Food Safety Measures in Japan

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JAPAN
Self Introduction

1990-1996    Nagoya University Medical School (MD)
1996-1997    Clinical Training at National Hospitals
1997-        Ministry of Health, Labour and Welfare (MHLW)
              -Health Insurance Division
              -Ministry of Environment (Environment Safety Division)
              -Food Safety Division (Standard and Evaluation Division)
              -Mental Health Division
              -International Affairs Division
2008-2011    World Health Organization (WHO)
              -External Relations Officer, General Management Cluster, Headquarter
2011-2012    Director, Cancer Control Office, MHLW
2012- Present     Director, International Food Safety Office, MHLW

2004        Harvard School of Public Health (MPH)
2007        Nagoya University Graduate School of Medicine (PhD)
Food Self-sufficiency Rate

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

Current Status of Imported Foods

- The number of import notifications
- Weight of the imports

- 2,180,000 cases
- 32,150,000 tons
## Recent changes in Japan’s food safety administration

### <Main events, etc.>

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
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<tbody>
<tr>
<td>March 1996</td>
<td>Following outbreak of BSE in the UK, imports of British beef and processed beef foods were prohibited.</td>
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<td>May 1996</td>
<td>Major outbreak of food poisoning caused by O-157.</td>
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<td>June 2000</td>
<td>Snow Brand Milk Products Co. food poisoning case</td>
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<td>June 2001</td>
<td>Confirmation of the first BSE infected cow in Japan</td>
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<td>February 2002</td>
<td>Detection of residual agricultural chemicals exceeding standard in Chinese frozen spinach</td>
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<td>December 2003</td>
<td>Confirmation of first BSE infected cow in the US, and prohibition of US imports</td>
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<td>June 2007</td>
<td>The Meat Hope Co. false labeling incident</td>
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<td>December 2007</td>
<td>Food poisoning caused by Chinese frozen gyoza</td>
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<td>September 2008</td>
<td>Tainted rice distribution incident</td>
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<tr>
<td>March 2011</td>
<td>TEPCO Fukushima Daiichi Nuclear Power Station accident</td>
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<td>April 2011</td>
<td>Food poisoning from raw meat</td>
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### <Administrative response>

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tr>
<td>May 1996</td>
<td>Partial revision of the Food Sanitation Act (introduction of HACCP, etc.)</td>
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<td>October 2001</td>
<td>• Total ban on bone-and-meat feed (MAFF)</td>
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<tr>
<td>June 2002</td>
<td>• Start of 100% inspection of beef cattle</td>
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<td></td>
<td>• Enactment of the BSE Special Countermeasures Law</td>
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<tr>
<td>August 2002</td>
<td>Partial revision of the Food Sanitation Act (creation of system for blanket prohibition of imports and sales)</td>
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<tr>
<td>May 2003</td>
<td>Enactment of the Food Safety Basic Law</td>
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<tr>
<td>May 2003</td>
<td>Partial revision of the Food Sanitation Act (introduction of positive list for residual farm chemicals, etc., introduction of system for renewing general sanitation management process approval facilities, implementation of monitoring and guidance plans, etc.)</td>
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<tr>
<td>July 2003</td>
<td>Launch of the Food Safety Commission</td>
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<td>September 2009</td>
<td>Launch of the Consumer Agency</td>
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<tr>
<td>March 2011</td>
<td>Response to radioactive material in food</td>
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<tr>
<td>October 2011</td>
<td>Standards set for meat for raw consumption</td>
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Schema of Risk Analysis

Risk Assessment

Risk Management

Risk Communication
Risk Analysis in Japan

Risk Assessment
Risk Management
Risk Communication

Food Safety Commission
MHLW / MAFF / CAA*

*MHLW: Ministry of Health, Labour and Welfare
MAFF: Ministry of Agriculture, Forestry and Fisheries
CAA: Consumer Affairs Agency
Risk Analysis

- Risk analysis is the process of preventing accidents and minimizing risk as much as possible, for protecting the health of the people, when there may be exposure to certain hazards, and not for clearing up the aftermath.

Risk Assessment

- Implementation of risk assessment
  Assess the probability and extent of adverse impacts of hazardous substances in food.

  - Food Safety Commission
    - Food Safety Basic Law

Risk Management

- MHLW
  - Sets criteria for inclusion in foods.
  - Watches over conformity to the criteria.

  - Food Sanitation Act, etc.

- MAFF
  - Sets criteria for use agricultural chemicals and levels in feed and fertilizer.
  - Control on veterinary drugs, etc.

  - Agricultural Chemicals Regulation Act
  - Act on Safety Assurance and Quality Improvement of Feeds, etc.

- Consumer Agency
  - Sets criteria on food labeling.
  - Watches over conformity to the criteria.

  - Food Sanitation Act
  - Health Promotion Law
  - JAS Law, etc.

Risk Communication

- Disclosure of food safety related information
- Opportunities for the consumers to express their views

General coordination by the Consumer Agency
Risk Analysis at Codex

Risk Assessment
- FAO / WHO
- JECFA / JEMRA
- JMPR

Risk Management
- Codex

Risk Communication
Office of International Food Safety

• General coordination of international affairs related to food safety
  = multilateral negotiation + bilateral negotiation
  – Codex Alimentarius Commission
  – WTO (World Trade Organization)
    • SPS Agreement
  – TPP, RCEP, APEC, OECD, WHO, FAO
  – EPA/FTA
  – Other multilateral and bilateral issues
Administrative Structure for Food Safety

- **Food Safety Commission** (Risk assessment)
- **MAFF** (Risk management)
- **Consumer Agency** (Risk Communication)
- **Consumer Commission**

**Central**

- **MHLW** (Risk management)
  - Mutual collaboration

**Local**

- **Prefectures** (47)
- **Cities with public health centers** (71)
- **Special wards** (23)

**Public Health Centers** (495)

- Provide information, hear public opinion

**Quarantine stations** (32)

- Approval, inspection of HACCP
- Registration, surveillance and guidance

**Local Bureaus of Health and Welfare** (7)

- Monitoring
- Inspection order

**Registered laboratory services**

- Consultation, notification

**Imported foods, etc.**

- Request inspection

**Surveillance, administrative guidance**

**Food business operators**

- Safe food product

**Consumers**

*As of April, 2014*
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
2 Imported food inspection center
13 quarantine stations providing consultations on importing food and related products
399 food sanitation inspectors

* As of FY 2013
Outline of the Monitoring System for Imported Food

Exporting countries

- Sanitation Measures in the Exporting countries
  - Managing the use of agricultural chemicals
  - Issuing certifications
  - Examination, etc. before exporting

Implementing monitoring based on the imported food monitoring and guidance plan

- Bilateral discussions to appeal to exporting countries to comply with Japanese food sanitation regulations
- On-site inspections as required

Importing

- Pre-consultations and guidance

- Notification and assessment at the quarantine stations

Import Inspection System

- Records of violations, Information on exporting countries
  - Raw materials/production method, and so on

Implementing monitoring based on the Imported Food Monitoring and Guidance Plan of each prefecture

- Ordered inspection
- Monitoring inspection
- Voluntary inspection guidance

- Cleared
- Not cleared

- Collection, disposal, or reshipment

In-country

- Hygienic inspection based on the Imported Food Monitoring and Guidance Plan of each prefecture

- Report when a violation is found

Consumers

- Collecting information on food safety by Food Safety Commission and National Institute of Health Science
Outline of the Import Inspection System

Combined Inspection: Import prohibition

Inspection orders
(100%)

One time violation
One more time violation or Emergent health hazard

Strengthening monitoring inspections (30%)

One time violation

Monitoring inspections
Guiding inspections, etc.

Violation rate
\[ \frac{1,053}{2,180,000} = 0.05\% \]

Source: preliminary figures in FY2012

*not overlapped

82,448 cases
220,000 cases

95,301 cases
57,350 cases*

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

**Inspection order (100%)**

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

- No violations for two years
- No violations in 300 inspections for one year

**Reinforcement of monitoring inspection (30%)**

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

**Normal monitoring inspection (10%)**

Cancellation Requirements
Recall system of violated foods in Japan

Individual prefectures having jurisdiction over the manufacturer

Detection of violation
- Inspections at individual prefectures
- Food poisoning

Notification

Publish on the website

Individual prefectures

Surveillance

Report

If necessary, Recall order, etc.

Manufacture

MHLW

Other prefecture

Other prefecture

Other prefecture

MAFF

CAA

NFSFD

Information sharing regarding food poisoning outbreak

If the goods are distributed to other prefectures, Provide Information

Provide Information

Publish on the website
Steps to lifting the import ban on beef (BSE)

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 MHLW

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

Lifting the import ban
Process of the Designation of Food Additives

**Risk Assessment**

Food Safety Commission

- Assess toxicity data
  - Chronic toxicity study
  - Carcinogenicity study
  - Teratogenicity study, etc.

- ADI (draft)

- Public comments

- Establish ADI

**Ministry of Health, Labor and Welfare**

- Confirm application

- Examine documents

- Effectiveness and standards

- Request for risk assessment

**Risk Management**

- Review ADI
- Examine standards

- WTO Notification
- Public comments

- Draft Ministerial Ordinance

- Consultation

- Report

**Consumer Affairs Agency**

- Consultation

- Response

**Food Sanitation Council**

- Committees
Relationship with WTO (1)


• SPS (Sanitary and Phytosanitary) Agreement
  – Members shall ensure that any sanitary or phytosanitary measure is based on scientific principles, and is not maintained without sufficient scientific evidence
  – Members shall base their sanitary and phytosanitary measures on international standards
Relationship with WTO (2)

International standards in SPS;

a. For food safety → **Codex standards**

b. For animal health → OIE (World Organisation for Animal Health) standards

c. For plant health → IPPC (International Plant Protection Convention) standards
Relationship with WTO (3)

• Members may introduce higher level of measures than international standards;
  – if there is a scientific justification
  – if determined to be appropriate by risk assessment

• Members may face WTO dispute, if it is not justified.

(after joining TPP)  SPS+

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Recent Topic

More Science-based Measures

• Acute Reference Dose (ARfD)
• The number of Residue Trial Data
• Import Tolerance from developing countries
• Guideline for application of food additive
• Risk assessment of Flavoring Agent
• Gap in the standard for food additive
• Testing and Sampling / ISO 17025
• GM (Self-Cloning, Natural Occurrence etc)