

## Food Safety Legal System in Japan -Contaminants-

27 November 2019  
MAFF

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## Laws on Food Safety

1. Food Safety Basic Law (2003)
  - a. Implementation of risk assessment
  - b. Establishment of the Food Safety Commission
  - c. Established in the aftermath of BSE crisis
2. Food Sanitation Act (under the Ministry of Health, Labour and Welfare, and the Consumer Affairs Agency)
3. Act for Establishment of the Ministry of Agriculture, Forestry and Fisheries
  - a. "ensuring food safety at the production level" is included in the responsibilities

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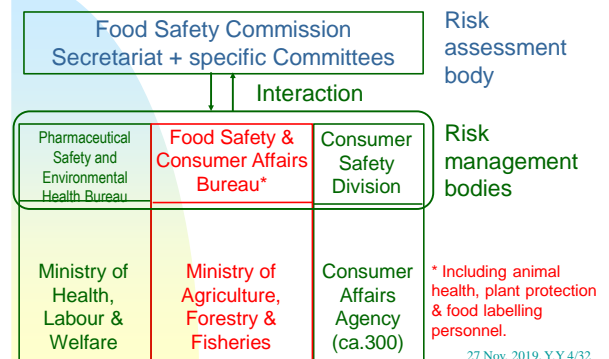
## Other Related Laws

1. Laws for production materials with some impacts on food safety (MAFF)
  - a. Pesticides (significant revision in 2018)
  - b. Veterinary drugs
  - c. Feeds
  - d. Fertilizers (proposed revision)
  - e. GMOs
  - f. Laws on the environment and other chemicals (Ministry of the Environment, Ministry of Economy, Trade and Industries)

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## Division of Responsibilities Related to Food Safety (current)



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## MAFF

## Biggest Turning Point Ever

First Bovine Spongiform Encephalopathy case in September 2001 in Japan

1. The Government could **not** give detailed information **in time**
  - a. The mass media started to write what they thought or imagined
2. The Government had to **correct** the information they had given **multiple times**
3. The Government had said, "BSE will never occur in Japan!"

The Government lost the trust and confidence of the general public. (not so high even before)

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## Structural Changes Made in the Government

From 1 July 2003

1. **Food Safety Commission**
  - a. Newly established under the Cabinet Office; independent from other ministries
  - b. To conduct risk assessment
2. Restructuring of existing ministries:
  - a. **Food Safety Department** under the "Pharmaceuticals and Food Bureau" of **MHLW** ← Food Sanitation Department (now "Pharmaceutical Safety and Environmental Health Bureau")
  - a. New **Food Safety and Consumer Affairs Bureau in MAFF** ← Restructuring inside the ministry (scrap & build concept)

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## Introduction of New Principles in MAFF

1. Viewpoint of **consumers**
2. **Science** as a basis of decision-making
  - a. Already the SPS Agreement and the Codex Alimentarius Commission emphasized the need for science
  - b. Confusion in Japan: Ask university professors and researchers to do the job
3. **Risk analysis**, in particular, **risk management**
  - a. MAFF established the **Standard Operating Procedures of Risk Management** for use by MAFF and MHLW

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4. **Food chain approach**
  - a. Became common around 2000 (trigger: dioxin contamination of feed in Belgium)
  - b. MAFF has the advantage (closer to the industries)
5. **Emphasis on transparency**
  - a. The Government did not disclose information if they thought it inappropriate → more disclosed
6. **Active participation in international activities**
  - a. Went to Codex meetings and said nothing or only when opposed → Contribute in discussions, provide scientific data, and recently serve as chair of electronic WGs

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**MHLW**

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## Structure and Responsibilities of the MHLW in Food Safety

1. Headquarters: Pharmaceutical Safety and Environmental Health Bureau
2. Regional Bureaus of Health and Welfare
3. Quarantine stations (including imported food inspections)

Working in collaboration with local governments, such as public health centers

Major responsibilities

- Risk management related to food sanitation

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## Standards for Food and Additives

1. Food sanitation Act
  - Art.6: Ban on the distribution of rotten, toxic or harmful foods and additives
  - Art. 10: Restrictions on the sales of additives
  - Art. 11: Establishment of standards for foods and additives

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2. Notice on the standards for foods & additives
  - a. Foods:
    - 1) Antibiotics: not to be contained
    - 2) MRLs for pesticides, etc. (incl. ND)
    - 3) Contaminants
    - 4) Pathogenic microorganisms
    - 5) GM foods
  - b. Additives
    - 1) Specification for each additive
    - 2) Manufacturing practice
    - 3) Use levels

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## Standards and Other Regulations under the Food Sanitation Act

### Foods

- Chemical residues in foods (pesticides, feed additives and veterinary medicines):  
Maximum Residue Limits set for 794 substances
- Contaminants  
Heavy metals, mycotoxins, etc.:  
Maximum levels set for Cd, Methyl Hg, Aflatoxins, Patulin, DON.
- Microorganism  
Viable cell count, Coliform group, Salmonella spp., Vibrio parahaemolyticus, etc.
- GM foods and additives

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- Food additives  
Designated additives: 454  
Natural origin or GAS additives: 365
- Apparatus, containers/packages
- Toys for infants
- Detergents

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## So-called “Positive List” for Residues

1. Pesticides
2. Veterinary drugs
3. Feed additives with pharmaceutical functions
4. List of combinations of food/residue that require testing
5. Utilizes Codex MRLs
6. Also based on residue trials for the registered pesticides
7. Uses MRLs in AU, CA, EU, NZ, and US
8. “Positive list” for inspection

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## Food Consumption Survey

1. Nutrition survey has been conducted annually on one day in November
2. In order to verify the MLs and MRLs, it is necessary to conduct exposure assessment
3. For this purpose, consumption data from four seasons with multiple days are needed.
4. In 2005-2007, a survey was conducted for this purpose
5. After many years, diet habits may have changed
6. For estimating acute exposure with high percentile consumption, we need more samples

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## Inspection and Testing of Foods Imported into Japan

Based in the information provided by MHLW

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## Two Types

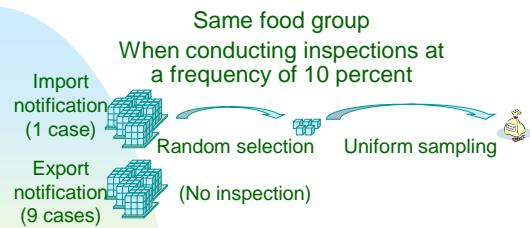
- By the quarantine stations of the MHLW
  - 13 quarantine stations
  - Additional 18 branches of the above
- "Monitoring Inspection", and
- "Inspection Order"
 

When there are many past violation cases.
- "Notification of import" is mandatory according to the law

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## "Monitoring Inspection"



- Frequency:** Random on a basis of the annual plan
- Subjects of inspection:** Each food group, (not by countries or producers).
- Sampling:** From the statistically determined number of consignments.

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## "Inspection Order"



- Frequency:** At the time of importation, for all the imported foods for which import-notification documents were submitted.
- Subjects of inspections:** Each producing country and each food group. When food with a high possibility of violation can be restricted by the producer, inspection is to be conducted by the appropriate producer.
- Sampling:** From the statistically determined number of consignments.

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## Sampling (example)

Inspection for agricultural chemicals

Number of notifications	Number of consignments to be opened	Sample volume
≤ 50	3	1 kg
51 – 150	5	1 kg
151 – 500	8	1 kg
501 – 3200	13	1 kg
3201 – 35000	20	1 kg
≥ 35001	32	1 kg

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## Calculation of the Number of Samples for "Monitoring Inspection"

- All imported foods are classified into **171 food groups** according to the total consumption of the targeted food, probability of violation, and past status of import, etc.
- The number of samples to be collected for the inspection is tentatively determined as **299**, for the inspection categories (agricultural chemicals, antibiotic products, food additives, constituent specification, toxigenic fungi, GM foods, and irradiated foods). Statistically, with 299 samples, it is possible to detect at least one non-compliant sample when the violation rate is 1% with 95% probability.

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

Violation rate (v)	Probability of finding one non-compliant sample (P)				
	99.9%	99.0%	95%	90.0%	66.0%
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  $n$  samples can be calculated as  $P=1-(1-v)^n$

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## “Monitoring Inspection”

On-site inspection for “monitoring inspection”

- ◆ At a warehouse, a food sanitation inspector conducts on-site inspection to **collect samples**
- ◆ Necessary packages are chosen randomly and samples are collected
- ◆ The number and volume of sample depends on what are to be tested/analyzed and the size of consignment



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## Tests for Compliance (examples):

1. Pathogenic microorganisms (enterohemorrhagic *E.coli* O26, O103, O104, O111, O121, O145 and O157, *Listeria monocytogenes*, etc.)
2. Antibacterial substances (antibiotics, synthetic antimicrobials), hormones, etc.
3. Residues of agricultural chemicals (organo-phosphorous, carbamates, pyrethroids, etc.), organochlorines, etc.



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1. Food additives (preservatives, coloring agents, sweeteners, antioxidants, anti-mold agents, etc.)
2. Standards for constituents, etc.:
  - a. Items stipulated in the standards (bacterial count, coliform bacteria, etc.),
  - b. marine biotoxins (diarrhetic & paralytic shellfish poisons), etc.
3. Mycotoxins: aflatoxins, deoxynivalenol, patulin, etc.
4. Genetically modified organisms (GMOs): genetically modified foods not having been assessed for safety in Japan
5. Irradiated foods: with or without of irradiation

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## Risk Management of Contaminants

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## Risk Management of Contaminants

1. MLs established by MHLW for foods
2. MLs established by MAFF for feeds
3. Both are based on the “As Low as Reasonably Achievable” concept (explained later)
4. Codes of practice established by MAFF for prevention and/or reduction of contamination (to improve the safety)
5. Occurrence data developed mostly by MAFF
  - a. Risk profiles
  - b. Priority list of hazards

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## Risk Management of Contaminants in Food in MHLW

1. Refer to Codex MLs considering:
  - a. Contamination situation among foods consumed in Japan
  - b. Consumption of the foods containing the contaminant
2. If it is not possible to use Codex MLs
  - a. Request the industries to reduce contamination
  - b. If necessary, establish MLs applying the ALARA principle on the occurrence data
3. If no significant risk, consider in the future
4. If the situation is specific or unique to Japan, consider establishment of ML(s)

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## Some Advantages of Collaboration

1. Ministry of Health, Labour and Welfare
  - a. Food Sanitation Act (co-jurisdiction-CAA)
  - b. Establishes maximum (residue) levels for contaminants, food additives, pesticide and veterinary drug residues, migrants, etc.
2. Ministry of Agriculture, Forestry and Fisheries
  - a. Laws related to the safety and quality of materials used for agriculture: feed, pesticides, veterinary drugs, fertilizers, etc.(maximum levels in feed & fertilizers)
  - b. Access to and authority over the industries and sites of production, manufacturing, etc. of food

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Thank you for your attention!

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