Japan

Food and Agricultural Import Regulations and Standards Report

2018 FAIRS Annual Country Report

Approved By:
Christopher Riker

Prepared By:
Japan staff

Report Highlights:
This report is an overview and update of Japan’s general legal and technical requirements for food and agricultural imports. U.S. food and agricultural suppliers to Japan are recommended to consult with local importers and appropriate U.S. regulatory agencies for the most current local requirements prior to shipping. For more information on Japan’s certificate requirements, see FAS/Japan’s Food and Agricultural Import Regulations and Standards 2018 FAIRS Export Certificate Report at http://gain.fas.usda.gov/Pages/Default.aspx.
NOTE: This report was prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service at the U.S. Embassy/Tokyo for exporters of U.S. agricultural products. While great care was taken in the preparation of this report, the information provided may not be completely accurate due to either changes in policies since its preparation, or because clear and consistent information about these policies was not available at the time of publication. It is highly recommended that U.S. exporters verify the relevant import requirements with their foreign customers, who normally have the most updated information on local requirements and can research such matters with local authorities, prior to exportation. FINAL IMPORT APPROVAL OF ANY PRODUCT IS SUBJECT TO THE IMPORTING COUNTRY’S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

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Section I. General Food Laws

There are seven major laws in Japan governing food and agricultural products including imports:
1) the Food Safety Basic Act, 2) the Food Sanitation Act, 3) the Health Promotion Law, 4) the
Japan Agricultural Standards Law, 5), the Plant Protection Law, 6) Act on Domestic Animal
Infectious Diseases Control, and 7) the Food Labeling Law.

The Food Safety Basic Act sets the principles for developing a food safety regime and establishes
the role of the Food Safety Commission (FSC), a food-related risk assessment body.

The Food Sanitation Act, under the jurisdiction of the Ministry of Health, Labor and Welfare
(MHLW), a food risk management agency, aims to protect people’s health by ensuring the safety
and sanitation of foods and beverages. The Food Sanitation Act \(^1\) sets specifications and
standards for foods and beverages, food apparatus, food containers and packages, additives,
contaminants, and agrochemical residues, and prohibits the sale and imports of foods and
beverages containing harmful substances. The Food Sanitation Act also sets the monitoring
guidelines, plans, and inspection measures for both domestic and imported foods and beverages,
and establishes penalties for failing inspections.

The Health Promotion Law (Japanese only), also under the jurisdiction of MHLW, aims to
improve public health by setting guidelines and implementing measures to promote people’s
improved health. One of the measures is promoting nutrition management, under which a

\(^1\) The Act was revised in June 2018 and MHLW enforcement of most revisions will not begin until 2020. The major
revisions pertaining to imported foods that have been proposed are to require public health attestations for dairy
products and some seafood (e.g., puffer fish and fresh consumption oyster) and Hazard Analysis Critical Control
Point (HACCP) based sanitation management for some products such as meat (see JA8103). The revision also
includes the introduction of a positive list system for food container and packaging materials (see JA8045).
system to label “Food for Special Dietary Uses” is established (Prime Minister’s approval is required for labeling for foods that are suitable for special dietary uses for infant, children, pregnant women, sick people, etc.).

The Law concerning Standardization etc. of Agricultural and Forestry Products (JAS Law) which is administered by the Ministry of Agriculture, Forestry and Fisheries (MAFF), is a voluntary quality assurance system for foods, beverages (excluding alcohols) and forestry products.

The Plant Protection Law and the Act on Domestic Animal Infectious Diseases Control are also administered by MAFF as Japan’s national plant protection and animal health authority. Both laws aim to prevent pests and diseases from spreading and establishing in Japan by requiring inspections for domestic and imported plants. Both also establish import control policies.

The Food Labeling Law, which is under the purview of the Consumer Affairs Agency (CAA), sets food labelling standards (e.g., Countries of Origin Labeling requirements, allergen labeling, expiration date labeling, foods with functional claims, etc.) as well as penalties in the event of a violation.

Section II. Food Additives Regulations

Food additives are regulated under the Food Sanitation Act which only permits those food additives which are assessed and designated as safe by MHLW for use in food and beverages (i.e., a positive list system). Imported products found to contain residues from unapproved additives will not be permitted for sale.

There are four categories of additives: Designated Additives, Existing Additives, Natural Flavoring Agents, and Ordinary Foods Used as Food Additives. See MHLW’s website for definitions for these categories. It is important to note that an approved substance in the “Designated Additives” category may be limited to use on a specific product at a set level and only for a specific use. For a full list of substances approved as Designated Additives, as well as their approved uses and tolerances, please refer to the MHLW website listed above and the Japan Food Chemical Research Foundation’s (JFCRF) Standards for Use of Food Additives website. Compounds used as processing aids (such as infiltration-supporting agents) or antimicrobial treatments, vitamins, minerals and amino acids, and flavoring agents are defined as food additives under the Food Sanitation Act while these substances are not defined as food additives by the Codex Alimentarius Commission.

Among the four categories of food additives, the additives that often cause the most issues for regulatory non-compliance for U.S. products exported to Japan are “designated food additives.” Non-compliance with Japanese regulations can occur for various reasons, including a different levels/concentrations of use, limitations on the scope of use (e.g., the substance is allowed for all types of foods in the United States, but only for a limited scope of food in Japan), and/or specifications of the food additive. For additional information, please see the “Standards for

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2 The Food Sanitation Act defines “additives” as substances which are used by being added, mixed or infiltrated into food or by other methods in the process of producing food or for the purpose of processing or preserving food.
Use, according to Use Categories, effective from September 21, 2018” and refer to the columns entitled “Target Foods,” “Maximum Limits,” and “Limitation for Use.”

To facilitate customs clearance, the following information should be provided at the time of import:

1. The chemical names and content in parts per million (ppm) of all synthetic additives with tolerance levels set by MHLW;
2. Names of all natural food additives;
3. Artificial colors identified by their chemical name and international color index number. Natural color descriptions must also be provided to determine acceptability for the specific product exported; and,
4. Artificial flavors identified by their chemical name as they appear on the Japanese approved additive list for the specific product exported.

Food Additive Approval Process
MHLW reviews applications for the approval of new food additives and the approval of new uses (e.g., use of additives for new target foods) as well as the tolerances for additives that have been previously approved. Although MHLW is the contact point for the application, after a completeness check the application is sent to the FSC for a risk assessment of the substance. After completion of the risk assessment, the FSC reports the result to MHLW. MHLW, as the risk management body, then decides the specific application level for each food on the list of approved food additives. This is generally based on the concept of the acceptable daily intake (ADI) of the substance (which the FSC may propose to set), depending on the known toxicity of the substance. However, there have been cases where the FSC does not establish an ADI when the toxicity of the substance is indicated.

MHLW looks at all of the products in which a certain additive is used prior to granting approval. For example, a preservative approved at a certain level for margarine may not be approved as a preservative for mayonnaise, depending on the scope of the food category which the application covers (in case the estimated dietary exposure from existing applications is close to, or exceeds, its ADI). In the above example, for the additive to be approved for use in mayonnaise, an applicant would have to supply MHLW with the relevant technical data to demonstrate that additional use would not exceed the ADI. The application procedure for approval of new food additives or new uses of approved additives is described in detail in MHLW’s Guidelines for Designation of Food Additives and for Revision of Standards for Use of Food Additives.

In 2014, MHLW established the Food Additive Designation Consultation Center (FADCC) to assist companies with applications for food additive use in Japan. MHLW has noted that the FADCC, located in the National Institute of Health Sciences and staffed by former food additive regulatory specialists, will help companies to prepare more complete applications, thereby reducing the time to obtain regulatory approval. The FADCC provides consultations free of charge; however all interaction must be face-to-face. Since interactions are only in Japanese, the FADCC requests that non-Japanese applicants be accompanied by an interpreter, as necessary.
Additives in Alcohol

Additives used in alcoholic beverages require additional approval by Japan’s National Tax Agency (NTA) under the Liquor Tax Act (in Japanese only). Per Japan’s Food Sanitation Act, MHLW approval is required before an application can be submitted to the NTA. The NTA’s requirements (in Japanese only) for applications are as follows:

1. Name of the material to be specified;
2. Item of liquor that the additive will be blended with;
3. Purpose of use;
4. Usage guidelines;
5. Efficacy and component analysis;
6. Production method;
7. Name of the commercial product for which the material to be specified will be used, names of all the constitutive materials and their respective weights;
8. Manufacturer’s name and address; and,
9. Sales agency’s name and address.

Section III. Pesticides and Other Contaminants

On May 29, 2006, Japan introduced a positive list system\(^3\) for agricultural chemical residues, feed additives, and veterinary drugs (hereinafter referred to as agricultural chemicals) in food under the Food Sanitation Law. Upon implementation of this system, MHLW announced provisional maximum residue levels (MRLs) for 758 agricultural chemicals, in addition to roughly 10,000 existing official MRLs. These MRLs remain “provisional” until they are reviewed, and while many have already finished the process, reviews of the remaining MRLs will continue until completion of the project. Since 2006, MHLW has requested the FSC to perform risk assessments for a total of 599 of 758 substances, 447 of which had been completed as of October 30, 2018. Together, the approved MRLs and the provisional MRLs make up the “positive list.” Foods found to contain residues that exceed the MRLs on the positive list are considered in violation of the Food Sanitation Act and are barred from entering Japan at the port.

A single violation can lead to “enhanced monitoring” (increasing the inspection rate to 30 percent) for all imports of the same product from that country. After reaching 60 clean tests (among the entire industry, excluding the violator), MHLW will lift the enhanced monitoring. Alternatively, if no further detection occurs for one year following the initial violation, even if the requirement of 60 clean tests has not yet been reached, the 30 percent enhanced industry-wide monitoring can be lifted.

At the same time, MHLW will hold and test 100 percent of the violator’s (exporter’s) shipments, during which each shipment of the same commodity from the exporter has to be tested by Japan to show the residue level is below the Japanese acceptable MRL before clearing.

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\(^3\) The system establishes maximum residue limits (MRLs) for the combination of a substance and a crop, and prohibits the distribution of foods that contain agricultural chemical residues above established MRLs, and residues above a certain level if MRLs have not been established.
customs. After 60 clean tests from the violating exporter, MHLW will lift the 100 percent hold and test requirement. Additionally, the 100 percent hold and test policy on the violating exporter can be lifted after one year from the date of the initial violation, even if the requirement of 60 clean tests has not yet been reached, if there are no additional detections. For additional information, please consult “(2) Imported Foods Monitoring and Guidance Plan” found at MHLW’s “Imported Foods Inspection Services Home Page.”

After two violations of a specific MRL by two different operators, all imports of the same product from that country may be subject to an “Inspection Order” (100 percent hold and test). In this case, MHLW requires 300 clean tests in one year, or two years with no further violations, before lifting the “Inspection Order.”

For chemical-commodity combinations that have no official or provisional MRLs, a uniform tolerance of 0.01 ppm as the maximum allowable limit for most chemicals is applied. Please note that MHLW has also listed 20 agrochemicals and other chemical substances known as "not detected" (i.e. zero tolerance) that are banned from use in foods. In addition, there are 71 exempted substances that have been determined to not pose adverse health effects.

MHLW has established its own crop categorization for the designation of MRLs, which may differ from U.S. crop categorizations (see MHLW Food Classifications). For a comparison of U.S. and Japanese MRLs, see the Global MRL Database™.

For residues in processed foods that do not have specific MRLs, MHLW will test the product based on the relative proportion of ingredients to that of the final product. Therefore, U.S. exporters may to be asked for recipes or the percentage of the ingredients concerned.

Additional information about Japan’s positive list system, including actual MRLs, can be found on MHLW’s Positive List System webpage (in English).

Monitoring of Chemical Residues
Monitoring for chemical residues is conducted by MHLW’s quarantine offices (for imported crops) and local government laboratories (for both imported and domestically produced crops, mostly collected from retail shelves). The purpose of the monitoring is to check whether crops and livestock products in the marketplace comply with established MRLs and other food safety regulations. Any product found to contain a substance in violation of MRL regulations will not be permitted for sale in Japan.

Since 1985, MHLW has conducted surveys of residues, including pesticides and veterinary drugs without MRLs, to obtain basic data for the establishment of MRLs. For additional information, the Japan Fiscal Year (JFY) 2016 report can be found on MHLW’s website. Monitoring test results generally indicate that less than 0.1 percent of the samples tested are above the established MRLs. Crops not meeting the standards and specifications of the Food Sanitation Act, including MRLs, must be discarded, re-exported, or re-directed to non-food use. Each year MHLW develops a specific monitoring plan, and after a violation, a modified monitoring plan will be issued.
Establishment of MRLs for Agrochemicals

To establish an MRL, concerned parties must submit an application to MHLW, which will go through an extensive review process, including a risk assessment by the FSC. The documentation required for evaluation usually includes data on acute toxicity, sub-acute toxicity, chronic toxicity, carcinogenicity, reproductive toxicity, teratogenicity, mutagenicity, pharmacokinetic and general pharmacological parameters, animal metabolism, and plant metabolism, as well as residue data (for commodities treated with target pesticides). Details of the application procedure for establishment and revision of MRLs used outside of Japan are available on MHLW’s website.

Please note that the executive summary of the application should be in Japanese, but other accompanying documents, such as study reports, may be written in English. MHLW does not require translation of the original reference articles.

In 2013, MHLW began accepting applications for Import Tolerances even if the MRL for an agrochemical has not yet been finalized in the exporting country. The current system allows for the review process to begin 12 to 15 months earlier than the prior system which previously required the establishment of a standard in the exporting country. For additional information, please see JA3023.

Other Contaminants and Contributing Factors of a Violation

Officials look for the following items in foods susceptible to naturally occurring harmful substances or that may be contaminated with harmful substances or germs during the manufacturing process. Please note that the list includes some items for which MHLW no longer requires testing. However, MHLW may test for these again, at any time, as they are still under the inspection order:

1. Aflatoxin levels in peanuts, peanut products (including peanut butter), pistachios, processed products containing pistachios (30 percent or more), other tree nuts, spices, and some grain products such as corn;
2. Enterohemorrhagic E. coli O26, O103, O111 and O157 (beef, horse meat, and unheated meat products to be consumed without further cooking, such as natural cheese);
3. Norovirus (bivalves and other shellfish to be eaten raw);
4. Hepatitis A Virus (bivalves and other shellfish to be eaten raw);
5. Mercury (fish and shellfish);
6. PCB (beef, pork, fish and shellfish);
7. Poisonous fish;
8. Shellfish poisons (diarrhea poison and paralytic poison of bivalves);
9. Cyanogen (butter beans, white beans, saltani beans, etc.);
10. Methanol in distilled liquors and wines;
11. Gossypol in cottonseeds other than for oil extraction;
12. Salmonella in meat meant to be consumed raw;
13. Listeria (unheated meat products to be consumed without further

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4 A procedure to introduce foreign MRLs to Japan.
cooking and natural cheese);
14. Trichina in game birds, etc;
15. Radioactive substances, usually in foods of European origin; and,
16. Decomposed or deteriorated foods of all kinds.

Irradiation
Although irradiation is used as a tool to eliminate foodborne pathogens and prevent food poisoning in many countries, it is not permitted in Japan. The one exception to this rule is potatoes, which may be irradiated to suppress germination (and which also must be labeled). Irradiation inspection is conducted for a wide range of foods including (but not limited to) livestock foods (e.g., meats and dairy), seafood (e.g., fish and shellfish), agricultural foods (e.g., vegetables, fruits and nuts) and processed foods containing livestock, seafood and agricultural products.

For further details, please refer to section IV-vii of the “Implementation of Imported Foods Monitoring Plan for FY 2018”. Please also see “Schedule 1” from the above-referenced “Implementation of Imported Foods Monitoring Plan for FY 2018.” This schedule lists items subject to irradiation inspection as well as their monitoring frequency in a given year.

Section IV. Packaging and Container Regulations

In accordance with Article 16 of the MHLW Food Sanitation Act:

No person shall sell, manufacture, or import with the intent to sell or use in business any apparatus, container, or package which contains or bears toxic or injurious substances and may injure human health, or any apparatus, container, or package which may injure human health by having harmful influence on foods and additives through contact therewith.

MHLW has established specifications for synthetic resins, metal cans, and containers/packages made of glass, ceramic, enamel, or rubber. For further details, please refer to the following information sources:

1. Chapter I - Food, Additives, Apparatus and Containers and Packaging under the Ordinance for Enforcement of the Food Sanitation Act;
2. Chapter III - Apparatus and Containers and Packaging under the Food Sanitation Act; and,

Private industry is required to pay all costs associated with recycling. For imported products, part of the recycling cost is borne by importers, who are also responsible for making sure that there are appropriate recycling labels on all packaging and containers used for imported goods. However, some Japanese importers may ask their overseas suppliers to assist in supplying appropriate recycling labeling. More details can be found on the Ministry of Economy, Trade and Industry’s website and in JA3022.
In June 2018, the Government of Japan revised the Food Sanitation Act to introduce a positive list system for food packaging materials (for additional information, see JA8045). The positive list targets synthetic resins used in the manufacture of food containers in Japan, and the containers used for foods imports. MHLW is compiling a provisional list of container materials used by domestic industry and foreign suppliers. MHLW intends to implement the new system in JFY 2020 (April 2020 – March 2021), at which time only packaging materials whose safety has been assessed, and that MHLW has designated for use, will be permitted in the Japanese market.

Section V. Labeling Requirements

Mandatory Processed Food Labeling

The Japanese Diet established a comprehensive Food Labeling Law on June 28, 2013 (for additional information, see JA7078). The law requires that the label on retail packages for imported processed food products include the following information in Japanese:

- Name of the product;
- Country of origin of the finished product;
- Name and address of the importer;
- Ingredients, other than additives, in descending order of weight percentage;
- Food additives in descending order of weight on a separate line from other ingredients;
- The net weight in metric units only. A system of average net weight tolerances of packages or certain commodities is set by the Measuring Law;
- Best-before date (see instruction);
- Storage instructions;
- Labeling of certain genetically engineered (GE) ingredients as “GE” or “GE non-segregated” where the genetically modified content of the labeled ingredient is not identity preserved (for additional information on current GE labeling requirements, see Table 4 of JA6050, but note that these requirements are under revision as explained below);
- Allergen labeling
  - As required by the CAA on foods containing any of the seven ingredients known to cause significant allergic reactions: shrimp, crab, wheat, buckwheat, egg, dairy products, and peanut. The CAA also recommends that any of the following 20 additional allergens be listed on the label when present in the food: abalone, squid, salmon roe, orange, cashew nut, kiwi fruit, beef, walnut, sesame, salmon, mackerel, soybean, chicken, banana, pork, matsutake mushroom, peach, yam, apple, and gelatin (see details).

The minimum font size required for labels is principally 8-point for characters. It is recommended that the importer double-check the labels to ensure conformity. Please note that the development and approval of all labels compliant with Japanese food labeling regulations are the sole responsibility of Japanese importers. Application of Japanese language labels in the United States may be requested by Japanese customers, but is not required by the GOJ.
Mandatory Fresh Food Labeling
Fresh food products have only general labeling obligations (with special labeling obligations for certain food items\(^5\)): name of the product and its country of origin are mandatory. If the food is genetically engineered or irradiated there may be additional labeling requirements (see below).

Food Additives
The labeling of food additives, including post-harvest fungicides, is mandatory in Japan and administered by the CAA. Japan’s requirements mandate that most additives be labeled by their substance names (e.g., DL-Alanine), but some must be labeled with their function and substance name (e.g., preservative (sorbic acid)). In an effort to facilitate consumer understanding, however, there are additional exceptions. Some substances are allowed to be labeled using their more commonly known names (e.g., “Vitamin C” instead of “Sodium L-ascorbate”) while others are permitted to be labeled using their collective names (e.g., flavoring agents, acidifiers, etc.). Details on Japan’s specific labeling requirements can be found on the CAA’s website (in Japanese only) and on the Japan External Trade Organization’s (JETRO) website (at page 21).

Biotech Labeling Requirements
Currently three types of GE claims may be made on food labels in Japan: Non-GE, GE, and Non-segregated. Non-GE labeling is voluntary, but GE and non-segregated labeling are mandatory if the products are classified as such. To make non-GE labeling claims about foods or ingredients, the commodities must be handled under an identity preservation system and segregated from other GE and non-segregated products. Also the non-GE product (e.g., grains) cannot contain more than five percent of GE components. If test results demonstrate more than five percent of GE components are contained therein, the product needs to be labeled as non-segregated. If the product is identity-preserved as GE, it has to be labeled as GE. If the product is distributed without identify preservation (either as GE or non-GE), it has to be labeled as non-segregated (regardless of the percentage of GE or non-GE in the product).

Note: Readers are encouraged to review the “Imminent Changes to Japan’s Labeling Requirements” section below to familiarize themselves with changes that are expected to Japan’s biotech labeling requirements.

Country of Origin Labeling (COOL) for Certain Ingredients
There are 22 food groups and five food items for which country of origin labeling (COOL) requirements are in effect for ingredients used in foods manufactured in Japan (see Appendix II herein or the CAA’s website (in Japanese only) for the full list). This requirement is not mandatory for imported processed foods (just the country of origin of the finished product itself).

Note: Readers are encouraged to review the “Imminent Changes to Japan’s Labeling Requirements” section below to familiarize themselves with changes that are expected to Japan’s COOL requirements.

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\(^5\) These certain food items include: 1) rice, 2) beans which contain cyanide, 3) shiitake mushroom, 4) citrus, 5) meat, 6) milk, 7) eggs with shell, 8) seafood, 9) processed seafood for raw consumption (excluding oysters and pufferfish), 10) pufferfish for cooking, 11) pufferfish for raw consumption, 12) frozen fresh seafood, and 13) oysters for raw consumption. For additional information, see the CAA’s website (in Japanese only).
Alcoholic Beverage Labeling
Japan’s Liquor Tax Act defines alcoholic beverages as beverages with an alcohol content of one percent or higher (those that contain less than one percent are handled as soft drinks). The labeling of alcoholic beverage is governed by the Food Labeling Law, and more specific administrative instructions for alcohol labeling are stipulated under the Act on Securing of Liquor Tax and on Liquor Business Associations (in Japanese only). Labeling requirements vary depending on the category to which the exported alcoholic products are classified. For a summary of alcohol beverage labeling requirements, please see “Section II. Labeling” for alcoholic beverages published by JETRO in 2011. The NTA also provides more contemporary detailed explanations on alcohol labeling regulations (in Japanese only) and answers to frequently asked questions (in Japanese only).

On October 30, 2018, the NTA implemented “Labeling Standards for the Manufacturing Process and Quality of Wine, etc.,” Japan’s first national wine product labeling standards (see JA5020 and JA8092). Under these new standards, a “Japan Wine” label will be permitted for wine that is produced and bottled in Japan and which only uses grapes harvested in Japan. Wines produced in Japan, but using imported ingredients will now be labeled as “Domestically Produced Wine.” More information about alcoholic beverage labeling can be found on the NTA’s website (in Japanese only) and on JETRO’s website.

Animal Products
Japanese importers are responsible for appropriately labeling meat and meat products in the Japanese market. Labels that comply with Japanese food labeling regulations are generally not required for imported meat and meat products to successfully clear through customs and quarantine inspections. However, a Japanese importer may ask a U.S. producer for detailed product information (including ingredients and processing diagrams) in order to develop an appropriate Japanese language label and/or to ensure that MAFF and MHLW quarantine officials have sufficient information to evaluate the product for Japanese regulatory compliance. Most animal products exported to Japan from the United States are required to be accompanied by official USDA-issued export certificates. For a list of required certificates, please consult the 2018 FAIRS Export Certificate Report. Exporters are also advised to consult the following websites: FSIS Export Library – Japan and APHIS iREGS.

Voluntary Nutritional Labeling and Nutrition Claims
Manufacturers/importers can emphasize nutritional claims, such as “rich in”, “containing” or “enhanced.” To do so, however, they must meet minimum content level standards required by the Food Labeling Standards Appendix Table 12 (in Japanese only). Claims that include the terms “no”, “less” or “reduced” with regard to calories, fat, saturated fatty acid, cholesterol, sugar or sodium, must also meet maximum content standards required by the Food Labeling Standards Appendix Table 13. For example, when a “no sodium” or “low or less sodium” claim is made, the sodium content must be lower than 5 mg and must not be greater than 120 mg per 100 g of food, respectively. When a “no fat” or “low or less fat” claim is made, the fat content must be lower than 0.5 g and must not be greater than 3 g per 100 g of food, respectively. For additional details, see the CAA’s website (in Japanese only).

Foods with Health Claim and for Special Uses
Japan has strict rules on functional and nutritional claims on food labeling. It is not allowed to
claim health functions for general food products.

Under the Health Promotion Law, food products, which are approved for special dietary uses, are certified as Food for Special Dietary Uses (FOSDU) and required to label a FOSDU/FOSHU logo. The categories of FOSDU include 1) foods for sick people, 2) powdered formula for pregnant/lactating women, 3) infant powdered/liquid formula, 4) foods for the elderly with difficulty in swallowing/masticating and 5) Foods for Specified Health Uses (FOSHU).

FOSHU is a subset of FOSDU and refers to foods containing ingredients with functions for health and officially approved to claim physiological effects on the human body. FOSHU is intended to be consumed for the maintenance and/or promotion of health or special health uses by people who wish to control certain health conditions, including blood pressure or blood cholesterol. In order to sell a food as FOSHU, the assessment for the safety of the food and effectiveness of the functions for health is required, and the claim must be approved by the CAA and cleared by MHLW. Additional information can be found in JA5025 or on the CAA website (in Japanese only).

When certain supplemental nutrition on the Food Labeling Standards Appendix Table 11 (Japanese only) exists in the food products (processed food or fresh food), manufacturers and/or importers may emphasize health claims (Foods with Nutrient Function Claims (FNFC)). The contained nutritional component must be between the minimum and maximum value on the Table. There is no need to submit documents to the government, but it is required to use identical wording (both claims and notes on the intake) from the Standards. Additional information can be found in JA5025 or on the CAA website (in Japanese only).

Food with Functional Claims (FFC) allows companies to display a product’s specific health benefit and an associated area of the human body on retail food packaging under the food business operator’s own responsibility. FFC not only includes processed products, but also fresh food. The FFC registration process is more affordable and faster than the registration process for Food for FOSHU. Additional information can be found in JA5025 and on the CAA’s website (in Japanese only).

Japan Agricultural Standard (JAS) Labels

6 Infant liquid formula was newly added on August 8, 2018. See details in JA8062.
The voluntary JAS labeling system for food and forest products allows sellers to identify certain product specifications which meet quality standard expectations for Japanese consumers. MAFF amended the JAS Law on June 16, 2017, to allow the display of JAS labels for production, handling, and testing methods. The revision also allows private interests to propose new JAS standards. Additional information can be found in JA8095 or on MAFF’s website.

Misleading Representations
Any products sold in Japan must follow the Act against Unjustifiable Premiums and Misleading Representations (established in 1962) monitored by CAA. Misleading representations are strictly prohibited by the law. For additional information, see the CAA’s website.

Forthcoming Changes to Japan’s Labeling Requirements
Nutritional Labeling: The Food Labeling Law’s nutritional labeling requirements have a five-year transition period and do not go into effect until April 2020. At that time, nutritional labeling will be mandatory for five basic nutritional components in processed foods: 1) calories (kilocalories); 2) protein (grams); 3) fat (grams); 4) carbohydrate (grams); and 5) sodium (salt equivalent grams). Once in effect in 2020, the CAA also recommends labeling the amount of saturated fat and dietary fiber, but these recommendations are not mandatory. Labeling other nutritional components, such as fatty acids, cholesterol, sugars, minerals, and vitamins is also voluntary. However, if a certain nutritional component is shown on the package of a product, it is required to include the nutritional component on the label (see “voluntary labeling” section below). The content of each component per unit of food can be decided but must be provided (e.g., 100 g, 100 ml, 1 serving (need to specify), etc.). Note the U.S. nutritional fact panel is not acceptable, and thus manufacturers/importers need to convert nutritional values into the Standard’s format.

Country of Origin Labeling (COOL) Requirements for Ingredients: Japan’s COOL requirements for ingredients were amended on September 1, 2017, and will be fully implemented in Japanese Fiscal Year 2022 (which begins April 1). The rule change requires Japanese food manufacturers to identify the country or countries where the main ingredient, by weight, was manufactured on the label of all domestically produced products. This requirement will not be mandatory for imported processed foods (just the country of origin of the finished product). For additional details on the revisions to Japan’s COOL labeling requirement, please see the CAA’s website, JA7048 and JA7132.

GE Food Labeling: In April 2017, the CAA initiated a review of Japan’s GE labeling requirements and focused on three specific topics for review: 1) the types of foods to be labeled, 2) the threshold for requiring GE labeling, and the 3) the appropriateness of “non-GE” labeling. On March 14, 2018, the CAA’s Expert Committee concluded its review and proposed: 1) “Non-GE” labeling be allowed only when there is no detection of GE, 2) identity preserved (IP) products with inadvertent GE content of up to five percent (which had been permitted to be labeled as “non-GE”) should have a new description, such as
“Identity preserved to avoid commingling of GE ingredient,” to more precisely represent the products, and 3) non-IPed products (currently described as “non-segregated”) should have a different designation to more precisely represent the products. For additional information, see JA8017 and JA8082.

Section VI. Other Specific Standards

Foods from Biotechnology
The GOJ requires both an environmental and food safety assessment of GE products before they can be exported to Japan. No food or beverages or their ingredients may contain “materials” produced through recombinant DNA techniques that have not been approved by the GOJ. As of November 26, 2018, Japan has approved 319 GE events for food use (see MHLW’s website).

MHLW coordinates Japan’s food safety assessment for GE plants and animals. Upon receipt of an application that has been prepared in accordance with guideline requirements, MHLW will ask the FSC’s expert committee to begin a risk assessment to determine biological characteristics and the potential impact on public health. MHLW and the FSC maintain a science-based approval process. Varieties of genetically engineered plants that have been approved include soybeans, canola, corn, potatoes, sugar beets, cotton and papaya. MHLW monitors imports for unapproved varieties of biotechnology in order to enforce its zero tolerance for varieties whose safety has not been officially confirmed by the GOJ. Any shipment found to contain an unapproved variety may not be imported into Japan. Additional information can be found at JA8086.

Non-protein food additives produced by genetically modified organisms also have to be “checked” by MHLW and the FSC. Although the products (e.g., amino acids) are highly purified and contain no DNA fragment, the technical providers need to consult with MHLW on the level of purification and substantial equivalence with the products produced by conventional methods.

As the Japanese environmental safety review is based on the Cartagena Biosafety protocol, an environmental safety review – conducted by MAFF – is required only for living modified organisms (LMOs). Both the Biotechnology Innovation Organization and CropLife release product launch stewardship policies for their members to minimize regulatory discrepancies in approval timing with trading partners. MAFF also performs feed safety assessments (where appropriate) for biotechnology products.


NOTE: There is no precedent for GE animal review, and there is currently no FSC food safety review guideline for GE animals.
Organic Foods
Japan’s organic food standards were established in the Japan Agricultural Standards (JAS) Law, and are enforced by MAFF. The JAS Law, regulations pertaining to organic foods, and other food labeling regulations are available on MAFF’s website.

On January 1, 2014, the United States and Japan entered into an equivalency arrangement for organic plant products (including fungi and plant-based processed products). The arrangement does not include animal products or products for animal feed. However, effective April 26, 2017, Japan began to accept certified organic animal feed from countries that share organic equivalency with Japan (for additional information, see JA7059).

For additional details about the U.S.-Japan organic equivalency arrangement, please refer to the USDA/Agricultural Marketing Service (AMS)/National Organics Program (NOP) website.

Fruits and Vegetables and Unprocessed Grain Products
Certain fresh fruits and vegetables are currently prohibited under Japan’s quarantine law, including apricots, bell peppers, chilies, eggplant, peaches, pears, radishes, sweet potatoes and yams (see http://www.pps.go.jp/english/law/list2.html). For more information, contact your local APHIS office or consult the USDA-APHIS website.

Frozen Fruits and Vegetables That Are Permitted Entry
Frozen fruits and vegetables which are permitted entry by the Japanese government in their fresh form (not heated prior to freezing) may be certified by U.S. producers and exporters, state Departments of Agriculture, or USDA’s Agricultural Marketing Service. Certification requires that the following information be placed on the shipper’s invoice, which will accompany the product:

1. Date of product freezing;
2. Temperature of freezing (must be at least zero degrees Fahrenheit);
3. Name and signature of responsible company official or representative;
4. Title of company;
5. Date of signature;
6. Name of company;
7. Product description; and,
8. Quantity of product being shipped.

It is possible that, if certain conditions stipulated in Article 32-4 of Ordinance for Enforcement of the Food Sanitation Act are met upon arrival of the initial shipment of a frozen product (e.g., no entry violations in the preceding three years, etc.), the GOJ may waive the document and/or inspection requirements for all subsequent shipments for a period of one year.

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8 Port official acceptance may be subject to verification.
Forest Products
As previously noted, the JAS is a voluntary but widely used product standard system administered by MAFF. When forest products are used for construction, Japan’s Building Standards Law (BSL) requires that products are JAS certified. Products that are not certified to JAS must obtain approval from the Minister of Land, Infrastructure, Transportation and Tourism (MLIT); however, this process is costly and difficult. Accordingly, virtually all engineered wood products, such as glulam, laminated veneer lumber, or plywood, are certified to JAS. Currently, nine forest products have JAS Standards, and they are reviewed at a minimum of every five years (for additional information, see JA7131 and JA8028). JAS certification for product for export to Japan is overseen by a Registered Overseas Certified Body (ROCB). The current list of approved ROCBs can be found on MAFF’s website.

The BSL requires the use of JAS certified dimension lumber for 2x4 construction, but MLIT also recognizes graded lumber products of North American grading agencies (e.g., Pacific Lumber Inspection Bureau, West Coast Lumber Inspection Bureau, Western Wood Products Association, and others) as being equivalent to JAS. Some engineered products, such as wood-plastic composites, preserved lumber, and fireproof lumber, are subject to the Japan Industrial Standards (JIS), a voluntary standard system administered by the Japanese Industrial Standards Committee.

Japan’s Ministry of Environment administers the Green Purchasing Act, which mandates a verification of the legality of wood products used in government-funded projects. The guidelines for verifying the compliance of wood products are available at: https://www.goho-wood.jp/world/outline/doc/outline.pdf. Private-sector solutions to verifying legality, such as the American Hardwood Export Council’s Responsible Procurement Policy, may be one strategy for compliance with this policy.

On May 20, 2017, MAFF’s Forestry Agency implemented “the Act on the Promotion of Use and Distribution of Legally-Harvested Wood and Wood Products” (the Clean Wood Act, see JA7080 and JA8002). Although the registration system under the Clean Wood Act is voluntary, Japanese forest products buyers may request documentation from suppliers to demonstrate legality. More information about the Clean Wood Act is available at the Clean Wood Navi website.

Imported woody biomass, such as wood pellets, for biomass power facilities under the Feed-in Tariff scheme, requires proof of legality, such as chain-of-custody forest certification. The Forestry Agency suggests different ways to certify the woody biomass in the guideline at: http://www.rinya.maff.go.jp/j/riyou/biomass/hatudenriyou_guideline.html (in Japanese only).

Section VII. Facility and Product Registration
Establishments producing beef and beef products for export to Japan must be listed on the AMS Official Listing of Approved Suppliers for the USDA QSA Program for Japan under the LT30 QSA Program.

Establishments producing ovine and caprine meat and meat products (including lamb) for export to Japan must be listed on the AMS Official Listing for Ovine and Caprine Export Verification Programs for Japan.
Exporters of oysters for raw consumption and exporters or packers of oysters must be on the Interstate Certified Shellfish Shippers List (ICSSL).

There are no other specific facility registration requirements for export to Japan.

As described in the Import Procedures section below, quarantine and customs officials evaluate import notifications for individual shipments; there is no product registration requirement. However, MHLW administers several voluntary product registration processes that serve to expedite the import quarantine process. These programs are listed on the MHLW’s website. (Please note that these processes are customarily initiated by Japanese importers rather than U.S. exporters.)

Section VIII: Other Certification and Testing Requirements

There are several levels of testing which may be requested by the GOJ to facilitate importation into Japan.

Although, pre-export testing may not be required, it can be helpful in the case of a new or unknown product that will be exported to Japan. MHLW may recommend that a Japanese importer deliver a small sample of the product to the Japanese customs and MHLW port inspectors’ offices with a certificate guaranteeing compliance with required product regulations. During the review process, the Japanese official may request the importer to test the sample at a MHLW-registered domestic laboratory.

However, if the exporter/importer tests the product at an MHLW-registered laboratory in the United States, prior to shipment, and attaches the test results to confirm the product specification, the test at the port can be waived. For more information, see “U.S. Laboratories Certified by the Government of Japan” below.

Prefectural-level health authorities (with over 7,000 inspectors in Japan) also perform random tests on samples from domestic and imported products located in local retailers. For more information on the relationship between national and local government testing systems, please refer to MHLW’s website.

For information regarding what certificates are required for import, please refer to the December 2018 FAIRS Certification report available at: https://gain.fas.usda.gov/Pages/Default.aspx

Sometimes, there is confusion between the “test requirement by Japanese Government (or Japanese port officials)” and a test that an importer/distributor would like to establish confidence that a product meets Japanese food safety standards. It is worthwhile for exporters to understand the difference between the mandatory requirements in Japanese regulations versus a business decision by importers seeking to reduce their risk.

Laboratories Certified by the Government of Japan
MHLW has certified certain U.S. laboratories as eligible to test foods and beverages for compliance with Japan’s Food Sanitation Act for export to Japan. If an analytical certificate from a laboratory approved by MHLW accompanies the shipment, and the certificate is complete and satisfactory, no additional tests for the products will be required by MHLW when the product is inspected at the port of entry into Japan. A full list of MHLW-registered U.S. laboratories, a.k.a. “Foreign Official Laboratories”, is available on MHLW’s website.

To be added to the list of MHLW registered Foreign Official Laboratories, the laboratories have to be government affiliated laboratories or laboratories approved or designated by the government. The laboratories also must carry out inspection by internationally recognized methods (such as AOAC method). For details, please visit MHLW’s site for Foreign Official Laboratories.

**Section IX. Import Procedures**

Firms interested in importing food, food additives, containers/packages, or any other food related apparatus into Japan must submit a Notification Form of Importation of Foods, etc. to the Food Sanitation Inspection Section of the MHLW Quarantine Stations. The Quarantine Station will examine the product to determine if it conforms to the Japanese Food Sanitation Act. Products that require examination will be inspected on the spot at a designated bonded warehouse. Samples will be taken and forwarded for laboratory analysis. The product will be allowed entry into Japan once it is examined and found to be in compliance with Japanese food regulations. The Notification Form will receive a stamp of approval if the food requires no examination and is found to be in compliance with the Japanese Food Sanitation Law. Please refer to the flowchart below.

Additional details on food importing procedures can be found at: http://www.mhlw.go.jp/english/topics/importedfoods/1.html. JETRO’s detailed Q&A on imported foods may also be of interest and is available online at: https://www.jetro.go.jp/costarica/mercadeo/handbook_importedfoods.pdf
Procedures of Import Notification of Foods and Related Products

When products are imported as commercial samples or for “internal company consideration,” and it is clear that the products will be used to decide whether or not to import the product in the future, then the Notification Form is not required. However, depending upon the product and/or the Quarantine
Station, Customs officials may require a memorandum or other document attesting that the product is a sample only and to be used for “internal company consideration.” While there are no set restrictions on the volume of products permitted for entry as commercial samples, the volume should not exceed a reasonable or justifiable amount.

When products are being imported to only be exhibited at a trade fair and will be neither sold nor contracted for, then the Notification Form is not required. However, if the product is to be distributed to an unspecified number of individuals in the general public, even free of charge, then all standard import procedures must be followed, including import notification. As with commercial samples, depending upon the product and/or the Quarantine Station, Customs officials may require a memorandum or other document attesting that the product is only to be used “for exhibition at a trade fair.” While there are no set restrictions on the volume of products permitted entry for tradeshow exhibition purposes, the volume should not exceed a reasonable or justifiable amount.

It is recommended to consult with importers in advance of importation and MHLW quarantine stations, to minimize the possibility of delays or disruptions at the border.

**Required Importation Documents**

Import documents required for entry into Japan are as follows:

1. Import notification - two copies of Notification Form of Importation of Foods, etc;
2. Export certificate (if necessary);
3. Test results (if necessary);
4. Documents showing ingredients, additives and the manufacturing process (e.g., manufacturer’s certification) (if necessary), etc.


Cargo found in violation of the Food Sanitation Act must be re-exported, destroyed, diverted to non-food use (if applicable), or otherwise discarded. In addition, processed foods that are imported for the first time must contain additional documents with more detailed information than that stated on the import notification, including information about the raw materials, ingredients, and manufacturing processes. Importing companies should be able to guide exporters through the required steps and the appropriate level of detail needed for these documents.

**Advance Filing Rules for Maritime Container Cargo Information**

For risk assessment, Japan Customs requires shipping companies or Non-Vessel-Operating Common Carrier (NVOCC) to electronically submit information on maritime container cargoes to be loaded on a vessel intended for entry into a port in Japan, in principle 24 hours before departure of the vessel from a port of loading. Further information can be found at Japan Customs’ website.

**Section X. Copyright and/or Trademark Laws**

**Copyright and Trademark Laws**

International registration of trademarks under the Madrid Protocol is available in Japan. For more information on Japan’s trademark registration, please refer to the Japan Patent Office website.
Protected Geographical Indications

The “Act on Protection of the Names of Specific Agricultural, Forestry and Fishery Products and Foodstuffs” (Geographical Indication (GI) Act) protects the names of certain products as intellectual property and allows for the registration of foreign products for protection in Japan. A list of approved food, agricultural, forestry and fishery products GIs are available on MAFF’s website at: http://www.maff.go.jp/e/policies/intel/gi_act/register.html and http://www.maff.go.jp/e/policies/intel/gi_act/designation.html. A list of approved alcoholic beverage GIs are available at the National Tax Agency website at: http://sakefanworld.info/sake_GI/what_en.html. For additional information, see, e.g., JA5008, JA5016, and JA8065.

Regional Collective Trademarks

Since 2006, members of certain associations can own Regional Collective Trademarks, which consist of “the name of the region” and “the common name of goods or services.” As of February 2018, there were 621 registered regional collective trademarks, and 361 were food products (including three foreign products such as Canada Pork). Regional Collective Trademarks are different from GIs in that they have specific owners while GI products become common assets of a region. For additional information, see the Japan Patent Office website (in Japanese only).
Appendix I. Government Regulatory Agency Contacts

The following are names and address of offices you can contact to receive detailed information on regulations and requirements to import into Japan.

**Japan Customs**
Address: 3-1-1 Kasumigaseki, Chiyoda-ku, Tokyo

**Import Duties**
Import duties can be found at Japan’s Tariff Schedule. If you are not sure about product classification and the duties, you can make inquiries to the Customs Counselor Offices through email. The email addresses of Customs Counselor Office can be found at [http://www.customs.go.jp/question_e.htm](http://www.customs.go.jp/question_e.htm).


Customs Answer (FAQ) – Information on importation into Japan: [http://www.customs.go.jp/english/c-answer_e/customsanswer_e.htm](http://www.customs.go.jp/english/c-answer_e/customsanswer_e.htm)

**Ministry of Health, Labour, and Welfare (MHLW)**
Address: 1-2-2, Kasumigaseki, Chiyoda-ku, Tokyo

**Food Safety Standards** (Food additives, MRLs, etc.)

Standards and Evaluation Division
Department of Human Health and Environment Pharmaceutical Safety and Environmental Health Bureau
Tel: 81-3-3595-2341

**Food Safety Monitoring** (Imported Food Monitoring Policy)

Office of Import Food Safety
Department of Human Health and Environment Pharmaceutical Safety and Environmental Health Bureau

MHLW Quarantine Stations
[https://www.mhlw.go.jp/english/topics/importedfoods/1-2.html](https://www.mhlw.go.jp/english/topics/importedfoods/1-2.html)
Ministry of Agriculture, Forestry and Fisheries (MAFF)
Address: 1-2-1, Kasumigaseki, Chiyoda-ku, Tokyo

Animal Health and Quarantine
Animal Health Division, Food Safety and Consumer Affairs Bureau, MAFF
Tel: 81-3-3502-5994

MAFF Animal Quarantine Station: http://www.maff.go.jp/aqs/english/
11-1, Haramachi, Isogoku, Yokohama City, Kanagawa 235-0006
Inquiries can be sent to Animal Quarantine Stations listed at:

Plant Health and Quarantine
Plant Protection Division, Food Safety and Consumer Affairs Bureau, MAFF
Tel: 81-3-3502-5976

MAFF Plant Quarantine Stations: http://www.maff.go.jp/pps/j/information/languages.html#en
Address: Kitanakadori, Naka-ku, Yokohama City, Kanagawa 231-0003
Inquiries can be made through the website at:
http://www.maff.go.jp/pps/j/introduction/english_exp.html#faq

State-Traded Rice, Wheat and Barley
Grain Trade and Operation Division, Crop Production Bureau, MAFF
Tel: 81-3-6744-0585

Standards and Conformity Assessment Policy Office, Food Manufacture Affairs Division,
Food Industry Affairs Bureau, MAFF
Tel: 81-3-6744-7180

Forestry Products
Forest Agency, Wood Products Trade Office
Tel: 81-3-3502-8063

Fisheries Products
Japan Fisheries Agency, Fishery Products Trade Office
Tel: 81-3-3501-1961

Address: 3-1-1, Kasumigaseki, Chiyoda-ku, Tokyo, 100-8958
Tel: 81-3-3507-8800

Food Labeling Regulations
World Trade Organization (WTO) Enquiry Points
Standards Information Service International Trade Division Economic Affairs Bureau
Ministry of Foreign Affairs
Address: 2-2-1, Kasumigaseki, Chiyoda-ku Tokyo
Tel: (81) 3 5501 8344 (International)
Fax: (81) 3 5501 8343 (International)
Email: enquiry@mofa.go.jp

Each member government is responsible for the notification procedures associated with agreements under the WTO. Issues in this report relate to the Sanitary, Phytosanitary (SPS) and Technical Barriers to Trade (TBT) Agreements. WTO obligations include notifying to the WTO any significant trade-related proposals that are not substantially the same as international standards, providing copies of the proposed regulation upon request, allowing time for comments, and also providing upon request copies of other relevant documents on existing regulations related to food and agriculture. Information on Japan’s regulations, standards and certification procedures can also be obtained through the Enquiry Point listed below:

Additional Assistance can be obtained by contacting:

U.S. Department of Agriculture’s Office of Agricultural Affairs in Tokyo, Japan
Embassy of the United States of America
Office of Agricultural Affairs
Unit 9800 Box 475
DPO AP 96303-0475
Tel: 81-3-3224-5102
Fax: 81-3-3589-0793
E-mail: agtokyo@fas.usda.gov
Website: http://www.usdajapan.org/
Twitter: @USDAJapan
Appendix II – Current List of Ingredients for which Country of Origin Labeling is Required

Agricultural processed foods (9 food groups):
1. Dried mushrooms, vegetables and fruits (excluding those flaked or powdered)
2. Salted mushrooms, vegetables and fruits
3. Boiled or steamed mushrooms, vegetables, pulses and bean jams (excluding those canned, bottled or retort pouched)
4. Mixed vegetables, mixed fruits, other mixtures of vegetables, fruits and mushrooms (excluding those mixed without cut)
5. Green tea and packaged or bottled green tea beverage
6. Rice cake
7. Roasted shelled peanuts, roasted peanuts, fried peanuts and roasted beans
8. Sugar cane sugar and its products
9. Alimentary konjac products

Processed meat (5 food groups):
10. Seasoned meat (excluding those processed by heating, or those frozen after processed)
11. Boiled or steamed poultry meat and eggs (excluding those canned, bottled or retort pouched)
12. Slightly roasted meat
13. Prepared meat with deep-fry batter (excluding those processed by heating, or those frozen after heated)
14. Ground meats and other mixed meats (including meats or ground meats with their form shaped)

Processed seafood (8 food groups):
15. Unsalted and dried fish and shellfishes, salted and dried fish and shellfishes, boiled and dried fish and shellfish, tangle, dried laver, roasted laver and other dried seaweeds (excluding those chopped, minced or powdered)
16. Salted fish, shellfishes and seaweeds
17. Seasoned fish, shellfishes and seaweeds (excluding those processed by heating, those frozen after heated and those canned, bottled or retort pouched)
18. Kelp roll with fish
19. Boiled or steamed fish, shellfishes and seaweeds (excluding those canned, bottled or retort pouched)
20. Slightly roasted fish and shellfishes
21. Prepared fish and shellfishes with deep-fry batter (excluding those processed by heating, or those frozen after heated)

Combination food (1 food group):
22. Mixtures of fresh foods other than those described in 4 and 14 (excluding those mixed without cut)

Individual food item (4+1 food items):
23. Pickled vegetables
24. Frozen vegetables
25. Processed eels
26. Fried bonito flakes
27. Rice ball

Source: CAA’s website