Uncertainty in risk assessment

Robert Luttik

Level of protection in first tier (introduction)

Exposure

The European Directive does not provide guidance for the level of conservatism in the exposure assessment either.

However, in the surface water document of the Forum for the co-ordination of pesticide fate models and their use (FOCUS) the percentile drift values for one or more applications are chosen in such a way that the models aim to obtain an overall 90th percentile drift loading for the entire season in the receiving surface water (FOCUS 2001).

The first tier approach for birds is based on the 90th percentile of the residue data.

Level of protection in first tier (introduction)

Unfortunately, the European Directive 91/414/EEC does not contain an explicit definition of the level of protection required when assessing risks to for instance birds or to aquatic invertebrates (nor for other environmental risks).

However, the directive describes to a certain extent how first tier risk assessment should be carried out, e.g. by defining the number of species to be tested and what uncertainty factor should be used.

$$\frac{EXPOSURE}{TOXICITY} \leq ASSESSMENT\ FACTOR$$

Level of protection in first tier (introduction)

<u>Assessment factor</u>

The acute exposure toxicity ratio (ETR) is compared with values specified in Annex VI of Directive 91/414/EEC, e.g. 100 for aquatic organisms or 10 for birds.

These values can be regarded as assessment factors (AF) that allow for various uncertainties affecting the ETR.

There is no explicit documentation or justification of what they cover. They are generally interpreted as relating to uncertainties on the toxicity side only and are not intended to account for uncertainties in the exposure estimation.

Level of protection in first tier (introduction)

Toxicity

Acute risk assessment for birds in Europe requires only one bird species (LD50) to be tested, either a quail species or the mallard duck.

In most cases, however, two toxicity tests are available for birds, e.g. for the bobwhite quail and the mallard duck (US EPA requirements). In that case in Europe the lowest toxicity value is used in the risk assessment.

For aquatic risk assessments in the EU often only one invertebrate species is tested, e.g. the daphnid *Daphnia magna* (LC50).

Level of protection in first tier (introduction)

The first aim of this presentation is to provide information on the level of protection that is provided by the first tier risk assessment when decisions are made for the authorisation of sprayed pesticides, e.g. for birds and for aquatic invertebrates.

The second aim of this presentation is to show what the implication for first tier risk assessment will be when implementing the advice of the EFSA, by using the geometric mean of the two available birds species instead of using the lower of the two.

Level of protection in first tier (methods)

One way to assess the level of protection is to estimate the percentages of species that will be affected at the highest concentration/dose that is considered to be safe in the current regulatory scheme, i.e. when the ETR is equal to the AF.

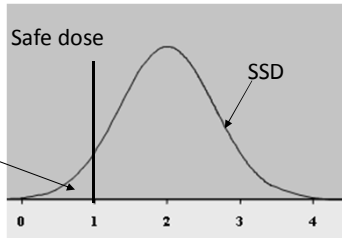
The outcome of a real risk assessment based on these data would be that the compound would just be allowed on the market without asking for additional information.

Level of protection in first tier (methods)

The 'safe' concentration can be compared with a species sensitivity distribution (SSD) based on all toxicity data available to assess what proportion of species would be affected at this 'safe' concentration.

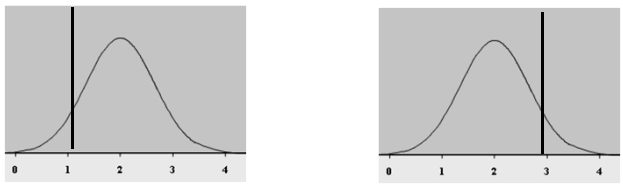
For invertebrates the formula is equal to
PEC or 'safe concentration' = L(E)C50 / 100
and for birds it equals
PED or 'safe dose' = LD50 / 10.

Proportion of species affected



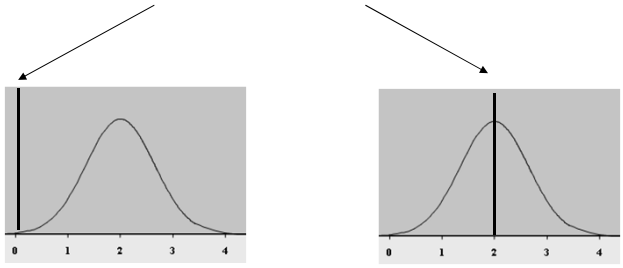
Level of protection in first tier (methods)

Toxicity value available



Level of protection in first tier (methods)

Safe concentration = toxicity value / SF



	Difference between lowest and highest toxicity value			
	1-10	10-100	100-1000	≥ 1000
Number of compounds	122	100	30	3

Level of protection in first tier (methods)

The aquatic database used for the calculations in this paper is a research database of the National Institute of Public Health and the Environment (RIVM) in the Netherlands and is described in De Zwart (2002). From this database only the acute data for crustaceans and pesticides were used.

The avian database on acute toxicity data for pesticides was made available by Environment Canada. Methods used to assemble this database were outlined in Mineau et al. 2001. The current database was updated in January 2007.

Level of protection in first tier (results)

Fraction of species, exceeding their toxicity endpoint when ETR = AF (crustaceans and birds).

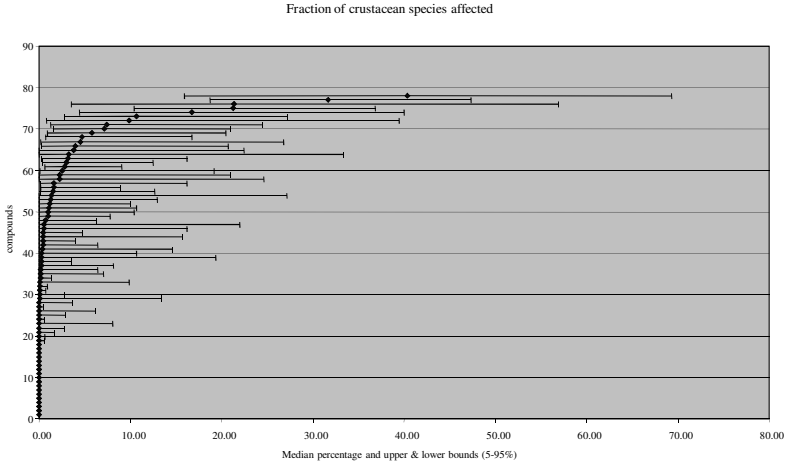
Group	Toxicity	Fraction of species not covered (%)				Number of compounds
	endpoint	mean	std	minimum	maximum	
Crustaceans	LC50	2.9	6.9	< 0.01	40.3	78
Birds (based on lowest standard test species)	LD50	2.6	5.0	< 0.01	21.1	69
Birds (based on mean of standard test species)	LD50	6.5	8.8	< 0.01	31.5	69

Level of protection in first tier (results)

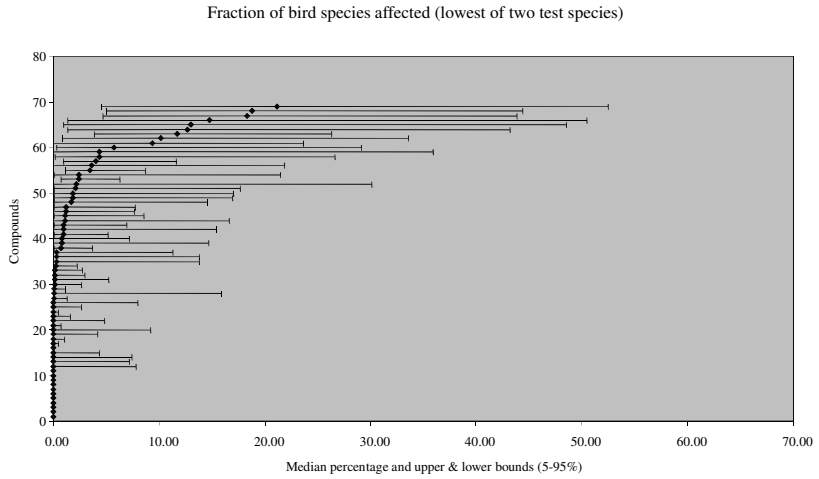
Percentages of compounds in particular classes of fraction of species not covered by the AF

Group	Percentages of compounds in each class of % of species not covered by the AF					n
	FA < 0.01%	FA 0.01-0.1%	FA 0.1 - 1%	FA 1-10%	FA >10%	
Crustaceans	29	13	21	29	8	78
Birds (lowest)	25	14	20	29	12	69
Birds (mean)	16	10	19	25	30	69

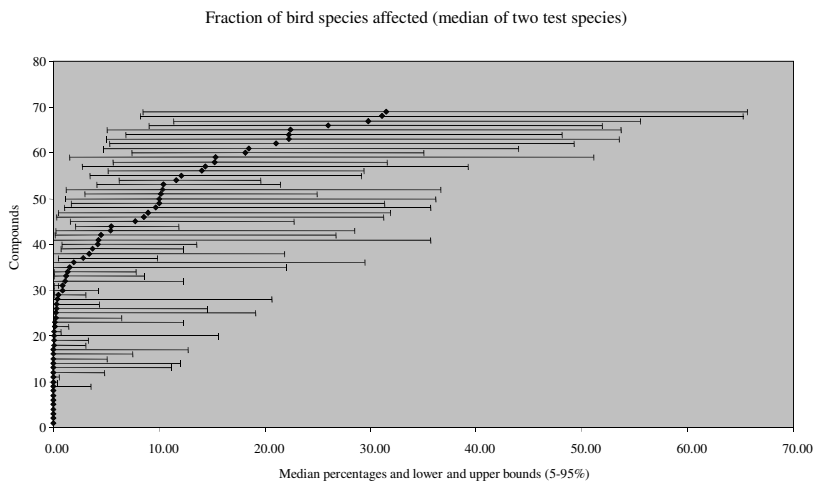
Level of protection in first tier (results)



Level of protection in first tier (results)



Level of protection in first tier (results)

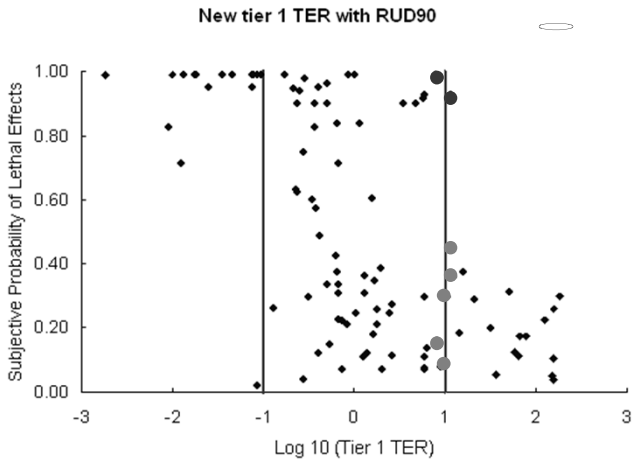


Average percentage not covered by Assessment factor

Standard species tested: percentage of ratios not covered by the specific assessment factor

Assessment factor	Insects	Crustaceans	Fish	Bird	Bird	Bird
	Chironomus spec.	*Daphnia magna*	*Oncorhynchus mykiss*	Bobwhite quail	Mallard duck	Japanese quail
100	**6.4%**	**4.5%**	**0.7%**	0.0%	1.3%	0.0%
10	21.4%	16.0%	5.0%	**4.4%**	**17.8%**	**3.9%**

What are we predicting?



Level of protection in first tier (conclusions)

- **The level of protection varies between groups of organisms (not shown is this presentation),**
- **The level of protection varies widely between compounds,**
- **Sometimes the outcome is very conservative but sometimes not conservative at all,**
- **It is also shown that what we have found theoretically, is also underpinned by mortality in field studies at exposure concentrations equal to the first tier assumptions.**
- **Not shown but the level of protection does also vary between groups of compounds (for example, variation in toxicity among crustacean species tends to be higher for insecticides then for herbicides),**

Acknowledgement

Peter Craig
Dept. of Mathematical Sciences, Durham University Durham, United Kingdom.

Pierre Mineau
National Wildlife Research Centre, Science and Technology Branch, Environment Canada.

Andy Hart and Willem Roelofs
The Food and Environment Research Agency, United Kingdom.