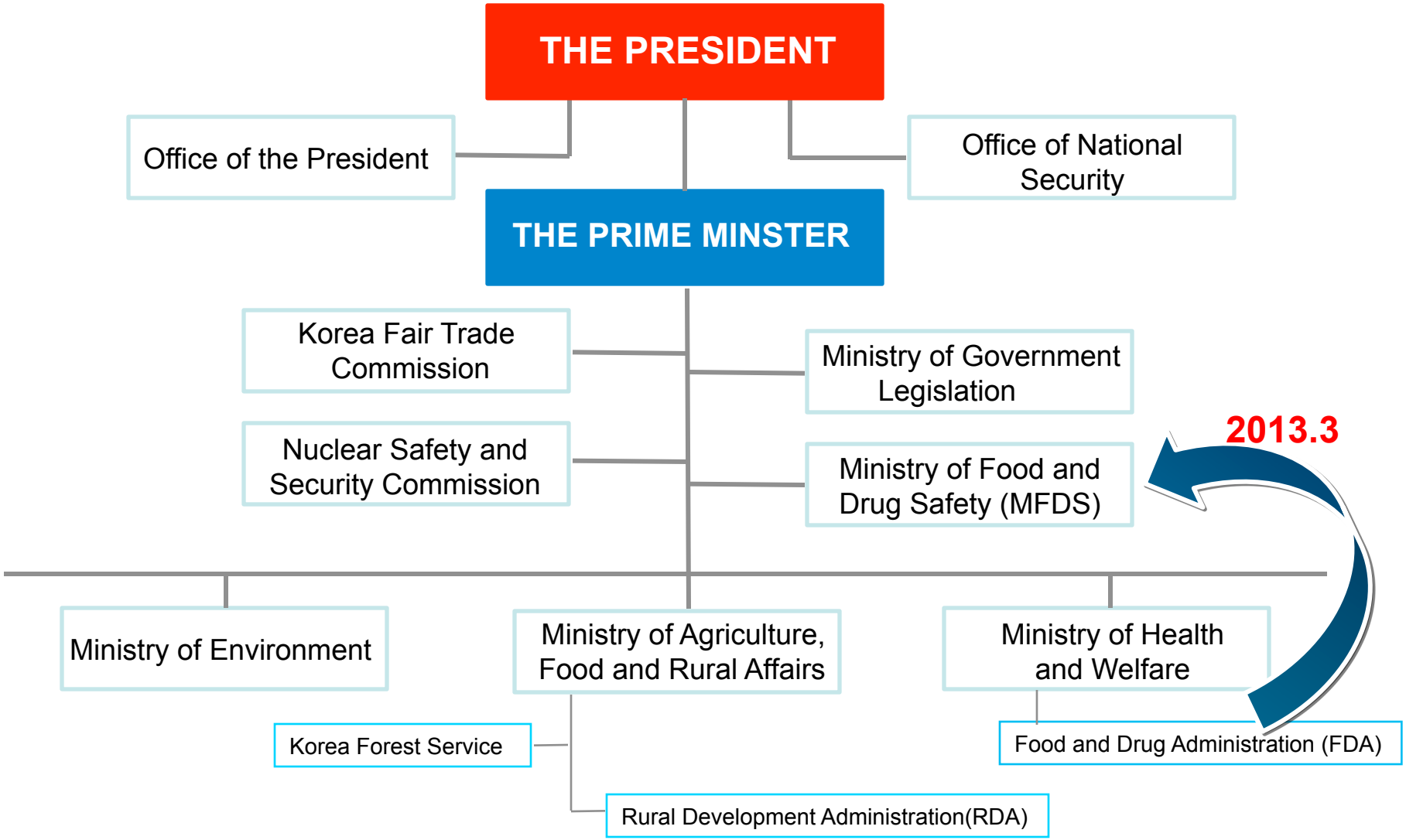
MINISTRY OF
FOOD AND DRUG SAFETY

Import Tolerance and Positive List System of pesticide i n Korea

06.18.2014

Food Standard Division,
Food Standard Department, MFD
S

Introduction of MFDS and set MRL in Korea



Management of pesticides in Korea

❖ 3 different organizations and their Roles

1. Ministry of Environment
   - Control pesticides in environment
2. Ministry of Agriculture, Food, and Rural Affairs
   - Rural Development Administration(RDA)
     - Registration for domestic usage
       MRL setting for feeds
3. Ministry of Food and Drug Safety (MFDS)
   - Food Standard Division : MRL setting for domestic and imported foods
   - National Institute of Food and Drug Safety Evaluation
     - Pesticide and Veterinary Drug Residue Division : Risk assessment

Trends of imported foods in Korea

www.foodnara.go.kr/importfood

❖ Increasing imported foods

→ Increasing concern for imported foods!

Trends of imported foods in Korea

❖ Imported Items and exporting countries have changed!!

For fruits, imported amount (based by money) has increased 3.3 times (286→ 929 million dollars) for last 10 years (’03~’13)

1) Top 5 fruits (order by imported amount)
’03 : Orange (39.4%), Banana (31.8%), Kiwifruit (7.9%), Grape (7.5%)
,
Pineapple (5.9%)
’13 : Banana (27.3%), Orange (21%), Grape (20.3%), Cherry (9.7%), Pineapple(6.6%)
❖ Lemon (2.8%), Mange (2.6%), Grapefruit (1.5%)

2) Grape
’03 : Chile (64.1%), USA (35%)
’13 : Chile (76.7%), USA(16.3%), Peru (6.6%), Turkey (0.2%)

3) Mango
’03 : Philippine (97.4%), Thailand (1.9%)
’13 : Thailand (1.9%), Philippine (80.3%), Taiwan (17.8%)

Pesticide MRLs in Korea

Pesticide MRLs have been established for **440 pesticides** and **211 commodities** in Korea.

<Pesticide MRLs in Foods>

농 약 명(Chemical name)	페이지(Page)
(1) 이민옥타딘(Iminoctadine)	42
(2) 글루포시네이트[Glufosinate(ammonium)]	42
(3) 글리포세이트(Glyphosate)	42
(4) 나프로파마이드(Napropamide)	42
(5) 노르플루라존(Norflurazon)	42
(6) 니트라피린(Nitrapyrin)	42
(7) 다미노자이드(Daminozide)	43
(8) 다이아지논(Diazinon)	43
(9) 델타메쓰린(Deltamethrin)	43
(10) 도딘(Dodine)	44
(11) 멥틸디노캡(Meptyldinocap)	44
(12) 디디티(DDT : p,p'-DDT, o,p'-DDT, p,p'-DDD 및 p,p'-DDE의 합계) : Sum of p,p'-DDT, o,p'-DDT, p,p'-DDD and p,p'-DDE	44
(13) 디메치핀(Dimethipin)	44
(14) 디메토에이트(Dimethoate)	44
(15) 디설포톤(Disulfoton)	44
(16) 디우론(Diuron)	45
(17) 디메칠디치오카바메이트(Dimethyldithiocarbamates)	45
(18) 디캄바(Dicamba)	45
(19) 디코폴(Dicofol)	45
(20) 디쿼트(Diquat)	46
(21) 디크로보스(Dichlorvos:DDVP)	46
(22) 디크로프루아니드(Dichlofluanid)	46
(23) 디클로란(Dicloran)	47
(24) 디클로베닐(Dichlobenil)	47
(25) 디클로포프-메칠(Diclofop-methyl)	47
(26) 디페노코나졸(Difenoconazole)	47
(27) 디페닐아민(Diphenylamine)	47
(28) 디펜아미드(Diphenamid)	47
(29) 디프루벤주론(Diflubenzuron)	48

<Pesticide MRLs in Ginseng>

농 약 명(Chemical name)	페이지(Page)
(1) 디디티 : p,p'-DDT, o,p'-DDT, p,p'-DDD 및 p,p'-DDE의 합계 (DDT : Sum of p,p'-DDT, o,p'-DDT, p,p'-DDD and p,p'-DDE)	146
(2) 메타락실 (Metalaxyl)	146
(3) 비에치시 : a, ß, γ 및 d-BHC의 합계 (BHC : Sum of a, ß, γ and d-BHC)	146
(4) 알드린 및 디엘드린 (Aldrin & Dieldrin)	146
(5) 엔드린 (Endrin)	146
(6) 카벤다짐 (Carbendazim)	146
(7) 퀸토젠 : 퀸토젠과 펜타클로로아닐린 및 메칠펜타클로로페닐설파이드의 합계량 (Quintozene : PCNB)	146
(8) 디에토펜카브 (Diethofencarb)	147
(9) 디페노코나졸 (Difenoconazole)	147
(10) 싸이퍼메쓰린 (Cypermethrin)	147
(11) 아족시스트로빈 (Azoxystrobin)	147
(12) 토릴플루아니드 (Tolylfluanid)	147
(13) 톨크로포스-메칠 (Tolclofos-methyl)	147
(14) 이민옥타딘 (Iminoctadine)	147
(15) 피리메타닐 (Pyrimethanil)	147
(16) 펜헥사미드 (Fenhexamid)	148
(17) 시아조파미드 (Cyazofamid)	148
(18) 싸이프로디닐 (Cyprodinil)	148
(19) 크레속심-메칠 (Kresoxim-methyl)	148
(20) 에틸렌비스디치오카바메이트 (EBDC[Ethylenebis(dithio-carbamate)s])	148
(21) 카두사포스 (Cadusafos)	148
(22) 티아크로프리드 (Thiacloprid)	148
(22) 펜시쿠론 (Pencycuron)	148
(23) 후루디옥소닐 (Fludioxonil)	148

Current establishment of pesticide MRLs

❖ **MRLs have been established for individual crops, crop gro ups, or 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		

(42) 메토프렌(Methoprene) ADI : 0.07 mg/kg b.w./day

◎ 잔류물의 정의(Residue definition) : Methoprene

귀리(Oat)	5.0	버섯류(Mushrooms)	0.2	옥수수(Corn)	5.0
땅콩(Peanut)	2.0	보리(Barley)	5.0	조(Millet)	5.0
메밀(Buckwheat)	5.0	수수(Sorghum)	5.0	호밀(Rye)	5.0
밀(Wheat)	5.0	쌀(Rice)	5.0		

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

No MRL, then pesticide MRLs

- If non-registered pesticides, they should not be detected in food.

→ Non-detection levels are determined from LOQ of the analytical methods.

- 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 products

See the Classification of Food Raw Material in Korea Food Code.

→ Classification of foods in Korea is not 100% matched with Codex classification.

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

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밀(Wheat)	5.0	쌀(Rice)	5.0		

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

❖ 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, 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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밀(Wheat)	5.0	쌀(Rice)	5.0		

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

Promoting New regulations in Korea

❖ Positive list system(PLS) will be enforced.

- Accuracy of risk assessment has been challenged.

  → Currently, if MRL of a certain commodity is not established, MRLs o f Codex or tentative residue limits in similar products are applied.

  → Science-based risk assessment is needed and people want transp arency in setting MRLs.

- Before 2000, MRLs were adopted from one of foreign countries witho ut scientific data. Thus, we are re-evaluating the current MRLs

  → MRLs of the pesticides, which are not registered in Korea, will be deleted from Korean Food Code.

- So, it is necessary to evaluate the safety of the pesticides, which com pounds are not registered in Korea, to protect human health.

Promoting New regulations in Korea

- PLS is not a new policy in the world.

  → **MRLs of non-registered pesticides : < 0.01 ppm**

  → Australia, EU, Japan and USA adapted this system already.

- Before starting PLS, import tolerance is already adapted.

  Exemption List and Group MRL will be considered.

  → Application of exemption process is the same as import tolerance.

Any comments and opinions on the PLS will be open to con sumers, producers and importers.

Exemptions for pesticide MRL in food

Total 57 ingredients are in Exemption list.

No.	Active ingredient
1	1-메틸사이클로프로펜 (1-Methylcyclopropene)
2	기계유(Machine oil)
3	데실알코올(Decylalcohol)
4	모나크로스포륨타우마슘케이비시3017 (Monacrosporium thaumasium KBC3017)
5	바실루스 서브틸리스 디비비1501(Bacillus subtilis DBB1501)
6	바실루스 서브틸리스 시제이-9(Bacillus subtilis CJ-9)
7	바실루스 서브틸리스 엠27(Bacillus subtilis M 27)
8	바실루스 서브틸리스 엠비아이600(Bacillus subtilis MBI600)
9	바실루스 서브틸리스 와이1336(Bacillus subtilis Y1336)
10	바실루스 서브틸리스 이더블유42-1(Bacillus subtilis EW42-1)
11	바실루스 서브틸리스 제이케이케이238(Bacillus subtilis JKK238)
12	바실루스 서브틸리스 지비365(Bacillus subtilis GB0365)
13	바실루스 서브틸리스 케이비401(Bacillus subtilis KB401)
14	바실루스 서브틸리스 케이비씨1010(Bacillus subtilis KBC1010)
15	바실루스 서브틸리스 큐에스티713(Bacillus subtilis QST713)
16	바실루스 아밀로리퀴파시엔스 케이비씨1121 (Bacillus amyloliquefaciens KBC1121)
17	바실루스 푸밀루스 큐에스티2808(Bacillus pumilus QST2808)
18	보르도 혼합액(Bordeaux mixture)
19	뷰베리아 바시아나지에이치에이(Beauveria bassiana GHA)
20	뷰베리아 바시아나티비아이-1(Beauveria bassiana TBI-1)
21	비티 아이자와이(Bacillus thuringiensis subsp. aizawai)
22	비티 아이자와이 엔티423(Bacillus thuringiensis subsp. aizawai NT0423)
23	비티 아이자와이 지비413(Bacillus thuringiensis subsp. aizawai GB413)
24	비티 쿠르스타키(Bacillus thuringiensis subsp. kurstaki)
25	비티 쿠르스타키(Bacillus thuringiensis var. kurstaki)
26	석회황(Calcium polysulfide, lime sulfur)
27	스트렙토마이세스 고시키엔시스 더블유와이이324 (Streptomyces goshikiensis WYE324)
28	스트렙토마이세스 콜롬비엔시스 더블유와이이20 (Streptomyces colombiensis WYE20)
29	스프레더 스티커(Spreader sticker)
30	폴리에틸렌 메틸 실록세인(Polyethylene Methyl Siloxane)
31	아이비에이 (IBA, 4-indol-3-ylbutyric acid)
32	아이에이에이 (IAA, Indol-3-ylacetic acid)
33	알킬설폰화알 킬레이트의 나트륨염 (Sodium salt of alkylsulfonated alkylate)
34	알킬아릴 폴리에톡시레이트(Alkylaryl polyethoxylate)
35	암펠로마이세스 퀴스콸리스 에이큐94013 (Ampelomyces quisqualis AQ94013)
36	옥시에틸렌 메틸 실록세인(Oxyethylene methyl siloxane)
37	지베렐린류(Gibberellin A_3, Gibberellin A_{4+7})
38	칼슘 카보네이트(Calcium carbonate)
39	코퍼 설페이트 베이식(Copper sulfate basic)
40	코퍼 설페이트 트리베이식(Copper sulfate tribasic)
41	코퍼 옥시클로라이드(Copper oxychloride)
42	코퍼 하이드록사이드(Copper hydroxide)
43	트리코덴마 하지아늄 와이씨 459(Trichoderma harzianum YC 459)
44	패니바실루스 폴리믹사 에이시-1(Paenibacillus polymyxa AC-1)
45	패실로마이세스 퓨모소로세우스 디비비-2032 (Paecilomyces fumosoroseus DBB-2032)
46	폴리나프틸 메탄 설폰산 디알킬 디메틸 암모니움염 (PMSAADA) (Polynaphthyl methane sulfonic acid dialkyl dimethyl ammonium)
47	폴리에테르 폴리실록세인(Polyether modified polysiloxane)
48	폴리옥시에틸렌 메틸 폴리실록세인(Polyoxyethylene methyl Polysiloxane)
49	폴리옥시에틸렌 알킬아릴에테르(Polyoxyethylene alkylarylether)
50	폴리옥시에틸렌 지방산 에스테르(Polyoxyethylene fatty acid ester(PFAE))
51	황(Sulfur)
52	니즈(polynaphtyl methane sulfonic + polyoxyethylene fatty acid ester)
53	소듐 리그노 설포네이트(Sodium ligno sulfonate)
54	심플리실리움 라멜리콜라 비씨피(Simplicillium lamellicola BCP)
55	트리코더마 아트로비라이드 에스케이티-1(Trichoderma atroviride SKT-1)
56	파라핀, 파라핀오일(Paraffin, Paraffinic oil)
57	펠라르곤산(Pelargonic acid)

Promoting New regulations in Korea

- PLS is not a new policy in the world.

  → **MRLs of non-registered pesticides : < 0.01 ppm**

  → Australia, EU, Japan and USA adapted this system already.

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Comparison before and after PLS

Current (NLS)

❖MRLs of registered pesticide
→ Food code is applied

❖ MRLs of non-registered pesticide
→ Codex MRLs or MRLs for similar agricultural /livestock/ aquatic products are applied
It is permitted to distribute the food with pesticide residue level not exceeding the MRLs.

※ Actually, the compounds have not been inspected.

After PLS adoption

❖MRLs of registered pesticide
→ Food code is applied

❖ MRLs of non-registered pesticide
- It is not permitted to distribute the food with pesticide residue level exceeding 0.01 ppm.

❖ Compounds authorized by MFDS
- Not harmful compound
→ “Exemption list”
- Harmful compound
→ “Non-detection list”

Detailed plan of PLS

❖ PLS will be adopted with “2-steps”

1) **First step, Tropical fruits, Nuts and seeds**

- ~~Advanced Notice (2014.06), Date of Enforcement (2017.01.01)~~

Tropical Fruits	Banana, Pineapple, Kiwifruit, Mango et al.
Nuts and seed	Pecan, Walnut, Peanut, Pistachio, Coffee beans et al.

2) Second step, other products

- Advanced Notice (expected 2016.01)

Date of Enforcement (expected 2018. 01)

Please apply the import tolerance for Tropical fr uit, nuts and seeds first!!

Guidelines for Establishment of Pesticide MRLs in Food

- Notice No. 2012-15 of the KFDA(2012. 04.23.)
- Advanced Notice No. 2014-84 of the MFDS (2014.04.09.)

Purpose

- To clarify procedures of establishment of MRLs
- To obtain scientific transparency and predictability in establishment of MRLs

1. Scope of application for the establishment of MRLs
2. Steps for the Establishment of MRLs
3. Scope of Materials Submitted for MRLs
4. Procedure to submit an application for establishment of MRLs

※ The English version of guidelines is available at

http://www.mfds.go.kr/eng/index.do > MFDS NEWS > News & Notice

*** Guidelines for establishment of pesticide and veterinary drug MRLs in food**

Scope of Application

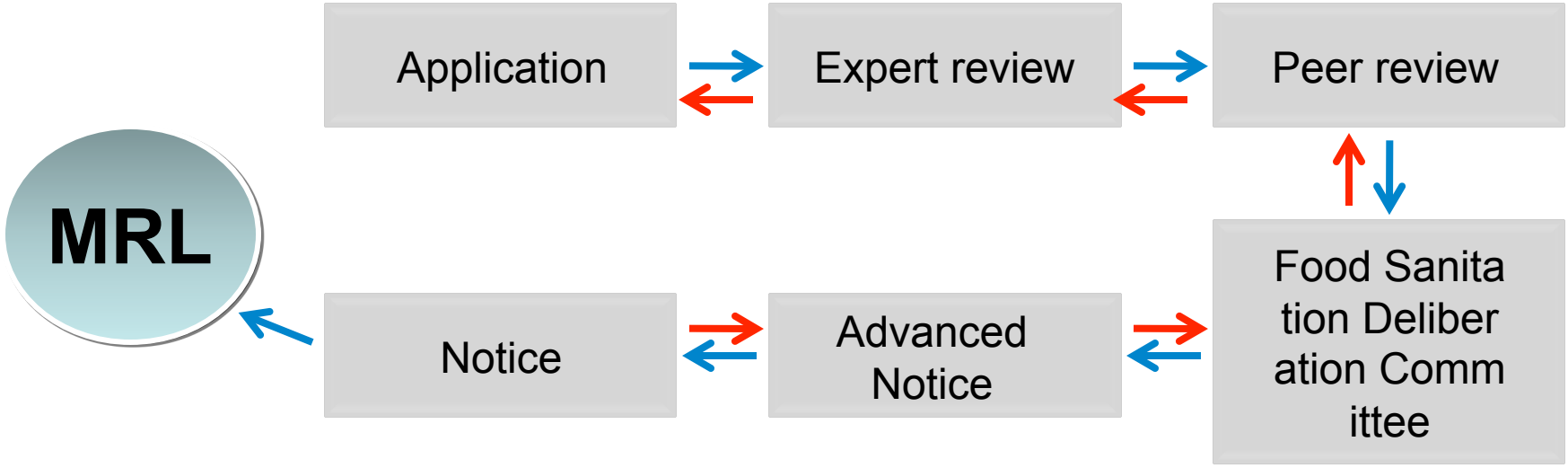
Pesticide MRLs in imported foods

1) Pesticides have MRLs and these MRLs are used in overseas, albeit not used or registered domestically

2) Pesticides used in the past, and have remained in the environment for a long period and require a MRL

3) Pesticides which be needed to set MR by the Commissioner determination

MRL setting procudure in imported foods



Application for MRLs

1. **Application via on-line**

   MFDS has an on-line system for civil affairs (http://minwon.mfds.go.kr)

2. **Processing Time**

   - Establishment of MRL : 12 months (365 days)

   - Change or Exemption of MRL : 7 months (210 days)

3. **Processing Cost**

   1) Toxicity data

   - Establishment of MRL : 30,000,000 KRW per commodity

   - Change or Exemption of MRL : 10,000,000 KRW per commodity

   2) Residual data

   - Establishment, Change or Exemption of MRL :

   5, 000,000 KRW per commodity

MFDS civil affairs' webstie (http://minwon.mfds.go.kr)

Requirements for establishment of MRLs

1) Data

- New compound: Toxicity data and Residual data
- Registered compound (add new commodities) : Residual data only

2) Analytical methods to quality and quantify chemicals

3) Submit chemical standard

- New compound at least 5g of chemical and 1g of each metabolite

❖ Miscellaneous data (but, it will be helpful!)

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

❖ Toxicity data

1. Acute oral toxicity studies
   - Oral toxicity, dermal toxicity, inhalation toxicity, neurotoxicity eye irritation, dermal irritation, dermal sensitization
2. Sub-chronic toxicity studies
   - Repeated dose 90-day oral toxicity, Repeated dose 90-day inhalation toxicity, Repeated dose 90-day neurotoxicity, Repeated 21 or 28-day dermal toxicity, Repeated dose 28-day delayed neurotoxicity
3. Chronic toxicity studies
   - Repeated dose chronic oral toxicity, Carcinogenicity
4. Genetic toxicity studies
   - Developmental and reproductive toxicity studies
5. Teratogenicity studies
6. Metabolism and pharmacokinetics
7. Other toxicity data deemed necessary by the Commissioner in determining the establishment of MRL.

❖ Residue Data

1. Basic information

- Physicochemical characteristics
- Applicable diseases and insect pests

2. Supervised trials for crops results

- Field description, pesticide application methods (and tools), sample collecti on 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

: Import Tolerance

1) Do you have any form for the application?

A: Yes. On-line application via MFDS website.

The application should be filled in Korean.

2)Could a person with no legal entity in Korea apply for the petition directly?

A: Anyone can apply for the import tolerance directly, But should be available to contact with us (phone, e-mail, etc.).

3) Is English acceptable?

A: Yes, English report is acceptable including the data. But, summary report should be written in Korean.

4) How long will it take for the review and establishment of import MRLs after applying?

A : It will take 365 days for a new compound, and 210 days for the additional establishment or alleviation of MRL.

Q&A: Import Tolerance

5) The necessary information/data might be different between pesticides, whether the Korean domestic registration exist (already reviewed the toxicity data) or not. May we understand that only the residue data would be sufficient for the application of the import MRLs?

A : When the pesticide is already registered for other commodities, the residue data are sufficient for the application of the import MRLs

6) Is there any priority list for the evaluation of import tolerance?

A : There ~~are~~ is no priority list. We evaluate the data according to the application number. First come, first see!!

7) Where can we ask questions regarding MRL establishment, or any question about pesticide?

A: Food Standard Division (e-mail : mdfs4797@korea.kr, hckim77@korea.kr ,TEL : + 82-43-719-2434, or FAX: +82-34-719-2400)

MINISTRY OF
FOOD AND DRUG SAFETY

Thank you