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#### **Report Highlights:**

The People's Republic of China (PRC) is preparing for commercial cultivation of domestically developed genetically engineered (GE) crops. Key developments since the last report include regulatory changes to facilitate variety registration of GE crops for domestic cultivation, variety registration standards for GE corn and soybeans, and the PRC's first ever regulations on gene-edited plants. The PRC favors domestic biotech developers by prohibiting foreign investment in the sector and through its approval process which lacks transparency and predictability.

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#### **Executive Summary**

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

The PRC continues to prohibit foreign agricultural biotechnology developers' foreign direct investment in the biotech sector and 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." See Chapter 1, Part 1, sections a) and b) for additional information on the PRC's approval process.

Since the publication of the <u>2021 Agricultural Biotechnology Annual</u> report, the PRC has taken meaningful regulatory steps towards commercial cultivation of GE crops and in developing regulatory frameworks for gene-edited products. These include:

- On January 21, 2022, the Ministry of Agriculture and Rural Affairs (MARA) released its Decree No. 2 of 2022, announcing the revised Administrative Measures for the Safety Assessment of Agricultural GMOs. The finalized Measures, which were previously notified to the WTO under (SPS N CHN 1241), came into force on January 21, 2022. The Measures change the nature of biosafety assessments from being on a "crop variety and event" basis to solely on an "event" basis. The change facilitates variety registration of GE crop varieties for domestic cultivation and may provide for the biosafety assessment of GE crops containing "stacked" traits, according to industry sources.
- On January 24, 2022, MARA issued "Guidelines for Safety Evaluation of Gene-Edited Plants for Agricultural Use (Trial)", which for the first time establish application procedures and requirements for gene-edited plants. The Guidelines establish application procedures and requirements for genome-edited plants that do not introduce exogenous genes. The Guidelines define genome-edited plants for agricultural use as plants and their products obtained by targeted modification of specific genomic sites with genetic engineering technology, which are used for agricultural production or agricultural product processing. The Guidelines do not indicate a process for determining how to classify gene-edited products within each risk category, nor do they provide specific types of data accepted.
- On May 10, the National Development and Reform Commission (NDRC) issued the "14th Five-Year Plan for Bioeconomic Development," with the intention to accelerate breakthroughs and achieve scientific and technological self-reliance in four key areas of bioeconomic development, including bio-agriculture and bioenergy.
- June 8, 2022, the PRC's National Crop Variety Registration Committee (NCVRC) published <u>National Registration Standards for Genetically Engineered Soybean Varieties</u> (Trial) and National Registration Standards for Genetically Engineered Corn Varieties

(<u>Trial</u>). The publication of these standards established a clear set of requirements for local developers applying for variety registration of GE corn and soybeans.

• On July 22, 2022, MARA published a revised "Guideline for Safety Assessment of Genetically Modified (GM) Plants" (hereafter referred to as "Guideline") for public comments. The Guideline aligns MARA's technical guidance with the January 2022 updated "Administrative Measures for the Safety Assessment of Agricultural GMOs." The Guideline applies to bio-safety certificate application for both domestic production (cultivation) and importation as processing materials. The draft Guideline strikes the word "variety" and replaces it with "plants" or "events". This revision aligns with language contained in the updated "Administrative Measures for the Safety Assessment of Agricultural GMOs", which modified the nature of biosafety assessments from being on a "crop variety and event" basis to solely an "event" basis. Additionally, the draft Guideline adds "sequence determination" as a method to analyze integration of an inserted sequence in plant genome. This language appears to open the possibility of utilizing next generation sequencing (NGS).

Since the publication of the <u>2021 Agricultural Biotechnology Annual</u> report, the PRC has issued two tranches of new and renewed biosafety certificates. These include:

- On December 27, 2021, MARA issued biosafety certificates for 34 biotech crops approved for import as processing materials (including two new GE cotton events and the renewal of 32 other events), and 31 certificates for domestic cultivation and production (including 16 renewed GE cotton events, two renewed animal vaccines, one renewed feed additive enzyme, eight new GE cotton events and four new GE corn events).
- On April 29, 2022, MARA issued biosafety certificates for 11 biotech crops approved for import as processing materials (including one new GE soybean event and the renewal of 10 other events), and 36 certificates for domestic cultivation and production (including 17 renewed GE cotton events, four new GE corn events, six renewed animal vaccines, and nine new animal vaccines).

The PRC does not accept safety testing data obtained by trials conducted outside of China without conducting verification trials, which duplicate most of the safety testing conducted in third countries. This remains a major concern for foreign developers and the international community because they incur additional costs and lose control over the timeline to conduct the trials and the trial results.

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

The below list contains links to all FAS China agricultural biotechnology related GAIN Reports issued since the publication of the 2021 China Agricultural Biotechnology Annual report:

1. Agricultural Biotechnology Annual 2021 CH2021-0128

- 2. <u>GE Crop Herbicide Use Rules for Registration Comments Invited CH2021-0158</u>
- 3. GE Corn and GE Soybean Varietal Registration Standards Open for Comment CH2021-0160
- 4. Agriculture GMOs Safety Assessment Administrative Measures Notified to the WTO CH2021-0165
- 5. Final Seed Law Published CH2021-0185
- 6. New and Renewed Biosafety Certificates Issued CH2022-0003
- 7. Planting Seed 2021 Annual CH2022-0005
- 8. Final Seed Regulations Published CH2022-0013
- 9. Agriculture GMOs Safety Assessment Administrative Measures Finalized CH2022-0014
- 10. MARA Issues First Ever Gene-Editing Guidelines CH2022-0015
- 11. Supreme People's Court Strengthens Seed Variety Protections CH2022-0031
- 12. MARA Issues Additional New and Renewed Biosafety Certificates CH2022-0059
- 13. Agriculture Key Component of Bio-economy Five-Year Plan CH2022-0065
- 14. New Food Materials and Additives including GMM Derived Enzymes Approved CH2022-0069
- 15. GE Soybean and Corn Variety Standards Issued | CH2022-0070
- 16. <u>PRC Approves New Food Materials and Additives including GMM Derived Enzymes</u> <u>CH2022-0071</u>
- 17. <u>PRC Issues Draft Guideline for Safety Assessment of Genetically Modified Plants for</u> <u>Comments - Short Deadline CH2022-0084</u>

## Chapter 1: Plant Biotechnology

## Part A: Production and Trade

#### a) Research and Product Development

Despite decades of research by Chinese biotech developers, China has not commercialized any GE products, with the exception of cotton and papaya. However, local developers have applied for and received biosafety certificates for the cultivation of GE rice, corn, and soybeans in regions across China (see Appendix 3 for a list of biotech crops approved for cultivation). The commercialization of GE crops has hitherto been prevented by a lack of standards for GE products and regulations for GE crop variety registration. Over the past year, the PRC has significantly advanced its regulatory framework for the cultivation of GE crops and local developers now have a clear pathway towards cultivation for GE corn and soybeans.

Chinese developers have applied for safety approvals or approvals for cultivation abroad, and two Chinese developed traits have completed consultations with the U.S. Food and Drug Administration. In 2018, Huazhong Agricultural University completed its <u>consultation with the U.S. Food and Drug Administration on Huahui No.1 rice product</u>, which received a biosafety certificate from MARA in 2009 (the biosafety certificate was renewed in 2014 and 2021). On February 27, 2019, Beijing Da-Bei-Nong Technology Group, a private Chinese firm, <u>received approval from the Argentine government to cultivate its herbicide-resistant soybean</u> (DBN09004-6, link in Chinese) in Argentina. Following the approval in Argentina, this event obtained the biosafety certificate for food, feed, and processing (import) in China in June 2020, meaning it can be exported to China from Argentina.

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 and as

a critical aspect of China's productivity and food security. Recent examples include a special research program called the National Major Science and Technology Projects of China for Breeding New Biotech Varieties (the National Major Projects, 2006-2020) ended in 2020. The Projects received funding of 24 billion Yuan (approximately U.S. \$3.5 billion), half of which came from central and local governments, with the rest being private sector investment.

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

#### **b)** Commercial Production

MARA's 2016 roadmap for the commercialization of GE crops prioritized non-food use GE crops (such as cotton), then GE crops for indirect food use (such as soybeans and corn), and finally GE food use crops (such as rice and wheat). Since 1997, China has commercialized six GE products (cotton, tomato, sweet pepper, petunia, poplar, and papaya), but only papaya and cotton are in commercial production today. Recent regulatory measures indicate the PRC is moving towards commercial cultivation of corn and soybeans with some industry sources predicting GE corn and soybeans will receive variety registrations and be available to plant as early as Spring 2023.

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

The GE products approved for commercial production in China can be found on MARA's <u>website</u> for biotech (link in Chinese). Most biosafety certificates for cultivation are for domestically developed varieties of Bt cotton, which are approved for cultivation in three agroecological zones (Xinjiang, Yellow River Basin and Yangtze River Basin).

**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 2021, China exported 9,259 tons of cotton valued at \$21.5 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 2021, China exported 9,618 tons of papaya, valued at \$13 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 burdensome and unpredictable approval process for GE products imported for feed and processing poses numerous challenges for foreign developers. Additionally, China's lack of a low-level presence (LLP) policy may result in detained and rejected shipments, including those that may be considered "non-GMO". China does not allow the importation of GE seeds for commercial cultivation. Please refer to the "Import Approval Procedures" section of this report for additional information on the regulatory process for biosafety approval for importing GE products for feed and processing.

## e) Food Aid

China provides limited volumes of food aid, primarily corn, rice, and sorghum to Sub-Saharan African countries. China has not approved any major biotech food products for domestic cultivation, and all food aid is comprised of conventional products. China is not a recipient of food aid.

## f) Trade Barriers

China's prohibition of foreign investment in the biotechnology sector remains the most significant barrier to overseas companies. The <u>2021 Special Administrative Measures for Foreign</u> <u>Investment Access</u> (also known as the "Negative List", link in Chinese) was jointly issued by NDRC and MOFCOM on December 27, 2021. The Measures continue the prohibition on foreign biotech developers from conducting research or seed production in China.

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

China's regulatory approval process for GE traits includes several provisions that decrease the predictability and transparency of the regulatory review causing unnecessary delays and additional costs, particularly for foreign developers. These include requirements that events already be approved in their country of origin and requirements for environmental safety trials and feeding trials be conducted in China by MARA designated institutions. Throughout the review process, applicants are often subject to requests for additional material and data that can delay season sensitive plantings for field trials. Additionally, the National Biosafety Committee (NBC), which typically only convenes twice per year, frequently rejects applications or requests further information from developers resulting in some applications languishing for more than a

decade in the approval process. Subsequent applications are not reviewed by the same NBC panels and can result in new NBC members asking previously answered questions. Dates for NBC meetings are also closely held by MARA, with members themselves called to attend on short notice. Once approved by the NBC, applications must still undergo a final MARA review. Post contacts have reported that on numerous occasions, despite being approved by the NBC, MARA has returned applications to the review process for additional information.

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

## **Part B: Policy**

## a) Regulatory Framework

China's agricultural biotech regulatory framework is outlined in the State Council<sup>1</sup>'s "Administrative Rules for Safety of Agriculture GMOs" (issued in 2001 and revised in 2017). According to the Rules, MARA holds the primary responsibility for the approval of biotech products for import and domestic cultivation, as well as the development of agricultural biotech policies and regulations.

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

- Administrative Measures for the Safety Assessment of Agriculture GMOs (issued on January 5, 2002, revision issued on November 30, 2017 and January 21, 2022);
- Administrative Measures for Safety of Agriculture GMO Imports (issued on January 5, 2002; revision issued on November 30, 2017);
- Administrative Measures on Labelling of Agriculture GMOs (issued on January 5, 2002; and latest revision issued on November 30, 2017);
- Measures for the Review and Approval of Agricultural GMOs for Processing (issued on July 1, 2006);
- Technical guidance, standards, and procedures released through MARA public notices;
- AQSIQ Decree 62 "<u>Administrative Measures of Inspection and Quarantine on Entry-Exit</u> <u>GM Products</u>" (implemented on May 24, 2004, latest revision issued in April, 2018).

Legal term (in Chinese)	Legal term (in English)	Laws and Regulations where term is used	Lega Definition (in English)
农业转基因 生物	Agricultural genetically modified organisms (GMOs)	Administrative Rules for Safety of Agriculture GMOs	Agricultural genetically modified organisms refer to animals, plants, microorganisms and their products whose genetic structures have been modified by genetic engineering technology for the use of agricultural production or

<sup>&</sup>lt;sup>1</sup> The State Council is the chief administrative authority in China and 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.

			processing.
农业转基因 生物安全	The safety of agricultural GMOs	Administrative Rules for Safety of Agriculture GMOs	The safety of agricultural GMOs refers to the prevention of dangers or potential risks posed by agricultural GMOs to humans, animals, plants, microorganisms and the ecological environment.
基因工程技 术	Genetic engineering technologies	Administrative Measures for the Safety Assessment of Agriculture GMOs	Genetic engineering technologies: technologies that input reconstructed DNA molecules by using DNA reconstruction technology or by physical, chemical, or biological methods.
基因	Gene	Administrative Measures for the Safety Assessment of Agriculture GMOs	Gene: structural unit that controls the function of biological genetic substances, mainly referring to a DNA segment with genetic information.
基因组	Genetic group	Administrative Measures for the Safety Assessment of Agriculture GMOs	Genetic group: sum of chromosomes and non- chromosome genetic substances of a given organism.
目的基因	Purpose genes	Administrative Measures for the Safety Assessment of Agriculture GMOs	Purpose genes: genes that modify the genetic composition of receptor cells and deliver their genetic effect.
受体生物	Receptor organisms	Administrative Measures for the Safety Assessment of Agriculture GMOs	Receptor organisms: organisms into which reconstructed DNA molecules are input.
农业用基因 编辑植物	Gene-edited plants	Guidelines for Safety Evaluation of Gene-Edited Plants for Agricultural Use (Trial)	Gene-edited plants for agricultural use refer to plants and their products obtained by targeted modification of specific genomic sites with genetic engineering technology and used for agricultural production or agricultural product processing.

#### The National Biosafety Committee (NBC)

The NBC was established by MARA to conduct reviews of domestic and foreign applications for biosafety certificates for cultivation and import. The term limit of NBC members is five years. Members have diverse backgrounds in biotech research, production, processing, inspection/quarantine, food safety, and environmental protection. 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. MARA Decree 7 [2016] provides that the NBC shall

hold no less than two meetings per year and removed the deadlines for submitting the application for biosafety certificate for consideration before a meeting. The NBC's final recommendations are supposed to be released 20 working days after each meeting.

On December 7, 2021, <u>MARA announced the member list for the Sixth NBC</u> (link in Chinese), which is composed of 76 scientists.

#### Additional Responsibilities Held by MARA

In addition to its primary responsibility of approving biotech products for import and domestic production, MARA leads development of the overall government policy and technical guidance related to agricultural biotechnology. The National Technical Committee for the Standardization of Biosafety Management of Agricultural GMOs is responsible for drafting and revising technical standards for biotech products, including standards for safety assessments, testing, and detections. It consists of 41 experts from Chinese research institutes and universities. Similar to the NBC, the Development Center for Science and Technology (DCST), an affiliate of MARA, serves as the Committee's Secretariat.

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 across China that conduct environmental and food safety testing. MARA provincial level departments are responsible for monitoring field trials, GE plant processing facilities, the seed market, and labeling.

#### **Other Government Agencies**

- The General Administration of Customs of the People's Republic of China (GACC) is responsible for testing agricultural and food products for GE content at Chinese ports of entry.
- The National Forestry and Grassland Administration (NFGA) is responsible for the approval of forestry products for research, domestic production, and import based on its own biotech regulatory policies related to wood products.
- The Ministry of Ecology and Environment (MEE) is the lead agency in the negotiation and implementation of the Cartagena Biosafety Protocol, which China ratified on April 27, 2005.
- The Joint-Ministerial Conference for Biosafety Management of Agricultural Genetically Modified Organisms is an overarching coordinating body which meets irregularly to discuss and coordinate major issues in biosafety management of agricultural biotech products. The group consists of 12 government bodies under the State Council that include: MARA, MEE, GACC, Ministry of Science and Technology (MOST), NDRC, MOFCOM, the National Health Commission (NHC), and others.
- The State Administration for Market Regulation (SAMR) is the authority for comprehensive market oversight, law enforcement with respect of market supervision and administration, and coordination on the supervision and administration of food safety nationwide. When GE foods are distributed in the Chinese market, SAMR reviews the product labels to ensure compliance with labelling requirements.

#### **Import Approval Procedures**

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

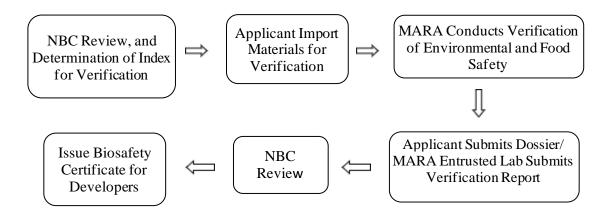
MARA is responsible for the review and issuance of biosafety certificates for imported biotech products for food, feed, and processing (FFP). The Administrative Measures for Safety of Agriculture GMO Imports outline the requirements for importing biotech products. The Measures require a foreign seed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

After receiving the application, MARA's GMO Biosafety Office will designate domestic institutions to conduct environmental safety (field trials) and food safety (feeding studies) tests to verify data provided by the seed developer. These tests are government funded. The reports generated from verification tests and application are then reviewed by the NBC.

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

MARA's guidance on the process, application form, on-line-application process, and status of applications can be found at the <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



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

Chinese importers must obtain a "Biosafety Certificate for Agricultural Biotechnology (Import)" for each consignment of a GE product that they intend to import. The MARA-issued certificate is given to the importer and presented to local Customs during the inspection and quarantine process. Each certificate can only be used for one consignment and is valid for six months after issuance. An importer is required to present the following materials to apply for the certificate:

- 1. Copy of the Biosafety Certificate for Agricultural Biotechnology (Import) Issued to Foreign Developers;
- 2. Registration for Safety Management of Agricultural Biotechnology Import (Used for Processing Materials) (the application form); and
- 3. Intended safety control measures.

Importers have informed foreign exporters that MARA's documentation requirements are nebulous and continue to increase. If MARA determines that an application complies with the requirements, they have 25 working days to review and issue the certificate.

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 traders can be submitted on-line.

#### **Domestic Cultivation Approval Procedures**

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

According to China's Seed Law, five major crops (rice, wheat, corn, cotton, and soybean) are subject to variety registration in China. The Administrative Measures for Major Crops Variety Registration released by MARA in July 2016 provides that the measures for variety registration of GE crops (except for GE cotton) will be developed (by MARA) separately. However, until 2022, MARA had not published standards for variety registration for major GE crops other than cotton.

On January 21, 2022, MARA published <u>Decree No. 2 of 2022</u>, which amended Administrative Measures for Major Crops Variety Registration. The amended Measures add application procedures and requirements for GE variety registration. They also amended the Administrative Measures for Crop Seed Production and Operation License with additional requirements for GE seed production and operation. These amendments, for the first time, provide a pathway for commercial cultivation of GE food crops in China. Please refer to <u>GAIN Report CH2022-0013</u> <u>Final Seed Regulations Published</u> for more information of the amendments of the regulations.

Following the updates to GE variety registrations, on June 8, 2022, the PRC's National Crop Variety Registration Committee (NCVRC) published the <u>National Registration Standards for</u>

<u>Genetically Engineered Soybean Varieties (Trial) and National Registration Standards for</u> <u>Genetically Engineered Corn Varieties (Trial)</u> (link in Chinese) with immediate effect. The publication of these standards established a clear set of requirements for local developers applying for variety registration of GE corn and soybeans; a further indication of the PRC's intention to move towards commercial cultivation of GE food crops in the near term. Please refer to <u>GAIN Report CH2002-0070 GE Soybean and Corn Variety Registration Standards Issued</u> for unofficial translations of the two standards.

## **b)** Approvals

Since the publication of the <u>2021 Agricultural Biotechnology Annual</u>, MARA has issued two tranches of new and renewed biosafety certificates. As required under the Phase One Agreement, the validity period of newly issued and renewed certificates is 5 years.

On December 27, 2021, MARA issued biosafety certificates for 34 GE crops approved for import as processing materials. These included two new GE cotton events and the renewal of 32 other events. On the same date MARA issued 31 biosafety certificates for domestic cultivation. These included 16 renewals for GE cotton events, two renewed animal vaccines, one renewed feed additive enzyme, eight new GE cotton events and four new GE corn events).

On April 29, 2022, MARA issued biosafety certificates for 11 GE crops approved for import as processing materials. These included one new GE soybean event and the renewal of 10 other events. On the same date MARA issued 36 certificates for domestic cultivation and production. These included 17 renewed GE cotton events, four new GE corn events, six renewed animal vaccines, and nine new animal vaccines.

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

## c) Stacked or Pyramided Event Approvals

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

The PRC requires field trials of biotech products for the purpose of import approval, research, and domestic cultivation, but it does not publicly release information on the number of field trials or types of products or traits tested. Industry contacts and media reports indicate that in 2021, MARA carried out various pilot projects in Inner Mongolia and Yunnan provinces for herbicide resistant soybeans and insect and herbicide resistant corn. Events from major local developers are believed to have been included in the pilot projects, including some corn and soybean events that received biosafety certificates for cultivation. For reference, see China Daily: <u>GM corn</u>, <u>soybean earn safety approval after pilot program</u>.

## e) Innovative Biotechnologies

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

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

#### f) Coexistence

The PRC does not have a coexistence policy.

#### g) Labeling and Traceability

The PRC's biotech labeling regulations, governed by the Administrative Measures on Labelling 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 11042300<sup>2</sup>);
- 3. Rapeseed for planting, rapeseeds, rapeseed oil, and rapeseed meal;
- 4. Cottonseed; and
- 5. Tomato seed, fresh tomato, and tomato paste.

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

<sup>&</sup>lt;sup>2</sup> According to the China's Customs Import and Export Tariff, HS codes 11022000, 11031300, and 11042300 refer to maize (corn) flour, corn groats/meal/pellets, and corn hulled/rolled/flaked/pearled/sliced/kibbled).

On July 27, 2020, the State Administration for Market Regulation (SAMR) issued revised <u>Measures on Supervision and Management of Food Labeling</u> for public comment. Article 25 of the draft requires that production and trading of genetically modified foods conspicuously mark the text "Genetically Modified" in food labeling. The Draft also prohibits labeling from emphasizing substances that are not contained or not added. For instance, foods not using GE food materials shall not be marked "GMO-free" or "non-GMO."

## h) Monitoring and Testing

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

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

Though not official guidance, scientists from the Chinese Academy of Inspection and Quarantine (CAIQ) and China Agricultural University (CAU) published a paper titled <u>A Universal</u> <u>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 a LLP policy for biotech imports. Considering the PRC's zero tolerance for unapproved biotech products in imports and the large volume of imported GE products, this is a significant barrier to trade. The PRC has participated in the Global LLP Initiative as an observer; most recently at the virtual meeting in 2020.

Under the <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 China also agreed to organize experts to conduct further studies on the issue of LLP and to collaborate internationally on practical approaches to addressing LLP.

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

## j) Additional Regulatory Requirements

Please refer to the <u>Annual China Seed Report available in the USDA GAIN report system</u> which covers seed variety registration issues and policy.

## k) Intellectual Property Rights (IPR)

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

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

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

Please refer to <u>GAIN Report CH2021-0185 Final Seed Law Published</u> for more information of the amended Seed Law.

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

## I) Cartagena Protocol Ratification

The PRC signed the Cartagena Protocol on Biosafety (CPB) to the United Nation's Convention on Biological Diversity in 2000 and ratified it in 2005. In 2011, the PRC announced that the protocol would also apply to the Hong Kong Special Administrative Region. As a party to the Protocol, the PRC adopted the <u>Biosecurity Law</u> on October 17, 2020. The Biosecurity Law came into force on 15 April 2021. China submitted <u>the Fourth National Reports on Implementation of</u>

<u>the Cartagena Protocol on Biosafety</u> in October 2019, covering China's implementation of CPB from September 2015 to September 2019.

Part I of the tenth meeting of the Conference of the Parties serving as the meeting of the Parties to the CPB was held October 11-15, 2021 (Online) in Kunming, China. Part II will be held on December 5-17, 2022, in Montreal, Canada. The MEE serves as the PRC's liaison agency and sends delegates to participates in the CPB convention.

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

#### m) International Treaties and Forums

In recent years, Chinese participants have attended virtual workshops as part of the APEC High Level Policy Dialogue on Agricultural Biotechnology (HLPDAB) but participation in most inperson international conferences remains limited due to the PRC's zero-COVID policy.

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

The annual U.S.-China High-Level Biotechnology Joint Working Group (BWG) was established in 2002 to address bilateral biotechnology issues of mutual interest and is attended by FAS and MARA. A Technical Working Group (TWG) was established in 2003 to supplement the policy discussions and is attended by the Animal and Plant Health Inspection Service, Food and Drug Administration, and Environmental Protection Agency and MARA. The location alternates between the U.S. and China. The most recent BWG and TWG meetings were held in 2018. The two sides exchanged updates regarding products under development and in the approval pipeline, revisions to regulations and rules in both countries, and other issues of interest. It remains to be seen if and when the next BGW and TWG may be held.

#### n) Related Issues

#### **Oversight and Enforcement**

Each year, MARA releases an annual Biosafety Oversight Working Plan that includes reports of detected violations. On February 28, 2022, MARA released its <u>2022 Biosafety Oversight</u> <u>Working Plan</u> (link in Chinese), which listed six key tasks: 1) Strengthen the supervision of research and experimentation; 2) Strictly supervising the South-breeding base in Sanya, Hainan province; 3) Strictly managing variety registration; 4) Strengthening the supervision of seed production and operation; 5) Strict import processing supervision; and 6) tracking and monitoring of the planting area. Previous incident report highlights include:

- 2021 There were nine cases reported, including four cases of illegal corn seed sales in Liaoning, Jilin, Heilongjiang and Xinjiang, four cases of research institutes/seed developers violating rules about cotton research and trials, and one case of research institute violating rules about GE wheat intermediate trials.
- 2019 MARA announced ten cases of violations to the agriculture biosafety rules, including four intermediary experiments (two corns and two cotton), and five cases of illegal production of corn seeds (in Shaanxi, Xinjiang, Heilongjiang, Liaoning, and Jilin). The last case was a grains/oil processing company, which spilt GE soy when it was transported from port to the processing facility.
- 2018- MARA announced seven cases of seed companies conducted trails of GE corns without proper registering/reporting with MOA.
- 2017 MARA announced eleven cases of research institutes conducting trials of GE corns, rice, and sugar cane without proper registering/reporting with MOA.

## Part C: Marketing

## a) Public/Private Opinions

After years of efforts by the PRC government addressing public misperceptions towards biotech through press conferences and training for journalists and local government officials, mainstream media reports about agriculture biotechnology appear neutral and rational. Both traditional and social media are being used to explain China's biosafety regulatory work to the public.

MARA is working with its peer ministries to eliminate misleading claims or statements in product labels and advertisements, particularly the claims on and labeling of vegetable oil products. With these efforts, false and misleading stories or articles circulating in the mainstream media are rare. Additionally, false stories on social media, and in on-line forums, are corrected in a timely basis.

Although false reports and stories are decreasing, concerns about biotechnology exist.

MARA is constantly requested to publicly disclose information on safety assessment applications and reviews. Members of the National People's Congress's Consultative Committee (NPC) require MARA to provide timely responses to their biotech inquiries.

## b) Market Acceptance/Studies

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

## **Chapter Two: Animal Biotechnology**

China is a leader in animal biotech research. The Key Scientific and Technological Grant of China for Breeding New Biotech Varieties was launched in 2008 and supports research on GE animal species including swine, cattle, and sheep. Despite heavy investment and advanced research, China has not approved any livestock clones, GE animals, or products derived from animal biotech for commercial use. Multiple Chinese research teams have announced progress in research of transplantation using organs from gene-edited pigs; in recent years, Chinese scientists have successfully cloned a variety of animals, including mules, cats, rats, and ferrets. The technology of feline cloning is expected to play a role in studying animal diseases, developing new drugs, and protecting endangered species.

#### Part D: Production and Trade

#### a) Product Development

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

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

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

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

#### **b)** Commercial Production

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

#### c) Exports

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

#### d) Imports

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

#### e) Trade Barriers

N/A

## **Part E Policy**

## a) Regulatory Framework

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

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

## **b)** Approvals

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

## c) Innovative Biotechnologies

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

## d) Labeling and Traceability

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

#### e) Additional Regulatory Requirements N/A.

## f) Intellectual Property Rights (IPR)

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

#### g) International Treaties and Forums

The PRC sends officials to high-level conferences for GE animals but mainly as observers. Chinese scientists maintain frequent and close contact with foreign peers. In May 2021, the 88<sup>th</sup> Annual General Session of the World Organization for Animal Health (OIE) was held virtually. Dr. Huang Baoxu, OIE Delegate from China and a researcher with the China Animal Health and Epidemiology Center (CAHEC), was elected chairman of OIE Regional Commission for Asia, the Far East and Oceania (AFEO) on May 28, 2021.

## h) Related Issues

N/A

## Part F: Marketing

#### a) Public/Private Opinions

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

#### b) Market Acceptance/Studies

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

#### **Chapter Three: Microbial Biotechnology**

At present, only enzymes produced from microbial biotechnology have a path to get approved in China. Since the issuance of the last biotech annual report, the NHC has approved the use of 12 such enzymes in two batches to be used as food additives in food production. The food ingredient industry, particularly multinationals in China, is actively seeking clarification from the PRC government about the regulatory process to approve other food ingredients derived from biotech sources, this is an agreed item in Annex 16 - Agricultural Biotechnology of the Economic and Trade Agreement.<sup>3</sup>

<sup>&</sup>lt;sup>3</sup> 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.

#### Part G: Production and Trade

#### a) Commercial Production

At present, the PRC only reviews applications for food enzymes produced from microbial biotechnology that are composite products made with microbial biotechnology where the biotech microbe has been removed, such as enzyme preparations used in food processing. Once approved, there is no distinction between enzymes produced through biotech microbes versus conventional production methods (e.g., natural extraction, chemical synthesis, etc.).

#### b) Exports

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

#### c) Imports

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

#### d) Trade Barriers

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

## Part H: Policy

## a) Regulatory Framework

## Applying for Approval of Enzymes Derived from Microbial Biotechnology

The application process for the approval of new varieties of enzymes is the same as that for new varieties of food additives. An application should be submitted to the NHC pursuant to the Administrative Measures for New Variety of Food Additives [Ministry of Health (MOH, now NHC) Decree 73], the Provisions for Application Submission and Acceptance of New Variety of Food Additives, and the Notice Concerning Regulating Approving of New Food Additive Variety (MOH Public Notice [2011] No.29)<sup>4</sup>. NHC will then conduct a risk assessment of the ingredient and determine whether it can be approved.

<sup>&</sup>lt;sup>4</sup> Instructions on the application procedures and material requirements can be found on the <u>NHC website</u> (in Chinese, scroll down to New Variety Food Additive Applications - 食品添加剂新品种审批).

Additionally, enzymes derived from microbial biotechnology are reviewed for their safety. Through intra-agency coordination, the safety assessment of microbial biotechnology is conducted in the following steps:

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

Once approved by the NHC, the 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 <u>National Food Safety</u> <u>Standard – Standard for Uses of Food Additives (GB 2760)</u> (see Table C.3) when the standard is revised. In April 2021, China notified a <u>revised draft of GB 2760</u> to the WTO SPS Committee for comments, which contains a list of 60 enzyme preparations for food processing use (page 155 of the report).

## **b)** Approvals

Since the publication of the <u>2021 Agricultural Biotechnology Annual</u>, the NHC has issued several announcement approving enzymes from microbial biotechnology as new food additives.

The NHC "No. 1 Announcement on 32 'Three New Foods' I Including Guanshan Cherry Blossoms" and "No. 2 Announcement on 36 'Three New Foods' Including Chlamydomonas reinhardtii,"<sup>5</sup>, were announced on March 1, 2022 and May 11, 2022, respectively. Announcement No. 1 approved 32 new food materials and additives for use in China, of which four are enzymes derived from GMMs. Announcement No. 2 approved 36 new food materials and additives for use in China, of which seven are enzymes derived from GMMs. Please refer to <u>GAIN Report</u> <u>CH2022-0071 PRC Approves New Food Materials and Additives Including GMM Derived Enzymes</u> for more information on the announcements.

On September 7, 2022, the NHC released its <u>No. 5 Announcement on seven "Three New Foods"</u> <u>Including Lactase</u>, which approved seven new food materials and additives for use in China, including one enzyme (Lactase) derived from GMMs.

Enzymes that have received approval since the beginning of 2021 are noted in Table 1 below.

<sup>&</sup>lt;sup>5</sup> "Three new foods" refers to new food raw materials, new varieties of food-related products and new varieties of food additives.

No.	酶 Enzyme	来源 Host	供体 <b>Donor</b>
1	葡糖淀粉酶	李氏木霉	李氏木霉
	Glucoamylase	Trichoderma reesei	Trichoderma reesei
2.	阿拉伯呋喃糖苷酶	李氏木霉	Talaromyces pinophilus
	Arabinofuranosidease	Trichoderma reesei	
3.	多聚半乳糖醛酸酶	黑曲霉	黑曲霉
	Polygalacturonase	Aspergillus niger	Aspergillus niger
4.	果胶裂解酶	李氏木霉	黑曲霉
	Pectinlyase	Trichoderma reesei	Aspergillus niger
5.	麦芽四糖水解酶	地衣芽孢杆菌	施氏假单胞菌
	Maltotetraohydrolase	Bacillus licheniformis	Pseudomonas stutzeri
6.	木聚糖酶	李氏木霉	Talaromyces leycettanus
	Xylanase	Trichoderma reesei	
7.	α-葡萄糖苷酶	李氏木霉	黑曲霉
	Alpha-glucosidase	Trichoderma reesei	Aspergillus niger
8.	乳糖酶	地衣芽孢杆菌	两歧双歧杆菌
	Lactase	Bacillus licheniformis	Bifidobacterium bifidum
9.	羧肽酶	黑曲霉	黑曲霉
	Carboxypeptidase	Aspergillus niger	Aspergillus niger
10.	脂肪酶	黑曲霉	黄色镰刀菌
	Lipase	Aspergillus niger	Fusarium culmorum
11.	α-淀粉酶	李氏木霉	白曲霉
	Alpha-amylase	Trichoderma reesei	Aspergillus kawachii
12.	蛋白酶	李氏木霉	李氏木霉
	Protease	Trichoderma reesei	Trichoderma reesei
13.	葡糖异构酶	锈棕色链球菌	锈棕色链球菌
	Glucose isomerase	Streptomyces rubiginosus	Streptomyces rubiginosus
14.		多行汉逊酵母	异孢镰刀菌
	Lipase	Hansenula polymorpha	Fusarium hetreosporum
15.	B-淀粉酶 β-amylase	地衣芽孢杆菌	弯曲芽孢杆菌
	(Novozyme)	Bacillus licheniformis	Bacillus flexus
16.	α-淀粉酶	地衣芽孢杆菌	嗜纤维菌
	Alpha-amylase	Bacillus licheniformis	Cytophaga sp.

 Table 1. China: Approved Enzymes from Microbial Biotechnology

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 Phosphoinositide phospholipase C (DSM)	荧光假单胞菌 Pseudomonas fluorescens	从土壤中分离的编码磷 酸肌醇磷脂酶 C 基因 的微生物
21.	α-淀粉酶 α-amylase	黑曲霉 Aspergillus niger	微小根毛霉 <i>Rhizomucor pusillus</i>
22.	多聚半乳糖醛酸酶 Polygalacturonase	李氏木霉 Trichoderma reesei	塔宾曲霉 Aspergillus tubingensis
23.	果胶酯酶 Pectin esterase	李氏木霉 Trichoderma reesei	塔宾曲霉 Aspergillus tubingensis
24.	磷酸肌醇磷脂酶 C Phosphoinositide Phospholipase C	地衣芽孢杆菌 Bacillus licheniformis	假单胞菌 Pseudomonas sp.
25.	磷脂酶 C Phospholipase C	地衣芽孢杆菌 Bacillus licheniformis	苏云金芽孢杆菌 Bacillus thuringiensis
26.	木聚糖酶 Xylanase	李氏木霉 Trichoderma reesei	柔曲高温多孢菌 Thermopolyspora flexuosa
27.	葡糖淀粉酶 Glucoamylase	黑曲霉 Aspergillus niger	密粘褶菌 Gloeophyllum trabeum
28.	脂肪酶 Lipase	李氏木霉 Trichoderma reesei	尖孢镰刀菌 Fusarhum oxysporum
29.	4-α-糖基转移酶 4-α- glucanotransferase	苍白空气芽孢杆菌 Aeribacillus pallidus	
30 (new approval	磷脂酶 A1	米曲霉	红聚颈腔菌
in March	Phospholipase A1	Aspergillus oryzae	Valsaria rubricosa

2022)			
31(new approval	麦芽糖淀粉酶	地衣芽孢杆菌	嗜热脂解地芽孢杆菌
in March 2022)	Maltogenic amylase	Bacillus licheniformis	Geobacillus stearothermophilus
32(new approval	葡糖氧化酶	李氏木霉	尼崎青霉菌
in March 2022)	Glucose oxidase	Trichoderma reesei	Penicillium amagasakiense
33(new approval	脂肪酶	李氏木霉	黑曲霉塔宾变种
in March 2022)	Lipase	Trichoderma reesei	Aspergillus niger var. tubingensis
34(new approval	β-葡聚糖酶	枯草芽孢杆菌	枯草芽孢杆菌
in May 2022)	β-glucanase	Bacillus subtilis	Bacillus subtilis
35(new approval	蛋白酶	枯草芽孢杆菌	克劳氏碱性卤杆菌
in May 2022)	Protease	Bacillus subtilis	Alkalihalobacillus clausii
36(new approval	海藻糖酶	李氏木霉	李氏木霉
in May 2022)	Trehalase	Trichoderma reesei	Trichoderma reesei
37(new approval	磷脂酶 A1	黑曲霉	Talaromyces
in May 2022)	Phospholipase A1	Aspergillus niger	leycettanus
38(new approval	葡糖氧化酶	黑曲霉	产黄青霉
in May 2022)	Glucose oxidase	Aspergillus niger	Penicillium chrysogenum
39(new approval	乳糖酶	枯草芽孢杆菌	德氏乳杆菌保加利亚亚 种 Lactobacillus
in May 2022)	Lactase	Bacillus subtilis	delbrueckii subsp. Bulgaricus
40(new approval	植酸酶	黑曲霉	塔宾曲霉
in May 2022)	Phytase	Aspergillus niger	Aspergillus tubingensis

41(new	乳糖酶	黑曲霉	米曲霉
approval			
in	Lactase	Aspergillus niger	Aspergillus oryzae
September			
2022)			

## 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

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

#### e) Additional Regulatory Requirements

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

#### **Food Additive Production**

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

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

Enzyme preparations used in food processing are listed in Table C.3 - List of Enzyme Preparation for Foods and Their Sources. Table C.3 specifies that enzymes can be used in food processing and the sources of the enzymes. The current GB 2760 in effect was released in 2014 and implemented in May 2015; enzymes produced from microbial biotechnology, which were approved subsequent to the release of GB 2760 are likely to be included in the updated GB 2760 currently under development.

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

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

## f) Intellectual Property Rights (IPR)

N/A.

## g) Related Issues

N/A.

## Part I: Marketing

## a) Public/Private Opinions

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

## b) Market Acceptance/Studies

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

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

Partner Country	Quantity (1,000 Tons)			
Turther Country	2019	2020	2021	2022 (JanAug.)
World	52	4	9	21
Vietnam	21	1	7	6
Thailand	1	0	1	0
Indonesia	10	0	1	1

#### China: Cotton Exports (HS 520100)

## China: Cotton Imports (HS 520100)

Partner Country	Quantity (1,000 Tons)			
Turther Country	2019	2020	2021	2022 (JanAug.)
World	1,847	2,158	2,142	1,361
United States	360	978	829	882
Brazil	505	618	644	294
India	206	253	409	31
Australia	398	117	35	5
Sudan	40	32	26	21

## China: Corn Imports (HS 100590)

Partner Country	Quantity (Million Tons)

	2019	2020	2021	2022 (JanAug.)
World	4.79	11.24	28.35	16.93
United States	0.32	4.34	19.83	11.73
Ukraine	4.14	6.24	8.2	4.9

## China: Soybean Imports (HS 120190)

Partner Country	Quantity (Million Tons)				
Farmer Country	2019	2020	2021	2022 (Jan-Aug.)	
World	88.51	100.31	96.47	61.33	
Brazil	57.68	64.28	58.15	40.92	
United States	16.94	25.87	32.27	18.21	
Argentina	8.79	7.46	3.78	0.46	
Uruguay	2.07	1.66	0.87	0.80	
Russia	0.73	0.69	0.55	0.44	

## China: Distillers Dried Grains Imports (HS 230330)

Partner Country	Quantity (1,000 Tons)			
Farmer Country	2019	2020	2021	2022 (Jan-Aug.)
World	141	182	307	82
United States	140	182	307	82

## China: Rapeseed Imports (HS 12051090)

Partner Country		Quantity (	1,000 Tons)	
Farmer Country	2019	2020	2021	2022 (Jan-Aug.)
World	2,494	3,756	2,531	796
Canada	2,357	2,315	2,438	796
Australia	134	439	93	0
Russia	4	1	1	0

## China: Rapeseed Meal Imports (HS 230641)

Partner Country	Quantity (1,000 Tons)			
Tarther Country	2019	2020		2022 (Jan-Aug.)
World	1,578	1,886	2,032	1,530
Canada	1,427	1,496	1,579	1,115

United Arab	100	225	410	271
Emirates	100	555	418	3/1

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

Partner Country	Quantity (1,000 Tons)				
Tartiler Country	2019	2020	2021	2022 (Jan-Aug.)	
World	1,615	1,931	2,153	669	
Canada	963	1,034	914	194	
United Arab Emirates	204	362	366	132	
Russia	153	217	339	280	
Germany	0	20	110	5	
Australia	49	72	46	5	
France	3	69	43	0	
Ukraine	116	62	56	0	
Kazakhstan	60	33	4	22	

## China: Sugar Beet Pulp Imports (HS 230320)

Partner Country		Quantity	(1,000 Tons)	
i unior country	2019	2020	2021	2022 (Jan-Aug.)
World	28	165	404	209
Egypt	17	106	350	173
Russia	1	41	37	30
Ukraine	10	18	17	6

No.	Event	Approval Issued Date	Developer	Biosafety certificate validity
1	HaHB4 genetically resistant soybean IND-ØØ41Ø-5 (new approval in April 2022)	April 22, 2022	Rosario Agricultural Biotechnology Institute Inc. (Bioceres)	Apr. 22, 2022-Apr.21, 2027
2	Transgenic cp4epsps Herbicide Tolerant Soybean MON89788 (renewal)	August 28, 2008	Bayer CropScience	Apr. 22, 2022-Apr.21, 2027
3	Transgenic Insect-Resistant Soybean DAS-81419-2 (renewal)	December 2, 2019	Corteva	Apr. 22, 2022-Apr.21, 2027
4	Transgenic improves soybean quality traits 305423 (renewal)	November 3, 2011	Corteva	Apr. 22, 2022-Apr.21, 2027
5	Herbicide-tolerant soybean 305423×GTS40-3-2 Advance (renewal)	December 11, 2014	Corteva	Apr. 22, 2022-Apr.21, 2027
n	Herbicide Tolerant Soybean A5547-127 (renewal)	December 11, 2014	BASF	Apr. 22, 2022-Apr.21, 2027
7	Herbicide Tolerant Maize T25 (renewal)	April 6, 2004	BASF	Apr. 22, 2022-Apr.21, 2027
8	Herbicide-tolerant sugar beet H7-1 (renewal)	April 20, 2009	Bayer CropScience Kowalsch Seeds Europe AG	Apr. 22, 2022-Apr.21, 2027
9	Herbicide tolerant oilseed Canola Ms8Rf3 (renewal)	April 6, 2004	BASF	Apr. 22, 2022-Apr.21, 2027
10	Herbicide-tolerant Canola T45 (renewal)	April 6, 2004	BASF	Apr. 22, 2022-Apr.21, 2027
11	Terbicide-tolerant Canola Oxy-235 (renewal)	April 6, 2004	BASF	Apr. 22, 2022-Apr.21, 2027
12	Insect resistant corn MON810(renewal)	February 20, 2004	Bayer CropScience	Dec.17, 2021 - Dec.16, 2026

**Appendix 2: Biotech Crops Approved for Import as Processing Materials** 

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

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

44	Insect-Resistant soybean MON87751 (renewal)	Jun. 11, 2020	Monsanto Far East Ltd.	Jun. 11, 2020-Jun. 11, 2025
45	Herbicide-tolerant corn MON87427 (renewal)	July 16, 2017	Monsanto Far East Ltd.	Jun. 11, 2020-Jun. 11, 2025
46	Virus Resistant Papaya 55-1	December 2, 2019	USDA ARS, Pacific Basin Agricultural Research Center, University of Hawaii	Dec. 02, 2019-Dec. 02, 2022
47	Improved quality soybean MON87705 (renewal)	June 12, 2017	Monsanto Far East Ltd.	June 11, 2020-June 11, 2025
48	Herbicide resistant corn DAS-40278-9 (renewal)	June 12, 2017	Dow AgroSciences	June 11, 2020-June 11, 2025
49	Insect resistance and herbicide tolerance corn Bt11×GA21 (renewal)	November 3, 2011	Syngenta Crop Protection	June 11, 2020-June 11, 2025
50	Insect resistance corn MIR162 (renewal)	December 11, 2014	Syngenta Crop Protection	June 11, 2020 – June 11, 2025
51	Insect resistant corn 5307 (renewal)	July 16, 2017	Syngenta Crop Protection	June 11, 2020 – June 11, 2025
52	Insect resistant cotton DAS-24236-5 (new approval in December 2021)	December 17, 2021	Corteva Agriscience	Dec. 17, 2021-Dec. 16, 2026
53	Insect resistant cotton DAS-21023-5 (new approval in December 2021)	December 17, 2021	Corteva Agriscience	Dec.17, 2021-Dec. 16, 2026
54	Herbicide tolerant cotton 1445 (renewal)	February 20, 2004	Bayer CropScience	Dec.17, 2021 - Dec.16, 2026
55	Herbicide tolerant Flex cotton MON 88913 (renewal)	December 20, 2007	Bayer CropScience	Dec.17, 2021 - Dec.16, 2026
56	Insect resistant cotton 531(renewal)	February 20, 2004	Bayer CropScience	Dec.17, 2021 - Dec.16, 2026
57	Insect resistant cotton 15985 (renewal)	July 20, 2006	Monsanto Far East Ltd.	Dec. 02, 2019-Dec. 02, 2024
58	Herbicide tolerant cotton GHB614	December 30, 2010	BASF	Dec. 29, 2020-Dec. 28, 2025

	(renewal)			
59	Insect resistant cotton COT102 (renewal)	December 31, 2015	Syngenta Crop Protection	Dec. 29, 2020-Dec. 28, 2025
	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	Dec. 20, 2018 -Dec.20, 2023
-	Insect resistant and herbicide tolerant cotton T304-40 (renewal)	April 10, 2014	BASF	Dec. 20, 2018 -Dec.20, 2023
63	Insect resistant corn MON863 (renewal)	June 25, 2004	Monsanto	Certificate expired
	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 been changed.

<b>Appendix 3: Biotech Crops Approved for</b>	Cultivation (Rice,	Corn, Soybean and Papaya	a, excluding Cotton)
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No.	Event	Developer	<b>Ecological Zone</b>	Biosafety certificate validity
1	Insect resistant rice Hua Hui 1	Hua Zhong Agriculture University	Hubei Province	August 17, 2009 – August 17, 2014 (renewed in 2014; expired in 2019; renewed in 2021: Feb. 10, 2021-Feb. 9, 2026)
2	Insect resistant rice Xian You 63	Hua Zhong Agriculture University	Hubei Province	August 17, 2009 – August 17, 2014 (renewed in 2014; expired in 2019; renewed in 2021: Feb. 10, 2021-Feb. 9, 2026)

3	Phytase Corn BVLA430101	Biotech Research Institute of China Academy of Agricultural Sciences	Shandong Province	August 17, 2009 – August 17, 2014 (renewed in 2014; expired in 2019)
4	Virus resistant Papaya	South China Agriculture University	Guangdong Province (expanded to South China since 2010)	July 20, 2006, renewed in 2010, 2015 and 2020; current certificate valid for Dec. 29, 2020-Dec. 28, 2025
5	Pest resistant and herbicide tolerant corn DBN9936	Beijing DaBeiNong Biotechnology Co., Ltd.	North China spring corn area	Dec. 2, 2019 – Dec. 2, 2024
6	Pest-resistant and herbicide tolerant corn Ruifeng 125 (former Shuangkang 12-5)	Hangzhou Ruifeng Biotechnology Co., Ltd. and Zhejiang University	North China spring corn area	Dec. 2, 2019 – Dec. 2, 2024
7	Pest-resistant and herbicide tolerant corn Ruifeng 125	Hangzhou Ruifeng Biotechnology Co. Ltd.	Summer corn area covering the Yellow River, Huaihe River, Haihe River region	Feb. 10, 2021-Feb. 9, 2026
8	Pest-resistant and herbicide tolerant corn Ruifeng 125	Hangzhou Ruifeng Biotechnology Co.	Northwest corn area	Feb. 10, 2021-Feb. 9, 2026
9	Herbicide-resistant soybean SHZD32-01	Shanghai Jiaotong University	South China soybean area	Dec. 2, 2019 – Dec. 2, 2024
10	Herbicide-tolerant corn DBN 9858	Beijing DaBeiNong Biotechnology Co., Ltd.	North China spring corn area	Jun. 11, 2020 – June 11, 2025
11	Herbicide-tolerant soybean Zhonghuang 6106	Crop Science Institute of CAAS	Huanghuaihai summer soybean area	Jun. 11, 2020 – June 11, 2025
12	Herbicide-tolerant soybean Zhonghuang 6106	Crop Science Institute of CAAS	North China spring soy area	Feb. 10, 2021-Feb. 9, 2026
13	Herbicide-tolerant corn DBN 9858	Beijing DaBeiNong Biotechnology Co., Ltd.	Summer corn area covering the Yellow River, Huaihe River, Haihe River region	Dec. 29, 2020-Dec. 28, 2025

14	Herbicide-tolerant corn DBN 9858	Beijing DaBeiNong Biotechnology Co., Ltd.	South China corn area	Dec. 29, 2020-Dec. 28, 2025
15	Herbicide-tolerant corn DBN 9858	Beijing DaBeiNong Biotechnology Co., Ltd.	Southeast China corn area	Dec. 29, 2020-Dec. 28, 2025
16	Herbicide-tolerant corn DBN 9858	Beijing DaBeiNong Biotechnology Co., Ltd.	Northwest corn area	Dec. 29, 2020-Dec. 28, 2025
17	Pest resistant and herbicide tolerant corn DBN 9936	Beijing DaBeiNong Biotechnology Co., Ltd.	Summer corn area covering the Yellow River, Huaihe River, Haihe River region	Dec. 29, 2020-Dec. 28, 2025
18	Pest resistant and herbicide tolerant corn DBN 9936	Beijing DaBeiNong Biotechnology Co., Ltd.	South China corn area	Dec. 29, 2020-Dec. 28, 2025
19	Pest resistant and herbicide tolerant corn DBN 9936	Beijing DaBeiNong Biotechnology Co., Ltd.	Southeast China corn area	Dec. 29, 2020-Dec. 28, 2025
20	Pest resistant and herbicide tolerant corn DBN 9936	Beijing DaBeiNong Biotechnology Co., Ltd.	Northwest corn area	Dec. 29, 2020-Dec. 28, 2025
21	Pest-resistant and herbicide tolerant corn DBN9501	Beijing DaBeiNong Biotechnology Co., Ltd.	North China spring corn area	Dec. 29, 2020-Dec. 28, 2025
22	Herbicide tolerant soybean DBN9004	Beijing DaBeiNong Bioechnology Co., Ltd.	North China spring soybean area	Dec. 29, 2020-Dec. 28, 2025
23	Pest resistant corn ND207 (GMO formerly known as "2A-7")	China Forestry Seed Group Co., Ltd. China Agricultural University	North China spring corn area	Dec. 17,2021-Dec. 16. 2026
24	Pest resistant corn ND207 (GMO formerly known as "2A-7")	China Forestry Seed Group Co., Ltd. China Agricultural University	Summer corn area covering the Yellow River, Huaihe River, Haihe River region	Dec. 17,2021-Dec. 16. 2026

25	Pest resistant corn Zheda Ruifeng 8 (GMO formerly known as "GAB-3")	Hangzhou Ruifeng Biotechnology Co.Ltd.	South China corn area	Dec. 17,2021-Dec. 16. 2026
26	Pest resistant and herbicide tolerant corn DBN3601T(GMO formerly known as "DBN9936×DBN9501")	Beijing DaBeiNong Bioechnology Co., Ltd.	Southwest corn area	Dec. 17,2021-Dec. 16. 2026
27	Herbicide resistant corn nCX-1 transgenic CdP450 and cp4epsps	Hangzhou Ruifeng Biotechnology Co., Ltd.	South China corn area	Apr. 22, 2022-Apr.21, 2027
28	Pest resistant and herbicide tolerant corn Bt11xGA21	China Seed Group Co., Ltd.	North China spring corn area	Apr. 22, 2022-Apr.21, 2027
29	Pest resistant and herbicide tolerant corn Bt11xMIR162xGA21	China Seed Group Co., Ltd.	South China corn area, Southwest China corn area	Apr. 22, 2022-Apr.21, 2027
30	Hherbicide-tolerant corn GA21	China Seed Group Co., Ltd.	North China spring corn area	Apr. 22, 2022-Apr.21, 2027

#### Attachments:

No Attachments