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Regulatory Process Getting More Unpredictable, Additional Requirements on Trials and Data for Approvals

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Report Highlights:
On January 8, 2019, the Chinese Ministry of Agriculture and Rural Affairs (MARA) announced approval of five new biotech traits in imported crops for processing, the first new approvals since June 2017. In June 2018 and November 2018, the National Bio-Safety Committee (NBC) was convened where China reviewed new events and the applications for certificate renewals. Also in 2018, MARA amended the regulations on safety assessment, import approval, and labeling of agricultural "GMOs" without notifying the changes to the World Trade Organization (WTO) nor soliciting comments from stakeholders. The revised rules impose additional in-country trials and studies on new biotech events as part of the dossier submission process. While research on conventional biotechnology continues in China, the Chinese Government is developing policies on genome editing and monitoring the development of policy in foreign countries, including the United States.

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Executive Summary

To date, China only approves the importation of genetically engineered (GE) crops for further processing into animal feed and vegetable oil. With the exception of GE papaya and cotton, China has not approved any GE food or feed crops for domestic cultivation. Further, when foreign companies asked to submit an application for domestic cultivation, MARA informed them that China's foreign direct investment restrictions prohibit the domestic cultivation of foreign developed biotech events.

The regulatory regime under which new GE events are reviewed in China underwent numerous changes in 2017 and 2018, evolving into a more onerous, less science-based system.

Government Restructuring Has Limited Impact on Biotech Regulatory System, Affects Customs and Trade Facilitation at Ports

The Chinese Government announced a large restructuring of Ministries and Agencies in March 2018. The Ministry of Agriculture (MOA) was renamed the Ministry of Agriculture and Rural Affairs (MARA), and a number of rural development related financial functions from the Ministry of Finance and Ministry of Commerce were integrated into the new MARA. The roles and responsibilities of MOA's Department of Science, Technology and Education, the GMO Safety Office, the Development Center for Science and Technology (DCST), the offices that implement China's biotechnology regulations, were not affected. The restructuring also moved the entry-exit inspection and quarantine jurisdiction of the previous General Administration of Quality Inspection and Quarantine (AQSIQ) to the General Administration of Customs (GACC).

No Progress on the Commercialization of GE Corn and Soy

Biotechnology is designated as a strategic emerging industry in China, and the government invests billions of dollars in research via key special programs. In 2016, the State Council released the 13th Five-year Plan for National Science and Technology Innovation, which set the goal commercializing a new generation of 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 are eagerly waiting for MARA's approval of their domestically developed events, which have been in the MARA approval pipeline for a long time. However, two years after the 2016 publication of the 13th Five-year Plan, no GE corn or GE soy event has obtained the bio-safety certificate for cultivation.

Only Five New Event Approvals Since July 2017

On January 8, 2019, MARA announced the approval of five new biotech traits in crops to be imported for food, feed, and processing (FFP) use. These are the first new approvals since June 2017. Presently, there are five events developed by the international biotech companies that are pending MARA's final import approval. Of the five events, three remain from the 100-Day Action Plan agreement where China committed to complete review of a total of eight products. Of the three remaining from the 100-Day Action Plan, two alfalfa events have been pending for over seven years, resulting in frequent rejection of alfalfa shipments due to trace detections of unapproved GE traits. Chinese domestic developers are also anxiously waiting for approval for cultivation, and some domestic developers are reportedly facing severe financial pressure due to slow regulatory approval. Many Chinese developers have taken their traits overseas to seek regulatory approval for cultivation in other markets with an aim to receive import approval in China.

Chinese Regulatory System Remains Opaque and Informal

In 2017, the State Council abolished the fees biotech event developers and Chinese importers paid for administrative approvals and for MARA's bio-safety certificates. Approvals are issued to developers for new events, and certificates are issued to importers for individual consignments of GE product imports. MARA also revised procedures and rules for safety assessment, safety review of agriculture "GMO" imports, and labeling to implement the State Council's direction in November 2017.

According to the revised Regulations, MARA will entrust qualified technical institutes to conduct trials (field trials and feeding studies) after receiving applications for a biosafety certificate. Developers no longer need to pay MARA to conduct the trials; MARA-designated institutes conduct the trials utilizing a Chinese Government budget. Shortly after this change, MARA sent letters to individual biotech applicants requesting that additional in-China trials and studies be completed and developers provide testing methods and testing materials for those events in the regulatory approval process. While the Chinese Government indicates that these additional requirements are part of the revised regulations, these revisions were not notified the WTO for trading partner comment, creating much confusion among biotech developers and trading partners alike.

Data transportability – where countries accept safety testing data generated in the country that developed the product or from another country that has conducted a safety review – remains a major concern for foreign developers and the international community alike. Despite numerous exchanges between industry and government and China on data transportability in the past two years, MARA has shown no willingness in accepting data obtained by trials conducted abroad without conducting verification trials in China.

Oversight and Enforcement

For years, MARA's GMO Office has included illegal growing of biotech crops in its oversight and enforcement plans. In the past couple of years, Chinese media has reported the illegal growing of GE crops in Xinjiang, Shaanxi, Gansu, Jilin, and Hainan provinces. In response to MARA's continued

detection of illegal growing, some Chinese scientists have suggested that commercializing GE crops is not only a solution to the illegal growing but would also spur the modernization of the whole seed industry value chain.

Public Opinion

By working with the mainstream media and other government agencies, MARA continues a public communication campaign aimed at correcting misinformation about agricultural biotechnology. However, misinformation about GMO safety still spreads widely through Chinese social media outlets, such as WeChat and Weibo. Consumer and public perception polling indicates that the Chinese public's support for and acceptance of food derived from agricultural biotechnology remains low despite those government efforts.

Chapter One: Plant Biotechnology

Part A Production and Trade

a) Product Development

Despite years of research and effort on the part of Chinese biotech developers, China has not yet commercialized any GE grain or oilseed traits. In 2009, MARA granted the first biosafety certificates for food and feed crops to two Chinese developed insect-resistant rice varieties and one high phytase corn variety. The bio-safety certificates for these traits were renewed by MARA in 2014. However, MARA did not issue final approval for cultivation of these products, and these products 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 event, which was one of the rice varieties that received bio-safety certificates in 2009.

In 2016, MARA published the roadmap for the commercialization of GE crops, which 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). Despite this "roadmap," MARA has not publically showed a plan for what or when events will be commercialized. Additionally, MARA does not publish information on ongoing domestic biotech research and development. According to MARA publications on deregulation, major crops undergoing field trials (either the intermediary experiment or environmental release stage) include insect resistant corn, high lysine corn, insect resistant soybeans, and wheat that is less prone to pre-harvest sprouting. Public sources report that there has been significant research into GE wheat, including stress-resistant (drought tolerant, saline-alkali tolerant) and higher protein events.

As noted above, China has invested heavily in biotech research and seed development, primarily through publicly funded research institutes and universities. In 2008, China approved a special research program to develop new GE varieties over 15 years through the Key Scientific and Technological Grant of China for Breeding New Biotech Varieties. Total funding was 24 billion Yuan (approximately $3.5 billion),

half of which came from central and local governments, and the rest was 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 objective is to develop new traits, such as insect, disease, and stress resistance. The list of the new biotech breeding projects funded by the grant is available at the National Science and Technology Report Service (in Chinese).

On June 29, 2018, China's National Development and Reform Commission (NDRC) and the Ministry of Commerce (MOFCOM) released "The (2018 Edition) Special Administrative Measures for Foreign Investment Access (The Negative List)." The announcement revised the list of economic sectors that are prohibited or restricted from foreign investment or, conversely, which economic sectors are open to foreign investment. In the 2018 announcement, NDRC removed foreign investment restrictions on planting seed development and production for all crops, except wheat and corn. Wheat and corn seed investment still require Chinese majority shareholders. For all other crops, foreign investors can be the majority shareholder of a business operating in China. This announcement gives multinational seed developers an opportunity to expand their presence here. However, China's stringent prohibition on foreign biotech developers remains unchanged; international companies cannot conduct biotech research or biotech seed production in the country.

b) Commercial Production

China's total agricultural area of GE crops continued to decline in 2018 to an estimated 2.78 million hectares, according to a report by the International Service for the Acquisition of Agro-Biotech Applications (ISAAA). This makes China the 8th largest producer of GE crops by area. In 2017, China planted 2.78 million hectares of GE cotton and about 8,500 hectares of GE virus resistant papaya. Due to lower prices and high stockpiles, China's total cotton growing area has continuously declined. However, GE cotton adoption remains steady at around 95% of total area. 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. According to ISAAA statistics, the economic benefits China gained from planting biotech crops from 1996 to 2016 was $19.6 billion.

The GE products approved for commercial production in China can be found on MARA's website for biotechnology. In general, biotech crop cultivation is approved on a province basis. The vast majority of safety 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 the biosafety certificate for cultivation, they indicate the agro-ecological zones where the crop will be grown. Accordingly, the field trials will be conducted in the region, and the information would be included in the final bio-safety certificate application.

c) Exports

China is a large exporter of GE cotton products, including cotton fiber, cottonseed meal, and cottonseed oil.

d) Imports

China is a large importer of biotech soybeans, cotton, corn, DDGs, 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 traits. 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. Since China has not approved any major biotech food crops, all of the food aid is comprised of non-biotech crops.

China is not a recipient of food aid.

f) Trade Barriers

China's regulatory approval process for GE traits includes a number of provisions that lengthen the time it takes to complete the regulatory review. These include local environmental safety and rat feeding trials, which each dictate that the studies must be conducted in China for the data to be accepted by China. In 2016 and 2017, MARA revised relevant regulations without notifying the WTO 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 and studies to the battery of evaluations required to progress through the Chinese regulatory process.

Following MARA's "completeness check" of an application, China's NBC review and approval process has delayed import approvals for developers. For example, the NBC consistently asks questions unrelated to the intended use of the product. In some cases, these delays have surpassed seven 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 biotechnology regulatory environment for agriculture is outlined in the State Council'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 agricultural crops for import and domestic cultivation, as well as the development of agricultural biotechnology policies and regulations.

The State Council Administrative Rules are implemented by the following Measures:

- Administrative Measures for the Safety Assessment of Agriculture GMOs;
- Administrative Measures for Safety of Agriculture GMO Imports;
- Administrative Measures on Labelling of Agriculture GMOs;
- Measures for the Review and Approval of Agricultural Genetically Modified Organisms for Processing;
- 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".

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 gene edited products fall in the scope of China's GMO regulations, and could be regulated as a GMO. However, MARA indicated that new regulations are under development that may provide a simplified regulatory process for some gene edited products in the future.

Recent Revisions of Regulations and Rules

In January 2017, the State Council announced the decision to standardize some aspects of administrative approvals for certain sectors (State Council - Guo Fa [2017] No. 8). In the area of agricultural biotechnology, the State Council no longer requires the applicants to pay for MARA to conduct in-country field trials, rat feeding studies, and compositional safety testing required for import and cultivation approval.

In October 2017, the State Council issued Order 687 that revised the Administrative Regulations for Safety of Agricultural Genetically Modified Organisms, originally released in 2001. The Revision echoed the changes in the State Council - Guo Fa (2017) No. 8 decision that MARA will entrust qualified technical institutes to conduct field trials and feeding studies at no cost to the biotech developers after receiving applications for the biosafety certificate. MARA will also organize the NBC to conduct the safety assessment. With the revision, it is MARA's responsibility to entrust qualified institutes to conduct the trials, and funding for the trials will come from the Chinese Government budget instead of the applicants.

In November 2017, MARA issued the Decree [2017] No.8 that revised the rules for safety assessment, import approvals, and labeling of GMOs. These revisions aimed to incorporate the State Council's changes into these regulations.

MARA Import Approval Procedure

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

MARA is responsible for the review and issuance of biosafety certificates for imported biotechnology 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 an agricultural 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 event in its domestic market and the product has undergone tests showing no harm to animals, plants, or the environment.

After receiving the application for biosafety certificate, the GMO Safety Office of MARA will designate authorized domestic institutions to conduct environmental safety (field trials) and food safety (animal feeding) tests to verify data provided by the seed developer. These tests are conducted using government funding. The reports generated from verification tests along with the application are then reviewed by the NBC, which should convene no less than two times every year.

After each meeting, the NBC is requested to inform MARA of its decisions. The traits 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 developers resubmit the application dossier with the required data or explanation for review at a subsequent NBC meeting. MARA guidance, 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 the NBC meetings are not formalized, remain highly variable, and dependent to external, political factors.

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

Chinese importers must obtain a "Biosafety Certificate for Agricultural Biotechnology (Import)" for each consignment of a GE commodity they intend to import. The MARA-issued certificate is given to the importer and presented to Customs during the inspection and quarantine process. Each certificate

can only be used for one shipment and is valid for six months after issuance. To apply for the certificate, an importer is required to present the following materials:

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.

If an application complies with the requirements, MARA has 25 working days to review and issue the certificate. 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.

MARA's Domestic Cultivation Approval Procedure

Once the bio-safety certificate is issued, a domestic developer wanting to commercialize a new trait in China needs to seek provincial approval to produce biotech crops domestically in China. The last approvals of this nature occurred in 2017 for seven cotton events.

The (2018 Edition) Special Administrative Measures for Foreign Investment Access (The Negative List) released by MOFCOM and NDRC prohibits foreign investment (of any kind) in the selection and cultivation of new varieties of crops and production of seeds. 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 crops.

National Biosafety Committee (NBC)

The NBC, established by MARA, conducts the review of domestic and foreign applications for biosafety certificates for cultivation and import. The Revised Administrative Measures for Safety Assessment of Agricultural GMOs" (MARA Decree 7 [2016]) changed the term of NBC members from three years to five years.

In 2016, the fifth NBC was established with 75 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 Committee, it is comprised of academics and institute researchers. The Development Center of Science and Technology, an affiliate of MARA, serves as the Secretariat of the Committee.

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

As of the publishing of this report, MARA claims that two NBC meetings were convened during calendar year 2018 one in June and one in November 2018.

Additional Responsibilities Held by MARA

In addition to its primary responsibility of approving agricultural biotech crops for import and domestic production, MARA also has the lead in developing 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 Ministries' Biotechnology Responsibilities

The government restructuring moved the import and export inspection and quarantine functions of AQSIQ and its local inspection and quarantine offices (CIQs) to GACC. GACC is now in charge of the testing of agricultural and food products for GE content at Chinese ports of entry.

The State Forestry Administration (SFA) 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 detections.

There are around 40 MARA-authorized centers across China that conduct environmental safety, food safety, and detection testing. MARA provincial level departments are responsible for monitoring field trials of biotech products, GE plant processing facilities, the seed market, and labeling.

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), National Development and Reform Commission (NDRC), MOFCOM, the National Health and Family Planning Commission (former Ministry of Health), and others. The conference is mostly used to coordinate biotech policies.

b) Approvals

On January 8, 2019, as a result of the NBC meeting in November 2018, MARA publically announced the approval of five new biotech traits in crops to be imported for FFP use. These approvals are the first new approvals since June 2017.

To date, MARA has approved the importation of five different GE crops for FFP use: soybeans, corn, canola, cotton, and sugar beet. The first biosafety certificate for the importation of foreign products was issued in 2004. A full list of biotech crops approved for FFP import is included in Appendix 2.

c) Stacked Event Approvals

China does not have a specific policy for approving stacked traits. When reviewing varieties with stacked traits, MARA requires applicants to submit information on each individual trait presents in the variety.

d) Field Testing

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

e) Innovative Biotechnologies

Chinese scientists associated with the China Academy of Sciences (CAS) and the China Academy of Agricultural Sciences (CAAS) are making impressive progress in innovative biotechnology. They have published dozens of papers about CRISPR technology. However, without clear regulations, the researchers lack the motivation to move the products further along the path for commercialization.

China closely monitors foreign policies on genome editing but has not yet released its own policies. MARA officials have revealed that policies are under development and will be released in 2019. MARA is paying very close attention to the U.S. Food and Drug Administration and U.S. Environmental Protection Agency, and other countries' regulatory agencies concerning how those organizations regulate genome editing.

f) Coexistence

China does not have a co-existence 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[1]);

[1] 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).

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, two years have elapsed, and the rule has not been released.

In recent years, MARA has been working with its sister ministries to regulate the GMO-related contents of advertisements, prohibiting the use of "non-GMO" as a claim in advertisements of products made of crops 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".

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", jointly issued by the State Administration of Market Regulation, MARA, and the National Health Commission (NHC) 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 the Ministry of Environmental Protection (MEP) through their affiliated testing institutes. At ports, Customs test imported products for unapproved biotechnology events. MARA tests domestic crops and conducts safety assessment experiments, and MEP conducts environmental safety tests.

China has a zero tolerance for unapproved biotechnology traits 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 events in the exporting country but tests 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 crops, and MARA-developed standards are often targeted to testing for specific events.

i) Low Level Presence (LLP) Policy

China does not have low level presence policy for biotech imports. With its zero tolerance for unapproved biotechnology traits in imports and the large import volume of GE crops, this is a potential threat to trade. In past years, China has participated in the Global LLP Initiative as an observer.

j) Additional Regulatory Requirements

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

On November 4, 2015, China's National People's Congress (NPC) announced an amendment to the Seed Law. This was the first change to the Seed Law since it was enacted in 2000. The revised Seed Law reduced the number of major crops subject to variety registration requirements from 28 to five (rice, wheat, corn, cotton, and soybean). Seed companies also no longer need approval to introduce a registered variety to a similar ecological region in another province.

On April 7, 2017, MARA released the "Administrative Measures for Non-Major Crop Variety Record Filing", which was implemented on May 1, 2017. Echoing the Seed Law, the Measures provided a list of 29 non-major crops that are now subject to seed variety record filing before launching in the market. The Measures also include guidance for application, review, and approval of the record filing for the 29 non-major crops. This change reduces the test requirements for non-major crops to be cultivated in China.

Please refer to the Annual China Seed Report (December 2018), which provides updated information on seed variety registration issues and policy.

k) Intellectual Property Rights (IPR)

China's Seed Law and the Administrative Measures for Plant Variety Protection govern intellectual property rights protection for agricultural biotechnology. Both were amended and revised in 2016. Intellectual property rights protection in 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 to the 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 Cartagena Protocol convention each year.

m) International Treaties and Forums

Major biotechnology producing countries, including the United States, routinely engage China regarding its slow biotechnology approval system. China's slow biotechnology approval system has delayed the global adoption of new varieties.

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

The annual U.S.-China High-Level Biotechnology Joint Working Group (BWG) was established in July 2002 as a way to address bilateral biotechnology issues of mutual interest. A technical subgroup (TWG) was established in July 2003 to supplement the policy discussions. The most recent BWG and TWG meetings were held in August 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. The 2019 BWG and TWG is expected to be held in China on new and continuing topics 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. NHC reviews the dossiers and decide 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 making. 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 work flow for GMMs requires further clarity between NHC and MARA. Additionally, NHC has not clarified the regulatory process to approve food additives derived from GE sources. The United States continues to engage China on this area of regulatory coherence.

Part C Marketing

a) Public/Private Opinions

The Chinese government is increasing its outreach efforts to address public misperceptions towards biotechnology 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.

MARA is also working with its sister ministries to eliminate misleading claims or statements in product labels and advertisements, particularly the claims 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.

Despite these efforts, public opponents of biotechnology are still strong. MARA is constantly requested to publically disclose information on safety assessment applications and reviews. Members of the NPC Consultative Committee also mandate MARA to provide timely responses to their biotechnology inquiries.

b) Market Acceptance/Studies

A number of public surveys of Chinese perceptions of agricultural biotechnology have been released in recent years. In 2016, Shanghai Jiaotong University launched a nationwide survey of consumer awareness, knowledge, and opinion on GE food. The survey was published as an article in the scientific journal *Nature* in June 2018. The study showed that 11.9%, 41.4%, and 46.7% of respondents have a positive, neutral, or negative view on GE food respectively.

A minority of respondents (11.7%) claimed they understand the basic principles of GE technology; most were either "neutral" or "unfamiliar with GM technology". The majority of respondents (69.3%) obtained their information on GE food through the internet, and 64.3% of respondents thought that media coverage was predominately negative on GE food. The reasons given by consumers in favor of or against the use of GE food were complex, as demonstrated by the response of 13.8% of respondents who felt GE technology was a form of bioterrorism targeted at China. MARA and the science community generally expressed a positive attitude toward GM food, but the percentage of respondents that trusted the government and scientists was only 11.7% and 23.2% respectively. In post-survey comments, respondents made suggestions on how the industrialization of GE technology might impact the future of China's food supply and value chains. For more information, please see the *Nature* article at the following link.

Chapter Two Animal Biotechnology

China is a leader in animal biotechnology research. The Key Scientific and Technological Grant of China for Breeding New Biotech Varieties launched in 2008 supports the research of GE animals species covered include swine, cattle, and sheep. Despite the heavy investment and advanced research, China has not yet approved any livestock clones or GE animals or products derived from animal biotechnologies for commercial use.

Part A Production and Trade

a) Product Development

The central government invests heavily in basic research for animal biotechnology. Research institutes can apply to MARA and Ministry of Finance (MOF) 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.

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 agriculture.

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 biotechnology 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. 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 biotechnology can be granted. Like plant biotechnology, MARA starts the review of dossiers for animal biotech products only after an event is deregulated in an exporting country.

b) Approvals

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

c) Innovative Biotechnologies

Chinese scientists are making continuous 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 Measures for Agricultural GMO Labeling Administration (MARA Decree 10). However, as China has not yet commercialized any GE animals, specific measures for GE animal labeling are available.

e) Intellectual Property Rights (IPR)

Currently, gene and DNA fragments are subject to protection provided by the Patent Law of China. GE animals still fall into a legal gap in China's IPR protection regulations. The existing regulations about biotechnology focus on safety and do not address the issue of 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.

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

Partner Country	Quantity (Metric Tons)			
	2015	2016	2017	2018
World	28,916	7,757	17,083	47,349
Vietnam	16,288	2,043	11,008	16,265
Indonesia	3,417	1,237	2,845	15,348

China Cotton Imports

Partner Country	Quantity (Million Tons)			
	2015	2016	2017	2018
World	1.67	0.90	1.155	1.575
United States	0.53	0.26	0.51	0.53
Australia	0.25	0.22	0.26	0.42
Brazil	0.14	0.08	0.066	0.185
India	0.33	0.12	0.11	0.17
Uzbekistan	0.175	0.09	0.09	0.06

China Corn Imports

Partner Country	Quantity (Million Tons)			
	2015	2016	2017	2018
World	4.73	3.17	2.83	3.52
Ukraine	3.85	2.66	1.82	2.93
United States	0.46	0.22	0.76	0.3

China Soybean Imports

Partner Country	Quantity (Million Tons)			
	2015	2016	2017	2018
World	81.74	83.23	95.54	88.03
Brazil	40.13	38.04	50.93	66.08
United States	28.41	33.66	32.85	16.64
Canada	1.07	1.455	2.05	1.79
Argentina	9.44	8.01	6.58	1.46
Uruguay	2.32	1.66	2.57	1.2
Russia	0.37	0.4	0.5	0.815

China Distillers Dried Grains Imports

Partner Country	Quantity (Million Tons)			
	2015	2016	2017	2018
World	6.82	3.067	0.391	0.148
United States	6.818	3.066	0.39	0.147

China Sugar Beet Pulp Imports

Partner Country	Quantity (Tons)			
	2015	2016	2017	2018
World	1,007	261	53,433	59,290
United States	0	0	47,307	41,299
Ukraine	0	0	6,018	16,738
Vietnam	1,007	211	95	842

Appendix 2: Biotech Crops Approved for Import as Processing Materials

No.	Event	Developer	Biosafety certificate validity
1	Pest resistant corn 5307	Syngenta Crop Protection	July 16, 2017-July 16, 2020
2	Herbicide tolerance corn MON 87427	Monsanto Far East Ltd.	July 16, 2017-July 16, 2020
3	Herbicide tolerance corn FG72	Bayer CropScience	Dec. 31, 2016-Dec. 31, 2019
4	MON87705 Soy	Monsanto Far East Ltd.	June12, 2017-June 12, 2020
5	Herbicide resistant corn DAS-40278-9	Dow AgroSciences	June12, 2017-June 12, 2020
6	Herbicide resistant soybean MON89788	Monsanto Far East Ltd.	June12, 2017-June 12, 2020
7	Insect resistance and herbicide tolerance corn Bt11×GA21	Syngenta Crop Protection	June12, 2017-June 12, 2020
8	Quality improvement soybean 305423	Pioneer	June12, 2017-June 12, 2020
9	Soybean A5547-127	Bayer CropScience	June12, 2017-June 12, 2020
10	Soybean 305423×GTS40-3-2	Pioneer	June12, 2017-June 12, 2020
11	Corn MIR162	Syngenta Crop Protection	June12, 2017-June 12, 2020
12	Herbicide tolerant Flex cotton MON 88913	Monsanto Far East Ltd.	June12, 2017-June 12, 2022
13	Herbicide resistant corn T25	Bayer CropScience	June12, 2017-June 12, 2020
14	Herbicide resistant Canola Oxy-235	Bayer CropScience	June12, 2017-June 12, 2020
15	Herbicide resistant Canola T45	Bayer CropScience	June12, 2017-June 12, 2020
16	Herbicide resistant Canola Ms8Rf3	Bayer CropScience	June12, 2017-June 12, 2020
17	Herbicide resistant sugar beet H7-1	Monsanto Far East Ltd.	June12, 2017-June 12, 2020
18	Insect resistant cotton 531	Monsanto Far East Ltd.	June12, 2017-June 12, 2022
19	Herbicide tolerant cotton 1445	Monsanto Far East Ltd.	June12, 2017-June 12, 2022
20	Quality-Improved Soybean MON 87769	Monsanto Far East Ltd.	Dec.31, 2015 - Dec.31, 2018
21	Herbicide tolerant Soybean MON 87708	Monsanto Far East Ltd.	Dec.31, 2015 - Dec.31, 2018
22	Insect resistant cotton COT102	Syngenta Crop Protection	Dec.31, 2015 - Dec.31, 2020
23	Alpha-amylase corn 3272	Syngenta Crop Protection	Dec.31, 2015 - Dec.31, 2018
24	Drought Tolerant corn MON87460	Monsanto Far East Ltd.	Dec.31, 2015 - Dec.31, 2018

No.	Event	Developer	Biosafety certificate validity
25	Herbicide tolerant Soybean CV127	BASF	Dec.31, 2015 - Dec.31, 2018
26	Insect resistant soybean MON 87701	Monsanto Far East Ltd.	Dec.31, 2015 - Dec.31, 2018
27	Insect resistant soybean MON87701 x MON89788	Monsanto Far East Ltd.	Dec.31, 2015 - Dec.31, 2018
28	Insect resistant cotton 15985	Monsanto Far East Ltd.	Dec.31, 2015 - Dec.31, 2020
29	Herbicide resistant cotton LLCotton25	Bayer CropScience	Dec.31, 2015 - Dec.31, 2020
30	Herbicide resistant soybean A2704-12	Bayer CropScience	Dec.31, 2015 - Dec.31, 2018
31	Herbicide tolerant corn NK603	Monsanto Far East Ltd.	Dec.31, 2015 - Dec.31, 2018
32	Insect resistant and herbicide tolerance corn MON88017	Monsanto Far East Ltd.	Dec.31, 2015 - Dec.31, 2018
33	Insect resistant corn MON89034	Monsanto Far East Ltd.	Dec.31, 2015 - Dec.31, 2018
34	Insect resistant corn MIR604	Syngenta Crop Protection	Dec.31, 2015 - Dec.31, 2018
35	Herbicide resistant corn GA21	Syngenta Crop Protection	Dec.31, 2015 - Dec.31, 2018
36	Herbicide tolerant soybean GTS40-3-2	Monsanto Far East Ltd.	Dec. 20, 2015-Dec. 20, 2018
37	Insect resistant corn 59122	Du Pont/Dow AgroSciences	Dec. 20, 2015-Dec. 20, 2018
38	Insect resistant corn TC1507	Du Pont/Dow AgroSciences	Dec. 20, 2015-Dec. 20, 2018
39	Insect resistant corn MON810	Monsanto Far East Ltd.	Dec. 20, 2015-Dec. 20, 2018
40	Insect resistant corn BT176	Syngenta Crop Protection	Dec. 20, 2015-Dec. 20, 2018
41	Insect resistant corn BT11	Syngenta Crop Protection	Dec. 20, 2015-Dec. 20, 2018
42	Herbicide resistant Canola Topas19/2	Bayer CropScience	Dec. 20, 2015-Dec. 20, 2018
43	Herbicide resistant Canola Ms1Rf1	Bayer CropScience	Dec. 20, 2015-Dec. 20, 2018
44	Herbicide resistant Canola Ms1Rf2	Bayer CropScience	Dec. 20, 2015-Dec. 20, 2018
45	Herbicide tolerant Canola GT73	Monsanto Far East Ltd.	Dec. 20, 2015-Dec. 20, 2018
46	Insect resistant and herbicide tolerant cotton GHB 119	Bayer CropScience	Apr.10, 2014 - April 10, 2019
47	Insect resistant and herbicide tolerant cotton T304-40	Bayer CropScience	Apr.10, 2014 - April 10, 2019
48	Herbicide resistant cotton GHB614	Bayer CropScience	Dec. 30, 2015 -Dec.30, 2020

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