

Regulations of Inspection of Imported Foods and Related Products

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Article 1 These regulations have been established according to Paragraph 1 of Article 27 of the Act Governing Food Sanitation.

Article 2 The spot check and examination (hereinafter referred to as ‘the inspection’) of imported food and food additives, food utensils, food containers, food packaging or food cleansers, and other related products (hereafter referred to as ‘products’) shall be performed according to these regulations. The inspection items of the abovementioned products are described and announced by competent authorities according to health and safety risk management principles.

Article 3 For the abovementioned products, the importer (hereinafter referred to as ‘obligatory inspection applicants’) shall submit the following documents to the inspection enforcement authority or its appointed agencies (organizations) (hereinafter referred to as ‘inspection authorities’) to carry out the inspection:

1. An application form for inspection.
2. A declaration form for basic information of imported foods.
3. A copy of application for import declaration.
4. Necessary health and safety certificates required by the competent authority.

The application can be submitted electronically.

Article 4 Products conforming to the Act Governing Food Sanitation upon inspection are allowed to be imported. Products that conform to one of the following situations can be exempt from inspection:

1. Products to be imported are issued with a certificate of inspection by the government of the country of origin who has signed an inspection waiver reciprocity agreement with the government of the Republic of China.
2. Products to be imported for personal use by personnel of a foreign country’s embassy or consulate in the Republic of China, or persons entitled to diplomatic immunity.
3. Articles to be imported for personal use/non-sale purposes, exhibition

or R&D and testing purposes, and the amount or quantity of the articles do not exceed the maximum limit prescribed and announced by the competent authority for inspection waiver purposes, or an inspection waiver has been approved by the competent authority.

Article 5 In addition to documentation review (as prescribed in Article 3), and inspecting and checking (hereinafter referred to as ‘verification’) of items, packaging, appearance and labelings of products on-site, the inspection authority can carry out the product inspection with the following measures:

1. Batch-by-batch inspection: The inspection is carried out for each submitted batch of product.
2. Randomly-selected batch inspection:
 - (1)Regular randomly-selected batch inspection: The inspection is performed based on a 2-5% inspection rate.
 - (2)Reinforced randomly-selected batch inspection: The inspection is performed based on a 20-50% inspection rate.
3. Batch-by-batch verification: The on-site inspection for products not selected in the batch-by-batch inspection and randomly-selected batch inspection.
4. Product certification registration: For products that have been manufactured in conformance with health and safety criteria certified by mutual agreements and are registered at the competent authority, such products can be imported if the result of documentation review conforms to regulations.

For the abovementioned inspections, verification, and certification, if necessary, the inspection authority shall take samples of an appropriate amount to conduct sensory, chemical, biological, or physical laboratory examination .

A notification of the food and relevant products import admitted is issued by the inspection authority for products passing the measures prescribed in the former two items.

Article 6 Products applied for inspection that belong to one of the following situations shall be inspected on a batch-by-batch basis, and the inspection authority will carry out the inspection only if an test and analysis report of the applied product is provided.

1. Products proved to cause significant harm to humans according to domestic and foreign product safety information or scientific evidence.
2. Products designated for batch-by-batch inspection are listed in the annual inspection plan for imported products by the competent

authority.

3. Products with the same origin and commodity classification code of the Republic of China (hereafter referred to as ‘CCC Code’) as preceding batches of products belonging to reinforced randomly-selected batch inspections of the same obligatory inspection applicant, and whose inspection results do not conform to regulations.
4. The competent authority, out of considerations of healthy and safety, determine that it is necessary to carry out the inspection on a batch-by-batch basis.

Prior to completion of the batch-by-batch inspection procedures for the preceding batch, the batches re-applied for inspection to such batch of products shall be subject to inspection on a batch-by-batch basis.

Article 7 Products applied for inspection that belong to one of the following situations shall be inspected on a reinforced randomly-selected batch basis:

1. Products designated for reinforced randomly-selected batch inspection are listed in the annual inspection plan for imported products by the competent authority.
2. Products applied for inspection originally belongs to batch-by-batch inspection, and the same obligatory inspection applicant has imported five consecutive batches of such products from the same origin and CCC Code, and whose laboratory examination results conform to regulations. However , if the preceding batch before these five consecutive batches of the same obligatory inspection applicant failed to conform to regulations, then the quantity of these five consecutive batches of such products shall be three times greater than the preceding batch of unqualified products.
3. Products with the same origin and CCC Code as preceding batches of products belonging to regular randomly-selected batch inspection of the same obligatory inspection applicant, and whose inspection results do not conform to regulations.
4. The competent authority, out of considerations of healthy and safety, determine that it is necessary to carry out the inspection on a reinforced randomly-selected batch basis.

Article 8 Products applied for inspection that belong to one of the following situations shall be inspected on a regular randomly-selected batch basis:

1. Products designated for regular randomly-selected batch inspection are listed in the annual inspection plan for imported products by the competent authority.

2. Products applied for inspection originally belongs to reinforced randomly-selected batch inspection, and the same obligatory inspection applicant has imported five consecutive batches of such products from the same origin and CCC Code, and whose laboratory examination results conform to regulations.

However, if the preceding batch before those five consecutive batches of the same obligatory inspection applicant fail to conform to regulations, then the quantity of these five consecutive batches of such products shall be three times greater than the preceding batch of unqualified products.

Article 9 Products applied for inspection that belong to one of the following situations shall be inspected on a batch-by-batch verification basis:

1. Products designated for batch-by-batch verification are listed in the annual inspection plan for imported products by the competent authority.
2. Products belong to the same obligatory inspection applicant and the preceding batch of such products from the same origin (of manufacture) and CCC code, whose Chinese labeling of the product failed to conform to the regulation.

If all five consecutive batches of such products designated for batch-by-batch verification and of the same obligatory inspection applicant conform to regulations, then the same products for future import can be exempt from batch-by-batch verification.

However, if the preceding batch before those five consecutive batches of the same obligatory inspection applicant failed to conform to the Chinese labeling regulations, then the quantity of these five consecutive batches of such products shall be three times greater than the preceding batch of unqualified products.

Article 10 Products applied for inspection that belong to one of the following situations, the competent authority may require the related industries (importers and manufactures) or government of the exporting country to provide written documentations before a given date to explain the reasons for non-conformance, an improvement plan with preventative measures. After the documentation review and the improvement of conformance is verified, the inspection by the original inspection procedures will be conducted:

1. Same product applied for batch-by-batch inspection of the same obligatory inspection applicant does not conform to regulations in the second inspection.

2. Products belong to the same origin of CCC Code, and whose inspection results do not conform to regulations for three times within six months .

Article11 Products applied for inspection that belong to one of the following situations, the competent authority may temporarily suspend the application for inspection:

1. Products mentioned in the preceding article and the written documentations provided are not approved upon review.
2. Products mentioned in the preceding article that the required written documentations are not provided before the given date or the following imported products applied for inspection still do not conform to regulations before the given date.

For inspection applications whose applications have been temporarily suspended, related food industries, the country of exportation and its competent government organization may apply for the removal of the suspension, and the import applications will be re-accepted after approval of suspension removal.

Article12 Starting on the 15th day before the import date, the obligatory inspection applicant, or his/her representative shall file an application to the inspection authority at the port where the products are to be imported. If the representative files the application, an identification document for the representative shall be provided. Businesses making such representation for profit may collect a letter of authorization and register at the inspection authority.

Article13 The samples required for inspection shall be taken free-of-charge from the food importer by the inspection authority. After collecting the samples, the authority shall issue a receipt for sampling to customs officials and the obligatory inspection applicant.

Article14 Inspectors shall conduct random sampling for inspection and the obligatory inspection applicant shall not interfere in this process. The maximum number of amount of sampling shall be limited to what is required for laboratory examination and sample retention purposes. If imported food samples are difficult to be sampled at the port, the inspection authority shall designate an alternative sampling location.

Article15 When sampling, the inspection authority shall cooperate with customs officials for the product subject to customs inspection. The inspection authority shall notify on-site customs officials before sampling from containers with customs inspection waivers.

- Article16 Examination shall be conducted in the order of sampling. However, the inspection laboratory shall first inspect products that applied for re-examination according to these regulations.
- Article17 After having conducted the sampling of products applied for inspection, due to requiring five or more days for examination at the laboratory, or sampling of such products is difficult in a container yard, or the product is perishable, the inspection authority may issue a Notice of Prior Release for Import for customs clearance since the necessity of examination. However, for products designated for batch-by-batch inspection shall be retained at border until finishing of examination. The obligatory inspection applicant shall bear the responsibility for the safety and storage of products imported with a prior release. If the confirmed storage location does not conform to the actual storage location, or products are started using before receiving the import permit, the inspection authority may temporarily suspend acceptance of an application for prior release of imports by the obligatory inspection applicant for six months period.
- Article18 After the products applied for inspection conform to the regulations, the obligatory inspection applicant can apply to the inspection authority for a notification of the food and relevant products import admitted. The obligatory inspection applicant can claim remaining samples by presenting the sampling receipt within 15 days after receipt of the notice of inspection results. However, for samples with short shelf life, the inspection authority shall dispose of the samples directly.
- Article19 Products that fail to conform to regulations, a notification of noncompliance for import food and relevant products shall be issued, and the obligatory inspection applicant can apply for re-examination to the original inspection authority within 15 days after receipt of the notification of results. Applications for re-examination is limited to one time only, and are performed by the original testing laboratory using remaining samples for the re-testing. Remaining samples of products that do not conform to regulations shall be destroyed after the end of the period of application for re-examination.
- Article20 Imported products that do not conform to regulations upon inspection shall be disposed of in one of the following ways:
1. Returned or destroyed by the obligatory inspection applicant.
 2. For products approved for reconditioning by the competent authority according to relevant laws, the obligatory inspection applicant shall

keep the original application to apply the prior release. Such products are not permitted for sale unless such products are applied again for inspection to the local sanitation authority after reconditioning and found to be consistent with regulations.

3. For products approved for relabeling by the competent authority or inspection authority according to relevant laws, the obligatory inspection applicant shall keep the original application to apply the prior release. Such products are not permitted for sale until their corrected labels have been approved.

If imported products that have been released via a prior release notice do not conform to regulations mentioned in the preceding paragraph, the competent authority shall order the obligatory inspection applicant to retrieve and return, destroy, or recondition the product according to the relevant laws.

Article21 When conducting on-site inspections according to these regulations, inspectors shall carry their identification documents with them.

Article22 These regulations are effective as on January 1, 2011.