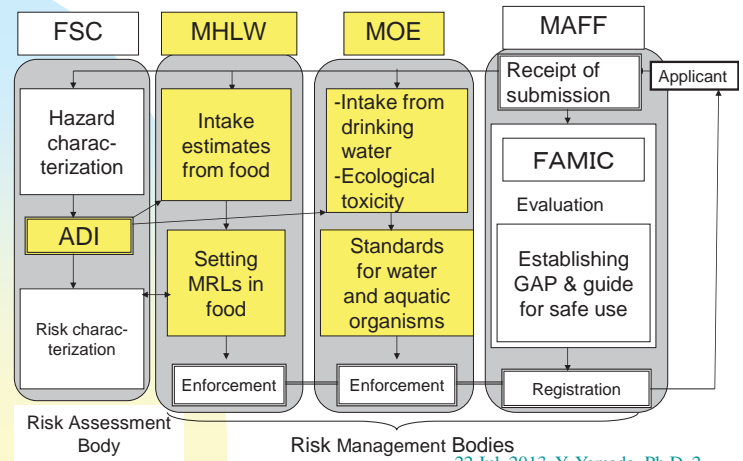


Japan's So-called "Positive List" of Pesticide and Veterinary Drug Residues and Related Issues

Yukiko Yamada, Ph.D.

AC Registration and MRLs Setting



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Basic Principles of "Positive List"

According to the Ministry of Health, Labour and Welfare (MHLW) responsible for the positive list:

- The daily dietary intake of agricultural chemical residues should not exceed 80% of the ADI.
- In order to test food commodities, MRLs are necessary.

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"Positive List"?

- List of chemical/food commodity combinations to be regulated/tested.
- To prohibit the distribution of foods containing residues of pesticides or veterinary drugs above MRLs
- Different meaning from a positive list of food additives, which contains permitted uses of food additives
- Banned chemicals are included

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Chemicals Included in "Positive List"

- Agricultural chemicals, i.e., pesticides
- Veterinary drugs
- Feed additives (vitamins or additives related to the quality of feed are not included)
- Not only those used in Japan but also those used overseas

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Chemicals Not Subject to "Positive List"

- No potential to cause harm to human health even if present in food at a certain level
- Those pesticides specified in the Agricultural Chemical Regulation Law
- Those for which no MRLs were set in other countries and whose uses were not restricted.

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Foods Included in “Positive List”

- Conceptually all foods including processed foods
- Shown on the list are agricultural produce, i.e., vegetables, fruits, cereals, nuts, foods of animal origin

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Positive List System for Agricultural Chemical Residues

【 Previously 】

Pesticides, Feed Additives, and Veterinary Drugs

Chemicals for which MRLs are established

283 substances

MRLs for 250 pesticides and 33 veterinary drugs

Foods with chemicals above the MRLs are excluded from the market

Chemicals for which no MRLs are established

If foods are found to contain chemicals, they could be sold in the market.

【 Positive List System 】 May 29, 2006-

Pesticides, Feed Additives and Veterinary Drugs

Chemicals for which MRLs are established

799 substances

Establishment of provisional MRLs for agricultural chemicals, considering Codex MRLs, Japanese registration withholding limits, and other standards established based on scientific evaluation

758 substances

Acceleration

Foods with chemicals above the MRLs are excluded from the market

Chemicals for which no MRLs are established

Establishment of a certain level that is determined to pose no adverse health effects

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

65 substances

Not subject to the positive list system

©MHLW

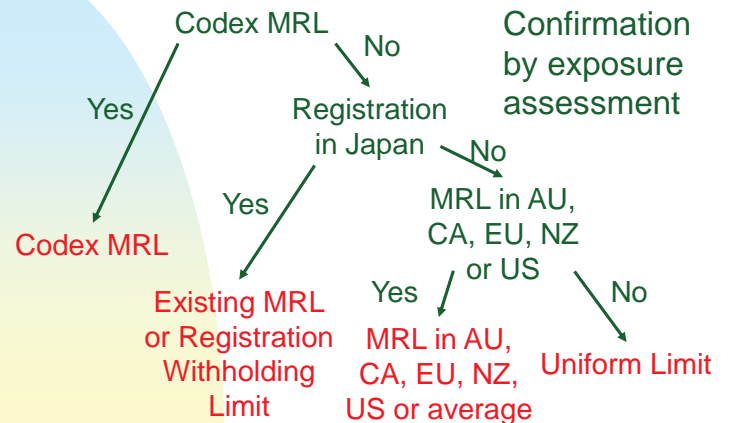
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“Positive List” contains

- New standards using Codex MRLs and others for 758 chemicals (- >799)
- Uniform Limit at 0.01 ppm
- Designation of 65 exempted chemicals
- Analytical methods were developed for testing and inspection

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Procedure for “Positive List”



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Special Consideration of antimicrobials

- Antibiotics and antibacterials shall not be contained in any food

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Naturally Occurring Chemicals

When the ingredients of pesticides are identical to naturally occurring substances in food and remain at quantities equivalent to naturally occurring concentrations

→ Uniform limit of 0.01 ppm does not apply in principle

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Processed Foods

- For the processed foods for which Codex MRLs have been recommended, the Codex MRLs are used as the provisional MRLs.
- The Codex rule applies.
- If no Codex MRLs exist, initially use 0.01 ppm for judgment and then study violation probability for individual products.

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Some Problems

- Risk assessment takes long time
- Slow to follow the changes in Codex
- Short-term dietary exposure assessment is yet to start
- It is not possible to know whether the value is import tolerance or MRL for registered use
- MHLW says, "MRLs are safety-based standard."
- Obsolete data requirements for registration

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Reformation of Pesticide Registration

Principles for reformation (2007 -)

- Law-based & hazard-based → risk-based
 - Decision-making on a basis of scientific data / information taking into account magnitude of risk
- Participation in international rule-making in the Codex Alimentarius Commission, OECD, etc.
- Harmonization with their rules
- Transparent decision-making through risk communication with all stakeholders

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Reformation Agreed new approach

- Increased No. of trials
 - Major crops (22) 2 → 6 trials
 - Semi-major crops (34) 2 → 3 trials
 - Minor crops (Others) 2 trials
- Potential decrease in requirements
 - Development of crop groups
 - Acceptance of data on indoor trials conducted outside of Japan, but GAP must be same as Japan
- Quality assurance of analysis

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Reformation Agreed new approach (2)

- Guidelines for Livestock Metabolism and Feeding Studies
 - Criteria for need for these studies established
 - on a basis of residues in feed crops and the animal dietary burden
 - for already registered AC taking into consideration potential maximum animal dietary burden and fat-solubility
 - Animal Feeding Table already established and provided to OECD

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Reformation Ongoing work

- Development of Crop Groups
 - Based on the Codex Classification
 - Reflecting the commodities in Japan
 - Harmonization of portions to be analyzed with those of Codex
- Selection of Representative Crop
 - Representative crop(s) for each group for group MRL and registration
 - Actual use of ACs in Japan considered
 - No. of trials for each representative crop
 - Stepwise process for crop groups

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Maximum Levels for Contaminants in Foods

- Previously, allocation of portions of TDI to food commodities
- It was decided to use the ALARA Principle applied to surveillance data
 - Example: Cd in rice
 - In the feed area the ALARA Principle had been used.

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MRL/ML for Feed (MAFF)

- Pesticide residues and contaminants (mostly heavy metals and mycotoxins) are subject to regulation
- Pesticide residues: following the JMPR methodology
- Contaminants: following Codex General Standard on Contaminants and Toxins in Foods and Feeds. Use of the ALARA Principle
- For pesticides, MRLs for foods of animal origin are also estimated.

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Import tolerance for food and feed

- When a new MRL is needed or a higher MRL is need for food/feed exported to Japan
- Request MHLW (food) or MAFF (feed) to establish import tolerance
- Anybody can apply
- No charge
- Data requirements are found on the MHLW or MAFF website in English

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Information on Website

- Positive List
<http://www.mhlw.go.jp/english/topics/foodsafety/positivelist060228/>
- Application for Import Tolerance
<http://www.mhlw.go.jp/english/topics/foodsafety/residue/index.html>
- Available in English

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**Thank you for
your attention!**