

Required Report: Required - Public Distribution

Date: November 26, 2021

Report Number: CH2021-0128

Report Name: Agricultural Biotechnology Annual

Country: China - People's Republic of

Post: Beijing

Report Category: Biotechnology and Other New Production Technologies

Prepared By: Alan Hallman and FAS China Staff

Approved By: Adam Branson

Report Highlights:

Since the last report, high-level officials in the People's Republic of China (PRC) have made strong public statements emphasizing the importance of biotechnology development taking place within China. While the regulatory system for biotechnology has not changed over the last year, the Biosecurity Law of China came into effect in April 2021. Several PRC ministries have stated that they are going to develop implementing rules for the law, including the Ministry of Agriculture and Rural Affairs (MARA). The National Health Commission (NHC) regularly approves applications for enzymes derived from microbial biotechnology, which are used as food ingredients in food production.

Table of Content

Executive Summary.....	4
Chapter 1: Plant Biotechnology	6
Part A: Production and Trade	6
a) Product Development	6
b) Commercial Production	7
c) Exports.....	8
d) Imports	8
e) Food Aid	8
f) Trade Barriers	8
Part B: Policy	9
a) Regulatory Framework	9
b) Approvals	14
c) Stacked or Pyramided Event Approvals	14
d) Field Testing.....	14
e) Innovative Biotechnologies	14
f) Coexistence	14
g) Labeling and Traceability	15
h) Monitoring and Testing.....	15
i) Low Level Presence (LLP) Policy	16
j) Additional Regulatory Requirements	16
k) Intellectual Property Rights (IPR)	17
l) Cartagena Protocol Ratification.....	17
m) International Treaties and Forums.....	18
n) Related Issues	18
Part C: Marketing	19
Chapter Two: Animal Biotechnology	19
Part D: Production and Trade	19
a) Product Development	19
b) Commercial Production	20
c) Exports.....	20
d) Imports	20
e) Trade Barriers	20
Part E Policy	21
a) Approvals	21
b) Innovative Biotechnologies	21
c) Labeling and Traceability	21
e) Intellectual Property Rights (IPR)	21
f) International Treaties and Forums.....	22
g) Related Issues	22
Part F: Marketing	22
h) Public/Private Opinions	22
i) Market Acceptance/Studies	22

Chapter Three: Microbial Biotechnology	22
Part G: Production and Trade	23
a) Commercial Production	23
b) Export	23
c) Imports	23
d) Trade Barriers	23
Part H: Policy.....	23
a) Regulatory Framework	23
b) Approvals	24
c) Labeling and Traceability	26
d) Monitoring and Testing.....	26
e) Additional Regulatory Requirements	27
f) Intellectual Property Rights (IPR)	27
g) Related Issues	27
Part I: Marketing	27
a) Public/Private Opinions	27
b) Market Acceptance/Studies	27
 Appendix 1: China’s Trade in Biotech Crops (Source: GACC).....	 28
 Appendix 2: Biotech Crops Approved for Import as Processing Materials...31	 31
 Appendix 3: Biotech Crops Approved for Cultivation	 35

Executive Summary

China's regulatory system for biotechnology remains unchanged since the issuance of the 2020 Biotech Annual report.

Except for GE papaya and cotton, China has not yet approved any GE food or feed products for domestic cultivation, although biosafety certificates have been issued for cultivation of some domestically developed products.

MARA has repeatedly informed foreign agricultural biotechnology developers that China's foreign direct investment restrictions prohibit the cultivation of foreign-developed biotech products in China.

Despite active research and development, China has no regulations for genome editing; MARA has stated that products obtained through gene editing will be regulated as genetically engineered products, but with simplified procedures.

China committed to several reforms of its agricultural biotechnology policies and procedures under Chapter 3, Annex 16 of the Economic and Trade Agreement, which entered into force on February 15, 2020.

More GE Corn and Soybean Traits Obtained Biosafety Certificates for Cultivation

On January 11, 2021, MARA issued biosafety certificates for two new events along with three renewals (for foreign developers). On February 4, 2021, MARA issued biosafety certificates for cultivation purpose to two domestic traits; on April 7, MARA issued another two lists of approvals, including renewed biosafety certificates for the already approved rice and cotton traits, expansion of cultivation area of two already approved traits (one soybean and one corn), and 101 new cotton traits.

Currently there are ten domestically developed traits holding biosafety certification (for cultivation) that are waiting for variety registration for commercialization (this count does not include GE cotton and papaya). However, China still has not published a regulation establishing a pathway to variety registration for GE crops other than cotton and papaya.

Appendix 2 provides the full list of biotech products approved in China with valid biosafety certificates.

Biotech is designated as a strategic emerging industry in China, and the government invests billions of dollars in research via national major projects. In 2016, the State Council released the 13th Five-year Plan for National Science and Technology Innovation, which set a goal for commercializing a new generation of *Bacillus thuringiensis* (Bt) cotton, Bt corn, and herbicide-tolerant soybeans by 2020. Thus far no corn or soybean events have been commercialized. The 14th Five-year Plan for National Science and Technology Innovation has not been released.

According to MARA’s roadmap for commercialization of GE crops, China has 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) for commercialization and cultivation.

While many countries/regions are simplifying their safety assessment regulations, authorities in China show no willingness to accept safety testing data obtained by trials conducted outside of China without conducting verification trials. This remains a major concern for foreign developers and the international community because they lose control over the timeline to conduct the trials and the trial results.

MARA encourages Indigenous Innovation of Agricultural GMOs and Regulating the Transfer of Biological Materials

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

Brief Sketch of Approval Process and Role of Biosafety Certificates

After receiving approval in a foreign country, foreign developers can apply for a “Biosafety Certificate for Food, Feed, and Processing (Foreign Developers)”. This requires getting approval for importing materials for trials conducted in China and the review and verification of trial results. Once this is completed, MARA may issue a “Biosafety Certificate for Food, Feed, and Processing (Foreign Developers)”.

Importers of a product need to supply a copy of the “Biosafety Certificate for Food, Feed, and Processing (Foreign Developers)” along with other documents to receive a “Biosafety Certificate (Trader).”

A Chinese developer would apply for a “Biosafety Certificate (For Production and Use)” during the development process. A locally developed event would also need to be approved through the variety registration process. Variety registration for GE crops has only been granted to cotton and papaya events.

Details of these processes are provided in the body of the report.

Chapter 1: Plant Biotechnology

Part A: Production and Trade

a) Product Development

Despite decades of research by Chinese biotech developers, China has not commercialized any GE products, with the exception of cotton and papaya.

New Biosafety Certificates for Cultivation Purpose

2021 New Approvals

On January 11, 2021, MARA issued four biosafety certificates to two GE corn traits, DBN 9858 and DBN 9936. DBN 9936 obtained a biosafety certificate for cultivation in the north China spring corn region in December 2019; DBN 9858 obtained the certificate in June 2020. The new batch of biosafety certificates issued to the traits basically expanded the geographical regions permitted to grow the two corn traits to the whole country. On the same day, the biosafety certificate for GE papaya Huanong No. 1 for cultivation in south China was renewed.

On February 4, 2021, MARA issued biosafety certificates for cultivation to two new domestically developed GE food and feed products – pest-resistant and herbicide tolerant corn DBN9501 in the north China spring corn region and herbicide tolerant soybean DBN9004 in the north China spring soybean region.

Two months later, on April 7, 2021, MARA renewed biosafety certificates of the two rice traits and one corn trait that were approved in 2009.

However, before commercialization can occur, the varieties must be registered with MARA's Seed Industry Management Department.

Chinese developers are applying 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 [consultation with the U.S. Food and Drug Administration on Huahui No.1 rice product](#), 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, [received approval from the Argentine government to cultivate its herbicide-resistant soybean](#) (DBN-09004-6, 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.

In a June 2020 *Nature* article, [“Excessive Chinese concerns over Genetically Engineered Food Safety are Unjustified”](#), Dr. Li Yunhe with the Chinese Academy of Agricultural Sciences' (CAAS) Institute of Plant Protection pointed out that, “Although great economic, ecological and social benefit have been realized with the adoption of Bt cotton in China, this experience has not facilitated adoption of GE food crops because of excessive concern over the safety of GE food.

For example, although two Bt rice lines, Bt Shanyou 63 and Huahui No. 1, were issued biosafety certificates in 2009, and Huahui No. 1 was approved for consumption by the U.S. Food and Drug Administration in 2018, the lines have not been planted commercially in China”.

The 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. According to the Long-Term and Mid-Term National Development Plan for Science and Technology (2006-2020), the GE and novel technology development program focused on crop (rice, wheat, corn, and cotton) and animal (swine, cattle, and sheep) research.

The [Special Administrative Measures for Foreign Investment Access](#) (the Negative List, link in Chinese) jointly issued by the National Development and Reform Commission (NDRC) and the Ministry of Commerce (MOFCOM) in June 2020 continues to prohibit foreign biotech developers from conducting research or seed production in China; however, it relaxed restrictions on wheat breeding, requiring Chinese shares of no less than 34 percent for wheat seed breeding and production (the 2019 Negative List required Chinese sides to take at least 51 percent of shares in a wheat seed breeding and production company). The 2021 Negative List is under development.

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.

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

The GE products approved for commercial production in China can be found on MARA’s [website](#) 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 agro-ecological zones (Xinjiang, Yellow River Basin and Yangtze River Basin). When developers submit applications for biosafety certificate for cultivation, they indicate the agro-ecological zones where the product will be grown. Accordingly, the field trials will be conducted in that region, and the trial information will be included in the final biosafety certificate application.

c) Exports

China is an exporter of GE cotton products, mainly cotton fiber. In 2020, China exported 4,701 ton of cotton, valued \$7,191,402.

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. China's unpredictable approval process and lack of a low-level presence (LLP) policy may result in detained and rejected shipments. For example, alfalfa shipments that contain unapproved GE varieties are occasionally detained and rejected. Please refer to Appendix 1 for China's trade in biotech crops.

China does not allow the importation of GE seeds for commercial cultivation.

e) Food Aid

China provides food aid (corn, rice, and sorghum) to mainly 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 regulatory approval process for GE traits includes several provisions that decrease the predictability and transparency of the regulatory review causing unnecessary delays. These include requirements that environmental safety trials and feeding studies be conducted in China. In 2016 and 2017, MARA revised these regulations without notifying the World Trade Organization or soliciting public comments. MARA also did not provide a transition period for implementing the revised rules. In 2018, as noted above, MARA added additional in-country testing to the battery of evaluations required for products to progress through the Chinese regulatory process.

Following MARA's "completeness check" which ensures that all the required materials are submitted comprising the application, China's National Biosafety Committee's (NBC) review and approval process has delayed import approvals for developers. Pursuant to the "Administrative Measures for the Safety Assessment of Agriculture GMOs" issued by MARA, the NBC convenes no less than two times each year. However, without clear instruction from MARA on when the meetings are held, it is becoming more difficult to assemble an adequate number of NBC members to convene the meeting. NBC members continue to ask previously answered questions, causing the rejection of applications. In some cases, the cumulative time for China's review of a product has exceeded 10 years from when the product was first approved in the product's domestic market.

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. Under the Phase One Agreement, China committed to certain steps when addressing LLP occurrences to facilitate trade.

Part B: Policy

a) Regulatory Framework

Regulatory Structure

The agricultural biotech regulatory environment is outlined in the State Council¹'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 with a subsequent revised draft issued on November 12, 2021)²;
- Administrative Measures for Safety of Agriculture GMO Imports (issued on January 5, 2002, and latest 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 (implemented on July 1, 2006);
- Technical guidance, standards, and procedures released in form of MARA public notices;
- AQSIQ Decree 62 "[Administrative Measures of Inspection and Quarantine on Entry-Exit GM Products](#)" (implemented on May 24, 2004, latest revision issued in April, 2018).

MARA has said that genome edited products will fall within the scope of China's "GMO" regulations and will be regulated as a GMO, with simplified procedures.

In October 2020, China promulgated the [Biosecurity Law](#) (link in Chinese), which came into effect on April 15, 2021. The law addresses several biosecurity elements, including bioterrorism, infectious disease management, biotechnology development, biodiversity protection, microbial resistance, and human and biological resource management. After promulgation of the Law, MARA indicated that MARA rules for agriculture biotechnology will be revised pursuant to the Law. No revision has been announced.

¹ 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.

² On November 12, 2021 MARA solicited Comments on Revisions to the Administrative Measures for the Safety Assessment of Agricultural GMOs in its website. The revisions are provided in the [USDA GAIN report CH2021-0139](#). The revision has not yet been finalized.

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.

In 2016, the fifth NBC was established with 74 members from different research institutions and universities. 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. The Development Center for Science and Technology (DCST), an affiliate of MARA, serves as the 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.

The Fifth NBC's term will end in September 2021, when new members will be nominated and selected to form the Sixth NBC. In mid-November, 2021, [MARA announced the candidates for the Sixth NBC for public comments](#) (link in Chinese), which is composed of 76 scientists. By the issuance of this report, the list has not yet been finalized.

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 related to agricultural biotechnology. MARA also manages and distributes government funds to Chinese institutes and universities for the research and development of biotech crops.

Other Governmental Biotechnology Responsibilities

The General Administration of Customs of the People's Republic of China (GACC) is responsible for testing of agricultural and food products for GE content at Chinese ports of entry. The State Forestry Administration 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 Environmental Protection (MEP) is the lead agency in the negotiation and implementation of the Cartagena Biosafety Protocol, which China ratified on April 27, 2005.

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.

There are approximately 40 MARA-designated institutes across China that determine the characteristics of events and 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.

China has an overarching coordinating body called the Joint-Ministerial Conference for Biosafety Management of Agricultural Genetically Modified Organisms, 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, MEP, GACC, Ministry of Science and Technology (MOST), NDRC, MOFCOM, the National Health Commission (NHC, former Ministry of Health), and others. The conference is mostly used to coordinate biotech policies.

The State Administration for Market Regulation (SAMR) is the authority for comprehensive market oversight, law enforcement in respect of market supervision and administration, and the comprehensive coordination on the supervision and administration of food safety nationwide. When GE foods are distributed in the Chinese market, SAMR reviews the product labels to ensure their compliance with labelling requirements. The [Implementing Regulations of the Food Safety Law](#) released in October 2019 provide that “(p)roduction 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.” SAMR will be the developer of these regulations and is responsible for their enforcement.

MARA Import Approval Procedure

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

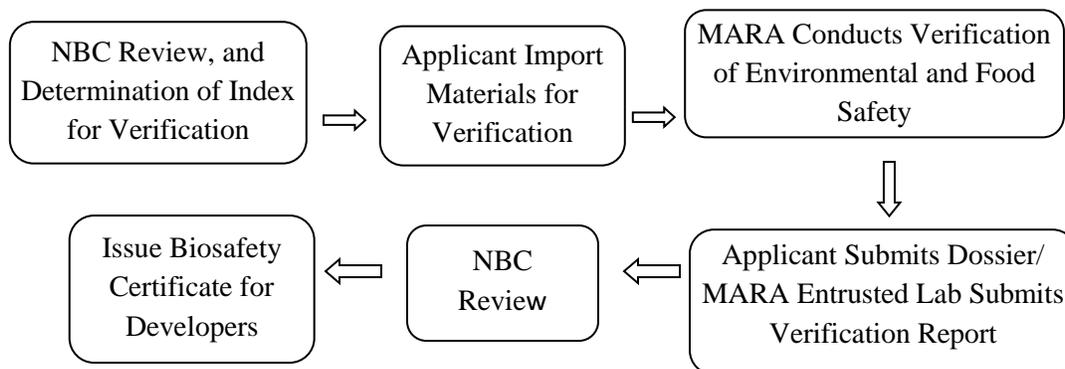
MARA is responsible for the review and issuance of biosafety certificates for imported biotech products for food, feed and processing (FFP) use. The Administrative Measures for Safety of Agriculture GMO Imports outline the requirements for importing biotech products. The Measures require a foreign seed developer to submit the application for a biosafety certificate for agricultural biotech for developers 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 several materials and certifications, proving the exporting country allows for the use and sale of the product in its domestic market and the product has undergone studies showing no harm to animals, plants, or the environment.

After receiving the application for biosafety certificate, 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, which is required by domestic law to convene no less than two times annually (see below for more information on the NBC).

After each meeting, the NBC informs MARA of its decisions. The products that pass NBC review are subject to MARA’s administrative review before receiving the biosafety certificate. 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. MARA also rejects the application – which MARA maintains restarts the twenty-four-month timeframe for approval of the event. MARA’s guidance on the process, application form, on-line-application process, and status of applications can be found at the [MARA official website’s page for administrative approvals](#). The specific timing of NBC meetings is not formalized, remains highly variable, and is dependent on external political factors. Below is a simple flow chart of the approval procedure for biosafety certificate for imports:

Simplified Flow Chart of the Approval for Biosafety Certificate



According to Chapter 3, Annex 16, Paragraph 2 of the Phase One Agreement:

“China shall implement a transparent, predictable, efficient, science- and risk-based regulatory process for safety evaluation and authorization of products of agricultural biotechnology. For agricultural biotechnology products for feed or further processing, China shall significantly reduce, to no more than 24 months, the average amount of time between:

- (a) the submission of a formal application for authorization of such a product; and
- (b) the final decision on approval or disapproval of the product.”

In or around September 2020, MARA posted several documents related to the biosafety approval and import processes for foreign developers on its [website for administrative approvals \(website in Chinese\)](#). MARA did not make a formal announcement when posting the documents, nor has it notified the WTO for comment from trading partners.

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 shipment 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. The MARA guidance on this process, application form, on-line-application process, and status of applications can be found at the [MARA website for administrative approvals \(website in Chinese\)](#).

In December 2020, MARA issued [Public Notice \[2020\] No. 376 \(link in Chinese\)](#), announcing that applications for Biosafety Certificate for Agricultural Biotechnology (Import) to traders can be submitted on-line, i.e. hardcopy of application forms and materials are no longer required.

Domestic Cultivation Approval Procedure

A domestic developer wanting to commercialize a new product for cultivation in China needs a MARA biosafety certification 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.

The [Special Administrative Measures for Foreign Investment Access](#) (the Negative List, link in Chinese) jointly issued by the NDRC and MOFCOM in June 2020 continues to prohibit foreign biotech developers from conducting research or seed production in China; however, it relaxed restrictions on wheat breeding, requiring Chinese shares of no less than 34 percent for wheat seed breeding and production (the 2019 Negative List required the Chinese side to take at least a 51 percent share in a wheat seed breeding and production company). According to MOFCOM, the 2021 Negative List is being developed.

MOFCOM Catalogue of Technologies Prohibited or Restricted to be Imported

On July 23, 2021, MOFCOM released a notice in its website soliciting comments on the revised "Catalogue of Technologies Prohibited or Restricted to be Imported". 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". To import technologies in the restricted catalogue, an applicant would need to follow [MOFCOM Guidance for Licensing of Import and Export of Restricted Technologies](#) (link in Chinese) for specific requirements and procedures.

The draft Catalogue could be found at [MOFCOM website](#) (link in Chinese).

b) Approvals

On January 11, 2021, the Chinese Ministry of Agriculture and Rural Affairs (MARA) issued biosafety certificates for the import of two new events along with three renewals. On February 4, 2021, MARA issued biosafety certificates for cultivation to two domestic traits; on April 7, MARA issued another two lists of approvals, including renewed biosafety certificates for the already approved rice and cotton traits, expansion of cultivation area of two already approved traits (one soybean and one corn), and biosafety certificates for cultivation to 101 new cotton traits.

As required under the Phase One Agreement, the validity period of the newly issued and the renewed certificates is 5 years.

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

China does not have a specific policy for approving stacked events. MARA encourages developers to apply for bio-safety certificates for stacked events, rather than individual traits. However, the process and specific requirements for stacked event review and approval are not available. On November 12, 2021, MARA published in draft, for comment, its [“Decision to Revise the Administrative Measures for the Safety Assessment of Agricultural GMOs”](#) which, when final, could allow the biosafety assessment of stacked traits.

d) Field Testing

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

e) Innovative Biotechnologies

Chinese scientists associated with the China Academy of Sciences (CAS), China Academy of Agricultural Sciences (CAAS) and universities are progressing in innovative biotechnology and publishing papers about Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) technology. MARA has said that genome edited products will fall within the scope of China’s “GMO” regulations and will be regulated as a “GMO”. China closely monitors other countries’ policies on genome editing, including those of the U.S. Food and Drug Administration and Environmental Protection Agency but has not yet released its own policies on gene editing.

f) Coexistence

China does not have a coexistence policy.

g) Labeling and Traceability

China'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 11042300³);
3. Rapeseed for planting, rapeseeds, rapeseed oil, and rape seed meal;
4. Cottonseed; and
5. Tomato seed, fresh tomato, and tomato paste.

On various occasions, MARA and Chinese scientists have stated that China will establish a threshold for GE labeling, changing the labeling requirements from qualitative to quantitative. However, several years have elapsed, and the rule has not been released.

The [Implementing Regulations of the Food Safety Law](#) released in October 2019 state: "Production and trading of genetically modified foods (in China) should be conspicuously marked; the measures for marking (the production and trading) will be developed by the food safety supervision and administrative department of the State Council together with the agricultural administrative department of the State Council." As such, the production facilities that process GE crops, such as the production lines that crush oil from GE soy, or the counters selling GE foods need to have clear signs that they are processing/selling GE products. This requirement for marking GE foods is echoed by the [draft Measures on Supervision and Management of Food Labeling](#) developed by SAMR, which is intended to replace the Administrative Provisions on Food Labeling released by the former General Administration of Supervision, Inspection and Quarantine (AQSIQ) in August 2007.

In recent years, MARA has been working with its sister ministries to regulate the GMO-related content of advertisements, prohibiting the use of "non-GMO" as a claim in advertisements of products where no GE version has been approved for sale in China or where no GE version exists. [The Draft Measures on Supervision and Management of Food Labeling \(Draft\)](#) specified that, "Food labeling shall not use 'Not containing GMO', 'Non-GMO' or similar text to introduce foods that do not use genetically modified food materials," and that, "Production and trading of genetically modified foods should conspicuously mark the text 'Genetically Modified' in the food label." The Measures, though pending finalization, reflect the position of the Chinese government against misleading labels.

h) Monitoring and Testing

Testing of biotechnology products is carried out primarily by MARA, GACC, and MEP through their designated testing institutes. At ports, local Customs tests imports for unapproved biotech products. MARA tests domestic crops and conducts safety assessment experiments, and MEP conducts environmental safety tests.

³ 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).

China has a zero tolerance for unapproved biotech products in imports. In practice, labs have varying testing sensitivities and capabilities; although, all use highly sensitive polymerase chain reaction (PCR) testing. This means that the import tolerance can range from 0.1 percent to 0.01 percent or even less. The variability, high testing sensitivity, and lack of a set threshold for positive results create the risk that shipments will be rejected due to cross contamination from reused shipping containers or pollen blown in from another field. It can also result in cases where a shipment tests negative for unapproved products in the exporting country but positive when it arrives in China.

MARA, GACC, and MEP have developed national and industry standards for biotech testing, all of which use PCR testing methodologies. Though the standard numbers suggest they are voluntary, they are believed to be *de facto* mandatory and are adhered to within China. The standards adopted by GACC tend to focus on specific products, and MARA standards often target specific traits.

While submitting applications for biosafety certificates, foreign developers are required to provide testing methodologies and reference materials along with the application.

i) Low Level Presence (LLP) Policy

China does not have LLP policy for biotech imports. Considering China's zero tolerance for unapproved biotech products in imports and the large volume of imported GE products, this is a significant barrier to trade. China sometimes participates in the Global LLP Initiative as an observer; it did not attend in 2019 but did participate in the virtual meeting in 2020.

Under the Phase One Agreement, China 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.

j) Additional Regulatory Requirements

MARA Seed Variety Registration for Cultivation: Amendment of the Seed Law

In 2021, China's seed industry received attention from high level officials, and was a top for President Xi. In the first half of 2021, high-level officials emphasized that germplasm and breeding are key to China's agricultural stability and food security.

According to the revised Seed Law of 2015, only five major crops are subject to variety registration requirements in China (rice, wheat, corn, cotton, and soybean).

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.

On November 12, 2021, MARA published its "[Decision on Amending Some Seed Industry Regulations \(Draft for Comments\)](#)" on its website. The deadline for comments is December 12,

2021 and the amendments are not final as of the issuance of this report. The Decision facilitates the ability of developers of genetically engineered (GE) crop varieties to apply for seed variety registration as well as for a Production and Operation License.

In 2017, MARA implemented the “Administrative Measures for Non-Major Crop Variety Record Filing”. Echoing the Seed Law, the Measures provided a list of 29 non-major crops that are now subject to seed variety record filing before commercialization. The Measures also included guidance for application, review and approval of the record filing for the 29 non-major crops. This change reduced the testing requirements for non-major crops to be cultivated in China.

Regulations for varietal registration of biotech crops other than cotton and papaya haven’t been approved. So commercial production of biotech crops other than cotton and papaya is not permitted.

Please refer to the [Annual China Seed Report available in the USDA GAIN report system](#) which covers seed variety registration issues and policy. Also, please note section “n” of this report for additional information on MARA’s regulatory enforcement.

k) Intellectual Property Rights (IPR)

Revised in 2015, China’s Seed Law and the Administrative Measures for Plant Variety Protection govern intellectual property rights protection for agricultural biotech. IPR protection for seeds remains a major challenge in China. Misbranding and illegal reproduction of seeds remain rampant despite government efforts to crack down on such practices.

Revised Seed Law for Public Comments

A draft amendment to the Seed Law was released for public comment on August 20, 2021. The amendment expands intellectual property rights for new plant varieties, extends and improves the level of protection, and attempts to stimulate domestic innovation. The draft amendment strengthens plant variety protections (PVP), particularly for essentially derived varieties (EDV). [USDA GAIN report CH2021-0100](#) provides unofficial translation of the draft law.

In the March 2021 National Seed Congress, almost every speaker emphasized the need to strengthen IPR protection and enforcement. Working towards this, China established the Intellectual Property Court of Hainan Free Trade Port, the fifth intellectual property court in the country.

On March 23, 2021, the Supreme People’s Court released “[Several Provisions on the Specific Application of Legal Issues in the Trial of Disputes over Infringement of the New Plant Varieties Rights](#)” (draft for public comments) (link in Chinese), which intends to clarify the new plant variety judgment rules, to further unify the judicial judgment standards and increase judicial protection.

l) Cartagena Protocol Ratification

China signed the Cartagena Protocol on Biosafety (CBP) to the United Nation’s Convention on Biological Diversity in 2000 and ratified it in 2005. In 2011, China announced that the protocol would also apply to the Hong Kong Special Administrative Region. The Ministry of Ecology

and the Environment (MEE) sends delegates to participate in the CBP convention annually. The 2020 United Nations Biodiversity Conference was postponed due to the COVID-19 pandemic; high level opening ceremonies took place in October 2021 in Yunnan province, and the in-person negotiations are planned to run late April to early May 2022.

m) International Treaties and Forums

Major biotech producing countries, including the United States, routinely engage China regarding its slow biotechnology approval system in international fora. However, in 2019 and 2020, the Chinese government's international engagement was limited. Chinese participants attended several virtual workshops during the April 2021 APEC High Level Policy Dialogue on Agricultural Biotechnology (HLPDAB). Biotechnology is also included in the Economic and Trade Agreement between the United States and China.

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.

n) Related Issues

Oversight and Enforcement

Each year, MARA releases an annual Biosafety Oversight Working Plan that includes reports of detected violations.

- 2021 - There were eight cases reported, including illegal corn seed production in Liaoning, Jilin and Xinjiang (two cases in Xinjiang), four cases of research institutes/seed developers violating rules about cotton research and trials, and two cases of detecting unapproved genes in cotton traits applying for bio-safety certificate for production purpose.
- 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 was found spilling GE soy when the soy 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 Chinese 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 still 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

In 2020 and 2019, there were no new nation-wide surveys of public acceptance of biotech in China. 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 central government invests 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 [National Science and Technology Report Service](#) (link in Chinese).

In June 2020, a research team with Xijing Hospital in Xi'an, Shaanxi province announced that it has transplanted a liver, a heart and a kidney from a gene-edited pig to three monkeys, respectively. The monkeys receiving the heart and kidney died in seven and one day, respectively, but the one receiving the liver had lived 18 days when the report was released. Scientists hope transplantation using organs from gene-edited pigs can address a human organ shortage.

Scientists from CAAS, Huazhong Agricultural University, and University of Guelph, Canada, published research in the international biology journal *eLife* in early 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 delta-coronavirus. Meanwhile, the GE pig has normal meat-production and reproductive performance. See: [eLife Journal](#) article. Since the occurrence of African Swine Fever (ASF) in summer 2018, biotechnology is being considered as a possible solution to resist the disease. See: [GARA GAP Analysis Report of November 2018](#).

In March 2018, a team of scientists from Jinan University and Chinese Academy of Sciences (both are in Guangdong province) established a pig model of Huntington's disease (HD) using genetic engineering technology. They anticipate that the pigs could be used to test treatments for HD, which is caused by a gene encoding a toxic protein that causes brain cells to die. A paper about the research was published in *Cell* in March 2018.

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

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

d) Imports

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

e) Trade Barriers

N/A

Part E Policy

Regulation of GE Animals

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 status of application can be found at the [MARA’s website for administrative approvals](#) (link in Chinese). However, this regulation lacks implementation rules or specific policies that regulate 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 animal biotech products only after a trait is deregulated in an exporting country.

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

a) Approvals

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

b) 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.

c) 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). Since China has not commercialized any GE animals, specific measures for GE animal labeling are not available.

d) Additional Regulatory Requirements

N/A.

e) 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.

f) International Treaties and Forums

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

g) Related Issues

In January 2021, a research team at Qingdao Agricultural University in Shandong province announced that it had succeeded in cloning a cat. The research director explained that the cat was cloned from a piece of skin acquired from a female jungle cat, which was cultured into many somatic cells and were kept frozen for further use. Researchers replaced nuclei of recipient oocytes with those from the somatic cells of the jungle cat. Embryos were transferred to surrogate mother cats, who gave birth to the cloned jungle cat. Note: As of the publication of this GAIN report, the scientific work is not available in an academic/scientific journal but has been covered in broad-based media.

Scientists anticipate strong demand for cloned animals in the pet market.

Part F: Marketing

h) Public/Private Opinions

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

In 2020, Emmanuelle Charpentier and Jennifer Doudna were awarded the Nobel Prize in Chemistry. Wide publicity of the two female scientists improved public acceptance of the technology, though the public may feel differently for products developed from the technology.

i) 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 much 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 National Health Commission has approved the use of 15 such enzymes in four batches to be used as food additives in food production. The food ingredient industry, particularly the multinationals in China, is actively seeking clarification from the Chinese 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.⁴

Part G: Production and Trade

a) Commercial Production

At present, China 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.).

According to the [National Food Safety Standard for Use of Food Additives \(GB 2760-2015\)](#), China has approved the use of 54 enzyme preparations to be used in food processing. However, the specific commercial production status of food ingredients originating from microbial biotechnology is not available.

b) Export

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, China 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 - with approvals announced in January, February, April and July.

Part H: Policy

a) Regulatory Framework

Applying for Approval of Enzymes Derived from Microbial Biotechnology

⁴ 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.

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)⁵. NHC will then conduct a risk assessment of the ingredient and determine whether it can be approved.

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 by NHC 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. In April 2021, China notified the [revised draft of GB 2760](#) to the WTO SPS Committee for comments, which contains a list of 60 enzyme preparations for food processing use (page 155 of the report).

b) Approvals

NHC has announced the approval of the following enzymes from microbial biotechnology as new food additives. Enzymes that have received approval since the beginning of 2021 are noted in Table 1.

⁵ Instructions on the application procedures and material requirements can be found on the [NHC website](#) (in Chinese, scroll down to New Variety Food Additive Applications - 食品添加剂新品种审批).

Table 1. China: Approved Enzymes from Microbial Biotechnology

No.	酶 Enzyme	来源 Host	供体 Donor
1	葡糖淀粉酶 Glucoamylase	李氏木霉 <i>Trichoderma reesei</i>	李氏木霉 <i>Trichoderma reesei</i>
2.	阿拉伯呋喃糖苷酶 Arabinofuranosidase	李氏木霉 <i>Trichoderma reesei</i>	<i>Talaromyces pinophilus</i>
3.	多聚半乳糖醛酸酶 Polygalacturonase	黑曲霉 <i>Aspergillus niger</i>	黑曲霉 <i>Aspergillus niger</i>
4.	果胶裂解酶 Pectinlyase	李氏木霉 <i>Trichoderma reesei</i>	黑曲霉 <i>Aspergillus niger</i>
5.	麦芽四糖水解酶 Maltotetraohydrolase	地衣芽孢杆菌 <i>Bacillus licheniformis</i>	施氏假单胞菌 <i>Pseudomonas stutzeri</i>
6.	木聚糖酶 Xylanase	李氏木霉 <i>Trichoderma reesei</i>	<i>Talaromyces leycettanus</i>
7.	α -葡萄糖苷酶 Alpha-glucosidase	李氏木霉 <i>Trichoderma reesei</i>	黑曲霉 <i>Aspergillus niger</i>
8.	乳糖酶 Lactase	地衣芽孢杆菌 <i>Bacillus licheniformis</i>	两歧双歧杆菌 <i>Bifidobacterium bifidum</i>
9.	羧肽酶 Carboxypeptidase	黑曲霉 <i>Aspergillus niger</i>	黑曲霉 <i>Aspergillus niger</i>
10.	脂肪酶 Lipase	黑曲霉 <i>Aspergillus niger</i>	黄色镰刀菌 <i>Fusarium culmorum</i>
11.	α -淀粉酶 Alpha-amylase	李氏木霉 <i>Trichoderma reesei</i>	白曲霉 <i>Aspergillus kawachii</i>
12.	蛋白酶 Protease	李氏木霉 <i>Trichoderma reesei</i>	李氏木霉 <i>Trichoderma reesei</i>
13.	葡糖异构酶 Glucose isomerase	锈棕色链球菌 <i>Streptomyces rubiginosus</i>	锈棕色链球菌 <i>Streptomyces rubiginosus</i>
14.	脂肪酶 Lipase	多行汉逊酵母 <i>Hansenula polymorpha</i>	异孢镰刀菌 <i>Fusarium hetreosporum</i>
15. (new approval in January 2021)	B-淀粉酶 β -amylase (Novozyme)	地衣芽孢杆菌 <i>Bacillus licheniformis</i>	弯曲芽孢杆菌 <i>Bacillus flexus</i>
16. (new approval in February 2021)	α -淀粉酶 Alpha-amylase	地衣芽孢杆菌 <i>Bacillus licheniformis</i>	嗜纤维菌 <i>Cytophaga sp.</i>
17. (new approval in February 2021)	乳糖酶 Lactase	枯草芽孢杆菌 <i>Bacillus subtilis</i>	两歧双歧杆菌 <i>Bifidobacterium bifidum</i>

No.	酶 Enzyme	来源 Host	供体 Donor
18. (new approval in February 2021)	蛋白酶 Protease	枯草芽孢杆菌 <i>Bacillus subtilis</i>	水生栖热菌 <i>Thermus Aquaticus</i>
19. (new approval in April 2021)	蛋白酶 Protease	枯草芽孢杆菌 <i>Bacillus subtilis</i>	解淀粉芽孢杆菌 <i>Bacillus amyloliquefaciens</i>
20. (new approval in April 2021)	磷酸肌醇磷脂酶C Phosphoinositide phospholipase C (DSM)	荧光假单胞菌 <i>Pseudomonas fluorescens</i>	从土壤中分离的编码磷酸肌醇磷脂酶C基因的微生物
21. (new approval in July 2021)	α -淀粉酶 α -amylase	黑曲霉 <i>Aspergillus niger</i>	微小根毛霉 <i>Rhizomucor pusillus</i>
22. (new approval in July 2021)	多聚半乳糖醛酸酶 Polygalacturonase	李氏木霉 <i>Trichoderma reesei</i>	塔宾曲霉 <i>Aspergillus tubingensis</i>
23. (new approval in July 2021)	果胶酯酶 Pectin esterase	李氏木霉 <i>Trichoderma reesei</i>	塔宾曲霉 <i>Aspergillus tubingensis</i>
24. (new approval in July 2021)	磷酸肌醇磷脂酶C Phosphoinositide Phospholipase C	地衣芽孢杆菌 <i>Bacillus licheniformis</i>	假单胞菌 <i>Pseudomonas sp.</i>
25. (new approval in July 2021)	磷脂酶C Phospholipase C	地衣芽孢杆菌 <i>Bacillus licheniformis</i>	苏云金芽孢杆菌 <i>Bacillus thuringiensis</i>
26. (new approval in July 2021)	木聚糖酶 Xylanase	李氏木霉 <i>Trichoderma reesei</i>	柔曲高温多孢菌 <i>Thermopolyspora flexuosa</i>
27. (new approval in July 2021)	葡糖淀粉酶 Glucoamylase	黑曲霉 <i>Aspergillus niger</i>	密粘褶菌 <i>Gloeophyllum trabeum</i>
28. (new approval in July 2021)	脂肪酶 Lipase	李氏木霉 <i>Trichoderma reesei</i>	尖孢镰刀菌 <i>Fusarium oxysporum</i>
29. (new approval in July 2021)	4- α -糖基转移酶 4- α -glucanotransferase	苍白空气芽孢杆菌 <i>Aeribacillus pallidus</i>	--

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; the enzymes produced from microbial biotechnology, which were approved from 2019 to 2021 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)

China Cotton Exports (HS 520100)

Partner Country	Quantity (Metric Tons)			
	2018	2019	2020	2021 (Jan.-Oct.)
World	47,244	52,055	4,701	3,681
Malaysia	3,053	20	3,362	0
Vietnam	16,249	21,383	754	3,397

China Cotton Imports (HS 520100)

Partner Country	Quantity (Million Tons)			
	2018	2019	2020	2021 (Jan.-Oct.)
World	1.57	1.85	2.16	1.91
United States	0.53	0.36	0.98	0.78
Brazil	0.185	0.505	0.62	0.51
India	0.17	0.206	0.25	0.4
Australia	0.42	0.398	0.12	0.03
Sudan	0.03	0.04	0.03	0.02

China Corn Imports (HS 100590)

Partner Country	Quantity (Million Tons)			
	2018	2019	2020	2021 (Jan.-Oct.)
World	3.52	4.79	11.24	26.23
Ukraine	2.93	4.14	6.24	7.26
United States	0.3	0.32	4.34	18.87

China Soybean Imports (HS 120190)

Partner Country	Quantity (Million Tons)			
	2018	2019	2020	2021 (Jan.-Oct.)
World	88.04	88.51	100.31	79.01
Brazil	66.08	57.68	64.28	52.28
United States	16.64	16.94	25.87	22.57
Argentina	1.46	8.79	7.46	2.43
Uruguay	1.2	2.07	1.66	0.59
Russia	0.823	0.73	0.69	0.49

China Distillers Dried Grains Imports (HS 230330)

Partner Country	Quantity (1,000 Tons)			
	2018	2019	2020	2021 (Jan.-Oct.)
World	148	141	182	221
United States	147	140	182	221

China Rapeseed Imports (HS 12051090, 12059090)

Partner Country	Quantity (Tons)			
	2018	2019	2020	2021 (Jan.-Oct.)
World	4,757,038	2,736,797	3,114,317	2,125,811
Canada	4,443,330	2,356,887	2,315,432	1,921,354
Australia	25,123	133,522	438,981	93,097
Russia	204,512	188,456	330,973	99,701
Mongolia	83,525	57,931	28,931	11,659

China Rapeseed Meal Imports (HS 230641)

Partner Country	Quantity (Tons)			
	2018	2019	2020	2021 (Jan.-Oct.)
World	1,298,965	1,577,842	1,885,631	1,746,364
Canada	1,275,391	1,427,428	1,496,300	1,364,374
United Arab Emirates	0	100,425	334,760	352,155
Kazakhstan	0	49,990	46,115	68
Australia	23,573	0	8,456	29,767

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

Partner Country	Quantity (Tons)			
	2018	2019	2020	2021 (Jan.-Oct.)
World	1,295,948	1,615,002	1,930,613	1,974,317
Canada	1,127,321	963,360	1,033,933	890,200
United Arab Emirates	2,892	204,228	362,205	327,727
Russia	81,053	152,835	217,391	273,812
Germany	192	145	19,655	106,643
Australia	11,161	49,376	71,711	45,884

France	3003	2683	68,614	43,000
Ukraine	37,025	116,401	62,016	41,184
Kazakhstan	23,358	59,836	33,390	4,003

China Sugar Beet Pulp Imports (HS 230320)

Partner Country	Quantity (Tons)			
	2018	2019	2020	2021 (Jan.-Oct.)
World	59,290	28,437	164,610	323,482
Egypt	0	17,498	105,840	273,528
Russia	51	715	40,918	33,022
Ukraine	16,738	10,221	17,615	16,735
Germany	360	0	236	197

Appendix 2: Biotech Crops Approved for Import as Processing Materials

No.	Event	Approval Issued Date	Developer	Biosafety certificate validity
1	Pest resistant and herbicide tolerant corn MON87411 (2021.1 new approval)	December 29, 2020	Bayer CropScience	Dec. 29, 2020-Dec. 28, 2025
2	Pest resistant and herbicide tolerant corn MZIR098 (2021.1 new approval)	December 29, 2020	Syngenta Crop Protection	Dec. 29, 2020-Dec. 28, 2025
3	Soybean DBN-09004-6	Jun. 11, 2020	Beijing DaBeiNong Biotechnology Co., Ltd.	Jun. 11, 2020-Jun. 11, 2025
4	Insect-Resistant soybean MON87751	Jun. 11, 2020	Monsanto Far East Ltd.	Jun. 11, 2020-Jun. 11, 2025
5	Herbicide-tolerant corn MON87427 (renew)	July 16, 2017	Monsanto Far East Ltd.	Jun. 11, 2020-Jun. 11, 2025
6	Soybean DAS-81419-2	December 2, 2019	Dow AgroSciences	Dec. 02, 2019-Dec. 02, 2022
7	Virus Resistant Papaya 55-1	December 2, 2019	USDA ARS, U.S. Pacific Basin Agricultural Research Center, University of Hawaii	Dec. 02, 2019-Dec. 02, 2022
8	Herbicide resistant corn T25	April 6, 2004	BASF	Dec. 02, 2019-Dec. 02, 2022
9	Herbicide resistance soybean A5547-127	December 11, 2014	BASF	Dec. 02, 2019-Dec. 02, 2022
10	Herbicide resistant soybean MON89788	August 28, 2008	Monsanto Far East Ltd.	Dec. 02, 2019-Dec. 02, 2022
11	Quality improvement and herbicide resistance soybean 305423×GTS40-3-2	December 11, 2014	Pioneer	Dec. 02, 2019-Dec. 02, 2022
12	Quality improvement soybean 305423	November 3, 2011	Pioneer	Dec. 02, 2019-Dec. 02, 2022
13	Insect resistant cotton 15985	July 20, 2006	Monsanto Far East Ltd.	Dec. 02, 2019-Dec. 02, 2024
14	Herbicide tolerant Canola T45	April 6, 2004	BASF	Dec. 02, 2019-Dec. 02, 2022
15	Herbicide tolerant Canola Oxy-235	April 6, 2004	BASF	Dec. 02, 2019-Dec. 02, 2022
16	Herbicide tolerant Canola Ms8Rf3	April 6, 2004	BASF	Dec. 02, 2019-Dec. 02, 2022

No.	Event	Approval Issued Date	Developer	Biosafety certificate validity
17	Herbicide resistant sugar beet H7-1	April 20, 2009	Monsanto Far East Ltd.	Dec. 02, 2019-Dec. 02, 2022
18	Herbicide tolerant canola RF3	December 20, 2018	BASF	Dec. 20, 2018-Dec. 20, 2021
19	Pest resistant and herbicide tolerant corn DP4114	December 20, 2018	Pioneer	Dec. 20, 2018-Dec. 20, 2021
20	Herbicide tolerance canola MON 88302	December 20, 2018	Monsanto Far East Ltd.	Dec. 20, 2018-Dec. 20, 2021
21	Herbicide tolerance soybean DAS-44406-6	December 20, 2018	Dow AgroSciences	Dec. 20, 2018-Dec. 20, 2021
22	Herbicide tolerance soybean SYHT0H2	December 20, 2018	Syngenta Crop Protection, BASF (original applicant: Bayer CropScience)	Dec. 20, 2018-Dec. 20, 2021
23	Improved quality soybean MON87705 (renew)	June 12, 2017	Monsanto Far East Ltd.	June 11, 2020-June 11, 2025
24	Herbicide resistant corn DAS-40278-9 (renew)	June 12, 2017	Dow AgroSciences	June 11, 2020-June 11, 2025
25	Insect resistance and herbicide tolerance corn Bt11×GA21 (renew)	November 3, 2011	Syngenta Crop Protection	June 11, 2020-June 11, 2025
26	Insect resistance corn MIR162 (renew)	December 11, 2014	Syngenta Crop Protection	June 11, 2020 – June 11, 2025
27	Insect resistant corn 5307 (renew)	July 16, 2017	Syngenta Crop Protection	June 11, 2020 – June 11, 2025
28	Herbicide tolerant cotton GHB614 (renew)	December 30, 2010	BASF	Dec. 29, 2020-Dec. 28, 2025
29	Insect resistant cotton COT102 (renew)	December 31, 2015	Syngenta Crop Protection	Dec. 29, 2020-Dec. 28, 2025
30	Herbicide tolerant cotton LLCotton25	December 20, 2006	BASF	Dec.31, 2015 - Dec.31, 2020
31	Herbicide tolerant corn FG72	December 31, 2016	BASF	Dec.20, 2018 - Dec.20, 2021
32	Quality-Improved Soybean MON 87769	December 31, 2015	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021
33	Herbicide tolerant Soybean MON 87708	December 31, 2015	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021

No.	Event	Approval Issued Date	Developer	Biosafety certificate validity
34	Quality improved corn 3272	May 21, 2013	Syngenta Crop Protection	Dec.20, 2018 - Dec.20, 2021
35	Drought Tolerant corn MON87460	May 21, 2013	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021
36	Herbicide tolerant Soybean CV127	June 6, 2013	BASF	Dec.20, 2018 - Dec.20, 2021
37	Insect resistant soybean MON 87701	June 6, 2013	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021
38	Insect resistant soybean MON87701 x MON89788	June 6, 2013	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021
39	Herbicide tolerant soybean A2704-12	December 20, 2007	BASF	Dec.20, 2018 - Dec.20, 2021
40	Herbicide tolerant corn NK603	July 8, 2005	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021
41	Insect resistant and herbicide tolerance corn MON88017	December 20, 2007	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021
42	Insect resistant corn MON89034	December 30, 2010	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021
43	Insect resistant corn MIR604	August 28, 2008	Syngenta Crop Protection	Dec.20, 2018 - Dec.20, 2021
44	Herbicide resistant corn GA21	February 20, 2004	Syngenta Crop Protection	Dec.20, 2018 - Dec.20, 2021
45	Herbicide tolerant soybean GTS40-3-2	February 20, 2004	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021
46	Insect resistant corn 59122	December 20, 2006	Du Pont/Dow AgroSciences	Dec.20, 2018 - Dec.20, 2021
47	Insect resistant corn TC1507	April 6, 2004	Du Pont/Dow AgroSciences	Dec.20, 2018 - Dec.20, 2021
48	Insect resistant corn MON810	February 20, 2004	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021
49	Insect resistant corn BT176	April 6, 2004	Syngenta Crop Protection	Dec.20, 2018 - Dec.20, 2021
50	Insect resistant corn Bt11	April 6, 2004	Syngenta Crop Protection	Dec.20, 2018 - Dec.20, 2021
51	Herbicide tolerant Canola Topas19/2	April 6, 2004	BASF	Dec. 20, 2018-Dec. 20, 2021
52	Herbicide tolerant Canola Ms1Rf1	April 6, 2004	BASF	Dec. 20, 2018 -Dec.20, 2021
53	Herbicide tolerant Canola Ms1Rf2	April 6, 2004	BASF	Dec. 20, 2018 -Dec.20, 2021
54	Herbicide tolerant Canola GT73	April 6, 2004	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021
55	Insect resistant cotton 531	February 20, 2004	Monsanto Far East Ltd.	June 12, 2017-June 12, 2022

No.	Event	Approval Issued Date	Developer	Biosafety certificate validity
56	Herbicide tolerant cotton 1445	February 20, 2004	Monsanto Far East Ltd.	June 12, 2017-June 12, 2022
57	Herbicide tolerant Flex cotton MON 88913	December 20, 2007	Monsanto Far East Ltd.	June12, 2017-June 12, 2022
58	Insect resistant and herbicide tolerant cotton GHB119	April 10, 2014	BASF	Dec. 20, 2018 -Dec.20, 2023
59	Insect resistant and herbicide tolerant cotton T304-40	April 10, 2014	BASF	Dec. 20, 2018 -Dec.20, 2023
60	Insect resistant corn MON863	June 25, 2004	Monsanto	Certificate expired
61	Herbicide resistant soybean 356043	December 30, 2010	DuPont	Certificate expired

Note: due to merger and acquisition of the developers, the owner of some of the certificates may have been changed.

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

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

No.	Event	Developer	Ecological Zone	Biosafety certificate validity
	tolerant corn Ruifeng 125	Biotechnology Co.		
9	Herbicide-resistant soy SHZD32-01	Shanghai Jiaotong University	South China Soybean Region	Dec. 2, 2019 – Dec. 2, 2024
10	Herbicide-tolerant corn DBN 9858	<i>Beijing DaBeiNong Biotechnology Co., Ltd.</i>	North China Spring Corn Region	Jun. 11, 2020 – June 11, 2025
11	Herbicide-tolerant soybean Zhonghuang 6106	Crop Science Institute of CAAS	Huanghuaihai Summer Soy Region	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	<i>Beijing DaBeiNong Biotechnology Co., Ltd.</i>	Summer corn area covering the Yellow River, Huaihe River, Haihe River region	Dec. 29, 2020-Dec. 28, 2025
14	Herbicide-tolerant corn DBN 9858	<i>Beijing DaBeiNong Biotechnology Co., Ltd.</i>	South China corn area	Dec. 29, 2020-Dec. 28, 2025
15	Herbicide-tolerant corn DBN 9858	<i>Beijing DaBeiNong Biotechnology Co., Ltd.</i>	Southeast China corn area	Dec. 29, 2020-Dec. 28, 2025
16	Herbicide-tolerant corn DBN 9858	<i>Beijing DaBeiNong Biotechnology Co., Ltd.</i>	Northwest corn area	Dec. 29, 2020-Dec. 28, 2025
17	Pest resistant and herbicide tolerant corn DBN 9936	<i>Beijing DaBeiNong Biotechnology Co., Ltd.</i>	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	<i>Beijing DaBeiNong Biotechnology Co., Ltd.</i>	South China corn area	Dec. 29, 2020-Dec. 28, 2025
19	Pest resistant and herbicide tolerant corn DBN 9936	<i>Beijing DaBeiNong Biotechnology Co., Ltd.</i>	Southeast China corn area	Dec. 29, 2020-Dec. 28, 2025

No.	Event	Developer	Ecological Zone	Biosafety certificate validity
17	Pest resistant and herbicide tolerant corn DBN 9936	<i>Beijing DaBeiNong Biotechnology Co., Ltd.</i>	Northwest corn area	Dec. 29, 2020-Dec. 28, 2025
18	Pest-resistant and herbicide tolerant corn DBN9501	Beijing DaBeiNong Biotechnology Co., Ltd.	North China spring corn area	Dec. 29, 2020-Dec. 28, 2025
19	Herbicide tolerant soybean DBN9004	Beijing DaBeiNong Bioechnology Co., Ltd.	North China spring soybean area	Dec. 29, 2020-Dec. 28, 2025

Attachments:

No Attachments