

Measures to Ensure Food Safety

Ministry of Health, Labour and Welfare, Japan



Introduction

- **MHLW implements various policies based on scientific knowledge.**
- **Information is shared with stakeholders including:**
 - **local governments;**
 - **consumers;**
 - **food business operators; and**
 - **other stakeholders.**

Today's Topics

- **Organization Structure**
- **Related Laws**
- **National and Local Governments**
- **Setting of Standards**
- **Import Check**
- **Export from Japan to EU**
- **Audit**

Government-wide Efforts toward Food Safety

Consumer Affairs Agency

Consumer Commission



Overall coordination, etc.

Food Safety Commission
(founded on July 1, 2003)

Risk evaluation
(Assessment of the effect of food on health)



Risk communication

Food Safety Basic Act
•Defines the basic principles
•Responsibilities and roles of individual stakeholders
•Basic policies for formulating policy measures.

Advisory

Reccommendations, etc.

Risk management

Ministry of Heath, Labour and Welfare,
Ministry of Agriculture, Forestry and Fisheries, etc.

Organization Structure of Department of Food Safety

Ministry of Health, Labour and Welfare

Pharmaceutical and Food Safety Bureau

Department of Food Safety

Policy Planning and Communication Division (15)

Office of International Food Safety (4)

Office of Quarantine Station Administration (14)

Standards and Evaluation Division (21)

Office of Health Policy on Newly Developed Food (5)

Inspection and Safety Division (15)

Office of Import Food Safety (14)

Office of Foodborne Disease Surveillance (5)

(Number of the officials) As of Nov. 2013

Relevant Laws on Food Hygiene

- ◆ Food Safety Basic Act
- ◆ Food Sanitation Act
- ◆ Ministerial Ordinance on Milk and Milk products
Concerning Compositional Standards, etc.
- ◆ Abattoir Law
- ◆ Poultry Slaughtering Business Control and Poultry
Inspection Law
- ◆ Law on special Measures Against Bovine Spongiform
Encephalopathy

Food Safety Basic Act (purpose)

(Article 1)

The purpose of this Act is to comprehensively promote policies to ensure food safety by establishing basic principles, by clarifying the responsibilities of the national and local governments, and food-related business operators and the roles of consumers, and establishing a basic direction for policy formulation, in order to ensure food safety.

Food Safety Basic Act (measures)

- ◆ Responsibilities of the National Government, Local Governments, Foods-related Business Operators (Article 6, 7, 8)
- ◆ Implementation of Assessment of the Effect of Food on Health (Article 11)

Food Sanitation Act (purpose)

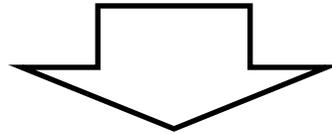
(Article 1)

The purpose of this Act is to prevent the sanitation hazards resulting from eating and drinking by enforcing the regulations and other measures necessary, from the viewpoint of public health, to ensure food safety and thereby to protect citizens' good health.

Food Sanitation Act (measures)

■Standards■

Criteria and Standards of food, food additive, apparatus, container and packaging (Article 11, 18)



■Monitoring and guidance■

- ◆ Guideline of monitoring and guidance and plan of those (Article 22, 23, 24)
- ◆ Inspection order (Article 26)
- ◆ removal for testing (Article 28)

Abattoir Law and Poultry Slaughtering Business Control and Poultry Inspection Law (purpose)

Abattoir Law

To establish regulations and take other measures necessary from the viewpoint of public health in order to ensure the proper management of abattoirs and slaughter and dressing of livestock for human consumption, so as to protect people's health. (Article 1)

Poultry Slaughtering Business Control and Poultry Inspection Law

To prevent any health hazard arising from poultry parts so as to safeguard public health by exercising necessary controls and other measures over a poultry slaughtering business from the viewpoint of public health and by establishing an appropriate poultry inspection system. (Article 1)

Abattoir Law and Poultry Slaughtering Business Control and Poultry Inspection Law (measure)

- ◆ Permission of abattoirs by the governor of the prefecture
- ◆ Inspection by the governor of the prefecture

Law on Special Measures Against Bovine Spongiform Encephalopathy (purpose)

(Article 1)

The purpose of this Law is to establish a system for stable supply of safe beef through such measures as the establishment of special measures to prevent the occurrence and spread of Bovine Spongiform Encephalopathy, thereby facilitating the protection of people's health as well as the sound development of beef cattle production and dairy farming, and beef-related manufacturing, processing, distribution, sales and food service businesses.

Law on Special Measures Against Bovine Spongiform Encephalopathy (measures)

(Article 7)

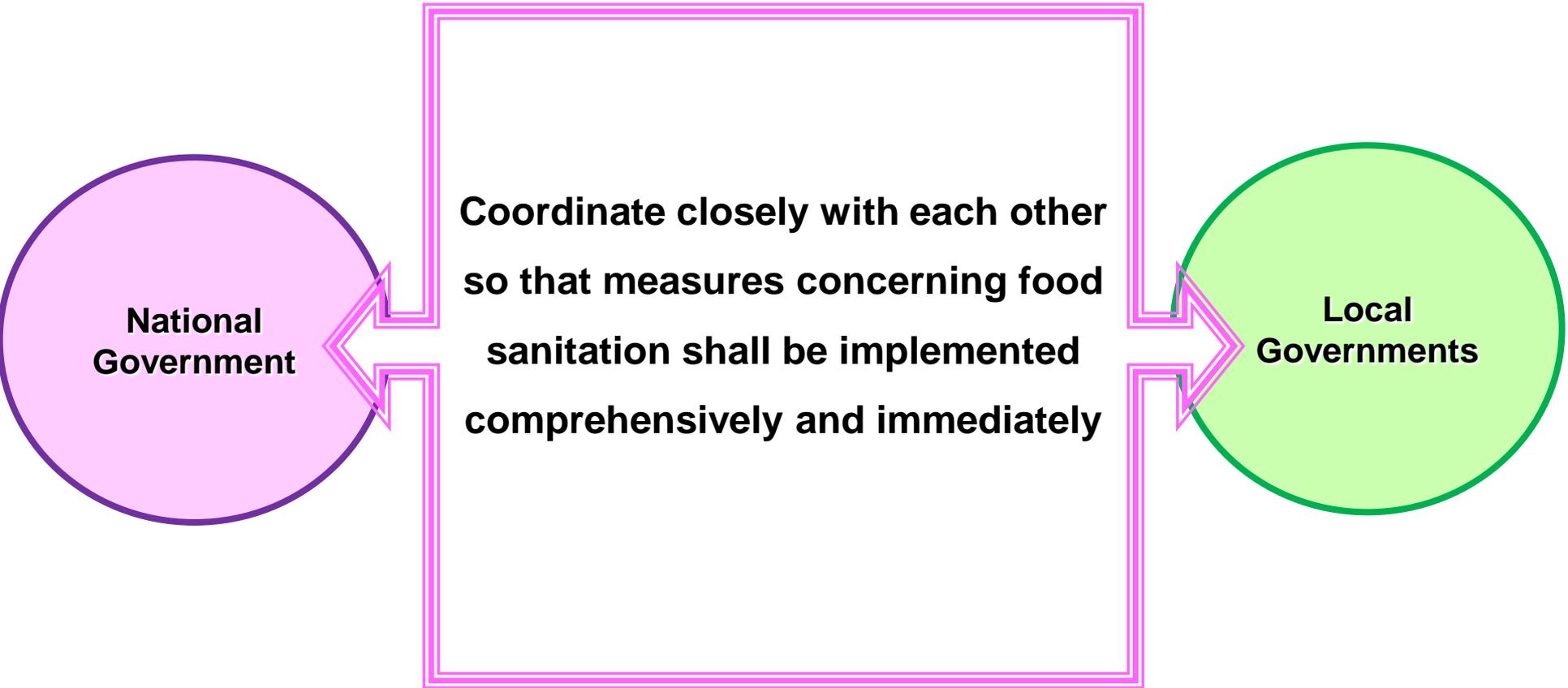
- ◆ Inspection for BSE at Abattoirs
- ◆ Specified Materials from cattle.

Responsibility of National and Local Governments

**National
Government**

**Coordinate closely with each other
so that measures concerning food
sanitation shall be implemented
comprehensively and immediately**

**Local
Governments**



Responsibility of National Government

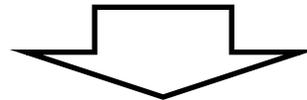
(Article 2) ※

- ◆ Disseminate the correct knowledge
- ◆ Collection, compilation, analysis and provision of information
- ◆ Promote research
- ◆ Enhance inspection capabilities
- ◆ Foster the human resources and enhance their capabilities
- ◆ Develop a system for conducting collection of information, carrying out research, and making inspections on imported foods, etc.
- ◆ Ensure international coalition
- ◆ Technical assistance for local governments

Responsibility of Local Governments

(Article 2) ※

- ◆ Disseminate the correct knowledge
- ◆ Collection, compilation, analysis and provision of information
- ◆ Promote research
- ◆ Enhance inspection capabilities
- ◆ Foster the human resources and enhance their capabilities



- ◆ Approval of the business(Article 52) ※
- ◆ Slaughter inspection 【based on other laws】
(cattle, horses, swine, sheep, goats and poultry)

Overall picture of regulations and control under the Food Sanitation Act

- **Setting restrictions and standards for food/additives, apparatus, containers and packaging, etc.**
- **Monitoring and guidance**
- **Administrative penalties on violations**

Setting restrictions and standards for food/additives, apparatus, containers and packaging, etc.

◆ **Restrictions**

◆ **Setting Standards**

Monitoring and guidance

◆ Domestically-distributed food

Monitoring and guidance by food sanitation inspectors in individual prefectures.

◆ Imported food

Monitoring and guidance by food sanitation inspectors (staff of quarantine stations) at the quarantine stations in seaports and airports.

Administrative penalties on violations

An administrative penalty will be imposed on a violation of a law

- disposal order
- cancellation of the business license and prohibition/suspension of business, etc.
- fine

Guidelines and plans for monitoring and guidance

(in the context of Articles 22 to 24)

Guidelines for monitoring and guidance on food sanitation

**Monitoring and Guidance
plan
For imported food**

**Local government plan for
monitoring of
and guidance on food
sanitation**

**Formulation, Modification → Gather opinions of the public and residents
The progress of the implementation of the plan → Publicizing**

Monitoring and guidance are planned on a yearly basis at both national and prefectural government levels and are implemented in accordance with the plans.

Guidelines for monitoring of and guidance on food sanitation

(Article 22)

- ◆ Basic directions
- ◆ Monitoring and guidance items to be particularly focused on
- ◆ Basic monitoring and guidance items
- ◆ Important issues concerning the implementation of monitoring and guidance

Monitoring and Guidance plan for Imported Food

(Article 23)

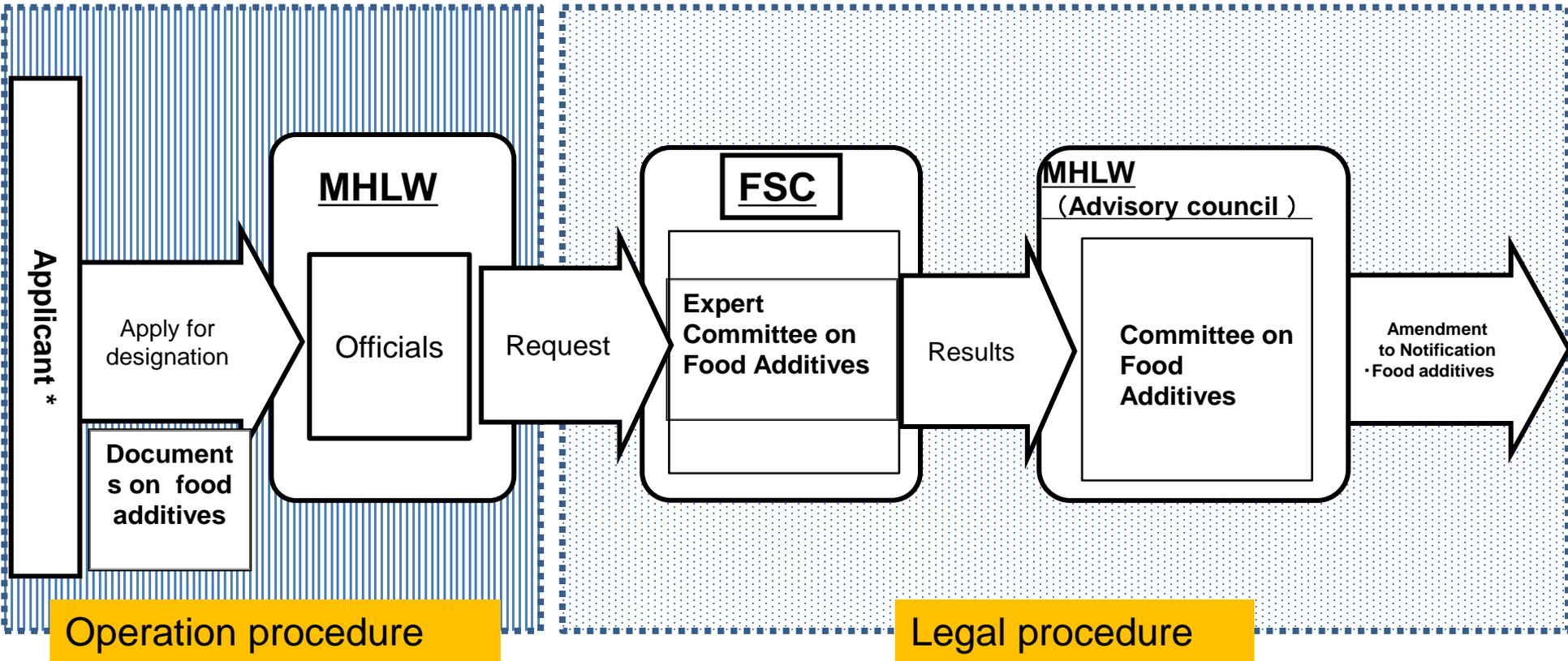
- ◆ Monitoring and guidance items to be particularly focused on
- ◆ Promotion of voluntary sanitation management among importers.
- ◆ Necessary issues concerning the implementation of monitoring and guidance

Local government plan for monitoring of and guidance on food sanitation

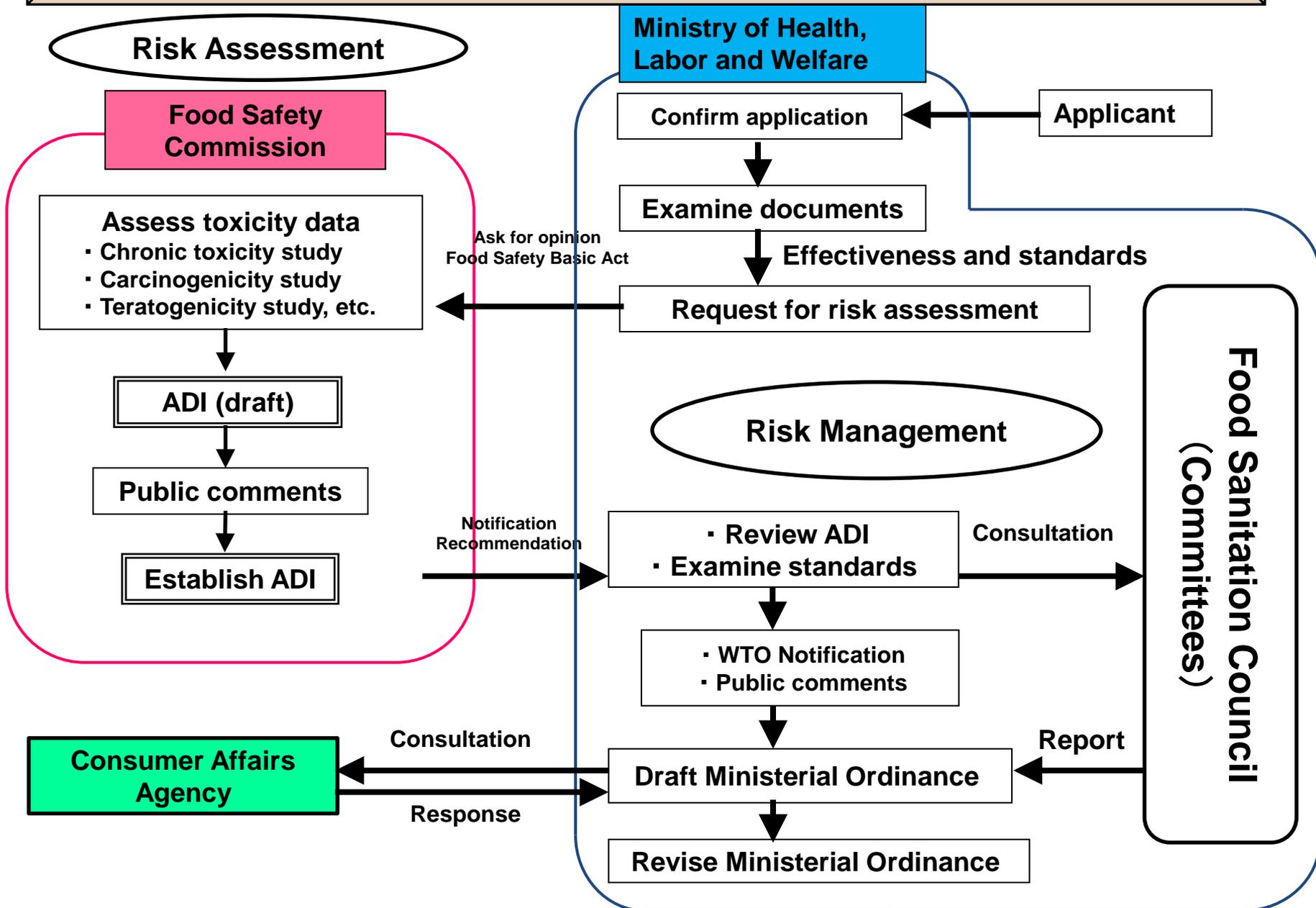
(Article 24)

- ◆ Monitoring and guidance items to be particularly focused on
- ◆ Promotion of voluntary sanitation management among food-related business operators
- ◆ Matters concerning the securing of coordination between said prefecture and other relevant administrative organs including neighboring prefectures.
- ◆ Necessary issues concerning the implementation of monitoring and guidance

Procedure for the Designation of Food Additives



Process of the Designation of Food Additives



Designation Process for internationally commonly used food additives (Road Map)

Approximately One Year (excluding the time required for collection of further data and documents)

Risk Evaluation

Open and scientific discussion

Food Safety Commission

Preparation

Preparing documents and data for expert examination

Further data and documents

Food Additives Expert Committee

Public Comments

Food Safety Commission (Plenary)

Notification of Evaluation Results

(Examples of undesignated 15 items)
 + Isopropanol (solvents and flavourings)
 + Calcium Oxide (nutrients, yeast foods, and other substances)
 + Others

Independence/Cooperation

Ministry of Health, Labour and Welfare

Pre Examination

Review by experts

Request for risk evaluation by the FSC

Preparing for additional data necessary for the evaluation

Request and submit

Pharmaceutical Affairs and Food Sanitation Council

Review of Setting Standard and Specification for Food Additives

WHO Notification And Public Comments

Consultation on draft of notice

Consumer Affairs Agency

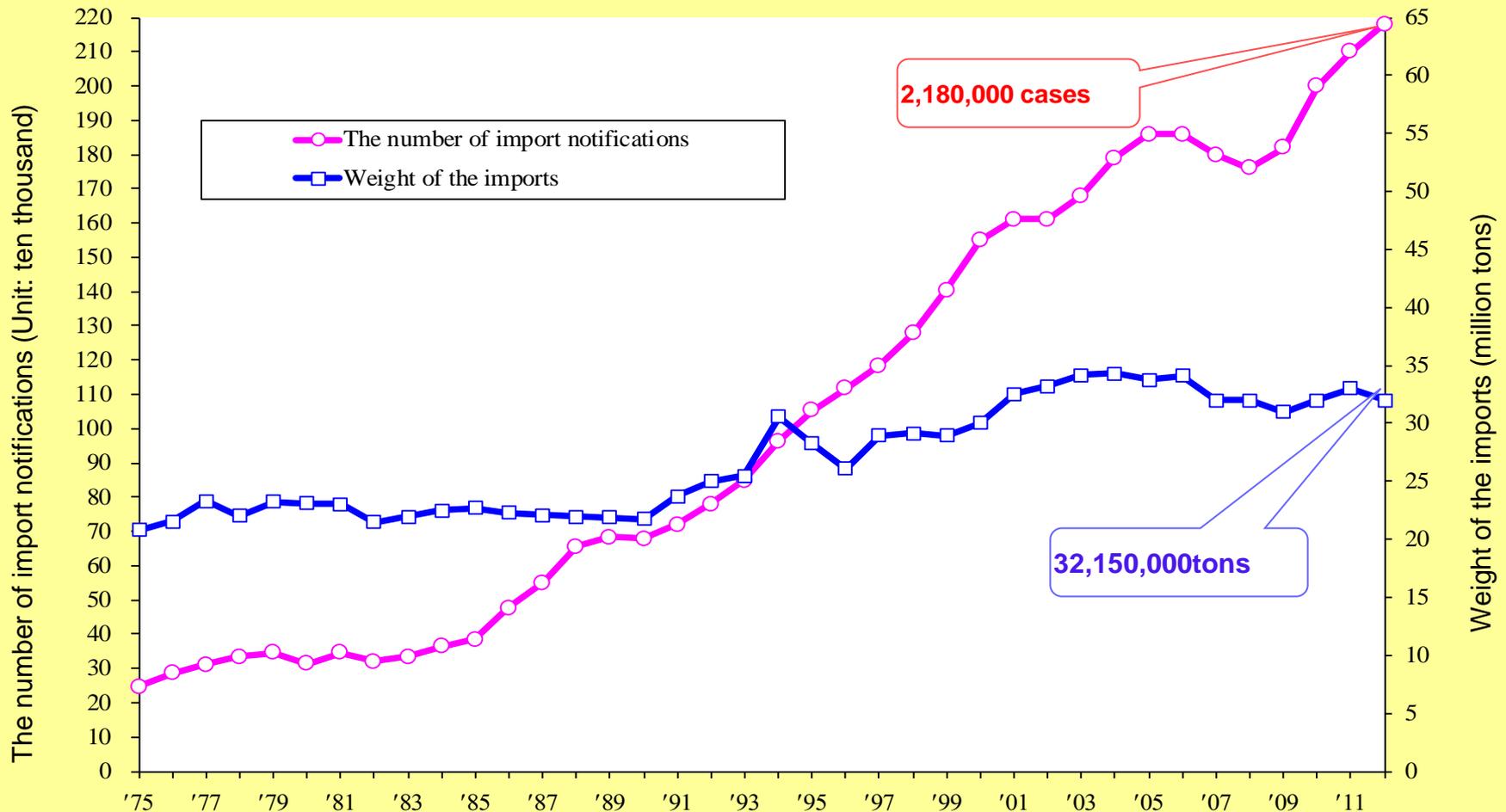
Designation

Open and Scientific Discussion

Risk Management

Current status of food import

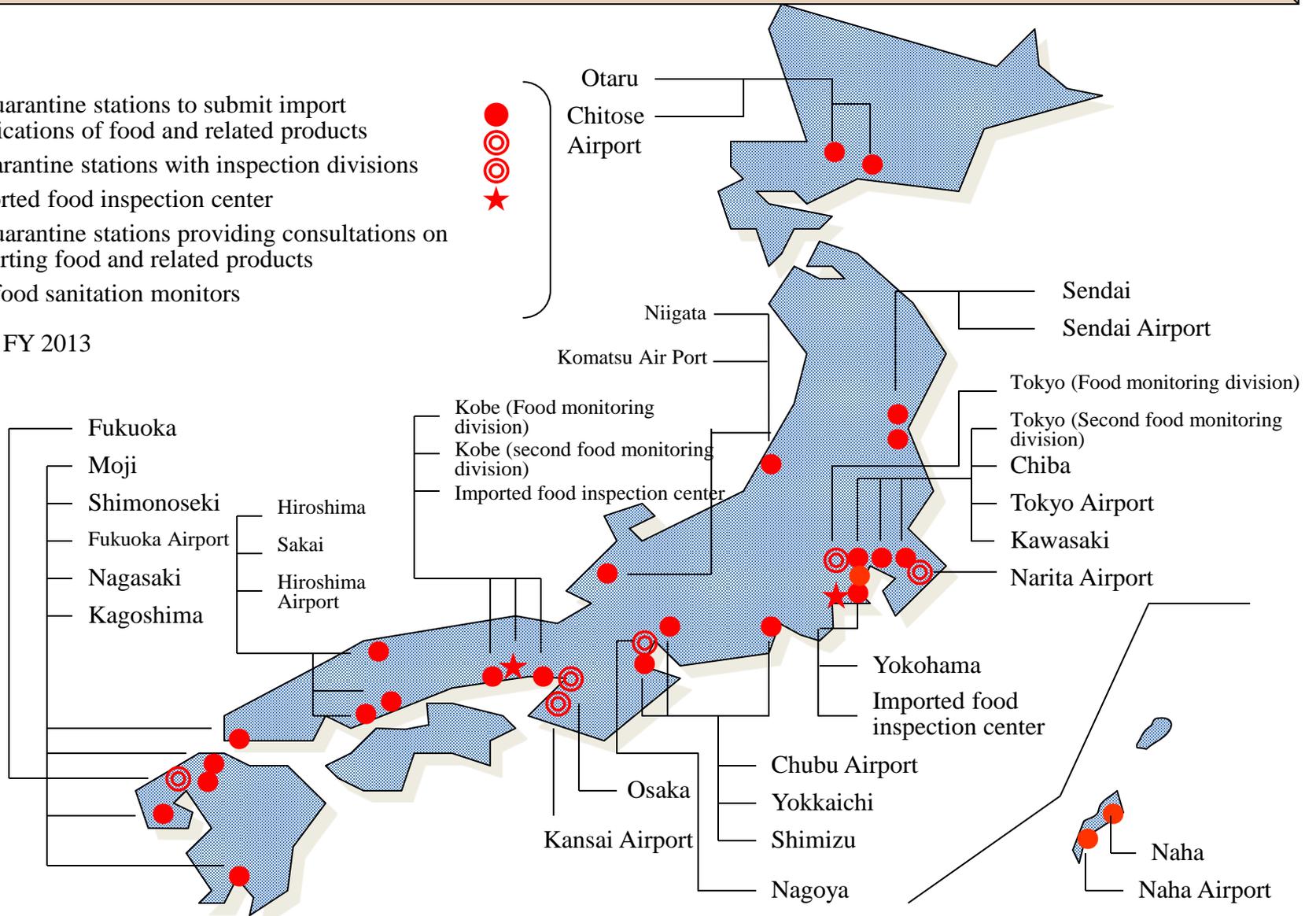
- The number of notifications of food imports is on the rise. The latest data shows approximately two million items notified.
- Imported food accounts for about 60% of food in Japan.
 - *Japan's self-sufficiency is about 40% (on a caloric basis.)



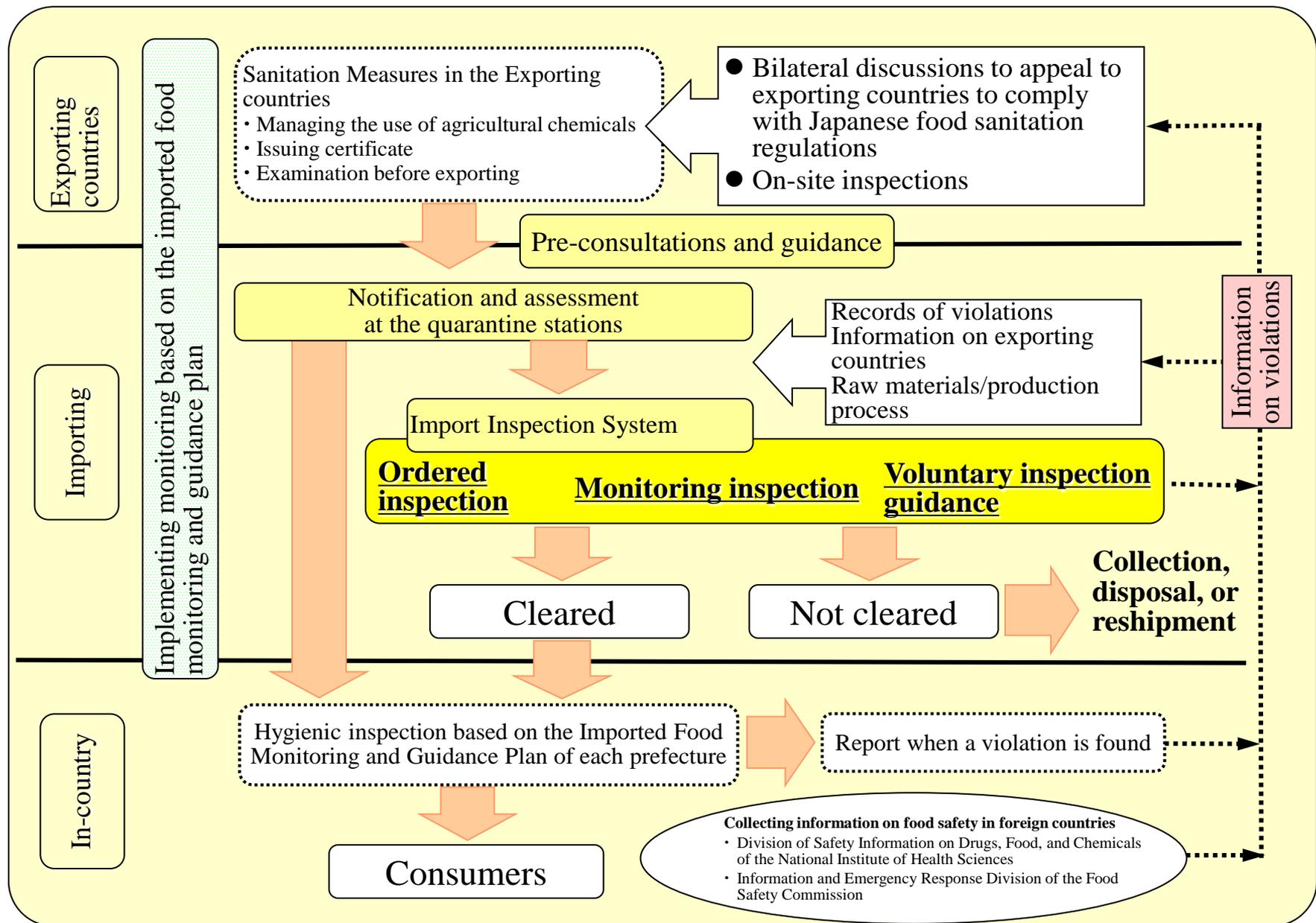
Places to Submit Import Notifications of Foods and Related Products

32 quarantine stations to submit import notifications of food and related products
 6 quarantine stations with inspection divisions
 Imported food inspection center
 13 quarantine stations providing consultations on importing food and related products
 399 food sanitation monitors

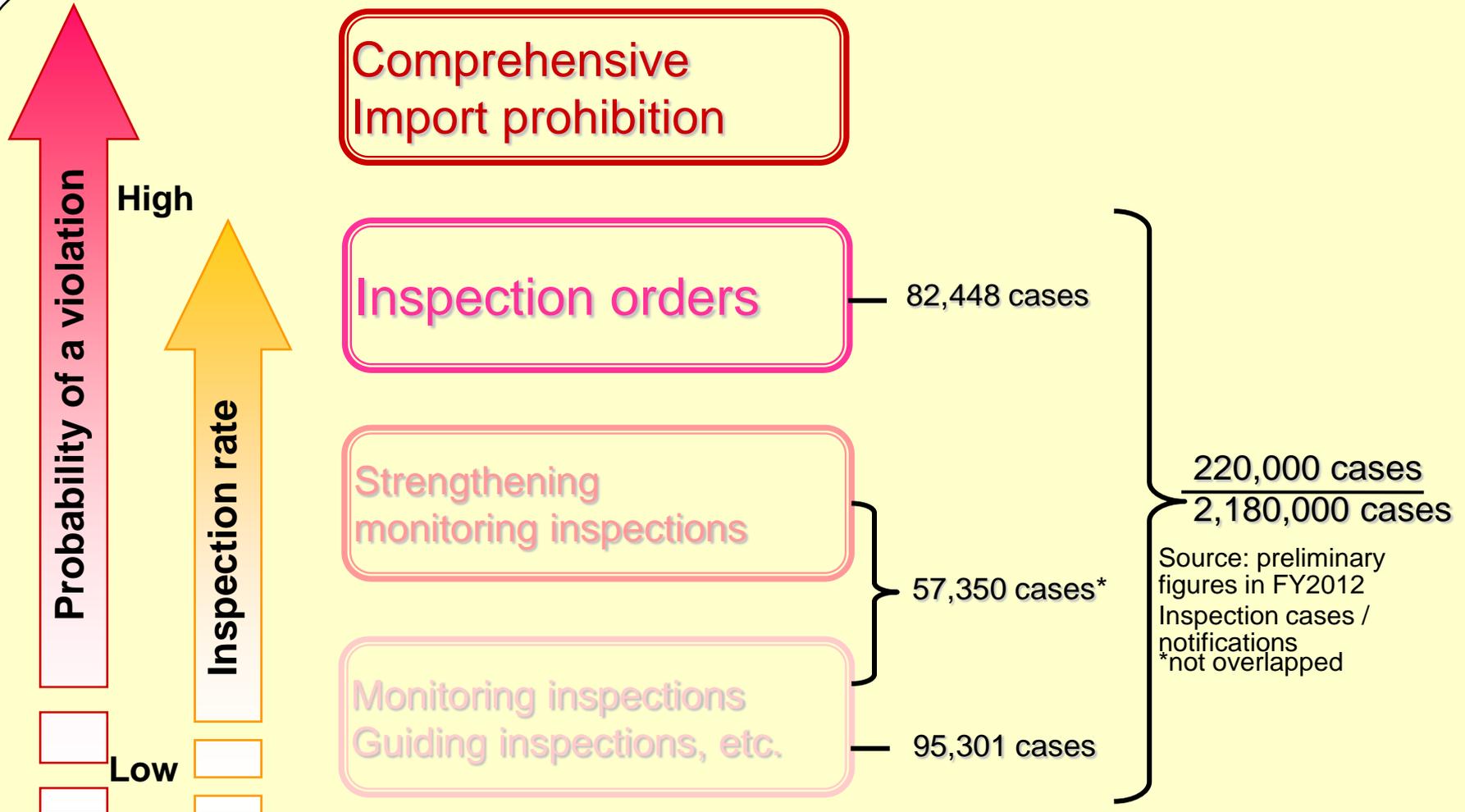
* As of FY 2013



Outline of the Monitoring System for Imported Food



Outline of the Import Inspection System



* The number of cases of monitoring inspections is 93,066 in total.
(Some overlap regarding the inspection items.)

Inspection Orders by the Minister of Health, Labour and Welfare

Requirements for ordering inspections

Emergence of health hazards

Danger of health hazards

Caused by the same producing country, manufacturer, or food processing company regarding the same imported food (Example: E. coli O-157, Listeria, Aflatoxin, etc.)

Violation

Order inspection immediately

Pesticide residue
Veterinary medicine

Violation

Increase the frequency of monitoring inspections

Violation

Order inspection if violation is assumed highly probable

Dropping inspection orders

The exporting country has established measures against a recurrence.
It is confirmed that the violated food is not going to be imported again.

Cancellation Requirements

Inspection order

(e.g.) Parsley: difenoconazole: Italy
Horseradish: difenoconazole: Austlia

MHLW has confirmed the effectiveness of the preventive measures taken by the exporting country.

- No violations for two years (e.g. residual agricultural chemicals)
- No violations in 300 inspections for one year (e.g. residual agricultural chemicals)

Reinforcement of monitoring inspection (30%)

- No violations for one year
- No violations in 60 inspections

Normal monitoring inspection

※e.g. Leek: difenoconazole: Belgium

Cancellation

Cancellation

Cancellation

Steps to lifting the import ban on beef

1. Issue questionnaire from Japan to concerned member countries

2. Review of response and additional question if necessary

3. Working level consultation

4. On-site investigation

5. Consultation to Food Safety Commission

6. Risk assessment and report by the Food Safety Commission to the MHLW

7. Arrange specific import requirement according to the result of assessment and On-site investigation

Lifting the import ban

Recall System of Imported Foods

- Food Safety Commission
- National Institute of Health Sciences
- Website of each country
- Alert information of international organization etc.

Obtaining information

Check the status of importation

No Records

Continuation of information gathering

Have Records

Confirmation of the presence or absence of relevant lot for importers and government of export countries

Reinforcement of import surveillance

Absence

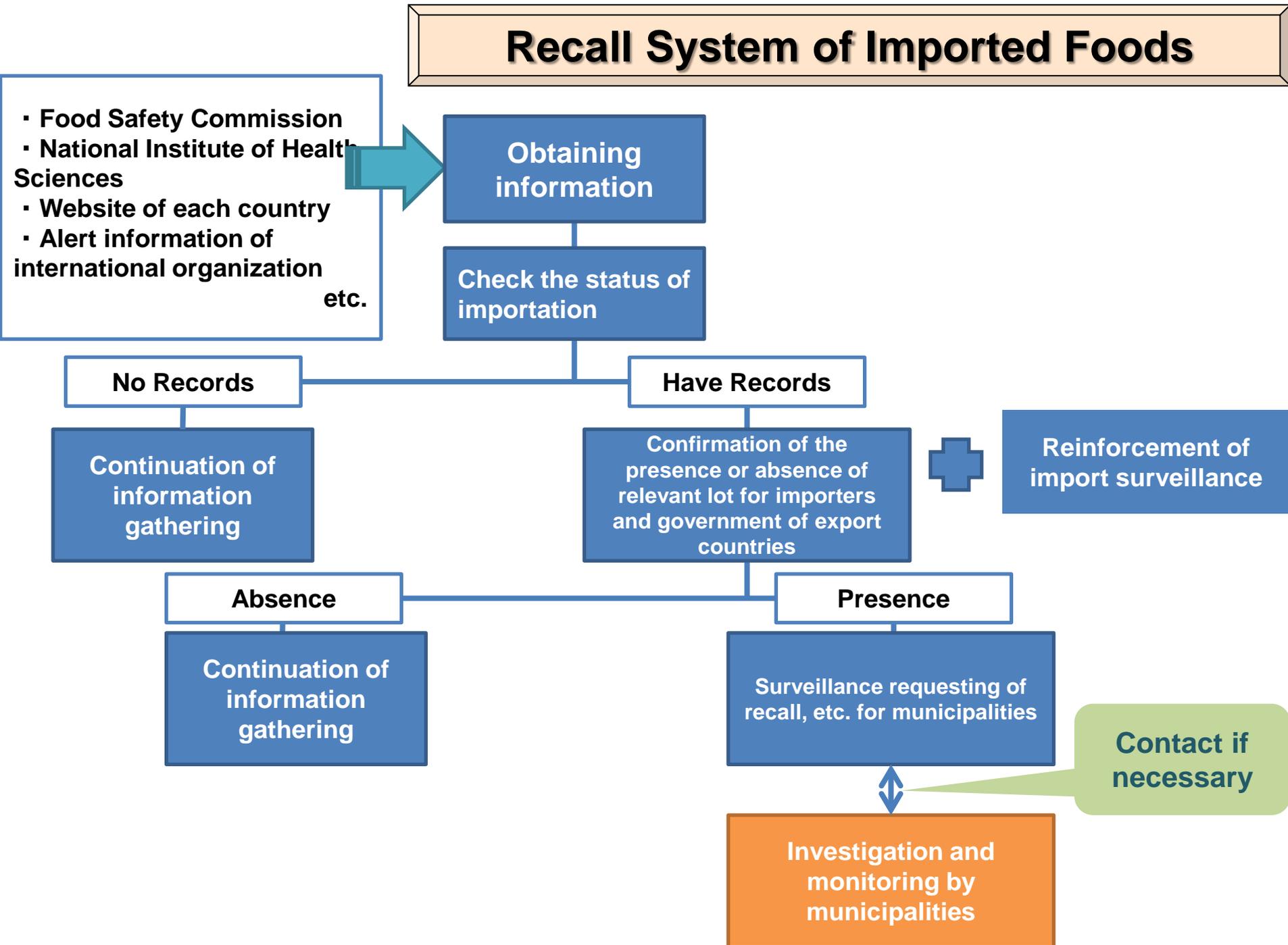
Continuation of information gathering

Presence

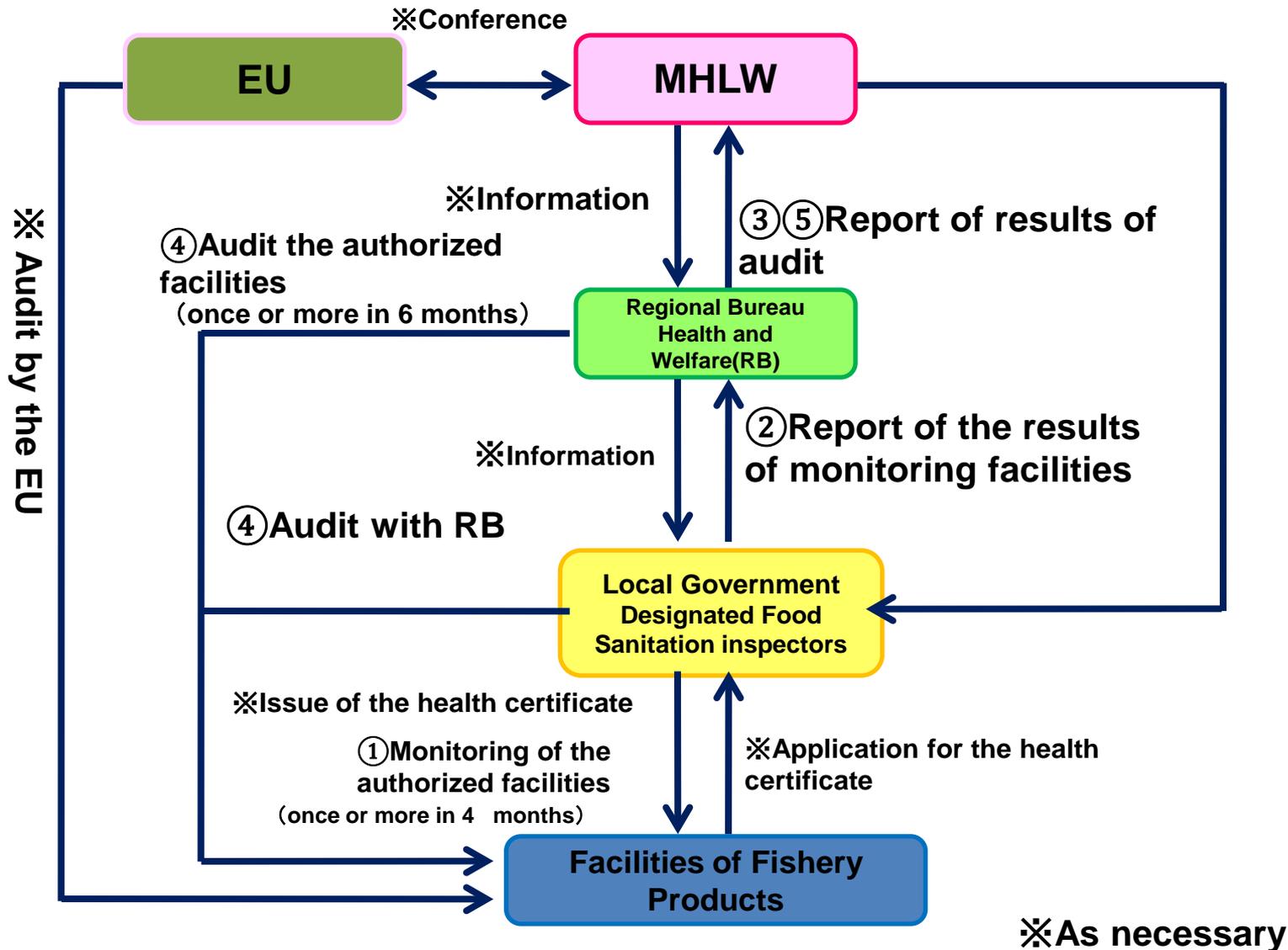
Surveillance requesting of recall, etc. for municipalities

Contact if necessary

Investigation and monitoring by municipalities

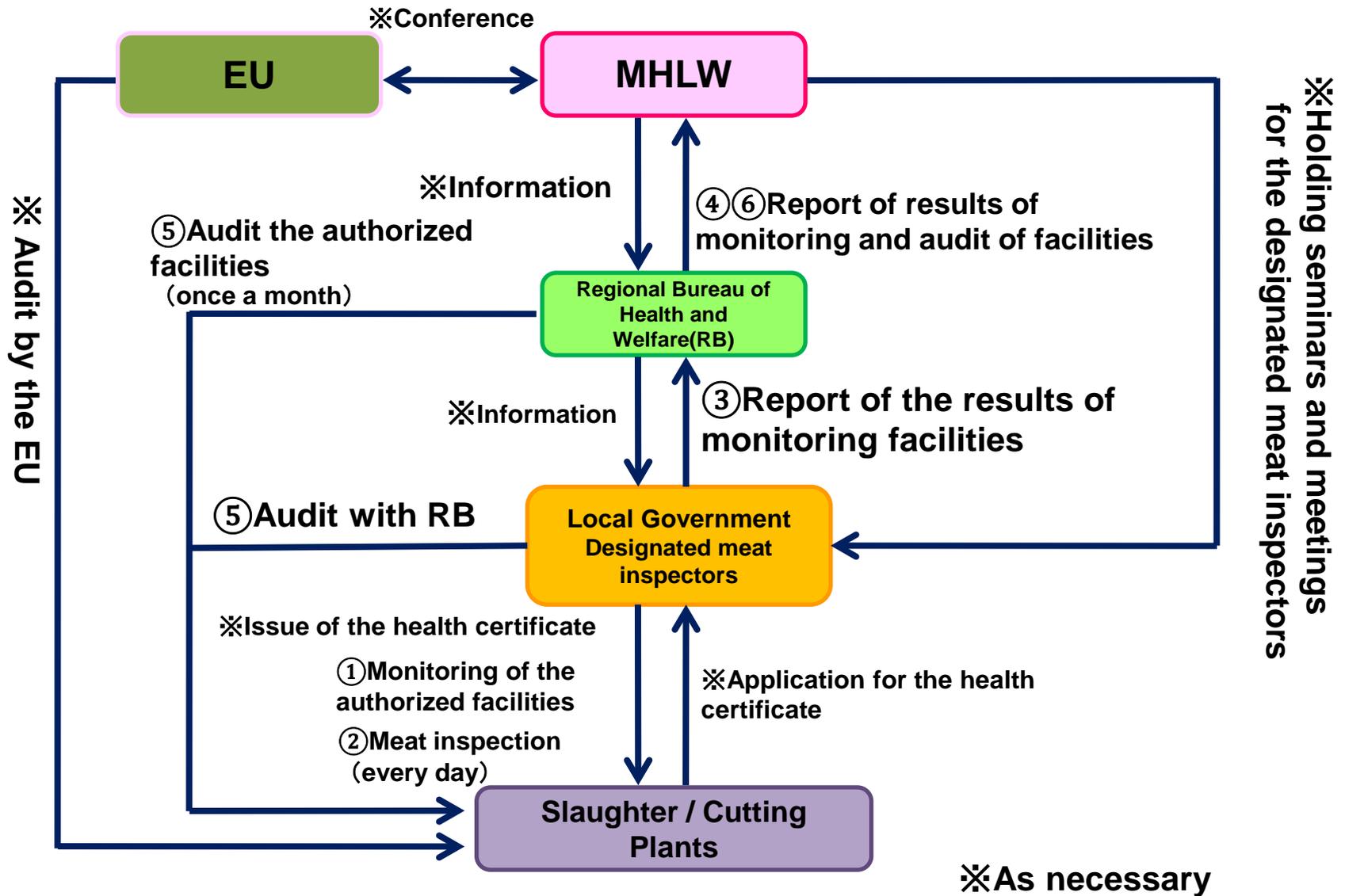


Monitoring system for facilities (Fishery Products for Export to the EU)



※Holding seminars
for the designated Food Sanitation inspectors

Monitoring system for facilities (Beef for Export to the EU)



Audit related to Food Safety

Ministry of Health,
Labour and Welfare

Exporting countries

Regional bureaus of
Health and Welfare

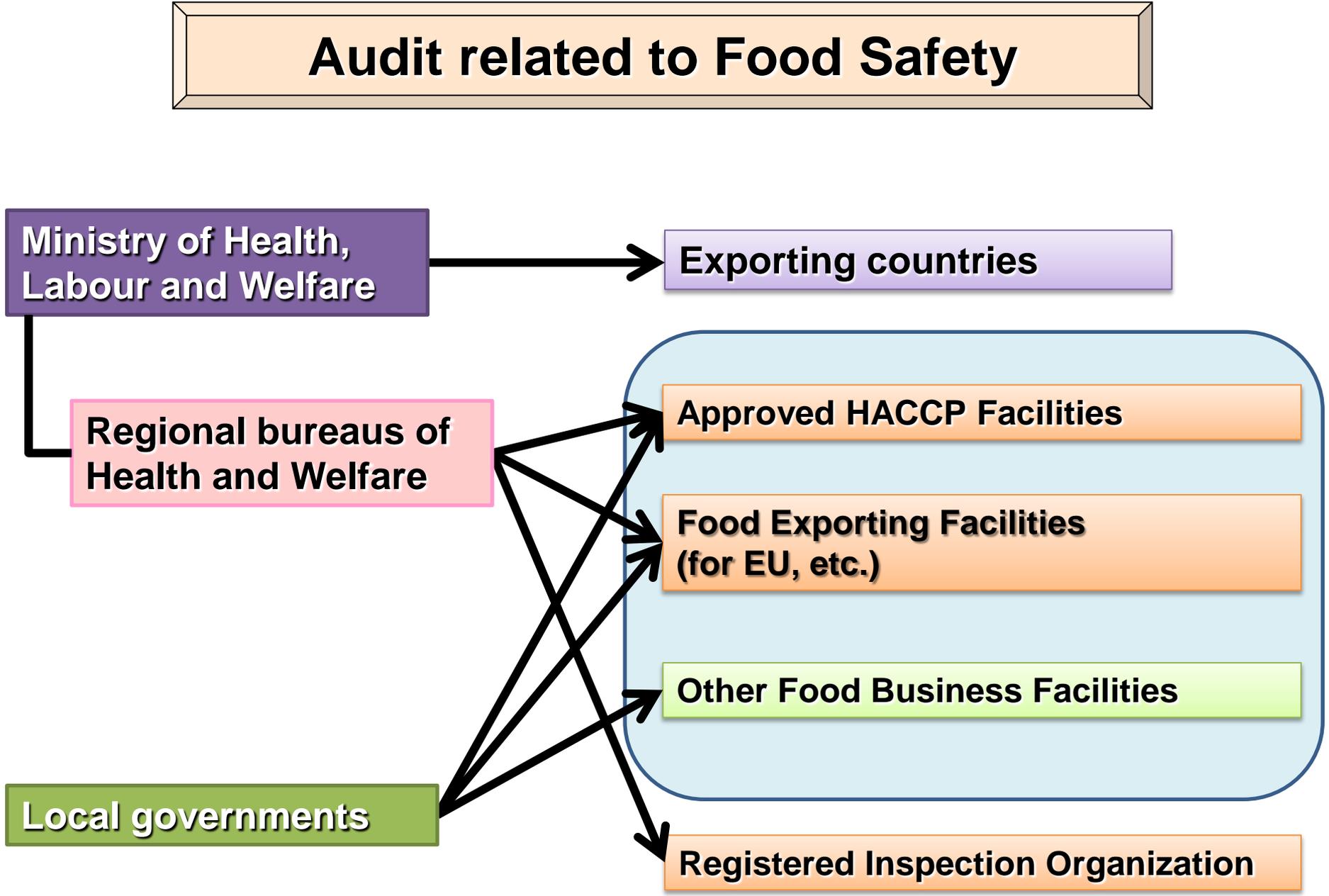
Approved HACCP Facilities

Food Exporting Facilities
(for EU, etc.)

Other Food Business Facilities

Local governments

Registered Inspection Organization



Audit in Exporting Countries (1)

❖ **Lifting the import ban on beef (BSE, Food Sanitation Act Article 9)**

- ◆ On-site investigation before risk assessment
- ◆ After risk assessment, on-site investigation of the system for management of export program (Before lifting the import ban)
- ◆ Periodic on-site audit after lifting the import ban

❖ **Equivalence Evaluation of Meat and Poultry at Abattoirs and meat processing plants (Food Sanitation Act Article 9, Health Certificate)**

- ◆ On-site investigation before/after import starting if necessary

Audit in Exporting Countries (2)

- ❖ **Processing standards of oyster for raw consumption (Food Sanitation Act Article 11)**
 - ◆ Check control of harvesting area of oyster before import starting (coliform bacteria MPN in sea water).
- ❖ **Other**
 - ◆ On-site audit after incident occurs
 - ◆ System investigation to prevent hygiene problem

Beef Audit (US and Canada)

- ❖ **Frequency** : Once a year after lifting the import ban
- ❖ **Audit** : Entrance meeting, on-site audit of plant and Exit meeting
- ❖ **Notification**
- ❖ **Report of Audit**
 - **Submission of Report and Comments**
- ❖ **Publication of Result**
- ❖ **Cost allocation**

Overview of food safety administration (summary)

Assuring safety of food, taken in by all the people of Japan in their everyday life, thereby protecting their health

◆ **Response based on the latest scientific findings**

→ Risk analysis

(Risk assessment, risk management, risk communication)

◆ **Initiatives based on mutual collaboration among diverse stakeholders, including the national government, municipalities, food-related business operators and consumers.**

→ Easy-to-understand communication, interactive opinion exchange

◆ **Sanitation control based on laws (e.g., the Food Sanitation Act)**

→ Scientific references, planned monitoring and guidance (PDCA), recall instructions, etc.

THANK YOU FOR YOUR ATTENTION

