

EUFRAM

Concerted action to develop a European Framework for probabilistic risk assessment of the environmental impacts of pesticides¹

Work Package 8

CASE STUDY SUMMARIES 2003-2004²

This document contains summaries of the following EUFRAM case studies:

CASE STUDY 1: Carbaryl Aquatic risk Assessment

CASE STUDY 3: Risk to aquatic organisms arising from exposure to 'HERBURON' via spray drift

CASE STUDY 4: Acute risks to skylarks arising from a summer cereal spray

CASE STUDY 5: Risk assessment for an organophosphate insecticide under Mediterranean conditions

Note: These case studies were completed in the first 2 years of the project. They played an important role in developing the EUFRAM framework, but do not closely follow the current version of the framework. Therefore, new case studies are being developed for Volume 1 of the EUFRAM report, to act as worked examples of the framework. These will be available at www.eufram.com from 4 October 2005.

¹ EUFRAM is supported by European Commission's 5th Framework Programme (www.cordis.lu), contract number QLK5 - CT 2002 01346. Further information and news about EUFRAM is provided at www.eufram.com.

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CASE STUDY 1: CARBARYL AQUATIC RISK ASSESSMENT

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This case study assesses the risk to aquatic invertebrates from exposure to the insecticide Carbaryl via spray drift. A probabilistic exposure estimate is produced from the Ganzelmeier spray drift data and is compared with probabilistic expressions of effects on invertebrates (Species Sensitivity Distributions; SSD's), considering that the sensitivity to Carbaryl is linked to the ecology (habitat, feeding behaviour) of a species. Example results are given below:

Expression of exposure	Expression of effects (examples)	Results of risk assessment (examples)
probabilistic distribution of PEC _{sw} in agricultural ditch arising from drift, for 10 m no-spray buffer zone	5 th percentile of LC50 of all aquatic invertebrate species (1.5 µg L ⁻¹)	effects endpoint is exceeded for 90% of exposure events
	exposure concentration with no long-term effects on plankton filter feeder species (10 µg L ⁻¹)	effects endpoint is exceeded for 29% of exposure events
	5 th percentile of pulsed-exposure LC50 of high-current habitat species (28 µg L ⁻¹)	effects endpoint is exceeded for 6% of exposure events
90 th percentile PEC _{sw} in agricultural ditch arising from drift, for 10 m no-spray buffer zone (21 µg L ⁻¹)	probabilistic distribution of LC50 of all aquatic invertebrate species	exposure exceeds standard LC50 of 36% of all invertebrate species
	probabilistic distribution of LC50 of plankton filter feeder species	exposure exceeds LC50 of 99% of plankton filter feeder species
	probabilistic distribution of pulsed-exposure LC50 of high-current habitat species	exposure exceeds pulsed-exposure LC50 of 3% of high-current habitat species
probabilistic distribution of PEC _{sw} in agricultural ditch arising from drift, for 10 m no-spray buffer zone	probabilistic distribution of LC50 of all aquatic invertebrate species	29% probability that 24% of all aquatic invertebrate species are affected
	probabilistic distribution of LC50 of plankton filter feeder species	29% probability that 54% of plankton filter feeder species are affected
	probabilistic distribution of pulsed-exposure LC50 of high-current habitat species	5% probability that 6% of high-current habitat species are affected

Description of the issue

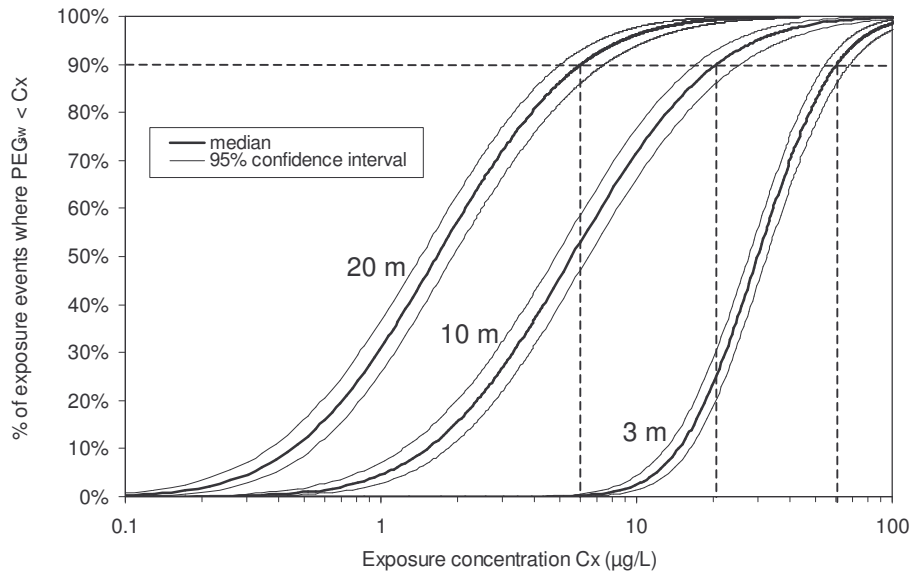
The carbamate insecticide Carbaryl has a worst case use pattern in orchards, with a single application rate of 1290 g a.i. ha⁻¹. The most sensitive non-target species for Carbaryl are aquatic invertebrates. Because of its rapid dissipation in soil and water, there is (1) no relevant exposure of aquatic systems via run-off or drainflow, (2) only short-term exposure in aquatic systems, and (3) no accumulation of residues between multiple applications. Consequently, spray drift is the only relevant route of aquatic exposure.

This probabilistic risk assessment refers to effects of Carbaryl on invertebrate species in agricultural ditches adjacent to orchards, from short-term exposure via spray drift.

Probabilistic exposure assessment

Log-normal distributions were fitted to the Ganzelmeier spray drift data and were transformed into probabilistic distributions of instantaneous Carbaryl concentrations in agricultural ditches. Data for different drift distances were evaluated separately. The distributions of concentrations account for the variability of individual spray events; the uncertainty of the curve-fitting was expressed by 95% confidence intervals around the median distributions (Figure 1).

Figure 1: Distributions of exposure concentrations (with 95% confidence intervals of the curve fit) for drift distances of 3 m, 10 m and 20 m. The realistic worst case of deterministic risk assessments, the 90th percentile of each distribution, is also indicated.



Probabilistic effects assessment

The effects of Carbaryl were quantified by laboratory standard acute LC₅₀ values for 34 aquatic invertebrate species (1.7 to 3700 µg L⁻¹). Log-normal Species Sensitivity Distributions (SSD's) were fitted to the full set of LC₅₀ values, as well as to the following ecologically defined sub-sets: Species from high-current habitats (e.g. streams with high flow), species from medium-current habitats (e.g. ditches with moderate flow), species from calm-water habitats (e.g. ponds with no flow) and species that are plankton filter feeders (e.g. Daphnids).

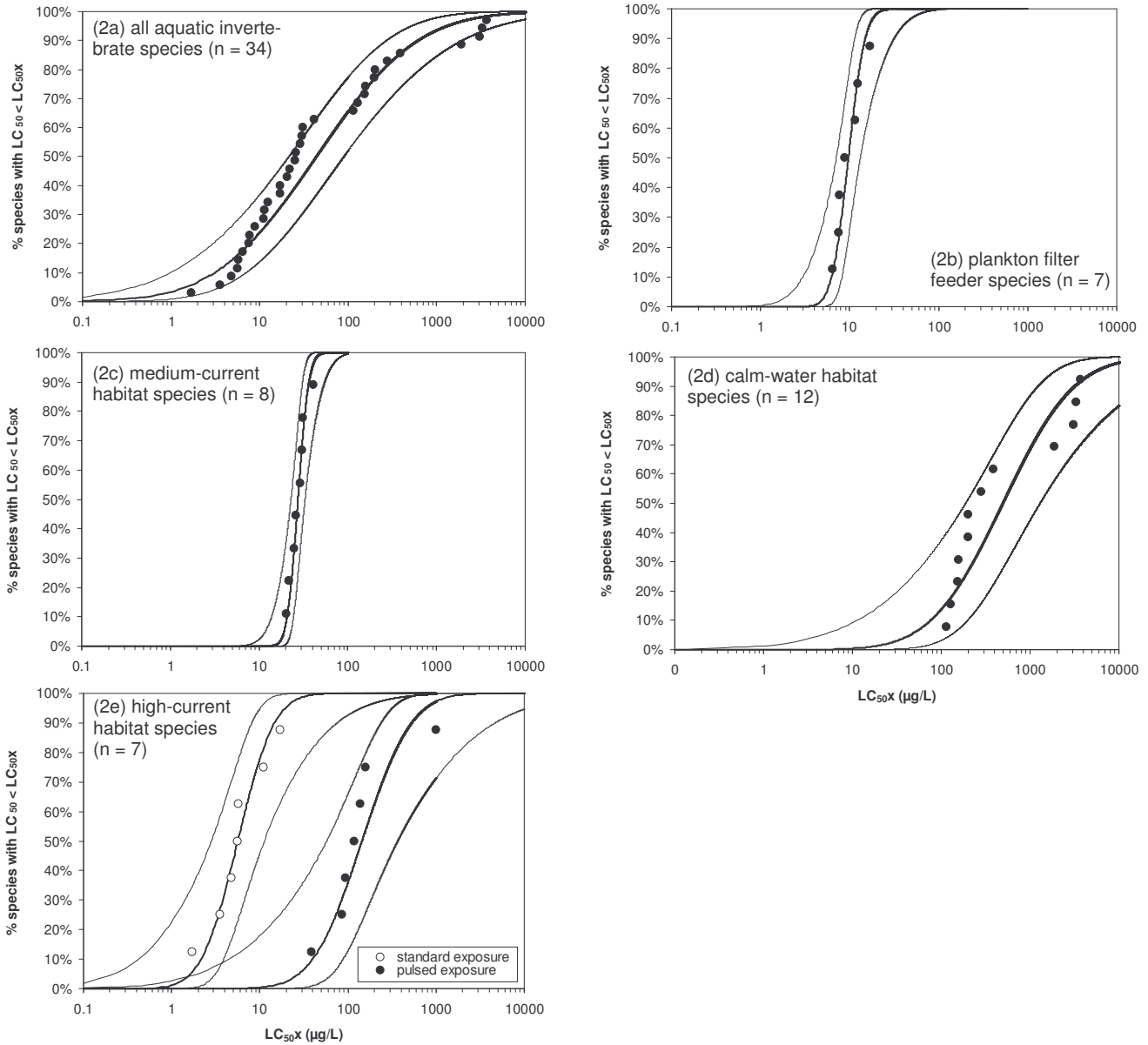
This split of the effect data is based on the assumption that the sensitivity to Carbaryl mainly depends on the absorption of Carbaryl by organisms which in turn is a function of the rate of water exchange at their biological membranes. Therefore, a higher sensitivity is expected for species from fast flowing habitats and species with a high throughput of water (such as plankton filter feeders).

The SSD's are presented in Figure 2. For all aquatic invertebrate species, the SSD consists of several distinct clusters and has a large variability of LC₅₀ values (Figure 2a). The SSD's of the ecologically defined groups (Figures 2b-e) consistently have a much smaller variability (with the exception of four calm-water species with very low sensitivity). This supports the validity of the approach to conduct separate risk assessments for ecologically defined species groups.

The split approach allows to conduct habitat-specific risk assessments, and in particular to consider that in high-current habitats the exposure from drift is highly transient. Laboratory studies with three high-current habitat species showed that the LC₅₀ for pulsed exposure exceeds the standard LC₅₀ by an average factor of 33 (+/- 29). The standard LC₅₀ of four other high-current habitat species were extrapolated to an LC₅₀ under pulse exposure conditions with that average factor; these data were used for the further risk assessment (see Figure 2e).

CASE STUDY 1: Carbaryl Aquatic risk Assessment

Figure 2: SSD's of LC₅₀ values (with the measured values and 95% confidence intervals of the curve fit) for all tested species and for ecologically defined species groups. For high-current habitat species the SSD's of standard LC₅₀ values and pulse exposure LC₅₀ values (partly extrapolated) are shown.



Probabilistic risk assessment with fixed effect concentration

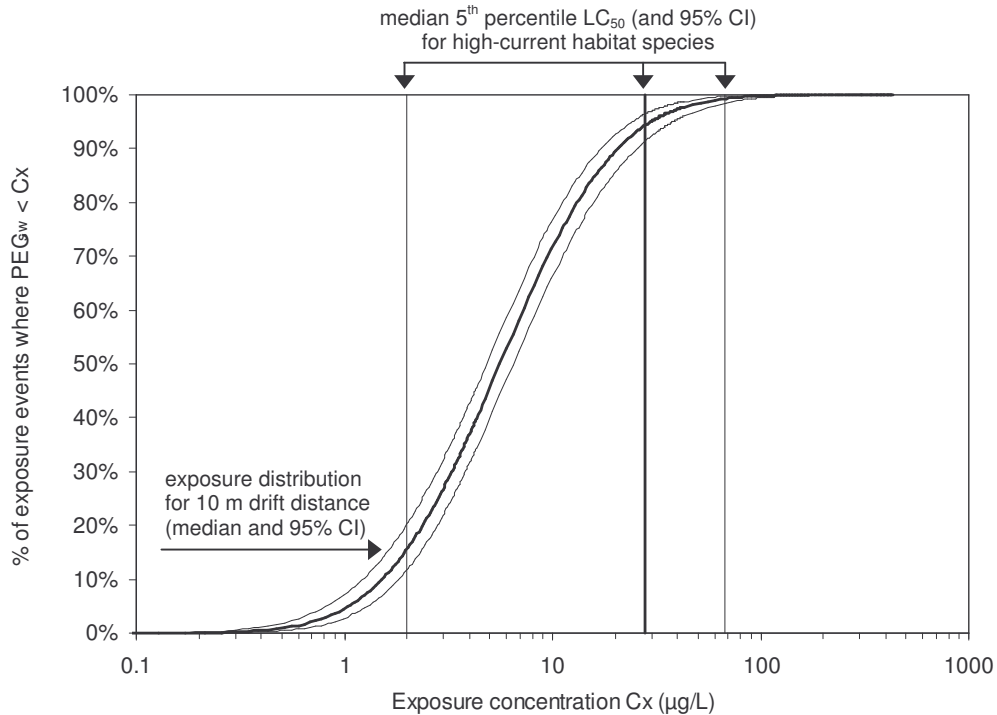
The distributions of exposure concentrations were compared to selected concentration levels at which effects were considered acceptable. Generally, that acceptable concentration was set to the 5th percentile LC₅₀ (the HC₅ value; see Table 1). For plankton filter feeder species, data from two microcosm studies indicated full recovery from short-term effects at initial exposure concentrations of 10 µg/L; that concentration was considered acceptable for plankton filter feeders.

Table 1: Median 5th percentile LC₅₀ values (HC₅ values, with 95% confidence intervals) for all tested species and for the ecologically defined species groups (see also Figure 2).

all aquatic invertebrate species	high-current habitat spp. (pulsed exposure)	medium-current habitat spp.	calm-water habitat spp.
1.5 (0.4 - 3.7) µg/L	28 (2 - 67) µg/L	19 (12 - 23) µg/L	45 (5 - 128) µg/L

CASE STUDY 1: Carbaryl Aquatic risk Assessment

Figure 3: Comparison of the probabilistic exposure distribution for 10 m drift distance and the 5th percentile LC₅₀ value, for the high-current habitat species. For both exposure and effects the median and the 95% confidence interval are given.



The ecological acceptability of the selected concentrations is supported by field data for a small river, where there were no observable effects on aquatic invertebrates from a peak concentration of 12.6 µg/L.

For the example in Figure 3 (10 m drift distance, high-current habitat species), the result of the probabilistic risk assessment can be expressed as follows:

With a 10 m buffer zone in place, 5.7% (95% CI: 3.6% to 8.6%) of all exposure events (spray drift of Carbaryl to a high-current agricultural ditch adjacent to an orchard) cause exposure concentrations that affect 5% of all species in that habitat.

Probabilistic risk assessment with fixed exposure concentration

The distributions of effect concentrations were compared to a selected exposure concentration. That exposure concentration was set to the 90th percentile of the exposure distribution (for each distance; Table 2), which was assumed to describe a realistic worst case exposure situation.

For the example in Figure 4 (10 m drift distance, high-current habitat species), the result of the probabilistic risk assessment can be expressed as follows:

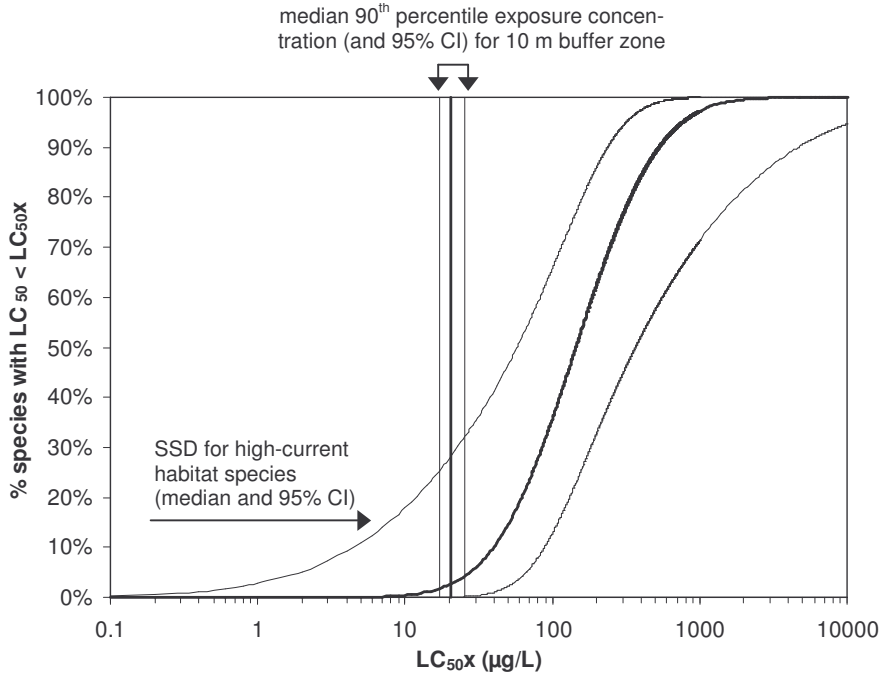
With a 10 m buffer zone in place, 2.8% (95% CI: < 0.1% to 28.6%) of all species are affected by exposure events (spray drift of Carbaryl to a high-current agricultural ditch adjacent to an orchard) that have a 10% probability of occurrence.

Table 2: Median 90th percentile exposure concentration for different drift distances (with 95% confidence intervals; see also Figure 1)

3 m distance	10 m distance	20 m distance
61 (55 - 68) µg/L	21 (17 - 25) µg/L	6.1 (5.1 - 7.5) µg/L

CASE STUDY 1: Carbaryl Aquatic risk Assessment

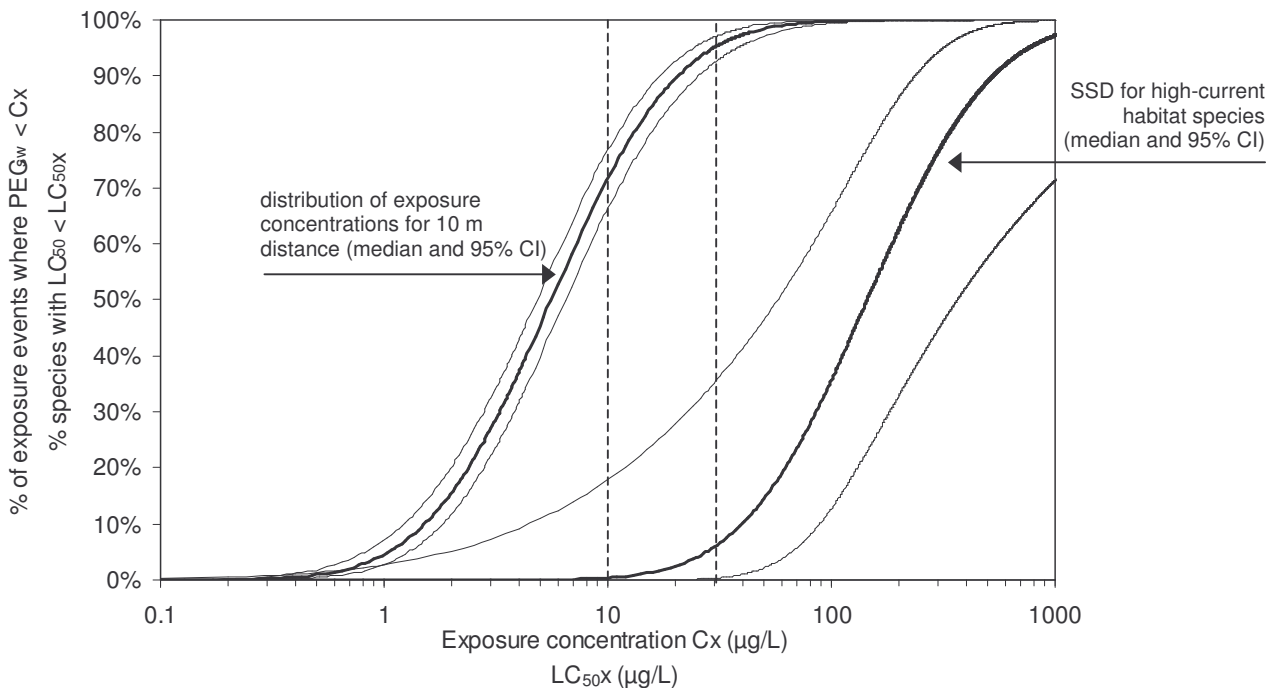
Figure 4: Comparison of the probabilistic effect distribution for high-current habitat species and the 90th percentile exposure concentration for a 10 m buffer zone. For both exposure and effects the median and the 95% confidence interval are given.



Probabilistic risk assessment with distributions of exposure and effects

The distributions of effect concentrations were compared to the distributions of exposure concentrations (for each distance). As an example, Figure 5 combines the SSD for the high-current habitat species and the distribution of exposure concentrations for 10 m distance.

Figure 5: Comparison of the probabilistic effect distribution for high-current habitat species and the probabilistic exposure distribution for a 10 m buffer zone. For both exposure and effects the median and the 95% confidence interval are given. The examples in the text are based on the indicated concentration levels of 10 µg L⁻¹ and 30 µg L⁻¹.



CASE STUDY 1: Carbaryl Aquatic risk Assessment

For the example in Figure 5 (10 m drift distance, high-current habitat species; evaluation for concentration levels of $10 \mu\text{g L}^{-1}$ and $30 \mu\text{g L}^{-1}$), results from the probabilistic risk assessment can be expressed as follows:

With a 10 m buffer zone in place, there is a 4.9% probability (95% CI: 3.0% to 7.6%) that 5.9% (95% CI: < 0.1% to 35%) or more of all species will be affected by an exposure event with spray drift of Carbaryl to a high-current agricultural ditch adjacent to a treated orchard.

With a 10 m buffer zone in place, there is a 28% probability (95% CI: 23% to 34%) that 0.4% (95% CI: < 0.1% to 18%) or more of all species will be affected by an exposure event with spray drift of Carbaryl to a high-current agricultural ditch adjacent to a treated orchard.

Uncertainties not considered within the analyses

Several possible sources of variability and uncertainty in exposure and effects are not included in the assessment. Some of these, which could be significant, are listed below.

Factors which are likely to increase the estimated risk are (1) uncertainties in the vertical distribution of pesticide in the water column, (2) uncertainties in extrapolating effects from individual species to a population, (3) uncertainties in extrapolating effects from standard to pulsed exposure, and (4) uncertainties arising from the definition of the ecological species groups.

Factors which are likely to decrease the estimated risk are (1) the variability in exposure due to variable drift deposition across the water surface, (2) the variability of exposure due to variable wind direction, (3) uncertainty and variability with regard to interception by riparian vegetation, and (4) uncertainty and variability with regard to the actual application rate.

Overall, the estimated risk is expected to decrease and the assessment to be conservative.

CASE STUDY 3: RISK TO AQUATIC ORGANISMS ARISING FROM EXPOSURE TO ‘HERBURON’ VIA SPRAY DRIFT

Colin Brown (University of York and Central Science Laboratory), Sabine Beulke (Central Science Laboratory), Paul van den Brink (Alterra)

This study assesses the risk to aquatic macrophytes arising from exposure via spray drift to the hypothetical herbicide ‘herburon’. Initial deterministic modelling shows that spray drift is the primary route of exposure for aquatic habitats under UK conditions. A probabilistic estimate of exposure is produced for a natural agricultural landscape that accounts for the uncertainty and variability in landscape features and spray drift deposition. Exposure distributions are compared with probabilistic expressions of effects on macrophytes at the species and community level. Results are summarised below:

Expression of exposure	Expression of effects	Key results of the risk assessment
Maximum PEC _{SW} from deterministic FOCUS Step 4 modelling including a 5-m no-spray buffer	Smallest ecotoxicity endpoint for standard test species (120-hr EC50 for <i>Lemna gibba</i> = 7 µg L ⁻¹)	Smallest TER < 10 in all six scenarios simulated ^a
Probabilistic distribution of instantaneous concentrations in ditch arising from drift accounting for variability and uncertainty in landscape features and pesticide deposition. Distribution calculated with and without a 5-m no-spray buffer (results in this table are for exposure with the buffer)	Smallest ecotoxicity endpoint (120-hr EC50 for <i>Lemna gibba</i> = 7 µg L ⁻¹)	TER < 10 in 68% of the exposure events considered (95% uncertainty interval 47-75%)
	Probabilistic expression accounting for uncertainty in generating species sensitivity distributions from small number of species (9 aquatic macrophytes); median HC5 = 7 µg L ⁻¹ ; 95% uncertainty interval = 4.1-11.1 µg L ⁻¹)	Median HC5 exceeded in 3.8% of the exposure events considered (95% uncertainty interval 0.8-7.7%) > 5% of species affected in 4.6% of the exposure events considered (95% uncertainty interval 0.2-13.4%)
	Lowest mesocosm NOEC for effects on community metabolism (5 µg L ⁻¹)	NOEC for clear effects exceeded in 7.6% of exposure events (95% uncertainty interval 2.5-13.2%)
	Lowest mesocosm NOEC for effects on community metabolism with no recovery within 8 weeks (15 µg L ⁻¹)	NOEC for clear effects with no recovery within 8 weeks exceeded in 0.2% of exposure events (95% uncertainty interval 0-0.7%)

^a The smaller TER value was taken where two water bodies were associated with a scenario

Description of the issue

‘Herburon’ is a urea herbicide which is proposed for use as an SC formulation (500 g a.i. L⁻¹) on a wide range of crops including cereals and vegetables. The worst-case GAP involves a single pre-emergence application to winter oilseed rape at 1500 g a.i. ha⁻¹. Initial deterministic modelling shows that spray drift is the primary route of exposure for aquatic habitats under UK conditions.

Probabilistic exposure calculation

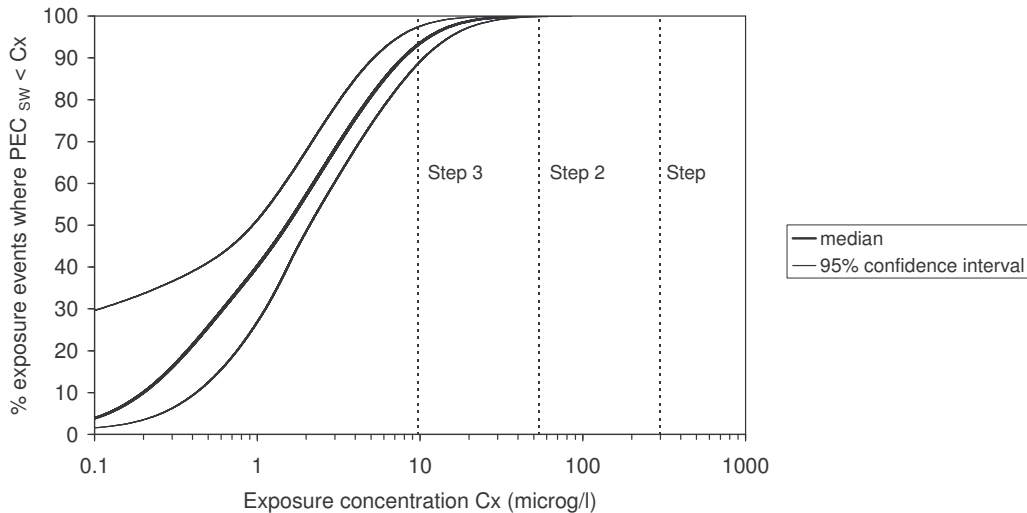
A probabilistic exposure assessment is undertaken for the Coleshill catchment in Oxfordshire, UK that is the area immediately surrounding the location of the FOCUS SW D2 weather station. A distribution of instantaneous concentrations of herburon in agricultural ditches arising from spray drift is calculated accounting for variability in individual spray events, the morphology of individual ditches and the bankside vegetation associated with these ditches. Uncertainty in the calculation

CASE STUDY 3: Risk to aquatic organisms from 'HERBURON'

arising from sampling uncertainty in drift experiments, the interception of spray drift by a certain type of bankside vegetation and the pesticide application rate is expressed using 95% uncertainty intervals around the median distribution of exposure concentrations. These are derived within a 2-D Monte Carlo framework.

The analysis suggests that the concentration predicted for the D2 scenario at Step 3 corresponds to the 93.2 percentile exposure concentration (95% uncertainty interval 88.7-97.4%) for winter oilseed rape fields in the Coleshill catchment assuming that every field is treated and has ditches adjacent.

Comparison of deterministic and probabilistic versions of the exposure assessment



Species-level risk assessment (standard test species and a species sensitivity distribution)

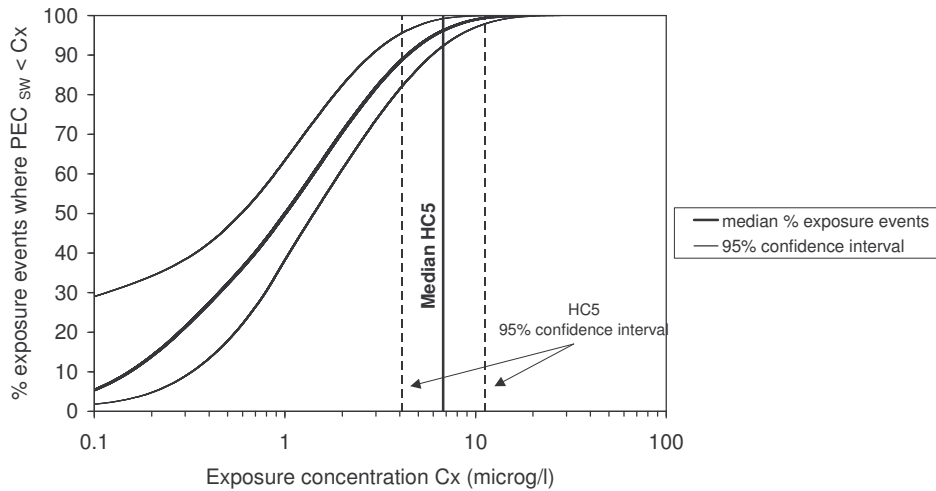
The exposure distribution is compared with a fixed endpoint for a single macrophyte test species ($7 \mu\text{g L}^{-1}$, 120-hr EC50 value for *Lemna gibba*) or probabilistic expressions of effects on macrophytes at the species and community level. 120-hr EC50 values for herburon are available for nine higher aquatic plant species. A species sensitivity distribution (SSD) is generated assuming a normal distribution. A probabilistic expression of effects is then calculated accounting for the uncertainty in generating species sensitivity distributions from a small number of measurements.

The analysis indicates that growth of more than 5% of the macrophyte species will be affected in 4.6% of the exposure events (95% uncertainty interval 0.2-13.4%).

The assessment is based on 120-hr laboratory EC50 values. The assessment ensemble is winter oilseed rape fields in the Coleshill catchment assuming that every field is treated, has a ditch adjacent and that a 5-m no-spray buffer is imposed.

CASE STUDY 3: Risk to aquatic organisms from 'HERBURON'

Comparison between the cumulative distribution of PEC_{SW} values and the HC5 derived from a species sensitivity distribution (the chart includes 95% uncertainty intervals for estimates of exposure and effects)



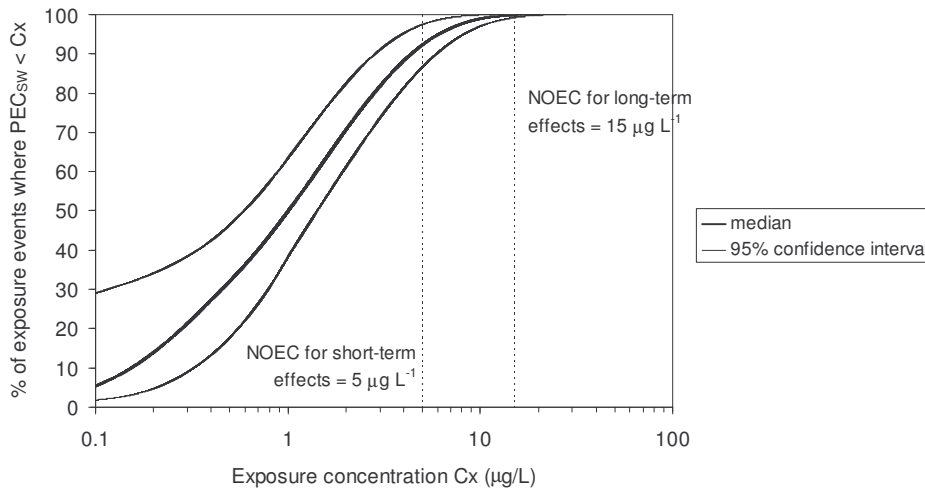
Community-level risk assessment (NOEC from a mesocosm experiment and predictions with PERPEST)

The assessment endpoint at the community level is prevention of unacceptable effects on communities of aquatic organisms. The probabilistic expression of exposure is compared with NOEC values from two replicate outdoor mesocosm experiments with herburon (lowest NOEC for clear effects on community metabolism = 5 µg L⁻¹; lowest NOEC for clear effects on community metabolism with no recovery within 8 weeks = 15 µg L⁻¹).

The analysis indicates that the instantaneous concentration of herburon in a ditch will exceed the NOEC for effects on community metabolism in outdoor mesocosm experiments (5 µg L⁻¹) in 7.6% of the exposure events (95% uncertainty interval 2.5-13.2%). The lowest NOEC for clear effects with no recovery within 8 weeks (15 µg L⁻¹) will be exceeded in 0.2% of the exposure events (95% uncertainty interval 0.2-0.7%).

The assessment ensemble is winter oilseed rape fields in the Coleshill catchment assuming that every field is treated, has a ditch adjacent and that a 5-m no-spray buffer is imposed.

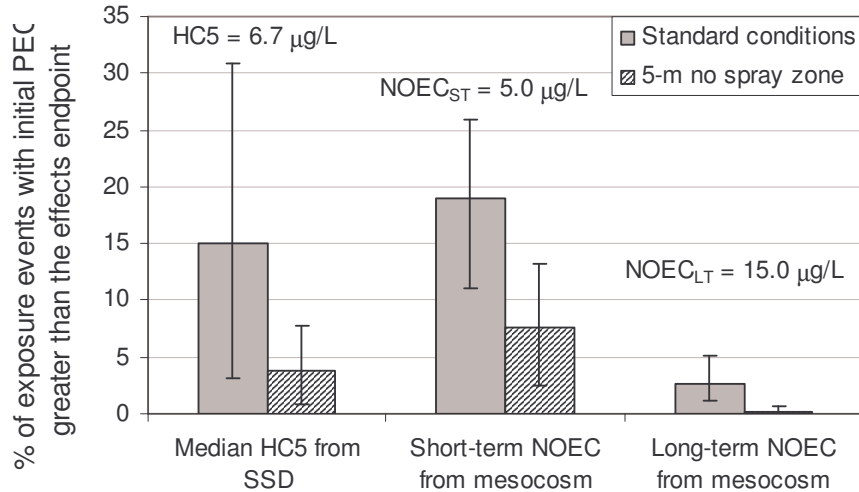
Comparison between the cumulative distribution of PEC_{SW} values and endpoints from an outdoor mesocosm experiment (the chart includes 95% uncertainty intervals for estimates of exposure and effects)



CASE STUDY 3: Risk to aquatic organisms from 'HERBURON'

The chart below shows the frequency with which the initial PEC is predicted to exceed the different effects endpoints. Results are shown for exposure calculated either with or without a 5-m no-spray buffer.

Overall frequency that exposure of ditches in the Coleshill catchment would result in clear effects on community metabolism in a mesocosm study (mean (bars) and 95% uncertainty interval)



Uncertainties not considered within the analyses

A number of possible sources of variability and uncertainty in exposure and effects were not included in the assessment. Factors which are likely to increase the estimated risk are (i) the variability in exposure concentrations arising from the variation of drift deposition across the water surface, (ii) uncertainties in the vertical distribution of pesticide in the water column, and (iii) uncertainties in extrapolating effects from individual macrophyte species to a population. Factors which are likely to decrease the estimated risk are (i) the deviation of drift deposition on a surface below ground level from measured deposition at the same level as the treated area, (ii) interception by riparian vegetation or aquatic plants, (iii) reduction in initial exposure concentration due to sorption to sediment or macrophytes. Overall, the estimated risk is expected to decrease and the assessment made in this study is conservative.

Case Study 4: Acute risks to skylarks arising from a summer cereal spray

January 2005

Willem Roelofs (CSL), Joe Crocker (CSL),
Andy Hart (CSL), Jim Siegmund (Cadmus)

This case study presents a probabilistic assessment of the acute risk to skylarks arising from exposure to a fictitious pesticide applied as a single spray to cereals in summer. Following current European regulatory practice, the risk was expressed as a toxicity-exposure ratio. Probability distributions were defined for the parameters that determine exposure and a species sensitivity distribution was adopted to model toxicity.. Whenever possible, the model accounts for inherent variability in the model parameters and for the sampling uncertainty that arises from estimating those parameters from small datasets. Probabilistic results were compared with current deterministic regulatory methods in the EU. We conclude that the uncertainty of TER estimates is relatively high, even when not all sources of uncertainty have been quantified.

Description of the issue

Birds feeding on arable feeds may be at risk from pesticides used there.. Therefore, we need to characterise this risk. Current regulatory practise is to estimate the potential risk for individual birds. Skylarks (*Alauda arvensis*), are omnivorous birds that feed their chicks on insects (Donald et al., 2001; Green, 1978; Poulsen et al., 1998) forage extensively and also breed in cereal fields in Britain. Skylarks are relatively small (and so have a high food intake to body mass ratio), and are likely to ingest pesticide-contaminated forage. They are therefore likely to be good specific (rather than generic) indicators for pesticide-related effects on birds in cereals systems, and so were used in the case study.

Deterministic Risk Assessment

Current first-tier assessment of the acute risks to birds and mammals from pesticides is based on calculation of a deterministic toxicity/exposure ratio (TER) for several predefined scenarios. These scenarios are based on indicator species, crop and crop stage at time of application of the pesticide and are used to determine acute, short-term and long-term exposure estimates which are compared to toxic endpoints. The endpoint that is used to estimate the TER in the first tier EU risk assessment is the lowest available toxicity value (LD50). The estimated daily uptake of the pesticide is estimated by:

$$\text{Equation 1} \quad ETE = \frac{FIR}{BW} \cdot C \cdot AV \cdot PT \cdot PD$$

Table 1: Parameters that can be used to estimate the theoretical exposure (ETE).

- FIR: Food intake rate of indicator species (gram fresh weight per day)
- BW: Body weight of indicator species (g)
- C: Concentration of compound in fresh diet (mg/kg)
- AV: Avoidance factor (1 = no avoidance, 0 = complete avoidance)
- PT: Fraction of diet obtained in treated area (number between 0 and 1)
- PD: Fraction of food type in diet (number between 0 and 1; one type or more types)

The first tier standard exposure scenarios are intended to be conservative in nature, using realistic worst case assumptions for the parameters but they only consider exposure through contaminated food. The first tier approach is deterministic: the input parameters (LD50, pesticide residues, food intake rate, dietary composition, etc.) are fixed point estimates and pesticide application occurs at fixed dates.

Table 2: Standard scenario for acute exposure estimate from the EU guidance document on Risk Assessment for Birds and Mammals (EC, 2002).

Parameter	Selected parameter for assessment
Toxicity	Lowest LD50
Crop	Cereals (Late)
Indicator Species	Insectivorous Birds
Category	Small Insects
RUD (90th percentile)	52
MAF	N/A (= 1)
FIR / BW	1.04
Number of applications	1
Percentage of food in diet	100%
Percentage of food from treated field	100%
Avoidance of treated food	No avoidance

Probabilistic Risk Assessment

In reality, the factors that determine exposure and toxicity vary between individuals and in time and this will likely have a major influence on the magnitude of the predicted risk.

Estimating Toxicity

For the probabilistic model of toxicity, a species sensitivity distribution approach was used, based on the work by Luttik and Aldenberg (1995). One of the main problems when conducting an avian risk assessment for a pesticide is the limited number of toxicity data that are available, often no more than two species' LD50s. The information provided by only two data points is very limited and the best fitting distribution is likely to have unmanageably wide confidence bounds. In consequence, information must be obtained from other sources. Luttik and Aldenberg (1995) suggest using an estimator of the variance derived from a historical database of toxicity data (this method is described in the EU Guidance Document as acceptable for use in refined assessments; EC, 2002 p. 23).

Another complication in avian risk assessments is that the position of the focal species in the species sensitivity distribution is unknown and thus uncertain as well. As a consequence, instead of the default Luttik & Aldenberg approach (which extrapolates the 5th percentile species), we account for the uncertainty of the skylark by sampling its relative position from the normal distribution.

The toxicity data that were available for our pesticide are presented in Table 3.

Table 3: Toxicity Data

Species	LD50 (mg/kg BW)
Japanese quail	30
Northern bobwhite	77
Mallard duck ^a	>2000

^aThe mallard duck LD50 was derived from a limit dose study.

Estimating Exposure

To estimate exposure, probability distributions were assigned to the parameters in Table 1. Ideally, the distributions for these parameters represent the variability between individual skylarks in a skylark population that may be observed under field conditions. The probabilistic method will estimate the highest pesticide intake on a day-by-day basis and the highest exposure in time was used to calculate TERs.

Estimating Risk

To separate the uncertainty of the parameter distributions from the variability between individual skylarks in a population, a 2D Monte Carlo method was used, the outer loop of the simulation representing uncertainty, with individual variability represented by the inner loop. For example, suppose we have limited data on food intake rate that suggests it is normally distributed with mean x and standard deviation s . However, because the mean and standard deviation are taken from a sample, they represent *estimates* of the true mean and standard deviation, about which we are uncertain. We can quantify this uncertainty taking values for the mean and standard deviation from their uncertainty distributions. Having picked a value for mean and standard deviation in the outer loop, the model then proceeds to generate values from (in this case) a normal distribution to represent the individual variability in food intake rate.

Results

Deterministic

The realistic worst case deterministic TER, calculated using the insectivorous small bird scenario resulted in a TER of 1.6, indicating reason for concern as the value is lower than ten.

Probabilistic

Table 4 shows pre-defined percentiles and their uncertainty intervals. The median skylark, has a TER of 38.9 with a 95% uncertainty interval ranging from 3.5 (the 2.5th uncertainty limit) to 546.7 (the 97.5th uncertainty limit). The worst-case 90th percentile skylark (90% of the skylarks have a TER higher than this individual) has a TER of 10 with a 95% uncertainty interval ranging from 0.9 to 123. The TER of the 90th percentile skylark equals the threshold value of current EU regulatory practice, which means that 10% of the skylarks are exposed above the EU threshold value. In addition, the uncertainty of the 90th percentile is skylark is quite high, so the fraction of the skylark population that is exposed above the threshold level may be higher than 10%.

Table 4: Uncertainty limits of selected TER percentiles for three model runs.

	Uncertainty Limit									
	0.5	2.5	5	25	50	75	95	97.5	99.5	
50	1.9	3.5	4.7	16.6	38.9	92.0	333.7	546.7	1284.3	
90	0.5	0.9	1.3	4.4	10.1	23.2	76.8	123.3	287.7	
95	0.4	0.7	1.0	3.3	7.5	17.2	56.3	88.9	224.0	
99	0.2	0.4	0.6	1.9	4.5	10.0	33.6	51.5	133.0	

The model returns another statistic to estimate what fraction of species has a TER lower than a predefined threshold (Table 5). In this table, the percentage of individuals that have a TER lower than the a given TER limit is shown, together with uncertainty bounds. The median estimate of the percentage of species with TERs less than the current EU threshold value (10) is 10% but it may be as few as 0% or as many as 66%.

Table 5: Probability that the TER is smaller than a selected value, $P(\text{TER} < X)$, with uncertainty limits. The median (e.g. 50th percentile) probability that the TER is smaller than 100 is 62% with a 95% uncertainty interval ranging from 6.6% to 79%.

		Uncertainty Limit								
	TER < X	0.5	2.5	5	25	50	75	95	97.5	99.5
X	1	0.0	0.0	0.0	0.0	0.0	0.1	5.6	13.0	32.2
	5	0.0	0.0	0.0	0.1	1.5	12.9	51.1	57.7	66.9
	10	0.0	0.0	0.0	1.1	9.8	35.3	62.2	66.3	72.9
	100	0.5	6.6	17.7	51.6	62.0	68.4	76.6	79.0	83.0

Limitations

A summary of limitations and their potential influence on the assessment outcome is presented in Table 6. Overall, we conclude that some assumptions may lead to an overestimation of risk, but the majority are more likely to under-estimate it.

Table 6: Overview of uncertainties that were not quantified and indications of the effect on the outcome of the assessment

Uncertainty	Uncertainty Type	Expected effect on result	
		Magnitude of uncertainty	Direction
Other routes of exposure	Omission	Large	Underestimation of risk (but normally not considered in EU risk assessments)
All parameters	Measurement errors	May be significant for some parameters, e.g. toxicity and DEE	Either way
PT _{time} to PT _{diet}	Extrapolation	Small	Either way
Dietary Fraction	Extrapolation (use of long-term population variance for short-term individual variance)	Large	Underestimation of risk
Concentrations	Extrapolation of RUD and DT50 from other pesticides	May be considerable	Either way
Concentrations	Extrapolation of RUD from plants to insects	May be considerable	EU guidance may over-estimate risk
Representativeness of standard species used in toxicity tests	Extrapolation	Needs evaluation.	Either way
Representativeness of data on PT	Extrapolation	Moderate (data from relatively few sites).	Either way.
Avoidance	Omission	Assumed no avoidance for this fictional pesticide	Overestimation of risk-
Distribution fit	Statistical	Small	Either way
Dependencies between concentrations on different food types (probably positive)	Omission	Could be substantial	Underestimate variance of exposure and hence frequency of low TERs.

Implications for decision-making

The EU regulatory decision criterion for acute avian risk from pesticides is that the TER should exceed 10. In other words, birds should consume no more than 1/10 of an LD50 of pesticide per day. A threshold TER value of ten is presumably intended as a safety margin, allowing for uncertainties in the risk calculation. In the model described above, uncertainties are explicitly included in the risk calculation and it would therefore be appropriate to compare these results with a TER of 1, *unless* the decision-maker wants to reserve some margin of safety to allow for other sources of uncertainty not included in the model.

As stated earlier, Figures 2 and 3 estimate that the percentage of skylarks with TER<1 will be 0%, with a 95% uncertainty interval of 0 - 13%. This result has to be considered together with the limitations of the analysis (Table 6), which suggest that the assessment may underestimate the true level of risk. If the decision-maker felt uncomfortable about these limitations it may be possible to modify the assessment to take account of them. If the decision-maker felt uncomfortable about the upper end of the uncertainty interval (13%) then consideration could be given to obtaining more data to reduce the uncertainty.

An essential part of a real assessment would be consideration of other lines of evidence including field data that cannot be directly incorporated into model, but as this is a fictional pesticide such data are lacking. Any such discussion would need to evaluate the other lines of evidence critically and consider any associated uncertainties, just as for the probabilistic assessment. (For example, very few avian mortalities due to approved use of pesticides are detected in the UK, despite the existence of an official scheme for investigating reported incidents. However, consideration has to be given to the likelihood of detection, taking account of factors such as the small size and inconspicuous colouring of skylarks and the vegetative cover in their habitat.)

A full interpretation could also include some consideration of the possible consequences at population level. This would need to consider the likelihood of mortality due to pesticide, its magnitude relative to natural sources of mortality in the population, the current status and resilience of the population, and the decision-maker's protection goals (in the UK, a government target for reversing the decline in farmland birds). This evaluation would be easier if the assessment endpoints included distributions for mortality as well as TERs.

Finally, we note that the key results of the probabilistic assessment can be summarised in very simple terms, e.g. the median estimate for the percentage of skylarks with TER<1 is 0%, with an upper 95% uncertainty bound of 13%

CASE STUDY 5: RISK ASSESSMENT FOR AN ORGANOPHOSPHATE INSECTICIDE UNDER MEDITERRANEAN CONDITIONS

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This case study presents the risk of an organophosphate insecticide to aquatic organisms under Mediterranean conditions. The deterministic approach based on the EU uniform principles using the generic scenario showed a potential risk for aquatic invertebrates for spray drift exposure. Therefore, a probabilistic approach for drift is included. But Mediterranean area is susceptible for run-off and soil erosion due to its climate, topography and soil characteristics. Drift was compared with two additional approaches based on river-basin exposure models, considering Mediterranean conditions. The effect assessment is also refined using the species sensitivity distribution approach.

Results are summarised below:

Edge of field scenario

Expression of Exposure	Expression of Effects	Key results of the risk assessment
Maximum PEC _{sw} from EU standard drift scenario 3-m and 50-m no-spray zones	Lowest ecotoxicity value for invertebrates (48h-EC ₅₀ <i>Daphnia magna</i> = 0.014 µg ai/l)	TER values lower than 100 for both buffer zones.
Probabilistic approach for drift exposure accounting variability and uncertainty in pesticide deposition	SSD for acute toxicity data (from 24 to 96 hours exposure studies) of aquatic invertebrates	95 th percentile of TER worst case value (95 th for exposure and 5 th for effects) = 0.54. TER values lower than 1 indicating that effects on sensitive species cannot be disregarded.

Local river-basin scenario

Expression of Exposure	Expression of Effects	Key results of the risk assessment
Probabilistic approach considering total losses (combination of drainage, runoff and soil erosion)	SSD for acute toxicity data (from 24 to 96 hours exposure studies) of aquatic invertebrates	90 th percentile of worst case TER (95 th for exposure and 5 th for effects) = 0.01 The results indicate a very high probability for effects on sensitive species.

Regional river-basin scenario

Expression of Exposure	Expression of Effects	Key results of the risk assessment
Probabilistic approach based on soil erosion as relevant exposure route	SSD for acute toxicity data (from 24 to 96 hours exposure studies) of aquatic invertebrates	90 th percentile of worst case TER (95 th for exposure and 5 th for effects) = 1561 The likelihood for concentrations exceeding the 5% percentile of the SSD distribution is very low suggesting that the likelihood for effects on the ecosystems of receiving bodies is also very low.

Description of the issue

The organophosphate insecticide is frequently used on different crops. This case study covers the risk assessment for the use on olive groves, at a single application rate of 960 g ai/ha. Spray drift, drainage, soil erosion and run-off will be considered as relevant exposure routes for aquatic habitats. Three different exposure scenarios will be considered: edge of field scenario, local river-basin scenario and regional river-basin scenario.

Edge of field scenario

Probabilistic exposure calculations

The distribution of the Predicted Environmental Concentrations in surface water (PEC_{sw}) was determined from the standard scenario for spray drift at a single application rate of 960 g ai/ha, with a buffer zone of 50 meters. A 2-D Monte Carlo analysis using Crystal Ball software was carried out.

Drift raw data were fitted to a normal distribution. The mean value of 0.18 was selected while the uncertainty in the value representing the standard deviation of the normal distribution was accounted using a uniform distribution covering the 95% confidence interval obtained for this parameter (from 0.06 to 0.07).

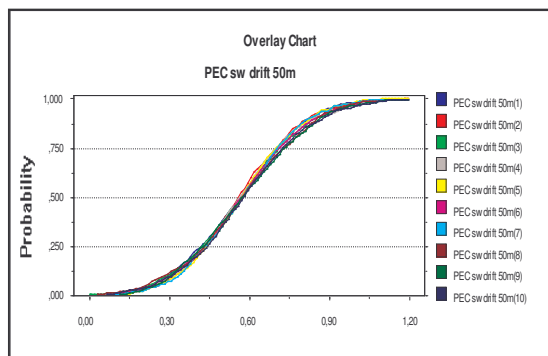


Figure 1. Predicted concentration of the organophosphate insecticide in surface water based on a spray drift at 50 meters (2-D Monte Carlo simulation)

The probabilistic approach for exposure indicates that the 50th percentile exposure concentration for a spray drift buffer zone of 50 meters is 0.57 µg/l.

Species Sensitivity distribution

The Species Sensitivity Distribution of the acute toxicity data for 85 aquatic invertebrates from standard laboratory studies was estimated. Toxicity data were fixed to a normal distribution using the log-transformed data. The mean value of 0.62 was selected while the standard deviation was presented as a uniform distribution from 0.74 to 1.01 (corresponding to the 95% confidence interval). A 2-D Monte Carlo analysis was carried out.

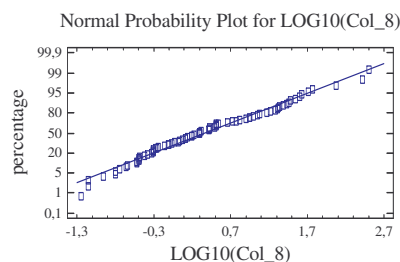


Figure 2. SSD for acute toxicity data on aquatic invertebrates (Raw data comes from Crane et al (2003) with some modifications).

Probabilistic Risk Assessment

The results of the 2-D Monte Carlo analysis for exposure (distributions of the 95th percentile for drift) and SSD-based effects (5th percentile) were combined in order to obtain a Toxicity Exposure Ratio. Results are showed in the following table:

Percentiles	TER drift
0.0%	0.27
2.5%	0.30
5.0%	0.32
50.0%	0.42
95.0%	0.54
97.5%	0.56
100.0%	0.62

All TER values are lower than 1 indicating that effects on sensitive species cannot be disregarded

Local river-basin scenario

Probabilistic exposure calculations

The scenario predicts the concentration provoked by the first rainfall event occurred after the pesticide application and assumes two different variables based on Monte Carlo analysis. The first variable is the time between the application and the rainfall event. It considers that a rainfall event may occur with the same probability during a period of time of seven days from the pesticide application and estimates the remaining amount of pesticide at the time of the rainfall event considering the persistence of the insecticide in soil.

The second variable is the magnitude of this rainfall event. A direct relationship between the magnitude of the event and the increase in river flow was assumed. Real data on daily river flow changes for the Ebro river system were used. A 2-D Monte-Carlo analysis was carried out. Period of time between pesticide application and rainfall event, number of rainfall events per year, precipitation and soil degradation of the insecticide are considered in this estimation as

variability; daily river flow changes were considered as uncertainty in this probabilistic approach.

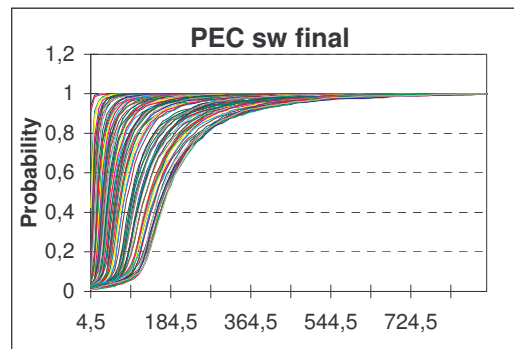


Figure 3. Predicted concentration of the organophosphate insecticide in surface water based on a local river basin scenario (2-D Monte Carlo simulation)

Species Sensitivity distribution

The SSD is the same described above (edge of field scenario).

Probabilistic Risk Assessment

The results of the 2-D Monte Carlo analysis for exposure (distributions of the 95th percentile for drift) and SSD-based effects (5th percentile) were combined in order to obtain a Toxicity Exposure Ratio. Results are showed in the following table:

Percentiles	TER worst case
0%	0.00
10%	0.00
20%	0.00
30%	0.00
40%	0.00
50%	0.00
60%	0.00
70%	0.00
80%	0.00
90%	0.01
100%	6.09

The results indicate a very high probability for getting TERs well below 1, suggesting a clear risk.

Regional river-basin scenario

Probabilistic exposure calculations

Due to the high Koc of the pesticide, soil erosion was considered the main exposure route at the regional level. In this case, the method is based on real data of soil losses from crop and non-crop areas, obtained through the

combination of digitalized landscape use and soil losses maps. For the Monte Carlo analysis it is assumed that the ratio of contaminated/uncontaminated soil reaching the water body is similar to the ratio of soil losses

CASE STUDY 5: Risk assessment under Mediterranean conditions

from treated/non-treated areas. The final concentration of the organophosphate insecticide in the water body is estimated from the amount of suspended matter and the concentration of insecticide in the eroded soil.

A 2-D Monte-Carlo analysis was carried out. Soil degradation of the pesticide, period of time between pesticide application and first rainfall event and rate of erosion was considered as variability; load of suspended matter was considered as uncertainty in this approach.

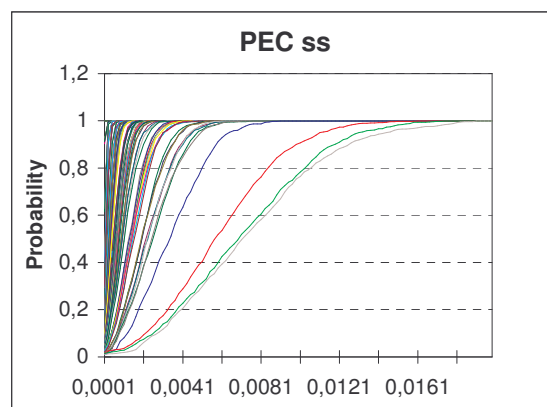


Figure 4. Predicted concentration of the organophosphate insecticide in surface water based on a regional river basin scenario (2-D Monte Carlo simulation)

Species Sensitivity distribution

Micro and mesocosms data indicate that the toxicity of the insecticide applied as soil slurry is similar to that obtained for spray applications. Thus, the hypothesized reduction in bioavailability associated to soil-bound particles is not observed, at least for this insecticide, and therefore, the waterborne toxicity tests can be used for this assessment. The SSD is the same described above (edge of field scenario).

Probabilistic Risk Assessment

The results of the 2-D Monte Carlo analysis for exposure (distributions of the 95th percentile for drift) and SSD-based effects (5th percentile) were combined in order to obtain a Toxicity Exposure Ratio. Results are showed in the following table:

Percentiles	TER worst case
0%	9.80
10%	88.05
20%	152.69
30%	223.50
40%	285.80
50%	386.40
60%	512.88
70%	677.17
80%	968.00
90%	1560.85
100%	10313.83

These estimations indicate TERs well above 1. The likelihood for concentrations exceeding the 5% percentile of the SSD distribution is very low suggesting that the likelihood for effects on the ecosystems of receiving bodies is also very low. The concentration of suspended matter in the receiving body seems to be the most critical factor and it should be notice that concentrations much higher than those used in this assessment have been reported for some Mediterranean rivers.