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Voluntary - Public

Date: 5/29/2019

GAIN Report Number: JA9058

Japan

Post: Tokyo

Japan 222nd Food Safety Group

Report Categories:

Sanitary/Phytosanitary/Food Safety

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Report Highlights:

On May 24, 2019, Japan's Ministry of Health, Labor and Welfare (MHLW) announced revisions to Japan's Food Sanitation Act and other relevant ordinances. Since these amendments are currently notified to WTO as [G/SPS/N/JPN/638](#) and [G/TBT/N/JPN/625](#), there will be no exclusive comment period for embassies in Japan. Interested U.S. parties are encouraged to share their comments and/or concerns with USDA's enquiry point (us.spsenquiry@fas.usda.gov). For potential inclusion in the U.S. official position, please send your comments by June 10, 2019.

Keyword: JA9058

General Information:

(The following is taken from Japan's distribution at the 222nd Food Safety Group Meeting)

<The manner of submitting comments>

The Ministry of Health, Labour and Welfare (MHLW) will amend the Cabinet Order and Ordinance for Enforcement of the Food Sanitation Act and other relevant ordinances as shown in this document. Please provide comments in writing by **Thursday, June 6, 2019**. After the given date, comments should be directed to the enquiry point in accordance with the WTO/SPS Agreement and the WTO/TBT Agreement.

The SPS notification for the Agenda Item 1 was published on April 25, 2019. For (d), the TBT notification was also published on April 24, 2019.

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Item 1. The amendment to the Cabinet Order and Ordinance for Enforcement of the Food Sanitation Act and other relevant ordinances

The government of Japan is planning to amend the Cabinet Order and Ordinance for Enforcement of the Food Sanitation Act and other relevant ordinances in order to enforce the amendment to the Food Sanitation Act (hereinafter referred to as “Act”) promulgated in June 2018.

Background

- The amendment to the Act was established in June 2018 and its summary was previously informed to the WTO as G/SPS/N/JPN/552 in January 2018.
- In response to the establishment of the amendment to the Act, the government of Japan is planning to amend the Cabinet Order and Ordinance for Enforcement of the Food Sanitation Act and other relevant ordinances to introduce food hygiene control based on HACCP principles to food business operators, to ensure safety of imported foods and legalize administration related to food export, to improve sanitary regulations for utensils, containers and packaging, to revise the licensing system for food business, and to establish a notification system for food business and a reporting system for food recalls.
- Cabinet Order and Ordinance for Enforcement of the Food Sanitation Act and other relevant ordinances will be amended in the summer of 2019. Most of these amendments will come into effect in the summer of 2020*.

*(d) and (e) will come into effect in the summer of 2021.

Outline of the amendments

<Cabinet Order and Ordinance for Enforcement of the Food Sanitation Act (hereinafter referred to as “the Cabinet Order” and “the Ordinance” respectively), Ordinance for Enforcement of the Slaughterhouse Act, and Ordinance for Enforcement of the Poultry Slaughtering Business Control and Poultry Meat Inspection Act (hereinafter referred to as “the Poultry Processing Act”)>

(a) Requirement of food hygiene control based on HACCP principles

- The standards for food hygiene control and its plan to be developed by food business operators are to be stipulated by Ordinance and Ordinances for Enforcement of the Slaughterhouse Act and the Poultry Processing Act and to be equivalent with the contents of the Codex General Principles of Food Hygiene (CAC/RCP 1-1969).
- Food business operators described in item (ii) of paragraph (1) of Article 51 of the Act (the ones for whom some flexibility is applied in terms of HACCP implementation) are to be specified by the Cabinet Order as follows, also taking into consideration of the Codex General Principles of Food Hygiene:

1. Among manufacturers or processors of food and food additives, the one with food handlers not exceeding 50 people at a facility;
2. Among manufacturers or processors of food and food additives, the one who retails food or food additives mainly in a shop adjacent to the facility where it manufactures or processes food or food additives;
3. food business operator who cooks food;
4. food business operator who stores, transports or sells packaged food or food additives only, or any other food business operator to be specified by the Ordinance as such who are able to conduct necessary hygiene control by following good hygiene practice stipulated in item (i) of paragraph (1) of Article 51 of the Act.

○ With regard to the hygiene control at slaughterhouses and poultry processing facilities, standard procedures for Prefectural governments to verify hygiene plans at facilities will be developed.

(b) Revision of licensing system and establishment of notification system for food business

- Reclassify the current 34 categories of food business requiring business license (such as catering, processing and manufacturing of specific food items *etc.*) into about 32 categories, for each of which facility criteria should be established by Prefectural governors according to the provisions of Article 54 of the Act.
- The facility criteria described in Article 54 of the Act will be stipulated by the Ordinance and they should be taken into consideration by Prefectural governors when establishing their own facility criteria. These facility criteria will be divided into general criteria covering all types of food business and business-specific criteria.

Exemption from notification

- Food businesses described in paragraph (1) of Article 57 of the Act as they are likely to impose low impact on public health and thus to be exempted from notification are to be specified by the Cabinet Order as follows:
 1. business which sells or stores packaged food or food additives resistant to decomposition or deterioration resulting in impairment of its safety when stored at room temperature for a prolonged period of time (including vending machines);
 2. business which does not directly handle food, such as food importers and sellers of utensils/containers/packaging for food and food additives;
 3. business which stores or transports food or food additives at the request of customers based on a contract (except cold-storage business);
 4. business manufacturing food utensils, containers and packaging (limited to food utensils, containers and packaging using materials other than those specified by paragraph (3) of Article 18 of the Act).

(c) Establishment of a reporting system for food recalls

Exemption from reporting a recall

- The conditions described in the chapeau of item (ii) of paragraph (1) of Article 58 of the Act as there is no concern of adverse health effects and thus to be exempted from reporting a recall are the cases where the food or food additive in question will already have passed its expiration date or best before date by the time when the food business operator recognizes any violation of the Act or its possibility.

Procedures for reporting of recalls for food business operators and Prefectural governors

- With regard to a recall, the items to be notified (by a food business operator to a Prefectural governor or by a Prefectural governor to the Minister of Health, Labour and Welfare), according to the provisions in paragraph (1) of Article 58 of the Act, are as follows:
 1. the name and address of the food business operator who conducts a recall (in the case of a juridical person, its name and the location of the office). If this food business operator is not a manufacturer of the food or food additives to be recalled, also the name and address of the manufacturer (in the case of a juridical person, its name and the location of the office);
 2. the trade name, the generic name, the contents of labelling and any other information necessary to specify the food or food products to be recalled;
 3. the reason why the food or food additives to be recalled is considered to fall under either item in paragraph (1) of Article 58 of the Act (the reason why the recall is necessary);
 4. the sales destinations, and sales date and quantity of each destination (identified at the point of the commencement of the recall);
 5. the date of commencement of the recall;
 6. the methods of the recall;
 7. with or without of actual cases of adverse health effects resulting from the consumption of the food or food additives to be recalled;
 8. (*for Prefectural governors only*) the degree of risk of adverse health effects which could be caused by the recalled food or food additives.

(d) Improvement of sanitary regulations for utensils, containers and packaging considering international consistency

- The material specified by the Cabinet Order according to paragraph (3) of Article 18 of the Act (The material subject to the Positive List: specifications and standards) is synthetic resin.
- The following issues are established according to the guideline for safety assurance in the manufacture etc. of food utensils, containers and packaging (https://www.mhlw.go.jp/english/topics/foodsafety/containers/dl/guidelin_e-english.pdf).

- ✓ The standards specified by the Ordinance according to item (i) of paragraph (1) of Article 52 of the Act (The standards of the prerequisite programs)
- ✓ The standards specified by the Ordinance according to item (ii) of paragraph (1) of Article 52 of the Act (The standards of Good Manufacturing Practice)
- ✓ Matters for information provision specified by the Ordinance according to paragraph (1) and (2) of Article 53 of the Act (Obligation to provide information by the business operators who manufacture and sell utensils, containers, and packaging; and obligation to make effort to provide information by the business operators who manufacture and sell raw materials)

Matters for explanation specified in paragraph (1) and (2) of Article 53 of the Act are as follows:

1. Information confirms the following points: the products using the materials specified by the Cabinet Order according to paragraph 3 of Article 18 of the Act are those specified in item (i) or (ii) of paragraph (1) of Article 53 of the Act, or the raw materials using the materials specified by the Cabinet Order are appropriate as raw materials used for the products satisfy the item (i) or (ii)
 2. Information confirms the subjects of above information 1
- The Positive List (specifications and standards) and the exceptions of regulations by the List (migration levels that are no concern relevant to human health) will be established separately.

(e) Ensuring safety of imported foods and Legalizing administration related to food export

- Products newly added to those which are specified by the Ordinance according to paragraph (2) of Article 10 of the Act (imported foods to which a health certificate must be attached) are milk and milk products, excluding butter oil, processed cheese, ice cream products, formulated milk powder, liquid infant formula, milk drink and products storable at room temperature (hereafter, “milk products”).
- For milk or milk products, the matters specified by the Ordinance according to paragraph (2) of Article 9 of the Act (matters to be described in an health certificate) are as follows;
 1. For meat, milk or organs of livestock or poultry, the types of livestock or poultry, and for meat products, milk or milk products, the names and the types of meat, milk or organs of ingredient
 2. The quantity and the weight
 3. The address and name of the consignor (for a juridical person, its name and location)
 4. The address and name of the consignee (for a juridical person, its name and location)

5. The following matters concerning the name, etc. of the agency which conducted the inspections
 - (1) For milk or milk products, the name of the agency which issued an certificate, or the name and title of the official who signed the certificate
 - (2) For meat products, milk or milk products, the production facility where said products were manufactured
 6. The fact that production of milk or milk product was carried out in a sanitary manner based on equal or better criteria than those of Japan for sale for human consumption
 7. The date (day and month) when the production of meat products, milk or milk products was carried out
- Regarding an health certificate for milk and milk products, the detailed information requested to exporting countries is described in Annex 1.
 - Foods specified by the Ordinance according to paragraph (1) of Article 11 of the Act (imported foods requiring hygiene control by HACCP) are meat and offal derived from livestock and poultry.
 - Procedures to designate exporting countries, regions or establishments by the Minister of Health, Labour and Welfare according to paragraph (1) of Article 11 of the Act are described in Annex 2.
 - Foods specified by the Ordinance according to paragraph (2) of Article 11 of the Act (foods requiring to demonstrate the status of hygiene control at the places of production in terms of food hygiene) are oysters for eating raw and puffer fish.
 - the matters specified by the Ordinance according to paragraph (2) of Article 11 of the Act (matters to be certified for foods requiring to demonstrate the status of hygiene control at the places of production in terms of food hygiene) are as follows;
 1. For puffer fish, the type (scientific name)※
 2. The quantity and the weight
 3. The address and name of the consignor (for a juridical person, its name and location)
 4. The address and name of the consignee (for a juridical person, its name and location)
 5. The name, address and registration number of the facility where processing or, for oysters for eating raw, purification is performed
 6. The following matters on waters where the product is harvested etc.
 - (1) For oysters for eating raw, the waters where they were harvested
 - (2) For puffer fish, the waters where it was caught※
 - (3) The fact that the product was processed in a sanitary manner
 7. The date of the following matters, e.g. harvest
 - (1) For oysters for eating raw, the harvest

(2) For puffer fish, the fishing

8. The fact that the product was processed in a sanitary manner based on equal or better criteria than those of Japan in the facility authorized by the government of the exporting country for oysters for eating raw and, for puffer fish, the facility supervised by the government

※ For puffer fish, the waters and the types are limited to ones authorized for export.

Contents which the MHLW requires to exporting countries on a health certificate for milk and milk products (draft)

1. Objectives of request for information

According to Item 2, Article 10 of the amended Food Sanitation Act, Japan requires countries exporting milk or milk products to Japan to attach a health certificate to them. MHLW needs to confirm that exporting countries can demonstrate that milk or milk products exported to Japan meets requirements under the Act, such as “milk and/or milk product has been produced from raw milk obtained from healthy animals” and “the fact that production was carried out in a sanitary manner based on equal or better criteria than those of Japan”. For this purpose, MHLW will request the exporting countries to provide information on its laws and regulations related to such food.

2. Information requested

MHLW will ask exporting countries to provide answers to the following questions (Yes or No, or description) with indicating the relevant provision number of the relevant laws and regulations, and to attach copies of such laws and regulations.

1. Laws and regulations regulating milk and milk products

I-1. Outlines of regulations on milk and milk products (the names of the relevant laws and regulations, provisions covering requirements to be certified, such as “milk and/or milk product has been produced from raw milk obtained from healthy animals” and “the fact that production was carried out in a sanitary manner based on equal or better criteria than those of Japan” etc.)^{*}

- * Particular information to be included in the relevant laws and regulations
 - Standards for milk processing plants and milk product manufacturing plants
 - Standards on hygiene control in such plants (if they are in alignment with the Codex relevant guidelines (CAC/RCP1-1969、CAC/RCP57-2004) , provide the information)
 - Specifications of milk and milk products (general and by each item), standards for manufacturing and storage, standards for use of food additives and standards for packages

I-2. The scope of milk and/or milk products in the relevant regulations in the exporting country

I-3. Whether or not milk and/or milk products imported from other countries are used as ingredients for milk and/or milk products exported to Japan (if yes, the way to make sure that the ingredients are processed or manufactured in a sanitary manner)

II. Official control systems for manufacturing and exporting milk and milk products

- II-1. The name of competent authorities (CAs) in charge of development and implementation of the regulations above, the organization chart and the number of officers involved
- II-2. Systems of supervision and inspection by CAs for processing plants (relationship between national and local governments, whether or not there is their competence of inspection and on-site investigation etc.)
- II-3. Whether or not processing plants shall not be established without permits from the CAs (if yes, whether or not the CAs concerned may cancel permits)
- II-4. The CAs and procedures to issue a health certificate (whether or not the exporting country has already issued it for export to other countries)
- II-5. Existing formats of health certificates to other countries and Japan (related to animal health)
- II-6. How to make sure to use raw milk obtained from healthy animals (e.g. guidance to farmers, test of raw milk etc.)

III. The status of introduction of HACCP based hygiene control

- III-1. Whether or not hygiene control based on HACCP is obliged in the exporting country (if yes, whether or not any guideline on HACCP-based hygiene control is developed by the government or industry associations. If yes, please provide the guideline.)

IV. The status of implementation of official observation by competent authorities and hygiene control by facilities (including the status of compliance with the relevant laws and regulations)

- IV-1. The number of processing plants in the exporting country (the latest data), the number of supervision/inspection for them and the results (for the last three years)
- IV-2. Voluntary test program that owners of processing plants implement to ensure compliance with the relevant regulations
- IV-3. Sampling and test program on microorganisms, residues of antibiotics, specifications (e.g. alcohol test) etc. for export of milk and/or milk products, and the test result for the latest one year (if such program applies to all products, regardless domestically distributed or exported, test results of domestic ones can be included in the data)
- IV-4. Summaries of issues that have occurred in the past year (non-compliances with the relevant regulations above, e.g. residue of veterinary drug)

Designation of countries, regions or establishments eligible to export meat and poultry meat by the Minister of Health, Labour and Welfare based on the paragraph 1 of Article 11 of the amended Food Sanitation Act

1. Backgrounds

The amended Food Sanitation Act requires implementation of hygiene control based on HACCP for imported food defined by the Ministerial Ordinance (meat and poultry meat), and the food shall not be imported for sale, unless the Minister of Health, Labour and Welfare recognizes that they are manufactured or processed in a country or region, or at an establishment which takes HACCP based control measures. This measure is along with requirement of food hygiene control based on HACCP principles for food business operators in Japan according to Article 50-2.2 of the amended Act.

2. Requirements for designation of a country or region, or an establishment which takes HACCP based control measures recognized by the Minister of Health, Labour and Welfare

- The government of designated export country shall certify and inspect an establishment complying with requirements for export of meat and poultry meat to Japan
- The government shall provide a list of establishments which meet the requirements for export of such food to Japan
- The Ministry of Health, Labour and Welfare (MHLW) periodically audits to review the system of the exporting country.

* Before the enforcement of the amended Act, the government of export country shall present MHLW copies of the laws and regulations, the relevant information, as well as information ensuring that the control system described above is established based on guidelines which will be notified by MHLW. MHLW will discuss with exporting country and conduct on-site investigation, in order to confirm that their control system such as the scheme to ensure the establishment to perform hygiene control based on HACCP and the supervisory framework by the government is equivalent or better to those in Japan.

* In case that it is impossible for the government of exporting country to take the procedures mentioned above points described in 2, the establishment which is willing to be designated may apply for the designation to MHLW, through the government of the exporting country,

in accordance with procedures set by MHLW.

3. Timelines (related to enforcement of the amended Act)

MHLW will discuss with the countries etc. which have already exported meat and/or poultry meat to Japan, so that it can notify such countries etc. as a ministerial announcement by June 2021 (i.e. by the end of 1 year transitional period after the enforcement of the amended Act).