The Nineteenth Seminar

for

Visiting Food Hygiene Experts

—2006—

Policy Planning and Communication Division
Standards and Evaluation Division
Inspection and Safety Division

Department of Food Safety
Pharmaceutical and Food Safety Bureau
Ministry of Health, Labour and Welfare

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<For reference: the HACCP system>

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Part I

Administration of Food Safety

Part I　Administration of Food Safety

Introduction

The purpose of the administrative work concerning food safety is to protect the health of the public through the strengthening measures for the assurance of food safety.

Japan carries out food safety work under the Food Safety Basic Law (enacted in May 2003) and related laws, including the Food Sanitation Law, the Abattoir Law, and the Poultry Slaughtering Business Control and Poultry Inspection Law. The related laws also include the Law of Temporary Measures for Enhancing the Control Method of the Food Production Process and the Health Promotion Law. The work covers a wide range of responsibilities from regulating the manufacture, import, and sale of food, food additives, and food apparatus and containers/packages to providing necessary information to consumers and businesses.

This document outlines the food sanitation work. For details, please consult the attached documents and tests prepared by each division responsible for this study program.

1. Structure and responsibilities of the Department of Food Safety

All ministries and agencies in Japan were reorganized as of January 6, 2001. The Ministry of Health and Welfare and the Ministry of Labour have been merged into one ministry named the Ministry of Health, Labour and Welfare (MHLW). The administration of food safety is now under the jurisdiction of the Department of Food Safety under the Pharmaceutical and Food Safety Bureau. The structure and its main responsibilities are given below. The entire organization of the Ministry is accessible on the MHLW web site (http://www.mhlw.go.jp). For relationship between national and local governments, see Diagram 1.

Department of Food Safety, Pharmaceutical and Food Safety Bureau

- Policy Planning and Communication Division (General coordination of responsibilities under the jurisdiction of the Department of Food Safety, risk communication)
  - Office of International Food Safety (General coordination of international affairs under the jurisdiction of the Department)
  - Office of Port Health Administration (Quarantine business, inspection of imported food)
- Standards and Evaluation Division (Establishment of specifications/standards for food, food additives, pesticide residues, animal drug residues, food containers, and food labeling)
  - Office of Health Policy on Newly Developed Food (Labeling of specified uses, nutrition labeling standards, foods with health claims, dietary supplements, safety assessment of genetically modified foods)
- Inspection and Safety Division (Food inspection, health risk management such as measures for food poisoning, safety measures for poultry and livestock meat, dissemination and promotion of the HACCP approach, GLP, measures for environmental contaminants, sanitary control of rendering plants)
  - Office of Import Food Safety (Assurance of import food safety)

Diagram 1.

Relationship between national and local governments

- Ministry of Health, Labour and Welfare
  - Pharmaceutical and Food Safety Bureau
    - Department of Food Safety
      - Policy Planning Division
        - Office of International Food Safety
        - Office of Port Health Administration
      - Standards and Evaluation Division
        - Office of Health Policy on Newly Developed Food
      - Inspection and Safety Division
        - Office of Import Food Safety
  - Pharmaceutical Affairs and Food Sanitation Council
  - National Institute of Health Sciences
  - National Institute of Health
  - National Institute of Public Health
  - Related Health Bureaus
- Regional Bureau of Health and Welfare
  - Food Sanitation Division
    Health and Welfare Division
- Prefectural governments, Municipal Governments
  - Health Authorities
    - Food Sanitation Div. — Food Sanitation Inspectors — 7,911 Inspectors
    - Health Centers
      - Food Sanitation Inspectors — 7,911 Inspectors
      - Meat Inspectors, Poultry Inspectors — 2,662 Meat inspectors
    - Meat Inspection Centers — Meat Inspectors, Poultry Inspectors — 2,662 Meat inspectors; 2,780 Poultry inspectors
    - Public Health Laboratories
  - Related Authorities
- Quarantine Stations — Food Inspection Div. — Food Sanitation Inspectors (314) *

Note: The numbers are as of the end of fiscal 2004, and the number marked with asterisk (*) is as of April 2006.

2. Outline of the administration of food safety

The food safety administrative work is based on the Food Safety Basic Law (enacted in May 2003), the Food Sanitation Law, the Abattoir Law, the Poultry Slaughtering Business Control and Poultry Inspection Law, and other related laws.

There has been a growing concern and distrust of food safety among the Japanese public, triggered by various problems involving the occurrence of BSE in 2001. Under such circumstances Japan has enacted the Food Safety Basic Law, a comprehensive law to ensure food safety for the purpose of protecting the health of the public, as well as has developed related laws. In the wake of the development of these laws, Japan has introduced a risk analysis approach to food safety work.

The approach is to scientifically assess risks (expressed as the probability and degree of adverse health effects) and develop necessary measures based on the risk assessment. The risk analysis consists of three components: risk assessment—assess risk scientifically; risk management—implement necessary measures based on risk assessment; and risk communication—exchange information and opinions among related people representing the people including public, government, and academia. The Food Safety Basic Law is responsible for the risk assessment, and the Food Sanitation Law and other related laws are responsible for the risk management. The risk assessment is in practice conducted by the Food Safety Commission established under the Food Safety Basic Law (See Diagram 2).

The Food Sanitation Law covers various responsibilities. They include the establishment of standards and specifications for food, additives, apparatus, and food containers/packages; inspection to see whether these established standards are met; the hygiene management of the manufacture and sale of food; and business license. (See Diagram 3) The Abattoir Law and the Poultry Slaughtering Business Control and Poultry Inspection Law cover the regulation of livestock meat and fowl meat including inspection systems for meat. In addition, the publication of relevant information and international cooperation in study and research are an important part of the food safety work.

To achieve those responsibilities, local governments play an important role, as well. The local governments conduct inspection of and give advice to food-related businesses. They grant a license to businesses that operate within the jurisdiction concerned, and suspend licensed businesses and/or revoke operation if they violate the law. They also conduct food testing. These activities are executed through health centers under the jurisdiction concerned.

Imported foods are inspected by 31 quarantine stations placed across Japan under the central government.

Diagram 2

NEW MEASURES FOR FOOD SAFETY

~RISK ANALYSIS~

RISK ASSESSMENT

Food Safety Commission

- To conduct a risk assessment.
- To recommend that agencies in charge of risk management implement necessary measures for food safety, based on the risk assessment results.
- To monitor the risk management by related agencies.
- To collect and analyze domestic and international information on food safety hazards.
- To comprehensively manage total risk communication including activities of the risk management agencies.

Food Safety Basic Law

RISK MANAGEMENT

MHLW

- Quarantine Stations
- Regional Bureaus of Health and Welfare
- Health Centers, etc.

Risk management for food safety

Food Sanitation Law, etc.

MAFF

- Regional Agricultural Administration Offices
- Centers for Food Quality, Labeling and Consumer Services, etc.

Risk management for agricultural, livestock, and fishery production.

Agricultural Chemicals Regulation Law, etc.

RISK COMMUNICATION

- Disclosure of information on food safety
- Ensuring opportunities for consumers to express their opinions

Diagram 3.

Overview of Administration of Food Safety

Ministry of Health, Labour and Welfare (Risk Management)

Food Safety Comission (Risk Assessment)

Mutual cooperation
Execution of comprehensive risk communication

Ministry of Agriculture, Forestry and Fisheries (Risk Management)

Foods, Additives, Apparatus, and Containers/Packages

1. Establish specifications/standards
   → Prohibit the sale of noncompliant foods.
   Food additives, pesticides residues, veterinary drug residues, GM foods, apparatus/containers.
2. Establish labeling standards
   → Prohibit the sale of noncompliant foods.
   Allergic food ingredients, GM foods.
3. Designate food additives
   → Prohibit the use of unlisted additives.
4. Prohibit the sale of newly developed foods.
5. Prohibit the sale of foods for specified health uses
6. Prohibit the sale of harmful foods.
7. Prohibit he sale of meat of diseased animals.
8. Formulate guidelines for inspection and guidance.
9. Formulate inspectiona and guidance plan for imported foods.
10. Establish standards for preventative measures against contamination with harmful substances.

HACCP (Hazard Analysis and Critical Control Points) system

1. Approve the type of foods or facilities.
2. Renewal of approval.
3. Establish standards f6r manufacturing/processing and sanitary control
   → Revoke approval in case of noncompliance.

Quarantine Stations (31)*

Hygiene inspection for imported foods

Food sanitation inspectors (314) *

Inspection

Notification

Consulting

Pharmaceutical Affairs and Food Sanitation Council

(Hadle matters under authority of the Council, based on the Law)

Reporting

Guidance

Report

Prefectural and Municipal Governments

1. Formulate inspection and guidance plan for food hygiene.
2. Establish standard for business facilities by business type.
3. Establish standards for management/operation of business facilities.
4. License businesses.
5. Inspect food related businesses and distributed foods and give guidance.
6. Revoke business licenses, and prohibit and suspend business operations.

Regional Bureau of Health and Welfare (7)*

Food Sanitation Division

Food sanitation inspectors (42) *

Imported foods

Check whether Specificatios/ standards are met.

Approval/renewal/ change.

Application fees.

Application

Busines license

1. Product examination (Examination of food colors)
2. Examination order (Cases where hazards may occur)

1.Approval/renewal
2.Site-inspection
3. Revocation of approval

Meat Inspection Laboratories

(119)

Meat inspection
Meat inspectors
(2,662)

Public Health Centers

(549)*

Inspect and guide businesses

Food sanitation inspectors
(7,911)

Registered laboratories (78 labs and 100 facilities)*

Meat inspetion

Approval of establishment

Inspection/ guidance

Inspection fees

Inspection

Abattoirs

(221)

Food related businesses

1. Facilities requiring business licenses, e.g., restaurant businesses (2,637,897).
2. Facilities not requiring business licenses (1,457,358).

"Comprehensive sanitation-controlled manufacturing process" (HACCP) approved facilities (565)*

Note: The statistics were as of the end of fiscal 2004. The statistics marked with asterks "*" were as of April 1, 2006.

3. Relevant statutes

Various laws are responsible for the food safety administrative work: (1) the Food Safety Basic Law, (2) the Food Sanitation Law, (3) the Confectionery Hygienists Law, (4) the Abattoir Law, (5) Special Measures Law Concerning Bovine Spongiform Encephalopathy, (6) the Poultry Slaughtering Business Control and Poultry Inspection Law, (7) the Rendering Plants Control Law, (8) the Law on Temporary Measures for Enhancing the Control Method of the Food Production Process, and (9) the Health Promotion Law. This section outlines these laws.

(1) Food Safety Basic Law

(a) Basic principles and purpose

Basic principles

—To protect human life and health
—To ensure food safety at each stage in the food supply chain
—To respond in line with the latest scientific knowledge and international trends for food safety

Purpose

In consideration of the vital importance to appropriately respond to changes in the environment surrounding the diet and life style of the public, including advances in science and technology and the progress of globalization, this law is to comprehensively promote policies to ensure food safety by establishing basic principles, clarifying the responsibilities of national and local governments and food related businesses as well as consumers' roles, and establishing a basic direction for policy formulation in regards to the assurance of food safety.

(b) Responsibilities and roles

i. Responsibility of the national government

—The national government must comprehensively formulate and implement policies to ensure food safety.

ii. Responsibility of local governments

—Local governments must, as necessary, formulate and implement policies with an appropriate sharing of roles with the national government.

iii. Responsibilities of food business operators

— Food business operators must recognize that they are primarily responsible for ensuring food safety and take necessary measures on a timely basis.

— Food business operators must make efforts to provide precise and adequate information to the consumers.

iv. Role of consumers

—Consumers should deepen their knowledge and understanding about food safety, and use the provided opportunities for expressing their opinions.

(c) Ensuring food safety through risk analysis

i. Risk analysis

In principle, policies to ensure food safety must be formulated, revised, and repealed, based on the following risk analysis approach.

- Risk assessment

—The risk assessment is under the responsibility of the Food Safety Commission, an administrative agency independent of the agencies that are responsible for risk management.

—The risk assessment must be based on the latest scientific knowledge.

- Risk management

—Relevant government agencies must establish food safety standards, based on risk assessment results, taking into account the opinions of interested parties, such as consumers.

— Relevant government agencies must implement provisional risk management measures in a prompt and appropriate manner, when necessary from a preventive viewpoint.

- Risk communication

—Relevant government agencies must publish information on the assurance of food safety.

—Relevant government agencies must provide interested parties, such as consumers, with opportunities to express their opinions.

ii. Establishment of an organization responsible for risk assessment (Food Safety Commission)

The Commission must execute the following responsibilities as an organization responsible for risk assessment.

—To execute the duties and tasks as the risk assessment organization.

—To formulate basic guidelines for risk analysis and crisis management.

(d) Enhancement of policies to ensure food safety

The Food Safety Basic Law stipulates

—Cooperation among administrative agencies.

—Enhancement of scientific investigations and studies as well as the security of human resources.

—Collection of domestic and international information.

—Appropriate operation of a food labeling system.

—Promotion of food education.

—Consideration of effects on the environment.

<Food Safety Commission >

Duties and tasks

i. Risk assessment

- Risk assessment

—The Commission must conduct a risk assessment for food safety, using a risk analysis approach.

—The Commission must recommend that related administrative agencies implement necessary measures for food safety, based on the risk assessment results.

—Transparency must be ensured in conducting the risk assessment.

—The risk assessment must target all foods. The risk assessment must also cover biological, chemical, and physical agents in, and conditions of, food with potential to pose adverse health effects (hazards). Pharmaceutical products are excluded from the risk assessment because their safety is separately ensured under other laws.

- Monitoring

—The Commission must monitor whether risk management agencies are implementing appropriate control measures in accordance with the recommendations of the Commission. The Commission must establish a framework to directly identify consumers' opinions.

- Comprehensive collection of information

—The Commission must comprehensively collect and compile domestic and

international information on hazards.

ii. Risk communication

—The Commission must exchange necessary information and opinions on the risk assessment conducted by the Commission with interested parties.

—The Commission must comprehensively manage total risk communication, including the risk communication conducted by risk management agencies.

—The Commission must establish a framework for communication between the Commission and other interested parties, including risk management agencies, consumers, and producers.

(2) Food Sanitation Law

Purpose

This law aims to prevent the occurrence of health hazards arising from eating and drinking by implementing regulations and other necessary measures from the standpoint of public health to ensure food safety, so as to protect the public health.

- The law is roughly divided two parts: 1) establishment of standards including specification and standards for food, standards for facilities, standards for management/operation, and standards for labeling; 2) inspections and guidance including inspection by national government at import and inspections and guidance by local and municipal governments for domestic food businesses.

(a) Establishment of standards

Specifications and standards for food

The law stipulates that the Minister of Health, Labour and Welfare may, from the standpoint of public health, establish compositional specifications for food and food additives and standards for the manufacturing, processing, and use of them, after hearing the opinion of the Pharmaceutical Affairs and Food Sanitation Council. Currently, various specifications and standards are specified in the Ministry of Health, Labour and Welfare Announcement. Products that do not comply with the established specifications and standards are prohibited from being manufactured, imported, sold, used, or otherwise handled.

The law also stipulates that the Minister may, from the standpoint of public health, establish specifications for apparatus and containers/packages intended for sale or for use in business, specifications for their raw ingredients, or standards for manufacturing methods of these products. Products that do not comply with the

established specifications and standards are prohibited from being manufactured, imported, sold, used, or otherwise handled.

Crops containing pesticides and related chemicals without residue standards will basically be enjoined from domestic distribution after the positive list system takes effect (within three years from May 30, 2003 when the law was amended). The Minister may establish provisional standards as an interim measure, based on use conditions in Japan and international standards.

Labeling standards

The law stipulates that the Minister may establish labeling standards for food, after hearing the opinion of the Council. Products that do not comply with the established standards are enjoined from domestic distribution.

Standards for facilities

Prefectural governors and municipal mayors may establish standards for facilities of businesses by the type of business that have significant influences of public health such as restaurants. Currently, 34 types of businesses are specified as targets. These standards cover structure, food handling equipment, water supply, and filth treating. Prefectural governments may license businesses, when their facilities meet the established standards. Also, they may revoke the license or suspend/prohibit the operation when the facilities do not meet these standards.

Standards for management and operation

Prefectural governors establish standards for measures to be taken for business facilities from the viewpoint of public health. These standards cover facility management, management for food handling equipment, food handling, and health management of food-handling personnel. Governors may revoke the license or suspend/prohibit the operation when the facilities do not meet these standards.

(b) Inspection system

Domestically distributed foods

Health centers (549 centers in total) under each prefectural and municipal government (127 governments) have food sanitation inspectors (7,911 inspectors in total) to visit food related facilities (about 4.10 million facilities) to conduct on-site inspection, in order to see whether the established standards for food and facilities are met.

Import notification

The law stipulates that persons who wish to import food, food additives, apparatus, or containers/packages intended for sale or use in business must notify the Minister each time they are imported. A notification is submitted to the quarantine station that has jurisdiction over the port/airport where costumes clearance is performed.

Examination order and other matter

The law stipulates that the Minister may order a person who import any food, food additive, apparatus, container, or package that is likely to violate this law, in light of circumstances in the production area or other circumstances including a previous violation case, to allow examinations performed by the Minister or a registered laboratory,* when the Minister determines that such action is necessary to prevent the occurrence of health hazards. No person who has received any examination order must sell or use in business any food or other target product until it undergoes the examination and such person receives a notice of the examination result. (Examination order)

At quarantine stations, food sanitation inspectors examine the submitted notification, give an examination order for products that are suspected to violate the law, and systematically monitor other products. Products that are found to violate the law as a result of examinations are discarded, reshipped, or otherwise treated.

* Registered laboratories: Impartial and independent organizations with testing ability that are registered with the Minister of Health, Labour and Welfare to carry out the tests specified in the law, such as examinations by minister's order.

Guidelines for monitoring and guidance, and monitoring and guidance plan

The Minister has formulated the guidelines for monitoring and guidance, which show major emphases of food safety monitoring and guidance conducted by the national and local governments. Based on the guidelines, the Minister annually prepares and publishes a monitoring and guidance plan for imported foods, as an implementation plan for testing imported foods. The results of tests conducted are annually published.

Based on these guidelines and plan, the local governments annually prepare and publish an implementation plan for monitoring and guidance, which is suited to local circumstances. Also, test results are published.

(c) Administrative dispositions and penalty for violation cases

The Minister or prefectural governors may order persons to dispose of or recall products, to correct noncompliant conditions of the business facilities, or to reship the cargo, or my revoke the license or prohibit all or part of the business when those

person violate the law. Persons who violate the law are punished by penal servitude of one year to three year, or by a fine of 50,000 to 3 million yen (up to 100 million yen for a corporation).

(3) Confectionery Hygienists Law

Purpose

The Confectionery Hygienists Law aims to contribute to the improvement and promotion of public health, through improving the qualifications of persons who engage in producing confections, by establishing a license for confectionery hygienists.

- Confectionery Hygienists are persons who pass certain tests given by Prefectural governors, obtain a license, and engage in producing confections. Standards for the tests are established by the Minister.

- No person other than a licensed confectionery hygienist may be called a confectionery hygienist, or a similar name.

(4) Abattoir Law

Purpose

The Abattoir Law aims to protect the health of the public, by implementing regulations and other measures necessary in the view of public health, for the purpose of ensuring proper management of slaughterhouses (218 facilities) and processing of food-use livestock.

- Any person who wishes to establish facilities to slaughter (slaughterhouses) and dress livestock (cattle, horses, swine, sheep, goats) intended for food use must obtain permission from the prefectural governor or the mayor of the city.

- No livestock intended for food use must be slaughtered or dressed in any place other than a slaughterhouse.

- Livestock inspections are required at the following three stages:
  — Before being slaughtered or dressed: ante-mortem inspection.
  — Before slaughtered livestock is dressed: ante-dressing inspection.
  — Before dressed livestock is carried out of the slaughterhouse: post-dressing inspection.

No part of the livestock including meat, viscera, blood, bones, skin may be carried out of the slaughterhouse before they are inspected.

- No person may be provided with the meat or viscera of livestock dressed in any place other than a slaughterhouse, or the meat or viscera carried out without receiving a post-dressing inspection, with intent to sell for food use.

- Inspections are conducted by livestock inspectors (2,629) who are employees of prefectures or cities with health centers.

- When prefectural governors and mayors of cities with health centers determine, as a result of inspection, that animals are not fit for food use, due to the existence of disease, they may prohibit the slaughtering or dressing of the livestock, or may take other appropriate measures.

(5) Special Measures Law Concerning Bovine Spongiform Encephalopathy

Purpose

This law aims to establish a system to provide a consistent supply of safe beef by establishing special measures for preventing the occurrence and spread of bovine spongiform encephalopathy (BSE), in order to contribute to the protection of public health and the wholesome promotion of cattle production, dairy farming, the business of beef manufacturing, processing, distribution, and sales, and the restaurant business.

Outline of regulations under the jurisdiction of the Ministry of Health, Labour, and Welfare*

(a) Formulation of a basic plan

- If BSE is confirmed or suspected, the Minister of Health, Labour, and Welfare must lay down a basic plan concerning measures to be taken by national and prefectural governments.

(b) Inspections, etc. concerning BSE at a slaughterhouse

- No one may carry the meat, offal, blood, or skin of any cattle of the age designated by the Ministry of Health, Labour and Welfare Ordinance or older out of the slaughterhouse before the cattle is tested by the governor of the prefecture concerned or the mayor of the city with health centers.

- Any person who establishes or manages a slaughterhouse must incinerate

* The Special Measures Law Concerning Bovine Spongiform Encephalopathy is under the jurisdiction of two ministries: the MHLW and the Ministry of Agriculture, Forestry and Fisheries.

specific risk materials, such as the brain and spinal cords of cattle, except when they are approved by the governor of the prefecture concerned or the mayor of the city with health centers for use in academic studies.

- In a slaughterhouse all cattle must be slaughtered or dressed in a way that can protect the dressed carcasses and edible offal from cross-contamination by specified risk materials.

(6) Poultry Slaughtering Business Control and Poultry Inspection Law

Purpose

This law aims to protect the health of the public, through the prevention of health hazards arising from any part of poultry, by implementing regulations and other measures necessary in the view of public health and by establishing a poultry inspection system.

- Any person who wishes to slaughter fowls (chickens, ducks, turkeys, and other fowls) and remove the feathers and viscera from their carcasses, must obtain permission for each processing plant from the prefectural governor or the mayor of the city with health centers or the ward. (about 3,000 plants nationwide)

- No poultry processing business person (hereafter referred to as a "poultry processor") may allow another person to operate his processing plan under his own name.

- Any poultry processor must appoint and station licensed hygiene managers at each processing plant to carry out hygiene management.

- Poultry inspection are required at the following three stages:

i. Before being slaughtered: ante-mortem inspection

Any fowl must undergo inspection by the prefectural governor or other appropriate person concerned.*

ii. Before the viscera is removed: feather-removal inspection

All carcasses must undergo inspection by the prefectural governor or other appropriate person concerned*, to check the conditions of their surfaces.

iii. After carcasses are eviscerated: post-evisceration inspection

All removed viscera and eviscerated carcasses must undergo inspection by the prefectural governor or other appropriate person concerned, to check the conditions of the viscera and the inside walls of the carcasses.

Note: The prefectural governors may allow persons designated by the Minister of Health, Labour, and Welfare to conduct part or all of the poultry inspections.

- No carcasses, eviscerated carcasses, meat, or other parts may be carried out of the poultry processing plant without passing poultry inspection.

- No person may be provided with any carcass, eviscerated carcass, meat, or other parts that were processed outside a processing plant, or with any carcass, eviscerated carcass, meat, or other parts that were carried out of a processing plant without passing inspection, with intent to sell for food use.

- When prefectural governors determine, as a result of inspection, that any parts are not fit for food use, due to the existence of disease, or because they were derived from a diseased fowl, they may prohibit poultry-processing, or may take other appropriate measures. (2,780 poultry inspectors nationwide)

(7) Rendering Plants Control Law

- The manufacture of leather, glue, fats/oils, fertilizers, feeds, and other products using parts of livestock (cattle, horses, swine, sheep, and goats) including meat, skin, bones, and organs as ingredients may only be conducted in rendering plants that have received a permit from the prefectural governor or other person concerned. (1,025 plants nationwide)

- The dressing, burying, or incinerating of dead livestock may only be conducted in dead livestock treating sites that have received a permit from the prefectural governor or other person concerned. (403 sites nationwide)

- Prefectural governors may order supervisors of dead livestock treating sites to take necessary measures, when they determine that structures and/or equipment at the dead livestock treating sites no longer comply with standards specified based on prefectural regulations, or when supervisors do not take required sanitary measures.

- When any person raises or impounds a number of animals (cattle, horses, swine, sheep, goats, dogs, chickens, ducks, and other animals specified by prefectural regulations) exceeding the number specified by prefectural regulations, in an area designated by the prefectural governor, the person must obtain a permit from the prefectural governor.

(8) Law on Temporary Measures for Enhancing the Control Method of the Food Production Process

Purpose

This law aims to contribute to the improvement and promotion of public health and to the sound development of food manufacturing or processing industries, by implementing measures for enhancing the management of food production process, for the purpose of preventing health hazards arising from food and ensuring the quality of food in food production process.

- The Ministry of Health, Labour and Welfare and the Ministry of Agriculture, Forestry and Fisheries (MAFF) must formulate and publicize a basic policy on the enhancement of the management of food production process.

- Accrediting organizations (i.e., organizations capable of accrediting food-related businesses as complying with certain criteria) designated by the MHLW and MAFF may establish and submit to the both ministries criteria for enhancing the management of production process, according to types of food, to receive accreditation as to that these criteria are appropriate in light of the basic policy.

- Food manufacturers and processors may formulate and submit to a designated accrediting organization a plan to enhance the management of food production for each manufacturing or processing facility process, according to types of food, based on the Ministry of Health, Labour and Welfare Ordinance and the Ministry of Agriculture, Forestry and Fisheries Ordinance, to receive accreditation as to that the plan complies with the accredited criteria.

- Accredited manufacturers and processors may receive a long-term, low-interest loan necessary for enhancing the management of production process, and may obtain preferential taxation.

(9) Health Promotion Law

Purpose

In light of the growing importance of the promotion of the health of the public in the wake of the rapid advance in aging and changes in the modes of diseases in Japan, this law aims to promote public wellness, through specifying basic points concerning the comprehensive promotion of the health of the public and to implement nutrition improvement programs and other measures necessary for promoting the health of the public.

Regulations under the jurisdiction of the Department of Food Safety

- Any person who wishes to label a food intended for sale with the statement to the effect that it is intended for certain special uses is required to obtain permission from the Minister. Foods intended for special uses are called foods for special dietary uses. These special uses include those for infants, young children, pregnant women, and ill people. This statement also includes the effect that the food enables a person who consumes it for a certain health purpose to achieve that purpose through its consumption. Foods required to bear such a statement are called foods for specified health uses. For more information, see the explanation under the heading of "Foods for special dietary uses" in Section 13.

- When the Minister or the prefectural mayor concerned determines that action is necessary, the Minister or mayor may require the officials concerned to visit manufacturing facilities, storage facilities, or marketing facilities for foods for special dietary uses, inspect foods, and collect samples of it within the quantity necessary for conducting tests.

- Any person who wishes to label a food intended for sale with nutrients or calories or any person who wishes to import a food bearing nutrition labeling for distribution in Japan is required to label the food with necessary information based on the nutrition labeling standards established by the Minister.

4. Specifications and Standards for food, food additives, apparatus, containers/packages, etc.

(1) Specifications and standards for food

The distribution of food in the domestic market is regulated by establishing specifications and standards. There are two categories for specifications and standards. One is those that apply generally to all foods; the other is those that apply specifically to individual foods. Currently, specifications or standards are established for about 30 individual food groups including nonalcoholic beverages, meat, and fish and shellfish. Individual specifications are established for heavy metals, microbial counts, and chemicals.

The Food Sanitation Law treats pesticides and veterinary drugs remaining in food as food components. Specifications for these components are established for individual substances on individual foods. There are seven target food groups for pesticide residues, including cereal grains, legumes and pulses, fruits, vegetables, nuts, tea leaves, and hops; four for veterinary drugs including meat and whale meat, fowl eggs, fish and shellfish, and oysters for raw consumption.

Standards include those for manufacturing, processing, preparing, and preserving.

(a) Pesticide residues

On May 29, 2006, Japan introduced a positive list system for agricultural chemicals (pesticides, veterinary drugs, and feed additives) based on the May 2003 amendment of the Food Sanitation Law. Under the positive list system, any food that contains a pesticide without residue standards is basically enjoined from domestic distribution. Pesticides, however, may remain in foods as long as residue levels are below a certain level that is determined to pose no adverse health effects.

In step with the amendment of the law, related laws have been modified. This has enabled the Ministry of Health, Labour and Welfare to establish MRLs for pesticides at the time of registration by the Ministry of Agriculture, Forestry and Fisheries.

An outline of the establishment of MRLs is given below. First, the acceptable daily intake (ADI) [1] is determined by multiplying the non-effect adverse effect level (NOAEL), [2] obtained from various toxicity studies using animals, by safety factors. [3] Then, MRLs are allocated to individual foods so that the theoretical maximum daily intake (TMDI) cannot exceed the ADI.

Japan conducts a few types of surveys from the viewpoint of food inspection and establish of MRLs. The surveys include residue surveys and diet studies. The former are to determine the quantity of residues in individual foods distributed in

the domestic market, and the latter are to estimate the intake of residues derived from the diet. Survey results are published each time.

Notes:

1. ADI (Acceptable Daily Intake)
   An estimate of the amount of a pesticide, expressed on a body weight basis, that can be ingested daily over lifetime without appreciable health risk.

2. No-Observed-Adverse-Effect Level (NOAEL)
   The highest dose of a substance that does not cause any detectable toxic effects in experimental animals.

3. Safety factor
   A factor is obtained, considering inter-species variability in between experimental animals, intra-species variability between humans, and other conditions.

(b) Veterinary drugs

In Japan, veterinary drugs that remain in foods are regulated under the law in the same manner as for pesticides. Veterinary drugs include chemically synthesized antimicrobials, antibiotics, and anthelminthics. Target animals range from livestock (such as cows and pigs) and poultry to fish/shellfish. Once residue standards (MRLs) are established under the law, food products that contain these drugs at levels exceeding the MRLs are enjoined from domestic distribution. MRLs are established for individual substances on individual parts of target animals, such as muscle and liver.

The Japanese Government had once prohibited the sale of food that includes antibiotics as a health hazard arising from the consumption of food (1957–1995). However, capable methods have been developed along with advances in scientific technology in recent years. This enabled the setting of standards of low levels that are unlikely to pose any adverse effects on humans even if the substance is consumed. In December 1995, Japan established first MRLs for veterinary drugs (six including oxytetracycline).

Based on the amendment of the law, the positive list system applies to veterinary drugs and feed additives as well as to pesticides.

(2) Specifications and standards for food additives

The law defines food additives as 1) substances that are used in the course of manufacturing food, or 2) substances that are used for the purposes of processing or preserving food. Food additives include both substances that will remain in finished products and substances that will not remain. The former include food colors and preservatives, and the latter include infiltration aids, which are removed before the completion of products.

No food additive is permitted for use if it is not designated by the Minister of

Health, Labour and Welfare. However, the two types of food additives are exempted from the designation by the Minister and may be used unless there are any problems with safety. They are substances appearing in the List of Existing Food Additives (i.e., substances that were already marketed or used on the date of the 1995 amendment of the law and appear in the List of Existing Food Additives), and natural flavoring agents. As of the end of July 2006, there were 360 designated food additives and 450 existing food additives.

A food additive is designated, normally based on an application made by a person who wishes to use it. After receiving an application, the Minister will ask the Food Safety Commission for opinions concerning health effects of the food additives. The Commission will conduct a scientific health risk assessment and establish the ADI. The MHLW will conduct risk management. It will have the Pharmaceutical Affairs and Food Sanitation Council discuss the adequacy of draft standards for the substance. In the discussion by the Council, the international evaluation as well as other countries' standards and specifications will be taken into account. Based on the Commission's recommendation and the Council's report, the MHLW will designate the substance as an approved food additive when the substance is proven safe and effective

Separately from the designation process mentioned above, the MHLW evaluates certain food additives for the purpose of designating them without any application from businesses. Target food additives must meet the standards given below. Currently, 46 substances and some flavoring agents fall under these target additives. The MHLW is examining substances for which the full documents on safety and usefulness are prepared.

Standards

Substances:

- for which a safety assessment has been finished by the JECFA (Joint FAO/WHO Expert Committee on Food Additives) and whose safety has been confirmed within a certain level and
- that are widely used in the United States and EU countries and whose necessity is considered to be high.

The MHLW reviews the safety of food additives along with advances in scientific technology. It is working to confirm the safety of existing food additives as well. The 2003 amendment of the law enabled the MHLW to prohibit the use of existing food additives by deleting them out of the list if their safety is doubtful or they are no longer in use. In February 2004, based on the amended law, the MHLW published a list of 38 existing food additives, which are no longer in use. In July the MHLW delisted madder color—a coloring agent obtained from plant roots—and prohibited its use in food. This urgent action stemmed from the interim report of a carcinogenicity study that found

madder color to be carcinogenic to the rat kidney. The MHLW based its decision on discussions by the Commission and the Pharmaceutical Affairs and Commission. The abovementioned 38 substances were delisted in December to prohibit their use.

(3) Specifications and standards for apparatus, containers/packages, etc.

The law applies to apparatus, containers/packages for food, toys, and detergents as well as food.

(a) Apparatus, containers/packages

There are three types of specifications for apparatus, and containers/packages: those applying generally to all products (hereinafter referred to as general specifications), those by material categories, and those by use categories. General specifications are established for metals, such as lead, iron, and aluminum, and for chemically synthesized coloring agents. Material categories total seven: glass, ceramic, enamel, synthesized resin, rubber, and metal cans. Use categories total five: containers for foods that are packed into containers and pasteurized under pressure, containers for nonalcoholic beverages, food-vending machines and containers that accompany a vending machine and with which the food is sold, apparatus for foods that are used for manufacturing edible ices, and apparatus or containers that are used for delivery of concentrates of nonalcoholic beverages for cup-unit vending machines or full-automatic nonalcoholic-beverage preparing machines.

The current standards are established for manufacturing.

(b) Toys and detergents

The law also applies to toys that are designated by the Minister as those that can pose health hazards to young children through direct contact with the mouth. Young children normally refer to those of preschool age. For toys, there are specifications for materials and standards for manufacturing.

The law also covers detergents used to wash food (vegetables and fruits only) and eating utensil. Specifications are established for arsenic, heavy metals, methanol, and standards are established for use.

Note: For detailed descriptions about specifications and standards for food, food additives, apparatus, containersp/ackages, etc., consult Part II *Establishment of Specifications and Standards Based on the Food Sanitation Law*. For individual specifications and standards, consult the publication by JETRO, *Specifications and Standards for Foods, Food Additives, etc. under the Food Sanitation Law* (Abstract).

(4) Harmful chemicals in food with provisionary regulatory limits and other

substances

Food may contain various chemicals in addition to normal food ingredients, and these chemicals are divided into two groups. One group includes food additives, pesticide residues, and veterinary drugs. The other includes mycotoxins, environmental contaminants, such as dioxin and PCB, and endocrine disrupting chemicals. The former chemicals (food additives, pesticide residues, and veterinary drugs) remain in food as a result of the intentional application or use in producing or processing foods (including crops and livestock) and are already explained in the above section. This section outlines environmental contaminants, natural toxins, and endocrine disrupting chemicals.

(a) Environmental contaminants

Environmental contaminants are derived from the living environment. Environmental contaminants in food include dioxins, PCB (polychlorinated biphenyl), and heavy metals such as mercury and cadmium.

There is a need to identify the consumption of those contaminants derived from normal foods and the degree of contamination of distributed foods.

Currently, provisional regulatory limits (maximum tolerable limits) are established for the following combinations of food groups and contaminants: PCB in general foods, mercury in fish and shellfish, organochlorine pesticides in milk, dieldrin in hard-shelled mussels, pesticides in meat. Also, Japan is conducting total diet studies for environmental contaminants to identify the consumption of these substances.

Reference: *Reference Documents related to Food Safety and Inspection*

1. Provisional regulatory limits for environmental contaminants and natural toxins
2. Total daily intake of dioxins from foods in Japan (1999 to 2004)

(b) Natural toxins

There are a few types of natural toxins derived from food. One type is aflatoxins, carcinogenic substances, which are produced by certain types of molds. They are found in certain foods (such as peanuts, other nuts, and spices) cultivated in tropical or subtropical areas. If aflatoxins are detected in such foods at the time of import (the detection limit is 10 ppb as aflatoxin B1), they are enjoined from import and domestic distribution.

Another type of natural toxins is marine toxins in seafood, which become a concern. They include globefish poison (tetrodotoxin), shellfish poison, and ciguatera poison. Seafood is regulated by various standards.

For globefish intended for food, the following are specified: sea areas where fishing is permitted, types of globefish permitted for consumption, and edible parts. Also, globefish-preparation establishments must have a licensed person, who can surely remove toxic parts from globefish, and obtain certification from the prefectural governor.

For shellfish poison, regulative limits are established for paralytic shellfish poison and diarrheal shellfish poison. If products contain poison at a level exceeding the corresponding limit, their collection is banned on the sea areas where they grow. Imported shellfish are inspected at import if necessary.

Certain types of fish containing ciguatera poison are enjoined from import and sale. Please see the appendix for provisional regulatory limits for natural toxins.

Reference: *Reference Documents related to Food Safety and Inspection*

1. Provisional regulatory limits for environmental contaminants and natural toxins

(c) Endocrine disrupting chemicals

In recent years, there has been an emerging concern that chemicals derived from our living environment may disrupt endocrine functions and have adverse effects on human health. These are called endocrine disrupting chemicals.

There have been various scientific discussions in the world on how to define the endocrine disrupting chemicals, because interactions between chemicals and the endocrine system are not clear. Currently, the IPCS (International Programme on Chemical Safety) under the WHO defines as the following:

"An endocrine disruptor is an exogenous substance or mixture that alerts function(s) of the endocrine system and causes adverse health effects in an intact organism, or its progeny, or (sub)populations."

There are many problems that remain to be resolved scientifically, including the presence or absence, type, and degree of disrupting effects. There are many types of chemicals that are considered to possibly have such functions. They include pesticide residues, plasticizers in plastic containers, and surfactants in detergents.

Therefore, the MHLW is comprehensively addressing this issue in cooperation with related agencies and foreign countries. For example, the MHLW participates in a program conducted by the OECD (Organization of Economic Cooperation and Development). This program is designed to develop screening methods using mammals, in order to develop detection methods for such chemicals and standardize methods for risk assessments.

5. Safety assurance of livestock and poultry meat

The Abattoir Law states that no cattle, horses, swine, sheep, or goats (hereinafter referred to as livestock) intended for food use may be slaughtered or dressed in any place other than a slaughterhouse. Any livestock must undergo inspection by meat inspectors from the local government concerned in a slaughterhouse before it is slaughtered or dressed.

Meat inspection begins with an ante-mortem inspection. Livestock will be permitted to be slaughtered if it passes this inspection. Then, it undergoes an ante-dressing inspection and is permitted to be dressed if it passes this inspection. Furthermore, it undergoes a post-dressing inspection to check the viscera and dressed carcass. After passing the full meat inspection, the livestock is permitted for food use. Necessary measures are taken for diseased animals (diseases include those that may infect humans), such as prohibition of slaughtering and dressing, and the disposal of all or any portion (including meat and viscera). Also, appropriate measures are taken for discarded animals and parts, in order not to be used as food.

Meat inspectors are local government employees who are licensed as veterinarians. Meat inspection is based on veterinary science, including macroscopic examination, palpation, and necropsy. If there are suspicious findings, detailed examinations are conducted bacteriologically and histopathogenically to comprehensively determine the presence or absence of any disease.

Persons who wish to slaughter chickens, ducks, turkeys, and other fowls (hereinafter referred to as poultry) and remove the feathers and viscera from their carcasses under the Poultry Slaughtering Business Control and Poultry Inspection Law must obtain permission from the prefectural governor or the mayor of the city or ward. Poultry processing plants must meet structures and facilities standards and hygiene management standards.

Poultry processors may distribute products for food use only after these products pass disease examinations conducted by the corresponding Prefectural Governors (conducted by licensed poultry inspectors). Disease examinations are conducted before and after slaughtering (after feather-removal and viscera-removal). If a fowl is infected by a disease that also can infect humans or if a fowl has abnormal conditions, all of the fowl or abnormal parts are removed.

Reference: *Reference Documents related to Food Safety and Inspection*

3. Statistical overview of livestock and poultry meat inspection

6. Safety Measures for BSE

(1) What is Bovine Spongiform Encephalopathy?

Bovine Spongiform Encephalopathy (hereinafter referred to as BSE) is one of a group of diseases known as Transmissible Spongiform Encephalopathies (TSE's), associated with a transmissible agent—an agent that transmits disease—that is yet to be fully identified.

(2) Measures taken for imported food

Since 1996, an increasing number of test results have suggested that vCJD may be associated with BSE infection. To date, however, there has been no data directly demonstrating BSE infectivity to humans.

As a preventive measure, after March of 1996, the Japanese Government began recommending that related businesses should refrain from importing beef, bovine offal, and their products produced in the United Kingdom, a high-incidence country, where preventive measures for the spread of BSE might not have been fully implemented. Also, Japan carefully handles even meat imported from countries with a low incidence, based on the decision—parts involving a high risk, such as the brain and spinal cord, should not be imported, even if these parts are derived from healthy cattle—according to the OIE (Office for Epizootic Diseases) recommendation.

In December 2000, the Ministry of Agriculture, Forestry and Fisheries decided to suspend the importation of beef and related products from European Union countries to prevent the spread of the disease into Japan (effective January 1, 2001). In response to this decision, the Ministry of Health, Labour and Welfare took action to ensure that those concerned knew about the import suspension measure. Also, the MHLW took an emergency measure, asking related businesses to refrain from importing bovine bone products from EU countries because these products were not covered by MAFF's action.

As described above, those administrative measures had been taken on an emergency basis. However, there were persistent occurrences of BSE in Europe, and public concern about food safety increased. In the circumstances, the MHLW has decided to take legal action under the Food Sanitation Law in step with MAFF's action under the Animal Infectious Diseases Control Law, in order to ensure that BSE would not be brought into Japan. On February 15, 2001, the MHLW amended the ministerial ordinance under the law, and Japan banned the import of beef, cattle offal, and their meat products from countries with the occurrence of BSE (EU countries,[1] Israel, Liechtenstein, Switzerland).

In addition, Japan banned the import of beef from the United state and Canada at the occurrence of BSE in these countries, based on Article 9 Paragraph 2 of the Food Sanitation Law. On December 12, 2005, Japan resumed importation from both countries, based on a report from the Food Safety Commission after bilateral

consultations between Japan and America and Canada. However, on January 20, 2006 Japan banned US beef again because veal containing the spinal cord arrived into Japan. Japan is confirming whether the programs to which both countries agreed are being carried out in an appropriate manner.

Note:

1. The EU countries mentioned in this section are Austria, Belgium, Czech, Denmark, Finland, France, Germany, Greece, Italy, Ireland, Luxembourg, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, The Netherlands, and the United Kingdom.
2. For provisions of the Food Sanitation Law that appear in this text, see Annex 8 to Part I.

(3) Measures taken in Japan

The MHLW has taken necessary action, based on the scientific evidence obtained since March 1996 when the potential transmittal of BSE to humans was suggested.

In April 1996, the MHLW amended the Enforcement Regulations under the Abattoir Law to regulate native-cattle meat. TSE's were added to the target diseases covered by meat inspection, and surveillance was conducted by observing clinical signs. In May 2001, a surveillance system was developed, and screening tests were started to check for abnormal prions in animals that showed clinical neurological signs.

In October 2001, the MHLW took several measures because the first BSE-infected animal in Japan was identified in September 2001. Under the system, nationwide BSE screening tests targeting all animals intended for food were started, and the removal and incineration of specified parts (skull (except cheek meat and tongue), spinal cord, the end of the intestinum tenue) obtained during meat processing became mandatory.

The MHLW has judged that measures for BSE should be taken based on scientific rationality, just like other food safety measures. In October 2004 the MHLW asked the FSC to conduct risk assessment to dertermine whether the existing national measures, including screening tests targeting all cattle, should be reviewed based on the assessment and validation compiled by the FSC in September 2004. Based on the report from the Commission, in May 2005 the MHLW specified the target ages for testing at 21 months or older. The regulation took effect in August.

The MHLW mandates the following treatments for sheep and goats intended for food. For animals aged 12 months or over, the head (except tongue and cheek meat), the spinal cord, and the placenta must be removed and incinerated. In addition, regardless of age, the tonsils, the spleen, and the small and large intestines (including lymph nodes) from all animals must be removed and incinerated. The local governments conduct BSE screening tests for sheep and goats aged 12 months or over as well as for

beef.

(4) Special Measures Law Concerning Bovine Spongiform Encephalopathy

The Special Measures Law Concerning Bovine Spongiform Encephalopathy (Law No.70, 2002) was promulgated on June 14, 2002 and went into effect on July 4, 2002.

This law requires MAFF and the MHLW to make a basic plan concerning measures to be taken by both national and prefectural governments when a BSE case is confirmed or suspected. Under the requirement of the law, in July of 2002 a basic plan was drawn up on the specific matters given below.

- Basic guidelines concerning measures to be taken.
- The period of the plan.
- Matters concerning preventive measures for the spread of BSE.
- Matters concerning the accurate communication of information.
- Matters concerning cooperation between related administrative organizations and prefectural and municipal organizations.
- Other important matters concerning measures to be taken.

Reference: *Reference Documents related to Food Safety and Inspection*

4. BSE Testing in Slaughterhouses
—Cumulative table from October 18, 2001 to June 27, 2006

7. Action taken against food poisoning

Once a food poisoning case occurs in Japan, various steps are taken based on the Food Sanitation Law. These steps include the investigation of causes, measures to prevent the spread of damage and recurrence, and report to the Ministry of health and Welfare.

First, the doctor who examined a poisoned person must notify the Director of the nearest health center within 24 hours. When receiving the notification or otherwise knowing the occurrence of a poisoning case, the Director must report in writing to the governor of mayor of the prefecture or municipality concerned after investigating the cause. The governor or mayor must then report in writing to the Minister of Health, Labour and Welfare.

In particular, when a serious food poisoning occurs, the corresponding local/municipal government must promptly notify the Minister by appropriate ways such as telephone and facsimile 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 recent four years, 1,850 food poisoning incidents were reported in 2002, 1,584 in 2003, 1,666 in 2004, and 1,545 in 2005.

In response to the reports, the MHLW carried out investigations to identify the cause and took several measures to prevent further spread. Some activities are being implemented on a regular basis.

Major measures and activities

- Established specifications and standards for meat, eggs, and fish and shellfish for raw consumption.
- Established guidelines for hygiene management at mass food-preparing facilities, which have potential to frequently cause food poisoning. General inspection is regularly conducted according to the established guidelines.
- Prepared leaflets for household use, showing necessary information, such as frequently asked questions and answers, to provide consumers with information as to how to prevent food poisoning (associated exclusively with enterohaemorrhagic *Escherichia coli* (O-157), noro-virus, hepatitis E virus, *Campylobacter, Vibrio vulnificus*).
- Established a manual for food poisoning investigations.
- Periodical investigations of the actual state of contamination of food with poisoning-causing bacteria.
- Developed highly-sensitive detecting methods of illness-causing

microorganisms, including enterohaemorrhagic *Escherichia coli* (O-157) and noro-virus.

- Prepared and publicized a medical treatment manual for enterohaemorrhagic *Escherichia coli* (O-157).

<Food poisoning cases associated with imported foods>

The MHLW has received reports on the incidents of dysentery caused by *S. sonnei* from late November 2001 to January 2002. The number of infected people rose to some 160 in 30 prefectures, mainly in western Japan until January 30, 2002.

An investigation has found that some of the infection cases were associated with oysters for raw consumption that were harvested in Korea. The MHLW determined that it should take emergency action covering broad areas to ensure food safety for the Japanese people. The MHLW issued an order to ban the import of Korean oysters for raw consumption on December 28, 2001. Oysters for cooking were excluded from that action. An outline is given below.

After discussion with the Korean Government, Japan resumed the import of Korean oysters on January 17, 2003, after Korea established a sanitary management system. The system includes the strengthening of sanitary management, such as for water used at the processing plants, and testing for dysentery on all lots of products intended for Japan. Oysters must be produced by designated plants and test negative for dysentery.

Reference: *Reference Documents related to Food Safety and Inspection*

5. Guidelines for hygienic management at mass catering facilities
6. Reported incidents of foodborne illness in Japan (1995–2005)

8. Comprehensive sanitation-controlled manufacturing process (Sanitary control over food based on HACCP)

The "Comprehensive sanitation-controlled manufacturing process" is a system established in 1995 when the Ministry of Health, Labour and Welfare partially amended the Food Sanitation Law. This is the first legal system for sanitary control based on the HACCP system.

Under this system, the Minister of Health, Labour and Welfare gives approval to individual manufacturing or processing facilities, according to food categories, if the Minister confirms, after document examinations and on-site examinations, that sanitation/hygiene is controlled appropriately for these food categories.

Based on the 2003 amendment of the law, the MHLW established a system for renewing approval. The approval must be renewed every three years.

The following food categories are subject to this system:

- Milk (cow's milk, processed milk, and similar products)
- Dairy products (including cream, ice cream and similar products, fermented milk, lactic acid bacterial beverages, milk drinks, and skimmed milk powder)
- Nonalcoholic beverages
- Meat products (including ham and sausages)
- Fish-paste products (including *Kamaboko* and fish ham/sausages)
- Foods packed into a container/package and pasteurized under pressure (canned foods and retort foods)

In the system, manufacturers or processors establish manufacturing or processing methods of the target foods and sanitary-control methods, based on the HACCP system, and the Minister confirms whether these established methods comply with the approval standards. The manufacturing or processing methods approved under the system are considered to meet the standards for manufacturing/processing under Article 11 Paragraph 1 of the law.

Therefore, the system enables the application of a wide variety of methods to food production without following the uniform standards, if safety is ensured at the individual manufacturing processes.

<For reference: The HACCP system>

The HACCP system is quite different from the previous hygiene management practice, which places importance on inspection of final products. The HACCP system is focused on preventing the occurrence of hazards and ensuring food safety throughout all food production process—from its raw state through finished products. Under the system, possible hazards on food safety are first predicted and processes to control these

hazards are identified as critical control points.

Manufacturers must prepare an operating plan for sanitary control, based on the seven principles and 12 tasks for the HACCP system established by the Joint FAO/WHO Food Standards Programme of Codex Alimentarius Commission.

7 principles and 12 tasks

Task 1. Assemble HACCP team
Task 2. Describe product
Task 3. Identify intended use
Task 4. Construct flow diagram
Task 5. On-site confirmation of flow diagram
Task 6. A hazard analysis (Principle 1)
Task 7. Determine critical control points (Principle 2)
Task 8. Establish critical limits for each CCP (Principle 3)
Task 9. Establish a monitoring system for each CCP (Principle 4)
Task 10. Establish corrective actions (principle 5)
Task 11. Establish verification procedures (Principle 6)
Task 12. Establish documentation and record keeping (Principle 7)

Reference: *Reference Documents related to Food Safety and Inspection*

7. Approval status of the comprehensive sanitation-controlled manufacturing process
8. Guidance documents for the approval system of the comprehensive sanitation-controlled manufacturing process

9. Safety assurance of exported foods

(1) Meat intended for the United States.

When meat products are exported to the United State, the processing establishments must meet hygiene standards specified by the United States Department of Agriculture. The Ministry of Health, Labour and Welfare certifies establishments, based on documents and on-site inspections. Establishments that have met the standards are certified as "foreign meat establishments." Target products are tested by inspectors appointed by the MHLW. When the products have passed testing, the MHLW issues a meat health certificate signed by the designated signer, who is appointed from among the appointed inspectors.

The certified establishments must manage the hygiene of their premises, based on the hygiene management standards and HACCP system. The appointed inspectors verify whether the hygiene management standards and HACCP standards are met. The establishments monitor the target products monthly to check for pesticide residues and veterinary drug residues, and they conduct coliform tests regularly and salmonella tests periodically. In addition, the establishments, on a monthly basis, undergo inspection by employees of the Regional Bureau of Health and Welfare.

(2) Seafood intended for the United States

When fish or fishery products are exported to the United States, these products must be manufactured or processed based on the federal regulations about the application of the HACCP, which was specified by the United States Food and Drug Administration.

The MHLW certifies processing establishments as "certified seafood processors exporting to the United States," when they comply with the requirements specified in the federal regulations. The certification procedures are based on the "Directives for handling seafood exported to the United States."

In 1999, the FDA inspected the processing establishments and judged that the certification system for seafood processors was adequate.

(3) Seafood intended for the EU countries

When fish or fisheries products are exported to the EU countries, the handling establishments of these products must meet hygiene requirements that are legally established by the EU. The handling establishments include all areas used for processing, packing, and storing. The requirements require hygiene management based on the HACCP system.

Specifically, the MHLW must monitor veterinary medicines in cultured finfish and shellfish. The MHLW designates sea areas for the production of bivalve molluscs,

and prohibits the production in other areas. The MHLW also must monitor shellfish toxin at harvest.

Those who wish to export fish or fishery products to the EU must obtain certification from the MHLW through examinations conducted by both the MHLW and the local government, based on the directives established by Japan. The directives include not only hygiene requirements the businesses concerned must observe, but also the issuance procedure for health certificates.)

Establishments that have passed examinations are certified as "establishments approved for the export of frozen or processed fish and fishery products to the European Union." The MHLW has food sanitation inspectors inspect the approved establishments regularly and issues a health certificate each time when products are exported.

In August 2005, the EU inspected the Japanese management system for aquatic products intended for the EU and determined the system to be adequate with minor problems. In March 2006, the MHLW revised the abovementioned direction, taking account of the problems the EU pointed out and the latest EU directive, which was implemented in early 2006.

(4) Seafood intended for China

The Chinese Government requests that exporting countries' governments issue health certificates for fish or fishery products to be imported to China. In response to the request, Japan issues a certificate for each cargo when target products are proven to meet the sanitary requirements specified by the Chinese Government. The prior examination includes document examinations and if necessary on-site examination conducted by the food sanitation inspectors enrolled in the local governments.

(5) Foods intended for Malaysia

The Malaysian Government requests that exporting countries' governments issue health certificates for meat and seafood products (animal meat and offal, and prawn/shrimp) to be imported to Malaysia. This request became effective on January 1, 2005. In response to the request, Japan will issue a health certificate for each cargo if target products are proven to meet sanitary requirements specified by the Malaysian government, based on examination conducted by local governments.

Reference: *Reference Documents related to Food Safety and Inspection*

9. List of foreign meat establishments.
10. Certification for Japanese seafood exported to the United States and the EU

10. Safety assurance of imported foods

The number of imported foods distributed in the domestic market has been increasing year by year. Currently, it reaches some 60% on a calorie basis. Since the enforcement of the WTO Agreement in 1995, the movement for liberalized international trade and deregulation of agricultural products has been going forward. On the other hand, in recent years, Japanese consumers' food preferences have diversified. Thus, a greater increase in food imports is expected. Such circumstances make the safety assurance of imported foods a more important duty in food safety administration.

In Japan, both national and local governments are responsible for the health inspection of imported foods. The national government carries out food inspection at quarantine stations when food products are imported. The local governments do it for imported foods distributed in the domestic market as well as domestically produced foods. The Ministry of Health, Labour and Welfare places some 300 food sanitation inspectors at 31 quarantine stations established at ports and airports across Japan as of April 2005 (Annexes 1 and 2).

The food sanitation inspectors at the quarantine stations mainly carry out the following duties: Check whether the food products comply with the Food Sanitation Law when import notifications are submitted to the quarantine stations; conduct monitoring tests of imported products according to the annual plan in order to identify violation cases; perform examinations by ministerial order for all products that are likely in violation of the law.

The MHLW currently has inspection centers (Center for Inspection of Imported Foods and Infectious Diseases) at two quarantine stations (Yokohama and Kobe) and inspection divisions at six quarantine stations (Narita Airport, Tokyo, Nagoya, Kansai Airport, Osaka, and Fukuoka) to strengthen the inspection system. The inspection centers concentrate on high-level analysis mainly of pesticide residues, veterinary drugs, and genetically modified foods. The inspection divisions conduct tests mainly for food additives and microorganisms. The MHLW applies GLP (Good Laboratory Practice) for examination management of testing laboratories to these inspection centers and divisions. Application of the GLP aims to maintain international technical levels at testing laboratories and ensuring the reliability of testing.

In April 2003, the MHLW newly established the Office of Import Food Safety within the Inspection and Safety Division of the Ministry of Health, Labour and Welfare. The office assumes exclusive responsibility to ensure the safety of imported foods, such as the safety of pesticide residues in imported foods.

(1) Imported food monitoring and guidance plan

The MHLW implements activities to assure imported food safety based on the imported food monitoring and guidance plan. The imported foods monitoring and

guidance plan is formulated annually by the Minister of Health, Labour and Welfare in light of the hygienic situations of producing sites of exporting countries, in order to conduct inspection and guidance of imported foods efficiently, effectively, and selectively. Before the plan is formulated, the Minister holds symposia to hear public opinion and exchange information among the national government and consumers.

The monitoring and guidance plan is based on the principle concept that the appropriate actions should be taken at three stages—"in exporting countries," "at Japan's ports and airports," and "at the domestic market." This is in response to the provision in the Food Safety Basic Law, stating that in order to ensure food safety, the national and local governments must take appropriate measures at each stage of the food supply processes in and outside Japan. The above concept is stipulated in the annual plans, along with specific measures to be taken at each stage.

(a) Import Inspection system

As already mentioned, the food inspection and guidance at the time of import is under the responsibility of quarantine stations. Specifically, the food sanitation inspectors check whether the food products comply with the law when import notifications are submitted to the quarantine stations. They also monitor target products for necessary parameters and provide guidance according to the degrees of likelihood of violation of the law, in light of violation records at the time of import or in domestic distribution, and hygiene information in exporting countries.

i. Comprehensive import prohibition system

This system prohibits the import or sale of all of certain foods produced in certain countries or regions, without conducting prior testing on individual products, if these foods have frequently violated the law or if they are very likely to continuously violate the law in light of management conditions at the producing sites.

ii. Examination order and monitoring tests

Examinations of imports are roughly categorized into two groups. One is examinations conducted by order of the Minister, and the other is monitoring tests.

Examinations by order are based on Article 26 Paragraph 3 of the law, and are conducted for food and other related substances that are suspected of violating the law, in light of hygiene conditions in the exporting countries and previous violations. If an examination order is applied to a certain product, that product will not be permitted to be imported unless it passes the examination each time it is imported. Examinations by order are conducted at laboratories registered with the MHLW, and examination fees are paid by the importers who receive the

examination orders.

Monitoring tests are aimed at discovering violations for individual foods. Tests are conducted scientifically and systematically, considering the amount imported and the violation ratio for each food group. When a food is being monitored, it can be distributed in the Japanese market without waiting for the test results. This is a major difference from examinations by order. Monitoring tests are based on the statistic concept. These tests are conducted by quarantine stations in accordance with the monitoring and guidance plan formulated in light of violation records and import records according to food groups.

The MHLW annually sets detailed test items for individual foods. The items include pesticide residues, veterinary drug residues, food additives, pathogenic microorganisms, mycotoxins, and genetically modified foods. The MHLW will conduct about 78,000 tests during fiscal 2006. If monitoring shows that products are in violation of the law, the MHLW will, as appropriate, strengthen inspections by increasing the frequency of tests and issuing examination orders.

iii. Publication of monitoring and guidance results

The MHLW publishes monitoring and guidance results twice a year in its interim report (statistics of the April-September period) and its final report (year-long statistics). These reports are available on the MHLW website:
http://www.mhlw.go.jp/english/topics/importedfoods/index.html

iv. Others

- Business discontinuance and suspension to importers

The amended Food Sanitation Law authorizes the Minister to discontinue or suspend the business of importers if they repeatedly import foods in violation of the law.

- Introduction of outsourcing

Monitoring tests for imported foods used to be conducted only by national organizations, the Centers for Inspections of Imported Foods and Infectious Diseases and other quarantine stations. The quarantine stations now outsource clerical work involved in monitoring tests to impartial and independent registered laboratories, which meet certain technical requirements, in response to the increasing number of food imports.

(b) Enhancement of safety and hygiene measures in exporting countries

The national government takes some actions to enhance safety and hygiene measures in the exporting countries if violative products are found. If the MHLW

decides to subject certain products to examination by Minister's order or intensive monitoring, the MHLW notifies the importers and the exporting countries' embassies in Japan of that decision, including target product names and items to be tested. Also, the MHLW asks the exporting countries' governments to identify the causes of violations promptly and to establish measures to prevent the recurrence.

In addition, through on-site investigation and bilateral consultations, the MHLW encourages the exporting countries to enhance their food safety measures, including the adequate application management of pesticides, veterinary drugs, and feed additives; the strengthening of inspection system; and the application of pre-shipment tests. In addition, the MHLW, as appropriate, provides technical cooperation by dispatching experts.

Chinese frozen spinach is an example. Because Chlorpyrifos, a pesticide, was frequently detected in Chinese frozen spinach at levels exceeding the Japanese residue standard, Japan strongly requested the Chinese Government to temporarily refrain from exporting frozen spinach to Japan. Through bilateral negotiations, Japan also requested China to introduce a registration system for processors that meet the requirements given below and to conduct pre-shipping tests for pesticide residues. Since Japan confirmed that the preventive measures taken by China were working well after on-site investigations, it lifted the restriction imposed on China and resumed the normal importation of frozen spinach from China.

Processors should:

—Directly manage spinach firms.

—Use spinach that has been harvested from firms implementing appropriate pesticide use and management practices.

—Introduce a system to enable the tracing of the spinach used from the harvest to the finished products.

—Conduct voluntary testing for pesticides at the three stages,“ harvest,” “processing,” and “shipping.”

(c) Voluntary hygiene management to be conducted by importers

The amended law stipulates that food business operators—including producers, manufacturers, importers, and distributors—should take responsibility for necessary measures to assure food safety. The business operators should acquire the proper knowledge and techniques, assure the safety of raw ingredients, and voluntarily conduct testing. They also should make and retain records of necessary information on food safety. The quarantine stations hold seminars and pre-import guidance targeting business operators, to facilitate voluntary hygiene management by business operators.

The MHLW responds to violative imported foods with strengthened

cooperation with local governments, especially on communication and recall when a violation is identified.

(2) Import procedure

When foods and related substances are imported, the following procedure is usually taken based on the law (Annexes 3, 4, and 5).

i. Import notification: An import notification form is submitted to the quarantine station concerned.

ii. Document examination: The import notification form and other documents submitted as necessary are subject to prior examination by food sanitation inspectors in the quarantine station. The documents include a hygiene certificate, a manufacturing method, the names of food additives used, and the result of testing. Examination is conducted, mainly based on the inspection results for the same kind of products that were previously imported. Results of testing conducted by a designated laboratory in or outside Japan are also acceptable.

iii. On-site testing: If the document examination has found that on-site testing is needed, necessary tests are conducted at a bonded area.

iv. Laboratory testing: If necessary, additional tests (physical, chemical, or biological tests) are conducted at the laboratory.

v. Compliance with the law: Products that comply with the law are permitted for import.

vi. Incompliance with the law: Products are reshipped, destroyed, or otherwise treated.

Besides these normal procedures, Japan uses several systems for import notification, in order to speed up and simplify the formalities for import notification. Following are outlines of these systems.

(a) Import notification through electric information processing system

In February 1996, then MHW introduced a computer-assisted system called FAINS (Food Automated Import Notification and Inspection System).

This system is aimed at simplifying and expediting import notification, and the system enables the effective use of various data, such as import history and test results for imported foods and other substances. The system has enabled the conduct of proper and efficient tests, based on the degree of possibility that the

substance violates the law.

In February 1997, the MHLW linked the FAINS to a computer-assisted operation system for customs clearance called NACCS (Nippon Automated Cargo Clearance System) (Annex 6). Also, in March 1998 it established an electronic transmission system between Japan and Australia, in order to transmit health certificates for meat and meat products specified under the law.

Currently, FAINS is used for about 90% of all notifications.

(b) Exemption from import notification

Certain types of foods for which there are few problems with safety are exempted from the submission of an import notification form. Target foods specified by the Enforcement Ordinances under the Food Sanitation Law (Cabinet Order No. 229) are:

> Copra, crude alcohol, crude animal and vegetable fats and oils for edible fats and oils, hops, molasses, raw salt, raw sugar, rapeseeds.

(c) Prior notification system

Importers may submit a notification on or after the seventh day prior to the expected date of the cargo's arrival. Notifications should be submitted to the quarantine station that has jurisdiction over the place of customs clearance for the cargo.

(d) Planned import

When certain types of substances are repeatedly imported, if the importer submits an import plan for those substances at the initial import and there is no food hygiene problem, the importers may be exempted from submitting an import notification form for the planned period of time.

(e) Acceptance of test results from official laboratories in exporting countries

At importing foods, Japan requests importers to submit the results of tests the importers have voluntarily conducted for compliance of the foods with requirements (e.g., use standards of food additives) based on the Japanese Food Sanitation Law. When tests have been performed by an official laboratory for a food, the results are accepted, and its importer is exempted from conducting the tests on the food. Under this system, official laboratories have to meet certain qualifications, and eligible laboratories are registered with the MHLW (Annex 7). The following outlines the system.

Qualification

Laboratories must be capable of conducting tests using AOAC methods (those prepared by the US Association of Official Analytical Chemists) and must be categorized into either of two groups:

i. Laboratories that are under the direct control of the national or state government of an exporting country (official laboratories).

ii. Laboratories that are certified or designated by the national or state government of an exporting country (designated laboratories).

Treatment of test results

Test results from qualified laboratories are treated equally to those from laboratories designated by the MHLW.

Exception

If sanitary conditions of the substance may change during transportation and test results may be affected, these tests are excluded from this system (e.g., bacteria and mycotoxins).

Pre-certification registration system

When Japan confirms that substances comply with the law prior to their import and registers the manufacturing or processing plants of them, regular inspections for these substances are exempted at import. This system enables the prevention of the import of substances in violation of the law and the assurance of the safety of imported substances in the course of manufacturing and processing in the exporting countries. As of April 2006, 76 substances are registered in 2 countries and 1 region.

11. Introduction of standards for business management (Good Laboratory Practice) into food-examination laboratories

In view of food safety and the global expansion of food distribution, it is very important to conduct testing for food sanitation adequately and swiftly. In 1995, Japan decided to require official laboratories that conduct tests based on the Food Sanitation Law to observe the Good Laboratory Practice (GLP) in compliance with ISO Guide 25.

The GLP provides standards for work management of testing laboratories should observe. The GLP aims to secure the reliability of studies and tests. It includes various duties to achieve the aim, including the preparation of standard operation procedures, internal and external inspections, and confirmation by the quality assurance section as to whether required duties, including testing, are adequately carried out.

In 1997, the ISO Guide 25-based GLP standards were introduced to public testing facilities (laboratories under the jurisdiction of national or local governments) and designated laboratories (institutions of public corporations designated by the Minister of Health, Labour and Welfare).*

In 2004, the GLP standards were revised to introduce the ISO/IEC 17025. In practice, testing laboratories manage the examination work based on the corresponding management manuals.

Note: The system for designated laboratories was abolished in February 2004. Laboratories wishing to conduct examination work based on the law must be registered with the Minister of Health, Labour and Welfare.

Reference: *Reference Documents related to Food Safety and Inspection*

11. Manual on how to manage examinations, etc. at testing laboratories

12. Foods produced by recombinant DNA technology

Foods produced by recombinant DNA technology refer to those produced using techniques in which genes that provide useful properties are taken out from organisms and inserted into target plants, in order to effectively utilize those properties or functions of the plants or other organisms that are used as foods. Hereinafter, these foods are referred to as GM foods, or genetically modified foods.

(1) Safety assessment

In recent years R&D of GM foods has been rapidly going forward in many countries, and new products have appeared in the marketplace. A growing number of GM foods are likely to distributed in the future. In the circumstances, Japan made the safety assessment of GM foods mandatory under the Food Sanitation Law on April 1, 2001. This activity is to prohibit the domestic distribution of GM foods that are not proven safe. Currently, Japan prohibits the import and sale of GM foods that do not undergo the safety assessment and their processed products.

The safety assessment is conducted by the Food Safety Commission in the Cabinet Office in accordance with the standards for safety assessment, which was established by the Commission. The assessment targets individual substances and is conducted for detailed items specified by the above standards. The items include the induction of allergies, the production of harmful substances, and derivative effects involved in recombinant DNA technology. As of June 2006, 75 types of foods and 13 types of food additives underwent the safety assessment.

GM foods are also subject to an evaluation by the Ministry of Agriculture, Forestry and Fisheries. The evaluation includes environmental effects of the cultivation of GM agricultural products and safety as animal foods.

(2) Monitoring tests at import

Quarantine stations monitor imported GM foods to see whether they have passed the safety assessment and whether they have followed the import notification process, based on the law. In fiscal 2005, 1,481 cases were tested and all cases were found negative.

Home-grown foods are monitored by local governments. As of June in fiscal 2006, there were five violation cases involving processed foods made of GM potatoes that had not undergone the safety assessment and one case involving papaya. These foods were recalled, or otherwise disposed of, based on the law.

Related information on GM foods is available at
http://www.mhlw.go.jp/topics/idenshi/index.html

Reference: *Reference Documents related to Food Safety and Inspection*

12. A list of products for which the safety assessment has been completed by the MHLW (As of February 14, 2006).
13. The procedure of the safety assessment of foods and food additives produced by recombinant DNA techniques in Japan.
14. Standards for the Safety Assessment of Genetically Modified Foods (Seed Plants)
15. Results of monitoring tests in fiscal 2005.

13. Foods with health claims and nutrition labeling

(1) Foods with health claims

Foods with health claims refer to foods that comply with the certain requirements established by the Minister of Health, Labour and Welfare and that are labeled with certain nutritional or health functions. These foods are categorized into two, according to differences in purpose and function: foods with nutrient function claims and foods for specified health uses.

"Foods with nutrient function claims" refers to foods that declare the functions of nutritional ingredients specified by the Ministry of Health, Labour and Welfare. Such a food may be freely manufactured and distributed without any permission from or notification to the national government, provided that it meets the established standards and specification.

"Foods for specified health uses" refers to all foods containing health functions that can have positive effects on human physiological functions. These foods are intended to be consumed for the maintenance or promotion of health or special health uses by people who wish to control health conditions, including blood pressure or blood cholesterol. When they are manufactured or distributed, permission by the national government is required after evaluation for the safety and effectiveness of proposed health functions based on sound science.

Foods for special dietary uses

Foods for special dietary uses refer to all foods are intended to be consumed by people with specific health conditions in dietetic therapy and for the purpose of maintaining and improving health.

At present, there are the following five categories for food for special dietary uses under the Health Promotion Law. The categories are

- Foods for the ill (single foods and packed meals),
- Milk powder for pregnant and lactating women,
- Formulated milk powder for infants,
- Foods for the aged, and
- Foods for specified health uses.

Foods for the ill are divided into the two groups: single foods and packed meals. Single foods are further divided into the six types—low-calorie foods, low-sodium foods, low-protein foods, no/low-protein and high-calorie foods, high-protein foods, allergen-removed foods, and lactose-free foods. Packed meals (serving-sized meals prepared by combining some main and side dishes) are divided into the four types—salt-reduced meals, meals for diabetes, meals for liver diseases, and meals for

adult obesity.

There are two types of "foods for the aged": foods for people with difficulty in masticating and foods for people with difficulty in both masticating and swallowing.

Foods for specified health uses are regulated in both categories: food with health claims categorized in the Enforcement Regulations under the Food Sanitation Law and food for special dietary uses categorized in the Enforcement Regulations under the Health Promotion Law.

When the foods mentioned above bear labeling to the effect that it is intended for any of the special uses given above, permission or approval is required from the Minister (prior approval is also needed when a food is labeled for specified health uses outside Japan with intent to market inside Japan). These foods must bear the specified mark to display a permission or approval. Furthermore, they must be labeled with information, given below, as prescribed in the Ministerial Ordinance under the Health Promotion Law.

- Product name
- Name and address of manufacturer (in the case of persons other than manufacturers, name and business place of the person who obtained the permission)
- Permitted/approved health claim (Annexes 9 and 10)
- Amount of nutrients, calories, and food ingredients
- Use-by date or best-before

  In the case of foods for specified health uses, a statement to the effect that it is a food for specified health use, contents, recommended daily intake, notices on consumption, proportion of the target nutrient to the corresponding nutrient reference value (NRV) (confined to nutrients with NRVs for which approval was given as a food for a special use), and a phrase, "Aim a balanced diet with grains, fish or meat, and vegetables."
- Notice about how to consume, prepare, and preserve
- Specified permission/approval mark

(2) Nutrition labeling

When labeled with calories or nutrients as specified by the Minister, foods other than those for specified health uses must comply with the Nutrition Labeling Standards prescribed under the Health Promotion Law (Annexes 11 and 12). When foods that have been labeled abroad are imported, the same standards must be met. The nutrients concerned are protein, fat, carbohydrate, minerals (such as sodium and calcium), and vitamins (such as vitamin A and vitamin B_1).

The Nutrition Labeling Standards cover nutrients that are specified in the Ministerial Ordinance for the reason that the deficiency or overintake of these nutrients may have a negative effect on the maintenance of health, based on the public's

consumption of these nutrients.

14. Global cooperation and information disclosure

(1) Global cooperation

As the distribution of food has expanded, cooperation with foreign countries and international organizations is indispensable in view of food safety and health protection.

Japan has been engaged in activities such as collaborative studies in cooperation with international organizations such as the WHO, FAO, OECD, and APEC, and the United States and EU countries.

Following are outlines of international organizations with which Japan is affiliated, and their activities in these organizations:

Joint FAO/WHO Codex Codex Alimentarius Commission (CAC)

The Joint FAO/WHO Codex Alimentarius Commission was founded in 1962, in order for the Food and Agricultural Organization and the World Health Organization to jointly establish international standards for foods that are important for global trade, for the purpose of protecting the health of consumers and ensuring fair practices in the food trade. Japan has actively cooperated with CAC activities by sending representatives to general assemblies and various codex committee sessions, since its affiliation in 1966. The Secretariat of the CAC is placed in Rome, Italy. There were 174 member countries (EC) as of July 2006. The CAC is comprised from 9 general substance committees, 11 commodity committees, an ad hoc intergovernmental task forces, and six regional coordinating committees.

The Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology was established at the CAC general assembly held in November 1999, aimed at establishing international standards for the safety assessment of foods derived from biotechnology (hereafter called “GM foods” referring to genetically modified foods). Japan was appointed as the presidency holder of the task force.

The task force held four sessions during the period from March 2000 through March 2003, and formulated the following three documents.

- Draft Principles of Risk Analysis for Foods Derived from Modern Biotechnology
- Draft guideline for Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (including the Draft Annex on the Assessment of Possible Allergenicity)
- Draft Guideline for Conduct of Food Safety Assessment of Food Produced using Recombinant-DNA Microorganisms (including the Draft Annex on the Assessment of Possible Allergenicity.

These guidelines were adopted and approved as Codex standards at the 26th session of the Codex Alimentarius Commission held in Rome in June 2003. The Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology accomplished its mission, and the dissolution was approved at the same session. However, a proposal for the reestablishment of the task force was made during the session, since there were still many issues to be discussed concerning foods produced using biotechnology. Japan was assigned to formulate a protocol for the new project.

The CAC adopted the reestablishment of Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology at the 27th session in June 2004. Japan is again assumeing the chairmanship of the new task force. The new task force is supposed to advance its task based on the previous outcome and submit a final report in 2009.

Organisation for Economic Cooperation and Development (OECD)

The Organization for Economic Cooperation and Development was established to promote international economic cooperation. It groups 30 developed industrial countries including the United States, EU countries, and Japan. Its purposes are 1) economic growth, 2) aid to developing countries, and 3) free and diversified expansion of trade.

The OECD aims to deepen common recognition and to coordinate policies made by the member countries.

The OECD has been addressing safety measures of pesticides and other chemicals, the coordination of regulations, and biotechnology at related committees, including the Committee for Scientific and Technological Policy, the Environment Policy Committee, and the Committee for Agriculture..

Issues on biotechnology have been taken up by the Summit Conferences of the Group of Eight Major Powers. At the Koln Summit in June 1999, G8 leaders decided that the OECD should discuss the safety of genetically modified foods and report to the Okinawa Summit in 2000. The OECD compiled a report in June 2000 and submitted it to the Okinawa Summit in July. At the Okinawa Summit, the OECD Edinburgh Conference (OECD New Biotechnology Food and Crops: Science, Safety and Society) held February 2000 was highly evaluated. The G8 leaders agreed to continue to support discussions held by the Codex ad hoc Intergovernmental Task Force (see the previous section) on the safety of foods produced using biotechnology. (The Codex commission's responsibility concerning the safety evaluation of foods produced using biotechnology was in response to the OECD request.)

The safety of foods produced using biotechnology is being discussed at the OECD task force on the safety of novel foods and animal foods. Japan also cooperates with the task force as a member country.

World Trade Organization Agreement (WTO agreement)

As the global distribution of food expands, differences in food regulation between countries have given rise to trade barriers. In the circumstances, the Sanitary and Phytosanitary Agreement (SPS Agreement) was concluded at the Uruguay Round of the General Agreement on Tariffs and Trade, specifying respect for international standards and the assurance of the transparency of measures. The SPS is aimed at minimizing negative effects food hygiene regulations may have on international trade. Japan ratified the Agreement in 1994. Member countries should coordinate with the SPS agreement when they establish and review food standards.

Japan proposed at the General Board Meeting in July 1999 that a meeting to discuss new issues of genetically modified foods should be established under the WTO. Furthermore, Japan proposed at the third WTO ministerial conference (November 30 – December 3, 1999, in Seattle) that a meeting under the WTO should evaluate safety and review labeling concerning genetically modified foods. However, the proposal has not been finalized, since the ministerial meeting was broken off.

Ministers met in Doha, Qatar, in November 2001(Fourth Ministerial Conference) and decided to open a new round (the Doha Round) following the Uruguay Round to strengthen the free global trade system. Members are conducting a new round of negotiations.

Asia Pacific Economic Cooperation (APEC)

The Asia Pacific Economic Cooperation was founded in 1989 to provide an opportunity to discuss various issues without any binding force, in response to growing needs for mutual cooperation in the Asian Pacific area. This organization is actively working with the goal of expanding trade and investment within the region.

Asia-Europe Meeting (ASEM)

The Asia-Europe Meeting was founded in 1996, aimed at strengthening the relationship between Asia and Europe, which has been relatively weak in comparison with the relationships between Europe and North America and Asia and North America. The ASEM conducts dialogs and cooperation within the region concerning various areas not only of economy but also of politics and culture.

(2) Information disclosure

The promotion of food safety requires the prompt and exact provision of necessary information.

Various matters concerning food safety are discussed by the Pharmaceutical Affairs and Food Sanitation Council, at the request of the Ministry of Health, Labour and Welfare. Meetings are in principle open to the public, and the proceedings (or summaries) of council sessions and accompanying documents are also publicized on its

web site (http://www.mhlw.go.jp), unless the publication of meetings leads to the restriction of comments by council members, which may badly affect fair and neutral discussion.

Before the MHLW establishes and revises regulations, it publishes the underlying concepts and invites comments from the public, based on the Food Sanitation Law and the Administrative Procedure Act. Also, before the MHLW enforces a new system, it will notify related industries in advance, and if necessary, will prepare leaflets to disseminate the information.

The Food Safety Basic Law stipulates that the national and local governments should exchange information and opinions on health risks with the public and academia (risk communication). In addition, the Food Sanitation Law stipulates that the MHLW should hear public opinion before it establishes standards, guidelines, and plans, and should regularly exchange information with the public. In response to these directions, the MHLW is strengthening the approach to risk communication, by working together with the Food Safety Commission.

Annexes

1. Map of imported food inspection offices at quarantine stations
2. List of quarantine stations
3. Food import system
4. Procedure for imported food inspection
5. Import notification form
6. FAINS/NACCS interface
7. Number of foreign official laboratories
8. Excerpts from the Food Sanitation Law (Articles 4 Paragraphs 1, 2, 4 and 5; Article 6; Article 9 paragraph 2; Articles 10; Article 11 Paragraphs 1, 2, and 3; Articles 12, 16, and 18; and Article 26 Paragraph 3)
9. Categories by health use of permitted/approved foods for specific health uses
10. Instances of labeling for permitted/approved foods for specific health uses
11. Outline of regulation on nutrition labeling
12. Nutrition labeling standards

Annex 1.

Imported Food Inspection Offices at Quarantine Stantions
Ministry of Health, Labour and Welfare

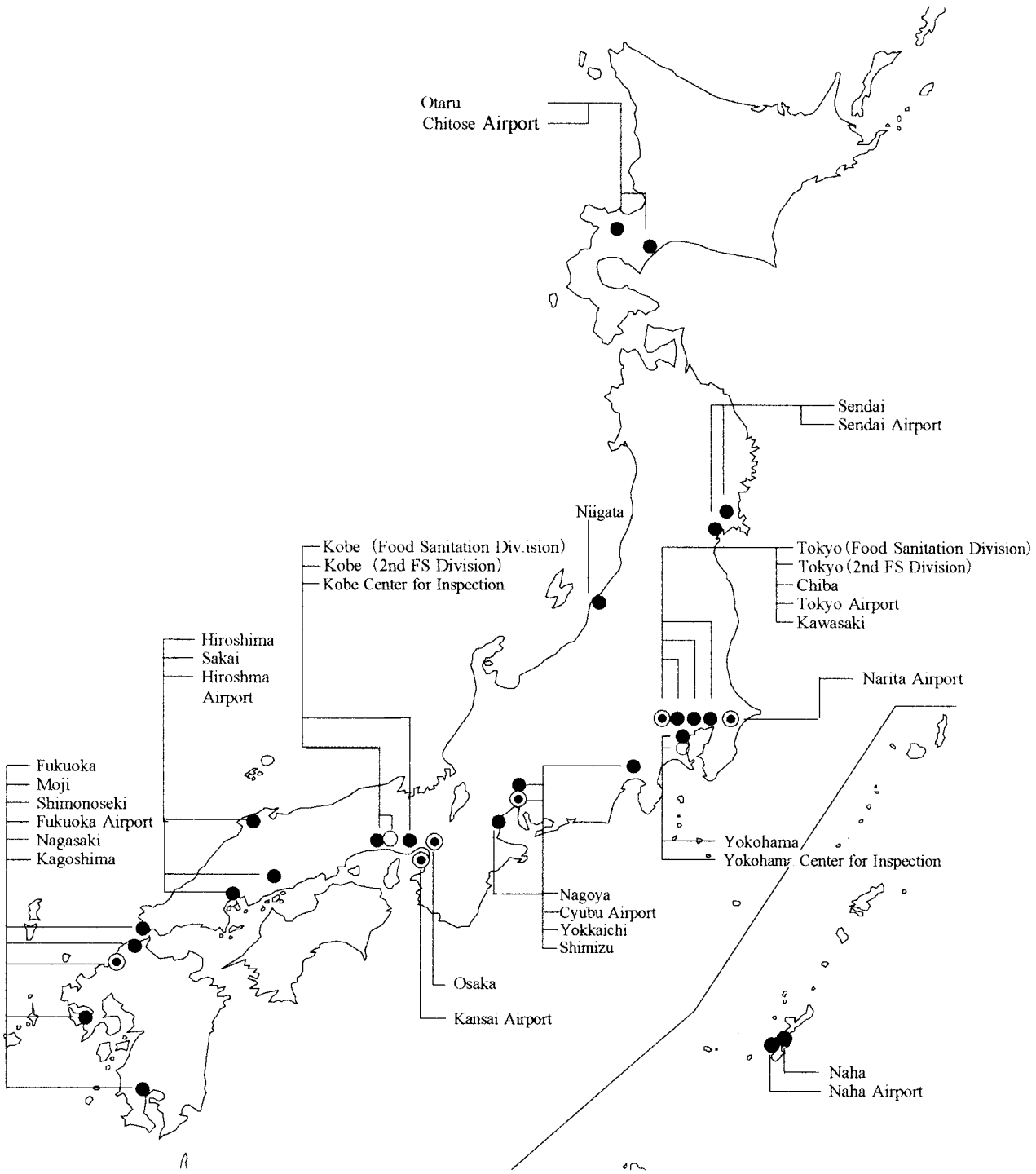
As of April 1, 2006

● Quarantine stations that handle import notifications (31 stations)

◉ Qarantine stations that have Inspection Division

○ Center for Inspections of Imported Foods and Infectious Diseases

314 Food Sanitation Inspectors



Annex 2.

List of Quarantine Stations

April 1, 2006

No.	Name of Station	Name of Branch and Office)	Address	Phone (FAX)	Place of Customs Clearance of Cargo
1	Otaru Quarantine Station		5-3, Minato-cho Otaru, Hokkaido, 047-0007	0134-32-4304 (0134-25-6069)	Hokkaido Pref. (excluding the area covered by Chitose Airport Branch)
2		Chitose Airport Branch	In Chitose Airport, Bibi, Chitose, Hokkaido, 066-0012	0123-45-7007 (0123-45-2357)	Hokkaido Pref. (Chitose Airport only)
3	Sendai Quarantine Station		3-4-1, Josandori, shiogama, Miyagi Pref., 985-0011	022-367-8102 (022-362-3300)	Aomori Pref., Iwate Pref., Miyagi Pref., (excluding Sendai Airport), Akita Pref., Yamagata Pref., Fukushima Pref.
4		Sendai Airport Branch	Aza Minamihara, Shimomasuda, Natori-shi, Miyagi Pref., 989-2401	022-383-1854 (022-383-1856)	Miyagi Pref .(Sendai Airport only)
5	Narita Airport Quarantine Station		2159, Tennamino, Oaza-Komaino, Narita, Chiba Pref., 282-8691	0476-32-6741 (0476-32-6742)	Chiba Pref. (Narita, Daiei-machi in Katori-gun, Tako-machi in Katori-gun and Shibayama-machi in Sanbu-gun only)
6	Tokyo Quarantine Station (1st Food Sanitation Division)		2-56, Aomi, Kohto-ku, Tokyo, 135 -0064	03-3599-1520 (03-5530-2153)	Ibaragi Pref., Tochigi Pref., Gunma Pref., Saitama Pref., Tokyo Pref., (excluding the area covered by Tokyo Airport Branch), Yamanashi Pref., Nagano Pref.
7	Tokyo Quarantine Station (2nd Food Sanitation Division)		2-1-1, Hamamachi, Funabashi, Chiba Pref., 273-0016	047-437-1381 (047-437-1585)	Chiba Pref. (Noda,Kashiwa, Nagareyama, Matudo, Kamagaya, Funabashi, Narashino, Urayasu, Ichikawa and Sekiyado and Shonan in Higashi Katushika-gun only)
8		Chiba Branch	1-12-2, Chuo Minato, Chuo-Ku, Chiba, Chiba Pref., 260-0024	043-241-6096 (043-241-7281)	Chiba Pref. (excluding the area covered by Narita Airport Quarantine Station and Tokyo Quarantine Station (2nd Food Sanitation Division)
9		Tokyo Airport Branch	3-4-4,Haneda Kuko,Ota-ku, Tokyo, 144-0041	03-5756-4858 (03-5756-4859)	Tokyo Pref. (Tokyo International Airport only)

Annex 2.

No.	Name of Station	Name of Branch and Office)	Address	Phone (FAX)	Place of Customs Clearance of Cargo
10		Kawasaki Branch	6-10, Higashi Ogishima, Kawasaki-ku, Kawasaki, Kanagawa Pref., 210-0869	044-277-0025 (044-288-2499)	Kanagawa Pref. (Kawasaki only)
11	Yokohama Quarantine Station		1-1, Kaigandori, Naka-ku, Yokohama, Kanagawa Pref., 231 -0002	045-201-0505 (045-212-0640)	Kanagawa Pref. (excluding the area covered by Kawasaki Branch)
12	Niigata Quarantine Station		1-5-4, Ryugashima, Niigata, Niigata Pref., 950-0072	025-244-4405 (025-241-7404)	Niigata Pref.
13	Nagoya Quarantine Station		11-1, Tsukiji-cho, Minato-ku, Nagoya, Aichi Pref., 455-0045	052-661-4133 (052-655-1808)	Gifu Pref., Aichi Pref. (excluding the area covered by Nagoya Airport Branch)
14		Shimizu Branch	9-1, Hinode-cho, Shizuoka, Shizuoka Pref., 424-0922	0543-52-4540 (0543-53-1364)	Shizuoka Pref.
15		Chubu Airport Branch	Toyoba, Toyoyama-cho, Nishi-Kasugai-gun, Aichi Pref., 480-0202	0568-28-2524 (0568-28-5909)	Aichi Pref. (Nagoya Airport only)
16		Yokkaichi Branch	5-1, Chitose-cho, Yokkaichi, Mie Pref., 510-0051	0593-52-3574 (0593-51-7666)	Mie Pref. Wakayama Pref. (Shingu and Higashimuro-gun only)
17	Osaka Quarantine Station		4-10-3, Chikko, Minato-ku, Osaka, 552-0021	06-6571-3523 (06-6575-1803)	Toyama Pref., Ishikawa Pref., Fukui Pref., Shiga Pref., Kyouto Pref., Osaka Pref. (excluding the area covered by Kansai Airport Quarantine Station), Nara Pref., Wakayama Pref. (excluding the area covered by Yokkaichi Branch)
18	Kansai Airport Quarantine Station		1, Senshu Kuko Minami, Sennan, Osaka Pref., 549-0021	0724-55-1290 (0724-55-1292)	Osaka Pref. (Kansai International Airport only)
19	Kobe Quarantine Station (1st Food Sanitation Division)		1-1, Toyahama-cho, Hyogo-ku, Kobe, Hyogo Pref., 652-0866	078-672-9655 (078-672-9662)	Hyogo Pref. (excluding the 2nd Food Sanitation Division), Okayama Pref., Tokushima Pref., Kagawa Pref.

Annex 2.

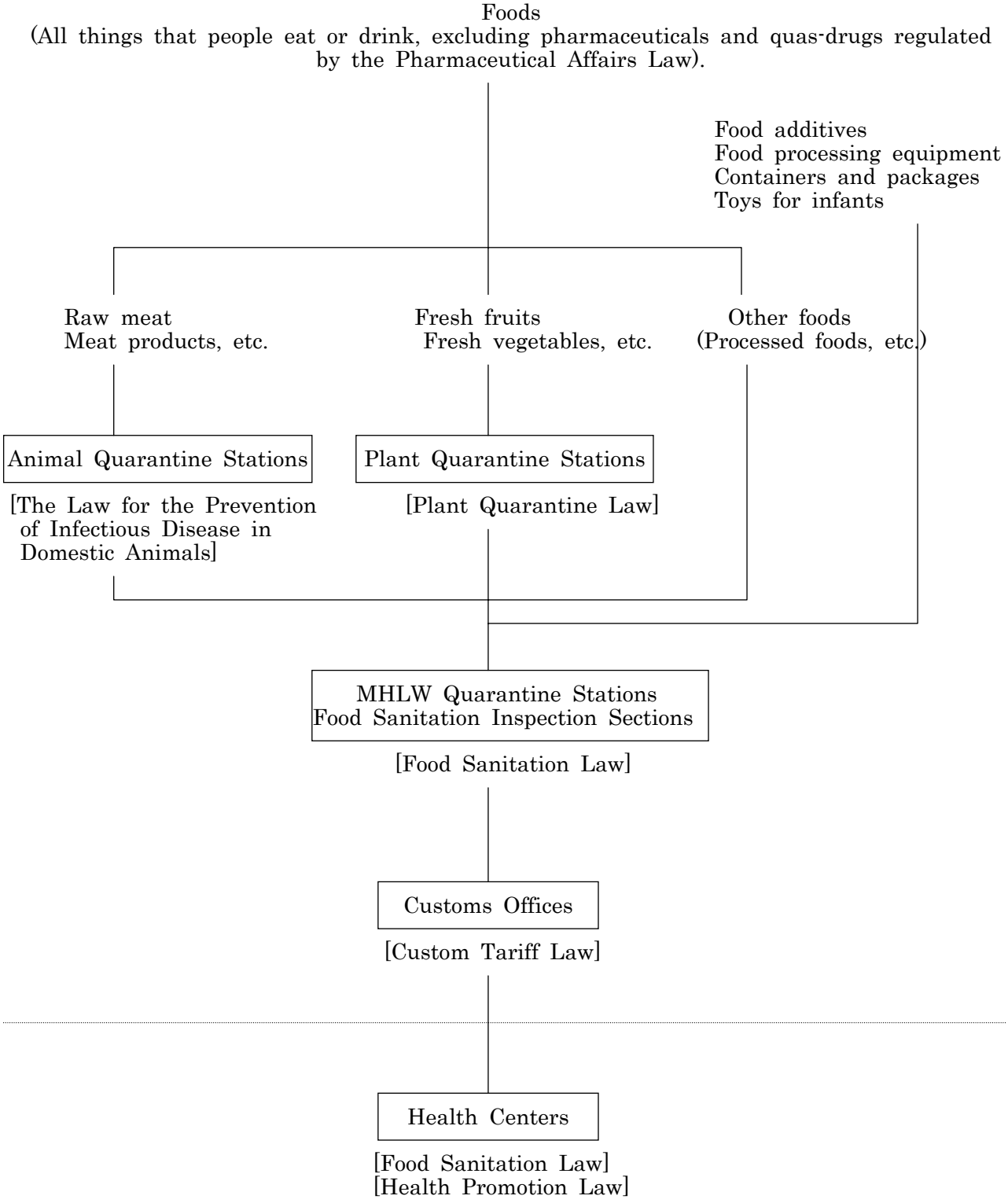
No.	Name of Station	Name of Branch and Office)	Address	Phone (FAX)	Place of Customs Clearance of Cargo
20	Kobe Quarantine Station (2nd Food Sanitation Division)		4-16, Koyo-cho, Higashi Nada-ku, Kobe, Hyogo Pref., 658-0031	078-857-1671 (078-857-1691)	Hyogo Pref. (Higashinada-ku and Nadaku in Kobe only)
21	Hiroshima Quarantine Station		3-10-17, Ujinakaigan, Minami-ku, Hiroshima, Hiroshima Pref., 734-0011	082-255-1379 (082-254-4984)	Hiroshima Pref. (excluding Hiroshima Airport), Ehime Pref., Kouchi Pref.
22		Sakai Office	9-1, Shouwacho, Sakaiminato, Tottori Pref., 684-0034	0859-42-3517 (0859-42-3517)	Tottori Pref., Shimane Pref.
23		Hiroshima Airport Branch	64-31, Aza Hiraiwa, Oaza Zennyuji, Hongo-cho, Toyotagun, Hiroshima Pref., 729-0416	0848-86-8017 (0848-86-8030)	Hiroshima Pref. (Hiroshima Airport only)
24	Fukuoka Quarantine Station		1-22, Okihama-cho, Hakata-ku, Fukuoka, Fukuoka Pref., 812-0031	092-271-5873 (092-282-1004)	Fukuoka Pref. (excluding the area covered by Moji Branch and Fukuoka Airport Branch), Saga Pref., Nagasaki Pref. (excluding the area covered by Nagasaki Branch), Kumamoto Pref., Oita Pref.
25		Moji Branch	1-3-10, Nishikaigan, Moji-ku, Kitakyushu, Fukuoka Pref., 801-0841	093-321-2611 (093-332-4129)	Fukuoka Pref. (Kita-kyushu, Noogata, Iizuka, Tagawa, Yamada, Yukuhashi, Buzen, Nakama, Onga-gun, Kurate-gun, Kaho-gun, Tagawa-gun, Miyako-gun and Chikujyou-gun only).
26		Shimonoseki Office	1-7-1, Higashiyanamato-cho, Shimonoseki, Yamaguchi Pref., 750-0066	0832-66-1402 (0832-66-8145)	Yamaguchi Pref.
27		Fukuoka Airport Branch	739, Oaza-Aoki, Hakataku, Fukuoka, Fukuoka Pref., 816-0051	092-477-0208 (092-477-0209)	Fukuoka Pref. (Fukuoka Airport only)
28		Nagasaki Branch	4-32-5, Tomachi, Nagasaki, Nagasaki Pref., 850-0952	095-878-8623 (095-878-8627)	Nagasaki Pref. (excluding Iki City and Tsushima City).

Annex 2.

No.	Name of Station	Name of Branch and Office)	Address	Phone (FAX)	Place of Customs Clearance of Cargo
29		Kagoshima Branch	18-2-31, Izumi-cho, Kagoshima, Kagoshima Pref., 892-0822	099-222-8670 (099-223-5297)	Miyazaki Pref., Kagoshima Pref.
30	Naha Quarantine Station		2-11-1, Minato-cho, Naha, Okinawa Pref., 900-0001	098-868-4519 (098-861-4372)	Okinawa Pref. (excluding the area covered by Naha Airport Branch)
31		Naha Airport Branch	174, Aza Kagamizu, Naha, Okinawa Pref., 901-0142	098-857-0057 (098-859-0032)	Okinawa Pref. (Naha Airport only)

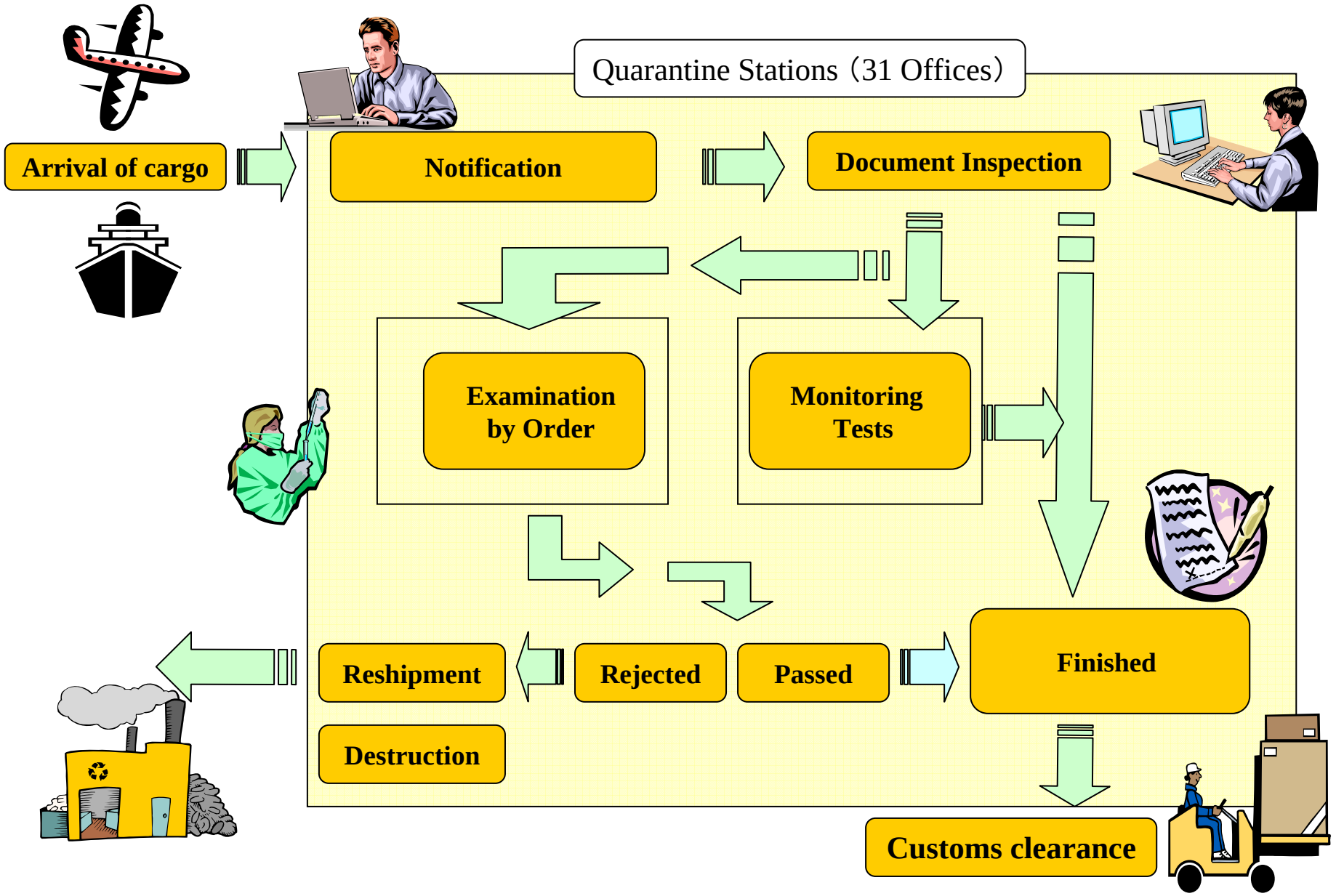
Annex 3.

Food Import System



Annex 4.

Procedure of Imported Food Inspection



Annex 5

Import Notification Form

Minister of Health, Labour and Welfare, Esq.

Name and address of importer (Or name of importing corporation and its address)

Notification Receipt Number	*1	Name	
Classification of Notification	Prior Notification / Planned Import	Address	
Code of Importer		(Telephone Number)	
Name and Code of Country of Production		Registration Number of Importer Responsible for Food Sanitation	
Name, Address and Code of Manufacturer			
Name, Address and Code of Manufacturing Factory			
Name and Code of Port of Loading		Date of Loading	_____(Month) _____(Day) _____(Year)
Name and Code of Port of Discharge		Date of Arrival	_____(Month) _____(Day) _____(Year)
Name and Code of Warehouse		Date of Storage	_____(Month) _____(Day) _____(Year)
		Date of Notification	_____(Month) _____(Day) _____(Year)
Marks and Numbers of Cargo		Accident Brief Explanation (if Yes)	Yes / No
Ship Name or Flight Number of Aircraft		Name and Code of Submitter	

1	Classification of Cargo	Food / Food Additive / Apparatus / Container-Package/ Toy	Continuous Import	Y • N	Sanitary Certificate Number	
Item Code					If the cargo includes processed food, describe its ingredients and their codes. If the cargo includes apparatuses, container/packages or toys, describe the raw materials and their codes.	
Description of Article						
Shipped Volume (Number of Units)						
Shipped Volume (Weight)				kg		
Usage and its Code					If the cargo includes food with additives, describe the names and codes of additives. If the cargo includes manufacturing agents in the additives, describe the names and codes of additives. (Additives used as flavoring agents are excluded for either case.)	*2
Kind of Package and its Code						*2
Registration Number 1						
Registration Number 2						
Registration Number 3						
If the cargo includes processed food, describe the method of manufacturing or processing, and its code.						

Remarks	Stamp for Receiving Notification

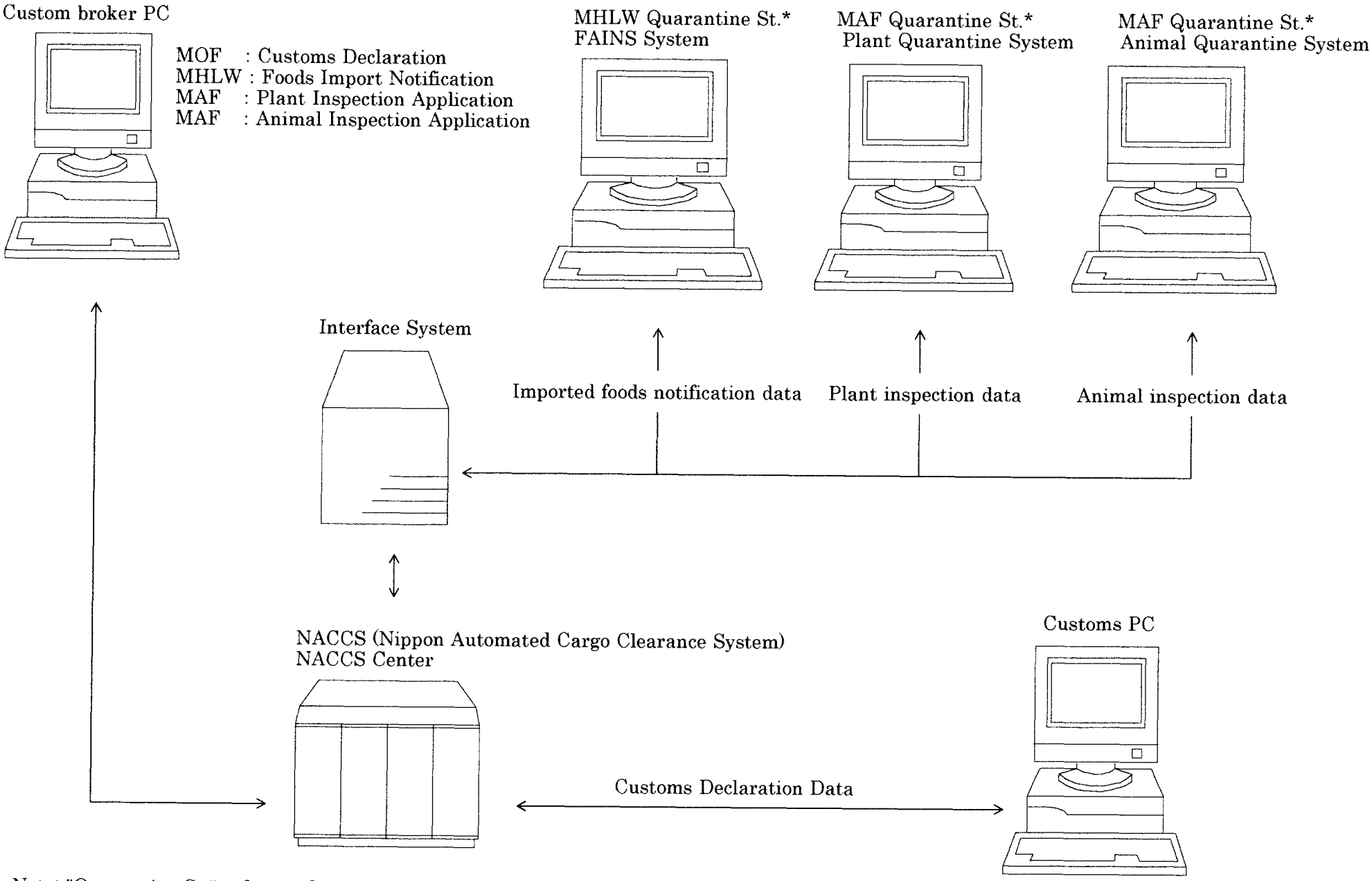
Notes:

*1: Do not write here.

*2: When the article in the cargo includes food additives that are generally supplied in food or drink and regulated by the relevant statutes, describe the names of the substances used. When the article includes manufacturing agents in the additives, excluding flavoring agents or food additives that are generally supplied in food or drink, write the names of the agents.

Annex 6.

FAINS/NACCS interface



Note: "Quarantine St." refers to Quatantine Station.

Annex 7.

Number of Foreign Official Laboratories

As of July 1, 2006

Nations and Areas	Japanese Name	Number
ARGENTINE REP.	アルゼンティン共和国	3
AUSTRALIA	オーストラリア	127
BOLIVARIAN REP. of VENEZUELA	ベネズエラ・ボリバル共和国	1
CANADA	カナダ	48
DEM. SOC. REP. of SRI LANKA	スリ・ランカ民主社会主義共和国	3
FED. REP. of BRAZIL	ブラジル連邦共和国	7
FED. REP. of GERMANY	ドイツ連邦共和国	831
FED. REP. of YUGOSLAVIA	ユーゴースラヴィア連邦共和国	17
FRENCH REP.	フランス共和国	455
GRAND DUCHY of LUXEMBOURG	ルクセンブルグ大公国	5
HELLENIC REP.	ギリシャ共和国	77
HONG KONG	香港	4
INDIA	インド	18
IRELAND	アイルランド	12
ISLAMIC REP. of PAKISTAN	パキスタン・イスラム共和国	1
KINGDOM of BELGIUM	ベルギー王国	82
KINGDOM of DENMARK	デンマーク王国	21
KINGDOM of MOROCCO	モロッコ王国	3
KINGDOM of NORWAY	ノールウェー王国	107
KINGDOM of SWEDEN	スウェーデン王国	30
KINGDOM of THAILAND	タイ王国	13
KINGDOM of the NETHERLANDS	オランダ王国	27
NEW ZEALAND	ニュー・ジーランド	95
PEOPLE'S REP. of CHINA	中華人民共和国	358
PORTUGUESE REP.	ポルトガル共和国	51
REP. of AUSTRIA	オーストリア共和国	18
REP. of BULGARIA	ブルガリア共和国	12
REP. of CHILE	チリ共和国	48
REP. of COLOMBIA	コロンビア共和国	3
REP. OF CROATIA	クロアチア共和国	7
REP. of CUBA	キューバ共和国	2
REP. of CYPRUS	キプロス共和国	1
REP. of FINLAND	フィンランド共和国	8
REP. of GHANA	ガーナ共和国	1
REP. of GUATEMALA	グァテマラ共和国	1
REP. of HONDURAS	ホンデュラス共和国	5
REP. of HUNGARY	ハンガリー共和国	22
REP. of ICELAND	アイスランド共和国	5
REP. of INDONESIA	インドネシア共和国	4
REP. of ITALY	イタリア共和国	290
REP. of KOREA	大韓民国	39
REP. of PARAGUAY	パラグアイ共和国	1
REP. of POLAND	ポーランド共和国	92
REP. of SINGAPORE	シンガポール共和国	4
REP. of SLOVENIA	スロヴェニア共和国	4
REP. of SOUTH AFRICA	南アフリカ共和国	1
REP. of the PHILIPPINES	フィリピン共和国	5
REP. of TURKEY	トルコ共和国	4
ROMANIA	ルーマニア	1
SLOVAK REP.	スロヴァキア共和国	1
SPAIN	スペイン	192
SWISS CONFEDERATION	スイス連邦	28
TAIWAN	台湾	8
THE CZECH REP.	チェッコ共和国	3
U. S. A.	アメリカ合衆国	78
UNITED KINGDOM	英国	117
UNITED MEXICAN STATES	メキシコ合衆国	51
Total　57 Nations/Areas		3,452

Annex 8.

Excerpts from the Food Sanitation Law

Articles 4 Paragraphs 1, 2, 4, and 5; Article 6; Article 9 Paragraph 2; Article 10; Article 11 Paragraphs 1, 2, and 3; Articles 12, 16, and 18; and Article 26 Paragraph 3

The following provisions are excerpts from the Food Sanitation Law. The full document is accessible at the website of JETRO.

http://www.jetro.go.jp/en/market/regulations/pdf/food2004nov-e.pdf

[Definitions]

Article 4. In this Law, the term "food" means all foods and drinks, provided, however, that this term does not include drugs and quasi-drugs prescribed in the Pharmaceutical Affairs Law.

2. In this law, the term "food additive" means all substances to be used in or on food, in the process of the manufacturing of food or for the purpose of the processing or preserving of food, by adding, mixing, infiltrating, or other means.

4. In this Law, the term "apparatus" means tableware, kitchen utensils, and machines, im plements, and other articles that are used for handling, manufacturing, processing, preparing, storing, transporting, displaying, delivering, or consuming food or food additives and that come into direct contact with food or food additives; provided, however, that this term does not include machines, implements, and other articles used for collecting food in agriculture and fisheries.

5. In this Law, the term "container/package" means articles in which foods or food additives are contained or packaged and in which foods and food additives are offered when such foods and food additives are delivered.

[Food and Additives Whose Sale is Prohibited]

Article 6. No person shall sell (hereinafter in this Law, the term "sell" includes supplying for purposes other than sale to the public or a large number of persons), or handle, manufacture, import, process, use, prepare, store, or display with intent to sell any food or additive given below:

(1) Those which are rotten, decomposed, or immature; provided, however, that this Subparagraph does not apply to articles that are generally deemed not to be injurious to human health and are deemed to be fit for human consumption.

(2) Those which contain or bear toxic or injurious substances or which are suspected to contain or bear these substances; provided, however, that this provision does not apply to the cases which are prescribed by the Minister of Health, Labour and Welfare as not injurious to

human health.

(3) Those which are either contaminated with or suspected to be contaminated with pathogenic microorganisms and which may injure human health.

(4) Those which may injure human health due to uncleanliness, the admixture or addition of extraneous substances, or any other causes.

[Prohibition of Sale, etc. of Meat, etc. Derived from Diseased Livestock and Poultry]

Article 9.
2. No person shall import, with intent to sell as a food, any meat or viscera of livestock or poultry or any product designated by the Ministerial Ordinance (hereinafter in this Paragraph, the meat, viscera, and products thereof mentioned above are referred to as "livestock meat etc.") unless it is accompanied with a certificate or a copy thereof issued by a governmental organization of the exporting country, stating that it is not meat or viscus nor any of the products derived from livestock or poultry which suffers from or is suspected to suffer from any of the diseases given in the preceding paragraph, which shows any of the abnormalities given in the preceding paragraph, or which has died of any reason before slaughtering, and describing other items prescribed by the Ministerial Ordinance (hereinafter in this Paragraph, any statements and necessary items mentioned above are referred to as "sanitation-related information").

[Prohibition of Sale, etc. of Food Additives, etc.]

Article 10. No person shall sell, or manufacture, import, process, use, store, or display with intent to sell any additive (excluding any natural flavoring agent and any substance that is generally provided for eating or drinking as a food and which is used as a food additive) or any preparation or food that contains such additive, unless the Minister of Health, Labour and Welfare designates it as not injurious to human health based upon the opinion of the Pharmaceutical Affairs and Food Sanitation Council.

[Establishment of Specifications and Standards for Food or Additives]

Article 11. The Minister of Health, Labour and Welfare, from the viewpoint of public health, may establish standards for methods of manufacturing, processing, using, preparing, or preserving food or additives intended for sale or may establish specifications for components of food or additives intended for sale, based upon the opinion of the Pharmaceutical Affairs and Food Sanitation Council.

2. Where specifications or standards have been established pursuant to the provisions of the preceding Paragraph, no person shall manufacture, process, use, prepare, or preserve any

food or food additive by a method not complying with the established standards; shall sell or import any food or food additive manufactured, processed, used, prepared, or preserved by a method not complying with the established standards; or shall manufacture, import, process, use, prepare, preserve, or sell any food or food additive not complying with the established specifications.

3. No person shall manufacture, import, process, use, prepare, store with intent to sell, or sell food that contains pesticides [those designated under the provision of Article 1-2 Paragraph 1 of the Agricultural Chemicals Regulation Law], substances designated under the provision of Article 2 Paragraph 3 of the Law concerning Safety Assurance and Quality Improvement of Feed, to be used in feed by adding, mixing, infiltrating, or other means, and ingredients of drugs, designated under the Article 2 Paragraph 1 of the Pharmaceutical Affairs Law for the purpose to be used for animals, above the level established by the Minister of Health, Labour and Welfare as not injurious to human health based upon the opinion of the Pharmaceutical Affairs and Food Sanitation Council; provided, however, that this paragraph does not apply to foods for which residue limits have been established as compositional specifications.

[Request for Cooperation from the Ministry of Agriculture, Forestry and Fisheries]

Article 12. The Minister of Health, Labour and Welfare may request from the Minister of Agriculture, Forestry and Fisheries the provision of information concerning components of a pesticide and other necessary cooperation, if the Minister determines that such action is necessary to establish quantitative limitations on ingredients of an agricultural chemical defined in the Agricultural Chemical Control Law, a feed additive defined in the Feed Additives Safety Control Law, or a veterinary drug defined in the Pharmaceutical Affairs Law (including a substance produced by a chemical change in the active ingredient), which may remain in foods, as specifications for food components prescribed in Article 11 Paragraph 1.

[Prohibition of Sale, etc. of Toxic or Injurious Apparatus or Containers/Packages]

Article 16. No person shall sell, manufacture or import with intent to sell, or use in business any apparatus or container/package which contains or bears toxic or injurious substances and may injure human health or any apparatus or container/package which may injure human health by having harmful influence on foods and additives through contact therewith.

[Establishment of Specifications and Standards for Apparatus or Containers/Packages]

Article 18. The Minister of Health, Labour and Welfare, from the viewpoint of public health, based upon the opinion of the Pharmaceutical Affairs and Food Sanitation Council, may

establish specifications for apparatus, containers/packages, or their raw materials intended for sale or for use in business, or may establish standards for methods of manufacturing apparatus or containers/packages.

2. Where specifications or standards have been established pursuant to the provisions of the preceding Paragraph, no person shall sell, or manufacture or import with intent to sell, or use in business any apparatus or container/package not complying with the established specifications; shall use any raw material not complying with the established specifications; or shall manufacture any apparatus or container/package by a method not complying with the established standards.

[Examination Order]

Article 26.

3. The Minister of Health, Labor and Welfare may order a person who imports any food, additive, apparatus, or container/package that is suspected to fall under one of the substances given in each of the Subparagraphs of Paragraph 1, or to fall under any of the foods prescribed in Article 10, in view of circumstances in the producing district and other circumstances, to allow examinations performed by the Minister of Health, Labour and Welfare or a registered laboratory, when the Minister of Health, Labour and Welfare determines that such action is necessary to prevent the occurrence of food health hazards.

Annex 9.

Categories by Health Uses of Permitted/Approved Foods for Specified Health Uses

As of May 30, 2006

Categories	Principal ingridients (ingredients exhibiting health functions)	No. of Aproval
Foods to regulate gastrointestinal conditions	Oligosaccharides, Lactulose, Bifidobacteria, Lactic acid bacteria, Dietary fiber (Indigestible dextrin, Polydextrol, Guar gum, Psyllium seed coat, etc.),	255
Foods for those who are concerned about blood sugar levels	Indigestible dextrin, Wheat albumin, Guave tea Polyphenol, L-arabinose, etc.	73
Foods for those with slight hypertension	Lactotripeptide, Casein dodecapeptide, Tochu leaf glycoside (Geniposidic acid), Sardine peptide, etc.	68
Foods for those with slight hypercholesterol	Chitosan, Soybean protein, Degraded sodium alginate	56
Foods less apt to cause tooth decay	Paratinose, Maltitose, Erythrytol, etc.	36
Cholesterol plus gastrointestinal conditions, Neutral fat plus cholesterol	Degraded Sodium alginate, Dietary fiber from psyllium seed coats, etc.	33
Foods for those who are concerned about blood neutral fat and body fat	Diacyl glycerol, etc.	29
Foods for those concerned about bone health	Soybean isoflavone, MBP (Milk basic protein), etc.	24
Foods to help absorb minerals	Calcium citrate malate, Casein phosphopeptide, Hem iron, fracuto-oligosaccharide, etc.	9
Total		583

Annex 10.

Instances of Labeling for Permitted/Approved Foods for Specified Health Uses

categories	Health uses	Remarks
Foods to regulate gastrointestinal conditions	This product adequately increases bifidobacteria in the intestine, and maintains proper gastrointestinal conditions.	Over consumption may lead to loose bowel movement. May cause loose bowel movement in those with certain health conditions or those with certain constitution.
Foods for those who are concerned about blood sugar levels	This product contains indigestible dextrin, dietary fiber, which slows the absorption of sugars. This is suitable for those who are concerned about blood sugar levels.	The consumption of this product will not help to cure certain illnesses. Consult a doctor before use if you have abnormal blood sugar levels or are being treated for diabetes. Over consumption may lead to loose bowel movement.
Foods for those with slight hypertension	This product is suitable for slightly hypertensive people.	This product is not a preventive or curative drug. Persistent consumption may induce coughing in those with a certain constitution. Stop using or consult a doctor if you have such symptoms.
Foods for those with slight hypercholesterol	This product is made of separated soybean protein and is specially treated so that the protein, which reduces serum cholesterol, can be easily absorbed. This is useful for those with slight hypercholesterol in improving the quality of their diet.	A single high dose will not help to cure certain illnesses or to promote health.
Foods less apt to cause tooth decay	This chocolate is less apt to cause tooth decay because it uses paratinose and tea polyphenol, which do not cause tooth decay.	The consumption of this product will not help cure toot decay.
Cholesterol plus gastrointestinal conditions, Neutral fat plus cholesterol	This product contains soluble-dietary fiber (degraded sodium alginate), which restrains the absorption of cholesterol and adjusts gastrointestinal conditions, and is adequately treated so as to be easy to drink. This is useful in improving the quality of diet by supplementing the shortage of dietary fiber. This is suitable for those with slight hypercholesterol and those who want to adjust gastrointestinal conditions. Drink it to refresh yourself.	Over consumption may lead to loose bowel movement. May cause loose bowel movement in those in certain health conditions or those with a certain constitution.
Foods for those who are concerned about blood neutral fat and body fat	This oil, composed mainly of diacyl glycerol, tends to restrain not only the rise in blood neutral fat after a meal, but also a gain in body fat.	High consumption will not help to cure certain illnesses or to promote health.
Foods for those concerned about bone health	This product is suitable for people concerned about bone health, since it contains soybean isoflavone that helps to maintain bone calcium.	This product is not intended for the cure or prevention of certain illnesses. High consumption will not help promote health.
Foods to help absorb minerals	This product is suitable for slightly anemic people who need an iron supplement.	This product is suitable as a food intended for dietary cure for slight anemia, but high consumption will not help to cure illnesses. Prior consultation with health experts, such as a doctor, pharmacist, and nutritionist, is desirable.

Annex 11.

Outline of Regulation on Nutrition Labeling

The regulation took effect on May 1, 2003, in the wake of partial amendment of the Health Promotion Law.

1. When labeling a food intended for sale with a particular nutrient and calorie level.
   e.g., Calcium: 100mg, reduced salt, Vitamin C: equivalent to 100 lemons, low fat.

2. Requirements:
   Declare the amount of the particular nutrient plus the principal nutrients and calorie level of the food.

When making a claim about the quantity of a particular nutrient using the tem, "high" or "low," in the case of sections 3 and 4 below, observe the corresponding standards established by the Minister of Health, Labour and Welfare as well as the requirements given in section 2.

3. A food bearing the claim, "able to supply a particular nutrient," must include the required level or more of that nutrient, according to the standards.
   e.g., Calcium-rich, source of vitamin A.

4. A food bearing the claim, "able to restrict calorie level or a particular nutrient," must include only the required level or less of calorie or that nutrient, according to the standards.
   e.g., Low-calorie, low-fat.

If a person does not comply with the established standards, the Minister recommends that the person label the food with the necessary information. If the person does not follow the recommendation, an order will be issued.

When the order is not observed,

Penalty up to 500,000 yen

Annex 12.

Nutrition Labeling Standards

Those who wish to make a claim about energy or a particular nutrient under the Health Promotion Law must observe the following requirements:

In general

1. Target items

In all cases, the nutrients given in A through E below must be indicated. If one or more of the nutrients given in F are claimed, the corresponding nutrients must be indicated. Indication must be in the order listed below.

A. Calorie
B. Protein
C. Fat
D. Carbohydrates (or sugars and dietary fibers)
E. Sodium
F. Others

Minerals: Calcium, Iron, Potassium, Phosphorus, Magnesium, Zinc, Copper, Manganese, Iodine, Selenium, Chrome.

Vitamins: Vitamin A, Vitamin B_1, Vitamin B_2, Vitamin B_6, Vitamin B_{12}, Niacin, Vitamin C, Vitamin D, Vitamin E, Vitamin K, Folic acid, Pantothenic acid, Biotin.

2. The information must be written in Japanese on its container or package in a manner that is easily readable without opening the container or package.

3. The amount of each nutrient must be indicated per 100g or 100ml, or per serving, per package, or per other appropriate unit. The amount must be expressed in the corresponding unit below.

A. Calorie: kilocalorie (kcal).
B. Protein: gram (g).
C. Fat: gram (g).
D. Carbohydrates: gram (g).
E. Minerals

Zinc, Calcium, Iron, Copper, Magnesium, and Sodium: milligram(mg).
If 1,000 mg or more of sodium is indicated, gram (g) can be used.

F. Vitamins

Vitamin A and Vitamin D: microgram (μg) or international unit (IU).
Niacin, Pantothenic acid, Vitamin B_1, Vitamin B_2, Vitamin B_6, Vitamin C, and Vitamin E: milligram (mg).
Biotin, Vitamin B_{12}, and Folic acid: microgram (μg).

4. When the amount of a nutrient is indicated as being a certain level, the actual level obtained using the specified method must be within the following range:

Calorie, Protein, Fat, Saturated fatty acid, Cholesterol, Carbohydrate, Sugars, Dietary fiber, and Sodium: ±20%
Vitamin A, Vitamin D, Vitamin E, Calcium, and Iron: −20% to +50%
Vitamin B_1, Vitamin B_2, Vitamin B_6, Vitamin B_{12}, Vitamin C, Niacin, Pantothenic acid, Biotin, and Folic acid: −20% to +80%

5. When the amount is indicated with upper and lower limits, the actual level obtained using specified method must be within the labeled range.

Claim using the term "high," "source of," or "fortified"

Target nutrients: Protein, Dietary fibers, Calcium, Iron, Zinc, Cupper, Magnesium, Niacin, Pantothenic acid, Biotin, Vitamin A, Vitamin B_1, Vitamin B_2, Vitamin B_6, Vitamin B_{12}, Vitamin C, Vitamin D, Vitamin E, and Folic acid.

For the above-mentioned target nutrients:

A. A food bearing the claim "high" or "rich" must contain the given level or more of the nutrient (see Table 1).

B. A food bearing the claim "source of a nutrient" or "containing a nutrient" must contain the given level or more of the nutrient (see Table 2).

For the above-mentioned target nutrients, a food bearing the claim that a specific nutrient is fortified to a certain level as compared with the reference food must satisfy the following requirements:

A. The reference food must be indicated, and

B. The fortified level must be the given level or more (see Table 2).

Claim using the term "non," "free" or "zero," or "low" or "reduced"

Target nutrients: Calorie, Fat, Saturated fatty acid, Cholesterol, Sugars (monosaccharides and disaccharides only, except sugar alcohols), and Sodium.

For the target nutrients:

A. A food bearing the claim “non,” “free,” or “zero” must contain the given level or less of the nutrient (see Table 3).

B. A food bearing the claim “low” or “light” must contain the given level or less of the nutrient (see Table 4).

For the target nutrients, a food bearing the claim that a specific nutrient is reduced by a certain level as compared with the reference food must satisfy the following requirements:

A. The reference food must be indicated, and

B. The reduced level must be the given level or more (see Table 4)

Claim using the expression “reduced-sodium soy sauce”

For soy sauce bearing the claim “reduced sodium,” sodium must be reduced by 20% or more as compared with ordinary products.

Table 1. Claim using the term, "high" or "rich"

Nutrient	Minimum level
Protein	15 g/100 g (solid), 7.5/100ml (liquid), 7.5/100 kcal
Dietary fiber	6 g/100 g (solid), 3 g/100ml (liquid), 3 g/100 kcal
Zinc	2.10 mg/100 g (solid), 1.05 mg/100 ml (liquid), 0.70 mg/100 kcal
Calcium	210 mg/100 g (solid), 105 mg/100 ml (liquid), 70 mg/100 kcal
Iron	2.25 mg/100 g (solid), 1.13 mg/100 ml (liquid), 0.75 mg/100 kcal
Cupper	0.18 mg/100 g (solid), 0.09 mg/100 ml (liquid), 0.06 mg/100 kcal
Magnesium	75 mg/100 g (solid), 38 mg/100 ml (liquid), 25 mg/100 kcal
Niacin	3.3 mg/100 g (solid), 1.7 mg/100 ml (liquid), 1.1 mg/100 kcal
Pantothenic acid	1.65 g/100 g (solid), 0.83 g/100 ml (liquid), 0.55 g/100 kcal
Biotin	14 μg/100 g (solid), 6.8μg/100ml (liquid), 4.5 μg/100 kcal
Vitamin A	135 μg/100 g (solid), 68 μg/100 ml (liquid), 45 μg/100 kcal
Vitamin B_1	0.30 mg/100 g (solid), 0.15 mg/100 ml (liquid), 0.10 mg/100 kcal
Vitamin B_2	0.33 mg/100 g (solid), 0.17 mg/100 ml (liquid), 0.11 mg/100 kcal
Vitamin B_6	0.30 mg/100g (solid), 0.15 mg/100 ml (liquid), 0.10 mg/100 kcal
Vitamin B_{12}	0.60 μg/100 g (solid), 0.30 μg/100 ml (liquid), 0.20 μg/100 kcal
Vitamin C	24 mg/100 g (solid), 12 mg/100 ml (liquid), 8 mg/100 kcal
Vitamin D	1.50 μg/100 g (solid), 0.75 μg/100 ml (liquid), 0.50 μg/100 kcal
Vitamin E	2.4 mg/100 g (solid), 1.2 mg/100 ml (liquid), 0.8 mg/100 kcal
Folic acid	60 μg/100 g (solid), 30 μg/100 ml (liquid), 20 μg/100 kcal

Table 2. Claim using the term, "containing" or "source of," or "fortified"

Nutrient	Minimum level
Protein	7.5 g/100 g (solid), 3.8 g/100ml (liquid), 3.8 g/100 kcal
Dietary fiber	3 g/100 g (solid), 1.5 g/100 ml (liquid), 1.5 g/100 kcal
Zinc	1.05 mg/100 g (solid), 0.53 mg/100ml (liquid), 035 mg/100 kcal
Calcium	105 mg/100 g (solid), 53 mg/100 ml (liquid), 35 mg/100 kcal
Iron	1.13 mg/100 g (solid), 0.56 mg/100 ml (liquid), 0.38 mg/100 kcal
Cupper	0.09 mg/100 g (solid), 0.05 mg/100 ml (liquid), 0.03 mg/100 kcal
Magnesium	38 mg/100 g (solid), 19 mg/100 ml (liquid), 13 mg/100 kcal
Niacin	1.7 mg/100 g (solid), 0.8 mg/100 ml (liquid), 0.6 mg/100 kcal
Pantothenic acid	0.83 g/100 g (solid), 0.41 g/100 ml (liquid), 0.28 g/100 kcal
Biotin	6.8 μg/100 g (solid), 3.4 μg/100 ml (liquid), 2.3 μg/100 kcal
Vitamin A	68 μg/100 g (solid), 34 μg/100 ml (liquid), 23 μg/100 kcal
Vitamin B_1	0.15 mg/100 g (solid), 0.08 mg/100 ml (liquid), 0.05 mg/100 kcal
Vitamin B_2	0.17 mg/100 g (solid), 0.08 mg/100 ml (liquid), 0.06 mg/100 kcal
Vitamin B_6	0.15 mg/100 g (solid), 0.08 mg/100 ml (liquid), 0.05 mg/100 kcal
Vitamin B_{12}	0.30 μg/100 g (solid), 0.15 μg/100 ml (liquid), 0.1 μg/100 kcal
Vitamin C	12 mg/100g (solid), 6 mg/100ml (liquid), 4 mg/100kcal
Vitamin D	0.75 μg/100 g (solid), 0.38 μg/100 ml (liquid), 0.25 μg/100 kcal
Vitamin E	1.2 mg/100 g (solid), 0.6 mg/100 ml (liquid), 0.4 mg/100 kcal
Folic acid	30 μg/100 g (solid), 15 μg/100 ml (liquid), 10 μg/100 kcal

Table 3. Claim using the term, "free," "zero," or "non"

Item	Maximum level
Energy	5 kcal/100 g or 100 ml
Fat	0.5 g/100 g or 100 ml
Saturated fatty acid	0.1 g/100 g or 100 ml
Cholesterol	5 mg/100 g or 100 ml*, 1.5 g saturated fatty acid/100 g (solid) or 0.75 g saturated fatty acid/100 ml (liquid), and Energy derived from saturated fatty acid: 10% of the total energy
Sugars	0.5 g/100 g or 100 ml
Sodium	5 mg/100 g or 10 0ml

Table 4. Claim using the term, "low," "light" or "less," or "reduced" or "cut off"

Item	Maximum level (or reduced level)
Energy	40 kcal/100 g (solid) or 20 kcal/100 ml (liquid)
Fat	3 g/100 g (solid) or 1.5 g/100 ml (liquid)
Saturated fatty acid	1.5 g/100 g (solid) or 0.75 g/100 ml (liquid) and Energy derived from saturated fatty acid: 10% of the total energy
Cholesterol	20 mg/100 g (solid) or 10 mg/100 ml (liquid) 1.5 g saturated fatty acid/100 g (solid) or 0.75 g saturated fatty acid/100 ml (liquid), and Energy derived from saturated fatty acid: 10% of the total energy
Sugars	5 g/100 g (solid) or 2.5 mg/100 ml (liquid)
Sodium	120 mg/100 g or 100 ml

Note: This requirement does not apply to a food for which the single serving size is 15g or less and in which saturated fatty acid accounts for 15% or less of the total fatty acid.