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Report Highlights:

In 2019, there have been no revisions or amendments to China's regulatory approval process for agriculture biotechnology. On December 30, 2019, the Chinese Ministry of Agriculture and Rural Affairs (MARA) issued biosafety certificates for two new events and renewed the biosafety certificates for ten other events. Following a short public comment period, MARA also granted the biosafety certificate for cultivation to 192 plant varieties, including one soybean and two corn products. Separately, the Chinese government has clarified the regulatory pathway for enzymes derived from genetically modified microorganisms (GMMs). Finally, MARA continues to develop regulations on agricultural innovative biotechnologies (e.g. genome edited) in response to international developments and interest from the Chinese research community to commercialize genome edited products.

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Executive Summary

On December 30, 2019, the Chinese Ministry of Agriculture and Rural Affairs (MARA) released the updated list of biotech products to be imported for food, feed, and processing (FFP) use, including two new products (DAS Soybean DAS-81419-2 and the USDA ARS/U.S. Pacific Basin Agricultural Research Center/University of Hawaii Papaya 55-1). The list also renewed ten biosafety certificates for previously approved events.

China's regulatory system for biotechnology primarily focuses on the approval of the GE crops for import for 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.

Additionally, MARA has repeatedly informed foreign agricultural biotechnology developers that China's foreign direct investment restrictions prohibit the domestic cultivation of foreign developed biotechnology (biotech henceforth) 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. The long-awaited regulations on genome editing have not yet been issued despite active Chinese domestic industry and public institute research and development.

Incremental Progress Towards Commercialization of GE Corn and Soy

On December 30, 2019, MARA issued a public notice in its website (link in Chinese), soliciting public comments on 192 domestic plant varieties that MARA intends to issue biosafety certificates for cultivation. The 192 plant varieties include 189 GE cotton products, one soybean product and two corn products. After the comment period, MARA issued the biosafety certificates for cultivation on January 21, 2020, the first such certificates issued since 2009. Before farmer commercialization, the next step will be variety registration by MARA's Seed Industry Management Department.

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. Motivated by this goal, several Chinese domestic companies eagerly waited for

MARA's approval of their domestically developed events, which were in the MARA approval pipeline for years.

Two New Events Approved For Import

On December 30, 2019, MARA released the updated list of biotech products to be imported for food, feed, and processing (FFP) use, including two new products (DAS Soybean DAS-81419-2 and the USDA ARS/U.S. Pacific Basin Agricultural Research Center/University of Hawaii Papaya 55-1). The list also renewed ten biosafety certificates for previously approved events. These approvals and renewals are the result of National Biosafety Committee (NBC) meetings held in September and December 2019.

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 applications for a biosafety certificate. A key change is that developers no longer need to pay MARA to conduct the trials; MARA-designated institutes conduct the trials utilizing the Chinese government budget. MARA's Development Center for Science and Technology (DCST) issued informal guidance or correspondence to applicants in 2018 informing them of this process. In summer 2019, DCST issued formal notices to applicants, providing detailed instructions about the additional materials required for testing and the deadline for submitting such materials (six months after issuance of the notices) to individual applicants. FAS/Beijing 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 much confusion among biotech developers and trading partners alike.

While many countries/regions are pursuing simplifying their safety assessment regulations based on 20+ years' experience and accumulated data on risk, China shows no willingness to simplify their regulatory process. This remains a major concern for foreign developers and the international community alike because they lose control over the regulatory timeline.

Oversight and Enforcement

For years, MARA's GMO Biosafety Office has included eliminating the illegal cultivation of biotech products in its oversight and enforcement plans. In February 2019, MARA announced (link in Chinese) that ten cases violated the agriculture biosafety rules, including four intermediary experiments, and five cases of illegal production of corn seed (Shaanxi, Xinjiang, Heilongjiang, Liaoning, and Jilin). In response to MARA's continued detection of illegal cultivation, some Chinese scientists suggest that commercializing GE crops is not only a solution to the illegal cultivation but would also spur the modernization of the whole seed industry value chain.

In its 2019 Biosafety Working Plan (link in Chinese), MARA pledged to include research, production, processing, trading and import in its biosafety oversight; the oversight will also cover the field trial bases, seed production bases, the South China Crop Breeding Area in Hainan province, and processing facilities. MARA will reinforce oversight of key issues (lab experiments, variety registration, seed production/trading, and labeling). Focus will be placed on the major grain production areas in northeast China, coastal areas with agricultural processing facilities, seed production bases in northwest and southwest China, and the South China Crop Breeding Areas.

Public Opinion

In the past year, reports by the mainstream media and other government agencies are generally positive; however, misinformation about biotech safety continues to be pervasive through Chinese social media outlets.

Chapter One: Plant Biotechnology

Part A: Production and Trade

a) Product Development

Despite decades of research by Chinese biotech developers, China has not yet commercialized any genetically engineered (GE) products, with the exception of cotton and papaya. On December 30, 2019, MARA released a notice (link in Chinese), and solicited comments on 192 plant varieties that MARA intended to issue biosafety certificates for cultivation. Shortly after the comment period MARA issued the biosafety certificates for cultivation. However, before commercialization can occur, the varieties must then be registered with MARA's Seed Industry Management Department.

In 2009, the Ministry of Agriculture and Rural Affairs (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, 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.

Despite these approvals, MARA did not issue the final approval for cultivation of these products, and they have not been officially commercialized. In 2018, Huazhong Agricultural University completed its consultation with the U.S. Food and Drug Administration on Huahui No.1 rice product (link in English), 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 can apply for the biosafety certificate for food, feed and processing in China to be exported to China.

In the June 2019 edition of the Plant Biotechnology Journal, scientists with the Crop Science Institute of the China Academy of Agriculture Sciences (CAAS) published a paper announcing that they had used genome editing to develop new soybean varieties adaptable to low-latitude areas, paving the way for breeding new species. There are many more examples of conventional biotechnology and genome editing research in China. As noted above, China has invested heavily in biotech research and seed development, primarily through publicly funded research institutes and universities.

The year 2020 will be 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 total funding of 24 billion Yuan (approximately $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 will focus on crop (rice, wheat, corn, and cotton) and animal (swine, cattle, and sheep) research. The list of the biotech breeding projects funded by the grant is available at the National Science and Technology Report Service (link in Chinese).

In July 2019, MARA's General Affairs Office issued the Notice for Applications for Adjusted Research Tasks on the National Major Projects, which proposed to adjust and add 12 research projects and funding projects to the National Major Projects. The 12 projects include the research and development of new varieties of insect-resistant GE corn and herbicide-tolerant and pest-resistant GE soybeans; surveillance and public education; accelerating the industrialization of GE corn and soybeans; and achieving breakthroughs in key core technologies, such as genome editing, directed multi-gene transfer, intelligent design, etc. Among the 12 projects, ten are relevant to corn and/or soybeans, and more emphasis was put to commercialization of GE corn and soybeans in China.

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) continues to prohibit foreign biotech developers from conducting biotech research or GE seed production in China.

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% 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 (link in Chinese) for biotech. Most biosafety certificates for cultivation are for domestically developed varieties of Bacillus thuringiensis (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 of the 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 to 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, these delays have surpassed eight years from when the product was first approved in the product's domestic market.

Additionally, the lack of a LLP policy in China means that the world's largest importer of animal feed has a zero tolerance for unapproved GE events, which is a significant barrier to 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, 2019).

Technological advancement, including new breeding technologies, requires regulators to update the existing regulatory system and testing methods. 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. However, MARA also indicated that new regulations are under development and may provide a simplified regulatory process for some genome edited products in the future.

MARA Import Approval Procedure

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

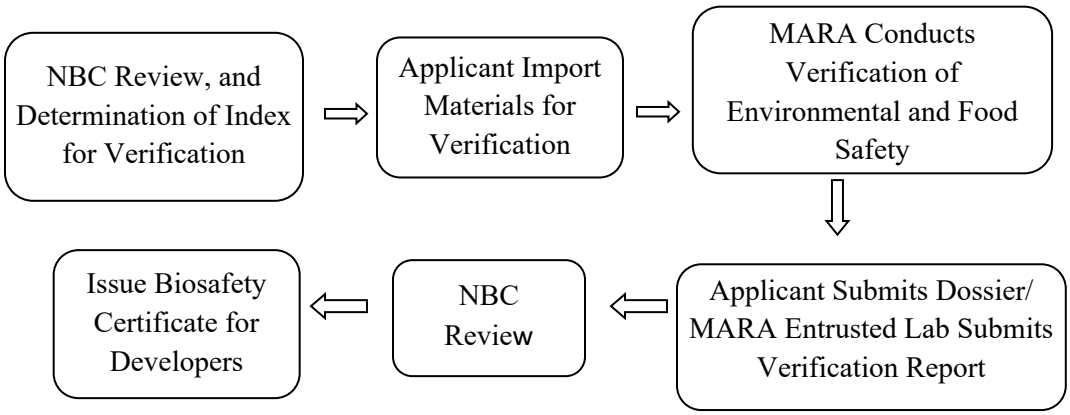
MARA is responsible for the review and issuance of biosafety certificates for imported biotech products for food, feed, and processing use (FFP). The Administrative Measures for Safety of Agriculture GMO Imports outline the requirements for importing biotech products. The Measures require a foreign seed developer to submit the application for biosafety certificate to

[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.

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:



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 products 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 official website's page for administrative approvals.

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 certificates 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 certificate.

The 2019 the Negative List prohibits foreign investment (of any kind) in the selection and breeding of GE crops, livestock and poultry, and aquatic seedlings. The production of GE seeds (seedlings) is also prohibited. To date, this has been interpreted to mean that China does not allow foreign biotech developers to apply for biosafety certification for domestic cultivation of GE products.

The NBC

The National Biosafety Committee (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 of Science and Technology (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.

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.

Other Governmental Biotechnology Responsibilities

General Administration of Customs (GACC) is responsible for testing of food and agricultural 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 and administrative officials and is responsible for drafting and revising technical standards for biotech products, including standards for safety assessments, testing, and detection. Members of the Committee are experts from Chinese research institutions and universities.

China also 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 (GAIN Report Link) released in October 2019 provide that "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." SAMR will be the developer of these regulations and its responsible for their enforcement.

b) Approvals

On December 30, 2019, the Chinese Ministry of Agriculture and Rural Affairs released the updated list of biotech products to be imported for food, feed, and processing (FFP) use, including two new products (DAS Soybean DAS-81419-2 and the USDA ARS/U.S. Pacific Basin Agricultural Research Center/University of Hawaii Papaya 55-1). The list also renewed ten biosafety certificates for previously approved events. Since MARA began approving imported GE products for FFP use, China has approved six different crops: soybeans, corn, canola, cotton, sugar beet and papaya. The first biosafety certificate for import of foreign products was issued in 2004. A full list of approved biotech products for FFP 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 the China Academy of Agricultural Sciences (CAAS) are progressing in innovative biotechnology and publishing dozens of 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 foreign policies, including those of the U.S. Food and Drug Administration and Environmental Protection Agency, as well as other countries' regulatory agencies, on genome editing but has not yet released its own policies. MARA officials have disclosed that policies are under development and will be published soon.

f) Coexistence

China does not have a coexistence policy.

g) Labeling

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
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 (GAIN Report Link) released in October 2019 provide that "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." With such measures, the production facilities/production lines that process GE crops (such as the production lines that produce oil from GE soy) or the counters selling GE foods need to have clear signs that they are processing/selling GE products.

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. Non-GMO labels can be used for products for which GE versions are available, but the labeling must be accurate and cannot use misleading words such as "heathier" or "safer".

[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).

This was repeated in the "Public Notice of the State Administration of Market Regulation, MARA, and the National Health Commission concerning Reinforcing Administration of Edible Vegetable Oil Labelling" in June 2018. The Notice requires that:

> Genetically engineered edible vegetable oil should follow relevant provisions and indicate (the GE content) clearly in the product label and descriptions. For the (crop) that China has not yet approved for imports as processing materials, and crops that have not yet received commercialization grow approval in China, or the crop that do not have GE variety or processed products of the GE variety, the label and description should not contain the characters "Non-GMO".

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 potential threat to trade. In the past, China participated in the Global LLP Initiative as an observer but did not attend the conference in 2019.

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. This would potentially fulfill a pledge in the 13th Five-year Plan for National Science and Technology Innovation.

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 (March 2019), which provides an update on 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 is expected to take place in late 2020 in Kunming, Yunnan, China.

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, the Chinese government did not participate in international fora related to agriculture biotech.

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 yearly. The most recent BWG and TWG meetings were held in 2018. The two sides exchanged updates of products under development and in the approval pipeline, discussed revisions to regulations and rules in both countries, and other issues of interest.

n) Related Issues

Enzyme and food additive products produced from genetically modified microorganisms (GMMs)

The NHC accepts applications for enzymes produced from GMMs, reviews the dossiers, and decides whether MARA experts (NBC members) need to assess the product's safety. If so, the dossier is passed to MARA for review (not the full set of NBC review, rather an assessment of the product). The review decision then is sent to NHC for its final decision. If the product does not need to be assessed by the NBC, NHC will review the product as it reviews other non-GE enzymes.

However, recent engagement with industry has demonstrated that the workflow for GMM-derived products requires further clarity between NHC and MARA. Additionally, NHC has not clarified the regulatory process to approve other food ingredients derived from biotech sources. The United States continues to engage China on this area of regulatory coherence. In 2019, a dozen or so GMM-derived product applications have passed the NBC review and are pending NHC review; one was approved in December 2019.

Part C: Marketing

a) Public/Private Opinions

The Chinese government is increasing its outreach efforts to address public misperceptions towards biotech through press conferences and training for journalists and local government

officials. Both traditional and social media are being used to explain China's biosafety regulatory work.

In 2018, MARA launched the "Nationwide GMO Science Education Tour" together with the China Association of Agricultural Science Societies and the Societies' local branches, and local governments to improve the public's understanding of biotech. Scientists, government officials, and journalists are invited to give lectures in universities about agricultural biotech.

MARA is also working with its sister 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 have become very rare. Additionally, false stories on social media, such as the Weibo, WeChat, and on-line forums, are corrected in a timely basis.

Although the false reports or stories are decreasing, opponents of biotech are still 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 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 animals species including swine, cattle, and sheep. Despite heavy investment and advanced research, China has not yet approved any livestock clones, GE animals, or products derived from animal biotech for commercial use.

Part A: Production and Trade

a) Product Development

The central government invests heavily in basic research for animal biotech. Research institutes can apply to MARA and Ministry of Finance for research funding. Research has mainly 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).

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 B Policy

a) Regulatory Framework

Regulation of GE Animals

Animal biotech is also 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 official website's page for administrative approvals (link in Chinese). However, this regulation lacks implementation rules or specific policies that regulate animal biotech research, production, or trade. MARA needs to issue further direction before regulatory approvals for animal biotech can be granted. Like plant biotech, MARA starts the review of dossiers for animal biotech products only after a trait is deregulated in an exporting country.

b) Approvals

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

c) Innovative Biotechnologies

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

d) Labeling and Traceability

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

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 about 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 2019, Chinese delegation attended the 87th World Organization for Animal Health (OIE) held in Paris, France, but GE animals was not discussed.

Part C: Marketing

a) Public/Private Opinions

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

b) Market Acceptance/Studies

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

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

China Cotton Exports (HS 520100)

Partner Country	Quantity (Metric Tons)			
	2016	2017	2018	2019 (Jan.-Nov.)
World	7,738	17,000	47,244	48,745
Vietnam	839	10,958	16,249	19,340
Indonesia	1,237	2,845	15,348	10,238

China Cotton Imports (HS 520100)

Partner Country	Quantity (Million Tons)			
	2016	2017	2018	2019 (Jan.-Nov.)
World	0.90	1.15	1.57	1.69
Brazil	0.08	0.066	0.185	0.42
Australia	0.22	0.26	0.42	0.37
United States	0.26	0.51	0.53	0.33
India	0.12	0.11	0.17	0.2
Uzbekistan	0.09	0.09	0.06	0.08

China Corn Imports (HS 100590)

Partner Country	Quantity (Million Tons)			
	2016	2017	2018	2019 (Jan.-Nov.)
World	3.17	2.83	3.52	4.06
Ukraine	2.66	1.82	2.93	3.57
United States	0.22	0.76	0.3	0.26

China Soybean Imports (HS 120190)

Partner Country	Quantity (Million Tons)			
	2016	2017	2018	2019 (Jan.-Nov.)
World	83.23	95.54	88.03	78.97
Brazil	38.04	50.93	66.08	52.84
United States	33.66	32.85	16.64	13.85
Argentina	8.01	6.58	1.46	7.49
Canada	1.455	2.05	1.79	2.25
Uruguay	1.66	2.57	1.2	1.88
Russia	0.4	0.5	0.815	0.63

China Distillers Dried Grains Imports (HS 230330)

Partner Country	Quantity (Million Tons)			
	2016	2017	2018	2019 (Jan-Nov)
World	3.067	0.391	0.148	0.121
United States	3.066	0.39	0.147	0.120

China Rapeseed Imports (HS 12051090, 12059090)

Partner Country	Quantity (Tons)			
	2016	2017	2018	2019 (Jan-Nov)
World	3,565,017	4,747,066	4,757,038	2,591,754
Canada	3,437,622	4,511,939	4,443,330	2,242,608
Russia	19,396	63,810	204,512	168,148
Australia	63,230	55,000	25,123	133,522
Mongolia	44,768	116,317	83,525	47,475

China Rapeseed Meal Imports (HS 230641)

Partner Country	Quantity (Tons)			
	2016	2017	2018	2019 (Jan-Nov)
World	503,655	943,430	1,298,965	1,482,731
Canada	496,683	923,534	1,275,391	1,345,831
United Arab Emirates	0	0	0	87,045
Kazakhstan	0	0	0	49,854
Australia	6,972	19,896	23,573	0

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

Partner Country	Quantity (Tons)			
	2016	2017	2018	2019 (Jan-Nov)
World	699,751	757,007	1,295,948	1,465,087
Canada	601,829	669,658	1,127,321	854,464
United Arab Emirates	4,102	2,599	2,892	180,331
Russia	11,730	19,292	81,053	144,170
Ukraine	11,996	7,918	37,025	112,419
Kazakhstan	4,776	8,720	23,358	56,889
Australia	29,939	41,136	11,161	48,181

China Sugar Beet Pulp Imports (HS 230320)

Partner Country	Quantity (Tons)			
	2016	2017	2018	2019 (Jan.-Nov.)
World	261	53,433	59,290	26,722
United States	0	47,307	41,299	0
Egypt	0	0	0	16,498
Ukraine	0	6,018	16,738	10,221

Appendix 2: Biotech Crops Approved for Import as Processing Materials

No.	Event	Developer	Biosafety certificate validity
1	Soybean DAS-81419-2 (new approval)	Dow AgroSciences	Dec. 02, 2019-Dec. 02, 2022
2	Papaya 55-1 (new approval)	USDA ARS, U.S. Pacific Basin Agricultural Research Center, University of Hawaii	Dec. 02, 2019-Dec. 02, 2022
3	Herbicide resistant corn T25 (renew)	BASF	Dec. 02, 2019-Dec. 02, 2022
4	Soybean A5547-127 (renew)	BASF	Dec. 02, 2019-Dec. 02, 2022
5	Herbicide resistant soybean MON89788 (renew)	Monsanto Far East Ltd.	Dec. 02, 2019-Dec. 02, 2022
6	Soybean 305423×GTS40-3-2 (renew)	Pioneer	Dec. 02, 2019-Dec. 02, 2022
7	Quality improvement soybean 305423 (renew)	Pioneer	Dec. 02, 2019-Dec. 02, 2022
8	Insect resistant cotton 15985 (renew)	Monsanto Far East Ltd.	Dec. 02, 2019-Dec. 02, 2024
9	Herbicide resistant Canola T45 (renew)	BASF	Dec. 02, 2019-Dec. 02, 2022
10	Herbicide resistant Canola Oxy-235 (renew)	BASF	Dec. 02, 2019-Dec. 02, 2022
11	Herbicide resistant Canola Ms8Rf3 (renew)	BASF	Dec. 02, 2019-Dec. 02, 2022
12	Herbicide resistant sugar beet H7-1 (renew)	Monsanto Far East Ltd.	Dec. 02, 2019-Dec. 02, 2022
13	Herbicide tolerance canola RF3 (2019.1 new approval)	BASF (original applicant: Bayer CropScience)	Dec. 20, 2018-Dec. 20, 2021
14	Pest resistant and herbicide tolerant corn DP4114 (2019.1 new approval)	Pioneer	Dec. 20, 2018-Dec. 20, 2021
15	Herbicide tolerance canola MON 88302 (2019.1 new approval)	Monsanto Far East Ltd.	Dec. 20, 2018-Dec. 20, 2021
16	Herbicide tolerance soybean DAS-44406-6 (2019.1 new approval)	Dow AgroSciences	Dec. 20, 2018-Dec. 20, 2021
17	Herbicide tolerance soybean SYHT0H2 (2019.1	Syngenta Crop Protection	Dec. 20, 2018-Dec. 20, 2021

No.	Event	Developer	Biosafety certificate validity
	new approval)	BASF (original applicant: Bayer CropScience)	
18	MON87705 Soy	Monsanto Far East Ltd.	June 12, 2017-June 12, 2020
19	Herbicide resistant corn DAS-40278-9	Dow AgroSciences	June 12, 2017-June 12, 2020
20	Insect resistance and herbicide tolerance corn Bt11×GA21	Syngenta Crop Protection	June 12, 2017-June 12, 2020
21	Corn MIR162	Syngenta Crop Protection	June 12, 2017-June 12, 2020
22	Insect resistant corn 5307	Syngenta Crop Protection	July 16, 2017-July 16, 2020
23	Herbicide tolerance corn MON 87427	Monsanto Far East Ltd.	July 16, 2017-July 16, 2020
24	Herbicide resistant cotton GHB614	Bayer CropScience	Dec. 30, 2015 -Dec.30, 2020
25	Insect resistant cotton COT102	Syngenta Crop Protection	Dec.31, 2015 - Dec.31, 2020
26	Herbicide resistant cotton LLCotton25	Bayer CropScience	Dec.31, 2015 - Dec.31, 2020
27	Herbicide tolerance corn FG72	BASF (original applicant: Bayer CropScience)	Dec.20, 2018 - Dec.20, 2021
28	Quality-Improved Soybean MON 87769	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021
29	Herbicide tolerant Soybean MON 87708	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021
30	Quality improved corn 3272	Syngenta Crop Protection	Dec.20, 2018 - Dec.20, 2021
31	Drought Tolerant corn MON87460	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021
32	Herbicide tolerant Soybean CV127	BASF	Dec.20, 2018 - Dec.20, 2021
33	Insect resistant soybean MON 87701	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021
34	Insect resistant soybean MON87701 x MON89788	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021
35	Herbicide resistant soybean A2704-12	BASF (original applicant: Bayer CropScience)	Dec.20, 2018 - Dec.20, 2021
36	Herbicide tolerant corn NK603	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021
37	Insect resistant and herbicide tolerance corn	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021

No.	Event	Developer	Biosafety certificate validity
	MON88017		
38	Insect resistant corn MON89034	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021
39	Insect resistant corn MIR604	Syngenta Crop Protection	Dec.20, 2018 - Dec.20, 2021
40	Herbicide resistant corn GA21	Syngenta Crop Protection	Dec.20, 2018 - Dec.20, 2021
41	Herbicide tolerant soybean GTS40-3-2	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021
42	Insect resistant corn 59122	Du Pont/Dow AgroSciences	Dec.20, 2018 - Dec.20, 2021
43	Insect resistant corn TC1507	Du Pont/Dow AgroSciences	Dec.20, 2018 - Dec.20, 2021
44	Insect resistant corn MON810	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021
45	Insect resistant corn BT176	Syngenta Crop Protection	Dec.20, 2018 - Dec.20, 2021
46	Insect resistant corn BT11	Syngenta Crop Protection	Dec.20, 2018 - Dec.20, 2021
47	Herbicide resistant Canola Topas19/2	BASF (original applicant: Bayer CropScience)	Dec. 20, 2018-Dec. 20, 2021
48	Herbicide resistant Canola Ms1Rf1	BASF (original applicant: Bayer CropScience)	Dec. 20, 2018 -Dec.20, 2021
49	Herbicide resistant Canola Ms1Rf2	BASF (original applicant: Bayer CropScience)	Dec. 20, 2018 -Dec.20, 2021
50	Herbicide tolerant Canola GT73	Monsanto Far East Ltd.	Dec.20, 2018 - Dec.20, 2021
51	Insect resistant cotton 531	Monsanto Far East Ltd.	June 12, 2017-June 12, 2022
52	Herbicide tolerant cotton 1445	Monsanto Far East Ltd.	June 12, 2017-June 12, 2022
53	Herbicide tolerant Flex cotton MON 88913	Monsanto Far East Ltd.	June12, 2017-June 12, 2022
54	Insect resistant and herbicide tolerant cotton GHB 119	BASF (original applicant: Bayer CropScience)	Dec. 20, 2018 -Dec.20, 2023
55	Insect resistant and herbicide tolerant cotton T304-40	BASF (original applicant: Bayer CropScience)	Dec. 20, 2018 -Dec.20, 2023

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

Attachments:

No Attachments