A Progress Report for Advancing Ecological Assessment Methods in OPP:

A Consultation with the

FIFRA Scientific Advisory Panel

Overview Document

Meeting Scheduled for
April 6 - 7, 2000

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(In Alphabetical Order)

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I. Background and History of the Initiative

In May 1996, the Environmental Fate and Effects Division (EFED) within the Office of Pesticide Programs (OPP) presented two ecological assessment case studies to the FIFRA Scientific Advisory Panel (SAP) for review and comment on its methods and procedures. While recognizing and generally reaffirming the utility of the current assessment process, the SAP offered a number of suggestions for improvement. Foremost among the suggestions was to move beyond the present single point deterministic assessment process and to develop the tools and methodologies necessary to do a probabilistic assessment of risk. Such an assessment would estimate the magnitude and probability of the expected impact and define the level of certainty and variation involved in the estimate.

The recommendations of the SAP were consistent with issues that risk managers within OPP have raised in the past. That is, risk managers have often posed questions about the magnitude of the risk described for a particular pesticide, the probability of the risk occurring, and had questions related to the certainty and uncertainty of the evaluation.

Following the recommendations of the SAP and building on the work of several dialogue groups (Aquatic Dialogue Group, Avian Effects Dialogue Group, and the Aquatic Risk Assessment and Mitigation Dialogue Group), OPP began an initiative to develop and validate tools and methodologies for conducting probabilistic assessments that address terrestrial and aquatic risk. These methodologies are intended for use by OPP to evaluate effects of pesticides to terrestrial and aquatic species, and therefore needed to be developed within the context of the FIFRA regulatory framework.

This initiative has been divided into the following three parts. Phase I focused on the technical development of probabilistic tools and methodologies. Phase II consists of the development of a plan to implement probabilistic tools and methods to evaluate the ecological risk to fish and wildlife from pesticides. Phase III will be the actual implementation of probabilistic assessments within OPP. This Overview Document and the accompanying Technical Progress Reports focus on Phase II. However, for background purposes, both Phase I and II are described in Sections I.A. and I.B.

A. Phase I - ECOFRAM

Phase I was conducted by the Aquatic and Terrestrial Workgroups referred to as The Ecological Committee on FIFRA Risk Assessment Methods (ECOFRAM). These workgroups were further divided into Effects and Exposure Workgroups. They were comprised of experts drawn from government agencies, academia, contract laboratories, environmental advocacy

groups, and industry and were tasked with identifying and developing probabilistic tools and methods for terrestrial and aquatic assessments under the FIFRA regulatory framework. (A list of ECOFRAM members is in Appendix 1.) They were also asked to identify developmental information and validation needs to ensure that their approaches support an assessment process that is scientifically defensible. Both workgroups volunteered their time and devoted a great deal of effort to addressing the task at hand and should be recognized for their contribution. Their conclusions and recommendations were summarized in the Draft Aquatic Workgroup Report and the Draft Terrestrial Workgroup Report, which were completed in April 1999.

After completion of the ECOFRAM draft reports, the Agency held two workshops (June 22 - 24, 1999) to provide EPA with scientific review, comment, and discussion of the reports. This also provided a good opportunity for ECOFRAM members to gain peer input. Although ECOFRAM members presented posters and papers during professional meetings throughout the developmental process, they were eager to share the results of their efforts with a wide audience through more intensive discussions. The workshop provided an opportunity for ECOFRAM members to discuss the draft reports with scientists who had not participated in the developmental process and who could provide ECOFRAM members with recommendations and comments to help finalize the reports.

Participants in the June workshop also included a broad representation of affiliations and represented the scientific disciplines necessary to conduct a thorough review. Participants included members of academia, industry, EPA's Office of Research and Development, OPP's Environmental Fate and Effects Division, state agencies, and others. (Appendix 2 provides a list of workshop participants.)

A summary of Draft Aquatic and Terrestrial Workgroup Reports and the June workshop comments are presented in the Terrestrial and Aquatic Technical Progress Reports accompanying this Overview Document. If a Panel member would like to review the draft ECOFRAM reports and workshop comments directly, in whole or in part, they may be accessed through the homepage for this initiative. The address for this homepage is as follows:

www.epa.gov/oppefed1/ecorisk/index.htm.

B. Phase II - Evaluation and Implementation

EFED has begun Phase II by forming the Probabilistic Risk Assessment Implementation Team within EPA, which is charged with developing an implementation plan for the Agency that incorporates probabilistic tools and methods for the evaluation of potential ecological risk from pesticide exposure. This team is responsible for the technical evaluation and review of the ECOFRAM reports and workshop comments, which were used as a starting point for developing an approach for implementing changes to the current deterministic assessment process. This overview and the accompanying technical reports provide a progress report.

II Purpose of This Consultation

The purpose of this consultation is to provide the SAP with an update regarding the progress of this initiative and to seek comments and recommendations on EFED's approach to moving forward. EFED has spent considerable time evaluating the ECOFRAM reports and the comments made during the June workshop and has begun to develop an approach to implementation. EFED recognizes that there are many unresolved issues and questions and thus seeks guidance from the SAP on these issues and questions before proceeding further. EFED believes that input from the SAP very early on in the development of an approach to implementation is critical to the success of this initiative.

This Overview Document provides a summary of the goals and objectives for implementing probabilistic tools and methods, provides a brief overview of the conceptual risk assessment model described in the accompanying Technical Progress Reports and describes other aspects of implementation, such as training and outreach. A description of the aquatic and terrestrial approach to probabilistic assessments is provided in the Technical Progress Reports along with a discussion of the potential modifications or additions to data requirements and research needs.

EFED is interested in any general comments and recommendations from the SAP regarding the Technical Progress Reports as well as this Overview Document. In addition, EFED requests that the SAP respond to specific questions regarding the Aquatic and Terrestrial Progress Reports. The questions have been provided under separate cover.

III. Goals and Objectives

When beginning Phase II, EFED identified goals and objectives for implementing probabilistic tools and methods. These goals and objectives are to:

- Implement an ecological risk assessment process that incorporates probabilistic techniques to provide an estimate on the magnitude and probability of risk;
- Develop risk assessment methods under the FIFRA regulatory framework and with the consideration of time and resource constraints;
- Develop an approach to account for the broad spectrum of responses to pesticide exposure, particularly those of greater sensitivity not accounted for in current testing and assessments;
- Provide assessments which more realistically reflect actual use scenarios and field conditions;
- Develop a process that builds upon existing data requirements for registration;
- Utilize, wherever possible, existing data bases and create new ones from existing data sources to minimize the need to generate additional data;
- Focus additional data requirements on reducing uncertainty in key areas; and

- Focus refined, higher tier probabilistic assessment methods on pesticides believed to pose the greatest concern.

To fulfill these goals, EFED began with the technical evaluation and review of the draft ECOFRAM reports, including their recommendations for implementing probabilistic tools and methods, their proposed models, and suggested changes to current data requirements. EFED also reviewed the comments and recommendations made during the peer review workshop.

Once this was completed, EFED began to develop an approach to probabilistic risk assessments. A brief overview of this process is described in the next section. In developing this conceptual process, EFED has considered the goals and objectives identified above.

IV. Overview of the Proposed Conceptual Risk Assessment Process

EFED's proposed approach to the implementation of probabilistic assessments consists of establishing four Levels of Refinement, with guidance to assist risk managers in determining when to move to higher levels. Early levels will provide more simplistic assessments and conservative assumptions, while higher Levels of Refinement will provide increasingly realistic biological effects and exposure scenarios. Only those pesticides that have been judged to potentially pose the most serious risk, and which may warrant regulatory action, will move to the higher levels. Other pesticides will become candidates for early mitigation measures. Data requirements, in addition to those currently in place, are focused at each level on those parameters for which there is the least confidence; uncertainty can only be reduced by the collection of additional data.

This process is not intended to necessarily proceed in a step-wise fashion; a pesticide which has certain characteristics could proceed to a higher level without moving through each level in a linear fashion. For example, a pesticide could proceed directly from Level I to Level III or from Level II to Level IV. This could occur if the results of the assessment conducted at the lower level (1) predict a very high level of risk and (2) if it is determined that the next sequential level of assessment would not alone provide the level of analysis needed to adequately characterize the impact and support the risk management decision at hand. However, all of the data required at the next sequential lower level would still be required.

Section IV.A. provides an overview of the Levels of Refinement and Section IV.B. provides a discussion of the development of the guidance to move between the levels.

A. Levels of Refinement

The conceptual risk assessment process for both aquatic and terrestrial assessments begins with Level 1. Level 1 is a conservative screening step intended to identify those pesticides which would clearly pose "acceptable" risk. Therefore, information is not provided on the magnitude and probability of risk. The assessment is conducted using the current deterministic risk assessment methodology plus extrapolation factors to account for inter-species variation in

sensitivity. The data presently required are also used, with some limited modifications. The resulting risk quotients will be compared to a Level of Concern (LOC). (The LOCs currently used will be re-evaluated with respect to the effects of extrapolation factors, which would be used under the new assessment process.) Some of the pesticides will fall below the LOC and move forward in the registration and re-registration processes ("acceptable" risk) without the need for further analysis or risk mitigation. Those that do not pass this "safety screen", move to higher Levels of Refinement, where additional analyses will be conducted.

Level 2 assessments begin to express risk in terms of the probability and magnitude of effects. They will still rely on point estimates for some parameters, where little or no data are available for probability distributions. However, for other parameters, expert judgement and available published data are used to establish reasonable hypothetical distributions of exposure and effects parameters. These distributions may largely be generic and need not be species or pesticide/use specific. Examples include distributions of residues on avian food items and metabolism of pesticides within and between soil and water.

Through sensitivity analysis, Level 2 assessments will identify the parameters that provide the greatest contribution to the variability and uncertainty of the assessment's conclusions. Risk managers will then compare the assessment's predictions of ecological effects (tempered with an understanding of the impacts of assessment uncertainty) to the expected benefits of pesticide registration. If the predictions of effects are too uncertain to make a regulatory decision, the assessment's discussion of uncertainties will provide risk managers with an idea of the increased importance of moving to a higher Level of Refinement. If the prediction indicates that a risk may not be serious enough to warrant a higher Level of Refinement but is still of concern, these pesticides may become candidates for mitigation measures designed to reduce exposure, thus focusing the higher Levels of Refinement on those pesticides presenting the greatest potential risk.

It should be noted that EFED believes that Levels I and II may eventually merge because Level II can also provide a screening tool to identify those pesticides that are "safe" in addition to identifying those that are candidates for risk mitigation or for higher Levels of Refinement. However, risk managers have expressed an interest in keeping Level I, at least during the short-term, because they are familiar with the type of assessment (based on risk quotients) conducted at this level. (Further discussion is provided in Section IV.B.)

Level 3 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 2 assessment's sensitivity analysis as those contributing the most to risk assessment uncertainty. Data collection and additional exposure modeling will focus on these parameters as well as on specific use scenarios of concern. For aquatic assessments, exposure modeling may provide information on regional differences in exposure when a concern is indicated in Level 2

high-end exposure modeling. Data collection may also focus, to the extent possible, on taxa or species of most concern.

The risk management decision to further refine the assessment process, like the decision at Level 2, will be predicated on an understanding of the areas of uncertainty in the Level 3 assessment and the likely improvements expected from additional data collection and analysis in Level 4.

Level 4 assessments provide the highest level of refinement and would focus on those pesticides which potentially warrant major regulatory action on the basis of ecological risk. These assessments offer highly specific pesticide use scenarios and incorporate additional data to establish the spatial and temporal pattern of exposure for species of concern. Additionally, data may be required to reduce the uncertainty associated with using effects data generated in laboratories for test species other than the focal species of concern. These data might include laboratory testing of the focal species themselves, and effects testing conducted under actual field conditions of pesticide use. It is anticipated that Level 4 assessments, with their associated complexity in data requirements and analysis, would be required only for those specific pesticides presenting the most serious potential effects on the environment.

B. Guidance to Move Between the Levels of Refinement

EFED believes that an essential component of this multi-tiered process for ecological risk assessment is to provide clear and publicly available guidance to the regulated industry, other stakeholders and the public on the types of risk outcomes at each level which would indicate the need for further refinement by moving to higher levels of analysis. This guidance for moving to higher Levels of Refinement would focus on the ecological risks and their attendant uncertainties identified at the lower tiers. Examples of exposure and effects parameters which play an integral role in the decision to refine risks further include the following:

- The nature of the toxic effect,
- The likelihood that the effect will occur given the estimated environmental concentrations of the pesticide and its degradates from agricultural use(s),
- The uncertainty surrounding the most important variables affecting the predicted risk, and
- The number and types of organisms potentially affected, as well as other factors.

However, since the higher Levels of Refinement are data and resource intensive for both the Agency and industry, they should be reserved for only those chemicals which have the potential for significantly impacting the environment. Therefore, it is incumbent upon the risk assessors and risk managers to work closely together to understand the risk predictions and the uncertainties associated with them in the early levels of analysis, and to consider the need for further refinement in light of other factors which must also be considered in the regulatory decision-making process.

Since FIFRA requires the balancing of risks and benefits when managing ecological risks, the risk managers must also consider, for example, (1) the availability of other alternatives and

their effectiveness for the same crop/pest combination, (2) the likelihood that the risk is understood well enough to be mitigated, (3) the ability to mitigate through measures short of not allowing a use or uses, (4) the data needed to reduce uncertainties in the estimates of the magnitude and likelihood of the risks, (5) the importance of reducing the likelihood of impacts on sensitive areas of the environment, and (6) the time constraints on completing the risk assessment for decision-making.

In addition to the consideration of the above factors, there are procedural questions which must also be addressed in regard to new and existing chemicals prior to moving to higher Levels of Refinement. Developing guidance and making it publicly available accommodates new chemicals, since registrants could assess the findings of their data against the Levels of Refinement guidance, and determine what additional information must be developed for their pesticide prior to submission to the Agency for review.

However, the process is more complicated for existing chemicals seeking new uses, reregistration or tolerance reassessment. For example, the Agency has made the commitment to reassess tolerances for those pesticides most toxic to humans and many of these are scheduled for tolerance-related decisions in the next few years. Many of these chemicals are known to produce adverse ecological effects. Identifying data requirements and calling in these new data might cause a serious delay, which would be incompatible with the reassessment schedule depending on the type of data needed. In some cases, data previously collected or voluntarily submitted to the Agency may be sufficient for higher tiered probabilistic ecological assessments. Thus, it is important to note that improving ecological risk assessments for new and old chemicals may necessitate separate schedules and strategies, instead of creating one process suitable for both categories of pesticides.

V. Other Aspects of Implementation

As indicated previously, training and outreach are also part of the implementation process. The following two sections describe these aspects of the process.

A. Training

Training is a critical element of implementing probabilistic techniques. Risk assessors within EFED and outside of EFED will need to know how to conduct a probabilistic assessment, interpret them, and communicate the results. They will also need to understand their limitations.

EFED scientists will be trained through a series of courses, which cover the use of risk assessment software, basic and advanced statistics, and how to conduct a probabilistic assessment. Training has already begun for the first 25 scientists who will be trained initially and should be able to critically evaluate any probabilistic assessments that are provided for EFED's review and be ready to make first attempts at conducting a probabilistic assessment. Once the initial group of 25 are trained, EFED will review the training courses, make any necessary revisions, and then proceed to train the next group of 25 scientists. Once EFED has finalized its probabilistic risk

assessment tools and methods, additional courses will be developed based on these tools and methods and accompanying standard evaluation procedures.

Training for scientists outside of OPP has also been discussed and will likely be similar to the courses developed for EFED once the assessment tools are finalized. Training may include short courses at professional meetings such as the Society for Environmental Toxicology and Chemistry. These scientists could include members of industry, academia, and contractor laboratories.

B. Outreach

EFED believes that outreach is an essential element to implementing a probabilistic approach to ecological risk assessment. Risk managers, external stakeholders, and others need to be informed about the progress being made and have opportunities to provide comment and input throughout the developmental process. Precedent for this has already been set during ECOCFRAM, where EFED along with Aquatic and Terrestrial Workgroup members participated in a wide range of outreach activities throughout the ECOFRAM process.

In reference to implementation, risk manager involvement throughout the implementation process is absolutely essential to ensure that the assessment tools and methods developed address risk management needs. EFED has already begun a series of briefings for the risk managers and other OPP divisions which provide an overview of the Levels of Refinement. As the work progresses, EFED will consider including an example of a probabilistic assessment for discussion. A comparison with the probabilistic assessments conducted for human health and how they differ may also be of value. In addition, EFED has formed a workgroup with representation from both OPP risk management divisions to assist in developing the guidance to move between the Levels of Refinement and to ensure risk management involvement.

EFED also believes that outreach to various stakeholders is important to obtain support for implementing a tiered approach. As a result, EFED plans to develop a new web site to include all of EFED's methods, tools, assumptions and models. This will provide the registrant community with the information they need to understand EFED's environmental risk assessments and know when they need to do more work to better understand or mitigate risk. The web page will also provide the public with information on the impacts of pesticides to fish and wildlife. The web site for ECOFRAM will still be available as well, and the final reports will be posted once they have been completed.

To inform the states and other stakeholders, EFED plans to continue presentations to the Pesticide Program Dialogue Committee and the State FIFRA Issues Research and Evaluation Group, which were briefed during the ECOFRAM process. However, EFED is expanding this effort to include the Tribes and is considering briefing the Tribal Pesticide Program Council (TPPC), sending the TPPC materials for their information, and providing articles in the tribal newsletters.

EFED is also planning a series of briefings for other agencies such as US Fish and Wildlife Service, EPA Regions, and other EPA offices such as the Office of Water and Office of Research and Development. In addition, appropriate public interest groups such as the American Bird Conservancy and others will be briefed according to their interest.

To ensure maximum scientific exchange and discussion, EFED plans to continue to participate in nationally recognized professional meetings. Similar to the sessons for ECOFRAM, interactive poster sessions and symposia are planned for future meetings of the SETAC and the American Chemical Society.

On the international front, EFED has briefed and will continually update the OECD Ad Hoc Risk Assessment Advisory Body and Canada's Pest Management Regualtory Agency. In addition, EFED plans to participate in the sessions on probabilistic ecological assessments scheduled at the SETAC World Congress in May. EFED will also be participating on the Steering Committee and will present several papers at the European Conference on Probabilistic Risk Assessment. EFED is also planning to participate in a Pellston Conference on uncertainty analysis.

VI. Next Steps

EFED is very eager to meet with the SAP and discuss the progress that has been made. Once EFED receives the SAP comments and recommendations from this meeting, EFED plans to consider these comments and will begin to address them and further develop and refine the process described in this overview and the accompanying Technical Progress Reports. EFED plans to meet with the SAP in the Fall for additional review and discussion on the progress that has been made in response to this meeting.

To ensure that implementation of probabilistic assessments is a transparent process which is open to public participation and to ensure that the public has adequate opportunity for addressing key science policy issues, OPP is planning to issue a Science Policy Paper later this summer. OPP believes that there is great benefit from initiating notice and comment on the major science policy issues, including the implementation of probabilistic assessments. This Science Policy Paper will outline the process described in this Overview and the conceptual risk assessment progress envisioned to address magnitude and probability of ecological risk.

Appendix 1

List of ECOFRAM Workgroup Members

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