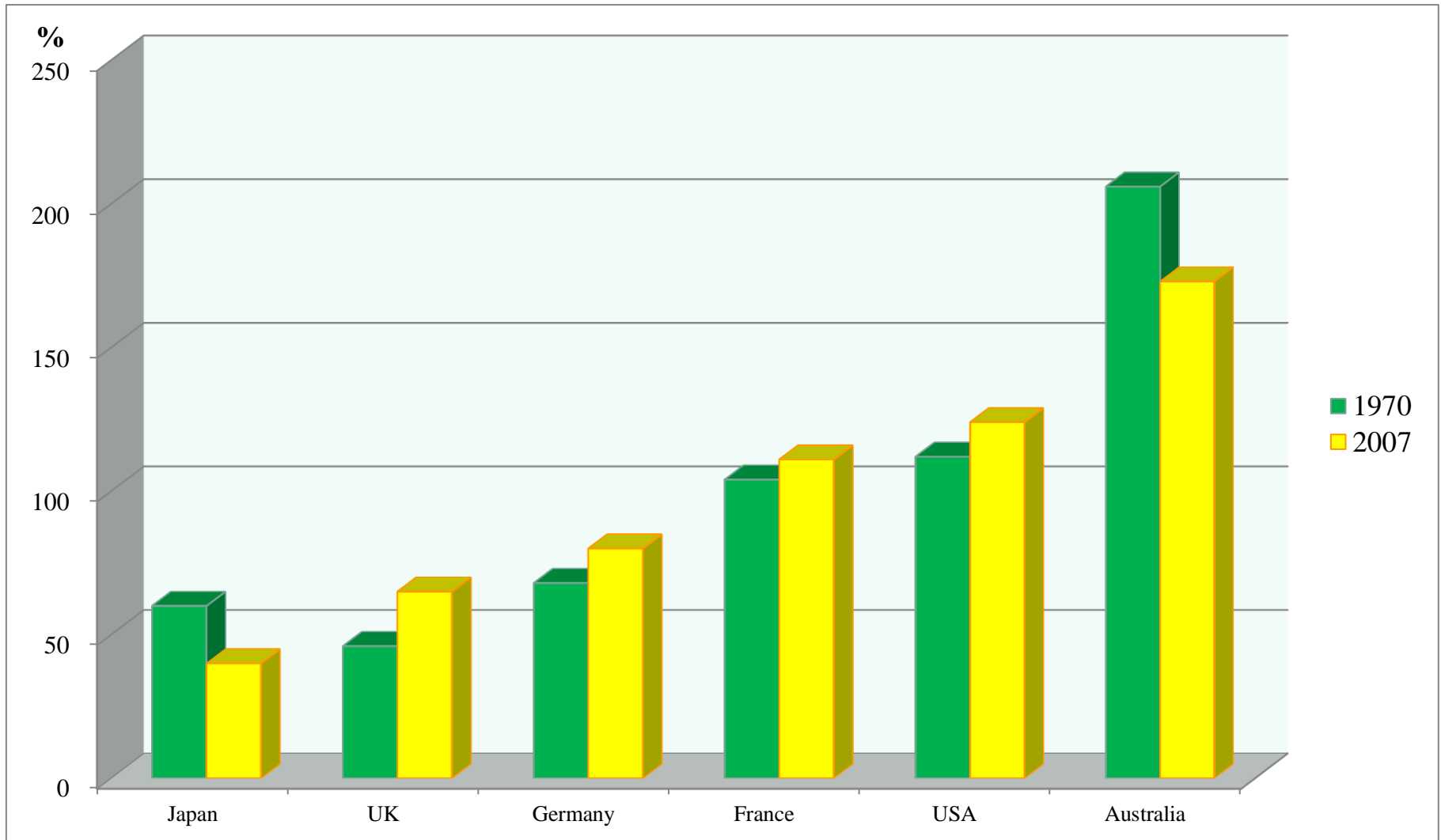


Ensuring the Security of Imported Foods

October 25, 2012

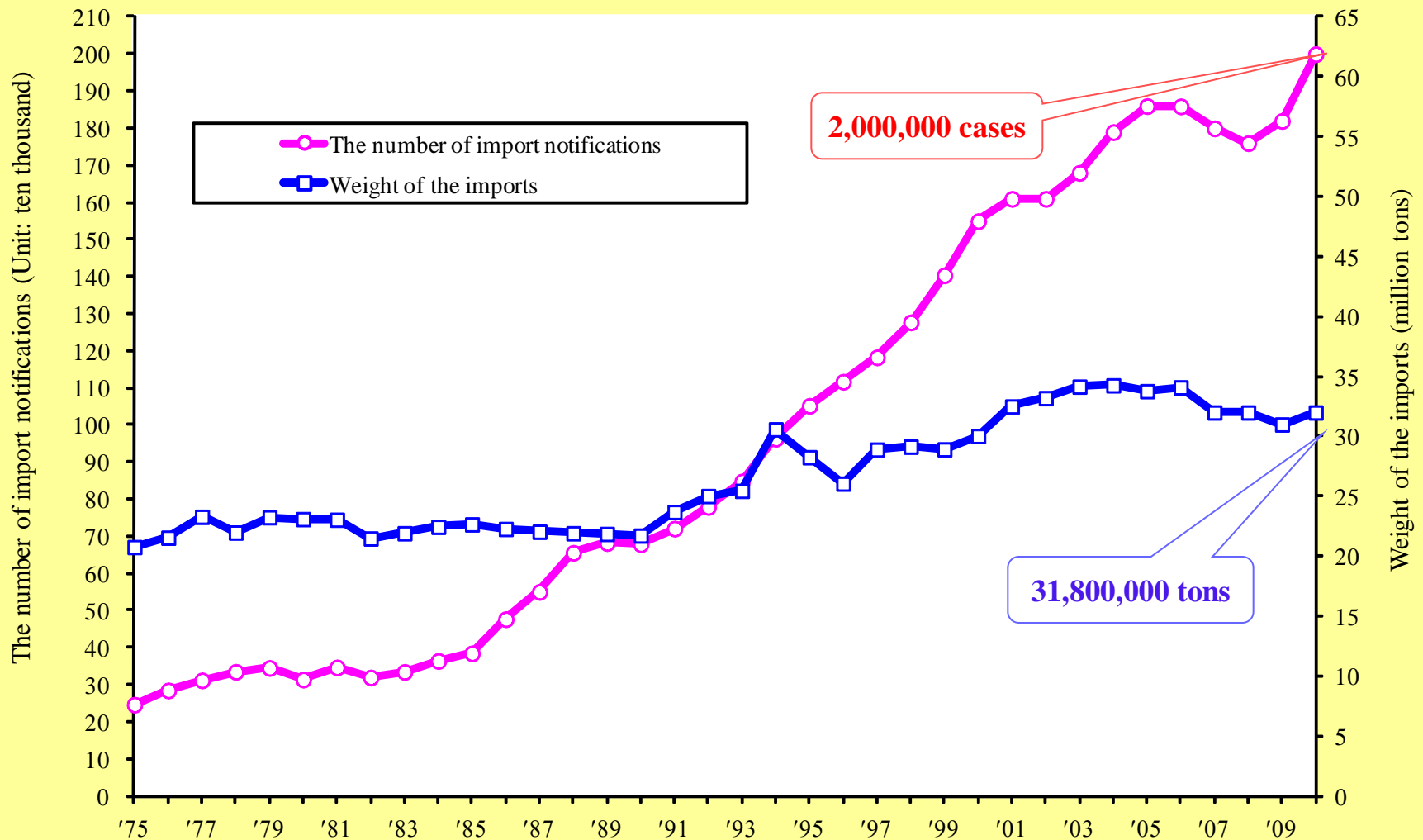
Department of Food Safety, Ministry of Health, Labour and Welfare

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

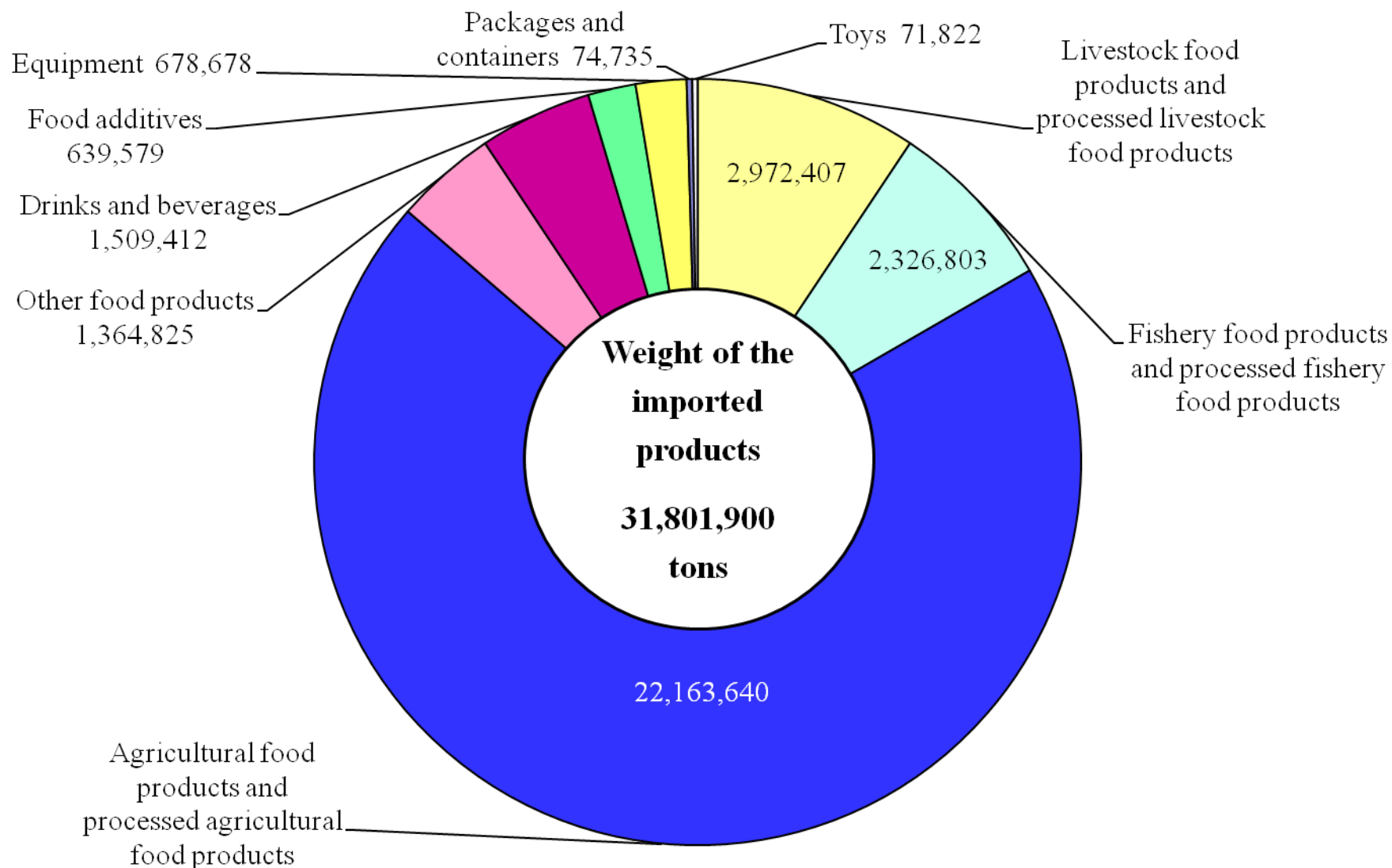


Source: Table of the Total food self-sufficiency ratio on a Calorie Supply Basis (MAFF)

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



Import Situation of Food and Related Products (FY2010)



Plan of Inspection and Guidance of Imported Food

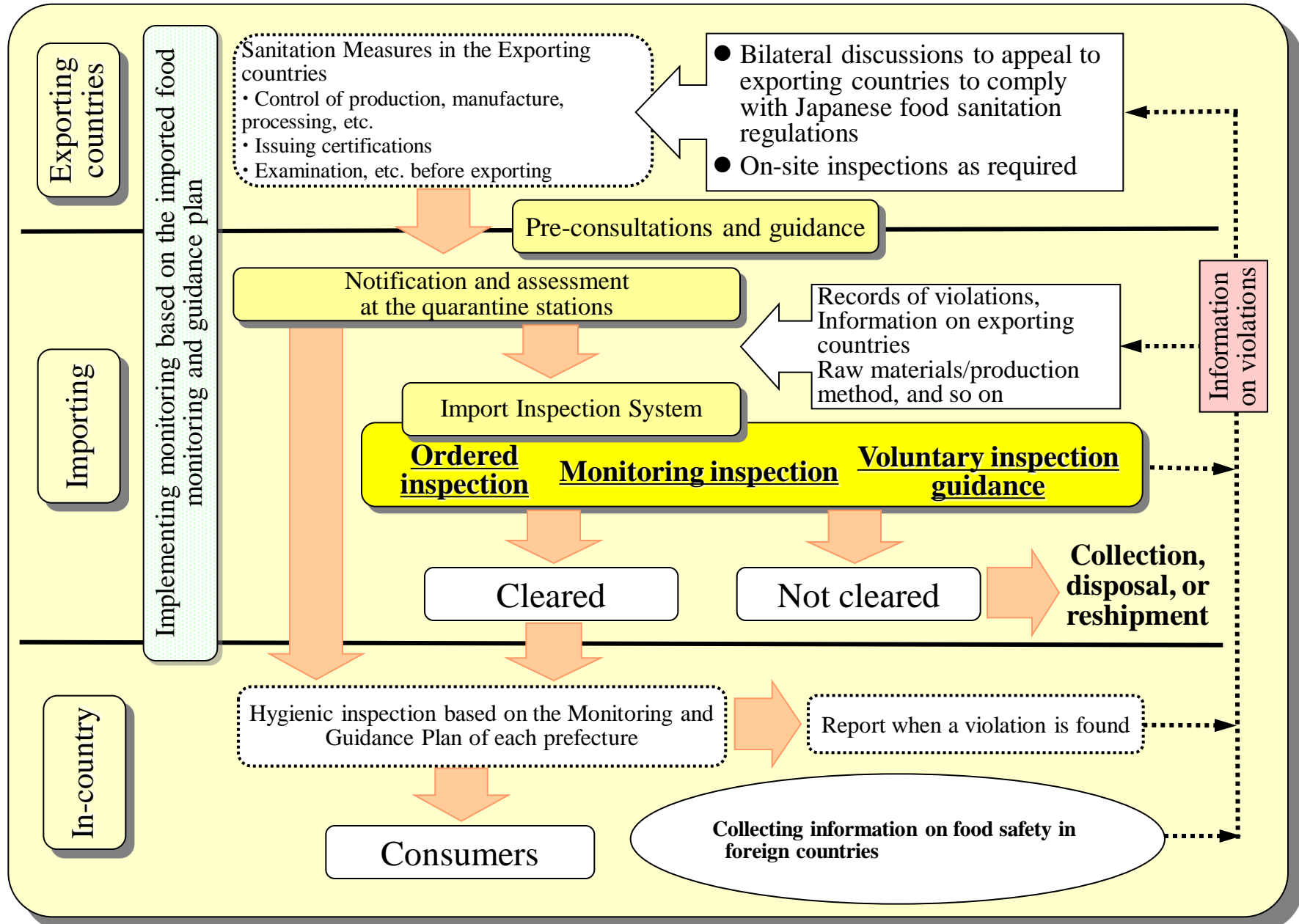
Food Sanitation Law (Law No. 233 of 1947)

❖ 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.

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)

Survey and discussion in export countries FY2010 ①

(excerpt)

Country	Item	Purpose of survey / matter of discussion	Result (excerpt)
Thailand	Agricultural food product	Survey of control system, discussion and field survey of firms	<p>【Survey of control system】</p> <ul style="list-style-type: none"> •National government and local government carry out hygiene control of pesticide residue about exporting food to Japan. •National government covers setting standards, export inspections, issue of export certifications, etc.. •Local government directs appropriate use of pesticide residue during cultivation. •Adopt the lowest level of pesticide residue in the export countries. <p>【Field survey】</p> <ul style="list-style-type: none"> •Survey: <ul style="list-style-type: none"> ➢the guidance status about use of pesticide residue on farm. ➢the storage conditions of pesticide residue ➢the management status in packing plant •Indication point (based on the field survey) <ul style="list-style-type: none"> ➢Additional inspection items of long-term pesticide residue on soil inspection before planting. ➢Measures for prevention of spread of pesticide residue (because of lack of measures)

Survey and discussion in export countries FY2010 ②

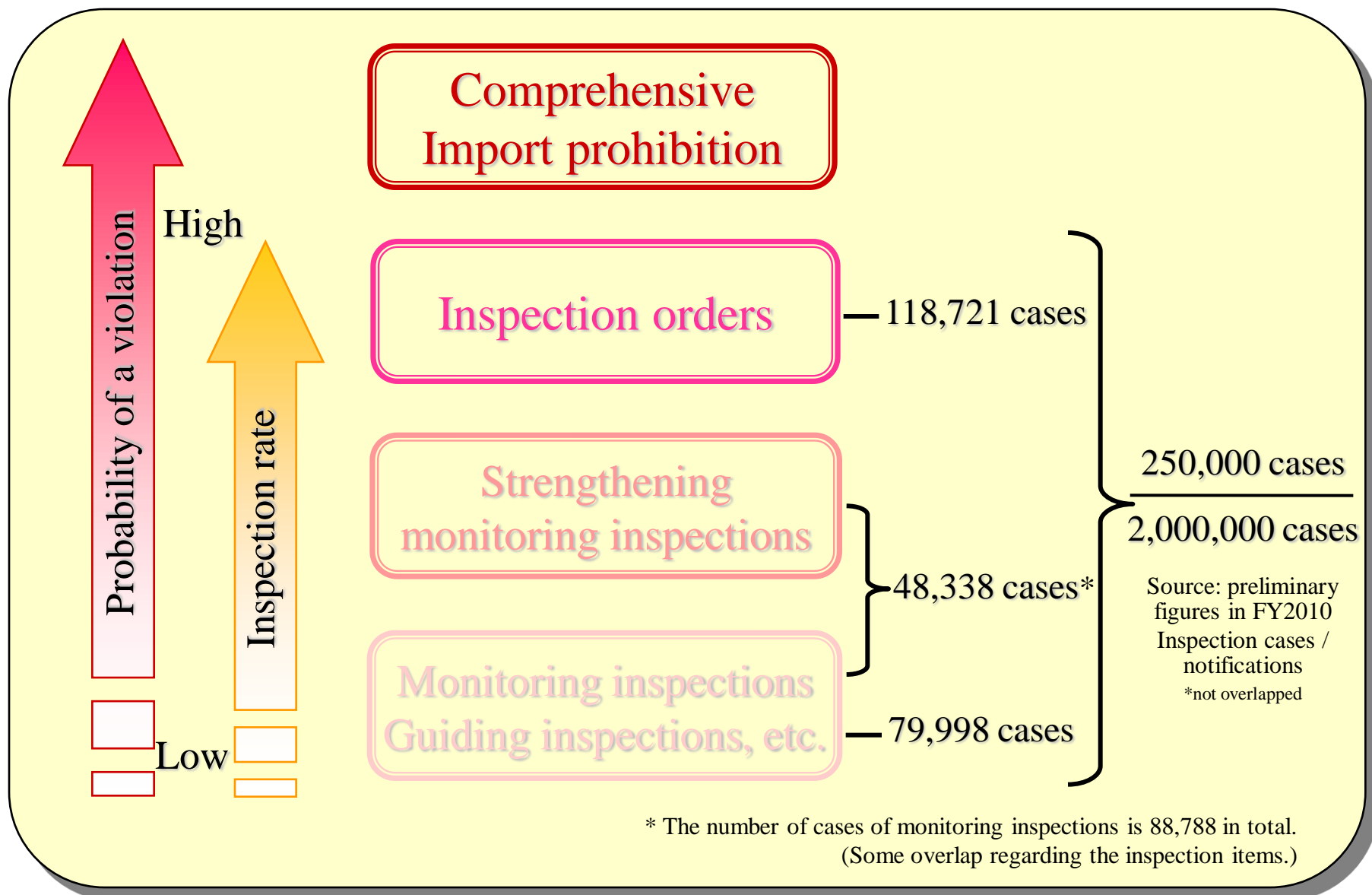
(excerpt)

Country	Item	Purpose of survey / matter of discussion	Result (excerpt)
South Korea	Fishery food product	Survey of control system, discussion and field survey of processing plants	<p>【Survey of control system】</p> <ul style="list-style-type: none"> •Food safety control organization is composed 6 organizations. (ex. Ministry for Food, Agriculture, Forestry and Fisheries (MFAFF) / Animal, Plant and Fisheries Quarantine and Inspection Agency (QIA)) •MFAFF covers the safety control during production of exporting agricultural food. •Rural Development Administration covers the instruction of farmer and technical guidance. •QIA covers waters management, Inspection of exporting fishery foods (about shellfish poison)that follow the hygiene control at the exporting countries, etc.. <p>【Field survey】</p> <ul style="list-style-type: none"> •Survey: <ul style="list-style-type: none"> ➢Hygiene control for the plant of shelled ark shells ➢Gathering circumstance of freshwater clam and constricted tagelus •Indication point (based on the field survey) <ul style="list-style-type: none"> ➢Control of hypochlorous acid water at the plant of shelled ark shells. ➢Improvement of health control for staffs

Emergency Responses Based on Overseas Information

- ❖ Collecting overseas information about the safety of foods
 - ◆ Division of Safety Information on Drugs, Food, and Chemicals of the National Institute of Health Sciences
 - ◆ Information and Emergency Response Division of the Food Safety Commission
- ❖ When the food item in question has already been imported into our country, surveillance on the distribution status, collection of the food, and inspections at the time of import will be tightened.

Outline of the Import Inspection System



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**

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 (FY2011 Monitoring Plan)

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.

Inspection Order Items by Country (excerpt)

(as of the April 2012)

Countries or regions	Foods	Examples of inspection items	Conditions
All importing countries (17 items)	Puffer fish	Distinguishing the fish	Only in cases where different kinds of puffer fish are found in an on-site inspection
	Salted salmon roe	Nitrite	
	Cassava and its processed products (except for starch)	Cyanogen compounds	
China (28 items)	Chicken and its processed products	Furazolidone	
	Eel and its processed products	Malachite green	
	Shrimp and its processed products	Chlortetracycline	
	Clams and their processed products (except for scallop with only the ligament)	Paralytic shellfish toxin, Diarrhetic shellfish toxin	Products excepting those certified to be from fresh water by the Chinese government
	Large peanuts	Acetochlor, BHC(benzene hexachloride)	
	Oolong tea	Triazophs	
	Sea urchin for raw consumption	<i>Vibrio parahaemolyticus</i>	Limited to products processed by the manufacturers that are separately indicated
Thailand (11 items)	Bananas and its processed products	Cypermethrin	Excluding fresh banana exported by the exporters separately indicated
	Okra and its processed products	EPN	Excluding fresh okra exported by the exporters separately indicated
Taiwan (6 items)	Cultured eel and its processed products	Fenitrothion	
	Carrot and its processed products(simple processing only)	Methamidophos Acephate	

17 items of all exporting countries and 99 items of 26 countries and one region (as of the April 2012)
 List of ordered inspection items <http://www.mhlw.go.jp/english/topics/importedfoods/11/dl/11-04a.pdf>

Importers' Business Suspension/Prohibition

❖ Purpose

- ◆ To have the importers, who are repeatedly violating the law, correct their violation, prevent recurrences, and take necessary sanitary measures

❖ Requirements for considering imposing penalties

- ◆ All the importers' inspection results will be reviewed every quarter of the year. **If the violation rate of the latest 60 inspections is 5% or over when their violation is determined,** imposition of a penalty will be considered.
- ◆ Those importers who are subject to penalties are instructed **to review their safety control when they import foods, etc. and take measures against recurring violations.** They are also requested to submit written reports within a set time frame.
- ◆ After receiving the guidance stated above, if the violated situation does not seem to be improving, **the importers' business suspension/prohibition will be ordered based on Article 55, paragraph 2 of the Law.**

(Results of guidance)

2008; 30 companies, 2009; 36 companies, and 2010; 42 companies

Thank you for your kind attention