

REGULATIONS FOR SYSTEMATIC INSPECTION OF IMPORTED FOOD (DRAFT)

Promulgated on February 11, 2014
Amended on October 17, 2014
Amended on August 4, 2017
Amended on September 17, 2018
Amended on September 26, 2019
Amended on September 11, 2024

Article 1 These Regulations are formulated in accordance with the provisions of Paragraph 2 of Article 35 of the Act Governing Food Safety and Sanitation (hereinafter referred to as “this Act”).

Article 2 The terms used in these Regulations are defined as follows:

1. “Systematic inspection” refers to inspection of the food safety and sanitation management system and the supervisory measures taken by the governments of the exporting country (territory).
2. “Inspection authority” refers to the Food and Drug Administration, Ministry of Health and Welfare.
3. “Document review” refers to the review of systematic inspection documents and information provided by the government authorities of the exporting country (territory).
4. “On-site inspection” refers to the systematic inspection conducted by the inspectors designated by the inspection authority in the exporting country (territory).
5. “Designated certificate” refers to the certificate issued by the government authorities of the exporting country (territory) stating compliance with the food safety and sanitation management regulations.

The issuance of the certificate in Subparagraph 5 of the preceding paragraph shall follow the format, content, or other relevant matters mutually agreed upon by the inspection authority and the government of the exporting country (territory).

Article 3 The scope of products subjected to systematic inspection is outlined in the attachment.

Article 4 The exporting country (territory), before exporting products as listed in Paragraph 1, Article 35 of this Act, shall submit an application to the inspection authority through the information system established by the inspection authority, accompanied by relevant documents and information. The inspection authority shall review the application through the following procedures:

1. Review the document and information submitted by the government authorities of the exporting country (territory). The inspection authority may request the government authorities of the exporting country (territory) to submit the additional documents and information within a specified period.
2. On-site inspection shall be conducted after the document review.
3. Upon completion of the on-site inspection, the procedures of designed certificate shall be carried out by the inspection authority and the government of the exporting country (territory). The government authorities of the exporting country (territory) shall submit a list of designated cutting plants, processing plants, warehouses, aquaculture facilities, fishing vessels, and other establishments (hereinafter collectively referred to as " establishments "), along with other necessary documents and information.
4. Evaluate the systematic inspection results and the equivalence with the food safety and sanitation management system and the supervisory measures of the importing country.

The inspection authority, based on the evaluation results in the preceding paragraph, shall make one of the following decisions and notify the government authorities of the exporting country (territory):

1. Approval of market access that products produced by all or part of the designated establishments of the exporting country (territory).
2. Disapproval of market access.

Products that are subjected to systematic inspection of these regulations but have not granted approval as stipulated in the preceding paragraph shall not be eligible to apply for border inspection under the provisions of Article 30 of this Act, except for any of the following circumstances:

1. Urgent needs for people's livelihood.

2. Situations specified in Article 8.

Article 5 The products have been granted import approval of Subparagraph 1 of Paragraph 2 of the preceding Article but with any of the following circumstances, the inspection authority may considering the situation, request the exporting country (territory) to submit relevant documents and information for further document review and/or on-site inspection to ensure the equivalence of the food safety and sanitation management system of the exporting country (territory) with the importing country:

1. Significant changes in the food safety and sanitation management system of the exporting country (territory).
2. Occurrence of significant food safety and sanitation incidents within the territory of the exporting country (territory).
3. The food and related products exported from the exporting country (territory) to importing country or other countries are found to have serious violations of regulations upon border inspection.
4. Other circumstances deemed necessary by the inspection authority.

If the exporting country (territory) does not submit relevant documents or information or declines on-site inspection as required in the preceding paragraph, or if, the inspection authority deems it necessary to suspend imports based on the results of document review or on-site inspection, the inspection authority may suspend the importation of the relevant products.

Article 6 For any deficiencies found in the results of on-site inspections as stipulated in the preceding two articles, the inspection authority may request the exporting country (territory) to submit a corrective report within a specified period. The inspection authority may conduct on-site reinspection if couldn't confirm the corrective action with document review.

In case of any of the following circumstances, the expenses of on-site inspections shall be borne by the exporting country (territory):

1. Reinspection as stipulated in the preceding paragraph.
2. On-site inspection of the application for new establishments or new items by the exporting country (territory) after the inspection authority makes the decision of approval based on Subparagraph 1, Paragraph 2 of Article 4.

3. On-site inspection of the reapplication by the exporting country (territory) after the inspection authority makes the decision of disapproval based on Subparagraph 2, Paragraph 2 of Article 4.

The inspection authority may request the exporting country (territory) to bear the expenses of on-site inspections other than those mentioned in the preceding paragraph as it deems necessary.

Article 7 The bearing of expenses stipulated in the preceding article shall follow the agreement, if such an agreement has been entered into, between the exporting country (territory) and the importing country on the scope and method of bearing the inspection expenses.

Article 8 Products subject to the systematic inspection under these Regulations, with a record of importation prior to the date specified for the implementation of systematic inspection in the attached table of these Regulations, may be exempted from application for systematic inspection within the original scope of product importation.

The inspection authority may designate specific establishments for the products which are exempt from application for systematic inspection as stipulated in the preceding paragraph.

The inspection authority may request that the exporting country (territory) apply for systematic inspection according to these Regulations when it suspects changes of risk levels of products in the preceding paragraph considering the following conditions:

1. The regulatory status of the exporting country (territory) regarding food safety and sanitation.
2. Results of border inspections or domestic market inspection of the imported products.
3. No record of border inspection for the imported product in the specified period.
4. Domestic and/or foreign food safety alerts and the content of monitoring reports issued by the food safety monitoring agencies.
5. Content of relevant domestic and/or international food safety scientific literature or reports.

Article 9 For an exporting country (territory) don't apply for systematic inspection upon notification based on the third paragraph of the preceding article, the inspection authority may proceed in accordance with the provisions of main texts lies in Paragraph 3 of Article 4.

Article 10 These Regulations shall be implemented from the date of promulgation, unless otherwise specified.

Attachment Scope of Products Subject to Systematic Inspection

| Type | Item | Remarks |
|------------------|---|--|
| Meat Products | Livestock and poultry products classified as Codes 02, 0504, 1601 and 1602 of the Harmonized System Codes (HS Codes) established by the World Customs Organization. | <ol style="list-style-type: none"> 1. Products on the left column subject to importation rules F01 or F02. 2. Products in Code 160210 are excluded. |
| Fishery Products | Animal origin fishery products classified as Codes 03, 1604 and 1605 of the Harmonized System Codes (HS Codes) established by the World Customs Organization. | <ol style="list-style-type: none"> 1. Products on the left column subject to importation rules F01 or F02. 2. The product category take effect from January 1, 2018. |
| Dairy Products | Animal origin dairy products classified as Codes 0401 to 0406, 19011000907, 19019021004, 19019022003, 19019024, 19019025, 19019026, 19019027, 19019029, 19019030, and 9806 of the Harmonized System Codes (HS Codes) established by the World Customs Organization. | <ol style="list-style-type: none"> 1. Products on the left column subject to importation rules F01 or F02. 2. This category takes effect from January 1, 2018, except for Codes 19011000907, 19019021004, and 19019022003, which take effect from January 1, 2020, and Codes 19019024, 19019025, 19019026, 19019027, 19019029, and 19019030, which take effect from January 1, 2025. |
| Egg products | Eggs and egg products classified as Codes 0407, 0408, 350211, and 350219 of the Harmonized System Codes (HS Codes) established by the World Customs Organization. | <ol style="list-style-type: none"> 1. Products on the left column subject to importation rule F01. 2. This category takes effect from January 1, 2019, except for products under importation rule F01 and without B01, which takes effect from January 1, 2025. |

| Type | Item | Remarks |
|--------------------------|--|---|
| Animal fat and oil | Products classified as Code 15 of the Harmonized System Codes (HS Codes) established by the World Customs Organization. | <ol style="list-style-type: none"> 1. Products on the left column subject to importation rules B01 and F01. 2. This category takes effect from January 1, 2019. |
| Cervidae origin products | Other non-meat cervidae origin products produced in chronic wasting disease (CWD) in deer, classified as Code 0507 of the Harmonized System Codes ((HS Codes) established by the World Customs Organization. | <ol style="list-style-type: none"> 1. Products on the left column subject to importation rules F01 or F02. 2. This category takes effect from January 1, 2020. |