रण संदे की किया अभिकार

Korean MRL setting & Positive List System

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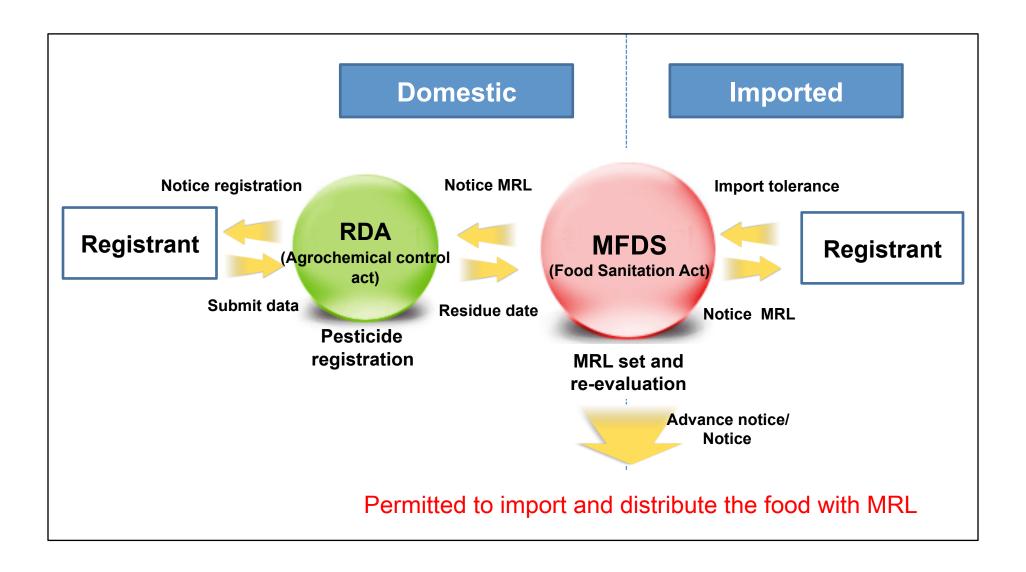


Outline

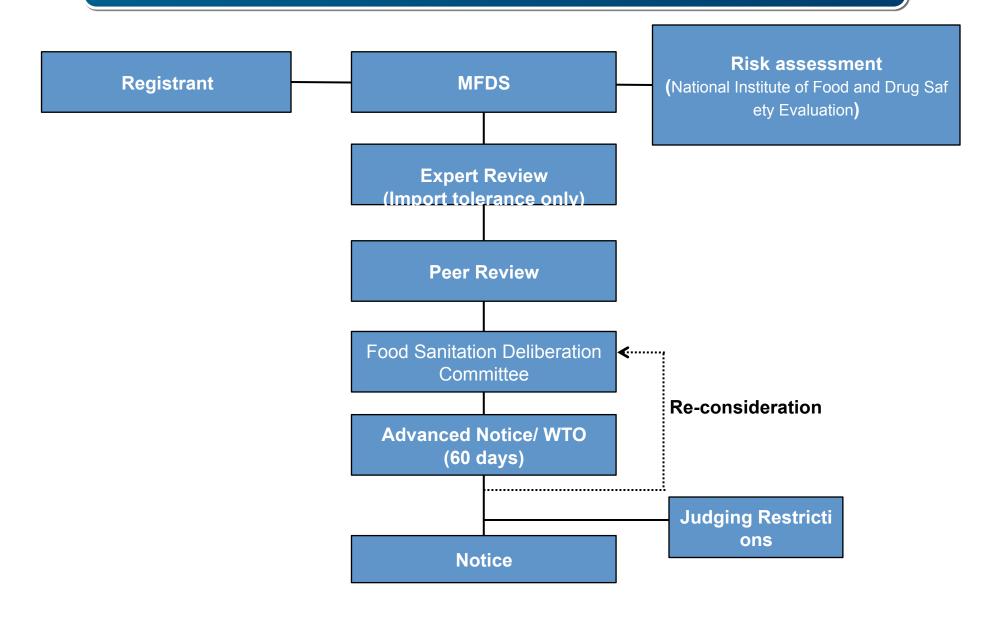
Principles of MRL setting

Changes in Pesticide residue control

Procedure of MRL setting



Procedure of MRL setting



Principles of MRL setting

Basic principle

- Set MRLs which have no harm by consumption of the pesticide residue
 - Risk Cup: TMDI ≤ 80% of ADI
 (10% potable water, 10% environment)

Basic policy

- Domestic foods : Set MRL of registered pesticides under "Agrochemicals Controls Act"
- Imported foods: Set MRL of pesticides which are registered abroad, submit data, and have no harm evaluated by MFDS risk assessment

Current pesticide MRL System

MRLs have been established for individual crops or crop groups, and processed foods in Korea.

For example,

(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		

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(42) 메토프렌(Methoprene) ADI: 0.07 mg/kg b.w./day
       ◎ 잔류물의 정의(Residue definition): Methoprene (cis형태와 trans형태의 합)
 귀리(Oat)
                              버섯류(Mushrooms)
                                                      0.2 옥수수(Com)
                                                                                 5.0
 땅콩(Peanut)
                              보리(Barley)
                                                      5.0 조(Millet)
                          2.0
                                                                                 5.0
 메밀(Buckwheat)
                              수수(Sorghum)
                                                          호밀(Rve)
                                                                                 5.0
                                                      5.0
                                                      5.0
                          5.0
 밀(Wheat)
                               쌀(Rice)
```

Food code (Eng.) is available in MFDS websit now!

Current principle to set provisional MRL

If registered pesticide which residue limit for an agricultural product was not established, tentative limits shall be applied by the following order.

First, the Codex standard

Second, the lowest of the MRL in similar agricultural product s

Third, lowest of the MRL, among MRLs of the pesticide detected

EX) Cyhalothrin of Cacao beans

1. Tentative MRL

- 1) MRLs for each crop in Food Code [Appendix 4]
 - → No Cyhalothrin MRL for Cacao beans
- 2) Codex MRL
 - → No MRL for Cacao beans
- 3) The lowest of the MRL in similar agricultural products

	Large classificati on	Small classification	Commodity
-	Tree Nuts and Oils eeds	Seeds for beverage s and sweets	Coffee beans, Cacao beans, Cola nuts, Guarana

→ Cyhalothrin MRL 0.05 ppm is applied to Cacao beans.

Positive List Systemn

- Reinforce Pesticide control in food from non-registered pesticid
 e.
 - Prevent excess use and misuse of pesticide.
 - Inhibit use of non-registered pesticides which are not evaluated by scientific assessment.
- If the pesticide is not registered and/or set MRL by import toler ance, its MRL ≤ 0.01 mg/kg
 - * Many countries such as Australia, Japan, Taiwan, and USA already are adapted PLS (Japan and EU: 0.01 mg/kg, USA: Not detection).

Change of pesticide control after PLS

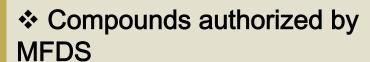
Current

- MRLs of registered pesticide
 - → Food code is applied
- MRLs of non-registered pesticide
 - → Provisional MRL are applied
 It is permitted to distrib

It is permitted to distribute the food with pesticide residue level not exceeding the MRLs.

After PLS

- MRLs of registered pesticide
 - → Food code is applied
- MRLs of non-registered pest icide
 - It is not permitted to distrib ute the food with pesticide residue level exceeding 0.0 1 ppm.



- Not harmful compound
 - → "Exemption list"
- Harmful compound
 - → "Non-detection list"



PLS Enforcement

First step :

"Tree Nuts and oilseeds" & "Tropical Fruit" Adv. Notice (14.7), Notice (Exp.15. 6)

Enforcement: 2016.12. 31

Large classificati on	Small classification	Commodity
	Peanut and Tree Nut	Chestnut, Walnut, Gingko nut, Pine nut, Peanut, Almond, Pecan, Cashews, Hazelnut, Macadamia, Pistachio, Acornetc.
Tree Nuts and Oils eeds	Oilseeds	Sesame, Cotton Seeds, Sunflower, Canola Seeds, Palm, Olive, Safflower etc.
Codo	Seeds for beverages and sweets	Coffee beans, Cacao beans, Cola nuts, Guarana
Fruit	Tropical Fruit	Banana, Pineapple, Kiwifruit, Avocado, Papaya, Mango, Gua va, Coconut, Lychee, Passion Fruit, Durian, Mangosteen etc.

Second step : All agricultural commodities
 Adv. Notice (Exp. 16. 6), Enforcement (Exp. 2018.1)

Scheduled to be deleted and remained MRLs after PLS

Ex. Peanut

,≤0.01 ppm

Scheduled to be Deleted MRL	Remained MRL
Acephate, Bentazone, BHC, Captan, Carbaryl:NAC, Carbopheno thion, Carboxin Chlorfenvinphos, Chlorobenzilate, Chlorpropham, Chlorpyrifos, Oyfluthrin, Cyhalothrin, Cypermethrin, Daminozide, Diazinon, Dichlofluanid, Diphenamid, Disulfoton, Ethiofencarb, Fenamiphos, FenbutatinOxide, Fenoxaprop-ethyl, Fensulfothion, Fentin, Fenvaler ate, Fluazifop-butyl, Iprodione, Malathion, Maleichydrazide, Metaaxyl, Methomyl, Methoprene, Methoxychlor, Norflurazon, Omethoate, Oxamyl, Parathion, Parathion-Methyl, Pendimethalin, Permethrin(Permetrin), Phorate, Pirimiphos-ethyl, Pirimiphos-methyl, Propargite, Propiconazole, Pyrethrins, Sethoxydim, Thiobencarb, Trifluralin	Alachlor, Aluminium Phosphide (Hydrogen phosphide), Benom yl, Bitertanol, Carbendazim, Carbofuran, Carbosulfan, Chloroth alonil, Difenoconazole, Dithiocarbamates, Ethalfluralin, Ethopr ophos(Ethoprop), Fenitrothion:MEP, Fluxapyroxad, Hexaconaz ole, Mancoseb, Metolachlor, Napropamide, Tebuconazole, Tefl
50	23

List of scheduled to be deleted and reminded MRLS for Nuts and Tropical fruits are available.

Scheduled to be deleted MRLs after PLS

Commodity	Current MRLs	Scheduled to be de leted MRLs	Remained MRLs
Peanut	73	50	23
Chest nut	51	31	18
Cotton Seeds	72	69	3
Almond	50	44	6
Canola Seeds	40	23	17
Pine nut	23	21	2
Sesame	62	27	35
Coffee	29	23	6
Cacao Beans	20	20	-
Pecan	51	46	5
Pistachio	24	22	2
Sunflower Seeds	38	34	4
Walnut	43	39	4

Scheduled to be deleted MRL after PLS

Commodity	Current MRL	Scheduled to be d eleted MRL	Remained MRL
Banana	44	39	5
Mango	31	28	3
Avocado	33	31	2
Kiwi	56	29	27
Pineapple	42	37	5
Papaya	27	26	1

Currently, some commodities such as Lychee and Mangosteens do not have a ny MRLs at all!

2011~14 Detected Pesticide Residues

Current provisional MRLs are applied, However, 0.01 ppm will be applied after PLS.

Group	Commodity	Test compoun d	Result	MRL	Reference
	Almond	2,4-D	0.03	0.2	Domestic MRL (scheduled to be deleted)
	Peanut	Chlorpyrifos	0.02	0.5	Domestic MRL (scheduled to be deleted)
	Sesame	Fenvalerate	0.03	0.5	Domestic MRL (scheduled to be deleted)
Tree	Sunflower seed	Imazalil	0.02	0.05 (cotton seed)	
nuts	Coffee	Bifenthrin	0.02	0.05 (chest nut)	
	Coffee	Chlorpyrifos	0.03	0.05 (Codex)	
	Coffee	Imazalil	0.04	0.05 (Cotton Seed)	
	Coffee	Prochloraz	0.04	0.05 (Other Agri. Product)	

Currently provisional MRLs are applied, However, 0.01 ppm after PLS

Group	Commodity	Test compound	Result	MRL	Reference
	Banana	Bifenthrin	0.02	0.1 (Codex)	
	Banana	Carbendazim	0.1	0.2 (Codex)	
	Banana	Chlorpyrifos	0.02	2 (Codex)	
	Banana	Chlorpyrifos	0.02	2 (Codex)	
	Banana	Imazalil	0.07	2	Domestic MRL (scheduled to be deleted)
Tropical Fr uit	Mango	Chlorpyrifos	0.05	0.5	Domestic MRL (scheduled to be deleted)
	Mango	Endosulfan	0.1	0.5 (Codex)	
	Mango	Fenthion	0.1	0.2 (Kiwi)	
	Mango	Iprodione	0.2	0.02 (Banana)	New MRL from 2014
	Mango	Malathion	0.02	0.5	Domestic MRL (scheduled to be deleted)
	Mango	Phenthoate	0.03	0.2 (Pear)	
	Mango	Prochloraz	0.1	0.05 (Banana)	

Additionally, Please note below

- Change the test items for the first close inspection
 - Adjust based on items for non-complying pesticides
- > Expending test items for random sample inspection
 - 286 ('15) → expected 400 ('17)
- Expending test items for single-residue analysis monitoring
 - reduce periodic time of inspection (15yr→ 5yr)

Check before Importing food to Korea

- History of detection
 (What were detected previously?)
- 2) Registered and MRL status in Korea
 - → If not, please submit application for IT soon

Import tolerance

Import tolerance?

 A system to assess the safety of foods with residual pesticide f or which domestic MRLs are not set and used in accordance wi th the regulations of foreign countries. If there is no safety con cern, MRLs for the relevant foods are established.

Background

- Positive List System (PLS)^{*} enforcement
- Relevence reference :

Food Sanitation Act 7-3 (Requesting the establishment of MRLs for pesticides), Enforcement Rule of FSA Article 5. 2 (Establish ment of MRLs for pesticide and veterinarian drugs) & Article 5. 3 (Revising MRL)

Caution for application

- Application via on-line MFDS has an on-line system for civil affairs (http://minwon.mfds.go.kr)
- 2. Processing Time
 - Establishment of MRL : 365 days
 - Change or Exemption of MRL: 210 days
- 3. Processing Fee (per commodity)
 - 1)Toxicity data
 - Establishment of MRL: 30,000,000 KRW
 - Change or Exemption of MRL: 10,000,000 KRW
 - 2) Residual data
 - Establishment, Change or Exemption of MRL :
 5, 000,000 KRW

5. Requirement Data

- 1) New compound
 - Toxicity data and Residual data (2 copies)
- 2) Registered compound (add new commodities) :
 - Residual data only (2 copies)
- * Toxicity data : Acute oral toxicity, Sub-chronic toxicity , Chronic toxicity, Genetic toxicity,

 Teratogenicity, Metabolism and pharmacokinetics etc
- * Residue data : Physicochemical characteristics, Applicable diseases and insect pests,

 Supervised trials for crops etc.
- 3) Other helpful data
 - Usage and registration status in other countries
 - MRLs in Codex and other countries

6. Number of Field Trials

- Minimum of 6 trials
- 3 trials /commodity for Minor Crop
- In the case of herbicide (which shows no residue), MFDS accept the data with higher treatment amount than GAP

7. Standard

- For new compound, parent compound 5g and 1g/metabolite
- MFDS might ask more standard for analysis method develop and other reasons

8. Update!

- Group MRL application is possible.
- Proportionality rule (0.3~4 x a.i.) will be applicable for data which are approved by C odex.

MRLs by Import tolerance

112 MRLs (22 Pesticide, 56 Commodities, 24 MRLs w/ advanced notices)

NO	Pesticide	Commodities	Notice No.
1	Glufosinate	Cotton Seeds	2010-58(2010.7.23)
2	Acetochlor	Wheat	2012-131(2012.12.27)
3	Acetochlor	Sorghum	2012-131(2012.12.27)
4	Acetochlor	Corn	2012-131(2012.12.27)
5	Azoxystrobin	Lemon	2012-1(2012.1.20)
6	Azoxystrobin	Orange	2012-1(2012.1.20)
7	Azoxystrobin	Grapefruit	2012-1(2012.1.20)
8	Fenpropathrin	Cherry	2012-1(2012.1.20)
9	Fludioxonil	Lemon	2012-1(2012.1.20)
10	Fludioxonil	Orange	2012-1(2012.1.20)
11	Fludioxonil	Grapefruit	2012-1(2012.1.20)
12	Oxyfluorfen	Tree nuts	2012-131(2012.12.27)
13	Oxyfluorfen	Soybean	2012-131(2012.12.27)
14	Oxyfluorfen	Cotton Seeds	2012-131(2012.12.27)
15	Oxyfluorfen	Banana	2012-131(2012.12.27)
16	Oxyfluorfen	Peach	2012-131(2012.12.27)
17	Oxyfluorfen	Apricot	2012-131(2012.12.27)
18	Oxyfluorfen	Avocado	2012-131(2012.12.27)
19	Oxyfluorfen	Cabbage	2012-131(2012.12.27)
20	Oxyfluorfen	Corn	2012-131(2012.12.27)

^{*} mark [appendix 4] in food code means that the MRL is set by IT.

Residue database

www.foodnara.go.kr/residue/main.do



Import tolerance application statues



실명의약품안전체 잔류물질정보(Pesticides and Veterinary Drugs Information)

농약(PESTICIDES) ~

동물용의약품(VETERINARY DRUGS) ~

자료실(DOWNLOADS) ~

관련사이트(RELATED SITES) ~

농약(Pesticides)

잔류화학물질의 올바른 이해가 여러분의 식탁을 풍요롭게 합니다



농약(Pesticides) >

수입식품 중 농약잔류허용기준 설정 진행 사항 Import tolerance application status

농약정보 Pesticide Information

잔류허용기준 MRLs in Pesticide

농약표준품 Pesticide Standards

농약분석정보 Pesticide Analytical Manual

수입식품 중 농약잔류허용기준 설정 진행 사항 Import tolerance application status



잔류농약 안전관리



동물용의약품 안전관리

수입식품 중 농약잔류허용기준 설정 진행	해 사하(Import tolorance	application status
エロゴム ひ マゴビエリマイエ さら ど	3 7 3 (IIII) OIL LURIAILE	application status

신청일을 선택	I	농약명을 입력하세요.	Ć	

Ć	대상식품을 입력하세요.	
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비원하다는	이러시네스
신성인사득	입력하세요

검색

: 총 27건, 현재페이지: 1/2

No.	농약명	대상식품	신청일	검토완료예정일	신청회사	비고
1	Mancozeb	banana	2015-05-14	2016-08-02	Dow agro/UPL	
2	chlorpyrifos	coffee	2015-05-11	2016-07-28	Dow agro	
3	glyphosate	wheat	2015-04-20	2016-07-08	Monsanto	
4	Cyflumetofen	grapefruit	2015-03-27	2016-06-16	BASF	
5	Cyflumetofen	orange	2015-03-27	2016-06-16	BASF	

