Establishment of Pesticide MRLs in JAPAN

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Standards and Evaluation Division,
Department of Environmental Health and Food Safety,
Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare
Ensuring Food Safety based on Risk Analysis

Risk Assessment

Food Safety Commission

Food Safety Basic Act

Risk Management

Ministry of Health, Labour and Welfare

Food Sanitation Act, etc.

Ministry of Agriculture, Forestry and Fisheries

Agricultural Chemicals Regulation Act
Feed Safety Act, etc.

Risk Communication
Regulations on Pesticide Residues under Positive List System (since May 2006)

Previous regulations

Pesticides in food

MRLs for Pesticides.

Others Unregulated

Regulations as of May 2006

Pesticides in food

MRLs for Pesticides.

Substances without specific MRLs shall not exceed Uniform standard
Relationship between Intake and Human Health Effect

Intake of a substance (amount of exposure)

Actual use level

ADI

(1/100)

No observed adverse effect level

Lethal amount

Human health effect

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Confirm that TMDI (theoretical maximum daily intake) does not exceed 80% of the ADI (Acceptable Daily Intake).

Confirm that chemical intake from every food does not exceed ARfD.

Take into consideration vulnerable groups: infants, children, pregnant women, and elderly people.

Set MRLs, according to each crop, farm animal, and fishery product.
Exposure Estimate on the bases of ADI and ARfD

Estimate of **total intake** from every foods (=long term exposure estimate)

Safety Level (80% of ADI)

Estimated Exposure amounts

Pesticide Intake from Food A

Pesticide Intake from Food B

Pesticide Intake Form Food Z

Estimate of **intake** from every foods (= Short term exposure estimate)

Safety Level (ARfD)

Estimated Exposure amounts (for every foods)

Pesticide Intake from Food A

Pesticide Intake from Food B

Pesticide Intake from Food Z
How to Set Pesticide MRLs

- MRLs should be set higher enough than the measured values to overcome the variance of actual residue levels derived from various factors including:
  - Species
  - Climate
  - Growing conditions

Note: It is likely that the test results of pesticide residues in agricultural products often follow a lognormal distribution pattern.

MRLs should be set higher enough to ensure that they will not be exceeded by the actual residue levels when the pesticides are used properly.
Import Tolerance (IT) System

• The IT system enables the Japanese government to set MRLs for pesticides in food products that are imported in Japan.

• Applicants can request the MHLW to newly set MRLs or set MRLs higher than the corresponding Japan’s MRLs.

• Applicants required to submit documents supporting the safety of target pesticides.
The Examples of required documents

- Acute oral toxicity tests
- Acute dermal toxicity tests
- Acute inhalation toxicity tests
- Skin irritation tests
- Eye irritation tests
- Skin sensitization tests
- Acute neurotoxicity tests
- Acute delayed neurotoxicity tests
- 90-day repeated dose oral toxicity tests
- 21-day repeated dermal toxicity tests
- 90-day repeated inhalation toxicity tests
- Repeated dose oral neurotoxicity tests
- 28-day repeated delayed neurotoxicity tests
- 1-year repeated dose oral toxicity tests
- Carcinogenicity tests
- Reproductive toxicity tests
- Teratogenicity tests
- Mutagenicity tests
- Pharmacology tests
- Tests in regard to prospective fate in animals
- Tests in regard to prospective fate in plants
- Tests in regard to prospective fate in soil
- Tests in regard to prospective fate in water
- Tests in regard to the properties, stability, degradability, etc. of active ingredients
- Tests in regard to persistence in crops
Thank you for listening

For further information on Import Tolerance applications, please go to: