### **Ecological Risk Assessment Considerations for Pesticides**

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#### Introduction

We refer to the activity of predicting the probability of adverse effects of pesticide residues on the environment (which includes universally all of the terrestrial and aquatic organisms) as ecological risk assessment. The phrase implies that we are protecting ecosystems, but in fact, the process has been mired in determining the risk to individuals within laboratory populations of various species of test organisms. The concepts of risk assessment commonly applied for predicting the probability of adverse effects on humans have been adopted for assessing environmental scale risks. However, human health risk assessment has the advantage of being able to focus on one species, albeit rodents are commonly used as the surrogate species for us. In human health risk assessment, the single individual is important. However, recent changes associated with the risk-based focus of the U.S. Food Quality Protection Act has promoted an orientation toward potential population level effects from aggregate exposure to pesticide residues in food, water, and around residential settings.

In contrast to human health risk assessment, ecological risk assessment would ideally focus on functions of populations, communities and ecosystems [1]. For species that reproduce often and produce many eggs for potential fertilization, loss of an individual within a population is not significant because population ecology would remain unaffected. However, loss of sufficient numbers of breeding adults would be significant for population ecology, but again say nothing about community and ecosystem level effects. Thus, the state of ecological risk assessment for pesticides as used by regulatory agencies today is much like that of human health risk assessment—focused on the effects to individuals. However, changes have been underfoot to consider at one time many more species reactions and the dynamic nature of the residues they are likely to be exposed to.

This presentation will focus on the state of ecological risk assessment as it is used by the U.S. Environmental Protection Agency during its deliberations for determining registration eligibility of pesticides. It will illustrate an example of how EPA assesses and characterizes ecological risk, both for new compounds and older compounds that have rich databases. The move from deterministic to probabilistic risk assessment will be supported as an improvement over the simplistic use of the most sensitive species and residue data obtained from computer models.

### U.S. Regulatory Use of Ecological Risk Assessment for Pesticide Residues

The Federal Insecticide, Fungicide, and Insecticide Act (FIFRA) is the statutory law that regulates pesticide technology in the U.S. The law was amended in 1972 by the Federal Environmental Pesticide Control Act (FEPCA) to "prevent unreasonable adverse effects on the environment." The basic methodology is adopted from human health risk assessment but modified for use with terrestrial and aquatic target species. The process consists of four elements: hazard identification, dose-response assessment, exposure assessment, and risk characterization. For ecological risk assessment, the hazard and dose-response elements are melded together. Over the years, EPA has developed guidelines for conducting various toxicity tests that will yield information useful to ecological risk characterization. The guidelines for over 55 required tests can be accessed from the Internet [2]. In essence, the hazard has been simplified to characterizing either acute toxicity or chronic toxicity by estimation of the LC50 or NOAEC (for aquatic organisms) or the LD50 or NOAEL (for terrestrial organisms). The chronic toxicity tests simulate exposure that would occur during developmental and reproductive periods.

Exposure assessment for aquatic organisms consists of generating residues by modeling movement into a standard pond [3]. The pond is 2 ha in area and 1 m in depth, and it receives runoff and spray drift from a surrounding 10-ha watershed. Several models are used to predict an expected environmental residue (EEC)—GENEEC, PRZM, and EXAMS. Using the agricultural practices data (for example, cropping system, rate and number of applications, application equipment), the models generate residue data immediately after application, and 21 and 60 days later.

For exposure of terrestrial organisms, EPA assumes the residues will be depositing on short grasses, tall grasses, broadleaf plants and insects, and seeds. The residue values for these compartments are determined with the aid of a published nomogram [4, 5]. The residues in these compartments are high because EPA assumes a direct overspray of the food material and consequently exposure to foraging nontarget organisms.

With one recent exception--the ecological risk assessment for re-registration of the herbicide atrazine--environmental monitoring data is used only in an advisory capacity to determine the reasonableness of the risk assessment outcome. Indeed, EPA seems to avoid environmental monitoring data because sampling is often not conducted in a manner that would uncover the peak or worst-case residues. For characterization of aquatic exposures, this argument seems somewhat disingenuous because often the EXAMS model for estimating residues over time does not use an appropriate kinetic parameter for dissipation or degradation. Lack of an aquatic degradation parameter often results in extraordinarily high residues persisting for 60 days. Thus, most environmental monitoring data is likely to be reflective of a situation occurring 60 days after application, and therefore it can be interpreted to represent realistic chronic residues.

## Risk Characterization—Deterministic Methods

Currently, EPA relies on deterministic risk characterization. From the array of single species acute and chronic toxicity studies, the agency chooses the most sensitive species. A risk quotient (RQ), which is analogous to the hazard quotient (HQ), is calculated as the ratio of the estimated environmental concentration to the toxicological endpoint for the most sensitive species (LC50, LD50, NOAEC, NOAEL). The meaning of the resulting ratio moves into the realm of risk management as EPA has devised an index for concluding whether exposure is above their levels of concern. For example, quotients below 0.5 and 0.05 pose no concerns for risk of acute toxicity for non-endangered and endangered species, respectively. Quotients below 1 pose no concerns for risk of chronic toxicity.

## Risk Characterization—The New Paradigm of Probabilistic Analysis

In the mid-1990's, EPA convened an array of scientists to review its methodology for conducting ecological risk assessments. The process known as ECOFRAM resulted in a draft methodology that would employ four tiers of analysis. Tier I would be analogous to the deterministic risk assessment described above. Tier I analyses are extremely conservative and designed to reduce the possibility of making false negative conclusions (i.e., a conclusion of no harm when an acute hazard actually exits).

Tier I analyses are good screening tools for prioritization of which pesticides should be examined in more detail. Thus, pesticides that meet the acceptable risk standards under a Tier I analysis do not need further assessment in the absence of any new data and resources can be conserved. Tier I analyses, however, can result in a lot of false positives (concluding harm when in fact none is likely). Higher tier levels of analysis are more likely to minimize false positive conclusions by increasing the amount, detail, and scope of data considered. Residue data is likely to include results from environmental monitoring. More importantly, the full distributions of toxicity data and residue data would be used to estimate risk.

Probabilistic risk analysis overlays the distribution of toxicity data on the distribution of residue data. Risk is the area overlapped by the two distributions as shown in Figure 1. The distribution curves can be transformed by probit analysis to straight-line cumulative probability functions [6]. The cumulative probability functions can be combined into a joint probability function to make decisions about the probability of exceeding the residue concentration or dose associated with a specific degree of effect.

### Idealistic Ecological Risk Assessment

Probabilistic ecological risk assessment has some limitations [1]. First it is definitely data intensive and therefore costly in terms of resources needed. Second, the effects that might accrue through biomagnification in the food web are not specifically dealt with except through an examination of physicochemical properties. Third, the outcome given any level of desired protection still has to be judged for social

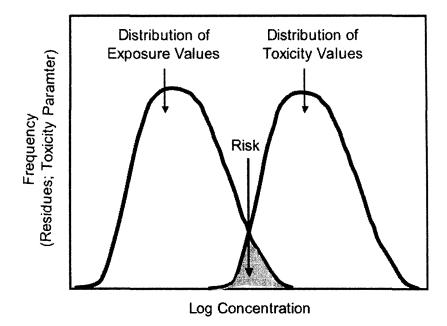


Figure 1. Graphical presentation of probabilistic risk assessment. Risk is represented by the overlap in distribution of the residue (exposure) data and the toxicity parameter data (LC50; NOAEC; etc.). Drawing was modified from [6].

acceptability (a risk management function). Nevertheless, probabilistic methods allow a better utilization of all existing data and give a more realistic analysis of likelihood that an adverse effect will occur. However, the analysis still suffers from an inability to answer more specific questions about what is likely to happen at the level of populations, communities, and ultimately ecosystems.

A comparatively new approach in ecotoxicology is the use of population or demographic toxicology [7]. This approach considers the intrinsic rate of increase of a population and is amenable to examining interacting populations of several species at different trophic levels. This approach to understand the risk from exposure at higher levels of organization has not been incorporated into the aforementioned probabilistic risk assessment technique. However, if population and community ecology could be linked to probabilistic analysis, then ecological risk assessment in the future will be truer to its goal of predicting the likelihood of adverse effects on ecosystems.

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