

Establishment of Pesticide MRLs in Korea

2013. 11. 7.

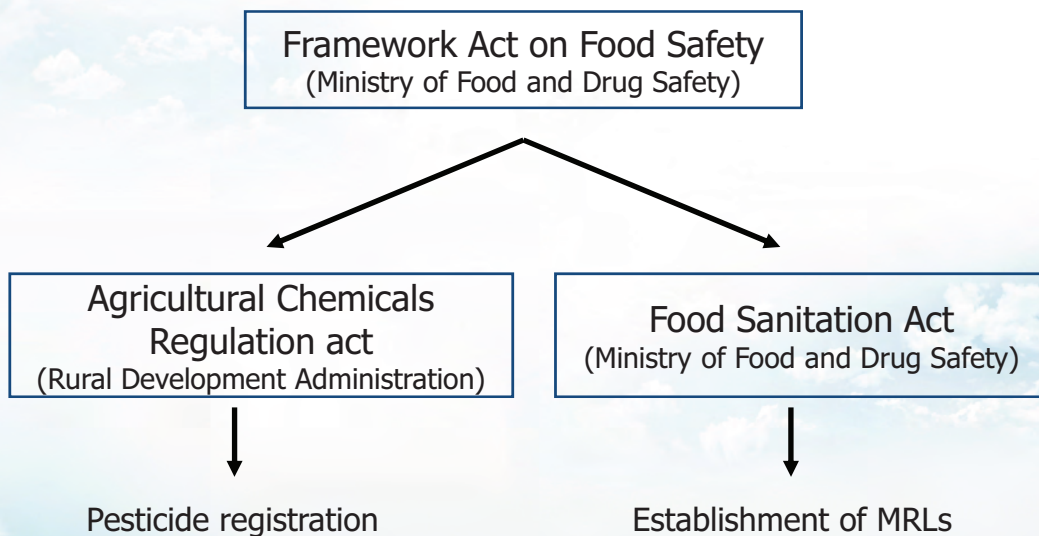
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Regulations (Act, Notice, etc)

Legislative Authorities



※ **Water Quality and Ecosystem Conservation Act**

→ Establishment of MRL for drinking water, use of pesticide in golf course

Food Sanitation Act

● Food Sanitation Act

- Article 7 (Standards and Specifications concerning Foods or Food Additives)
 - Food standard (pesticide, veterinary drug, heavy metal, food additives standard, *etc.*)
- Article 7-3 (Request for the establishment of the pesticide MRL, *etc.*)
 - Any person who intend to request for the establishment of the pesticide MRL in foods may submit related data to the MFDS Commissioner.
 - Detailed matters concerning methods, procedures for request and the scope of related data, *etc.* shall be determined by Ordinance of the Prime Minister.
- Article 92 (Fees)
 - A person who applies for import tolerance.

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● Implementing Regulations in Food Sanitation Act

(Pre-announcement of Legislation, October 18, 2014)

– Article 5-2

(Request for the establishment of the pesticide MRL)

- ① A person who intent to request the establishment, amendment and exemption of the MRL shall submit an application form with toxicology data and residue data to the Commissioner.
- ② The Commissioner shall establish the MRL by deliberating the suitability.
- ③ Except as otherwise provided for in this Act, detailed matters concerning procedures for request, methods for the establishment of the MRL, *etc.* shall be determined by the Commissioner.

– **Annex 26 (2)**

Evaluation for the establishment of the pesticide MRL

1) Review of toxicology data

- New : ₩30,000,000
- Revision : ₩10,000,000

2) Review of residue data

- Individual food : ₩5,000,000

Food Code

- **[Appendix 8] Guidelines for establishment of Pesticide and Veterinary Drug MRLs in Food**

- **Scope of Application**
- **Review for establishing new MRL, revising existing MRLs and exempting from the setting of the MRL**
- **Expert review panel and its operation**
- **Scope of Materials submitted for the establishment of pesticide MRLs**
- **Method for the establishment of MRLs at each step**

Related Data for the Setting of MRLs

In case of the setting of MRLs for a compound, related data is requested by the MFDS as follows.

❖ Toxicity data

- Acute Oral Toxicity Studies(Oral toxicity, Dermal toxicity, Inhalation toxicity, Eye irritation, Dermal irritation, Dermal sensitization, Neurotoxicity)
- Sub-Chronic Toxicity Studies (90 day oral toxicity, 21/28 day dermal toxicity, 90 day inhalation toxicity, 90 day neurotoxicity, 28 day delayed neurotoxicity)
- Chronic Toxicity Studies(Repeated dose chronic oral toxicity, Carcinogenicity)
- Genetic toxicity studies
- Development and reproductive toxicity studies

- Teratogenicity studies
- Metabolism and pharmacokinetics
- Other toxicity data deemed necessary by the Commissioner in determining the establishment of maximum residue limit.

❖ Residue Data

- Basic information (Physicochemical characteristics, Applicable diseases and insect pests)
- Supervised trials for crops results
 - Field description, Pesticide spraying tools and methods, Sample collection methods, Sample analysis method and recovery test result, Residue trial data, Storage stability, Proposed MRL, Guidelines on safe use
- Livestock, poultry, egg and milk residue data (directly, carry-over through feed ingestion)
- Plant metabolism data
- Other residue data deemed necessary by the Commissioner in determining the establishment of MRL

❖ **Processing study**

❖ **Miscellaneous**

- Usage and registration status in other countries
- MRL establishment status in Codex and other countries
- Impurity information regarding the product

※ Of related data above, if there is theoretical and/or technical reason to explain that some data is meaningless to conduct the tests theoretically and/or technically, the data may be omitted.

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Pesticide MRLs in Food

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Establishment of pesticide MRLs in Foods

- ◆ The MFDS have established pesticide MRLs for specific crops or crop groups, and processed foods in Korea.
- ◆ For example: Tetraconazole MRLs were established for pome fruit (a crop group) and dried red pepper (a processed food).

(297) Tetraconazole, ADI : 0.0073 mg/kg b.w./day					
Green & Red Pepper(Fresh)	1.0	Mandarin	2.0	Tomato	2.0
Red Pepper(Dried)	3.0	Watermelon	0.2	Sweet Pepper	1.0
Pepper Leave	1.0	Cucumber	1.0	Squash	0.2
Perilla Leaves	15	Korean Melon	1.0	Wild grape	3.0
Strawberry	1.0	Pome fruits	1.0		

Pesticide residue DB : <http://fse.foodnara.go.kr/residue>

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Pesticide MRLs in Korea

- **432 Pesticide** MRLs were established for **213 commodities** in Korea.

I. 농산물의 농약잔류허용기준(MRLs for Agricultural Products)

1. 식품공전 번호순 (Index of pesticides)

농약명 (Chemical name)
(1) 이민옥타딘 (Iminoctadine)
(2) 글루포시네이트 [Glufosinate(ammonium)]
(3) 글리포세이트 (Glyphosate)
(4) 나프로파미드 (Napropamide)
(5) 노르플루라존 (Norflurazon)
(6) 니트라피린 (Nitrapyrin)
(7) 다미노자이드 (Daminozide)
(8) 다이아지논 (Diazinon)
(9) 델타메쓰린 (Deltamethrin)
(10) 도단 (Dodecane)
(11) 메틸디노캡 (Meptyldinocap)
(12) 디디티 (DDT : p,p'-DDT, o,p'-DDT, p,p'-DDD 및 p,p'-DDE) : Sum of p,p'-DDT, o,p'-DDT, p,p'-DDD and p,p'-DDE
(13) 디메치핀 (Dimethipin)
(14) 디메토에이트 (Dimethoate)

농산물(Agricultural Products)

번호 (No)	품명 (Commodity)	기준수 (No of MRLs)	페이지 (Page)	번호 (No)	품명 (Commodity)	기준수 (No of MRLs)	페이지 (Page)
1	가지 (Eggplant)	80	150	26	기타감귤류 (Other Citrus Fruits)	42	165
2	감 (Persimmon)	97	151	27	기타견과류 (Other nuts)	14	166
3	감귤류 (Citrus Fruits)	12	153	28	기타곡류 (Other Cereal Grains)	16	166
4	감자 (Potato)	132	154	29	기타과실류 (Other Fruits)	21	167
5	갯 (Mustard leaf)	5	156	30	기타농산물 (Other Agricultural Product)	105	167
6	강낭콩 (Kidney bean)	18	156	31	기타버섯류 (Other mushrooms)	16	169
7	건조과실류 (Dried fruits)	2	156	32	기타서류 (Other potatoes)	3	170
8	건조기타식물류 (Dried other plants)	1	157	33	기타종실류 (Other seeds)	21	170
9	건조채소류 (Dried vegetables)	2	157	34	기타채소류 (Other vegetables)	24	170

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Applicability of pesticide MRLs

❖ If a MRL is not established,

- Generally, the pesticide not registered in Korea should not be detected in foods. Non-detection levels are determined at LOQ of the analytical method.
- If a pesticide is detected in the product, where the residue limit for an agricultural product was not established, the following tentative limits shall be applied.

First, the Codex standard shall be applied.

Second, the lowest of the MRL in question specified for similar agricultural products shall be applied. ([See the similar products in Classification of Food Raw Material in Korea Food Code.](#))

Third, lowest of the MRL shall apply to the detected pesticide.

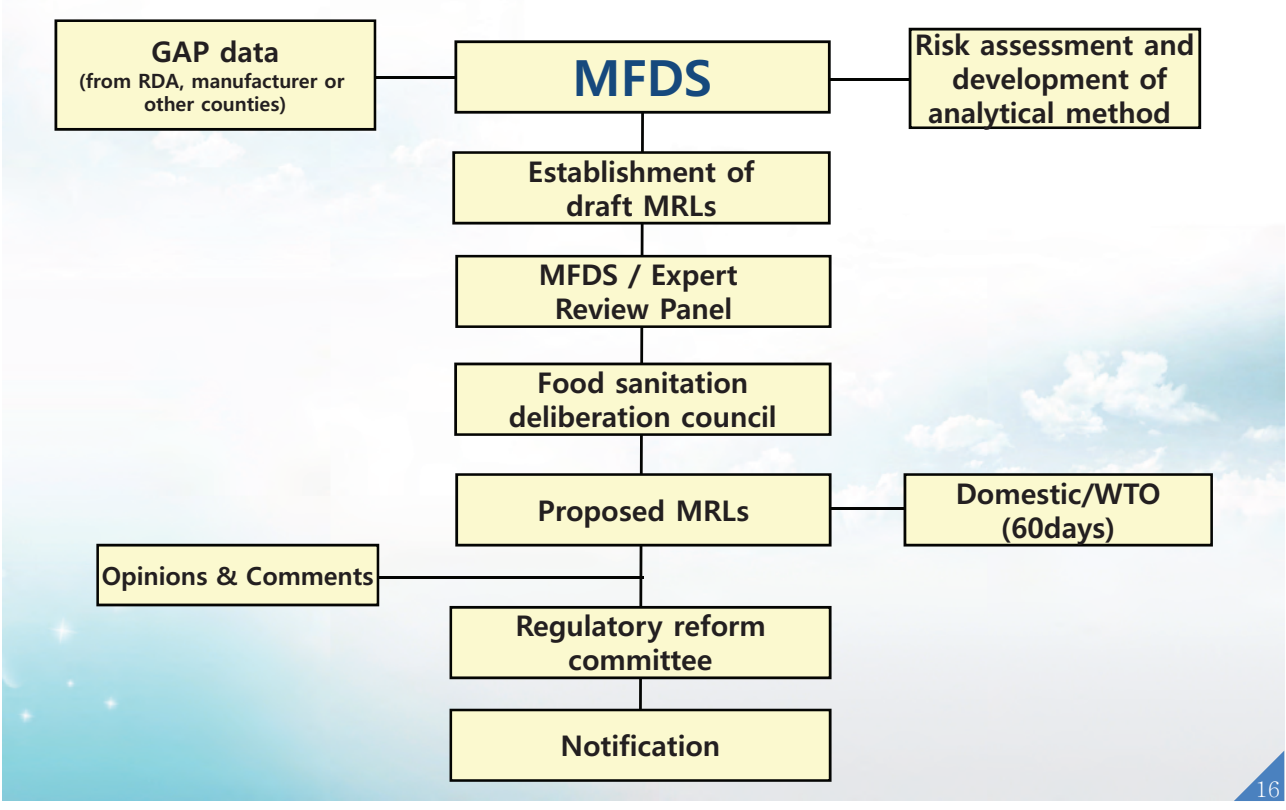
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❖ Example of Classification of Fruits for pesticide MRL

Type	Group	Commodity
Fruits	Pome fruits	Apple, Pear, Chinese quince, Persimmon, Pomegranate, etc.
	Citrus fruits	Mandarin orange, Orange, Grapefruit, Lemon, Korean lemon, Lime, Kumquat, Trifoliate orange, Citron etc.
	Stone fruits	Peach, Jujube, Apricot, Plum, Nectarine, Japanese apricot, Cherry, Korean-type cherry etc.
	Berries and other small fruits	Grape, Strawberry, Fig, Mulberry, Bilberry or Cranberry, Currant, Berry, Boxthorn, Schizandra, Wild grape, Rubus coreanus (Including wild berry, Raspberry) etc.
	Tropical fruits	Banana, Pineapple, Kiwifruit(Actinidia chinensis planch), Avocado, Papaya, Date palm, Mango, Guava, Coconut, Lychee, Passion fruit, Durian, etc.

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Procedure for establishment of MRLs



Toxicological evaluation

- * In environmental change
- * Physical, Chemical Property
- * Human toxicity
- * Animal toxicity

Safety evaluation (ADI = NOAEL/SF)



- * Capacity change (High → Low)
- * Mid-Insertion (Animal data → Human data)
- * Human body exposure amount (ADI, RfD)

Exposure assessment

Safety assurance

Exposure ≤ ADI →
 Exposure ≥ ADI → → Management decision

Hazard identification – Chlorantraniliprole

- IUPAC name: 3-Bromo-N-[4-chloro-2-methyl-6-(methylcarbamoyl)phenyl]-1-(3-chloropyridin-2-yl)-1H-pyrazole-5-carboxamide(M.W. 483.15)
- Formulation : 5% WP
- ADI : 2 mg/kg b.w./day (FAO/WHO)
 - NOAEL 158 mg/kg b.w./day, Safety factor : 100
- Acute toxicity : Rat LD₅₀ oral(2,000 mg/kg bw)
- Short term toxicity
 - Target/critical effect : kidney & haematotoxicity at high dose level
 - Relevant oral NOAEL : 90-d rat(73 mg/kg bw/d), 90-d mice(384 mg/kg b.w./day)
- Long term toxicity and carcinogenicity
 - Target/critical effect : kidney at high dose level
 - Relevant oral NOAEL : Mouse(158 mg/kg b.w./day)
- Genotoxicity : No genotoxic potential

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Magnitude of the Residue studies

Crop	Pesticide Formulation	Applicable disease& insect	Supervised trials			Safe use standard		Proposed MRL
			Days after treatment	No. of App.	Highest residue	Pre-harvest interval	No. of app.	
Persimmon	3% WG	Moths	21	2	<0.02	7	3	0.5
			14	2	<0.02			
			7	2	0.04			
			21	3	<0.02			
			14	3	<0.02			
			7	3	0.05			
Lettuce	5% WG	Moths	1	2	2.58	3	2	7.0
			3	2	2.34			
			5	2	1.77			
			1	3	3.30			
			3	3	2.79			
			5	3	2.32			

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Exposure assessment

- ADI : 2 mg/kg b.w./day
110 mg/person (2 mg.kg b.w./day × 55 kg)

Food	Draft MRL (mg/kg)	Food intake (kg/day)	Pesticide intake (mg)
Persimmon	0.5	0.0164	0.0082
Lettuce	7.0	0.0039	0.0273

TMDI	0.0355
TMDI/ADI (%)	0.0323

- **Conclusion**
 - TMDI/ADI(%) <80% → Proposed MRL

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Procedure for Import tolerance

- Follow the same procedures of the setting MRLs for national agricultural products
- Harmonization of CODEX MRL
- Detailed methods according to CODEX guideline
 - cGAP
 - Legal GAP data
 - Residue data of the maximum application
 - Maximum number of application
 - In compliance with GAP
 - Within ±25% of GAP
 - Proposed MRLs using OECD calculator

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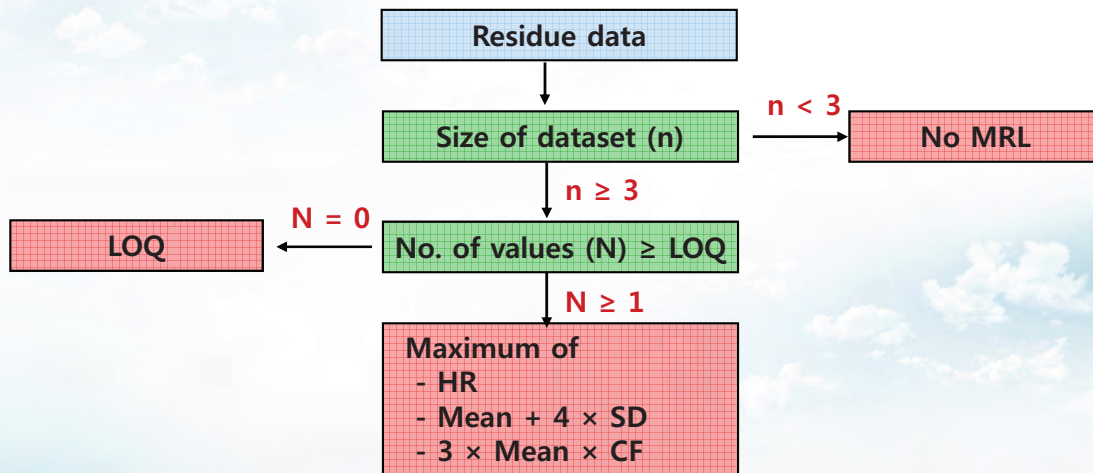


Fig. Logic of OECD calculator (2011)

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Working with the OECD MRL Calculator

- Example : $n < 3$

Residues (mg/kg)	
0.430	
0.490	

Total number of data (n)	2
Percentage of censored data	0%
Number of non-censored data	2
Lowest residue (LR)	0.430
Highest residue (HR)	0.490
Median residue (STMR)	0.460
Mean	-
Standard deviation (SD)	-
Correction factor for censoring (CF)	-

Proposed MRL estimate

- Highest residue (HR)	-
- Mean + 4 SD	-
- CF x 3 Mean	-
Unrounded MRL	-
Rounded MRL	-

MRL calculation not possible.

[Too small data set]

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● Example : n = 3

Residues (mg/kg)	
0.430	
0.490	
0.850	

Total number of data (n)	3
Percentage of censored data	0%
Number of non-censored data	3
Lowest residue (LR)	0.430
Highest residue (HR)	0.850
Median residue (STM _R)	0.490
Mean	0.590
Standard deviation (SD)	0.227
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

- Highest residue (HR)	0.850
- Mean + 4 SD	1.499
- CF x 3 Mean	1.770
Unrounded MRL	1.770
Rounded MRL	2

High uncertainty of MRL estimate.
[Small dataset]

● Example : fully censored dataset (<LOQ) → selects HR

Residues (mg/kg)	
0.010	*
0.010	*
0.020	*
0.020	*
0.020	*
0.020	*
0.020	*
0.040	*
0.040	*
0.040	*
0.040	*
0.040	*
0.040	*
0.040	*
0.040	*
0.040	*

Total number of data (n)	16
Percentage of censored data	100%
Number of non-censored data	0
Lowest residue (LR)	0.010
Highest residue (HR)	0.040
Median residue (STM _R)	0.040
Mean	0.031
Standard deviation (SD)	0.012
Correction factor for censoring (CF)	0.333

Proposed MRL estimate

- Highest residue (HR)	0.040
- Mean + 4 SD	0.079
- CF x 3 Mean	0.031
Unrounded MRL	0.040
Rounded MRL	0.04

High uncertainty of MRL estimate.
[High level of censoring]

● **Example : Mean + 4 × SD**

Residues (mg/kg)	
0.180	
0.230	
0.440	
0.650	
1.300	
2.300	
3.200	

Total number of data (n)	8
Percentage of censored data	0%
Number of non-censored data	8
Lowest residue (LR)	0.180
Highest residue (HR)	3.200
Median residue (STMR)	0.975
Mean	1.213
Standard deviation (SD)	1.077
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

- Highest residue (HR)	3.200
- Mean + 4 SD	5.521
- CF x 3 Mean	3.638
Unrounded MRL	5.521
Rounded MRL	6

● **Example : 3 × Mean × CF**

Residues (mg/kg)	
0.010	*
0.010	*
0.010	*
0.010	*
0.010	*
0.010	*
0.010	*
0.010	*
0.010	*
0.010	*
0.010	

Total number of data (n)	9
Percentage of censored data	89%
Number of non-censored data	1
Lowest residue (LR)	0.010
Highest residue (HR)	0.010
Median residue (STMR)	0.010
Mean	0.010
Standard deviation (SD)	0.000
Correction factor for censoring (CF)	0.407

Proposed MRL estimate

- Highest residue (HR)	0.010
- Mean + 4 SD	0.010
- CF x 3 Mean	0.012
Unrounded MRL	0.012
Rounded MRL	0.015

High uncertainty of MRL estimate.
[High level of censoring]

● **Example : 3 × Mean × CF**

Residues (mg/kg)	
0.510	
0.680	
0.790	
0.450	
0.280	
0.270	
0.680	
0.660	
0.520	
0.310	
0.360	

Total number of data (n)	11
Percentage of censored data	0%
Number of non-censored data	11
Lowest residue (LR)	0.270
Highest residue (HR)	0.790
Median residue (STMR)	0.510
Mean	0.501
Standard deviation (SD)	0.183
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

- Highest residue (HR)	0.790
- Mean + 4 SD	1.232
- CF × 3 Mean	1.503
Unrounded MRL	1.503
Rounded MRL	1.5

● **Example : HR (Unusually high residue value)**

Residues (mg/kg)	
0.010	
0.010	
0.020	
0.020	
0.020	
0.020	
0.020	
0.030	
0.030	
0.030	
0.030	
0.040	
0.040	
0.040	
0.040	
0.050	
0.060	
0.070	
0.080	
0.330	

Total number of data (n)	20
Percentage of censored data	0%
Number of non-censored data	20
Lowest residue (LR)	0.010
Highest residue (HR)	0.330
Median residue (STMR)	0.030
Mean	0.050
Standard deviation (SD)	0.069
Correction factor for censoring (CF)	1.000

Proposed MRL estimate

- Highest residue (HR)	0.330
- Mean + 4 SD	0.324
- CF × 3 Mean	0.149
Unrounded MRL	0.330
Rounded MRL	0.4

Positive List System (PLS)

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Status of imported foods

● Inspection of imported foods : 2007-2011 year

<Unit : cases, thousand tons, Million US dollars>

Classification	2007	2008	2009	2010	2011
Case	270,163	254,809	255,341	293,988	312,723
Weight	11,799	11,731	11,301	12,905	13,471
Amount	8,449	9,860	8,434	10,358	13,212
Reject (Rate)	1,448 (0.54%)	1,020 (0.40%)	1,229 (0.48%)	1,143 (0.39%)	1,015 (0.32%)

Increasing Every years 

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Promoting New regulations in Korea

❖ Positive list system(PLS) will be adopted.

◆ Background

- Increasing food imports, accuracy of risk assessment has been challenged because the imported foods are applied with Codex MRLs or tentative residue limits in similar agriculture products, livestock products and aquatic products without the appropriate evaluation.
- Where the compound was not registered in Korea, It is necessary to evaluate the safety of the pesticide to protect human health.

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◆ Recently, the following works have being processed.

- Before 2000, Korea adopted MRLs from the regulation of foreign countries, not based on scientific data.
The MRLs should be re-evaluated for public health.
- ➔ The pesticide and veterinary drug MRLs, which are not registered in Korea, may be deleted from Korea Food Code.
 - See Withdrawn MRLs List (next presentation)
- Exemption list will be developed.
- The pesticide will be listed, where the compound should not be detected in foods because it may be harmful to human health.

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List of pesticide MRLs to be deleted

<Example>

현행	개정안
[별표 4] 농산물의 농약 잔류허용기준	[별표 4] 농산물의 농약 잔류허용기준
(1) (생략)	(1) (현행과 같음)
(2) ~ (4) (생략)	(2) ~ (4) (현행과 같음)
(5) 노르플루라존(Norfurazon)	<삭제>
(6) 니트라피린(Nitrapyrin)	<삭제>
(7) 다미노자이드(Daminozide)	<삭제>
(8) 다이아지논(Diazinon) (생략)	(8) 다이아지논(Diazinon) (현행과 같음)
가지 0.1	<삭제>
고구마 0.1	<삭제>
고사리 0.5	<삭제>
귀리 0.1	<삭제>
기타감귤류 0.1	<삭제>
기타곡류 0.1	<삭제>
기타콩류 0.1	<삭제>

현행	개정안
(28) 디펜아미드(Diphenamid)	<삭제>
(29) (생략)	(29) (현행과 같음)
(30) 리누론(Linuron) (생략)	(30) 리누론(Linuron) (현행과 같음)
귀리 0.2	<삭제>
면실 0.2	<삭제>
밀 0.2	<삭제>
셀러리 0.5	<삭제>
수수 0.2	<삭제>
아스파라거스 3.0	<삭제>
호밀 0.2	<삭제>
(31) 마이클로부타닐(Myclobutanil) (생략)	(31) 마이클로부타닐(Myclobutanil) (현행과 같음)
가지 1.0	<삭제>
당근 1.0	<삭제>
마늘 1.0	<삭제>
망고 1.0	<삭제>
모과 1.0	<삭제>
밀 0.3	<삭제>
바나나 2.0	<삭제>

Exemption list

<Pesticide>

제 2. 식품일반에 대한 공통기준 및 규격

5. 식품일반의 기준 및 규격

10) 농약의 잔류허용기준

(1) (생략)

(2) 농산물의 농약 잔류허용기준

- ① 농산물의 농약 잔류허용기준은 [별표 4]와 같다.
- ② 아래의 성분에 대하여는 잔류허용기준 설정을 면제한다.

번호	농약 목록
1	1-메틸사이클로프로펜(1-Methylcyclopropane)
2	기계유(Machine oil)
3	나트륨리그노설포네이트(Sodium ligno sulfonate)
4	덤실알코올(Decylalcohol)
5	모나크로스포룸타우마솜케이비시9017(<i>Monacrosporium thumasiatum</i> KBC3017)
6	바실루스서브틸리스디비비1501(<i>Bacillus subtilis</i> DBB1501)
7	바실루스서브틸리스케이제이9(<i>Bacillus subtilis</i> CJ-9)
8	바실루스서브틸리스엠 27(<i>Bacillus subtilis</i> M 27)
9	바실루스서브틸리스엠비아이600(<i>Bacillus subtilis</i> MB600)
10	바실루스서브틸리스와이1336(<i>Bacillus subtilis</i> Y1336)
11	바실루스서브틸리스이더블유42-1(<i>Bacillus subtilis</i> EW42-1)
12	바실루스서브틸리스케이케이제이238(<i>Bacillus subtilis</i> JKK238)
13	바실루스서브틸리스지비365(<i>Bacillus subtilis</i> GB0365)
14	바실루스서브틸리스케이비401(<i>Bacillus subtilis</i> KB401)
15	바실루스서브틸리스케이비시1010(<i>Bacillus subtilis</i> KBC1010)
16	바실루스서브틸리스큐에스티713(<i>Bacillus subtilis</i> QST713)
17	바실루스아밀로리퀴파시엔스케이비시1121(<i>Bacillus amyloquelicifera</i> KBC1121)
18	바실루스루밀루스큐에스티2808(<i>Bacillus pumilus</i> CST2808)
19	보르도혼합액(Bordeaux mixture)
20	뷰티리아바시이나지케이치케이(<i>Beauveria bassiana</i> CHA)
21	뷰티리아바시이나지케이비아이-1(<i>Beauveria bassiana</i> TBI-1)
22	비티아이자와이(<i>Bacillus thuringiensis</i> subsp. aizawai)
23	비티아이자와이엔티423(<i>Bacillus thuringiensis</i> subsp. aizawai NT0423)

24	비티아이자와이제비413(<i>Bacillus thuringiensis</i> subsp. aizawai GB413)
25	비티쿠르스타키(<i>Bacillus thuringiensis</i> subsp. kurstaki)
26	비티쿠르스타키(<i>Bacillus thuringiensis</i> var. kurstaki)
27	석유류(Petroleum oils)
28	석회황(Lime sulfur)
29	스트렙토마이세스고시키엔시스더블유와이324(<i>Streptomyces goshikiensis</i> WYE324)
30	스트렙토마이세스콜롬비엔시스더블유와이20(<i>Streptomyces colombiensis</i> WYE20)
31	스프레더스티커(Spreader sticker)
32	실록세인(Siloxane)
33	아이비에이(IBA, 4-indol-3-ylbutyric acid)
34	아이에이에이(IAA, Indol-3-ylacetic acid)
35	알킬설포네이트알킬레이트의나트륨염(Sodium salt of alkylsulfonated alkylate)
36	알킬아릴폴리옥시에테르(Alkyl aryl polyethoxylate)
37	암펠로마이세스퀴스칼리시에이큐94013(<i>Ampelomyces quisqualis</i> AQ94013)
38	야자유지방산, 글리세롤, 무수지방산의 중합체(Polymer of coconut oil fatty acids, Glycerol, and phthalic anhydride)
39	옥시에틸렌 메틸실록세인(Oxyethylene methyl siloxane)
40	지베렐린류(Gibberellin A ₃ , Gibberellin A ₄)
41	칼슘카보네이트(Calcium carbonate)
42	코퍼설페이트베이식(Copper sulfate basic)
43	코퍼설페이트트리베이식(Copper sulfate tribasic)
44	코퍼옥시클로라이드(Copper oxychloride)
45	코퍼하이드록사이드(Copper hydroxide)
46	트리코델마하지아눔와이제 459(<i>Trichoderma harzianum</i> YC 459)
47	패니바실루스폴리믹사에이시-1(<i>Panibacillus polymyxa</i> AC-1)
48	페실로마이세스푸모소레우스디비비-2032(<i>Pezizomyces fumosoroseus</i> DBB-2032)
49	폴리(디메틸실록세인)디메틸아릴폴리옥시에테르(Trimethyl silyl dimethyl aryl polyoxyethylene) (PMGADA)
50	폴리에테르폴리실록세인(Polyether modified polysiloxane)
51	폴리옥시에틸렌 메틸실록세인(Polyoxyethylene methyl polysiloxane)
52	폴리옥시에틸렌 알킬아릴 에테르(Polyoxyethylene alkylaryl ether)
53	폴리옥시에틸렌 지방산 에스테르(Polyoxyethylene fatty acid ester)(PFAE)
54	황(Sulfur)

Change of Pesticide regulation in Korea

Current

- ❖ Pesticide for which the MRLs are set (registered compounds)
→ Food code is applied
- ❖ Pesticide for which no MRLs have been set (not registered compounds)
 - Codex MRLs and MRLs for similar agricultural /livestock/ aquatic products is applied →
It is permitted to distribute the food in which the pesticide residue level not exceed the MRLs.



After the PLS adopted

- ❖ Pesticide for which MRLs are set (registered compound)
→ Food code is applied
- ❖ Pesticide for which no MRLs have been set (not registered compounds)
 - It is not permitted to distribute the food in which pesticide residue level exceed 0.01 ppm.
- ❖ Compounds authorized by the Ministry of Food and Drug Safety (MFDS)
 - Not harmful compounds
→ "Exemption list"
 - Harmful compounds
→ "Non-detection list"

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- If a country or producing company which object to re-evaluate a compound, they are able to request the import tolerance.
- It is expected that more than of 150 import tolerances will be requested until 2015.
- As re-evaluating the MRLs of pesticide, the MRLs will be revised and established reasonably and harmoniously with the Codex MRLs.
- Group MRLs will be extended.
- The methods using GC-MS/MS and LC-MS/MS will be established for detecting pesticide residues

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- Comments on the PLS will be collected from consumers, producers and importers.
- The PLS will come into effect in 2016

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Establishment of CODEX MRLs

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Activities of Korea in Codex

❖ Codex MRLs for a minor crop commodity

- ◆ Korean government has invested much time and cost for establishing the Codex MRLs for ginseng(one of the minor crop)

REP11/PR Appendix III (2011)				
	Commodity	MRL (mg/kg)	Step	Note
224	Difenoconazole			
	VP 0061 Beans, except broad bean and soya bean	0.7	5/8	
	MO 0105 Edible offal (mammalian)	0.2	5/8	
	VR 0604 Ginseng	0.5	5/8	
229	Azoxystrobin (2012)			
	SB 0716 Coffee beans	0.02	5/8	
	VR 0604 Ginseng	0.1	5/8	
229	Azoxystrobin (2013)			
	FT 0289 Carambola	0.1	5/8	
	DV 0604 Ginseng, dried including red ginseng	0.3	5/8	
	DM 0604 Ginseng, extracts	0.5	5/8	

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❖ Food classification for Persimmon

- ◆ Korea classifies persimmon as a pome fruit as same as apples and pears, because of the persimmon's product shape, the way it is cultivated and the traits of pesticide residue are similar.
- ◆ Korea proposed that persimmon should be re-classified from 'Tropical and subtropical fruits' to 'Pome fruits' to codex.
 - Persimmon grows in Shandong province, China and Hwa-buk province, temperate zones in China, the central and southern regions of the Korean Peninsula as well as Korea's East coast.
 - And, pesticide residue patterns of the persimmon are completely different from that of 'Tropical and subtropical fruits' such as banana.



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FOOD CLASSIFICATION MATERIAL ON PERSIMMONS

■ **Outline of Persimmon**

- Scientific name : Diospyrus kaki var. kaki
- Common name : Oriental Persimmon,
- Local name : Gam (Korea), Shi (China), Kaki(Japan)
- Traits : Deciduous plant mainly cultivated in temperate regions of Eastern Asia.



- Origin : China
- General Information : With regard to species that belong to Genus Diospyrus, 40 different varieties of persimmons grow in tropical areas. However, those persimmons are classified differently from edible persimmons. Diospyrus Kaki var. kaki that we use as a fruit is cultivated in a temperate zone as a deciduous plant. Diospyrus Kaki var. kaki grows in Shandong province, China and Hwa-buk province, temperate zones in China, the central and southern regions of the Korean Peninsula as well as Korea's East coast.

The Attached : Field trials in Korea (Residue Levels)

● Amitraz

Commodity	Formulation	Dilution	Volume (L/10a)	Pesticide rate (kg ai/10a)	PHI days	Number	Residues (mg/kg)
Persimmon	20% EC	1,000	500	0.1	35	2	<0.04
					25	2	<0.04
					25	3	<0.04
					15	3	<0.04
Pear	20% EC	1,000			21	2	0.21
					14	2	0.23
					21	3	0.27
					14	4	0.36
Apple	20% EC	1,000	500	0.1	20	2	0.29
					30	3	0.42
					20	3	0.23
					10	3	0.27
					20	4	0.43
					10	4	0.39

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❖ Food classification for Chinese jujube

- ◆ Korea has been suggested some comments that Chinese jujube (stone fruits) has been classified wrong category(tropical fruits) in Codex food classification.
 - In contrast to Indian jujube, mainly cultivated in India and Pakistan, Chinese jujube has been cultivated in temperate regions of Eurasia including eastern Asia, Germany, and Russia.
 - In the field trials on 15 other pesticide components on stone fruits, residues on the jujube are similar to residues on other stone fruits such as apricot, plum and peach.
- ◆ Concerning the notification for revision of classification for stone fruits in 'US EPA propose rule', Korea also proposed that Chinese jujube should be classified as stone fruits.

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FOOD CLASSIFICATION MATERIAL ON CHINESE JUJUBE

■ Outline of Chinese Jujube

- Scientific name: *Ziziphus jujuba* Mill
- Common name: Chinese Jujube, Jujube
- Local name: Zao(China), Daechu(Korea), Natsume(Japan)
- Traits: Deciduous plant mainly cultivated in temperate regions of East Asia.
- Origin: China
- General information on *Ziziphus*: *Ziziphus* is the authentic name of jujube genus on the basis of Gray Index and Kew Index, though *Zizyphus* is frequently used. The genus *Ziziphus* contains about 100 species, most of which occur in tropical and subtropical areas. Tropical species of *Ziziphus* include Indian Jujube (*Z. mauritiana*) and Joã (*Ziziphus joazeiro*; FI-). In contrast to tropical species, Chinese Jujube (*Ziziphus jujuba*) occurs in temperate regions including China, Korea, and Japan. The deciduous *Ziziphus* species is widely cultivated in temperate regions. Jujube is the term used for the fruits of *Ziziphus jujuba*, also the fruits of *Ziziphus spp.*

■ Supporting information II: Chinese Jujube, a stone fruit



Fresh Jujube having stone



Dried Jujube

■ The Attached: Field trials in Korea (Residue Levels)

• Difenconazole

Commodity	Formulation	Dilution	Volume (L/10a)	Pesticide rate (kg ai/10a)	PHI days	Number	Residues (mg/kg)
Jujube	10.7% SC	5,000	600	0.0128	21	3	0.28
					14	3	0.36
					7	3	0.42
					14	4	0.38
					7	4	0.56
Peach	10% SC	2,000	500	0.025	7	5	0.59
					14	4	-0.005
					21	4	0.027
					14	5	0.149
					7	5	0.209
Cherry	10% SC	2,000	400	0.02	14	2	0.09
					7	2	0.19
					14	3	0.13
					7	3	0.33
					14	4	0.17
					7	4	0.42

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CODEX ALIMENTARIUS COMMISSION



**Food and Agriculture
Organization of
the United Nations**



**World Health
Organization**

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.net

REP11/PR

CODEX COMMITTEE ON PESTICIDE RESIDUES

Shanghai, China, 23 - 28 April 2012

Group 003 Stone fruits

102. A Delegation proposed to move "Apricot" and/or "Apricot, Japanese" from Subgroup 003C Peaches to Subgroup 003B Plums as the sizes of these fruits were similar and significantly smaller than those of peach and nectarine which might give rise to different residues levels in the fruits. However, the Committee did not agree with the proposal as the surface of these fruits was more similar to peaches than to plums.

Group 005 Assorted Tropical and Subtropical Fruits – Edible Peel

103. The Committee agreed to transfer "Jujube, Chinese" from Subgroup 005A - Assorted tropical and subtropical fruits, edible peel, small to Subgroup 003B Plums due to similar growing conditions and pesticide residue patterns. The Committee further noted that the description of Group 003 needed amendment to stone fruit-like fruits from temperate climate, such as Jujube, Chinese.

104. The Committee agreed to transfer "Persimmon, Japanese" to Group 002 Pome Fruits as the fruit was similar to pome fruits in relation to water content, percentage of sugar and similar use pattern for pesticide, residue behaviour and portion to the commodity to which the MRL apply. The Committee further noted that the description of Group 002 needed amendment to pome fruit-like fruits from temperate climate, such as Persimmon, Japanese.

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❖ Proposals to working group in 2012, 2013

- In Working group for Foods and Feeds Classification in 2012 and 2013, Korea proposed to add some Korean agricultural products to Codex food classification.

: Kimchi cabbage, Cham-chwi, Cham-na-mul, *etc.*



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Suggestion for the setting of CODEX MRLs for minor crops


- **Regional/International Joint Review and Cooperation for the Setting of Codex MRLs for Minor Crops**
 - Regional/International cooperation on the generation of residue data for minor crops in which countries have common interests
- **Extend of the group MRLs**
 - Minor crops including vegetables, assorted tropical and sub-tropical tropical fruits, nuts and seeds, *etc.*

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감사합니다

Thank you



Pesticide Registration System in Japan

Yoshiyuki TAKAGISHI

Agricultural Chemicals Office
Plant Products Safety Division
Food Safety and Consumer Affairs Bureau



1

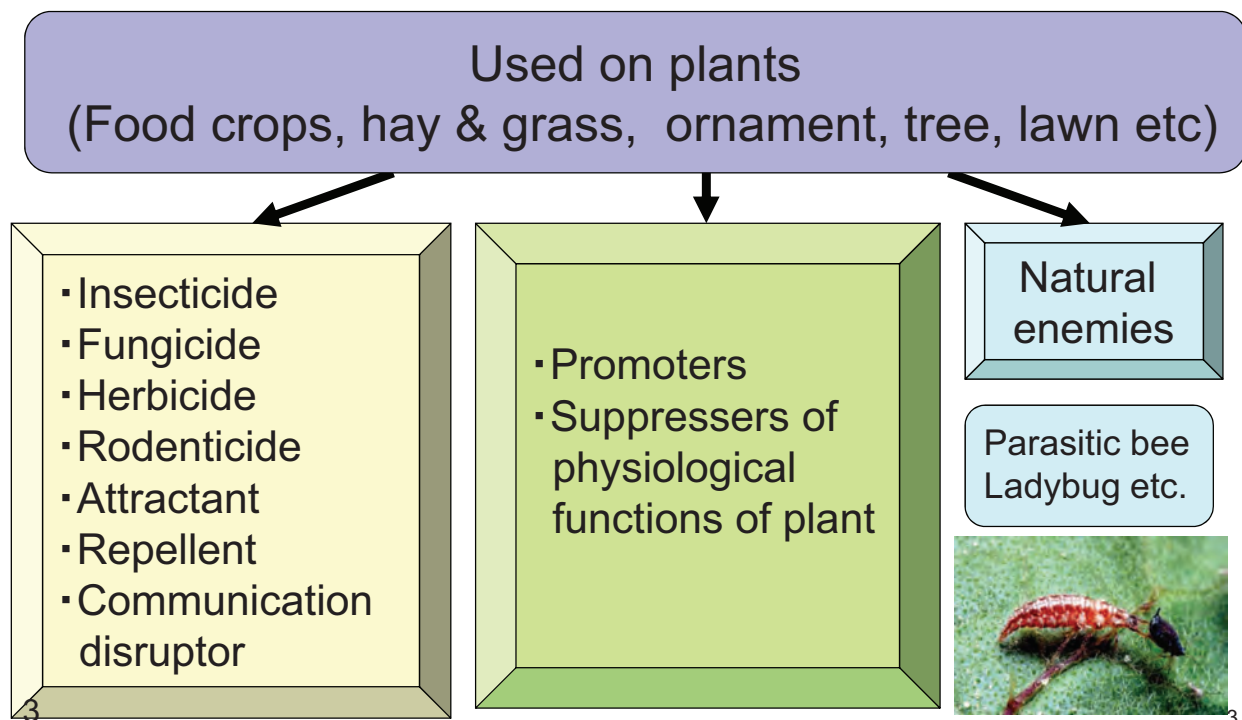


Contents

- Current pesticide registration system in Japan
- Establishment of MRLs (including import tolerance)
- Reformation of the registration system

2

Scope of *Pesticides* (Agricultural Chemicals) under the Law



Laws Concerning Registration and MRL setting of *Pesticides* (Agricultural Chemicals)

■ Agricultural Chemicals Regulation Law

- MAFF (Ministry of Agriculture, Forestry and Fisheries)
- MOE (Ministry of Environment)

■ Food Sanitation Law

- MHLW (Ministry of Health, Labor and Welfare)

■ Food Safety Basic Law

- FSC (Food Safety Commission)

Outline of Regulation (1)

ACs Regulation Law

Prohibition of manufacture / import of pesticides not registered in Japan



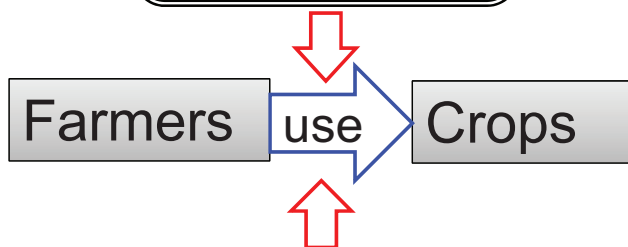
- **Prohibition** of the sale of unregistered pesticides
- Order to **recall** illegal and/or unsafe pesticides

5

Outline of Regulation (2)

ACs Regulation Law

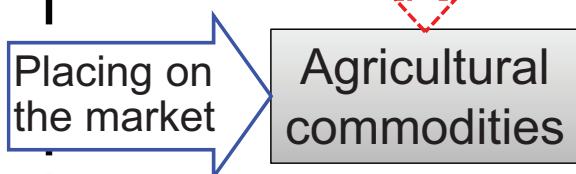
Obligation to follow GAP



Prohibition of using unregistered pesticides

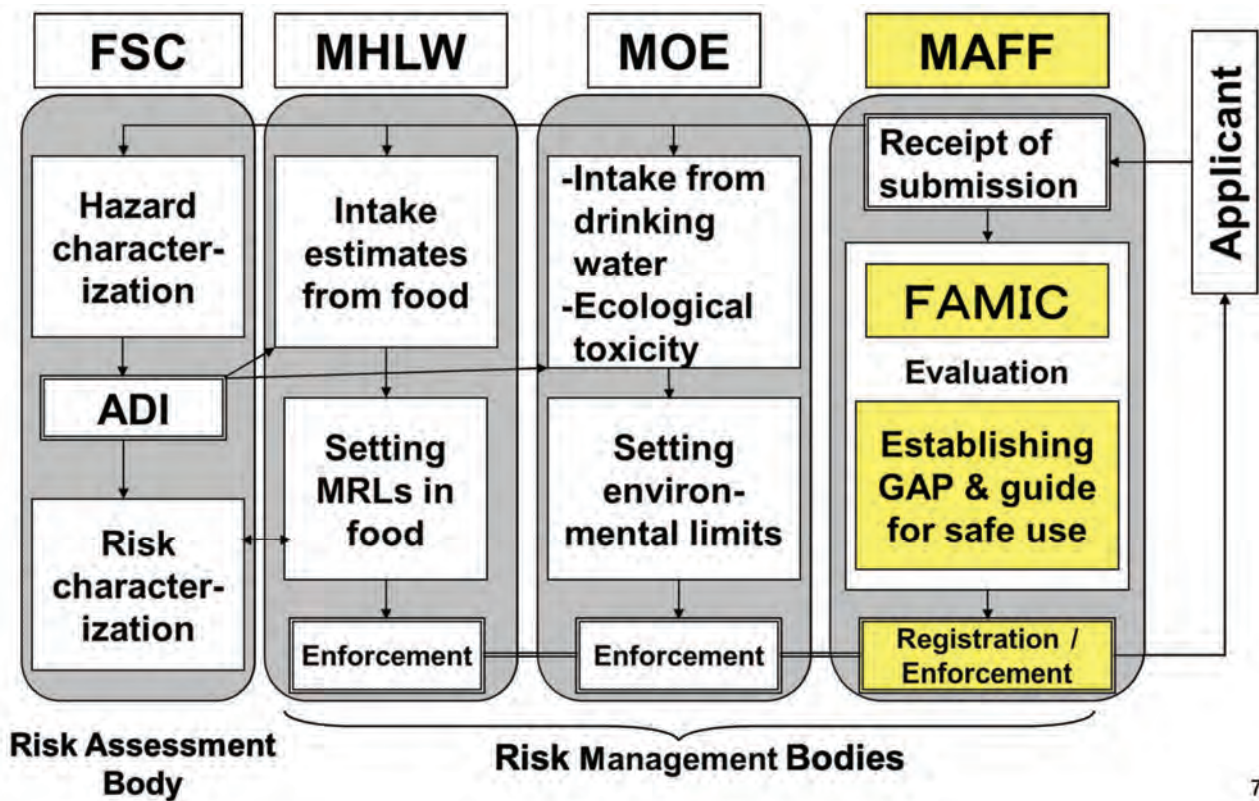
Food Sanitation Law

Monitoring / enforcement of MRLs



6

Pesticide Registration and MRLs Setting



7

Required Data for Registration (1)

■ Quality of AC formulation

- Active ingredient & auxiliary substances (content, method of analysis)
- Physical and chemical properties
- Specification & samples (technical grade, formulation(s))
- Stability

■ Efficacy / Phytotoxicity

- Field test results

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Required Data for Registration (2)

■ **Safety**

- Toxicology (acute/subchronic/chronic toxicity, carcinogenicity, neurotoxicity, teratogenicity, mutagenicity, irritation etc.)
- Plant / animal metabolism
- Residues in crops
- Environmental fate (soil, water)
- Ecotoxicology (fish, aquatic invertebrate, algae)
- Method of Analysis

■ **Use Pattern (GAP)**

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Establishment of MRLs (including Import Tolerance)

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MRLs for Foods in Japan

- Responsibility of MHLW
- “Positive List”: pesticide / commodity combination to be tested
- Based on the results of supervised residue trials according to GAP in Japan (for registered pesticides)
- Harmonization with Codex MRLs as much as possible
- Portions to which MRLs apply are not the same as Codex MRLs

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MRLs for Feeds and Foods of Animal Origin

- Estimated by MAFF, in principle, following the process used by JMPR (if data are available)
 - ✓ Review residue data on feed crops or crops whose byproducts may be fed to animals
 - ✓ Using OECD Calculator to estimate MRLs
 - ✓ Calculate potential highest total intake from feed (worst case scenario) using the table of feed rations in Japan
 - ✓ Using the above intake and the result of livestock feeding study to estimate MRLs for foods of animal origin

□ MRLs for feeds



Established by MAFF under the Law Concerning Safety Assurance and Quality Improvement of Feeds

□ MRLs for foods of animal origin



Legalized by MHLW under Food Sanitation Law

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Import Tolerance for food and feed (1)

- Established upon application to MHLW (food) or MAFF (feed) for:
 - Pesticide registered in a country (not in Japan)
 - Food or feed crops
 - ✓ For which the pesticide can be used
 - ✓ In which residues were expected
 - ✓ Expected to be exported to Japan
- Specific points for feeds
 - As import of feed from AU, CA & US accounts for ca. 90% of the total import, IT is established only for feed imported from these countries

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Import Tolerance for food and feed (2)

- Anybody can apply provided that an appropriate contact person in Japan is identified
- No charge
- Language
 - Monograph in Japanese
 - Individual study reports can be in English or Japanese

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Required Data for IT application

- Studies should be conducted in compliance with the GLP requirements.
- The following studies are not required:
 - Efficacy / phytotoxicity studies
 - Studies on operator exposure and by-stander exposure
 - Studies on environmental safety
- Livestock metabolism and feeding studies are required to establish ITs for feed and/or animal commodities
- Otherwise, similar to those for registration

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For more information on MRLs (including IT) for Food and Feed

- MRL Database
 - for Food:
<http://www.m5.ws001.squarestart.ne.jp/foundation/search.html>
 - for Feed:
http://www.famic.go.jp/ffis/feed/r_safety/r_feeds_safety22.html#pesticides
- Application for IT:
 - for Food (MHLW)
<http://www.mhlw.go.jp/english/topics/foodsafety/residue/index.html>
 - for Feed (MAFF)
http://www.famic.go.jp/ffis/feed/obj/21_11433_1.pdf

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Reformation of the Registration System

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Principles of the Reformation (2007-)

- Law-based & hazard-based to risk-based
 - Decision-making on a basis of scientific data and information taking into account magnitude of risk
- Participation in international rule-making in Codex Alimentarius Commission, OECD, etc.
- Harmonization with these rules
- Transparent decision-making through risk communication with all stakeholders

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Agreed New Approach (1)

Revision of “Guidelines for Residue Trials”(2014-)

- Increase of No. of trials
 - Major crops (22) 2 → 6 trials
 - Semi-major crops (34) 2 → 3 trials
 - Minor crops (others) 2 trials (unchanged)
- Acceptance data on indoor trials conducted in other countries (same GAP)
- Harmonization of portions analyzed
- Quality assurance of analysis

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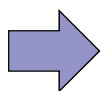


Agreed New Approach (2)

■ Development of Crop Groups

- Based on the Codex Classification
- Reflecting the reality in Japan
- Harmonization of portions to be analyzed with those of Codex

Leading to potential decrease of requirements



Providing opportunity to cover minor crops

For more information, please see the following website :
http://www.maff.go.jp/j/nouyaku/n_sassin/sakumotu.html

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Agreed New Approach (3)

■ Selection of Representative Crops

- Representative crop(s) for each crop group for group MRL and registration
- Taking actual use of pesticides in Japan into consideration
- No. of trials for each representative crop
- Stepwise process for crop groups

➔ Simplification of requirements for registration

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Agreed New Approach (4)

■ Guidelines for Livestock Metabolism and Animal Transfer Studies (2017/18-)

- Required for new pesticides whenever residues are detectable on feed crops
 - For existing pesticides, data submission prioritized taking account of maximum theoretical dietary burden and fat-solubility
- Animal Feeding Table already established and provided to OECD

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Agreed New Approach (5)

■ Efforts for enhanced participation in Global Joint Review:

- Improvement of format of application documents including introduction of OECD-style dossier
- Preparation of monograph and evaluation report for each pesticide
- Acceptance of electronic files
- Acceptance of study reports in English
- Education and training of evaluators (including English): training courses

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Special Consideration for Minor Crops

- A Group MRL can cover minor commodities in the group.
- In addition,
 1. Decrease of data requirement:
Efficacy/ Phytotoxicity: 6 → 2 trials
 2. Cooperative system for data generation and information sharing is established among MAFF, prefectures and related stakeholders.
 3. Cost for data generation by prefectural institutes are supported by MAFF.

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Thank you for listening



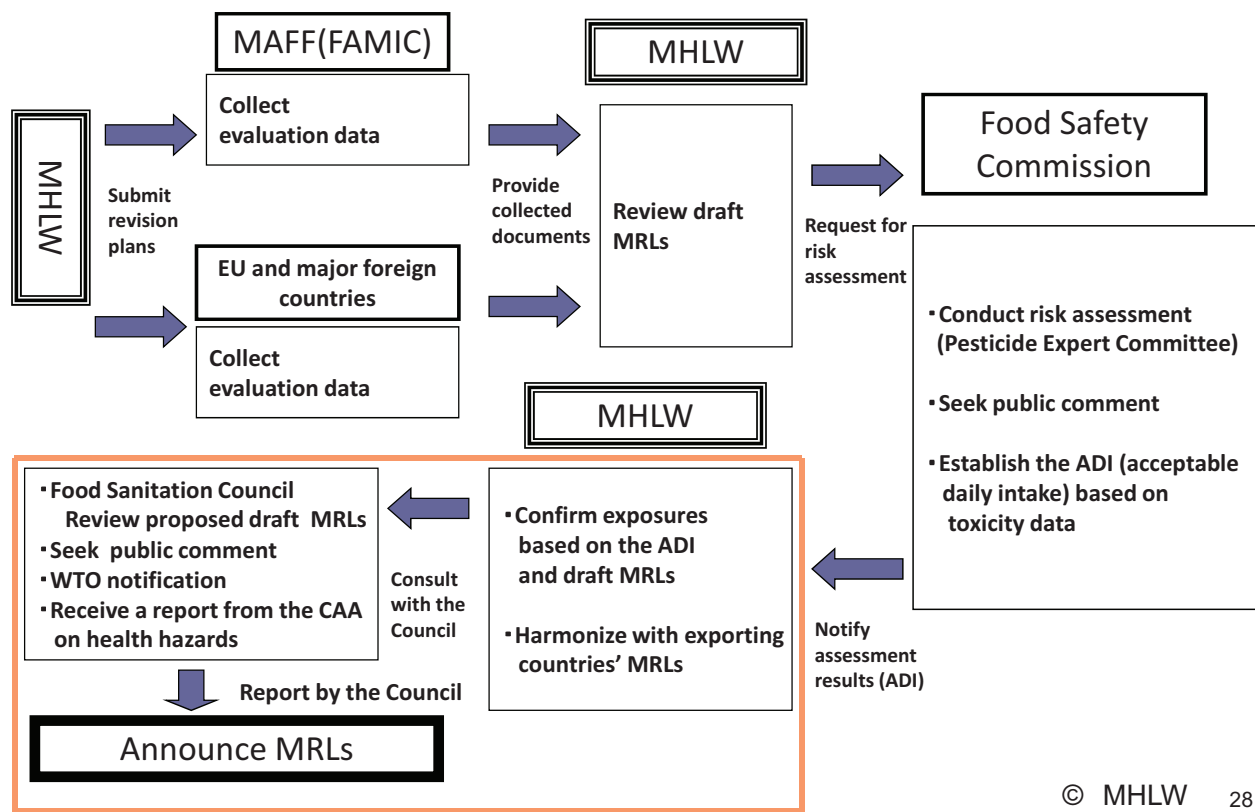
Back-up Slides

“Provisional MRLs” for Foods under “Positive List”

- In 2006, “Provisional MRLs” were established for 758 chemicals (— > 799) considering :
 - Codex
 - National MRL (registered pesticides)
 - MRLs in AU, CA, EU, NZ and US
- Provisional MRLs are under revision by MHLW
 - MHLW will ask FSC to evaluate all chemicals for which provisional MRLs have been established

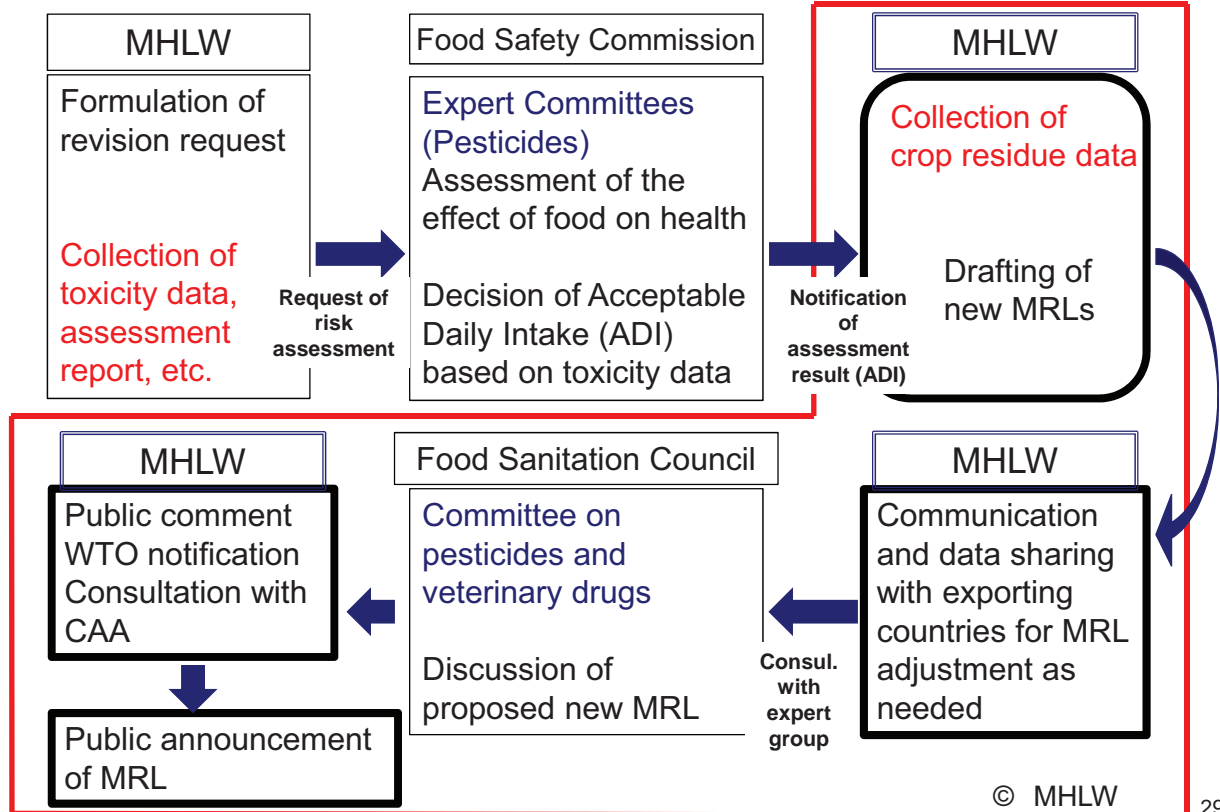
27

Revision of Provisional MRLs



© MHLW 28

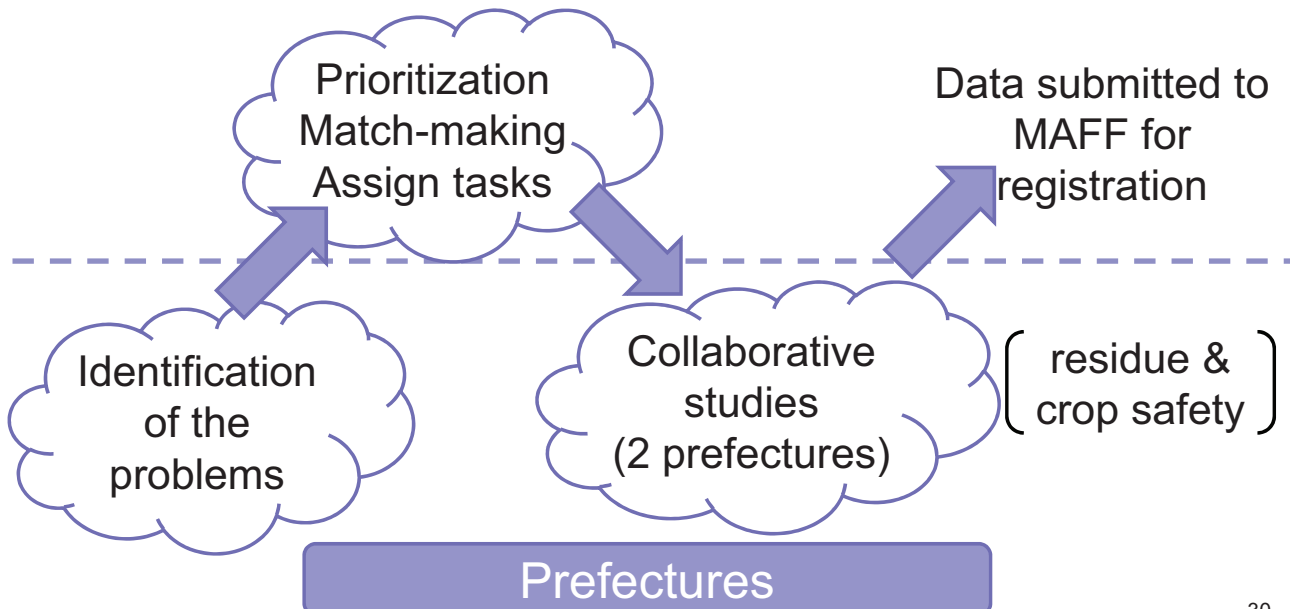
Process of Establishment of IT for Food



Cooperative Data Production

National Consultative Meeting

MAFF, Regional Offices, Agricultural Chemicals Inspection Station, other stakeholders






Financial Support to Data Production

- Costs for:
 - Efficacy /phytotoxicity studies
 - Residue trials

by prefectural institutes for the registration of pesticides for minor crops are eligible for support by MAFF (50%)

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Currently Registered Pesticides (As of September 2013)

Formulations	4,342
Active ingredients	555

Distinction of Agricultural Chemicals

- Formulations (e.g. granular, emulsion)
- Contents of A.I. (e.g. 5% and 10% A.I.)
- Mixture with other A.I.(e.g. A.I. "A" and A.I. "B")
- Trade marks

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Comparison of Data Requirements in Japan with those in EU & USA

(1) Toxicity

- Similar except requirement for developmental neurotoxicity studies

(2) Residues

- Smaller number of required supervised residue trials
- Rotational crop studies: conditional
- Processing studies: voluntary
- Metabolism & feeding study in livestock: not necessary except excretion in milk

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Supervised Field Trials Required (in 2008)

	JMPR	EU	USA	Japan
No. of trials (Major crop)	6-10	16 for 2 zones	8-20	2 or more (Analysis: cross check)
GLP	○1	○	○	○2

NB 1: GLP principles or in compliance with national regulations ensuring the quality of residue data.

2: Started in April 2008 and full compliance required from April 2011.

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Required Data for Registration (3)

~ *for microbial pesticides* ~

■ Specific Requirements

- Biological characterization of the microorganism
- Single intravenous administration study
- Cell culture study (for viral pesticides) ...etc

■ Exemptions

- Repeated dose (long-term)
 - Crop residue (if no adverse health effect expected)
 - Effects on non-target organisms (if adverse effects can be ruled out or exposure is unlikely)
- ...etc

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Examples of GAP

Emulsion

Crop	Target insects	Spray conc. (dilution fold)	PHI (day)	No. of appl.	Appl. method
Cabbage	Aphids Cabbage moss	1000	30	2	spray
	Green caterpillar	1500			
Tomato	Aphids Spider mites	1000	1	2	spray

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Potential New Approach

~ Elements of risks to be evaluated ~

- Health effects of short-term intake of pesticides (ARfD and NESTI)
- Evaluation of acceptable occupational exposure level (AOEL) and exposure assessment for operator, worker and by-stander

~ New concept in the registration system ~

- Periodic reevaluation of registered pesticides
 - review of all data submitted in accordance with the requirements at the time of reevaluation

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MRLs Setting Process In China

Wu Zhifeng

ICAMA of MOA, China

1/20/2014



Outline

1. Brief Introduction of ICAMA.

2. Food Safety Related Laws and Regulations

3. MRLs Setting Process:

- Agencies responsible for the management and establishment of MRLs
- Protocols for MRL establishment
- Current situation of MRLs in China.
- Challenges and future outlook

4. Efforts to Register and Establish MRLs for Minor Uses.

5. Cooperation at the Regional or International Level.

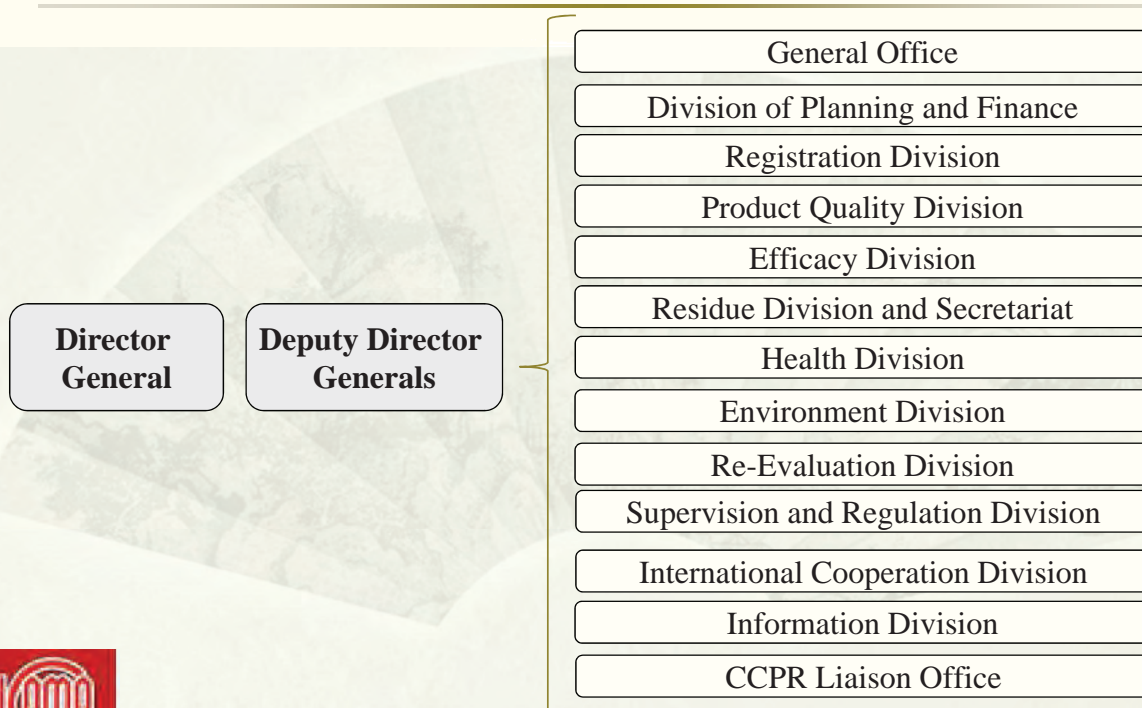


ICAMA

- Institute for the Control of Agrochemicals, Ministry of Agriculture
- National authority for pesticide registration and management
- Over 150 staff
- 13 divisions
- Undertakes relevant responsibilities of the secretariat of the National Pesticide Review Committee



ICAMA Organizational Structure



Food safety related laws and regulations

- **Food Safety Law** of the People's Republic of China, promulgated on 28 Feb.2009 and implemented on 1 June 2009;
- **Law on the Quality and Safety of Agricultural Products** of the People's Republic of China, promulgated on 29 Apr.2006 and implemented on 1 Nov. 2006;
- **Pesticide Management Regulations** of the People's Republic of China, promulgated and implemented on 8 May 1997; revised on 29 Nov 2001 and 8 Jan. 2008.



Food safety related laws and regulations

Food Safety Law

- **Article 19** Food safety standards are compulsory. No other compulsory food standards shall be formulated except the food safety standards.
- **Article 20** Food safety standards shall specify: (1) **limits** of pathogenic microorganism, **pesticide residues**, veterinary drug residues, heavy metals, pollutants and other substances that jeopardize people's health; Limits of residues of pesticides and veterinary drugs in food, methods and protocols of inspection **shall be formulated by competent health and agriculture departments of the State Council.**



Food safety related laws and regulations

Food Safety Law

- **Article 23** National food safety standards shall be reviewed and approved by National Standard Review Committee of Food Safety, which is composed of experts on medicine, agriculture, food, nutrition, etc. and representatives of relevant departments of the State Council. **The establishment of national food safety standards shall be based on the result of food safety risk assessment**, take into full consideration the result of risk assessment of the quality and safety of agricultural products for food use, refer to the result of relevant international standards and the result of international food safety risk assessment and widely consult opinions of food producers, dealers and consumers.



Food safety related laws and regulations

Law on the Quality and Safety of Agricultural Products

- **Article 11** The state establishes and improves the system of standards of the quality and safety of agricultural products. **Standards of the quality and safety of agricultural products are compulsory technical norms.**
- **Article 14** Agricultural competent department and other relevant departments are responsible for the implementation of standards of quality and safety of agricultural products.



Food safety related laws and regulations

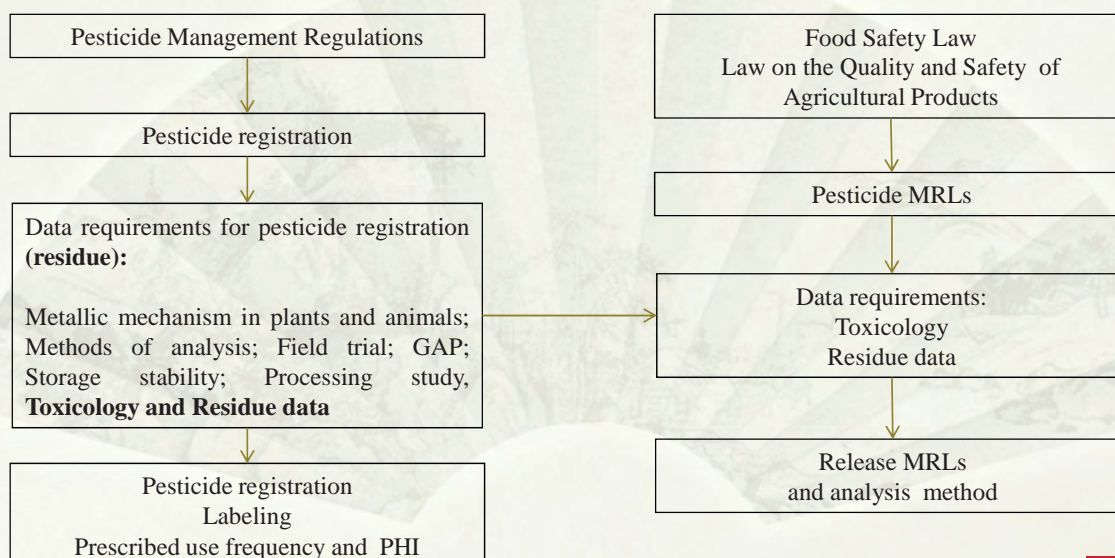
Pesticide Management Regulations

- **Article 2** The Ministry of Agriculture is responsible for pesticide registration, use, supervision and management in China, and shall develop or participate in the development of national and industrial standards on pesticide safe use, pesticide product quality and pesticide residues.
- **Article 3** ICAMA is responsible for nation wide pesticide registration. Institutes for the control of agrochemicals affiliated to agricultural departments of the people's governments of provinces, autonomous regions and municipalities directly under the central government shall assist in pesticide registration within their administrative regions.



Food safety related laws and regulations

Diagram of legal basis



MRLs Setting Process

- Agencies responsible for the management and establishment of MRLs.
- Protocols for MRL establishment.
- Current situation of MRLs in China.
- Challenges and future outlook.



Agencies responsible for the management and establishment of MRLs

(1) National Food Safety Commission (Feb. 2010)

- Director: Mr. Li Keqiang
- Deputy Director: Mr. Hui Liangyu and Wang Qishan
- Members: 15 governmental departments
- **Responsibilities:**
 - Analyze food safety **situation**;
 - Study, plan and **provide guidance** to food safety related work;
 - **Put forward important policy** measures concerning food safety supervision;
 - **Urge the implementation of responsibilities** of food safety supervision.



Agencies responsible for the management and establishment of MRLs

(2) National Standard Review Committee of Food Safety (20 Jan. 2010)

- Composition: 350 members from 10 specialized sub-committees and 20 departments in the fields of industry and information, agriculture, trade, industry and commerce, quality inspection, food and drug supervision, etc.
- **Responsibilities:**
 - **Review national food safety standards;**
 - Put forward suggestions for the implementation of national food safety standards;
 - Provide consultation on major issues related to national food safety standards
 - Undertake other work related to food safety standards.



Agencies responsible for the management and establishment of MRLs

- Sub-committees: 10 specialized sub-committees were established under the committee, namely sub-committees for food production, microorganisms, codes of production and operation, nutrition and special dietary foods, methods and protocols of inspection, pollutants, food additives, food-related products, **pesticide residues** and residues of veterinary drugs.
- Sub-committees for **pesticide residues** and veterinary drug residues were set up within MOA.



Agencies responsible for the management and establishment of MRLs

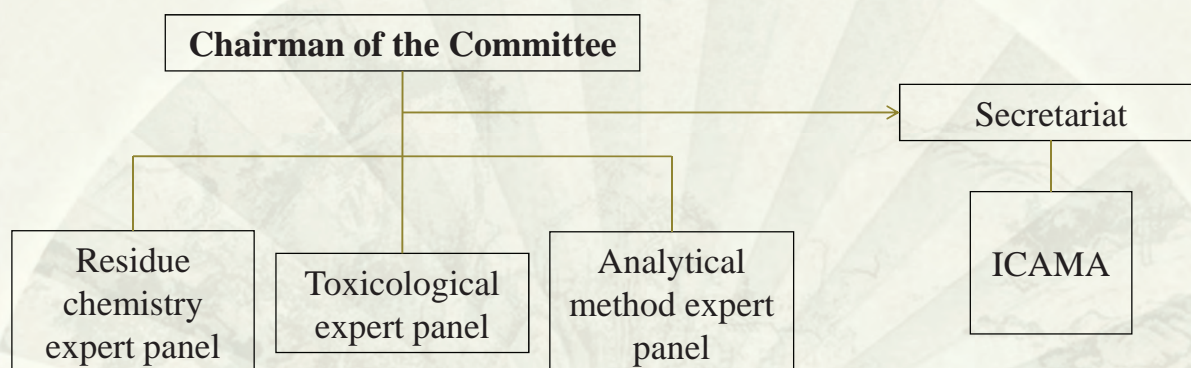
(3) National Review Committee of Pesticide Residue Standards (2010.4.12)

- Composition: 42 members from departments of agriculture, health, industry and information, commerce, quality inspection, food and drug, etc and 7 agency members.
- Responsibility: **review national standards of pesticide residues**, review plan for the establishment and revision of national pesticide residue standards and long-term program, put forward suggestions concerning the implementation of policies of pesticide residue standards and technical measures, and provide consultation to major issues related to national pesticide residue standards.
- **The Secretariat: set up within ICAMA, is responsible for routine management of the committee.**



Agencies responsible for the management and establishment of MRLs

Structure of the National Review Committee of Pesticide Residue Standards



Protocols for MRLs Establishment

Guidelines for MRLs Establishment

- Practical Guideline for **Risk Analysis** on Pesticide Residues in Agricultural Commodities and Foods.
- Guideline for **Establishment of MRLs** for Pesticides in Agricultural Commodities and Foods.
- **Crop Categorization** for Establishment of Pesticide MRLs.



Protocols for MRLs Establishment

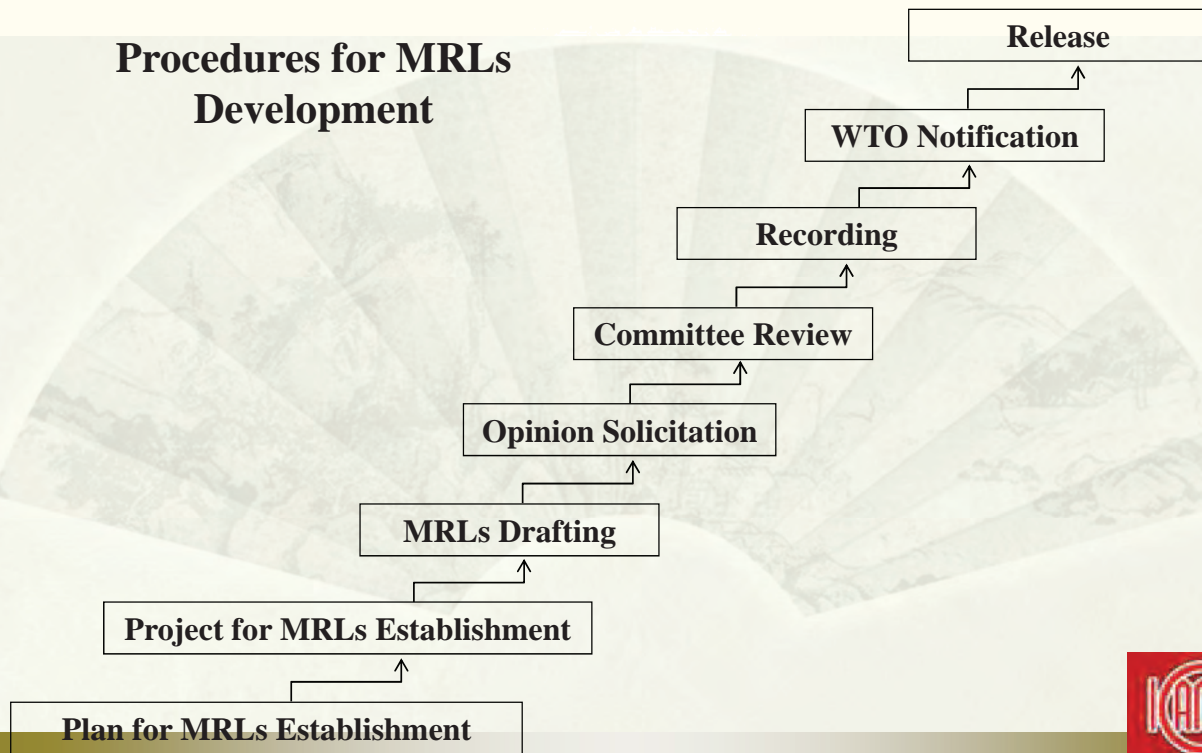
Guidelines for Trials

- Guidelines for **Pesticide Residue Trials** (NY/T 788-2004).
- **Sampling Methods for Pesticide Residue Analysis** (NY/T 789-2004).
- **Good Laboratory Practice** for Pesticide Residue Trials (NY/T 1493-2007).



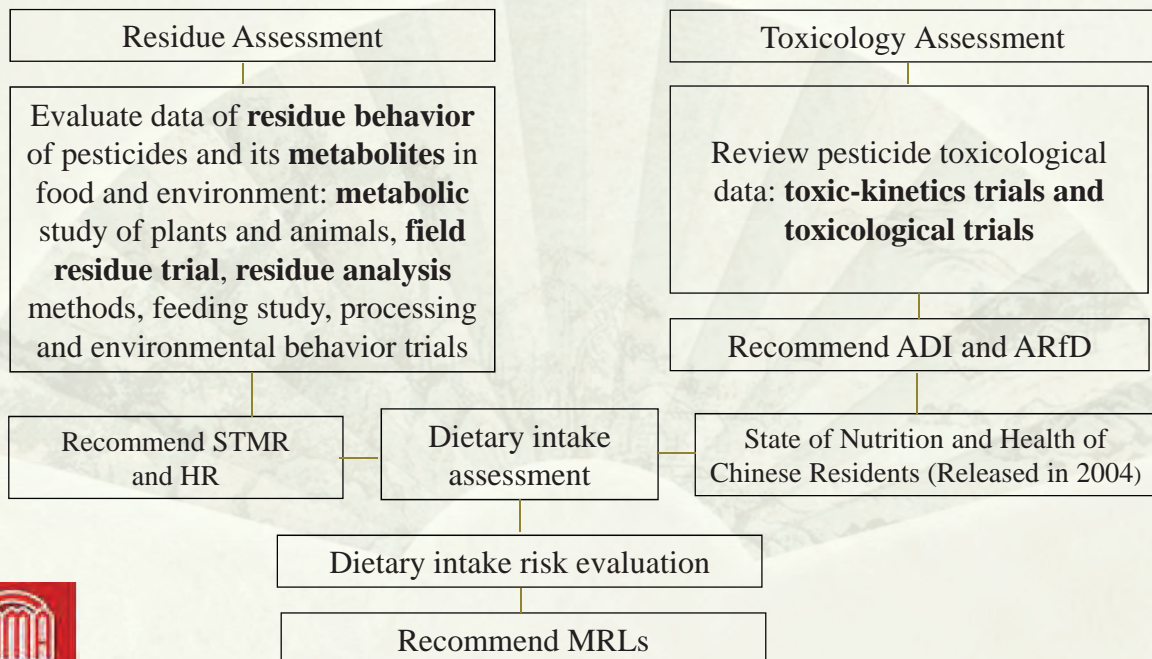
Protocols for MRLs Establishment

Procedures for MRLs Development

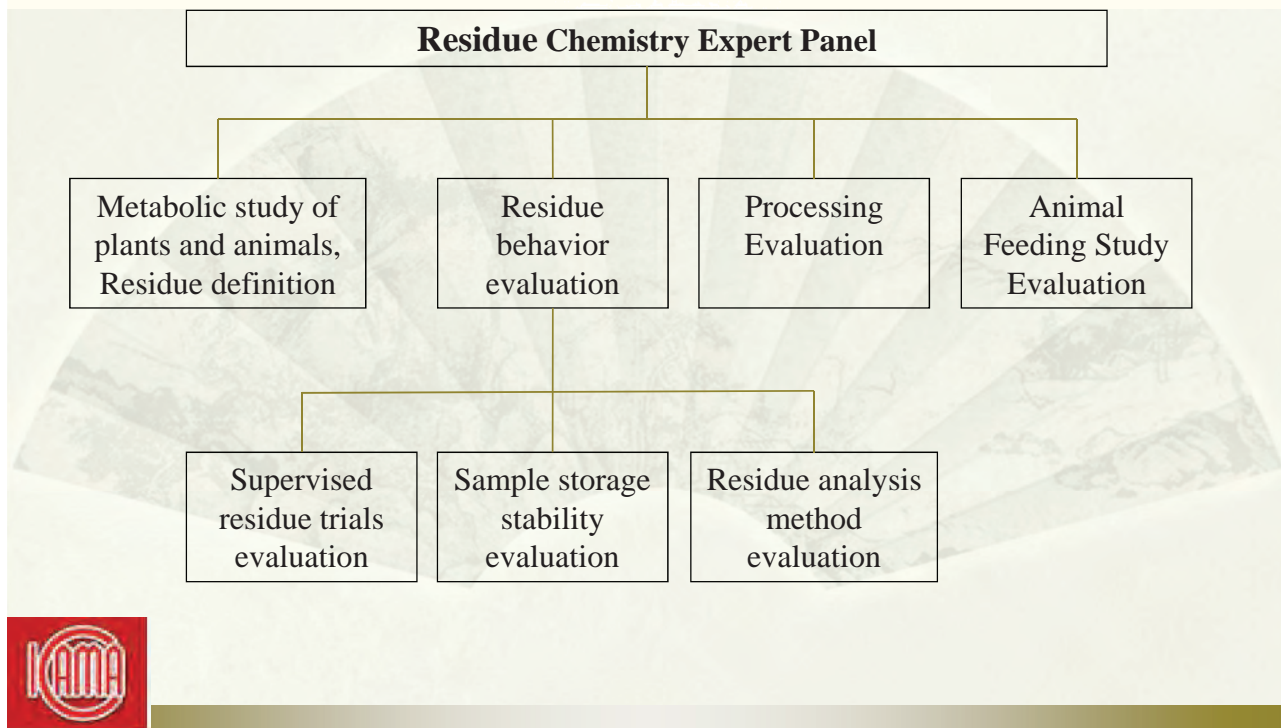


Protocols for MRLs Establishment

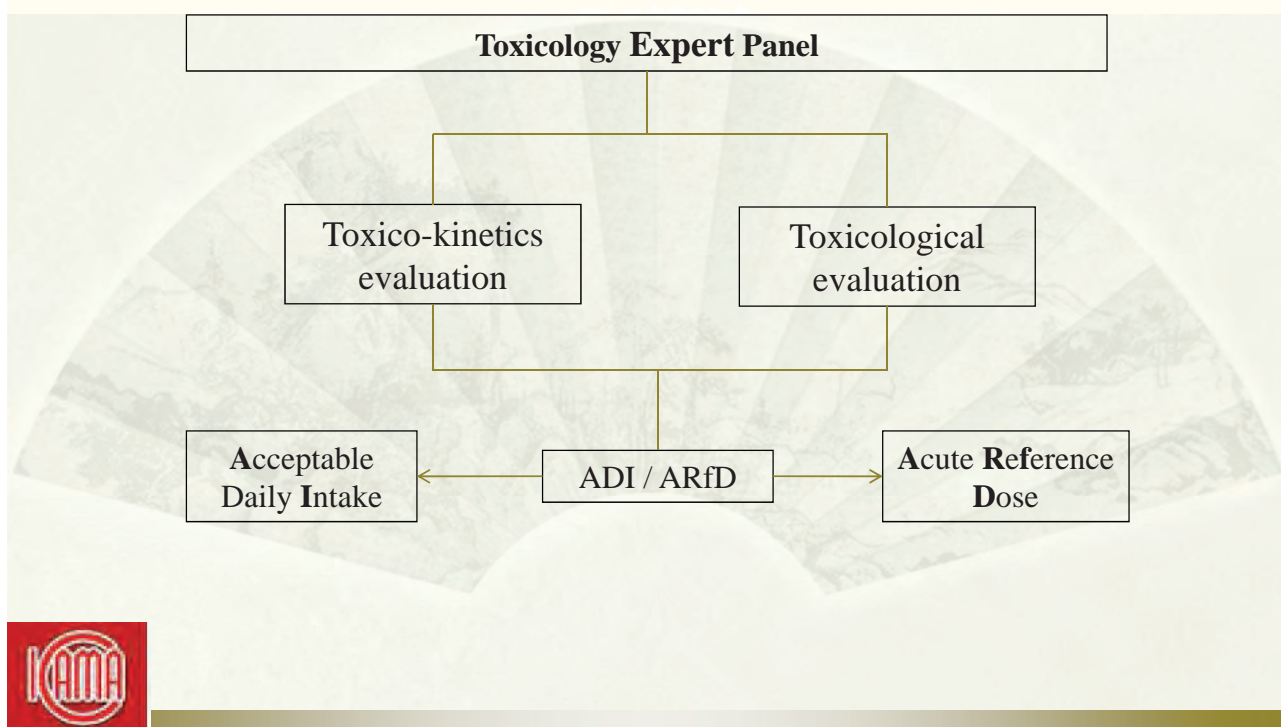
Procedures for the establishment of MRLs in foods



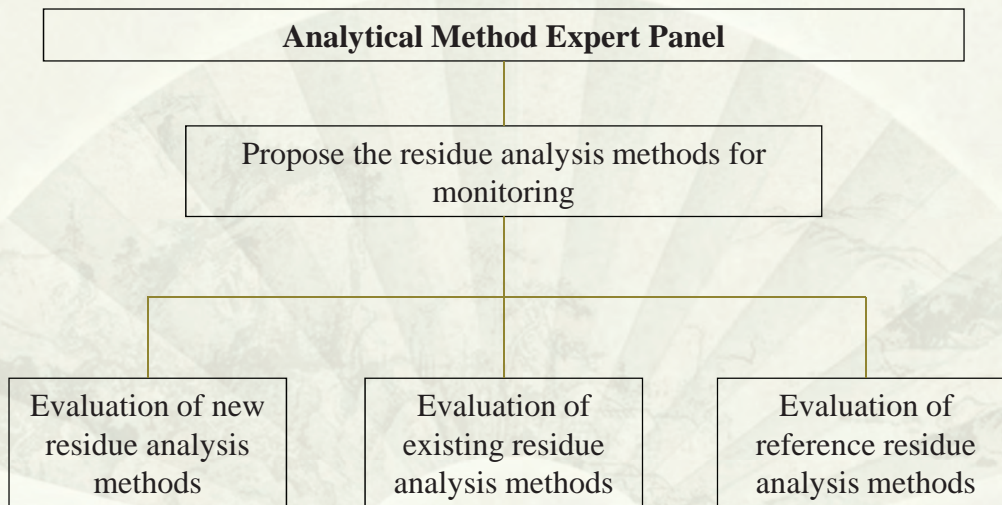
Protocols for MRLs Establishment



Protocols for MRLs Establishment



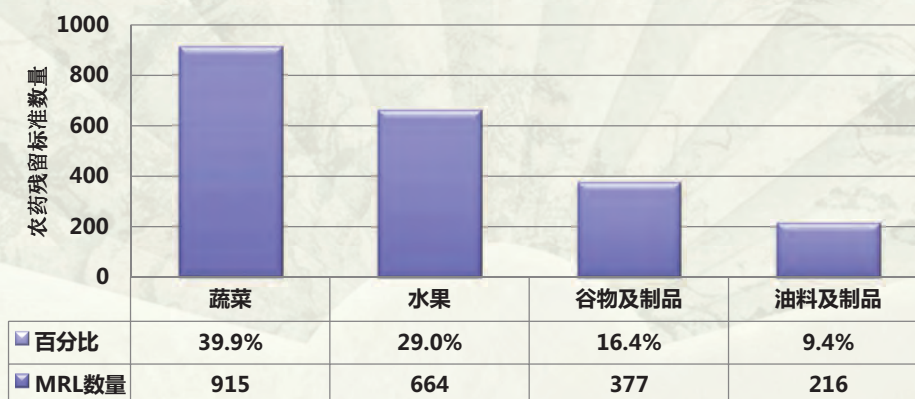
Protocols for MRLs Establishment



Current Situation of MRLs in China

MRLs established in foods

- 2,293 MRLs covering 322 pesticides in around 260 crops or foods (groups) have been established and implemented by 1 March 2013;
- 94.7% MRLs are for vegetables, fruits, cereals and oil crops.



Challenges and Future Outlook

Challenges

- Thousands of agricultural commodities and even more processed products;
- Complex and diversified farming system and cultivating practices ;
- A huge number of pesticide applicators and disparity in equipment and skills;
- Increasing of International Trade of food;
- Improve the basic data and clear communication with the public ;
- Environment awareness and trends for food safety.

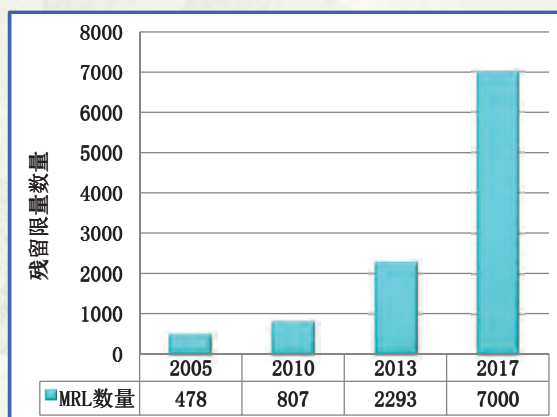


Challenges and Future Outlook

Future Outlook

Accelerate establishment of MRLs in agricultural commodities.

- By the end of 2017, We would like 7,000 MRLs to be established, basically covering all agricultural commodities.
- Synchronize registration review and MRLs establishment.



Challenges and Future Outlook

Gradually realize synchronization of national and international standards

- Accelerate the **conversion** of CAC standards to national standards;
- Convert over **1,200** CXLs of 103 pesticides into national standards in 2013;
- Actively participate in the establishment of international standards, in particular CAC standards.

Strengthen international exchange and cooperation

- Conduct bi-lateral exchange and workshop;
- Seminar on MRLs establishment for minor crops with the US;
- Conduct technical training.



Challenges and Future Outlook

Accelerate the development of pesticide residue analysis methods

- Multi-residue analysis methods;
- Special analysis methods;

Improve standards for setting procedures and technical norms

- technical protocols or normative documents;
- revise pesticide residue trial guidelines;
- establish SOPs;

Improve fundamental data

- toxicological, dietary
- residue trials



Efforts to register and establish MRLs for minor uses

- A few pesticide products registered in minor crops.
- Industries are unwilling to invest in registration of minor use due to low rate of return.
- ICAMA has organized several joint trails in lotus root, cane shoots, Matrimony vine, Chinese medicinal herbs and other minor crops(red bayberry, chrysanthemum tea, leek, etc.)
- ICAMA has been trying to issue “ Data Requirement of Minor Use Pesticide Registration” to encourage the registration for minor use.
- ICAMA has been applying a program to support the MRLs establishing for minor crops.



Cooperation at the Regional or International Level

ICAMA's effort for harmonization of pesticide registration and regulation.

- Sharing the information and technology with southeast Asia countries.
- Holding conferences and training courses to exchange experience
- Has Attended the global joint review meetings as a observer.
- Will host the joint review with two new ingredients of Dupont and Dow Company.



***Thank you for your
Attention***

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