

2022 MRL Harmonization Workshop
May 25-26, 2022
San Francisco, CA

Taiwan MRL Positive List Update & Enforcement

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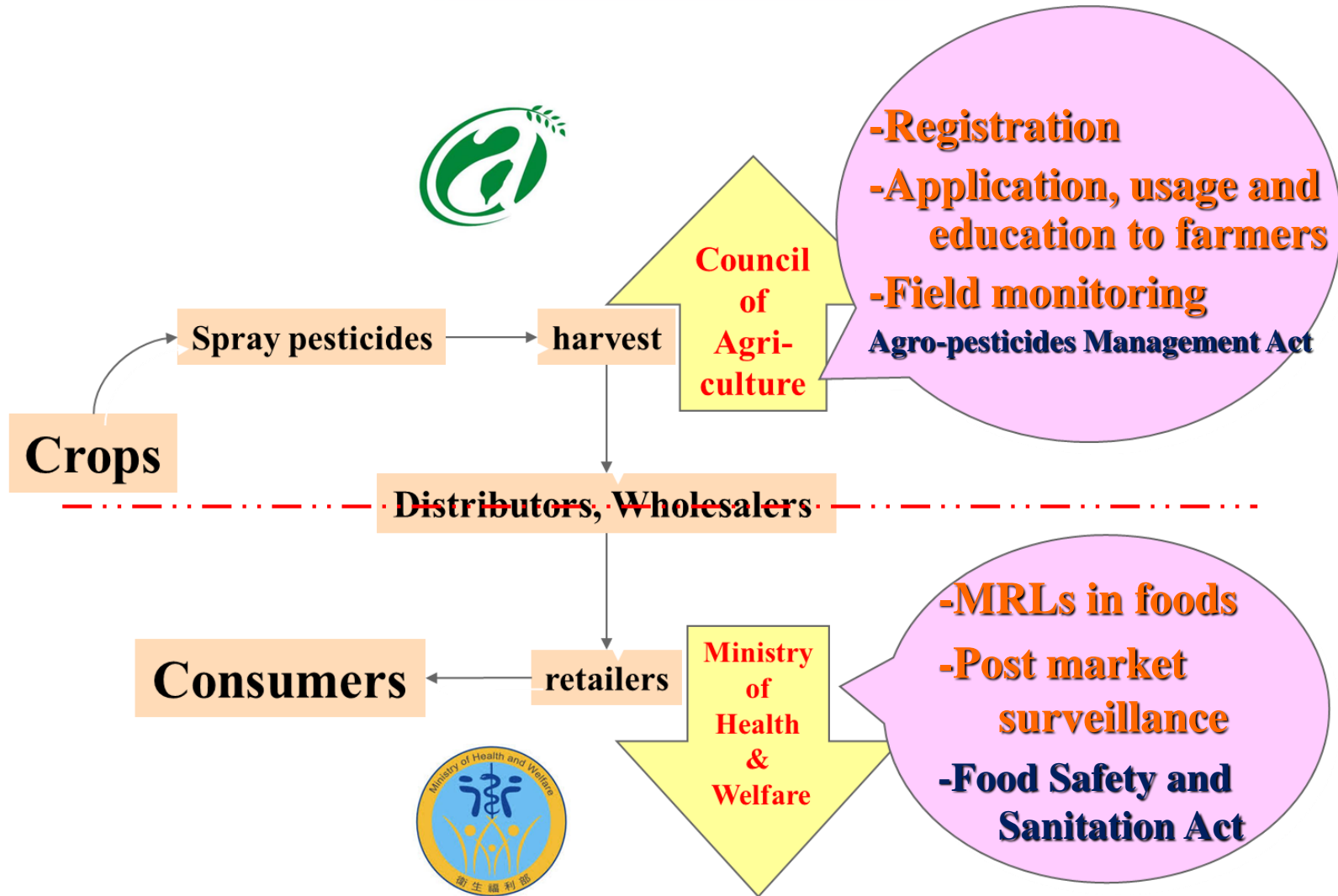
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Food and Drug Administration

<http://www.fda.gov.tw/>

Outline

- Positive List System
- Enforcement
- MRL Establishment
- Future Prospects

Government Agencies for Pesticides Management in Taiwan



Introduction

- In Taiwan, imported food and agricultural products must comply with a range of laws designed to protect human health and prevent the introduction of animal and plant pests or diseases.
- Taiwan's "[Act Governing Food Safety and Sanitation](#)" went into force on February 5, 2014. It designates the [Ministry of Health and Welfare](#) as the central competent authority responsible for [food safety](#). All major laws, regulations, rules, and ordinances concerning food safety are based on Act Governing Food Safety and Sanitation.

Introduction

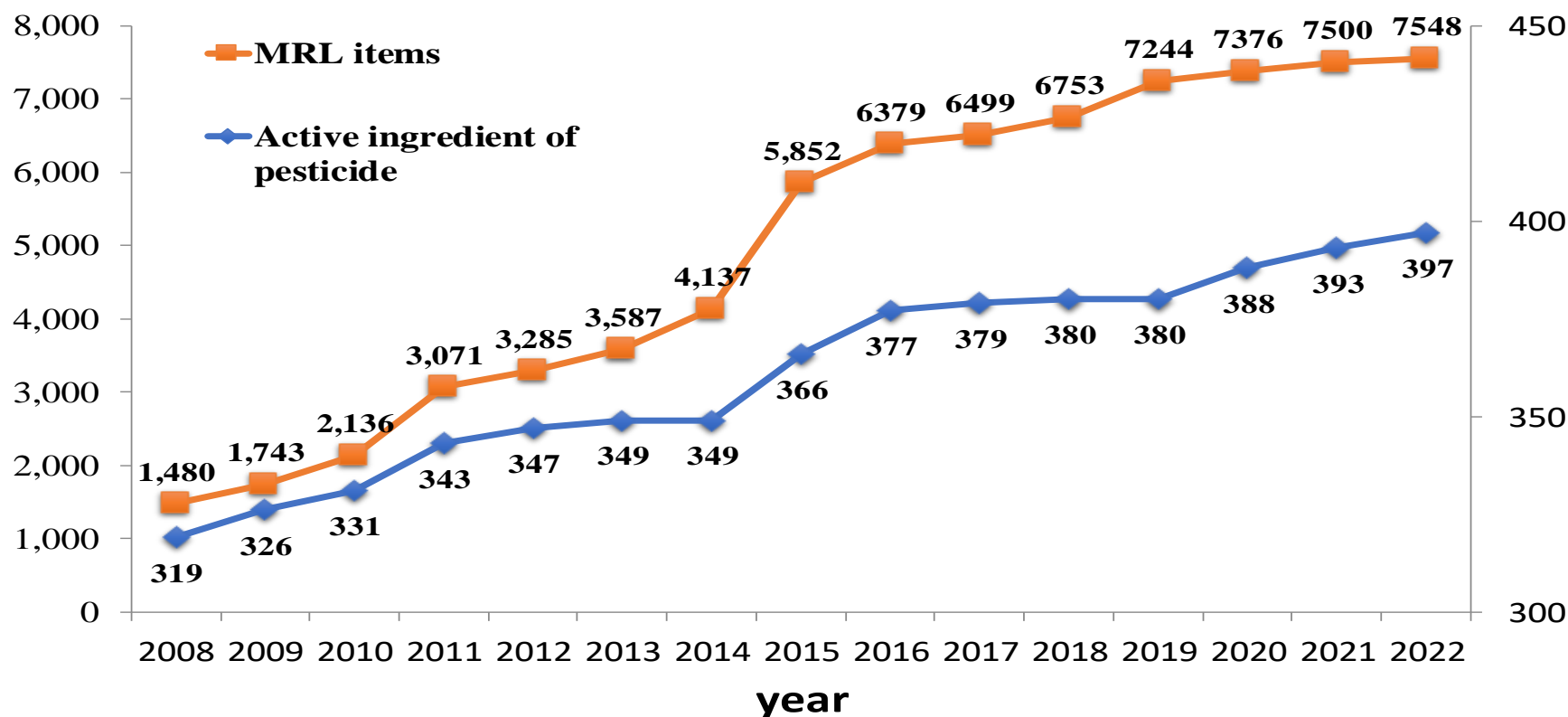
- According to [Article 15](#) of Act Governing Food Safety and Sanitation, [food with pesticide residue exceeding the permissible tolerance](#) shall not be manufactured, processed, prepared, packaged, transported, stored, sold, imported, exported, presented as a gift or publicly displayed.
- The standards governing the permissible tolerance of pesticide residue shall be prescribed by the central competent authority through consultation with the relevant authorities.

Introduction

- Taiwan Food and Drug Administration, Ministry of Health and Welfare is responsible for **establishing maximum residue limits** (MRLs).
- All food products, imported and domestic, must comply with "**Standards for Pesticide Residue Limits in Food**", which lists allowable residue tolerances.
- Taiwan Food and Drug Administration accepts **MRL applications** on imported products from interested parties. The application process is open and transparent. It is free of charge.

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.



Standards for Pesticide Residue Limits in Foods

- **Article 1**

The Standards are prescribed in accordance with the provisions of the second paragraph of Article 15 of the Act Governing Food Safety and Sanitation.

- **Article 2**

Both the maximum residue limits referred in the Standards and the actually examined residues of pesticides are calculated on the basis of the weights of the produces in the forms on market.

The examination of pesticide residues shall include the pesticide itself and its metabolites.

- **Article 3**

The pesticide residues in foods except animal products shall meet the Standards for the Pesticides Residue Limits in foods Table and Extraneous Residue Limits Table, as Appendix Table 1 and Table 2. Pesticides not listed in the Table shall not be detected.

Standards for Pesticide Residue Limits in Foods

- **Article 4**

Pesticides listed in the Appendix Table 3 are highly safe, it is not necessary to set the maximum residue limits and examine their residues.

- **Article 5**

No residue shall be detected for the pesticides prohibited for use by the agriculture authority, unless other regulations apply. The names of such pesticides are listed in the Appendix Table 4.

- **Article 6**

The classification of crops referred in the Standards for pesticide residue limits in foods Table are listed in the Appendix Table 5.

- **Article 7**

The Standards shall be implemented from the date of promulgation.

Standards for Pesticide Residue Limits in Foods

- 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 7,548 MRLs in this standard

Standards for Pesticide Residue Limits in Foods

Appendix Table 1

Pesticide Name	Crop Category	MRL(ppm)	Remark
2,4-D	Asparaguses	1.0	Herbicide
2,4-D	Cherries	0.2	Herbicide
2,4-D	Citrus	2.0	Herbicide
2,4-D	Cranberries	0.1	Herbicide
2,4-D	Grapes	0.1	Herbicide
2,4-D	Sugarcane	0.05	Herbicide
Abamectin	Almonds	0.01	Insecticide
Abamectin	Apples	0.02	Insecticide
Abamectin	Citrus	0.01	Insecticide
Abamectin	Fruit vegetables	0.02	Insecticide
Abamectin	Leaf vegetables with small leaves	0.05	Insecticide
Abamectin	Leaf vegetables with wrapped leaves	0.02	Insecticide

Standards for Pesticide Residue Limits in Foods

Appendix Table 2
Extraneous Residue Limits

Pesticide Name	Crop Category	Maximum Residue Limit (ppm)
Chlordane	Ginseng (fresh)	0.02

- The extraneous residue limits refer to the standards of residues arising from persistent compounds in the environment that were once used as pesticides.

Standards for Pesticide Residue Limits in Foods

Appendix Table 3 List of Pesticide MRLs Omitted

Pesticide Name		
Azadirachtin	Cytokinins	Potassium hydrogen carbonate
<i>Bacillus subtilis</i>	DL-methionine	Riboflavin
<i>Bacillus thuringiensis</i>	Fatty alcohols	Sex pheromone of <i>Spodoptera exiqua</i>
Blasticidin-S	IBA	Sex pheromone of <i>Spodoptera litura</i>
Calcium carbonate	Lime & Sulfur	Sodium nitrophenol
CITCOP	NAA, sodium salt	Streptomycin
Copper chelate	n-Decanol	Sulfur
Copper oxychloride	Nonylphenol coppersulfonate	Tetracycline
Copper sulfate	Oxytetracycline	Tribasic copper sulfate
Cupric hydroxide	Petroleum oils	Validamycin A
Cuprous oxide	Polyoxins	

Standards for Pesticide Residue Limits in Foods

Appendix Table 4
Pesticide Prohibited for Use

Pesticide Name					
Organic mercury	Chlorobenzilate	Daminozide	Dienochlor	Smite	Fensulfothion
Endrin	Toxaphene	Folpet	EPN	Conen	Formothion
DDT	PCP-Na	Cyhexatin	Azocyclotin	Buthiobate	Cycloprate
Heptachlor	EDB	PCNB	TPTA	Ditalimfos	Pyracarbolid
Aldrin	γ-BHC (Lindane)	Dinocap	TPTH	Carbophenothion	Aziprotryne
Dieldrin	Dinoseb	Dinobuton	Zineb	Demephion	Glyodin
BHC	Cyanazine	Aldicarb	Binapacryl	Mephosfolan	Etrimfos
Leptophos	Dichloropropane Dichloropropene	Chlornitrofen, CNP	Methyl Bromide	Dialifos	Promecarb
Nitrofen	Fenchlorphos	Tetradifon	Benzoximate	Salithion	Fensulfothion
DBCP	Captafol	MNFA (Nissol)	Chlorophylate	Bromophos	Formothion
Prothoate (40%EC)	Mecarbam (35%EC)	Endosulfan			

Standards for Pesticide Residue Limits in Foods

Appendix Table 5

Classification of Crops for the Pesticide Residue Limits in Foods

Rice	Wheat and Barley	Other cereals and crops	Leaf vegetables with wrapped leaves	Leaf vegetables with small leaves
Dry beans	Melon vegetables	Fruit vegetables	Roots, bulb and tuber vegetables	Peas and beans
Sprouts	Melons	Pome	Large berries	Small berries
Drupe	Tree nuts	Citrus	Mushrooms	Herbs and spices
Sugarcane	Tea			

Standards for Pesticide Residue Limits in Foods

Appendix Table 5

Classification of Crops for the Pesticide Residue Limits in Foods

Large berries

Banana, papaya, pineapple, kiwi fruit, sweet sop, avocado, pitaya, passion fruit, mangosteen, durian, rambutan, pomegranate, etc.

Small berries

Grape, strawberry, carambola, wax apple, guava, caneberry (raspberry, blackberry, etc), cranberry, blueberry, mulberry, fig, black currant, etc.

Fruit vegetables

Tomato, eggplant, sweet pepper, hot pepper, daylily, Lycii fructus, okra, roselle, etc.

Melon vegetables

Cucumber, baby cucumber, bitter melon, luffa, wax gourd, pumpkin, bottle gourd, vegetable pear, oriental pickling melon, summer squash, etc.

Standards for Pesticide Residue Limits in Foods

Website Link:

<http://www.fda.gov.tw/ENG/lawContent.aspx?cid=16&id=304>

Food and Drug Administration, Department of Health

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Food

Standards for Pesticide Residue Limits in Foods

【Update Date : 2022-04-19】
【Announced Date : 2008-10-21】
【Amended Date : 2022-04-19】

Standards for Pesticide Residue Limits in Foods

Links

- Standards for Pesticide Residue Limits in Foods

Security Policy | Privacy Policy

ADD : No.161-2, Kunyang St, Nangang District, Taipei City 11561, Taiwan (R.O.C.) MAP
TEL : 886-2-2787-8000
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無障礙標準 2.0 GOV

Official Analytical Methods for Pesticide Residue in Foods

Promulgated, Jul 10, 2012

Amended, Sep 9, 2013

Amended, Jul 3, 2014

Amended, Aug 31, 2017

Amended, May 10, 2019

Method of Test for Pesticide Residues in Foods - Multiresidue Analysis (5)

1. Scope

This method is applicable for the determination of 380 pesticide residues (abamectin etc. listed in the attached tables) in fruits and vegetables, crops, dried beans, tea, spice plants and other herbs.

Table 1. MRM parameters and LOQs of 193 pesticides including abamectin etc. and the internal standard (LC-MS/MS positive ion mode)

No.	Analyte	Quantitative ion pair			Qualitative ion pair			LOQ (ppm)		
		Precursor ion (<i>m/z</i>) > product ion (<i>m/z</i>)	Cone voltage (V)	Collision energy (eV)	Precursor ion (<i>m/z</i>) > product ion (<i>m/z</i>)	Cone voltage (V)	Collision energy (eV)	Fruit and vegetable ^a	Crop ^b	Tea ^c
1	Abamectin	890.5 > 567	17	16	890.5 > 305	17	17	0.01	0.01	0.05
2	Acephate	184 > 143	18	8	184 > 125	18	18	0.01	0.02	0.05
3	Acetamiprid	223 > 56	20	15	223 > 126	20	15	0.01	0.02	0.05
4	Acibenzolar-S-methyl	211 > 136	34	32	211 > 91	34	18	0.01	0.02	0.05
5	Aldicarb	208 > 116	10	8	208 > 89	10	8	0.01	0.02	0.02
6	Aldicarb sulfone	223 > 86	20	5	223 > 166	20	5	0.01	0.02	0.02
7	Aldicarb sulfoxide	207 > 89	16	10	207 > 132	16	10	0.01	0.02	0.02
8	Alloxymid (sodium)	324 > 234	25	15	324 > 266	25	11	0.01	0.02	0.05
9	Ametoctradin	276 > 149	35	30	276 > 176	35	30	0.01	0.02	0.05
10	Ametryn	228 > 186	32	19	228 > 96	32	25	0.01	0.02	0.05

Official Analytical Methods for Pesticide Residue in Foods

Website Link:

<http://www.fda.gov.tw/ENG/SiteList.aspx?sid=10358&s=814>

Analytical Methods - Food - Analytical Methods & Research - Science and Research - Food and Drug Administration, Department of Health

www.fda.gov.tw/ENG/SiteList.aspx?sid=10358&s=814

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Science and Research

- Testing Service and Process
- Fee-Charging Standards for Lot Release, Reference Materials, and Testing of Foods, Drugs and Cosmetics
- Analytical Methods & Research
- Statistics

Analytical Methods

Category :

Regional search :

No.	Title	Date
1	Method of Test for Pesticide Residues in Foods- Test of Ethylene Oxide	2022-04-28
2	Method of Test for Pesticide Residues in Foods - Multiresidue Analysis (6)	2022-04-28
3	Method of Test for Pesticide Residues in Livestock and Poultry Products - Test of 2,4-D and Fenbutatin Oxide	2022-04-28
4	Method of Test for Pesticide Residues in Livestock and Poultry Products- Multiresidue Analysis	2021-01-18
5	Method of Test for Pesticide Residues in Foods - Test of Dithiocarbamates, Fungicides (2)	2020-01-13
6	Method of Test for Pesticide Residues in Foods - Multiresidue Analysis (5)(380)	2020-01-13

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Evolution and Development of Official Analytical Methods

Improvement of extraction method

Traditional liquid-liquid extraction



Time-consuming,
Large solvent
consumption

12 hour



Diatomaceous
earth column

Improve
extraction rate

8 hour

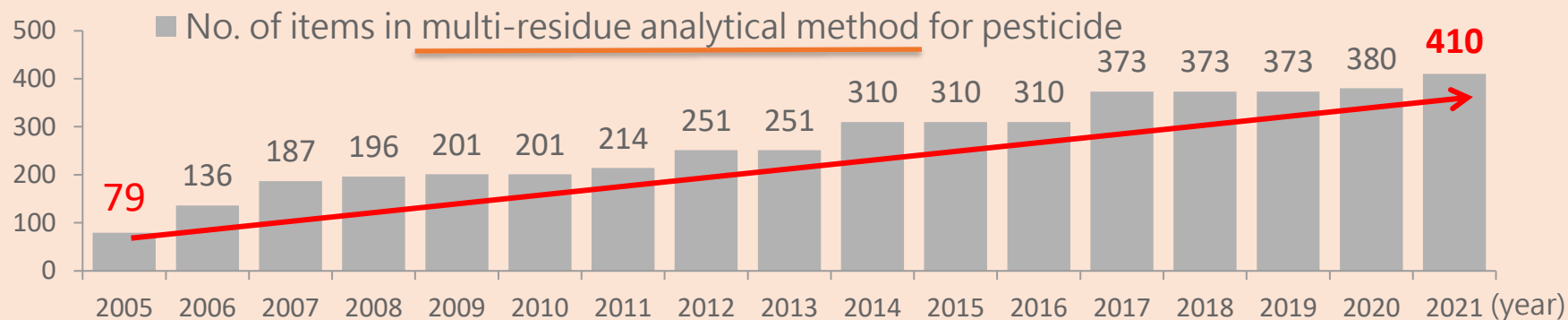
QuEChERS
technique



Fast, easy, eco-
friendly, stable and
safe to operate

1 hour

Evolution and Development of Official Analytical Methods



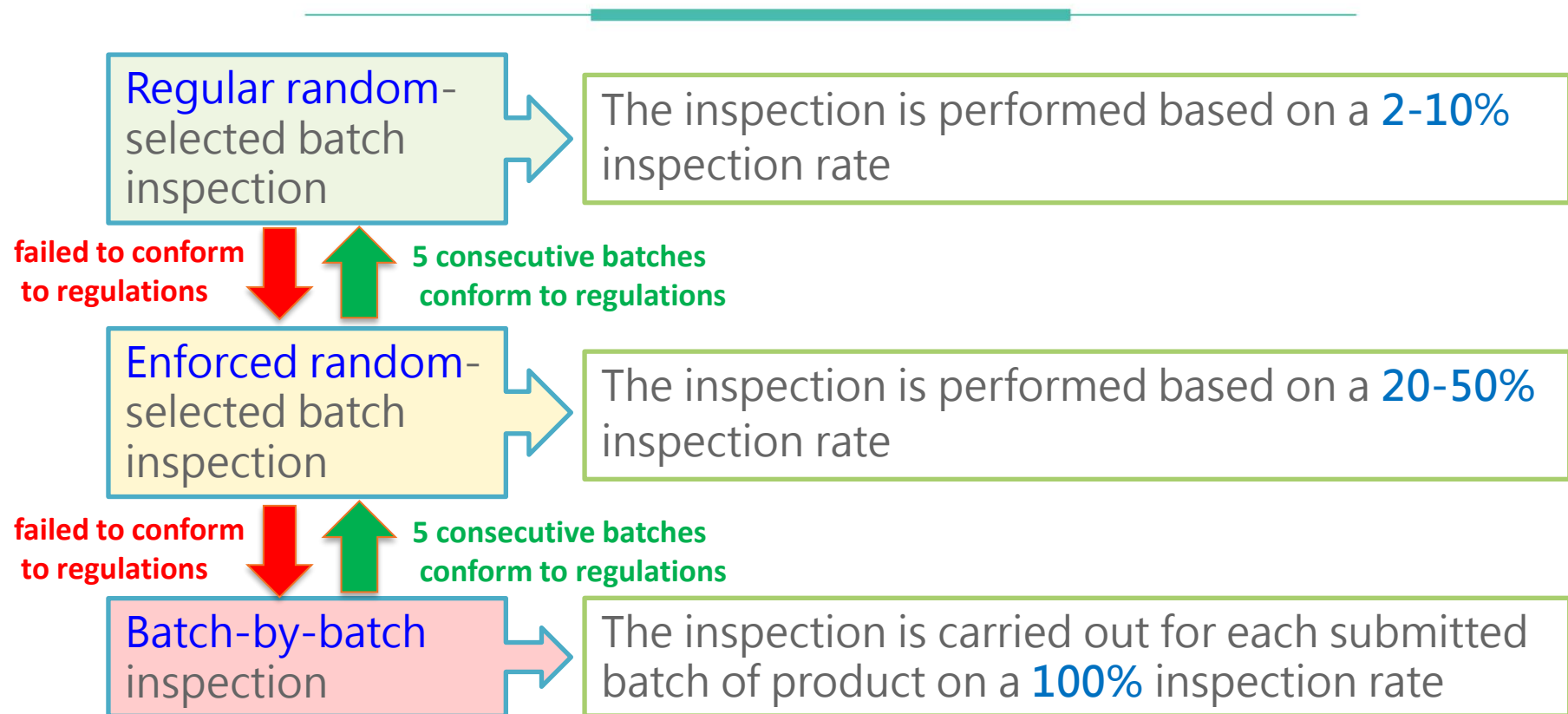
Total number of testable items for pesticide methods: **450**

- The analytical methods, including extraction methods and analytical instruments are the same as most developed countries in the world.

Frequency of Inspection for Imported Food at the Border

- Imports of fruit, vegetables, meat and other food products are subject to inspection by TFDA inspectors at the port of entry for pesticide residues, veterinary drug residues, heavy metals, mycotoxins and so on.
- According to the “Regulations of Inspection of Imported Food and Related Products” , after a single violation, the inspection frequency of the same commodity imported by the same importer will be elevated (e.g. from 2-10% regular random inspection rate to a 20-50% reinforced inspection rate).
- Following two consecutive violations, inspections may increase from the elevated 20-50% rate to 100% batch-by-batch inspections.

Frequency of Inspection for Imported Food at the Border



- The "Regulations of Inspection of Imported Foods and Related Products" was amended in June 2019.

Website Link:

<http://www.fda.gov.tw/ENG/lawContent.aspx?cid=5094&id=3068>



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Penalties for Violations

- Imported Food not complying with pesticide residue standards **at the border** will be **returned or destroyed**.
- Domestic Food not complying with pesticide residue standards **in the market** will be **recalled**.
- All imports are subject to border inspection upon arrival. Local products are also subject to surveillance and monitoring.
- Whether imported or domestic food is subject to the same laws and regulations, violations are subject to the same penalties.

MRL Establishment

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

Procedures for Establishing MRLs

- Domestic MRLs:

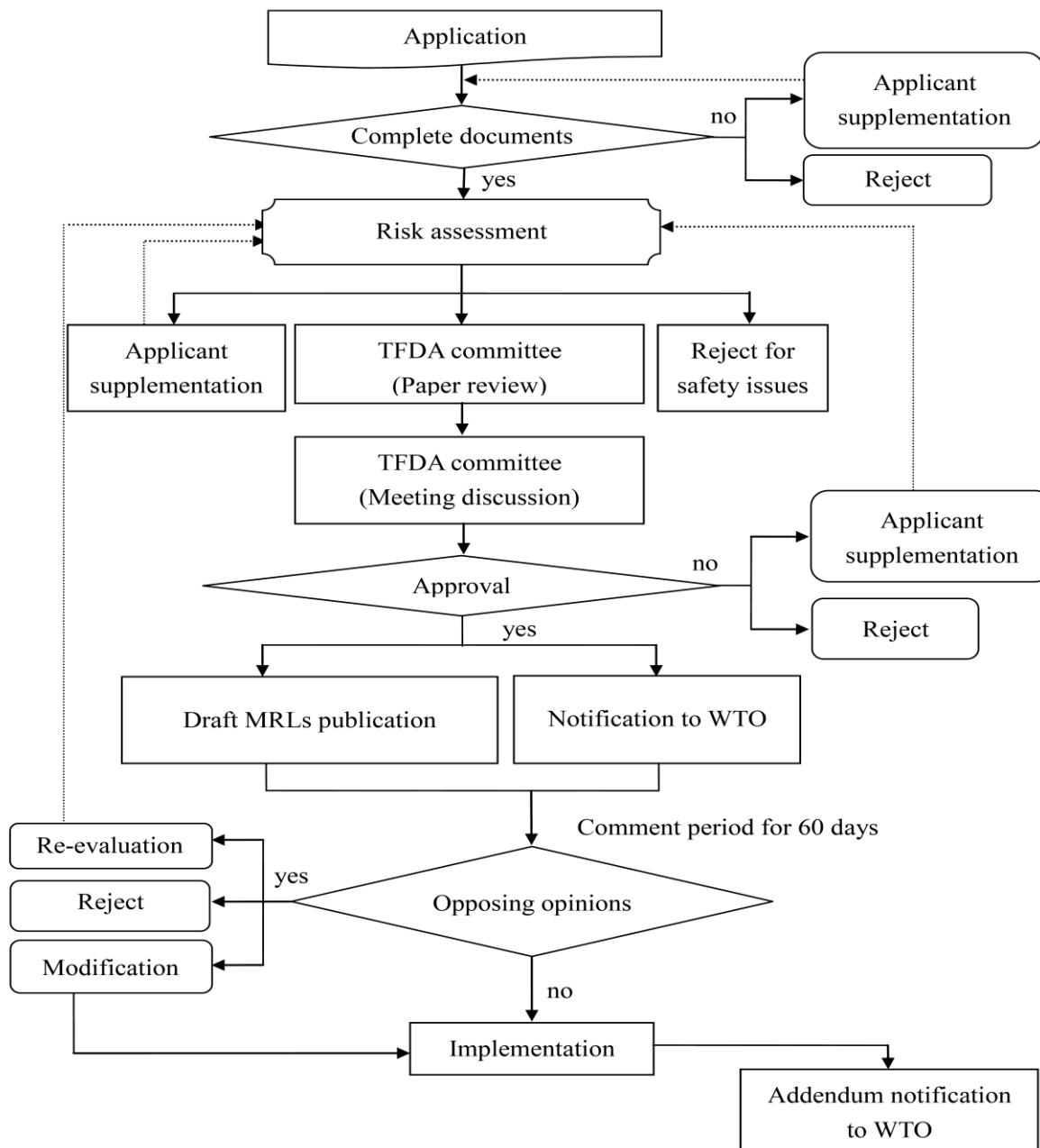
- Council of Agriculture (COA) evaluates toxicity, metabolism situations, etc. of applied pesticides and proposes a MRL.
- Ministry of Health and Welfare (MOHW) takes proposed data of COA into consideration and conducts the assessment of Taiwanese dietary exposure for an official MRL.
- The result of evaluation approved by advisory committee of MOHW will become an official MRL.

- Import MRLs:

- MOHW receives an application from the trading countries or industries and conducts an evaluation of all necessary documents.
- The result of evaluation approved by advisory committee of MOHW will become an official MRL.

➡ Follow the national treatment principle of WTO, the official MRLs apply to both domestic and imported crops.

Procedures for Establishing MRLs



Relevant Agencies



<https://tnfcds.nhri.edu.tw/index.php?action=index>



<http://www.fda.gov.tw/EN/index.aspx>



<http://www.baphiq.gov.tw/homeweb5.php>



<http://www.tactri.gov.tw/e-intro.asp>

The Information Required to Submit for Establishing MRLs

- 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

Website Link:

<https://www.fda.gov.tw/TC/site.aspx?sid=37&r=734730225>



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Dietary Exposure Assessment

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



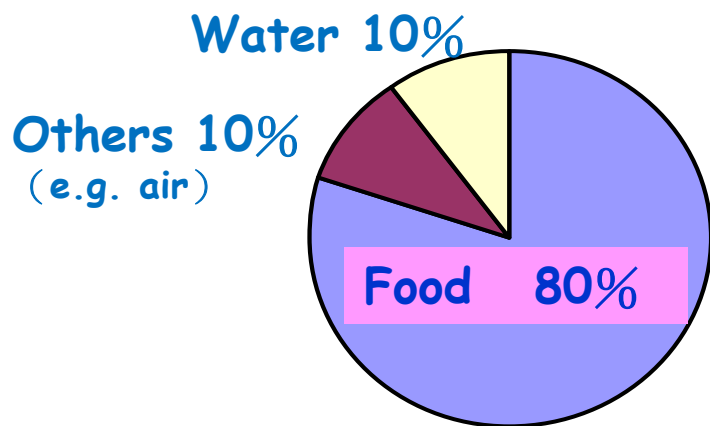
÷ Safety Factor (100)

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

≥ 80%ADI → adjust or reject proposed MRLs

MRL Inquiry System for 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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熱門關鍵字：食品添加物 營養標示 非登不可 基因改造

公告資訊 機關介紹 業務專區 法規資訊 便民服務 出版品 政府資訊公開 個人化服務 **1**

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or

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3

● 農委會提送審查中案件查詢

Access the homepage of TFDA:
(<http://www.fda.gov.tw/TC/ResidueApplyQuery.aspx>)

Future Prospects

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



Q&A
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