





Ministry of Health, Labour and Welfare

# 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.

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### 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 in the MHLW

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.

#### The Ministry of Health, Labour and Welfare

Under the Food Sanitation Act and other related acts, the MHLW 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 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.



#### > 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, 80 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 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 Sanitation Act Amendment**

#### Background

Since the last amendment of the Food Sanitation Act in 2003, the circumstance of food safety has been changing - globalization of food has developed because of increasing import food and wider variety needs of food, e.g. increasing demand of pre-cooked foods, eating out (gaishoku) and taking away (chushoku).

Besides, wide-area food poisoning incident caused by enterohemorrhagic E. coli, etc. and adverse health effects of Health Foods have occurred, so it is necessary to respond to these issues.

Also, as Olympics and Paralympics are going to be held in Tokyo in 2020, food hygiene control system compatible with the international standards is required.

Taking into account the present conditions and issues regarding food hygiene, the amendment of the Food Sanitation Act was promulgated on June 2018.

### The seven points of amendment

- Reinforcement of wide-area food poisoning incident response
  - Coordinate and cooperate between the MHLW and local governments to prevent outbreak and expansion of food poisoning. The MHLW newly establish "council for wide area cooperation", in an emergency, is uti-

lized to manage the incident.

2. Institutionalization of food hygiene control based on HACCP principles for all food business operators

HACCP is a hygiene control system that controls hazards such as contamination of pathogenic microorganisms, foreign objects etc. throughout the process from receiving raw materials to shipping final product based on scientific evidence. As a general rule, request all food business operators to implement hygiene control based on HACCP principles, in addition to prerequisite program. Considering the burden to small businesses, the MHLW promotes making guides for HACCP implementation.

3. Obligation to notify health damage incident caused by intake of their food products containing the designated ingredients or components.

In case health damage incidents are caused by ingredients and components that designated by the Minister of Health, Labour and Welfare occur, food business operators are required to notify health damage cases to government.

#### Introducing a positive list system for food containers and packaging

Introduce a positive list system for food containers and packaging. Under the system, only substances with those safety evaluated are allowed to be used.

5. Establishment of notification system and reviewing of licensing system for food business

Create a notification system for food business, as well as review business types requiring licenses, based on business conditions.

#### 6. Obligation to notify food recall information to governments

Establish a mechanism for food business operators to report on their voluntary recall information to governments and for governments to provide the information to public through the website.

#### 7. Further enhancement of Import and export food safety certification

- ▶ To ensure safety of import food, require hygiene control with HACCP to meat etc. and health certificate for dairy and seafood products, as a strengthened control in exporting countries.
- Create legal provision for food export, e.g. food export related procedure by local governments.

### A date of enforcement

This Act shall come into effect as from the date specified by a Cabinet Order within a period not exceeding two years from the day of promulgation.

(However, for point 1, within a period not exceeding one year, and for point 5 and 6, within a period not exceeding three years.)

### **Food Poisoning**

governments, etc.

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 2017, the MLHW amended "the Hygienic Control Manual for Large-Scale Cooking Facilities". which shows important management items during cooking process in order to prevent food poisoning at large scale cooking facilities based on the concepts of HACCP, following the case of enterohemorrhagic E. coli O157 food poisoning attributed to "sliced cucumber flavored with red Shiso"in nursing homes in 2016 and the large sized case of norovirus food poisoning attributed to "Shredded nori" in 2017.

Also, following the Enterohemorrhagic E. coli infection/food poisoning that broke out across the Kanto Region in 2017 as a background, the MHLW amended the Food Sanitation Act as below. In order to prevent occurrence and expansion of interregional food poisoning cases, the related parties' obligation to cooperate is explicitly stipulated, and as a framework of such cooperation, the MHLW may establish a council for wide area cooperation which is composed of relevant parties of the national and local governments etc. When an urgent response is required, the MHLW may utilize the council to address interregional food poisoning cases.

By sharing information among the national and local governments at the councils, the MHLW seek to detect interregional food poisoning cases at an early stage, and to conduct effective investigation to determine the cause, etc. In addition, the MHLW develop requirement of food hygiene control based on HACCP principles, which is highly effective to prevent food poisoning and aligned with the international standards.



# Food Hygiene Control Based on HACCP Principles

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

The amendment of the Food Sanitation Act was promulgated on June 2018, and all food-related business operators (FBOs) (including manufactures, processors, restaurants, caterers, retailers etc.) are required to implement food hygiene control based on HACCP principles.

The date of enforcement is specified by Cabinet Order within a period not exceeding two years from the date of promulgation, but for one year from the date of enforcement, all FBOs can apply the present standards.

FBOs will be required to create hygiene control plans and to record the status of its implementation.

The MHLW continues to support FBOs in implementing food hygine 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.

### All FBOs create hygiene control plans by themselves.

#### 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)]

#### 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
- Manufacturing, processing and cooking business operators aiming only for retail sales at the same location
- Business types that provide a wide range of food items with frequent changes in menus
- igoplus Business types that can be handled with general good hygiene practice

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.
Organize periodic meetings for reaching common understanding, sharing information and having communication among stakeholders such as the central government, local governments, FBOs etc. to promote HACCP implementation. 7 regional meetings also take place to consider regional issues.
Encourage local governments to support FBOs who try to introduce HACCP, and publicize its records including all the processes of introduction, the problems and the solutions during the project and the results as a model case.
Introducing FBOs on the website who try to introduce and implement the HACCP-based food hygiene control.
Introduction textbooks and videos for HACCP implementation as well are available on website. • Introduction textbook for HACCP implementation at food manufacturing • Model plan for HACCP implementation at food manufacturing • Introduction for HACCP implementation at food manufacturing (video) • Textbook for food hygiene control based on the HACCP principles

### 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 consumed as foods or beverage before, or those 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 health damage caused by products and provides consumers with information for raising their awareness about health effects.

#### Partial amendment of the Food Sanitation Act and other related acts

This amendment has introduced the following measures in order to prevent health damage: (1) a designation system by the Minister of Health, Labour and Welfare for the ingredients and components that requires particular care when contained in food; and (2) a notification system that requires business operator to report health damage cases to governments when they are caused by intake of their food products containing the designated ingredients or components.

The MHLW is also going to request the business people who manufacture or sell foods containing the designated ingredients or components to manage the manufacturing appropriately and to ensure food safety on the ingredients and products by establishing specifications and standards for the designated ingredients and components.





X About health damage information caused by "so-called health foods", the MHLW continue to carry out voluntary information collection based on notice.

#### Specific Measures

Specific measures at manufacturing stage	<ul> <li>Ensuring safety of materials (publication search and toxicology test (when diet experience is not sufficient)</li> <li>Ensuring safety by good manufacturing practice (GMP) (manufacturing management and quality management in the whole process)</li> <li>Ensuring the efficiencies (adaptation of the third-party certification system)</li> </ul>
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.
Providing information for consumers	<ul> <li>Website on health foods         https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/hokenkinou/index.html         Brochure " Appropriate Use of Health Foods"         https://www.mhlw.go.jp/file/06-Seisakujouhou-11130500-Shokuhinanzenbu/0000113706.         pdf         Website by the National Institute of Health and Nutrition         "Information System on Safety and Effectiveness of Health Foods"         https://hfnet.nibiohn.go.jp/     </li> </ul>

# Utensils, Containers and Packaging, etc.

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.

#### Utensils, Containers and Packaging

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.

And, the MHLW introduces a Positive List System that basically allows substances with those safety are evaluated to be used for synthetic resin Utensils, Containers and Packaging for food by 2020.

#### "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 and Detergent

The MHLW also establishes specifications and Standards for toys and detergent to prevent health and hygiene hazards that are likely to be caused as a result of the use of these products.

The regulation apply to toys designated by the Minister of Health Labour and Welfare as those likely to harm the health of infants when they touch such toys, and to detergents used for cleaning mainly vegetables and fruits.

Specifications and Standards fo	r Safety of Utensils, Containers and Packaging, Toys and Detergent
Food Sanitation Act Article 1 Article 1	6 : Banning of sales of harmful or toxic utensils, containers and packaging 8 : 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 Applica Establis Article	ion with modification of Article 62 : of sales and other business activities of harmful or toxic toys and detergent ment of specifications and standards for toys and detergent 52 : Designation of toys applicable for regulations
<toys applicable="" for="" reg<br="">Those likely to harm the health</toys>	ulations (designated toys)> of infants when they touch such toys (Article 78 of the Regulation)

Specific Measures	
Establish a system to enhance the safety of Utensils, Containers and Packaging	Design the specific frameworks to introduce the Positive List System for Utensils, Containers and Packaging.
Preparation and enforcement of specifications and standards for Utensils, Containers and Packaging.	Prepare test methods, etc. stipulated in the 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.

### Imported Foods

Japanese food self-sufficiency rate is about 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.

As a result of the amendment of the Food Sanitation Act, the following measures will take place to ensure safety of imported food.

For meat: food hygiene control by HACCP in exported countries will be required.

For milk products and fishery products : Attachment of health certification will be required.

#### 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.



Inspection system at importation		Specific I	Measures
High Comprehensive import ban Total number of not Inspection order Enforcement of monitoring Low Monitoring inspection Guidance inspection, etc.	High Comprehensive import ban Total number of inspection / Number of notifications (FV 2017) Inspection order	Inspection order	Food products with high possibility of violation of the Food Sanitation Act (e.g., contamination with carcinogenic substances (mycotoxin) 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.
	Low Monitoring inspection Guidance inspection, etc.	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.

# **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.



Testing food samples for radioactive materials

#### 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	50
Drinking water	10

#### Transition of violation rate of radioactive cesium in foods



at the provisional regulation values.

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		
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.		
All test results conducted by local governments, are collected and disclosed on the Website of the MHLW *1.		
Restriction of distribution or consumption directed by the national government (the Nuclear Emergency Response Headquarters) are notified on the Website of the MHLW *2.		
Website of the MHLW "Measures for Radioactive Materials 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		

### 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.



### **Specific Measures**

Making safety assessment obligatory	<ul> <li>Safety assessment was made obligatory in April 2001</li> <li>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.</li> </ul>
Research and assessment for safety	Development of detection methods for GM foods and assessment of allergic property of proteins are conducted.

## 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)

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.

#### **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)).
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, Brazil, Norway, Denmark, Sweden, Italy, Switzerland, Liechtenstein and Austria)

# **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 adopted as a priority if there are CODEX standards set for the specific food. If the MHLW cannot adopt 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<sup>\*</sup>.

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.



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

Specific Measures		
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	
Measures for dioxins	Estimation of intake levels from ordinary diet (total diet study)	

# 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).



\*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

Establishment of standards, etc.

Establish residue limits for agricultural chemicals in foods.
 Develop analytical methods for agricultural chemicals in foods.

Monitoring and intake study

Conduct monitoring for residual levels of agricultural chemicals in foods.
 Conduct a market basket study of agricultural chemicals intake via foods.

### 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.



Establishing specification and standards for food additives	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.
Ensuring the safety of existing food additives	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.
Conducting surveys on intake levels of food additives	Collect samples from foods on the market place, identify food additives in the samples, and measure their levels to examine whether the total levels are within the corresponding ADIs (acceptable daily intake: maximum amount of a substance to which an individual can exposed to on a daily basis over his/her life span without causing any harmful effects).

### Specific Measures

### Policy Planning Division for Environmental Health and Food Safety Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare

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 EN http://www.mhlw.go.jp/english/policy/health-medica l/food/index.html