



### What can you do when risk assessment goes wrong?

When a risk assessment cannot show that your product is safe it is important to have a refinement strategy. The refinements shown below have been selected from techniques used by Enviresearch. In many cases reanalysis of the data is all that is required.

#### Terrestrial vertebrates

The estimated theoretical expose (ETE) can be refined according to the guidance document Sanco/4145/2000.

##### Residue in food

The residue per unit dose (RUD) and time weighted averaging factor ( $f_{TWA}$ ) can be refined and the long-term exposure of herbivores reassessed if residue decline on vegetation data are available.

##### Avoidance

If data on avoidance are available, refinement of the avoidance factor (AV) can be made.

##### Diet

The proportion of the diet obtained in the treated area (PT) or the factor representing the different food types in the diet (PD) can be refined if adequate data are available, that latter can be obtained from the Pesticides Safety Directorate.

#### Terrestrial invertebrates

##### Bees

Restrictions to application timings in order to protect bees can be specified on the label. Higher tier toxicity studies may also be useful.

##### Non-target arthropods

Label restrictions can protect this group of organisms as can recommending the use of buffer zones. Higher tier toxicity testing may also be appropriate.

##### Earthworms

The no observed effect concentration (NOEC) can be converted from g/ha to mg/Kg for long-term risk assessment. The exposure assessment can also be refined by using models, considering interception and by using measured field concentrations. It may also be useful to consider using a lower application rate or restricting to greenhouse use.

#### Aquatic organisms

**Time weighted average:** Refinements to the Predicted Environmental Concentration of a compound in surface water ( $PEC_{sw}$ ) can be achieved by using time-weighted average  $PEC_{sw}$  in place of maximum values. This is only applicable if the criteria specified in sanco/3268/2001 are met.

**Drift:** If drift is a contributing factor then buffer distances can be adjusted. Knowledge of the application method (e.g. low drift nozzles) may also help arrive at more realistic  $PEC_{sw}$ .

**Drainflow:** Problems with drainflow can be addressed by reanalysis of the sorption and degradation data and recalculating the  $PEC_{sw}$ . If this is not appropriate then higher tier modelling such as FOCUS STEP 3 and probabilistic or geospatial techniques can be used.

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