

Pesticide Risk Mitigation Engine

Policy on Multiple Data Points

Goal: To ensure scientific credibility and robustness of evaluation tools.

Multiple data points for the same endpoint of concern are anticipated; these repeat endpoints may show a large degree of variability. For example, repeat toxicity testing in birds showed that half of the test results using full probit-designed studies were beyond a factor of two from the original test.

General policies:

1. Different types of data may be treated differently; e.g. toxicity data may be accepted from multiple sources in order to reflect inter-species variation whereas fate and chemistry data may be taken from a single trusted source.
2. a. When the decision has been made to accept data from several sources, the geometric mean will normally be used to settle any differences between duplicate values.

b. When the decision has been made to take data from a single source, preference will be given to data that have been vetted by a regulatory or equivalent body (e.g. 'CORE' EPA toxicity data or NRCS-selected fate and physico-chemical properties).
3. In assessing the toxicity of pesticides, use of a single indicator species will be avoided whenever possible to ensure that inter-species variation is incorporated as much as possible; this is widely acknowledged to be one of the largest sources of uncertainty in risk assessments.
4. When toxicity data are available for several species, we will use a species sensitivity distribution or a sampling strategy approximating a species sensitivity approach.
5. Where there are different accepted toxicity values for the same receptors (e.g. the availability of both acute and chronic toxicity 'Population Adjusted Doses' -- EPA's new version of Allowable Daily Intakes -- as well as information on oncogenic potential to assess human toxicity), indicators will be built to address this multiplicity of endpoints to the extent possible.
6. Toxicity endpoints with questionable validity will not be used. For example, serious questions on the validity of the five-day dietary test in birds have been raised (Mineau et al. 1994). These test results will not be used in our project.

7. “No-effect” levels are often reported and used for regulatory purposes despite abundant criticism (e.g. Chapman et al. 1996; Crane and Newman 2000). It has been suggested that a better approach would be to carry out a full regression of effect (e.g. egg hatchability) against dose and to look for a certain level of effect (e.g. a 10% deficit) across all studies. This is referred to as the ECx approach where EC stands for ‘effective concentration’ and x the chosen value – whether 5, 10, 50% or any other value. However, chronic toxicity test data (regardless of the species studied) are often not well suited to an ECx approach because of the multiplicity of possible endpoints (e.g. not only egg hatchability but also chick weight and survival are measured in the same study), the difficulty in integrating all of these endpoints into a single metric and the difficulty of arranging the dose levels so that they ‘bracket’ either all possible endpoints or that integrative one. Therefore, we will continue to use No-Effect levels where these remain the ‘industry standard’.

Literature cited

- Chapman, P.M., Caldwell, R.S., Chapman, P.F. 1996. A warning: NOECs are inappropriate for regulatory use. *Environmental Toxicology and Chemistry* 15(2):77-79.
- Crane, M., Newman, M.C. 2000. What level of effect is a no observed effect? *Environmental Toxicology and Chemistry* 19(2):516-519.
- Mineau, P., B. Jobin, A. Baril. 1994. A critique of the avian 5-day dietary test (LC50) as the basis of avian risk assessment. Technical Report Series. No. 215. Environment Canada, Canadian Wildlife Service, Ottawa. 23 pp.