

Preceding sample test for import clearance of food and food related products

Introduction

Under article 27 of the Food Sanitation Act (hereafter FSA), to ensure the safety of imported foods and related products, importers are not allowed to sell and use those items as merchandise unless they submit import notification to Minister of Health, Labour and Welfare. "Foods and related products" include foods, food additives, apparatuses, containers/packages and toys for infants." Import notifications" is a process to submit "Notification Form for Importation of Foods, etc." (hereafter Notification Form) to apply the MHLW for the permission of import. Notification Form is accepted by MHLW quarantine stations at each port and airport. At MHLW quarantine stations, food sanitation inspector inspects the documents to judge whether the item meets the regulations under the FSA. When necessary, they will order the cargo inspection. This cargo inspection includes, Inspection Order, Monitoring Inspection and Voluntary Inspection. As part of the importer's voluntary hygiene control, Voluntary Inspections are conducted on a regular basis. Through Voluntary Inspection, importers can confirm if the foods and related products comply with standards of FSA, check the status of the use of food additives (inappropriate use, overuse, use of non-designated additives, etc.), the presence of contamination by pathogenic microorganisms and the content of adverse and toxic substances (aflatoxins, cyanide compounds, radioactive substances, residual pesticides, etc.)."

There are three ways of Voluntary Inspections;

- [1] Inspection conducted by a Registered Conformity Assessment Bodies by sampling a part of the cargo in custody in a bonded state.
- [2] Inspection conducted by Registered Conformity Assessment Bodies with Preceding Sample before the cargo arrives in Japan.
- [3] Inspection conducted by Foreign Official Laboratories in the exporting country prior to the export.

This is an article about the preceding sample test described in [2] above, which is an effective method for Voluntary Inspection for food additives, appliances, containers and packaging, and toys for infants.

What is Preceding Sample?

Preceding Samples are samples imported for inspection prior to importation of cargo. Preceding Samples are not used for sales or business purposes, so importers do not need to submit import notification. The inspection conducted on this preceding sample is named as "Inspection for Foods, etc. for which Import Notification is not made".

Preceding sample should be unopened and delivered to Registered Conformity Assessment Bodies directly from the manufacturer or exporter in accordance with Notification ¹⁾ of August 2009.

Preceding Sample Inspection Results are now accepted at Quarantine Stations

The inspection results of Preceding Sample were not accepted at quarantine stations as the proof

of the compliance with the FSA unless the item is preregistered (Item Preregistration System) and certain requirements are satisfied (for details, see JFRL News Vol.3 No.17 Jun.2010). However, in April 2015, it changed. Namely, the inspection results of Preceding Sample became able to be accepted as the proof the compliance with the FSA without satisfying those certain requirements even though the item is not preregistered. Or, more precisely, the inspection results of Preceding Sample became able to be treated in the same manner as the case of preregistered item on condition that the following two documents are submitted with the Notification Form.

- Form for Confirmation of Inspection Results for Foods, etc. for which import notification is not made (hereafter referred to as the "Confirmation Form")³⁾
- Notification of inspection result based on Confirmation Form

Requirements for Notification of Inspection Results

The requirements for the Notification of inspection result of the Preceding Sample are the same for the case of Item Preregistration System. The requirements are stated on Confirmation Form as follows.

Requirement 1: The following matters shall be stated,

- (1) Test sample is sent directly from the manufacturer or exporter to a Registered Conformity Assessment Bodies (excluding the case when an unopened sample is sent through an inspection by an Administrative Organ such as Customs) and used for an inspection.
- (2) Name, part number, JAN code, manufacturer name, etc. that identify the sample
- (3) Raw materials, materials, etc.
- (4) The inspection has been performed after confirming that the documents listed in 2 pertain to the sample.

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- (5) Color photograph is attached for the purpose of confirming the color and patterns of the sample.

Requirement 2: The following documents prepared by the manufacturer, etc. shall be attached.

- (1) Name, part number, JAN code, manufacturer name, etc., that identify the sample / Invoices, bills of lading (B/L), etc. to certify that the sample was directly sent from the manufacturer, etc. to Registered Conformity Assessment Bodies."
- (2) Catalogs, photographs, etc. that identify the sample
- (3) Documents certifying the raw materials, ingredients, and manufacturing methods for which the applicable standards are identified (limited to cases where the samples are processed foods)

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- (4) Drawings / Developed drawings that shows the structure of the product. (In case when the sample is a part of assembled product.)

Requirement 1 above must be included in the Notification of inspection result if the purpose of the request is Preceding Sample inspection. Requirement 2 must be obtained from the manufactures (or the place of manufacture, exporters) by requesting them. The documents need to be enclosed with Preceding Sample. (Invoice can be sent separately from Preceding Sample.)

Precautions for documents prepared by manufacturers

The exporter should make sure for the manufactures to satisfy following points when they make the documents for requirement 2 above.

- [1] When the exporter sends Preceding Sample to Registered Conformity Assessment Bodies, the name of the manufacturer or the manufacturing site must be stated in the invoice.
- [2] Product photographs must be made in color. In case of food additives, photographs of its appearance (or its package) is enough.
- [3] It is not necessary to indicate JAN code (Japanese Article Number: a universal product ID number) if the product does not have it, but the product number is necessary in principle to identify the product.
- [4] It is important to match all product names, product numbers, etc. between documents.
- [5] It is important that the name and address of the manufacturer, the place of manufacturing match the description in Notification Form which is to be submitted to the quarantine station at the time of import. (Examples of mismatching description with Notification Form are the abbreviation of the company name instead of its official name, the address of other office instead of the factory address, the name of managing company instead of factory name, etc.)

Advantages of Preceding Sample Inspection

There are two major advantages when Preceding Sample inspection is used for import clearance of food additives, apparatus, containers and packaging, and baby toys.

- [1] It enables to confirm whether the products conform to the FSA and prevent the import of nonconforming products before importing products,

Table 1 shows the number of violation cases of the FSA through monitoring inspections and voluntary inspections for apparatus being bonded and also the number of nonconforming cases of apparatus through inspection on Preceding Samples at JFRL. It shows that considerable number of nonconforming products were prevented to be imported in advance.

Table1 The number of violations (nonconforming cases) of the FSA in apparatus

| | FY 2015 | FY 2016 |
|--|---------|---------|
| Number of violation cases through monitoring inspections and voluntary inspections * | 30 | 49 |
| Number of nonconforming cases of preceding sample inspection (tested by JFRL) | 32 | 31 |

*: “Statistics on Imported Foods Monitoring”, Number of cases that have become violations after “Import notification” is submitted.

[2] The information required for completing Notification Form, is included in the result of Preceding Sample inspection and in the attached documents (documents prepared by the manufacturer, etc.). Therefore, the importer can avoid the troubles that imports will not be permitted due to lack of information.

Inspection parameters not applied to Preceding Sample Inspection

Some inspection parameters cannot be accepted as Preceding Sample inspection.

Parameters for inspection orders, microbial-related parameters (e.g., Aerobic plate count, coliform bacteria, aflatoxins) must be inspected in cargo for sale (e.g., cyclamic acid), and some parameters such as cyanogens, GMO, radioactive materials etc. must be inspected each time they are imported.

Closing Remarks

The flow of imports of foods is shown on the next page for reference.

JFRL supports our clients with their process of Preceding Sample inspection. Please do not hesitate to contact us. (<http://www.jfrl.or.jp/item/import/index.html>)

Reference

- 1) Annual Notification No. 0807-3 of August 7, 2009 (Partial Amendment to the Standards for Supervision and Guidance of Imported Foods, etc.)
- 2) Notification No. 1111-1 "Item Registration" dated November 11, 2009
- 3) Office contact dated April 22, 2015, "Handling of Inspection Results for Foods, etc. for which Import Notification is Not Made," annex "Confirmation of Inspection Results for Foods, etc. for which Import Notification is not made"
- 4) MHLW website: Imported food monitoring
http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/yunyu_kanshi/index.html

Flow of import of food, etc.

