

Ecological Risk Assessment
Scheme in Current Pesticide
Management Act of Korea

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Ecological Risk Assessment Scheme in Current Pesticide Management Act of Korea

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Introduction

□ Ecological Risk Assessment

Estimating the likelihood or probability that adverse effects (e. g., mortality to single species of organisms, or reductions in Populations of non - target organisms due to acute, chronic, and reproductive effects, or disruption in community and ecosystem level functions) will occur, and occurring, or have occurred.

(US / EPA, 1986)

□ Pesticides and Ecological Effect

- ▶ Characteristics of ecological effect by pesticides use
 - Acute, chronic or combined
 - Secondary effect on non-target organisms
 - Bio-magnification of lipophiles through food chain
- ▶ Difficulty of identifying ecological effect factors
 - Various factors are involved and interacted, such as other chemicals, habitat damage, water contamination, etc.

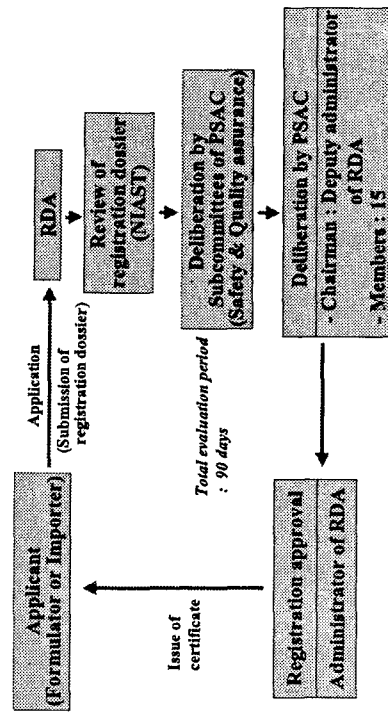
□ Milestones of ecological risk assessment

- Increase the public concern on wildlife and environmental conservation
- Accumulate the scientific knowledge on ecological effect and exposure assessment of pesticides through national research project
- Meet today's regulatory triggers and safety profiles
- Harmonize with the international organization's systems, especially OECD
- Represent the domestic environmental situation for the assessment

Pesticide registration scheme in Korea

- **Regulatory Statute : Pesticide Management Act(PMA)**
 - Promulgated PMA in 1957 for the first time
 - Since then, revised and re-enforced 11 times
- **National Authority : Rural Development Administration(RDA)**
 - ┌ A pesticide is unable to be regally used if it has not been registered by the Administrator of RDA.┐
 - ┌ RDA evaluates the pesticide to ensure that it will not have any adverse effects on humans, environment and non-target species.┐

□ Pesticide registration procedure

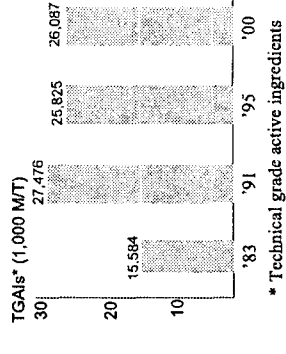


NIAST : National Institute of Agricultural Science & Technology
 PSAC : Pesticide Safety Advisory Committee

□ Trends on use pattern of Pesticides during last two decades

○ Registered formulations ○ Produced tonnage at factory gate

Category	* As of Mar. 2000	
	'80	'90 2000*
Total	233	478
Fungicide	79	172
Insecticide	104	185
Herbicide	35	90
Others	15	21
		37



* Technical grade active ingredients

□ Recent substantial changes in ecological risk assessment

	Pre-2000	Post-2000
Data requirement & Test guidelines	Fish toxicity	Fish toxicity Algae, Daphnia, Avian, Honeybees, Earthworm, Silkworm Fish bioconcentration
Fish toxicity class	Based on Carp LC ₅₀	Based on carp & loach LC ₅₀
Risk Assessment	Toxicity only One step	Compare toxicity with exposure Tier approach

□ Required local data for registration

- Registration applicant should 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
 - Efficacy & Phytotoxicity : 98
 - Physicochemical properties : 24
 - Crop & Environmental residue : 47
 - Toxicity & Ecotoxicity : 14

□ Data requirements for ecological risk assessment

Non-target organisms	Kind of data required for risk assessment		
	1st Step	2nd Step	3rd Step
Fish	Acute toxicity Bioconcentration	ELS Life cycle	Field testing
Daphnia	Acute immobilization	Reproduction	-
Avian	Acute toxicity (oral & dietary)	Reproduction	Field testing
Earthworm	Acute toxicity	Reproduction	Field testing
Honeybee	Acute toxicity (oral & contact)	Foliage residue tox.	Field testing

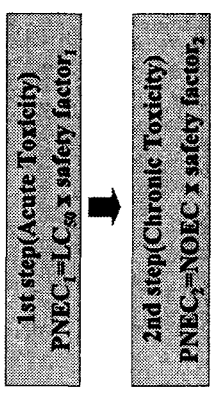
□ Data requirements details in 1st step assessment

Data required	Test substance		Remark for *
	TGAI	EP	
Fish acute LC ₅₀	R	R*	Additional test for paddy use (loach) If log Pow >3
Fish bioconcentration	CR*	CR*	Required paddy use only
Daphnia acute EC ₅₀	R	CR*	Required only paddy use with high water solubility
Algae growth inhibition	CR*	CR*	
Avian acute LC ₅₀	R	R	
Earthworm acute LC ₅₀	R	R	
Honeybee acute	R	R	
Silkworm/ natural enemy	CR	CR	

TGAI : Technical grade of the active ingredient,
 R : required, EP : End-use product
 CR : conditionally required

□ Assessment of hazard data on test organism

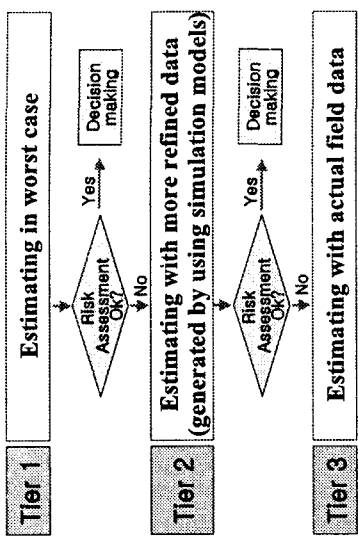
- Hazard data to be used
 - Acute : LC50, LD50, EC50
 - Reproductive, chronic : NOEC
- Estimation of Predicted No Effect Concentration(PNEC)



□ Estimating PEC in worst case

Non-target organism	Exposure route	Scenarios or presumption for estimating PEC
Aquatic	Water	All applied pesticide solved in 5 cm paddy water with no interception by rice, no degradation
Bird	Food	Daily food intake for bird -herbivorous : goose(3kg) → 900g food/day -insectivorous : blue tit(11g) → 8g food/day -earthworm eating: song thrush(89g) → 22g food/day * Considering residue data of food types
Earthworm	Soil	All applied pesticide accumulated in the top 5 cm soil with no interception by crop, no degradation

□ Estimation of predicted environmental concentration(PEC)



□ Comparison of toxicity and exposure

⇒ Estimating the potential of adverse effects

TER (Toxicity Exposure Ratio) = Toxicity / PEC (EU/OECD)
RQ (Risk Quotient) = PEC / Toxicity (USA)
Hazard Potential
High when RQ high / TER low
Low when RQ low / TER high

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□ Risk reduction means in pre-assessment step

- **Formulation improvement**
: water based solvent(WG, ME)
- **Modification of use pattern**
: use rate, timing, site, etc.
- **Run-off reduction**
: buffer zone, water holding period in paddy
- **Drift reduction**
: labeling, buffer zone, adjuvant use.

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□ Regulatory risk criteria (RDA Notification 2000-2)

	Presumption of no risk	Presumption of risk	
		Restricted use	Unacceptable
Acute toxicity			
Aquatic organisms	$PEC < 1/10LC_{50}$	$1/10LC_{50} \leq PEC < 1/2LC_{50}$	$PEC \geq 1/2LC_{50}$
Birds	$PEC < 1/10LC_{50}$	$1/5LC_{50} \leq PEC < LC_{50}$	$PEC \geq LC_{50}$
Chronic toxicity			
Non-target organisms	$PEC < \text{chronic NEL}$	-	$PEC \geq \text{chronic NEL}$

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□ Restricted use guidelines related to fish toxicity

Class	Sale	Use
I	Retailers should keep records on buyer's name, purchase amount. Certificated retailers only should deal and sale	Not allowed to use at hazard-concern sites where the sprayed pesticides would introduced into fish farm, reservoir, or tap-water collection basin.
II	-	Not allowed to use extensively at a time at hazard-concern sites like above.
III	-	Aerial control not allowed in paddy near "protection area for tap-water collection"

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
□ Classification based on fish toxicity

Class	LC_{50} for Carp (48hr, mg/L)
I	< 0.5
II	$0.5 \sim 2$
III	> 2

Note

- Toxicity for other species except carp should be considered for the pesticides used in paddy rice
- Even though a chemical is classified as II or III based on its LC_{50} (higher than 0.5 mg/L),
- in case the amount of the active ingredient of the chemical used is more than 0.1kg/10a, the quotient of LC_{50} expressed in ppm divided by the a.i. amount used per 10a expressed in kg is less than 5 \Rightarrow it can be classified as I.

□ Precautionary label statement and pictogram

Non-target organism	Criteria	Statement	Pictogram
Fish	I	<i>This product is extremely toxic to fish</i>	
	II	<i>This product is toxic to fish</i>	
Bird	LD 50<100mg/kg	<i>This product is toxic to bird</i>	
Honeybee	LD50 <1.14g/bee	<i>This product is toxic to bees. Do not apply this pesticide when Bee may forage on the plants.</i>	
Silkworm	IGR, OPs, Pyrethroids	<i>This product is toxic to silkworm. Do not contaminate mulberry or culturing facilities</i>	

Comparison of Preliminary RA between Korea and EU

○ Example A (fungicide for ginger root rot)

Exposure values

Application rate : 45 g ai/10a
 Use pattern : Low crop
 Worst-case drift rate / Deposition onto water body : 4% (4%) / 1.8 g
 Depth of water body : 30 cm
 Predicted Environmental Concentration : 0.006 mg/l

Effect Values

Tier I	mg/l	TER	Concern ?	
			KOREA (Trigger 10)	EU (Trigger 100)
Fish acute LC50	>10	>1,667	No	No
Daphnia EC50	0.20	33	No	Yes
Algae EC50	61	10,167	No	No

Conclusion :

Korea : No potential for impact on aquatic organisms.
 EU : No potential for impact on fish and algae. May be at risk to invertebrates, so further investigation may be required

○ Example B (fungicide for apple)

Exposure values

Application rate : 33.33 g ai/10a
 Use pattern : Fruit crop
 Worst-case drift rate / Deposition onto water body : 4% (20%) / 1.3 g (6.7 g)
 Depth of water body : 30 cm
 Predicted Environmental Concentration : 0.0044 mg/l (0.022 mg/l)

Effect Values

Tier I	mg/l	TER	Concern ?	
			KOREA (Trigger 10)	EU (Trigger 100)
Fish acute LC50	4.67(2.2)	1,051(100)	No	Yes
Daphnia EC50	4.2	945(191)	No	No
Algae EC50	1.7	383(77)	No	No

Conclusion :

Korea : No potential for impact on aquatic organisms.
 EU : No potential for impact on algae and invertebrates. May be a risk to fish, so further investigation may be required.
 * Half-life in water-80 days : consider long-term effects

○ Example C (herbicide for rice paddy)

Exposure values

Application rate : 18 g ai/10a
 Use pattern : Applied directly to water
 Deposition rate onto water body : 18 g
 Depth of water body : 5 cm
 Predicted Environmental Concentration : 0.36 mg/l

Effect Values

Tier I	mg/l	TER	Concern ?	
			KOREA (Trigger 10)	EU (Trigger 100)
Fish acute LC50	10	28	No	Yes
Daphnia EC50	>100	>278	No	No
Algae EC50	>100	>278	No	No

Conclusion :

Korea : No potential for impact on aquatic organisms.
 EU : No potential for impact on algae and invertebrates. May be a risk to fish, so further investigation may be required.
 * Tier II may be required because of use pattern

Comparison of Parameters Applied in Preliminary ERA between Korea and EU

Parameters	Korea	E	U
Toxicity Data	Acute Data (Tier I)	Acute and Tier II Data	
Test Substance	Technical, Formulation (fish)	Tier I : Technical, Formulation Tier II : Technical, Formulation (CR)	
Exposure Parameters : Drift rate	4.0%	Depending on crop and distance	
Water depth	30cm	30cm	
Trigger : Acute	10	100	
Chronic	X	10	
Persistence in water	X	O	

Issues in ERA of Pesticide in Korea

- Native Species
- Enlargement of Data Requirement
- Consideration of Environmental Fate
- Refinement of Exposure Scenario
- Harmonization of Decision- Making
- GLP

Native Species Requirement

* Q: In the interest of international harmonization, the test guidelines for toxicity to fish and birds have an expanded list of acceptable species. Some of these species are not native to North America. *Would the Panel discuss the utility of these non-native species as surrogates for the array of native American species for which the Agency performs risk assessments ?*

* PANEL RESPONSE

Non-native species could be used as surrogates as long as there is sufficient data in the literature to determine the relative sensitivity compared to native species. It is expected that these data will be used to supplement existing data on native species; however, *these data should not replace the primary emphasis on use of native species.*
(FIFRA Scientific Advisory Panel, Federal Register, 1996)

U.S. FIFRA Pesticide Data Requirements

- 158.80 Acceptability of data
- (c) *Data developed in foreign countries*
The agency considers all applicable data developed from laboratory and field studies anywhere to be suitable to support pesticide registration except for data from tests which involved field test sites or a test material, such as a native soil, plant, or animal, that is not characteristic of U.S. Once comparability has been established, the agency will assess the acceptability of the data

□ Native Species Requirement

- EU directive 91/414/EEC annex 1:
 - 'Full national approval in one member state should be recognized in other member states. *National approval can only then be denied if it can be demonstrated that local conditions are different, requiring additional supporting data.* (Development of agrochemicals in Europe, Requirements and Strategic Issues, Huntington Life Science 1997)
 - 'Any deviations from the requirements must be fully justified.'

□ Comparison of International Ecotoxicity Testing Requirements

Type of Data	EU		Australia		Canada		US		Japan		Korea	
	T	F	T	F	T	F	T	F	T	F	T	F
Basic test for Non-target Organisms	O	O	>80%	>80%	>80%	X	O	X	O	X	O	
Honey bees LD50	O	<80%	<80%	<80%	X	>80%	X	<80%	X	X	O	X
Honey bees residues on foliage	O	<80%	<80%	<80%	X	<80%	X	<80%	X	X	X	X
Field testing for Pollinators	O	<80%	<80%	<80%	X	<80%	X	<80%	X	O	Δ	X
Slitworm	O	O	>80%	<80%	O	>80%	X	X	X	X	O	X
Earthworm acute	O	X	>80%	<80%	O	>80%	X	X	X	X	O	X
Soil microorganism	O	X	>80%	<80%	O	>80%	X	X	X	X	X	X
Acute oral LD50	O	O	O	<80%	O	<80%	O	<80%	O	X	O	<80%
Acute dietary LD50	-	-	O	<80%	O	<80%	O	<80%	O	X	O	X
Avian reproduction	O	-	<80%	<80%	>80%	>80%	O	X	X	X	X	X

□ Aquatic Organisms

Type of Data	EU		Australia		Canada		US		Japan		Korea	
	T	F	T	F	T	F	T	F	T	F	T	F
Aquatic Toxicity	O	O	O	<80%	O	<80%	O	<80%	O	O	O	O
Fish acute (F.W)	O	>80%	<80%	<80%	O	<80%	O	<80%	X	X	X	X
Fish acute (F.C)	O	O	<80%	<80%	O	<80%	O	<80%	O	O	O	Δ
Daphnia acute	O	O	<80%	<80%	<80%	<80%	<80%	<80%	O	X	X	X
Fish acute (M/E)	X	O	>80%	<80%	<80%	<80%	X	>80%	O	X	X	X
Daphnia reproduction	Δ	-	<80%	<80%	<80%	<80%	X	>80%	X	X	X	X
Fish ELS/chronic	O	-	<80%	<80%	<80%	<80%	X	<80%	X	X	Δ	X
Field test	Δ	-	<80%	<80%	>80%	X	<80%	X	X	X	X	X
Bioconcentration	Δ	-	>80%	<80%	>80%	<80%	O	<80%	O	O	O	Δ
Sediment	O	O	>80%	<80%	>80%	<80%	O	<80%	O	O	O	Δ
Algae growth inhibition	Δ	-	>80%	<80%	>80%	<80%	O	<80%	O	O	O	Δ

□ Toxic to Aquatic Organisms

* Toxic to aquatic organisms and persistent in water
 F: Freshwater, W: Warmwater, C: Coldwater, M/E: Marine/Estuarine