Appendix I. Overview and History of Tiered Risk Assessment Framework

I.1. History and Goals of EPA's Initiative to Refine the Ecological Assessment Process for Pesticides

I.1.1. Background, Goals and Objectives

On May 29-31, 1996, the United States Environmental Protection Agency (referred to in this document as "EPA" or "the Agency") presented two ecological case studies to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) for review and comment on the ecological risk assessment process. While recognizing and generally reaffirming the utility of EPA's deterministic assessment process, which is based on the risk quotient method, the SAP offered a number of suggestions for improvement (FIFRA SAP, 1996a and 1996b). Foremost among their suggestions was a recommendation to move beyond the single point assessment process by developing the tools necessary to conduct a probabilistic assessment of risk. Such an assessment would estimate the magnitude and probability of the expected impact to a given organism and define the level of certainty and variation involved in characterizing risk in the assessment.

The recommendations of the SAP were consistent with questions raised previously by risk managers in EPA. For pesticides undergoing the regulatory process, questions were often posed regarding the magnitude of the risk, the probability of the risk occurring, and the certainty of the evaluation.

In addition, the Agency, as a whole, had also recognized over the last decade the potential value of probabilistic risk assessments in supporting risk management decisions. As a result, the Agency developed policy and guidance documents to define the role of probabilistic risk assessments in various Program offices and to promote and facilitate the highest quality and consistent application of probabilistic tools and methods, where appropriate. Some of the guidance that was issued includes:

- Risk Assessment Guidance for Superfund (RAGS), Volume I (U.S. EPA, 1989): Addresses the use of quantitative uncertainty analysis in risk assessment.
- Guidelines for Exposure Assessment Final (U.S. EPA, 1992): Emphasizes the importance of adequately characterizing variability and uncertainty in risk estimates conducted in the Agency's Superfund program.
- Memorandum on Risk Characterization Policy and Guidance (U.S. EPA, 1995): Emphasizes the importance of adequately characterizing variability and uncertainty.

In 1997, EPA began an initiative to refine the ecological risk assessment process within the context of FIFRA, with consideration of recommendations of the SAP, Agency guidance and issues raised by Agency regulators. The Agency began by identifying the following goals and objectives:

- Develop a conceptual approach to refine the ecological assessment process;
- Incorporate probabilistic tools and methods to provide an estimate on the magnitude and probability of effects as well as the level of certainty and variation in the assessment;
- Address the broad spectrum of responses to pesticide exposure;

- Reflect more realistic actual use scenarios and field conditions;
- Build upon existing data requirements for registration;
- Utilize, wherever possible, existing databases and create new ones from existing data sources to minimize the need to generate additional data; and
- Focus additional data requirements on reducing uncertainty in key areas.

I.1.2. Ecological Committee on FIFRA Risk Assessment Methods

In 1997, once the goals were identified, the Agency formed the Ecological Committee on FIFRA Risk Assessment Methods (ECOFRAM), which was composed of experts drawn from government agencies, academia, contract laboratories, environmental advocacy groups, and industry. ECOFRAM was tasked with identifying and developing probabilistic tools and methods for terrestrial and aquatic assessments under the FIFRA regulatory framework. The conclusions and recommendations of ECOFRAM were summarized in the Draft Aquatic Workgroup and the Draft Terrestrial Workgroup Reports (ECOFRAM, Terrestrial Workgroup, 1999; ECOFRAM, Aquatic Workgroup, 1999).

In June 1999, the Agency held two public workshops to obtain external review and comment from scientists who had not participated in the developmental process. Participants in the workshops included a broad representation of affiliations and represented the scientific disciplines necessary to conduct a thorough review. Written comments were submitted by all reviewers (ECOFRAM, Peer Input Workshop, 1999).

Once the reports and the peer review workshops were completed, the Agency formed the Refined Risk Assessment Implementation Team (Implementation Team), which was charged with developing a plan to incorporate probabilistic tools and methods into the assessment process. After evaluating the ECOFRAM reports and workshop comments, the Implementation Team developed a conceptual approach for implementing changes to the current deterministic assessment process, using the reports and workshop comments as a starting point. This approach, which was evaluated and endorsed by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) in 2000 (FIFRA SAP, 2000), is based on a four-level risk assessment scheme (US EPA 2000a, 2000b, and 2000c) and is described below.

After proposing the four-level risk assessment scheme, the Implementation Team focused on developing pilot models and on conducting terrestrial and aquatic case studies for "ChemX." The development of the terrestrial case study along with the SAP peer review meetings that were held in 2001 and 2004 led to the development of TIM (v.3.0), which is the focus of this Technical Guidance Document.

I.2. Overview of Conceptual Risk Assessment Process

Once the ECOFRAM reports and the peer review workshops were completed, the Agency developed a plan to incorporate probabilistic tools into the risk assessment process. The plan included a four-level risk assessment scheme, which was presented to the SAP in 2000 (FIFRA SAP, 2000). Lower levels provide more simplistic assessments and use more conservative assumptions, while higher levels include probabilistic methods and provide increasingly realistic biological effects and exposure scenarios. Data requirements, in addition to those currently in place, are focused at each level on those variables for which there is the least confidence and where uncertainty can only be reduced by the collection of additional data. This section provides an overview of the Levels of Refinement and a discussion of the factors that should be considered when moving from one level to another.

I.2.1. Levels of Refinement

In total, there are four possible Levels of Refinement in the risk assessment process. These are summarized in **Table I1**, with emphasis on avian models.

Table I1. Levels of refinement.

Level	Basic description	Risk metric	Avian model
I	Conservative analysis designed to "screen out" situations where there is reasonable certainty of no risk concerns. Relies upon conservative estimates of exposure and effect.	Risk Quotient (RQ) and Level of Concern (LOC)	T-REX (v.1.5)
II	Refined analysis built upon data used in Tier I, with added consideration of available data to incorporate variability and uncertainty. May still be conservative and general in nature.	Probability and magnitude of effect	TIM (v.3.0), MCnest
III	Refined probabilistic analysis, with exploration influence of uncertainty and variability associated with model parameters driving predictions. Moves away from general applications to incorporate more biologically and spatially explicit scenarios.	Probability and magnitude of effect	TIM, MCnest
IV	Site-specific, environmentally relevant, species specific data generated under relevant pesticide use conditions.	Field study, previous lines of evidence	TIM, MCnest

The conceptual risk assessment process for both aquatic and terrestrial assessments begins with Level I, in which effects and exposure data are integrated to evaluate the potential for adverse ecological effects to non-target species. Level I provides a screening level assessment based on the calculation of a risk quotient (RQ) in which a point estimate of exposure is divided by a point estimate of effects; the magnitude and probability of risk are not evaluated in a Level I assessment. In this assessment, the estimated environmental concentration, based on maximum application rates and/or rates associated with other label options such as typical uses, is compared to an effects level, such as an acute or chronic toxicity value. For terrestrial animals, RQs are calculated using the T-REX model (USEPA, 2012). In this level, exposure assumptions, are generally conservative. For example, in T-REX, RQs are based on estimates of pesticide exposure based on initial residues on food from the upper bound of a distribution of residues.

Once the risk quotient is calculated, it is compared to the Agency's Levels of Concern (LOCs) (US EPA, 2004b). These LOCs provide the Agency with criteria to analyze potential risk to non-target organisms and to consider the need for regulatory action. In some cases, the RQ will be found to fall below the LOC, which implies that pesticide use is predicted to pose minimal risk when used according to the label. Therefore, there is no need for further analysis or risk mitigation. However, those pesticides for which the RQ does exceed the LOC may be evaluated in terms of risk reduction measures and may also move to a higher Level of Refinement.

The next level of assessment, Level II, provides an estimate of the probability and magnitude of effects in vulnerable areas. Although this level provides point estimates for some parameters where little or no data are available for generating probability distributions, reasonable hypothetical distributions of exposure and effects parameters may be established using expert judgment and available published data. These distributions may be largely generic and are not necessarily species- or pesticide-use specific. Examples include distributions of residues on avian food items (not just the upper bound) and metabolism of pesticides within and between soil and water. Through sensitivity analysis, Level II assessments will identify the input variables that provide the greatest contribution to the variability and uncertainty of the assessment's risk estimates and conclusions. For terrestrial birds, TIM is used for Level II assessments.

Level III assessments will provide more refined predictions of the probability and magnitude of impacts. They will focus on exposure and effects parameters identified in the Level II assessment's sensitivity analysis as those contributing the most to risk assessment uncertainty.

Level IV assessments will provide even more refined predictions as well as specific pesticide use scenarios, with an emphasis on field collected data from targeted studies.

I.2.2. Considerations in Moving Between the Levels of Refinement

The Agency believes several factors should be considered when moving to a higher level of analysis. These factors include both ecological as well as risk management considerations.

On the ecological side, the types of information that could be considered in determining whether or not to conduct a Level II assessment include the nature of the toxic effect; the number and types of organisms potentially affected; the feeding and behavior patterns of wildlife in and around the treated fields; the environmental fate characteristics of the pesticide, such as its persistence or potential to bioaccumulate; and the levels of the pesticide and its toxicologically significant degradates in the surrounding media. In addition, other lines of evidence such as monitoring or incident data, the level of exceedance above the LOC, and the uncertainty associated with the most important variables affecting the risk estimate should also be considered.

From a risk management perspective, examples of what may be considered include the benefits of the pesticide being evaluated and the availability of alternative pesticides and their effectiveness for the same crop/pest combination, the ability to potentially mitigate the risk, programmatic issues and societal values.

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