Taiwan MRL List and Regulatory Implementation

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Outlines

- Pesticides Management
- MRL Settlement
- Dietary Exposure Assessment of Pesticides
- Future Works

Pesticides management in Taiwan

Crops

Spray pesticides → harvest

Distributors, Wholesalers

retailers → Consumers

Dep. Of Agri.

- Registration
- Application,usage and education to farmers
- Field monitoring

Agro-pesticides Management Act

Min. Of Health & Welfare

- MRLs in foods
- Post market surveillance

Food Safety Act

Standards for Pesticide Residue Limits

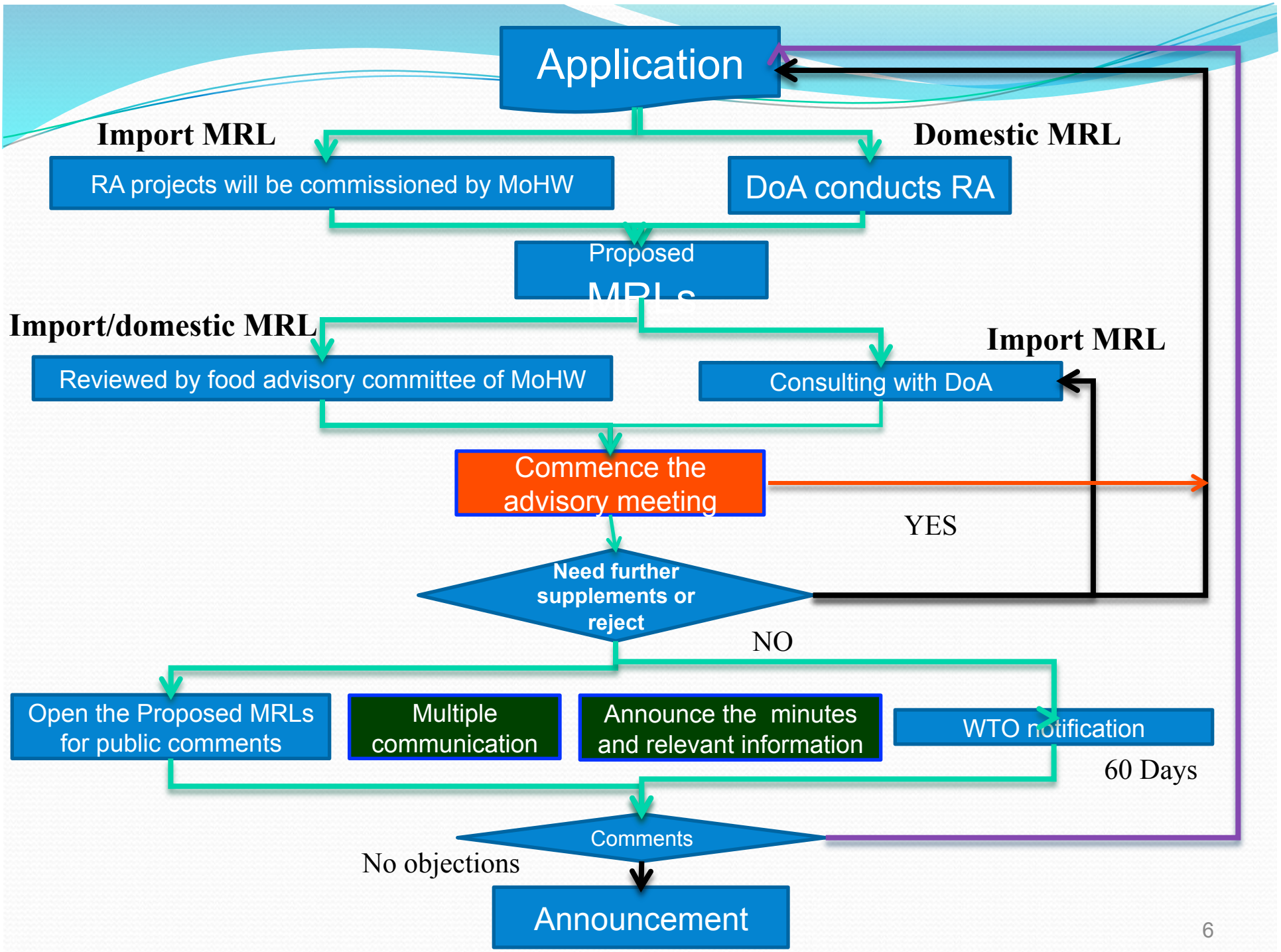
- According to Article 15 of Act Governing Food Safety and Sanitation
- Food or food additive with pesticide residue exceeding the permissible tolerance shall not be manufactured, processed, prepared, packaged, transported, stored, sold, imported, exported, presented as a gift or publicly displayed.
- The standards governing the permissible tolerance of pesticide residue shall be prescribed by the central competent authority through consultation with the relevant authorities.
- The pesticide residues in foods shall meet the standards for the pesticides residue limits in foods table. Pesticides no listed in the table shall not be detected. (Positive list)

Procedures for settlement of MRLs

- **Domestic MRLs:**
- **Dep. Of Agriculture evaluates toxicity, metabolism situations, etc. of applied pesticides and proposes a MRL.**
- **Dep. Of Health takes DOA's proposed data into consideration and counts Taiwanese dietary pattern 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 will be approved by MoHW's advisory committee and become an official .**

By the national treatment principle of WTO, any official MRLs applied to domestically produced and imported crops.

No MRLs, no acceptable residues.


Application
Import MRL
Domestic MRL
RA projects will be commissioned by MoHW
DoA conducts RA
Proposed
Import/domestic MRL
Import MRL
Reviewed by food advisory committee of MoHW
Consulting with DoA
Commence the advisory meeting
YES
Need further supplements or reject
NO
Open the Proposed MRLs for public comments
Multiple communication
Announce the minutes and relevant information
WTO notification
60 Days
Comments
No objections
Announcement

Requirements for establishing the tolerance of pesticide residue on import crops

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 in foreign countries (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 (1), other minor crops at least submit 1 trial data.

Requirements for establishing the tolerance of pesticide residue on import crops

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)
(7)Reference Dose (RfD)
13.Metabolism in animal
14.Metabolism in plant
15. Analytical methods
16.Residue trial data
17.MRLs and ADI
18.International banned and restricted data of applied pesticide

Requirement of crop field trials(Oct. 11, 2013) -domestic registration/Import tolerance

AI-Registration unapproved	AI-Registration approved (foreign or domestic report)		
At least 3 trials (foreign or domestic report), 2 entirely trials+ 1 Verification trial [a]	Minor use	Major use	
	At least 1 trial-no limit of report	unregistered crop/ pest	Registered crop/ pest
		At least 3 trials, 2 entirely trials+ 1 verification trial (3 verification residue trials are OK) [b]	At least 1 trial -no limit of 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.

Major Crops in Taiwan

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

Cultivation area > 2,000 ha or productive value > 0.5 billion NT$
Average in 2009-2011

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

MRL Settlement

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

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

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

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.tactri.gov.tw/e-intro.asp

Dietary Exposure Assessment

- **Chronic Exposure**
  - **Exposure over the live time of the residue in a commodity**
- **Acute Exposure**
  - **Short term exposure**

Example-Fluxapyroxad/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 with OECD calculator. Finally try to harmonize with international standards.

Food No. 1051304129 Amended, December 12, 2016

Standards for Pesticide Residue Limits in Foods

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	0.02	Insecticide

Year	Pesticide No.	MRL items	AI-MRL exemption
2016	377	6,379	32

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 Pesticide		
Azadirachtin	Cytokinins	Potassium hydrogen carbonate
Bacillus subtilis	DL-methionine	Riboflavin
Bacillus thuringiensis	Fatty alcohols	Sex pheromone of *Spodoptera exiqua*
Blasticidin-S	IBA	Sex pheromone of *Spodoptera litura*
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

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)

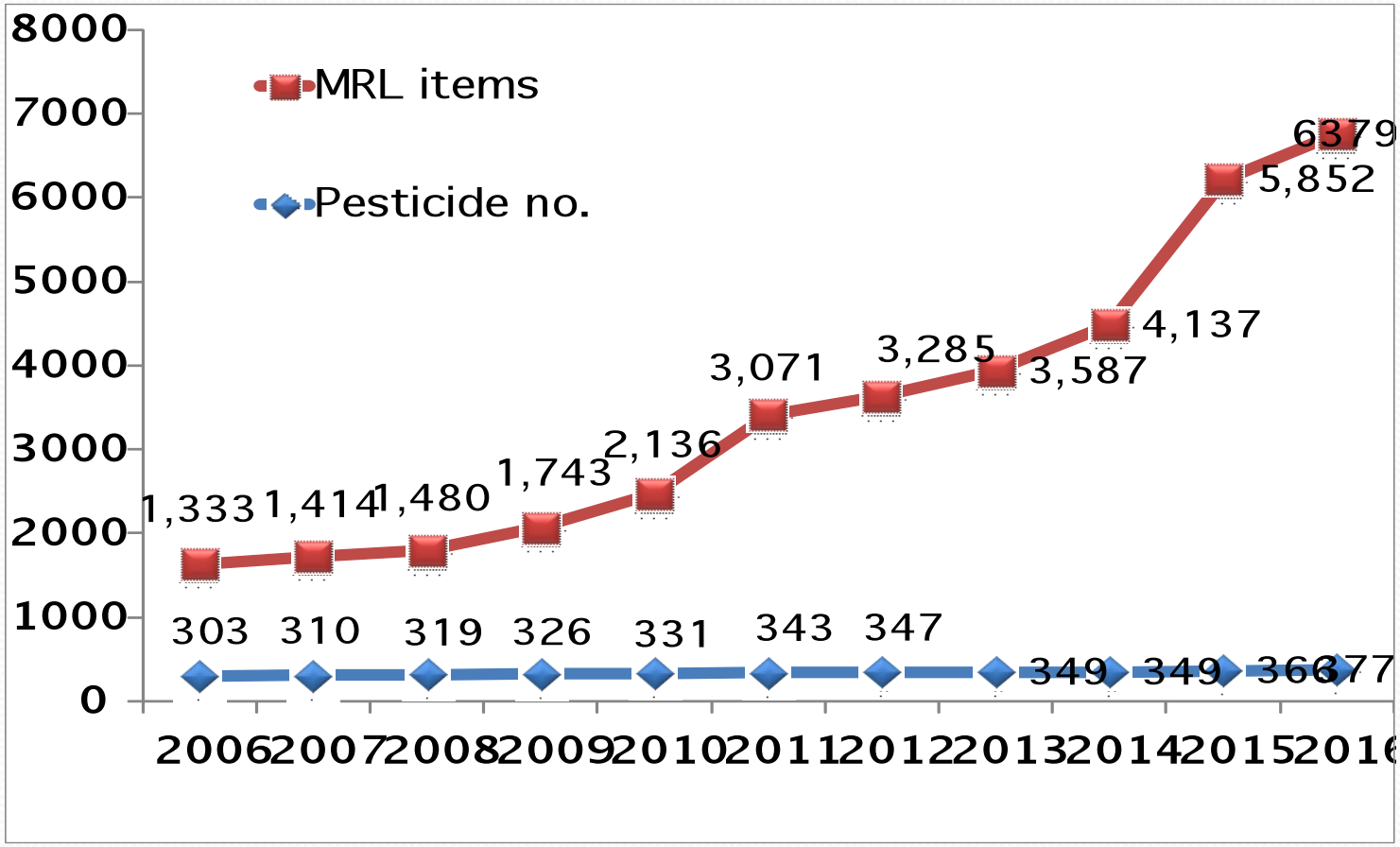
Group	Crops
7. Root, bulb and tuber vegetables	Radish, carrot, ginger, onion, potato, bamboo shoot, asparagus, co-ba, taro, sweet potato, yam, cassava, beetroot, shallot, Chinese onion, lilii bulbus, burdock, yam bean, etc.
8. Mushrooms	Mushrooms, Jew's ear, White jelly fungi, etc.
9. Fruit vegetables	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, asparagas bean, cowpea, kidney bean, lima bean, broad bean, , goa bean, navy bean, pinto bean, etc.
12. Melons	Watermelon, melon, cantaloupe, etc.
13. Large berries	Banana, papaya, pineapple, kiwi fruit, sweet sop, avocado, pitaya, passion fruit, mangosteen, durian, rambutan, pomegranate, etc.

Appendix Table 5

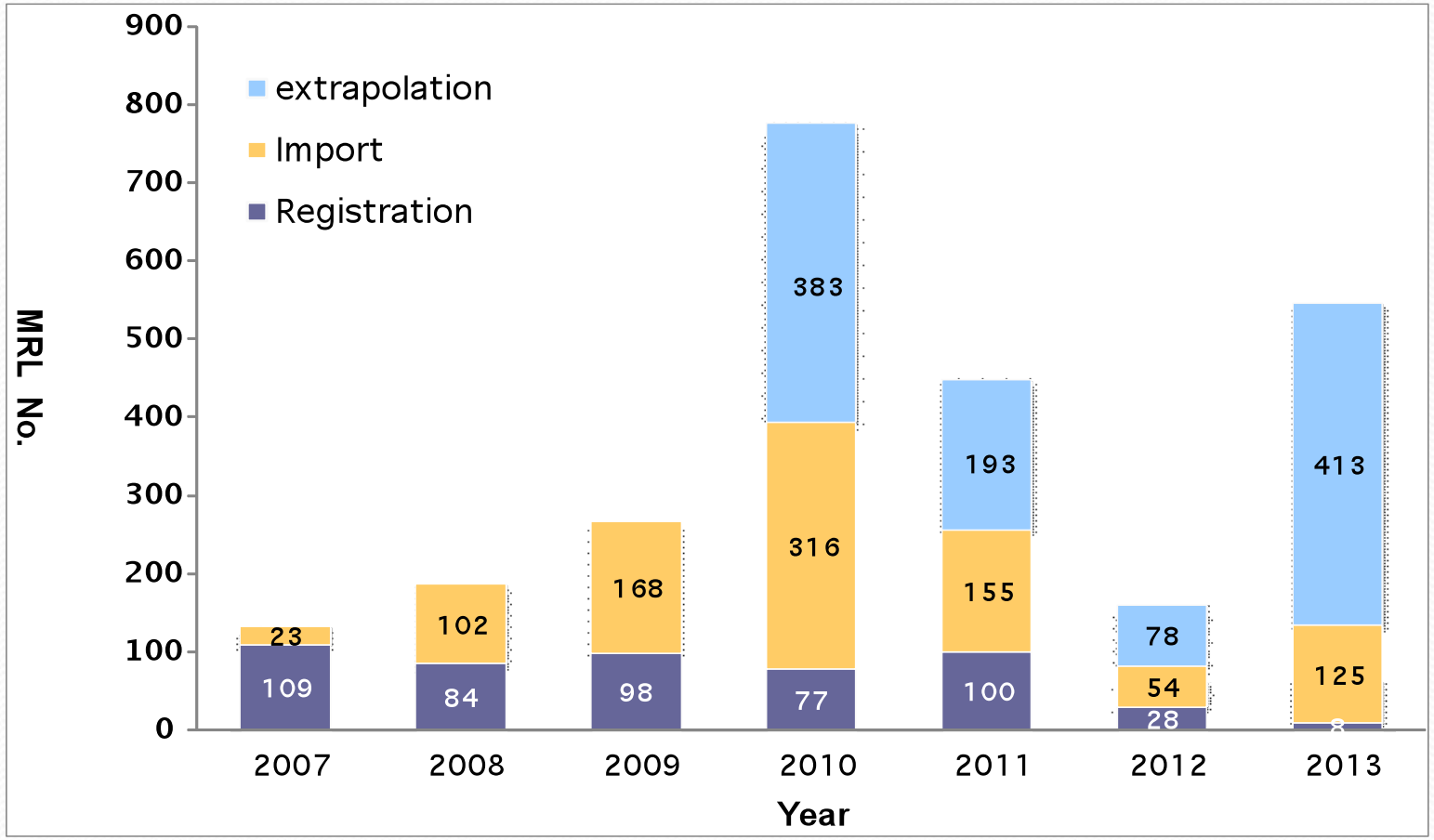
Classification of Crops for the Pesticide Residue Limits in Foods(3/3)

Group	Crops
14. Small berries	Grape, strawberry, carambola, wax apple, guava, caneberry (raspberry, blackberry, etc), cranberry, blueberry, mulberry, fig, black currant, etc.
15. Drupe	Mango, longan, litchi, olive, etc.
16. Pome	Apple, pear, peach, plum, prune, cherry, apricot, nectarine, jujubes, persimmon, Indian jujubes, loquat, quince, hawthorn, etc.
17. Citrus	Citrus fruit, lemon, pomelo, grapefruit, lime, etc.
18. Tea	Tea, etc.
19. Sugarcane	Sugarcane, etc.
20. Tree nuts	Coconut, almond, walnut, pecan, hazelnut (filbert), Macadamia nut, etc.
21. 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.

MRLs development in 2006-2016



MRL sources and distribution



Penalties for violations

- **Article 44 of Food Safety and Sanitation Law**
  - **60,000~ 200 million NT dollars; for serious situation, the business will be suspended immediately.**

Future works

- **Global joint review & international cooperation**
- **Residue definition in residue standards**
- **MRL exemptions criteria**
- **Update standards of animal product**
- **GLP reports**
- **Enhance link of pesticide use patterns & MRLs**

Thanks for your patience