



Measures to
Ensure Food
Safety



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) and the Consumer Affairs Agency (CAA) formulate and implement 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.

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All dates in this pamphlet is correct as of December, 2024

● 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.

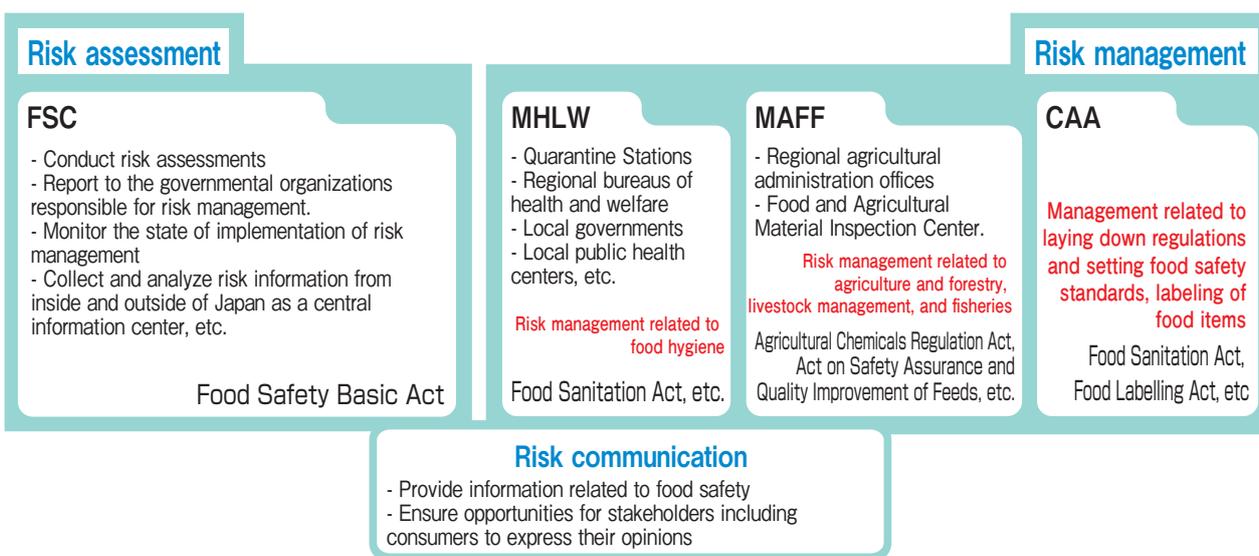
“Risk Analysis” is an internationally acknowledged principle consisted of three components: 1) risk assessment— assessing risk scientifically, 2) risk management— implementing necessary measures based on risk assessment results, and 3) risk communication— exchanging information and opinions among members, 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)



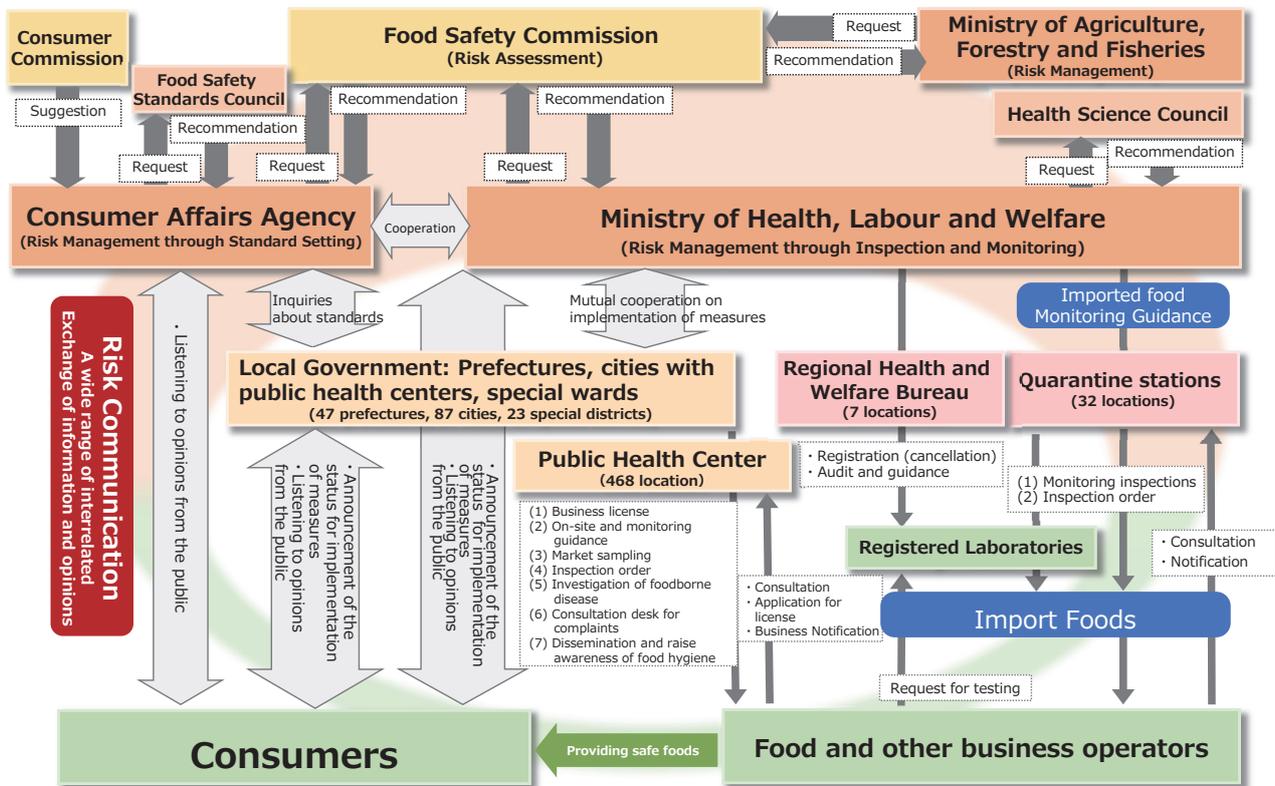
► Roles of Food Safety Management Organizations

• The CAA and the MHLW

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

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

Development of Food Sanitation Policies



• 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 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, 87 municipalities with public health centers, and 23 special wards of Tokyo Metropolis. 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 licenses for specific type of food manufacturers. If a food manufacturer violates the ordinance, the local governments suspend or revoke its licenses.

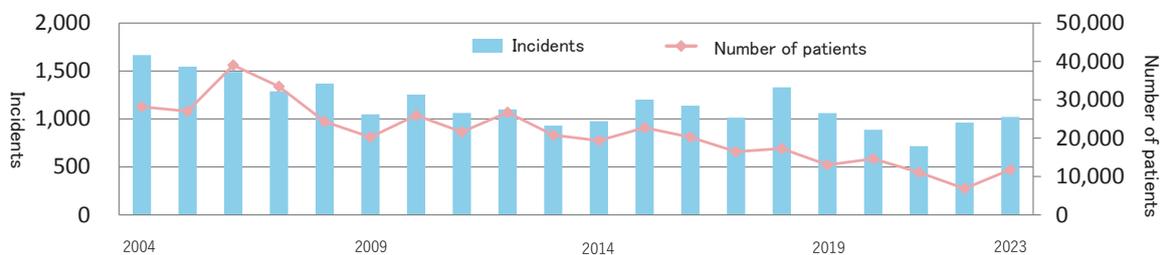
Local governments formulate inspection and guidance plan for foods distributing in domestic marketplace. Activities according to the plan are executed by Public health centers.

1 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.

In the wake of the widespread, sporadic outbreaks of enterohemorrhagic *E. coli* O157 infection and food poisoning in the Kanto and other regions in 2017, the Food Sanitation Act was amended to explicitly stipulate related parties' obligation to cooperate and collaborate with each other in order to prevent the occurrence and expansion of interregional food poisoning incidents. As a framework for such cooperation, the MHLW established a council for wide-area cooperation which is composed of the national and local governments and other related parties for each region. When an urgent response is required, the MHLW may utilize the council to address interregional food poisoning incidents. In addition, the MHLW have introduced a requirement of food hygiene control based on HACCP principles, which is highly effective to prevent food poisoning and aligned with the international standards.

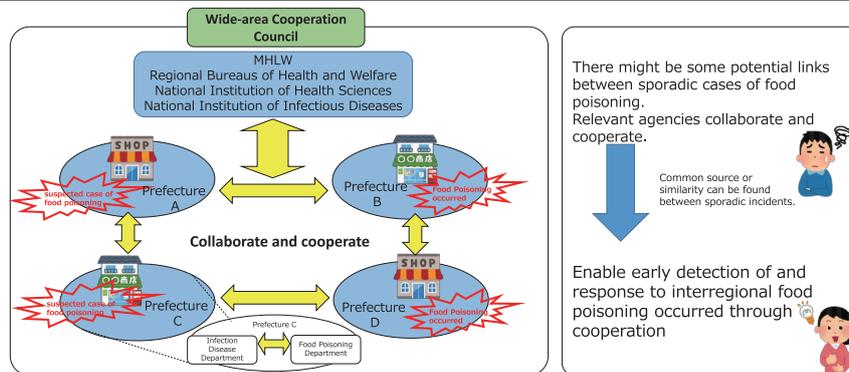
Trend of Food Poisoning Prevalence



Reinforcement of wide-area food poisoning incident response

○ Reinforcement of wide-area food poisoning incident response
(Article 21-3 : Establish of Wide-area Cooperation Council)

- MHLW and prefectures establish Wide-area Cooperation Council in each region to respond to widespread foodborne outbreaks.
- Members of wide-area cooperation council share and exchange information to detect early widespread outbreaks due to common sources.
- Members of Wide-area Cooperation Council conduct investigation effectively and efficiently and provide information properly.



Specific Measures

Intensive inspection in summer and yearend	On-site inspection at food business facilities and product sampling tests For details, visit the following website: https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/shokuhin/syokuchu/01.html#1-3	
Sampling tests conducted by local governments, etc.	Testing of bacterial pathogens, viruses, agricultural chemical residues, food additives, etc. For details, visit the following website: https://www.e-stat.go.jp/stat-search/files?page=1&toukei=00450027&tstat=000001031469	
Networking with local governments, etc.	Efficient use of - The Food Sanitation Synthetic Information Processing System - The Food business Application System for licenses, export certificates and report of food recalls (FAS)	

2 Imported Foods

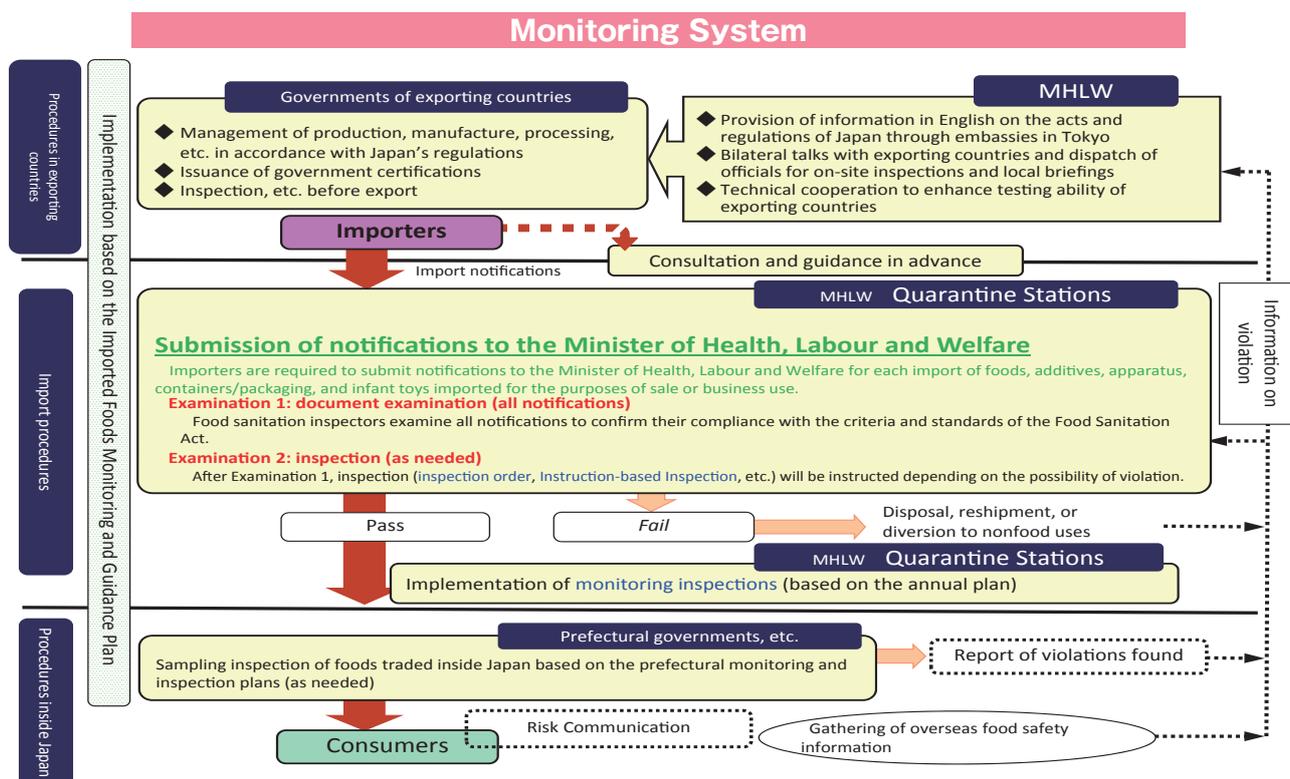
Japanese food self-sufficiency rate is about 40% on a caloric basis. Foods are imported from various countries. To ensure the safety of import foods, the MHLW monitors and inspects them at the quarantine stations located at 32 international airports and seaports.

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.

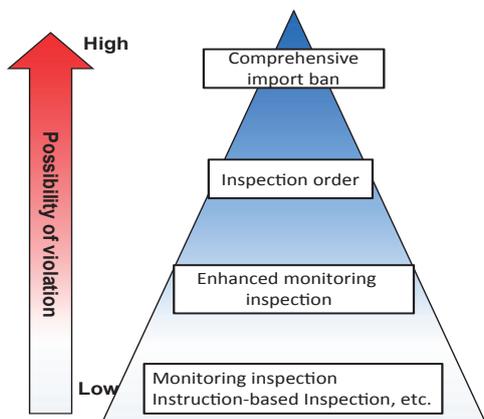
Imported Foods Monitoring and Guidance Plan

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 system at importation



Inspection order

Food products that are high possibility for violation of the Food Sanitation Act (e.g., contamination with carcinogenic substances (mycotoxins) 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.

Instruction-based inspection

Instructions are given to importers to conduct testing for foods that are imported for the first time or that are continuously imported.

Information available

Information on monitoring and guidance under the Imported Foods Monitoring and Guidance Plan and statistical information, etc.
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/shokuhin/yunyu_kanshi/kanshi/index.html



3 Food Hygiene Control based on HACCP principles

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

In principle, all food-related business operators (FBOs) engaged in manufacturing, processing, cooking, selling etc. are required to implement food hygiene control based on HACCP principles.

FBOs must ;

- ① formulate sanitation control plans, and familiarize employees with the plans.
- ② formulate operation manuals, if necessary.
- ③ keep and store records
- ④ verify the effectiveness of sanitation control plans and review them periodically.

MHLW continues to support FBOs in steadily implementing food hygiene control based on HACCP principles.

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.

Overall view of food hygiene control based on HACCP principles

In principle, all food-related business operators (FBOs) engaged in manufacturing, processing, cooking, selling etc. are required to implement food hygiene control based on HACCP principles.

Efforts for managing especially important processes to prevent occurrence of food safety hazards (Food hygiene control by HACCP)

Food-related business operators (FBOs) create their plans depending on raw materials, manufacturing methods etc. which they use based on the Codex HACCP 7 Principles and manage them by themselves.

[Targeted FBOs]

- ◆ Large-scale FBOs
- ◆ Slaughterhouses [Establisher of slaughterhouse, administrator of slaughterhouse and slaughter]
- ◆ Poultry processing centers [Poultry processing business operators (excluding designated small poultry process business operators)]

⇒See here for details



Efforts based on characteristics, etc., of food handled (Food hygiene control incorporating HACCP approach)

Sanitation management is conducted based on the simplified approach using the guide created by each industry organization as reference.

[Targeted FBOs]

- ◆ Small-scale FBOs, etc.

⇒See here for details



Scope of Application of food hygiene control based on HACCP principles.

- The business of harvesting food in agriculture and fisheries falls outside the scope of application of food hygiene control based on HACCP principles.
- Those engaged in the following businesses, which have little impact on public health, are required to conduct general hygiene control as a FBO, but are not required to make a hygiene control plan and keep records on the implementation status of hygiene control (excluding the business operators that notify Foods with Function Claims (FFC) and those approved for Foods for Specified Health Uses (FOSHU))
 - ① Business of importing food or food additives
 - ② Business specialized in food or additives storage or transport (excluding frozen and refrigerated warehousing business)
 - ③ Business of distributing packaged foods that are not likely to cause food hygiene hazards due to spoilage, decay or other deterioration in quality even after long-term storage at normal temperature
 - ④ Business of importing or distributing utensils, containers or packaging
- Institutional food service facilities which serve meals for schools, hospitals and other institutions whose major business purpose is not profit are also required to conduct food hygiene control based on HACCP principles, except for those that provide less than 20 meals each time.

Specific Measures

Assistance to prepare and review guides to make hygiene control plan

Assist to prepare and review the guides to make hygiene control plan, made by food-related business organizations.

Those guides are made available on website.

https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000179028_00001.html



Information available

Provide information on the webpage: HACCP

https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/shokuhin/haccp/index.html



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.

Along with the reviewing the measures, in April 2017, the BSE testing for healthy slaughtered cattle was abolished.

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

Bovine Spongiform Encephalopathy (BSE)

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.

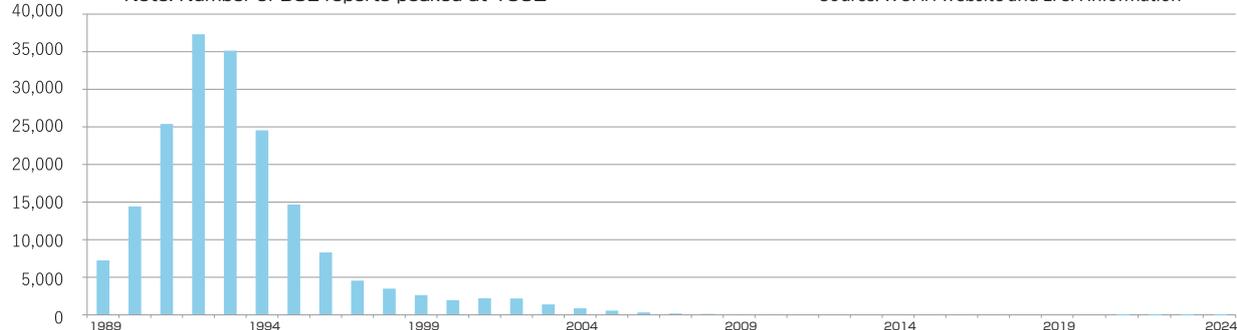
To this end, the cattle organs where abnormal prion protein is accumulated (e.g., brain, spinal cord and ileum) are designated as "specific risk materials" (SRM) and many countries legally prohibit the use of these parts for human consumption.

Change in BSE Cases in the World

37,316 animals

Note: Number of BSE reports peaked at 1992

Source: WOAHP website and EFSA information



Specific Measures

Measures at Slaughterhouses

BSE testing for cattle those showing behavioural or neurological signs at ante-mortem inspection by official veterinarians.

Removal and incineration of SRMs (head and spinal cord (> 30 month); tonsil and distal ileum (regardless of age)).

For details, visit the following website: https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/shokuhin/bse/domesticmeasures.html



Measures at meat processing facilities, meat sellers, food manufacturers, etc.

Prohibition of the use of vertebral column (excluding those from cattle aged 30 months or younger kept in BSE free countries) in foods, etc.

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, the Netherlands, Ireland, Poland, Brazil, Norway, Denmark, Sweden, Italy, Switzerland, Liechtenstein, Austria, the United Kingdom, Spain, Finland and Germany).

On-site inspection

Regularly dispatch officials to check and verify whether meat processing facilities comply with the conditions for beef shipped to Japan (age segregation, SRM removal, etc.).

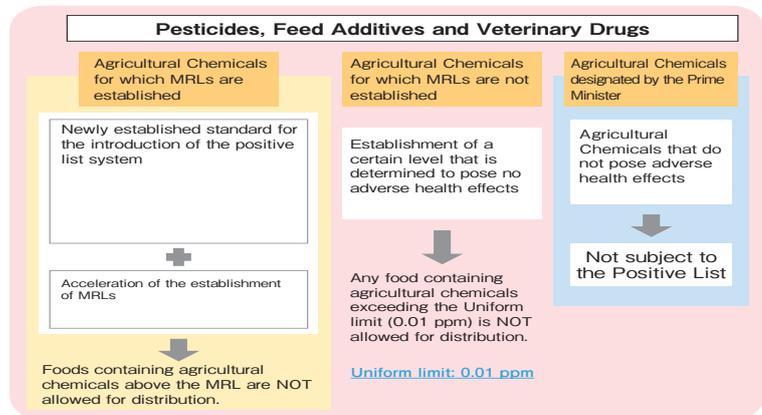
5 Agricultural Chemical Residues in Foods (Positive List System)

The Prime Minister sets residue limits for all pesticides, 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 limit.

In Japan, a positive list system has been implemented to prohibit the distribution of any foods that contain agricultural chemicals at concentrations exceeding maximum residue limit (MRL) in the domestic marketplace.

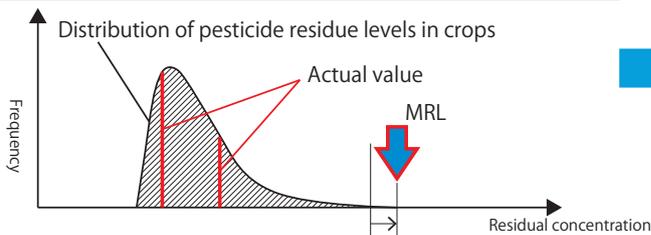
To give an example, foods containing pesticides, for which specific MRL have not been set, at a level exceeding the uniform limit, the distribution of such product is prohibited in Japan.

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



Method for setting MRLs

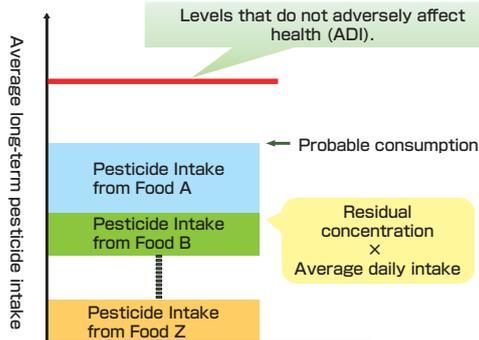
Even if a pesticide is used in the same manner, the actual residue levels vary. Therefore, the distribution of values estimated from the actual values obtained in residue trials is taken into account to set the MRL.



To put it simply, when pesticides are used properly, the residue level does not exceed the established MRL.

Risk-management based on ADI

Estimate the long-term average consumption of individual pesticides and confirm that they do not exceed ADI.

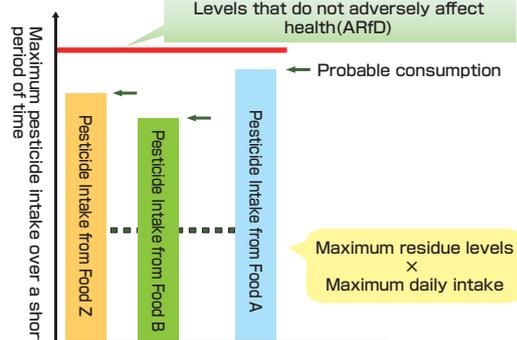


Estimated by aggregating intakes for each food

ADI: Acceptable daily intake that is considered to have no adverse health effects if humans continue to consume daily for a lifetime

Risk-management based on ARfD

Estimate the short-term maximum intake of individual pesticides and confirm that they do not exceed ARfD.



Estimated for individual foods

ARfD: Acute reference dose that is considered to have no adverse health effects after 24 hours or shorter ingestion by humans

Specific Measures

Establishment of MRLs, etc.

- Establish MRLs for agricultural chemicals in foods.
- Develop analytical methods for agricultural chemicals in foods.

Intake study

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

Information available

Provide information on the webpage: "Residues of Pesticides, Animal Feed Additives and Veterinary Drugs in Food"
https://www.caa.go.jp/en/policy/standards_evaluation/residues_of_pesticides



6 Radionuclides in Foods

The MHLW has established the limits for radionuclides 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 radionuclides 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 Radionuclides 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 Radionuclides in Foods

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

The limits are set so that if foods are consumed for the lifetime, the effects from radionuclides in the foods satisfy the sufficiently small and safe level (not more than 1 mSv/year) that is consistent with an intervention exemption level adopted by Codex.

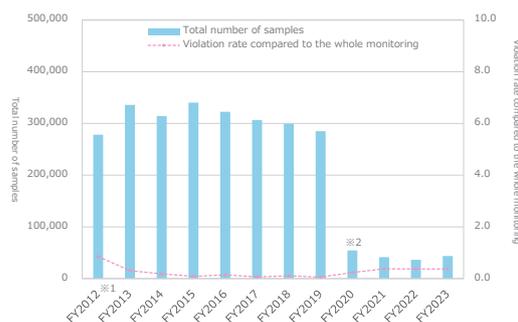
Limits for Radioactive Cesium in Foods

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



Testing food samples for radioactive materials

Transition of violation rate of radioactive cesium in foods



※1 For the period from March 18, 2011 to March 31, 2012 carried out the inspection at the provisional regulation values.

※2 Decrease in the total number of inspections due to the end of beef inspections for all cattle as a result of revised guidelines in FY2020.

The annual effective doses from radioactive cesium in foods were 0.1 % or less of 1 mSv/year as the basis of setting of the current limits.

Specific Measures

Setting limits	The provisional regulation values for radionuclides 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 available	Website of the MHLW “Measures for Radionuclides in Foods,” is updated. (*1, 2: This information is included.) JP https://www.mhlw.go.jp/shinsai_jouhou/shokuhin.html EN https://www.mhlw.go.jp/english/topics/2011eq/index_food.html Website of the CAA “Radioactive materials in foods” https://www.caa.go.jp/policies/policy/standards_evaluation/food_pollution/criterion



7 Contaminants in Foods

The MHLW continuously conducts some surveys to collect the latest data on contaminants in foods. The CAA 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 CAA regulates contaminants by setting standards based on Article 13 of the Food Sanitation Act.

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

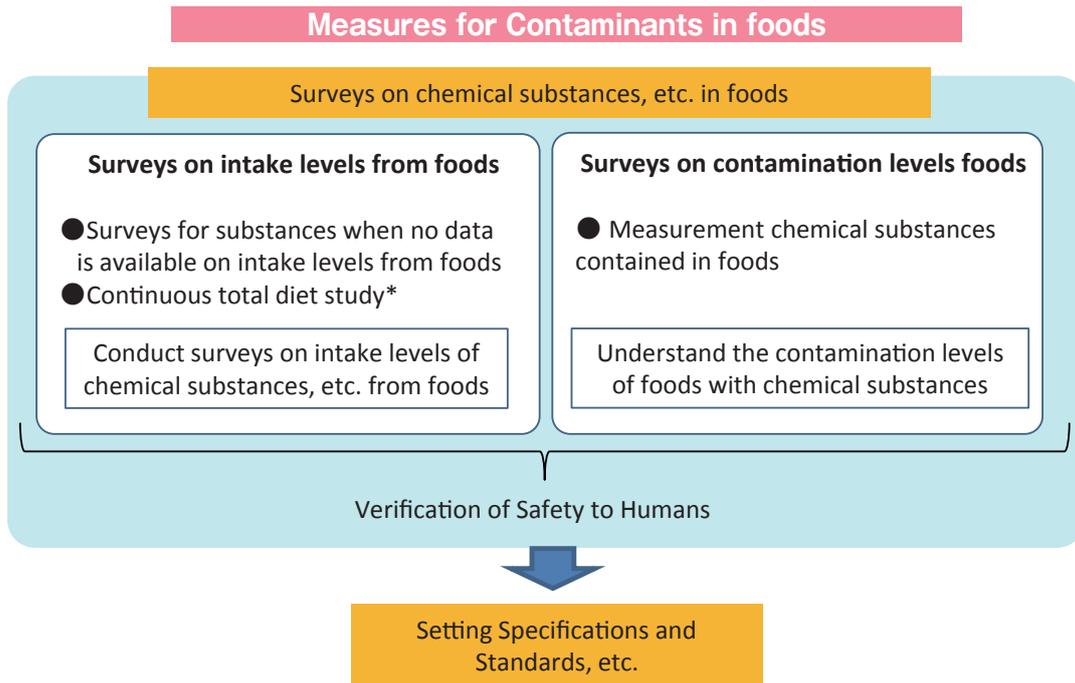
The MHLW surveys the concentrations of contaminants contained in foods and the levels of intake by consumers to utilize as basic data for risk reduction measures.

What is the Codex Alimentarius Commission?

It is an international intergovernmental organization established in 1963 by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). With the primary aim of protecting consumer health and ensuring fair food trade, Codex has been developing international standards for foods. As of September 2022, 188 countries and one organization (the European Union) have membership.

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.



*Total diet study: A survey method to understand how much specific substances, such as chemicals, are actually consumed through foods in a person's normal diet.

Specific Measures

Measures for methyl mercury	<ul style="list-style-type: none"> • Establishment of provisional regulation values for methyl mercury contained in seafood, etc. • Education of expectant mothers
Measures for cadmium	<ul style="list-style-type: none"> • Establishment of standards for cadmium contained in rice • Promotion of measures to reduce cadmium levels in agricultural areas
Measures for dioxins	Estimation of intake levels from ordinary diet (total diet study)

8 Food Additives

Before a food additive is authorized, the CAA verifies its effectiveness and whether its use is unlikely to cause adverse health effects. If needed, the CAA 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, generally, they do not have a long history of human consumption unlike foods.

The CAA consults the FSC and authorizes the use of them only when they do not have risks of harming human health.

The CAA continuously takes adequate measures to review the safety of authorized food additives, for example, by surveying daily intake levels per person.

Types of food additives (as of March 31, 2024)

- **Designated additives: 476 items**

Additives designated by the Minister of Health, Labour and Welfare after the safety has been assessed and demonstrated (sorbic acid, xylitol, etc.)

- **Existing additives: 357 items**

Additives exceptionally approved for use and marketing without designation as a "designated additive" after the amendment of the Food Sanitation Act in 1995, because they have already been used in Japan and have a long history of human consumption (gardenia color additive, tannin, etc.).

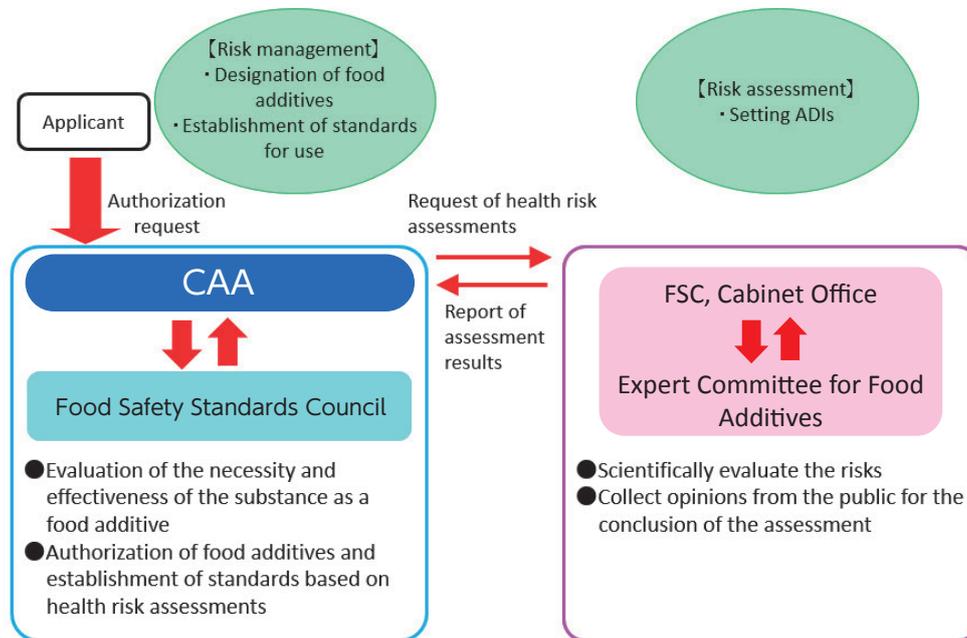
- **Natural flavoring agents: Approx. 600 items**

Natural substances obtained from animals and plants that are used to flavor foods (e.g., vanilla flavoring agents, crab flavoring agents, etc.)

- **Ordinary foods used as food additives: Approx. 100 items**

Substances that are generally provided for eating or drinking as foods and also used as food additives (strawberry juice, agar, etc.)

New designation of food additives



Specific Measures

Establishing standards for constituents and use	Set requirements to be met (e.g., impurities and assay) to ensure that distributed food additives have stable quality. Set the upper limits of each additive that can be used in individual foods (standards for use) to ensure that adverse health effects will not be caused by excessive consumption.
Conducting surveys on intake levels of food additives	Examine the type and amount of additives in foods actually procured from the market to determine whether they fall within the range of the corresponding acceptable daily intake (ADI: daily intake estimated to be free of adverse health effects even if a person continues to consume daily for life).
Ensuring the safety of existing food additives	Conduct safety assessment of existing additives. Remove from the list of existing additives those that have not already been used.

9 So-called “Health Foods”

A variety of foods are distributed as so-called “health foods.” The MHLW and the CAA 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 so-called “health foods.” They include such items that are in unique forms such as tablets and capsules.

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 associated with products and provides consumers with information for raising their awareness about health effects.

For all foods, food business operators must make efforts to provide information on adverse health effects associated with their products. In addition, the Regulations for Enforcement of the Food Sanitation Act were revised to require the business operators that notify Foods with Function Claims (FFC) and those approved for Foods for Specified Health Uses (FOSHU), to provide adverse health effect information associated with their products to prefectural governors. Information of cases is collected to MHLW, and MHLW considers whether food hygiene measures are necessary and publishes the results.

Foods containing the designated ingredients

Some so-called “health foods” contain an ingredient which could cause adverse health effects, particularly if used inadequately (alkaloid, hormone, etc.) As health hazards occurred due to the lack of uniform content of ingredients attributable to inadequate manufacturing control and the AI (adequate intake) not determined based on scientific evidence, the following four ingredients were designated as Foods containing the designated ingredients in order to prevent such incidents from reoccurring.

- Coleus (*Plectranthus barbatus* Andr.)
- Celandine (*Chelidonium majus* L. var. asiaticum (H.Hara) Ohwi)
- White Kwao Krua (*Pueraria candollei* var. mirifica)
- Black cohosh (*Actaea racemosa* L.)

Foods containing designated ingredients do not cause immediate health hazards. However, the occurrence of health hazards cannot be denied depending on the method of use and the method of intake. Therefore, FBOs that manufacture such foods are required to notify health hazard information and adopt Good Manufacturing Practice.

Collecting adverse health effects information associated with so-called “Health Foods”

Food			
So-called “Health Foods”			
Foods with Health Claims (Food Labeling Act)			
Foods for Specified Health Uses (FOSHU)	Foods with Function Claims (FFC)	Foods with Nutrient Function Claims (FNFC)	Other
<ul style="list-style-type: none"> ● For all food, obligation to make efforts to provide information on adverse health effects (The Regulations for Enforcement of the Food Sanitation Act, Appended Table 17 (ix)(b)) Regardless of seriousness, business operators that obtain adverse health effects information (limited to those diagnosed by a doctor) must make efforts to report the information. Adverse health effects information associated with so-called “Health Foods” are processed as written in “Guidelines to prevent adverse health effects by so-called “Health Foods” and quasi drugs” (MHLW Notice dated March 13, 2024) * No exact deadlines 			
<ul style="list-style-type: none"> ● For Food containing designated ingredients, mandatory provision of notification on adverse health effects (Food Sanitation Act, Article 8) “Notice on Food containing designated ingredients” (MHLW Notice dated April 17, 2020) * Serious case within 15 days * Non-serious case within 30 days 			
FOSHU guidelines (Notice by CAA) In case of obtaining information that death and serious sickness may arise, report to the Commissioner of CAA within 30 days	CAA guidelines (Notice by CAA) Regardless of seriousness, in case of “adverse health effect and the spread possible” report promptly * No exact deadlines		
<Revised rules> <ul style="list-style-type: none"> ● For FOSHU and FFC, mandatory provision of providing information on adverse health effects (The revised Regulations for Enforcement of the Food Sanitation Act, Appended Table 17 (ix)(c)) The rules for providing information are: as written in “Providing information on adverse health effects associated with FFC etc.” (MHLW Notice dated August 23, 2024) • Within 15 days when there are more than two cases with the same symptom approx. within 30 days • However, within 15 days for single serious case * 			

* Death, hospitalized case where a doctor evaluates as serious, un-hospitalized case where a doctor evaluates as serious. These cases must be provided even with a single case

Specific Measures

Specific measures at manufacturing stage

- Preparing guidelines to ensure the safety of raw materials for food products marketed in tablet, capsule, etc.
- Preparing Good Manufacturing Practice guidelines for food products marketed in tablet, capsule, etc.
- Requiring FBOs manufacture food products containing designated ingredients, etc. to adopt Good Manufacturing Practice.

Collection of information on health damage and enforcement of countermeasures

- Information is more actively collected, including cases where causality is unclear.
- Mandatory notification of health damage caused by foods containing designated ingredients

Providing information for consumers

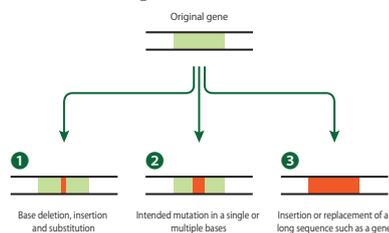
- Improving the webpage on so-called “health foods”
- Disseminating and raising awareness of the correct use of so-called “health foods”
- Enhancing the National Institutes of Biomedical Innovation, Health and Nutrition’s Information system on safety and effectiveness for health Foods

10 Foods Derived from Biotechnology

The CAA comprehensively examines the safety of foods and additives obtained by using new biotechnologies, such as recombinant DNA technology and genome editing technology.

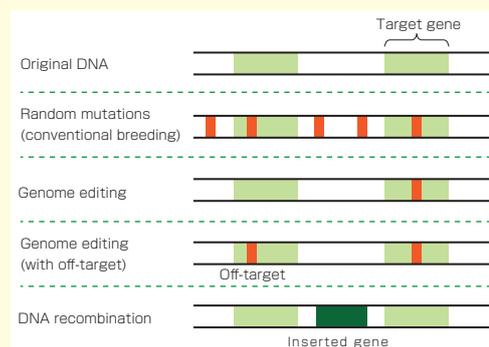
Recombinant DNA technology is a technique in which DNA removed from an organism is manipulated outside the cell and incorporated into DNA in a cell. Although this technology has already been applied as a breeding technology, genetically modified foods obtained with this technology ("GM foods") are not permitted to be distributed in the market unless they have been judged to have no safety problems after undergoing safety assessment. The safety assessment of GM foods is conducted by the Food Safety Commission (FSC) composed of experts upon request from the CAA. Following the assessment, the CAA announces and authorizes the distribution of GM foods for which no safety problems are found.

In genome editing technology, enzymes that recognize specific nucleotide sequences are used in the cell to cleave specific parts of the nucleotide sequence. Subsequently, the DNA repair machinery of the organism operates, resulting in changes in DNA sequences, such as (1) base deletion, insertion and substitution, (2) intended mutation in a single or multiple bases, and (3) insertion or replacement of a long sequence, such as a gene. Foods obtained with this technology are so-called genome-edited foods. Before the distribution of genome-edited foods, notification to the CAA is required for the publication of safety information. However, if a gene is incorporated in such foods, the same procedures as for GM foods are required.



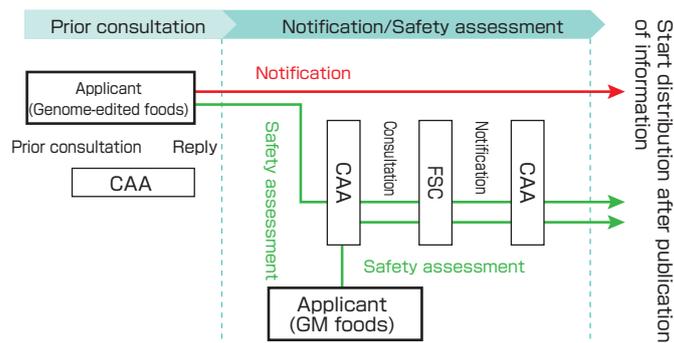
What is "Off-Target"

Conventional breeding using crossing or naturally occurring or artificially induced mutations results in random mutations. In contrast to a very low probability of mutating a target gene in conventional breeding, genome editing technology allows a high probability of specifically mutating a target gene. Nonetheless, an unintended mutation may occur, which is called an off-target. DNA recombination involves the insertion of a new gene.



Crops have been improved by using naturally occurring or artificially induced mutations and then crossing them. Although many unintended mutations occur in conventional breeding, the unfavorable nature of the breed is excluded in the breeding process (crossing and selection), making it a variety with superior properties. In genome-edited foods, off-targets arising from genome editing can be removed through crossing and selecting.

Procedures for ensuring the safety of foods derived from biotechnology



Specific Measures

Handling of genetically modified foods	<ul style="list-style-type: none"> • 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.
Handling of genome-edited foods	Advance consultation and notification systems started in October 2019.
Research and assessment for safety	Conduct research including development of detection methods for GM foods and collection of information on new foods derived from biotechnology.

11 Apparatus, Containers and Packaging, etc.

To ensure the safety of apparatus, containers, packaging, toys, and detergents, the CAA establishes specifications and standards for these products, and prohibits the use of raw materials that do not meet the specifications and the manufacturing of the products by using methods that do not meet the standards.

▶ Apparatus, Containers and Packaging (ACP)

The specifications and standards include (1) general specifications applied to all ACP and their raw materials, (2) specifications by material type, (3) specifications by application that requires considerations for safety, and (4) manufacturing standards.

In addition, the Positive List System was introduced in June 2020. Under this system, only substances assessed as safe are permitted to be used as raw materials for ACP.

Order for Enforcement of the Food Sanitation Act specifies that the substance subject to the Positive List System is synthetic resin, and the base materials and additives that are raw materials of synthetic resin are regulated by the Positive List as general specifications applied to all ACP. In the list, the base materials are categorized into 21 types of polymers and about 850 substances are listed as the additives. Substances that are not listed on the list cannot be used as raw materials of synthetic resin used for ACP.

For facilities manufacturing ACP, general hygiene management and manufacturing management systems have been established as necessary measures for public health. To prevent occurrence of health problems, it is important to manage the manufacturing process. The MHLW has provided guidelines for manufacturing management, which are helpful as a reference for ACP manufacturers.

▶ Toys and Detergents

For toys and detergents as well, specifications and standards have been established to prevent hygiene hazards caused by food consumption and to protect health of the people.

The regulations apply to the toys designated by the Minister of Health, Labour and Welfare and the Prime Minister as those likely to cause harm to the health of infants by coming into contact with the products, and to the detergents used for cleaning mainly vegetables and fruits.

“Apparatus”

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

“Containers and packaging”

Articles that contain or wrap food or food additives and are offered “as is” when delivering food or food additives.

Specific Measures

Establishment of systems to enhance the safety of ACP	Introduce positive list systems for food ACP. (List substances assessed as safe, and effectively operate the systems through manufacturing management and information sharing.)
Preparation and enhancement of specifications and standards for ACP	Prepare testing methods stipulated in the specifications and standards.
Ensuring of safety of recycled materials	Prepare guidelines for the use of recycled plastic and paper for ACP.

Food Inspection and Safety Division Public Health Bureau, Ministry of Health, Labour and Welfare

Phone : 03-5253-1111

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Food Safety Standards and Evaluation Division, Consumer Affairs Agency

Phone : 03-3507-8800

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