya and makes China the 7th largest producer of GE crops by area in the world. GE cotton adoption in China remains steady at around 95 percent of total area. According to ISAAA statistics, the economic benefits China gained from planting biotech crops from 1996 to 2018 totaled \$23.2 billion).

The GE products approved for commercial production in China can be found on MARA’s [website](#) (link in Chinese). Most biosafety certificates for cultivation are for domestically developed varieties of Bt cotton, which are approved for cultivation in three agroecological zones (Xinjiang, Yellow River Basin, and Yangtze River Basin). GM corn and soybean are approved for cultivation in most of China’s major producing areas, including North China spring corn/soybean area, South China corn/soybean area, Yellow River Basin, Huaihe River Basin. See Appendix 3 for more information on agroecological zones of China’s biotech crops approved for cultivation.

Note: When developers apply for a biosafety certificate for cultivation, they are required to indicate the agro-ecological zone(s) where the product will be grown. Accordingly, field trials will be conducted in that region, and the agro-ecological zone(s) will be included in the final biosafety certificate application.

c) Exports

China exports limited volumes of GE products. In 2022, China exported 33,703 tons of cotton valued at \$105 million, a high percentage of which can be assumed to be GE cotton – as GE cotton accounts for approximately 95 percent of planted area. The figures do not reflect China’s textile and apparel exports, many of which contain both domestic and imported GE cotton fiber. In 2022, China exported 8,003 tons of papaya, valued at \$9 million. Over 80 percent of papaya exports were shipped to Hong Kong. China does not export cotton or papaya to the United States.

d) Imports

China is a large importer of GE soybeans, cotton, corn, Distiller's Dried Grains with Solubles (DDGS), rapeseed/rapeseed meal/ rapeseed oil, and sugar beet pulp for feed and processing. These products are imported from numerous trading partners, including the United States, Brazil, Argentina, Canada, and India, among others. Please refer to Appendix 1 for China's trade in biotech crops. The PRC's burdensome and unpredictable approval process for GE products imported for feed and processing poses numerous challenges for foreign developers. Additionally, China's lack of a low-level presence (LLP) policy may result in detained and rejected shipments, including those that may be considered "non-GMO". China does not allow the importation of GE seeds for commercial cultivation. Please refer to the "Import Approval Procedures" section of this report for additional information on the regulatory process for biosafety approval for importing GE products for feed and processing.

e) Food Aid

The PRC provides limited volumes of food aid, primarily corn, rice, and sorghum to Sub-Saharan African countries and officials have made donations to Southeast Asia nations when droughts and disasters affect local food and agricultural product distribution and availability. Given the limited scale of pilot GE cultivation, it is believed that all food aid is comprised of conventional products. China is not a recipient of food aid.

f) Trade Barriers

The PRC's prohibition of foreign investment in the biotechnology sector remains the most significant barrier to overseas seed development companies. Business organizations, such as the American Chamber of Commerce in China, have [cited](#) the PRC's prohibition in recent annual reports. The [2021 Special Administrative Measures for Foreign Investment Access](#) (also known as the "Negative List", link in Chinese) was jointly issued by NDRC and MOFCOM on December 27, 2021. The Measures continue the prohibition on foreign biotech developers from conducting research or seed production in China.

On November 5, 2021, MOFCOM released the [Catalogue of Technologies Prohibited or Restricted to be Imported](#) (link in Chinese). The catalogue of technologies restricted for imports includes: "GE plant seeds and seedlings, seedlings of livestock and poultry, aquatic fingerlings, and strains of agricultural microorganisms obtained through modern biotechnology means."

Several aspects of China's regulatory approval process for GE traits decrease predictability and transparency, causing unnecessary delays and additional costs, particularly for foreign developers. These include requirements that events already be approved in their country of origin and that environmental safety trials and feeding trials be conducted in China by MARA-designated institutions. Throughout the review process, applicants are subject to requests for additional material and data that can delay season sensitive plantings for field trials. Additionally, the National Biosafety Committee (NBC), which typically only convenes twice per year, frequently rejects applications or requests further information from developers resulting in some applications languishing for more than a decade in the approval process. Subsequent applications are not reviewed by the same NBC panels and can result in new NBC members asking previously answered questions. Dates for NBC meetings are also closely held by MARA,

with members themselves called to attend on short notice. Once approved by the NBC, applications must still undergo a final MARA review. Post contacts have reported that on numerous occasions, despite being approved by the NBC, MARA has returned applications to the review process for additional information.

Additionally, the lack of an LLP policy in China means the world's largest importer of animal feed has a zero tolerance for unapproved GE events, which is a significant barrier to trade (see Chapter 1, Part B, Section (i) of this report for further information).

Part B: Policy

a) Regulatory Framework

The PRC's agricultural biotech regulatory framework is outlined in the State Council's² Administrative Rules for Safety of Agriculture GMOs (issued in 2001 and revised in 2017). According to the Rules, MARA holds the primary responsibility for the approval of biotech products for import and domestic cultivation, as well as the development of agricultural biotech policies and regulations.

The State Council's Rules are implemented by the following Measures:

- Administrative Measures for the Safety Assessment of Agriculture GMOs (issued on January 5, 2002; revisions issued on November 30, 2017, and January 21, 2022);
- Administrative Measures for Safety of Agriculture GMO Imports (issued on January 5, 2002; revision issued on November 30, 2017);
- Administrative Measures on Labelling of Agriculture GMOs (issued on January 5, 2002; revision issued on November 30, 2017, and October 17, 2023 for public comments);
- Measures for the Review and Approval of Agricultural GMOs for Processing (issued on July 1, 2006; latest revision issued on April 25, 2019);
- Technical guidance, standards, and procedures released through MARA public notices; AQSIQ Decree 62, [Administrative Measures of Inspection and Quarantine on Entry-Exit GM Products](#) (implemented on May 24, 2004; updated 2019 (link above), [latest revision](#) issued in March, 2023).

The latest revision of the Administrative Measures of Inspection and Quarantine for Entry-Exit GM Products revised the permit system for agricultural GE products that are transferred to other markets through the PRC territory. The revision removes requirements that GE products passing through China to other markets receive a permit to do so. Article 11 of the revised Measures stipulates the inspection and quarantine requirements for GE products that transit through China.

On January 13, 2023, MARA published a finalized revised [Guideline for Safety Assessment of Genetically Modified \(GM\) Plants](#). The Guideline applies to bio-safety certificate applications for both domestic production/cultivation and importation for processing use. The finalized Guideline makes only minor changes to the draft version, which was published for public comments in July

² The State Council is the chief administrative authority of the PRC government and is comprised of the Premier, Vice Premiers, State Councilors, and Ministers responsible for the Council's constituent departments. MARA's Minister is a member of the State Council.

2022 (see GAIN Report [CH2022-0084](#)). Substantive changes compared with the previous Guideline include:

- 1) The new Guideline changes the nature of biosafety assessments from being on a “crop variety and event” basis to solely on an “event” basis, bringing it into alignment with the Administrative Measures for the Safety Assessment of Agriculture GMOs as revised in January 2022.
- 2) In addition to Polymerase chain reaction (PCR) and Southern blotting, sequence determination is added as a method to analyze integration of a/an inserted sequence in plant genomes.
- 3) Suitable ecological areas for major GM crops are newly listed in the Guideline. It is required that at least one production trial site should be set in each major ecological area for the application of cultivation safety certificate of an event.

Legal Term (in Chinese)	Legal Term (in English)	Laws and Regulations Where Term is Used	Legal Definition (in English)
农业转基因生物	Agricultural genetically modified organisms (GMOs)	Administrative Rules for Safety of Agriculture GMOs	Agricultural genetically modified organisms refer to animals, plants, microorganisms and their products whose genetic structures have been modified by genetic engineering technology for the use of agricultural production or processing.
农业转基因生物安全	The safety of agricultural GMOs	Administrative Rules for Safety of Agriculture GMOs	The safety of agricultural GMOs refers to the prevention of dangers or potential risks posed by agricultural GMOs to humans, animals, plants, microorganisms and the ecological environment.
基因工程技术	Genetic engineering technologies	Administrative Measures for the Safety Assessment of Agriculture GMOs	Genetic engineering technologies: technologies that input reconstructed DNA molecules by using DNA reconstruction technology or by physical, chemical, or biological methods.
基因	Gene	Administrative Measures for the Safety Assessment of Agriculture GMOs	Gene: structural unit that controls the function of biological genetic substances, mainly referring to a DNA segment with genetic information.
基因组	Genetic group	Administrative Measures for the Safety Assessment of Agriculture GMOs	Genetic group: sum of chromosomes and non-chromosome genetic substances of a given organism.
目的基因	Purpose genes	Administrative Measures for the Safety Assessment of Agriculture	Purpose genes: genes that modify the genetic composition of receptor cells and deliver their genetic effect.

		GMOs	
受体生物	Receptor organisms	Administrative Measures for the Safety Assessment of Agriculture GMOs	Receptor organisms: organisms into which reconstructed DNA molecules are input.
农业用基因编辑植物	Gene-edited plants	Guidelines for Safety Evaluation of Gene-Edited Plants for Agricultural Use (Trial)	Gene-edited plants for agricultural use refer to plants and their products obtained by targeted modification of specific genomic sites with genetic engineering technology and used for agricultural production or agricultural product processing.

The National Biosafety Committee (NBC)

Article 9 of the Administrative Rules for Safety of Agriculture GMOs stipulates that “the agricultural competent authority of the State Council shall strengthen the safety assessment and management of agricultural GMO research and testing and establish the NBC to be responsible for the safety assessment of agricultural GMOs. The NBC is composed of experts engaged in agricultural GMO research, production, processing, inspection and quarantine, sanitation, and environmental protection.” Article 5 of the Administrative Measures for the Safety Assessment of Agriculture GMOs stipulates that the term limit of NBC members is five years.

The NBC conducts reviews of domestic and foreign applications for biosafety certificates for cultivation and import. Government officials no longer hold positions on the NBC; however, the Development Center for Science and Technology (DCST), an affiliate of MARA, serves as the Committee’s Secretariat.

The NBC is divided into two expert groups: 1) biotech plants and microbial biotechnology, and 2) animals and animal-use microorganisms. “Administrative Measures for the Safety Assessment of Agriculture GMOs” stipulates that the NBC shall hold no less than two meetings per year.

On December 7, 2021, [MARA announced the member list for the Sixth NBC](#) (link in Chinese), which is composed of 76 scientists.

Additional Responsibilities Held by MARA

In addition to its primary responsibility of approving biotech products for import and domestic production, MARA leads development of overall government policy and technical guidance related to agricultural biotechnology. In July 2017, MARA announced the establishment of [the National Technical Committee for the Standardization of Biosafety Management of Agricultural GMOs](#) (link in Chinese), which is responsible for drafting and revising technical standards for biotech products, including standards for safety assessments, testing, and detections. It consists of three technical working groups, namely ingredients, food, and environment, with 37 experts from Chinese research institutes and universities. Similar to the NBC, the DCST, an affiliate of MARA, serves as the Committee’s Secretariat. On September 22, 2023, the second Technical Committee for Standardization was elected in Beijing. MARA has not issued a public notice

announcing the members of the committee. MARA also manages and distributes government funds to Chinese institutes and universities for the research and development of biotech crops. There are approximately 40 MARA-designated institutes that conduct environmental and food safety testing. Provincial level agricultural departments are responsible for monitoring field trials, GE plant processing facilities, the seed market, and labeling.

Other Government Agencies

- The General Administration of Customs of the People's Republic of China (GACC) is responsible for testing agricultural and food products for GE content at Chinese ports of entry.
- 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, which China ratified on April 27, 2005.
- The Joint-Ministerial Conference for Biosafety Management of Agricultural Genetically Modified Organisms, which is stipulated in Article 5 of the Administrative Rules for Safety of Agriculture GMOs, is an overarching coordinating body which meets irregularly to discuss and coordinate major issues in biosafety management of agricultural biotech products. The group consists of 12 government bodies under the State Council that include: MARA, MEE, GACC, Ministry of Science and Technology (MOST), NDRC, MOFCOM, the National Health Commission (NHC), and others.
- NHC reviews and approves ingredients derived from genetically modified microorganisms (GMMs) for food use. See Chapter 3 for more.
- The State Administration for Market Regulation (SAMR) is the authority for comprehensive market oversight, law enforcement with respect of market supervision and administration, and coordination on the supervision and administration of food safety nationwide. When GE foods are distributed in the Chinese market, SAMR reviews the product labels to ensure compliance with labelling requirements.

Import Approval Procedures

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

MARA is responsible for the review and issuance of biosafety certificates for imported biotech products for food, feed, and processing (FFP). The Administrative Measures for Safety of Agriculture GMO Imports outline the requirements for importing biotech products. The Measures require a foreign seed developer to apply for a biosafety certificate to the Administrative Service Hall, commonly known as MARA's "Front Desk." This office is responsible for accepting applications and issuing responses to applicants. The application must contain materials and certifications proving the exporting country allows for the use and sale of the product in its domestic market and that the product has undergone studies showing no harm to animals, plants, or the environment.

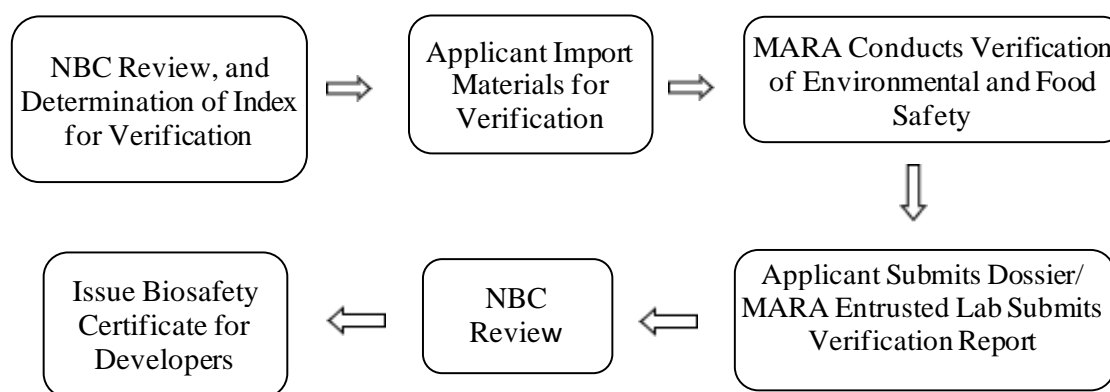
After receiving the application, MARA's GMO Biosafety Office will designate domestic institutions to conduct environmental safety (field trials) and food safety (feeding studies) tests

to verify data provided by the seed developer. These tests are government funded. The reports generated from verification tests and the application are then reviewed by the NBC. According to industry sources, some applications have been exempted from field trials in recent years, as products that obtain biosafety certificates for import for processing will not be planted and thus do not pose a similar level of environmental risk.

After each meeting, the NBC informs MARA of its decisions. The products that pass NBC review are subject to a final MARA administrative review before receiving the biosafety certificate (it is not uncommon for MARA to return applications to the NBC). If the NBC requests additional data or information on an application, the developer must resubmit the application dossier with the required data or explanation to be reviewed at a subsequent NBC meeting. Timely submission of additional information does not guarantee the application will be reviewed at the following NBC meeting.

MARA’s guidance on the process, application form, on-line-application process, and status of applications can be found at the [MARA official website’s page for administrative approvals](#). The specific timing of NBC meetings is not formalized, remains highly variable, and is dependent on external political factors.

Simplified Flow Chart of the Approval for Biosafety Certificate



Biosafety Certificate for Agricultural Biotechnology (Import) Issued to Overseas Traders

Each consignment of a GE product must obtain a “Biosafety Certificate for Agricultural Biotechnology (Import)” issued by MARA for customs clearance. According to [the Guideline How the Overseas Traders Apply for Biosafety Certificate for Agricultural Biotechnology \(import\)](#) (link in Chinese), the applicant of the certificate must be an enterprise or institution outside of China. Each certificate can only be used for one consignment and is valid for six months from date of issuance.

MARA’s guideline states that the following materials are required to apply for the certificate:

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Catalog of application materials (one copy of the paper materials, and one copy of the scanned PDF version of the paper materials on a CD)

1. Agricultural GMOs Import Safety Management Registration Form³(Used for Processing Materials) (original copy)
2. The Biosafety Certificate for Agricultural GMOs (Import) Issued by MARA to Foreign Developers (copy);
3. Corresponding safety management and preventive measures (original copy);
4. For overseas companies who export an agricultural GMO event from a country or region to China for the first time, they shall provide a license document that the exporting country or region has allowed the agricultural GMO event to be used for the corresponding purpose and put on the market (need to provide official documents and Chinese translations), except for those provided by overseas developers during the import safety assessment process. **(Post Comment:** this requirement is applied on a per event basis and not a per exporting company basis. This requirement is often fulfilled by the developer during the application process).
5. GE soybean imports can apply for trade and physical delivery of futures on the premise of ensuring that the final use of the product is raw materials for processing. To do so, the applicants need to tick the “processing raw materials (used for trade and physical delivery of futures” in the commodity use column of the "Agricultural GMOs Import Safety Management Registration Form ". **(Post Comment:** This clause applies to imported GE soybeans that are not directly imported for crushing. For example, the GE soybeans imported for state reserves may be held in storage for an extended period before being crushed. This option allows for import of the GE soybeans without providing processing plant information at time of import.)

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From the date of submission, MARA has 25 working days to review the application and issue the certificate.

In December 2020, MARA issued [Public Notice \[2020\] No. 376 \(link in Chinese\)](#), announcing that applications for Biosafety Certificate for Agricultural Biotechnology (Import) to overseas traders can be submitted [on-line](#) (link in Chinese). From October 2021, this biosafety certificate can also be applied from the [Single Window](#) of GACC (in Chinese). Both portals are in Chinese. Accordingly, exporters may need assistance from a local agent or representative to ensure required information is entered correctly.

Domestic Cultivation Approval Procedures

A domestic developer wanting to cultivate a new GE product in China requires a MARA biosafety certificate for cultivation. After obtaining the biosafety certificate for cultivation, the developer needs to apply for plant variety registration with MARA’s Seed Industry Management Department. After completion of variety registration, the product can be commercially cultivated in the geographical regions designated in the variety’s registration records. Foreign developers are prohibited from conducting research, seed production, or cultivation of GE products in China.

³ When filling out the form online, if the product being applied for is not listed in the product catalog, such as alfalfa, the applicant can select the last "Customize" option and enter the product name.

According to China's Seed Law, five major crops (rice, wheat, corn, cotton, and soybean) are subject to variety registration in China. On January 21, 2022, MARA published [Decree No. 2 of 2022](#), which amended Administrative Measures for Major Crops Variety Registration. The amended Measures add application procedures and requirements for GE variety registration. They also amended the Administrative Measures for Crop Seed Production and Operation License with additional requirements for GE seed production and operation. These amendments, for the first time, provide a pathway for commercial cultivation of GE food crops in China. Please refer to [GAIN Report CH2022-0013 Final Seed Regulations Published](#) for more information of the amendments of the regulations.

Following the updates to GE variety registrations, on June 8, 2022, the PRC's National Crop Variety Registration Committee (NCVRC) published the [National Registration Standards for Genetically Engineered Soybean Varieties \(Trial\) and National Registration Standards for Genetically Engineered Corn Varieties \(Trial\)](#) (link in Chinese) with immediate effect. The publication of these standards established a clear set of requirements for local developers applying for variety registration of GE corn and soybeans, further indicating the PRC's intention to move towards commercial cultivation of GE food crops in the near term. Please refer to [GAIN Report CH2002-0070 GE Soybean and Corn Variety Registration Standards Issued](#) for unofficial translations of the two standards.

b) Approvals

Since the publication of the [2022 Agricultural Biotechnology Annual](#) report, the PRC has issued two tranches of new and renewed biosafety certificates. As required under the Phase One Agreement, the validity period of newly issued and renewed certificates is 5 years.

On January 13, 2023, MARA issued biosafety certificates for 10 biotech crops approved for import as processing materials (including three new GE cotton events, one new GE rapeseed event, two new GE sugarcane events, two new GE alfalfa events, and two renewed GE cotton events), and 38 certificates for domestic cultivation and production (including two new GE corn events, one new GE soybean event, three new animal vaccines, 29 renewed GE cotton events, and three renewed animal vaccines).

On April 28, 2023, MARA issued 113 certificates for domestic cultivation and production (including one new GE soybean event and 112 renewed GE cotton events) and the first ever biosafety certificate for a gene-edited soybean event. The approval of China's first ever gene-edited plant for domestic cultivation comes just over a year after MARA issued Guidelines for Safety Evaluation of Gene-Edited Plants for Agricultural Use (Trial), which for the first time established application procedures and requirements for gene-edited plants.

Since MARA began approving import of GE products for FFP use in 2004, China has approved six different crops: soybeans, corn, canola, cotton, sugar beet and papaya. A full list of biotech products approved for FFP import is in Appendix 2.

c) Stacked or Pyramided Event Approvals

The PRC does not have a specific policy for approving stacked events. MARA Decree No. 2 of 2022, on revised "Administrative Measures for the Safety Assessment of Agricultural GMOs" changed the nature of biosafety assessments from being on a "crop variety and event" basis to

solely on an “event” basis, which industry sources believe provides for the biosafety assessment of GE crops containing “stacked” traits. Please refer to [GAIN Report CH2022-0014 Agricultural GMOs Safety Assessment Administrative Measures Finalized](#).

d) Field Testing

The PRC requires field trials of biotech products for the purpose of import approval, research, and domestic cultivation, but it does not publicly release information on the number of field trials or types of products or traits tested.

e) Innovative Biotechnologies

On January 24, 2022, MARA issued “Guidelines for Safety Evaluation of Gene-Edited Plants for Agricultural Use (Trial)”, which for the first time establish application procedures and requirements for gene-edited plants. The Guidelines establish application procedures and requirements for genome-edited plants that do not introduce exogenous genes. For genome-edited plants that introduce exogenous genes, application for safety evaluation must still be made in accordance with the [Guideline for Safety Evaluation of Genetically Modified Plants](#) (link in Chinese). The Guidelines define genome-edited plants for agricultural use as plants and their products obtained by targeted modification of specific genomic sites with genetic engineering technology, which are used for agricultural production or agricultural product processing. For additional information, please see USDA [GAIN Report CH2022-0015 MARA Issues First Ever Gene-Editing Guidelines](#).

MARA has said that genome edited products fall within the scope of China’s “GMO” regulations and will be regulated as “GMOs” but have held out the possibility of a streamlined process for gene-edited plants that do not pose a risk to food, feed, or environmental safety.

On April 28, 2023, MARA issued [the Rules for Review of Gene-Edited Plants for Agricultural Use \(Trial\)](#) (link in Chinese), which clarifies the classification criteria and requirements for evaluating gene-edited plants. The Guideline released in January 2022 classified gene-edited plants into four categories based on the risk profile of the target trait but did not indicate a process for determining how to classify gene-edited products within each risk category or provide specific types of acceptable data. The Review Rules expand upon the processes established under the Guideline by providing additional information in three areas: molecular characteristics, environmental safety, and food safety.

The Review Rules also state that evaluations of molecular characteristics, environmental safety, and food safety can all be carried out in the intermediate test stage. If data from the test stage show that the target trait does not increase the environmental safety risk, the safety certificate can be applied directly after passing the evaluation. If the data obtained in the intermediate test stage indicate that the target trait may increase environmental safety risks, environmental release or production tests need to be carried out, and safety certificates can only be applied after passing the safety evaluation. For additional information, please see GAIN Report [MARA Updates Rules for Review of Gene-Edited Plants for Agricultural Use | CH2023-0080](#).

f) Coexistence

The PRC does not have a coexistence policy.

g) Labeling and Traceability

The PRC's biotech labeling regulations, governed by the Administrative Measures on Labeling of Agriculture GMOs, require mandatory labeling of products that are produced from GE materials or contain the following GE substances:

1. Soybean seeds, soybeans, soybean flour, soybean oil, and soybean meal;
2. Corn seeds, corn, corn oil, and corn flour (including corn flour under HS codes 11022000, 11031300, and 11042300⁴);
3. Rapeseed for planting, rapeseeds, rapeseed oil, and rapeseed meal;
4. Cottonseed; and
5. Tomato seed, fresh tomato, and tomato paste.

These measures are expected to be updated based on Administrative Measures on Labeling Agricultural Genetically Modified Organisms (GMOs) (Draft for Comments), published by MARA on October 17, 2023. The draft measures update product listings in the Agricultural GMOs Labeling Catalog, removing soybean planting seeds, corn planting seeds, rapeseed/canola planting seeds, cotton planting seeds, tomato planting seeds, fresh tomatoes, and tomato paste and adding soy protein, soybean dregs, kibbled/broken corn, corn meal, cottonseed oil, cottonseed meal, alfalfa, and papaya. Other significant updates the establishment of a three percent labeling threshold for products listed in the catalog.

The revised draft also requires that “organisms that China has not issued agricultural GMO biosafety certificates, the word 'non-GMO' must not be used on product label and manual.” This revision aligns with the revised Measures on Supervision and Management of Food Labeling, which was released by the State Administration for Market Regulation (SAMR) for public comments in July 2020. The SAMR measures prohibit using “Not containing GMO,” “Non-GMO,” or similar text to introduce foods that do not use genetically modified food materials.

The [Implementing Regulations of the Food Safety Law](#) released in October 2019 state: “Production and trading of genetically modified foods (in China) should be conspicuously marked; the measures for marking (the production and trading) will be developed by the food safety supervision and administrative department of the State Council together with the agricultural administrative department of the State Council.” As such, the production facilities that process GE crops, such as the production lines that crush oil from GE soy, or the counters selling GE foods need to have clear signs that they are processing/selling GE products.

h) Monitoring and Testing

Testing of biotechnology products is carried out primarily by GACC, MARA, and MEE through their designated testing institutes. GACC is responsible for testing products at ports of entry and may reject any cargoes found to contain unapproved biotech products. MARA tests domestic crops and conducts food and feed safety assessments. MEE conducts environmental safety tests. While submitting applications for biosafety certificates, foreign developers are required to provide testing methods and reference materials along with the application.

⁴ According to the China's Customs Import and Export Tariff, HS codes 11022000, 11031300, and 11042300 refer to maize (corn) flour, corn groats/meal/pellets, and corn hulled/rolled/flaked/pearled/sliced/kibbled).

On March 6, 2020, Standardization Administration of China (under SAMR) issued [National Standard GB/T38505-2020: General Detection Methods of Genetically Modified Products](#), which specifies the qualitative testing methods for genetically modified products. This standard is applicable to the general testing of genetically modified components in rice, corn, soybean, rapeseeds, potato, sugar beet, alfalfa, and their processed products by real-time fluorescent PCR.

Though not official guidance, scientists from the Chinese Academy of Inspection and Quarantine (CAIQ) and China Agricultural University (CAU) published a paper titled [A Universal Analytical Approach for Screening and Monitoring of Authorized and Unauthorized GMOs](#) in the LWT-Food Science and Technology journal in May 2020, which introduces a universal analytical approach for screening GE presence in food and feed products.

i) Low Level Presence (LLP) Policy

The PRC does not have an LLP policy for biotech imports. Considering the PRC's zero tolerance for unapproved biotech products in imports and the large volume of imported GE products, this is a significant barrier to trade. The PRC has participated in the Global LLP Initiative as an observer; most recently at the virtual meeting in 2020.

Under the [Phase One Economic and Trade Agreement](#) (see Annex 16, sections 8 – 10), the PRC made certain commitments in how it would address LLP occurrences to facilitate trade. The United States and the PRC also agreed to organize experts to conduct further studies on the issue of LLP and to collaborate internationally on practical approaches to addressing LLP.

To avoid customs clearance issues, U.S. exporters of non-GMO crops for food use should ensure products exported to China do not contain GE materials and ensure importers are aware of PRC policies on unapproved biotech products.

j) Additional Regulatory Requirements

Please refer to the [Agricultural Biotechnology Annual 2022 | CH2022-0112](#) which covers seed variety registration issues and policy.

k) Intellectual Property Rights (IPR)

Article 25 of the Patent Law of the People's Republic of China provides that patent rights shall not be granted for animal and plant varieties; while the patent rights may be granted for the production methods of the animal and plant variety products. Therefore, in China, intellectual property rights for plants, including GE plants, are protected by plant variety rights (Plant Variety Protection). However, events and their associated gene fragments, proteins, etc. are patentable. According to the [China National Intellectual Property Administration's Patent Search and Analysis database](#), some foreign and domestic events have been granted patents.

On December 24, 2021, the NPC published the amended Seed Law. The new law came into effect on March 1, 2022. The full text of the amended law can be found on the NPC's [website](#) (link in Chinese). The amendments to the Seed Law strengthen provisions for the protection of intellectual property rights in the following aspects:

- 1) Expanded the protection scope: The new seed law stipulates that the scope of protection for new plant varieties extends from the propagation material of the authorized variety to the harvesting material obtained without permission using the propagation material of the authorized variety.
- 2) Expands the protection links: Compared with the original seed law, the protection links of variety rights have been expanded from the original three links (production, reproduction, and sales) to eight links by adding links for "processing for reproduction, promising sales, import, export, and storage" have been added, providing more opportunities for variety rights holders to claim their rights.
- 3) Establishes the essentially derived varieties (EDV) system: establishes a benefit sharing mechanism between the owner of the original variety and the owner of the derived variety, and further encourages original innovation of plant breeding.
- 4) Improves the compensation system for infringement on new plant variety rights: increases the compensation standard, and increases the protection for the owner of the variety rights.

Please refer to [GAIN Report CH2021-0185 Final Seed Law Published](#) for more information of the amended Seed Law.

On March 2, 2022, the Supreme People's Court of China issued an opinion clarifying the requirements for criminal trials related to seeds. Entitled "Guiding Opinions on Further Strengthening the Criminal Trial Work Involving Seeds", the opinion covers the application of law to seed-related crimes, and improvement of relevant enforcement mechanisms. This Opinion is latest in a trend of messaging and policies by the PRC to strengthen variety protection and encourage a market environment for the seed industry with intellectual property protections for the seed industry. Please refer to [GAIN Report CH2022-0031 Supreme People's Court Strengthens Seed Variety Protections](#) for more information on the Guiding Opinions.

On November 21, 2022, MARA released [the People's Republic of China Plant Variety Protection Regulations \(Revised Draft for Comments\)](#) (link in Chinese) for public comment. The amendments to the PVP regulations strengthen provisions for the protection of variety rights in the following aspects:

- (1) Make provisions on the Essentially Derived Varieties (EDV) system;
- (2) Expand the scope of protection and the links of protection;
- (3) Extend the term of protection. The revised draft extends the protection period of variety rights, from 20 years to 25 years for woody and vine plants, and from 15 years to 20 years for other plants;
- (4) Improving measures for handling infringement and counterfeiting cases;
- (5) Clarify the circumstances of the restoration of rights.

MARA has not issued a final or updated version of the draft. Please refer to [USDA GAIN Report China Releases Plant Variety Protection Regulations for Comment | CH2022-0127](#) for more information on the revision of the PVP regulations.

1) Cartagena Protocol Ratification

The PRC signed the Cartagena Protocol on Biosafety (CPB) to the United Nation's Convention on Biological Diversity in 2000 and ratified it in 2005. In 2011, the PRC announced that the

protocol would also apply to the Hong Kong Special Administrative Region. As a party to the Protocol, the PRC adopted the [Biosecurity Law](#) on October 17, 2020. The Biosecurity Law came into force on April 15, 2021. China submitted [the Fourth National Reports on Implementation of the Cartagena Protocol on Biosafety](#) in October 2019, covering China's implementation of CPB from September 2015 to September 2019.

Adopted as a supplementary agreement to the CPB, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization aims to contribute to the conservation and sustainable use of biodiversity by providing international rules and procedures in the field of liability and redress relating to living modified organisms. The Nagoya Protocol was adopted on October 29, 2010 and entered into force on October 12, 2014. The PRC acceded to the Protocol on June 8, 2016. The Protocol entered into force for China on September 6, 2016 and does not apply to the Hong Kong or Macao Special Administrative Regions.

m) International Treaties and Forums

In recent years, Chinese participants have attended workshops as part of the APEC High Level Policy Dialogue on Agricultural Biotechnology (HLPDAB), including participants from MARA and CAAS at the July 2023 meeting in the United States.

Biotech Working Group (BWG) and Technical Working Group (TWG)

In years past, the U.S. and China frequently held bilateral discussions on agricultural biotechnology. The U.S.-China High-Level Biotechnology Joint Working Group (BWG) was established in 2002 to address bilateral biotechnology issues of mutual interest and was attended by FAS and MARA. Similarly, a Technical Working Group (TWG) was established in 2003 to supplement policy discussions and was attended by the Animal and Plant Health Inspection Service (APHIS), FDA, Environmental Protection Agency (EPA), and MARA. The location typically alternated between the U.S. and China. Neither the BWG nor TWG have been held since 2018.

n) Related Issues

Oversight and Enforcement

Each year, MARA releases an annual Biosafety Oversight Working Plan that includes reports of detected violations. On April 28, 2023, MARA released its [2023 Biosafety Oversight Working Plan](#) (link in Chinese), which listed five key tasks: 1) Strengthen the supervision of research and experimentation; 2) Strictly manage variety registration; 3) Strengthen the supervision of seed production and operation; 4) Strict import processing supervision; and 5) Intensify efforts to popularize genetically modified science. Previous incident report highlights include:

- 2022 – There were six cases reported, including 2 unapproved environmental release experiments with corn, 2 GE soybean sales violating GE labelling rules, and 2 illegal GE corn experiments conducted.
- 2021 - There were nine cases reported, including four cases of illegal corn seed sales in Liaoning, Jilin, Heilongjiang, and Xinjiang, four cases of research institutes/seed

developers violating rules about cotton research and trials, and one case of research institute violating rules about GE wheat intermediate trials.

- 2019 - MARA announced ten cases of violations to the agriculture biosafety rules, including four intermediary experiments (two corn and two cotton), and five cases of illegal production of corn seeds (in Shaanxi, Xinjiang, Heilongjiang, Liaoning, and Jilin). The last case was a grains/oil processing company, which spilt GE soy when it was transported from port to the processing facility.
- 2018- MARA announced seven cases of seed companies conducted trails of GE corns without proper registering/reporting with MOA.
- 2017 – MARA announced eleven cases of research institutes conducting trials of GE corns, rice, and sugar cane without proper registering/reporting with MOA.

Part C: Marketing

a) Public/Private Opinions

Years of efforts by the PRC to address public misperceptions towards biotech through press conferences and training for journalists and local government officials, and mainstream media reports about agriculture biotechnology appear to have reduced negative perceptions among the public. Both traditional and social media are used to explain the PRC's biosafety regulatory work to the public and MARA is working with its peer ministries to eliminate misleading claims or statements in product labels and advertisements. On the MARA website, a special [Scientific Publicity of Biotechnology](#) promotes biotechnology knowledge, such as the safety of GM foods, and the PRC's labeling regulations on GM products.

As the PRC moves closer to commercial cultivation of GE corn and soybeans, which will enter the food chain, state media has taken leading role in promoting the advantages and safety of GE technologies, as in this [CCTV video](#).

b) Market Acceptance/Studies

No new nation-wide surveys of public acceptance of biotech in China have been released in recent years. Please refer to the 2018 Agricultural Biotechnology Annual for previous studies.

Chapter Two: Animal Biotechnology

China is a leader in animal biotech research. The Key Scientific and Technological Grant of China for Breeding New Biotech Varieties was launched in 2008 and supports research on GE animal species including swine, cattle, and sheep. Despite heavy investment and advanced research, China has not approved any livestock clones, GE animals, or products derived from animal biotech for commercial use.

Multiple Chinese research teams have announced progress in research of transplantation using organs from gene-edited pigs; in recent years, Chinese scientists have successfully cloned a variety of animals, including mules, cats, rats, and ferrets. The technology of feline cloning is expected to play a role in studying animal diseases, developing new drugs, and protecting endangered species. According to ISAAA, researchers from China used [CRISPR technology on silkworms](#) to produce stronger silk. The resulting fiber is considered better compared to other

commercial synthetic fibers. Other [reports](#) indicate extensive use of CRISPR and other new technologies in animal research.

Part D: Production and Trade

a) Product Development

The PRC has invested in basic research for animal biotech. Research institutes can apply to MARA and the Ministry of Finance for research funding. Research is focused on medicine production, improving the quantity and quality of milk, and improving quality of meat and wool. A list of the research projects funded by the Key Scientific and Technological Grant of China for Breeding New Biotech Varieties can be found at the [National Science and Technology Report Service](#) (link in Chinese).

Recent research includes scientists from Guangzhou Institute of Biomedicine and Health who developed a human-like kidney in pigs using engineered human pluripotent cells and injecting them into the genetically engineered embryo of a pig. The research result was published in Cell Stem Cell in August 2023. See [Scientists Take a Step Closer to Growing Human Organs for Transplants](#).

Scientists from the Chinese Academy of Agricultural Sciences (CAAS), Huazhong Agricultural University, and University of Guelph, Canada, research in the international biology journal [eLife Journal](#) in September 2020 about a pig species that can resist three major infectious diseases using gene-editing technology. The research suggests that it can resist porcine reproductive and respiratory syndrome (PRRS) virus and transmissible gastroenteritis virus and show decreased susceptibility to porcine deltacoronavirus. Meanwhile, the GE pig has normal meat-production and reproductive performance. Since the occurrence of African Swine Fever (ASF) in summer 2018, biotechnology is being considered as a possible solution to resist the disease. See: [GARA GAP Analysis Report of November 2018](#).

Scientists from Shenzhen Institute of Agricultural Genomics of CAAS and their collaborators published [Safety evaluation of transgenic and genome-edited food animals](#) in “Trends in Biotechnology” in late November 2021. The article proposes to rationally optimize the regulatory system of gene editing products according to the characteristics of gene editing products and promote the industrialization of gene edited animal products. The article points out that after the completion of gene editing, agricultural breeding can eliminate unintended effects such as off-targets through multi-level screening, until the optimal individual is selected for production applications.

In May 2021, the journal Nature-Communications published [research](#) by a team from the School of Animal Science and Technology, Yangzhou University. The article introduces theoretical research on methodological system of reversing chicken somatic cells (fibroblasts) into primordial germ cells to reproduce progeny and solving the problem of somatic cell cloning in avian animals.

b) Commercial Production

Some GE animal projects have long been ready to apply for biosafety certificates for commercialization. However, they remain in the research stage because MARA does not have definitive regulatory guidelines for animal biotech.

c) Exports

The PRC does not export GE animals, livestock clones, or products from these animals.

d) Imports

The PRC does not import GE animals, livestock clones, or products from these animals.

e) Trade Barriers

N/A

Part E Policy

a) Regulatory Framework

Animal biotechnology is subject to the State Council's "Administrative Rules for Safety of Agriculture GMOs (revised in 2017)". The MARA guidance, application form, on-line application process, and the status of applications can be found at the [MARA's website for administrative approvals](#) (link in Chinese). However, this regulation lacks implementation rules or specific policies for animal biotech research, production, or trade. MARA has not issued further direction on regulatory approvals for animal biotech. Like plant biotech, MARA starts the review of dossiers for foreign developed animal biotech products only after a trait is deregulated in an exporting country.

In April 2021, the [Biosecurity Law](#) (link in Chinese) came into effect. The law addresses several biosecurity elements, including bioterrorism, infectious disease management, biotechnology development, biodiversity protection, microbial resistance, and human and biological resource management. MARA indicated that MARA rules for agriculture biotechnology will be revised pursuant to the Law, but no revisions have been announced. The law and its implementing regulations may affect laboratory research on GE animals.

b) Approvals

The PRC has not approved any GE animals for domestic commercialization, nor has China approved the importation of GE animals for processing.

c) Innovative Biotechnologies

Chinese scientists are making progress in the research of genome edited animals using innovative biotechnologies, particularly for medical purposes. However, the government has not yet developed policies/regulations to regulate innovative biotechnologies in animals.

d) Labeling and Traceability

GE animal labeling is subject to the Administrative Measures on Labelling of Agriculture GMOs (issued on January 5, 2002; latest revision issued on November 30, 2017). China has not commercialized any GE animals and specific measures for GE animal labeling are not available.

e) Additional Regulatory Requirements N/A.

f) Intellectual Property Rights (IPR)

Currently, gene and DNA fragments are subject to protection provided by the Patent Law of China. However, GE animals fall into a legal gap in China's IPR protection regulations. The existing regulations for biotech focus on safety and do not address IPR protection for developers or breeders.

g) International Treaties and Forums

The PRC sends officials to high-level conferences for GE animals but mainly as observers.

Chinese scientists maintain frequent and close contact with foreign peers. In May 2021, the 88th Annual General Session of the World Organization for Animal Health (OIE) was held virtually.

Dr. Huang Baoxu, OIE Delegate from China and a researcher with the China Animal Health and Epidemiology Center (CAHEC), was elected chairman of OIE Regional Commission for Asia, the Far East and Oceania (AFEO) on May 28, 2021.

h) Related Issues

N/A

Part F: Marketing

a) Public/Private Opinions

Public concern and underdeveloped pathways between public research institutes and industry make commercialization of GE animals challenging in China.

b) Market Acceptance/Studies

Although no official surveys are available, the market/public acceptance towards the sale and use of livestock clones, offspring of clones, GE animals, genome-edited animals, and products is low. The acceptance for such products for medical purposes is more positive.

Chapter Three: Microbial Biotechnology

On October 7, 2023, the National Health Commission (NHC) announced approval of 2'-fucosyllactose (2'-FL), a purified human milk oligosaccharide (HMO) derived from genetically modified microorganisms (GMMs), for use as a food nutrition fortifier in infant formula. The approval is NHC's first for a GMM-derived food ingredient outside the enzyme category. Since the issuance of the last biotech annual report, the NHC also has approved the use of 12 GMM-

derived enzymes to be used as food additives in food production, and MARA has approved the use of 9 GMMs for animal use. The PRC's regulatory process to approve all categories of GMM-derived food ingredients is a topic addressed in Annex 16 (Agricultural Biotechnology) to Chapter 3 of the Economic and Trade Agreement.⁵

Part G: Production and Trade

a) Commercial Production

At present, the PRC only permits the commercial use of GMM-derived food ingredients when those ingredients are purified.

b) Exports

There are neither official statistics nor estimates of China's export of microbial biotechnology products. However, China exports alcoholic beverages, dairy products, and processed products that may contain microbial biotech-derived food ingredients.

c) Imports

Trade data not available. Microbial biotech-derived food ingredients likely are in Chinese imports of alcoholic beverages, dairy products, and processed products, where microbial biotech derived ingredients are commonly used in global production.

d) Trade Barriers

As part of the Economic and Trade Agreement, the PRC committed to establish a regulatory process for all food ingredients derived from microbial biotechnology by February 2021. No new regulations have been released, however reviews of enzymes produced from microbial biotechnology are conducted regularly.

Part H: Policy

a) Regulatory Framework

Applying for Approval of GMM-Derived Food Ingredients

Outside the enzyme category, the PRC has not yet clarified the application requirements and evaluation process for new varieties of GMM-derived food ingredients.

For enzymes, the application process for new GMM-derived varieties is the same as that for new varieties of all other food additives. An application should be submitted to the NHC pursuant to the Administrative Measures for New Variety of Food Additives [Ministry of Health (MOH, now NHC) Decree 73], the Provisions for Application Submission and Acceptance of New Variety of Food Additives, and the Notice Concerning Regulating Approving of New Food

⁵ Paragraph 6 of the Annex 16: China shall, within 12 months of the date of entry into force of this Agreement, establish and make public a simplified, predictable, science- and risk-based, and efficient safety assessment procedure for approval of food ingredients derived from genetically modified microorganisms.

Additive Variety (MOH Public Notice [2011] No.29).⁶ NHC will then conduct a risk assessment of the ingredient and determine whether it can be approved.

GMM-derived enzymes are also reviewed for their safety. Through intra-agency coordination, the safety assessment is conducted in the following steps:

- NHC accepts applications for enzymes produced from microbial biotechnology, reviews the dossiers, and decides whether MARA technical experts (NBC members) need to assess the product's safety;
 - If a biosafety assessment is required for the GE microbe and ingredient, the dossier is passed to MARA for review (not the full set of NBC review, rather an assessment of the product). The assessment is conducted following the provisions of the State Council's "Administrative Rules for Safety of Agriculture GMOs", the Administrative Measures for the Safety Assessment of Agriculture GMOs and the Guideline for the Conduct of Food Safety Assessment of Microbial Biotechnology for Animal Use. The review decision then is sent to NHC for its approval of the enzyme.
 - If the product does not need to be assessed by the NBC, NHC will review the product as it reviews other enzymes. The whole regulatory process takes approximately two years to complete.

Once approved by the NHC, enzymes derived from microbial biotechnology will be announced as new varieties of enzyme preparations used in food processing and can be used in foods. The newly approved enzymes will gradually be included in the [National Food Safety Standard – Standard for Uses of Food Additives \(GB 2760\)](#) (see Table C.3) when the standard is revised. In April 2021, China notified a [revised draft of GB 2760](#) to the WTO SPS Committee for comments, which contains a list of 60 enzyme preparations for food processing use (page 155 of the report). Currently, only primary agricultural products have labeling requirements. Industry contacts report that the NHC is working on possible labeling requirements for food additives derived from GMMs.

b) Approvals

Since the publication of the [Agricultural Biotechnology Annual 2022](#), the NHC has issued four announcements approving new food ingredients derived from microbial biotechnology.

On March 2, 2023, the NHC released its [2023 No. 1 Announcement on 28 "Three New Foods" including *Leuconostoc pseudomesenteroides*](#), which approved 28 new food materials and additives for use in China, including six enzymes derived from GMMs. See [NHC Approves New Food Materials and Additives including GMM Derived Enzymes | CH2023-0037](#) for more information of the announcement.

⁶ Instructions on the application procedures and material requirements can be found on the [NHC website](#) (in Chinese, scroll down to New Variety Food Additive Applications - 食品添加剂新品种审批).

⁷ "Three new foods" refers to new food raw materials, new varieties of food-related products and new varieties of food additives.

On May 6, 2023, NHC released its [2023 No. 3 Announcement on 14 "Three New Foods" Including Blueberry Anthocyanins](#), which approved 14 new food materials and additives for use in China, including one enzyme derived from GMMs.

On August 1, 2023, NHC released its [2023 No. 5 Announcement on 8 "Three New Foods" Including Sorbifolia Seed Kernels](#), which approved 8 new food materials and additives for use in China, including one enzyme derived from GMMs.

On October 7, 2023, NHC released its [2023 No. 8 Announcement on 15 "Three New Foods" including Peach Gum](#), which approved 15 new food materials and additives for use in China, including one enzyme and two food nutrition fortifier derived from GMMs.

All GMM-derived food ingredients that have received NHC approval since the beginning of 2021 are noted in Table 1 below.

Table 1. China: Approved GMM-Derived Food Ingredients

Food Nutrition Fortifiers			
No.	Name	Host	Donor
1. (newly approved in October 2023)	2'-岩藻糖基乳糖 2'-Fucosyllactose (2'-FL)	大肠杆菌K-12 DH1 MDO E. coli	螺杆菌 (<i>Helicobacter</i> spp.)
		K-12 DH1 MDO	
		大肠杆菌K-12 MG1655 E. coli K-12 MG1655	螺杆菌 (<i>Helicobacter</i> spp.)
		大肠杆菌BL21(DE3) E. coli BL21(DE3)	奈瑟菌 (<i>Neisseria</i> spp.)
2. (newly approved in October 2023)	乳糖-N-新四糖Lacto-N-neotetraose	大肠杆菌K-12 DH1 MDO E. coli K-12 DH1 MDO	奈瑟菌 (<i>Neisseria</i> spp.) 和螺杆菌 (<i>Helicobacter</i> spp.)
Enzymes			
No.	酶 Enzyme	来源 Host	供体 Donor
1	葡糖淀粉酶 Glucoamylase	李氏木霉 <i>Trichoderma reesei</i>	李氏木霉 <i>Trichoderma reesei</i>
2.	阿拉伯呋喃糖苷酶 Arabinofuranosidase	李氏木霉 <i>Trichoderma reesei</i>	<i>Talaromyces pinophilus</i>
3.	多聚半乳糖醛酸酶 Polygalacturonase	黑曲霉 <i>Aspergillus niger</i>	黑曲霉 <i>Aspergillus niger</i>
4.	果胶裂解酶 Pectinlyase	李氏木霉 <i>Trichoderma reesei</i>	黑曲霉 <i>Aspergillus niger</i>
5.	麦芽四糖水解酶 Maltotetraohydrolase	地衣芽孢杆菌 <i>Bacillus licheniformis</i>	施氏假单胞菌 <i>Pseudomonas stutzeri</i>

6.	木聚糖酶 Xylanase	李氏木霉 <i>Trichoderma reesei</i>	<i>Talaromyces leycettanus</i>
7.	α -葡萄糖苷酶 Alpha-glucosidase	李氏木霉 <i>Trichoderma reesei</i>	黑曲霉 <i>Aspergillus niger</i>
8.	乳糖酶 Lactase	地衣芽孢杆菌 <i>Bacillus licheniformis</i>	两歧双歧杆菌 <i>Bifidobacterium bifidum</i>
9.	羧肽酶 Carboxypeptidase	黑曲霉 <i>Aspergillus niger</i>	黑曲霉 <i>Aspergillus niger</i>
10.	脂肪酶 Lipase	黑曲霉 <i>Aspergillus niger</i>	黄色镰刀菌 <i>Fusarium culmorum</i>
11.	α -淀粉酶 Alpha-amylase	李氏木霉 <i>Trichoderma reesei</i>	白曲霉 <i>Aspergillus kawachii</i>
12.	蛋白酶 Protease	李氏木霉 <i>Trichoderma reesei</i>	李氏木霉 <i>Trichoderma reesei</i>
13.	葡糖异构酶 Glucose isomerase	锈棕色链球菌 <i>Streptomyces rubiginosus</i>	锈棕色链球菌 <i>Streptomyces rubiginosus</i>
14.	脂肪酶 Lipase	多行汉逊酵母 <i>Hansenula polymorpha</i>	异孢镰刀菌 <i>Fusarium heterosporum</i>
15.	B-淀粉酶 β -amylase (Novozyme)	地衣芽孢杆菌 <i>Bacillus licheniformis</i>	弯曲芽孢杆菌 <i>Bacillus flexus</i>
16.	α -淀粉酶 Alpha-amylase	地衣芽孢杆菌 <i>Bacillus licheniformis</i>	嗜纤维菌 <i>Cytophaga sp.</i>
17.	乳糖酶 Lactase	枯草芽孢杆菌 <i>Bacillus subtilis</i>	两歧双歧杆菌 <i>Bifidobacterium bifidum</i>
18.	蛋白酶 Protease	枯草芽孢杆菌 <i>Bacillus subtilis</i>	水生栖热菌 <i>Thermus Aquaticus</i>
19.	蛋白酶 Protease	枯草芽孢杆菌 <i>Bacillus subtilis</i>	解淀粉芽孢杆菌 <i>Bacillus amyloliquefaciens</i>
20.	磷酸肌醇磷脂酶C Phosphoinositide phospholipase C (DSM)	荧光假单胞菌 <i>Pseudomonas fluorescens</i>	从土壤中分离的编码磷酸肌醇磷脂酶C基因的微生物
21.	α -淀粉酶 α -amylase	黑曲霉 <i>Aspergillus niger</i>	微小根毛霉 <i>Rhizomucor pusillus</i>
22.	多聚半乳糖醛酸酶 Polygalacturonase	李氏木霉 <i>Trichoderma reesei</i>	塔宾曲霉 <i>Aspergillus tubingensis</i>

23.	果胶酯酶 Pectin esterase	李氏木霉 <i>Trichoderma reesei</i>	塔宾曲霉 <i>Aspergillus tubingensis</i>
24.	磷酸肌醇磷脂酶C Phosphoinositide Phospholipase C	地衣芽孢杆菌 <i>Bacillus licheniformis</i>	假单胞菌 <i>Pseudomonas sp.</i>
25.	磷脂酶C Phospholipase C	地衣芽孢杆菌 <i>Bacillus licheniformis</i>	苏云金芽孢杆菌 <i>Bacillus thuringiensis</i>
26.	木聚糖酶 Xylanase	李氏木霉 <i>Trichoderma reesei</i>	柔曲高温多孢菌 <i>Thermopolyspora flexuosa</i>
27.	葡糖淀粉酶 Glucoamylase	黑曲霉 <i>Aspergillus niger</i>	密粘褶菌 <i>Gloeophyllum trabeum</i>
28.	脂肪酶 Lipase	李氏木霉 <i>Trichoderma reesei</i>	尖孢镰刀菌 <i>Fusarium oxysporum</i>
29.	4- α -糖基转移酶 4- α - glucanotransferase	苍白空气芽孢杆菌 <i>Aeribacillus pallidus</i>	--
30	磷脂酶A1 Phospholipase A1	米曲霉 <i>Aspergillus oryzae</i>	红聚颈腔菌 <i>Valsaria rubricosa</i>
31	麦芽糖淀粉酶 Maltogenic amylase	地衣芽孢杆菌 <i>Bacillus licheniformis</i>	嗜热脂解地芽孢杆菌 <i>Geobacillus stearothermophilus</i>
32	葡糖氧化酶 Glucose oxidase	李氏木霉 <i>Trichoderma reesei</i>	尼崎青霉菌 <i>Penicillium amagasakiense</i>
33	脂肪酶 Lipase	李氏木霉 <i>Trichoderma reesei</i>	黑曲霉塔宾变种 <i>Aspergillus niger var. tubingensis</i>
34	β -葡聚糖酶 β -glucanase	枯草芽孢杆菌 <i>Bacillus subtilis</i>	枯草芽孢杆菌 <i>Bacillus subtilis</i>
35	蛋白酶 Protease	枯草芽孢杆菌 <i>Bacillus subtilis</i>	克劳氏碱性卤杆菌 <i>Alkalihalobacillus clausii</i>
36	海藻糖酶 Trehalase	李氏木霉 <i>Trichoderma reesei</i>	李氏木霉 <i>Trichoderma reesei</i>
37	磷脂酶A1 Phospholipase A1	黑曲霉 <i>Aspergillus niger</i>	<i>Talaromyces leycettanus</i>
38	葡糖氧化酶 Glucose oxidase	黑曲霉 <i>Aspergillus niger</i>	产黄青霉 <i>Penicillium chrysogenum</i>

39	乳糖酶 Lactase	枯草芽孢杆菌 Bacillus subtilis	德氏乳杆菌保加利亚亚种 Lactobacillus delbrueckii subsp. bulgaricus
40	植酸酶 Phytase	黑曲霉 Aspergillus niger	塔宾曲霉 Aspergillus tubingensis
41	乳糖酶 Lactase	黑曲霉 Aspergillus niger	米曲霉 Aspergillus oryzae
42 (newly approved in March 2023)	氨基肽酶 Aminopeptidase	米曲霉 Aspergillus oryzae	米曲霉 Aspergillus oryzae
43(newly approved in March 2023)	蛋白酶 Protease	李氏木霉 Trichoderma reesei	樟绒枝霉 Malbranchea sulfurea
44(newly approved in March 2023)	磷脂酶 A2 Phospholipase A2	李氏木霉 Trichoderma reesei	烟曲霉 Aspergillus fumigatus
45(newly approved in March 2023)	麦芽糖淀粉酶 Maltogenic amylase	酿酒酵母 Saccharomyces cerevisiae	嗜热脂解地芽孢杆菌 Geobacillus stearothermophilus
46(newly approved in March 2023)	木聚糖酶 Xylanase	地衣芽孢杆菌 Bacillus licheniformis	地衣芽孢杆菌 Bacillus licheniformis
47(newly approved in March 2023)	羧肽酶 Carboxypeptidase	米曲霉 Aspergillus oryzae	米曲霉 Aspergillus oryzae
48(newly approved in May 2023)	D-阿洛酮糖-3-差向 异构酶 D-psicose 3-epimerase	枯草芽孢杆菌 Bacillus subtilis	瘤胃球菌 CAG55 Ruminococcus sp. CAG55
49(newly approved in August 2023)	溶血磷脂酶 (磷脂酶 B)	Lysophospholipase (lecithinase B) 李氏 木霉	Trichoderma reesei Aspergillus nishimurae
50(newly approved in October 2023)	丝氨酸蛋白酶 Serine protease	地衣芽孢杆菌 Bacillus licheniformis	葱绿拟诺卡氏菌 Nocardiosis prasina

c) Labeling and Traceability

As the enzymes derived from microbial biotechnology are considered common enzymes, there are no specific labeling requirements.

d) Monitoring and Testing

There are no additional monitoring or testing requirements specific to GMM-derived food ingredients.

e) Additional Regulatory Requirements

Food ingredients derived from microbial biotechnology, after approval, are considered to be food additives produced by traditional methods. Thus, they are subject to the following food additive requirements.

Food Additive Production

Food additive production is subject to licensing requirements. Only facilities that have “food additive production” listed in their operating licenses can produce food additives.

National Food Safety Standard - Standards for Uses of Food Additives (GB 2760)

Enzyme preparations used in food processing are listed in Table C.3 - List of Enzyme Preparation for Foods and Their Sources. Table C.3 specifies that enzymes can be used in food processing and the sources of the enzymes. The current GB 2760 in effect was released in 2014 and implemented in May 2015 (please refer to [GAIN Report CH2015-3508](#) for full translation of the standard); enzymes produced from microbial biotechnology, which were approved subsequent to the release of GB 2760 are likely to be included in the updated GB 2760 currently under development. After the release of the standard GB 2760, China published a series of supplementary announcements (link in Chinese) to add new food additives including enzyme preparations to the list, which have been included in Table 1 above.

On April 13, 2021, China notified a revised draft of the [National Food Safety Standard for Use of Food Additives \(GB2760\)](#) to the WTO SPS Committee as G/SPS/N/CHN/1217. The comment period has ended and the final updated version hasn't been officially published.

National Food Safety Standard for Food Additive - Enzyme Preparations Used in Food Processing (GB 1886.174)

The Standard applies to enzyme preparations for foods that are permitted for use in GB 2760. It provides the terms and definitions of enzyme preparations used in food processing, enzyme activity, and antibacterial activity; the standard also provides the product categorization (solid and liquid), and technical requirements (for raw materials and for product). It is not the guidance for the use of such enzymes.

f) Intellectual Property Rights (IPR)

N/A.

g) Related Issues

N/A.

Part I: Marketing

a) Public/Private Opinions

FAS China does not know of any opposition or concern by the public towards such products.

b) Market Acceptance/Studies

There is no distinction between the approved enzymes derived from microbial biotechnology and from the common food additives in use, thus there is no known study about market acceptance of such ingredients available in China.

Appendix 1: China's Trade in Biotech Crops (Source: GACC)

China: Cotton Exports (HS 520100)

Partner Country	Quantity (1,000 Tons)			
	2020	2021	2022	2023 (Jan.-Aug.)
World	4	9	34	5
Bangladesh	0	0	15	2
Vietnam	1	7	10	2
Thailand	0	1	0	0
Indonesia	0	1	1	1

China: Cotton Imports (HS 520100)

Partner Country	Quantity (1,000 Tons)			
	2020	2021	2022	2023 (Jan-Aug)
World	2,158	2,142	1,927	858
United States	978	829	1,132	466
Brazil	618	644	577	154
India	253	409	31	24
Australia	117	35	20	98
Sudan	32	26	22	27

China: Corn Imports (HS 100590)

Partner Country	Quantity (Million Tons)			
	2020	2021	2022	2023 (Jan-Aug)
World	11.24	28.35	20.62	14.91
United States	4.34	19.83	14.86	6.02
Ukraine	6.24	8.2	5.26	5.21

China: Soybean Imports (HS 120190)

Partner Country	Quantity (Million Tons)			
	2020	2021	2022	2023 (Jan-Aug)
World	100.31	96.47	90.29	71.67
Brazil	64.28	58.15	54.39	48.00
United States	25.87	32.27	28.74	19.97
Argentina	7.46	3.78	3.65	1.55
Uruguay	1.66	0.87	1.79	0
Russia	0.69	0.55	0.69	0.93

China: Distillers Dried Grains Imports (HS 230330)

Partner Country	Quantity (1,000 Tons)			
	2020	2021	2022	2023 (Jan-Aug)
World	182	307	83	53
United States	182	307	83	53

China: Rapeseed Imports (HS 12051090)

Partner Country	Quantity (1,000 Tons)			
	2020	2021	2022	2023 (Jan-Aug)
World	3,756	2,531	1,868	3,677
Canada	2,315	2,438	1,868	3,677
Australia	439	93	0	0
Russia	1	1	0	0

China: Rapeseed Meal Imports (HS 230641)

Partner Country	Quantity (1,000 Tons)			
	2020	2021	2022	2023 (Jan-Aug)

World	1,886	2,032	2,213	1,386
Canada	1,496	1,579	1,736	1,104
United Arab Emirates	335	418	430	244

China: Rapeseed Oil Imports (HS 151411, 151419, 151491, 151499)

Partner Country	Quantity (1,000 Tons)			
	2020	2021	2022	2023 (Jan-Aug.)
World	1,931	2,153	1,061	1,489
Russia	217	339	545	854
United Arab Emirates	362	366	185	161
Canada	1,034	914	227	107

China: Sugar Beet Pulp Imports (HS 230320)

Partner Country	Quantity (1,000 Tons)			
	2020	2021	2022	2023 (Jan-Aug)
World	165	404	317	263
Egypt	106	350	256	133
Russia	41	37	55	126
Ukraine	18	17	6	3

Appendix 2: Biotech Crops Approved for Import as Processing Materials

No.	Event	Approval Date	Issued	Developer	Biosafety certificate validity
1	Trans bar, barnase and barstar genes tolerant to herbicides, improved canola MS11	September 28, 2023		BASF	Sept. 28, 2023-Sept. 27, 2028
2	Trans- 2mepsps and hppdPfw336-1Pa gene herbicide tolerant cotton GHB811 (new approval in January 2023)	January 5, 2023		BASF	Jan. 5, 2023-Jan.4, 2028
3	Trans- dmo and bar gene herbicide tolerant cotton MON88701 (new approval in January 2023)	January 5, 2023		Bayer CropScience	Jan. 5, 2023-Jan.4, 2028
4	Trans- aad-12 gene herbicide tolerant cotton DAS-81910-7 (new approval in January 2023)	January 5, 2023		Corteva	Jan. 5, 2023-Jan.4, 2028
5	Trans-c gat4621gene herbicide tolerant Canola DP73496 (new approval in January 2023)	January 5, 2023		Pioneer International Seed Company*	Jan. 5, 2023-Jan.4, 2028
6	Trans- cry1Ab gene insect resistant sugarcane H7-1 CTC175-A (new approval in January 2023)	January 5, 2023		Brazilian Sugar Cane Technology Center	Jan. 5, 2023-Jan.4, 2028
7	Trans- cry1Ab gene insect resistant sugarcane CTC91087-6 (new approval in January 2023)	January 5, 2023		Brazilian Sugar Cane Technology Center	Jan. 5, 2023-Jan.4, 2028
8	Trans- cp4epsps gene herbicide tolerant alfalfa J101 (new approval in January 2023)	January 5, 2023		Bayer CropScience Land O' Lakes	Jan. 5, 2023-Jan.4, 2028

9	Trans- cp4epsps gene herbicide tolerant alfalfa J163 (new approval in January 2023)	January 5, 2023	Bayer CropScience Land O' Lakes	Jan. 5, 2023-Jan.4, 2028
10	HaHB4 genetically resistant soybean IND-ØØ41Ø-5	April 22, 2022	Rosario Agricultural Biotechnology Institute Inc. (Bioceres)	Apr. 22, 2022-Apr.21, 2027
11	Transgenic cp4epsps Herbicide Tolerant Soybean MON89788 (renewal)	August 28, 2008	Bayer CropScience	Apr. 22, 2022-Apr.21, 2027
12	Transgenic Insect-Resistant Soybean DAS-81419-2 (renewal)	December 2, 2019	Corteva	Apr. 22, 2022-Apr.21, 2027
13	Transgenic improves soybean quality traits 305423 (renewal)	November 3, 2011	Corteva	Apr. 22, 2022-Apr.21, 2027
14	Herbicide-tolerant soybean 305423×GTS40-3-2 Advance (renewal)	December 11, 2014	Corteva	Apr. 22, 2022-Apr.21, 2027
15	Herbicide Tolerant Soybean A5547-127 (renewal)	December 11, 2014	BASF	Apr. 22, 2022-Apr.21, 2027
16	Herbicide Tolerant Corn T25 (renewal)	April 6, 2004	BASF	Apr. 22, 2022-Apr.21, 2027
17	Herbicide-tolerant sugar beet H7-1 (renewal)	April 20, 2009	Bayer CropScience Kowalsch Seeds Europe AG	Apr. 22, 2022-Apr.21, 2027
18	Herbicide tolerant oilseed Canola Ms8Rf3 (renewal)	April 6, 2004	BASF	Apr. 22, 2022-Apr.21, 2027
19	Herbicide-tolerant Canola T45 (renewal)	April 6, 2004	BASF	Apr. 22, 2022-Apr.21, 2027
20	Terbicide-tolerant Canola Oxy-235 (renewal)	April 6, 2004	BASF	Apr. 22, 2022-Apr.21, 2027
21	Insect resistant corn MON810(renewal)	February 20, 2004	Bayer CropScience	Dec.17, 2021 - Dec.16, 2026

22	Drought Tolerant corn MON87460 (renewal)	May 21, 2013	Bayer CropScience	Dec.17, 2021 - Dec.16, 2026
23	Insect resistant and herbicide tolerance corn MON88017 (renewal)	December 20, 2007	Bayer CropScience	Dec.17, 2021 - Dec.16, 2026
24	Insect resistant corn MON89034 (renewal)	December 30, 2010	Bayer CropScience	Dec.17, 2021 - Dec.16, 2026
25	Herbicide tolerant corn NK603 (renewal)	July 8, 2005	Bayer CropScience	Dec.17, 2021 - Dec.16, 2026
26	Herbicide tolerant soybean GTS40-3-2 (renewal)	February 20, 2004	Bayer CropScience	Dec.17, 2021 - Dec.16, 2026
27	Insect resistant soybean MON 87701 (renewal)	June 6, 2013	Bayer CropScience	Dec.17, 2021 - Dec.16, 2026
28	Quality-Improved Soybean MON 87769 (renewal)	December 31, 2015	Bayer CropScience	Dec.17, 2021 - Dec.16, 2026
29	Insect resistant soybean MON87701 x MON89788 (renewal)	June 6, 2013	Bayer CropScience	Dec.17, 2021 - Dec.16, 2026
30	Herbicide tolerant Soybean MON 87708 (renewal)	December 31, 2015	Bayer CropScience	Dec.17, 2021 - Dec.16, 2026
31	Herbicide tolerant Canola GT73 (renewal)	April 6, 2004	Bayer CropScience	Dec.17, 2021 - Dec.16, 2026
32	Herbicide tolerant canola MON 88302 (renewal)	December 20, 2018	Bayer CropScience	Dec.17, 2021 - Dec.16, 2026
33	Pest resistant and herbicide tolerant corn DP4114 (renewal)	December 20, 2018	Corteva Agriscience	Dec.17, 2021 - Dec.16, 2026
34	Insect resistant corn 59122 (renewal)	December 20, 2006	Corteva Agriscience	Dec.17, 2021 - Dec.16, 2026
35	Insect resistant corn TC1507 (renewal)	April 6, 2004	Corteva Agriscience	Dec.17, 2021 - Dec.16, 2026
36	Herbicide tolerant Soybean CV127	June 6, 2013	BASF AgriChem	Dec.17, 2021 - Dec.16, 2026

	(renewal)			
37	Herbicide tolerant soybean A2704-12 (renewal)	December 20, 2007	BASF Seed	Dec.17, 2021 - Dec.16, 2026
38	Herbicide tolerance soybean DAS-44406-6 (renewal)	December 20, 2018	Corteva Agriscience	Dec.17, 2021 - Dec.16, 2026
39	Herbicide tolerant Canola Ms1Rf1 (renewal)	April 6, 2004	BASF Seed	Dec.17, 2021 - Dec.16, 2026
40	Herbicide tolerant Canola Ms1Rf2 (renewal)	April 6, 2004	BASF Seed	Dec.17, 2021 - Dec.16, 2026
41	Herbicide tolerant canola RF3 (renewal)	December 20, 2018	BASF Seed	Dec.17, 2021 - Dec.16, 2026
42	Herbicide tolerant Canola Topas19/2 (renewal)	April 6, 2004	BASF Seed	Dec.17, 2021 - Dec.16, 2026
43	Insect resistant corn Bt11 (renewal)	April 6, 2004	Syngenta Crop Protection	Dec.17, 2021 - Dec.16, 2026
44	Insect resistant corn BT176 (renewal)	April 6, 2004	Syngenta Crop Protection	Dec.17, 2021 - Dec.16, 2026
45	Herbicide resistant corn GA21 (renewal)	February 20, 2004	Syngenta Crop Protection	Dec.17, 2021 - Dec.16, 2026
46	Quality improved corn 3272 (renewal)	May 21, 2013	Syngenta Crop Protection	Dec.17, 2021 - Dec.16, 2026
47	Insect resistant corn MIR604(renewal)	August 28, 2008	Syngenta Crop Protection	Dec.17, 2021 - Dec.16, 2026
48	Herbicide tolerance soybean SYHT0H2 (renewal)	December 20, 2018	Syngenta Crop Protection, BASF Seed	Dec.17, 2021 - Dec.16, 2026
49	Herbicide tolerant corn FG72(renewal)	December 31, 2016	Syngenta Crop Protection	Dec.17, 2021 - Dec.16, 2026
50	Pest resistant and herbicide tolerant corn MON87411 (renewal)	December 29, 2020	Bayer CropScience	Dec. 29, 2020-Dec. 28, 2025
51	Pest resistant and herbicide tolerant corn MZIR098 (renewal)	December 29, 2020	Syngenta Crop Protection	Dec. 29, 2020-Dec. 28, 2025
52	Soybean DBN-09004-6 (renewal)	Jun. 11, 2020	Beijing DaBeiNong Biotechnology	Jun. 11, 2020-Jun. 11, 2025

			Co., Ltd.	
53	Insect-Resistant soybean MON87751 (renewal)	Jun. 11, 2020	Monsanto Far East Ltd.	Jun. 11, 2020-Jun. 11, 2025
54	Herbicide-tolerant corn MON87427 (renewal)	July 16, 2017	Monsanto Far East Ltd.	Jun. 11, 2020-Jun. 11, 2025
55	Virus Resistant Papaya 55-1	December 2, 2019	USDA ARS, Pacific Basin Agricultural Research Center, University of Hawaii	Dec. 02, 2019-Dec. 02, 2022
56	Improved quality soybean MON87705 (renewal)	June 12, 2017	Monsanto Far East Ltd.	June 11, 2020-June 11, 2025
57	Herbicide resistant corn DAS-40278-9 (renewal)	June 12, 2017	Dow AgroSciences	June 11, 2020-June 11, 2025
58	Insect resistance and herbicide tolerance corn Bt11×GA21 (renewal)	November 3, 2011	Syngenta Crop Protection	June 11, 2020-June 11, 2025
59	Insect resistance corn MIR162 (renewal)	December 11, 2014	Syngenta Crop Protection	June 11, 2020 – June 11, 2025
60	Insect resistant corn 5307 (renewal)	July 16, 2017	Syngenta Crop Protection	June 11, 2020 – June 11, 2025
61	Insect resistant cotton DAS-24236-5 (new approval in December 2021)	December 17, 2021	Corteva Agriscience	Dec. 17, 2021-Dec. 16, 2026
62	Insect resistant cotton DAS-21023-5 (new approval in December 2021)	December 17, 2021	Corteva Agriscience	Dec.17, 2021-Dec. 16, 2026
63	Herbicide tolerant cotton 1445 (renewal)	February 20, 2004	Bayer CropScience	Dec.17, 2021 - Dec.16, 2026
64	Herbicide tolerant Flex cotton MON 88913 (renewal)	December 20, 2007	Bayer CropScience	Dec.17, 2021 - Dec.16, 2026
65	Insect resistant cotton 531(renewal)	February 20, 2004	Bayer CropScience	Dec.17, 2021 - Dec.16, 2026
66	Insect resistant cotton 15985 (renewal)	July 20, 2006	Monsanto Far East Ltd.	Dec. 02, 2019-Dec. 02, 2024

67	Herbicide tolerant cotton GHB614 (renewal)	December 30, 2010	BASF	Dec. 29, 2020-Dec. 28, 2025
68	Insect resistant cotton COT102 (renewal)	December 31, 2015	Syngenta Crop Protection	Dec. 29, 2020-Dec. 28, 2025
69	Herbicide tolerant cotton LLCotton25 (renewal)	December 20, 2006	BASF	Dec. 29, 2020-Dec. 28, 2025
70	Insect resistant and herbicide tolerant cotton GHB119 (renewal)	April 10, 2014	BASF	Jan. 5, 2023-Jan.4, 2028
71	Insect resistant and herbicide tolerant cotton T304-40 (renewal)	April 10, 2014	BASF	Jan. 5, 2023-Jan.4, 2028
72	Insect resistant corn MON863 (renewal)	June 25, 2004	Monsanto	Certificate expired
73	Herbicide resistant soybean 356043 (renewal)	December 30, 2010	DuPont	Certificate expired

Note: Due to mergers and acquisitions of developers, the owner of some of the certificates may have changed

**Appendix 3: Biotech Crops Approved for Cultivation
(Rice, Corn, Soybean and Papaya, excluding Cotton)**

No.	Event	Developer	Ecological Zone	Biosafety certificate validity
1	Insect resistant rice Hua Hui 1	Hua Zhong Agriculture University	Hubei Province	August 17, 2009 – August 17, 2014 (renewed in 2014; expired in 2019; renewed in 2021: Feb. 10, 2021-Feb. 9, 2026)
2	Insect resistant rice Xian You 63	Hua Zhong Agriculture University	Hubei Province	August 17, 2009 – August 17, 2014 (renewed in 2014; expired in 2019; renewed in 2021: Feb. 10, 2021-Feb. 9, 2026)
3	Phytase Corn BVLA430101	Biotech Research Institute of China Academy of Agricultural Sciences	Shandong Province	August 17, 2009 – August 17, 2014 (renewed in 2014; expired in 2019)
4	Virus resistant Papaya	South China Agriculture University	Guangdong Province (expanded to South China since 2010)	July 20, 2006, renewed in 2010, 2015 and 2020; current certificate valid for Dec. 29, 2020-Dec. 28, 2025
5	Pest resistant and herbicide tolerant corn DBN9936	Beijing DaBeiNong Biotechnology Co., Ltd.	North China spring corn area	Dec. 2, 2019 – Dec. 2, 2024
6	Pest-resistant and herbicide tolerant corn Ruifeng 125 (former Shuangkang 12-5)	Hangzhou Ruifeng Biotechnology Co., Ltd. and Zhejiang University	North China spring corn area	Dec. 2, 2019 – Dec. 2, 2024
7	Pest-resistant and herbicide tolerant corn Ruifeng 125	Hangzhou Ruifeng Biotechnology Co. Ltd.	Summer corn area covering the Yellow River, Huaihe River, Haihe River region	Feb. 10, 2021-Feb. 9, 2026
8	Pest-resistant and herbicide tolerant corn Ruifeng 125	Hangzhou Ruifeng Biotechnology Co.	Northwest corn area	Feb. 10, 2021-Feb. 9, 2026

9	Herbicide-resistant soybean SHZD32-01	Shanghai Jiaotong University	South China soybean area	Dec. 2, 2019 – Dec. 2, 2024
10	Herbicide-tolerant corn DBN 9858	Beijing DaBeiNong Biotechnology Co., Ltd.	North China spring corn area	Jun. 11, 2020 – June 11, 2025
11	Herbicide-tolerant soybean Zhonghuang 6106	Crop Science Institute of CAAS	Huanghuaihai summer soybean area	Jun. 11, 2020 – June 11, 2025
12	Herbicide-tolerant soybean Zhonghuang 6106	Crop Science Institute of CAAS	North China spring soy area	Feb. 10, 2021-Feb. 9, 2026
13	Herbicide-tolerant corn DBN 9858	Beijing DaBeiNong Biotechnology Co., Ltd.	Summer corn area covering the Yellow River, Huaihe River, Haihe River region	Dec. 29, 2020-Dec. 28, 2025
14	Herbicide-tolerant corn DBN 9858	Beijing DaBeiNong Biotechnology Co., Ltd.	South China corn area	Dec. 29, 2020-Dec. 28, 2025
15	Herbicide-tolerant corn DBN 9858	Beijing DaBeiNong Biotechnology Co., Ltd.	Southeast China corn area	Dec. 29, 2020-Dec. 28, 2025
16	Herbicide-tolerant corn DBN 9858	Beijing DaBeiNong Biotechnology Co., Ltd.	Northwest corn area	Dec. 29, 2020-Dec. 28, 2025
17	Pest resistant and herbicide tolerant corn DBN 9936	Beijing DaBeiNong Biotechnology Co., Ltd.	Summer corn area covering the Yellow River, Huaihe River, Haihe River region	Dec. 29, 2020-Dec. 28, 2025
18	Pest resistant and herbicide tolerant corn DBN 9936	Beijing DaBeiNong Biotechnology Co., Ltd.	South China corn area	Dec. 29, 2020-Dec. 28, 2025
19	Pest resistant and herbicide tolerant corn DBN 9936	Beijing DaBeiNong Biotechnology Co., Ltd.	Southeast China corn area	Dec. 29, 2020-Dec. 28, 2025
20	Pest resistant and herbicide tolerant corn DBN 9936	<i>Beijing DaBeiNong Biotechnology Co., Ltd.</i>	Northwest corn area	Dec. 29, 2020-Dec. 28, 2025

21	Pest-resistant and herbicide tolerant corn DBN9501	Beijing DaBeiNong Biotechnology Co., Ltd.	North China spring corn area	Dec. 29, 2020-Dec. 28, 2025
22	Herbicide tolerant soybean DBN9004	Beijing DaBeiNong Bioechnology Co., Ltd.	North China spring soybean area	Dec. 29, 2020-Dec. 28, 2025
23	Pest resistant corn ND207 (GMO formerly known as "2A-7")	China Forestry Seed Group Co., Ltd. China Agricultural University	North China spring corn area	Dec. 17,2021-Dec. 16. 2026
24	Pest resistant corn ND207 (GMO formerly known as "2A-7")	China Forestry Seed Group Co., Ltd. China Agricultural University	Summer corn area covering the Yellow River, Huaihe River, Haihe River region	Dec. 17,2021-Dec. 16. 2026
25	Pest resistant corn Zheda Ruifeng 8 (GMO formerly known as "GAB-3")	Hangzhou Ruifeng Biotechnology Co.Ltd.	South China corn area	Dec. 17,2021-Dec. 16. 2026
26	Pest resistant and herbicide tolerant corn DBN3601T (GMO formerly known as "DBN9936×DBN9501")	Beijing DaBeiNong Bioechnology Co., Ltd.	Southwest corn area	Dec. 17,2021-Dec. 16. 2026
27	Herbicide resistant corn nCX-1 transgenic CdP450 and cp4epsps	Hangzhou Ruifeng Biotechnology Co., Ltd.	South China corn area	Apr. 22, 2022-Apr.21, 2027
28	Pest resistant and herbicide tolerant corn Bt11xGA21	China Seed Group Co., Ltd.	North China spring corn area	Apr. 22, 2022-Apr.21, 2027
29	Pest resistant and herbicide tolerant corn Bt11xMIR162xGA21	China Seed Group Co., Ltd.	South China corn area, Southwest China corn area	Apr. 22, 2022-Apr.21, 2027
30	Hherbicide-tolerant corn GA21	China Seed Group Co., Ltd.	North China spring corn area	Apr. 22, 2022-Apr.21, 2027
31	Trans- cry1Ab, cry1F and cp4epsp gene insect-resistant and herbicide tolerant corn	Yuanlongping Agricultural High Technology Company; Institute of Biotechnology,	North Spring Corn Area	Jan. 5, 2023-Jan.4, 2028

	BFL4-2 (new approval in January 2023)	Chinese Academy of Agricultural Sciences		
32	Trans- maroACC gene herbicide tolerant corn CC-2 (new approval in January 2023)	China Forestry Seed Group Co., Ltd. China Agricultural University	North Spring Corn Area	Jan. 5, 2023-Jan.4, 2028
33	Trans- cry1Ab/vip3Da gene insect-resistant soybean CAL16 (new approval in January 2023)	Shanghai Academy of Agricultural Sciences	South Soybean Area	Jan. 5, 2023-Jan.4, 2028
34	Trans-mvip3Aa and pat genes insect resistant and herbicide tolerance soybean DBN8002(new approval in April 2023)	Beijing Dabeinong Biotechnology Co., Ltd.	Huanghuaihai Summer Soybean Area	Apr. 21, 2023-Apr.20, 2028

**Appendix 4: Gene-Edited Events Approved for Cultivation/Production
(Rice, Corn, Soybean and Papaya, excluding Cotton)**

No.	Event	Developer	Ecological Zone	Biosafety Certificate Validity
1	Mutations gmfad2-1a and gmfad2-1b genes improve quality in soybean AE15-18-1	Shandong Shunfeng Biotechnology Co., Ltd.	/	Apr. 21, 2023-Apr.20, 2028

Attachments:

No Attachments