

Regulations for Systematic Inspection of Imported Food

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

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

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

1. “Systematic inspection” means inspecting the food safety management system and the supervisory measures taken by the governments of the exporting country (territory).
2. “Inspection authority” means the Food and Drug Administration, Ministry of Health and Welfare.
3. “Document review” means reviewing the documentation relating to the food safety management system in the exporting country (territory) provided by the governmental authority of the exporting country (territory).
4. “On-site inspection” means the inspection authority designates inspectors to conduct the systematic inspection of the food safety management system in the exporting country (territory).

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

Article 4 To perform systematic inspection and evaluate the equivalence of the food safety management system of the exporting country (territory), the exporting country (territory) shall apply to the inspection authority with documents for approval of import of the product described in the above paragraph. Inspection authority shall conduct the documents review. If required, on-site inspection can be conducted following the document review.

The inspection authority may make the following decision based on the result of systematic inspection:

1. Market access approval for products of the establishments designated by competent authority of the exporting country (territory).
2. Market access approval for products of the establishments which have been inspected and qualified by the inspection authority.
3. Disapproval of the application for market access.

If necessary, inspection authority shall request the exporting country (territory) to provide the documents within the designated period when performing the pre-said document review.

Products which are subjected to the scope of this regulation, are not conforming to the paragraph 2 of this Article shall not apply for import inspection at border, except for the exemption according to Article 7 or according to the bilateral agreement with the exporting country (territory).

Article 5 For any exporting country (territory) that has been systematically inspected and been approved to import or that is exempted from systematic inspection in accordance with the provisions of Article 7, in case of any of the following, the inspection authority may request document review or on-site inspection to confirm the equivalence of the management system of the exporting country (territory).

1. Significant changes of food safety management system or the supervisory measures of the exporting country (territory).
2. Occurrence of significant food sanitation and safety incidents in the exporting country (territory).
3. Significant violation of the food or related product from the exporting country (territory) found by the inspection authority or other importing country (territory).
4. Any exporting country (territory) that is exempted from systematic inspection in accordance with the provisions of Article 7 or that has been finished systematically inspected more than three years, deemed

necessary to conduct documents review or on-site inspection by the inspection authority.

5. Food or related products which from the exporting country (territory) were determined as jeopardizing food safety.

Article 6 If the results of on-site inspection are non-compliant, the exporting country (territory) may be required to submit corrective actions, to the inspection authority for review before deadline. If required, on-site re-inspection might be performed again to verify the effectiveness of the corrective actions.

The expenses of on-site inspection shall be borne by the exporting country (territory) in the following circumstances:

1. Re-inspection of the paragraph 1 of this Article.
2. Application for expanding designated establishments in the case of the subparagraph 2 of paragraph 2 of Article 4.
3. Re-application for systematic inspection in the case of the subparagraph 3 of paragraph 2 of Article 4.

If necessary, the inspection authority will request the exporting country (territory) to bear the expenses of on-site inspection other than the circumstances of the paragraph 2 of this Article.

Article 7 Products, subjected to the scope of this regulation, had existed import records before promulgation of these Regulation might be exempted from the systematic inspection.

Article 8 These Regulations shall be implemented from the date of promulgation unless other specified.

Attachment Scope of Products Subject to Systematic Inspection

Type	Item	Remarks
Meat Products	Livestock and poultry products listed in 02, 0504, 1601 and 1602 of the Harmonized System Codes (HS Codes) established by the World Customs Organization.	Products on the left column subject to importation rules F01 or F02.
Fishery Products	Products listed in 03, 1604 and 1605 of the Harmonized System Codes (HS Codes) established by the World Customs Organization.	1. Products on the left column subject to importation rules F01 or F02. 2. These products come into enforcement from January 1, 2018.
Dairy Products	Products listed in 0401, 0402, 0403, 0404, 0405, 0406, 19011000907, 19019021004 and 19019022003 of the Harmonized System Codes (HS Codes) established by the World Customs Organization.	1. Products on the left column subject to importation rules F01 or F02. 2. The products listed in 19011000907, 19019021004 and 19019022003 of the Harmonized System Codes (HS Codes) come into enforcement from January 1, 2019 and the others are from January 1, 2018.

Egg products	Products listed in 0407, 0408 and 3502 of the Harmonized System Codes (HS Codes) established by the World Customs Organization.	1. Products on the left column subject to importation rules B01 and F01. 2. These products come into enforcement from January 1, 2019.
Animal oil products	Products listed in 15 of the Harmonized System Codes (HS Codes) established by the World Customs Organization.	1. Products on the left column subject to importation rules B01 and F01. 2. These products come into enforcement from January 1, 2019.
Products of cervidae origin	Products listed in 0507 of the Harmonized System Codes (HS Codes) established by the World Customs Organization, not classified as meat products, from CWD infected countries.	1. Products on the left column subject to importation rules F01 or F02. 2. These products come into enforcement from January 1, 2020.