



Introduction

Food is essential for people to maintain sustainable and healthy livings. Ensuring food safety is therefore important and many people have great concern with it.

The Ministry of Health, Labour and Welfare (MHLW) formulates and implements various food safety policies based on scientific knowledge in collaboration with many relevant bodies including consumers, food business operators and other stakeholders from various fields.

Table of Contents ◆ Scope of Food Safety Food Safety Regulatory Framework 3 Roles of Food Safety Management Organizations in MHLW 3 ◆ Measures by the Ministry of Health, Labour and Welfare 5 1. Food Poisoning 5 2. Imported Foods 6 3. Food Hygiene Control by HACCP 7 4. Bovine Spongiform Encephalopathy (BSE) 8 5. Agricultural Chemical Residues in Foods (Positive List System) 9 6. Radioactive Materials in Foods 10 7. Contaminants in Foods 11 8. Food Additives 12 9. Health Foods 13 10. Genetically Modified Foods 14 11. Utensils, Containers and Packaging, Toys and Detergent 15

Food Safety Regulatory Framework

A series of food safety incidents, which occurred during 2001 and 2002 such as BSE incidence and false food labeling, shook public trust in food safety and led to the restructuring of Japan's framework for food safety regulation in 2003.

"Risk Analysis" is an internationally acknowledged principle consisted of three components: 1) risk assessment— assessing risk scientifically, 2) risk management— implementing necessary measures based on risk assessment results, and 3) risk communication— exchanging information and opinions among members, such as risk assessors, consumers and business operators.

In the current framework in Japan, risk assessment body is completely separated from risk management body, and is placed into the Food Safety Commission (FSC) established in the Cabinet Office under the Food Safety Basic Act.

Risk management is conducted by three agencies; the Ministry of Health, Labour and Welfare (MHLW), the Ministry of Agriculture, Forestry and Fisheries (MAFF) and the Consumer Affairs Agency (CAA). They have responsibilities for developing necessary measures and regulations based on risk assessment results.

Risk communication is done by all these agencies.

Measures to Ensure Food Safety (risk analysis)

Risk assessment Risk management **Food Safety Commission** MHLW MAFF CAA - Quarantine Stations - Regional agricultural - Conduct risk assessments - Report to the governmental organizations Regional bureaus of administration offices health and welfare - Food and Agricultural responsible for risk management. Management related to - Local governments Material Inspection Center. Monitor the state of implementation of risk Local public health labeling of food items management Risk management related to centers, etc. Collect and analysis risk information from agriculture and forestry, inside and outside of Japan as a central Risk management relating to livestock management, and fisheries Food Sanitation Act, information center, etc. food hygiene Agricultural Chemicals Control Act, Health Promotion Act, etc. Food Sanitation Act, etc Food Safety Basic Act Feed Safety Act, etc. Risk communication - Provide information related to food safety

consumers to express their opinions

Roles of Food Safety Management Organizations in MHLW

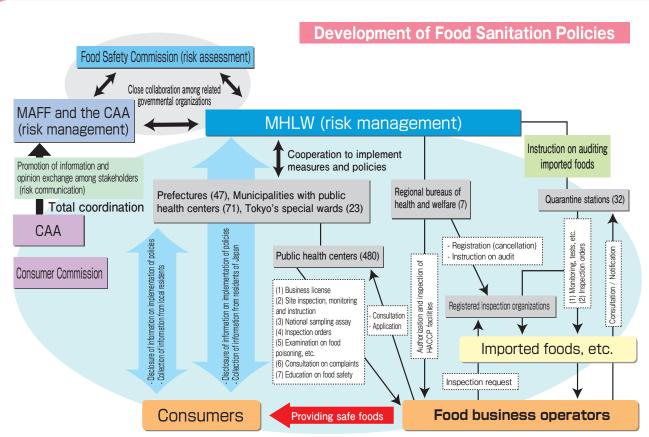
- Ensure opportunities for stakeholders including

There are various organizations under the MHLW, which include not only headquarters but also the regional bureaus of health and welfare and the quarantine stations, while ensuring cooperation with the local governments.

➤ Ministry of Health, Labour and Welfare

Under the Food Sanitation Act and other related laws, MHLW lays down regulations and set food safety standards for foods, food additives, pesticide and veterinary drug residues in foods, and food apparatus/containers and so on, as preventative measures and prohibits the distribution of harmful foods.

MHLW works closely with other governmental agencies and local governments, and ensures proper implementation of food safety measures.



*As of April 2016

> Regional Bureaus of Health and Welfare

Regional Bureaus of Health and Welfare are located in seven regions across the country; Hokkaido, Tohoku, Kanto-Shinetsu, Tokai-Hokuriku, Kinki, Chugoku-Shikoku, and Kyushu.

They register and inspect facilities introducing HACCP (Hazard Analysis and Critical Control Point) in cooperation with local governments and provide technical advice for hygienic practices based on HACCP approach.

Also, they register private laboratories as "Registered Laboratories" which operate food inspection business in compliance with GLP (Good Laboratory Practice) under the Food Sanitation Act.

> Quarantine Stations

There are 32 quarantine stations located at international seaports and airports. At the quarantine stations, food inspectors conduct document examination, inspect and monitor imported foods and related products, and guide importers on practical procedures of food import.

> Local Governments

There are 47 prefectural governments, 71 municipalities with public health centers, and 23 special wards of Tokyo Metropolis (as of April 2016). The local governments inspect local restaurants, food manufacturers and distributors. In case of an outbreak of food poisoning they investigate the cause.

Based on relevant ordinances, the local governments set hygiene standards. Another function of local government is issuance of business permits for specific type of food manufacturers. If a food manufacturer violates the ordinance, the local governments suspend or revoke its permits.

Local governments formulate inspection and guidance plan for foods distributing in domestic marketplace. Activities according to the plan are executed by Public health centers.

Food Poisoning

The MHLW provides consumers and business operators with information based on the latest findings to help them deepen understanding about food hygiene and safety to ensure the prevention of food poisoning outbreaks. In case of an outbreak, the MHLW will work together with relevant local governments to identify the cause and to try to stop the outbreaks in the early stages.

First, the doctor who examined a patient with food poisoning must notify the Director of the nearest health center within 24 hours. When receiving the notifications or otherwise knowing the occurrence of a poisoning case, the Director must report to the governor or mayor of the prefecture or municipality concerned after investigating the cause. The governor or mayor then reports to the MHLW.

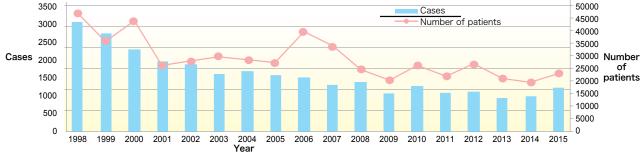
In particular, when a serious food poisoning occurs, the corresponding local/municipal government must promptly notify the Minister to prevent further spread.

The reported information is analyzed by the Pharmaceutical Affairs and Food Sanitation Council every year, and appropriate preventive measures are taken.

In 2011, the MHLW newly established standards for raw beef meat intended to be eaten raw under the Food Sanitation Act. If business operators serve and/or sell beef meat, they must use meat which meets the standards. In July 2012, the MHLW established standards for cattle liver and banned the sale of cattle liver intended to be eaten raw. This was based on a report on the detection of enterohemorrhagic E. coli in the inner part of cattle liver.

In 2015, the MHLW banned the sale of pork intended to be eaten raw. This was based on the decision that eating raw pork has high risk of infection with hepatitis E virus or other pathogens.

Trend of Food Poisoning Prevalence



Specific Measures	
Intensive inspection in summer and yearend	Numbers of on-site inspection at food business facilities and product sampling tests (fiscal 2015) On-site inspection: 604,369 facilities (summer) / 398,357 facilities (yearend) Sampling tests: 31,528 samples (summer) / 18,464 samples (yearend)
Surveilance of pathogen in food	A total of 2,302 tests were conducted with precut vegetables, meat, etc. (fiscal 2015).
Networking with local governments, etc.	Efficient use of the Food Sanitation Synthetic Information Processing System and the National Epidemiological Surveillance of Foodborne Disease (NESFD)
Developing Q&A on food poisoning caused by microorganisms and viruses, etc.	http://www.mhlw.go.jp/seisakunitsuite/bunya/kenkou_iryou/shokuhin/syokuchu/index.html (Japanese only)
Set up a system to receive emails on food-related health problems	A system was set up to directly receive information on food-related health problems. http://www.mhlw.go.jp/topics/bukyoku/iyaku/syoku-anzen/mail-madoguti/index.html

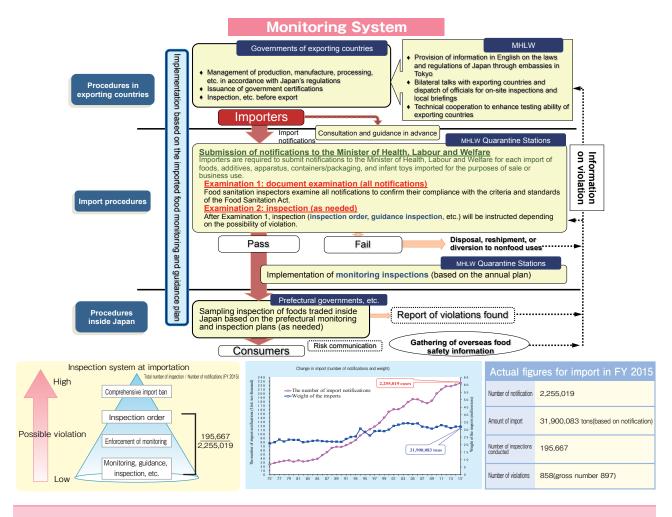
Imported Foods

Japan is a major food importer, with a food self-sufficiency rate of 40%. Foods are imported from various countries. To ensure the safety of import foods, the MHLW monitors and inspects them at the quarantine stations located at 32 international airports and seaports.

Based on the Imported Foods Monitoring and Guidance Plan, the MHLW carries out inspection of imported foods at the quarantine stations to verify their compliance with the Food Sanitation Act. When violation of the regulation is detected, proper measures are taken for the relevant products, including disposal or shipping back of the items to the country of origin.

Imported Foods Monitoring and Guidance Plan

The Imported Foods Monitoring and Guidance Plan is set each fiscal year to thoroughly, efficiently and effectively monitor a wide variety of imported foods and give guidance to relevant businesses in order to further ensure safety.



Specific Measures

Inspection of import notifications for foods, etc.	The MHLW inspects the import notifications for foods, etc. submitted by importers to examine the compliance of standards or specification of the foods with the Food Sanitation Act.
Inspection order	Food products that are highly possible for violation of the Food Safety Act (e.g., contamination with carcinogenic substances (mycotoxicosis) or pathogenic microorganism) are inspected at each time of import. Items that are subject to an inspection order must pass the inspection to be imported.
Monitoring inspection	In order to survey a wide variety of imported food items, inspection is conducted for residues of agricultural chemicals, microorganisms, food additives, etc.

Food Hygiene Control by HACCP

To accomplish the higher level of food safety by implementing the food hygiene control based on HACCP principles.

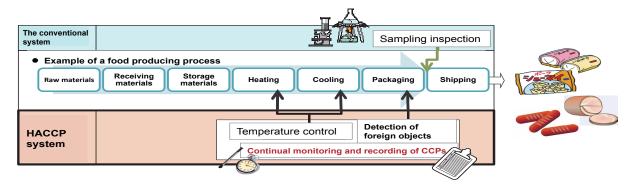
Twenty years have passed since the guidelines on the application of HACCP to food safety was adopted by the Codex Alimentarius Commission in 1997, and HACCP has been becoming more and more common as its application has been mandatory especially in developed countries and also a requirement for export to these countries.

Food hygiene control using HACCP systems can accomplish improvement of food safety by preventing foodborne diseases as well as facilitating the investigation of foodborne incidents. Thus, it can greatly benefit both food business operators (FBO) and consumers.

MHLW is now considering the mandatory implementation of HACCP-based food hygiene control under the Food Sanitation Act.

What is HACCP?

HACCP, an abbreviation for "Hazard Analysis and Critical Control Point", is a food hygiene control system in which FBOs assess hazards such as contamination of pathogenic microorganisms, foreign objects etc. throughout the process from receiving raw materials to shipping final products, and control the process focusing on the critical steps to remove or reduce these hazards to an acceptable level.



Specific Measures The Panel Meetings on International Standardization of Food Hygiene Control Consideration of mandatory have been held from March to December 2016. The final report was released implementation of HACCP at the end of December 2016. Organize periodic meetings for reaching common understanding, sharing Meetings on HACCP information and having communication among stakeholders such as the central government, local governments, FBOs etc. to promote HACCP implementation. Promotion 7 regional meetings also take place to consider regional issues. Encourage local governments to support FBOs who try to introduce HACCP, Project of HACCP and publicize its records including all the processes of introduction, the Implementation Model problems and the solutions during the project and the results as a model case. Project of "Challenge Introducing FBOs on the website who try to introduce and implement the HACCP-based food hygiene control. Implementation of HACCP" Introduction textbooks and videos for HACCP implementation as well as individual textbook by type of businesses are available on MHLW website. Developing learning · Introduction textbook for HACCP implementation at food manufacturing materials for introduction of · Model plan for HACCP implementation at food manufacturing HACCP · Introduction for HACCP implementation at food manufacturing (video) · Textbook for food hygiene control based on the idea of HACCP

4 Bovine Spongiform Encephalopathy (BSE)

The MHLW is comprehensively reviewing the measures for BSE based on the latest scientific findings in light of the declining risk of infection.

Since the first BSE case was reported in Japan in 2001, various measures, which were for example, restriction on feeding meat-and-bone meal to cattle, have been implemented both in and outside Japan. As a result, the BSE risk has declined substantially.

In response, the MHLW requested the FSC to conduct science-based evaluation mainly on the domestic test systems and the import conditions. Based on the assessment reported by the FSC, the MHLW has reviewed the measures for BSE as follows(as of December 2015);

<For domestic cattle>

- 1) The age for BSE testing: over 48 months.
- 2) The specific risk materials (SRM) to be removed: heads, spinal cords, vertebral column of the cattle over 30 months of age, and ileum and tonsils of the cattle of all ages.

<For imported cattle>

- 1) The age for beef imported to Japan: less than 30 months for the US, Canada, France, Netherlands, Ireland and Poland; less than 36 months for the Brazil.
- 2) SRM to be removed: ileum and tonsils of the cattle of all ages.

The MHLW will continue to review the current measures based on the assessment reported by the FSC.

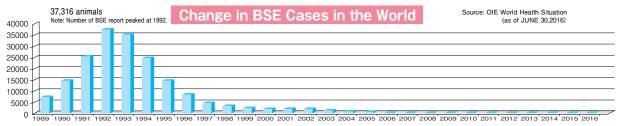
Bovine Spongiform Encephalopathy (BSE)

Since the first case of BSE was identified in the UK in 1986, infected cattle have been reported in some regions, including Europe, the US, Canada, Brazil and Japan.

When infected, the cattle accumulate abnormal prion protein (the cause of the disease) mainly in their brain, giving the brain a sponge-like appearance and causing abnormal behaviors, ataxia and other neurological symptoms, and eventually death of the animal.

The abnormal prion protein is considered to cause variant Creutzfeldt-Jakob disease when consumed by humans. When infected, humans will develop a sponge-form change of the brain, physiological disorders and abnormal behaviors.

To this end, the cattle organs where abnormal prion protein is accumulated (e.g., brain, spinal code and ileum) are designated as "specific risk materials" (SRM) and many countries legally prohibit the use of these parts for human consumption.



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Specific Measures		
Measures at Slaughterhouses	Separate management of the cattle subject to BSE testing(> 48 months old) and BSE testing by slaughter inspectors. Removal and incineration of SRMs (head and spinal code (> 30 month); tonsil and distal ileum (regardless of age)).	
Measures for meat processing facilities, meat sales businesses, and vertebral column processing businesses	Use of vertebral column (derived from cattle (age of 30 months or less) raised in a country where safety is confirmed) for foods.	
Import ban	Ban on import of beef and cattle-related foods from countries with BSE cases (except for beef and other products that meet certain conditions laid out based on the assessment by the Food Safety Commission from the US, Canada, France, Netherlands, Ireland, Poland, Norway, Denmark, Sweden, Italy, Switzerland and Liechtenstein)	
On-site inspection	Official inspectors regularly visit overseas facilities certified as eligible to export to Japan to verify the compliance of the specific conditions for export to Japan (age limitation of cattle and removal SRMs)	

5 Agricultural Chemical Residues in Foods (Positive List System)

The MHLW sets residue standards for all pesticides, animal feed additives and veterinary drugs ("agricultural chemicals" hereinafter) in foods and bans the sales and processing of food commodities that contain residues at a level exceeding the standards.

On May 29, 2006 the MHLW introduced the positive list system for agricultural chemicals remaining in foods—The aim of the positive list system is to prohibit the distribution of any foods which contain agricultural chemicals at amounts exceeding a certain level (0.01 ppm) in the Japanese marketplace unless specific maximum residue limits (MRLs) have been set. This activity has been based on the Act to Partially Revise the Food Sanitation Act (Act No. 55, 2003).

Positive List System for Agricultural Chemical Residues

Previous Regulation

Pesticedes, Feed additives and Veterinary Drugs

Agricultural Chemicals for which MRLs are established

MRLs for 250 Pesticides and 33 Veterinary Drugs



Agricultural Chemicals for which

allowed for distribution.

MRLs are not established

Any food for which MRLs are not established is allowed for distribution even if an agricultural chemical is found.

Enforcement of Positive List System (enacted on May 29, 2006)

Pesticides, Feed Additives and Veterinary Drugs

Agricultural Chemicals for which MRLs are established

Establishment of provisional MRLs for agricultural chemicals, considering Codex standards, Japanese registration withholding limits*, and other standards established based upon scientific evaluation

Acceleration of the establishment

Foods containing agricultural chemicals above the MRL are NOT allowed for distribution.

Agricultural Chemicals for which MRLs are not established

Establishment of a certain level that is determined to pose no adverse health effects

Any food containing agricultural chemicals exceeding the Uniform

limit (0.01 ppm) is NOT allowed for distribution.

Agricultural Chemicals s designated by MHLW

Agricultural Chemicals that do not pose adverse health effects



Not subject to the Positive List

Uniform limit: 0.01 ppm

*Registration withholding limits:

In terms of agricultural chemical residues in crops under the Agricultural Chemicals Regulation Act, the highest acceptable concentration limits of agricultural chemical residues had been established for commodity groups for some agricultural chemicals based on the result of exposure assessment until the introduction of the Positive List System in Japan. These limits have been used as one of the basis for establishing 'Provisional MRLs' under the Positive List System.

Specific Measures

Providing information for

consumers

Establishment of standards, etc.

>Develop analytical methods for agricultural chemicals in foods.

>Develop analytical methods for agricultural chemicals in foods.

**Conduct monitoring for residual levels of agricultural chemicals in foods.

**Conduct a market basket study of agricultural chemicals intake via foods.

ntake study ➤ Conduct a market baske

Provide relevant information on the MHLW website (Residues of Agricultural Chemicals in Foods)

JP http://www.mhlw.go.jp/seisakunitsuite/bunya/kenkou_iryou/shokuhin/zanryu/index.html

EN http://www.mhlw.go.jp/english/topics/foodsafety/positivelist060228/index.html

6 Radioactive Materials in Foods

The MHLW has established the limits for radioactive materials in foods. Local governments carry out pre-shipping tests on foods. The foods with exceeding the limits are refrained from distribution.

The current limits for the levels of radioactive materials in foods were set in April 2012.

The local governments test food samples based on the guidelines set by the national government to ensure that foods with exceeding the limits will not be distributed in a market. All of the test results are disclosed in the section, "Measures for Radioactive Materials in Foods," on MHLW's website.

If a number of cases exceeding the limits are found for a certain kind of products in a certain region, the shipment of the product from the same region will be restricted.

Appropriate measures are taken to ensure that foods in noncompliance with the limits will not be placed on the marketplace, including conducting tests before shipment.

Limits for Radioactive Materials in Foods

In April 2012, the limits for radioactive cesium in foods were set for each food group based on the Food Sanitation Act.

The limits are based on 1 mSv in a year consistent with an intervention exemption level adopted by codex.

Limits of Radioactive Cesium in Foods

Food group	Limit (Bq/kg)
General foods	100
Infant foods	50
Milk	
Drinking water	10

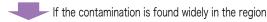


Testing food samples for radioactive materials

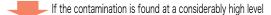
Procedure of the Measures



Excess the limits



Shipment is suspended for the specific region and item (Restriction of distribution based on the Act on Special Measures Concerning Nuclear Emergency Preparedness)



Consumption of the item is not allowed even for non-commercial (family) us (Restriction of consumption based on the Act on Special Measures Concerning Nuclear Emergency Preparedness)

The annual effective doses from radioactive cesium in foods were less than 1% of 1mSv/year as the basis of setting of the current limits.

Specific Measures

Setting limits	The provisional regulation values for radioactive materials in foods were set immediately after the accident at the Fukushima Daiichi Nuclear Power Plant of TEPCO. Later, limits were newly set with longer perspectives and enacted on April 1, 2012.
Disclosure of test results	All test results conducted by local governments, are collected and disclosed on the Website of the MHLW *1.
Restrictions of distribution	Restriction of distribution or consumption directed by the national government (the Nuclear Emergency Response Headquarters) are notified on the Website of the MHLW *2.
Information for available	MHLW's Website, "Measures for Radioactive Materials in Foods," is daily updated. (*1, 2: This information is also updated on this site.) JP http://www.mhlw.go.jp/shinsai_jouhou/shokuhin.html EN http://www.mhlw.go.jp/english/topics/2011eq/index_food.html

7 Contaminants in Foods

The MHLW continuously conducts some surveys to collect the latest data on contaminants in foods. The MHLW also sets standards for contaminants and reviews them if specific regulation is required.

The MHLW conducts surveys on levels of contaminants in foods distributed in Japan. When the results indicate the need of control, the MHLW regulates contaminants by setting standards based on Article 11 of the Food Sanitation Act.

When new regulations are set for food contaminants, the CODEX standards are adapted as a priority if there are CODEX standards set for the specific food. If Japan cannot adapt the CODEX standards in light of actual conditions of food production in Japan, the MHLW promotes measures to reduce the contaminants and shows appropriate standards or guideline levels based on the ALARA principle.

The MHLW surveys the concentrations of contaminants contained in foods and the levels of intake by consumers to utilize as basic data for risk reduction measures.

Codex Alimentarius Commission (CODEX)

CODEX is an intergovernmental organization established by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) in 1963. With the main goal "to protect the health of the consumers and ensure fair practices in the food trade," it develops international food standards and takes other measures as well. As of August 2016, CODEX has 187 member countries and one member organization (EU).

ALARA Principle

ALARA is an acronym formed from the phrase "As Low as Reasonably Achievable." It is the basic concept for measures for food contaminants.

Measures for Food Contaminants

Surveys on chemical substances, etc. in foods



Meats, seafood, vegetables, etc.

Dioxins, cadmium, etc.

Surveys on intake levels from foods

- $\bigcirc \mbox{Surveys}$ for substances when no data is available on intake levels from foods
- OContinuous surveys with the total diet method

Conduct surveys on intake levels of chemical substances, etc. from foods

Surveys on contamination levels of foods

OMeasurement chemical substances contained in foods

Understand the contamination levels of foods with chemical substances

Verification of Safety to Humans

Specific Measures

Measures for dioxins

Measures for methyl mercury

> Establishment of provisional regulation values for methyl mercury contained in seafood, etc.
> Education of expectant mothers

Measures for cadmium

> Establishment of standards for cadmium contained in rice
> Promotion of measures to reduce cadmium levels in agricultural areas

>Estimation of intake levels from ordinary diet (total diet study)

8 Food Additives

Before a food additive is authorized, the MHLW verifies its effectiveness and whether its use is unlikely to cause adverse health effects. If needed, the MHLW sets standards and requirements to ensure its safety.

Food additives are used in the process of manufacturing foods or for the purpose of processing or preserving foods. They include preservatives, sweeteners, coloring agents and flavoring agents.

While food additives largely contribute to today's distribution of a variety of foods, much caution is needed to ensure the safety of additives, which do not have a long history of human consumption unlike foods.

The MHLW consults the FSC and authorizes the use of them only when they do not have risks of harming human health. The MHLW continuously takes adequate measures to review the safety of authorized food additives, for example, by surveying daily intake levels per person.

Specific Measures

Classification of food additives (as of September 18, 2015)

Designated additives (449 items)

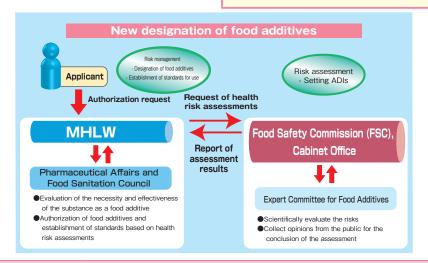
Substances that have been designated by the Minister of Health, Labour and Welfare to authorize the use of them, based on the safety assessment (e.g., sorbic acid and xylitol).

Existing food additives (365 items)

Substances that have been permitted for use and distribution without having gone through the designation process specified by the Food Sanitation Act for the reason that they had had a long history of consumption at the time of the revision of the act in 1995 (e.g., gardenia coloring agent, Japanese persimmon tannin).

Natural flavoring agents (approx. 600 items)
Substances that are derived from natural origins, including animals and plants, and used for flavoring food (e.g., vanilla flavoring and crab flavoring).

Ordinary foods used as food additives (approx. 100 items) Substances that are generally provided for eating or drinking as food and also used as food additives (e.g., strawberry juice and agar).



Set requirements to be met (e.g., impurities and assay) to ensure that distributed food Establishing specification additives have stable quality. and standards for food Set the upper limits of each additive that can be used in individual foods (standards for use) additives to ensure that adverse health effects will not be caused by excessive consumption Ensuring the safety of Verify the safety of existing food additives and impose a ban on production, sales, import, or other handling of food additives that have raised safety concern. existing food additives Collect samples from foods on the market place, identify food additives in the samples, and Conducting surveys on measure their levels to examine whether the total levels are within the corresponding ADIs intake levels of food (acceptable daily intake: maximum amount of a substance to which an individual can exposed additives to on a daily basis over his/her life span without causing any harmful effects).

Promoting global harmonization of designated additives

Promote the designation of 45 non-flavorings and 54 flavorings that have been selected as those recognized as safe and widely used overseas. As of September 18, 2015, 41 non-flavorings and 54 flavorings were designated.

Health Foods

A variety of foods are distributed as "health foods." The MHLW takes a wide range of measures, including inspection and guidance to business operators in stages from production to sales, collection of information on adverse health effects and provision of information to consumers.

As the people's interest in health issues has grown, many kinds of foods have been launched on the market as "health foods." They include such items that have not been used as foods or beverage before or that are in unique forms.

To ensure the safety of products that are supplied to consumers, the MHLW provides the guidelines which promote to produce these health foods by using the method of Good Manufacturing Practice. The MHLW also collects information on adverse health effects caused by products and provides consumers with information for raising their awareness about health effects.

through its Websites and brochures (see

Health foods

Foods that are sold or used as items useful for maintenance and improvement of health are generally referred to as "health foods." From the legal perspective, however, there is no explicit definition for the term, except for "food with health claims*" that is defined under the Health Promotion

* The scheme to manage food with health claims has been responsible of the Consumer Affairs Agency since September 2009.



Foods Drug Food with health claims Managed by the Consumer Affairs Agency Food with Drugs General foods Food for Food with nutrient (including specified function function health foods) health uses claims quasi drug) claims

below).

Specific Measures	
Specific measures at manufacturing stage	➤ Ensuring safety of materials (publication search and toxicology test (when diet experience is not sufficient) ➤ Ensuring safety by good manufacturing practice (GMP) (manufacturing management and quality management in the whole process) ➤ Ensuring the efficiencies (adaptation of the third-party certification system)
Collection of information on health damage and enforcement of countermeasures	Information is more actively collected, including cases where correlation is unclear. Note: Information regarding the current status of health foods and past health damage cases is provided to physicians and other concerned parties.
Consumer education	➤ Manufactures should label appropriate intake levels and cautions on the products. ➤ A certain level is ensured for the training systems and usage of advisory staff.
Providing information for consumers	>Website on health foods http://www.mhlw.go.jp/topics/bukyoku/iyaku/syoku-anzen/hokenkinou/ >Brochure "Appropriate Use of Health Foods" http://www.mhlw.go.jp/topics/bukyoku/iyaku/syoku-anzen/dl/kenkou_shokuhin00.pdf >Website by the National Institute of Health and Nutrition

"Information System on Safety and Effectiveness of Health Foods" http://hfnet.nih.go.jp/

Genetically Modified Foods and Food Additives (GM foods)

The safety assessment of foods and food additives produced by recombinant DNA techniques (hereafter GM foods) is mandatory under the Food Sanitation Act. The MHLW examines how the transplanted genes behave and whether harmful elements are generated, for example, to comprehensively assess the safety of GM foods.

With techniques of genetic engineering, genes with useful traits are transplanted from cells of an organism to another plant or other organism in order to give the useful traits to the recipient. To ensure the safety of the genetically modified products, it is required to ensure that no harmful elements have been generated as a result.

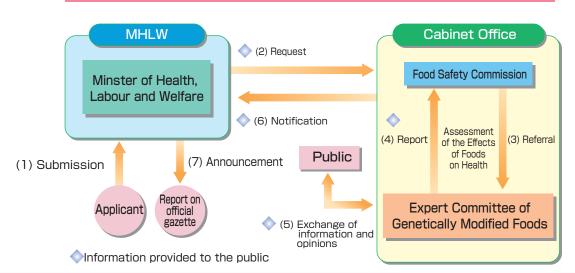
The MHLW ensures safety of GM foods through comprehensive assessment (safety assessment) based on scientific data and opinions of the FSC.

Without passing the safety assessment, GM foods and foods using those as raw materials, cannot be produced, imported or marketed. Manufacturing facilities must be authorized for compliance with the manufacturing criteria to manufacture GM foods.

GM foods

The term "GM foods" is referring to agricultural crops that are given new traits (e.g., pest or draught tolerance) through transplant of genes responsible for that trait from the cell of another organisms, as well as foods made with such crops and food additives using genetically modified microorganisms. Genetic engineering allows transferring of useful genes between different species. This makes it easier to give traits demanded by producers and consumers in a more efficient way. On the other hand, transplanted genes may have risk to generate allergy-induced proteins and other harmful substances.

Procedure for Safety Assessment



Specific Measures

Making safety assessment obligatory	➤ Safety assessment was made obligatory in April 2001 ➤ Banning of manufacturing, import and sales of GM foods that have not gone through safety assessment and foods, etc. that are made with such foods.
Inspection of imported foods	Imported foods are inspected at the time of import to prevent GM foods that have not gone through safety assessment from entering into markets.
Research and assessment for safety	Development of detection methods for GM foods and assessment of allergic property of proteins are conducted.

1 1 Utensils, Containers and Packaging, Toys and Detergent

To ensure the safety of utensils, containers, packaging, toys and detergent, the MHLW establishes specifications and standards for these products. The MHLW also prohibits the use of materials that do not meet the specifications and the manufacturing of them by using methods that do not meet standards.

The MHLW establishes specifications and standards for utensils, containers and packaging, toys and detergent to prevent health and hygiene hazards that are likely to be caused as a result of the use of these products.

Specifications and standards for utensils, containers and packaging include (1) general specifications that are applied for all utensils, containers, packaging and their materials, (2) specifications for different materials, (3) specifications applied for different usages that need special consideration, and (4) production standards.

Utensils, containers and packaging made with synthetic resin (plastics) are regulated according to the property of each material.

Therefore, specifications for specific synthetic resin are applied as needed in addition to the general specifications applied for all kinds of synthetic resin.

"Utensils"

Tableware, kitchen utensils, and other machines, implements, and other articles which are used for collecting, producing, processing, cooking, storing, transporting, displaying, delivering, or consuming food or food additives and which come into direct contact with food or food additives.

"Containers and packaging"

Articles which contain or wrap food or food additives and are offered "as is" when delivering food or food additives.

"Toys"

Toys designated by the Minister of Health, Labour and Welfare as those likely to harm the health of infants and young children through their direct contact with them (e.g., toys that are intended to be put into a mouth, like pacifiers, origami and building blocks).

Specifications and Standards for Safety of Utensils, Containers and Packaging, Toys and Detergent

Food Sanitation Act

Article 16: Banning of sales of harmful or toxic utensils, containers and packaging Article 18: Establishment of specifications and standards for utensils, containers and packaging

Specifications and standards for foods and food additives (notice)

Part III. Utensils, containers and packaging

General and material-specific specifications for utensils, containers and packaging as well as their materials

Usage-specific specifications and production standards for utensils, containers and packaging

Part IV. Toys
Specifications for toys or their materials
Production standards for toys

Part V. Detergent Specifications of composition for detergent Standards for use for detergent

Food Sanitation Act

Application with modification of Article 62:

Banning of sales and other business activities of harmful or toxic toys and detergent Establishment of specifications and standards for toys and detergent

Article 62: Designation of toys applicable for regulations

<Toys applicable for regulations (designated toys)>

Those likely to harm the health of infants when they touch such toys (Article 78 of the Regulation)

Specific Measures

Studying system to enhance the safety of utensils, containers and packaging on the regulation of utensils containers and packaging for foods" has been held open in public from August, 2016.

Preparation and enforcement of specifications and standards for foods, food additives, etc.

Prepare test methods, etc. stipulated in the specifications and standards, Newly establish specifications and standards.

Ensuring safety of recycled materials

Guidelines are developed for the use of recycled plastic and recycled paper for utensils, containers and packaging.

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