Chapter II. Charge to the Panel

A. Purpose of This Consultation

The purpose of this consultation is to provide the SAP with an overview of the Agency's updated Level II Terrestrial and Aquatic Models (Version 2.0), which were developed within the Environmental Fate and Effects Division (EFED), OPP. The previous version of these models was reviewed by the SAP during a session held on March 13 - 16, 2001 (U.S. Environmental Protection Agency, 2001a and 2001b).

Some modifications to the models were in response to the 2001 SAP comments and recommendations (FIFRA Scientific Advisory Panel, 2001). Other modifications were based on recommendations made by ECOFRAM (ECOFRAM, Terrestrial workgroup, 1999; ECOFRAM, Aquatic Workgroup, 1999). These recommendations, which were evaluated within the context of the 2001 SAP review, were discussed within the Agency and in national and international professional scientific meetings.

The Agency is interested in any general comments and recommendations from the SAP regarding the modifications to the models along with recommendations on meeting the objectives identified in the Agency's risk characterization guidance, namely transparency, clarity, consistency, and reasonableness (U.S. Environmental Protection Agency, 2000).

In addition, the Agency requests that the SAP respond to specific questions regarding the Terrestrial and Aquatic Level II Models (Version 2.0) that follow in the next two sections of this chapter.

B. Questions Regarding the Terrestrial Level II Model (Version 2.0)

1. Guild Parameters Used for Defining Generic Species. The process for defining generic species described in this document separated species into guilds based on three parameters: feeding substrate, nesting substrate, and food type.

a.) Please comment on the representative guilds used to define the generic organisms.

b.) Are there any additional parameters that need to be considered when defining the guilds and associated generic representatives for a Level II assessment? If so, please identify.

c.) Please provide direction on the appropriate application of the additional parameter(s) in defining the generic species and provide discussion on how the additional parameters will improve the characterization of the uncertainty in risk estimate.

2. Assigning Values to Generic Species Variables. Four variables were used to define a generic species: body weight, food type, frequency on field, and persistence factor. Values for each variable were established as follows:

Body Weight: Selected as the smallest species within each guild
Frequency on Field: Selected as the 95th percentile of available observations for species within the guild
Food Type: Assumed obligate feeders for granivore, insectivore, and herbivore acknowledging that omnivore exposures would be bracketed by these groups.
Persistence Factor: Values assigned to reflect past SAP comments that repetitive behavior patterns be included in the assessment.

a.) Please comment on whether the methods used for establishing values and their results appear to be appropriate for generic species for a Level II assessment.
b.) Does the SAP believe that more rigorous analysis is necessary or indeed possible for generic species? Or, should such an in-depth analysis be more appropriately applied at the species-specific level of assessment? Please explain.

3. Bimodal Feeding Pattern and Serial Correlation of Foraging Events. The model was modified to incorporate hourly choices for foraging areas, a bimodal feeding pattern, and to account for serial correlation in sequential foraging events.

a.) Please comment on the strengths and weaknesses of the modified algorithm in representing avian feeding behavior for the more vulnerable species in agro-ecosystems.
b.) Please provide additional suggestions for modifications in the algorithm to more closely represent avian activity patterns.
c.) Please provide direction on the appropriate application of the additional modifications and provide discussion on how the modifications will improve the characterization of the uncertainty in risk estimates.

4. New Puddle Algorithm. A new puddle algorithm was developed to account for a number of parameters that affect puddling after a rainfall event in agro-environments. The new algorithm addresses rainfall amount, rainfall duration, soil infiltration rates, evaporation, degradation and the stochastic nature of field topography and its relation to puddle formation and duration.

a.) Please comment on the overall model structure in relation to mimicking puddles in agro-environments, including any suggestions on modifications or additional parameters to considered that would improve pesticide concentration estimates in this environmental media.
b.) Please provide suggestions for assigning values to puddle input variables and for locating additional sources of information that may help in defining these values.

5. Air Concentration Estimation. . The model currently employs an equilibrium-based two compartmental model, for estimating pesticide air concentration in the plant canopy. Please comment on the merits and limitations of this approaches. Would the SAP provide suggestions on additional alternatives for estimating vapor phase concentrations that would be consistent with the physical/chemical property and environmental fate data available to the Agency as guideline information? Please comment on the merits and limitations of these additional

approaches.

6. Relating Inhalation Exposure to Oral Exposure Toxicity Endpoints: The absence of avian inhalation toxicity data and the need to track all exposure routes simultaneously has lead to the development of a method to relate inhalation exposures to oral-dose equivalents. The method uses the relationship between mammalian inhalation and oral acute toxicity endpoints along with an adjustment factor to account for some basic physiological differences between the mammalian and avian lungs assumed important to inhaled pesticide bioavailability.

a.) Please comment on whether OPP's proposed approach for relating inhalation exposure to oral-dose equivalents addresses SAP's previous comments concerning the use of the mammalian inhalation/oral relationship for estimating toxicity in birds.
b.) Please provide suggestions on alternatives for estimating avian inhalation toxicity that would be consistent with the kinds of toxicity data generally available to the Agency.

7. Estimating Dermal Exposure: The incidental dermal contact model relies on methods currently employed by the OPP's Health Effects Division that rely on estimates of foliar contact and dislodgeable foliar residues to estimate an external dermal dose.

a.) Please comment on applying this general approach to birds and whether any other model alternatives have been used for wildlife dermal exposure.
b.) If alternative models for estimating dermal exposure for birds are available, please discuss their advantages and limitations in comparison to the proposed model.
c.) Please comment on the following:

1.) The reliance on the lower leg and foot as the significant contact area for birds. Are other portions of avian anatomy significant? If so, which other areas should be included?
2.) Recognizing that the use of human foliar contact data has limitations, can the SAP share any insights on available data that would allow for a more specific foliar contact rate estimate for birds?
3.) Is the SAP aware of any data specific to pesticide foliar residue transfer coefficients for wildlife? If so, please identify.

8. Relating Dermal Exposure to Oral Exposure Toxicity Endpoints: The general absence of avian dermal toxicity data and the need to track all exposure routes simultaneously have lead to the development of a method to relate dermal exposures to oral-dose equivalents. The method uses existing avian dermal toxicity for a subset of pesticides to establish a relationship between avian dermal and oral acute toxicity endpoints. It is recognized that this approach is statistically limited with regards to the strength of that relationship, and that this method is constrained by the limited number of pesticide modes of action considered. Please provide suggestions regarding other route normalization techniques.

9. Physiologically-based Toxicokinetic Modeling. The methods developed to estimate risk from multimedia and different routes of exposure are based on external dose estimates that do not

directly account for physiological, morphological, and biochemical processes that underlie the toxicokinetic behavior of a pesticide. In human health and aquatic life risk assessments for drugs, and in some cases environmental contaminants, use of physiologically-based toxicokinetic (PB-TK) models, are beginning to be employed to derive internal dose estimates for more refined dose-response analyses and to support route-to-route and interspecies extrapolation. In this regard, PB-TK modeling was mentioned by the SAP during the 2001 review of the case studies.

a.) If you are aware of any developmental work on avian PB-TK models since 2001, please discuss. Is the SAP aware of information sources that have compiled measured physiological, morphological, and/or biochemical parameters that are required to develop avian PB-TK models? If so, please comment.

b.) Recognizing that research to support PB-TK models is a long-term and collaborative endeavor across the Agency and the scientific community, identifying potential applications in a risk assessment context can provide insights for prioritizing developmental efforts. In this regard, any suggestions by the SAP in terms of an incremental application of physiologically-based perspectives in problem formulation, analysis and/or the risk characterization phases of an assessment would be welcomed. In addition, any suggestions that may be helpful to the broader scientific community in terms of research priorities to develop avian PB-TK models would be appreciated.

C. Questions Regarding the Aquatic Level II Model (Version 2.0)

1. <u>Varying Volume Water Model</u> (VVWM). For aquatic risk assessments, OPP currently uses a water body fate model that has a fixed volume and does not consider hydrologic inputs and outputs. The SAP 2001 suggested that adding volume variations and overflow to the Level II fate model would improve the characterization of the water body and improve estimates of aquatic pesticide concentrations.

In response, a new model has been developed that allows volume variations and overflow in the water body. The new model also allows for meteorologically dependent parameters, such as temperature and wind speed, to vary on a daily basis, rather than a monthly basis, to better capture temporal variability. In addition, the model was constructed to improve runtime because of the potential use in Monte Carlo simulations.

a.) Please discuss the new model's capability to capture the most salient processes influencing the variations in water body volume, and also discuss the modification allowing daily variations in meteorological dependent variables.

b.) Inputs of mass on a given day are assumed to occur instantaneously. Please discuss the advantages and disadvantages of this assumption with specific consideration for the trade off between runtime, accuracy and the consideration that input data are given as daily values. What, if any, additional approaches regarding modeling input mass would the SAP recommend, please provide a discussion of the pros and cons as compared to the current method?

c.) What additional model characterization or documentation is required to ensure clarity and transparency?

2. <u>Exposure Model Testing</u>. The QA/QC testing of the aquatic Level II Version 2.0 exposure model demonstrated that the refined risk assessment shell is consistent with the Level II Version 1.0 shell (PE4) for launching PRZM and is compatible with all crop scenarios and meteorological files. The testing also showed that the dissipation algorithms in the VVWM are consistent with EXAMS and that the volume and overflow algorithms are correct. Evaluation of the VVWM showed the potential effect that a varying volume water body, using current standard field size and water body volume and surface area, can have on estimated environmental concentrations due to dilution, evaporation, and overflow.

a.) What additional testing, evaluation and/or sensitivity analysis can the SAP recommend to ensure that the aquatic Level II exposure model meets the Agency objectives of transparent processes, and clear, consistent and reasonable products suitable for risk characterization?

b.) Based on the evaluation performed using the VVWM under standard field (10 ha) and standard surface water scenario conditions (1 ha surface area, 20000 m^3 volume), please discuss the advantages or disadvantages to characterizing risk by replacing a single standard with multiple, crop scenario-specific standards at Level II.

3. <u>Field Drainage Area and Water Body Size Selection</u>. At Level II, the risk assessment approach is aimed at addressing the risk to aquatic species in high exposure, edge-of-field situations. The surrogate surface water used for Level II consists of a small, perennial surface water body at the edge of an agricultural field. This water body is capable of being supported by agricultural field runoff alone, and of supporting an aquatic community. Crop scenario-specific input values for field size, surface water volume, surface area, and depth were developed and systematically explored using three methods. The methods used readily available drainage area to volume capacity (DA/VC) ratios and associated water depth guidance for construction of small permanent surface waters of the continental U.S.

a.) The U.S. Department of Agriculture's (1997) DA/VC ratios and depth guidelines for construction of small permanent water supplies (e.g., irrigation, livestock, fish and wildlife) were used as the source of national and regional DA/VC ratios and associated water depths. What additional existing sources of national or regional DA/VC ratios for small, permanent surface waters (e.g., wetlands, pools, ponds) should be considered?

b.) Please describe the merits or limitations to the approaches and assumptions evaluated for using the U.S. Department of Agriculture's (1997) guidelines to derive field size, surface water volume, and surface area input values for specific crop scenarios? What, if any, additional approaches and assumptions should be considered?

c.) A default minimum depth was set as 0.01 m. What minimum depth would the SAP recommend as a criterion to evaluate the biological relevancy of the scenario?

d.) Simulations with the PRZM/VVWM were performed using both the crop-specific surface water area and volume and the historic standard values (DA/VC = 1.5 acres/acre-ft) to characterize effect on exposure outputs for a relatively arid growing region (DA/VC = 50 acres/acre-ft) and a wetter climate (DA/VC = 1 acre/acre-ft) for both a short-lived and long-lived pesticide. In addition, the effect on volume in the surface water body was characterized for all crop-specific scenarios. Please discuss what, if any, additional crop scenario/pesticide evaluations should be performed to further characterize the impact to exposure outputs, and/or to volume.

e.) What are the advantages or disadvantages to characterizing exposure for small, perennial surface waters at the edge of treated fields using the method selected for setting crop scenario-specific DA/VC ratio, depth, surface area and volume input values? What adjustments or changes to the method does the SAP recommend, and what are their advantages and disadvantages?

f.) Please describe the weaknesses and strengths of using simulated exposure concentrations from these crop scenario-specific water bodies as a surrogate for a low-order stream at the edge of a field, for a temporary pool or pond, and for a small tidal creek or estuary.

g.) Simulations with PRZM/EXAMS, a fixed volume surface water model, will be performed using both the crop-specific DA/VC approach and the historic standard values to characterize effect on exposure outputs for relatively arid growing regions (DA/VC = 50 and 80) and a wetter climate (DA/VC = 1) for both a short-lived and long-lived pesticide. Please discuss what, if any, additional crop scenario/pesticide evaluations should be performed to further characterize the impact to exposure outputs in a fixed volume situation.

h.) Please discuss sources or approaches for national or regional DA/VC ratios and associated water depth and size information for temporary pool and pond aquatic-life resources.

4. <u>Curve Number</u>. The SAP 2001 recommended that additional characterizations of variability should be given to those parameters in the exposure model that have a major impact on exposure concentrations. The curve number is perhaps the most influential parameter in PRZM, and it has been interpreted in recent literature as a random variable. PRZM currently treats the curve number as a function of soil moisture, although recent literature suggests that the curve number may more appropriately be interpreted as a random variable.

a.) Please discuss the pros and cons of assuming strict dependence of curve number on calculated soil moisture versus treatment as a random variable unrelated to soil moisture as a means of characterizing runoff variability? Please identify and discuss alternative methods.

b.) Since the curve number was not designed for use in continuous modeling, what problems may arise when the curve number is used in this manner? Could a probabilistic interpretation address some of these issues? If so, how?

c.) What is the impact on interpretation of probabilistic-simulated exposure values when the curve number is used as a random variable and autocorrelation of temporally varying physical properties that may impact run off is ignored?

d.) A lognormal distribution is being investigated to characterize variability in certain curve number parameters. Is it reasonable to assume such a distribution has stationary properties (constant mean and variance) for all rain events (e.g., large and small)?

Please provide rationale.

e.) Monte Carlo modeling is being investigated as a method of integrating the potential variability of curve numbers into exposure modeling. Can the SAP recommend other methods available to incorporate variable and uncertain curve numbers into a continuous runoff model. Please discuss the pros and cons of these methods versus Monte Carlo.