

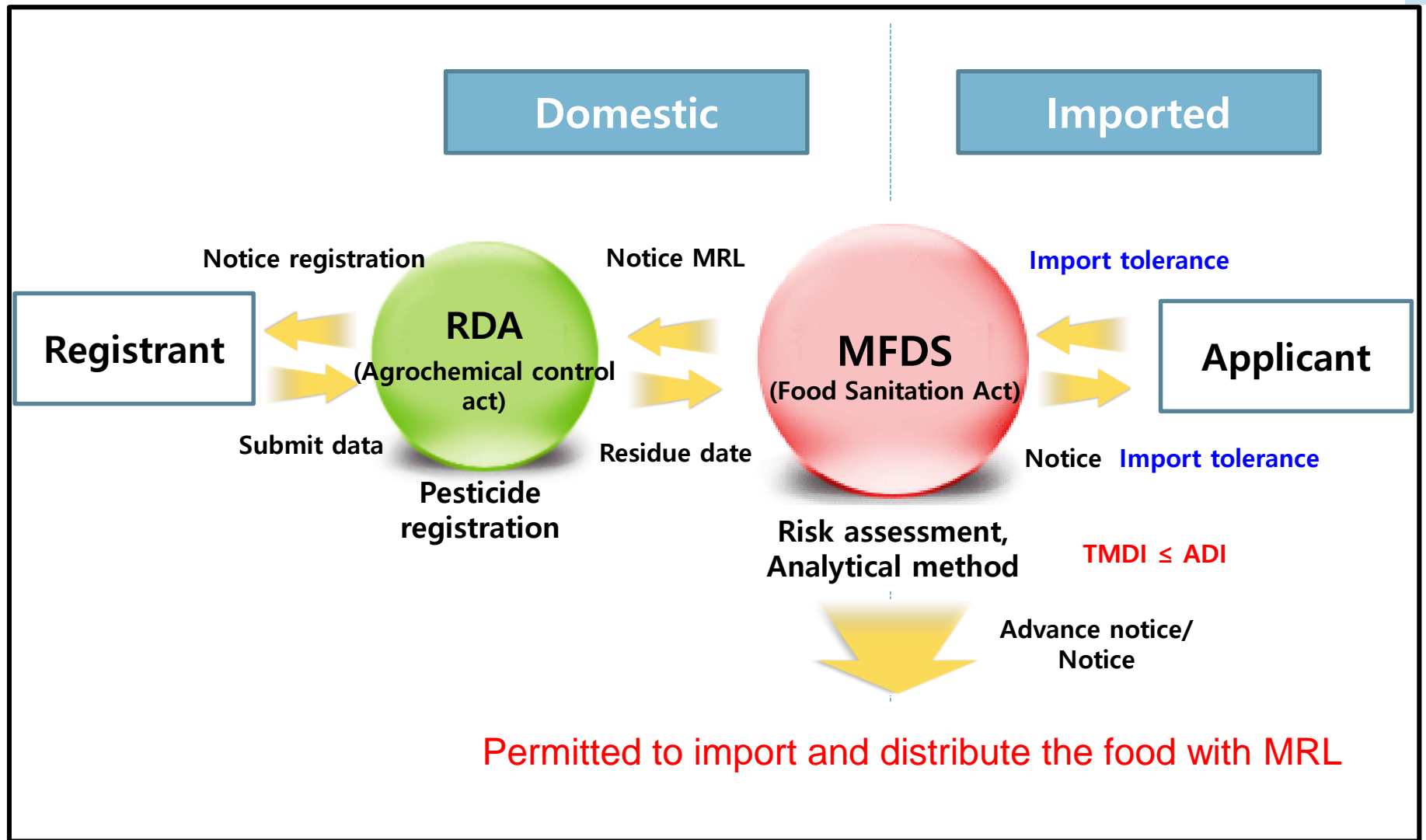
# Import Tolerance System in Republic of Korea

8<sup>th</sup> April 2019



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# Procedure for setting MRLs



# Positive List System (PLS)

- To Prevent use of non-registered pesticide
  - A default MRL of 0.01 mg/kg applies to any agricultural product for sale whose MRL is not listed under Annex 4 of Food Code

## Before

- ① MRLs with scientific evidence  
(Pesticide use registered or reviewed as IT)  
→ Apply the existing MRLs
  - ② no MRL  
→ Apply Codex MRLs and the lowest MRLs of similar crop
- Foods including Non-registered pesticide residues permitted

## After

- ① MRLs with scientific evidence  
(Pesticide use registered or reviewed as IT)  
→ Apply the existing MRLs
  - ② No MRL  
- Apply default MRL of 0.01 mg/kg
- Foods including Non-registered pesticide residues not permitted

# Import Tolerance (IT)

## 1. No mark

Registered in ROK

## 2. Marked with 'T'

Provisional MRL  
(= Temporary MRL)

## 3. Marked with '†'

Import Tolerance

(165) 펜뷰코나졸(Fenbuconazole) ADI : 0.03 mg/kg b.w./day

© 잔류물의 정의(Residue definition) : Fenbuconazole

감(Persimmon)	0.3	보리(Barley)	0.2 <sup>T</sup>	오미자(건조)(Schisandra berry(Dried))	3.0
감귤류(Citrus fruits)	0.5 <sup>†</sup>	복숭아(Peach)	2.0	오이(Cucumber)	0.3
고추(Chili pepper)	0.5	블루베리(Blueberry)	0.5 <sup>T</sup>	참외(Korean Melon)	0.2
딸기(Strawberry)	0.5	비름나물(Amaranth leaves)	3.0 <sup>T</sup>	체리(Cherry)	20 <sup>T</sup>
땅콩(Peanut)	0.1 <sup>T</sup>	사과(Apple)	0.7	취나물(Chwinamul)	30 <sup>T</sup>
레몬(Lemon)	1.0 <sup>†</sup>	살구(Apricot)	2.0 <sup>T</sup>	크랜베리(Cranberry)	10 <sup>T</sup>
매실(Japanese apricot)	2.0	석류(Pomegranate)	0.3 <sup>T</sup>	토마토(Tomato)	0.5
무(잎)(Radish(Leaves))	3.0 <sup>T</sup>	수박(Watermelon)	0.2	포도(Grape)	10 <sup>T</sup>
밀(Wheat)	0.1 <sup>†</sup>	쌀(Rice)	0.05	피망(Sweet pepper)	0.5
바나나(Banana)	0.02 <sup>†</sup>	쑥갓(Crown Daisy)	3.0 <sup>T</sup>	피칸(Pecan)	0.1 <sup>T</sup>
배(Pear)	0.5	오미자(Schisandra berry)	3.0		



## ■ Import Tolerance

- For pesticide use registered in foreign countries
- Set the MRLs if there is no safety concern
- After evaluation on Scientific evidence (Toxicology, Residue)

## ■ Key points for running IT system

- Regulatory basis (Food Safety Act)
- Resource (Experts and Budget)
- Principle for evaluation (Scientific and reasonable basis)
  - Manuals (FAO, Codex, EU...), OECD calculator, CXL



# History



## ■ To adopt Pesticide PLS

- Make the policy decision and flame up the plan in 2011
- Revise Food Safety Act and Food Code in 2013 ~ 2014
  - Request, data requirements, fee for IT
- Set IT system in 2014 (Members and Budget for IT)
- Enforce PLS in 2016 (Tree nuts and oil seed, Tropical fruits)
- Enforce PLS in 2019 (All agricultural products)
- Set ITs from 2010 ~

870 ITs have been reviewed until 2018  
(Expect) 250 ITs in 2019



# Procedure



- Application via on-line

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

- Period as working days

- Set or revise MRL : 365 / Exemption : 210 working days

- Fee

- 1) Review for Toxicology data

- New MRLs: KRW 30,000,000 (about \$25,000)
  - Exemption of MRL : KRW 10,000,000 (about \$8,500)

- 2) Review for Residue data

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



# Data requirements



- Summary (English and Korean)
- Label(GAP), MRL(applicant), Evaluation report(JMPR, EFSA...)
- Toxicology data
  - ✓ For new compound or not registered in Korea
- Residue data
  - ✓ For new use or revise existing MRL
  - ✓ At least 6 field trials for major crop
    - Minor crop (3 trials), Post harvest (4 trials)
  - ✓ With a reference to FAO Manual, under GLP



# Encouragement to applicants

- For generic compound

- Residue data ↔ Evaluation report from international organization or government
- Exemption of Korean-translated summary (~ Dec. 2019)

- One-to-one Advise

- For non-expert (Food manufacturer, Importer, etc.)
- Check national MRLs and data resource

- Review in advance of official application

- For all applicant
- To save cost and time
- Summary, Label and Proposed MRL by e-mail



# Recent Challenges



## ■ Residue definition

- National  $\neq$  Applicant
- Residue data of parent compound and metabolites  $\rightarrow$  Fine
- Only residue data of parent or metabolites  $\rightarrow$  Impossible

## ■ Minor Crop

- No residue data
- Solution : 3 trials, group MRL, Monitoring data ...

## ■ Principle

- Extrapolation, Proportionality, etc.
- Consider 'How can we accept this rule?'



THANK YOU FOR YOUR  
ATTENTION



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