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Report Highlights:

The People's Republic of China (PRC) continues to advance its agricultural biotechnology system for commercial cultivation of domestically-developed genetically engineered (GE) food and feed crops, specifically corn and soybeans. Since the last report, the PRC has taken steps towards commercial cultivation of GE crops, including the issuance of the first batch of GE corn and soybean seed production and operation licenses. Additionally, the Ministry of Agriculture and Rural Affairs (MARA) issued two new biosafety certificates and four renewed biosafety certificates for GE crops approved for import as processing materials and approved the country's first ever gene-edited wheat and corn for domestic cultivation. In September 2024, the PRC announced that genetically modified microorganisms (GMMs) can be used to produce new food raw materials, new varieties of food-related products and new varieties of food additives if the final product does not contain newly introduced gene fragments and GMMs.

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Executive Summary

The People's Republic of China (PRC) is the largest purchaser of genetically engineered (GE) commodities. In 2023, the PRC imported 99 million metric tons (MMT) of soybeans, 27 MMT of corn, and nearly 2 MMT of cotton. Even though the PRC imports GE commodities, the PRC has not yet approved any GE food or feed products for domestic commercial cultivation outside of designated pilot areas, except for GE cotton and papaya. The PRC, however, continues to advance its agricultural biotechnology development for commercial cultivation of domestically developed GE food and feed crops, specifically corn and soybeans.

On February 3, 2024, the Chinese Communist Party (CCP) Central Committee and the State Council unveiled the 2024 No. 1 Document that sets policy guidelines for agriculture and rural development. The document makes clear that food security remains a top priority for the CCP with a focus on improving crop yield. In reference to commercialization of GE crops, the document stated China will "promote the expansion and acceleration of industrialization of biobreeding." A local social media report, based on industry sources, indicated that China will start a three-year demonstration program for commercial cultivation of GE corn and soybean in 2024 with the completion of the three-year pilot program.

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." In addition, some of the PRC commitments under Chapter 3, Annex 16 of the Phase One Economic and Trade Agreement, which entered into force on February 15, 2020, remain unfulfilled, 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.

Since the publication of the <u>2023 Agricultural Biotechnology Annual</u> report, the PRC has taken steps towards commercial cultivation of GE crops, including the issuance of the first batch of GE corn and soybean seed production and operation licenses. Major updates include the following:

- On December 26, 2023, MARA announced the issuance of 26 GE corn and soybean seed production and operation licenses. The issuance of the GE corn and soybean production and operation licenses are another important step towards commercial cultivation of GE crops after MARA announced the registration of 51 GE corn and soybean varieties on December 7, 2023. However, even if a GE seed production and operation license is obtained, the approved GE corn and soybean varieties are only to be planted in PRC approved areas, which will limit the scale of planting in the near future.
- On January 4, 2024, MARA published a revised <u>General Directive for Labeling of Agricultural Seeds (Draft for Comments)</u> (link in Chinese). This mandatory national

¹ Trade Data Monitor, LLC using data from PRC customs.

standard specifies labeling content and label making requirements for seed labels of all crop seeds sold in China, including GE seeds. For GE seeds, the new draft requires that the seed label include event information stated in the biosafety certificate and a description of cultivation and uses, including the performance of the target trait and recipient variety information of backcross-breeding variety. The current standard does not require labeling of such information.

• On October 8, 2024, MARA announced the registration of 30 GE corn and soy varieties, including 27 GE corn varieties and three GE soybean varieties. This second list of GE corn and soybean varieties was released initially for public comment on March 19, 2024.

The PRC has issued three tranches of new and renewed biosafety certificates. These include the following:

- On January 18, 2024, MARA issued biosafety certificates for three biotech crops approved for import as processing materials (including one new GE corn event, one new GE soybean event, and one renewed GE cotton event), two new certificates issued for gene-edited soybean events for domestic cultivation and processing, 17 new certificates for domestic cultivation and processing (including 11 GE corn events, five GE soybean events, one GE cotton event), and five renewed and seven new certificates for genetically modified microorganisms (GMMs) for animal use.
- On May 8, 2024, MARA issued biosafety certificates for the first ever gene-edited wheat
 event and the first ever gene-edited corn event for domestic cultivation, one new biosafety
 certificate for one GE corn event for domestic cultivation and processing, four renewed
 and six new biosafety certificates for GMMs.
- On October 11, 2024, MARA issued biosafety certificates for three renewed GE crops approved for import as processing materials, one renewed certificate for GE papaya and one new certificate for GE cotton for domestic cultivation and processing, 14 renewed and four new biosafety certificates for GMMs for animal use, and 152 renewed certificates for GE cotton for domestic cultivation and processing.

The below list contains links to all FAS China agricultural biotechnology related GAIN Reports issued since the publication of the 2023 China Agricultural Biotechnology Annual report:

- 1. Agricultural Biotechnology Annual | CH2023-0143
- 2. Revised Draft Measures on Labeling Agricultural "GMOs" Notified | CH2023-0173
- 3. MARA Announces 51 Genetically Engineered Corn and Soybean Varieties Registered | CH2023-0185
- 4. China Issued First Batch of Genetically Engineered Corn and Soybean Seed Production and Operation Licenses | CH2023-0198
- 5. Revised Draft Cereals Seed Standards Published for Comment | CH2024-0004
- 6. WTO Notified Quality Grading Standard for Gramineous Seeds | CH2024-0006
- 7. Revised Draft Directive for Labeling of Agricultural Seeds Published for Comments | CH2024-0010

- 8. New and Renewed Biosafety Certificates Issued January 2024 | CH2024-0009
- 9. Revised Draft Oilseed Species Standard Published for Comment | CH2024-0013
- 10. Revised Draft Cereals Seed Standards Notified | CH2024-0025
- 11. Revised Draft General Directive for Labeling of Agricultural Seeds Notified | CH2024-0024
- 12. Revised Draft Oil Seed Standard Notified | CH2024-0029
- 13. NHC Approves New Food Materials and Additives including GMM Derived Enzymes | CH2024-0043
- 14. New Genetically Modified Corn and Soybean Variety Registration List Published | CH2024-0048
- 15. New and Renewed Biosafety Certificates Issued May 2024 | CH2024-0069
- 16. Planting Seeds Annual 2024 | CH2024-0073
- 17. NHC Approves GMM Derived Enzymes as Part of New Food Materials and Additives | CH2024-0102

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 outside of designated pilot areas, with the exception of GE cotton and papaya. However, local developers have applied for and received biosafety certificates for the cultivation of GE rice, corn, soybeans and gene-edited soybean, wheat, and corn in regions across China (see Appendix 3 for a list of biotech crops approved for cultivation). In addition to the above-mentioned crops that have obtained biosafety certificates, scientists and businesses are conducting biotechnology research and development on other crops, such as rapeseed, potatoes and tomatoes, according to industry sources.

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. China's "14th Five-Year Plan" National Agricultural and Rural Science and Technology Development Plan (link in Chinese) sets the following goals for key agricultural technologies including biotechnology by 2025: strive to achieve a series of basic theoretical breakthroughs in the fields of genomics, crop hybrid breeding, preventative veterinary medicine, and the mechanisms of major pests and diseases. The plan also listed biological breeding as one of the major scientific and technological issues that require breakthroughs to overcome the bottleneck of efficient genetic transformation of major agricultural animals and plants; established new technologies for efficient genetic transformation that do not rely on receptor genotypes and multi-gene superposition; integrated agricultural biogenetics, genome, metabolome and phenomics data to develop ploidy breeding with new technologies such as rapid domestication and cross-border improvement to achieve precise improvement of specialized traits of varieties.

China's recently published research articles include the following:

- Scientists from Shandong Agricultural University discovered that ZmPHR1 contributes to
 drought resistance by modulating phosphate homeostasis in maize. This study reveals the
 molecular mechanism of corn ZmPHR1 to enhance corn drought resistance by regulating
 phosphorus homeostasis and provides a theoretical basis and important genetic resources
 for cultivating new corn germplasm with high nutritional efficiency and wide
 environmental adaptability. The research result was published in Plant Biotechnology
 Journal in July 2024. See "ZmPHR1 contributes to drought resistance by modulating
 phosphate homeostasis in maize."
- Scientists from the John Innes Centre and the Agricultural Genomics Institute at Shenzhen, Chinese Academy of Agricultural Sciences (CAAS) uncovered untapped diversity in historic wheat collection and discovered that at least 60 percent of the genetic diversity found in a historic collection of wheat is unused. According to the scientists, the untapped diversity represents a great potential to improve modern wheat. The research results were published in the journal Nature in June 2024. See "Harnessing Landrace Diversity Empowers Wheat Breeding."
- Scientists from the Rice Research Institute of Guangxi Academy of Agricultural Sciences reported that the successful gene editing of grain size genes improves three-line hybrid rice parents to increase the appearance of quality and yield of hybrid rice. The research results were published in the journal Theoretical and Applied Genetics in June 2024. See "Rapid improvement of grain appearance in three-line hybrid rice via CRISPR/Cas9 editing of grain size genes."
- Scientists from Shandong Agricultural University discovered that REGENERATION FACTOR1 (REF1) is the primary local wound signal that instigates plant regenerative responses. This discovery suggests a convenient method for improving the transformation efficiency of difficult-to-transform crops by boosting their regeneration capacity. The research results were published in the journal Cell in May 2024. See "Peptide REF1 is a local wound signal promoting plant regeneration."
- Scientists from China Agricultural University revealed the function of the NAC transcription factor NOR-like1 gene in tomato fruit softening, which can significantly influence tomato quality and shelf life. The research results were published in the journal Postharvest Biology and Technology in April 2024. See "Tomato NAC transcription factor NOR-like1 positively regulates tomato fruit softening."
- Scientists from South China Agricultural University discovered that manipulating the expression of jasmonate (JA) pathway genes in rice can modulate diurnal flower-opening time to improve the yield of F1 hybrid seed production and reduce seed production costs. The research results were published in the Plant Biotechnology Journal in March 2024. See "Controlling diurnal flower-opening time by manipulating the jasmonate pathway accelerates development of indica—japonica hybrid rice breeding."
- Scientists from the Chinese Academy of Sciences and Qi Biodesign developed a new gene-edited toll CyDENT with a modular structure that breaks through the limitations of

CRISPR. This research creates a new base editing tool with broad genome targeting capabilities and high precision. The research results were published in the journal Cell in July 2023. See "Discovery of deaminase functions by structure-based protein clustering."

b) Commercial Production

MARA's 2016 <u>roadmap</u> 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.

In December 2023, MARA announced the registration of 37 GE corn varieties and 14 GE soybean varieties and issued 26 GE corn and soybean seed production and operation licenses, which cleared the regulatory obstacles for the commercial cultivation of GE corn and soybeans. However, even if a GE seed production and operation license is obtained, the approved GE corn and soybean varieties are only to be planted in PRC approved areas, which limits the scale of GE planting.

The February 2024 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, makes clear that food security remains a top priority with a focus on improving crop yield. In reference to commercialization of GE crops, the document stated China will "promote the expansion and acceleration of industrialization of bio-breeding."

At a press conference (link in Chinese) held in January 2024, MARA announced that the three-year pilot program for the commercial cultivation of GE corn and soybeans was successfully completed. In 2021, China launched a pilot program for the commercial cultivation of GE corn and soybeans. In 2023, the pilot scope was extended to 20 counties in 5 provinces: Hebei, Inner Mongolia, Jilin, Sichuan, and Yunnan. The pilot project proved that GE varieties have good performance in yield, efficiency, and cost saving compared with conventional varieties. MARA stated that it will steadily and orderly promote the commercial cultivation of GE products under the premise of strict supervision and strict risk control and expand the area in a standardized and orderly manner as required. According to social media report (link in Chinese), with the completion of the three-year pilot program, China will start a three-year demonstration program for commercial cultivation of GE corn and soybean starting in 2024. Industry sources (link in Chinese) predict that the planting area of GE corn and soybeans will reach 10 million mu (667,000 ha) in 2024 and may expand to 80-100 million mu (5.3-6.7 million ha) in three years.

The most recent report "Biotech Crops Drive Socio-Economic Development and Sustainable Environment in the New Frontier" released by the International Service for the Acquisition of Agro-Biotech Applications (ISAAA) in 2019 showed that China's GE crops area was 3.2 million hectares 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. Although no official data is available, Post estimates China's GE crops area at 3.5 million ha in 2024, including 2.8 million ha of GE cotton, 667,000 ha of GE corn and soybean, and 10,000 ha of GE papaya. According to GAIN report China Cotton and Products Annual 2024, China's MY2024/25 cotton planted area is forecast at 2.9

million ha, an estimated 2.8 million ha of this is GE cotton since GE cotton adoption in China remains steady at around 95 percent of total area. Industry estimates GE corn and soybean area at 667,000 ha in 2024, and GE papaya (link in Chinese) area is estimated at 10,000 ha.

The GE products approved for commercial cultivation in China can be found on MARA's website (link in Chinese). GE cotton is approved for cultivation in three agroecological zones (Xinjiang, Yellow River Basin, and Yangtze River Basin). GE 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 2023, China exported 7,017 metric tons of cotton (HS code 520100) valued at \$17 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 7,398 metric tons of papaya (HS code 080720), valued at \$11 million. Over 90 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. 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 to Southeast Asia nations when droughts and disasters affect local food and agricultural product distribution and availability. At a <u>press conference</u> (link in Chinese) in August 2024, China International Development Cooperation Agency (CIDCA) officials stated that the PRC has provided emergency food aid valued at nearly RMB 700 million (\$100 million) to more than 30 African countries in the past three years. In 2024, the PRC has reportedly

donated \$2 million to WFP as of July 2024, which is believed to be food donations. The PRC has also donated more than \$26 million of in-kind food donations (e.g., rice and wheat) to several African and Southeast Asian countries. 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. On September 8, the National Development and Reform Commission (NDRC) and the Ministry of Commerce (MOFCOM jointly issued the <u>Special Administrative Measures on Access to Foreign Investment (2024 edition) ("2024 National Negative List")</u> (link in Chinese), which continues the prohibition on foreign developers from conducting biotech research in China. There are no changes in the agriculture section compared to the 2021 Negative List released in December 2021.

Foreign developers are allowed to apply for the biosafety certificate for import in China only when a GE crop event has been approved in the country of origin for the same use. This policy results in asynchronous approval and creates an invisible delay with significant trade impacts. Additionally, the lack of an LLP policy in China means the world's largest importer of animal feed products has a *de facto* 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

i Table 1. China: Terminology of Plant Biotechnology

| Legal Term (in Chinese) | Legal Term (in English) | Laws and Regulations Where Term is Used | Legal Definition (in English) |
|----------------------------|----------------------------|---|--|
| 农业转基因 | Agricultural | Regulations on | Agricultural genetically modified |
| 生物 | genetically | Administration of | organisms refer to animals, plants, |
| | modified | Agricultural "GMO" | microorganisms and their products whose |
| | organisms | Safety | genetic structures have been modified by |
| | ("GMOs") | | genetic engineering technology for the use |
| | | | of agricultural production or processing. |
| 农业转基因 | The safety of | Administrative Rules | The safety of agricultural "GMOs" refers to |
| 生物安全 | agricultural | for Safety of | the prevention of dangers or potential risks |
| | "GMOs" | Agriculture "GMOs" | posed by agricultural "GMOs" to humans, |
| | | | animals, plants, microorganisms and the |
| | | | ecological environment. |
| 基因工程技 | Genetic | Administrative | Genetic engineering technologies: |
| 术 | engineering | Measures for the | technologies that input reconstructed DNA |
| | technologies | Safety Assessment of | molecules by using DNA reconstruction |
| | | Agriculture "GMOs" | technology or by physical, chemical, or |
| | | | biological methods. |
| 基因 | Gene | Administrative | Gene: structural unit that controls the |

| | | Measures for the | function of biological genetic substances, |
|---|--------------------|-----------------------|---|
| | | Safety Assessment of | mainly referring to a DNA segment with |
| | | Agriculture "GMOs" | genetic information. |
| 基因组 | Genetic group | Administrative | Genetic group: sum of chromosomes and |
| | | Measures for the | non-chromosome genetic substances of a |
| | | Safety Assessment of | given organism. |
| | | Agriculture "GMOs" | |
| 目的基因 | Purpose genes | Administrative | Purpose genes: genes that modify the |
| | | Measures for the | genetic composition of receptor cells and |
| | | Safety Assessment of | deliver their genetic effect. |
| | | Agriculture "GMOs" | |
| 受体生物 | Receptor | Administrative | Receptor organisms: organisms into which |
| | organisms | Measures for the | reconstructed DNA molecules are input. |
| | | Safety Assessment of | |
| | | Agriculture "GMOs" | |
| 农业用基因 | Gene-edited plants | Guidelines for Safety | Gene-edited plants for agricultural use refer |
| 编辑植物 | | Evaluation of Gene- | to plants and their products obtained by |
| ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | | Edited Plants for | targeted modification of specific genomic |
| | | Agricultural Use | sites with genetic engineering technology |
| | | (Trial) | and used for agricultural production or |
| | | | agricultural product processing. |

ii Legislation system on GE plants and their products

The Regulations on Administration of Agricultural Genetically Modified Organisms ("GMOs") Safety² (issued by the State Council³ in 2001 and revised in 2017) is the top biotech regulatory document. The regulations require that all practitioners engaged in the research, experiment, production, processing, marketing, import and export with respect to GMOs within the territory of the People's Republic of China must conform to these regulations. The regulations are implemented by the following measures:

- <u>Administrative Measures for the Safety Assessment of Agricultural "GMOs"</u> (issued on January 5, 2002; revisions issued on November 30, 2017, and January 21, 2022);
- <u>Administrative Measures for Safety of Agriculture "GMO" Imports</u> (link in Chinese, issued on January 5, 2002; revision issued on November 30, 2017);
- <u>Administrative Measures for Labeling Agricultural "GMOs"</u> (link in Chinese, issued on January 5, 2002; revision issued on November 30, 2017, and October 17, 2023, for <u>public comments</u>);
- Measures for the Review and Approval of Agricultural "GMOs" for Processing (link in Chinese, issued on July 1, 2006; latest revision issued on April 25, 2019);
- Administrative Measures of Inspection and Quarantine on Entry-Exit "GM" Products (implemented on May 24, 2004; updated 2019 (link above), <u>latest revision</u> (link in Chinese) issued in March, 2023);

² Article 22 and Article 49 were deleted in 2017 revision.

³ 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.

- <u>Guideline for Safety Assessment of "GM" Plants</u> (issued in 2006, latest revision issued in January 2023);
- <u>Guideline on Safety Inspection of Field Trials for "GM" Crops</u> (link in Chinese, issued in 2006);
- <u>Guidelines for Safety Evaluation of Gene-Edited Plants for Agricultural Use (Trial)</u> (issued in January 2022); and
- Technical guidance, standards, and procedures released through MARA public notices.

iii The Responsible Government Ministries for GE Plants

China's regulations of "GMOs" are mainly divided into two stages. The first stage is the administration of GMOs; the second stage is the administration of "GM" product labeling. According to Article 4 of the Regulations on Administration of Agricultural "GMOs" Safety, MARA has 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 National Biosafety Committee (NBC) under MARA is responsible for the safety evaluation of "GMOs."

MARA and the State Administration for Market Regulation (SAMR) are jointly responsible for the administration of "GM" product labeling. MARA is responsible for formulating relevant regulations on "GM" product labeling and supervising the labeling of "GM" animals and plants (including seeds, breeding livestock and poultry, and aquatic seedlings), microorganisms, "GM" animal and plant/microorganism products, etc.; SAMR is responsible for the administration of "GM" labeling of processed foods. In addition, the General Administration of Customs (GACC) participates in the first and second stages of supervision and is responsible for the inspection and quarantine of inbound and outbound "GM" products nationwide.

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," 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.

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.

⁴ Article 4: "The competent agricultural administrative department of the State Council is responsible for the nationwide supervision and administration of agricultural GMO safety."

Other Government Agencies

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.

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.

The Joint-Ministerial Conference for Biosafety Management of Agricultural Genetically Modified Organisms, which is stipulated in Article 5 of the Regulations on Administration of Agricultural "GMOs" Safety, is an overarching coordinating body that 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.

iv The National Biosafety Committee (NBC)

Article 9 of the Regulations on Administration of Agricultural "GMOs" Safety 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. The Administrative Measures for the Safety Assessment of Agriculture "GMOs" stipulates that the NBC shall hold no less than two meetings per year.

v Biosafety Certificate Approval Procedure

According to Guideline for Safety Assessment of "GM" Plants, there are two types of biosafety certificate for GE plants in China: biosafety certificates for imported biotech products as

processing materials and biosafety certificates for domestic cultivation. For imported biotech products, in addition to the biosafety certificate issued to the developer, each consignment of an imported GE product must obtain a biosafety certificate issued by MARA to overseas traders.

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

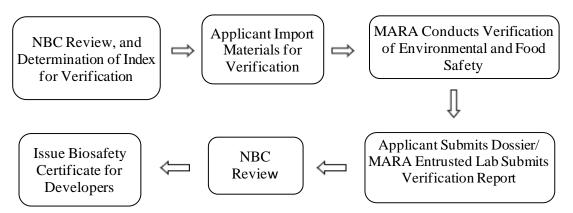
MARA is responsible for the review and issuance of biosafety certificates for imported biotech products for processing materials. The Administrative Measures for Safety of Agriculture "GMO" Imports outline the requirements for importing biotech products. According to the Guideline How the Overseas Developers Apply for Biosafety Certificate for Agricultural Biotechnology (import) for the First Time (link in Chinese), a foreign seed developer must apply for a biosafety certificate to MARA's 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 developers. 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 a 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 which is then reviewed at a subsequent NBC meeting. Still, 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 <u>MARA official website's page for administrative approvals</u>. 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 to Overseas Developers



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 <u>Guideline How the Overseas Traders Apply for Biosafety Certificate for Agricultural Biotechnology (import)</u> (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. Please refer to GAIN Report <u>China Agricultural Biotechnology Annual 2023</u> for detailed information on required application materials. From the date of submission, MARA has 25 working days to review the application and inform the review results (issue the certificate or rejection notice).

In December 2020, MARA issued <u>Public Notice [2020] No. 376 (link in Chinese)</u>, announcing that applications for Biosafety Certificate for Agricultural Biotechnology (Import) to overseas traders can be submitted <u>on-line</u> (link in Chinese). From October 2021, this biosafety certificate can also be applied from the <u>Single Window</u> 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.

Biosafety Certificate for Domestic Cultivation

A domestic developer wanting to cultivate a new GE product in China requires a MARA biosafety certificate for cultivation. See <u>Guideline How the Local Developers Apply for Biosafety Certificate for Cultivation</u> (link in Chinese) for application procedure. After obtaining the biosafety certificate for cultivation, the developer needs to apply for plant <u>variety registration</u> with MARA's Seed Industry Management Department if it is major crops (rice, wheat, corn, soybean, and cotton). After completion of variety registration, the producer and marketer of the GE variety needs to obtain a <u>seed production and operation license</u> to conduct relevant businesses. Then 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.

vi Regulatory Distinctions

According to Regulations on Administration of Agricultural "GMO" Safety, agricultural "GMOs" in China refers 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." From the definition of "GMO," there is no distinction made between GE plants containing DNA in the final form of the product and those that do not or whether they are living versus non-living.

b) Approvals

Since the publication of the <u>China Agricultural Biotechnology Annual 2023</u> report, the PRC has issued three tranches of new and renewed biosafety certificates. The validity period of newly issued and renewed certificates is 5 years.

On January 18, 2024, MARA issued biosafety certificates for three biotech crops approved for import as processing materials (including one new GE corn event, one new GE soybean event, and one renewed GE cotton event), two new certificates issued for gene-edited soybean events for domestic cultivation and processing, and17 new certificates for domestic cultivation and processing (including 11 GE corn events, five GE soybean events, one GE cotton event). For detailed information of the approval, please see GAIN Report New and Renewed Biosafety Certificates Issued - January 2024 | CH2024-0009.

On May 8, 2024, MARA issued biosafety certificates for the first ever gene-edited wheat event and the first ever gene-edited corn event for domestic cultivation and one new biosafety certificate for one GE corn event for domestic cultivation and processing. For detailed information of the approval, please see GAIN Report New and Renewed Biosafety Certificates Issued - May 2024 | CH2024-0069.

On October 11, 2024, MARA issued biosafety certificates for three renewed GE crops approved for import as processing materials, one renewed certificate for GE papaya and one new certificate for GE cotton for domestic cultivation and processing, 14 renewed and four new biosafety certificates for GMMs for animal use, and 152 renewed certificates for GE cotton for domestic cultivation and processing. For detailed information of the approval, please see GAIN New and Renewed Biosafety Certificates Issued - October 2024 | CH2024-0132

Since MARA began approving import of GE products for processing materials 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.

Chinese developers have received several safety approvals for cultivation abroad. Beijing DaBeiNong Technology Group Co., Ltd. (DBN) received approvals from Argentina to cultivate its herbicide-resistant soybean DBN09004-6 in February 2019, pest resistant soybean event DBN8002 in November 2022, and the stacked event DBN9004×DBN8002 in October 2023. In May 2024, the U.S. Department of Agriculture Animal and Plant Health Inspection Service (USDA APHIS) granted Qi Biodesign an exemption for its gene-edited soybeans. This is China's first gene-edited product to receive regulatory exemption in the United States.

c) Stacked or Pyramided Event Approvals

The PRC does not have a specific policy for approving stacked events. The 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 believes provides for the biosafety assessment of GE crops containing "stacked" traits. Please refer to <u>GAIN Report CH2022-0014 Agricultural "GMOs" Safety Assessment Administrative Measures Finalized</u>.

d) Field Testing

According to Article 13 of Regulations on Administration of Agricultural "GMOs" Safety: The testing of agricultural "GMOs" shall normally go through three stages (i.e., restricted field testing, enlarged field testing, and productive testing).

- Restricted field testing (intermediary trial) means a small-scale test conducted within a controlled system or under controlled conditions.
- Enlarged field testing (environmental release) means a medium-scale test conducted under natural conditions with appropriate safety measures.
- Productive testing means a large-scale test prior to production and application.

The PRC requires field testing 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 genome-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 Assessment of GM Plants.

MARA has said that genome edited products fall within the scope of PRC's "GMO" regulations and will be regulated as "GMOs" but has held out the possibility of a streamlined process for genome-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, 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.

f) Coexistence

The PRC currently 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 11042300⁵);
- 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 <u>Administrative Measures on Labeling</u> <u>Agricultural GMOs</u>

(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 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 "GM" food materials. As of September 2024, the final version of the measures has not been published (may update if it is released).

On January 4, 2024 MARA published a revised <u>General Directive for Labeling of Agricultural Seeds (Draft for Comments)</u>. This mandatory national standard specifies labeling content and label making requirements for seed labels of all crop seeds sold in China, including GE seeds. For GE seeds, the new draft requires that the seed label include event information stated in the biosafety certificate and a description of cultivation and uses, including the performance of the target trait and recipient variety information of backcross-breeding variety. The current standard does not require labeling of such information.

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

⁵ 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).

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.

On March 6, 2020, Standardization Administration of China (under SAMR) issued <u>National Standard GB/T38505-2020: General Detection Methods of GM Products</u> (link in Chinese), which specifies the qualitative testing methods for GM products. This standard is applicable to the general testing of GM 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) published a paper titled <u>A Universal Analytical Approach for Screening and Monitoring of Authorized and Unauthorized "GMOs"</u> 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.

Under the <u>Phase One Economic and Trade Agreement</u> (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

No known additional biotech-related regulatory requirements that negatively affect U.S. GE plant exports to China exist. MARA started to monitor the number of import certifications issued to the number of import certificates used late last year in an effort to reduce the number of unused import certificates.

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. For more

information on China's IPR protection on seeds and plant varieties, see Chapter 1, Part B, subparagraph k of China Agricultural Biotechnology Annual 2023.

1) Cartagena Protocol Ratification

The PRC signed the Cartagena Protocol on Biosafety (CPB) to the United Nation's Convention on Biological Diversity (CBD) 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 <u>Biosecurity Law</u> on October 17, 2020. The Biosecurity Law came into force on April 15, 2021. China submitted <u>the Fourth National Reports on Implementation of the Cartagena Protocol on Biosafety</u> 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.

Adopted as a supplementary agreement to the Cartagena Protocol on Biosafety, the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety 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 supplementary protocol entered into force on 5 March 2018, and the PRC has not yet acceded to the protocol.

As a party of CBD, China participates the bi-annual Conference of Parties to the UN Convention on Biological Diversity), and China was president of COP 15 held in Montreal in December 2022.

m) International Treaties and Forums

The PRC ratified the Codex Alimentarius in 1986, the International Plant Protection Convention (IPPC) in 2005, United Nations Framework Convention on Climate Change in 1994, and United Nations Convention to Combat Desertification in 1997.

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.

n) Related Issues

The 2024 No. 1 Document makes clear that food security remains a top priority for the PRC with a focus on improving crop yield on limited arable land. At a press conference in January 2024, MARA commended GE crops for good performance in increasing yields. In August 2023,

MARA published a <u>report</u> on GE crop cultivation pilot program. The report concluded that during the pilot program, the yield of GE corn and soybean increases by 5.6-11.6 percent. The report also praises the performance in sustainability 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. It appears that MARA believes GE crops have great potential to increase production to address food security and reduce chemical use to increase sustainability.

Part C: Marketing

a) Public/Private Opinions

The Chinese public has long had misperceptions of GE products due to some misleading and non--science-based media reports. 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.

The "14th Five-Year Plan" National Agricultural and Rural Science and Technology Development Plan (link in Chinese), released by MARA in December 2021, highlighted strengthening the scientific popularization of biological breeding and biotechnology applications. The Plan calls for efforts to build a biological breeding science popularization system with linkage between central and local governments, collaboration between propaganda departments and agricultural and rural departments, online and offline interaction, and linkage between mainstream media and new media. Entrepreneurs, scientists, stakeholders shall actively create various online and offline platforms for agricultural science popularization to strengthen the persuasiveness of science popularization on biotechnology. Biotechnology is also listed in the key areas for scientific popularization in The "14th Five-Year Plan" National Science and Technology Popularization Development Plan (link in Chinese) released by the Ministry of Science and Technology, the Publicity Department of the Chinese Communist Party, and China Association for Science and Technology in August 2022.

b) Market Acceptance/Studies

According to <u>GAIN Report Oilseeds and Products Update June 2024</u>, China's annual GE soybean oil consumption is estimated at around 16 million metric tons, accounting for over 25 percent of global soybean oil consumption and over 40 percent of China's total vegetable oil consumption. Although some public opinion is against GE products, it appears that it has not affected the sales of GE products for their very competitive prices.

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.

Part D: Production and Trade

a) Product Development

The PRC has invested in basic research for animal biotech. Research is focused on medicine production, improving the quantity and quality of milk, and improving quality of meat and wool. China has also made significant advances in animal cloning, including cloning the world's first monkey in 2017 and the world's first Arctic wolf in 2022.

Recent research results on cloning animals include the following:

- In January 2024, Chinese scientists announced the world's first successful cloning of
 endangered cattle breeds native to southwest China's Xizang Autonomous Region. The
 scientists cloned four male calves of each of the Zhangmu and Apeijiaza breeds, which
 are rare yellow cattle that live on the Qinghai-Xizang Plateau. The breeds are strategic
 resources for China as these breeds can help researchers breed varieties well adapted to
 the harsh high-altitude environment. See: China confirms first successful cloning of endangered Xizang cattle breeds.
- In January 2024, scientists from the Chinese Academy of Sciences published new research results in the journal Nature Communication, reporting the successful cloning of a healthy rhesus monkeys that survived to three years of age. This study is the first in the world to successfully use Somatic cell nuclear transfer (SCNT) technology to obtain healthy and surviving rhesus monkeys, laying the foundation for understanding the reprogramming process of primate SCNT and promoting the construction of accurately genetically modified rhesus monkey models. See: Reprogramming mechanism dissection and trophoblast replacement application in monkey somatic cell nuclear transfer.
- In February 2023, China Daily reported that Chinese scientists have cloned three "super cows" able to produce 18 metric tons of milk per year and more than 100 metric tons of milk over the course of their lifetimes, and the milk produced is no different from that produced by the clone's genetic parents. The research result may help reduce China's dependency on imported dairy cows. See: Cloned 'super cows' may help reduce reliance on imports.

Recent research results on GE animals include:

• Scientists from Jiangsu University of Science and Technology in China and partners explored using various techniques for GE silkworms, such as Transcription activator-like

effector nucleases (TALEN) and transposon-mediated transformation. These methods involve adding genes for specific silk proteins: a spider silk protein and a bagworm silk protein. The results showed that the engineered silkworms produced more of these new silk proteins (up to 64 percent) than regular silk. The silk fibers were also much tougher, some by as much as 86 percent. The research result was published in the journal PNAS Nexus in April 2024 tilted <u>Custom-designed</u>, <u>mass silk production in GE silkworms</u>.

- Scientists from Kunming Institute of Zoology of the Chinese Academy of Sciences found that inter-chromosome rearrangements very rarely disrupted the pre-existing 3D chromatin structure of ancestral chromosomes. However, some intra-chromosome rearrangements changed 3D chromatin structures compared to the ancestral configuration. The research result revealed evolutionary patterns of insect 3D chromatin structures and provide evidence that 3D chromatin structure changes can play important roles in the evolution of traits. The result was published in the journal Nature Communications in July 2024 titled Evolutionary patterns and functional effects of 3D chromatin structures in butterflies with extensive genome rearrangements.
- To investigate the phenotypic outcome and underlying genetic mechanism of human-specific SRGAP2C, scientists from Kunming Institute of Zoology of the Chinese Academy of Sciences generated transgenic cynomolgus macaques (Macaca fascicularis) carrying the human-specific SRGAP2C gene and conducted a series of experiments to reveal the important role of SRGAP2C in shaping human-specific brain phenotypes. The research result was published in the journal National Science Review in November 2023 titled Brain developmental and cortical connectivity changes in transgenic monkeys carrying the human-specific duplicated gene SRGAP2C.

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 has not issued any biosafety certificates for GE animals.

Some social media <u>reported</u> (link in Chinese) emerging demands for pet cloning in China. The report mentioned an online survey on "would you clone a deceased pet?" participated by over 100,000 people, and more than 26,000 people chose "yes" or "yes if financially affordable." Regarding the legality of pet cloning, some layers voiced that Chinese law explicitly prohibits the application of cloning technology to humans or human bodies but does not prohibit commercial pet cloning. According to the principle of "everything which is not forbidden is allowed," pet cloning is not illegal.

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 Regulations on Administration of Agricultural "GMOs" Safety (revised in 2017). The regulations are implemented by the following rules:

- Administrative Measures for the Safety Evaluation of Agricultural "GMOs" (revised in 2022, link in Chinese). The Annex II of this measures provides administrative measures for safety evaluation of GE animals.
- <u>Guideline for Safety Assessment of "GM" Animals</u> (link in Chinese) was published in January 2017.

Similar as GE plants, MARA and NBC hold the primary responsibility for GE animals. For detailed information, see Chapter 1, Part B, subparagraph a of this report.

Table 2. China: Terminology of Animal Biotechnology

| Legal Term | Legal Term (in | Laws and | Legal Definition (in English) |
|--------------|---|---|--|
| (in Chinese) | English) | Regulations Where | |
| | | Term is Used | |
| 转基因动物 | Genetically modified animals ("GM" animals) | Guideline for Safety Assessment of "GM" Animals | "GM" animals refer to animals and their products used for agricultural production or agricultural product processing, which are obtained by introducing exogenous fragments into receptors or directing the modification of receptor genes through genetic manipulation techniques such as microinjection, electroporation, particle bombardment, cell transformation, and |
| | | | viral introduction. |

b) Approvals

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

According to Guideline for Safety Assessment of "GM" Animals, there are two types of biosafety certificate for GE animals: 1) biosafety certificate for GE animals; 2) biosafety certificate for animals containing "GM" ingredients hybrid by approved GE animals and conventional breeds. Unlike GE plants, there is no biosafety certificate for imported GE animals.

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. Guidelines for Safety Evaluation of Gene-Edited Plants for Agricultural Use (Trial) was issued in January 2022, while guidelines for gene-edited animals have not been released yet.

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. MARA published a draft for comments in October 2023, but the final version has not been published yet). 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 became a member of the World Organization for Animal Health (WOAH, founded as the OIE) in May 2007. The 91st Annual General Session of the World Assembly of Delegates of WOAH was held in Paris, France, in May 2024. Huang Baoxu, WOAH Delegate from China and Director-General of the Bureau of Animal Husbandry and Veterinary Services of MARA, was re-elected as President of the WOAH Regional Commission for Asia and the Pacific.

Chinese representatives have been elected chairman or vice-chairman of the Asia-Pacific Committee for five consecutive terms since it joined WOAH in 2007, four experts have served as members of the technical committee, and 25 veterinary laboratories have been designated as WOAH reference laboratories or collaboration centers.

China is also a member of Commission on Genetic Resources for Food and Agriculture of Food and Agriculture Organization (FAO).

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

Since the issuance of the last biotech annual report, the NHC has approved the use of six genetically modified microorganisms (GMMs) derived enzymes to be used as food additives in food production. Of note, two of the six approved "GMMs" are 2'-fucosyllactose (2'-FL), a purified human milk oligosaccharide (HMO) for use as a food nutrition fortifier, particularly in infant formula, which was previously approved under NHC No. 8 Announcement (link in Chinese) on October 7, 2023. The two newly approved 2'-FL are from a different host and donor than the previous approval. MARA has approved the use of 17 "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.⁶

Part G: Production and Trade

a) Commercial Production

Before October 2023, the PRC had only approved GMM derived enzymes to be used as food additives in food production. Later, China approved two types of human milk oligosaccharides (HMOs) as food additives. On September 13, 2024, the PRC announced that GMMs can be used to produce new food raw materials, new varieties of food-related products, and new varieties of food additives if the final product does not contain newly introduced gene fragments and GMMs. For more information, see Chapter Three, Part H, subparagraph a of this report.

b) Exports

⁶ 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.

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 is 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

"GMM" is subject to the State Council's Regulations on Administration of Agricultural "GMOs" Safety (revised in 2017). The Regulations are implemented by the following rules:

- Administrative Measures for the Safety Evaluation of Agricultural "GMOs" (revised in 2022, link in Chinese). The Annex III of this Measures provides administrative measures for safety evaluation of GE animals
- <u>Guidelines for Safety Assessment of GMMs for Animal Use</u> (link in Chinese) was published in 2010 and revised in 2017).

Similar as GE plants, MARA and NBC hold the primary responsibility for "GMMs" for animal use. For detailed information, see Chapter 1, Part B, subparagraph a of this report. The National Health Commission (NHC) reviews and approves ingredients derived from "GMMs" for food use.

Applying for Approval of "GMM"-Derived Food Ingredients

On September 13, 2024, China's National Center for Food Safety Risk Assessment (CFSA), under NHC, released Requirements for Application Materials for Safety Evaluation of GMMs Used in Food Processing (Trial) (link in Chinese) to clarify the safety evaluation requirements for new food raw materials, new varieties of food-related products, and new varieties of food additives produced from GMMs. The release of this document signifies that, in addition to food additives, GMMs derived products without residual of exogenous genes and GMMs can also be used as new food raw materials and new varieties of food-related products. According to industry interpretation, NHC is responsible for evaluation and approval when the final products contain no residual exogenous genes and residual live cells of GMMs, which means these products do not need to undergo GMO safety approval from MARA. For detailed information on the

requirements, please refer to GAIN Report <u>China Expands Application of Genetically Modified</u> Microorganisms Derived Products in Food Processing | CH2024-0127.

The application process for new "GMM"-derived enzymes varieties is the same as that for new varieties of all other food additives. An application should be submitted to the NHC and instructions on the application procedures and material requirements can be found on the NHC website (link in Chinese). 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.
 - o 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) when the standard is revised. The standard regulates the usage principles, varieties permitted to be used, and the maximum use limits for food additives in food categories in China. On March 12, 2024, the PRC released the finalized GB2760-2024, which will enter into force on February 8, 2025. The revised standard contains a list of 66 enzyme preparations for food processing use (see Table C.3 List of Enzyme Preparation for Foods and Their Sources on page 250 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."

Table 3. China: Terminology of Microbial Biotechnology

| Legal Term (in Chinese) | Legal Term (in English) | Laws and Regulations Where Term is Used | Legal Definition (in English) |
|----------------------------|----------------------------|---|--|
| 动物用转基 因微生物 | Genetically modified | Guideline for Safety Assessment of | "GMMs" for animals refer to recombinant microorganisms and their products that are |

| | microorganisms | "GMMs" for Animals | used for animals in agricultural production |
|-------|------------------|----------------------|---|
| | (GMMs) for | Use | or agricultural product processing by using |
| | animal use | | genetic engineering technology to change |
| | | | the genome composition. |
| 食品工业用 | Enzyme | National Food Safety | Enzyme preparations for food industry |
| 酶制剂 | preparations for | Standard for Food | refers to enzyme preparations directly |
| | food industry | Additive - Enzyme | extracted from edible or inedible parts of |
| | | Preparations Used in | animals or plants, or fermented and |
| | | Food Processing (GB | extracted by microorganisms (including |
| | | 1886.174) | but not limited to bacteria, actinomycetes, |
| | | | and fungi) obtained by traditional breeding |
| | | | or genetic recombination technology, or |
| | | | further purified and formulated (may |
| | | | contain one or more active enzyme |
| | | | components), used in food industry, and |
| | | | have special catalytic activity |

b) Approvals

Since the publication of the <u>Agricultural Biotechnology Annual 2023</u>, the NHC has issued the following two announcements approving new food ingredients derived from microbial biotechnology:

- On March 13, 2024, the NHC released its 2024 No. 2 Announcement on 23 "Three New Foods" Including Dendrobium Protocorm (link in Chinese), which approved 23 new food materials and additives for use in China, of which five are products derived from "GMMs." Of note, 2'-fucosyllactose (2'-FL), a purified human milk oligosaccharide (HMO) for use as a food nutrition fortifier, particularly in infant formula, was previously approved under NHC 2023 No. 8 Announcement on October 7, 2023. The 2'-FL approved in the March 2024 announcement is from a different host and donor than the previous approval.
- On August 5, 2024, NHC released its <u>2024 No. 3 Announcement on Eight "Three New Foods" Including Arabinoxylan</u> (link in Chinese), which approved eight new food materials and additives for use in China, including one 2'-FL from a new host and donor.

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

Table 4. China: Approved GMM-Derived Food Ingredients

| Food Nutrition Fortifiers | | | |
|---------------------------|--------------------|---------------------------------------|-------------------|
| No. | Name | Host | Donor |
| 1. | 2'-岩藻糖基乳糖 | 大肠杆菌 BL21 star (DE3) | 大肠杆菌 O126 |
| | 2' -Fucosyllactose | Escherichia coli BL21 star | (Escherichia coli |
| | (2' -FL) | (DE3) (newly approved in August 2024) | O126)a |
| | | 谷氨酸棒状杆菌 ATCC | 滑动假土地杆菌 |
| | | 13032 Corynebacterium glutamicum | (Pseudopedobacter |
| | | ATCC 13032 (newly approved in | saltans)a |

| | | August 2024) | | |
|-----|--|-----------------------------------|--------------|-----------------------|
| | | 大肠杆菌 BL21(DE3) | | 幽门螺杆菌 |
| | | Escherichia coli BL21(DE3) (newly | | (Helicobacter pylori) |
| | | approved in March 2024) | | |
| | | 大肠杆菌 K-12 DH1 MDO I | E. coli K-12 | 螺杆菌 |
| | | DH1 MDO | | (Helicobacter spp.) |
| | | 大肠杆菌 K-12 MG1655 | | 螺杆菌 |
| | | E. coli K-12 MG1655 | | (Helicobacter spp.) |
| | | 大肠杆菌 BL21(DE3) E. col | i | 奈瑟菌 |
| | مادار الحجار الح | BL21(DE3) | | (Neisseria spp.) |
| 2. | 乳糖-N-新四糖 | 大肠杆菌 K-12 DH1 MDO | | 奈瑟菌(Neisseria |
| | Lacto-N-neotetraose | E. coli K-12 DH1 MDO | | spp.)和螺杆菌 |
| | | _ | | (Helicobacter spp. |
| | | Enzymes | | |
| No. | 酶 Enzyme | 来源 Host | | 供体 Donor |
| 1 | 葡糖淀粉酶 | 李氏木霉 | 李氏木霉 | |
| | Glucoamylase | Trichoderma reesei | Trichodern | na reesei |
| 2. | 阿拉伯呋喃糖苷酶 | 李氏木霉 | Talaromyc | es pinophilus |
| | Arabinofuranosidease | Trichoderma reesei | | |
| 3. | 多聚半乳糖醛酸酶 | 黑曲霉 | 黑曲霉 | |
| | Polygalacturonase | Aspergillus niger | Aspergillus | s niger |
| 4. | 果胶裂解酶 | 李氏木霉 | 黑曲霉 | |
| | Pectinlyase | Trichoderma reesei | Aspergillus | s niger |
| 5. | 麦芽四糖水解酶 | 地衣芽孢杆菌 | 施氏假单周 | |
| | Maltotetraohydrolase | Bacillus licheniformis | Pseudomon | nas stutzeri |
| 6. | 木聚糖酶 | 李氏木霉 | Talaromyc | es leycettanus |
| | Xylanase | Trichoderma reesei | | |
| 7. | α-葡萄糖苷酶 | 李氏木霉 | 黑曲霉 | |
| | Alpha-glucosidase | Trichoderma reesei | Aspergillus | s niger |
| 8. | 乳糖酶 | 地衣芽孢杆菌 | 两歧双歧村 | 千菌 |
| | Lactase | Bacillus licheniformis | | erium bifidum |
| 9. | | 黑曲霉 | 黑曲霉 | |
| | Carboxypeptidase | Aspergillus niger | Aspergillus | s niger |
| 10. | 脂肪酶 | 黑曲霉 | 黄色镰刀菌 | 莉 |
| | Lipase | Aspergillus niger | Fusarium o | |
| 11. | <u>α</u> -淀粉酶 | 李氏木霉 | 白曲霉 | |
| | Alpha-amylase | Trichoderma reesei | Aspergillus | s kawachii |
| 12. | | 李氏木霉 | 李氏木霉 | |
| | Protease | Trichoderma reesei | Trichodern | na reesei |
| 13. | 葡糖异构酶 | 锈棕色链球菌 | 锈棕色链斑 | 求菌 Streptomyces |
| | Glucose isomerase | Streptomyces rubiginosus | rubiginosu | |
| | | | J | |

| 14. | 脂肪酶 | 多行汉逊酵母 | 异孢镰刀菌 |
|-----|-----------------------|-----------------------------|---------------------------------------|
| | Lipase | Hansenula polymorpha | Fusarium hetreosporum |
| 15. | Β-淀粉酶 β- | 地衣芽孢杆菌 | 弯曲芽孢杆菌 |
| | amylase | Bacillus licheniformis | Bacillus flexus |
| 16. | (Novozyme) α-淀粉酶 | 地衣芽孢杆菌 | ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ |
| 10. | Alpha-amylase | Bacillus licheniformis | で目まり 生 |
| | | , , , | |
| 17. | 乳糖酶 | 枯草芽孢杆菌 | 两歧双歧杆菌 |
| | Lactase | Bacillus subtiis | Bifidobacterium bifidum |
| 18. | 蛋白酶 | 枯草芽孢杆菌 | 水生栖热菌 |
| | Protease | Bacillus subtiis | Thermus Aquaticus |
| 19. | 蛋白酶 | 枯草芽孢杆菌 | 解淀粉芽孢杆菌 |
| | Protease | Bacillus subtiis | Bacillus amyloliquefaciens |
| 20. | 磷酸肌醇磷脂酶 C | 荧光假单胞菌 | 从土壤中分离的编码磷酸肌醇磷 |
| 20. | Phosphoinositide | Pseudomonas fluorescens | 脂酶 C基因的微生物 |
| | phospholipase C | T sevide mendis juiereseens | 加西安区至四山加州 |
| | (DSM) | | |
| 21. | α-淀粉酶 | 黑曲霉 | 微小根毛霉 |
| | α-amylase | Aspergillus niger | Rhizomucor pusillus |
| 22. | 多聚半乳糖醛酸酶 | 李氏木霉 | 塔宾曲霉 |
| | Polygalacturonase | Trichoderma reesei | Aspergillus tubingensis |
| 23. | 果胶酯酶 | 李氏木霉 | 塔宾曲霉 |
| | Pectin esterase | Trichoderma reesei | Aspergillus tubingensis |
| 24. | 磷酸肌醇磷脂酶 C | 地衣芽孢杆菌 | 假单胞菌 |
| | Phosphoinositide | Bacillus licheniformis | Pseudomonas sp. |
| | Phospholipase C | | |
| 25. | 磷脂酶 C | 地衣芽孢杆菌 | 苏云金芽孢杆菌 |
| | Phospholipase C | Bacillus licheniformis | Bacillus thuringiensis |
| 26. | 木聚糖酶 | 李氏木霉 | 柔曲高温多孢菌 |
| | Xylanase | Trichoderma reesei | Thermopolyspora flexuosa |
| 27. | 岩神冷州畤 | 黑曲霉 | 密粘褶菌 |
| 41. | 葡糖淀粉酶 Glucoamylase | 黒曲毎 Aspergillus niger | 置柏僧国 Gloeophyllum trabeum |
| | · | | |
| 28. | 脂肪酶 | 李氏木霉 | 尖孢镰刀菌 |
| | Lipase | Trichoderma reesei | Fusarhum oxysporum |
| 29. | 4-α-糖基转移酶 | 苍白空气芽孢杆菌 | |
| | 4-α- | Aeribacillus pallidus | |
| | glucanotransferase | | |

| 30 | 磷脂酶 A1 | 米曲霉 | 红聚颈腔菌 |
|----|--------------------|-----------------------------|---|
| | Phospholipase A1 | Aspergillus oryzae | Valsaria rubricosa |
| 31 | 麦芽糖淀粉酶 | 地衣芽孢杆菌 | 嗜热脂解地芽孢杆菌 |
| | Maltogenic amylase | Bacillus licheniformis | Geobacillus stearothermophilus |
| 32 | 葡糖氧化酶 | 李氏木霉 | 尼崎青霉菌 |
| | Glucose oxidase | Trichoderma reesei | Penicillium amagasakiense |
| 33 | 脂肪酶 | 李氏木霉 | 黑曲霉塔宾变种 |
| | Lipase | Trichoderma reesei | Aspergillus niger var. tubingensis |
| 34 | β-葡聚糖酶 | 枯草芽孢杆菌 | 枯草芽孢杆菌 |
| | β-glucanase | Bacillus subtilis | Bacillus subtilis |
| 35 | 蛋白酶 | 枯草芽孢杆菌 | 克劳氏碱性卤杆菌 |
| | Protease | Bacillus subtilis | Alkalihalobacillus clausii |
| 36 | 海藻糖酶 | 李氏木霉 | 李氏木霉 |
| | Trehalase | Trichoderma reesei | Trichoderma reesei |
| 37 | 磷脂酶 A1 | 黑曲霉 | Talaromyces |
| | Phospholipase A1 | Aspergillus niger | leycettanus |
| 38 | 葡糖氧化酶 | 黑曲霉 | 产黄青霉 |
| | Glucose oxidase | Aspergillus niger | Penicillium chrysogenum |
| 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 | 黑曲霉 | 塔宾曲霉 |
| | Phytase | Aspergillus niger | Aspergillus tubingensis |
| 41 | 乳糖酶 | 黑曲霉 | 米曲霉 |
| | Lactase | Aspergillus niger | Aspergillus oryzae |
| 42 | 氨基肽酶 | 米曲霉 | 米曲霉 |
| | Aminopeptidase | Aspergillus oryzae | Aspergillus oryzae |
| 43 | 蛋白酶 | 李氏木霉 | 樟绒枝霉 |
| | Protease | Trichoderma reesei | Malbranchea sulfurea |
| 44 | 磷脂酶 A2 | 李氏木霉 | 烟曲霉 |
| | Phospholipase A2 | Trichoderma reesei | Aspergillus fumigatus |
| 45 | 麦芽糖淀粉酶 | 酿酒酵母 | 嗜热脂解地芽孢杆菌 |
| | Maltogenic amylase | Saccharomyces cerevisiae | Geobacillus stearothermophilus |
| 46 | 木聚糖酶 | 地衣芽孢杆菌 | 地衣芽孢杆菌 |
| | Xylanase | Bacillus licheniformis | Bacillus licheniformis |

| 47 | 羧肽酶 Carboxypeptidase | 米曲霉 Aspergillus oryzae | 米曲霉 Aspergillus oryzae |
|---|--|---|--|
| 48 | 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 | 溶血磷脂酶(磷脂酶 B) | Lysophospholipase (lecithinase B)李氏木霉 | Trichoderma reesei Aspergillus nishimurae |
| 50 | 丝氨酸蛋白酶 Serine protease | 地衣芽孢杆菌 Bacillus licheniformis | 葱绿拟诺卡氏菌 Nocardiopsis prasina |
| 51 (newly approved in March 2024) | 甜菊糖苷 Enzymatically produced steviol glycosides | 大肠杆菌 BL21 (DE3) Escherichia coli BL21 (DE3) | 甲基杆(Methylocaldum Szegediense),甜叶菊 (Stevia rebaudiana Bertoni)和马铃薯 (Solanum tuberosum) |
| 52(newly approved in March 2024) | D-阿洛酮糖-3-差向 异构酶 D-psicose 3- epimerase | 枯草芽孢杆菌 Bacillus subtilis | 闪烁梭菌 ATCC35704 Clostridium scindens ATCC35704 |
| 53(newly approved in March 2024) | 环糊精葡萄糖苷转 移酶 Cyclomaltodextin glucanotransferase | 热解蛋白无氧芽 孢杆菌 Anoxybacillus caldiproteolyticus | |
| 54(newly approved in March 2024) | 纤维素酶 Cellulase | 草酸青霉 Penicillium oxalicum | |

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 new <u>GB2760-2024</u> was released in March 2024 and will enter into force on February 8, 2025.

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). On February 8, 2024, NHC and SAMR jointed released the revised GB 1886.174-2024 (link in Chinese), which came into effect on August 8, 2024.

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

China: Cotton Exports (HS 520100)

| | | , | | |
|------------------|------------------------------|------|------|----------------|
| Donto on Country | Quantity (1,000 Metric Tons) | | | |
| Partner Country | 2021 | 2022 | 2023 | 2024 (JanAug.) |
| World | 9 | 34 | 7 | 12 |
| Bangladesh | 0 | 15 | 3 | 3 |
| Vietnam | 7 | 10 | 2 | 5 |
| Malaysia | 0 | 1 | 1 | 0 |
| Thailand | 1 | 0 | 0 | 0 |
| Indonesia | 1 | 1 | 0 | 1 |

China: Cotton Imports (HS 520100)

| Doute on Conneture | Quantity (1,000 Metric Tons) | | | |
|--------------------|------------------------------|-------|-------|----------------|
| Partner Country | 2021 | 2022 | 2023 | 2024 (Jan-Aug) |
| World | 2,116 | 1,927 | 1,950 | 2,143 |
| United States | 822 | 1,132 | 752 | 823 |
| Brazil | 637 | 577 | 572 | 900 |
| India | 399 | 31 | 36 | 73 |
| Australia | 32 | 20 | 271 | 175 |
| Sudan | 26 | 22 | 52 | 16 |

China: Corn Imports (HS 100590)

| Doute on Country | Quantity (Million Metric Tons) | | | |
|------------------|--------------------------------|-------|-------|----------------|
| Partner Country | 2021 | 2022 | 2023 | 2024 (Jan-Aug) |
| World | 28.35 | 20.62 | 27.12 | 12.52 |
| Brazil | 0 | 0 | 12.81 | 5.76 |
| United States | 19.83 | 14.86 | 7.14 | 2.04 |
| Ukraine | 8.2 | 5.26 | 5.51 | 4.45 |

China: Soybean Imports (HS 120190)

| Cima: Soystan Imports (IIS 120150) | | | | |
|------------------------------------|--------------------------------|-------|-------|----------------|
| Partner Country | Quantity (Million Metric Tons) | | | |
| Farmer Country | 2021 | 2022 | 2023 | 2024 (Jan-Aug) |
| World | 95.72 | 89.22 | 98.61 | 70.48 |
| Brazil | 58.06 | 54.39 | 69.93 | 53.80 |
| United States | 31.62 | 27.80 | 23.48 | 12.84 |
| Argentina | 3.71 | 3.52 | 1.95 | 1.62 |
| Canada | 0.59 | 0.72 | 1.47 | 0.99 |
| Uruguay | 0.87 | 1.79 | 0 | 0.45 |
| Russia | 0.55 | 0.69 | 1.29 | 0.50 |

Note: This is using PRC customs data. USDA revised its trade figures for soybean imports for MY2022/23. Please see the 2024 Oilseeds and Products Annual for more information.

China: Distillers Dried Grains Imports (HS 230330)

| Doute on Country | Quantity (1,000 Metric Tons) | | | |
|------------------|------------------------------|------|------|----------------|
| Partner Country | 2021 | 2022 | 2023 | 2024 (Jan-Aug) |
| World | 307 | 83 | 137 | 178 |
| United States | 307 | 83 | 137 | 178 |

China: Rapeseed Imports (HS 12051090)

| Donto on Country | Quantity (1,000 Metric Tons) | | | |
|------------------|------------------------------|-------|------|----------------|
| Partner Country | 2021 | 2022 | 2023 | 2024 (Jan-Aug) |
| World | 2,531 | 1,868 | 5050 | 3,225 |
| Canada | 2,438 | 1,868 | 5050 | 3,225 |
| Australia | 93 | 0 | 0 | 0 |
| Russia | 1 | 0 | 0 | 0 |

China: Rapeseed Meal Imports (HS 230641)

| D G | Quantity (1,000 Metric Tons) | | | |
|-------------------------|------------------------------|-------|-------|----------------|
| Partner Country | 2021 | 2022 | 2023 | 2024 (Jan-Aug) |
| World | 2,032 | 2,213 | 2,353 | 1,815 |
| Canada | 1,579 | 1,736 | 1,723 | 1,318 |
| United Arab Emirates | 418 | 430 | 438 | 348 |

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

| Donton Country | Quantity (1,000 Metric Tons) | | | |
|-------------------------|------------------------------|-------|-------|-----------------|
| Partner Country | 2021 | 2022 | 2023 | 2024 (Jan-Aug.) |
| World | 2,153 | 1,061 | 2,359 | 1,166 |
| Russia | 339 | 545 | 1,338 | 674 |
| United Arab Emirates | 366 | 185 | 284 | 187 |
| Canada | 914 | 227 | 122 | 0 |

China: Sugar Beet Pulp Imports (HS 230320)

| enna. Sugar Beet 1 dip imports (115 250520) | | | | | |
|---|------------------------------|------|------|----------------|--|
| Partner Country | Quantity (1,000 Metric Tons) | | | | |
| | 2021 | 2022 | 2023 | 2024 (Jan-Aug) | |
| World | 404 | 317 | 436 | 380 | |
| Egypt | 350 | 256 | 218 | 37 | |
| Russia | 37 | 55 | 214 | 343 | |
| Ukraine | 17 | 6 | 3 | 0 | |

Source: Trade Data Monitor, LLC using data from PRC customs.

Appendix 2: Biotech Crops Approved for Import as Processing Materials

| | Appendix 2. Diotecti Crops Approved for Import as Frocessing Waterials | | | |
|----|--|-------------------------|--|--------------------------------|
| No | Event | Approval Issued Date | Developer | Biosafety certificate validity |
| 1 | Trans-cry1Ac and cry2Ab2 insect resistant cotton MON15985 (renewal) | July 20, 2006 | Bayer | Jan. 2, 2024-Jan.1, 2029 |
| 2 | Trans-mvip3Aa and pat genes insect resistant and herbicide tolerant soybean DBN8002 (new approval in January 2024) | January 2, 2024 | Beijing DaBeiNong Biotechnology Co., Ltd. | Jan. 2, 2024-Jan.1, 2029 |
| 3 | Trans- zmm28 and mo-pat genes herbicide tolerant corn DP202216 (new approval in January 2024) | January 2, 2024 | Pioneer International Seed Company* | Jan. 2, 2024-Jan.1, 2029 |
| 4 | Trans bar, barnase and barstar genes tolerant to herbicides, improved canola MS11 | September 28, 2023 | BASF | Sept. 28, 2023-Sept. 27, 2028 |
| 5 | Icotton GHB811 (new approval in January 2023) | January 5, 2023 | BASF | Jan. 5, 2023-Jan.4, 2028 |
| 6 | 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 |
| 7 | 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 |
| 8 | 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 |
| 9 | 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 |
| 10 | 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 |
| 11 | 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 |
| 12 | 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 |
| 13 | HaHB4 genetically resistant soybean IND-ØØ41Ø-5 | April 22, 2022 | Rosario Agricultural Biotechnology Institute Inc. (Bioceres) | Apr. 22, 2022-Apr.21, 2027 |
| 14 | Transgenic cp4epsps Herbicide Tolerant Soybean MON89788 (renewal) | August 28, 2008 | Bayer CropScience | Apr. 22, 2022-Apr.21, 2027 |

| 15 | Transgenic Insect-Resistant Soybean | December 2, | Corteva | Apr. 22, 2022-Apr.21, 2027 |
|----|--|----------------------|--|--------------------------------|
| | DAS-81419-2 (renewal) | 2019 | 0 0 2 1 0 7 10 | 11911 22, 2022 1191121, 2027 |
| 16 | Transgenic improves soybean quality traits 305423 (renewal) | November 3, 2011 | Corteva | Apr. 22, 2022-Apr.21, 2027 |
| 17 | Herbicide-tolerant soybean 305423×GTS40-3-2 Advance (renewal) | December 11, 2014 | Corteva | Apr. 22, 2022-Apr.21, 2027 |
| 18 | Herbicide Tolerant Soybean A5547-127 (renewal) | December 11, 2014 | BASF | Apr. 22, 2022-Apr.21, 2027 |
| 19 | Herbicide Tolerant Corn T25 (renewal) | April 6, 2004 | BASF | Apr. 22, 2022-Apr.21, 2027 |
| 20 | Herbicide-tolerant sugar beet H7-1 (renewal) | April 20, 2009 | Bayer CropScience Kowalsch Seeds Europe AG | Apr. 22, 2022-Apr.21, 2027 |
| 21 | Herbicide tolerant oilseed Canola Ms8Rf3 (renewal) | April 6, 2004 | BASF | Apr. 22, 2022-Apr.21, 2027 |
| 22 | Herbicide-tolerant Canola T45 (renewal) | April 6, 2004 | BASF | Apr. 22, 2022-Apr.21, 2027 |
| 23 | Terbicide-tolerant Canola Oxy-235 (renewal) | April 6, 2004 | BASF | Apr. 22, 2022-Apr.21, 2027 |
| | Insect resistant corn MON810(renewal) | February 20, 2004 | Bayer CropScience | Dec.17, 2021 - Dec.16, 2026 |
| 25 | Drought Tolerant corn MON87460 (renewal) | May 21, 2013 | Bayer CropScience | Dec.17, 2021 - Dec.16, 2026 |
| 26 | Insect resistant and herbicide tolerance corn MON88017 (renewal) | December 20, 2007 | Bayer CropScience | Dec.17, 2021 - Dec.16, 2026 |
| 27 | Insect resistant corn MON89034 (renewal) | December 30, 2010 | Bayer CropScience | Dec.17, 2021 - Dec.16, 2026 |
| 28 | Herbicide tolerant corn NK603 (renewal) | July 8, 2005 | Bayer CropScience | Dec.17, 2021 - Dec.16, 2026 |
| 29 | Herbicide tolerant soybean GTS40-3-2 (renewal) | February 20, 2004 | Bayer CropScience | Dec.17, 2021 - Dec.16, 2026 |
| 30 | Insect resistant soybean MON 87701 (renewal) | June 6, 2013 | Bayer CropScience | Dec.17, 2021 - Dec.16, 2026 |
| 31 | Quality-Improved Soybean MON 87769 (renewal) | December 31, 2015 | Bayer CropScience | Dec.17, 2021 - Dec.16, 2026 |

| 32 | Insect resistant soybean MON87701 x MON89788 (renewal) | June 6, 2013 | Bayer CropScience | Dec.17, 2021 - Dec.16, 2026 |
|----|---|----------------------|--------------------------|-----------------------------|
| 33 | Herbicide tolerant Soybean MON 87708 (renewal) | December 31, 2015 | Bayer CropScience | Dec.17, 2021 - Dec.16, 2026 |
| 34 | Herbicide tolerant Canola GT73 (renewal) | April 6, 2004 | Bayer CropScience | Dec.17, 2021 - Dec.16, 2026 |
| 35 | Herbicide tolerant canola MON 88302 (renewal) | December 20, 2018 | Bayer CropScience | Dec.17, 2021 - Dec.16, 2026 |
| 36 | Pest resistant and herbicide tolerant corn DP4114 (renewal) | December 20, 2018 | Corteva Agriscience | Dec.17, 2021 - Dec.16, 2026 |
| 37 | Insect resistant corn 59122 (renewal) | December 20, 2006 | Corteva Agriscience | Dec.17, 2021 - Dec.16, 2026 |
| 38 | Insect resistant corn TC1507 (renewal) | April 6, 2004 | Corteva Agriscience | Dec.17, 2021 - Dec.16, 2026 |
| 39 | Herbicide tolerant Soybean CV127 (renewal) | June 6, 2013 | BASF AgriChem | Dec.17, 2021 - Dec.16, 2026 |
| 40 | Herbicide tolerant soybean A2704-12 (renewal) | December 20, 2007 | BASF Seed | Dec.17, 2021 - Dec.16, 2026 |
| 41 | Herbicide tolerance soybean DAS-44406-6 (renewal) | December 20, 2018 | Corteva Agriscience | Dec.17, 2021 - Dec.16, 2026 |
| 42 | Herbicide tolerant Canola Ms1Rf1 (renewal) | April 6, 2004 | BASF Seed | Dec.17, 2021 - Dec.16, 2026 |
| 43 | Herbicide tolerant Canola Ms1Rf2 (renewal) | April 6, 2004 | BASF Seed | Dec.17, 2021 - Dec.16, 2026 |
| 44 | Herbicide tolerant canola RF3 (renewal) | December 20, 2018 | BASF Seed | Dec.17, 2021 - Dec.16, 2026 |
| 45 | Herbicide tolerant Canola Topas19/2 (renewal) | April 6, 2004 | BASF Seed | Dec.17, 2021 - Dec.16, 2026 |
| 46 | Insect resistant corn Bt11 (renewal) | April 6, 2004 | Syngenta Crop Protection | Dec.17, 2021 - Dec.16, 2026 |
| 47 | Insect resistant corn BT176 (renewal) | April 6, 2004 | Syngenta Crop Protection | Dec.17, 2021 - Dec.16, |

| | | | | 2026 |
|----|--|----------------------|---|-------------------------------|
| 48 | Herbicide resistant corn GA21 (renewal) | February 20, 2004 | Syngenta Crop Protection | Dec.17, 2021 - Dec.16, 2026 |
| 49 | Quality improved corn 3272 (renewal) | May 21, 2013 | Syngenta Crop Protection | Dec.17, 2021 - Dec.16, 2026 |
| 50 | Insect resistant corn MIR604(renewal) | August 28, 2008 | Syngenta Crop Protection | Dec.17, 2021 - Dec.16, 2026 |
| 51 | Herbicide tolerance soybean SYHT0H2 (renewal) | December 20, 2018 | Syngenta Crop Protection, BASF Seed | Dec.17, 2021 - Dec.16, 2026 |
| 52 | Herbicide tolerant corn FG72(renewal) | December 31, 2016 | Syngenta Crop Protection | Dec.17, 2021 - Dec.16, 2026 |
| 53 | Pest resistant and herbicide tolerant corn MON87411 (renewal) | December 29, 2020 | Bayer CropScience | Dec. 29, 2020-Dec. 28, 2025 |
| 54 | Pest resistant and herbicide tolerant corn MZIR098 (renewal) | December 29, 2020 | Syngenta Crop Protection | Dec. 29, 2020-Dec. 28, 2025 |
| 55 | Soybean DBN-09004-6 (renewal) | Jun. 11, 2020 | Beijing DaBeiNong Biotechnology Co., Ltd. | Jun. 11, 2020-Jun. 11, 2025 |
| 56 | Insect-Resistant soybean MON87751 (renewal) | Jun. 11, 2020 | Monsanto Far East Ltd. | Oct. 8, 2024-Oct.7, 2029 |
| 57 | Herbicide-tolerant corn MON87427 (renewal) | July 16, 2017 | Monsanto Far East Ltd. | Oct. 8, 2024-Oct.7, 2029 |
| 58 | Virus Resistant Papaya 55-1 | December 2, 2019 | USDA ARS, Pacific Basin Agricultural Research Center, University of Hawaii | Dec. 02, 2019-Dec. 02, 2022 |
| 59 | Improved quality soybean MON87705 (renewal) | June 12, 2017 | Monsanto Far East Ltd. | Oct. 8, 2024-Oct.7, 2029 |
| 60 | Herbicide resistant corn DAS-40278-9 (renewal) | June 12, 2017 | Dow AgroSciences | June 11, 2020-June 11, 2025 |
| 61 | Insect resistance and herbicide tolerance corn Bt11×GA21 (renewal) | November 3, 2011 | Syngenta Crop Protection | June 11, 2020-June 11, 2025 |
| 62 | Insect resistance corn MIR162 (renewal) | December 11, 2014 | Syngenta Crop Protection | June 11, 2020 – June 11, 2025 |
| 63 | Insect resistant corn 5307 (renewal) | July 16, 2017 | Syngenta Crop Protection | June 11, 2020 – June 11, |

| | | | | 2025 |
|----|---|----------------------|--------------------------|-----------------------------|
| 64 | Insect resistant cotton DAS-24236-5 (new approval in December 2021) | December 17, 2021 | Corteva Agriscience | Dec. 17, 2021-Dec. 16, 2026 |
| | Insect resistant cotton DAS-21023-5 (new approval in December 2021) | December 17, 2021 | Corteva Agriscience | Dec.17, 2021-Dec. 16, 2026 |
| 66 | Herbicide tolerant cotton 1445 (renewal) | February 20, 2004 | Bayer CropScience | Dec.17, 2021 - Dec.16, 2026 |
| 67 | Herbicide tolerant Flex cotton MON 88913 (renewal) | December 20, 2007 | Bayer CropScience | Dec.17, 2021 - Dec.16, 2026 |
| 68 | Insect resistant cotton 531(renewal) | February 20, 2004 | Bayer CropScience | Dec.17, 2021 - Dec.16, 2026 |
| 69 | Insect resistant cotton 15985 (renewal) | July 20, 2006 | Monsanto Far East Ltd. | Dec. 02, 2019-Dec. 02, 2024 |
| 70 | Herbicide tolerant cotton GHB614 (renewal) | December 30, 2010 | BASF | Dec. 29, 2020-Dec. 28, 2025 |
| 71 | Insect resistant cotton COT102 (renewal) | December 31, 2015 | Syngenta Crop Protection | Dec. 29, 2020-Dec. 28, 2025 |
| 72 | Herbicide tolerant cotton LLCotton25 (renewal) | December 20, 2006 | BASF | Dec. 29, 2020-Dec. 28, 2025 |
| | Insect resistant and herbicide tolerant cotton GHB119 (renewal) | April 10, 2014 | BASF | Jan. 5, 2023-Jan.4, 2028 |
| | Insect resistant and herbicide tolerant cotton T304-40 (renewal) | April 10, 2014 | BASF | Jan. 5, 2023-Jan.4, 2028 |
| 75 | Insect resistant corn MON863 (renewal) | June 25, 2004 | Monsanto | Certificate expired |
| 76 | 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 | (expanded to South China | July 20, 2006, renewed in 2010, 2015 and 2020; current certificate valid for Dec. 29, 2020-Dec. 28, 2025 |
| 5 | Transgenic CP gene disease-resistant papaya YK1601 | Institute of Tropical Biotechnology, Chinese Academy of Tropical Agricultural Sciences | South China | Approved in December 2018, renewed in October 2024; current certificate valid for Oct. 8-Oct.7, 2029 |
| 6 | Pest resistant and herbicide tolerant corn DBN9936 | Beijing DaBeiNong Biotechnology Co., Ltd. | North China spring corn area | Dec. 2, 2019 – Dec. 2, 2024 |
| 7 | 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 |
| 8 | 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 |

| 9 | Pest-resistant and herbicide tolerant corn Ruifeng 125 | Hangzhou Ruifeng Biotechnology Co. | Northwest corn area | Feb. 10, 2021-Feb. 9, 2026 |
|----|--|--|--|----------------------------------|
| 10 | Herbicide-resistant soybean SHZD32-01 | Shanghai Jiaotong University | South China soybean area | Dec. 2, 2019 – Dec. 2, 2024 |
| 11 | Herbicide-tolerant corn DBN 9858 | Beijing DaBeiNong Biotechnology Co., Ltd. | North China spring corn area | Jun. 11, 2020 – June 11, 2025 |
| 12 | Herbicide-tolerant soybean Zhonghuang 6106 | Crop Science Institute of CAAS | Isovnean | Jun. 11, 2020 – June 11, 2025 |
| 13 | Herbicide-tolerant soybean Zhonghuang 6106 | Crop Science Institute of CAAS | North China spring soy area | Feb. 10, 2021-Feb. 9, 2026 |
| 14 | 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 |
| 15 | Herbicide-tolerant corn DBN 9858 | Beijing DaBeiNong Biotechnology Co., Ltd. | South China corn area | Dec. 29, 2020-Dec. 28, 2025 |
| 16 | Herbicide-tolerant corn DBN 9858 | Beijing DaBeiNong Biotechnology Co., Ltd. | Southeast China corn area | Dec. 29, 2020-Dec. 28, 2025 |
| 17 | Herbicide-tolerant corn DBN 9858 | Beijing DaBeiNong Biotechnology Co., Ltd. | Northwest corn area | Dec. 29, 2020-Dec. 28, 2025 |
| 18 | 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 |
| 19 | Pest resistant and herbicide tolerant corn DBN 9936 | Beijing DaBeiNong Biotechnology Co., Ltd. | South China corn area | Dec. 29, 2020-Dec. 28, 2025 |
| 20 | Pest resistant and herbicide tolerant corn DBN 9936 | Beijing DaBeiNong Biotechnology Co., Ltd. | Southeast China corn area | Dec. 29, 2020-Dec. 28, 2025 |
| 21 | Pest resistant and herbicide tolerant corn DBN 9936 | Beijing DaBeiNong Biotechnology Co., Ltd. | Northwest corn area | Dec. 29, 2020-Dec. 28, 2025 |
| 22 | Pest-resistant and herbicide tolerant corn DBN9501 | Beijing DaBeiNong | North China spring corn | Dec. 29, 2020-Dec. 28, 2025 |

| | | Biotechnology Co., Ltd. | area | |
|----|---|---|---|-----------------------------|
| 23 | Herbicide tolerant soybean DBN9004 | Beijing DaBeiNong Bioechnology Co., Ltd. | North China spring soybean area | Dec. 29, 2020-Dec. 28, 2025 |
| 24 | Pest resistant corn ND207 (GMO formerly known as "2A-7") | | North China spring corn area | Dec. 17,2021-Dec. 16. 2026 |
| 25 | 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 region | Dec. 17,2021-Dec. 16. 2026 |
| 26 | 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 |
| 27 | 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 |
| 28 | Herbicide resistant corn nCX-1 transgenic CdP450 and cp4epsps | Hangzhou Ruifeng Biotechnology Co., Ltd. | South China corn area | Apr. 22, 2022-Apr.21, 2027 |
| 29 | Pest resistant and herbicide tolerant corn Bt11xGA21 | China Seed Group Co., Ltd. | North China spring corn area | Apr. 22, 2022-Apr.21, 2027 |
| 30 | 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 |
| 31 | Hherbicide-tolerant corn GA21 | China Seed Group Co., Ltd. | North China spring corn area | Apr. 22, 2022-Apr.21, 2027 |
| 32 | Trans- cry1Ab, cry1F and cp4epsp gene insect- resistant and herbicide tolerant corn BFL4-2 | Yuanlongping Agricultural High Technology Company; Institute of Biotechnology, Chinese Academy of Agricultural Sciences | North Spring Corn Area | Jan. 5, 2023-Jan.4, 2028 |
| 33 | Trans- maroACC gene herbicide tolerant corn CC-2 | China Forestry Seed Group Co., Ltd. | North Spring Corn Area | Jan. 5, 2023-Jan.4, 2028 |

| | | China Agricultural University | | |
|----|--|--|--|----------------------------|
| 34 | Trans- cry1Ab/vip3Da gene insect-resistant soybean CAL16 | Shanghai Academy of | South Soybean Area | Jan. 5, 2023-Jan.4, 2028 |
| 35 | Trans-mvip3Aa and pat genes insect resistant and herbicide tolerance soybean DBN8002 | | Huanghuaihai Summer Soybean Area | Apr. 21, 2023-Apr.20, 2028 |
| 36 | Trans cry1Ab and epsps genes insect resistant and herbicide tolerant corn DBN9936 (renewal) | Beijing DaBeiNong Biotechnology Co., Ltd. | National wide | Jan. 2, 2024-Jan.1, 2029 |
| 37 | Trans cry1Ab/cry2Aj gene insect resistant corn Ruifeng 125 (renewal) | Biotechnology Co, Ltd. | Northern spring corn area, northwest corn area, Huanghuaihai summer corn area | Jan. 2, 2024-Jan.1, 2029 |
| 38 | Polymer cry1Ab, epsps, vip3Aa19, pat gene insect resistant and herbicide tolerant corn DBN3601T (new approval in January 2024) | Beijing DaBeiNong Biotechnology Co., Ltd. | National wide | Jan. 2, 2024-Jan.1, 2029 |
| 39 | Transgenic CdP450 and cp4epsps genes herbicide tolerant corn nCX-1 (new approval in January 2024) | Hangzhou Ruifeng Biotechnology Co, Ltd. | National wide | Jan. 2, 2024-Jan.1, 2029 |
| 40 | Polymer cry1Ab, pat, mepsps gene insect resistant and herbicide resistant corn Bt11×GA21 (new approval in January 2024) | China Seed Group Co., Ltd. | National wide | Jan. 2, 2024-Jan.1, 2029 |
| 41 | Polymer cry1Ab, pat, vip3Aa20, mepsps gene insect resistant and herbicide-resistant corn Bt11×MIR162×GA21 (new approval in January 2024) | China Seed Group Co., Ltd. | National wide | Jan. 2, 2024-Jan.1, 2029 |
| 42 | Trans mepsps gene herbicide tolerant corn GA21 (new approval in January 2024) | China Seed Group Co., Ltd. | National wide | Jan. 2, 2024-Jan.1, 2029 |
| 43 | Trans epsps and pat genes to herbicide tolerant soybean DBN9004 (new approval in January 2024) | Beijing DaBeiNong Biotechnology Co., Ltd. | National wide | Jan. 2, 2024-Jan.1, 2029 |
| 44 | Trans cry1Ab/vip3Da gene insect resistant soybean | Hangzhou Ruifeng | National wide | Jan. 2, 2024-Jan.1, 2029 |

| | CAL16 (new approval in January 2024) | Biotechnology Co, Ltd. | | |
|----|---|--|---------------|--------------------------|
| 45 | Trans g2-epsps and gat genes herbicide resistant soybean Zhonghuang 6106 (new approval in January 2024) | Crop Sciences Institute of Chinese Academy of Agricultural Sciences, China Seed Group Co., Ltd. | National wide | Jan. 2, 2024-Jan.1, 2029 |
| 46 | Polymer cry1Ab, cry2Ab, CdP450, cp4epsps gene insect resistant and herbicide tolerant corn Zhejiang University Ruifeng 8×nCX-1 (new approval in January 2024) | Hangzhou Ruifeng Biotechnology Co, Ltd. | National wide | Jan. 2, 2024-Jan.1, 2029 |
| 47 | Polymer cry1Ab/cry2Aj, g10evo-epsps, CdP450, cp4epsps gene insect resistant and herbicide tolerant corn Ruifeng 125×nCX-1 (new approval in January 2024) | Hangzhou Ruifeng Biotechnology Co, Ltd. | National wide | Jan. 2, 2024-Jan.1, 2029 |
| 48 | Trans cry2Ab, cry1Fa, cry1Ab and epsps genes insect resistant and herbicide tolerant corn LP026-2(new approval in January 2024) | Longping Biotechnology (sea south) Co., Ltd. | National wide | Jan. 2, 2024-Jan.1, 2029 |
| 49 | Trans epsps and pat genes herbicide tolerant corn LW2-1 (new approval in January 2024) | Longping Biotechnology (sea south) Co., Ltd. | National wide | Jan. 2, 2024-Jan.1, 2029 |
| 50 | Trans am79epsps gene herbicide tolerant corn WYN17132 (new approval in January 2024) | Zhejiang Xin'an Chemical Group Co., Ltd. | National wide | Jan. 2, 2024-Jan.1, 2029 |
| 51 | Trans cry1Ab and am79epsps genes insect resistance and herbicide tolerance Corn WYN041 (new approval in January 2024) | Zhejiang Xin'an Chemical Group Co., Ltd. | National wide | Jan. 2, 2024-Jan.1, 2029 |
| 52 | Trans cp4epsps gene herbicide tolerant soybeans WYN341GmC (new approval in January 2024) | Zhejiang Xin'an Chemical Group Co., Ltd. | National wide | Jan. 2, 2024-Jan.1, 2029 |
| 53 | Transg mam79epsps gene herbicide tolerant soybeans WYN029GmA (new approval in January 2024) | Zhejiang Xin'an Chemical Group Co., Ltd. | National wide | Jan. 2, 2024-Jan.1, 2029 |
| | Transfection of cry1Ab, cry3Bb and cp4epsps genesinto insect-resistant and herbicide-tolerant corn BBL2-2(new approval in May 2024) | Beijing Origen Seed Co., Ltd. Institute of Biotechnology, | National | May 7, 2024-May 6, 2029 |

| | Chinese Academy of Agricultural Sciences, Beijing Boai Yuanshang Biotechnology Co., Ltd. | | |
|--|--|--|--|
|--|--|--|--|

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 |
| 2 | Mutated GmELF3a gene to improve soybean physiological traits 25T93-1 (new approval in January 2024) | Shandong BellaGen Biotechnology Co., Ltd. | National wide | Jan. 2, 2024-Jan.1, 2029 |
| 3 | Mutated GmFAD2-1A and GmFAD2-1B gene to improve quality traits soybean P16 (new approval in January 2024) | Qi-Biodesign Biotechnology Company Limited | National wide | Jan. 2, 2024-Jan.1, 2029 |
| 4 | Mutated Br2 gene to improve yield traits maize 179AC19-13-13 (new approval in May 2024) | Shandong BellaGen Biotechnology Co., Ltd. | National | May 7, 2024-May 6, 2029 |
| 5 | Mutated TaMLO-A1, TaMLO-B1, TaMLO-D1 and TaMLOX genes in disease-resistant wheat MLO-KNRNP (new approval in May 2024) | Qi-Biodesign Biotechnology Company Limited the Institute of Genetic and Developmental Biology, China Academy of Sciences | National | May 7, 2024-May 6, 2029 |

Attachments:

No Attachments