

Procedural Guidelines for Issuance of Certificates of Free Sale

1. Purpose

These Procedural Guidelines set forth the procedures for issuing a written certificate evidencing that the subject food products have been manufactured in Japan and are readily available for sale in Japan without restriction for submission or presentation to the competent customs clearance-related or other organizations of the country to which they are to be exported (hereinafter a “Certificate of Free Sale” or “Certificates of Free Sale”), as well as any other necessary matters.

For clarity, a Certificate of Free Sale is not intended to certify the safety of individual exported food products, and this measure is not purported to prevent other organizations and authorities from issuing any certificate to the same effect.

2. Coverage

A Certificate of Free Sale will be issued for the certain food products as prescribed in the Food Sanitation Act (No. 233 Act of December 24, 1947, as amended) of such types as are manufactured and/or processed, and are in the form for sales through retail stores and any other channels in Japan (other than the food products for which sanitation certificates are separately issued by the Ministry of Health, Labour and Welfare), Japan.

3. Requirements for Issuing a Certificate of Free Sale

Food Products for which a Certificate of Free Sale is to be issued must satisfy all of the following requirements.

- (1) The subject food products have been manufactured and/or processed in Japan.
- (2) The subject food products are or could be sold in Japan.
- (3) That the subject food products have not been manufactured and/or processed by the manufacturer (including the production site; hereinafter the same applies) subject to an improvement order, rescission of permission or business prohibition or suspension involving its facilities under the Food Sanitation Act or the related laws and regulations or

the relevant local ordinances, etc. (except in cases where it is confirmed that the corrective or other measures have been taken appropriately).

For the avoidance of doubt, no certificate will be issued to the relevant exporter for a period of three (3) years after any one of the following facts is detected: when it becomes clear that the exporter and its affiliated operators have committed any wrongdoing in taking steps under these Procedural Guidelines; when it turns out that the subject exported food products constitute a breach of the Food Sanitation Act or the related laws and regulations or the relevant local ordinances, etc.; when the exporter has obtained the Certificate of Free Sale for any purpose other than its primary purpose; or when there is any other reasonable cause. (When the Food Sanitation Division of the Health and Welfare Department of the competent Regional Bureau of Health and Welfare (hereinafter the “Food Sanitation Division”) identifies any of those facts, it must give the Inspection and Safety Division, Department of Environmental Health and Food Safety, Pharmaceutical and Environmental Health Bureau, Ministry of Health, Labour and Welfare, Japan (hereinafter the “Inspection and Safety Division”) prompt notice thereof. The Inspection and Safety Division will, in turn, provide the relevant Food Sanitation Division with the relevant information, and the Food Sanitation Division receiving such information should take the above-mentioned actions.)

- (4) That it can be verified that the subject food products have not been opened or otherwise handled and appropriate controls have been maintained after they are shipped by the manufacturer.
- (5) That for the food products for which the expiration dates have been designated, it is not difficult to be consumed in the countries to which they are to be exported within the designated period of time.

4. Procedures for Issuing a Certificate of Free Sale

- (1) The exporter shall confirm that it will be required to submit or present a Certificate of Free Sale in the import procedure of the country to which the food products are to be exported.
- (2) The exporter shall check with the manufacturer of the food products to be exported by way of a “Confirmation” (Form No. 1 attached hereto) that such manufacturer is not subject to an improvement order or any other action under the related laws and regulations or the

relevant local ordinances, etc. Also, if the food products have been manufactured and/or processed solely for the purpose of export, the exporter shall check with the manufacturer what the differences between the food products for export and their similar type of products for the domestic market are, and that such differences do not pose any problem under the Food Sanitation Act.

- (3) The exporter shall prepare a “Confirmation” (Form No. 1 attached hereto) and an “Application for Issuance of a Certificate of Free Sale” (Form No. 2 attached hereto), as well as a “Certificate of Free Sale” (Form No. 3 attached hereto) (the exporter shall fill out Sections 1 through 3, and “Invoice Number” and “Export Date” entries of the Form No. 3 in English. If the country to which the food products are exported is the Republic of Turkey, the exporter shall use the Form No.3-2 instead of the Form No. 3 and indicate the required items in English.) and, after confirming that there is no error in the covenants of the application form, submit them accompanied by copies of the business approval under Article 52 of the Food Sanitation Act or the business approval and other required documents under the relevant local ordinances, etc. (hereinafter the “Business Approval and Other Documents), for the food products manufactured and/or processed solely for the purpose of export, a document explaining the difference(s) from the manufacturer’s similar type of products for the domestic market and that such differences do not pose any problem under the Food Sanitation Act, invoices, a packing list, packages of food products to be exported, and transaction-related documents showing the sources, etc. of the products to the competent Food Sanitation Division, as shown in Exhibit hereto, having jurisdiction over the location of the exporter by the day before the tenth (10th) business day at the competent Regional Bureau of Health and Welfare prior to the export date (please note that an application form can be sent by postal mail or by e-mail. When submitting by postal mail, a self-addressed stamped envelope should be enclosed together with the above-mentioned documents. Also, please pay attention to the number of mailing days and the number of the business days, as the date on which the application form arrives at the Food Sanitation Division is treated as the submission date, and the date on which the Food Sanitation Division sends a reply is treated as the issue date. When submitting by e-mail, the instructions in the Annex should be followed.).

In addition, please note that if the application form is submitted on and after the day before the tenth (10th) business day prior to the export date, it may be difficult for the Food Sanitation Division to issue a certificate by the third (3rd) business day prior to the export date.

Copies of the Business Approval and Other Documents need to be verified against their original documents by the prefectural government or other relevant authority. Notwithstanding the foregoing, those copies will be accepted for the time being, even if they are not verified against their original documents, except in cases where there is any special reason.

- (4) The exporter of food products that require no Business Approval and Other Documents to manufacture shall submit a “Confirmation of Operating Conditions, Etc.” (Form No. 4 attached hereto) to be issued by the competent prefectural government or other relevant authority in charge of the location of the manufacturing site of those exported food products to the effect that the subject food products have not been manufactured by the manufacturer subject to the improvement order or any other action under the Food Sanitation Act or the related laws or regulations or the relevant local ordinances, etc. (the same form of a certificate evidencing that fact, if issued by the prefectural government or other relevant authority, is also acceptable) in lieu of the Business Approval and Other Documents.
- (5) If the application documents are submitted pursuant to Paragraph (3) above, the Food Sanitation Division will issue a “Certificate of Free Sale” (Form No. 3 attached hereto) after assigning an issue number and affixing a (red or bright red) seal to be used for the certificate form under No. 6 of 0107 issued by the Department of Food Safety, dated January 7, 2013, entitled “*Partial Amendment to ‘About the Treatment of Aquatic Food to Be Exported to the South Korea’*” on the Certificate of Free Sale (Form No. 3 attached hereto) by the third (3rd) business day at the competent Regional Bureau of Health and Welfare prior to the export date.

For clarity, the first two digits of the issue number shall be FS, which is followed by the applicable two-digit code of the competent Regional Bureau of Health and Welfare (Hokkaido Regional Bureau of Health and Welfare: HK; Tohoku Regional Bureau of Health and Welfare: TK; Kanto-Shinestu Regional Bureau of Health and Welfare: KS, Tokai-Hokuriku Regional Bureau of Health and Welfare: TH; Kinki Regional Bureau of Health and Welfare: KK; Chugoku-Shikoku Regional Bureau of Health and Welfare: CS; and Kyushu Regional Bureau of Health and Welfare: KY) and the last two digits of the year (i.e., the fiscal year ending March 31 each year), plus the issue number starting with 00001 on the fifth and subsequent digits (e.g., FSHK1300001).

- (6) If the Food Sanitation Division issues a Certificate to the applicant pursuant to Paragraph (5) above, it shall retain its copy and the relevant documents for a period of three (3) years from the date on which it is issued.
- (7) The Food Sanitation Division will summarize the status of issuing Certificates of Free Sale for each quarter using the form to be separately designated and make a report thereon to the Inspection and Safety Division, Department of Environmental and Food Safety, Pharmaceutical and Environmental Health Bureau, Ministry of Health, Labour and Welfare, Japan by the end of next month or, if there is no Certificate issued during the relevant month, inform it thereof.

5. Cautions

- (1) Issuance of these Certificates of Free Sale is part of the administrative services to facilitate smooth exports based on the assumption described in Section 1 above, and it is subject to a delay in issuing the certificates without prior notice, temporary suspension of issuing the certificates, and change or other restatement of these Procedural Guidelines. Any loss or other damage that may result from any of the actions mentioned above cannot be indemnified.
- (2) Issuance of these Certificates of Free Sale is part of the administrative services to facilitate smooth exports based on the assumption described in Paragraph (1) above, and applications for issuance may be submitted to the extent necessary for the import procedures in the countries to which the food products are to be exported.
- (3) The issuance of Certificate of Free Sale in accordance with the Form 3-2 is based on the agreements between the governments of Japan and Turkey. Items to be indicated in the Form will not be added or deleted in response to a request of the exporter.
- (4) The exporters will gather information about hygienic regulations and other conditions of the countries to which the food products are to be exported, and endeavor to secure voluntary sanitation management, for example, by conducting inspections as appropriate.
- (5) If it is confirmed or presumed based on the notice or other communication of the country to which the food products have been exported that the hygienic conditions of the exported

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food products are not good, the Inspection and Safety Division will ask for cooperation of the competent prefectural government or other authority in charge of the relevant operators, and conduct investigations into those operators and give those operators other guidance. The exporter will be responsible for the safety of the exported food products, as well as for transport, storage and other management of those exported food products, and provide cooperation on investigations and others.