# The summary of the amendment to the Food Sanitation Act

The government of Japan is planning to amend the Food Sanitation Act.

## **Background**

Approximately 15 years have passed since the last revision of the Food Sanitation Act, and in the meantime, dietary pattern and the environment surrounding food in Japan has been changing, such as increasing demand for precooked food and eating-out due to the increase of double-income households and elderly single households, and interest in health foods, as well as the progress of globalization of foods because of increase of imported foods.

Also, to control the occurrence and expansion of interregional food poisoning cases and to suppress the number of food poisoning incidents which is now slowing its pace of decline, further hygiene control by food business operators (FBOs) and appropriate response by national and local governments are urgent issues.

In addition, bearing in mind the Tokyo Olympic Games and the Paralympic Games in 2020 and aiming for further promotion of food export, food hygiene control consistent with the international standards is also required.

Based on these circumstances, in order to ensure food safety, the government of Japan is planning to amend the Food Sanitation Act and other relevant laws taking into consideration the opinions of concerned parties such as consumers, FBOs and experts.

## Outline of the amendment

(a) Strengthening measures taken by national and local governments for interregional food poisoning cases

In order to prevent occurrence and expansion of interregional food poisoning cases, national and local governments shall mutually cooperate. As a framework of such cooperation, the Minister of Health, Labour and Welfare may establish a council for wide area cooperation which is composed of relevant parties of the national and local governments etc.

When urgent response is required, the Minister of Health, Labour and Welfare may utilize the council to address interregional food poisoning cases.

## (b) Requirement of food hygiene control based on HACCP principles

In order to increase the level of food hygiene control by food business operators (FBOs) in Japan and to be aligned with the international standards, FBOs\* including operators of slaughterhouses and poultry processing plants shall develop and comply with a plan on food hygiene control, adapted to their own situations (e.g. manufacturing methods and raw materials) covering both good hygiene practices such as maintenance and cleaning of the facilities and control measures critically important to prevent or eliminate specific hazards. For certain category of FBOs, some flexibility will be applied taking into account the nature and size of the operation.

\* Industries considered having a low impact on public health will be excluded from the scope (e.g. business that only sells packaged foods that can be stored at room temperature)

The current "comprehensive hygiene control manufacturing process approval system" (Food Sanitation Act Article 13) (i.e. ministerial certification of individual FBOs who conduct hygiene control based on HACCP principles) is rescinded. However, the mechanism will be maintained allowing FBOs to manufacture food in methods different from the manufacturing and processing standards provided in the Food Sanitation Act when the Minister of Health, Labour and Welfare individually confirms that they take appropriate measures to prevent the occurrence of food hygiene hazards.

- (c) Establishment of an adverse event reporting system for foods containing the designated substances\*
- \* The substances and/or ingredients with a probability that the uncontrolled use of those may cause serious adverse health consequences will be designated by the Minister of Health, Labour and Welfare.

To prevent serious adverse events, FBOs that sell foods containing the designated substances shall report health-related adverse events associated with the use of their products to the Ministry of Health, Labour and Welfare through local governments.

In addition, relevant stakeholders shall cooperate with the Minister of Health, Labour and Welfare for a survey on an adverse event and provide related information. (d) Improvement of sanitary regulations for utensils, containers and packaging for food and food additives considering international consistency

In order to ensure the safety of utensils, containers and packaging, and to ensure international consistency of regulations, FBOs associated with these products shall not sell those made of raw materials, such as synthetic resins, for which specifications are not established, except cases that the Minister of Health, Labour and Welfare specifies as having no risk to human health. In addition, the manufacturers shall comply with the codes of good manufacturing practices.

Manufacturers and sellers of utensils, containers and packaging shall provide the business entities where the products are sold with information that the products conform to the relevant specifications. Also manufacturers and sellers of the raw materials shall endeavor to provide the manufacturers of utensils, containers and packaging with the relevant information if requested.

(e) Revision of licensing system and establishment of notification system for food businesses

Prefectural governments shall take into consideration the criteria to be specified by the Ordinance of the Ministry of Health, Labour and Welfare when establishing their own food business licensing requirements in the prefectural ordinance, which now greatly differ from prefecture to prefecture.

(Note) The category of food businesses requiring license which are specified by the Cabinet Order will also be reviewed in light of the current situation.

Those who intend to operate food business shall notify their local government prior to doing so. Food related businesses with little impact on public health will be exempt.

### (f) Establishment of a reporting system for food recalls

When a food is in violation of the Food Sanitation Act and is recalled, the manufacturers or sellers shall notify the prefectural governor of initiation progress of the recall, unless any food safety hazard etc is not expected to occur. The governor who received the information shall report it to the Minister of Health, Labour and Welfare.

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

Foods requiring measures to control processes particularly important to prevent occurrence of adverse health effects\*, food hygiene control based on HACCP principles, in exporting countries shall not be imported, unless they are manufactured at a facility where the competent authorities of the exporting country confirm that such measures are taken.

\*Foods such as meat and poultry meat, etc. are assumed.

In addition, when importing food of which risk may increase depending on hygiene practices\*, health certificate issued by the exporting country which describes the status of hygiene control shall be attached.

\* Milk, milk products, oysters to be eaten raw and puffer fish are assumed.

Export food-related measures such as issuance of health certificates and other necessary measures by local governments are stipulated.

#### (h) Other

Necessary provisions, such as provisions on administrative measures, penalties and transitional measures are developed.

(end)