Registration & Management Policy of Pesticide in Korea

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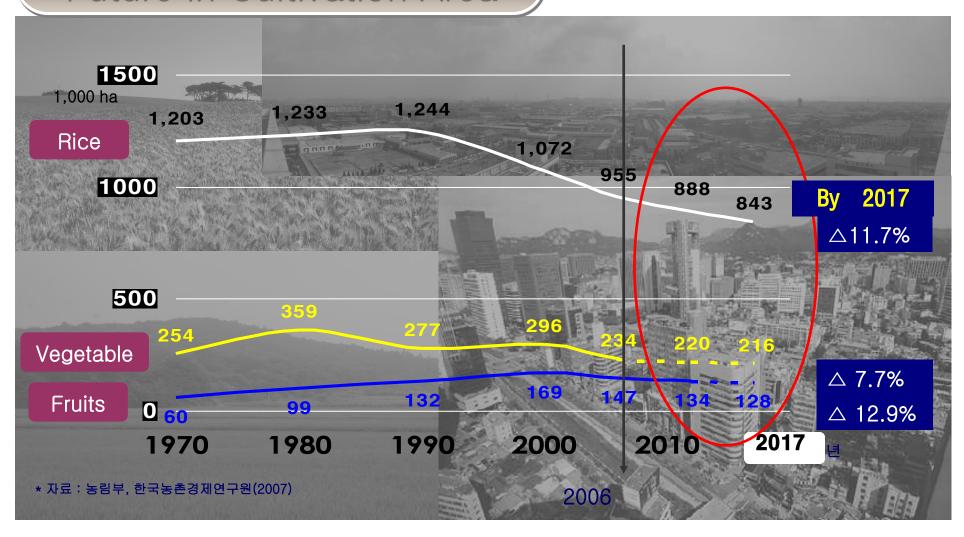
National Institute of Agricultural Science, RDA

Agriculture situation in Korea /

Change in Agricultural Conditions

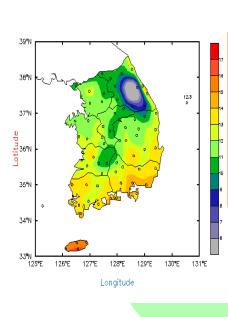
- ✓ Reduction of Agricultural Importance by Changes to Industrial Nation
 - Small Portion in GDP : 1.9% (2016)
 - Farmers Population: 5.0%, 38.4% Older than 65 years(2016)
- ✓ Agricultural income being reduced
 - Annual Income of Farming family : 32,121k won('10) → 37,215k won('15)
- ✓ Change in Life Pattern, Increasing Demand for Organic Food

Future in Cultivation Area



Climate Change

Future Climate Change: About 1° Increase over 1904 to 2000: Expect 0.15° ~0.45° increase every 10 years



Change in Crops

- Variety of Crops
- Spring comes earlier
- Transplanting ▷ Direct sowing
- Cultivation area being changed
- Southern part: Subtropical

Change in Pest

- Various pest outbreaks
- Subtropical pest and weeds
- Survival of pests in winters
- Virus disease in cold area
- O Cultivation of Blueberry, Mango, Banana et al
- 60-80% of several tropical fruits in Department Store : Domestics

2 Pesticides Registration

Pathogenic diseases, insect pests and weeds

Classification	Total	Disease	Pest	Weed
Recorded	4,618	1,539	2,618	461
Outbroken in crop	1,537	574	625	338
To be controlled	100	36	42	22
Exotic	273	22	33	218

Change of Social Recognition

- Importance in agricultural production increase
- Stable supply of effective pesticides.

Safe pesticide with low toxicity and residue.

Eco-friendly pesticides for health and environment.

Pesticide Industry

- Multinational company joined to domestic market after WTO
 - Market share : ('15) 45 %
- Tendency to convert volume-directed to profit-directed management
- Negative reputation of pesticide & organic farming expanded due to agro-product food safety
 - Market disruption by imitated Bio-control Agents
- Growth of pesticide industry slowed though manufacturing capacity surplus

Change in Pesticide Management Act

- Promulgated PMA in 1957 for the first time.
- Since then, revised and re−enforced 11 times.

Commodity Permission

August 28, 1957

- Tested & assessed by NAMIO, Registered by MAFF

Commodity Notification

December 31, 1980

Tested & assessed by NIPR, Notified and registered by MAFF
 Any company can register the notified pesticides with the supply certificate of technical grade a.i. and formulation recipes.

Full - Registration

December 7, 1996

- Tested & assessed by NAS, Registered by RDA

MAFF: Ministry of Agriculture, Forestry and Fishery,

RDA: Rural Development Administration

NIPR: National Institute of Pesticide Research

NAMIO: National Agricultural Material Inspection Office

Requirements for pesticide business license

Category

Man-power

Facilities & Equipment

Manufacturing

Highly educated & qualified Lab: Chemical & Biological Store house: > 165 sq. m

(Leasable)

Experimental field: over 1 ha

Formulation facilities

- -EC, SL
- -SC
- -DP, WP, SP
- -GR Extruding
- -GR Impregnating Coating
- -Non-selective herbicides
- Other

TGAIS

Same as M
Same as M
Same as M
Unnecessary
TGAI facilities
- Reactors or
Fermentors
-Drying
-Packing etc.

Importing

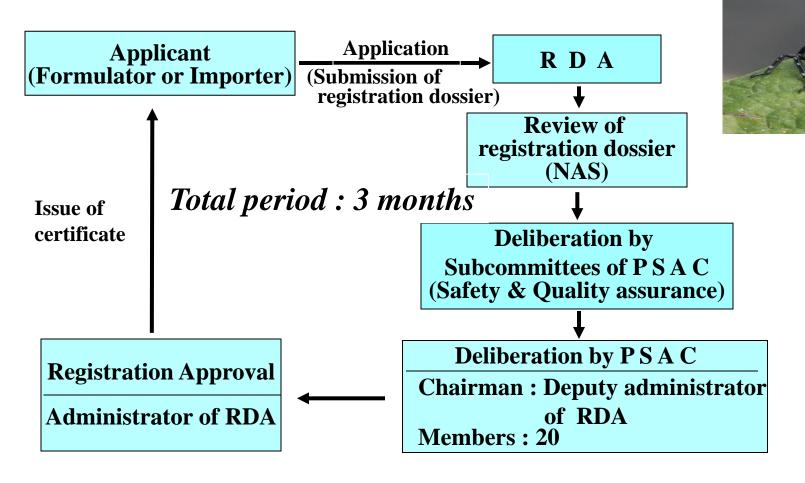
Same as M Same as M Same as M (Leasable for TGAI only)

TGAIS: Technical grade of the active ingredient substance

Roles of RDA

- Pesticide Registration
 - Test Guidelines, Safety Evaluation, Re-evaluation
- Pesticide Management
 - Permission of Manufacturers & Suppliers,
 Quality Control of Pesticides at Market or in Factory

Pesticide Registration Procedure



PSAC: Pesticide Safety Advisory Committee

Data Requirement for Registration

- Submit domestically produced data on chemical stability, bio-efficacy, phytotoxicity, toxicity and persistence.
- All the tests for local data should be generated from the officially recognized organizations.
- ****** Currently recognized organizations for producing local data < testing institute: 117 (2015.6.31)>
 - Efficacy & Phytotoxicity, Crop & Environmental residue Physico-chemical properties, Toxicity & Eco-toxicity
 - < GLP testing institute : 17> = env. Toxicity & mam. toxicity

Data Requirement

Chemical identity

Shelf-life

Physico-chemical property parameters

- A.I. contents
- Impurity profiles

Efficacy

Fungicide, Insecticide: 3 field tests

Herbicide: 6 field tests (2 to 3 years)

Phytotoxicity

Target crops

- Standard & double dose
- **Carry-over crops**
- Regional adaptability
- -Herbicides for paddy rice Tank-mixing compatibility
- O Most trials are modulated by Korea Crop Protection Association.
- O Physico-chemical property parameters are confirmed by NAS.

KCPA: The Korea Crop Protection Association

- continued

Toxicology

- Acute oral for mice
- O Acute dermal for rats
- Primary skin& Eye irritationfor rabbits
- O Skin sensitization for guinea pig

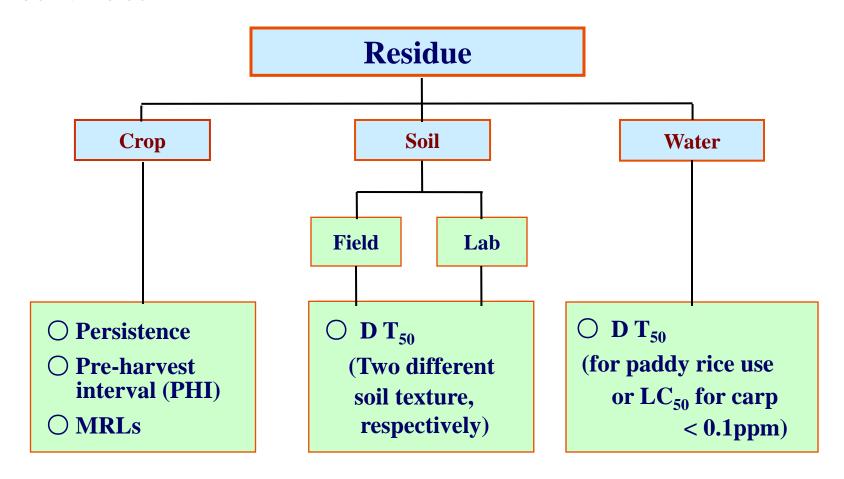
Ecotoxicology

- O Carp LC₅₀ test
- O Daphnia magna

LC₅₀ test

- ***** Additional test for paddy rice use
 - Loach LC₅₀

- continued



Additional Data Requirement

Toxicology		Ecotoxicology		
Data Remarks		Data	Remarks	
Subacute		Daphnia	For paddy rice	
Chronic		Algae		
Mutagenecity	Battery of 3 tests	Avian		
Reproduction	•	Earthworm		
Carcinogenecity	7	Silkworm or Natural enemy		
Teratogenecity		Bioaccumulation	> Log Pow 3	
Acute delayed neurotoxicity	ChE inhibitors only	Honeybee	_	
Animal metabolism*				

^{*} Metabloism and fate study in plant/soil/water are required due to tier approach

Registered Pesticides in Korea

481 A.I.s (Chemicals >98%)

1,870 Formulated Products

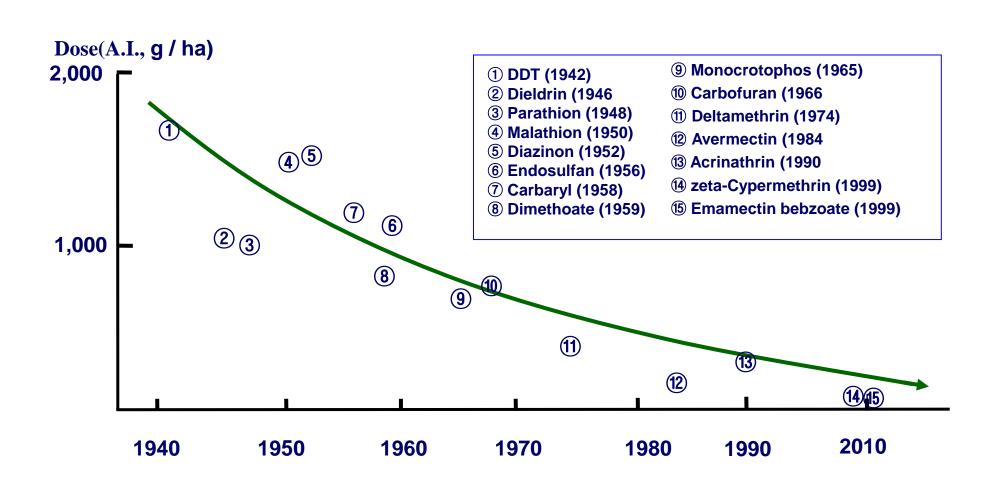
Biocides(21 A.I.s, 35 products)

Registration of Products

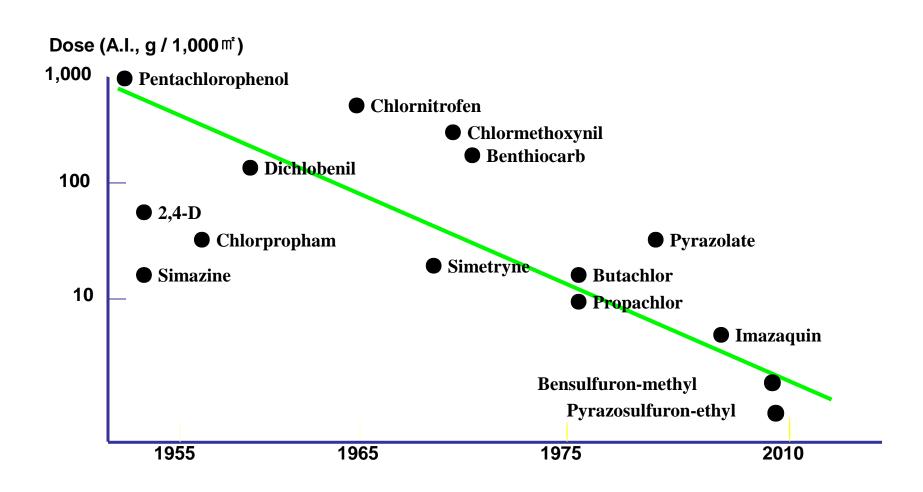
Year	'81	'90	'00	'15
Total	230	467	941	1,837
Fungicide	72	156	295	607
Insecticide	100	185	352	521
Herbicide	37	90	234	565
Other	21	36	60	144

- ~1981 Permission, 1981~96 Notice, 1996~ Registration
- **Every 10 years No. of Pesticide products increased rapidly.**

Insecticide A.I. Input / ha



Herbicide A.I. Input / ha













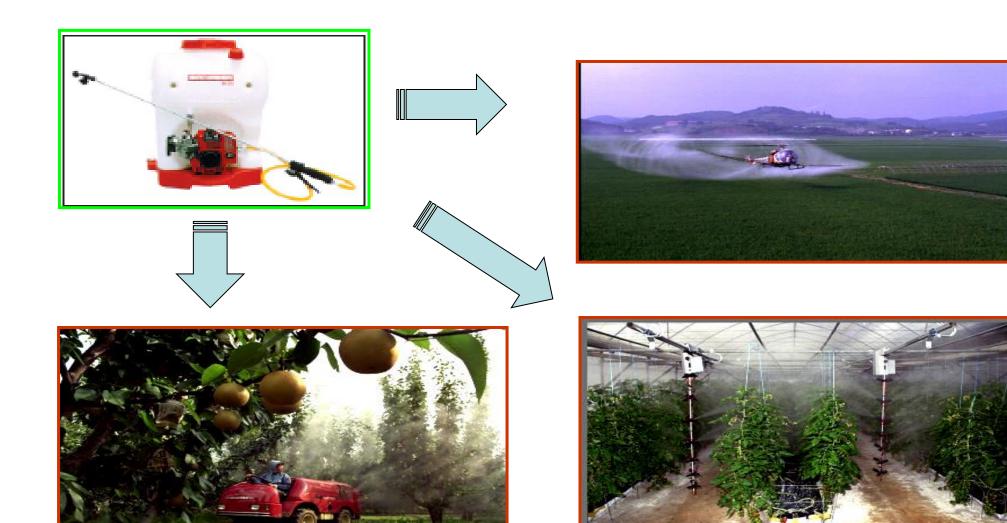








Recent Spraying



New Formulation Technology







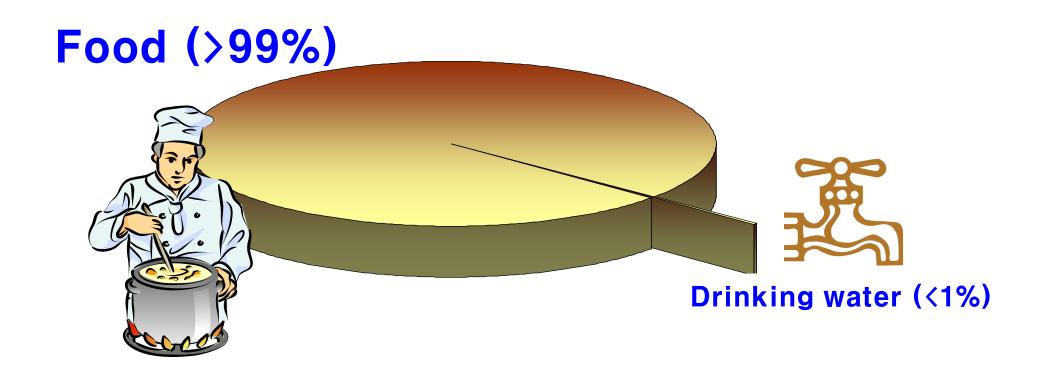


Safe Usage of Pesticides

Pesticide Safety Regulation on Crops

- NAQS: MRLs before Market
- MFDA: MRLs on the Market
- RDA: PHIs(Pre-harvest Intervals)
- Min. of Environment: Water, Soil
 - NAQS : National Agricultural Products Quality Management Service

Dietary Intake of Pesticides



Setting the Korean MRLs

Calculating the NOAEL from Animal Tests(Monkey, Dogs)

Apply 1/100 ~ 1/1000 of NOAEL as Acceptable Daily Intake (FAO/WHO)

Considering the Dietary Amounts of each food and Residues
Each country has its own MRLs

** MFDA (441 A.I.s, 7,333 items)

Setup the Safe Use Guidelines not violate the MRLs
Notice the SUG by RDA

- Violation Fee to Farmers (<\$ 500)

Applicability of MRLs

- Korea MRL for Each Food
- CODEX Standards
- Lowest Value within Large Group
- Lowest Value within Small Groups

(Nuts, Vegetables, Fruits)

Korean MRLs Examples

(Unit: mg/kg)

Pesticide	Potato	Onion	Lettuce	Cabbage	Cucumber	Apple
Carbendazim	-	2.0	5.0	2.0	0.5	2.0
Chlorothalonil	0.1	1.0	-	5.0	1.0	2.0
EPN	0.1	_	0.1	0.2	0.1	0.2
Diazinon	0.1	0.5	0.1	0.1	0.1	0.5
Imidacloprid	0.3	-	5.0	3.5	0.5	0.5
Metalaxyl	0.05	0.2	2.0	0.1	1.0	0.05

^{* 7333} items (2015. 12.)

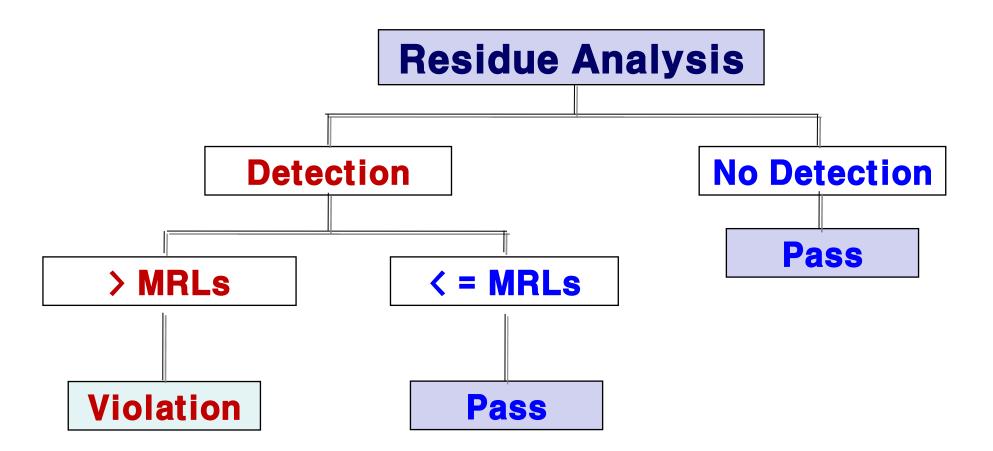
Monitoring Offices for Residues

- Food(before Markets): NAQS*
- Food(at Markets): MFDA
- Water, Soil: Ministry of Environment (RDA, NAQS)

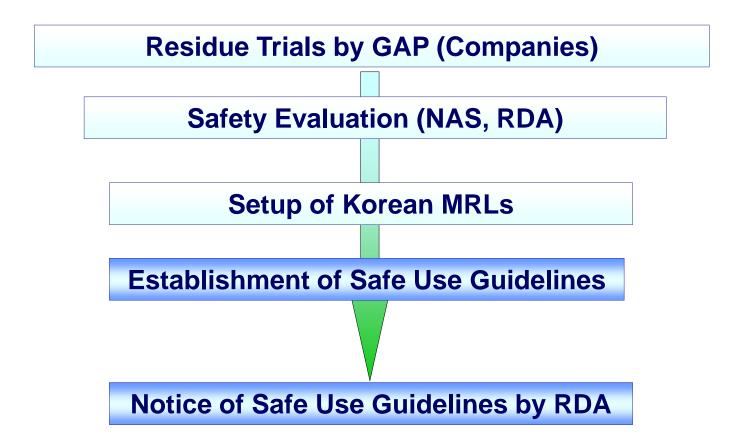
Monitoring Targets (NAQS)

Types	Main Monitoring Targets
Residues	320 Pesticides considering Usage amounts
Heavy Metals	Cadmium and Lead in 10 Main crops
Pathogenic Microbes	6 Pathogenic Microbes
Fungal Toxins	6 Toxins including Aflatoxin B1
Antibiotics	84 Veterinary medicines

Evaluation of Residues

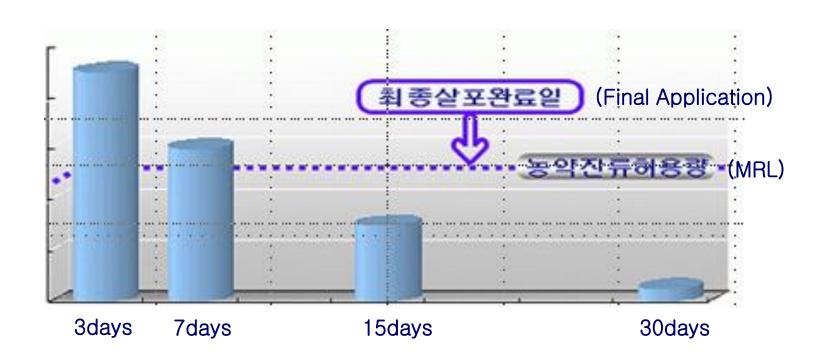


Scheme of Safe Use Guidelines



*All registerated pesticides established SUG

Set Up of Safe Use Guidelines



Trials for Minor Usage

■ Government Supports the Minor Usage since 1998

	Crop	Pesticide	Pests
Trials	91	450	1,886
Registration	77	240	832
Rate(%)	85	54	44

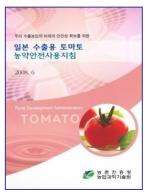
• Budgets for Minors for 2016: \$ 3.0 million (RDA)

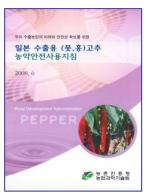
Export Crops

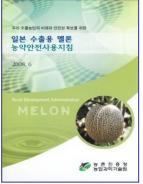
To secure the Safety, not to violate the foreign MRLs

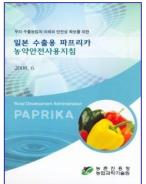
- \square Safe Guidelines for Export Agro-products (2003 ~)
 - O Publishing the guidance books for 28 crops exporting to 11 nations
 - Distributing to and educating for 2,000 farmers every year













Guidance books for export crops

4 Pesticides Management

Market Conditions

- Size of Pesticide Market: 15 B\$
- Most A.I.s imported: >91% (320 m\$)
- Domestic A.I.s: 48 m\$(34% export)
- Import: USA, France, China, India,
 UK, Germany

□ Pesticide Management Offices

MAFRA

Pesticide Control Act, Establishment of Policy

RDA

Pesticide Registration, Quality Control, Registration of Industry, Pesticide Use Guidelines, Education of New Pesticide Salers

NAS

Pesticide Analysis, Review of Dossiers

Province or City

Pesticide Quality Surveillance

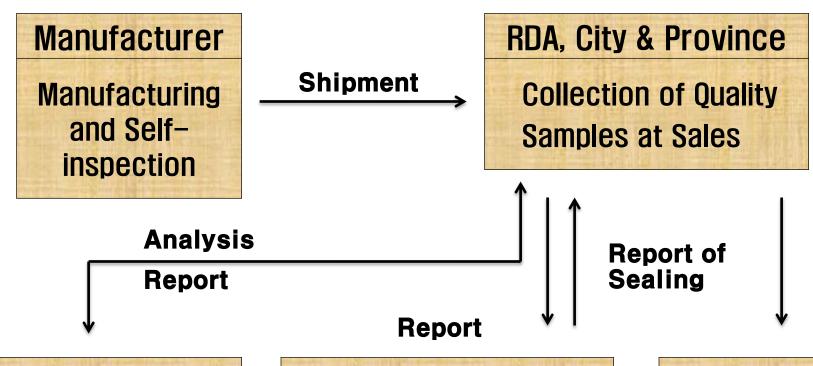
City, County

Sales Registration, Pesticide Quality Surveillance, Violation Fee, Observation of Safe Use Guidelines

NAOS

Safety Control before Market

Quality Control of Circulation Pesticides



NAAS

A. I., Analysis of Properties

City · Province

Poor Quality Population, Stock-Taking, Sealing Manufacturer

Removal of Poor Quality Products

☐ Regulations of A. I.s

Pesticide	No.	Direction
Highly Toxic	5	. No newly registration, Restricted Sales
EDs	57 (Carbaryl)	. No new and more registration
Toxicity B2 (Captan)	10 (Captan)	. No newly registration, Restricted Sales
EBDC s (ETU)	16 (Mancozeb)	. No newly registration
Paraquat	-	. Banned since 2011
Molinate	11	. No Production & Sales since July, 2008

Reevaluation of safety

Regular Reevaluation of Pesticides every 10 years

* No. of Pesticides Cancelled for 10 years : 280 products

Irregular safety reevaluation: 37 Pesticides Cancelled

Causing	Pesticides		
Acute Toxicity	12 (Aldicarb, Chlorfenvinphos, Dialifos, Phosalone et al)		
Residues in Soil	12 (BHC, PCNB, Chlordane, Toxaphene, DDT et al)		
Residues in Crops	5 (Chlordimeform, Lead arsenate, PTA-B, PMA, Phosvel)		
Carcinogen et al	9 (Captafol, DEA-MH, Fenoprop, Maneb, et al)		

Emergency Reevaluation

- > Reevaluation of pesticides banned by U.S. & EU: 158 A.I.s
- 1st Reevaluation: Cancellation 18, Data requirement for Worker safety 23
- > Reevaluation continue by 2017
 - * Regular reevaluation: 117

- Details of Pesticides Labeling
- Product Name : Front Side, Larger(>1/2 of Brand Name)
- Easily Understanding of Principal Information for Safety
- Not Use the Pictures Misunderstood as Beverages
- Allowing Extra Instruction Papers for Small Label Size



Labeling

Insecticide

Instructions

Brand

Crops Usages Dilution

> Pre-Harvest intervals



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Active Substance

