Pesticide Regulation System in Japan

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Contents

I. Food Safety Approach in Japan
II. Pesticide Regulation
III. Application of Import Tolerance
IV. Positive List
V. Official Journal of Food Safety Commission of Japan
FOOD SAFETY APPROACH IN JAPAN
Risk Analysis for food safety in Japan

FSCJ

Risk Assessment
- Identification of risk
- Monitoring the implementation conditions of Risk management measures

MHLW, MAFF, CAA and other related agencies

Risk Management
- Setting of Maximum Residue Limits
- Setting Standards and criteria, Import requirements etc.
- Inspection, Surveillance, Guidance etc.

Science-based

Policies

Cost-benefit

Stakeholders

Technical-aspects

Risk Communication

Mutual understanding and opinion exchange among participants on risk communication, such as consumers, business operators etc.
Food Safety Basic Act (Enforced 16 May 2003)

- Protection of the health of Japanese citizens is the top priority
- Introduction of Risk Analysis Principle to food safety administration
- Establishment of Food Safety Commission (FSCJ) as a part of Japanese Cabinet Office, independent from risk managing ministries (1 July 2003)
- FSCJ’s Mission is to conduct science-based risk assessment in an objective, neutral and impartial manner
**FSCJ Organization - Whole**

**Food Safety Commission of Japan (FSCJ): Commissioners**
- Susumu Kumagai (Chairperson)
- Hiroshi Satoh (Deputy Chairperson), Yasushi Yamazoe (Deputy Chairperson), Kunitoshi Mitsumori (Deputy Chairperson)
- Katsue Ishii, Kiyoko Kamiyasuhira, Masatsune Murata

**12 Expert Committees (218 experts, 1 Chair for each committee)**
- Planning
- Food additives
- Pesticides
- Veterinary medicinal products
- Apparatus and containers/packages
- Chemical and Contaminants
- Microorganisms and Viruses
- Prions
- Natural toxins and mycotoxins
- Chemical Substances
- Genetically modified foods
- Novel foods
- Feed, fertilizers

**Secretariat**
- Director-General
- Deputy Director-General
- General affairs Division
- First Risk Assessment Division
- Second Risk Assessment Division
- Information, Recommendation and Public Relations Division
- Director for Information Analysis
- Director for Risk Assessment Coordination
- Director for Risk Communication

Restructured in May 2013
PESTICIDE REGULATION
Laws concerning regulation of pesticides

**Risk Management**

- **Agricultural Chemicals Regulation Law**
  - Registration of pesticides / Inspection of manufacturing sites, dealers and users
  - Setting standards for water and aquatic organisms

- **Food Sanitation Law**
  - Setting Maximum Residue Limits (MRLs)

**Risk Assessment**

- **Food Safety Basic Act**
  - Setting toxicological reference values such as ADI and ARfD
Agricultural Chemicals Regulation Law
(Enforced 1 July 1948)

- To improve the quality of agricultural chemicals and to ensure their safe and proper use by introducing an agricultural chemical registration system to regulate their sale and use
- Contributing to the conservation of our living environment as well as the protection of human health and stable agricultural production

Food Sanitation Law (Enforced 24 December 1947)

- To prevent the sanitation hazards resulting from eating and drinking by enforcing the regulations and other measures necessary, from the viewpoint of public health
- Ensure food safety and thereby to protect citizens’ good health
Regulatory framework for pesticides in Japan

Manufacturers
- Application for registration
- Registration

Ministry of Agriculture, Forestry and Fisheries
- Establishing standards for pesticides use

Ministry of Health, Labour and Welfare
- Setting MRLs
- Designation of poisonous and deleterious substances

Ministry of Environment
- Establishing standards for withholding of pesticides registration
- Establishing environmental standards for water, soil and others

Food Safety Commission
- Identification of hazard
- Risk assessment
- Establishment of an ADI/ARfD

Survey on pesticide residue conducted by public health department of local governments

Survey on pesticide use conducted by agricultural department of local governments

Request for setting MRLs

Consultation

Hearing opinions

Notifying a result of risk assessment

Consultation

Environmental monitoring conducted by environmental department of local governments
Domestic Procedure (1)

- **FSC**
  - Hazard characterization
  - ADI/ARfD
  - Risk characterization
  - Enforcement

- **MHLW**
  - Intake from food
  - Setting estimates from food
  - Setting MRLs in food
  - Enforcement

- **MOE**
  - Intake from drinking water
  - Ecological toxicity
  - Setting standards for water & aquatic organisms
  - Enforcement

- **MAFF**
  - Receipt of submission
  - FAMIC
  - Evaluation
  - Establishing GAP & guide for safe use
  - Registration

**Applicant**
Domestic Procedure (2)

FSC
- Hazard characterization
  - ADI/ARfD
  - Risk characterization

MHLW
- Intake estimates from food
  - Setting MRLs in food
  - Enforcement

MOE
- Intake from drinking water
- Ecological toxicity
- Setting standards for water & aquatic organisms
- Enforcement

MAFF
- Receipt of submission
  - FAMIC
  - Evaluation
  - Establishing GAP & guide for safe use
  - Registration

Applicant
Domestic Procedure (4)

- FSC
  - Hazard characterization
  - ADI/ARfD
  - Risk characterization
  - Enforcement

- MHLW
  - Intake estimates from food
  - Setting MRLs in food
  - Enforcement

- MOE
  - Intake from drinking water
  - Ecological toxicity
  - Setting standards for water & aquatic organisms
  - Enforcement

- MAFF
  - Receipt of submission
  - FAMIC
  - Evaluation
  - Establishing GAP & guide for safe use
  - Registration

Applicant
APPLICATION OF IMPORT TOLERANCE
MRLs Setting for Import Tolerances (1)

FSC

Hazard characterization

ADI/ARfD

Risk characterization

MHLW

Receipt of Request

Intake estimates from food

Setting MRLs in food

Enforcement

Applicant
MRLs Setting for Import Tolerances (2)

- **FSC**
  - Hazard characterization
  - ADI/ARfD
  - Risk characterization

- **MHLW**
  - Receipt of Request
  - Intake estimates from food
  - Setting MRLs in food
  - Enforcement

Applicant
MRLs Setting for Import Tolerances (3)

FSC

Hazard characterization

ADI/ARfD

Risk characterization

MHLW

Receipt of Request

Intake estimates from food

Setting MRLs in food

Enforcement

Applicant
Guideline for “Import Tolerances”

• Guideline for Application for Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals used outside Japan

(Notification No. 0205001, 5 February 2004 from Director-General, Department of Food Safety, MHLW)

Application of Import MRL

Any person may apply to the Minister of Health, Labour and Welfare for the establishment or revision of MRLs for an agricultural chemical in the case that the chemical is approved in a country for foods exported to Japan.

If the applicant is abroad, an appropriate contact person in Japan should be identified to handle the application.
Data Requirements

<Establishment of MRLs>

• A set of toxicity data and residue data given in “Data Requirements for Supporting Registration of Pesticides” (excluding effects of aquatic animals and plants, effects on beneficial creatures other than aquatic animals and plants, and study data on water contamination)

(Notification No. 12-Nouan-8147, 24 November 2000 from Director-General, Agricultural Production Bureau, MAFF)

http://www.acis.famic.go.jp/eng/shinsei/index.htm
<Revision of MRLs>

• Residue data on target commodities
• If new findings on safety and residue of the applied pesticide have been obtained after MRL was established, documents on the findings should be submitted.

* Applicant must have toxicity data, but the submission shall be made upon request of the MHLW.
• GLP Compliance
In principle, studies should comply with the GLP requirements. If data quoted from studies not conducted by the applicant, prior permission should be obtained from the study authors unless they have been publicized in scientific journals.

• Language
The executive summary should be in Japanese. Other accompanying documents, such as study reports may be written in English. Documents in other languages are not acceptable.
POSITIVE LIST
“Positive List” System

Pesticides, Feed Additives & Vet. Drugs

**Chemicals for which MRLs are established**
- Establishment of provisional MRLs for agricultural chemicals containing Codex Standards, Japanese registration withholding limits, and other standards establishing based upon scientific evaluation
- Acceleration of the establishment of MRLs
- Foods containing chemicals above the MRLs are enjoined from domestic distribution

**Chemicals for which MRLs are not established**
- Establishment of a certain level that is determined to pose no adverse health effects (Uniform limit)
  - 0.01 ppm
- Foods found to contain chemicals above the level are enjoined from domestic distribution

**Chemicals designated by MHLW**
- Chemicals that do not pose adverse health effects
- Not subject to the positive list system
Previous Regulation

Pesticides, Feed Additives & Vet. Drugs

Chemicals for which MRLs are established

- MRLs for 250 pesticides and 33 vet. drugs
- Foods containing chemicals above the MRLs are enjoined from domestic distribution

Chemicals for which MRLs are not established

- Basically, even foods found to contain chemicals are not enjoined from distribution
Official Journal of Food Safety Commission of Japan

Available on J-Stage https://www.jstage.jst.go.jp/browse/foodsafetyfscj
Food Safety is…
A peer-reviewed open-access electronic online journal in English published by the FSCJ.

(published quarterly)

This journal features four types of articles;
- Original articles
- Short communications
- Reviews
- Risk assessments conducted by FSCJ.

Papers dealing with the following areas are particularly welcome:
1. pathogenicity or toxicity of biological, physical, or chemical agents concerning food safety;
2. occurrence of biological, physical, or chemical agents in the food chain with emphasis on food safety;
3. epidemiology or control of food-borne illnesses;
4. safety evaluation of novel foods including nanomaterials, genetically modified organisms, etc.
For further information, please visit our website:
http://www.fsc.go.jp/english/topics/fsc_journal_e1.html
Thank you for your attention!