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AQSIQ to Require Importers to Review Overseas Food Producers (Draft Measures)

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Report Highlights:

In September 2015, the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) released for public comment the Draft Administrative Measures for Importers' Review and Inspection on Overseas Establishments that Export Food Products to China. The draft measures instruct importers of certain products to review relevant documents and conduct on-site inspections of foreign establishments from which products are sourced. Specifically, products subject to these measures are infant formula products, food for special medical uses, health food, meat, fresh and frozen seafood for direct consumption, rice, bulk vegetable oil.

The domestic commenting period has ended. The draft measures have not yet been notified to the World Trade Organization.

This report contains an unofficial translation of the draft measures as announced in September 2015.

Executive Summary:

In September 2015, the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) released for public comment the Draft Administrative Measures for Importers' Review and Inspection on Overseas Establishments that Export Food Products to China. The draft measures carry out the requirements referenced under Article 94 of the 2015 Food Safety Law stating "...Importers shall establish a review system for overseas exporters and producing enterprises..." The draft measures instruct importers of certain products to review relevant documents and conduct on-site inspections of foreign establishments from which products are sourced. 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." Specifically, products subject to these measures are infant formula products, food for special medical uses, health food, meat, fresh and frozen seafood for direct consumption, rice, bulk vegetable oil.

Domestic commenting period has ended. The draft measures have not yet been notified to the World Trade Organization.

This report contains an unofficial translation of the draft measures as announced in September 2015.

General Information:

BEGIN TRANSLATION

Administrative Measures for Importers' Review and Inspection on Overseas Establishments that Export Food Products to China

(Draft for Comments)

Article 1 [Purpose] To ascertain the role of China-bound food importers as the primary undertaker of quality and safety-related accountability and offer guidance to the importers in respect of the implementation and review of food quality and safety control throughout the production, shipping and storage of China-bound offshore food items, so as to ensure compliance with the provisions of the pertinent Chinese laws, administrative regulations and the requirements of national food safety standards, these *Measures* are hereby drafted in accordance with the provisions of the *Food Safety Law of the People's Republic of China*.

Article 2 [Application] These *Measures* shall apply to the review by importers of their imported foods and offshore exporters and manufacturers, as well as the supervision and inspection on the part of border entry/exit quarantine institutions of the reviews done by the importers described above.

Article 3 [Definition and interpretation] The Importer Review, for the purposes of these *Measures*, refers to the comprehensive evaluation carried out by importers on offshore manufacturers and exporters for the purpose of determining the compliance of their companies and products with the

Food Safety Law and the provisions of other pertinent Chinese laws and administrative regulations, and the requirements of national food safety standards.

Article 4 [Party implementing the review] The Party Implementing the Review mentioned in these *Measures* shall refer to the importers based within China, that is, the importers based within mainland China (excluding Hong Kong and Macau) who enter into trading contracts with foreign counterparts.

Article 5 [Overall requirements] The importer shall devise written review programs in respect of all China-bound food it imports and the offshore exporters and manufacturers it deals with, and shall organize the implementation review as planned, so as to make sure that the China-bound foods are in compliance with the requirements of Chinese laws and regulations.

The review program shall, as a minimum standard, include elements such as the review subject, terms, content, frequency and member of review taskforce.

Article 6 [Review content] The content of the review done by the importer shall include compliance review and the review of quality and safety control system and food protection system.

1. **Compliance review.** Importers shall conduct reviews as to whether its offshore exporters, manufacturers and China-bound foods are in compliance with the requirements of pertinent Chinese laws and regulations, including:
 - 1) If the offshore exporters have registered in China; if the offshore manufacturers required to be registered in China have already done so;
 - 2) If the imported foods shall be accompanied with qualification certificates;
 - 3) If the imported foods are in compliance with the requirements of the national food safety standards in China;
 - 4) If the imported pre-packaged foods have Chinese labels or mandatory Chinese specifications, whether the label or specification is in compliance with the requirements of the national food safety standards in China; if the offshore exporters and manufacturers shall be responsible for the contents contained in the labels and specifications.
2. **Review of the quality safety control system and the food protection system.** Offshore manufacturers shall establish and implement a China-bound food safety control and protection scheme as per the requirements of the Guidance on China-bound Food Safety Risk Control and Protection Scheme (Appendix 1). Importers shall carry out compliance review of the above schemes implemented by offshore manufacturers, and the review shall encompass everything contemplated in the Guidance on China-bound Food Safety Risk Control and Protection Scheme.

Article 7 [Terms of review] The importer shall carry out the review by way of written review, on-site review, among others.

1. **Written review.** The importer shall request from offshore exporters and manufacturers for the certificates of the contents stipulated in Article 6 hereof, and shall carry out written reviews on the paperwork mentioned above.
2. **On-site review.** The importer is encouraged to carry out on-site review at the offshore premises of manufacturers and exporters on the contents stipulated in Article 6 hereof, so as to ascertain if the quality safety risks of the products planned to be imported are under effective control.

The importer shall carry out on-site reviews in the following events: 1. For the importers of products set out in Appendix 2 hereof, at least one on-site review shall be carried out on every offshore manufacturer and exporter of the imported products every three years; 2. In the event that the importer believes, upon written review, that the offshore manufacturer or exporter is unable to effectively control the quality safety risks of the products, on-site review shall be carried out immediately.

The importer may engage third party institutions, qualified as per relevant national regulations, to carry out written reviews and on-site reviews.

Article 8 [Application of review results] The importer shall, based on the review results, establish a list of qualified offshore manufacturers and exporters for every imported food item and implement dynamic management. The importer shall not import China-bound foods from the offshore manufacturers and exporters that failed to pass the review or do not cooperate with the reviews carried out by the importer.

Article 9 [Keeping of review records] The importer shall record the process and results of the review in a truthful and complete manner, and the records shall be kept for a minimum of two years.

Article 10 [Review report and filing] Upon the end of the review, the importer shall generate a written report. The scope of the written report shall cover all imported foods and the corresponding offshore exporters and manufacturers, and the content of which shall cover all requirements contained in Articles 5, 6, 7, 8, 9 hereof. Upon completion of the review, the importer shall file the report to the direct subordinate inspection and quarantine bureau of the jurisdiction where the importer is registered. The report shall be filed at least once a year. If quality safety problems that might directly affect the imported foods are discovered during the review, the importer shall promptly report such cases to the direct subordinate inspection and quarantine bureau of the jurisdiction where the importer is registered.

Article 11 [Evaluation of and amendment to the review program] The importer shall carry out at least one retrospective inspection of the review program a year and shall timely amend the program as needed, so as to ensure the review program meets the demand of quality and safety control of imported foods.

The importer shall promptly amend the review program in any of the following event:

1. The imported food has been involved in quality and safety noncompliance on a number of occasions or serious noncompliance issues have occurred (e.g., mixing with inferior or counterfeit products);

2. The importer has been subject to severe regulation or punishment by inspection and quarantine institutions in connection with the quality and safety issues of its imported foods;
3. The imported food has been found to include new potential hazards (e.g., change in the source of material or product formula);
4. Changes in the pertinent laws and regulations of China or export country (region);
5. Other circumstances where an amendment to the review program is required.

Article 12 [Supervision and administration] All direct subordinate inspection and quarantine bureaus shall, on regular basis or from time to time, carry out random supervisory inspections of the reviews on offshore exporters and manufacturers conducted by the importers registered in their jurisdiction.

Article 13 [Noncompliance sanctions] In the event that the importer is in violation of the provisions of Article 94.2 of the Food Safety Law and fails to establish and adhere to the review systems of offshore exporters or manufacturers, fails to review as required the imported foods, offshore exporters and manufacturers included in the mandatory review catalog, or fails, upon carrying out the review, to submit the annual review report to quarantine institutions as required, the inspection and quarantine institution shall issue a warning in accordance with Article 129 of the Food Safety Law and may adopt the following measures:

1. Order the importer to rectify the problem in a period of six months, and implement enhanced inspection measures within such period, and require the importer to provide testing reports with respect to the pertinent products and items at the time of filing for inspection;
2. The importers having implemented rectification efforts but remain incompliant upon the expiry of the rectification period shall be included in a list of under-performing food importers, on whose imported products shall be imposed full-spectrum inspections on a batch-by-batch basis. The cost of the inspection and test shall be for the account of the importer, until it fully rectifies the problem and becomes compliant;
3. The importers that refuse to carry out rectification shall be subject to a penalty of over RMB 5,000 and up to RMB50,000; in severe cases, the importer shall be ordered to suspend its food importing and operation and its food importer registration shall be revoked.

Article 14 [Interpretation] These *Measures* shall be subject to the ultimate interpretation by the AQSIQ.

Appendices:

1. Guidance on China-bound Food Safety Risk Control and Protection Scheme (tentative)
2. Catalog of products for which on-site review is mandatory

Appendix 1:

Guidance on China-bound Food Safety Risk Control and Protection Scheme (tentative)

Article 1 [Primary purpose of the guidance] To ascertain the role of manufacturers as the primary undertaker of responsibilities, effectively control the quality safety risks of China-bound foods and reduce the occurrence of man-made and intentional pollution incidents, provide China-bound food importers with guidance over the review of offshore manufacturers, and to ensure the safety of China-bound foods, this *Guidance* is hereby developed.

Article 2 [Primary implementing party] The primary implementing party of this *Guidance* shall be the production and processing companies of offshore China-bound foods (“manufacturers”).

Article 3 [Definition of the scheme] The China-bound food safety risk control and protection scheme contemplated in this *Guidance* refers to the relevant food safety risk prevention, control and protection measures established by enterprises throughout the raw material, production and export processes of the entire supply chain of China-bound foods, for the purpose of ensuring the quality and safety of China-bound foods, minimizing the natural, man-made mixing or intentional pollution and destruction risks to food items caused by biological, chemical and physical factors.

Article 4 [Composition of the scheme] China-bound food manufacturers shall set up written China-bound food safety risk control and protection schemes and shall effectively implement the same as planned. The China-bound food safety risk control and protection scheme shall, as a minimum standard, consist of the following sections:

1. Hazard analysis;
2. Prevention and control measures;
3. Monitoring procedures;
4. Remedial procedures;
5. Verification procedures;
6. Recall plan;
7. Record keeping procedures.

Article 5 [Hazard analysis] The manufacturers and importers shall identify and evaluate all known and foreseeable food safety and protection hazards to determine the likelihood and severity of the hazards. The identification and analysis of hazards shall at least include the evaluation of the following aspects:

1. Exterior: the peripheral area of the plant, lighting, pedestrian and vehicular entry/exit control, all entrances of the plant, entrances of production locations, windows and ventilation outlets;

2. Interior: the design layout, interior facilities (emergency lighting, video monitor system) of production locations and areas for personal belonging storage;
3. Processing: addition of raw and auxiliary materials, mixed processing areas, area signage, product transport and conveyance monitoring;
4. Storage: design of storage warehouse, staff entry/exit, warehouse entry/exit control and management, storage and management of toxic/hazardous compounds;
5. Supply chain: evaluation by raw/auxiliary material and packaging material vendors on the food risk safety control and food protection abilities; evaluation by companies on the compliance of the shipping conditions and moving process of materials and finished products;
6. Water supply system: source of processing water, intermediary storing equipments, water processing system, protection and repair of water supply system and daily water quality inspection;
7. Personnel: background check, identification, training and communication of related staff and manager;
8. Information management: the generation and circulation of food safety information, food protection information (intentional pollution information) and the information reports, product testing reports during the implementation of food safety risk control and protection schemes;
9. Laboratory: layout of laboratory, staff entry/exit, maintenance and use of reagents and drugs, control and management of samples and live strains; lab testing ability review: this shall include the items to be tested, testing facilities, equipments and devices, testing process, testing personnel credentials, training program, instrument calibration and labeling; the credentials of engaged external labs and commissioning contracts.
10. If the manufacturers have organized the production of China-bound foods as per the requirements of China's national food safety standards, if the offshore exporters have verified the compliance of food with China's national food safety standards.
11. Other aspects that shall be focused on.

Article 6 [Hazardous elements] The manufacturers shall, as a minimum standard, consider the following risk factors when devising their food safety and protection hazard risk schemes:

1. Biological hazards (including micro organisms, parasites, and endemics);
2. Chemical hazards;
3. Physical hazards;
4. Radioactive hazards;
5. Natural toxins;

6. Pesticide and veterinary drug residual;
7. Decomposed substance;
8. Allergen;
9. Man-made mixing, e.g. illegally adding unapproved food additives;
10. Naturally occurred hazards that are not introduced by men;
11. Intentional pollution hazards, e.g., poisoning;
12. Religious factors, e.g., kosher food;
13. Other hazards as provided in related food safety regulations and standards in China.

Article 7 [Prevention and control measures] The manufacturer shall develop prevention and control measures for the potential hazards contained in the evaluation results, including process control measures, food allergen control measures, hygiene control measures and food protection measures.

1. Process control refers to the measures on relevant operation procedures, actual production operation and those that are able to reduce the likelihood of hazards as much as possible. The following shall be implemented in the production and processing process: raw/auxiliary material quality and safety control, additives, toxic/hazardous substances, management of packaging material; production, storage and shipping process quality and safety control.
2. Allergen control shall minimize the cross-contamination of allergens. This includes providing physical protection to eliminate or minimize dust, aerosols and splashes; produce and process different allergen or non-allergen foods in varying areas or timeframes, and special attention shall be paid to the cleaning of production equipments; effectively control the movement of instruments. The allergen message on food labels shall comply with the requirements in force in China and be marked correctly.
3. Hygiene control shall be implemented as per the hygiene system requirements and shall achieve the purpose of preventing cross-contact and cross-contamination between foods and unclean substances and preventing the cross-contamination between processed and unprocessed foods. Offshore exporters and manufacturers of China-bound foods may carry out hygiene control throughout the process of food production, storage and shipping, in accordance with the requirements of National Food Safety Standard: General Hygiene Codes on Food Companies (GB14881), National Food Safety Standard: Hygiene Codes on Food Operation Process (GB31621), and the General Provisions on Food Hygiene of the export country (region) or the Codex Alimentarius Commission (CAC).
4. Food protection measures refer to the measures employed by enterprises to prevent intentional damages to foods through effectively controlling the production and logistics of food, these measures can be either the newly added control measures of companies to target man-made

damages, or the existing measures of such companies in other food safety and hygiene management systems that are able to achieve the purpose of safety protection.

With respect to the weak links in the food safety protection by food companies identified in the food hazard analyses, the pertinent hazards shall be targeted and specific protection measures be developed for enhanced protection efforts.

Article 8 [Monitoring procedure] The manufacturers shall establish a monitoring procedure to ensure the correct implementation of the prevention and control procedures. The monitoring procedure shall encompass all prevention and control measures and the monitoring shall be set at a frequency so as to be able to timely discover the improper or invalid implementation of the measures.

Article 9 [Remedial measures] The development of remedial measures shall take into account the following:

1. It shall ensure that, in the event of improper or ineffective implementation of the prevention and control measures or the occurrence of unforeseen adverse impact, suitable measures can be adopted to effectively reduce the likelihood of repetition of the problem;
2. It shall be able to ensure that all food items adversely affected undergo a safety evaluation and effectively disposed of;
3. Without ascertaining if the product has been contaminated or correctly labeled, and without being able to determine if the product is uncontaminated or correctly labeled, it shall be made sure that the affected products could not enter into market circulation.

Article 10 [Verification procedure] Verification of the following can be carried out through on-site inspection, environment monitoring and product testing, as well as other suitable ways:

1. The implemented control measures are sufficient to control the identified hazards and are able to visibly reduce the occurrence of hazards;
2. The managers have effectively monitored the entire process of the company's production and processing work;
3. The remedial measures adopted by the managers are correct, thorough and sustainable;
4. In the event of changes to food materials, production environment and process and the occurrence of new threats, renewed analyses and evaluations shall be carried out on the China-bound food safety risk control and prevention scheme.

Article 11 [Recall procedure] The manufacturers shall establish a recall and emergency treatment scheme, including the recall steps, and shall identify the owners of the following responsibilities:

1. Directly inform the distributors of how to return or deal with problematic products;
2. Inform the public of all risks and hazards related to the problematic products;

3. Implement effective inspections to verify that the recall measures have been implemented;
4. Appropriately deal with the recalled products, e.g., re-treat, re-process, shift its purpose or destroy the same;
5. In the event that problems are discovered in the safety protection of products, evaluations shall be carried out timely as to the degree the products are affected; the products that cannot be ruled out from being affected by the hazards shall also be timely recalled;
6. Identify the point of contact that shall report to the supervisory bodies, quality inspection administration of own country and the China-based importers on the recall details.
7. Annual recall drills to verify the efficacy of the recall procedures.

Article 12 [Record keeping procedure] The manufacturers shall keep good records of their development and implementation of plans and keep the same in good custody. The required records shall at least include written food safety schemes, prevention and control measure records, remedial measure records, verification records and staff training records.

The scheme and related records must be kept on the premises of the company concerned; other records may be kept off the company's premises upon the implementation meeting six months, but shall be readily available for retrospective inspections.

Article 13 [Development of scheme] The food safety schemes must be developed by qualified persons. A qualified person refers to the persons having received and passed the training on food HACCP and food protection schemes, or are in possession of sufficient work experience and able to establish and apply the food safety system.

[Management team] The manufacturers shall set up a management team for the food safety risk control and protection scheme, which shall include one or more qualified persons while other members must be familiar with raw/auxiliary food material, packaging material, processing, hygiene, safety protection, site management and sales, among others; support from external experts can be sought if and when necessary.

When devising the schemes, the duties and authorities of the members of the management team shall be identified to ensure that all members shall partake in the development, implementation and verification, among other processes, of the schemes, in accordance with their duties.

Article 14 [Implementation of scheme] The implementation of the China-bound food safety risk control and protection scheme shall meet the following requirements:

1. Approval: the approval from the highest-ranking manager shall be obtained;
2. Provision of resources: the highest-ranking manager shall ensure to provide the pertinent managerial personnel and staff with necessary resources;
3. Training: all related staff shall undergo necessary training and training results shall be evaluated;

4. Operation control: all measures and procedures shall be continually and effectively implemented and records shall be taken;
5. Communication: an effective internal and external communication mechanism shall be established, implemented and maintained to make sure that the company's own staff members carry out timely and effective communication over the planned manners and have the responsibility and awareness of supervising and reporting suspicious developments; effective communication shall be ensured between companies and their sales chain, the suppliers in the supply chain, consumers and government bodies, as well as other stakeholders.

Article 15 [Re-evaluation of scheme] The managers of manufacturers shall re-evaluate the China-bound food safety risk control and protection schemes in the event of the following:

1. Three years have elapsed from the passing of the scheme or the last evaluation;
2. The production process of the manufacturer has had significant changes, which the manager believes would generate new potential hazards or significantly increase the likelihood of the identified risks;
3. The manager discovers new information relating to the existence of potential hazards in food items;
4. The prevention and control measures are not implemented as planned and the relevant remedial measures are yet to be established;
5. The prevention and control measures have been proven to be invalid;
6. Related information shows that there exists the possibility of intentional damage to food safety.

Appendix 2

Catalog of products for which on-site review is mandatory

1. Baby formula
2. Food for specific medical purposes
3. Health supplements
4. Meat
5. Frozen/fresh seafood to be eaten raw
6. Rice

7. Un-bottled vegetable oil