

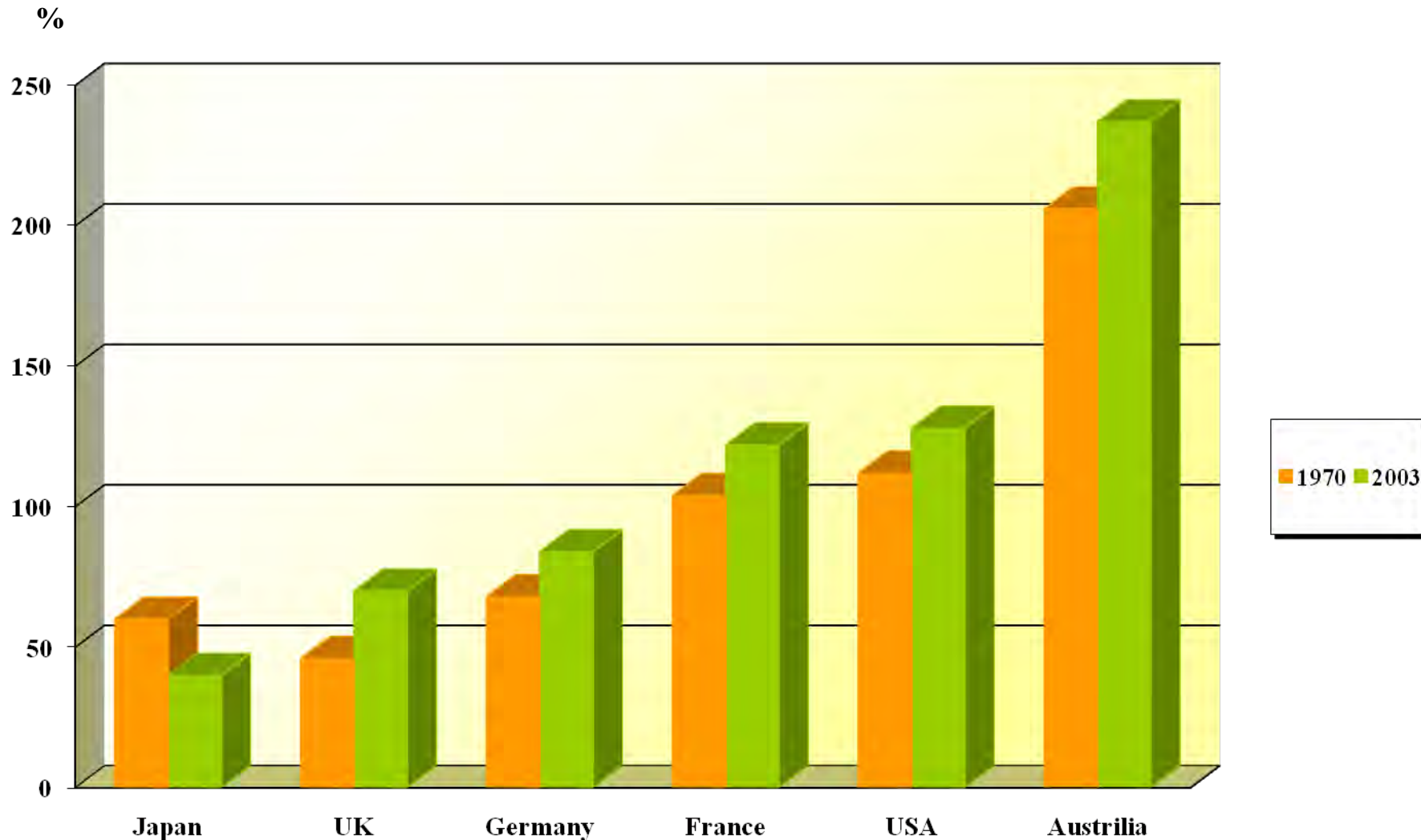
Ensuring the Security of Imported Foods

September, 19, 2013

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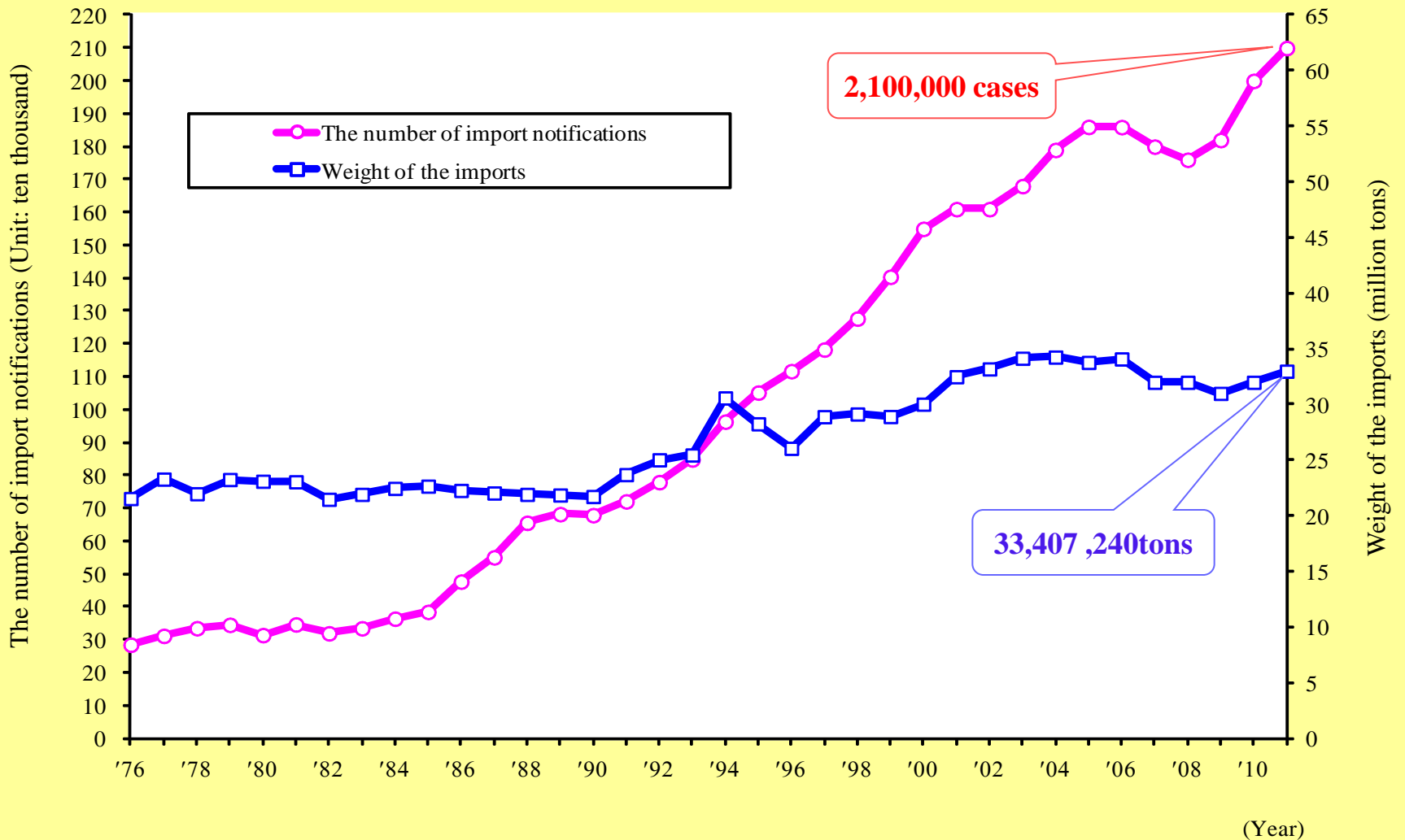
Office for Imported Food Safety Policy, Inspection and Safety Division,
Department of Food Safety, Ministry of Health, Labour and Welfare

Total Food Self-sufficiency Ratio in Major Developed Countries (on a calorie basis)

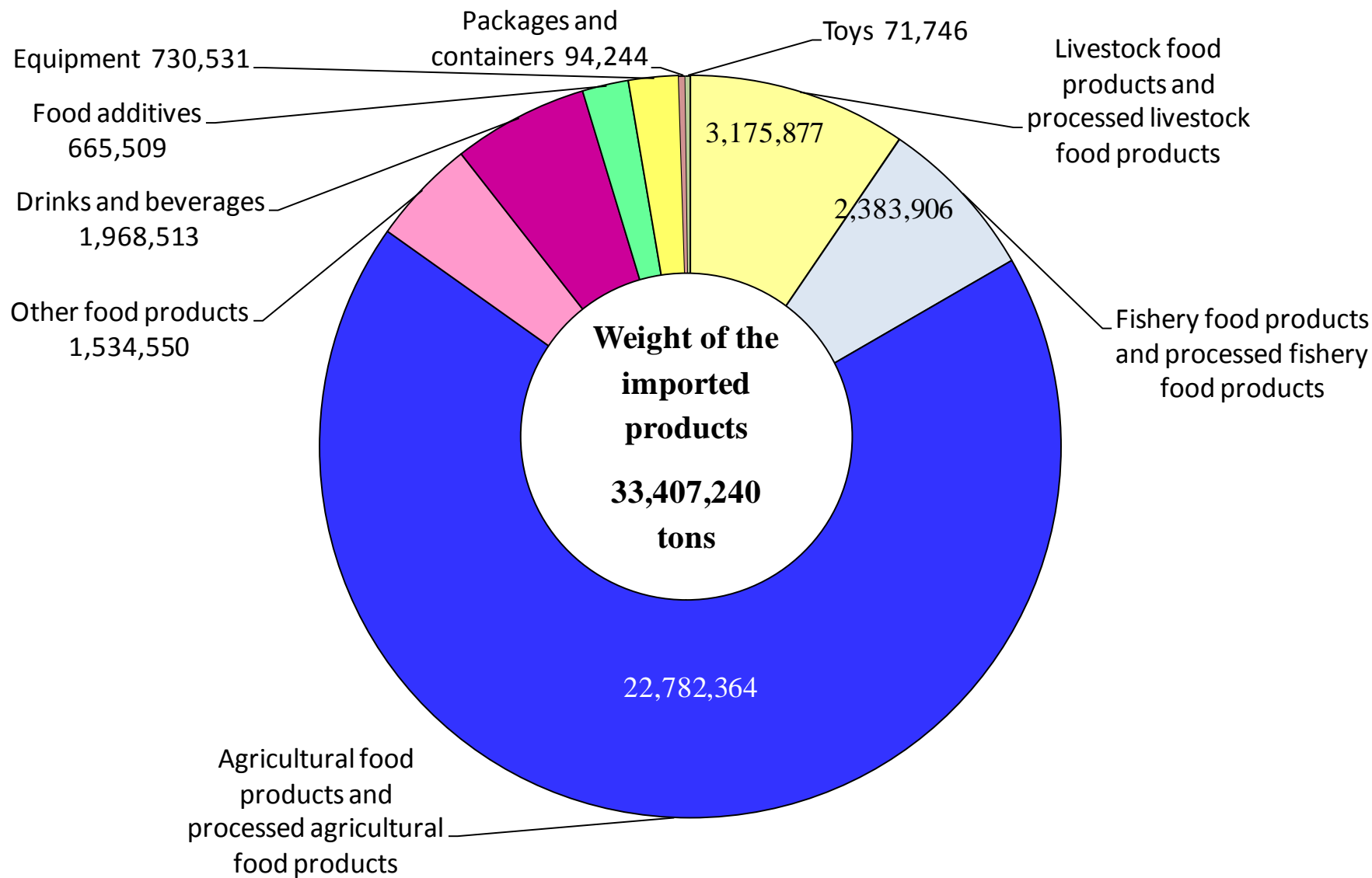


Source: Table of the Total food self-sufficiency ratio on a Calorie Supply Basis (MAFF)

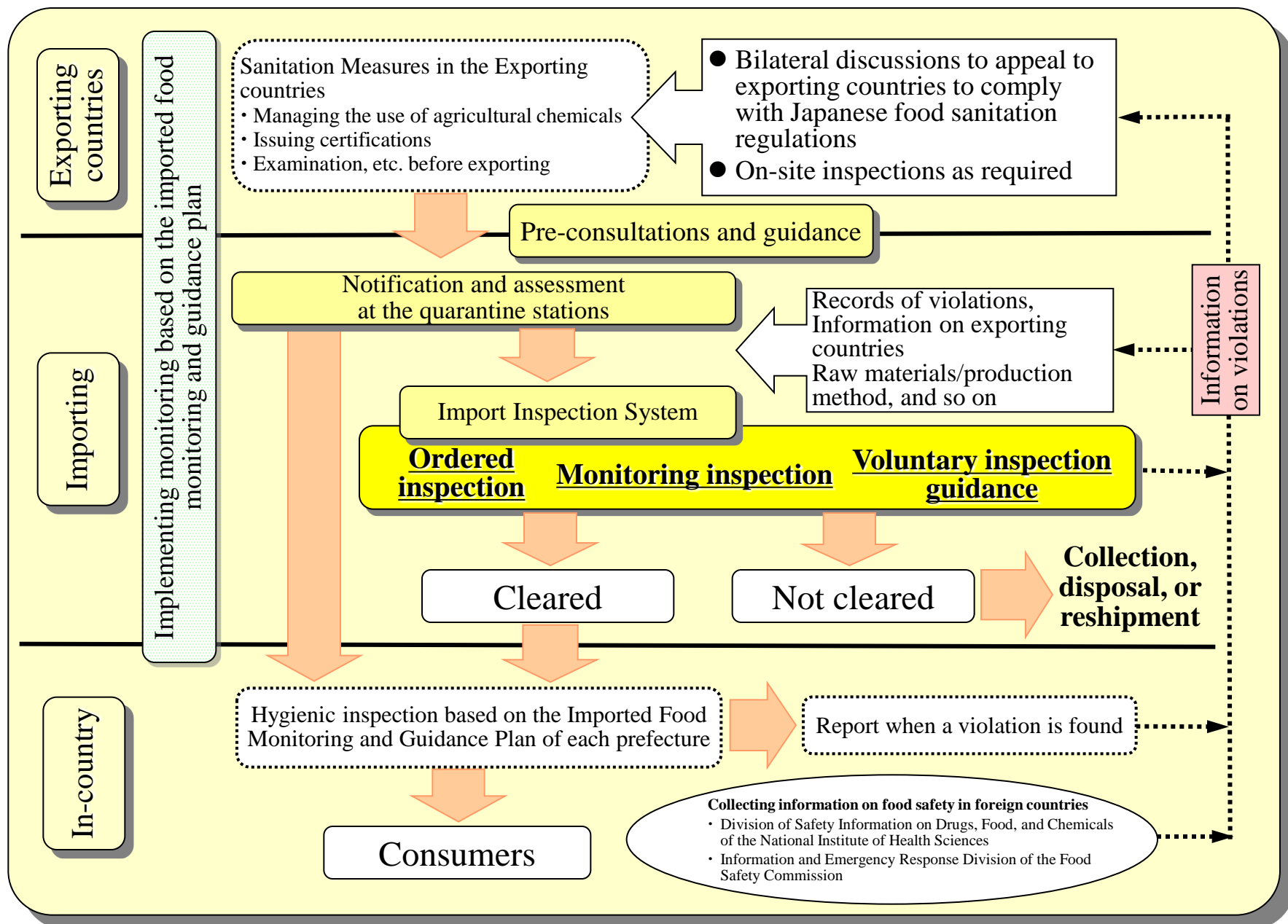
The Number of Import Notifications for and weight of Foods and Related Products



Import Situation of Food and Related Products (FY2011)



Outline of the Monitoring System for Imported Food



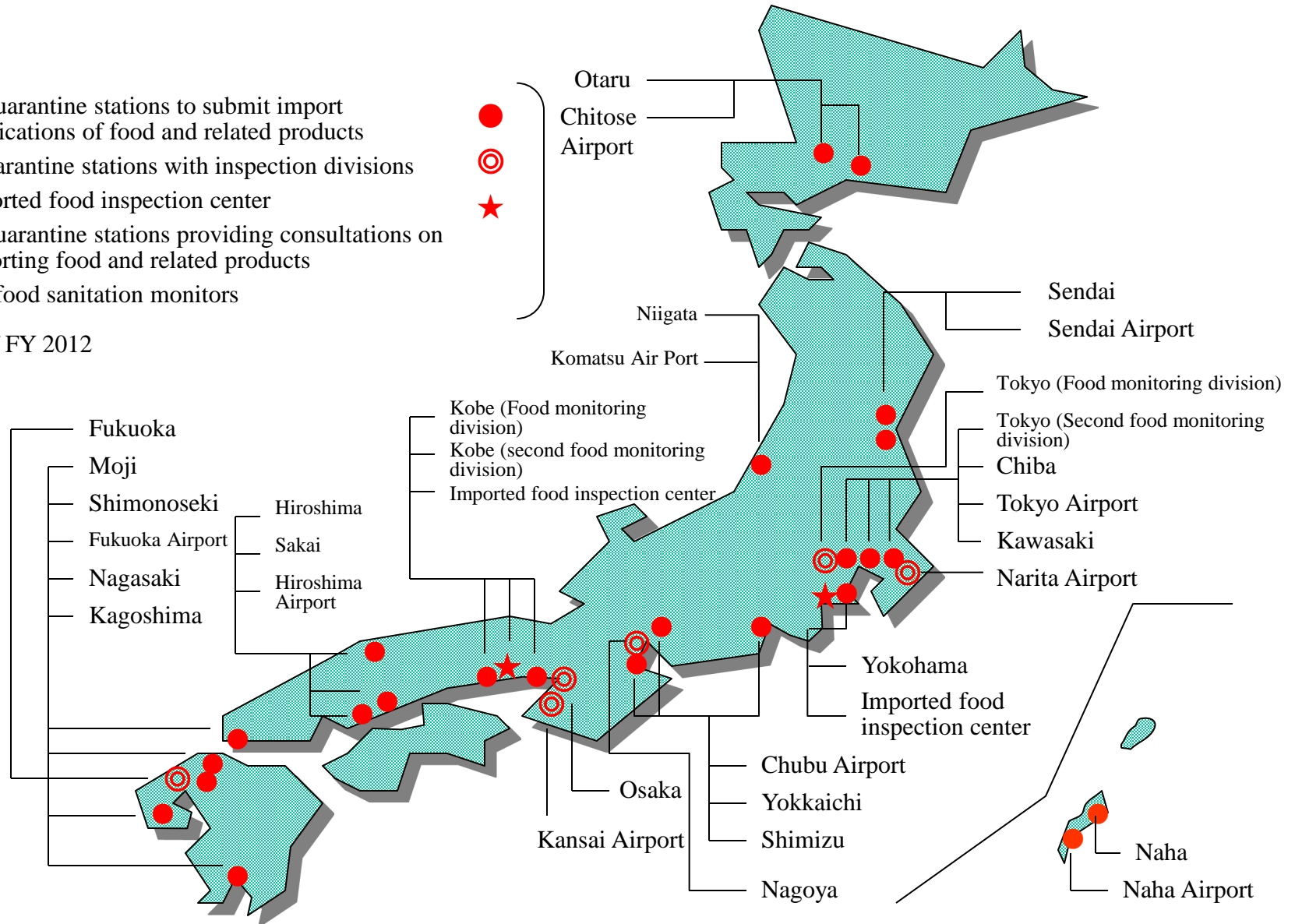
Promotion of Sanitation Measures in Exporting Countries

- ❖ **Dissemination of information about our country's food sanitation regulations**
 - ◆ Provision of the English-versions of information about the Plan of Inspection and Guidance of Imported Food and the results
 - ◆ Provision of the English-version of information regarding food sanitation regulations
 - ◆ Information provision for embassies in Tokyo and importing agents
- ❖ **Bilateral discussion and field investigation, etc.**
 - ◆ Clarifying the causes of violations through bilateral discussion and requesting to take measures to prevent recurrences based on the discussion
 - ◆ Verifying sanitation measures for the production stage in the exporting countries through field investigations
 - ◆ Collecting information about sanitation measures in exporting countries from a preventive viewpoint and evaluating their measures
- ❖ **Technical assistance for exporting countries**
 - ◆ Dispatching specialists and accepting trainees through the Japan International Cooperation Agency (JICA)

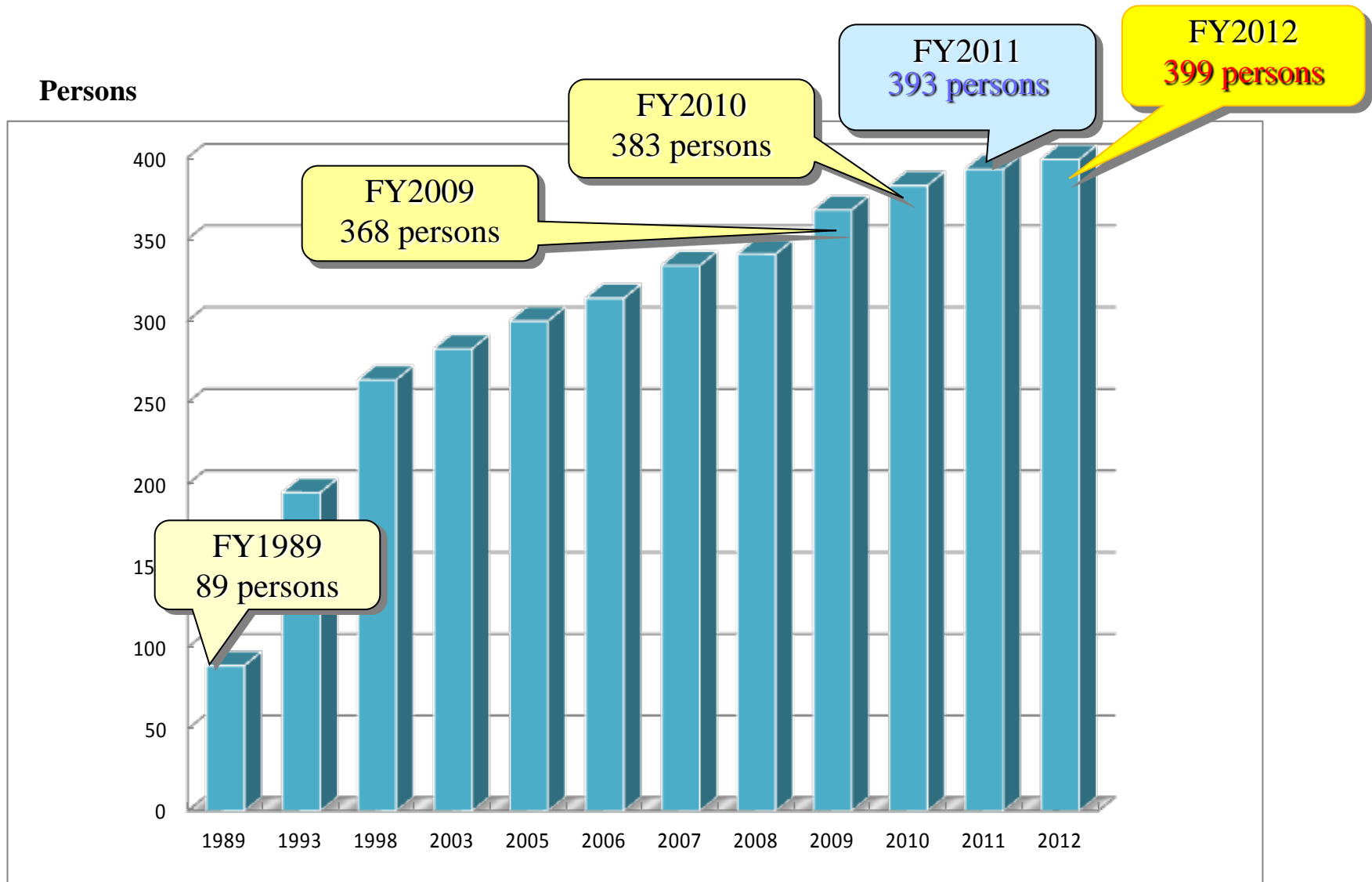
Places to Submit Import Notifications of Foods and Related Products

- 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 2012



Annual Trends in Development of Food Sanitation Inspectors at Quarantine Stations



Submission of an Import Notification for Foods and Related Products

Those who intend to import foods and related products should submit a notification to the Minister of the Ministry of Health, Labour and Welfare. (Article 27 of the Food Sanitation Law)

Notification items

- ❖ Name and address of the importer
- ❖ Product name, quantity, and weight of the foods or related products, types of packages, and purpose
- ❖ Names of additives used in the foods and related products
- ❖ Raw materials, production methods, and processing methods of processed foods
- ❖ Identification of genetically GMOs/IP handling
- ❖ Components of used food additives
- ❖ Materials used in the equipment, containers and packages, and toys
- ❖ Occurrence of cargo accidents

and other related matters

Inspection System at the Time of Importation

❖ Guidance and inspections, etc.

- ◆ These inspections are instructed to the importers by the government to be conducted regularly (including the first import) **as part of their voluntary sanitation control. The status of using pesticides or food additives, as well as the information about violated foods concerning pesticides or food additives is used as reference** when conducting these inspections.

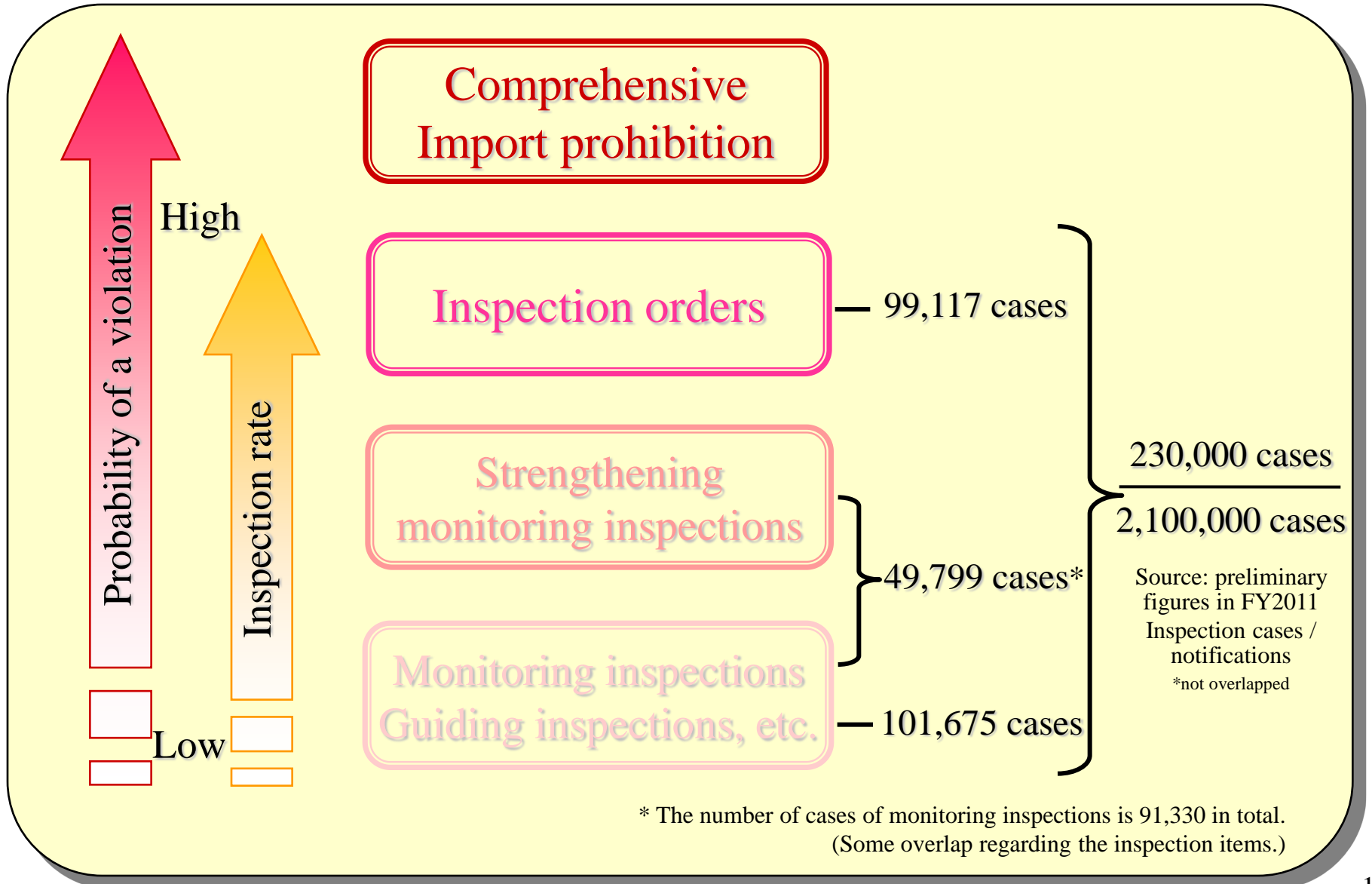
❖ Monitoring inspections

- ◆ These inspections are conducted by the government based on their annual plan **to monitor a wide variety of imported foods concerning the status of food sanitation, and to take necessary measures, such as intensifying inspections at the time of importation.**
- ◆ The expenses of these inspections are paid by the government, and **the importers are allowed to import foods without waiting for the results of the inspections.**

❖ Inspection orders

- ◆ These inspections are ordered to the importers to be conducted at each time of import on certain foods with higher possibilities of violation. **These foods are those that were found to be violating laws** during voluntary inspections, monitoring inspections, and sampling inspections conducted in Japan
- ◆ The expenses of these inspections are paid by the importers, and **the importers are not allowed to import foods without waiting for the results of the inspections**

Outline of the Import Inspection System



How to Calculate the Number of Monitoring Inspections (1)

- (1) All imported foods are classified into **168 groups**, according to the nation's total amount of intake of the targeted food, probability of violation, and past status of import, etc.
- (2) The number of samples to be collected for the inspections is tentatively specified as **299 samples***, according to the inspection categories (residual agricultural chemicals, antibiotic products, additives, component specification, toxigenic fungi, genetically modified foods, and irradiated foods). This number was calculated to detect non-compliance with a certain degree of statistical liability.

* The number is based on the CODEX Maximum Residue Limits (MRLs). With this number of samples it is possible to detect 1% or less of non-compliance with 95% reliability.

(Reference) Recommended Methods of Sampling for the Determination of Pesticide Residues for Compliance with MRLs (CAC/GL 33-1999)

| | | Probability of finding one non-compliance sample (P) | | | | |
|-------------------------------|------|--|-------|------------|-------|-------|
| | | 99.9% | 99.0% | 95.0% | 90.0% | 60.0% |
| Violation rate of samples (V) | 10% | 66 | 44 | 29 | 22 | 9 |
| | 5% | 135 | 90 | 59 | 45 | 18 |
| | 1% | 688 | 459 | 299 | 230 | 92 |
| | 0.5% | 1,379 | 919 | 598 | 460 | 183 |
| | 0.1% | 6,905 | 4,603 | 2,995 | 2,302 | 916 |

Statistically, where **v** is the actual violation rate in the lot, and **n** is the number of samples (in the case of random selection), the probability (**p**) of finding at least one non-compliance sample in **n** can be calculated as **P=1-(1-v)ⁿ**

How to Calculate the Number of Monitoring Inspections (2)

- (3) Based on the number of samples in (2), the number of inspections for the monitoring inspections is specified according to food groups as well as inspection categories, considering **the number of imported foods, their volume, their past violation rate, and the impact of violations on public health.**

(Example) Calculation of the number of inspections for imported rice

| Inspection category | Residual agricultural chemicals | Antibiotic products | Additives | Component specification, etc. | Toxigenic fungi | Genetically modified foods | Irradiated foods | Total |
|--|---------------------------------|---------------------|-----------|-------------------------------|-----------------|----------------------------|------------------|--------------|
| Basic number of inspections | 299 | 299 | 299 | 299 | 299 | 299 | 299 | 2,093 |
| The number of required inspections was determined according to the number of imported foods, their volume, their past violation rate, and the impact of violations on public health in order to specify the number of required inspections for each inspection category. | | | | | | | | |
| Number of inspections | 299 | 119 | 0 | 119 | 299 | 200 | 0 | 1,036 |

Inspection Orders by the Minister of Health, Labour and Welfare

Requirements for ordering inspections

Emergence of health hazards

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

Danger of health hazards

Violation

Order inspection immediately

Pesticide residue
Veterinary medicine

Violation

Increase the frequency of monitoring inspections

Violation

Order inspections if violation is assumed highly probable

Dropping inspection orders

Once it is confirmed that the violated food is not going to be imported again, since the exporting country has established measures against a recurrence or other cases.

Results of Monitoring and Guidance Based on the Imported Foods Monitoring and Guidance Plan for FY2011

❖ **Status of notifications, inspections, and violations**

❖ Number of notifications: 2,096,127

❖ Inspection cases: 231,776 (Inspection rate: 11.1%)

(inspection orders: 99,117, monitoring inspections: 49,799, guidance and inspections, etc.: 101,675)

❖ Total number of violations: 1,257 (0.1% of all notifications)

❖ **Implementation status of monitoring inspections**

❖ Approximately 106 % were implemented for 86,117 cases of scheduled inspections

❖ **Items that are newly selected to be subject to strengthened monitoring**

❖ 79 items from 33 countries and one region

❖ **Items that are newly selected to be subject to inspection orders**

❖ 16 items from 9 countries and one region

❖ **Items that are subject to inspection orders**

❖ 17 items of all exporting countries and 79 items from 27 countries and one region (as of March, 2012)

Major violations against the Food Sanitation Law (FY2011)

| Violating article | | Number of violations | Component percentages (%) | Details of major violations |
|-------------------|---|--|---------------------------|---|
| 6 | Foods that are prohibited to sell | 354 | 27.1 | Aflatoxin contamination in corn, peanuts, cassia torea, job's tears, nutmeg, dried fig, cotton seed etc.; poisonous fish contamination; detection of diarrhetic shellfish toxin; detection of cyanide; detection of Listeria from uncooked meat products; and decay, deterioration and fungus formation due to accidents during the transport of rice, wheat, rape seed, soy bean, etc. |
| 9 | Restrictions on sales, etc. of diseased meat, etc. | 5 | 0.4 | No hygiene certificate attached |
| 10 | Restrictions on sales, etc. of food additives, etc. | 79 | 6.0 | Contains undesigned additives such as tertiary butylhydroquinone (TBHQ), cyclamic acid, azorubin, potassium sodium tartrate, quinoline yellow, brilliant black BN, acid yellow, iodized salt, carbon monoxide, patent blue V, methyl parahydroxybenzoate etc. |
| 11 | Standards and specifications for foods or food additives | 768 | 58.8 | Violation of standards for constituents for vegetables or frozen vegetables (violation of standards on residual agricultural chemicals), violation of standards for constituents for marine products and processed products thereof (violation of standards on residual veterinary drugs, violation of standards on residual agricultural chemicals), violation of standards for constituents for other processed foods (coli form bacteria, etc.), violation of standards on use of additives (sulfur dioxide, polysorbate, sorbic acid, etc.), and violation of standards for constituents for additives. |
| 18 | Standards and specifications for apparatus or containers and packages | 82 | 6.3 | Violation against specifications standards for equipment, containers and packages, violation against material specifications for raw materials |
| 62 | Mutatis mutandis application for toys, etc. | 18 | 1.4 | Violations of criteria for toys or their raw materials |
| Total | | 1,306 (total) 1,257 (notified violations) | | |

Reference Information

Plan of Inspection and Guidance of Imported Food

Food Sanitation Law (Law No. 233 of 1947)

❖ Article 23: Plan of Inspection and Guidance of Imported Food

The Minister of Health, Labour and Welfare shall establish every fiscal year, according to the principle, plan of practice of inspection and guidance of the next year on the import of food, food additives, equipment and containers/packages, carried out by the state (shall be called, hereinafter, as “plan of inspection and guidance of imported food”).

- (2) Plan of inspection and guidance of imported food shall be established on the following items.
 1. In view of circumstances in the producing district and other circumstances, items to be inspected and guided concentratedly
 2. Items to be guided for persons engaged in import business, concerning practice of self-imposed examination of food sanitation
 3. Other items necessary for the performance of the inspection and guidance
- (3) The Minister of Health, Labour and Welfare shall establish plan of inspection and guidance of imported food, and shall officially announce it when he established or changed the plan.
- (4) The Minister of Health, Labour and Welfare shall officially announce on the actual circumstance of the practice of plan of inspection and guidance of imported food.

Regulations to Assure the Safety of Imported Foods and the Responsibilities of Related Parties (2)

Food Sanitation Law (Law No. 233 of 1947)

❖ Article 2 Responsibilities of the National Government and Local Governments

The State, prefectures, and cities that are specified by the government ordinance based on the provisions of Article 5, Paragraph 1 of the Community Health Law (hereinafter referred to as “cities that can establish health centers”) and special wards shall take the necessary measures to disseminate correct information concerning food sanitation through educational activities and PR activities and to collect, organize, analyze, and provide information on food sanitation. They shall also take measures to promote research on food sanitation, enhance inspection abilities concerning food sanitation, develop human resources engaging in the improvement of food sanitation, and enhance the quality of such employees.

- (2) The State, prefectures, cities that can establish health centers, and special wards shall cooperate closely with each other so that measures for food sanitation shall be implemented comprehensively and promptly. The State shall develop a system to collect, organize, analyze, and provide information, as well as conduct research on food sanitation, and to perform food sanitation inspections with regard to imported foods, additives, apparatus, and containers and packaging.
- (3) The State shall also take the measures necessary to ensure international cooperation. At the same time, the State shall provide prefectures, cities that can establish health centers, and special wards with the necessary technical assistance in order for them to pursue their responsibilities specified in the preceding two paragraphs.

❖ Article 3 Responsibilities of Food Business Operators

Food business operators shall, of their own responsibility, strive to obtain knowledge and acquire techniques to ascertain the safety of the food they import and/or use in business, and the safety of additives, apparatus, or containers and packaging. They shall also make efforts to ensure the safety of raw materials of such food and products, conduct self-imposed inspections, and take other necessary measures.

Regulations to Assure the Safety of Imported Foods and the Responsibilities of Related Parties (1)

The Food Safety Basic Law (Law No. 48 of 2003)

❖ **Article 4 Appropriate Measures at Each Stage of the Food Supply Process**

Food safety shall be ensured by taking the necessary measures appropriately at each stage of the Food Supply Process in Japan as well as outside Japan.

❖ **Article 6 Responsibilities of the National Government**

The national government shall be responsible for formulating and implementing comprehensive policies to ensure the safety of food on the code of basic principles for ensuring the safety of food, which is stipulated in the preceding three articles (hereinafter referred to as the "Basic Principles").

❖ **Article 7 Responsibilities of Local Governments**

Local governments shall be responsible, pursuant to the Basic Principles, and based on an appropriate role-sharing with the national government, for formulating and implementing policies to ensure the safety of food according to natural and socioeconomic characteristics of the particular region in the local government.

❖ **Article 8 Responsibilities of Food-Related Business Operators**

Business operators that import food shall be responsible for appropriately taking the necessary measures to ensure the safety of food at each stage of Food Supply Processes. This will be done according to the code of the Basic Principles and recognizing that they bear the primary responsibility for ensuring the safety of food when conducting their business activities.