ECOFRAM (U.S. EPA Workgroup on Probabilistic Risk Assessment for Pesticides): Overview and Aquatic Progress Report

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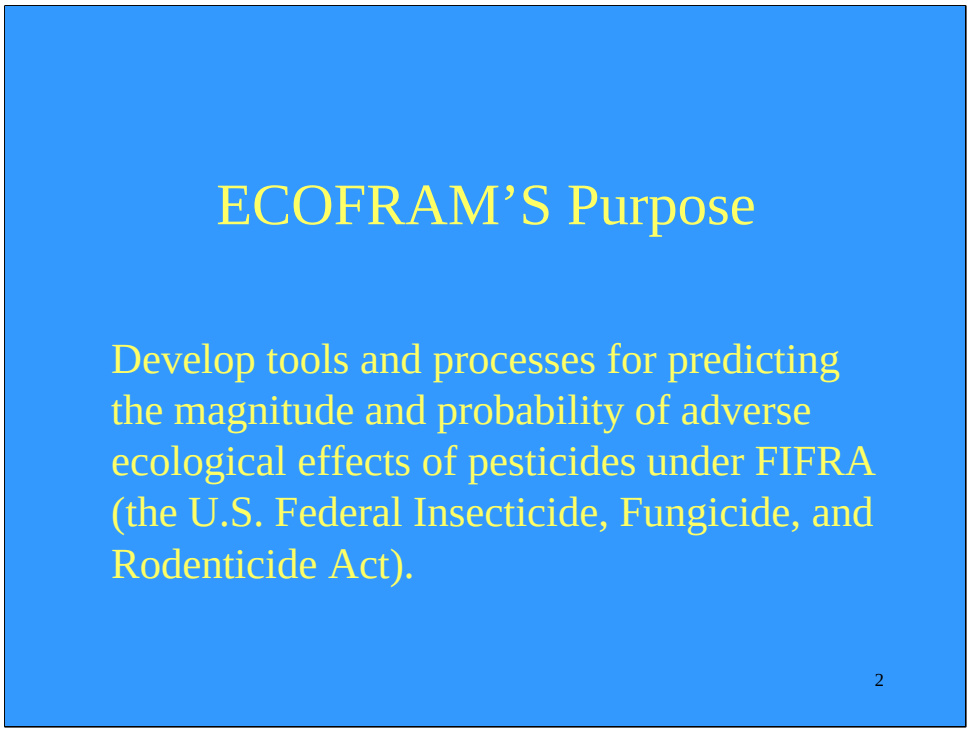
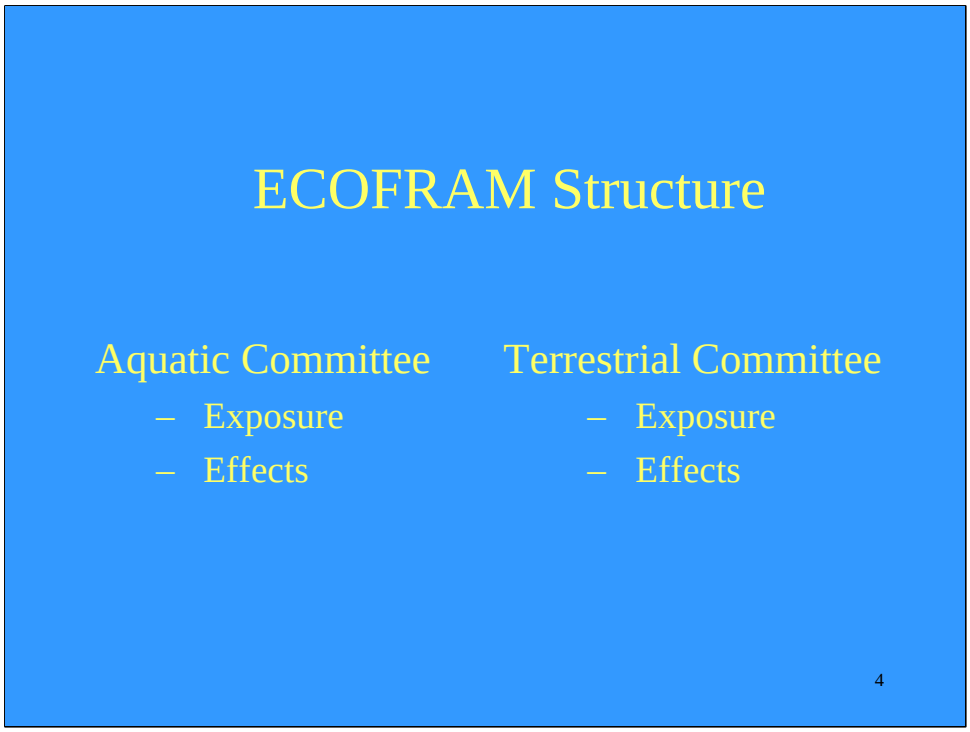
Last year, the U.S. Environmental Protection Agency organized a workgroup called ECOFRAM to explore the use of probabilistic methods in the ecological risk assessment of pesticides. The group of about 40 experts has been meeting nearly every month since last June, and expects to complete its report in the fall of this year. I'm going to give you an introduction to ECOFRAM and a progress report from the Aquatic Committee. Andy Hart will follow me with a report from the Terrestrial Committee. I've put this summary together with the help of Paul Hendley, who chairs the Aquatic Exposure subcommittee of ECOFRAM, and Ingrid Sunzenauer, who manages ECOFRAM within EPA.



ECOFRAM stands for "Ecological Committee On FIFRA Risk Assessment Methods." FIFRA is the Federal Insecticide, Fungicide, and Rodenticide Act, the legislation covering registration of pesticides in the United States. Until now, ecological risk assessment under FIFRA has relied on the risk quotient method, similar to the TER or PEC/PNEC used in other parts of the world. It is EPA's intention to improve ecological risk assessments by developing tools and processes for predicting the magnitude and probability of adverse ecological effects. ECOFRAM has interpreted its charge broadly. We are not confining our discussions to strictly probabilistic methods, but are looking at all possible ways to reduce or quantify uncertainty in ecological risk assessments.

ECOFRAM's participants include scientists from government agencies (mainly the EPA, but also from other agencies including the U.S. Geological Survey, the Florida Bureau of Pesticides, Environment Canada, the Canadian Wildlife Service, and UK MAFF), the pesticide industry, academia, consultants, and non-governmental organizations.



ECOFRAM is organized into an Aquatic Committee and a Terrestrial Committee, each of which has a subcommittee on exposure and a subcommittee on effects. Most of the work goes on at the the subcommittee level, but the groups do get together regularly to coordinate our efforts and make sure we are working in the same direction.

Stages of Exposure Analysis

- Step 1a: Screening estimate
- Step 1b: High runoff scenarios
- Step 2: Widespread range of scenarios
- Step 3: Toolchest of modeling options

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The Aquatic Exposure subcommittee has defined a process for exposure analysis comprised of several steps—we are avoiding the word "tier" at the moment to avoid misinterpretation. The first step is a screening estimate using a very simple, highly conservative model, now called GENEEC (for Generic EEC, or Generic Estimated Exposure Concentration). GENEEC is considered a worst-case model, and it is used only to sort out pesticides that clearly pose no ecological threat, so the work can focus on the other ones. The next step, Step 1b, is also worst-case, but it takes into account more of the physical/chemical properties of the pesticide. Step 1b uses the PRZM and EXAMS II models, coupled with actual soil and weather data that are available for several regions of the country and types of crop. If the pesticide is still indicated to be a potential hazard, the analysis continues with a wide range of scenarios intended to pinpoint the situations where the hazard is greatest. The final step, Step 3, involves what the group is calling a "toolchest" of options for determining more precisely the magnitude and likelihood of exposures.

Exposure Analysis Improvements

- Landscape analysis (proximity of use to water bodies; % of crop in watershed; number of ponds affected)
- New fate measurements, microcosms
- Regional or use-pattern scenarios
- Probabilistic data through Monte Carlo approaches

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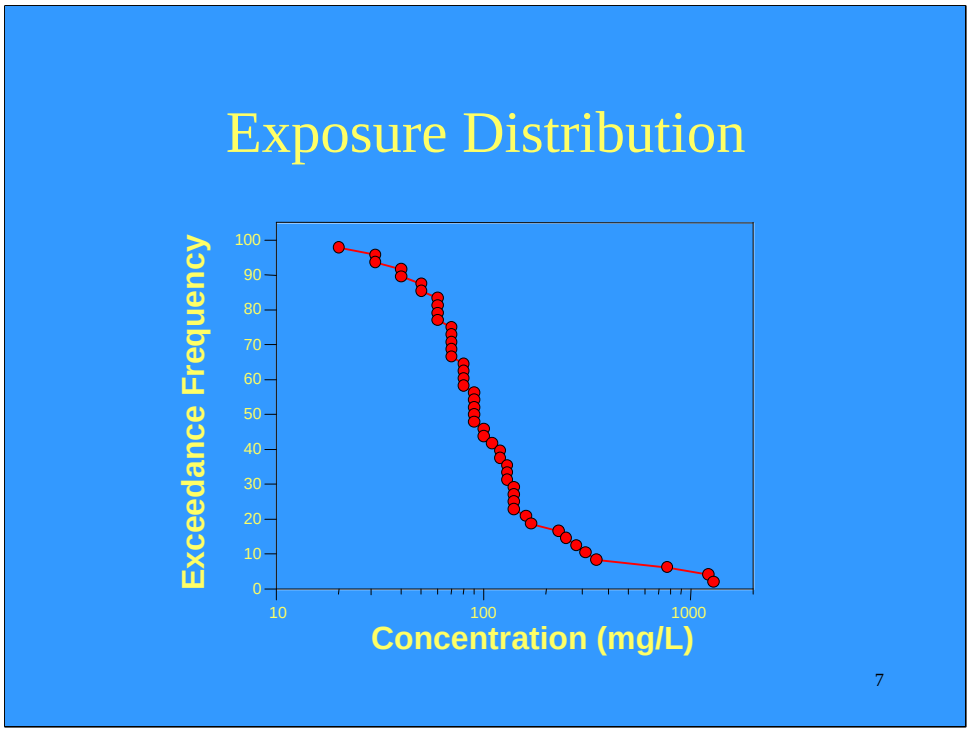
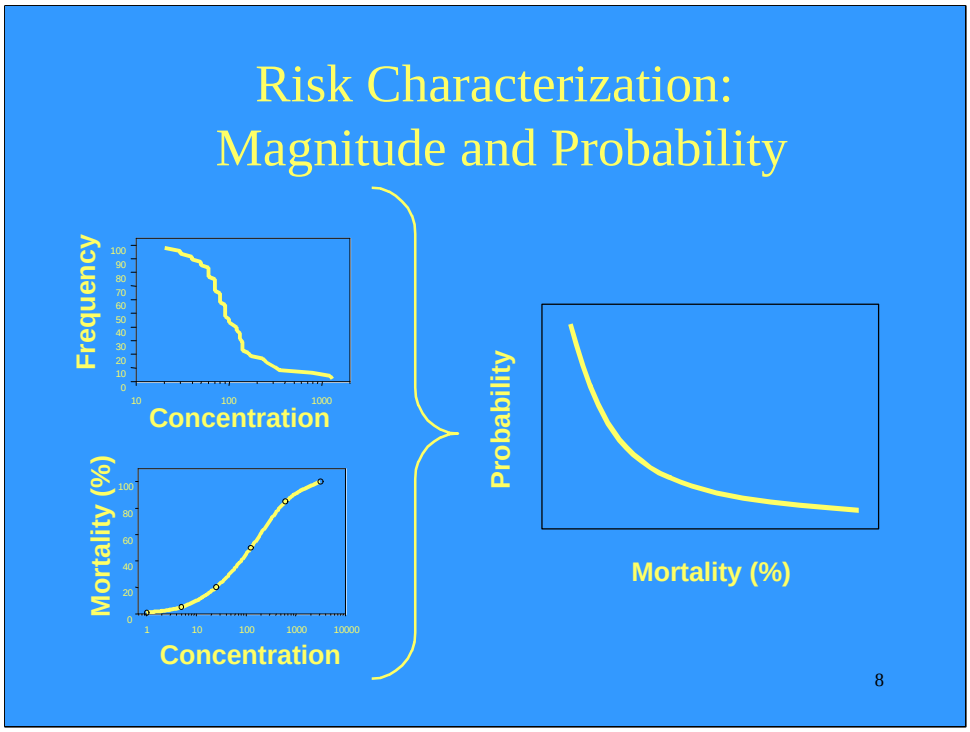
The tools in this toolchest include landscape analysis, which takes into account the proximity of water bodies to fields, the nature of the buffer areas between fields and water, the percent of the watershed to which the pesticide is applied, and the distribution of water bodies in the area. EPA's standard scenario in the past has been, for example, a pond immediately adjacent to a cotton field receiving maximum pesticide application and subject to high runoff. Landscape analysis has shown that this combination is relatively rare, that in fact most ponds are separated from fields by buffer areas, that very few ponds are surrounded by cotton fields, that the wind doesn't always blow from the same direction, and so on. Steve Maund will present an example of this kind of analysis when he discusses the risk assessment of pyrethroids later in this session.

Other tools in the toolchest include new environmental fate measurements—parameters such as aquatic degradation and foliar washoff that are not routinely measured now but are often important in the exposure modeling. Microcosms, or "fate-o-cosms" as the group has called them, are controlled experimental systems simulating natural environments. More regional or use-specific scenarios are being developed, for example for turf, where standard agricultural models are difficult to apply. And the group is exploring applications of Monte Carlo approaches for setting the parameters of the various models.



At most steps beyond Step 1, the output of the exposure analysis looks something like this: a curve showing the frequencies of exceeding different exposure concentrations. In this case, the plot shows the distribution of maximum concentrations from 56 exposure episodes over 11 years in a river subject to runoff from a hypothetical application, generated using PRZM and EXAMS. At the simplest level, one could relate this distribution to some measurement of ecological effect, such as the LC50 for the most sensitive fish tested, and determine the probability that the LC50 would be exceeded. For example, if the LC50 was 300 mg/L, it would be exceeded in approximately 10 percent of the exposure episodes—in this case, about once every two years.



This is very useful information, but it is still based on a very simple measure of ecological effect, the LC50. We would like to estimate the probability of other levels of effect, not just the LC50 for one species of fish. For example, if we use the entire dose-response relationship for the species, rather than just the LC50, we can combine it with the exposure distribution to derive a relationship that shows the probability of different levels of mortality, not just 50% mortality. We can then characterize the risk with a statement such as, "There is a 20 percent probability of 10 percent mortality in this species" or "There is a 2 percent probability of 80 percent mortality in this species." We believe that this kind of risk characterization gives more useful information to the risk managers—those who must make decisions about the relative risks and benefits of the pesticide—than simply a ratio, or the probability of exceeding the LC50.

Extrapolating to Population Endpoints

- Lower tiers:
  - Generic life table analysis and age/stage models to interpret effects on individual survival and reproduction in terms of population-level impacts
- Higher tiers:
  - Resource management models, population distribution models, metapopulation models to predict effects on key populations

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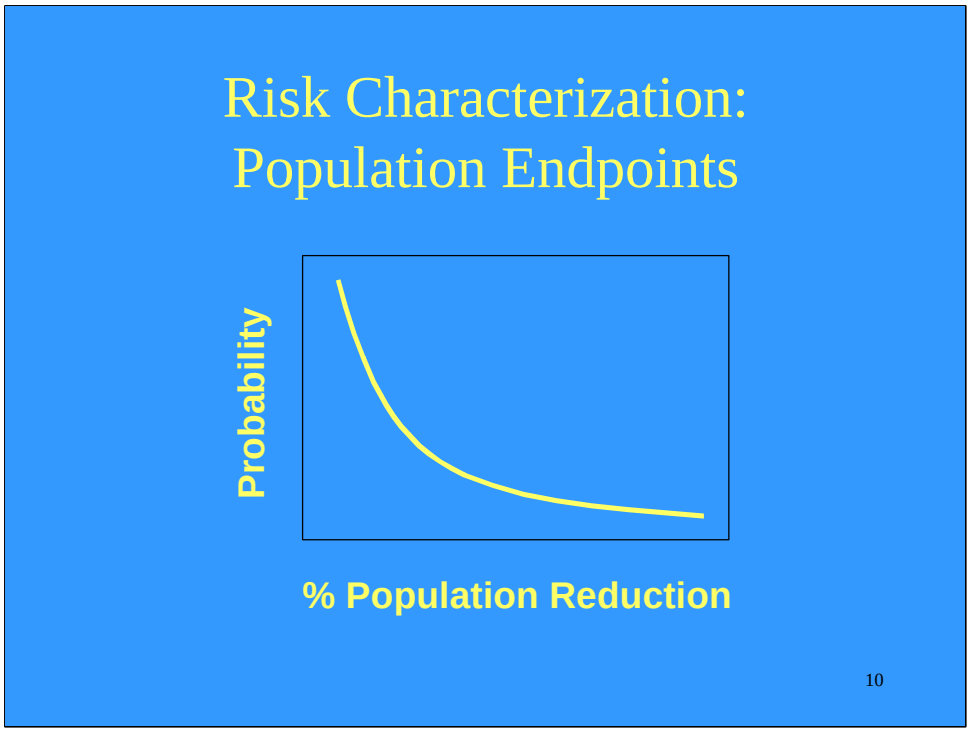
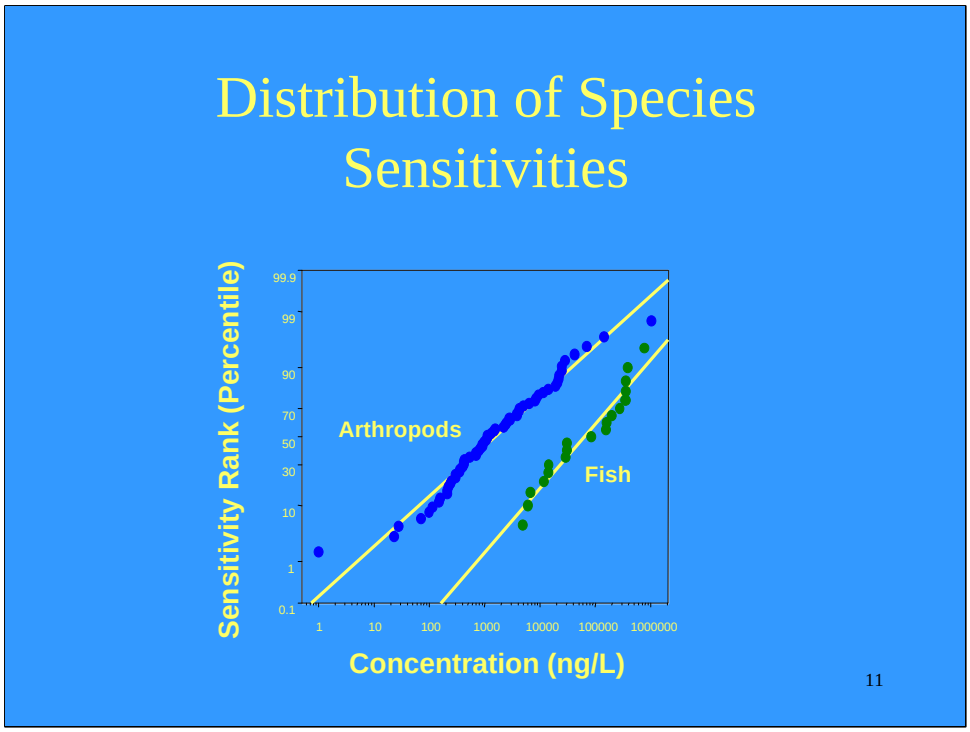
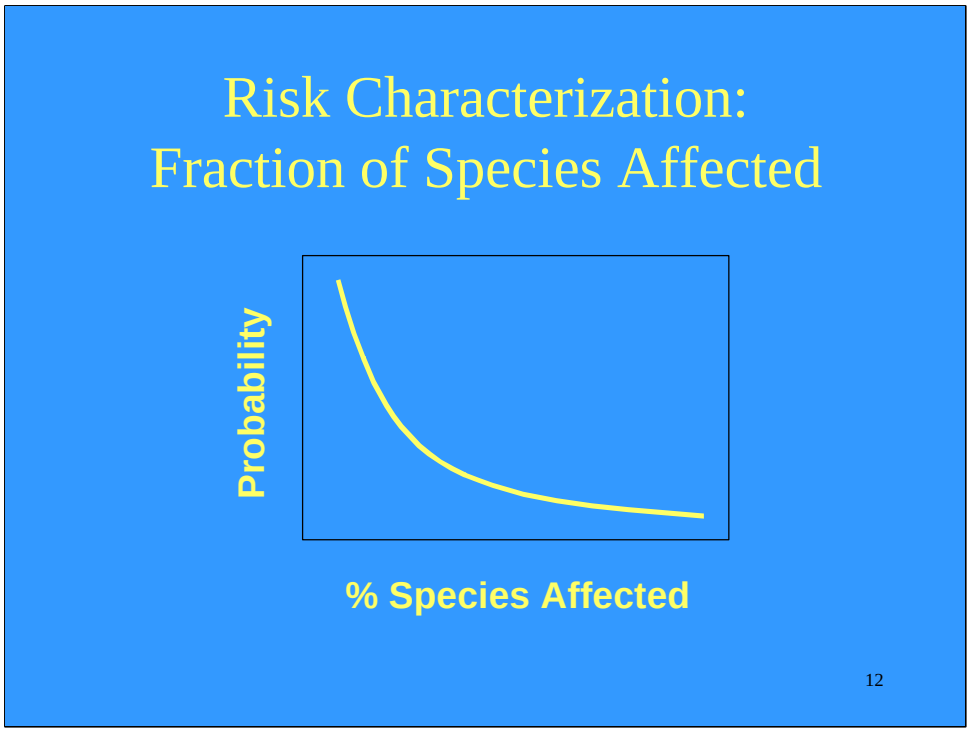
We recognized early on that percent mortality in a laboratory toxicity test does not give direct information about effects on natural populations. However, a variety of population models are available that can be used to extrapolate from percent mortality to population endpoints such as percent reduction in abundance, time to recover, or likelihood of local population extinction. We are developing generic relationships for representative life history strategies that can be used in the lower tiers of an assessment to convert percent mortality (or other toxicity test endpoint) to population endpoints. Population models would not be run for every chemical at lower tiers—rather, these generic relationships will be applied. At higher tiers, if necessary, more sophisticated models such as those used for fisheries management, population distribution models, and metapopulation models could come into play; but these can require a great deal of data for accurate predictions, and are therefore reserved for the higher tiers of the assessment.



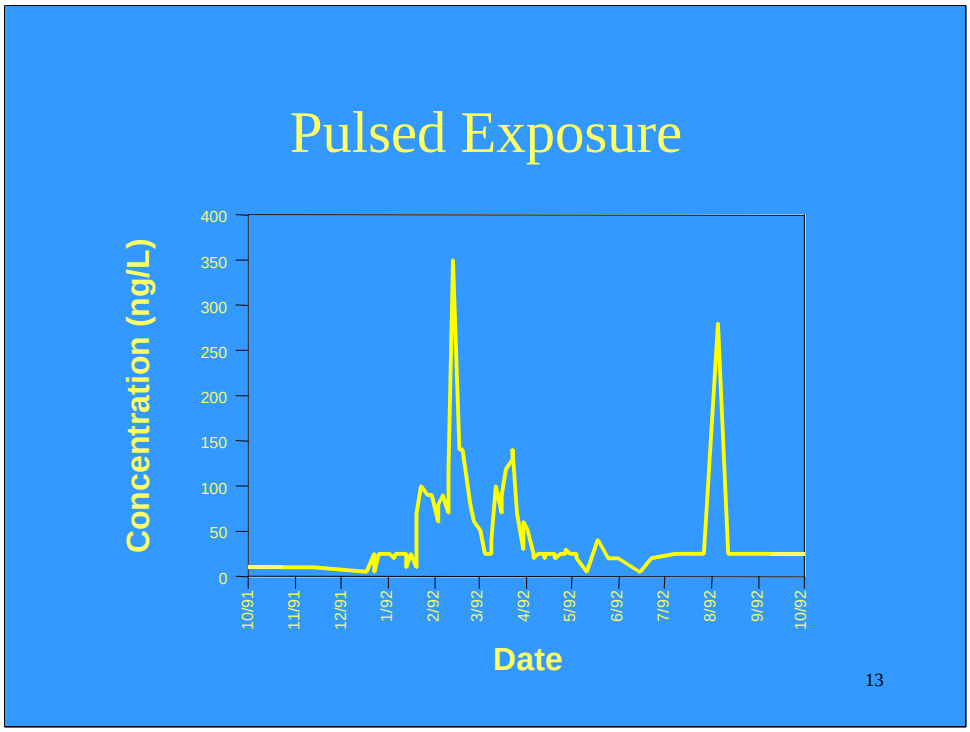
If, even at the lower tiers, we can use the generic relationships I referred to to convert percent mortality to a population endpoint, we can generate a risk characterization that looks like this. We can express the risk with a statement such as, "There is a 30 percent probability of reducing the population of Species X by 10 percent" or "There is a 10 percent probability that the population will take 4 months to recover."



Up to now, I have been speaking about effects on single species only. We want to estimate the potential effects on all species in an ecosystem. There are a number of pesticides for which we have quite a large toxicity database—large enough to allow us to describe the distribution of species sensitivities. In most cases, the distributions of LC50s can be described by a lognormal relationship. By analyzed these large datasets, we have found that 8 data points are sufficient to define these distributions adequately.



And from distributions of species sensitivities, we can characterize risk in this way. We can make statements like, "The probability of affecting more than 10% of all arthropod species is 18%."



One source of uncertainty in aquatic risk assessment of pesticides is that laboratory studies that form the basis of our analysis of both acute and chronic effects are conducted using constant exposure concentrations, while in nature, concentrations of pesticides vary widely over time. We are discussing several approaches to this difficult problem.

Tools for Assessing Effects of Pulsed Exposures

- Laboratory simulation
  - Vary peak height, exposure duration, exposure frequency, recovery time
- Tissue residue modeling
  - Calculate uptake, depuration, body residue; relate effects to body residue
- Population modeling
  - Critical time to recovery

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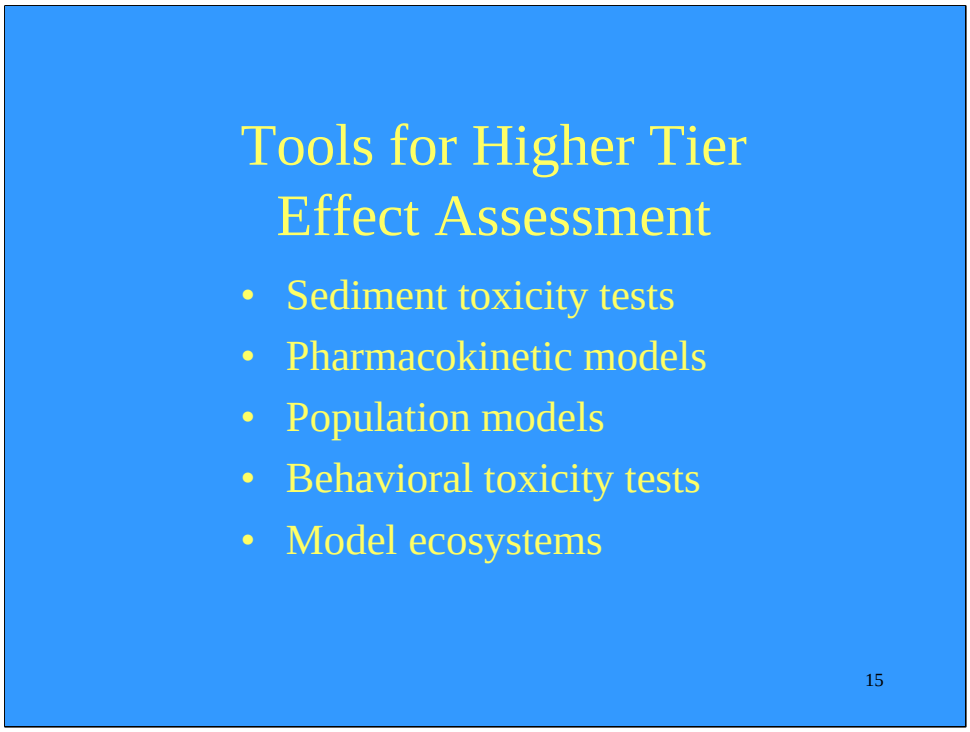
First, laboratory tests simulating time-varying exposure regimes. Second, models of chemical uptake and depuration that allow calculation of tissue concentrations under time-varying exposure conditions, coupled with dose-response relationships based on internal tissue concentrations rather than external concentrations. We're also discussing how population models can be used to predict effects of repeated exposures, and estimate the time needed for population recovery between exposures.



Finally, we are reviewing some of the tools that can be used at the highest tiers of ecological risk assessment—another "toolchest," this time for analysis of effects. They include sediment toxicity tests, pharmacokinetic models, sophisticated population models, behavioral toxicity tests, and microcosms and mesocosms. These tools can be used as needed, depending on the issues that arise at lower tiers of the risk assessment.

So the Aquatic Committee of ECOFRAM has discussed a number of tools and approaches all aimed at quantifying or reducing the uncertainty of ecological risk assessments. We are working toward probabilistic descriptions of pesticide exposure patterns, and techniques for extrapolating effects from measurement endpoints (like LC50s) to assessment endpoints (like population impacts and effects on multispecies assemblages). Much of our remaining task will be to integrate these tools into a logical sequential risk assessment process that will allow registration decisions to be made as efficiently as possible. We plan to send our draft report out for peer review near the end of this year.