

A Probabilistic Model and Process to Assess Risks to Aquatic Organisms

Questions for the FIFRA Scientific Advisory Panel

- 1. Exposure Model Input Parameter Variability.** In addressing the regional effects to the farm pond, we have used the exposure model matrix by looking at the combination of 3 pHs, 3 field-to-pond size ratios, and 2 soil aerobic metabolism rates, without changing the meteorological data. We are currently pursuing development of an exposure model to include the following parameters as variable inputs into PRZM/EXAMS: field/pond size, Kd, soil aerobic metabolism, application date, pond depth, and pH. What other parameters should be considered as variable distributions? Would the Panel please list other recommendations or suggestions for refining this approach, considering our purpose of PRA?
- 2. Exposure Distribution Profile Selection.** The exposure component of the aquatic risk assessment model uses 36 year rainfall data to generate 36 annual maxima for exposure concentrations. Two approaches were employed in establishing an exposure distribution profile: a theoretical fitted distribution using Monte Carlo analysis and an empirical distribution using a bootstrap method. Both methods performed similarly except in the tails of the distributions. The empirical distribution is preferred due to its objectivity and speed of calculation. What should the criteria be for choosing between theoretical and empirical methods?
- 3. Interspecies Variability.** In developing a sensitivity curve for freshwater fish with the available data, species' data were combined into their respective families. This was done because all families except salmonids had a single representative species, whereas, salmonids had four representatives. The aim was not to skew the sensitivity data by the over-representation with salmonids. The geometric mean of the multiple species and/or multiple tests with the same species was used in establishing points along this curve. What does the Panel think of this approach? Please provide alternative recommendations, if any, for dealing with limited data sets.
- 4. Effects Input Distribution.** The extrapolation of fish sensitivities used a lognormal distribution of toxicity (LC50s) and a normal distribution of the dose-response slopes. What does the Panel think of this approach and which other approaches could have been used?
- 5. Extrapolation with Limited Data.** Since only one acceptable toxicity test was available for an aquatic invertebrate, an extrapolation using toxicity profiles of other compounds in the same pesticide family to determine the average sensitivity of the tested species and extrapolate a species sensitivity distribution was employed. What does the Panel think of this approach? What are the Panel members opinions on alternative approaches that may be used for establishing a sensitivity profile across diverse invertebrate taxa when one or a very few tests are available?

6. **Taxa Aggregation.** Freshwater taxa were separated from marine taxa in this case study. Since the marine data sets were limited to a single test species, toxicity profiles for that species were used in the assessment and no sensitivity distribution across taxa performed. Data from other related pesticides for marine species were also not available as in the case for freshwater invertebrate taxa. What is the Panel's opinion of separating toxicity data from marine organisms from data on freshwater organisms for purposes of establishing sensitivity profiles? Would the Panel please provide an alternate recommendation, if it has one?

7. **Chronic Assessment.** Available chronic data were limited and, therefore, fewer scenarios were considered sufficient to cover the range of outcomes. An exceedence probability approach was taken to evaluate the potential of chronic effects. What alternative approaches to evaluating chronic effects could have been taken?

8. **Estimation of Species Sensitivity.** In this case study, probabilistic assessments were performed for specific species (e.g., bluegill sunfish and rainbow trout) and for extrapolated species (e.g., 5th percentile sensitive and 50th percentile sensitive). What is the Panel's view on the adequacy of this approach?

9. **Model Parameterization.** Four parameters were varied in each Monte Carlo analysis performed for a specific organism associated with a given scenario: the magnitude and shape of the exposure curve and the slope and intercept of the dose response curve. What parameters does the Panel believe should be varied in the lower tiers of a probabilistic risk assessment? For the case study, toxicity data from standard toxicity test protocols with a narrow range of animal age and size and test condition were used. What does the Panel believe with respect to the expression of generic effects ignoring size, age, feeding, respiration rate, etc.? Is the generic prediction approach sufficient or should the model include consideration of variations in these parameters?

10. **Routes of Exposure .** Due to the high solubility (~700 ppm) of ChemX in water, dietary and sediment associated routes of exposure were not considered. Does the Panel agree that this is sufficient for ChemX? What are the Panel's thoughts on when these additional routes should be considered, in terms of specific physico-chemical parameters and values?