Korean Positive List System and Import tolerance

2016. 6. 1

Hyochin Kim
Livestock Product Standard Division
Ministry of Food and Drug Safety

Management of pesticides in Korea

Three different organizations and their roles

1. **Ministry of Food and Drug Safety (MFDS)**
   - Livestock Product 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 and analytical method development

2. **Ministry of Agriculture, Food, and Rural Affairs**
   - Rural Development Administration(RDA)
     - Registration for domestic usage for foods and feeds

3. **Ministry of Environment**
   - Control pesticides in environment

식품의약품안전처

Outline

1. Positive List System

2. Import tolerance

식품의약품안전처

Positive List System

Positive List System

Positive List System

If the pesticide is not registered and/or

set MRL by import tolerance, its MRL < 0.01 mg/kg

Why?

Reinforce Pesticide management in food

- ✓ Prevent excess use and misuse of pesticide.
- ✓ Inhibit use of non-registered pesticides which are not evaluated by scientific assessment.

Current pesticide MRL System

- **MRLs for individual crops or crop groups, and processed foods**

  Food code [Annex 4] : Agricultural product, [Annex 5] : Ginseng product, and [Annex 6] : Livestock product

Ex)

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

◎ 잔류물의 정의(Residue definition) : Methoprene (cis형태와 trans형태의 합)

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		

Risk cap of MRL setting: TMDI ≤ 80% of ADI

(10% portable water, 10% residential environment)

Provisional MRLs

- No MRLs, then

Principle of Provisional MRLs

① The Codex standard

② Not applied ①, then the lowest of the MRL in similar agricultural products

③ Not applied ①, ②, then lowest of the MRL, among MRLs of the pesticide detected

→ Inaccurate intake information (another reason for PLS)

Changes after PLS

Current System

❖ MRLs of registered pesticide /IT
➡ Food code is applied

❖ MRLs of non-registered pesticide
➡ Provisional MRL are applied

❖ Need MRLs?
➡ Import tolerance

PLS

❖ MRLs of registered pesticide /IT
➡ Food code is applied

❖ MRLs of non-registered pesticide
➡ Deletion from Annex 4
and NO provisional MRL
* uniform level(0.01ppm)

❖ Need MRLs?
➡ Import tolerance

Positive List System

1st: Nuts/seeds and Tropical fruits

Enforcement : **16.12.31**

Notice No.2015-78(15.10.29)

Large classification	Small classification	Commodity
Tree Nuts and Oilseeds	Peanut and Tree Nuts	Peanut, Chestnut, Walnut, Gingko nut, Pine nut, Almond, Pecan, Cashews, Hazelnut, Macadamia, Pistachio, Acorn etc.
	Oilseeds	Sesame, Cotton Seeds, Sunflower, Canola Seeds, Palm, Olive, Safflower etc.
	Seeds for beverages and sweets	Coffee beans, Cacao beans, Cola nuts, Guarana

* MRLs of no-registered pesticide → uniform level**(same time with 2nd PLS enforcement)**

2nd: Other crops

Enforcement: Expected 2018.12

Positive List System

	1st PLS (2016.12.31)	2nd PLS (2018. 12 exp)
Crops	Nuts/Seeds Tropical fruits	All crops
Provisional MRL	**No** for Nuts/Seeds & Tr opical fruits Yes for other crops	No for all crops
Deletion for non-registered MRLs i n Annex 4	NO	YES

Provisional MRLs (current)

- No MRLs, then

Principle of Provisional MRLs

① The Codex standard

② Not applied ①, then the lowest of the MRL in similar agricultural products

③ Not applied ①, ②, then lowest of the MRL, among MRLs of the pesticide detected

→ Inaccurate intake information (another reason for PLS)

Provisional MRLs w/ 1st PLS

- No MRLs, then (2016.12.31~ 2nd PLS)

Principle of Provisional MRLs

① The Codex standard

② Not applied ①, then the lowest of the MRL in similar agricultural products

③ If MRL for nuts and seeds, and tropical fruits is not established, default MRLS of 0.01 mg/kg will be adapted.

④ Not applied ①, ②, then lowest of the MRL, among MRLs of the pesticide detected.

Provisional MRLs w/ 2nd PLS

After 2nd PLS enforcement, there are no provisional MRLs

Principle of Provisional MRLs

① The Codex standard

② Not applied ①, then the lowest of the MRL in similar agricultural products

③ If MRL for nuts and seeds, and tropical fruits is not established, default MRLS of 0.01 mg/kg will be adapted.

④ Not applied ①, ②, then lowest of the MRL, among MRLs of the pesticide detected.

Not available

Detected pesticides from inspection

- Examples with analysis results of import inspection

Crops	Pesticide	Result (ppm)	MRL (ppm)
Lychee	Cypermethrin	0.1	2 (CODEX)
Mango	Endosulfan	0.1	0.5 (CODEX)
Mango	Fenthion	0.1	0.2 (Kiwi)
Sesame seeds	Malathion	0.1	2.0 (Non-registered but list as other oils seeds)

Provisional MRLs 0.01 ppm will be applied after PLS.

→ Need MRL? Apply import tolerance

식품의약품안전처

Import tolerance

Import Tolerance

Import Tolerance

A system to assess the safety of foods with residual pesticide for which domestic MRLs are not set and used in accordance with the regulations of foreign countries.

If there is no safety concern, MRLs for the relevant foods are established.

Application

On-line application (www.foodsafetykorea.go.kr)

Import Tolerance

1. Application via on-line

- http://www.foodsafetykorea.go.kr

2. Processing time

- Establishment of MRL : 365 working days
- Change or Exemption of MRL : 210 working days

  * Complementation: Max. 2 times, 6 months

3. Processing cost

1) Toxicology data (per pesticide)

- New MRLs: 30,000,000 KRW (app. $25,000)
- Change or Exemption of MRL : 10,000,000 KRW (app. $8,500)

2) Residue data

- Pesticide: 5,000,000 KRW (per crop) (app. $4,500)
- Veterinary drug: 10,000,000 KRW (per animal) (app. $8,500)

Import Tolerance

4. Data Requirement

1) IT for non-registered pesticide in Korea (Food code [Annex 8])

- 2 hard copies of Toxicology date and summary
- 2 hard copies of residue date and summary

2) Additional MRLs for crops

- 2 hard copies of residue date and summary

* Summary should be prepared in Korean, and residue data in either English of Korean.

* For Generic pesticide, it might be possible to use evaluation reports (such as CODEX JMPR evaluation) instead of original residue data.

3) Miscellaneous

- Registration and MRLs in Codex and other countries
- Standard (depending on residue definition)

Import Tolerance

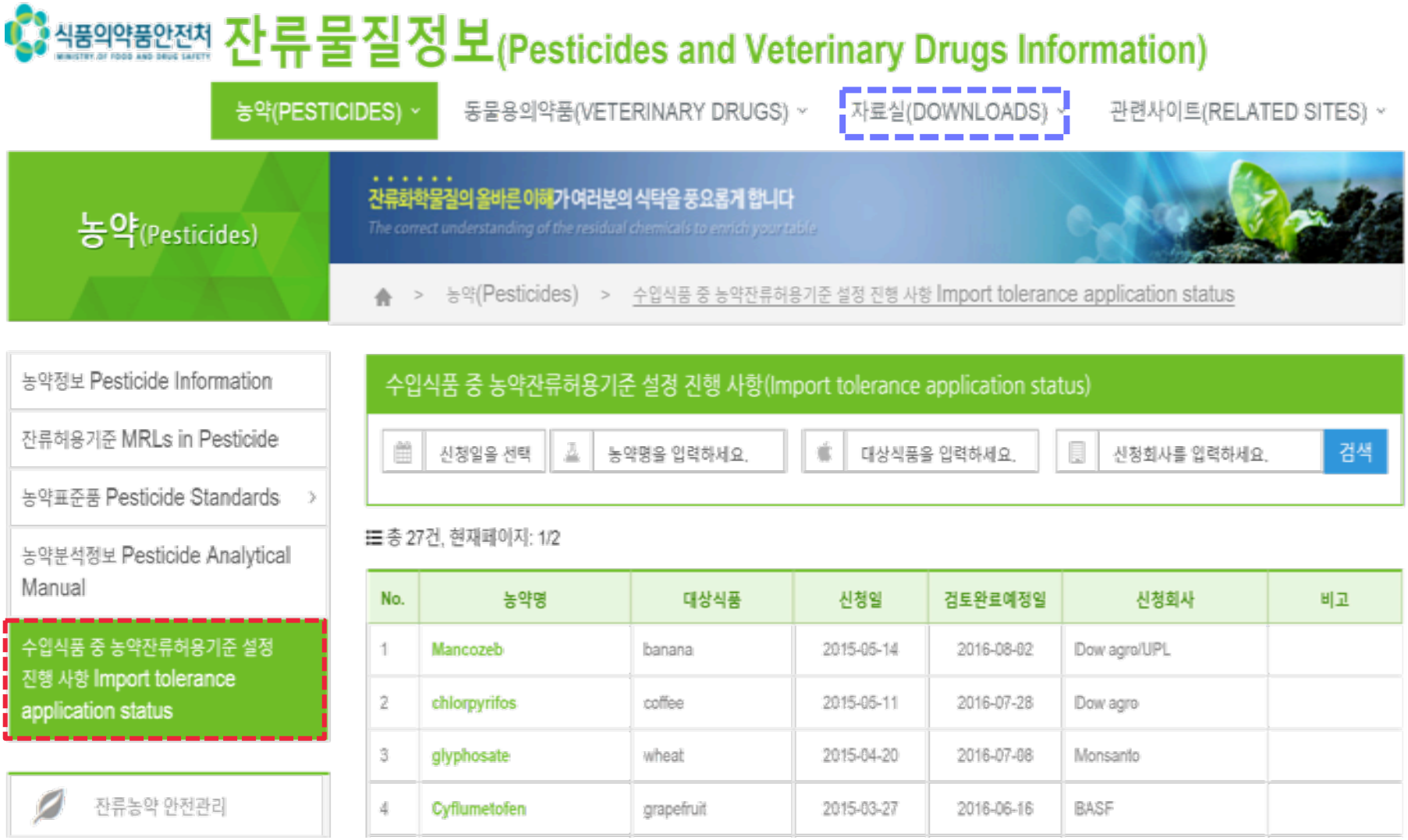
5. Principle of MRL setting

- Minimum of 6 field trials for major crop, 3 for minor crop
- Use OECD calculator to estimate MRL (harmonization w/ codex MRLs)
- In the case of herbicide (which shows no residue),
  LOQ level will be MRL.
- Basically, MRLs are established for individual crops.
  Except, Tree nuts, Citrus, Tropical fruits, and Pulse(Legume)
- Proportionality rule (0.3~4 x a.i.) will be applicable for data
  which are approved by Codex.

List of Exempted Pesticides

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 케이비시1010(Bacillus subtilis KBC1010)
15	바실루스 서브틸리스 큐에스티713(Bacillus subtilis QST713)
16	바실루스 아밀로리퀴파시엔스 케이비시1121 (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	트리코델마 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)

More information?



http://www.foodnara.go.kr/residue

THANK YOU!