

Experience Sharing on Current Practice in
..... Establishing Import Tolerances for
Pesticide Residues in Food

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Food and Drug Administration

Introduction

- Food and Drug Administration is responsible for **establishing maximum residue limits** (MRLs). All food products, imported and domestic, must comply with "Standard for Pesticide Residue Limits in Food", which lists allowable residue tolerances.
- We accept **MRL applications** on imported products from interested parties. The application process is open and transparent. It is free of charge.
- The purpose of this presentation is to share information in setting import tolerances.

Broad Principles of Setting MRLs



Based on Scientific Evidence

- The levels at which the MRLs set are in consideration with local dietary patterns and intake levels, and ultimately are established on the basis of risk assessment results
- Using internationally accepted risk assessment methodologies
- Refer to “APEC Import MRL Guideline for Pesticides”



Refer to International Standard

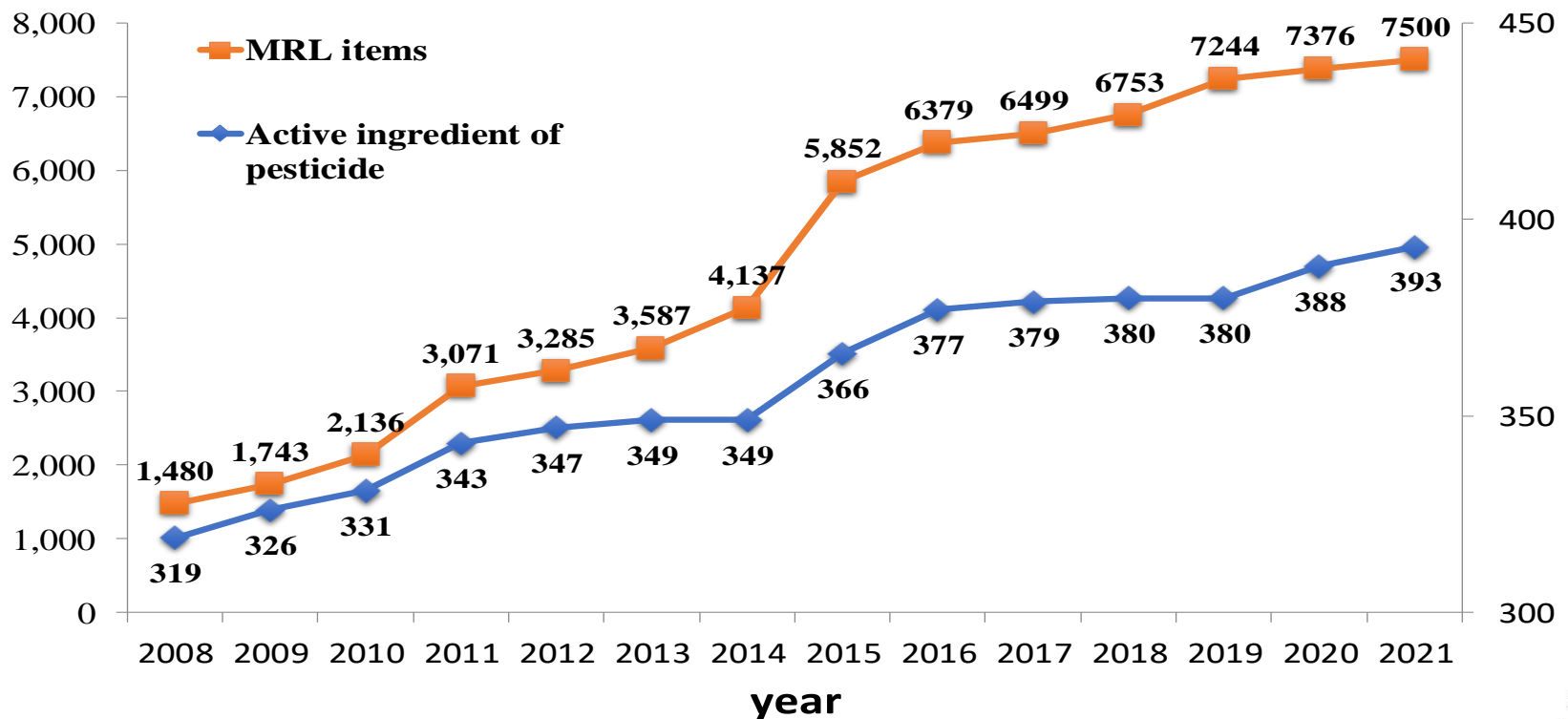
- Establishing pesticide MRLs with international standards as references
- Codex, US, EU, Japan, Australia, etc.
- Consistent with WTO SPS obligations

Standards for Pesticide Residue Limits in Foods

- According to Article 15 of “Act Governing Food Safety and Sanitation”
- Consist of 5 Appendix Tables
 - Appendix Table 1- Maximum Residue Limits
 - Appendix Table 2- Extraneous Residue Limits
 - Appendix Table 3- List of Pesticide MRLs Omitted
 - Appendix Table 4- Pesticide Prohibited for Use
 - Appendix Table 5- Classification of Crops for the Pesticide Residue Limits in Foods
- There are currently **7,500** MRLs in this standard

Positive List System

- A positive list system managing the pesticide residues in foods is set starting from 2008.
- Pesticides not listed in the standard shall not be detected in foods.
- The default tolerance for most pesticide residues is 0.01 ppm (limit of quantification of the analytical method)

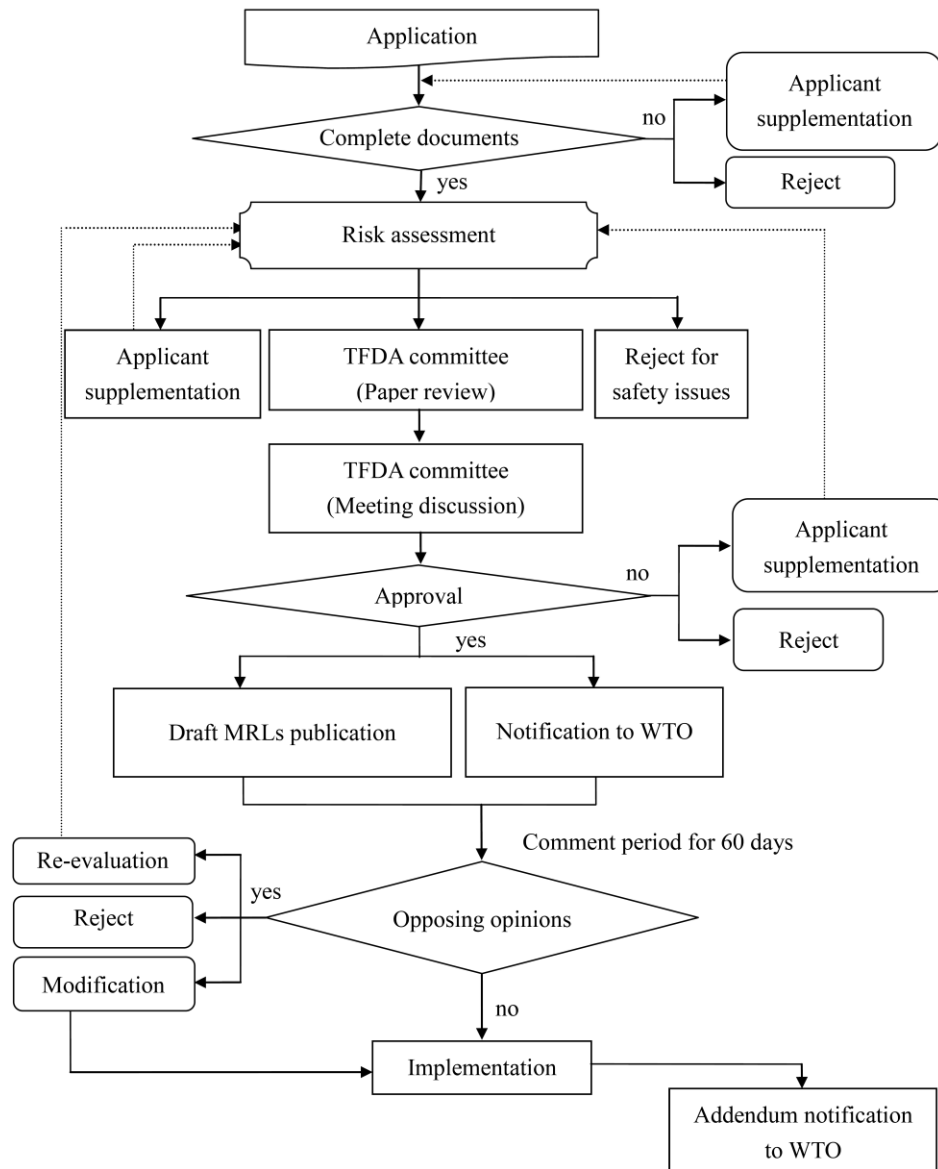


The Information Required to Submit

- Applicant information
- Common name
- Commercial name or code
- Chemical name
- Chemical Abstracts Service (CAS) Number
- Chemical class
- Functional class
- End-product name, content (%), and any risk impurity
- Commercialized countries
- Registered use (GAP)
- Physical & chemical characteristics (GLP)
- Toxicology data (GLP)
- Metabolism in animal (GLP)
- Metabolism in plant (GLP)
- Analytical methods
- Residue trial data (GLP)
- International banned and restricted data, MRLs and ADI of applied pesticide



Procedures for Establishing MRLs



Dietary Exposure Assessment

No Observed Adverse Effect Level (**NOAEL**)



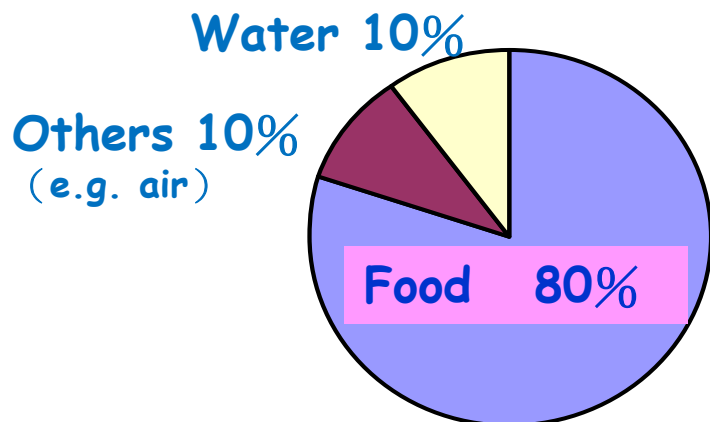
÷ **Safety Factor (100~1000)**

Acceptable Daily Intake per kg body weight (**ADI**)



× **average weight (60 kg)**

The acceptable daily intake per person



Upper limits for ADI

TMDI (theoretical maximum daily intake):

< 80% ADI → **accept proposed MRLs**

≥ 70%, < 80% ADI → **assessment for the groups susceptible to pesticides (infants, children, etc.)**

≥ 80% ADI → **adjust or reject proposed MRLs**

Online Search for MRL Application Status

- For facilitating the **transparency of application progress** for import tolerances, we have set up a **MRL inquiry system** for applicants to check the progress of their applications online.

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● 農委會提送審查中案件查詢 (目前無待審案件)

Summary

Based on Science for Safety

- Set reasonable pesticide MRLs to protect public health and safety by following the scientific principles

Facilitating Trade

- International cooperation to harmonize import MRLs, taking both food safety and trade facilitation into consideration

Risk Communication

- Strengthen risk communication to public

Thank you for your patience



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