

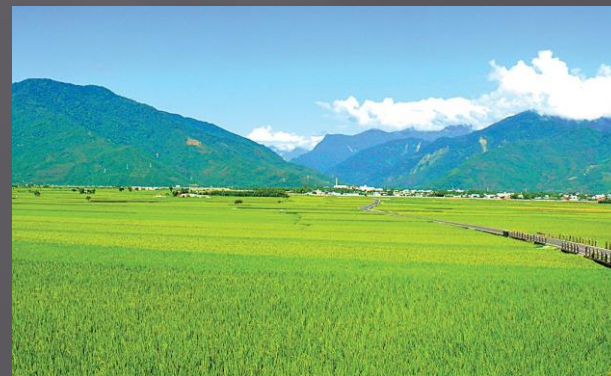
Pesticide Regulation and MRL Establishment in Taiwan

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Outlines

- ▣ Introduction
- ▣ Pesticides Regulation
- ▣ MRL Establishment
 1. Procedures
 2. Requirements
 3. Principles
- ▣ Future Prospects

Introduction



Taiwan is situated in the West Pacific between Japan and the Philippines. The total area is around 36,197 square kilometers, with a population of around 23 million.

Introduction

- ▣ Known as the heart of Asia for its central location and fusion of cuisines, Taiwan is a bustling food hub dependent on agricultural imports.
- ▣ Because of its small land area and high urbanization rate, Taiwan has a relatively small agricultural sector and relies on imports for domestic use.
- ▣ The United States is Taiwan's top supplier of agricultural products, with 31 percent market share.
- ▣ Taiwan was the seventh largest export market for U.S. food and agricultural products in 2017, valued at US\$3.41 billion.

Ref: Food and Agricultural Import Regulations and Standards Report. FAIRS Country Report. 2018.

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**," or the Food Safety and Sanitation Act (FSSA), went into force on February 5, 2014. The FSSA designates **the Ministry of Health and Welfare** (MOHW) as the central competent authority responsible for food safety. **All major laws, regulations, rules, and ordinances concerning food safety/quality are based on the FSSA.**

Introduction

- ▣ The key implementing agencies are the Taiwan Food and Drug Administration (TFDA) and the Council of Agriculture (COA).
- ▣ TFDA was established as an agency within the Ministry of Health and Welfare on January, 1, 2010. The agency is modeled after the U.S. Food and Drug Administration. COA is responsible for animal and plant quarantine.



Introduction

- ▣ MOHW is responsible for establishing and promulgating maximum residue limits (MRLs) in Taiwan.
- ▣ Taiwan does not automatically adopt MRLs established by Codex as default standards. All imports are subject to border inspection upon arrival. Local products are also subject to surveillance and monitoring.

Introduction

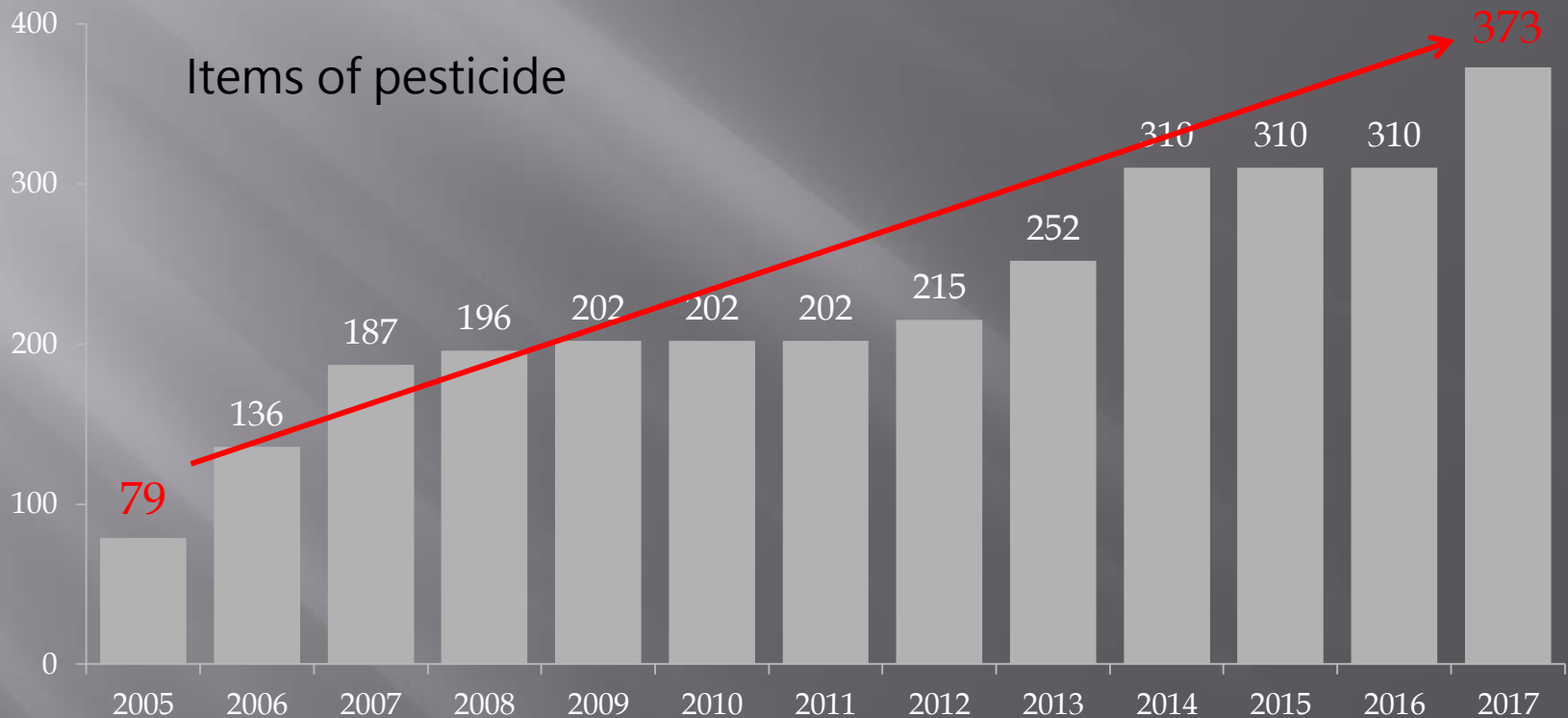
- ▣ Taiwan establishes pesticide MRLs with international standards as references and also based on scientific principles. Furthermore, the levels at which the MRLs are set will depend on the dietary pattern and total dietary intake level in Taiwan, and they will eventually be established on the basis of risk assessments. The process of evaluating the pesticide MRLs of imported crops follows the same principles as mentioned above, in line with the process for establishing the pesticide MRLs of domestic crops.

Introduction

- ▣ Imports of fruit, vegetables, meat and other food products are subject to inspection and testing by TFDA inspectors at the port of entry for pesticides, animal drugs and other contaminants such as heavy metals.
- ▣ According to the “Regulations of Inspection of Imported Food and Related Products”, TFDA decides the initial frequency of testing. 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.

Introduction

Development of **Multi-residues Analytical Method** for Pesticide in Food



2017.08.31 (TFDA Official Method)

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

→Monitor **373** items of pesticide in foods using mass spectrometry

Pesticide Regulation

Pesticides Management in Taiwan



**Council
of
Agri-
culture**

- Registration
 - Application, usage and education to farmers
 - Field monitoring
- Agro-pesticides Management Act**

Spray pesticides

harvest

Crops

Distributors, Wholesalers

Consumers

retailers

**Ministry
of
Health
&
Welfare**

- MRLs in foods
- Post market surveillance
- Food Safety and Sanitation Act



Regulation for Pesticide Residue Limits

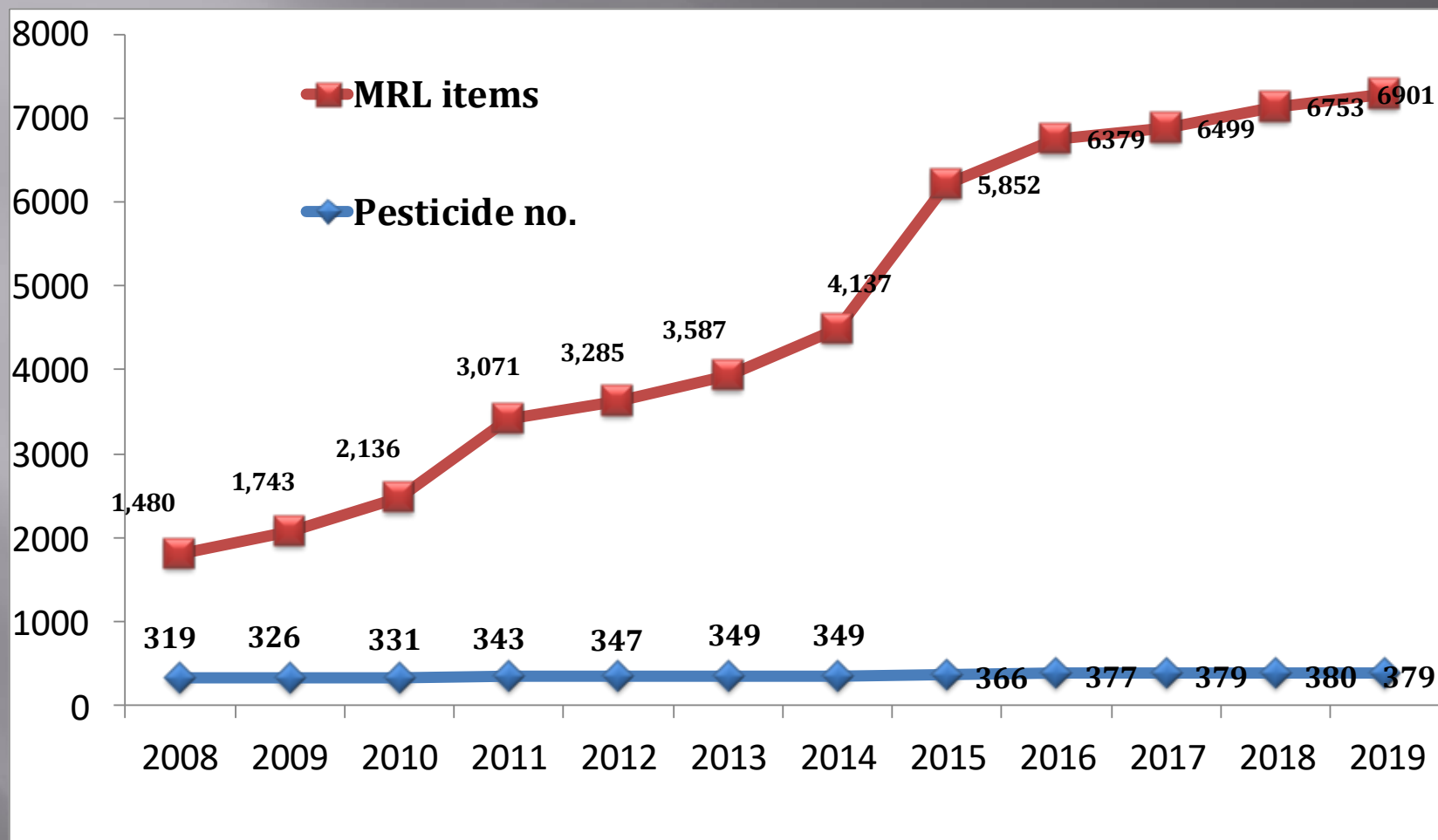
- According to Article 15 of **Act Governing Food Safety and Sanitation**.
- Food with pesticide residue exceeding the permissible tolerance shall not be manufactured, processed, prepared, packaged, transported, stored, sold, imported, exported, presented as a gift or publicly displayed.
- The standards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

Standards for Pesticide Residue Limits in Foods

- ▣ Since 2008, the standards have been amended for 51 times.
- ▣ The pesticide residues in foods shall meet the standards for the pesticides residue limits in foods table. Pesticides not listed in the table shall not be detected. (Positive list)

Update	Pesticide No.	MRL items	AI-MRL exemption
May, 2019	379	6,901	32

MRLs Establishment during 2008-2019



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

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.

Appendix Table 3

List of Pesticide MRLs Omitted

Name of Pesticides		
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	

Appendix Table 4

Pesticide Prohibited for Use

Name of Pesticide					
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			

Appendix Table 5

Classification of Crops for the Pesticide Residue Limits in Foods(1/3)

Group	Crops
1. Rice	Paddy rice, dry land rice, etc.
2. Wheat and barley	Barley, wheat, oat, rye, etc.
3. Other cereals and crops	Corn, sorghum, etc.
4. Dry beans	Soybean, peanut, mung bean, small red bean, scarlet runner bean, pigeon pea, cowpea (dry), safflower seed, rapeseed, sunflower seed, cottonseed, etc.
5. Leaf vegetables with wrapped leaves	Cruciferous leaf vegetables with wrapped leaves (cabbage, cauliflower, Chinese cabbage, broccoli, Brussels sprouts mustard, big stem mustard, kohlrabi, Brussels sprouts), head lettuce, artichoke, etc.
6. Leaf vegetables with small leaves	Cruciferous leaf vegetables with small leaves (Chinese mustard, edible rape, qing-jiang-cai, Chinese kale, cabbage sprout, leaf-radish, leaf-mustard, shepherd's purse, kale, mustard sprout, broccoli sprout, radish sprout), leaf lettuce, cos lettuce, garland chrysanthemum, Gynura's Deux Couleurs, Gynura Oralis Hay, fireweed, leaved chrysanthemum, Camphorweed, green garlic, spring onion, Chinese chive, leek sprout, chive flower, celery, water spinach, spinach, leaf-beet, leaf-sweet potato, basil, chayote shoots, perilla, etc.

Appendix Table 5

Classification of Crops for the Pesticide Residue Limits in Foods(2/3)

Group	Crops
7. Root, bulb and tuber vegetables	Radish, carrot, ginger, onion, potato, bamboo shoot, asparagus, co-ba, taro, sweet potato, yam, cassava, beetroot, shallot, Chinese onion, lili bulb, burdock, yam bean, etc.
8. Mushrooms	Mushrooms, Jew's ear, White jelly fungi, etc.
9. Fruit vegetables	Tomato, eggplant, sweet pepper, hot pepper, daylily, Lycii fructus, okra, roselle, etc.
10. Melon vegetables	Cucumber, baby cucumber, bitter melon, luffa, wax gourd, pumpkin, bottle gourd, vegetable pear, oriental pickling melon, summer squash, etc.
11. Peas and beans	Snap bean, pea, vegetable soybean, hyacinth bean, asparagus bean, cowpea, kidney bean, lima bean, broad bean, , goa bean, navy bean, pinto bean, etc.
12. Sprouts	Soybean sprout, alfalfa sprout, etc.
13. Melons	Watermelon, melon, cantaloupe, etc.
14. Large berries	Banana, papaya, pineapple, kiwi fruit, sweet sop, avocado, pitaya, passion fruit, mangosteen, durian, rambutan, pomegranate, etc.

Appendix Table 5

Classification of Crops for the Pesticide Residue Limits in Foods(3/3)

Group	Crops
15. Small berries	Grape, strawberry, carambola, wax apple, guava, caneberry (raspberry, blackberry, etc), cranberry, blueberry, mulberry, fig, black currant, etc.
16. Drupe	Mango, longan, litchi, olive, etc.
17. Pome	Apple, pear, peach, plum, prune, cherry, apricot, nectarine, jujubes, persimmon, Indian jujubes, loquat, quince, hawthorn, etc.
18. Citrus	Citrus fruit, lemon, pomelo, grapefruit, lime, etc.
19. Tea	Tea, etc.
20. Sugarcane	Sugarcane, etc.
21. Tree nuts	Coconut, almond, walnut, pecan, hazelnut (filbert), Macadamia nut, etc.
22. Herbs and spices	Rose, chrysanthemum, lotus, camomile, lavender, mint, lemon grass, rosemary, pepper(black and white), star anise, foeniculi fructus, fiveleaf gynostemma, crataegi fructus, polygonati, amomi, cardamom, nutmeg, etc.

Penalties for Violations

- ▣ Article 44 of Food Safety and Sanitation Law
 - 60,000 to 200 million New Taiwan dollar (about 2,000 to 6 million US dollar)
 - Noncompliance with Taiwan's pesticide standards will result in the recall and the rejection of the products
 - For serious situation, the business will be suspended immediately



MRL Establishment

1. Procedures

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 COA's proposed data into consideration and conducts the assessment of Taiwanese dietary exposure for an official MRL.

▣ Import MRLs:

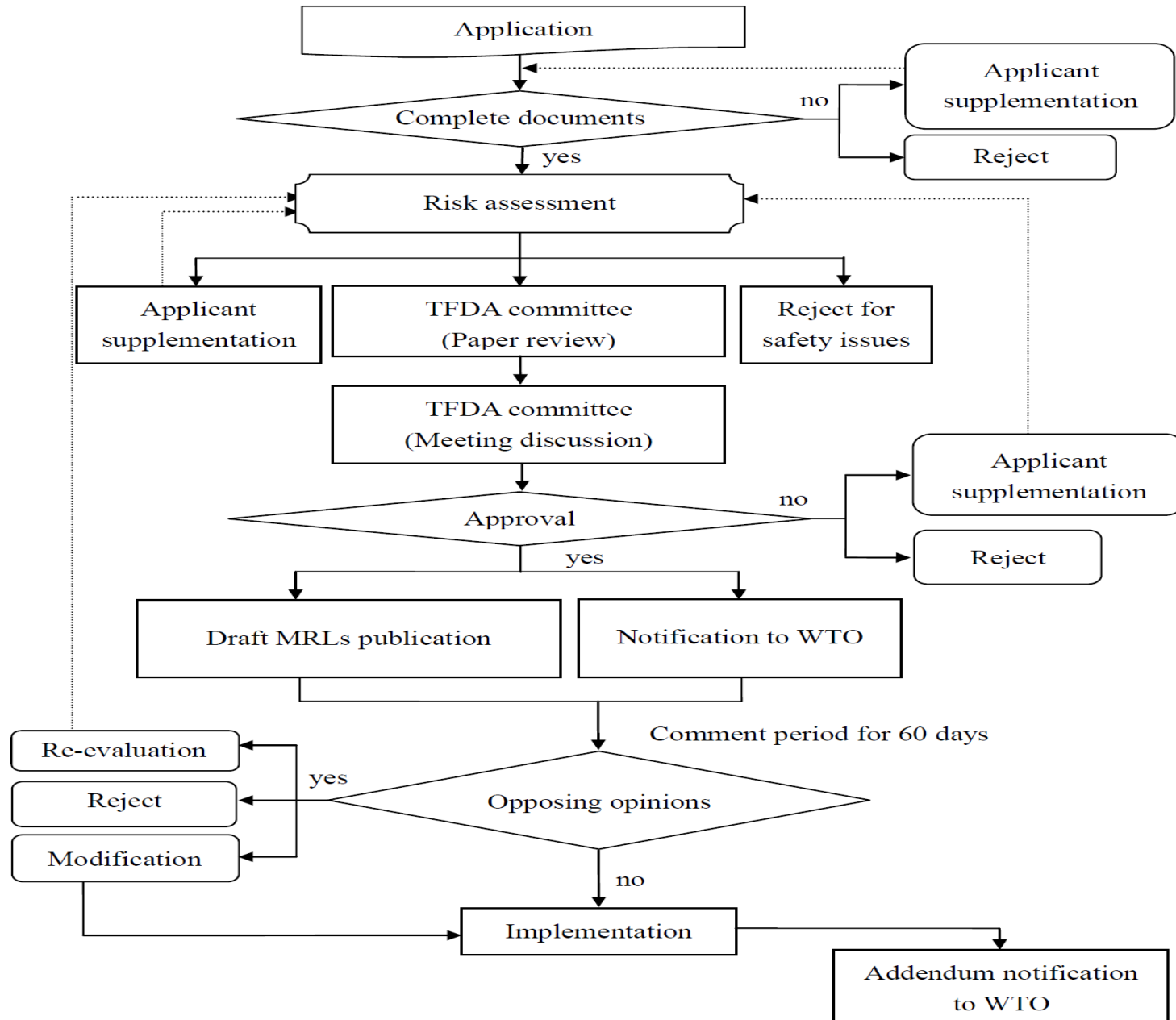
- ▣ MOHW receives an application from the trading countries or industries and conducts an evaluation of all necessary documents.
- ▣ The result of evaluation approved by MOHW's advisory committee will become an official MRL.

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

Procedures for Establishing MRLs

- After the applications of import tolerances on crops or animal products were received, they will soon be passed on to professional agency such as COA's TACTRI (Taiwan Agricultural Chemicals and Toxic Substances Research Institute) for the evaluations. Once the preliminary assessment was done, TFDA will submit the cases to "Food Sanitation, Safety and Nutrition Advisory Committee" for reviewing. After reviewing, the draft MRLs will be published for public consultation for 60 days and will notify to WTO/SPS for WTO members to comment. If there is no objection, the MRLs will then publish and enter into force.

Procedures for Establishing MRLs




Procedures for Establishing MRLs

APEC Compendium of Government Administration in Setting Maximum Residue Limits for Pesticides

Begin |  Click

Pesticide maximum residue limit (MRL) establishment

Chinese Taipei

 CHOOSE YOUR COUNTRY



Language applicable to an MRL application

English

Is import MRL application lodged electronically or with a hard copy by post?

Either

Application Fees (\$USD)

N/A

How long does it take for an import MRL application to be considered and finalised?

1~2 years

How is the applicant notified of the decision?

official letter or TFDA website

Describe the process for notifying stakeholders of proposed import MRL establishment, for example, via WTO notification and/or competent authority's website

WTO and TFDA website

 Previous

Next 

MRL Establishment

2. Requirements

Requirements for Establishing the Tolerance of Pesticide Residue on Crops (1/2)

1. Applicant
2. Common name
3. Commercial name or code
4. Chemical name
5. Chemical Abstracts Service (CAS) Number
6. Chemical class
7. Functional class: ☐Insecticide ☐Fungicide ☐Herbicide ☐Others
8. End-product name, content (%), and any risk impurity
9. Commercialized countries
10. Registered use (GAP) and its original efficacy documentation which supported the registration (submitted in accordance with the applied crops). Field trial numbers depend on applied crops. More than **3 trials data** should be submitted for domestic **major crops**, other minor crops at least submit 1 trial data.

Requirements for Establishing the Tolerance of Pesticide Residue on Crops (2/2)

11. Physical & chemical characteristics (GLP)
12. Toxicology data (Not required only for domestic registered pesticide)
 - (1) Acute oral toxicity
 - (2) Subchronic toxicity tests (at least 2 animals)
 - (3) Chronic feeding toxicity study and oncogenicity study (at least 2 animals)
 - (4) Reproductive study-2 generation
 - (5) Teratogenicity study (at least 2 animals)
 - (6) Mutagenicity tests (Test items including bacteria, cell and in vivo tests)
13. Metabolism in animal
14. Metabolism in plant
15. Analytical methods
16. Residue trial data (GLP)
17. International banned and restricted data, MRLs and ADI of applied pesticide

Requirement of Field Trials -Domestic Registration

Un-registered AI	Registered AI (foreign or domestic report)		
	Minor use	Major use	
At least 3 trials (foreign or domestic report), 2 entire trials+ 1 Verification trial ^a	At least 1 trial-GLP report	unregistered crop/pest	Registered crop/pest ^c
		At least 3 trials, 2 entire trials+ 1 verification trial (3 verification residue trials are acceptable) ^b	At least 1 trial –GLP report

a: At least proceed 1 crop field residue trial in Taiwan.

b: ADI lower than 0.002 mg/kg-bw/day or never registered on edible crops, at least proceed 1 entirely trial in Taiwan.

c: If applying for registration of a pesticides mixture, it is required that each AI of the mixtures has been registered in the same scope of use.

Major Crops in Taiwan

Cultivation area > 2,000
hectare or productive
value > NT\$ 0.5 billion
per year



No.	Crop	group	No.	Crop	group	No.	Crop	group
1	Paddy rice	Cereals	24	Potato		47	Peach	
2	Wheat		25	Co-ba		48	Litchi	
3	Corn		26	Tomato		49	Tankan	
4	Small red bean	Beans and Seeds	27	Chinese cabbage		50	Prune	
5	Peanut		28	Lettuce		51	Pear	
6	sesame		29	Garlic		52	Jujube	
7	Pak-choi	Vegetables	30	Green onion		53	Guava	
8	Vegetable soybean		31	Ginger		54	Sweet sop	
9	Cabbage		32	Water spinach		55	Ponkan	
10	Sweet potato(including leaf)		33	Radish		56	Coconut	
11	Bamboo shoot		34	Pumpkin		57	Grape	
12	Watermelon		35	golden mushroom		58	Pineapple	
13	Taro		36	pepper		59	Wax apple	
14	Celery		37	Strawberry	Fruits	60	Longan	
15	Cauliflower		38	Cantaloupe		61	pitaya	
16	Melon		39	Pomelo		62	lemon	
17	Onion		40	Papaya		63	Tea	Special
18	Cucumber		41	Plum		64	Sugarcane	
19	Carrot		42	Mango		65	Lily	Flowers
20	Bitter melon		43	Loquat		67	Rose	
21	Eggplant		44	Persimmon		68	Chrysanthemum	
22	Chinese chive		45	Orange		69	Orchid	
23	Mushroom		46	Banana				

MRL Establishment

3. Principles

Principles for Food Safety Standards

- Basic requirements
- Based on science: in line with Codex principles and FAO risk analysis
- Refer to Taiwan's situation
- Refer to international rules (CODEX, USA, Canada, EU, Japan, Australia and NZ)
 - Harmonization with international rules
 - Scientific evidences
 - Appropriate management models
- Food business owners could apply for an approval in condition of providing necessary documents

How is the MRL Decided?

Example-Fluxapyroxad in barley

各國農藥殘留容許量

藥劑中文普通名：氟克殺				藥劑英文普通名：Fluxapyroxad				
作物	建議容許量	Codex	美國	歐盟	日本	澳洲	韓國	中國
蘋果		0.9 (pome fruits)						
大麥	2	2						
菜豆(乾)		0.3 (bean, dry)						
油菜籽		0.8 (oilseed)	(Group 20)	0.9	0.9	(oilseed)	0.8	

Refer to the residue field trial test, use pattern, recommended MRL and calculate by OECD calculator. Finally try to harmonize with international standards.

Dietary Exposure Assessment

- ▣ **Chronic Exposure**

- Exposure over the lifetime to the residues in a commodity

- ▣ **Acute Exposure**

- Short term exposure

Dietary Exposure Assessment

NOAEL, No Observed Adverse Effect Level



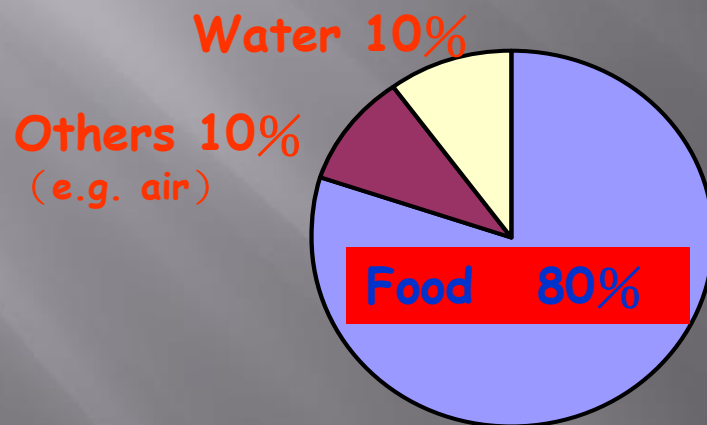
÷ **Safety Factor (100~1000)**

ADI, Acceptable Daily Intake per kg body weight



× **average weight (60 kg)**

The acceptable daily intake per person



Up limits for ADI

$$\sum \text{MRL}_i \times F_i < 80\% \text{ ADI}$$

$\sum \text{MRL}_i \times F_i \geq 70\%, < 80\% \rightarrow$ **assessment for the groups susceptible to pesticides**

$\sum \text{MRL}_i \times F_i \geq 80\% \text{ ADI} \rightarrow$ **restrictions**

(F : food intake)

Relevant Agencies



 **國家攝食資料庫**
National Food Consumption Database

National Health Research Institute
<http://intakes.nhri.org.tw/>

National Health Research Institutes All rights reserved.



 **衛生福利部食品藥物管理署**
FDA Food and Drug Administration, Ministry of Health and Welfare

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



 **Bureau of Animal and Plant Health Inspection and Quarantine,**
Council of Agriculture, Executive Yuan



 **行政院農業委員會 農業藥物毒物試驗所**
Taiwan Agricultural Chemicals and Toxic Substances Research Institute
Council of Agriculture (TACTRI/COA)

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

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

Online Search for Import Tolerance Application Status

- ▣ For facilitating the transparency of application progress, TFDA has set up a **MRL inquiry system** in 2018 for the applicants to **check the progress of their applications online**.

Online Search for Import Tolerance Application Status

Access the homepage of Taiwan Food and Drug Administration :
(<http://www.fda.gov.tw/TC/ResidueApplyQuery.aspx>)

... | 回首頁 | 網站導覽 | English | 雙語辭彙 | 常見問答 | 為民服務信箱 | 衛生局專區 | RSS |

 **衛生福利部食品藥物管理署**
Taiwan Food and Drug Administration

請輸入關鍵字 ☒ 站內 ☐ 站外 搜尋 進階搜尋

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

... 個人化服務

專區首頁

加入會員

人民申請案件

藥證查詢系統

校園食材

進口農藥殘留容許量申請案查詢

... 目前位置：首頁 > 個人化服務 > 進口農藥殘留容許量申請案查詢

請「輸入公文文號」或是「輸入公司帳號及查詢碼」查詢

請輸入文號： ← Registered number

查詢 ← 3

公司帳號： ← Applicant's account

查詢碼： ← Applicant's password

送件日期(起)： 至 送件日期(迄)：

送件日期：(為提升搜尋效能，請設定送件日期縮小搜尋範圍，格式範例如：送件日為104年6月5日須輸入2015/6/5~2015/6/30)

查詢 ← 3

or

Online Search for Import Tolerance Application Status

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

查詢結果

公文文號	公司名稱	收件日期	農藥名稱	農藥英文名稱	申請品項	更新日期	案件狀態	備註
		2011年04月21日	亞托敏	Azoxystrobin	onion, bulb	2018年10月22日	已訂容許量	
		2009年03月02日	(新藥)2,6-二異丙基萘 (Disopropylnaphthalene)	2,6-DIPN	potato	2018年10月22日	已訂容許量	
		2009年03月02日	滅芬諾	Methoxyfenozide	Cherry	2018年10月22日	已訂容許量	
		2009年03月02日	滅芬諾	Methoxyfenozide	Cranberry	2018年10月22日	已訂容許量	
		2009年03月02日	賽速安	Thiamethoxam	cherry	2018年10月22日	已訂容	

Future Prospects

- Continue to set safe and reasonable import tolerances by following the scientific principles of setting MRLs of pesticides
- International cooperation to harmonize import MRLs, taking care of food safety and trade facilitation at the same time.
- Strengthen risk communication to public.



Thank you for
your attention!