

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT POLICY

Required Report - public distribution

Date: 1/11/2018 GAIN Report Number: CH 17075

China - Peoples Republic of

Food and Agricultural Import Regulations and Standards -Narrative

FAIRS Country Report

Approved By: Michael Ward Prepared By: Jennifer Clever and FAS Beijing Staff

Report Highlights:

China's food regulatory regime continues to evolve. In 2017, China issued numerous new regulations and measures to reflect the requirements introduced under the 2015 Food Safety Law. Most notably, China notified a revised draft of the Regulations for the Implementation of the Food Safety Law in August 2017. As part of these implementation efforts, China notified revisions to inspections and quarantine regulations (AQSIQ Decree 144) in September. China issued technical documents and guidelines to implement registration requirements for special foods (CFDA Decrees 24 and 26). Similarly, in 2017, China announced plans to develop standards for limits on agrochemicals residues. Starting January 1, 2018, China is expanding the application of Cross Border E-Commerce (CBEC) policies on imports to five more cities: Hefei, Chengdu, Dalian, Qingdao and Suzhou. Lastly, also in 2017, China reopened its market and issued new procedures allowing U.S. beef imports.

This report attempts to capture the key Chinese food standards and provisions that relate to imported products destined for the Chinese market. It also notes changes or modifications to existing standards. Given China's current dynamic food regulatory environment, it is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers prior to shipping goods to the Chinese market.

Food and Agricultural Import Regulations and Standards - Narrative

Executive Summary:

In 2017, the Chinese Government's efforts to modernize its food safety regime continued with the development and revision of multiple laws, regulations, and rules with a view towards a more coordinated and authoritative system.

Most notably, in August 2017, China notified the World Trade organization (WTO) a <u>Revised Draft</u> Regulations pertaining to the Implementation of the 2015 Food Safety Law [see Section II of this report]. Similarly, China notified revisions to a handful of regulations for the oversight of imported and exported food products. After the China Food and Drug Administration (CFDA) introduced registration requirements for infant formula recipes (CFDA Decree 26), and foods for special medical purposes (CFDA Decree 24) in 2016, CFDA issued technical documents and rules to implement the registration process [see Section VIII of this report].

According to the State Council's 2017 Key Tasks on Food Safety Work, China aims to encourage the alignment of the Chinese food safety standards with corresponding international standards. To this end, China will develop 1,000 new Maximum Residue Limits (MRLs) standards, and 100 veterinary drug residue standards. China will also announce regulations for the establishment of pesticide/veterinary drug residue limits on imported agricultural products (import MRLs). China will initiate the development of a "uniform limit" standard based on product categories. The annual national food safety standard plan issued by the National Health and Family Planning Commission (NHFPC) reveals that a few dairy-related standards released in 2010 may also be revised within a year.

Seeking to inform the Chinese public about China's food import situation and its efforts, in July 2017, China's General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) released the 2016 White Paper on the Safety and Quality of Imported Foods. According to the White Paper, the trade of imported foods in China was characterized as having slower growth rate, diversified origins, and diversified categories and varieties. The Paper also highlighted entry ports with high concentration of imports, and identified bulk imports that have become important supply sources for the Chinese domestic market. The White Paper also provided statistics on major categories of foods denied entry, their origins, and major causes for import rejections.

It is important to note that Chinese regulatory authorities continue to consider new measures to reflect the requirements provided under the 2015 Food Safety Law. For example, in June 2017, Chinese import authorities notified a proposed measure that would require official certification for all imported foods. Later, in September, China announced a two-year transitional period delaying implementation of this proposed measure to October 1, 2019 [see Section III].

In addition, starting January 1, 2018, the Ministry of Commerce will extend the application of Cross Border E-Commerce policies on imports to Hefei, Chengdu, Dalian, Qingdao and Suzhou from the current ten cities: Tianjin, Shanghai, Hangzhou, Ningbo, Zhengzhou, Guangzhou, Shenzhen, Chongqing, Fuzhou and Pingtan [see Section III].

Lastly, after a fourteen year hiatus, in 2017, U.S. beef was once again approved to be exported to China. As a result, China issued new procedures for the importation of U.S. beef [See Section IX].

This report attempts to capture the key Chinese food standards and provisions that relate to imported products destined for the Chinese market and highlights modifications to existing standards. However, given China's current dynamic food regulatory environment, it is highly recommended that U.S. exporters

verify the full set of import requirements with their foreign customers prior to shipping goods to this market.

Report Format

This report is the *China Food and Agricultural Import Regulations and Standards (FAIRS) Working Index*. It is a working index of major regulations and standards pertaining to food and agricultural imports, some of which have been translated by the Office of Agriculture Affairs of the U.S. Embassy in Beijing and submitted as GAIN reports. Such reports can be accessed by clicking the hyperlinked-text in this report. These reports can also be accessed through the Foreign Agricultural Service website at "www.fas.usda.gov" under the Attaché Reports section. Please check the FAS website periodically for the most current FAIRS Working Index.

Please note that these translations are UNOFFICIAL and should be used only as guidelines. Exporters are advised to thoroughly discuss all regulatory and implementation details with their Chinese customers. It is important to note that the Chinese regulations may not be consistently implemented at each individual port. Many regulations are short on specifics, and interpretations can differ from port to port and from ministry to ministry.

For answers to specific questions, U.S. exporters are encouraged to contact any of the FAS offices throughout China, or the Foreign Agricultural Service in Washington, DC. Contact information can be found in Appendix 2 of this Report.

Disclaimer

This report was prepared by the Office of Agriculture Affairs of the USDA/Foreign Agriculture Service in Beijing, China for U.S. exporters of domestic food and agricultural products. While every possible care was taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies was not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are best equipped to consult with local authorities, before any goods are shipped. FINAL IMPORT APPROVAL OF ANY PRODUCT IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

Exe	ecutive Summary:
Rej	port Format
Dis	claimer
Co	ntents4
I.	Chinese Food Safety Regulators7
	1. China Food and Drug Administration (CFDA)7
	2. Ministry of Agriculture (MOA)7
	3. National Health and Family Planning Commission (NHFPC)7
	4. The General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ)7
	5. Ministry of Commerce (MOFCOM)
	6. Ministry of Public Security
II.	General Food Laws
	1. The Food Safety Law
	2.Law on Farm Product Quality and Safety9
	3.Consumer Rights Protection Law10
	4. Law on the Inspection of Import and Export Commodities and its Implementation Rules10
	5.Law on the Entry and Exit Animal and Plant Quarantine and its Implementation Rules11
	6. Special Rules of the State Council to Reinforce the Safety Supervision and Management of Food and Other Products
	7.Grains Law11
III.	Food Safety Regulations, Rules and Standard Structure
	1. AQSIQ Administrative Measures for the Safety of Imported and Exported Foods (Decree 144)11
	2.Entry-Exit Inspection and Quarantine Process Management Rules
	3. AQSIQ Proposed Certificate Requirement for Imported Foods (known as Measure 327)12
	4. Rules for the Implementation of Bad Records Administration on Imported Food12
	5. Traceability
	6.Food Recall Regulation
	7.E-commerce
	8. New Food Materials
	9. The National Food Safety Standards
IV.	Food Additive Regulations
	1.Food Additives

Contents

	2. Flavoring Substances and Flavors17
	3. Nutritional Fortification Substances
V.	Pesticides, Veterinary Drug and Other Contaminants
	1. Pesticide Registration and Establishment of Maximum Residue Level
	2. Maximum Levels of Mycotoxins in Foods
	3. Maximum Levels of Contaminants in Foods
	4. Pathogen Limits for Food
VI.	Packaging and Container Requirements
VII	Labeling Requirements
VII	I. Facility and product registration requirements
	1. The AQSIQ Administrative Measures for Registration of Overseas Manufacturers of Imported Food (Decree 145)
	2.Record Filing for Foreign Exporters/Agents of Food Products and Consignee of Imported Food Products to China (2015 Update to AQSIQ Public Notice [2012] No. 55)22
	3. AQSIQ Notice concerning Soliciting Comments on the "Administrative Measures for Importers' Review and Inspection on Overseas Establishments that Export Food Products to China"
	4. CFDA Registration/Record Filing of Special Foods
	5. Good Manufacturing Practices
IX.	Product Specific Regulations and Standards
	1.Dairy
	1) Specific Regulations for Dairy Imports
	2) National Food Safety Standards for Dairy Products
	2. Special Foods
	1) Infant formula
	2) Foods for Special Medical Purposes (FSMP)
	3) Health foods
	3. Meat and Poultry Products
	1) Regulations
	2) National Standards for Meat and Poultry Products
	4. Vegetable Oil
	5.Biotech
	6. Grains
	7. Feed and Feed Additives
	8.Organic food

9.Seafood	41
10. Measures on Inspection, Quarantine, Supervision and Administration of Animal Products	•
Appendix:	
1. Government Regulatory Agency Contacts	
2. Other Import Specialist Contacts	
3. Framework of the China's National Food Safety Standards	
4. Full list of the existing national food safety standards	

General Information

I. Chinese Food Safety Regulators

1. China Food and Drug Administration (CFDA)

CFDA is the food safety overseer in China, its responsibilities include:

- Develop draft laws, regulations, policies, plans for the oversight of food, drugs, medical devices and cosmetics;
- Recall and dispose of problematic products;
- Prevent regional food and drug safety risks caused by system defects;
- Conduct food inspection, and investigate major violations of the Food Safety Law;
- Establish a unified public food safety information system, which discloses information regarding major food safety issues;
- Respond to and investigate food and drug safety incidents; CFDA makes sure the investigation results are followed by remedial actions and punishment;
- Guide local authorities' food and drug supervision and enforcement work;
- Serve as the coordinator when several ministries are involved in a food safety incident.
- Handle new registration and inspection requirements for infant formula recipes, health foods, and foods for special medical purposes.

The Food Safety Commission Office (FSCO) rests within the CFDA and serves as the coordinator when several ministries are involved in responding to food safety issues. However, the FSCO does not have enforcement authority.

2. Ministry of Agriculture (MOA)

MOA supervises and regulates quality and safety of agricultural products for food use in the domestic production chain before the products enter the wholesale, retail or processing market. MOA oversees the quality and use of veterinary drugs, feed, feed additives and other agricultural inputs (such as pesticides and fertilizers). MOA supervises and regulates the quality and safety of livestock slaughter and raw milk purchases. MOA is the regulator of agricultural biotechnology in China.

3. National Health and Family Planning Commission (NHFPC)

NHFPC is responsible for conducting food safety risk assessments and the development of food safety standards. NHFPC's work includes setting basic standards for foods, food additives and food-related products (disinfectants), hygienic requirements for food production/operations, and testing regulations and methodologies for contaminants, mycotoxins, and pathogens. NHFPC also conducts food risk surveillance, and is responsible for notifying the CFDA of any detected risks.

4. The General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ)

AQSIQ supervises and regulates production of food-related products, such as food packaging materials, containers and food processing tools, etc. It also oversees safety, quality, plant and animal health issues pertaining to food and agricultural imports and exports. AQSIQ collects and analyzes information on the safety of food imports and exports. Upon the discovery of a food safety incident or outbreak abroad that may impact China's domestic market or the detection of severe food safety problems in imported foods, AQSIQ must immediately initiate an early risk warning and take control measures. AQSIQ also has the authority to draft and announce import rules (in the form of Decrees) on its own. Specific Departments within AQSIQ also now have the responsibility to implement new registration requirements on specific commodity areas such as grain and oilseeds, and live seafood. At the provincial level, AQSIQ conducts inspection Quarantine of imports and exports of food products through its enforcement bodies, China Inspection Quarantine (CIQs). It is worth noting that consistency regarding testing procedures, results, and unpublished local directives remains highly variable among CIQs. AQSIQ also serves as China's World Trade Organization (WTO) Enquiry Point for Sanitary and Phytosanitary measures (SPS), as well as Technical Barriers to Trade (TBT) measures.

China's Certification and Accreditation Administration (CNCA)

The Certification and Accreditation Administration (CNCA) is an institution directly under the AQSIQ. It exercises the administrative responsibilities of unified management, supervision and overall coordination of certification and accreditation activities across the country. CNCA is also responsible for registration of foreign food producing facilities that export certain products to China (Decree 145), and the administration of the compulsory product certification system and its implementation [see Section VIII for a full list of products currently subject to Decree 145].

5. Ministry of Commerce (MOFCOM)

MOFCOM develops plans and policies for catering services and the distribution of alcohol products. It also has the lead on issues related to the WTO. MOFCOM also serves as China's SPS National Notification Authority (NNA), responsible for sending WTO Notifications pertaining to SPS and TBT measures once an issuing agency agrees to notify trading partners.

6. Ministry of Public Security

The Ministry of Public Security is in charge of supervising and instructing the criminal investigation portion of food and drug violations. The 2015 Food Safety Law expands the scope of food and drug violations that are considered criminal.

II. General Food Laws

The legal framework for food safety management in China is mainly composed by the Food Safety Law, the Law on Agricultural Product Quality Safety, the Consumer Rights Protection Law, and the Import and Export Commodity Inspection Law.

1. The Food Safety Law

The 2015 Food Safety Law

At the end of April 2015, the National People's Congress (NPC, China's legislator) announced the revised Food Safety Law (the 2015 Food Safety Law), which was implemented on October 1, 2015. Containing 154 articles in ten chapters, the 2015 Food Safety Law:

- Establishes the integrated domestic food safety regulatory and enforcement authority (the CFDA);
- Emphasizes oversight of the food producing process rather than the finished product;
- Holds food producers and traders accountable for food safety incidents caused by problematic food products;
- Leads towards a risk prevention orientation;
- Imposes stringent oversight of specials foods (health foods, infant formula foods, and formula foods for special medical purposes);
- Imposes more severe punitive measures (including criminal penalties).

The Law imposes several new requirements: registration of infant formula recipes; on-site evaluations of foreign exporters and producing enterprises by food importers; recalls of food products by importers. The Law also addresses food safety under the fast booming E-commerce platforms.

The Implementing Rules of the Food Safety Law (Revised Draft)

On August 14, 2017, China notified the World Trade Organization (WTO) of the "Regulations on the Implementation of the Food Safety Law of the People's Republic of China (Revised Draft)" as SPS 1055. The revised draft regulations are in support of the implementation of China's <u>2015 Food Safety</u> <u>Law</u>. As of this report, the draft implementing regulations do not have a determined date of enforcement; however, the <u>Key Tasks of Food Safety Work in 2017</u> pledges to "speedily revise the Regulations on the Implementation of the Food Safety Law".

Background on the Revised Draft

The Revised Draft Implementing Regulations constitutes the third iteration of the Draft Implementing Rules and the only version notified to the World Trade Organization. The China Food and Drug Administration (CFDA) released the first draft in December 2015. In October 2016, the State Council's Legislative Affairs Department released the first revision to the draft. This latest version contains ten chapters and 98 articles, including general principles on risk monitoring and assessment for food safety; food safety standards; the production and marketing of food; food inspection; food import and export; handling of food safety incidents; supervision and management. The Revised Draft also outlines legal responsibilities and provides supplementary provisions. China's notification to the WTO signals that China may be moving closer to finalizing the draft.

In comparison with the first draft and the first revision, the current draft contains far less articles (first Draft had 200 articles, the first revision had 208 articles, and the current draft only has 98 articles). Some of the major changes are focused in the sections pertaining to food safety standards, food production and operation, supervision and management, and the legal responsibilities for food producers and regulators.

The Food Safety Law was promulgated two years ago. However, the absence of implementing rules has delayed the implementation of some of the requirements provided in the Law. Hence, it should be expected that after the Implementing Rules are finalized and released, some existing measures, including major regulations, will need to be revised or developed to reflect changes in the Implementing Rules.

2. Law on Farm Product Quality and Safety

Another pillar of the Chinese food safety legal system is the Law on Farm Product Quality and Safety, which pertains to the quality and safety management on primary edible products derived from agriculture (edible agricultural products¹), as well as agricultural inputs (pesticides and fertilizers). Once edible agricultural products have entered the market, these products are subject to the 2015 Food Safety Law.

The Law on Farm Product Quality and Safety was promulgated in 2006, and the Ministry of Agriculture (MOA) has initiated the revision of this law to reflect recent changes in the food safety regulatory system. According to the "Key Tasks regarding Food Safety Work in 2017" released by the State Council in April 2017, China will initiate the revision of the "Law on Farm Product Quality and Safety" within a year. As of this report, there is no further clarity on the timing of this revision.

3. Consumer Rights Protection Law

In late October 2013, China passed the Amendment of the "Consumer Rights Protection Law", which came into force on March 15, 2014. In consideration of consumer safety and food safety related incidents, the Amendment added language to address issues pertaining to on-line shopping, product recall, and compensation to consumers. Observers highlight that this Amendment, together with the enactment of the 2015 Food Safety Law, shows that legislators are resolute in improving China's food safety environment.

Implementing Rules for the Consumer Rights Protection Law

In mid-November 2016, the State Council released the Draft Implementing Rules for Consumer Rights Protection Law² for public comments. Among other issues, the Draft Rules seek to address the long debated issue of "professional buyers/consumers." These individuals and entities have reportedly been taking advantage of the new relevant food safety regulations/rules by making claims of wrongdoing and seeking compensation at the expense of traders/producers. However, major food manufacturers opine that the Draft Rules do not offer greater clarity to the definition of "consumer" and this is still allowing the "professional buyers" to carry on with their current activities.

It is worth noting that the Consumer Right Protection Law and the Food Safety Law have inconsistent provisions regarding to amount of punitive fines. The definition of what constitutes a "severe" offense, which ultimately determines the amount of the fine, also remains unclear. Domestic and foreign food manufacturers and operators are working to find solutions to address these inconsistencies.

U.S. exporters and food operators in China are advised to exercise extra caution to ensure products circulating in the Chinese market meet corresponding standards. In particular, careful attention should be paid to labeling even the labeling of traditionally traded products. Labeling errors have reportedly been the highest cause of non-compliance complaints submitted by the "professional buyers/consumers."

4. Law on the Inspection of Import and Export Commodities and its Implementation Rules

This Law and its implementing rules apply to all import and export commodities, including food products, which are listed in the "Catalog of Import and Export Commodities that are Subject to Inspection."³ The

¹ Edible agricultural products cover primary products, such as vegetables, melons, fruits, unprocessed meats, etc., while foods refer to finished products or materials for human consumption or products that are traditional treated as both foods and medicine.

² For full text of the Draft Implementing Rules for the Law on the Protection of the Rights and Interests of Consumers in Chinese please visit <u>http://zqvj.chinalaw.gov.cn/readmore?listType=1&id=1488&1482144749402</u>.

³ The Catalogue is adjusted by the AQSIQ regularly, and is announced by AQSIQ public notices.

Law provides guidelines for product clearance at the Chinese customs, and a checklist of documents needed.

5. Law on the Entry and Exit Animal and Plant Quarantine and its Implementation Rules

The Law on the Entry and Exit Animal and Plant Quarantine and its implementation rules regulates the quarantine of import and export of food products.

6. <u>Special Rules of the State Council to Reinforce the Safety Supervision and Management of</u> <u>Food and Other Products</u>

The Special rules were promulgated on July 26, 2007 as the State Council Order No. 503. It stipulates that producers of foods and agricultural products for export will guarantee their export products comply with standards or contract conditions. In addition, relevant authorities (AQSIQ and MOFCOM) will maintain good and bad records of producers and traders who export products. The Special Rules also demand that imports must comply with the mandatory requirements of technical specifications such as national food safety standards.

7. Grains Law

First issued by the State Council's Legislative Affairs Office in November 2014, the Grain Law was submitted to the National People's Congress (NPC) in February 2015 for promulgation. Once promulgated, the Grains Law will apply to grain production, distribution and consumption within the territory of China. "Grain" refers to cereals and their finished products, soybeans and tubers.

According to the "<u>Key Tasks regarding Food Safety Work in 2016</u>" released by the State Council (China's Cabinet) in April 2016, China was scheduled to push forward the formulation and revision of the "Grains Law." However, there were no further developments on the revision during 2017. The internal approval process for the Law is still expected to be lengthy; drafts of the Law have not been notified to the WTO.

III. Food Safety Regulations, Rules and Standard Structure

1. AQSIQ Administrative Measures for the Safety of Imported and Exported Foods (Decree 144)

On September 13, 2011, AQSIQ issued Decree 144 pertaining to Administrative Measures for the Safety of Imported and Exported Foods, which came into force on March 1, 2012. The Measures are the core regulations for the inspection and oversight of food imports and exports. It established the principal requirements, including the foreign food producer registration, foreign food exporter/trader record filing system, good/bad record system, the import food inspection, and the risk alert mechanism. The Measures also grant inspectors of the AQSIQ local branches (China Inspection and Quarantine, CIQ) the authority to conduct on-site inspections of foreign food manufacturing facilities, verify documents, and detain products that fail to comply with regulations.

On September 13, 2017, China notified the World Trade Organization of the draft "<u>Measures for the</u> <u>Supervision and Administration of Import and Export Food Safety</u>" as SPS 1056, which is a revision of the AQSIQ Decree 144. It is expected that the revised Measures will be released in 2018 for implementation.

2. Entry-Exit Inspection and Quarantine Process Management Rules

On October 16, 2017, AQSIQ released the Entry-Exit Inspection and Quarantine Process Management Rules. The Rules do not impose new requirements for the entry-exit inspection and quarantine of all imports, but does specify inspection and quarantine procedures. Outlined procedures include acceptance of a declaration for inspection and quarantine, examination and surveillance of documents, field and lab inspection and quarantine reports, isolation quarantine for animals and plants, quarantine treatment (if necessary), comprehensive evaluation, issuance of certificates and releases, as well as archiving. The Rules also define jurisdictions for AQSIQ and its local branches for each step of the processes. The Rules also provides sample testing frequencies on incoming shipments depending on risk and the traders' good track record.

3. AQSIQ Proposed Certificate Requirement for Imported Foods (known as Measure 327)

On June 19, 2017, China notified the "<u>Measures for the Administration of Certificates Attached to Foods</u> <u>Exported to China (Draft)</u>" to the WTO's Committee on Technical Barriers to Trade as <u>TBT 1209</u>. The TBT notification provides the scope of products affected, description of the content in the certificate, the objective and rationale of the Measure, and a link to the full text of the Measure.

Citing Article 92 of the <u>2015 Food Safety Law</u>, AQSIQ first proposed the measure in April 2016. As first proposed, the measure required all products imported to China be accompanied by an official certificate, including products considered low-risk (such as cookies, pasta, biscuits, etc.)

The proposed date of entry into force was October 1, 2017. However, on September 25, 2017, China notified the World Trade Organization of an Addendum to the Measure, granting a two-year transitional period on the implementation of the measures to September 30, 2019. Please refer to the GAIN report "China Announces a Two-year Transitional Period on a Proposed Certificate Requirement for Imported Foods" for more details.

4. Rules for the Implementation of Bad Records Administration on Imported Food

On April 14, 2014, AQSIQ released the final version of the Implementing Rules regarding Bad Record Administration of Imported Food, which came into force on July 1, 2014. According to the Rules, foreign manufacturing establishments and exporters, domestic importers, and agents of imported foods that violate certain food safety regulations in import/export will be announced regularly. The Rules also sets the "three-strike" provision, i.e. removing a company's registration after three certain types of violations.

5. Traceability

In 2016, China reinforced the development of the traceability system for edible agricultural products and foods, particularly infant formula foods, meat products, dairy products, edible vegetable oil, and Chinese liquor.

The **Opinion of the State Council's** General Office for Accelerating the Construction of the Traceability System for Key Commodities (Guo Fa Ban [2015] No. 95), issued in January 2016, pledges to push forward the development of traceability systems for edible agricultural products and foods. The Opinion sets the objectives to establish the whole traceability cooperation mechanism for quality and safety of edible agricultural products, and to promote the interconnection of traceability management and market access. Producers of infant formula food, meat products, dairy products, edible vegetable oil, liquor and other food products are required to establish a quality and safety traceability system, and to take responsibility for the quality and safety of their products.

After the State Council's opinion, CFDA has released a series of regulations addressing the issue:

- In January 2016, CFDA released the Guiding Opinions to Edible Oil Producer for Food Safety Traceability System⁴, which provides for the scope of edible oils that are required to establish the traceability, and the information to be recorded in the system;
- In January 2016, CFDA released the Notice Requiring Infant Formula Powder Producers to Record Food Safety Traceability Information⁵. Under this Notice, Chinese infant formula powder producers are required to record information including product formula R&D, raw/auxiliary materials, production process control, management of products, sales, risk information, and food recall, etc.;
- In April 2016, CFDA solicited comments on the Opinion to Further Improve the Food and Drug Traceability System (Draft for Comments). It echoes the State Council's No.95 Opinion and requires food producers/traders to construct traceability systems, giving priority to infant formula foods, meat products, dairy products, edible oil and Chinese liquor; the CFDA draft Opinion reveals that the system will be implemented by product categories;
- In November 2016, CFDA solicited comments on the "Guiding Opinions for Food Producers and Traders to Establish the Food Safety Traceability System (Draft for Comments)"; the Guiding Opinion, once finalized, will be a reference for food producers and traders in establishing the traceability system, and will be used by the local CFDA officials in their supervision work. It provides the scope of food producers and traders, and the information to be recorded in the system.
- In March 2017, in its Public Notice pertaining to provisions for Food Producers/Operators to Establish Food Safety Traceability System ([2017] No.39)6, CFDA urges food producers and operators to establish food safety traceability systems. These systems will be used to record and keep food quality and safety information and will enable the traceability of the flow of products and their sources. The Notice also outlines the information items to be recorded in the system.

In addition, during 2016, news media revealed that the Ministry of Finance (MOF) and the Ministry of Commerce (MOFCOM) planned to take one year and half to complete the construction of a pilot traceability system covering meat, vegetables, Chinese herbal or traditional medicine, and dairy products as a demonstration project. Cities in four provinces were selected for the demonstration project – Shandong, Shanghai, Ningxia and Xiamen. The central budget plans to provide support of RMB 700 million for the demonstration project (200 million to Shandong, Ningxia and Shanghai, respectively; 100 million for Xiamen). According to the news article, when the demonstration project is complete, cities will share their experiences with a view toward establishing a nationwide traceability system. As of this report, it is unclear whether the traceability systems implemented by CFDA and the individual provincial pilot projects will overlap.

6. Food Recall Regulation

⁴ For full text in Chinese please visit: <u>http://www.sfda.gov.cn/WS01/CL1611/141160.html</u>

 ⁵ For full text in Chinese please visit: <u>http://www.cfda.gov.cn/WS01/CL0053/141140.html</u>
⁶ For full Chinese text of the CFDA Public Notice [2017] No.39, please visit

http://www.sda.gov.cn/WS01/CL1830/171362.html

The Administrative Measures for Food Recalls (CFDA Decree 12)⁷

The changes of the regulatory system and the amendment of the Food Safety Law called for a more feasible practice to approach food recalls, including shifting the authority to conduct food recalls from AQSIQ to CFDA. Food recalls are categorized into three grades depending on the seriousness and degree of emergency of the food safety risks.

In March 2015, CFDA published the Administrative Measures for Food Recalls (Decree 12), which came into force on September 1, 2015. Decree 12 stipulates that food producers and traders will be accountable for food safety and will honor their obligations regarding termination of trade, recall and treatment/disposal of unsafe food products. There were no new developments on Food Recall regulations during 2017.

7. E-commerce

In November, 2017, the National People's Congress (NPC) published the second draft of a new e-Commerce Law that is expected to take full effect in 2018. The U.S. Government and Industry are both actively monitoring the proposed new regulation to determine its impact on trade. The U.S. Government, in cooperation with industry associations, are providing comments and asking clarifying questions to China on the draft laws.

Cross Border e-Commerce is defined by China as the process of buying foreign products directly from foreign retailers and suppliers via internet, without the specific need for an intermediary business entity in China.

The Cross Border e-Commerce (CBEC) channel was established by a series of pilot policy announcements by the General Administration of Customs in 2014. Due to the exemption of import taxes under certain conditions, the retail price of CBEC goods can be significantly lower compared to the same goods imported via traditional trade. Additionally, the product compliance checks under CBEC are similar to that of China's luggage product checks, which are on average shorter and less restrictive (e.g., lower CIQ sampling rates).

In 2016, the Chinese government (i.e., 11 ministries and commissions of China) created a "positive list" containing 1,293 items, of which about 150 are food or agricultural products that are allowed to enter China through CBEC⁸. The goods included in the positive list are exempted from submitting an import license to Customs. However, products under CFDA rules (such as special foods including infant formula) require registration prior to import. Items not on the positive list will not be allowed entry via CBEC. The regulations for registration and filing requirements are set to change in January 2018. As of the publishing of this report, no further guidance has been provided.

In 2016, two new rules "Tax Policy for Cross-Border E-Commerce Retail Imports" and "List of Imported Commodities for Retail in Cross-Border E-Commerce" were coupled with stronger implementation from the Chinese authorities to level the playing field between CBEC and conventional trade. The changes outlined in the 2016 regulations greatly affected the different taxes (e.g., import tax, value-added tax, and consumption tax) for CBEC products. The government later decided to offer a grace period for implementation of the 2016 regulations, and are not enforcing the new tax policies at this time.

 ⁷ For full Chinese text of the CFDA Decree 12, please visit <u>http://www.sfda.gov.cn/WS01/CL1197/115580.html</u>.
⁸ The Positive list can be found here:

http://gss.mof.gov.cn/zhengwuxinxi/zhengcefabu/201604/P020160407628544745898.pdf http://gss.mof.gov.cn/zhengwuxinxi/zhengcefabu/201604/P020160415822493955077.pdf

The GAIN report "<u>Chinese Government Policies Change for Cross-Border e-Commerce</u>" provides a more detailed description of these policies.

In November 2017, the Ministry of Commerce (MOFCOM) said that the policies and measures for CBEC imports will be expanded to five more cities from the current ten. As of January 1, 2018, the CBEC policies will also apply to Hefei, Chengdu, Dalian, Qingdao and Suzhou from the current ten cities: Tianjin, Shanghai, Hangzhou, Ningbo, Zhengzhou, Guangzhou, Shenzhen, Chongqing, Fuzhou and Pingtan.

8. New Food Materials

On July 12, 2013, NHFPC issued Decree No. 1, the Administrative Measures for Safety Review of New Food Materials, which became effective on October 1, 2013. The Measures specify the definition and scope of new raw food materials, the procedure to apply for approval of new food materials, and dossier requirements. Please note that biotech foods, health foods, and new varieties of food additives are not subject to these Measures.

On October 15, 2013, the NHFPC released the "Provisions for Application and Acceptance (of the Application) for New Food Materials" and the "Standard Procedures for Safety Review of New Food Materials."⁹ These Procedures provide specific guidance as how to apply for permission for new food materials.

9. The National Food Safety Standards

By the end of 2017, China has issued over 1,200 national food safety standards, and has preliminarily established the national food safety standard framework.

Appendix 4 of the report provides the full list of the existing national food safety standards issued by the Ministry of Health (which later became the NHFPC) since 2010.

According to the "<u>Project Initiation Plan for National Food Safety Standards Work in 2017</u>", NHFPC will revise and develop a handful of national food safety standards in 2017, including standards related to dairy products, infant formula, and mycotoxin, which are expected to be notified to the WTO in 2018 or 2019.

Treatment of Imported Foods without National Food Safety Standard

Article 93 of the Food Safety Law provides that in the case of importing food for which national food safety standards are not available, overseas exporters, overseas producing enterprises, or their entrusted importers should submit their implemented national (regional) standards or international standards to the NHFPC. The NHFPC will review relevant standards and decide whether to temporarily apply such standards if they comply with the requirements for food safety. Likewise, the NHFPC should formulate the corresponding national food safety standards in a timely manner. The importation of food made from new food raw materials or imports of a new variety of food additive or food-related products are subject to Article 37 of the Food Safety Law. Under the Law, CIQs inspect imported food, food additives, and Food-Related Products in accordance with the NHFPC requirements. Inspection results are expected to be made available to the public.

⁹ For full text of the NHFPC notice, please visit: http://www.nhfpc.gov.cn/sps/s3585/201311/e8dc7f4ec58444f8bbf32ec079d7e905.shtml

In April 2017, NHFPC issued the Notice for Regulating the Standard Review of Imported Foods without National Food Safety Standard.¹⁰ The Notice identifies the National Food Safety Risk Assessment Center (CFSA) as the entity to conduct the technical review of standards on imported foods without a national food safety standard in accordance to the existing procedures for standard management. The Notice also states that foreign exporter, producer, or the entrusted importer can submit applications to CFSA. However, the notice does not provide further details as to how applicants can make submissions and does not provide specific guidance as to the treatment of traditionally traded products vs. new-to-market products.

IV. Food Additive Regulations

1. Food Additives

China applies a positive list with respect to food additives. Only additives listed on the National Food Safety Standard for Use of Additives (GB2760-2014) are allowed to be used in food products. Late 2017, NHFPC released the revised GB 2760 for domestic review; it is expected that the draft standard will be notified to the WTO shortly.

To apply for approval of a new additive, or expansion of use of a listed additive, the applying company can submit an application to the NHFPC pursuant to the Administrative Measures for New Variety of Food Additives (known as MOH Decree 73) and the "Provisions for Application Submission and Acceptance of New Variety of Food Additives," and the Notice concerning Regulating Approving of New Food Additive Variety (MOH Public Notice [2011] No.29). NHFPC will then conduct a risk assessment of the additive and determine whether the additive can be added to the positive list.

Instructions on NHFPC application procedures and material requirements can be found on the <u>NHFPC</u> website (scroll down to New Variety Food Additive Applications - 食品添加剂新品种审批).

Given the complexity of the application process, it is strongly recommended that the applicant work through contracted staff in China/Beijing. Outside of the language barrier, many steps in the process require delivery of materials/documents in person. Foreign governments are not listed as valid entities to apply for new additives.

In China, food additive production is subject to the licensing requirements. Only facilities that have "food additive production" listed in its license are allowed to produce food additives.

To address the issue of certain imported products containing food additives without a Chinese national food safety standard, AQSIQ and MOH (later NHFPC) joint notice on "Relevant Applicable Standards for Inspection on Import Food and Food Additives" stipulates that importers must submit an application for import permit to the NHFPC along with relevant safety assessment materials. Once the import permit is granted, importers can present the permit to the quarantine and inspection authorities at ports (CIQs) to clear the products. In the standard review and consolidation, NHFPC is gradually unifying the number of national standards for food additives. In the future, the food additive standard numbers will all start with GB 1886.

It is important to note that under the 2015 Food Safety Law, as all imported products must comply with Chinese standards, the NHFPC is currently reviewing the above practice and determining how to best

¹⁰ A GAIN report with the translation of this notice will be available soon. For full text of the NHFPC notice in Chinese please visit <u>http://www.nhfpc.gov.cn/sps/s3593/201704/15031a65db34492eab8fb5819e9cb466.shtml</u>

handle traditionally imported food products containing food additives that do not yet have a Chinese food safety standard.

Main Food Additive Standards

The four most important standards relating to food additives are the Standard for Use of Food Additives, the General Standard for the Labelling of Food Additives, the Standard for Blended Food Additives, and the Standards of Uses of Additives in Food Containers and Packaging Materials:

Date of issuance	Effective Date	Standard Number	Standard-in Chinese	Standard-in English
4/20/2011	6/20/2012	GB2760- 2015	食品添加剂使用标准	Standard for Use of Food Additives
11/29/2013	6/1/2015	GB29924- 2013	食品添加剂标识通则	General Standard for the Labeling of Food Additives
7/15/2011	9/5/2011	GB26687- 2011	复配食品添加剂通则	Standard for Blended Food Additives
10/19/2016	10/19/2017	GB 9685- 2016	食品接触材料及制品用添加 剂使用标准	Standards for Uses of Additives in Food Containers and Packaging Materials

2. Flavoring Substances and Flavors

In 2014, the NHFPC developed the two basic standards for flavoring substances and flavors. Since the system-wide food standard review, flavoring substances and flavors are categorized as food additives.

Date of issuance	Effective Date	Standard Number	Standard-in Chinese	Standard-in English
11/29/2013	6/1/2014	GB 29938- 2013	食品用香料通则	General Standard for Flavoring Substances and Natural Flavoring Complexes
4/29/2014	11/1/2014	GB 30616- 2014	食品用香精	Food Additive Flavorings (Compounded Flavors)

3. Nutritional Fortification Substances

Nutritional fortification substances refer to the artificially chemosynthetic or natural nutrients or other nutritional components to be added to foods in order to improve their nutrient components.

On March 15, 2012, China issued the Standard Regarding Nutritional Fortification Substances in Foods (GB 14880-2012), which became effective on January 1, 2013. The Standard provides a positive list of nutritional fortification substances allowed for use, defines the purposes of using nutritional fortification, and identifies the food categories that allow the use of the substances, and sources of the substances.

For substances that could be categorized as either nutritional fortification substances or food additives, if the purpose of use is to improve the nutrition component in food, the substances must comply with the Standard Regarding Nutritional Fortification Substances in Foods (GB14880-2012). If the substance is used as a food additive, it must comply with provisions of the Standards for Uses of Food Additives (GB2760-2011).

V. Pesticides, Veterinary Drugs and Other Contaminants

The 2015 Food Safety Law stipulates that China must impose stringent administration rules for the use of pesticides. The Law also urges the elimination of extremely toxic pesticides with high residues, facilitates research and application of substitutive products, and also encourages the use of highly efficient and low-toxic pesticides with low residues.

Regulations on the Management of Pesticides (State Council Decree 677)

On March 16, 2017 the State Council released the "Regulations on the Management of Pesticides" (State Council Decree 677), which was implemented on June 1, 2017. These Regulations pertain to the registration, production, distribution, and use of pesticides. These Regulations were first promulgated in 1997 as State Council Decree 216, and later revised in 2001.

The Key Tasks on Food Safety Work for 2017 pledges to expedite the development of standards for pesticide residue limits in vegetables and special agricultural products, and the standards for veterinary drug residue limits in minor species, livestock, poultry, and aquatic products. China plans to develop 1,000 new MRL standards, 100 vet drug residue standards, and review and consolidate testing methods for pesticide and veterinary drug residue limits. China is expected to announce regulations for developing pesticide/veterinary drug residue limits in imported agricultural products; China will initiate the development of the "uniform limit" standards based on product categories".

1. Pesticide Registration and Establishment of Maximum Residue Level

Pesticide registration:

China maintains a pesticide registration system. All pesticide producers that sell or export pesticides to China need to register the production facility and the pesticide itself with the Ministry of Agriculture. The registration is valid for five years and can be renewed.

Guide for Establishment of Maximum Pesticide Residue Limit (MRL) in Foods

In October, 2015, MOA announced the Guide, which outlines the common procedures for setting MRLs, conditions to review existing MRLs, frequency of MRL review (15 years for MRL, five years for temporary MRL and Codex Extraneous MRL or EMRL), special circumstances for temporary MRL/EMRL/exemption, etc.

Registration of Import Tolerances:

At present China does not have a formal registration process to establish import tolerances for agrochemicals without Chinese MRLs. However, according to MOA, regulations for establishing import tolerance are currently under consideration.

Maximum Residue Level of Pesticides in Foods

MOA has pledged to establish 10,000 MRLs by 2020. On December 18, 2016, NHFPC, MOA and CFDA jointly released the National Food Safety Standard - <u>Maximum Residue Limits for Pesticides in</u> Foods (GB 2763-2016), which was implemented on June 18, 2017.

Adopting CODEX MRL Standards

In November 2015, MOA released a public notice soliciting comments on two draft standards for MRLs. One of these drafts defers to CODEX MRLs for 1,190 MRLs for 105 pesticides. As of this report, some of the limits deferring to CODEX in the draft standard have already been notified through various notifications to the WTO.

2. Maximum Levels of Mycotoxins in Foods

On March 17, 2017, China released the National Food Safety Standard of Maximum Levels of Mycotoxins in Foods (GB2761-2017), which sets limits for Aflatoxin B1, Aflatoxin M1, Deoxynivalenol, Patulin, Ochratoxin A and Zearalenone in foods. The Standard became effective on September 17, 2017.

3. Maximum Levels of Contaminants in Foods

On March 17, 2017, China released the National Food Safety Standard of Maximum Levels of Contaminants in Foods (GB2762-2017), which sets maximum levels of lead, cadmium, mercury, arsenic, tin, nickel, chromium, nitrite, nitrate, benzo (a) pyrene, N-dimethyl nitrosamine, polychlorinated biphenyl and 3-chloro-1,2 propanediol in foods. The standard became effective on September 17, 2017.

4. Pathogen Limits for Food

On December 26, 2013, China released the national food safety standard of Pathogen Limits for Food (GB 29921-2013). This standard provides indexes for pathogen in foods, limits and testing methods which apply to pre-packaged foods (not including canned foods). The standard became effective on June 1, 2014.

VI. Packaging and Container Requirements

The 2015 Food Safety Law defined food packaging materials and containers as "the products made of paper, bamboo, wood, metal, porcelain, plastic, rubber, natural fiber, chemical fiber, or glass and used to contain food or additives, or coating in direct contact with food or additives." The Law also requires that foods for direct consumption must be contained in small packages, or use non-toxic and clean packaging material and containers. The containers for storing, transporting and loading/unloading foods must be safe, harmless, keep (foods) in clean condition, and prevent food contamination, etc. Accordingly, a series of hygienic and safety standards were announced to address the issue:

Date of issuance	Effective Date	Standard Number	Standard-in Chinese	Standard-in English
4/25/2012	10/25/2012	GB 14930.2- 2012	消毒剂	Disinfectant
4/25/2012	10/25/2012	GB 11676- 2012	有机硅防粘涂料	Anti-coherent silicone coating
4/25/2012	10/25/2012	GB 11677- 2012	易拉罐内壁水基改性环氧树 脂涂料	Water soluble epoxy internal coatings of food beverage cans
5/17/2012	11/17/2012	GB 9686- 2012	内壁环氧聚酰胺树脂涂料	Epoxy Polyamide Resin Coating
11/21/2011	12/21/2011	GB 9684- 2011	不锈钢制品	Stainless Steel Products

9/21/2015	9/21/2016	GB 31603- 2015	食品接触材料及制品生产通 用卫生规范	General Hygiene Regulation for Food contacting Materials and Their Products
9/22/2015	9/22/2016	GB 31604.1- 2015	食品接触材料及制品迁移试 验通则	General Rules for Migration Testing of Food Contacting Materials and Products
10/19/2016	10/19/2017	GB 4806.1- 2016	食品接触材料及制品通用安 全要求	General Safety Requirements of Food Contact Materials and Articles
10/19/2016	10/19/2017	GB 9685- 2016	食品接触材料及制品用添加 剂使用标准	Standards for Uses of Additives in Food Containers and Packaging Materials
10/19/2016	4/19/2017	GB 4806.3- 2016	搪瓷制品	Enamel Products
10/19/2016	4/19/2017	GB 4806.4- 2016	陶瓷制品	Ceramic Products
10/19/2016	4/19/2017	GB 4806.5- 2016	玻璃制品	Glass Products
10/19/2016	4/19/2017	GB 4806.6- 2016	食品接触用塑料树脂	Resins for Food Contact Plastic Materials and Articles
10/19/2016	4/19/2017	GB 4806.7- 2016	食品接触用塑料材料及制品	Food Contact Plastic Materials and Articles
10/19/2016	4/19/2017	GB 4806.8- 2016	食品接触用纸和纸板材料及 制品	Food Contact Paper and Paper Board Materials and Articles
10/19/2016	4/19/2017	GB 4806.9- 2016	食品接触用金属材料及制品	Food Contact Metal Materials and Articles
10/19/2016	4/19/2017	GB 4806.10- 2016	食品接触用涂料及涂层	Food-contact Coating and Coating Layers
10/19/2016	4/19/2017	GB 4806.11- 2016	食品接触用橡胶材料及制品	Food Contact Rubber Materials and Articles

VII. Labeling requirements

Although not directly affecting food safety, labeling is reported by the import inspection authorities as one of the major reasons for noncompliance and has created a lot of consumer complaints. Pursuant to the 2015 Food Safety Law, pre-packaged food must be labeled and must include the following information:

- Name, specification, net content, and date of production;
- Table of ingredients or formulation;
- Producer name, address and contact information;
- Shelf life;
- Code of product standard(s);
- Storage requirements;
- Generic name of the food additives as used in the national standard;
- Production License Number; and
- Other information that must be indicated in accordance with applicable laws, regulations, and food safety standards.

The labels of staple and supplementary foods for infant consumption and other specific populations must also list main nutritional ingredients and their contents.

In December 2017, AQSIQ released a letter to the China WTO SPS/TBT Enquiry Point about its intent to notify the Administrative Measures for Inspection and Supervision on Labels of Imported and Exported Pre-packaged Foods.¹¹ The Measures:

- Instruct foreign exporters, foreign producers and domestic importers to ensure compliance of the label with Chinese regulations and standards;
- List the documents required in CIQ inspection of the products;
- List the inspections to be conducted in reviewing labels;
- List actions to be taken in case labels of imported pre-packaged foods fail to comply with relevant regulations and standards.

On January 9, 2018, China notified the measure to the WTO, the comment period for trading partners ends on March 11, 2018. The measures will come into force on October 1, 2018¹².

¹¹ For full Chinese text of the measures, please visit http://jckspaqj.aqsiq.gov.cn/sjwj/201712/t20171218_509044.htm

 $^{^{12}}$ An unofficial translation of the measure will be available soon as a GAIN report.

A series of national food safety standards were developed to provide specific guidance on product labelling:

Date of issuance	Effective Date	Standard Number	Standard-in Chinese	Standard-in English
4/20/2011	4/20/2012	GB7718- 2011	预包装食品标签通则	Standard for the Labelling of Prepackaged Foods
10/12/2011	1/1/2013	GB28050- 2011	预包装食品营养标签通则	Standard for Nutrition Labelling of Prepackaged Foods
11/29/2013	6/1/2015	GB29924- 2013	食品添加剂标识通则	General Standard for the Labeling of Food Additives
12/26/2013	5/1/2015	GB13432- 2013	预包装特殊膳食用食品标签	Labelling of Pre-packaged Foods for Special Dietary Uses

In December 2016, CFDA began requiring infant formula powder producers to review their infant formula labels to ensure that the labels are in compliance with the relevant laws, regulations, rules and standards. More specific information is provided in the Infant Formula section of this report.

Labelling of agriculture biotech products is governed by the Administrative Measures for Agricultural GMO, which is discussed in item 5 in Section IX, of this report.

VIII. Facility and Product Registration Requirements

1. AQSIQ Administrative Measures for Registration of Overseas Manufacturers of Imported Food (Decree 145)

On March 22, 2012, AQSIQ released the Administrative Measures for Registration of Overseas Manufacturers of Imported Food (AQSIQ Decree 145), which was implemented on May 1, 2012. The Measures require foreign food production facilities that export to China be registered with the China's Certification and Accreditation Administration (CNCA).

On December 21, 2015, AQSIQ released the latest <u>Implementation Catalogue for Registration of</u> <u>Overseas Manufacturers of Imported Food</u>, which requires the registration for meat, seafood, dairy, infant formula, and cubilose (bird nest) production facilities.

U.S. meat production facilities under the jurisdiction of USDA Food Safety Inspection Service (FSIS) are exempt from CNCA's full registration requirements. However, U.S. beef facilities must be listed on CNCA's registration website. For more information on how these facilities register, please see <u>GAIN CH</u> <u>17033</u>. In addition, U.S. processed meat facilities are not exempt from registration. FSIS is working with AQSIQ to determine how U.S. processed meat facilities will meet the CNCA registration requirements. It must also be noted that registration requirements vary by commodity.

The registration lists are accessible at: http://www.cnca.gov.cn/ywzl/gjgnhz/jkzl/, the lists are updated by CNCA on a regular basis depending on the commodity.

2. <u>Record Filing for Foreign Exporters/Agents of Food Products and Consignee of Imported</u> Food Products to China (2015 Update to AQSIQ Public Notice [2012] No. 55)

In 2012, AQSIQ launched the system for record filing of foreign exporters/agents of food products and consignee of imported food products to China. Since October 1, 2012, exporters and the consignees of certain food categories file their information at http://ire.eciq.cn in order to get their shipments released at customs. In 2015, AQSIQ conducted an <u>electronic upgrade</u> to the system, but information requirements and product coverage remain the same as in 2012. The <u>GAIN report CH 12057</u> offers Q&A about the record filing system.

3. AQSIQ Notice concerning Soliciting Comments on the Draft "<u>Administrative Measures for</u> <u>Importers' Review and Inspection on Overseas Establishments that Export Food Products to</u> China"

The 2015 Food Safety Law requires that importers review relevant documents by their foreign suppliers (exporters and producers). If the imported food products fall within the seven categories listed below, importers are required to conduct on-site inspection of their overseas exporters and producers. The importers must properly keep the review/inspection records; otherwise, they are subject to punitive measures.

The Draft Measures also provide the "Guidance for Food Safety Risk Control and Protection Plan of Food Exports to China (Trial)" and the "Catalogue of Products that Must Have On-site Inspection". The Catalogue contains seven product categories:

- Infant formula products;
- Food for special medical uses;
- Health food;
- Meat;
- Fresh and frozen seafood for direct consumption;
- Rice;
- Bulk vegetable oil.

According to the "<u>Key Tasks regarding Food Safety Work in 2016</u>" released by the State Council in April 2016, CFDA and AQSIQ will launch the regulations that require food importers to review their foreign suppliers. However, as of this report, the status of the proposed draft is still pending.

4. CFDA Registration/Record Filing of Special Foods

The 2015 Food Safety Law introduced the concept of "special foods", which cover infant formula, foods for special medical purposes (FSMP), and health foods. Article 74 of the 2015 Food Safety Law stipulates that: "China implements stringent supervision and administration of special foods such as health foods, foods for special medical purposes, and infant formula food."

In support of the implementation of Article 74, in 2016, CFDA released Decree 22 for record filing/registration of health foods, Decree 24 for registration of foods for special medical purposes (FSMP), and Decree 26 for registration of infant formula recipes. Since then, CFDA has been publishing working rules and technical requirements for the registration, facility inspections, and record filing.

In 2017, CFDA established the Special Food Registration Department, which handles registration/record filing of special foods, develops/implements technical regulations and working rules, and conducts inspections/audits.

CFDA Working Rules for On-site Audit for Special Food Registration¹³

On November 21, 2017, CFDA released the "Working Rules for On-site Audit for Special Food Registration" for public comment. The Draft Rules provide the procedures for arranging and conducting on-site audit, items to be reviewed, and feedback of the audit results, as well as the forms to be used in the audits.

Administrative Measures for the Registration of Recipes for Formula Powder Products for Infants and Young Children (CFDA Decree 26)

The Measures announced in June 2016 provide the requirements and procedures for the registration of infant formula recipes. The measures also elaborate on the requirements for labeling and product descriptions. The Measures were implemented on October 1, 2016, but CFDA granted a grace period of 15 months to January 1, 2018. For more details on Decree 26, please see the Infant Formula Section.

Administrative Measures for the Registration of Formula Foods for Special Medical Purposes (CFDA Decree 24)

In March 2016, CFDA published the Measures to regulate registration of FSMP produced and distributed in China, or imported into China. The Measures were implemented on July 1, 2016, but CFDA has granted a grace period until January 1, 2019, when the regulations will begin to be enforced. For more details on the registration requirements please see the Special Foods section.

Administrative Measures for Registration and Record Filing of Health Food (CFDA Decree 22)¹⁴

In February 2016, CFDA published the Measures to regulate registration and record filing of health foods that are produced and distributed in China, or imported into China. The Measures were implemented on July 1, 2016. The CFDA Decree 22 replaces the "Administrative Measures for Registration of Health Foods" issued by the former State Food and Drug Administration, (SFDA) in 2005.

On October 31, CFDA released the Revised Administrative Measures for Registration and Record Filing of Health Food for public comment.

In November 2016, CFDA published the Specific Rules for Review and Approval for Registration of Health Foods (2016 Edition)¹⁵, which provide detailed guidance for the application submission, acceptance, and review, as well as the forms to be submitted along with the applications.

5. Good Manufacturing Practices

The hygienic requirements for food production and operation, or good manufacturing practices (GMP), compose one of the four pillars of the Chinese national food safety standard framework (the other three are basic standards, standards of foods/food additives/food-related products and, testing methods and regulations).

China has released the following GMP standards:

¹³ For full Chinese text of the draft measures, please visit http://www.cfda.gov.cn/WS01/CL0782/217238.html

¹⁴ For full Chinese text of the measures, please visit http://www.cfda.gov.cn/WS01/CL0053/145380.html.

¹⁵ For full text of the Specific Rules in Chinese please visit: <u>http://www.cfda.gov.cn/WS01/CL0847/166399.html</u>.

Date of issuance	Effective Date	Standard Number	Standard-in Chinese	Standard-in English
3/26/2010	12/1/2010	GB12693- 2010	乳制品良好生产规范	Good Manufacturing Practice for Dairy Products
3/26/2010	12/1/2010	GB23790- 2010	粉状婴幼儿配方食品良好生 产规范	Good Manufacturing Practice for Powdered Formula for Infants and Young Children
12/26/2013	1/1/2015	GB29923- 2013	特殊医学用途配方食品良好 生产规范	Good Manufacturing Practice for Food for Special Medical Purpose
12/24/2014	5/24/2015	GB31621- 2014	食品经营过程卫生规范	Hygiene Regulations for Food Trading
5/24/2013	6/1/2014	GB14881- 2013	食品生产通用卫生规范	General Hygiene Regulation for Food Production
9/21/2015	9/21/2016	GB31603- 2015	食品接触材料及制品生产通 用卫生规范	General Hygiene Regulation for Food contacting Materials and Their Products
12/23/2016	12/23/2017	GB 8950- 2016	罐头食品生产卫生规范	Code of Hygienic Practice for the Production of Canned Foods
12/23/2016	12/23/2017	GB 8951- 2016	蒸馏酒及其配制酒生产卫生 规范	Code of Hygienic Practice for the Production of Distilled Liquor and Formulated Liquor
12/23/2016	12/23/2017	GB 8952- 2016	啤酒生产卫生规范	Code of Hygienic Practice for the Production of Beer
12/23/2016	12/23/2017	GB 8954- 2016	食醋生产卫生规范	Hygienic Specification for Vinegar Production
12/23/2016	12/23/2017	GB 8955- 2016	食用植物油及其制品生产卫 生规范	Code of Hygienic Practice for the Production of Edible Vegetable Oil
12/23/2016	12/23/2017	GB 8956- 2016	蜜饯生产卫生规范	Code of Hygienic Practice for the Production of Preserved Fruits
12/23/2016	12/23/2017	GB 8957- 2016	糕点、面包卫生规范	Code of Hygienic Practice for the Production of Pastry and Bread
12/23/2016	12/23/2017	GB12694- 2016	畜禽屠宰加工卫生规范	Code of Hygienic Practice for the Livestock and Poultry Slaughtering Enterprise
12/23/2016	12/23/2017	GB 12695- 2016	饮料生产卫生规范	Code of Hygienic Practice for the Production of Beverages
12/23/2016	12/23/2017	GB 12696- 2016	发酵酒及其配制酒生产卫生 规范	Code of Hygienic Practice for Fermented Alcoholic Beverages and their Integrated Alcoholic Beverages
12/23/2016	12/23/2017	GB 13122- 2016	谷物加工卫生规范	Code of Hygienic Practice for Grain Processing
12/23/2016	12/23/2017	GB 17403- 2016	糖果巧克力生产卫生规范	Code of Hygienic Practice for the Production of Candy and Chocolate
12/23/2016	12/23/2017	GB 17404- 2016	膨化食品生产卫生规范	Code of Sanitation Practice for the Production of Puffed Food

Date of issuance	Effective Date	Standard Number	Standard-in Chinese	Standard-in English
12/23/2016	12/23/2017	GB 18524- 2016	食品辐照加工卫生规范	Code of Hygienic Practice for Radiation Processing of Food
12/23/2016	12/23/2017	GB 20799- 2016	肉和肉制品经营卫生规范	Code of Hygienic Practice for the storage, distribution and sale of meat and meat products
12/23/2016	12/23/2017	GB 20941- 2016	水产制品生产卫生规范	Code of Hygienic Practice for the Production of Aquatic Products
12/23/2016	12/23/2017	GB 21710- 2016	蛋与蛋制品生产卫生规范	Code of Hygienic Practice for the Production of Egg and Egg Products
12/23/2016	12/23/2017	GB 22508- 2016	原粮储运卫生规范	Code of Hygienic Practice for the Storage and Transport of Unprocessed Food Grains
12/23/2016	12/23/2017	GB 31641- 2016	航空食品卫生规范	Code of Hygienic Practice for Airline Meals

China is also expediting the development of general hygienic regulations for food production and has notified the WTO of the following regulations. China is expected to finalize and announce these regulations in the near future:

SPS Notification No.	Standard Title (Chinese)	Standard Title (English)
880	冷藏乳制品贮运销售卫生规范	Sanitary Specifications for Storage and Marketing of Refrigerated Dairy Products
879	包装饮用水生产卫生规范	Sanitary Specifications for Production of Packaged Drinking Water
860 速冻食品生产卫生规范		Code of Hygienic Practice for Quick Frozen Products
859	食品用热加工香味料生产卫生 规范	Code of Hygienic Practice for Thermal Process Flavoring
651	食品添加剂生产卫生规范	Code of Hygienic Practice for Food Additives

IX. Product Specific Regulations and Standards

All agricultural and food products shipped to China must comply with the eligible laws and regulations listed in Section I of this report. In addition, specific products are subject to regulations and rules.

1. Dairy

Following a series of domestic food safety scandals since 2008, China has reinforced oversight of dairy products produced domestically or imported from abroad. Dairy imports must comply with a set of specific regulations and standards.

1) Specific Regulations for Dairy Imports

Measure for Dairy Product Import/Export Inspection and Quarantine Management (AQSIQ Decree 152)

On January 24, 2013, AQSIQ announced its Decree 152 on the Measure for Dairy Product Import and Export Inspection and Quarantine Management, effective May 1, 2013. For example, raw milk, raw milk products, pasteurized milk, and modified milk produced with the pasteurization process are subject to the provisions of the Decree 152. For a full scope of products subject to Decree 152, please see Article 2 in the above link. The Decree sets requirements for conducting assessments of food safety system oversight, food safety status, market access, inspection, certificates, and facility registration, etc. In 2013 and 2015, AQSIQ released the Public Notice [2013] No. 53 and Public Notice [2015] No.3 which constitute the implementation rules for Decree 152. ¹⁶

Regulating Sanitary Certificates for Dairy Imports

The AQSIQ Public Notice concerning the Regulating of Sanitary Certificates for Dairy Imports ([2009] No.125)¹⁷ requests the adoption of sanitary certificates for dairy products issued by competent authority in the exporting country. The U.S. Department of Agriculture (USDA) issues dairy sanitary certificates for exports to China, which can be obtained <u>here</u>.

Registration of Foreign Dairy Facilities that Export to China

As a part of the registration of overseas food manufacturers (AQSIQ Decree 145), AQSIQ Public Notice [2013] No.62¹⁸ of April 28, 2013 announced that foreign dairy producers that export products to China must also register with CNCA. The registration lists are located at: http://www.cnca.gov.cn/ywzl/gjgnhz/jkzl/, and are updated by CNCA on a semi regular basis.

2) National Food Safety Standards for Dairy Products

According to the NHFPC <u>Project Initiation Plan for National Food Safety Standards Work in 2017</u>, many of the national food safety standards for dairy products originally issued in 2010 will be revised/updated in 2017, which are expected to be notified to the WTO in 2018 or 2019.

Principle Standards:

Date of issuance	Effective Date	Standard Number	Standard-in Chinese	Standard-in English
3/26/2010	12/1/2010	GB 12693-2010	乳制品良好生产规范	Good Manufacturing Practice for Dairy Products

¹⁶ The Public Notice [2015] No.3 in Chinese could be found at:

http://www.aqsiq.gov.cn/xxgk_13386/jlgg_12538/zjgg/2015/201501/t20150119_430165.htm ¹⁷ The Public Notice [2009] No. 125 in Chinese could be found at:

 $[\]frac{\text{http://www.aqsiq.gov.cn/xxgk}_{13386/j1gg}_{12538/zjgg/2009/200912/t20091225}_{238363.htm}}{\text{The Public Notice [2013] No. 62 in Chinese could be found at:}$

http://www.aqsiq.gov.cn/xxgk_13386/jlgg_12538/zjgg/2013/201305/t20130503_355293.htm

Specific standards:

Date of issuance	Effective Date	Standard Number	Standard-in Chinese	Standard-in English
3/26/2010	6/1/2010	GB 19301-2010	生乳	Raw Milk
3/26/2010	12/1/2010	GB 19645-2010	巴氏杀菌乳	Pasteurized Milk
3/26/2010	12/1/2010	GB 25190-2010	灭菌乳	Sterilized Milk
3/26/2010	12/1/2010	GB 25191-2010	调制乳	Modified Milk
3/26/2010	12/1/2010	GB 19302-2010	发酵乳	Fermented Milk
3/26/2010	12/1/2010	GB 13102-2010	炼乳	Evaporated Milk and Sweetened Condensed Milk
3/26/2010	12/1/2010	GB 19644-2010	乳粉	Milk Powders
3/26/2010	12/1/2010	GB 11674-2010	乳清粉和乳清蛋白粉	Whey Powder and Whey Protein Powder
3/26/2010	12/1/2010	GB 19646-2010	稀奶油、奶油和无水奶油	Cream, butter and anhydrous milkfat
3/26/2010	12/1/2010	GB 5420-2010	干酪	Cheese
3/26/2010	12/1/2010	GB 25192-2010	再制干酪	Processed Cheese
3/26/2010	4/1/2011	GB 10765-2010	婴儿配方食品	Infant Formula
3/26/2010	4/1/2011	GB 10767-2010	较大婴儿和幼儿配方食品	Older infants and young children formula

2. Special Foods

The 2015 Food Safety Law introduced the concept of "special foods", which cover infant formula, foods for special medical purposes (FSMP), and health foods. Article 74 of the 2015 Food Safety Law stipulates that: "China implements stringent supervision and administration of special foods such health foods, foods for special medical purposes, and infant formula food." Hence, a number of regulations have been announced to regulate the products.

1) Infant formula

Administrative Measures for the Registration of Recipes for Formula Powder Products for Infants and Young Children (CFDA Decree 26)

The Measures were formulated pursuant to Article 74 and 81 of the Food Safety Law. Announced in June 2016, these Measures provide for requirements and procedures for registration of infant formula recipes, and elaborate on the requirements for labeling and product descriptions. The Measures were implemented on October 1, 2016, but CFDA granted a grace period of 15 months, i.e. the measures were enforced on January 1, 2018. However, infant formula with production date prior to January 1, 2018 will be allowed entry. Products manufactured after this date must be registered with CFDA to be allowed entry.

Under CFDA Decree 26: Different product formulas for the same age registered under the same business entity should demonstrate distinct differences. Each business entity, in principle, could register no more than nine (9) product formulas of three (3) formula series; each formula series includes formula powder

for infant (0 to 6 months, Stage 1), formula powder for older infant (6 to 12 months, Stage 2), and formula powder for young children (12 to 36 months, Stage 3).

CFDA's Center for Administrative Application Acceptance Service and Complaints/Reporting handles the receipt of registration applications; the CFDA Center for Health Food Evaluation handles the review of registration applications; CFDA's Food and Drug Inspection Center conducts on-site inspections/verifications for registration purposes; and the Provincial FDA cooperates with the Inspection Center for on-site inspections in its administrative region.

List of Registered Recipes

The list of infant formula recipes that have obtained CFDA registration can be found at the <u>CFDA</u> website.

Auxiliary Documents for Decree 26

Since the release of Decree 26, CFDA has been publishing working rules/technical requirements and guidelines for registration of infant formula recipes.

CFDA Working Rules for On-site Audit for Special Food Registration¹⁹

On November 21, 2017, CFDA released the "Working Rules for On-site Audit for Special Food Registration" for public comment. The Draft Rules provide the procedures for arranging and conducting the on-site audit, items to be reviewed, and feedback of the audit results, as well as the forms to be used in the audits.

- "Items and Requirements for Application Materials for Registration of Recipes for Formula Powder Products for Infants and Young Children" (Trial) and "Key Points and Judgment Principles for On-site Verification and Inspection on Registration of Recipes for Formula Powder Products for Infants and Young Children" (Trial)
 The two trial measures were published in late October 2016 as CFDA Public Notice [2016] No. 175; the Guidelines (in Chinese) can be viewed at the CFDA website.²⁰
- Guiding Principles on Technical Standards of Registered Labels for Infant Formula Recipe Registration (Trial)²¹

In May 2017, CFDA published the Public Notice [2017] No. 66 of the Guiding Principles on Technical Standards of Registered Labels for Infant Formula Recipe Registration, which provide requirements on product name in the label, format of the label, prohibitive requirements, and the optional contents in the label. The Guiding Principles entered into force on the date of its issuance.

As background, since December 2016, the CFDA requires infant formula powder producers to review their infant formula labels, make sure the labels are in compliance with the relevant laws, regulations, rules and standards.

The "Guiding Principles on Stability Study for Infant Formula Recipe Registration" (Trial) (Draft for Comment)"²²

¹⁹ For full Chinese text of the draft measures, please visit <u>http://www.cfda.gov.cn/WS01/CL0782/217238.html</u>

²⁰ Unofficial translation of the CFDA Public Notice [2016] No. 175 will be available on the GAIN reporting system in the near future.

²¹ For full Chinese text of the draft measures, please visit <u>http://www.sda.gov.cn/WS01/CL1830/173062.html</u>

²² For full Chinese text of the draft measures, please visit <u>http://www.cfda.gov.cn/WS01/CL0782/169260.html</u>

In January 2017, CFDA published two documents for public comment. Full texts of the Draft Guiding Principles (in Chinese) can be viewed at the <u>CFDA website</u>. The deadline for accepting public comment on the two technical guiding principles was February 20, 2017.

Principle Standards:

Date of issuance	Effective Date	Standard Number	Standard-in Chinese	Standard-in English
3/26/2010	12/1/2010	GB 23790- 2010	粉状婴幼儿配方食品 良好生产规范	Good Manufacturing Practice for Powdered Formula for Infants and Young Children

Specific Standards:

ſ	Date of issuance	Effective Date	Standard Number	Standard-in Chinese	Standard-in English
	3/26/2010	4/1/2011	GB 10765- 2010	婴儿配方食品	Infant Formula
	3/26/2010	4/1/2011	GB 10767- 2010	较大婴儿和幼儿配方食 品	Older Infants and Young Children Formula

AQSIQ Public Notice [2013] No.133 concerning Strengthening Administration of Imported Infant Formula Powder

The notice requests that foreign manufacturing facilities that export infant formula powder to China be registered with CNCA. Since May 1, 2014, China prohibits the importation of infant formula powder from unregistered foreign manufacturing facilities. According to the notice, China also prohibits the importation of infant formula powder with less than three months shelf-life when clearing the CIQ (China Inspection and Quarantine, AQSIQ's local branches). In addition, China prohibits the import of infant formula powder in bulk package, and the repackaging after importation. Imported infant formula powder must be packaged in the smallest retail package sold to consumers.

Effective on April 1, 2014, the Chinese label for imported infant formula powder must be directly printed on the smallest package for distribution before entering China, the label cannot be applied in China after import.

The CFDA Decree No. 43 concerning Banning Entrustment and OEM Production and Repackaging of Infant Formula Milk Powder

On November 27, 2013, CFDA announced its Decree No. 43, which stipulates that:

- Infant formula milk powder processing plants should not accept entrustments of other organizations or individuals to produce infant formula milk powder for them. Organizations or individuals should not entrust plants to produce infant formula milk powder by contracts or agreements.
- Plants should not produce infant formula milk powder for other brand owners or agents, or fraudulently use other brands.

- Plants should not produce infant formula milk powder in China, if plants registered their trademarks, company names, and addresses for infant formula milk powder production outside of China.
- Any organization or individual should not purchase infant formula milk powder and directly refill into tanks, bags and boxes or change the original packaging and labeling.
- Plants should not produce infant formula milk powder in different product names by using the same ingredients from the same raw and auxiliary materials.
- Plants should only use cow milk, sheep/goat milk or dairy products (including milk protein, lactose, etc.) to produce infant formula.

2) Foods for Special Medical Purposes (FSMP)

Administrative Measures for the Registration of Formula Foods for Special Medical Purposes (CFDA Decree 24)

In March 2016, CFDA published the Measures to regulate registration of FSMP produced and distributed in China, or imported into China. The Measures were implemented on July 1, 2016, but CFDA has granted a grace period until January 1, 2019, when the regulations will begin to be enforced.

List of Registered FSMP

On November 20, 2017, CFDA announced that three FSMP products produced by two companies obtained registration in its Public Notice, which is available at the <u>CFDA website</u>.

Auxiliary Documents for Decree 24

In July 2016, CFDA Public Notice [2016] No.123²³ released the four trial auxiliary documents for registration of FSMP, "Items and Requirements of Application Materials", "Samples and Requirements for Labels and Instructions", "Requirements for Stability Research", and "Key Points and Judgment Principles for On-site Verification and Inspection".

CFDA Working Rules for On-site Audit for Special Food Registration²⁴

On November 21, 2017, CFDA released the "Working Rules for On-site Audit for Special Food Registration" for public comment. The Draft Rules provide the procedures for arranging and conducting on-site audit, items to be reviewed, and feedback of the audit results, as well as the forms to be used in the audits.

CFDA Rules for Standardizing Naming of FSMP (Trial) (Draft for Public Comment)²⁵

In July 2017, CFDA released the Draft Rules for public comments; the Draft Rules clarifies composition of FSMP product name, terms/content that should not be included in product name, and terms that could be used to express attribute/function of the product. The comment period for these draft Rules has ended.

²³ For full text of the auxiliary documents in Chinese please visit: http://www.sda.gov.cn/WS01/CL1830/159121.html

²⁴ For full Chinese text of the draft measures, please visit <u>http://www.cfda.gov.cn/WS01/CL0782/217238.html</u>

²⁵ For full text of the draft rules, please visit <u>http://www.cfda.gov.cn/WS01/CL0782/175130.html</u>

CFDA Rules for Review of FSMP Production Licensing (Draft for Public Comment)²⁶

In January 2017, CFDA solicited public comments on the Rules for Review of FSMP Production Licensing. The comment period for these draft Rules has ended.

3) Health foods

Administrative Measures for Registration and Record Filing of Health Food (CFDA Decree 22)²⁷

In February 2016, CFDA published the Measures to regulate registration and record filing of health foods that are produced and distributed in China, or imported into China. The Measures were implemented on July 1, 2016. The CFDA Decree 22 replaces the "Administrative Measures for Registration of Health Foods" issued by the former State Food and Drug Administration, (SFDA) in 2005.

In November 2016, CFDA published the Specific Rules for Review and Approval for Registration of Health Foods (2016 Edition)²⁸, which provide detailed guidance for the application submission, acceptance, and review, as well as the forms to be submitted along with the applications.

Revised Administrative Measures for Registration and Record Filing of Health Food²⁹

On October 31, CFDA released the Revised Administrative Measures for Registration and Record Filing of Health Food for public comment. Major changes in the revised Measures include: authorization of CFDA Health Food Review Center to make the registration/record filing decisions in the name of CFDA, allows applicants to submit applications for registration renewal before the registration expires. The comment period for these draft Measures has ended. It is expected that the revised Measures will be released in 2018.

CFDA Guidance for Health Food Record Filing (Trial)³⁰

On May 2, CFDA published the Guidance, which came into force on the date of its issuance.

CFDA Opinions for Administration of Function Claims of Health Foods³¹ (Draft for Comment)

In mid-December 2016, CFDA published the Draft Opinions for comment, which contained two appendixes: "Opinions for Administration of Function Claims of Health Foods" (Draft for Comment) and the "Claims and Definition of Three Health Functions of Relieve Eye Fatigue, Improve Immunity, and Anti-Oxidation" (Draft for Comment). The comment period for these draft opinions has ended.

CFDA "Provisions concerning Auxiliary Materials Allowed in Health Foods for Record Filing and the Provisions for Use of Such Materials (Trial)" and the "Major Production Techniques for Production of Health Foods Record Filing"³²

The Provisions were released by CFDA on April 28, 2017, and entered into force on the date of their issuance.

²⁶ For full Chinese text of the draft rules, please visit <u>http://www.cfda.gov.cn/WS01/CL0782/169259.html</u>

²⁷ For full Chinese text of the measures, please visit <u>http://www.cfda.gov.cn/WS01/CL0053/145380.html</u>.

²⁸ For full text of the Specific Rules in Chinese please visit <u>http://www.cfda.gov.cn/WS01/CL0847/166399.html</u>.

²⁹ For full Chinese text of the measures, please visit <u>http://www.cfda.gov.cn/WS01/CL0847/172242.html</u>.

³⁰ For full Chinese text of the Guidance, please visit <u>http://www.cfda.gov.cn/WS01/CL0847/172243.html.</u>

³¹ For full Chinese text of the Draft Opinions, please visit <u>http://www.cfda.gov.cn/WS01/CL0782/167372.html</u>.

³² For full Chinese text of the Provisions, please visit <u>http://www.cfda.gov.cn/WS01/CL0847/172242.html</u>

3. Meat and Poultry Products

Like all other food products, meat and poultry imports are also governed by the 2015 Food Safety Law, the Law on Farm Product Quality and Safety, the Law on the Inspection of Import and Export Commodities, Law on the Inspection of Import and Export Commodities, and the Law on the Entry and Exit Animal and Plant Quarantine, as well as their implementing rules. In addition, meat and poultry imports must also comply with a series of regulations and standards to enter the Chinese market:

In 2017, U.S. beef was approved to be exported to China after a 14 year hiatus. The FAS GAIN report <u>Procedures for Exporting U.S. Beef to China</u> assists exporters and importers to generally understand the rules for shipping U.S. beef to China.

In addition, in late 2017, China announced plans to develop standards for veterinary drug residue limits in products from minor species, livestock, poultry, and aquatics.

1) Regulations

Regulations on Inspection and Quarantine of Entry-Exit of Meat Products (AOSIO Decree 136)

The AQSIQ Decree 136 regulates inspection and quarantine of meat products (excluding canned meat) imports and exports.

Administrative Measures for Quarantine and Approval of Animal and Plant Imports (AQSIQ Decree 170)³³

Released and implemented in November 2015, Decree 170 regulates the review and approval of quarantine of animal and plant imports to prevent entry of infectious animal diseases, parasitic diseases, harmful plant diseases, pests, weeds, and other harmful organisms. It specifies the procedures for application, approval, supervision, and use of the Quarantine and Inspection Permit (QIP). AQSIQ Decree 170 is an amendment to the Administrative Measures for Quarantine and Approval of Animal and Plant Imports (<u>AQSIQ Decree 25</u>).

Administrative Rules for Inspection and Quarantine on Entry Meat Products (AQSIQ Public Notice [2004] No. 49)

These Rules are the implementation rules for the AQSIQ Decree 25 (replaced by AQSIQ Decree 170 in 2016) and the Decree 26 (replaced by the AQSIQ Decree 136 in 2011). While the Decrees that these Rules implemented have changed the implementing rules have not changed. Notice No. 49 specifies the requirements on the inspection and quarantine authorities, importers, procedure of quarantine.

- AQSIQ releases the "List of Countries/Regions from which Meat Imports are Allowed, and Varieties/Purposes of Use", which is updated regularly on its website. The list can be found at: http://jckspaqj.aqsiq.gov.cn/xz/spxz/201303/t20130329_349307.htm.
- Notice No.49 requires that meat imports must enter China through the port designated on the QIP. A list of the ports that accept meat imports is maintained and updated by AQSIQ at: http://jckspaqj.aqsiq.gov.cn/xz/spxz/201106/t20110607_186590.htm.

³³ For full Chinese text of the Decree 170, please visit

http://www.aqsiq.gov.cn/xxgk_13386/jlgg_12538/zjl/2015/201512/t20151202_455475.htm. Unofficial translation of this Decree will be available on the GAIN reporting system in the near future.

• The meat imports must be kept at the cold storage facilities that are registered with the AQSIQ, and the AQSIQ publishes the list of the registered cold storages facilities at its official website.

AQSIQ Public Notice [2004] No.73 concerning Handling Quarantine Review of Animal and Plant Entering (into China)

The notice reiterates that Quarantine Import Permits (QIP's) be approved prior to signing contracts. It also provided a few amendments to the quarantine review practices. These include extending the validity of QIP's to six months; allowing QIP's to be annulled or voided in the event of a government issued warning or ban; requiring quarantine requirements specified in the QIP's be written into contracts; requiring GMO commodities be accompanied by import permits and safety certificates (for the GE event) at inspection, and requiring the names of suppliers and exporters of soybeans be provided in the QIP application forms.

2) National Standards for Meat and Poultry Products

National Food Safety Standard for Fresh (Frozen) Meat, Poultry Products (GB 2707-2016)³⁴

Published in late December 2016, this standard combines two existing standards on Fresh and Frozen Poultry Products (GB 16869-2005) and on Hygienic Standard for Fresh (Frozen) Meat of Livestock (GB2707-2005). This consolidated standard details the technical requirements for testing, hygiene, labeling, packaging, and storage requirements for fresh and frozen meat and poultry products. The standard went into force on June 23, 2017.

Hygienic Standard for Cooked Meat Products (GB2726-2016)³⁵

Published in late December 2016, this standard specifies the hygienic indexes and testing methods for cooked meat products, and hygienic requirements on food additives, production procedure, packaging, labeling, transportation and storage of cooked meat products. The standard applies to cooked meat (including dried cooked meat) products from fresh (frozen) poultry and livestock meat. This standard came into force on June 23, 2017. Presently, the United States does not have market access to export processed poultry, beef, or pork to China.

Other Recently Published Standards

In late December 2016, China published the following National Food Safety Standards. These were notified to the WTO in 2015.³⁶

Date of issuance	Effective Date	Standard Number	Standard-in Chinese	Standard-in English
12/23/2016	12/23/2017	GB12694- 2016	畜禽屠宰加工企业卫生规范	Code of Hygienic Practice for the Livestock and Poultry Slaughtering Enterprise
12/23/2016	12/23/2017	GB20799- 2016	肉和肉制品经营卫生规范	Code of Hygienic Practice for the Storage, Distribution and Sale of Meat and Meat Products

³⁴ Unofficial translation of the Standard for Fresh (Frozen) Meat, Poultry Products (GB2707-2016) will be available on the GAIN reporting system in the near future.

³⁵ Unofficial translation of the Standards will be available on the GAIN reporting system shortly

³⁶ Unofficial translation of the Standards will be available on the GAIN reporting system shortly.

4. Vegetable Oil

Edible oil shipments need to comply with the following requirements to enter the Chinese market:

Pursuant to AQSIQ Public Notice [2012] No.55, foreign oil exporters and Chinese oil importers must file their information at <u>http://ire.eciq.cn</u>.

Oil importers must present certifying documents proving that the oil imports meet relevant Chinese standards. Oil product exported to China for the first time must present testing reports for items listed in the "Hygienic Indices and Mandatory Indices Provided by National Food Safety Standards for Import Edible Vegetable Oil;" Products re-entering into China must provide a copy of the test reports, plus testing reports of the "CIQ Designated Indices for Import Edible Vegetable Oil."

The <u>Opinion of the State Council's General Office for Accelerating the Construction of the Traceability</u> <u>System for Key Commodities (Guo Fa Ban [2015] No. 95)</u>, issued in January 2016, requires vegetable oil producers to establish a quality and safety traceability system and to take responsibility for the quality and safety of their products.

Vegetable oil produced from GE crops is also subject to the <u>Administrative Measures of Inspection and</u> <u>Quarantine on Entry-Exit GM Products (AQSIQ Decree 62)</u>, which requires importers to present the Agricultural Biotech Safety Certificate and the "File for Review of Agricultural GMO Label" to CIQ inspectors.

In November 2015, China released the national food safety standard: <u>Edible Vegetable Oil Seeds (GB</u> <u>19641-2015</u>), which was notified to the WTO as G/SPS/N/CHN/997 in September 2015.

5. Biotech

Imports of agriculture biotechnology products are subject to strict oversight in China.

MOA holds the primary responsibility for the approval of biotech agricultural crops for import and domestic production, as well as the development of agricultural biotechnology policy. AQSIQ and its local inspection and quarantine offices (CIQs) are responsible for the nationwide management of inspection and quarantine for the entry and exit of all biotech products.

The biotechnology regulatory environment for agriculture is outlined in State Council's "<u>Administrative</u> <u>Rules for Safety of Agriculture GMO" of 2001</u>. They are implemented by MOA under Ministerial Decrees 8, 9 and 10. Domestic approval, import approval, and labeling are governed by the following Measures: Measures on the Safety Evaluation Administration of Agricultural Genetically Modified Organisms (GMOs), Measures on the Safety Evaluation Administration of Agricultural GMO Imports, and Measures on Agricultural GMO Labeling Administration.

The State Council is revising a number of regulations on administrative procedures in an effort to streamline how certain regulatory processes are conducted. Accordingly, MOA is revising regulations/rules to reflect the changes.

China's labeling regulations, governed by MOA Decree 10 (see <u>CH7053</u>), require the labeling of approved agricultural biotech products and prohibit the importation and sale of any unlabeled or mislabeled products. The types of products subject to mandatory labeling include:

1. Soybean seeds, soybeans, soybean powder, soybean oil, and soybean meal

- 2. Corn seeds, corn, corn oil, and corn powder
- 3. Rapeseed for planting, rapeseeds, rape oil, and rape meal
- 4. Cottonseed
- 5. Tomato seed, fresh tomato, and tomato paste

The <u>Agriculture Biotechnology</u> Annual GAIN report is a good resource, which provides more details on overall biotechnology environment in China.

Major Import and Export Inspection and Quarantine Regulations:

Administrative Measures of Inspection and Quarantine on Entry-Exit GM Products (<u>AQSIQ</u> <u>Decree 62</u>)

AQSIQ's Ministerial Decree 62 governs the steps that should be taken at customs when importing or exporting biotech goods.

Administrative Measures for Quarantine and Approval of Animal and Plant Imports (AQSIQ Decree 170)³⁷

Released and implemented in November 2015, Decree 170 regulates the review and approval of quarantine of animal and plant imports to prevent entry of infectious animal diseases, parasitic diseases, harmful plant diseases, pests, weeds, and other harmful organisms. It specifies the procedures for application, approval, supervision, and use of the Quarantine and Inspection Permit (QIP). This is an amendment to the Administrative Measures for Quarantine and Approval of Animal and Plant Imports (AQSIQ Decree 25).

AQSIQ Public Notice [2004] No.73 concerning Handling Quarantine Review of Animal and Plant Entering (into China)

The notice requires that GMO commodities imported into China be accompanied by import permits and safety certificates (of the GE event) at inspection, and requires the names of suppliers and exporters for soybeans be provided in QIP application forms.

6. Grains

China's Grains Law

As stated above, first issued by the State Council's Legislative Affairs Office in November 2014, the Grain Law was submitted to the National People's Congress (NPC) in February 2015 for promulgation. Once promulgated, the Grains Law will apply to grain production, distribution and consumption within the territory of China. "Grain" refers to cereals and their finished products, soybeans and tubers.

According to the "Key Tasks regarding Food Safety Work in 2016" released by the State Council (China's Cabinet) in April 2016, China was scheduled to push forward the formulation and revision of the "Grains Law." However, there were no further developments on the revision during 2017. The internal approval process for the Law is still expected to be lengthy; drafts of the Law have not been notified to the WTO.

³⁷ For full Chinese text of the AQSIQ Decree 170, please visit:

http://www.aqsiq.gov.cn/xxgk_13386/jlgg_12538/zjl/2015/201512/t20151202_455475.htm. Unofficial translation of this Decree will be available on the GAIN reporting system soon.
AOSIO Registration of Grain Exporters (AOSIO Decree 177)

In February 2016, AOSIO released the Administrative Measures of Inspection and Ouarantine for Entry and Exit Grain (AQSIQ Decree 177), which includes registration requirements for overseas production, processing, and warehousing enterprises that ship grains (including soybeans and pulses) to China. Decree 177 was implemented on July 1, 2016.

As a part of the implementation of Decree 177, AOSIQ asked foreign governments to provide a registration system for grain exporters and provide a list that China then publishes on their website. AQSIQ has indicated that it will use the list to monitor compliance with entry requirements for grain. In 2017, USDA agreed to provide AQSIQ with a list of U.S. exporters of commodities covered by the US Grain Standards Act. This list is currently being maintained by USDA's Federal Grain Inspection Service (FGIS) which operates under the United States Grain Standards Act (USGSA) of 1916, as amended.

It is important to note that while the USGSA pertains to U.S. entities shipping above 15,000 metric tons, entities that ship less than 15,000 metric tons who request and are approved for a waiver will also be included on the list provided to AQSIQ. Therefore, U.S. entities exporting or interested in exporting grain (including soybeans and pulses) to China must now be registered with FGIS. For more information about exporting grain and a link to the registration application can be found here: https://www.gipsa.usda.gov/fgis/exportinggrain.aspx.

Any questions comments or concerns pertaining to this issue can be sent to FGIS-DIIA@usda.gov.

Other Measures affecting Grain Purchase, Storage, Transportation, and Processing

On September 8, 2016, the National Development and Reform Commission (NDRC) published the "Regulatory Measures on Grain Quality and Safety" (NDRC Decree 42)³⁹, which was implemented on October 8, 2016. These measures affect the purchase, storage, transportation, processing and sales of grains (including wheat, rice, corn and coarse grains etc.) and finished product of grains, edible vegetable oil, oil plants, beans and potatoes. Grain procurement and storage must follow a quality safety monitor mechanism, which mainly includes quality grades, internal quality, moisture content, sprout and mold status, the leftover of agrochemicals, fungus and toxins, heavy metal, and other harmful contaminating substance. In addition, the Measures state grain quality standards and food safety standard requirements on grain purchase, storage (warehouse entry and exit inspection), transportation, processing and sales (grain inspection report, packaging and labeling). The Measures require the establishing of grain quality safety filing record system, safety tracing system, and a recall system. Grain inspections must be only conducted by licensed institutions, which must be independent, objective, follow confidentiality and accountability obligations. These Measures also outline procedures for inspection dispute settlement, grain safety incident settlement, as well as, stipulations for safety examinations by Chinese government regulatory agencies.

The Regulation on the Administration of Grain Circulation (State Council Decree 407)⁴⁰ was originally published in 2004 and was revised in 2016. The Decree applies to the purchase, sale, storage, transportation, processing, import and export of grain (wheat, rice, corn, coarse grain and finished product of grains) and other related business operations. The measures list general conditions to conduct grain

³⁸ A GAIN report on the Implementation of Decree 177 will be available soon.

³⁹ For full Chinese text of the NDRC Decree 42, please visit:

 $[\]frac{\text{http://www.chinagrain.gov.cn/n787423/c982018/content.html}}{^{40}}$ For full Chinese text of the State Council Decree 407 please visit: http://www.chinagrain.gov.cn/n316635/n746789/n746794/c898761/content.html

business, such as the application process for obtaining a grain purchasing license and requirements on storage facilities, transportation, record filing. The Decree also designates government agencies in charge of the general oversight of the grain market and instructs them to conduct inspections in accordance with laws and policies.

National Food Safety Standard for Grains (GB 2715-2016)

On December 23, 2016, NHFPC and CFDA released the National Food Safety Standard for Grains (GB2715-2016), which was implemented on June 23, 2017. This standard applies to unprocessed and processed grains for human consumption, which includes cereals, beans and tubers. The standard does not apply to raw materials for the processing of edible oils. A draft of this standard was notified to the WTO as SPS CHN 525 in June 2012.

Revised National Food Safety Standards on Grain Processing

On December 23, 2016, NHFPC and CFDA released the National Food Safety Standard for Code of Hygienic Practice for Grain Processing (GB 13122-2016), which entered into force on December 23, 2017. This Standard specifies the basic requirements and management rules for sites, facilities and personnel involved in raw materials procurement, processing, packaging, storage, and transportation in the processing of grains to rice, wheat flour, corn particles, corn flour, and other primary products by means of mechanical and other physical methods. A draft of this standard was notified to the WTO as SPS/CHN/1003 in September 2015.

Code of Hygienic Practice for Storage and Transportation of Raw Grains

On December 23, 2016, NHFPC and CFDA released the National Food Safety Standard for Code of Hygienic Practice for Grain Processing (GB 22508-2016), which will be implemented on December 23, 2017. This Standard applies to the storage and transport of unprocessed food grains, including hygienic requirements for raw grains, depot area environment, storage facility and equipment, transportation facilities and equipment, and safety control measures, etc. A draft of this standard was notified to the WTO as SPS/CHN/1001 in September 2015.

The State Council <u>Key Tasks on Food Safety Work for 2017</u> requires the State Administration of Grain and AQSIQ to "improve the grains quality and safety standard system."

7. Feed and Feed Additives

In China, feed and feed additives are subject to strict regulations. Companies need to complete the following three steps before they can export feed ingredients or additives to China:

1) Obtain an import registration license from the Ministry of Agriculture (MOA);

2) Apply for market access with the General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ); and

3) Register the manufacturing facility with AQSIQ (AQSIQ Decree 118).

This process can include an audit at the expense of the exporter. Products considered to be "traditionally traded" by AQSIQ can continue to be exported to China while they complete steps two and three.

The FAS GAIN report on the Roadmap to China's Challenging New Feed Regulatory System is a comprehensive introduction to the feed regulatory system in China.

In 2016, China Approved Market Access of U.S. Sugar Beet Pulp Pellets. On September 26, 2016, AQSIQ published the "Inspection and Quarantine Requirements for Importing U.S. Sugar Beet Pulp (AQSIQ Public Notice [2016] No. 97," which also lists 16 U.S. sugar beet pulp facilities approved to export U.S. sugar beet pulp to China. According to the Notice, effective immediately, approved exporters are certified to export U.S. sugar beet pulp pellets, which are now a registered feed ingredient with AQSIQ.

Major Feed and Feed additive regulations:

1) State Council Regulation on the Administration of Feed and Feed Additives (State Council Decree No. 609)

Decree 609 was released by the State Council on November 3, 2011, and entered into force on May 1, 2012. The Regulation identifies MOA's responsibilities in feed and feed additive oversight, including reviewing applications for feed/feed additive production, reviewing and approving applications for new feeds and feed additives, developing the catalogues of feed materials and feed additive varieties, and developing quality standards for such products. Foreign producers that export feed and feed additives to China must get the company and products registered with MOA, and need to sell their products through agents based in China. The regulations also set requirements on feed and feed additive labeling and punishments to violations of the regulations.

2) <u>Administrative Measures for Inspection, Quarantine of Imports and Exports of</u> <u>Feed and Feed Additives (AQSIQ Decree 118)</u>

AQSIQ Decree 118, echoing the State Council Decree 609, is the principle regulation for inspection and quarantine of feeds/feed additives imports and exports. Decree 118 requires that China only import feed and feed additives from foreign facilities that are registered with AQSIQ. To get registered, a facility must comply with domestic laws, regulations and standards, which must have the equivalent effect as the Chinese regulations and standards. The qualified companies will be recommended by the domestic government to AQSIQ for registration.

The Decree 118 also sets requirements on record filing for Chinese importers, package labeling, and Chinese feed exports.

3) Implementing Rules for the AQSIQ Decree 118 (AQSIQ Notice [2009] No. 372)

According to AQSIQ Notice No. 372, the explanation of Decree 118, AQSIQ will maintain a list of countries/regions which are eligible to export feed products to China, as well as a list of permitted products. AQSIQ would gradually finalize the phytosanitary certificates with major trading partners and develop and implement the safety and hygienic surveillance guidance for feed imports and exports.

Appendix I of No. 372 sets out the requirements on feeds and feed additive labeling.

The countries that are allowed to export feeds and feed additives to China and the list of allowed products are updated on a regular basis, which can be found at the AQSIQ website.

4) <u>Administrative Measures for Registration of Feed and Feed Additive Imports (MOA Decree</u> [2014] No.2) The Decree No.2 sets requirements on dossiers, samples, and procedure of applying for feed and feed additive registration.

5) <u>The Measures for Administration of New Feeds and New Feed Additives (MOA Decree</u> [2012] No. 4)⁴¹

New feed and feed additives must follow the Decree No. 4 in order to get the MOA approval for use in China. It provides requirements on the dossiers, sample, and procedure of applying for the approval.

6) The Feed Ingredient Catalogue

On June 1, 2012, China's Ministry of Agriculture (MOA) published Decree No. 1773, the Feed Ingredient Catalogue, which lists 87 single feed ingredients (including any feed except grains/oilseeds and their most basic/standard processed derivatives, e.g. soybeans/soy meal/soy oil or corn/corn meal/starch) that needed to have a product registration license by January 1, 2013. For various products, MOA Decree 1773 requires more ingredients to be listed or be labeled.

On December 19, 2013, MOA Public Notice No.2038 announced the revised Feed Ingredient Catalogue, which added eight ingredients in the Catalogue, adjusted the name or description of eight ingredients, and moved three products from the Feed Additive Catalogue to the Feed Ingredient Catalogue.

7) Feed Additive Catalogue⁴²

On December 30, 2013, MOA published the Feed Additive Catalogue (2013) as the MOA Public Notice No. 2045, which became effective on February 1, 2014. Only feed additives listed in the Catalogue are allowed in feed production and use.

Notice No.2045 also provides that the feed additives produced from genetically modified animal, plants and micro-organisms, and feed additives that contain GM substances must first obtain the biosafety certificates, and apply for approval according to the Measures for Administration of New Feeds and New Feed Additives (MOA Decree [2012] No. 4).

8) Feed Label Standard

On October 10, 2013, AQSIQ published the amended Feed Label Standard (GB 10648-2013), which came into effect on July 1, 2014. The mandatory feed labeling standard provides the basic principles for labelling of feed, feed additives, and feed ingredients, and requirements on the content and pattern of the label.

9) Hygienic Standard for Feeds

On September 28, 2016, China notified the Hygienic Standard for Feeds (G/SPS/N/CHN/1052) to the WTO. This standard includes maximum limits of toxic and hazardous substances and microorganisms in animal feed and test methods. The WTO comment period closed on November 27, 2016. However, this standard has not yet been finalized.

⁴¹ The [2012] No.4 Decree in Chinese could be found at: http://www.moo.gov.on/mullm/tage/b/201205/20120508_2610540

http://www.moa.gov.cn/zwllm/tzgg/bl/201205/t20120508_2619540.htm ⁴² The No.2045 Public Notice in Chinese could be found at: http://www.moa.gov.cn/zwllm/tzgg/bl/201205/t20120508_2619540.htm

8. Organic food

1) <u>Revised Administrative Measures on Organic Certification</u>

On November 20, 2013, AQSIQ announced its revised Administrative Measures for Organic Product Certification, which was implemented on April 1, 2014. The Measures are applicable to China's domestic certification, production, processing, importing and sales of organic products. Noticeable changes include, but are not limited to, that the content of organic ingredients must be equal to or above 95 percent and that the term "organic" must be listed on the product package and label.

2) <u>Implementation Rules for Organic Product Certification</u>

The Rules released by CNCA on December 2, 2011 are the implementation rules for the AQSIQ Administrative Measures. These rules specify the basic procedural and administrative requirements for certification institutions engaged in the certification of organic products to conduct certification for organic products.

3) National Standard of Organic Products GB/T 19630-2011

The standard is composed of four sections, namely production, processing, labeling and distribution, and the regulatory system.

4) CNCA maintains the list of certified organic products on its <u>website</u>

9. Seafood

Like meat imports, seafood imports are governed by the 2015 Food Safety Law, the Law on Farm Product Quality and Safety, the Law on the Inspection of Import and Export Commodities, Law on the Inspection of Import and Export Commodities, and the Law on the Entry and Exit Animal and Plant Quarantine, as well as their implementation rules. In addition, seafood imports must also comply with a series of regulations and standards to enter the Chinese market:

The Administrative Measures of Inspection, Quarantine, and Supervision on Entry and Exit Aquatic <u>Products (AQSIQ Decree 135)</u> is the umbrella regulation for the oversight of seafood imports and exports. The Measures require that foreign seafood manufacturing facilities register with AQSIQ or CNCA depending on the product category; that foreign exporters and Chinese importers maintain trading records; and that traders issue risk alerts, and conduct product recalls when necessary.

Registration of Foreign Processed Seafood Facilities (edible seafood/processed seafood products) (AQSIQ Decree 145):

Seafood products are one of the listed commodities in the <u>Implementation Catalogue for Registration of</u> <u>Overseas Manufacturers of Imported Food</u> (AQSIQ Decree 145). Registration requirements under Decree 145 dictate that foreign facilities exporting seafood products (edible aquatic animal/plant products) must be registered with CNCA.

Registration of Foreign Live Seafood Facilities AQSIQ Decree 183:

On July 26, 2016, AQSIQ published the <u>Administrative Measures for the Inspection, Quarantine and</u> <u>Supervision of Imports of Aquatic Animals (AQSIQ Decree No.183)</u>. These measures went into effect on September 1, 2016, and replaced AQSIQ Decree 44 enforced in November 2003. A draft version of the measures was notified to the WTO on March 15, 2016 as G/SPS/N/CHN/17/Rev.1. The measures stipulate the inspection, quarantine and supervision requirements for entry of live aquatic animals. The purpose of the measure is to implement risk-based supervision of inspection and quarantine requirements for entry of aquatic animals, and to implement classified and creditable supervision of enterprises. These administrative measures establish a quarantine access system and require foreign aquaculture farms and packaging enterprises to register with AQSIQ. Chinese importers will also be requested to register and to establish business records.

In late 2016, AQSIQ began the registration of U.S. aquaculture farms and facilities for non-edible live seafood (for ornamental or breeding purposes). As of January 2017, registration for edible live seafood was also just beginning. USDA and other U.S. agencies continue to work with AQSIQ to assist U.S. facilities to complete the registration. As of this report, traditional U.S. live seafood trade is expected to continue as the registration process unfolds.

In July 2016, AQSIQ launched the System of Designated Ports for Entry of Edible Aquatic Animals (AQSIQ Public Notice [2016] No.74)⁴³. The Notice provides basic requirements for ports that are designated to accept imports of edible aquatic animals and a list of the ports. In January 2017, AQSIQ released the public notice containing the second batch of ports designated to receive aquatic animals⁴⁴.

On November 13, 2015, NHFPC published the <u>National Food Safety Standard for Fresh and Frozen</u> <u>Aquatic Animal Products (GB 2733-2015)</u>. This standard was implemented on November 13, 2016. It applies to edible fresh and frozen aquatic animal products, including marine and freshwater products. A draft of the standard was notified to the WTO as SPS/CHN/687 in September 2014. Please note that the comment process has ended and that this standard is considered final.

10. Measures on Inspection, Quarantine, Supervision and Administration of Entry-Exit Non-Edible Animal Products (Decree 159)

On November 13, 2014, the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) issued Decree 159, the Measures on Inspection, Quarantine, Supervision and Administration of Entry-Exit Non-Edible Animal Products. The Measures became effective on February 1, 2015. AQSIQ Decree 159 applies to the inspection and quarantine of non-edible animal products for entry, exit or transit. These Measures do not apply to feed and feed additives of animal origin, animal breeding materials and biological materials of animal origin and their products. According to Decree 159, non-edible animal products that enter China are subject to quarantine access requirements, which include product risk analysis, assessment of the exporting country/region's regulatory system, determination of inspection and quarantine requirements, as well as registration of overseas manufacturing establishments.

⁴³ The AQSIQ Public Notice No.74 in Chinese could be found at:

http://www.aqsiq.gov.cn/xxgk_13386/jlgg_12538/zjgg/2016/201608/t20160803_471776.htm ⁴⁴ The List in Chinese could be found at: http://www.aqsiq.gov.cn/xxgk_13386/jlgg_12538/zjgg/2017/201702/t20170217_482958.htm

Appendix:

1. Government Regulatory Agency Contacts

China Food and Drug Administration (CFDA) 26 Xuanwumen Xi Da Jie, Xicheng District

Beijing, 100053 www.cfda.gov.cn

Ministry of Agriculture (MOA)

11 Nongzhanguan Nanli, Chaoyang District Beijing 100026 China www.moa.gov.cn

National Health and Family Planning Commission (NHFPC)

1 Xizhimenwai Nanlu, Xicheng District Beijing 100044 China www.nhfpc.gov.cn

General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ)

No. 9 Madiandonglu, Haidian District Beijing 100088 China www.aqsiq.gov.cn

Ministry of Commerce (MOFCOM)

No.2, Dong Chang An Street, Dongcheng District Beijng 100731 China www.mofcom.gov.cn

China's Certification and Accreditation Administration (CNCA)

Tower B, No.9, Ma Dian East Road, Haidian District Beijing 100088 www.cnca.gov.cn

2. Other Import Specialist Contacts USDA FAS Office of Agreements and Scientific Affairs in Washington D.C.

International Regulations and Standards Division Phone: (202) 720 1301 Fax: (202) 720-0433

USDA Office Contact Information in China

Agriculture Affairs Office Beijing

Contact:Bruce Zanin, Minister-Counselor for Agricultural AffairsPhone:(86-10) 8531-3600Fax:(86-10) 8531-3636Email: AgBeijing@fas.usda.gov

Agricultural Trade Office Beijing

 Contact:
 Mark Ford, Director

 Phone:
 (86-10) 8531-3950

 Fax:
 (86-10) 8531-3050

 Email:
 atobeijing@fas.usda.gov

Agricultural Trade Office Guangzhou

Contact: Levin Flake, Director Phone: (86-20) 3814-5310 Email: atoguangzhou@fas.usda.gov Email: info@atoguangzhou.org

Agricultural Trade Office Shanghai

Contact	: Ryan Scott, Director
Phone:	(86-21) 6279-8622
Fax:	(86-21) 6279-8336
Email:	atoshanghai@fas.usda.gov

Agricultural Trade Office Chengdu

Contact:Ms. Yvonne McDowell, DirectorPhone:(86-28) 8526-8668Fax:(86-28) 8526-8118Email:ATOChengdu@fas.usda.gov

Agricultural Trade Office Shenyang

Contact:	Roseanne Freese, Director
Phone:	(86-24) 2322-1198
Fax:	(86-24) 2322-1733
Email:	atoshenyang@fas.usda.gov

USDA Animal and Plant Health Inspection Service - China Office

- Contact: Dr. Murali Bandla, Regional Manager, Asia & Pacific
- Phone: (86-10) 8531-3030
- Fax: (86-10) 8531-3033
- Email: Murali.Bandla@aphis.usda.gov

3. Framework of the China's National Food Safety Standards



4. Full list of the existing national food safety standards

General Standards

No.	Date of issuance	Effective Date	GB Number	Standard-in Chinese	Standard-in English
1	3/17/2017	9/17/2017	GB 2761-2017	食品中真菌毒素限量	Maximum Levels of Mycotoxins in Foods
2	3/17/2017	9/17/2017	GB 2762-2017	食品中污染物限量	Maximum Levels of Contaminants in Foods
3	12/18/2016	6/18/2017	GB 2763-2016	食品中农药最大残留限量	Maximum Residue Level of Pesticides in Foods
4	12/26/2013	7/1/2014	GB 29921-2013	食品中致病菌限量	Pathogen Limits for Food
5	12/24/2014	5/24/2015	GB 2760-2014	食品添加剂使用标准	Standards for Uses of Food Additives
6	10/19/2016	10/19/2017	GB 9685-2016	食品接触材料及制品用添加剂使 用标准	Standards for Uses of Additives in Food Containers and Packaging Materials
7	3/15/2012	1/1/2013	GB 14880-2012	食品营养强化剂使用标准	Standard Regarding Nutritional Fortification Substances in Foods
8	4/20/2011	4/20/2012	GB 7718-2011	预包装食品标签通则	Standard for the Labelling of Prepackaged Foods
9	10/12/2011	1/1/2013	GB 28050-2011	预包装食品营养标签通则	Standard for Nutrition Labelling of Prepackaged Foods
10	12/26/2013	5/1/2015	GB 13432-2013	预包装特殊膳食用食品标签	The Labelling of Pre-packaged Foods for Special Dietary Uses
11	11/29/2013	6/1/2015	GB 29924-2013	食品添加剂标识通则	General Standard for the Labeling of Food Additives

Food Products

No.	Date of issuance	Effective Date	GB Number	Standard-in Chinese	Standard-in English
1	3/26/2010	12/1/2010	GB 5420-2010	干酪	Cheese
2	3/26/2010	12/1/2010	GB 11674-2010	乳清粉和乳清蛋白粉	Whey Powder and Whey Protein Powder
3	3/26/2010	12/1/2010	GB 13102-2010	炼乳	Evaporated Milk and Sweetened Condensed Milk
4	3/26/2010	6/1/2010	GB 19301-2010	生乳	Raw Milk
5	3/26/2010	12/1/2010	GB 19302-2010	发酵乳	Fermented Milk
6	3/26/2010	12/1/2010	GB 19644-2010	乳粉	Milk Powders
7	3/26/2010	12/1/2010	GB 19645-2010	巴氏杀菌乳	Pasteurized Milk
8	3/26/2010	12/1/2010	GB 19646-2010	稀奶油、奶油和无水奶油	Cream, butter and anhydrous milkfat
9	3/26/2010	12/1/2010	GB 25190-2010	灭菌乳	Sterilized Milk
10	3/26/2010	12/1/2010	GB 25191-2010	调制乳	Modified Milk
11	3/26/2010	12/1/2010	GB 25192-2010	再制干酪	Process(ed) Cheese
12	12/21/2010	2/21/2011	GB 25595-2010	乳糖	Lactose
13	4/20/2011	10/20/2011	GB 14963-2011	蜂蜜	Honey
14	11/21/2011	12/21/2011	GB 19295-2011	速冻面米制品	Quick Frozen Flour and Rice Products
15	9/15/2011	3/15/2012	GB 26878-2011	食用盐碘含量	Iodine Content in Edible Salt
16	8/6/2012	2/1/2013	GB 2757-2012	蒸馏酒及其配制酒	Distilled Spirits and Their Integrated Alcoholic Beverages
17	8/6/2012	2/1/2013	GB 2758-2012	发酵酒及其配制酒	Fermented Alcoholic Beverages and their Integrated Alcoholic Beverages
18	12/24/2014	5/24/2015	GB 2711-2014	面筋制品	Gluten Products
19	12/24/2014	5/24/2015	GB 2712-2014	豆制品	Bean Products
20	12/24/2014	5/24/2015	GB 2718-2014	酿造酱	Fermented Sauces
21	12/24/2014	5/24/2015	GB 7096-2014	食用菌及其制品	Edible Fungi and their Products

No.	Date of issuance	Effective Date	GB Number	Standard-in Chinese	Standard-in English
22	12/24/2014	5/24/2015	GB 9678.2- 2014	巧克力、代可可脂巧克力及其制品	Chocolate, Cocoa Butter Replacer and Its Products
23	12/24/2014	5/24/2015	GB 10133-2014	水产调味品	Aquatic Dressing
24	12/24/2014	5/24/2015	GB 13104-2014	食糖	National Food Safety Standard Sugars
25	12/24/2014	5/24/2015	GB 15203-2014	淀粉糖	Starch Sugar
26	12/24/2014	5/24/2015	GB 16740-2014	保健食品	Health Food
27	12/24/2014	5/24/2015	GB 17401-2014	膨化食品	Puffed Foods
28	12/24/2014	5/24/2015	GB 19298-2014	包装饮用水	Packaged Drinking Water
29	12/24/2014	5/24/2015	GB 19300-2014	坚果与籽类食品	Nuts and Seeds Products
30	9/22/2015	9/22/2016	GB 2713-2015	淀粉制品	Starch Products
31	9/22/2015	9/22/2016	GB 2714-2015	酱腌菜	Preserved Vegetables
32	9/22/2015	9/22/2016	GB 2720-2015	味精	Gourmet Powder
33	9/22/2015	9/22/2016	GB 2721-2015	食用盐	Food Grade Salt
34	9/22/2015	9/22/2016	GB 2730-2015	腌腊肉制品	Cured meat products
35	11/13/2015	11/13/2016	GB 2733-2015	鲜、冻动物性水产品	Fresh and frozen aquatic animal products
36	11/13/2015	11/13/2016	GB 2749-2015	蛋与蛋制品	Eggs and Their Products
37	11/13/2015	11/13/2016	GB 2759-2015	冷冻饮品和制作料	Frozen Beverages and Its Materials
38	11/13/2015	11/13/2016	GB 7098-2015	罐头食品	Canned Food
39	9/22/2015	9/22/2016	GB 7099-2015	糕点、面包	Pastries and Bread
40	9/22/2015	9/22/2016	GB 7100-2015	饼干	Cookies and Crackers
41	11/13/2015	11/13/2016	GB 7101-2015	饮料	Beverages
42	11/13/2015	11/13/2016	GB 10136-2015	动物性水产制品	Processed aquatic products of animal origin
43	11/13/2015	11/13/2016	GB 10146-2015	食用动物油脂	Edible Animal Oils
44	9/22/2015	9/22/2016	GB 14967-2015	胶原蛋白肠衣	National Food Safety Standard for Collagen Casings
45	11/13/2015	11/13/2016	GB 15196-2015	食用油脂制品	Edible Oil Products

No.	Date of issuance	Effective Date	GB Number	Standard-in Chinese	Standard-in English
46	11/13/2015	11/13/2016	GB 17325-2015	食品工业用浓缩液(汁、浆)	Concentrated Liquid (Juice, Plasm) for Food Industry
47	9/22/2015	9/22/2016	GB 17400-2015	方便面	Instant Noodles
48	11/13/2015	11/13/2016	GB 19299-2015	果冻	Jellies
49	11/13/2015	11/13/2016	GB 19641-2015	食用植物油料	Edible Vegetable Oil Seeds
50	11/13/2015	11/13/2016	GB 31602-2015	干海参	Dried Sea Cucumber
51	12/23/2016	6/23/2017	GB 2707-2016	鲜(冻)畜、禽产品	Fresh and Frozen Livestock and Poultry Products
52	12/23/2016	6/23/2017	GB 2715-2016	粮食	Grains
53	12/23/2016	6/23/2017	GB 2726-2016	熟肉制品	Cooked meat products
54	12/23/2016	6/23/2017	GB 14884-2016	蜜饯	Preserved Fruits
55	12/23/2016	6/23/2017	GB 14932-2016	食品加工用粕类	Food Processing Meal
56	12/23/2016	6/23/2017	GB 17399-2016	糖果	Candies
57	12/23/2016	6/23/2017	GB 19640-2016	冲调谷物制品	Reconstituted cereal products
58	12/23/2016	6/23/2017	GB 19643-2016	藻类及其制品	Algae and algae products
59	12/23/2016	6/23/2017	GB 20371-2016	食品加工用植物蛋白	Vegetable Protein for Food Processing
60	12/23/2016	6/23/2017	GB 31636-2016	花粉	Pollen
61	12/23/2016	6/23/2017	GB 31637-2016	食用淀粉	Food Starch
62	12/23/2016	6/23/2017	GB 31638-2016	酪蛋白	Casein
63	12/23/2016	6/23/2017	GB 31639-2016	食品加工用酵母	Yeasts used for food processing
64	12/23/2016	6/23/2017	GB 31640-2016	食用酒精	Edible alcohol

Special Foods

No.	Date of issuance	Effective Date	GB Number	Standard-in Chinese	Standard-in English
1	3/26/2010	4/1/2011	GB 10765-2010	婴儿配方食品	Infant Formula
2	3/26/2010	4/1/2011	GB 10767-2010	较大婴儿和幼儿配方食品	Older infants and young children formula
3	3/26/2010	4/1/2011	GB 10769-2010	婴幼儿谷类辅助食品	Cereal-Based Complementary Foods for Infants and Young Children
4	3/26/2010	4/1/2011	GB 10770-2010	婴幼儿罐装辅助食品	Canned Complementary Foods for Infant and Young Children
5	12/21/2010	1/1/2012	GB 25596-2010	特殊医学用途婴儿配方食品通则	General Standard of Formulas for Special Medical Purposes Intended for Infants
6	12/26/2013	7/1/2014	GB 29922-2013	特殊医学用途配方食品通则	Formulas for Special Medical Purposes
7	4/29/2014	11/1/2014	GB 22570-2014	辅食营养补充品	Complementary Food Supplement
8	11/13/2015	11/13/2016	GB 24154-2015	运动营养食品通则	General Standard for Sports Nutritional Food
9	11/13/2015	11/13/2016	GB 31601-2015	孕妇及乳母营养补充食品	Multi-nutrient supplementary food for pregnant and lactating women

Food Additive Quality Specifications

No.	Date of issuance	Effective Date	GB Number	Standard-in Chinese	Standard-in English		
1	7/15/2011	9/5/2011	GB 26687-2011	复配食品添加剂通则	Standard for Blended Food Additives		
2	11/29/2013	6/1/2014	GB 29938-2013	食品用香料通则	General Standard for Flavoring Substances and Natural Flavoring Complexes		
3	4/29/2014	11/1/2014	GB 30616-2014	食品用香精	Food additive Flavourings (compounded flavours)		
Othe	Other quality and specification standards: omitted						

Food-related Products

No.	Date of issuance	Effective Date	GB Number	Standard-in Chinese	Standard-in English
1	9/22/2015	9/22/2016	GB 14930.1-2015	洗涤剂	Detergent
2	4/25/2012	10/25/2012	GB 14930.2-2012	消毒剂(代替 GB 14930.2-1994)	Disinfectant (replacing GB 14930.2-1994)
3	9/22/2015	9/22/2016	GB 31604.1-2015	食品接触材料及制品迁移试验通则	General Rules for Migration Testing of Food Contacting Materials and Products
4	10/19/2016	4/19/2017	GB 4806.1-2016	食品接触材料及制品通用安全要求	General Safety Requirements of Food Contact Materials and Articles
5	9/22/2015	9/22/2016	GB 4806.2-2015	奶嘴	Nipple
6	10/19/2016	4/19/2017	GB 4806.3-2016	搪瓷制品	Enamel Products
7	10/19/2016	4/19/2017	GB 4806.4-2016	陶瓷制品	Ceramic Products
8	10/19/2016	4/19/2017	GB 4806.5-2016	玻璃制品	Glass Products
9	10/19/2016	4/19/2017	GB 4806.6-2016	食品接触用塑料树脂	Resins for Food Contact Plastic Materials and Articles
10	10/19/2016	4/19/2017	GB 4806.7-2016	食品接触用塑料材料及制品	Food Contact Plastic Materials and Articles
11	10/19/2016	4/19/2017	GB 4806.8-2016	食品接触用纸和纸板材料及制品	Food Contact Paper and Paper Board Materials and Articles
12	10/19/2016	4/19/2017	GB 4806.9-2016	食品接触用金属材料及制品	Food Contact Metal Materials and Articles
13	10/19/2016	4/19/2017	GB 4806.10-2016	食品接触用涂料及涂层	Food-contact Coating and Coating Layers
14	10/19/2016	4/19/2017	GB 4806.11-2016	食品接触用橡胶材料及制品	Food Contact Rubber Materials and Articles
15	10/19/2016	4/19/2017	GB 14934-2016	消毒餐(饮)具	Disinfected Tableware

Production and Operation GMP

No.	Date of issuance	Effective Date	GB Number	Standard-in Chinese	Standard-in English
1	5/24/2013	6/1/2014	GB 14881-2013	食品生产通用卫生规范	General Hygiene Regulation for Food Production
2	12/24/2014	5/24/2015	GB 31621-2014	食品经营过程卫生规范	Hygienic Practice for Food Operation
3	3/26/2010	12/1/2010	GB 12693-2010	乳制品良好生产规范	Good Manufacturing Practice for Dairy Products
4	3/26/2010	12/1/2010	GB 23790-2010	粉状婴幼儿配方食品良好生产规范	Good Manufacturing Practice for Powdered Formulae for Infants and Young Children
5	12/26/2013	1/1/2015	GB 29923-2013	特殊医学用途配方食品良好生产规范	Good Manufacturing Practice for Food for Special Medical Purpose
6	9/21/2015	9/21/2016	GB 31603-2015	食品接触材料及制品生产通用卫生规范	General Hygiene Regulation for Food contacting Materials and Their Products
7	12/23/2016	12/23/2017	GB 8950-2016	罐头食品生产卫生规范	Code of Hygienic Practice for the Production of Canned Foods
8	12/23/2016	12/23/2017	GB 8951-2016	蒸馏酒及其配制酒生产卫生规范	Code of Hygienic Practice for the Production of Distilled Liquor and Formulated Liquor
9	12/23/2016	12/23/2017	GB 8952-2016	啤酒生产卫生规范	Code of Hygienic Practice for the Production of Beer
10	12/23/2016	12/23/2017	GB 8954-2016	食醋生产卫生规范	Hygienic Specification for Vinegar Production
11	12/23/2016	12/23/2017	GB 8955-2016	食用植物油及其制品生产卫生规范	Code of Hygienic Practice for the Production of Edible Vegetable Oil
12	12/23/2016	12/23/2017	GB 8956-2016	蜜饯生产卫生规范	Code of Hygienic Practice for the Production of Preserved Fruits
13	12/23/2016	12/23/2017	GB 8957-2016	糕点、面包卫生规范	Code of Hygienic Practice for the Production of Pastry and Bread
14	12/23/2016	12/23/2017	GB12694-2016	畜禽屠宰加工卫生规范	Code of Hygienic Practice for the Livestock and Poultry Slaughtering Enterprise
15	12/23/2016	12/23/2017	GB 12695-2016	饮料生产卫生规范	Code of Hygienic Practice for the Production of Beverages
16	12/23/2016	12/23/2017	GB 13122-2016	谷物加工卫生规范	Code of Hygienic Practice for Grain Processing
17	12/23/2016	12/23/2017	GB 17403-2016	糖果巧克力生产卫生规范	Code of Hygienic Practice for the Production of Candy and Chocolate

No.	Date of issuance	Effective Date	GB Number	Standard-in Chinese	Standard-in English
18	12/23/2016	12/23/2017	GB 17404-2016	膨化食品生产卫生规范	Code of Sanitation Practice for the Production of Puffed Food
19	12/23/2016	12/23/2017	GB 18524-2016	食品辐照加工卫生规范	Code of Hygienic Practice for Radiation Processing of Food
20	12/23/2016	12/23/2017	GB 21710-2016	蛋与蛋制品生产卫生规范	Code of Hygienic Practice for the Production of Egg and Egg Products
21	12/23/2016	12/23/2017	GB 12696-2016	发酵酒及其配制酒生产卫生规范	Code of Hygienic Practice for Fermented Alcoholic Beverages and their Integrated Alcoholic Beverages
22	12/23/2016	12/23/2017	GB 22508-2016	原粮储运卫生规范	Code of Hygienic Practice for the Storage and Transport of Unprocessed Food Grains
23	12/23/2016	12/23/2017	GB 20941-2016	水产制品生产卫生规范	Code of Hygienic Practice for the Production of Aquatic Products
24	12/23/2016	12/23/2017	GB 20799-2016	肉和肉制品经营卫生规范	Code of Hygienic Practice for the storage, distribution and sale of meat and meat products
25	12/23/2016	12/23/2017	GB 31641-2016	航空食品卫生规范	Code of Hygienic Practice for Airline Meals

Nutritional Fortification Substances (Omitted)

Physical and Chemical Testing Methods (Omitted)

Micro-organisms Testing Methods (Omitted)

Toxicity Testing Methods and GMP (Omitted)

Veterinary Drug Residue Testing Methods (Omitted)