Required Report: Required - Public Distribution **Date:** December 08,2020

Report Number: CH2020-0161

Report Name: Agricultural Biotechnology Annual

Country: China - Peoples Republic of

Post: Beijing

Report Category: Biotechnology and Other New Production Technologies

Prepared By: FAS Beijing Staff

Approved By: Adam Branson

Report Highlights:

In 2020, China committed to a number of reforms to its agricultural biotechnology policies under the U.S.-China Economic and Trade Agreement ("Phase One Agreement"). On June 23, 2020, the Chinese Ministry of Agriculture and Rural Affairs (MARA) issued biosafety certificates for the import of two new events along with six renewals; the validity period for all certificates was 5 years. On July 15, 2020, MARA issued biosafety certificates for one corn event and one soybean event developed by Chinese entities. To date, 14 enzymes derived from microbial biotechnology have obtained approval from the National Health Commission for use as food ingredients.

Contents

Executive Summary

On June 23, 2020, MARA released the updated list of biotechnology (biotech henceforth) products to be imported for food, feed, and processing (FFP) use, including two newly approved products (Beijing Da-Bei-Nong Technology Group's herbicide-tolerant soybean DBN-09004-6, and the Bayer insect-resistant soybean MON87751). The list also cited biosafety certificate renewals for six previously approved events; the validity period for both the new and renewed certificates was 5 years. China's regulatory system for biotechnology primarily focuses on the approval of genetically engineered (GE) crops for import and further processing into animal feed and vegetable oil. Except for GE papaya and cotton, China has not yet approved any GE food or feed products for domestic cultivation despite issuing biosafety certificates for cultivation to some products by Chinese developers.

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

The regulatory regime under which new GE products are reviewed in China underwent numerous changes in 2017 and 2018, evolving into a more onerous, less science-based system. Regulations on genome editing have not been issued despite active Chinese domestic industry and public research institute research and development.

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

More GE Corn and Soybean Traits Obtained Biosafety Certificates for Cultivation

On July 15, 2020, MARA issued biosafety certificates for cultivation to herbicide-tolerant corn DBN9858 of Beijing Da-Bei-Nong Technology Group and herbicide-tolerant soybean Zhonghuang 6106 of Crop Science Institute of the Chinese Academy of Agricultural Sciences. Given the two GE corn products and one soybean product that obtained biosafety certificates for cultivation in January 2020, there are now five domestically developed traits 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 path to variety registration for GE crops other than cotton and papaya.

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 sets the goal for commercializing a new generation of Bacillus thuringiensis (Bt) cotton, Bt corn, and herbicide-tolerant soybeans by 2020.

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.

Chinese Regulatory System Remains Opaque and Informal

In late 2017, following the State Council's revision of the administrative rules for biosafety management, MARA revised the administrative measures for biosafety assessment, the safety review of agriculture "GMO" imports, and labeling provisions to implement the State Council's direction.

According to the revised administrative measures, MARA now entrusts qualified technical institutes to conduct regulatory testing (field trials and feeding studies) after receiving a biosafety certificate application. Developers no longer pay MARA to conduct the trials; MARA-designated institutes conduct the trials utilizing Chinese government funds. However, MARA does not share the testing results with developers. MARA's Development Center for Science and Technology (DCST) issued informal guidance or correspondences to applicants in 2018. In summer 2019, DCST issued formal notices to applicants individually, providing detailed instructions about the additional materials required for testing and the deadline for submitting such materials (six months after issuance of the notices). FAS/China understands such notices contain product specific requirements for seeds, purified protein, testing methods, etc.

While the Chinese government indicates that these additional requirements are part of the revised regulations, these revisions were not notified to the World Trade Organization (WTO) for Member State comment, creating confusion among biotech developers and trading partners alike.

While many countries/regions are pursuing simplifying their safety assessment regulations based on 25 years' experience and accumulated data on risk, authorities show no willingness to accept safety testing data obtained by trials conducted outside of China without conducting verification trials in China. 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.

Oversight and Enforcement

Each year, MARA releases the annual Biosafety Oversight Working Plan. In the most recent edition, released in January 2020, MARA pledged to include research, trials, seed production, trading, growing, processing and import activities into its biosafety oversight; special attention will be given to research institutes, seed production facilities and GMO processing/distribution enterprises; focus will be placed on the major grain production areas in northeast China, seed production bases in northwest and southwest China, and the South China Crop Breeding Areas.

Public Opinion

In recent years, reports about agricultural biotechnology by mainstream media and other government agencies are generally positive; however, misinformation about biotech safety is pervasive through Chinese social media outlets.

Chapter 1: Plant Biotechnology

Part A: Production and Trade

a) Product Development

Biotech is designated 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 sets the goal for commercializing a new generation of Bacillus thuringiensis (Bt) cotton, Bt corn, and herbicide-tolerant soybeans by 2020.

Despite decades of research by Chinese biotech developers, China has not commercialized any GE products, with the exception of cotton and papaya. From January 2020 to July 2020, China issued biosafety certificates for cultivation to five domestically developed GE food and feed products (three corn and two soybean products). However, before commercialization can occur, the varieties must be registered with MARA's Seed Industry Management Department.

In 2009, MARA approved the first biosafety certificates for food and feed products to two Chinese-developed insect-resistant rice varieties and one high-phytase corn variety. In 2014, the former Ministry of Agriculture (now MARA) renewed the biosafety certificates for these products. However, there is no MARA report that the three products received renewed biosafety certificates at the end of 2019, meaning the certificates have expired.

In 2018, Huazhong Agricultural University completed its consultation with the U.S. Food and Drug Administration on Huahui No.1 rice product, which was one of the Chinese-developed rice varieties that received a biosafety certificate from MARA in 2009. On February 27, 2019, Beijing Da-Bei-Nong Technology Group, a private Chinese firm principally engaged in the cultivation and promotion of seed products, 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".

This year marked the end of 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). 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 list of biotech breeding projects funded by the grant is available at the National Science and Technology Report Service (link in Chinese).

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).

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 agricultural area of GE crops increased slightly to 2.9 million hectares in 2018, according to the International Service for the Acquisition of Agro-Biotech Applications (ISAAA) report titled "Global Status of Commercialized Biotech/GM Crops in 2018". 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 2016 totaled $19.6 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. 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 would be included in the final biosafety certificate application.

c) Exports

China is a large exporter of GE cotton products, mainly cotton fiber.

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 have resulted in detained and rejected shipments. For example, alfalfa shipments that contain unapproved GE varieties are detained and rejected from time to time. 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 domestic environmental safety trials and feeding studies, which each require that the studies be conducted in China. In 2016 and 2017, MARA revised these regulations without notifying the World Trade Organization or soliciting public comments nor did MARA 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 (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 repeated questions unrelated to the intended use of the product, which causes undue delay in the regulatory process.

In some cases, the cumulative time for China's review of a product has exceeded 8 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 in order to facilitate trade.

Part B: Policy

a) Regulatory Framework

Regulatory Structure

The agricultural biotech regulatory environment is outlined in the State Council[1]'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, and latest revision issued on November 30, 2017);
- 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 Genetically Modified Organisms 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).

[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.

MARA is developing rules for regulating products developed by genome editing. MARA has said that genome edited products will fall within the scope of China's "GMO" regulations and will be regulated as a GMO.

The 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 DCST, an affiliate of MARA, serves as the Secretariat.

The NBC is divided into three expert groups: 1) biotech plants, 2) animals and microorganisms, and 3) food and feed. 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 generally released 20 working days after each meeting.

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 consists of 41 experts from Chinese research institutes and universities, which is responsible for drafting and revising technical standards for biotech products, including standards for safety assessments, testing, and detections.

There are around 40 MARA-designated institutes across China that conduct molecular characteristics, 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 its responsible for their enforcement.

MARA Import Approval Procedure

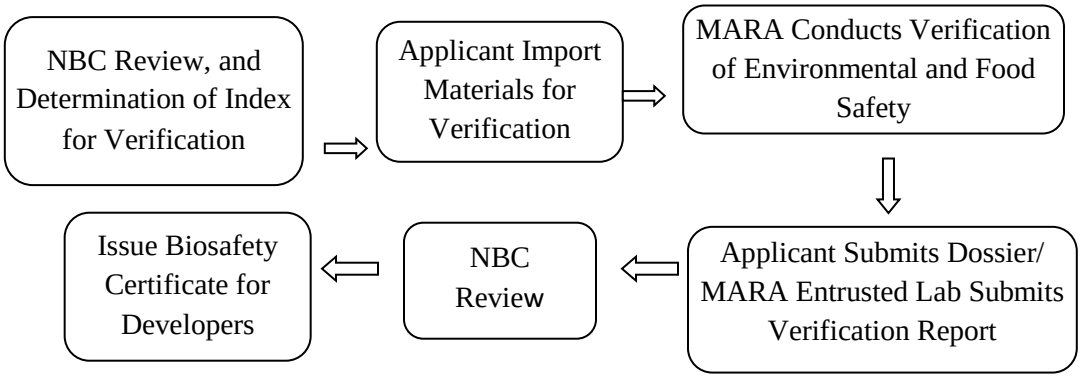
Biosafety Certificate for Agricultural Biotech (Import) Issued to Foreign Developers

MARA is responsible for the review and issuance of biosafety certificates for imported biotech products for 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 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 a number of 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. For applications that the NBC requests additional data or information, the developer must resubmit the application dossier with the required data or explanation to be reviewed at a subsequent NBC meeting. MARA's guidance on the process, application form, on-line-application process, and status of applications can be found at the MARA official website's page for administrative approvals. The specific timing of NBC meetings is not formalized, remains highly variable, and is dependent on external, political factors. 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."

Around September 2020, MARA posted on its website several documents related to the biosafety approval and import processes for foreign developers. MARA did not make any formal announcement when posting the documents online, 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.

Due to the COVID-19 pandemic, MARA has allowed traders to submit applications on-line.

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 completing 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).

b) Approvals

On June 23, 2020, MARA issued new biosafety certificates to two biotech products to be imported for FFP use: Beijing Da-Bei-Nong Technology Group's herbicide-tolerant soybean DBN-09004-6 and Monsanto Insect-Resistant soybean MON87751. At the same time, MARA renewed six biosafety certificates for previously approved events. 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 traits. When reviewing products with stacked traits, MARA requires applicants to submit information on each individual trait.

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

Scientists associated with the China Academy of Sciences (CAS) and CAAS are progressing in innovative biotechnology and publishing papers about Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) technology. However, without clear regulations scientists lack the ability to commercialize this research. 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.

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 11042300[2]);
3. Rapeseed for planting, rapeseeds, rapeseed oil, and rape seed meal;
4. Cottonseed; and

[2] 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).

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 intends 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.

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.

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 in order 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

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. MARA will likely release the measures in the near future so that the Chinese domestic biotech products that were recently granted biosafety certificates for cultivation, could be commercialized.

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.

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

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.

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 Environmental Protection sends delegates to participate in the CBP convention annually. The 2020 United Nations Biodiversity Conference was planned to take place in October 2020 in Kunming, Yunnan, China, but rescheduled to May 2021 in light of the COVID-19 pandemic.

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. The United States invited Chinese participants to several virtual workshops, such as the APEC High Level Policy Dialogue on Agricultural Biotechnology (HLPDAB) in August 2020.

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

N/A.

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.

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 or stories are decreasing, opponents of biotech are strong.

MARA is constantly requested to publicly disclose information on safety assessment applications and reviews. Members of the NPC Consultative Committee gave MARA a mandate 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 launched in 2008 and supports the research of GE animal species including swine, cattle, and sheep. Despite heavy investment and advanced research, China has not approved any livestock clones, GE animals, or products derived from animal biotech for commercial use.

Part D: Production and Trade

a) Product Development

The 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 has focused on medicine production, improving 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).

Scientists from CAAS, Huazhong Agricultural University, and University of Guelph, Canada, published research on the international biology journal eLife in early September 2020 about a pig species that can resist three major infectious diseases plaguing the animal using gene-editing

technology. The research suggests that it can resist porcine reproductive and respiratory syndrome virus and transmissible gastroenteritis virus, two highly infectious and lethal viruses that can cause significant losses to pig production, and show decreased susceptibility to porcine delta-coronavirus, which can result in deadly diarrhea in piglets. Meanwhile, the GE pig has normal meat-production and reproductive performance. See: eLife Journal article (link in Chinese). Since the occurrence of African Swine Fever (ASF) in summer 2018, biotechnology is being considered a possible solution to resist the disease. See: GARA GAP Analysis Report of November 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 biotech 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.

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 September 2020, a Chinese delegation attended the 87th World Organization for Animal Health (OIE) held in Paris, France, but GE animals was not discussed.

g) Related Issues

N/A.

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.

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 December 2019, 14 enzymes derived from microbial biotechnology have been approved as a new variety of food additive. 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, which is an agreed item in Annex 16 - Agricultural Biotechnology of the Phase One Agreement.[3]

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.). Thus, the specific commercial production status of food ingredients originating from microbial biotechnology is not available.

b) EXPORTS

Trade data not available. China exports alcoholic beverages, dairy products, and processed products, which 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.

---

[3] 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.

d) TRADE BARRIERS

As part of the Phase One Agreement, China has committed to establish a regulatory process for all food ingredients derived from microbial biotechnology by February 2021. USDA/FAS continues to engage MARA and the NHC on developments toward this new market access.

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)[4]. 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

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

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.

b) Approvals

Since December 2019, China has approved 14 enzymes from microbial biotechnology as new food additives:

No.	**Enzyme**	**Host**	**Donor**
1	Glucoamylase	*Trichoderma reesei*	*Trichoderma reesei*
2.	Arabinofuranosidease	*Trichoderma reesei*	*Talaromyces pinophilus*
3.	Polygalacturonase	*Aspergillus niger*	*Aspergillus niger*
4.	Pectinlyase	*Trichoderma reesei*	*Aspergillus niger*
5.	Maltotetraohydrolase	*Bacillus licheniformis*	*Pseudomonas stutzeri*
6.	Xylanase	*Trichoderma reesei*	*Talaromyces leycettanus*
7.	Alpha-glucosidase	*Trichoderma reesei*	*Aspergillus niger*
8.	Lactase	*Bacillus licheniformis*	*Bifidobacterium bifidum*
9.	Carboxypeptidase	*Aspergillus niger*	*Aspergillus niger*
10.	Lipase	*Aspergillus niger*	*Fusarium culmorum*
11.	Alpha-amylase	*Trichoderma reesei*	*Aspergillus kawachii*
12.	Protease	*Trichoderma reesei*	*Trichoderma reesei*
13.	Glucose isomerase	*Streptomyces rubiginosus*	*Streptomyces rubiginosus*
14.	Lipase	*Hansenula polymorpha*	*Fusarium hetreosporum*

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 - Enzyme Preparation for Food and Source List of the Standards. 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 2011; the enzymes produced from microbial biotechnology, which were approved in 2019 and 2020 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

Since the approved enzymes derived from microbial biotechnology are used as common food additives and they do not contain living genetically modified materials, 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)			
	2017	2018	2019	2020 (Jan.-Oct.)
World	17,000	47,244	52,055	4,701
Vietnam	10,958	16,249	21,383	754
Indonesia	2,845	15,348	6,294	80

China Cotton Imports (HS 520100)

Partner Country	Quantity (Million Tons)			
	2017	2018	2019	2020 (Jan.-Oct.)
World	1.15	1.57	1.85	1.61
Brazil	0.066	0.185	0.505	0.425
Australia	0.26	0.42	0.398	0.095
United States	0.51	0.53	0.36	0.77
India	0.11	0.17	0.206	0.17
Uzbekistan	0.09	0.06	0.078	0.095

China Corn Imports (HS 100590)

Partner Country	Quantity (Million Tons)			
	2017	2018	2019	2020 (Jan.-Oct.)
World	2.83	3.52	4.79	7.81
Ukraine	1.82	2.93	4.14	4.98
United States	0.76	0.3	0.32	2.52

China Soybean Imports (HS 120190)

Partner Country	Quantity (Million Tons)			
	2017	2018	2019	2020 (Jan.-Oct.)
World	95.54	88.04	88.51	83.22
Brazil	50.93	66.08	57.68	60.36
United States	32.85	16.64	16.94	14.01
Argentina	6.58	1.46	8.79	6.83
Canada	2.05	1.79	2.27	0.15
Uruguay	2.57	1.2	2.07	1.18
Russia	0.5	0.823	0.73	0.59

China Distillers Dried Grains Imports (HS 230330)

Partner Country	Quantity (1,000 Tons)			
	2017	2018	2019	2020 (Jan.-Oct.)
World	391	148	141	134
United States	390	147	140	134

China Rapeseed Imports (HS 12051090, 12059090)

Partner Country	Quantity (Tons)			
	2017	2018	2019	2020 (Jan.-Oct.)
World	4,747,066	4,757,038	2,736,797	2,434,047
Canada	4,511,939	4,443,330	2,356,887	1,765,266
Russia	63,810	204,512	188,456	209,613
Australia	55,000	25,123	133,522	438,981
Mongolia	116,317	83,525	57,931	20,187

China Rapeseed Meal Imports (HS 230641)

Partner Country	Quantity (Tons)			
	2017	2018	2019	2020 (Jan.-Oct.)
World	943,430	1,298,965	1,577,842	1,555,357
Canada	923,534	1,275,391	1,427,428	1,212,362
United Arab Emirates	0	0	100,425	291,619
Kazakhstan	0	0	49,990	46,183
Australia	19,896	23,573	0	5,193

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

Partner Country	Quantity (Tons)			
	2017	2018	2019	2020 (Jan.-Oct.)
World	757,007	1,295,948	1,615,002	1,617,160
Canada	669,658	1,127,321	963,360	882,233
United Arab Emirates	2,599	2,892	204,228	307,573
Russia	19,292	81,053	152,835	164,236
Ukraine	7,918	37,025	116,401	24,522
Kazakhstan	8,720	23,358	59,836	33,643
Australia	41,136	11,161	49,376	63,596

China Sugar Beet Pulp Imports (HS 230320)

Partner Country	Quantity (Tons)			
	2017	2018	2019	2020 (Jan.-Oct.)
World	53,433	59,290	28,437	147,256
Egypt	0	0	17,498	96,096
Ukraine	6,018	16,738	10,221	16,789
Russia	0	51	715	34,191

Appendix 2: Biotech Crops Approved for Import as Processing Materials

No.	Event	Approval Issued Date	Developer	Biosafety certificate validity
1	Soybean DBN-09004-6 (2020.6 new approval)	Jun. 11, 2020	Beijing DaBeiNong Biotechnology Co., Ltd.	Jun. 11, 2020-Jun. 11, 2025
2	Insect-Resistant soybean MON87751 (2020.6 new approval)	Jun. 11, 2020	Monsanto Far East Ltd.	Jun. 11, 2020-Jun. 11, 2025
3	Herbicide-tolerant corn MON87427 (renew)	July 16, 2017	Monsanto Far East Ltd.	Jun. 11, 2020-Jun. 11, 2025
4	Soybean DAS-81419-2	December 2, 2019	Dow AgroSciences	Dec. 02, 2019-Dec. 02, 2022
5	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
6	Herbicide resistant corn T25	April 6, 2004	BASF	Dec. 02, 2019-Dec. 02, 2022
7	Herbicide resistance soybean A5547-127	December 11, 2014	BASF	Dec. 02, 2019-Dec. 02, 2022
8	Herbicide resistant soybean MON89788	August 28, 2008	Monsanto Far East Ltd.	Dec. 02, 2019-Dec. 02, 2022
9	Quality improvement and herbicide resistance soybean 305423×GTS40-3-2	December 11, 2014	Pioneer	Dec. 02, 2019-Dec. 02, 2022
10	Quality improvement soybean 305423	November 3, 2011	Pioneer	Dec. 02, 2019-Dec. 02, 2022
11	Insect resistant cotton 15985	July 20, 2006	Monsanto Far East Ltd.	Dec. 02, 2019-Dec. 02, 2024
12	Herbicide tolerant Canola T45	April 6, 2004	BASF	Dec. 02, 2019-Dec. 02, 2022
13	Herbicide tolerant Canola Oxy-235	April 6, 2004	BASF	Dec. 02, 2019-Dec. 02, 2022
14	Herbicide tolerant Canola Ms8Rf3	April 6, 2004	BASF	Dec. 02, 2019-Dec. 02, 2022
15	Herbicide resistant sugar beet H7-1	April 20, 2009	Monsanto Far East Ltd.	Dec. 02, 2019-Dec. 02, 2022
16	Herbicide tolerant canola RF3	December 20, 2018	BASF	Dec. 20, 2018-Dec. 20, 2021
17	Pest resistant and herbicide tolerant corn DP4114	December 20, 2018	Pioneer	Dec. 20, 2018-Dec. 20, 2021
18	Herbicide tolerance canola MON 88302	December 20, 2018	Monsanto Far East Ltd.	Dec. 20, 2018-Dec. 20, 2021
19	Herbicide tolerance soybean DAS-	December 20, 2018	Dow AgroSciences	Dec. 20, 2018-Dec. 20, 2021

No.	Event	Approval Issued Date	Developer	Biosafety certificate validity
	44406-6			
20	Herbicide tolerance soybean SYHT0H2	December 20, 2018	Syngenta Crop Protection, BASF (original applicant: Bayer CropScience)	Dec. 20, 2018-Dec. 20, 2021
21	Improved quality soybean MON87705 (renew)	June 12, 2017	Monsanto Far East Ltd.	June 11, 2020-June 11, 2025
22	Herbicide resistant corn DAS-40278-9 (renew)	June 12, 2017	Dow AgroSciences	June 11, 2020-June 11, 2025
23	Insect resistance and herbicide tolerance corn Bt11×GA21 (renew)	November 3, 2011	Syngenta Crop Protection	June 11, 2020-June 11, 2025
24	Insect resistance corn MIR162 (renew)	December 11, 2014	Syngenta Crop Protection	June 11, 2020 – June 11, 2025
25	Insect resistant corn 5307 (renew)	July 16, 2017	Syngenta Crop Protection	June 11, 2020 – June 11, 2025
26	Herbicide tolerant cotton GHB614	December 30, 2010	BASF	Dec. 30, 2015 -Dec.30, 2020
27	Insect resistant cotton COT102	December 31, 2015	Syngenta Crop Protection	Dec.31, 2015 - Dec.31, 2020
28	Herbicide tolerant cotton LLCotton25	December 20, 2006	BASF	Dec.31, 2015 - Dec.31, 2020
29	Herbicide tolerant corn FG72	December 31, 2016	BASF	Dec.20, 2018 - Dec.20, 2021
30	Quality-Improved Soybean MON 87769	December 31, 2015	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021
31	Herbicide tolerant Soybean MON 87708	December 31, 2015	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021
32	Quality improved corn 3272	May 21, 2013	Syngenta Crop Protection	Dec.20, 2018 - Dec.20, 2021
33	Drought Tolerant corn MON87460	May 21, 2013	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021
34	Herbicide tolerant Soybean CV127	June 6, 2013	BASF	Dec.20, 2018 - Dec.20, 2021
35	Insect resistant soybean MON 87701	June 6, 2013	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021
36	Insect resistant soybean MON87701 x MON89788	June 6, 2013	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021
37	Herbicide tolerant soybean A2704-12	December 20, 2007	BASF	Dec.20, 2018 - Dec.20, 2021

No.	Event	Approval Issued Date	Developer	Biosafety certificate validity
38	Herbicide tolerant corn NK603	July 8, 2005	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021
39	Insect resistant and herbicide tolerance corn MON88017	December 20, 2007	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021
40	Insect resistant corn MON89034	December 30, 2010	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021
41	Insect resistant corn MIR604	August 28, 2008	Syngenta Crop Protection	Dec.20, 2018 - Dec.20, 2021
42	Herbicide resistant corn GA21	February 20, 2004	Syngenta Crop Protection	Dec.20, 2018 - Dec.20, 2021
43	Herbicide tolerant soybean GTS40-3-2	February 20, 2004	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021
44	Insect resistant corn 59122	December 20, 2006	Du Pont/Dow AgroSciences	Dec.20, 2018 - Dec.20, 2021
45	Insect resistant corn TC1507	April 6, 2004	Du Pont/Dow AgroSciences	Dec.20, 2018 - Dec.20, 2021
46	Insect resistant corn MON810	February 20, 2004	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021
47	Insect resistant corn BT176	April 6, 2004	Syngenta Crop Protection	Dec.20, 2018 - Dec.20, 2021
48	Insect resistant corn Bt11	April 6, 2004	Syngenta Crop Protection	Dec.20, 2018 - Dec.20, 2021
49	Herbicide tolerant Canola Topas19/2	April 6, 2004	BASF	Dec. 20, 2018-Dec. 20, 2021
50	Herbicide tolerant Canola Ms1Rf1	April 6, 2004	BASF	Dec. 20, 2018 -Dec.20, 2021
51	Herbicide tolerant Canola Ms1Rf2	April 6, 2004	BASF	Dec. 20, 2018 -Dec.20, 2021
52	Herbicide tolerant Canola GT73	April 6, 2004	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021
53	Insect resistant cotton 531	February 20, 2004	Monsanto Far East Ltd.	June 12, 2017-June 12, 2022
54	Herbicide tolerant cotton 1445	February 20, 2004	Monsanto Far East Ltd.	June 12, 2017-June 12, 2022
55	Herbicide tolerant Flex cotton MON 88913	December 20, 2007	Monsanto Far East Ltd.	June12, 2017-June 12, 2022
56	Insect resistant and herbicide tolerant cotton GHB119	April 10, 2014	BASF	Dec. 20, 2018 -Dec.20, 2023
57	Insect resistant and herbicide tolerant cotton T304-40	April 10, 2014	BASF	Dec. 20, 2018 -Dec.20, 2023
58	Insect resistant corn MON863	June 25, 2004	Monsanto	Certificate expired
59	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 (Corn and Soybean, 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)
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)
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 and 2015; current certificate valid for December 31, 2015 – December 31, 2020
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 and herbicide resistant corn Shuangkang (Double-Resistant) 12-5	Hangzhou Ruifeng Biotechnology Co., and Zhejiang University	North China Spring Corn Region	Dec. 2, 2019 – Dec. 2, 2024
7	Herbicide-resistant soy SHZD32-01	Shanghai Jiaotong University	South China Soybean Region	Dec. 2, 2019 – Dec. 2, 2024
8	Herbicide-tolerant corn DBN 9858	Beijing DaBeiNong Biotechnology Co., Ltd.	North China Spring Corn Region	Jun. 11, 2020 – June 11, 2025
9	Herbicide-tolerant soybean Zhonghuang 6106	Crop Science Institute of CAAS	Huanghuaihai Summer Soy Region	Jun. 11, 2020 – June 11, 2025

Attachments:

No Attachments