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Regulatory Process Continues Churning, Commercialization Not in Sight

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Report Highlights:

China is the largest importer of genetically engineered crops and one of the largest producers of GE cotton in the world, yet it has not approved any major GE food or feed crops for cultivation.

The State Council is revising a number of regulations on administrative procedures in an effort to streamline how certain regulatory processes are conducted. Related to agricultural biotechnology, these changes shifted the financial burden of a number of safety trials from biotech developers to the government. After the Ministry of Agriculture (MOA)'s new regulations are in place, MOA will be responsible for conducting safety trials for all biotech events utilizing the Chinese government budget.

Despite pledges made in the "13th Five-Year Plan for Science and Technology Innovation" to push forward commercialization of new domestic types of Bt corn, Bt cotton, and herbicide resistant soy by 2020, to date, no domestic event has received the bio-safety certificate necessary to commercialize. Meanwhile, technological advancement, including advancement in new breeding technologies, requires Chinese regulators to update the existing regulatory system and testing methods to account for rapid innovation.

Executive Summary:

Roadmap for Commercialization

Biotechnology is designated as a strategic emerging industry in China, and the government invests billions of dollars in research via key special programs funded by governing ministries.

To date, China only approves the importation of GE crops for further processing into animal feed and vegetable oil, and, with the exception of GE papaya and cotton, has not approved any other GE food or feed crops for domestic cultivation. Further, when foreign companies asked to submit an application for domestic cultivation, MOA informed them that China's foreign direct investment restrictions prohibit them from doing so.

In 2016, the State Council released the 13th Five-year Plan for National Science and Technology Innovation, which set the goal that China would commercialize a new generation of Bt cotton, Bt corn, and herbicide-tolerant soybeans by 2020. The Plan also pledges to establish a technical system for biosafety evaluation to guarantee safety of GE products. Motivated by this goal, several Chinese domestic companies are eagerly waiting for MOA's approval of their domestically developed events, which have been in the MOA approval pipeline for a long time.

Also in 2016, MOA revealed the roadmap for 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).

Biosafety Certificate for Import Approval

MOA approved one event for import at the end of 2016, two events in June 2017, and two events in July 2017. Trade in alfalfa continues to suffer from the market uncertainty created by the delay in approving two GE alfalfa traits. In the 2016/2017 marketing year, soybean imports (mainly GE soybeans) reached another all-time high of 93 million metric tons. Presently, there are an estimated ten traits that are pending MOA's final approval, including the two alfalfa traits. Some of these traits have been under Chinese regulatory review for over 5 years. Despite the slow and challenging review of new GE traits, China is expected to remain a significant importer of GE products.

Revision of Regulations

The State Council revised a number of regulations on administrative procedures in an effort to streamline how certain regulatory processes are conducted. Accordingly, the State Council members, including MOA, are revising procedures and rules to reflect the State Council guidance. In October, the State Council revised the Administrative Regulations for Safety of Agricultural Genetically Modified Organisms which was originally released in 2001. The Revised Regulations provide that MOA will entrust qualified technical institutes to conduct trials (field trials and feeding studies) after receiving applications for biosafety certificate. Related to agricultural biotechnology, these changes also shifted the financial burden of safety trials conducted in China from biotech developers to the government.

Oversight and Enforcement

For years, MOA's GMO Office has included rectifying the illegal growing of biotech crops in its oversight and enforcement plans.

Public Opinion

By working with the mainstream media and other government agencies, the Ministry of Agriculture has devoted time and resources to improving the quality of biotechnology reporting. However, rumors

about safety still spread widely through Chinese social media, such as Wechat and Weibo. Some recent surveys indicate that the Chinese public's acceptance biotechnology is actually decreasing.

CHAPTER ONE: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT:

Despite years of effort, China has not yet commercialized any GE grain or non-cotton oilseed traits.

In 2009, MOA granted the first biosafety certificates for food and feed crops to two Chinese developed insect-resistant rice varieties and one high phytase corn variety. These traits were renewed by MOA in 2014. However, MOA did not issue final approval for cultivation of these products.

In 2016, MOA revealed the roadmap for 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," MOA does not have a plan for what events will be commercialized when or in what order. Additionally, MOA does not publish information on ongoing domestic biotech research and development. According to MOA 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. 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 investment by the private sector. 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 585 new biotech breeding projects funded by the [grant is available at the National Science and Technology Report Service](#) (in Chinese), which provides the project name, project undertaker and report abstract.

Foreign investment in research and production of biotech plants, livestock, and aquatic products is prohibited. Foreign investment is allowed in conventional/hybrid seed production, but restricted to minority shares in joint ventures with Chinese companies.

b) COMMERCIAL PRODUCTION:

China's total agricultural area under GE crops declined in 2017 to 2.9 million hectares, according to a report by the International Service for the Acquisition of Agro-Biotech Applications (ISAAA). This area makes China the 8th largest producer of GE crops by area in the world.

In 2016, China planted 2.9 million hectares of GE cotton and about 8,550 hectares of GE virus resistant papaya. Due to lower prices and high stockpiles of cotton, China's total cotton area has continuously declined. However, GE cotton adoption remains steady at around 95% of total cotton 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 due to difficulties in bringing other products into commercial cultivation.

The GE products approved for commercial production in China can be found on MOA's [website](#) for biotechnology. In general, biotech crop cultivation is approved on a province by province basis and 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.

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, and sugar beet pulp for feed and processing. Once China approves GE alfalfa traits, China will also become an importer of GE alfalfa. China's unpredictable approval process and lack of a low level presence (LLP) policy have resulted in detained and rejected shipments and trade disruptions, such as the rejection of 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) mainly to Sub-Saharan African countries. Since China has not approved any major biotech food crops, all the food aid is comprised of non-biotech crops.

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 for new GE traits. 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. Following the Ministry of Agriculture's "completeness check" of the applications, China's National Biosafety Committee review and approval process has delayed import approvals for developers. This has delayed the overall commercialization of new, innovative GE traits throughout the world. In some cases these delays have amounted to over a five year delay from when the product was first approved in the product's home country market. Additionally, the lack of a low-level presence policy in China means that the world's largest importer of animal feed has a zero tolerance for unapproved GE traits in the over one hundred million metric tons of animal feed that the country imports annually.

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 GMO](#)" of 2001 (revised in 2017). MOA 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 MOA Measures:

- *MOA's Ministerial Decrees 8 [2002] "Administrative Measures on the Safety Evaluation of Agricultural Genetically Modified Organisms", which was revised in 2016 by MOA Decree 7 [2016];
- *MOA Decree 9 [2002]"Administrative Measures on the Safety of Agricultural GMO Imports";
- *MOA Decree 10 [2002]"Administrative Measures on the Agricultural GMO Labeling";
- MOA Ministerial Decree 59 [2006] "Measures for the Review and Approval of Agricultural Genetically Modified Organisms for Processing";
- Technical guidance, standards, and procedures released in form of MOA public notices;
- AQSIQ Decree 62 "[Administrative Measures of Inspection and Quarantine on Entry-Exit GM Products](#)"

*[GAIN Report CH7053](#) provides translation of the three Decrees. Note, FAS-Beijing will submit GAIN Reports of the revised Decrees in early 2018.

Technological advancement, including new breeding technologies, requires regulators to update the existing regulatory system and testing methods as well. MOA is considering policies for regulating gene-editing and micro-organisms, and Good Laboratory Practices (GLP) for labs that conduct assessments.

Recent Revisions of Regulations and Rules

In January 2017, the State Council announced the decision to clean up and 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 conduct in-country field trials, rat feeding studies and compositional safety testing required for importing materials as a pre-condition for agricultural biotech import approval and domestic cultivation approval.

Shortly after the State Council notice, in February 2017, the Ministry of Agriculture announced that the two items became "technical service items," and are still required for trait approval. However, MOA will now entrust a relevant Chinese government research institute to conduct the trials or testing, instead of requiring the applicants to do so.

In March 2017, the Ministry of Finance (MOF) and the National Development and Reform Commission (NDRC) issued a joint public notice (Cai Shui [2017] No.17) to remove/stop collecting 41 administrative fees from enterprises/individuals, including fees for in-country trials and studies for the agricultural biosafety certificate application process.

In October 2017, the Decision for Revising Some Administrative Regulations (State Council Order 687) revised the Administrative Regulations for Safety of Agricultural Genetically Modified Organisms which was originally released in 2001. The Revision echoed the changes in the State Council - Guo Fa (2017) No. 8 decision, i.e. MOA will entrust qualified technical institutes to conduct trials (field trials and feeding studies) after receiving applications for the biosafety certificate, and organize the NBC to conduct the safety assessment. With the revision, it is the Ministry of Agriculture's responsibility to

entrust qualified institutes to conduct the trials, and funding to conduct the trials will come from the Chinese government budget, instead of biotech developers.

Ministry of Agriculture Import Approval Procedure

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

The Ministry of Agriculture is responsible for the review and issuance of biosafety certificates for imported biotechnology products for food, feed and processing use (FFP).

MOA Decree 9 [2002] outlines the requirements for importing biotech products ([GAIN Report CH7053](#)). Decree 9 requires a foreign seed developer to submit the application for an agricultural biosafety certificate to the Administrative Examination and Approval Office, commonly known as MOA's "front desk." This office is responsible for accepting applications and issuing responses to applicants. The application must contain a number of materials and certification, which document that the exporting country allows for the use and sale of the product in its domestic market, and that the product has undergone tests showing no harm to animals, plants, or the environment.

After receiving the application for biosafety certificate, MOA 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 using government funding. The reports generated from verification tests along with the application then will be reviewed by the National Biosafety Committee (NBC), which convenes no less than two times every year. The NBC will inform MOA of its decisions after each review. The traits that pass NBC review are subject to MOA'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 explanations for review at the next NBC meeting. The MOA guidance, application form, on-line-application process, and status of application can be found at the [MOA official website's page for administrative approvals](#).

The MOA Regulations for the Review of Applications for Agricultural GMO Safety Certificate (Imports) Submitted for the First Time by Foreign Developers, released in 2013, provide the procedure of review of biosafety applications for new GE traits and include a detailed timeline for each regulatory step.

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

To export GE crops, foreign traders must obtain a "Biosafety Certificate for Agricultural Biotechnology (Import)." The certificate issued by MOA will be given to the importer and the latter will present the certificate to the China Inspection and Quarantine (CIQ, AQSIQ's branch at a port) that will conduct the inspection and quarantine of the imported consignment and clear the shipment. Each certificate can only be used for one shipment and is valid for six months after issuance. To apply for the certificate, a foreign trader 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)
3. Intended safety control measures

MOA has 25 working days to review and issue the certificate, if an application complies with requirements. The MOA guidance, application form, on-line-application process, and status of application can be found at the [MOA official website's page for administrative approvals](#).

Ministry of Agriculture's Domestic Production Approval Procedure

To produce biotech crops domestically in China, technology developers must pass a biosafety evaluation by the NBC and obtain a biosafety certificate issued by MOA. The approval process for biotechnology products for domestic cultivation involves five steps: research, intermediary experiment, environmental release, productive testing, and biosafety certification. Approvals are also sought at the provincial level in addition to national level review. After completing the five steps, products are eligible for biosafety certificates.

The [Catalogue of Industries for Guiding Foreign Investment \(Revision 2017\)](#) released by the Ministry of Commerce and the National Development and Reform Commission, prohibits foreign investment (including foreign investment where the Chinese party is the controlling shareholder) 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 developers to apply for biosafety certification for domestic cultivation of GE crops.

National Biosafety Committee (NBC)

The NBC, established by MOA, conducts the review of domestic and foreign applications for biosafety certificates for cultivation and import. According to the Revised Administrative Measures for Safety Assessment of Agricultural Genetically Modified Organisms" (MOA Decree 7 [2016]) the term of the NBC was extended from three years to five years.

In 2016, the fifth NBC was established with 75 members from different research institutions and universities. The membership has a diversified background in biotech research, production, processing, inspection/quarantine, food safety and environment protection. Government officials no longer hold positions in the Committee. The Development Center for Science and Technology, and affiliate of MOA, serves as the Secretariat of the Committee.

The NBC is divided into three expert groups: biotech plants, animals and microorganisms, food, and feed. The MOA 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.

Additional Ministerial Responsibilities

In addition to MOA's primary responsibility of approving agricultural biotech crops for import and domestic production, MOA also has the lead in the development of the overall government policy related to agricultural biotechnology. MOA manages and distributes government funds to Chinese institutes and universities for the research and development of biotech crops.

The General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) and its local inspection and quarantine offices (CIQs) are responsible for testing agricultural and food products for GE contents.

The State Forestry Administration (SFA) is responsible for the approval of forestry products for research, domestic production, and import, and also creates 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 MOA-authorized centers across China that conduct environmental safety testing, food safety testing and detection testing. MOA 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 agencies under the State Council that include: MOA, MEP, AQSIQ, Ministry of Science and Technology (MOST), National Development and Reform Commission (NDRC), Ministry of Commerce, and the National Health and Family Planning Commission (former Ministry of Health), etc. The conference is mostly used to coordinate biotech policy development which affects multiple ministries.

APPROVALS:

In 2017, five events received biosafety certificates for import as processing material. MOA also issued certificate renewals for a dozen of traits that were set to expire in 2017.

To date, MOA has approved the importation of five different GE crops for processing or feed 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 import as feed or processing material is included in Appendix 2 of this report.

b) STACKED EVENT APPROVALS:

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

c) FIELD TESTING:

China allows field trials of biotech crops for the purpose of import approval and research, but does not provide data on the number of field trials or types of crops / traits being tested.

d) INNOVATIVE BIOTECHNOLOGIES:

Chinese scientists associated with the China Academy of Sciences and the China Academy of Agricultural Sciences are making impressive progress in innovative biotechnology and have published dozens of papers about CRISPR technology.

MOA is considering how to regulate innovative biotechnology and regulations are expected to be released in the near future.

e) COEXISTENCE:

China does not have a co-existence policy.

f) LABELING:

China's biotech labeling regulations, governed by MOA Decree 10 [2002] ([GAIN Report CH7053](#)), 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
3. Rapeseed for planting, rapeseeds, rapeseed oil, and rape meal
4. Cottonseed
5. Tomato seed, fresh tomato, and tomato paste

On various occasions, MOA and Chinese scientists have stated that China will establish a threshold for GE labelling, changing the labelling requirements from qualitative to quantitative. It is expected that the new rules will be issued in one to two years.

In September 2014, China Central Television (CCTV) issued a notice to advertising agents notifying them that the State Administration of Industry and Commerce (SAIC) will strengthen regulatory oversight over advertisements including claims or statements regarding "GMOs". This move was taken after MOA contacted SAIC with concerns about misleading labeling.

In January 2015, MOA released the *Notice Concerning Guidance for GMO-related Advertisements*, which urged provincial agricultural authorities to work with the local commerce and food and drug authorities to reinforce supervision over GMO-related advertisements. The Notice prohibits the use of "non-GMO" 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 "healthier" or "safer."

g) MONITORING AND TESTING:

Testing of biotechnology products is carried out primarily by MOA, AQSIQ and the Ministry of Environmental Protection (MEP) through their affiliated testing institutes. AQSIQ tests imported products for unapproved biotechnology events, MOA tests domestic crops and conducts safety assessment experiments, and MEP conducts environmental safety assessments.

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 sensitivities, 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.

MOA, AQSIQ and MEP have developed national and industry standards for biotech testing, all of which use PCR testing methodologies. Although the standard numbers suggest they are voluntary, they are believed to be de facto mandatory and are adhered to within China. AQSIQ-developed standards tend to focus on specific crops, while MOA-developed standards are often targeted at testing for specific events.

h) LOW LEVEL PRESENCE (LLP) POLICY:

China has a zero tolerance for unapproved biotechnology traits in imports.

i) ADDITIONAL REGULATORY REQUIREMENTS

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

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

On April 7, 2017, the Ministry of Agriculture (MOA) 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, and include guidance for application, review and approval of the record filing if the crop is one of the 29 non-major crops. This change reduces the test requirements for non-major crops to be cultivated in China.

For more details of the seed variety registration, please refer to the Annual China Seed Report to be submitted by FAS Beijing in early 2018.

j) INTELLECTUAL PROPERTY RIGHTS (IPR):

China's Seed Law and MOA Administrative Measures for Plant Variety Protection govern intellectual property rights protection for agricultural biotechnology and were both 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.

k) CARTAGENA PROTOCOL RATIFICATION:

China signed onto the Cartagena Protocol on Biosafety to the Convention on Biological Diversity in 2000 and ratified the protocol in 2005. In 2011, China announced that the protocol would also apply to the Hong Kong Special Administrative Region. China participates in the Global LLP Initiative as an observer.

l) INTERNATIONAL TREATIES/FORA AND DIALOGUES:

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 and led to increased weed and pest pressure in developed and developing countries, alike.

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

The 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. To supplement the policy discussions, a technical subgroup (TWG) was established in July 2003. The most recent BWG and TWG meetings were held in July 2017 in Beijing. The two sides exchanged updates of products under development and in the approval pipeline, discussed revisions to regulations and rules in each country, and discussed other issues of interest.

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS:

The government is increasing its public outreach efforts to address public misperceptions towards biotechnology in the form of holding press conferences and launching trainings for journalists and local government officials. Both traditional and social media are being used to explain China's biosafety regulatory work.

MOA is also coordinating with its sister ministries to eliminate misleading claims or statements in product labels and advertisements.

With these efforts, false and misleading stories or articles circulating in the mainstream media have decreased. However, the emerging media, such as the Weibo, WeChat and on-line forums, has become an important tool for the dissemination of mis-information about agricultural biotechnology.

Meanwhile, public opponents of biotechnology have become more vocal and active in challenging the government. There have been a number of requests for MOA to disclose information, including questions from members of the National People's Congress Consultative Committee. MOA has been sued several times for violating requirements to disclose public information related to the agricultural biotech approval process and policy planning. Although the court had ruled in favor of MOA, MOA has had to devote time and resources to responding to these cases.

b) MARKET ACCEPTANCE/STUDIES:

The Research Jointly Conducted by the Science and Technology Daily and the China Academy of Science and Technology Development Strategy

In May 2017, the Science and Technology Daily and the China Academy of Science and Technology Development Strategy jointly released the Report of "Public's Attitude toward Biotechnology"¹, which reveals that the Chinese public's acceptance of biotechnology is decreasing.

Using a computer-aided telephone interview system, the program completed 1,200+ valid questionnaires in ten research regions nationwide. Analysis shows that 51.7% interviewees believe GMO foods are harmful to human health, and 42.8% believe biotech crops cause harm to the ecological environment. The survey also indicates that the majority of the public are against growing genetically engineered rice (65.2%) and do not want to eat GMO food (72.8%). The survey's leader explained that lacking a complete understanding of risks vs. benefits of biotechnology impacted the public's overall attitude of the technology.

The Key Project on "Science Education and Risk Communication for Biotechnology" Undertaken by the Tsinghua University

At the end of 2016, Tsinghua University, Shanghai Fudan University, Zhejiang University, China Science and Technology University, China Association for Science and Technology and the science publicity platform Guokr.com jointly kicked off the National Science and Technology Key Program of "Science Education and Risk Communication for Biotechnology". According to the program plan, the five-year long program will complete a nationwide poll on public awareness and perception of biotechnology by 2017. Supported by MOA, this research is expected to provide a more comprehensive and authoritative analysis of the public opinion of biotechnology in China.²

¹ Summary of the report is available at the Science and Technology Daily website:
http://digitalpaper.stdaily.com/http_www.kjrb.com/kjrb/html/2016-05/16/content_339007.htm?div=0

² Report of the Research Project can be found at the [Tsinghua University's website](#).

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 including 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 MOA and MOF for research funding. The National GE Animal Technology Research Center was established at Inner Mongolia University in September 2012, aiming to improve livestock variety development and animal breeding in China and to facilitate public education of GE animal technology. 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 could be found at the [National Science and Technology Report Service](#).

b) COMMERCIAL PRODUCTION:

Some GE animal projects have long been ready to apply for MOA biosafety certificates for commercialization, but lack definite MOA guidelines about how to move forward in the approval pipeline.

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 GMO](#)" of 2001 (revised in 2017). The MOA guidance, application form, on-line-application process, and status of application can be found at the [MOA official website's page for administrative approvals](#). However, this regulation lacks implementation rules or specific policies that regulate animal biotech research, production, or trade. Like plant biotechnology, MOA starts review of dossiers only after an event is deregulated in an exporting country. To date, there have been no applications submitted in China for a safety certificate for GE animal imports.

b) INNOVATIVE BIOTECHNOLOGIES:

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

c) LABELING AND TRACEABILITY:

GE animal labeling is subject to Measures for Agricultural GMO Labeling Administration (MOA Decree 10). However, as China has not yet commercialized any GE animals. No specific measures for GE animal labeling are available.

d) INTELLECTUAL PROPERTY RIGHTS (IPR):

GE animals still fall into a legal gap in China's IPR protection regulations. Currently, gene and DNA fragments are subject to protection provided by the Patent Law of China.

e) INTERNATIONAL TREATIES/FORA:

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 links between public research institutes and industry make commercialization of GE animals difficult in China.

b) MARKET ACCEPTANCE/STUDIES:

Although no official survey is 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: China Customs)

China Cotton Exports

Partner Country	Quantity (Metric Tons)			
	2014	2015	2016	2017 (Jan.-Sep.)
World	13,470	28,916	7,757	12,198
Vietnam	2,435	16,288	2,043	7,765
Indonesia	1,821	3,417	1,237	2,108
Korea North	2,037	1,401	2,043	1,316

China Cotton Imports

Partner Country	Quantity (Million Tons)			
	2014	2015	2016	2017 (Jan.-Sep.)
World	2.44	1.67	0.90	0.904
United States	0.55	0.53	0.26	0.441
Australia	0.50	0.25	0.22	0.198
India	0.82	0.33	0.12	0.093
Uzbekistan	0.17	0.175	0.09	0.062

China Corn Imports

Partner Country	Quantity (Million Tons)			
	2014	2015	2016	2017 (Jan.-Sep.)
World	2.6	4.73	3.17	2.28
Ukraine	0.96	3.85	2.66	1.49
United States	1.03	0.46	0.22	0.70

China Soybean Imports

Partner Country	Quantity (Million Tons)			
	2014	2015	2016	2017 (Jan.-Sep.)
World	71.4	81.74	83.23	71.45
Brazil	32	40.13	38.04	42.85
United States	30	28.41	33.66	20.68
Argentina	6	9.44	8.01	4.51
Uruguay	2.44	2.32	1.66	1.75
Canada	0.86	1.07	1.455	1.32

China Distillers Dried Grains Imports

Partner Country	Quantity (Million Tons)			
	2014	2015	2016	2017 (Jan.-Sep.)
World	5.415	6.82	3.067	0.375
United States	5.413	6.818	3.066	0.374

China Sugar Beet Pulp Imports

Partner Country	Quantity (Tons), 2017 (Jan.-Sep.)
World	33,674
United States	33,536
Vietnam	70
Ukraine	56
Germany	12

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	June12, 2017-June 12, 2020
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 LL Cotton25	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