

Draft Amendment on the Regulations of Inspection of Imported Foods and Related Products

Chapter 1 General Principles

Article 1 The regulations are duly enacted in accordance with Paragraph 3 of Article 33 of the Act Governing Food safety and Sanitation (hereinafter “the Act”).

Article 2 The terms herein are defined as follows:

1. Obligatory Inspection Applicant: A business entity that engaged in the importation of food, genetically modified food raw materials, food additives, food utensils, food containers or packaging, and detergents for food use (hereinafter referred to as “products”).
2. Inspection authority: The central competent authority or its commissioned organization, institution, corporation, or group.
3. Verification: Refers to an on-site examination conducted by inspection personnel to confirm the product name, specifications, and packaging, as well as an inspection of its appearance, characteristics, labeling, and other matters stipulated under food safety and sanitation-related laws and regulations.
4. Analysis: Refers to the process whereby inspection personnel collect samples and submit them to a laboratory for sensory and physical examination, as well as biological and chemical testing, based on the nature of the product.

Chapter 2 Application for Inspection

Article 3 Obligatory Inspection Applicant shall file an application for inspection to the inspection authority at the port of entry within fifteen (15) days prior to the entry date or upon arrival at the port.

If the application be filed by representative, an identification document for the representative shall be provided. If the representative is an individual, he/she shall submit his/her certificate of identification. If any entity, who undertakes application and declaration agent as business, shall submit its broker license, business license and identification documents to the inspection authority for future reference.

Article 4 Obligatory Inspection Applicant shall complete an inspection application form and a product information sheet and attach a photocopy of the import declaration along with other documents or information designated by the central competent authority or its delegated agency to apply for inspection with the inspection authority.

In accordance with Article 32 of the Act, the inspection authority may require Obligatory Inspection Applicant to provide other necessary documents and papers. The Obligatory Inspection Applicant shall not evade, obstruct or refuse. The forms of inspection in Paragraph 1 may be submitted by electronic files or

any other manner required by the inspection authority.

Article 5 Products for inspection application in the same inspection case number (hereinafter “same batch”) shall have the same import declaration, commodity classification code of the Republic of China (hereinafter “CCC Code”), product name, ingredients, brand, producer, and country of origin.

For the importation of the same category of products listed below, which are live, fresh, or refrigerated, such products may be combined into the same batch for inspection application. Products of different categories shall not be combined into the same batch for inspection application:

1. Fish.
2. Shrimp.
3. Crabs.
4. Shellfish and mollusks.

Article 6 Upon reviewing the documents and information submitted under Paragraphs 1 and 2 of Article 4, if the inspection authority finds deficiencies that can be rectified, it shall notify the Obligatory Inspection Applicant to make corrections within a certain deadline.

The Obligatory Inspection Applicant shall complete the corrections within 30 days from the date of receipt of the aforementioned correction notice. If the applicant fails to complete the corrections within the certain deadline, an extension may be requested. Such an extension shall be limited to one instance, with a maximum extension period of 30 days.

Article 7 For any Obligatory Inspection Applicant with one of the following situations, the inspection authority shall dismiss his/her application for inspection:

1. Failure to apply an inspection application pursuant to the provisions provided by Articles 4 or 5.
2. Where the inspection authority notifies a party to make corrections within a certain deadline pursuant to the provisions of the preceding Article, and such corrections are not made by the expiration of said deadline.
3. Repeated application for inspection of same batch products.

Chapter 3 Inspection Procedures

Article 8 The inspection authority may proceed with product inspection with the following inspection measures:

1. Batch-by-batch inspection: Products submitted for inspection shall be subject to verification and analysis on a per-batch basis.
2. Randomly-selected batch inspection: Products submitted for inspection shall be sampled based on the following sampling probabilities, and batches selected shall undergo verification and analysis:

(1) Reinforced randomly-selected batch inspection: 20%-50% inspection rate.

(2) Regular randomly-selected batch inspection: 2%-10% inspection rate.

3. Batch-by-batch verification: Products submitted for inspection shall be subject to verification on a per-batch basis.
4. Certification inspection: For products subject to agreements, protocols, or arrangements concluded between the central competent authority and the relevant authorities of the exporting country, the inspection method shall comply with the terms of such agreements.
5. Monitoring inspection: For specific products submitted for inspection, verification, and analysis shall be conducted on a per-batch basis.

For products not selected for inspection under Subparagraph 2 of the preceding paragraph or products subject to certification inspection under Subparagraph 4 of the preceding paragraph, such products may also be subject to verification or analysis if the inspection authority deems there to be a risk to safety or sanitation. For products subject to batch-by-batch verification under Subparagraph 3 of the preceding paragraph, the inspection authority may concurrently apply the inspection methods specified under Subparagraphs 1, 2, 4, or 5 of the preceding paragraph.

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

1. Products designated for batch-by-batch inspection under the annual product inspection plan (hereinafter the “inspection plan”) established by the inspection authority based on product safety and sanitation risks shall be inspected accordingly.
2. Products with the same origin and CCC Code as preceding batches of products belonging to reinforced randomly-selected batch inspections of the same Obligatory Inspection Applicant and whose analysis results do not conform to regulations.
3. For products applied to monitoring inspection and fail the analysis twice in a row.
4. Where the inspection authority determines that there is a risk of harm to safety and health based on domestic or international product safety and health information or scientific evidence.

For products subject to batch-by-batch inspection, if the same Obligatory Inspection Applicant applies for inspection of a different batch of the same product prior to the completion of the inspection process for a given batch, the batch-by-batch inspection shall still apply.

Article 10 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 inspection plan for imported products.
2. For products originally subject to batch-by-batch inspection under the preceding Article, subsequent imports of such products meeting one of the following conditions:
 - (1) For the same Obligatory Inspection Applicant, regarding products of the same origin and CCC Code, after a batch fails an analysis, five consecutive imported batches must all pass the analysis, and their total quantity must reach three times the quantity of the failed batch.
 - (2) In circumstances not covered by the previous item, regarding products of the same origin and same CCC Code for the same Obligatory Inspection Applicant, if they have never been imported before or the most recent imported batch did not fail the analysis, five consecutive imported batches must pass the analysis.
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 analysis results do not conform to regulations.
4. Apart from the three preceding subparagraphs, the inspection authority may determine that there is a potential risk to safety and hygiene based on domestic or international product safety and hygiene information or scientific evidence.

For products that should undergo batch-by-batch inspection, if the inspection authority determines there is a safety or hygiene hazard or potential risk, the second subparagraph of the preceding paragraph shall not apply, and a batch-by-batch inspection should still be conducted.

Article 11 Products applied for inspection that belong to one of the following situations shall be inspected on a regular randomly-selected batch basis:

1. Products do not apply to batch-by-batch inspection, reinforced randomly-selected batch inspection, certification inspection, or monitoring inspection.
2. Products that were originally subject to reinforced randomly-selected batch inspection according to the preceding article, if they meet one of the following requirements, their subsequent imports must conform to the following:
 - (1) For the same Obligatory Inspection Applicant, regarding products of the same origin and CCC Code, after a batch fails an analysis, five consecutive imported batches must all pass the analysis, and their total quantity must reach

three times the quantity of the failed batch.

(2) In circumstances not covered by the previous item, regarding products of the same origin and same CCC Code for the same Obligatory Inspection Applicant, if they have never been imported before or the most recent imported batch did not fail the analysis, five consecutive imported batches must pass the analysis.

For products that should undergo reinforced randomly-selected batch inspection, if the inspection authority determines there is a safety or hygiene hazard or potential risk, the second subparagraph of the preceding paragraph shall not apply and reinforced randomly-selected batch inspection must still be conducted.

Article 12 Products applied for inspection that belong to one of the following situations shall be verified on a batch-by-batch basis:

1. The Obligatory Inspection Applicant imports a product that is found not to comply with Subparagraphs 8 to 10 of Paragraph 1 of Article 15 or the provisions of Article 18 of the Act upon verification and subsequently applies for inspection again for a product from the same origin and under the same CCC Code.
2. Where the inspection authority determines that there is a risk of harm to safety and health based on domestic or international product safety and health information or scientific evidence.

For the batch-by-batch verification mentioned in the preceding paragraph, if one of the following conditions is met, the subsequent imported products shall be exempt from batch-by-batch verification and handled in accordance with the provisions of Article 8:

1. The same Obligatory Inspection Applicant has three consecutive batches pass verification after a batch fails verification for products from the same origin and under the same CCC Code. The total quantity of these three batches must be at least twice the quantity of the failed batch.
2. In cases not falling under the preceding subparagraph, the same Obligatory Inspection Applicant can apply for products from the same origin and with the same CCC Code, provided that they have either never imported those products or that their most recent imported batch had no verification failures. Additionally, the applicant must have imported three consecutive batches, all of which passed verification.

Article 13 The inspection authority may determine that certain products pose a risk to safety and health based on domestic or international product safety and health information or scientific evidence. In such cases, the authority may implement

monitoring inspections for those specific products, and the inspection method shall not be downgraded or relaxed based on the inspection results.

Chapter 4 Preferential Measure for Excellent Industry

Article 14 Import products belonging to the following situations may apply to the minimum inspection probability of a normal randomly-selected batch:

1. If the number of analysis batches within one year reaches ten or more, and all analysis results comply with the provisions, Obligatory Inspection Applicant may submit a quality control plan for imported products to the inspection authority and being approved.
2. If the number of analysis batches within one year reaches twenty or more, and all analysis results comply with the provisions.
3. If the number of analyzed batches within two years reaches thirty or more, and all analysis results comply with the provisions.

Any product applied to minimum inspection probability in accordance with the preceding paragraph that failed a border or market analysis shall cease to apply to preferential measures in the preceding paragraph.

Article 15 For those meeting the requirements of Subparagraph 1, Paragraph 1 of the preceding article, and where inspection results have consistently complied with regulations for two years from the date of adopting the minimum sampling probability for general batch sampling, only a document review as stipulated in Article 4 is required.

If necessary, the inspection authority may inspect products in the preceding paragraph by verification or analysis. If the result is not qualified, future import products of the Obligatory Inspection Applicant cease to apply to the preferential measures in the preceding paragraph.

Chapter 5 Inspection Operation

Article 16 The verification and sampling of imported products shall be conducted at the location where the products are stored. For products transported in full container loads, verification or sampling shall be conducted in a centralized inspection area or a specific area approved by the inspection authority. If the verification or sampling of such containers is time-consuming or presents other difficulties, the inspection authority may require the containers to be unpacked and moved into a warehouse for the process.

For the verification or sampling mentioned in the preceding paragraph, the Obligatory Inspection Applicant shall provide cooperation and may not designate specific samples.

The cooperation referenced in the preceding paragraph includes the following matters, with the associated costs borne by the Obligatory Inspection Applicant:

1. Provision or operation of necessary instruments, tools, machinery, or related equipment.
2. Handle tasks such as lifting containers, unpacking containers, moving items, unpacking packages, opening or closing boxes, opening or closing containers, or other actions necessary to achieve the purpose of the inspection according to the instructions of the inspection authority.

Article 17 The samples required for inspection may be taken free-of-charge by the inspection authority, provided that the amount of sampling shall be limited to the inspection requirement. After collecting the samples, the authority shall issue a receipt for sampling to the Obligatory Inspection Applicant.

Article 18 Analyze the imported product based on the sampling order. However, this does not apply to those requesting a re-analysis under the provisions of Article 39 of the Act.

Chapter 6 Prior Release

Article 19 For imported products not subject to batch-by-batch inspection, the inspection authority may issue a release notice allowing prior customs clearance after the Obligatory Inspection Applicant provides a bond affirming responsibility for safekeeping in accordance with the provisions of the first sentence of Paragraph 1, Article 33 of the Act if any of the following circumstances apply:

1. Where the analysis takes more than five days.
2. Where it is difficult to conduct verification or sampling.
3. Where the products are easily corrupted or deteriorated.
4. The product is directly loaded onto a cargo ship, and there is no storage facility at the dock.

For products subject to batch-by-batch inspection under the provisions of Paragraph 2, Article 10, the provisions of Subparagraph 3 of the preceding paragraph may be applied accordingly.

Article 20 For products released under a bond as stipulated in the preceding article, if any of the following circumstances apply, the inspection authority shall require the submission of a guarantee deposit before granting permission for release under the bond in accordance with the latter part of Paragraph 1, Article 33 of this Act:

1. Product subject to batch-by-batch inspection.
2. Product subject to reinforced randomly-selected batch inspection.
3. During the monitoring inspection period, if the analysis results show noncompliance, Obligatory Inspection Applicant applies for inspection of imported products.
4. The Obligatory Inspection Applicant fails to finish the process of inspection after elapse of sixty days from the inspection authority issued a prior release

notice and applies for prior release again.

5. When regular randomly-selected batch inspection is adopted, the Obligatory Inspection Applicant, subject to any disciplinary action set in Subparagraph 3, Article 51 of the Act within 180 days after the expiration of the administrative penalty, applies for prior release.

The guarantee deposit amounts for the preceding paragraph are specified as follows:

1. Subparagraph 1 of the preceding paragraph: Four times the Duty-paying value of the product.
2. Subparagraphs 2 to 4 of the preceding paragraph: Two times the Duty-paying value of the product.
3. Subparagraph 5 of the preceding paragraph: the Duty-paying value of the product.

Article 21 Paying the guarantee deposit in accordance with preceding article by an Obligatory Inspection Applicant shall be by financial-institutions-issued cashier's check, check, or postal order.

The inspection authority shall refund the guarantee deposit from the preceding paragraph if any of the following circumstances apply and there are no issues under Subparagraph 3, Article 51 of the Act:

1. The products applied conform to the regulations, and an import permit notification was obtained.
2. The products applied do not conform to the regulations but deal with them in accordance with the provisions Article 24.

In the aforementioned situation, the Obligatory Inspection Applicant may submit a statement to the inspection authority requesting that the deposit not be refunded. Within the amount of the deposit already paid, the applicant can provide a guarantee for the subsequent release of imported products, allowing the deposit to be reused cyclically. If the deposit is insufficient, it must be replenished before the guarantee for prior release can be issued.

When the Obligatory Inspection Applicant requests a refund of the deposit, the inspection authority shall return it without interest.

Chapter 7 Notification of Inspection Results

Article 22 When an imported product passes inspection and meets regulations, the inspection authority shall issue an import permit notification to the Obligatory Inspection Applicant through the Import Food Information System.

The Obligatory Inspection Applicant shall collect the remaining samples stored by the inspection authority within 15 days of receiving the permit notification using the sampling voucher. However, for samples with a short shelf life, the

inspection authority shall dispose of them directly.

Article 23 For products found to be noncompliant upon inspection, the inspection authority shall issue a notice of noncompliance to the Obligatory Inspection Applicant via the Import Food Information System.

The Obligatory Inspection Applicant can apply for re-analysis to the original inspection authority within 15 days upon the receipt of the notice of noncompliance in accordance with Article 39 of the Act. Application for re-analysis is limited to one time only and shall be performed by the original analysis laboratory using remaining samples for the re-analysis.

If an imported product fails inspection or re-analysis and does not comply with regulations, the inspection authority shall destroy the remaining samples after the deadline for requesting re-analysis has expired unless otherwise specified by law.

Article 24 Imported products that do not conform to regulations upon inspection shall be disposed of in one of the following ways by the Obligatory Inspection Applicant:

1. Return or destroy.
2. For products that do not comply with Article 17, Article 18 Paragraph 1, or violate Article 21 Paragraph 1 or 2 of the Act, an application may be submitted to the inspection authority to disinfect, modify, or implement appropriate safety measures within a certain deadline.
3. For products that violate Article 22, Article 24, Article 26, Article 27, or Paragraph 1 of Article 28 of this Act, the Obligatory Inspection Applicant may apply to the inspection authority for relabeling within a certain deadline.

When the Obligatory Inspection Applicant takes appropriate action in accordance with Subparagraph 2 or 3 of the preceding Paragraph, the inspection authority may approve the Obligatory Inspection Applicant to conduct disinfection, reconditioning, enforcement of appropriate safety measures or relabeling.

If imported products that have been released via a prior release notice fail an inspection, the inspection authority shall order the Obligatory Inspection Applicant to retrieve and take appropriate action in accordance with the provisions of Paragraph 1 of this Article.

Article 25 The inspection authority shall notify the customs office and the Obligatory Inspection Applicant of decisions or actions taken under these regulations via electronic data transmission.

Such notifications sent through the electronic data transmission system, Import Food Information System, shall be deemed delivered.

Chapter 8 Other Regulations of Inspection

Article 26 If an Obligatory Inspection Applicant imports products belonging to the same origin and CCC Code, and its analysis results do not conform to regulations two times within six months, the inspection authority may require the Obligatory Inspection Applicant to provide written document before a given date, to explain the reasons for noncompliance, and a proposed improvement plan with preventative measures.

If products belong to the same origin and CCC Code, and its analysis results do not conform to regulations three times within six months, the central competent authority or its delegated agency may require the government of the exporting country/area to provide written document before a given date, to explain the reasons for noncompliance, and a proposed improvement plan with preventative measures.

Article 27 If the Obligatory Inspection Applicant fails to provide written documentation within the deadline specified in the previous article, or if a product submitted for reinspection after receiving the prior notice still fails to meet requirements upon analysis, the inspection authority shall suspend the inspection application for products from the same origin and CCC Code submitted by that same applicant. If the government of the exporting country/area fails to provide a written document before the given date or after receiving the notification mentioned in the preceding article and following imported products applied for inspection still do not conform to regulations, the central competent authority or its delegated agency may temporarily suspend the inspection application for products from related industry and origin.

Chapter 9 Supplementary Provisions

Article 28 When conducting field inspection duties under the Regulations, inspection personnel shall present proof of their official duties or display a clearly identifiable insignia.

Article 29 The Act shall come into force on _____(XX Month XX Day, XX Year).