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農藥 環境 安全性 評價의 國際的인 調和

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International Harmonisation of Pesticide Environmental Safety Assessments

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ABSTRACT

Governments and industry have a growing interest in the harmonisation of environmental test methods and risk assessment procedures. OECD are currently producing a set of harmonised test guidelines for studying the environmental fate and ecological effects of pesticides. FAO has published an environmental risk assessment procedure. This procedure, which is similar to those used in US and Europe, is based on calculating the ratio of the toxicity of a pesticide to indicator organisms to their level of exposure to the pesticide. The exposure depends on both the concentration of the pesticide and its bioavailability. Ratios which indicate a pesticide will not produce a harmful effect have been established using ecological field studies. Examples are presented for assessing the risk to aquatic ecosystems, earthworms and honeybees.

Long-term field studies(up to 20 years) have also shown that pesticides can be used indefinitely without harming soil fertility. Herbicides can be used to avoid the ecologically damaging effects of using soil cultivations excessively for weed control.

INTRODUCTION

Global trade in pesticides, as well as food, is stimulating a growing interest in harmonising procedures for risk evaluation and registrations. International pooling of resources and expertise can both improve the quality of safety evaluations and reduce costs. The current diversity in data requirements, test methods and risk assessment procedures results in ;

: unnecessary repetition of studies

: waste of resource by national authorities carrying out independent evaluations of data

The food consumer and/or taxpayer ultimately pay for these inefficiencies.

The fate and ecotoxicity of pesticides is similar in all parts of the world where conditions are suitable for growing crops. Thus there is an opportunity to harmonise

: data requirements

: test methods

: data evaluation/risk assessment methods.

For example ; the degradation pathway of a

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pesticide in soil is the same in all soil types, worldwide. The rate of degradation can normally be adequately estimated from laboratory studies plus a knowledge of local soil moisture and temperature regimes. Only in cases or marginal safety, e.g. to rotational crops or concentrations in goundwater, might it be necessary to carry out local field studies. Similarly, the influence of soil type e.g. organic matter level, on the adsorption/leaching potential of a pesticide is the same in all countries.

The UN FAO(Food and Agriculture Organisation) and OECD(Organisation for Economic Co-operation and Development) are playing an important role in the international harmonisation of pesticide testing and safety evaluation. Groups of countries, such a members of the European Union, are also harmonising their registration procedures.

PRINCIPLES OF ENVIRONMENTAL RISK ASSESSMENT

There is general agreement that the environmental risk assessment is based on comparing the toxicity of a pesticide to an indicator organism with the level of exposure. This is illustrated by Fig. 1 taken from the FAO Guidelines on environmental criteria for the registration of pesticides(1989). The initial assessment is based on a comparison of the worst case level of exposure during, or immediately after, application with the toxicity to indicator organisms measured under applications are used to define the rail of toxicity to exposure that indicates a pesticide use will not present a threat to the environment.

If the toxicity : exposure ratio indicates there is a possible risk then further detailed studies might be required to refine the assessment, under more realistic conditions. It might also be necessary to modify the proposed uses of the pesticide to reduce the exposure levels and thus to reduce the risk(Fig. 1).

Data on the pesticide's persistence, mobility and bioaccumulation potential is used to assess if there is any long-term exposure. If there is long-term exposure this is taken into account in the risk assessment.

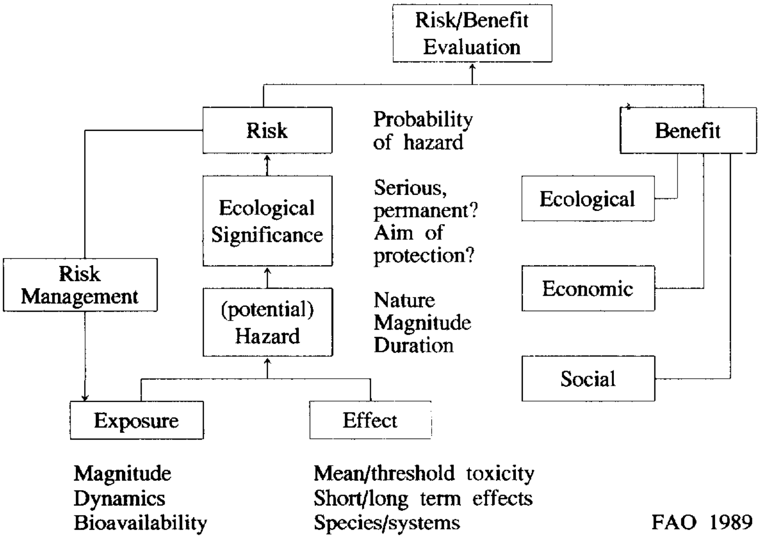

Fig. 1. Environmental Risk Assessment

The decision on whether or not a pesticide should be registered for a particular use is based on a comparison of the benefits from its use, compared with any remaining risks(Fig. 1).

EXPOSURE ASSESSMENT

For birds and mammals the main route of exposure is via their food. The highest concentrations occurs immediately after application and are estimated from the rate of application of the pesticide(Table 1). These values can be directly related to LC50 dietary toxicity values ; the LC50 value being expressed as mg pesticide/kg food. When the toxicity data are expressed as mg pesticide/kg body weight(LC50) then the estimation of exposure requires a knowledge of the amount of food consumption is 30% of the body weight whereas for larger animals(100g body weight or more) it is assumed to be 10% of the body weight.

Table 1. Typical environmental concentration immediately after application of 0.5kg ai/ha of pesticide(Hoerger and Kenega, 1972)

Material	Residue(mg/kg)
Grass	100
Leafy Crop	50
Grain	5
Small insects	20
Large insects	2
Soil(10cm deep)	0.5

For a few organisms, such as honeybees, the level of exposure is directly related to the rate of application in a spray(g ai/ha).

For pesticides applied to soil or small crops and weeds it is assumed 100% reaches the soil ; when applied to large weeds or crops it is presumed 50% reaches the soil. The concentration of residues in the top 10cm soil is then calculated from the rate of application(Table 1). Data on the frequency of application and persistence is normally expressed as the DT50 of extractable residues.

Exposure assessments also must take into account the bioavalability of the residues.

Using ^{14}C labelled pesticides it has been shown that all pesticides from 'bound' residues in soil (Table 2). These residues can only be extracted using very extreme conditions eg refluxing with concentrated alkali or acid, which destroys the soil particles and often the pesticide itself, thus making it difficult to measure the concentration of intact 'bound' residues.

Table 2. Examples of bound pesticide residue in soils(Calderbank 1989)

Structural type	Bound residues(% of applied)	Parent detected*
Herbicides Anilides and ureas	34 - 90	No
Bipyridyliums	10 - 90	Yes
Nitroanilines	7 - 85	No
Phenoxy	28	No
Phosphonate(glyphosate)	12 - 95	Yes
Triazines	47 - 57	Yes
Insecticides Carbamates	32 - 70	Yes
Organochlorines	7 - 25	?
Organophosphates	18 - 80	Yes
Pyrethroids	3 - 23	No
Fungicides Chlorophenols	45 - 90	Yes ?
Nitroaromatic(dinocap)	60 - 90	Yes ?

* Indicates where parent was positively identified. In cases with "No" or question mark, method of extraction may have decomposed parent molecule.

These 'bound' residues can be strongly bound parent molecule, strongly bound degradation fragments or material incorporated into the soil organic matter by micro-organisms, or a mixture of all three components. The significance of 'bound' residues has been a subject of much debate (Kaufman et al 1976, Calderbank 1989). Many studies have shown these 'bound' residues have a very low biological availability ; thus, uptake into crops is negligible and they have no effect on soil organisms. Due to their very low biological availability the rate of microbial degradation is slow, but sufficient to prevent them reaching harmful levels even after long-term use of pesticides(Calderbank, 1989). For example even when applied at 100 times the normal rate of application there was no significant uptake of bound paraquat residues by crops or earthworms(Table 3). 'Bound' soil residues are not included in the risk assessments because of their very low biological availability.

Pesticides enter water mainly by spray drift

Table 3. Unavailabiliy of 'bound' paraquat residues in soil following application of 90kg paraquat/ha, incorporated into top 15cm soil (100×normal rate of application)

'Bound' paraquat soil residues	40 mg/kg
Residues in barley grain	<0.01 mg/kg
Residues in carrots	0.01 mg/kg
Residues in earthworms	<0.05 mg/kg

Table 4. Worst case drift rates(% of application) at different distances from the treated area following application using tractor mounted sprayer(Ganzelmeier, 1993 a and b)

Distance(m)	% Drift
1	4.0
2	1.6
3	1.0
5	0.6
10	0.3
15	0.2
30	0.1

and run-off. Numerous studies have been carried out to assess spray drift from tractor mounted hydraulic sprayers. Typical worst case % drift values are given in Table 4. These data can be used to predict the maximum residues in adjacent water eg 5m distance from arable crop drift is 0.6% and this is equivalent to 0.0006mg/litre in water 1m deep assuming the crop was treated with 1kg/ha. Drift from hand held sprayers used for weed control will be much lower.

Contamination of surface waters by runoff of pesticides from treated fields can occur mainly in areas where agriculture is carried out on fields exceeding a certain slope or where subtropical thunderstorms cause heavy erosion. For the majority of plant protection agents runoff losses observed are 0.5% and lower(Wauchope, 1978). By assuming, for example, ≤0.5% runoff from a 1 hectare field treated with 1kg/ha into a 0.2 hectare pond of 1m depth the predicted concentration is ≤0.002mg/litre.

ECOTOXICITY

The toxicity of pesticide to a wide range of indicator organisms is measured under standard laboratory conditions. Organisms/tests in Europe and/or USA include ;

mammals(acute, dietary, reproduction)
birds(acute, dietary, reproduction)
plants
fish
Daphnia(acute, reproduction)
algae
honeybees(oral and contact)
earthworms
soil micro-organisms

The tests are carried out under conditions which maximise the bioavailability of the pesticide.

For example, aquatic studies are carried out in clean water and earthworm studies is soils with a relatively low adsorption capacity.

OECD is currently updating its guidelines to cover all these organisms. This should facilitate the international acceptance of standard ecotoxicity guidelines.

There are no standard guidelines for higher tier ecological studies. Any such studies have to be designed to answer specific questions.

RISK ASSESSMENT

The risk of an organism or group of organisms being adversely affected by a pesticide is determined by comparing the toxicity to indicator organisms with the level of exposure. This principle is illustrated using three examples ;

aquatic ecosystems
earthworms
honeybees

Aquatic Ecosystem

The no observed effect level(NOEL) or LC50 for fish, Daphnia and algae is compared with the predicted concentration in the water following normal use of the pesticide.

A key area of debate is what ratio should be equated with a conclusion that a pesticide does not present a risk to the aquatic environment. Thus, laboratory measured EC_{50} and NOEL values for fish, invertebrates and algae have been compared with effects of pesticides on pond ecosystems(Fig. 2). This has shown that there will be no concern if the predicted environmental concentration is <1/10 of LC50, or <chronic NOEL to fish, invertebrates and algae, ie there is unlikely to be any significant effect on the aquatic ecosystem(Rijtema *et al*, 1993). Although the aquatic ecosystem might contain organism organisms more sensitive to pesticide than those tested in the laboratory, this is counterbalanced by a more rapid decline in residue concentrations due to degradation, adsorption and dilution. Laboratory toxicity studies are normally carried out in 'clean' water ; in some studies, the concentration of the pesticides is also maintained constant by using a flow-through system. Effects under field conditions are also balanced by natural population processes.

Earthworms

The toxicity to earthworms is measured using *Eisenia foetida* in an artificial soil media(OECD-

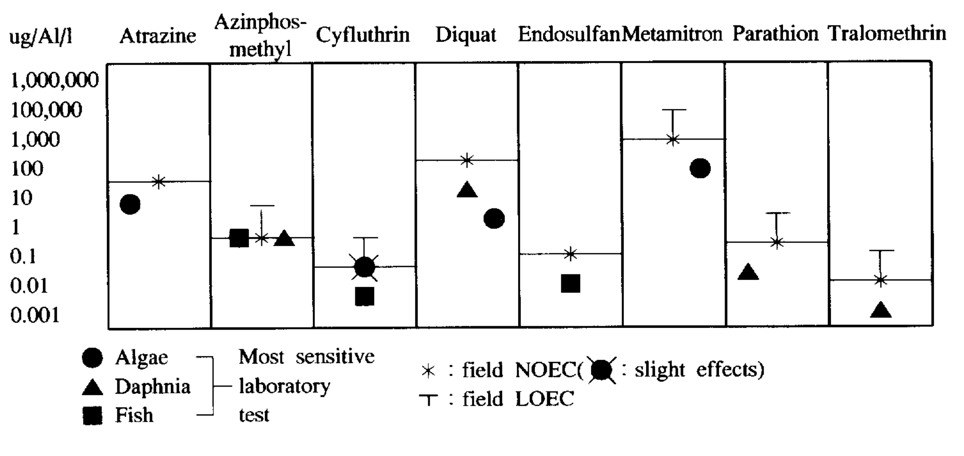

Fig. 2. Effects on aquatic organisms, comparison of lowest laboratory results and ecosystem NOEC

GUIDELINES 207 1987). The concentration in the soil following normal applications is calculated assuming a uniform distribution of the pesticide in the top 2.5cm soil and an average soil density of 1.5. Thus an application of 1kg ai/ha gives predicted concentration of 2.7mg ai/kg dry soil.

A comparison of the ratio of laboratory toxicity to predicted concentration with results from field studies has shown their will be no risk to earthworm populations if the predicted concentration is less tan 1/10 LC_{50} value in soil.

Honeybees

The best measure of exposure for pesticides sprayed onto crops where honeybees are present is the application rate of the active substance. This is used in conjunction with the contact toxicity to calculate a hazard ratio ;

$$\text{Hazard Ratio} = \frac{\text{Application rate(g ai/ha)}}{LD_{50}(\mu g \text{ ai/bee})}$$

Experience with a wide range of pesticides has shown if the ratio is <50 it will be safe to honeybees and if>2500 it is likely to be dangerous if, for example, it is sprayed onto flowering crops(Oomen, 1986). For hazard ratios between these values field testing might be necessary to determine if the pesticide will be safe when sprayed onto flowering crops. Hazard ratios for example insecticides are given in Table 5.

The UK Ministry of Agriculture, Fisheries and Food(MAFF) maintain a honeybee incident investigation scheme. An evaluation of the results from this scheme has confirmed that the pesticide applications classified as low risk(hazard ratio<50) have not caused any bee poisoning incidents. A more detailed analysis of the results of the scheme (A.D.M. Hart, personal communication) has shown that it may be possible to raise the hazard ratio threshold for low risk to 500 and the threshold for high risk could be lowered to 1,000.

Table 5. Comparison of honeybees toxicity values and application rates of insecticides

Insecticide	Contact LD_{50} (μg/bee)	Application Rate g/ha	Ratio
Pirimicarb	50	140	3
Phosalone	8.9	460	52
Cypemethrin	0.056	25	450
Dimethoate	0.12	350	2900
Triazophos	0.055	400	7300

Table 6. Earthworm populations in direct drilled(zero tillage) or ploughed clay soil(Ellis and Barnes, 1977)

	Number of Earthworms/m^2		
Year	Direct drilled	Ploughed	Direct drilled / Ploughed
1973	145	110	1.3
1974	345	218	1.6
1975	231	98	2.4
1976	197	50	3.9

LONG-TERM SAFETY

There have been concerns that the type of risk assessment described above might not detect long-term harmful effects, eg on soil fertility. However, long-term studies(20years) have shown that pesticides can be used indefinitely without harming soil fertility(Fryer et al. 1980, Bromilow et al. 1996).

It is now recognised that, used sensibly, herbicides can prevent the harmful effects of excessive cultivations used to control weeds. For example, the use of herbicides plus minimum tillage can prevent the harmful effects of soil cultivations on earthworms(Table 6).

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