

附件三：台灣發表專題-「Recent development on pesticide MRL  
setting and minor use in Taiwan」簡報

# Recent development on pesticide MRL setting and minor use in Taiwan



**Nov. 7, 2013**

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## Outline

- 1. Introduction of pesticide MRLs in Taiwan**
- 2. Principle of MRL setting**
- 3. Solution of minor use-  
pesticide extrapolation**
- 4. Future works**



# 1. Introduction of pesticide MRL in Taiwan



**Council of Agriculture** + **Ministry of Health and Welfare**  
**= Pesticide MRL**

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## 1. Introduction of pesticide MRL in Taiwan Acts of MRL and ministry authority

- ▶ **The Act Governing Food Sanitation:**  
**Ministry of Health and Welfare (MHW)**
- ▶ Review and announce MRL to Public (domestic/SPS)
- ▶ **Agro-Pesticide Act:**  
**Council of Agriculture (COA)**
- ▶ Pesticide registration and use pattern, estimate MRLs and recommendation to MHW



衛生福利部  
Ministry of Health and Welfare



行政院農業委員會  
COUNCIL OF AGRICULTURE, EXECUTIVE YUAN

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## 1. Introduction of pesticide MRL in Taiwan

# Residue standards in Taiwan

- 1. Crops:**  
*Standards for Pesticide Residue Limits in Foods*
- 2. Domestic animals:**  
*Standards for Pesticide Residue Limits in livestock and Poultry Products*

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## 1. Introduction of pesticide MRL in Taiwan

# Residue standards in Taiwan-crops

### Standards for Pesticide Residue Limits in Foods Food No. 1021350575 Amended, Sep. 26, 2013

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

Year	Pesticide No.	MRL items	AI-MRL exemption
2013	347	3,365	32

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## 1. Introduction of pesticide MRL in Taiwan

### Appendix table 4: classification of crops for the pesticide residue limits in foods

Group	Crop
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.
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, lillii bulbis, 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. Melons	Watermelon, melon, cantaloupe, etc.
13. Large berries	Banana, papaya, pineapple, kiwi fruit, sweet sop, avocado, pitaya, passion fruit, mangosteen, durian, rambutan, pomegranate, etc.
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.



## 1. Introduction of Pesticide MRL in Taiwan

### Administrations & assessment institutes

#### ▶ Related administration/Institute:

- 1. COA: BAPHIQ** (Bureau of Animal and Plant Health Inspection and Quarantine)  
**TACTRI** (Taiwan Agricultural Chemicals and Toxic Substances Research Institute)
- 2. MHW: TFDA** (Taiwan Food and Drug administration)

#### ▶ Major types of MRL application:

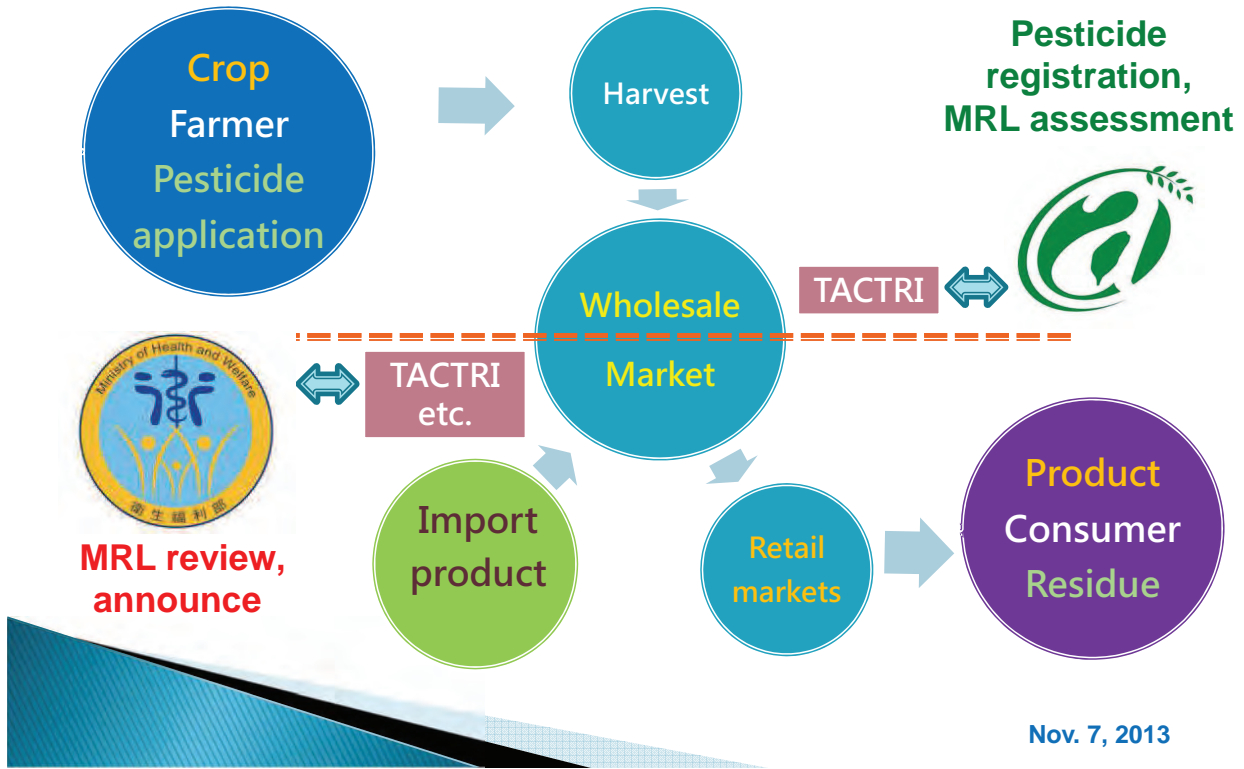
- 1. Pesticide registration- BAPHIQ+TACTRI**
- 2. Import tolerance - TACTRI (Sponsored by TFDA)**
- 3. Survey & Investigation- TACTRI, & other research institute (Sponsored by TFDA)**



# 1. Introduction of Pesticide MRL in Taiwan



## Pesticide management & MRL setting cooperation

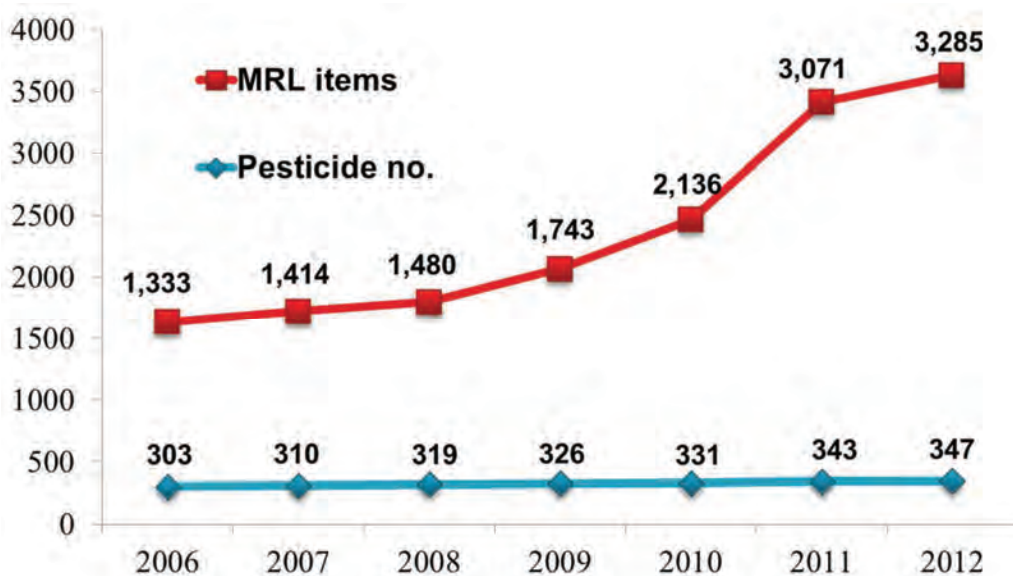


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# 1. Introduction of pesticide MRL in Taiwan

## MRLs development in 2006-2012



Increase more than 150% MRLs in the past 7 years

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## 1. Introduction of pesticide MRL in Taiwan MRL sources and distribution



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## 1. Introduction of pesticide MRL in Taiwan Residue standards in Taiwan-Animals

Standards for Pesticide Residue Limits in livestock and Poultry Products  
Food No. 1021350146 Amended, Aug. 20, 2013

Pesticide Name	Tissue	Species	Maximum Residue limit (ppm)	Symbols
2,4-D	Muscle	Livestock	0.05	
	Milk		0.05	
	Milk product		0.05	
	Egg		0.05	
Acephate	Muscle	Cattle, Pig, Poultry	0.1	
	Fat		0.1	
	Milk		0.1	
	Egg		0.1	
Aldicarb	Muscle	Livestock	0.01	
	Milk		0.01	
Aldrin & Dieldrin	Muscle	Livestock	0.2 (fat basis)	
	Milk		0.006	F
	Egg		0.1	

Year	Pesticide No.	MRL items
2013	71	244

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## 2. Principle of MRL setting



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## 2. Principle of MRL setting

### Factors in food intake risk assessment

**ADI:** Acceptable daily intake(mg/kg body weight/day)  
reference from Codex, EFSA, UAEPA, TACTRI...

**BW:** Average body weight, 60 kg/person

**Fi:** Daily food intake in each crop group (2001/2012)

**MRLi:** Highest MRL in each crop group

**HRI:** Highest residue in each crop group

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## 2. Principle of MRL setting

# Risk assessment for MRL setting

1. Crop residue (field trials & monitoring data)
2. Food intake risk assessment
  - A. Toxicology (NOAEL, ADI)
  - B. Food intake (Food consumption database)
3. Global MRL comparison (international harmonize)



$$\text{TMDI (Theoretical Maximum Daily Intake)} = \frac{\sum \text{MRL}_i \times F_i}{\text{ADI} \times 60 \text{ kg (mean body weight of consumers)}} = ? \% \text{ADI}$$



<80%ADI

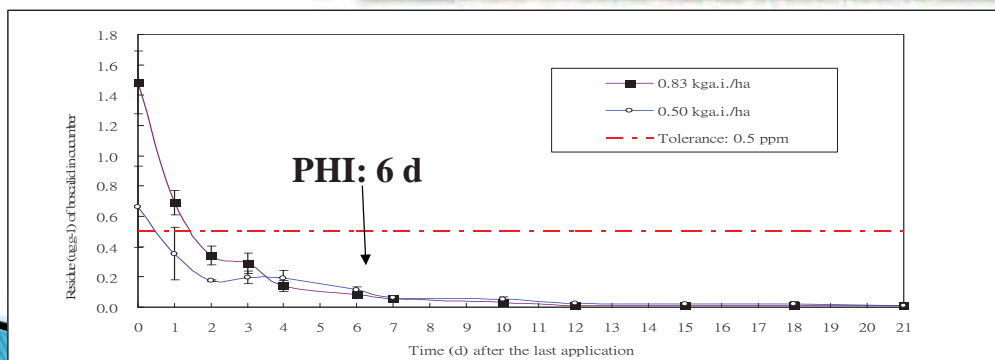
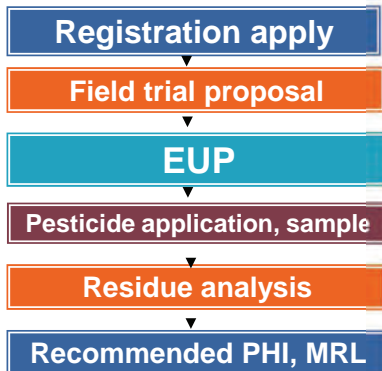
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## 2. Principle of MRL setting

# Registration-crop field trials(domestic)



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## 2. Principle of MRL setting

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

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

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.

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## 2. Principle of MRL setting

# Food consumption data comparison

No.	Crop Group	Previous ver. (2001) (kg/person/day)	Current ver. (2012) (kg/person/day)	Increase/ decrease(g)	%
1	Rice	0.17845	0.13131	-47.14	-26.42
2	Wheat and barley	0.07972	0.07724	-2.48	-3.11
3	Dry beans	0.06529	0.10816	42.87	65.66
4	Other cereals and crops	0.01773	0.00415	-13.58	-76.59
5	Leaf vegetables with wrapped leaves	0.06278	0.06670	3.92	6.24
6	Leaf vegetables with small leaves	0.14419	0.12198	-22.21	-15.40
7	Fruit vegetables	0.01235	0.02137	9.02	73.04
8	Melon vegetables	0.04140	0.03632	-5.08	-12.27
9	Peas and beans	0.01228	0.00909	-3.19	-25.98
10	Mushrooms	0.00182	0.00924	7.42	407.69
11	Root, bulb and tuber vegetables	0.06168	0.06688	5.20	8.43
12	Large berries	0.02636	0.03800	11.64	44.16
13	Small berries	0.03771	0.04860	10.89	28.88
14	Pome	0.03340	0.03857	5.17	15.48
15	Drupe	0.01207	0.00950	-2.57	-21.29
16	Melons	0.02710	0.01824	-8.86	-32.69
17	Citrus	0.05870	0.02711	-31.59	-53.82
18	Tree nuts	0.00073	0.00085	0.12	16.44
19	Sugarcane*	0.01535	0.01535	-	
20	Tea	0.00240	0.00767	5.27	219.58
21	Herbs and spices	0.00240	0.00103	-1.37	-57.08
	合計	0.89391	0.85736	-36.55	-4.09

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## 2. Principle of MRL setting

# Food consumption data-current version

### ▶ Data sources-general survey of consumer nutrition

1. 2001-2002: Children (6-12 yrs)
2. 2005-2008: Infant (0-6 yrs ) & Adult(above 19 yrs)
3. 2010: Junior high school student (13-15 yrs)
4. 2011: Senior high school student ( 16-18 yrs)

### ▶ Populations of consumer

1. 0-3yrs( $\leq 3$ ), 3-6 yrs( $3.1 \leq 6$ ), 6-12 yrs( $6.1 \leq 13$ ), 13-15 yrs, 16-18 yrs, 19-65 yrs (19.1-65), above 65 yrs( $>65.1$ ). All populations include the consumption data of male, female & total.
2. 19- $\leq$  49 yrs pregnantable female.

### ▶ National Estimated Daily Intake (NEDI)

1. HR: Highest residue from field monitoring data in each group
2. Long-term risk assessment

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## 2. Principle of MRL setting

# Populations comparison (rice consumption)

Age & gender	M(0-3)	F(0-3)	T(0-3)	M(3-6)	F(3-6)	T(3-6)	M(6-12)	F(6-12)	T(6-12)	M(65+)	F(65+)	
Group	Current ver. of Fi	Fi	Fi	Fi	Fi	Fi	Fi	Fi	Fi	Fi	Fi	
Rice	0.13131	0.07743	0.06165	0.06993	0.11033	0.08501	0.09801	0.1319	0.10321	0.11814	0.17424	0.1383

Age & gender	T(19-65)	M(19-65)	F(19-65)	M(12-16)	F(12-16)	T(12-16)	M(16-18)	F(16-18)	T(16-18)	T(65+)	FP(19-49)	
Group	Current ver. of Fi	Fi	Fi	Fi	Fi	Fi	Fi	Fi	Fi	Fi	Fi	
Rice	0.13131	0.13131	0.16599	0.09657	0.14652	0.09295	0.12044	0.14507	0.07857	0.11361	0.15606	0.08916

Population	Rice consumption (kg/person/day)	All consumption-crop (kg/person/day)	Ratio of agro-product(%)
19-65/total(T)	0.13131	0.85736	15.32
65+/male(M)	0.17424	0.92202	18.90
19-49/female(F)-pregnantable(P)	0.08916	0.77786	11.46

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## 2. Principle of MRL setting

### Example: Chlorantraniliprole-TMDI&NEDI

	Current ver. of Fi	T(19-65)	M(19-65)	F(19-65)	M(12-16)	F(12-16)	T(12-16)	M(16-18)	F(16-18)	T(16-18)	M(65+)	F(65+)	T(65+)	FP(19-49)
TMDI (mg/person/day)	1.965	1.965	1.963	1.967	1.409	1.322	1.367	1.32	1.023	1.179	2.411	2.119	2.263	1.788
%ADI	12.6	11.99	10.88	13.18	9.064	8.397	8.734	9.359	7.363	8.404	14.53	14.28	14.38	12.12
NEDI (mg/person/day)	0.324	0.324	0.325	0.323	0.206	0.195	0.201	0.198	0.15	0.175	0.407	0.368	0.387	0.287
%ADI	2.076	1.976	1.798	2.166	1.323	1.239	1.281	1.408	1.078	1.25	2.454	2.479	2.461	1.946

	Current ver. of Fi	M(0-3)	F(0-3)	T(0-3)	M(3-6)	F(3-6)	T(3-6)	M(6-12)	F(6-12)	T(6-12)
TMDI (mg/person/day)	1.965	0.387	0.318	0.354	0.871	0.752	0.813	1.158	1.128	1.144
%ADI	12.6	11.47	9.514	10.54	15.95	14.43	15.21	12.9	13.2	13.03
NEDI (mg/person/day)	0.324	0.058	0.039	0.048	0.126	0.106	0.116	0.181	0.179	0.18
%ADI	2.076	1.704	1.153	1.444	2.3	2.027	2.167	2.016	2.098	2.053

**TMDI: 7.363~15.95%ADI**  
**NEDI: 1.078~2.3%ADI**

HR in NEDI: crops field monitoring data, 2011-2012

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## 2. Principle of MRL setting

### Global Pesticide MRLs comparison

Country/Area	AI	MRLs	Remark
Codex <sup>a</sup>	179	3,831	
EU <sup>b</sup>	424	132,300	Default limit =0.01 ppm
Japan <sup>c</sup>	586 (+Vet drug=825)	13,854	Uniform limit =0.01 ppm
Taiwan <sup>d</sup>	347	3,365(crops) +244(animals)	122 Others* +85 Tea*-LOQ
United State <sup>e</sup>	372	11,727	

a. Codex: [http://www.codexalimentarius.net/mrls/pestdes/jsp/pest\\_q-e.jsp](http://www.codexalimentarius.net/mrls/pestdes/jsp/pest_q-e.jsp)

b. EU: [http://ec.europa.eu/sanco\\_pesticides/public/index.cfm](http://ec.europa.eu/sanco_pesticides/public/index.cfm)

c. Japan: <http://www.m5.ws001.squarestart.ne.jp/foundation/search.html>

d. Taiwan: <https://consumer.fda.gov.tw/Law/PesticideList.aspx?nodeID=520>

e. US: [http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=bd32aab1f2263d189c2ea7ae45c321e9&tpl=/ecfrbrowse/Title40/40cfr180\\_main\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=bd32aab1f2263d189c2ea7ae45c321e9&tpl=/ecfrbrowse/Title40/40cfr180_main_02.tpl)

(The total numbers of pesticide and MRL were just roughly calculated, may not show the current status.)

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## 2. Principle of MRL setting

### International harmonization: Chlorantraniliprole

MRL (ppm)	Taiwan	Codex	US	EU	Au	Japan	Korea
Pome/Apple	0.5	0.4	1.2	0.5	0.3	1.0	1.0
Cucumbers	0.3	0.3	0.5	0.3	0.2	0.3	0.5
Leafy vegetables/ Lettuce	10.0	20.0	13.0	20.0	15.0	20.0	7.0
Fruit vegetables/ Tomatoes	0.5	0.6	1.4	0.6	0.3	0.7	0.05*

\*MRL is for "Other Ag Products", applying if no Codex MRL or extrapolation is not applicable

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## 3. Solution of minor use-pesticide extrapolation



Minor crops in Taiwan

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## 2. Introduction of pesticide MRL in Taiwan

### Major crops in Taiwan (July 31, 2012)

No.	Crop	group	No.	Crop	group	No.	Crop	group
1	Paddy rice	Rice	23	Strawberry	Vegetables	45	Prune	Special
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		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	56	Betal			
13	Cauliflower	Vegetables	35	Papaya	Fruit trees	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		Cultivation area > 2,000 ha or productive value > 0.5 billion NT\$ Average in 2009-2011		
22	Mushroom		44	Tankan				

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## 3. Solution of minor use- pesticide extrapolation

### Combinations of pests and crops in Taiwan

Data sources	Crops	Pests	Combinations (use patterns)
Pests outbreak records	228	>300	>8,000
Plant protection manual (2010)	134	257	818
Extrapolation (appendix table 1~3)	271	270	7,933

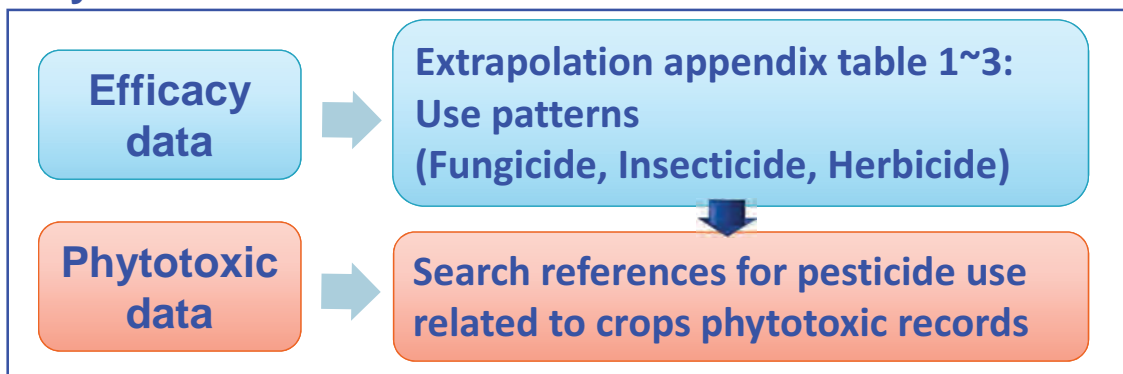
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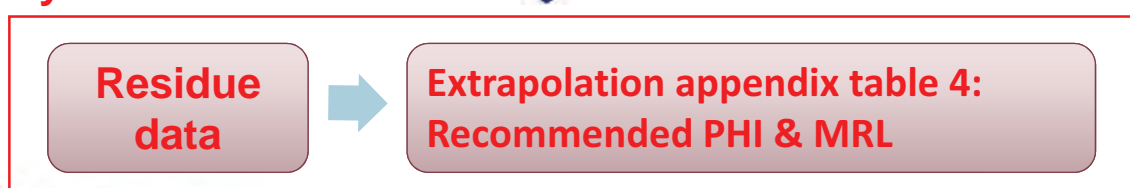
### 3. Solution of minor use- pesticide extrapolation

## Assessment procedure

### Efficacy assessment



### Safety assessment



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### 3. Solution of minor use- pesticide extrapolation

## Crop/pest groups for efficacy trials

(Extract from appendix table 1, ver. 3.2, May 21, 2013)

Crop group	Representative		Extrapolation spectrum	
	Crops	Diseases	Crops	Diseases
Vegetables	Cucumber, muskmelon, melon	Diseases	Cucurbitaceous crops	=Representative diseases
	Cucumber	Powdery mildews	Solanaceous crops	Powdery mildews
			Leguminosae crops	
			Carrot, great burdock	
			Strawberry	
			Indigowoad root	
Sesame				

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### 3. Solution of minor use- pesticide extrapolation

## Crop groups for residue trials

(Extract from appendix table 4, ver. 3.2, May 21, 2013)

No.	Crop group	No.	Crop group
1	Rice	10	Mushrooms
2	Wheat, barley and cereals	11	Citrus
3	Dry beans	12	Pome
4	Leaf vegetables with wrapped leaves	13	Other inedible-peel fruit
5	Leaf vegetables with small leaves	14	Other edible-peel fruit
6	Fruit vegetables	15	Tea
7	Melons	16	Sugarcane
8	Peas and beans	17	Tree nuts
9	Root, bulb and tuber vegetables	18	Coffee

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### 3. Solution of minor use- pesticide extrapolation

## Crop groups for residue trials

(Extract from appendix table 4, ver. 3.2, May 21, 2013)

Crop group	Crops in group		Representative crops
	Subgroups	Crops(agro-product name)	
Leaf vegetables with small leaves	Cruciferous	Chinese kale, edible rape, non-heading mustard(Chinese mustard), leafy-carrot etc.	Chinese kale, lettuce, garland chrysanthemum, spinach, water convolvulus, celery, leafy-sweet potato, non-heading mustard, Chinese mustard. <b>Choose one</b>
	Compositae	Lettuce, garland chrysanthemum etc.	
	Others	Celery, spinach, water convolvulus, leafy-sweet potato etc.	
	Alliaceae	Green onion, garlic, Chinese chive, shallot etc.	

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### 3. Solution of minor use- pesticide extrapolation

#### Example: Representative crops(RCs) & extrapolation spectrum on Vegetables Powdery mildews treatment

RCs for efficacy trial	Extrapolation spectrum	RCs for phytotoxic trial	RCs for residue trial	Extrapolation spectrum
Cruciferous crops, lettuce. <b>Choose one</b>	Cruciferous crops, Compositae crops, Leguminosae crops, spinach	=RC for efficacy trials	Soybean or peanut	2. Dry beans
			Chinese cabbage, cabbage, broccoli, sprouting broccoli, head lettuce. <b>Choose one</b>	3. Leaf vegetables with wrapped leaves
			Chinese kale, lettuce, garland chrysanthemum, spinach, water convolvulus, celery, leafy-sweet potato, non-heading mustard, Chinese mustard. <b>Choose one</b>	4. Leaf vegetables with small leaves(exc. Alliaceae crops)
			Green onion, garlic, Chinese chive. <b>Choose one</b>	5. Green onion, Chinese chive, garlic
			Green soybean, common bean, pea, asparagus bean. <b>Choose one</b>	8. Peas and beans
Cucumber, muskmelon, melon	Cruciferous crops		Cucumber	7. Melons

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### 3. Solution of minor use- pesticide extrapolation

#### Sources of extrapolation evaluation

Case source	Evaluated cases	Passed cases	Pending cases	Un-passed cases
Active re-evaluate	5,388	1,794	3,594	
Requirements of farmers	661	169	436	56
Companies apply	55	45	0	10
Field residue monitoring data	77	34	30	13

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### 3. Solution of minor use- pesticide extrapolation

## Benefit of pesticide extrapolation

Crop	2009	2010	2011	2012	Jan.-July, 2013	Total cases
Rice	79	0	5	0	0	84
Cereal	1	0	0	0	0	1
Vegetables	244	436	86	69	192	1,027
Fruit trees	22	251	433	26	83	825
Tea	20	12	4	0	4	40
Sum	366	699	538	95	279	1,977

\*More than 6,000 combinations of pest/crop(single item) with over 200 AIs of pesticide were evaluated

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## 4. 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

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*Thanks for your attention!!*



***Eight trigrams tea garden, Nantou county, Taiwan***

<http://www.swcb.gov.tw/album/index-1.asp?m=16&m1=13&m2=390&sid=69&page=1>

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