Regulations of Inspection of Imported Foods and Related Products

DOH Food No. 0900074645 Promulgated, December 14, 2001.
DOH Food No. 0960403095 Amended and promulgated on June 22, 2007; these regulations are effective as on July 1, 2007.
DOH Food No. 0991304411 Amended and promulgated on December 30, 2010 and the title was amended to "Regulations of Inspection of Imported Foods and Related Products".
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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: Business who imports food, food additives, food utensils, food packaging, or food cleansers, and other related products (hereinafter "products").
2. Inspection Authority: The central competent authority or its commissioned organization, institution, corporation or group.
3. Verification: The inspection authority check product name, specification and package of products applied for inspection. And exam its appearance, shape, properties, indication and other examination in accordance with laws and regulations.
4. Analysis: The inspection authority take samples and send to laboratories to conduct sensory, chemical, biological, or physical examination and experiment.

Chapter 2 Application for Inspection

Article 3 The Obligatory Inspection Applicant or Representative shall file an application for inspection to the inspection authority at the port of entry within fifteen (15) days prior to the entry date. 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 Applicants shall submit the following documents and papers to the inspection authority for inspection:

1. An application form for inspection.
2. A declaration form of product information.
3. A photocopy of application for import declaration.
4. Necessary documents and papers required by the Food and Drug Administration, Ministry of Health and Welfare (hereinafter as “TFDA”).

In accordance with Article 32 of the Act, the inspection authority may require Obligatory Inspection Applicants to provide other necessary documents and papers. The Obligatory Inspection Applicants shall not evade, obstruct or refuse.

The forms of inspection in Paragraph 1 may be by electronic files or any other manner required by TFDA.

Article 5 (Discard)

Article 6 Products for inspection application in the same shipment shall have the same import declaration、CCC code、product name、ingredients、brand、producer and country of origin.

If the import products were live, fresh or chilled fish, prawn, crab, shellfish, or belong to the same class from four classes of mollusk, the inspection authority may permit the applicant to apply different products in one inspection application.

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

1. Applicants fail to apply an inspection application pursuant to Article 4 or the preceding article of this regulation.
2. Incomplete inspection application form, product information declaration form or other related form, and fail to make correction within a limited period.
3. Repeated application for inspection for products mentioned in the previous article that have already been selected for batch inspection in accordance with Subparagraph 2, Paragraph 1, Article 8.

Chapter 3 Inspection Procedures

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

1. Batch-by-batch inspection: Inspect each submitted batch of product by on-site verification and sampling analysis basis.
2. Randomly-selected batch inspection: Randomly select each submitted batch of product by following inspection rate, and inspect the chosen product by on-site verification and sampling analysis.
   (1)Regular randomly-selected batch inspection: The inspection is performed based on a 2-10% inspection rate.
   (2)Reinforced randomly-selected batch inspection: The inspection is performed based on a 20-50% inspection rate.
3. Batch-by-batch verification: On-site inspect each submitted batch of product.
4. Certification inspection: Certificate Document inspection for an excellent industry which is registered by an entente or agreement between the health and safety competent authority of Taiwan and the exporting country.
5. Oversee inspection: For specific products, each submitted batch of product shall be inspected by on-site verification and sampling analysis. And the inspection rate is not changed by the inspection result.

For those products not be selected in randomly-selected batch inspection, the inspection authorize may exam extra by on-site verification and sampling analysis; For products be designated for batch-by-batch verification, the inspection authorize may exam extra by sampling analysis.

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 proved to cause 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 TFDA annual inspection plan (hereinafter as “inspection plan”) for imported products.
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. For products applied to oversee inspection and fail the inspection two batches in a row.
5. The inspection authority determines that it is necessary to carry out the inspection on a batch-by-batch basis.

Prior to the 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 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. Products applied for inspection originally belong 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 inspection authority determines that it is necessary to carry out the inspection on a reinforced randomly-selected batch basis.

For products applied to inspection originally belongs to batch-by-batch inspection, the inspection authority may not be restricted by the restrictions stipulated in the preceding paragraph based on its considerations of health and safety.

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 oversee inspection.
2. Products applied to 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.

For products applied to inspection originally belongs to reinforced randomly-selected batch inspection, the inspection authority may not be restricted by the restrictions stipulated in the subparagraph 2 of preceding paragraph based on its considerations of health and safety.

Article 12 If an obligatory inspection applicant imports products after failing on-site verification for products belong to the same origin country and CCC Code, those products shall be inspected on a batch-by-batch verification basis.

If three consecutive batches of products designated for batch-by-batch verification in preceding paragraph conform to regulations, and the total amount reach two times as the previous unqualified products, then the same products for future import can be exempt from batch-by-batch verification.

Article 13 The inspection authority may adopt oversee inspection on specific products based on considerations of health and safety.

Chapter 4 Preferential Measure for Excellent Industry

Article 14 Import products belong to following situations may apply to the minimum inspection rate of normal randomly-selected batch inspection.

1. Obligatory Inspection Applicants apply an imports product quality assurance project to inspection authority, and been approved and registered by inspection authority, and have ten consecutive batches of products pass the

randomly-selected batch inspection within one year.

2. Twenty consecutive batches of import products pass the randomly-selected batch inspection within one year.
3. Thirty consecutive batches of import products pass the randomly-selected batch inspection within two year.

Any product applied to minimum inspection rate in accordance with preceding paragraph failed a border inspection or market randomly-selected inspection, shall cease to apply to preferential measure in preceding paragraph.

Article 15 Obligatory Inspection Applicants import products in preceding article and all the inspected products conform to the regulations within two (2) years, then their future import products may be inspected on certification inspection basis in accordance with Article 4.

If necessary, the inspection authority may inspect products in preceding paragraph by on-site verification or sampling analysis. If the result is not qualified, future import products of the obligatory inspection applicant cease to apply to the preferential measures in preceding paragraph.

Chapter 5 Inspection Operation

Article 16 The samples required for inspection may be taken free-of-charge from the Obligatory Inspection Applicants by the inspection authority, but the amount of sampling shall be limited to the requirement of examination and sample retention purposes.

After collecting the samples, the authority shall issue a receipt for sampling to the Obligatory Inspection Applicants.

Article 17 Verifying and sampling of inspection shall conduct in the place where the products were stored. If the products were shipped in full container load, which shall be verifying and sampling in the centralized inspection area of port or where be approved by TFDA, but if it takes too long or has other difficult situations, TFDA shall ask to open container for warehouse delivery.

During the verifying and sampling in preceding paragraph, Obligatory Inspection Applicants shall cooperate accordingly and cannot appoint any specific sample.

Article 18 Examination shall be conducted in the order of sampling. However, the inspection authority shall first inspect products

that applied for re-examination according to these regulations.

Chapter 6 Prior Release

Article 19 Due to requiring five or more days for examination, or sampling of such products is difficult in a container yard, or the product is perishable, or the products in bulk and no warehouse in wharf, after the obligatory inspection applicant sign an affidavit of custodial responsibility, the inspection authority may issue a Notice of Prior Release for import for customs clearance.

The products designated for batch-by-batch inspection are not subject to the preceding paragraph and shall be retained at the border temporarily with the exception of putrescible products and products mentioned in Paragraph 2 of Article 10.

Article 19-1 If the product which applicated or labeled as Organic Agricultural Product, is substantiation of their compliance with the Act and other related laws and regulations, after the obligatory inspection applicant sign an affidavit of custodial responsibility, the inspection authority may issue a Notice of Prior Release for import for customs clearance before the applicant gets Approval Documents for Organic Agricultural Products.

Article 20 Products that falls into one of the following categories, and conformed to the preceding two Articles by the inspection authority, the authority may issue a prior release notice after the obligatory inspection applicant has paid a guarantee bond：

1. Product subject to Batch-by-batch inspection.
2. Product subject to Reinforced randomly-selected batch inspection.
3. Product subject to Oversee inspection that yield non-conforming results during the inspection period.
4. The obligatory inspection applicant fails to finish the process of inspection after elapse of ninety days from the inspection authority issued a prior release notice and applies for prior release notice again.

The amount of the guarantee bond shall be four-times of the product Duty-paying value for the products listed in subparagraph 1 of the preceding article, and double for the products listed in subparagraph 2 to 4 of the preceding article.

Article 21 Paying the guarantee bond in accordance with preceding article by an obligatory inspection applicant shall be by financial-institutions-issued cashier's check or check, or postal order.

With any of the following conditions and no violation of Subparagraph 3 of Article 51 of the Act, the obligatory inspection applicant may request the inspection authority to refund the guarantee bond.

1. After the products applied for inspection conform to the regulations, and earned a permission notice.
2. The products applied do not conform to the regulations but deal with them in accordance with the provisions Article 24.

Chapter 7 Issuance of Certifications

Article 22 After the products applied for inspection conform to the regulations, the inspection authority shall issue a permission notice to the obligatory inspection applicant. Obligatory inspection applicant may also apply to the inspection authority for a written permission notice.

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.

Article 23 Products that fail to conform to the regulations, a notification of noncompliance for import food and relevant products shall be issued.

The obligatory inspection applicant can apply for re-examination to the original inspection authority within 15 days upon the receipt of the notification of results. Application for re-examination is limited to one time only and shall be performed by the original inspection authority using remaining samples for the re-examination.

Remaining samples of products that do not conform to regulations shall be destroyed at the end of the period of application for re-examination.

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 do not conform to Article 17 or Article 18 of this Act or violate Paragraph 1 of Article 21 of this Act, the obligatory inspection applicant may apply to TFDA for disinfection, reconditioning or taking the enforcement of appropriate safety measures.
3. For products 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 TFDA for relabeling.

When the obligatory inspection applicant takes appropriate action in accordance with the Subparagraph 2 or 3 of the preceding Paragraph, the TFDA may issue a prior release notice to the obligatory inspection applicant and then takes 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.

Chapter 8 Other Regulations of Inspection

Article 25 If an obligatory inspection applicant import products belong to the same origin country and CCC Code, and its inspection results do not conform to regulations for two times within six months, the TFDA may require the obligatory inspection applicant to provide written document before a given date, to explain the reasons for non-conformance, and a proposed improvement plan with preventative measures.

If products belong to the same origin country and CCC Code, and its inspection results do not conform to regulations for three times within six months, the TFDA may require the government of the exporting country to provide written document before a given date, to explain the reasons for non-conformance, and a proposed improvement plan with preventative measures.

Article 26 If the obligatory inspection applicant or government of the exporting country/area fails to provide written document before the given date or after receiving the notification mentioned in the preceding article and following imported products applied for re-examination still do not conform to

regulations, the TFDA may temporarily suspend the inspection application of related industry, country of origin and products.

Chapter 9 Supplementary Provisions

Article 27 When conducting on-site inspections according to the regulations, inspectors shall carry their identification documents with them.

Article 27-1 The Certificate of course completion according to Article 5 herein before the amended and came into enforcement in October 18 2018 shall be still valid for the valid period.

Article 28 Except for Article 20 and 21 that were amended in January 27 2014 come into enforcement from June 19 2014, the other provisions shall come into enforcement from the date of promulgation.