July 20, 2004

MEMORANDUM

SUBJECT: Transmittal Of Minutes Of The FIFRA Scientific Advisory Panel Meeting Held March 30-31, 2004 Addressing A Set Of Scientific Issues Being Considered By The Environmental Protection Agency Regarding Refined (Level II) Terrestrial And Aquatic Models Probabilistic Ecological Assessments For Pesticides: Terrestrial

TO: James J. Jones, Director
Office of Pesticide Programs

FROM: Paul I. Lewis, Designated Federal Official
FIFRA Scientific Advisory Panel
Office of Science Coordination and Policy

THRU: Larry C. Dorsey, Executive Secretary
FIFRA Scientific Advisory Panel
Office of Science Coordination and Policy

Joseph J. Merenda, Jr., Director
Office of Science Coordination and Policy

Please find attached the minutes of the FIFRA Scientific Advisory Panel open meeting held in Arlington, Virginia from March 30-31, 2004. These meeting minutes address a set of scientific issues being considered by the Environmental Protection Agency regarding refined (Level II) terrestrial and aquatic models probabilistic ecological assessments for pesticides: terrestrial

Attachment

cc:

Susan Hazen
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Anne Lindsay
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Debbie Edwards
Steven Bradbury
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OPP Docket

<u>FIFRA Scientific Advisory Panel Members</u>

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SAP Report No. 2004-03

MEETING MINUTES

FIFRA Scientific Advisory Panel Meeting, March 30-31, 2004, held at the Sheraton Crystal City Hotel, Arlington, Virginia

A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding:

Refined (Level II) Terrestrial And Aquatic Models Probabilistic Ecological Assessments For Pesticides: Terrestrial

NOTICE

These meeting minutes have been written as part of the activities of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Scientific Advisory Panel (SAP). These minutes have not been reviewed for approval by the United States Environmental Protection Agency (Agency) and, hence, their contents do not necessarily represent the views and policies of the Agency, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names or commercial products constitute a recommendation for use.

The FIFRA SAP was established under the provisions of FIFRA, as amended by the Food Quality Protection Act (FQPA) of 1996, to provide advice, information, and recommendations to the Agency Administrator on pesticides and pesticide-related issues regarding the impact of regulatory actions on health and the environment. The Panel serves as the primary scientific peer review mechanism of the EPA, Office of Pesticide Programs (OPP) and is structured to provide balanced expert assessment of pesticide and pesticide-related matters facing the Agency. Food Quality Protection Act Science Review Board members serve the FIFRA SAP on an ad hoc basis to assist in reviews conducted by the FIFRA SAP. Further information about FIFRA SAP meeting minutes and activities can be obtained from its website at http://www.epa.gov/scipoly/sap/, the OPP Docket at (703) 305-5805 or edocket at http://docket.epa.gov/edkpub/index.jsp (OPP-2004-0005). Interested persons are invited to contact Paul Lewis, Designated Federal Official, via e-mail at lewis.paul@epa.gov.

In preparing these meeting minutes, the Panel carefully considered all information provided and presented by the Agency presenters, as well as information presented by public commenters. This document addresses the information provided and presented within the structure of the charge by the Agency.

SAP Report No. 2004-03

MEETING MINUTES: FIFRA Scientific Advisory Panel Meeting, March 30-31, 2004, held at the Sheraton Crystal City Hotel, Arlington, Virginia

A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding:

Refined (Level II) Terrestrial And Aquatic Models Probabilistic Ecological Assessments For Pesticides: Terrestrial

Mr. Paul Lewis
Designated Federal Official
FIFRA Scientific Advisory Panel
Date: July 20, 2004

Steven Heeringa, Ph.D.
FIFRA SAP Session Chair
FIFRA Scientific Advisory Panel
Date: July 20, 2004

Federal Insecticide, Fungicide, and Rodenticide Act
Scientific Advisory Panel Meeting
March 30-31, 2004

Refined (Level II) Terrestrial And Aquatic Models
Probabilistic Ecological Assessments
For Pesticides: Terrestrial

PARTICIPANTS

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Tammo Steenhuis, Ph.D. Professor, Agricultural and Biological Engineering Department, Cornell University, Ithaca, NY

PUBLIC COMMENTERS

Oral statements were made by:
David Fischer, Ph.D. (Bayer CropScience) on behalf of CropLife America
Nick Poletika, Ph.D. (Dow AgroSciences) on behalf of CropLife America

No written statements were provided

INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Scientific Advisory Panel (SAP) has completed its review of the set of scientific issues being considered by the Agency pertaining to its review of refined (Level II) terrestrial models for probabilistic ecological assessment of pesticides. Advance notice of the meeting was published in the *Federal Register* on February 20, 2004. The review was conducted in an open Panel meeting held in Arlington, Virginia, from March 30-31, 2004. The meeting was chaired by Steven Heeringa, Ph.D. Mr. Paul Lewis served as the Designated Federal Official. Mr. Joseph J. Merenda, Jr. (Director, Office of Science Coordination and Policy, EPA), Mr. Jim Jones (Director, Office of Pesticide Programs, EPA) and Steven Bradbury, Ph.D. (Director, Environmental Fate and Effects Division, Office of Pesticide Programs, EPA) provided opening remarks at the meeting. Ingrid Sunzenauer, M.S. (Office of Pesticide Programs, EPA) highlighted the goals and objectives of the session. Edward Fite, M.S. (Office of Pesticide Programs, EPA) and Timothy Barry, Sc.D. (Office of Policy, Economics, and Innovation, EPA) discussed the model architecture of the Level II terrestrial integration model. Edward Fite, M.S. (Office of Pesticide Programs, EPA) summarized the selection of generic species. Timothy Barry, Sc.D. (Office of Policy, Economics, and Innovation, EPA) reviewed the bimodal feeding pattern and Markov chain model. Dirk F. Young, Ph.D. (Office of Pesticide Programs, EPA) discussed the puddle model. Edward Odenkirchen, Ph.D. (Office of Pesticide Programs, EPA) and Christine Hartless, Ph.D. (Office of Pesticide Programs, EPA) presented the dermal exposure and effects model. Edward Odenkirchen, Ph.D. (Office of Pesticide Programs, EPA) discussed the inhalation exposure and effects model. Edward Fite, M.S. (Office of Pesticide Programs, EPA) presented the preliminary model testing results/next steps and also ended the session by presenting an introduction of the questions to the Panel.

CHARGE

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 led 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 led 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.

SUMMARY OF PANEL DISCUSSION AND RECOMMENDATIONS

The FIFRA Scientific Advisory Panel (the Panel) was charged with reviewing progress that has been made by the Agency regarding probabilistic risk assessment modeling. The Panel commends the Agency for initiating a Probabilistic Risk Assessment process in 1996, convening experts to develop the conceptual models, forming an Implementation Team, disseminating the modeling process to the scientific community and inviting periodic review by this and previous panels.

The Agency's terrestrial risk assessment paradigm currently has four levels.

Level I:	Screening level
Level II:	Initial estimate of probability and magnitude of effect. Relying on existing data sets. Planning for simplistic estimates of population impacts
Level III & IV	Probabilistic risk assessments

At this point, the Agency's modeling sophistication lies somewhere between Level II and Level III. Models are needed at Level II and higher to evaluate a high throughput of approximately 70 chemical products that are currently evaluated by the Agency each year.

The Panel commends the Agency for the technical efforts made in model development to date. Several innovative approaches have been employed and the number of parameters considered is extensive. The Agency's model has many positive aspects and a few areas that need improvement. Members of the Panel who served on past Panels regarding probabilistic modeling of terrestrial risks agree that the Agency has successfully included many of the suggestions made by previous Panels. Overall the Panel believed the model will be appropriate for use in Level II assessments after a few of their recommendations are addressed as presented below. More detail is given in the Panel's response to the Agency's charge to the Panel.

1. Frequency on field should incorporate foraging frequencies during breeding seasons. Foraging frequency and strategy should be determined for different crop types and different regions of the country. Time in edge habitat should be considered as presenting exposure when that habitat has received spray drift.
2. Feeding behavior should better incorporate the feeding strategies of breeding birds as these strategies are likely to be more representative of birds foraging in fields during planting and soon thereafter.
3. The bimodal feeding pattern is an improvement over past approaches, but probably does not represent avian foraging behaviors, especially when birds are brooding nestlings. Fortunately, the time in field is likely to be more important to dermal and inhalation exposures than to ingestion, because as long as the food intake is correctly estimated, the time to acquire that food does not alter oral intake.

4. Inhalation exposure should be better quantified by allowing toxicant volatilization from soil as well as plants. The maximum droplet size considered for inhalation exposure should not be limited. Larger sizes are brought into the upper respiratory tract and thus serve as a source of exposure.
5. Dermal exposure should better characterize foot morphology.
6. Inhalation effects need to be better defined through a larger data set and empirical data for birds. This is required as the actual detoxification capacity and rate may be different between birds and mammals.

The Panel's comments are based on our understanding of the Agency's desire to use the Level II Risk Assessment to make a specific regulatory decision to stop evaluation of a given product or require more sophisticated (higher tier) evaluation of the product. Having a discrete decision point that incorporates the Level II assessment will avoid a regulatory process where all products *de facto* proceed to Level III or IV assessments. If a decision is made to proceed to higher levels of evaluation, the outcome of Level II should focus the Agency's data-gathering efforts that will be essential for proper modeling in the more refined Level III or Level IV assessments.

With this in mind, it is important to note that the risk assessment paradigm has a feedback mechanism, wherein assessment outputs are evaluated through data acquisition and system monitoring. There is no indication that this is being done in the development of the current models. More troubling is the appearance that there is no intention to obtain appropriate data to improve parameter estimation and to validate model outcomes. The Panel strongly recommends that the Agency obtain data that validate critical modules within existing models and that can be used to refine distributions that will be needed in higher levels of the risk assessment process.

PANEL DELIBERATIONS AND RESPONSE TO THE CHARGE

The specific issues to be addressed by the Panel are keyed to the Agency's background documents, references and the Agency's charge questions.

Agency Charge

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.

Panel Response

Using a guild approach to identify generic species seems reasonable for Level II models. Many different criteria can be used to identify guilds, and the guilds selected should be those most relevant to assessments of the potential for pesticide exposure. Classifying birds on the basis of feeding substrate and food type are particularly germane to risk assessment, as these parameters determine where, and upon what, the birds will feed. Nesting substrate may also be a useful classification to the degree that it provides information about the likelihood of nest placement relative to the cropping unit being treated.

The generic species were based on the guild structure of birds using cornfields (Best et al. 1990). Unfortunately, more data describing the use of crop fields by birds are not available. The primary, if not sole data used are those Best et al. collected more than a decade ago, and are restricted to corn fields. Additional studies have been conducted and are described in the following paragraphs. Differences among crop types, regionally and seasonally, are likely to contribute significantly to the guild structure present in a given agroecosystem.

The guild composition of the bird community in cropping systems other than corn would be different. Orchard systems, for example, would likely have a greater proportion of birds feeding above the ground (in the canopy of shrubs and trees) than would be the case for rowcrop fields. Bird abundance data have been gathered for a variety of crop types, and the guild determinations should be based on the composition of the bird community associated with the crop type being evaluated. CropLife America (Best and Murray 2003) has compiled a database of avian field studies conducted on cornfields and cotton fields in different regions of the United States. There are also use data and diet composition from studies in corn (Brewer et al., 1990; Brewer et al., 1992), turf (Hummell et al., 1990) and orchards (Melott et al., 1990). The bird survey results from these and other studies could be used to define guilds more appropriate to specific crops and geographical regions. Empirical data on bird use of fields containing the relevant crop type should be used to determine the relative weighting (contribution) of the various guilds in "constructing" the generic species that is used in the risk assessment. Future efforts may be required to define generic species for different regions of the country, given that the current suite of species is based on a study of cornfields in one region of the United States.

Best and Murray (2003) acknowledge that as the height and basal area of the plant canopy increases, the species and feeding guilds of birds that frequent agricultural fields may change. This is almost certainly the case with rapidly growing crops. For example, as the growing season progresses in cornfields, barren, sparsely vegetated fields are transformed into fields dominated by dense vertical plant cover that can attain heights of over 2.5 m (Rodenhouse and Best 1994).

Several panelists believed that if the role of the Level II modeling is as suggested, species should be randomly selected from a species distribution weighted by the relative abundance of individuals within each species instead of selecting the smallest bird within each guild. This is important because species selection dictates the parameterization of other aspects of the models, i.e. frequency on/off the field and percent of diet from the fields. This approach also reduces/eliminates the possibility of mathematically constructing a generic species that is unrealistic. This is likely to become a more pressing issue at higher levels of the risk assessment progression.

Two practical considerations mitigate against over-reliance on developing a generic species. One is that whereas one intuitively thinks of cornfield birds as small sparrow-like passerines, several other classes of birds may be of concern in a risk assessment. Species such as harriers and other raptor or herbivorous waterfowl do not fit the model yet constitute important classes of birds whose fate may need to be assessed within the model. The second issue is that efforts to combine attributes of birds into a single generic species run the risk of creating a species that does not actually exist (e.g., a 64g nighthawk that spends all of its time on the ground). Other Panel members differed from this position since the Agency developed different generic species for different guilds.

While conservative assumptions are useful in deterministic models, a fully stochastic model should be more realistic, allowing the randomness in the model parameters to generate the extremes. In terms of the guilds, two conservative assumptions were made. Body weight was taken to be that of the smallest bird in the guild, and the frequency -on-field (FOF) was taken to be the upper 95th percentile. Some Panelists recommended that distributions be used where possible, and if distributions are unavailable that the lack of these distributions guide data collection needs for higher level risk assessments.

Agency Charge

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.

Panel Response

An important factor not included in the generic species approach is a consideration of seasonal changes in the use of treated fields by birds. The occurrence classifications of Best et al. (1990) for bird use of cornfields were based on composite census data summarized over a 2-month period. The use of those fields by individual species (and guilds) differed over that period. Because pesticide applications occur at specific times during the growing season, depending upon the pest being controlled, composite estimates of field use may be misleading. Most bird census data consist of repeated surveys, and although the results may be reported as a seasonal composite, the original data would often permit the development of seasonal-use profiles.

This can be illustrated by data that have been collected for cornfields (Best 2001). Bird use of cornfields in late April in Iowa is dominated by species that forage on the ground or in low herbaceous vegetation, with little use by species that forage in shrubs and trees. By early August the proportional field use by birds that forage on the ground or in low herbaceous vegetation has declined substantially and is similar to proportions of birds that feed on shrubs and trees. A similar seasonal shift occurs in alfalfa fields (Best, unpublished data). Such seasonal shifts in fields used by various avian guilds should be factored into the determination of generic species. Depending upon when a pesticide is applied (e.g., corn rootworm versus corn borer control), the most susceptible guild(s) change(s).

The current model minimizes the importance of plant development and foliation on the composition of the bird community using treated fields. Seasonal changes in bird use of crop fields do occur, and these affect body size distributions, the food type and foraging substrate used by birds, and the frequency of field use.

Effects of edge habitat on the guild structure of bird communities within pesticide-treated fields was not considered. Edge habitats do affect bird use of fields, and this effect can vary regionally (Best et al. 1990, Best and Murray 2003). For example, the bird species composition within cornfields bordered by herbaceous vegetation differs from that in cornfields adjacent to woodland (Best et al. 1990). To further illustrate this, effects of edge habitat on the frequency of cornfield use by birds is affected by the gradient in precipitation progressing from the Midwest to the more arid Southwest (Best and Murray 2003). A review of the number of species associated with edge habitats suggests that a spray-drift component should be added to the model.

Body size also has implications for the area of exposure and perhaps density. Because body size might also scale with foraging area, it is possible that as assessments progress from "the field" to regional and population applications that the smallest birds will not necessarily be at highest risk from an "incidence of mortality" or population standpoint. This was examined by Freshman and Menzie (1996) and Figure 1 illustrates how foraging-area scales cause variations in exposures at a local population level (incidence within the population) when the exposure field consists of patches of contamination (e.g., individual fields in a regional landscape).

In Figure 1, the incidence of exposure in a local population is influenced by the scale of foraging of individuals as well as the spatial scales of the contamination. The example also shows that when one moves from risk to an individual to risks to a group of individuals where that is expressed as an incidence, it is no longer the individuals with the smallest foraging area (often smaller sized individuals) that are necessarily at greatest risk. In higher level analyses, the Agency should consider the spatial scale of exposures and how this might influence selection of representative guilds and species within guilds.

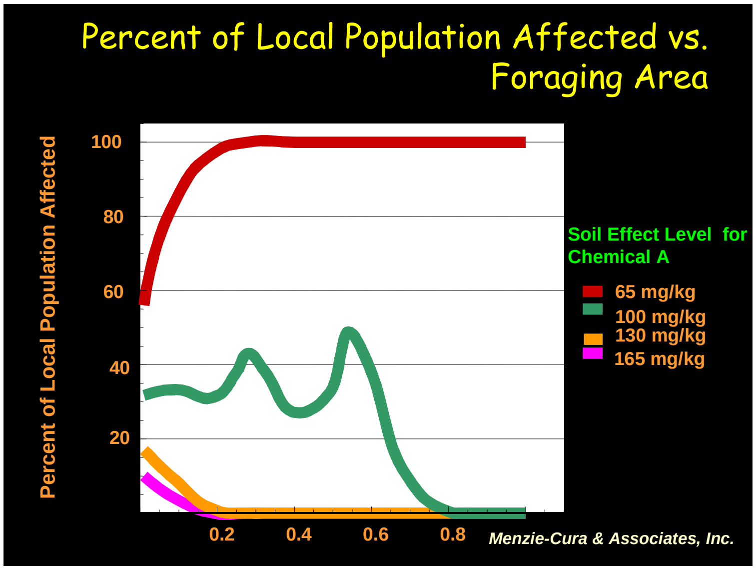

Figure 1. Effects of foraging area on avian population

Agency Charge

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.**

Panel Response

Future efforts may consider additional avian foraging guilds, such as scavengers and/or carnivores, which could receive elevated exposures from feeding on dead or dying small mammals and birds. This guild would only need to be considered for persistent and/or bioaccumulative pesticides. It may also be useful to consider average body weight of generic species rather than focusing only on the smallest member of the guild. This will help ascertain both worst-case risk and typical risk expected for the guild.

Feeding frequency will be an important aspect of exposure because of the way the exposure concentration data are handled. At present, the bird experiences (eats at) a pre-selected concentration for a particular time step. The fewer the meals, the greater the likelihood that a bird will get a toxic dose or non-toxic dose within a particular time step. If smaller birds eat many meals during the course of the day, then they integrate exposure across the field to some degree on a daily basis. This integration has the effect of decreasing the extreme exposures from a toxicological standpoint (they eat the highest and lowest concentrations but in smaller quantities). This could both decrease and increase the incidence of effect. In either case, the frequency and size of the meal will be an important factor in the model. Finally, an additional parameter that should be considered when defining guilds and associated generic representatives is incidental ingestion of soils for those birds that forage in or on the soil.

Agency Charge

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.

Panel Response

The value of a generic species varies markedly with the purpose of the modeling. If one wants to model a population (or other) endpoint accurately and realistically, the notion of a generic species that serves as a holistic integration of species attributes is reasonable. However, short of this full-scale model, there are many advantages to using the modeling process to explore the consequence of variation in attributes across birds. That is, one can ask what the relative effect on output would be if the bird considered were a 30g bird rather than a 60g bird or were an insectivore rather that a granivore. For such sensitivity analysis, one does not want a generic bird species but rather a bird whose attributes, whilst realistic, can be varied independently in a sensitivity analysis.

Against this background, some comments may be made about the current inputs. First, the diet and nesting behavior of birds seem to be good predictors of whether a species regularly occupies corn fields or regularly occupies the surrounding habitat. There does not seem to be much room for improving on the predictability obtained from these two variables and there may in fact be a risk of over-fitting the existing field data (Best et al. 1990) at the expense of maintaining more general predictive power. Any effort to go beyond what is currently achieved with these two variables needs to be tested with new datasets and it is questionable whether the effort is likely to bring about incremental gain.

Body weight

Body weight appears as a parameter at many points in the risk assessment model; it determines the metabolic rate used, determines the surface area of the bird in the dermal exposure component, appears in the toxicity calculations, and so on. It follows that seeking to specify a single weight to be used as an attribute of a generic species whose fate will subsequently be followed is a sub-optimal strategy. Instead, it makes more sense to retain body weight as a critical variable to be subjected to sensitivity analysis. This transforms the choice of weight of the "generic species" from a critical decision with uncertain consequences to one whose criticality is known: where sensitivity proves to be low, the model is insensitive to the choice of body weight and one can make a robust choice easily; where sensitivity proves to be high, one has learned immediately that determining the weight distribution of the birds in the exposure area will allow better quantification of uncertainty. A further refinement would be to weight the body size estimates according to the relative abundance of the various species represented by these body sizes. Thus, body sizes represented by more individuals within the avian community would then contribute proportionally more to the model simulation. Likewise, one could also draw from the entire distribution of frequencies on the field for the various species and weight them according to their relative occurrences as measured by census data. Bird survey information for the relevant crop could be used to provide the data inputs for body size and frequency on field. A major compilation of body weights for much of the U.S. avifauna is available (Dunning 1993) and provides a ready tool, by merging with abundance data for the field, to determine a distribution of weight-dependent effects.

Frequency on Field/Persistence Factors

Two other factors being considered by the Agency as pertinent to the delineation of a generic species are FOF and persistence. One must have some concern about the reliability of the FOF metric when edge species score more that 50% on the metric: is it realistic to have, by definition, a non-field species spending more than half of its time on the field? The quality of the data sources for these estimates may be the issue here. During field surveys the FOF metric could become inflated by a census bias against effectively detecting edge species while they are in the edge habitat. The other possibility is that the processing of the empirical data in search of an appropriate metric may have involved assumptions not met by the data. This suggests, as with body weight and other data incorporated in the model, that sampling from the empirical data distribution and calculating the resulting distribution of outcomes (and its sensitivity) would be a better analytical strategy than selecting a point metric.

The Panel agreed that one of the smaller species on field is the best selection for the generic species, because they are the most vulnerable species. Including low weight and high sensitivity as characteristics for the generic species offers a better representation of young birds or nestlings which are more sensitive and may cause more drastic population declines if removed from the population. Also at this level of refinement some conservatism is desired.

When considering the persistence metric, two scenarios exist. One is that of serial correlation, the idea that the state of the bird (e.g., feeding versus non-feeding) is a function of its state in a previous period. Some data (McFarland (1994) suggest that this effect takes place on the order of minutes, too short a resolution for the issue to matter with the one hour time step currently in use. The second pathway to overt persistence is that generated by territorial or similar behavior on the part of the bird. A territorial bird is indeed more likely to be seen feeding at a later time where it was seen feeding earlier but this is more a form of location preference than a true persistence. A practical line of investigation of this point that the Agency might consider is to conduct sensitivity analysis of the persistence variables as currently incorporated in the model. If the persistence variable proves to have low sensitivity, there may be a case for discontinuing its incorporation into the present model, on the grounds that assessing persistence empirically is then a difficult task with little significance for the behavior of the model.

As described above, a key idea is that greater reliance on exploring the consequences for the output of sampling across the empirical distributions of variables of potential interest is preferable to trying to determine the safe (in terms of risk minimization) values of specific inputs to use. Instead, one can bound the distribution of output in terms of what risk levels one will consider, with the use of distributions of input variables revealing how sensitive these bounds are to the individual variables. This is a general principle of stochastic modeling that should underlie further sophistication of the modeling approach being developed here.

Agency Charge

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.

Panel Response

Assuming obligate feeders for granivore, insectivore, and herbivore and acknowledging that omnivore exposures would be bracketed by these groups, this is a reasonable Level II approach. While this approach is supported by the Panel, the following issues should be recognized: (1) the guild omnivore encompasses the greatest number of bird species and it covers a broad range of proportional feeding on plant and animal foods; and (2) during the breeding season, many adult granivorous birds become omnivores, but the vast majority feed their young exclusively an animal food diet. Spatial aspects of exposure are also absent in the current model, and should be included in the future. Furthermore, the analysis does not currently incorporate changes in food habits associated with insect "knock down", i.e., greater availability of poisoned prey immediately following spray. Field use may vary immediately after chemical application. These behaviors should be evaluated at higher levels.

Given the paradigm suggested above, generic species (appropriately defined) are appropriate for Level II analyses. Focal species could then be included in Level III and IV models. Here, population impacts would also be modeled.

The Agency discounted the effect of seasonal changes in the height and basal area of the plant canopy when assigning values to generic species variables. Seasonal changes do occur and in many cases they can significantly influence both the body weights of birds on fields and their frequency on fields. Furthermore, both the foraging substrate and food type can change. For example, in cornfields the shift is from less consumption of seeds to more consumption of insects. Also the foraging substrate would change as well, from predominantly ground-dwelling food items to items found on the developing plants (as discussed in more detail in response to question 1). Assigning values to generic species variables should take into account temporal changes in food type, food substrate, and frequency of occurrence on fields.

Using the 5th percentile of body weights is conservative and could generate a generic species that does not exist. In a fully probabilistic assessment, a distribution of bird sizes within each guild is probably more appropriate. It should be noted that FOF is actually the 95th confidence interval on a mean value (not the 95th percentile). This may not be an appropriate statistic. Perhaps dealing with this as an uncertainty analysis selecting specific values for FOF would be more appropriate. An explanation of FOF parameterization is important for communication purposes. Treating FOF as a distribution may not be possible and may be confusing. Selected values represent a scenario approach. Such an approach is consistent with discussions at an earlier Monte Carlo workshop.

The only herbivores listed are Canada Geese and Widgeon. The Panel believes granivorous birds will consume some green herbaceous food. Does the model adequately cover these birds as noted previously? Many species change from granivorous to insectivorous during the breeding season, and the model should reflect avian feeding strategies during the season in which applications are planned. That is, if the planned use is during the spring-summer, granivorous birds should be adjusted to mostly insectivorous.

Agency Charge

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.

Panel Response

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. The Panel believed the general approach of the bimodal feeding pattern allows a more realistic description of time-dependent foraging and an improvement over the previously used 12-hour time step. However actual feeding patterns do not normally drop to zero at midday. This observation is based on a procedure which used two betapert distributions with non-overlapping time ranges. However, it is recognized that feeding intensity can take on a range of values that may be influenced predictably by daily and seasonal influences on the birds' operative temperature and breeding/migration status. Still other behaviors might be influenced by random events (e.g., flight from predators, other climate variables). Thus, the model, as presented, may not be representative for all species for all times of the year. However, the written description of the model shows the feeding pattern as a general mixture distribution that would not have this problem.

It is important to differentiate between the model as represented by equations in the code and the data used to drive the model. A stochastic modeling approach needs to be based on realistic ranges of data for all inputs. The model as presented in its written form is adequate to realistically describe foraging patterns. However, care must be taken with the constraints imposed on data input. Stochastic realizations using multiple sequential conservative assumptions can, and often do, lead to unreasonable outputs. Nonetheless, the stochastic modeling approach yields a range of plausible outputs when models are appropriate and reasonable data are used (e.g., bird mortality estimates). The risk manager then sets a level of protection that is used as a threshold for comparison to these plausible outcomes.

The algorithm used to generate the bimodal feeding pattern should be able to vary the periodicity and amplitude of the bimodal pattern to reflect deterministic and stochastic influences on bird behavior. For example, the Agency's background document indicated that the beginning and ending times of both the morning and afternoon feeding periods are assumed to vary randomly each day, within specified time windows. This is not likely the case. Beginning and ending feeding periods are influenced strongly by photoperiod which does not vary randomly. Moreover, adult altricial birds that are provisioning nestlings most likely would have a more uniform feeding distribution throughout the day (lower amplitude, i.e., smaller distance between peak and trough for feeding intensity). The transitions at midday would be more gradual. Additionally, egg laying can significantly alter the foraging behavior (duration/intensity) of females.

To achieve a more realistic bimodal foraging pattern, bird behavior could be defined by a mixture distribution where the time ranges for the morning and afternoon could overlap. If the morning and afternoon feeding regimes were to be defined by beta distributions instead of betapert distributions (requiring one more user input parameter for each portion of the day), more realistic scenarios could be modeled. The strength of a general approach also can be a short coming at times in that it allows data inputs that may not be realistic. Conceivably, one also could model a foraging behavior that was uniform across the daylight hours or was highest at midday. Similarly, a foraging pattern distribution could be developed that forces more food intake to occur in short periods of time than the bird can actually physically process.

Most Panel members agreed that the Markov chain approach allowed a realistic characterization of serial behavior. The Markov chain model allows the characterization of the bimodal feeding pattern typical of many bird species. It also can simulate a wide range of bimodal feeding patterns (e.g., different start and end times, different durations and intensities, etc). The major weakness of the feeding behavior algorithm is that it does not allow the use of distributions to represent frequency and persistence on field variables. Clearly, there will be much inter-individual variability for both of these variables and distributions should be used to represent this variability. In situations where data are lacking to develop distributions, then the Agency should consider re-phrasing the analysis to be specific only to individuals that spend a large component of their time on fields (e.g., 90%).

<u>Agency Charge</u>

b.) Please provide additional suggestions for modifications in the algorithm to more closely represent avian activity patterns.

<u>Panel Response</u>

The Panel was divided on the optimal time step of the model. Some members of the Panel believed that an even shorter time step (e.g., on the scale of minutes) would even better reflect avian foraging patterns, especially for small birds, given that many bird species move in and out of fields many times in an hour when they are actively foraging. However, it was also acknowledged that increasing the time step resolution would increase the computational time and data storage requirements for the simulations. Other Panel members believed that hourly time steps are a reasonable compromise between competing time step choices, especially for a Level II model in a tiered modeling system. Although, in most cases, birds that are not field residents likely feed at much shorter intervals, it may be that the 1 hour time steps reasonably reflect cumulative feeding activity. The serial correlation model allows the bird to stay feeding on the same field for several hours or to move off and on the field more rapidly. Finding the correct data to drive the model will be a challenging task. Radiotelemetry studies may provide the data that support different input choices. A sensitivity analysis should be conducted to assess the importance that shorter time steps on oral, dermal, and inhalation routes of exposure might have on mortality estimates.

The assumption that field-resident birds are off the field during non-foraging periods if they started the day off the field (and vice versa) is dubious for those species that nest or spend most of their time on the fields. This assumption impacts exposure estimates from dermal and inhalation routes of exposure. Exposure via these routes continues during non-foraging periods, but only if the birds are on the fields. Time on field should be based on a distribution of species weighted by their relative abundance per sampling effort (from census data). Therefore, as the model sophistication improves at Levels III and IV, the Agency should add the capability to use distributions for the frequency and persistence on field variables**.**

The use of Markov Chain models raised different perspectives by the Panel. The Markov Chain model should continue to be run during non-foraging times to account for bird movement in and out of fields. This information is required to properly estimate dermal and inhalation exposure during non-foraging times.

Other Panel members believed that the model could be simplified even further by removing the Markov chain aspect of the model. These Panel members believed that the gain in simplicity would ease computation burdens and concerns about transition probabilities affecting the output. It was determined that the bimodal distribution for feeding intensity could be reinterpreted as feeding intensity on the field. If the Markov chain model is to be retained, then the model should be modified to account for diurnal variation in the birds' movements (Klein and Macdonald, 1980).

One concern several Panel members had regarding the nature of generating the distributions for field persistence and transition probabilities was how the model predicted levels of risk when known biological processes were specified. For example, exposure to pesticides may alter the distribution or abundance of prey through time and thus affect energy return during foraging, which in turn will influence transition probabilities (e.g., low rate of energy return would yield low likelihood of returning to the foraging patch). Additionally, exposure to a pesticide also might induce illness which would promote conditioned avoidance of the foraging site or inactivity via pesticide induced anorexia. There is a need to model whether a bird temporarily stops eating when exposed to pesticide. Mineau (2001) suggested that small birds may be especially vulnerable to pesticide exposure because they cease eating and die from lack of food.

Simulations based on changing the distribution of field persistence to reflect well described biological processes would prove instructively valuable (i.e., determining the risk of mortality associated with various levels of site fidelity as might be influenced by foraging return rates or degree of illness, by implication, and degree of site avoidance).

It is not clear how residues on foods (seeds, foliage or animal matter) are determined or selected during the modeling process. Are these fixed values, or are they selected from a distribution? The latter would be preferred.

Birds with territories larger than individual fields and their edges, may also be impacted by chemical use as they may serve as integrators of broader contamination within agro-environments and suffer or benefit from chemical interactions. The tools for landscape level analyses are available and the Panel believed that this will help the Agency address issues of cumulative exposures and population impacts in higher tier analyses.

Agency Charge

b.) 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.

Panel Response

A sensitivity analysis should be conducted to assess the importance that shorter time steps for oral, dermal, and inhalation routes of exposure might have on mortality estimates.

Birds ingest soil particles, either as grit or incidentally. This fact should be considered in calculating dosage estimates. Processing rates for food could be included in refining on field occurrence and transitional probabilities.

Time on the field should be derived from radio telemetry studies characterizing the distributions of temporal field use. The Panel recognized that such detailed data may not be widely available. Thus, time on field should be based on a distribution of species weighted by their relative abundance per sampling effort (from census data).

Simulations for biologically-realistic scenarios should be run and compared to extant data on behavior patterns derived from telemetry or census data to determine whether the model adequately characterizes field behavior of birds.

The lower right diagram in Figure 3-2 of the Agency's background document most closely mimics bird feeding behavior. The most abrupt increase in feeding would likely occur just after an overnight fast and the most abrupt decrease would occur just before the overnight period. The transitions at midday would be more gradual. When considering whether organisms are reproductively active, it should be remembered that insect (pest) emergence and avian reproductive cycles are closely tied. In evaluating insecticides, reproductively-active birds should be assumed

The Agency's background document indicated that the beginning and ending times of both the morning and afternoon feeding periods are assumed to vary randomly each day, within specified time windows (p 11). This is not likely the case. Beginning and ending feeding periods are influenced strongly by photoperiod which does not vary randomly.

Current practice is to use Fletcher's (1994) summary statistics of mean and standard deviation to develop distributions of plant residues for model input. The Panel noted that environmental datasets for items like residues often are not normally distributed and the use of mean and standard deviation introduces bias into the distributions generated by such statistics. ECOFRAM attempted to assemble Fletcher's original datasets as well as those for insects. Because these inputs are basic to Model Version 2 risk analysis, the Panel believed it would be beneficial for the Agency to complete this process. The Agency might also consider using food datasets directly to eliminate a potential bias when a normal distribution (or some other distribution) is assumed, or at least re-evaluate the assumption of normal distribution by thorough re-examination of the data.

Regarding dissipation rate constants, it was noted that linear regression was used to generate first-order rate constants. Most often with dissipation datasets, the use of first-order linear regression does not provide a good fit to observation(s). The use of linear regression produces bias that can largely be removed through the use of nonlinear regression. Nonlinear regression provides a much better fit, and it is suggested that it be used instead to capture more adequately the observed patterns of dissipation.

There also appeared to be use of mean half-lives calculated from multiple half-life values. If means are used as input, then it is suggested rate constants from the regressions be averaged first and then calculate the corresponding half-life if desired. Performing the reverse (averaging the half-lives and then calculating rate constant) does not generate the same value as averaging of the rate constants themselves. Because it is the rate constant that is derived from the regression, it would be the more appropriate metric for averaging. As in the discussion on food residues, rate constants in nature are far from being constant and are not necessarily portrayed well by normal distributions. The Agency might consider using rate constant datasets directly rather than assume a normal distribution via the use of means and standard deviations.

Agency Charge

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.

Panel Response

Because the Panel's responses overlap the issues presented in questions A and B, the questions are answered as noted below. The Agency had the difficult task of further refining a puddle algorithm to account for a number of parameters that affect puddling, primarily during rainfall events in agro-environments. The improvements were based on the recommendation of the SAP in 2001 (FIFRA Scientific Advisory Panel, 2001) who indicated that although the Version 1.0 approach for modeling avian exposure through drinking water seemed reasonable, the puddle scenario should include consideration of amount and duration of rainfall, evaporation, soil infiltration rates, plant cover, temperature, chemical partitioning, chemical degradation, and topography.

The main purpose of the puddle algorithm is to simulate the quality of the drinking water for birds. Specifically, this routine calculates both the puddle duration and the pesticide concentration in a puddle on the field deterministically. The proposed algorithm addresses amount and duration of rainfall, soil infiltration rates, evaporation, degradation and the stochastic nature of field topography and its relation to puddle formation and duration.

The algorithm assumes that there is only one puddle in a field. During times that the puddle is dry, the birds are assumed to drink non-contaminated water. Pesticide mass balances are calculated separately for the field and for the puddle. The simulation distinguishes periods with and without rain. For periods without rain, the puddle algorithm calculates separate pesticide mass balances in a mixing zone in the field and in the puddle, assuming that pesticide dissipation follows a first-order reaction rate. During runoff-producing rainfalls, water from the field runs into the puddle. The algorithm for calculating the pesticide concentration assumes that the concentration in the mixing zone, runoff and percolation is the same at any time. After the rainfall, the puddle diminishes due to evaporation and infiltration into the soil.

The Panel found that the mathematical structure of the puddle algorithm was appropriately simple for Level II where only readily available data are being used. Later in this section, suggestions are made that could decrease the overall running time of the algorithm. This will then allow for including a stochastic representation of the process.

The Panel's comments on the puddle algorithm are divided into three sections. First the scenarios and the physical situation modeled are discussed, followed by possible changes in the algorithm that may be considered by EPA for possible inclusion. Finally the use of the puddle algorithm within the overall avian risk assessment is discussed.

Scenarios and Physical Situation Modeled

The current scenario of simulating only one rainfall event sometime after application was seen by several Panel members as a limitation. Because rainfall only occurs after application, the algorithm does not include direct overspray of existing puddles because it rains only subsequent to spray events. This will significantly underestimate risk because initial concentrations are likely greatest in shallow waters immediately after direct overspray. Model assumptions of instantaneous equilibrium of the pesticide concentration between sediment and water will likely underestimate risk from over-sprayed puddles even if the model includes these puddles at the time of spraying. Additionally, the model does not include capture by foliage and assigns all pesticides to the soil itself. Although this initially may appear to be a conservative assumption, it is not if the pesticide that is washed off the leaves is not immediately adsorbed by the soil. Because the time that equilibrium is reached is not in the current data base, a conservative assumption would be that there is no adsorption for a period directly after spraying. The duration of this period should be based on actual field experiments (Mellott et al., 1990; Brewer et al., 1990).

The Panel generally disagreed with the scenario of a single puddle in the field and puddle sizes that did not discriminate between different parts of the country. There are many different size puddles in a crop field. The shape and size of puddles may vary with crops, geographic locations, agricultural management practices, and many other factors. Although the concentration likely will not be much different between the puddles, the duration of water standing in the puddles will vary greatly between the different sizes. In terms of modeling of multiple puddles, another important issue is how to deal with the interactions among puddles in the field, which include both water quantity and quality interactions. To deal with a field scale problem, the Agency may need to account for the hydrodynamics and pesticide fate and transport in a number of puddles of varying sizes, and, in particular, their interactions. By all means, the relationship of the puddle (or puddles) and the field should be considered in the model.

Daily rainfall is currently used instead of shorter time steps. Intense rainfall of a given amount over short periods will run off much more than will light rains of the same total amount spread over a 24-hour period. This issue raises the point that multiple rainfall events should also be modeled. Longer modeled time intervals and multiple rain events are supported by data from field studies in which: 1) dormant spraying produced a bimodal mortality that occurred with one maximum in the first few days following application and a second over two weeks later (Cobb and Hooper, 1995; Cobb et al., 2000; Mellott et al., 1990) and 2) multiple rainfall events soon after pesticide application coincided with avian mortality (Brewer et al. 1990; Brewer et al, 1992; Mellott et al., 1990, Tank et al., 1992).

To discriminate between the formation of puddles in different regions, knowledge of the hydrology for the particular regions and field are important. For many years, it was believed that the occurrence of surface runoff was primarily controlled by the infiltration characteristics of the ground. Specifically, it was thought that runoff was generated whenever rainfall (or irrigation) occurs at a greater rate than the soil's infiltration capacity. This is termed either ”Hortonian runoff” or "infiltration excess overland flow". This process is very important in many areas of the country on bare fields with little organic matter (where significant soil crusting and/or surface sealing occur during rain events). In these areas, puddles form in depressions filled by runoff from the surrounding area.

However, the Hortonian runoff concept does not meaningfully explain storm runoff in many of the humid regions of the US, where the infiltration capacity of the ground is typically much greater than average rainfall intensities. Many researchers have found that the typical values published in soil surveys for disturbed samples underestimate the true field conductivity of vegetated soils by a factor of 10 or more due to the presence of preferential flow paths in the form of worm channels and root passages (Steenhuis et al, 1994; Walter et al., 2003). In these regions, runoff is most commonly generated on relatively small portions of the landscape that are susceptible to becoming completely saturated (i.e., the puddle areas). This runoff type is called saturation excess overland flow. Areas prone to saturation have either a high ground water table or a hardpan (fragipan) at shallow depth. Interflow in concave hillslopes can also result in the formation of saturated areas at the bottom of slopes, seeps and ditches. Puddles in these areas can be persistent during times of the year when precipitation exceeds the potential evaporation. In this case, the puddles are the source of the runoff and do not necessarily have run-on from surrounding areas. As rainfall continues, the saturated area grows in extent, increasing the area generating runoff (hence the term variable source area, VSA). Examples of regions in the USA where VSA hydrology is significant include the Northeast and the Pacific Northwest as well as forested mountain areas in the US. The Panel recommended that the Agency take a regional approach to puddle formation. Experts in each of the regions should give advice on the puddle formation characteristic. Simplifying the pesticide routine will allow the Agency to model several puddles on the field, all with the same concentration but with different depths and duration. As a starting point for further evaluation by the Agency, Onstad (1964) might have information about puddle characteristics.

In the current level II model, the puddle algorithm is entirely deterministic. One rainfall event is considered that occurs sometime after pesticide application. The time and occurrence are input parameters. If this rainfall event produces runoff, one puddle fills up in the middle of the field. The entirely deterministic nature of the model was questioned by the majority of the panel members because of the numerous sources of uncertainty as input parameters (e.g., mixing zone depth parameter, contributing area, puddle size, rainfall amount and duration). One Panel member noted that using conservative input values or assumptions will lead to extreme predictions (due to compounding conservatism), particularly given the number of variables required by the puddle model. Other panel members noted that large storms and multiple rainstorms should be considered.

Selecting and parameterizing distributions for all of the variables in the puddle model would be an onerous task. To deal with this issue, sensitivity and elasticity analyses should be employed to identify those variables that have the greatest influence on model predictions when uncertainty and variability are considered. Only the most influential variables need to be treated as distributions in future iterations of the model. This will be discussed in the following sections.

Model Structure

One of the basic underlying principles of the models at Level II was that only easily available data are required as model inputs. Therefore, the use of first-order degradation rates and linear adsorption partition coefficients are appropriate despite the fact that there are more sophisticated formulations available to describe degradation and adsorption. These assumptions may be too conservative only in the case of direct overspray onto a puddle.

Periods without rainfall

The mass of the pesticide disappears according to a first-order degradation rate for the pesticide adsorbed on the soil and in the water. The inclusion of separate degradation rates for sediment and soil is interesting but the data are not likely available. Assuming a single overall degradation rate, the amount of pesticides in the mixing layer is:

(1)

$$M_{1,mix} = M_{0,mix} \exp(-\mu t_e)$$

where $M_{1,mix}$ is the pesticide mass in the mixing zone at the time the storms starts, $M_{0,mix}$ is the initial mass in the mixing zone at time t=0 , t_e is time when the rainfall starts, μ is the overall first-order degradation rate in the mixing zone. Several panel members thought that additional pesticide removal mechanisms such as volatilization and/or photodegradation should be taken into account. Note that the units for the mass are kg/field or better kg per unit area. Here we will use the mass per unit area because that it is the more standard way of reporting the equation. We also will use metric units throughout.

Periods with rainfall

To model the dynamics of the puddle algorithm during periods with rainfall, both hydrology and pesticide transport contaminant hydrology need to be considered.

Hydrology

Understanding the hydrologic basis for water and contaminant transport is essential for meaningful monitoring of surface and subsurface water quality. The considerations of hydrology by the Agency seem to be based on the conventional “infiltration excess overland flow” because all parts of the landscape are participating in the runoff process. As mentioned above, in some areas saturation excess overland flow (where only part of the landscape is participating) is more common. However, because infiltration excess is more conservative, saturation excess and other runoff mechanisms do not have to be included in Level II analysis.

According to the model documentation, runoff starts as soon as the rainfall starts. This is unnecessarily conservative. As can be seen from the SCS equation (i.e., runoff starts only when p> Ia), viz:

(2)

which is equally valid for the English and metric systems. Thus q is the cumulative amount of runoff (cm), p is cumulative amount of rainfall (cm), S is storage of the watershed. I_a is initial abstraction or the amount of rainfall that occurs before runoff can start. There is much current debate on how to calculate the initial abstraction, I_a, and whether it is equal to 0.2 S, another fraction of S, or completely independent of it and should instead be calculated with, for example, the Thornthwaite Mather (1955) procedure (Steenhuis and van der Molen, 1986). The Agency should consider making this equation stochastic as presented later in the Agency’s presentation describing aquatic risk assessment.

Independent of the method chosen to calculate I_a a certain portion of the rainfall infiltrates before runoff occurs. Assuming steady-state rainfall using the metric system, the time that runoff starts after initiation of rainfall, t_r, is:

(3)

$$t_r = \frac{I_a}{p/T}$$

where T is the storm duration.

The runoff rate Q per unit area is then (again assuming steady state)

(4)

$$Q = \frac{q}{T - t_e}$$

The assumption of steady state rainfall and runoff rates needs to be tested. The 2001 SAP and one Panel member of the current Panel indicated that they likely wanted to include a realistic rainfall distribution, but it is doubtful (even if the rainfall distribution is known) if this refinement is necessary at Level II. As will be described later, it is the cumulative amount of rainfall that drives the pesticide losses during the rainfall event. The degradation of the pesticide (which is dependent on time) during the rainfall/runoff is likely only a small part of the total loss.

Contaminant Hydrology

The contaminant hydrology calculates the mass of pesticide in the field differently from that in the puddle.

Mass Of Pesticide On The Field

By assuming that the concentration of the pesticide in the mixing zone, percolation water and the runoff are identical, the amount of pesticide in the mixing zone can be simply written as a function of the total rain (Eq. 4) and as reported correctly in chapter 3 of the Agency's background document as Eq 3-30.

(5)

$$M_{mix} = M_{1,mix} \exp\left[- k_{field}\left(t - t_e\right)\right]$$

Note that k_{mix} and later renamed to k_{field} in the document is equal in its most elementary form to $k_{field}=(\mu + p/W)$ where μ is the first-order decay rate of the pesticide, W is the apparent water content per unit area of the mixing zone, and $W = H(\theta_s + \rho K_d)$ where H is the depth of the mixing zone θ_s= the saturated moisture content, ρ is the bulk density of the soil and K_d is the adsorption partition coefficient. Equation 5 can be rewritten as:

(6)

$$M_{mix} = M_{0,mix} \exp(-\mu t) \exp\left(-\frac{p}{W}\right)$$

In addition, note that evaporation is neglected during the rainstorm (which is fine). It should therefore be taken out of the mass balance of the water for the mixing zone in Eq. 3-32 in the Agency's background document.

For calculating the mass of the pesticides in Eq 6, the two important parameters for a given pesticide and mixing depth are the cumulative amount of rainfall and the amount of degradation after application. Eq 6 is insensitive to how much water infiltrates and runs off. This is not a deficiency in the field model. It is important to acknowledge this as it could be a significant simplification in the models. However, for calculation of the mass of pesticides in the runoff, the hydrology is important because it depends on the amount of runoff. However, unlike runoff models in which we are interested in the mass of pesticide leaving the field, for avian risk assessment we are only interested in the pesticide concentration in the puddles.

To calculate the mass of pesticide in the puddle, the current pesticide algorithm assumes that overland flow containing dissolved pesticides runs into the puddle. Soil loss is neglected. The puddle fills up and then the water and dissolved pesticides run out of the puddle. Degradation occurs as well. Inherent assumptions (not stated explicitly) in the derivations are that the puddle fills up but does not grow larger in time. There are steady state water fluxes; runoff starts when the rainfall begins; and there are equilibrium conditions for pesticide concentration in soil and water.

Neglecting soil loss poses a limitation that only a pesticide with an adsorption partition of approximately less than 10 cm^3/g can be simulated realistically. For others with higher adsorption partition values, the sediment in the runoff can contribute a significant part of the pesticide mass in the puddle. However, the concentration in the water might not be affected because the algorithm only considered a small mixing zone and soil that is moved has the same concentration as present in the puddle.

In order to calculate the mass of pesticide in the puddle, the current pesticide algorithm assumes that overland flow containing dissolved pesticides runs into the puddle. The algorithm only considered a small mixing zone and soil that is moved during runoff contains the same pesticide concentration as present in the puddle. Furthermore, soil loss is neglected. The puddle fills up and then the water and dissolved pesticides run out of the puddle. Degradation occurs as well. Inherent assumptions (not stated explicitly) in the derivations are that the puddle fills up but does not grow larger in time. There are steady state water fluxes; runoff starts when the rainfall begins; and there are equilibrium conditions for pesticide concentration in soil and water. The Panel suggested that the Agency could follow a simpler approach. First, the runoff should start after the initial abstraction is met. Thus, there is no water in the puddle until $p>I_a$. The concentration in the mixing zone at the time runoff starts can be derived directly from Eq. 6 as follows:

After the rainfall amount is greater than the initial abstraction the concentration in the runoff can be written for $P>I_a$ as:

(7)
$$C_{mix} = \frac{M_{0,mix}}{W}\exp(-\mu t)\exp\left(-\frac{I_a}{W}\right)\exp\left(-\frac{p-I_a}{W}\right)$$

which reduces again to Eq 6.

If the puddle size is small compared to the field, the dilution by rainfall of the water falling in the puddle is small compared to the overall contribution of the pesticide in the runoff. Therefore the simplifying assumption can be made that the pesticide concentration in the puddle is the same as the pesticide concentration in the mixing zone on the field (i.e., Eq 6). This will greatly speed up the calculation and makes the calculation of the puddle contributing areas unnecessary.

After the rain stops, the increase in concentration due to evaporation might be important for cases when the infiltration is much smaller than the evaporation and the pesticide has a long half life. Volatilization and photodegradation might be considered too. Because aerobic aquatic studies are performed in the dark, it is suggested that photolysis rates be added to the aerobic aquatic rates to approximate what takes place in the puddles. While most Panel members agreed, a few differed adding that the addition of these rate constants would double the hydrolysis contribution, which is a component of both photolysis and aerobic aquatic degradation. Conversely, as toxicant is degraded, there is no allowance for toxicity neutral degradation. In higher tiers, the Agency may need to consider transformation products that are of equal or higher toxicity to the parent compound.

If a new rainfall event occurs, the pesticide overland flow in the puddle soon will overwhelm any differences before the rain started. Thus, there is an assumption that the pesticide concentration in the puddle is the same as in the runoff from the rest of the field. The Agency should set a limit whereby evaporation cannot give a concentration higher than the water solubility of the chemical. It is possible that the K_d will accomplish this, but the model should be checked to make sure that at low puddle volumes the model does not allow the aqueous pesticide concentration to exceed the solubility.

Another possibility suggested by other Panel members is to simulate the rainfall and soil properties stochastically. The Agency might consider that the extent of puddling is a function of the rainfall amount. For example Steenhuis et al (1995) derived the extent of the fraction of the field within the puddle area.

Before time is invested in the additions suggested, a sensitivity analysis should be performed to determine if having multiple puddles changes the overall risk prediction significantly. Also the data might not be available under Level II. If there is no or minimal effect, then the modifications suggested may be omitted. It would be informative to present to future peer review panels any data demonstrating lack of model sensitivity to given parameters.

Puddle algorithm and the overall avian risk assessment

Overall, the text describing the puddle model is incomplete because it does not describe how birds will sample the puddles. The Agency indicated that if puddles are on the field, birds obtain drinking water from this source during the last hour of the feeding period. Otherwise, birds obtain necessary free water from dew in the first feeding hour of the day. This information should be added to the text. It is also not clear how birds choose from multiple puddles on the field (which presumably have different concentrations). A random walk model could be used to simulate puddle selection over time, but this is more likely a Level III approach. A simpler approach is likely required for Level II. Whatever the approach, it needs to be described.
It was noted that the number and size of puddles may influence wildlife use (songbirds vs. waterfowl).

One Panel member noted that other exposure pathways might include birds bathing in the puddles and then preening, which is a significant activity, or simple skin absorption from bathing.

The Level II model includes several routes of exposure (i.e., dermal, inhalation, drinking water ingestion from puddles) that are not included in the Level 1 model. For pesticides in which these routes of exposure are important, the ostensibly less conservative Level II model could lead to higher risk estimates than the Level I model. This situation needs to be rectified by adding the dermal, inhalation and puddle routes of exposure to the Level I model.

The SCS-CN method is used for runoff simulation in the new puddle model. Also, the simulated runoff from a certain "effective area" is assumed to fill the simulated puddle. Conceptually, using the SCS-CN method in such a way is inconsistent with the original methodologies/assumptions and thus can be questionable. First of all, there are many puddles of varying sizes in a crop field. The area of puddles is an essential portion of the field domain. According to the definition of the initial abstraction (I_a) in the SCS-CN method, it includes surface depression abstraction, infiltration, and evaporation. This means the initial abstraction has already included the water that fills puddles. The SCS-CN method also implies that all surface depressions (puddles) have been fully filled when the cumulative rainfall is greater than the initial abstraction and hence runoff starts. In addition, the simulated runoff is the water that should leave the field and flow towards an outlet through stream channels. Thus, the lumped SCS-CN method cannot provide any local overland flow information within the field and hence does not allow us to examine how a puddle is filled. The runoff simulated by using this method cannot be used to fill puddles. The Agency may need to consider these critical issues during the model modification.

<u>Agency Charge</u>

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.

Panel Response

The Agency's efforts to modify the existing PRZM algorithms are laudable. While the Panel believed that a simple model is the preferable approach, the extant model will benefit from the following:

(1) Consideration of air-soil interaction..
(2) Consideration of interaction of canopy air with the air above the canopy. Both of these interactions can be easily incorporated.
(3) Expand the model to allow evaluation of granular products.
(4) Expand the air modeling and associated inhalation exposure calculations to include edge habitat.

Even though soil volatility is not considered in the model, Equation E1-8 on P7 of Appendix E of the Agency's background document contains an expression for volatility from soil. This equation or some approach must be employed in the vaporization module of the model. Also, PRZM is a root zone model designed to predict runoff and not to predict pesticide inhalation. Therefore, the PRZM algorithms that used mean canopy assumptions need to be modified, but using the PRZM basis algorithms for pesticide diffusion from soil into air is a good starting point.

An alternative to the equations presented by the Agency is presented in the following equations. Beginning with the Agency's approach in Equation 3-51.

Figure 2. Possible Intermediate Complexity Model for Contaminant Movement Among the Soil Plant and Air Compartments Considered within the FIFRA Level II Probabilistic Risk Assessment.

The mass balance from Figure 2 follows.

and has the following steady state solution:

This approach allows simple solutions if rate constants are known or can be approximated, as seen in the following example.

When considering pesticide evolution from soils, it is also reasonably well known that when aerosols move through vegetative canopies, the canopies serve more as initial sinks then serve as sources at later time steps. Several studies provide some information regarding plant interaction with volatilized pollutants (McLachlan and Horstmann, 1998; Reiderer 1990; Smith and Thomas, 2001; Mueller and Hawker, 1994). It is entirely possible that the lower surfaces of lower-level vegetation can adsorb pesticides early in the flux event and then release these pesticides slowly. This could provide a time-dependent bimodal flux within the canopy. This type of phenomenon would explain the empirical data at lower heights (Chart 3B Appendix E, p.32 of the Agency's background document). More empirical data are needed especially at lower heights to allow evaluation of the need for such refinement in the model. This is because chemical behavior higher in the canopy is more thoroughly described in the literature.

The acceptance of air/soil partitioning as a mainstream research area of environmental chemistry has facilitated a reasonable body of literature containing empirical data for toxicant volatilization from soils. Most of these data for semivolatiles indicate reasonable correlation of volatilization with soil organic matter.

Concentrations of fumigants in air from fumigant application to soil have been modeled (Cryer, van Wesenbeeck and Knuteson 2003; Cryer and van Wesenbeeck 2001). This could be used to evaluate the final model designed by the Agency.

There is no degradation kinetic term in the atmospheric model. Photolytic degradation should be evaluated to see if such terms are likely to matter. If degradation does matter and conservatism is desired in Level II, degradation can be omitted until the Level III refinement.

A refinement that should be considered in higher levels is that gaseous diffusion (Da) is not dependent solely on molecular weight. While this may provide a reasonable first approximation, better estimates are available. There are several refinements to this estimation the first of which evaluates molecular volume and can be computed simply using equations derived by Arnold and described by Braman **(**1971**)**. Perhaps less well evaluated in atmospheric studies is the fact that for polar pesticides (OPs, carbamates, triazines) the potential for hydration is significant under normal atmospheric conditions. As an example, singly hydrated butanol has a measured diffusion coefficient that is 22% lower than that of anhydrous butanol (Cobb et al 1989, 1991). OP pesticide with a MW of 200 g/mole that was singly hydrated should have a decrease in Da that ranges from 5% to 18% compared to the anhydrous molecule. These ranges can be input into model simulations to determine if there is a reason to consider hydration in humid environments.

For avian exposure, the approach in Appendix F of the Agency's Background Document incorporates spray drift into areas off the field. This approach appears reasonable. The Agency should continue consideration of spray drift and transport via volatilization after application as shown in Appendix F. This would significantly alter the area of impact following application and will require probabilistic sampling estimation of forage, dermal, and inhalation exposure from edge habitat within the spray drift zone. At Level II, it is likely to be acceptable to assume that time in edge habitat will provide exposure to the average concentration in the edge.

It would be useful to have criteria established that would determine whether this module is turned on or turned off. For pesticides with a very low Henry's Law Constant or vapor pressure, exposure via inhalation would be very low. In these cases, there is little benefit to including this module in the exposure analysis.

Agency Charge

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.

Panel Response

This is a well-considered and carefully researched approach to addressing the SAP's previous comments. Within the limits of current knowledge, it probably reflects the best that can be done. The 3-fold increase in the lung relative to the oral route appears reasonable.

One of the uncertainties that should be mentioned involves the assumption that there is little difference between the physiology and anatomy of the avian and mammalian digestive tract. The approach, accounting for differences in the respiratory tract to derive an adjustment,- presumes that the relationship between bird inhalation and oral exposure is equivalent to the relationship between mammalian inhalation and oral after adjustment for differences in relative absorption via the lung. While this is a reasonable way to begin to account for differences in the absence of other information, the baseline "ratio" might not be equivalent. Differences exist between digestive systems and among digestive systems among feeding guilds for mammals and birds. One commenter also pointed out differences associated with subsequent metabolism and storage of chemicals depending on whether it is inhalation or oral administration; the comment suggests important interactions may be present. A few studies have determined relative toxicities among birds and mammals and evaluated mechanisms of differences among birds and mammals (Padilla and Veronesi, 1988; Novak and Padilla, 1986; Ehrich et al., 1992; Amsallem-Holtzman and Ben Zvi, 1997). It would be helpful to explore these responses at a qualitative and perhaps quantitative level with respect to absorbed dose. At present, this is best handled as an aspect of the uncertainty analysis.

The Panel believes that droplet size distribution for an aerosol spray represents an important parameter to be considered. It is likely that 7 µm is too small a cut-off for inhalation exposure. The cutoff for respirable particles/droplets might well be 10 µm, but the biggest aerosol droplet that will stay suspended in air is the maximum inhalable droplet size. These larger aerosols will stick to the nasal passages, and become an oral dose.

Sensitivity analyses will be a valuable tool for exploring the implications of adjustments to account for inhalation. It might also be useful to evaluate the implication of assuming that the entire inhaled administered dose is part of the oral administered dose.

Agency Charge

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.

Panel Response

The Panel's response to this question is divided into five parts.

1. Consider direct measurements and studies for chemicals and situations where sensitivity analyses suggest that this route may be important relative to other routes of exposure.

2. The inhalation of pesticide causes a two compartment response: 1) that fraction of the inhaled dose that reaches the lungs is the "respired" dose, and is rapidly absorbed into the pulmonary circulation, and goes to the systemic circulation without passing

through the liver for first-pass metabolism (either activation or catabolism); and 2) the fraction of the inhaled dose that sticks to nasal passages, trachea, and airsacs will be a slower acting dose, largely swept to the throat and swallowed, making it an oral dose. Part of the inhaled dose will volatilize in the airways and airsacs, making it a vapor phase dose, which will then be partly expired, and partly respired. Some of the dose in the trachea and air sacs will be taken into the circulation by slower diffusion, because of the reduced circulation compared to the lung. Empirical data will be needed to evaluate this.

3. The ability of organisms to survive a dose is largely controlled by esterases in the blood and detoxifying enzymes in the liver. The Panel believed that the forms and efficiency of these esterases are dissimilar in the blood of birds and mammals. Also the activation of OPs in liver or in other tissues should be evaluated. The Panel suggested evaluating characteristics such as lipophilicity and polarizability.

4. Droplet size has big implications for dose because it increases as the cube of the diameter (a 10 µm droplet is 8 times as large as a 5um droplet). The selected maximum respirable droplet size *is likely to be* too small. Sensitivity analyses would be useful for exploring the implications of a reasonable range of sizes. Upper bound in the model is 7 µm, but the Hayter and Besch data in Appendix D show that 7 µm is well respired, and no data exist for larger droplets. We need to know what the aerosol droplet distribution is before any assumptions can be made. Any droplet that gets through the nasal openings could be part of the oral component of the inhaled dose as discussed above.

5. The model does not include a pathway associated with the soil. The inhalation route only considers direct spray and volatilization from foliage, not volatilization from soil. However, in orchards 2/3 of spray hits the ground. What is the fraction in crops? This fraction should be included in the volatilization estimation. The fraction that hits the ground will change during the crop cycle. As more foliage develops, less spray will hit the ground. The model now incorporates changing foliage, and could adjust the proportion of spray hitting the ground.

Agency Charge

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.

<u>**Panel Response**</u>

The model does not factor in differences in foot morphology (e.g., webbed vs. non-webbed feet) although this could significantly affect exposure. For a ground bird, the surface area of the foot in contact with pesticide might be modeled as: the surface area of the foot times the hopping rate (number of hops per minute, or steps per minute for walkers) times the concentration of pesticide on the soil surface. Soil contact in this scenario would be cm^2/min. Saturation of body surface needs to be addressed, but this must be measured, not modeled.

The general model considers foliar contact but does not address dermal exposure through contact with soil or from 'wet' foliage immediately post spray when residues are most likely to be dislodged from the substrate. Nor does it include dermal absorption from foraging in puddles. The omission of contact with the soil raises concern given that many (if not most) application scenarios would result in some pesticide reaching the soil surface, and many of the birds associated with treated areas forage on the ground. Dermal exposure must include contact with soil. The ground-foraging birds all pick up pesticide through their feet. Raptors pick up spray by perching on sprayed limbs while perching/hunting in sprayed orchards, where they can find debilitated ground birds. Additionally, choice of carrier or adjuvants can influence dermal uptake. For example, absorption of parathion by hawks through their feet when perching in almond trees was facilitated by the dormant oil included in the formulation/tank mix. (Henderson et al.,1994)

The Agency's approach does not factor in the percent plant canopy coverage at the time of application and its effect on the proportion of pesticide applied to the ground versus intercepted by the plant canopy. Plant interception would differ before and after foliation and as crop plants emerge and develop. Temporal changes in the plant canopy coverage could, and should, be taken into account in higher tiers of the model.

Use of a pickers' hands model to simulate dermal exposure by birds does not seem adequate. The variance is very high, and may be due to different crop scenarios. Choosing the most appropriate crop analogy might help, but will still be very limited.

Dermal contact for the non-feeding period is underestimated. For ground birds it is continuous exposure from spray landing on soil. For raptors it is continuous contact with sprayed limbs. Henderson et al. (1994) demonstrated that red-tailed hawks in California typically receive significant dermal exposure to pesticides. Here, with respect to inhalation, air movement does not necessarily result in a decrease in airborne concentrations/depositions.

Topography and air temperature can influence concentrations of pesticides in the air through volatilization and movement to depressions with cooler air, e.g., prairie-potholes, that can serve as 'sinks'. Henderson et al. (1994) and Bartkowiak and Wilson (1995) both demonstrate very different kinetics for dermal absorption and effects. The empirical data from these studies should be incorporated into the model. Important issues that deserve attention are: (1) dermal absorption is slower than oral uptake, (2) time to effect with OPs is longer, and (3) time to recovery is very much longer (40 days vs. 3 days).

Face and eyes will be heavily exposed, but the surface area is small compared to feet and legs. The ophthalmic exposure does not need to be modeled, but may be a very important factor in irritation and sublethal injury. Plumage will not be a site of dermal absorption, and is probably covered adequately with the surface area model, but exposure from preening is dismissed as trivial. Experiments need to be done to measure preening ingestion, which may prove to be significant.

The Agency's background document indicated that for aerially-applied spray, all individual birds predicted to be in the field at the time of application are subject to dermal exposure from applied pesticide droplets. This assumption is based on an expected rapid rate of application by aerial equipment, with little opportunity for individuals to leave the field during application. However, for ground-applied sprays, dermal exposure to pesticide droplets is limited to those individuals that are predicted by the model to be on the field at the time of application. The limitation to in-field residents is based on an expectation that non-territory holding individuals will have the opportunity to exit the field in advance of the application equipment, but field residents will remain on field.

The model does assume that even residents will flush before application equipment when no vegetative cover is present. The issue is not so much whether birds are on or off the field at application, but rather their ability to avoid exposure to pesticide droplets. Birds certainly could, and probably usually do, move out of the way of application machinery. If for no other reason that that the application equipment is noisy. An exception might be birds that are incubating eggs on nests. The application equipment makes noise that the birds can hear before the equipment reaches them, thus giving them time to move. The time that the droplets stay suspended in the air is likely much shorter than the 60-minute time step,- probably seconds or only a few minutes. Thus when the birds move back to an area that has received a pesticide application, the droplets most likely would have settled out of the air column. Birds confined to territories can still move out of the way of application equipment until the droplets have settled since the application zone would only encompass a very small proportion of a territory at any given point in time.

Additionally, time in field does affect dermal exposure and the Agency should consider the effect of one hour time steps on the dermal dose as it is an important exposure parameter.

This raises the point that EQ 3-55 should have units of mg/kg/hr not mg/kg as stated. If a one hour time step is assumed, this difference is not important, but if, as other Panelists have suggested, the foraging behavior does not really occur in one hour steps, the dermal exposure may be improperly estimated. To better parameterize the dermal exposure scenario, the Panel believed it necessary to collect data for avian contact with foliage in greenhouse scenarios.

<u>Agency Charge</u>

8. <u>Relating Dermal Exposure to Oral Exposure Toxicity Endpoints</u>: 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.

<u>Panel Response</u>

Appendix H (dermal toxicity estimation) of the Agency's background document uses regression analysis to compare oral and dermal exposures. In addition to the points referenced above with regard to time course of effect and recovery, body size or species differences appear to be important factors in the correlation of oral and dermal dose. The data for Figure H-1 are based on the data given in Table H-1. Only six pesticides were tested on three different species, and these have been graphed in the accompanying figure comparing oral and dermal LD50 toxicities. The oral:dermal ratio of toxicity is very low for mallards, and generally higher for both house sparrows and quelea, indicating either a body size difference, or some other species differences. A more refined analysis needs to be performed on the data to determine the best relationship between oral and dermal toxicities, rather than a linear regression on the available data as presented in Figure 3 below.

Figure 3. Ratios of Oral to Dermal LD50s used within the FIFRA Level II Probabilistic Risk Assessment.

The correlation is very low on the plot (Table H-1, Figure H-1) which means that the simple linear regression will be relatively flat. Thus, the predicted dermal LD50 will be relatively insensitive to the given oral LD50. It is important to allow variability in dermal LD50 values about the predicted value. If one is looking for a relationship between oral and dermal toxicity, an error-in-variables model might be more appropriate than a simple linear regression. It is not clear that LD50 is the best point of comparison, but we at least have data on LD50. There are very few pesticides with oral and dermal toxicity data, other than OPs, and the analysis should not be interpreted beyond the OPs. The carbamates in particular do not show a regression relationship like the OPs.

The Panel encourages a close evaluation of avian and mammalian dosing processes for the dermal and oral routes of exposure, given that the regression analyses showed that the relationship between pesticide toxicity and exposure via the two routes of exposure is not strong. It may be that segregation of data by dosing regimes would increase regression strength even though it will decrease the number of data points within each regression.

The time course of dermal absorption and pesticide effects are very different from oral exposure. The prolonged recovery time following toxicant exposure may be critical in estimating the effects of sequential exposures. The data of Henderson et al. (1994) and Bartkowiak and Wilson (1995) must be verified and duplicated with other species and compounds. The time course of absorption and effect should be measured for other compounds besides parathion. The dermal depot for storage of chemicals needs to be identified and quantified for other compounds and carrier vehicles.

The preceding graph gave a very different look at the data for two reasons: the ratios of oral to dermal are computed for each case, rather than fitted by a regression, and the original units are used rather than logs (Figure 4). The graph has only one case per bar. A version of the same plot is given in Figure 4. It combines all compounds used with each species, and it also shows that the mallards are different from the house sparrows and queleas.

Figure 4. Differential Lethality of Insecticides to Three Avian Species (hs=house sparrow, ma=mallard, qu=quelea)

Considering the magnitude of the variance in the regression, there will be larger uncertainties for highly toxic compounds (low LD50s). This is not a trivial observation as highly toxic compounds are those likely to pose the most risk.

The adjuvant (carrier) effect will be critical in dermal absorption. Surfactants could greatly increase the absorption, and stickers could greatly increase the adhesion, buildup, and necessity for preening of compounds from skin and feathers.

Preening will result in an oral exposure following dermal exposure. This could be modeled in a manner similar to the inhalation-oral model, but the added complication of prolonged pesticide effect and recovery time with dermal exposure will complicate the model.

Agency Charge

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.

Panel Response

Several scientists have begun to explore PBTK (PBPK) models. The most sophisticated to date is that of Nichols (1994) and French (2002) for kestrels. Birds are being dosed and measured at USFWS and being modeled using adaptations of EPA's fish models as starting frameworks. The model and measurements are for methylmercury, which has little application for non-bioaccumulating pesticides. The model includes uptake by feathers, which would not be considered for most pesticides.

Drouillard and Norstrom (2000) are building a 2 compartment model for PCBs and herring gulls, but this has limited application except for DDT and other bioaccumulating pesticides. Krishnan has developed a model for hens with direct-acting pesticides, to avoid the added complication of metabolic activation. He has presented the model at meetings, but has not published it.

Modeling may have been conducted for pharmaceuticals or growth promoters in poultry, although few published data have been located to date (Pollet 1985).

Agency Charge

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.

Panel Response

The dermal exposure model and the inhalation model would be good additions to a model with two or three compartments. Similarly, modeling the oral exposure with inhalation exposure as a two- or three-compartment model, and obtaining better correlations with air sac surface uptake, tracheal uptake, and oral ingestion of substances swept from the trachea would be valuable.

In general, the number of physiological compartments for birds is large, and the data to support the compartments are few. This means that default assumptions need to be incorporated, making the models less accurate and less useful than lab and field measurements. The dermal data of Henderson et al. (1994) and Bartkowiak and Wilson (1995) are very good illustrations of the value of actual measurements. Similarly, the data of Mineau **(**1991**)**, showing that small birds are more vulnerable to pesticide exposure than large birds, perhaps due to the fact that they can starve to death in less than 12 hours, is important. Such an outcome would not be predicted in a PBPK model, unless that fact was known prior to the construction of the model. Perhaps a model that incorporated a feeding suppression factor could be constructed, but the added complexity of modeling fat storage, behavioral depression, differential recovery of appetite and direct pesticide effects, could make the model too complex and difficult to parameterize.

Physiological models could be improved through sensitivity analysis, by running the model with large variations for input parameters, and determining which individual parameters have the greatest influence on the outputs. Experimental testing of those parameters that are important would further refine the model.

The current efforts to model methylmercury cycling in aquatic carnivorous birds will give a much needed framework for other PBPK models. The extrapolation to rapid-acting pesticides, with very different metabolism should be attempted, but will need different parameters than a mercury model. Quite a lot of data exist for organophosphates, with measurements of brain and serum cholinesterases, and data for recovery time. This class of pesticides would be a good beginning for modeling with a few compartments.

The choice of bird species should be given consideration. Most of the FIFRA and OECD testing data are for bobwhites, mallards, and Japanese Quail. Passerines are the greatest proportion of species exposed in the field, and some pesticide exposure data exist for house sparrows, some for starlings, and some for quelea. Quail (Japanese or bobwhite) and house sparrows would seem to be the best species to begin modeling.

Models were developed at Savannah River Ecology Laboratory (SREL) during the 1990s for contaminant uptake by wildlife (Brisbin et al., 1990; Newman and Jagoe, 1996; Newman and Dixon, 1996). Modules of these models could be useful in the modeling activities. There is aldicarb data (Harper et al., 1999; Cobb et al., 2001) that evaluated transformation, excretion and concentrations in GI tracts. Work of numerous investigators over the years describes the age and species dependence for enzymatic development in much detail **(**Gates et al., 2001; Mayack and Martin, 2003; Gogal et al., 2002; Gard and Hooper, 1993; Tian and Paul, 2003).

The Panel provided additional comments in reference to the issues presented by the Agency. The Panel's comments are provided below

GENERAL COMMENTS

Conservatism Throughout the Model

As would be expected for a Level II model, the terrestrial model errs on the side of conservatism. However, there is concern about how the model incorporates conservatism. Currently, the model incorporates distributions for a few key parameters (e.g., body weight), but for most parameters, conservative point estimates are used (e.g., entire puddle algorithm, frequency on field, etc). The resulting degree of conservatism from this approach is opaque and potentially extreme. This is because of "compounded conservatism". Multiplying 95th percentiles for a series of input variables does not produce a 95th percentile output estimate, but rather a much higher percentile (typically >99th percentile). The more 95th percentiles or conservative input values multiplied together, the greater the compounded conservatism. The Level II Model has many input variables when all the modules are considered together. Thus, the potential for compounded conservatism is high. Using a mix of conservative and average input values does not solve the problem because ignoring major sources of uncertainty could lead to low probability-high consequence effects being missed. In any event, the amount of conservatism will remain opaque. A better approach for erring on the side of conservatism, yet using a fully stochastic approach is presented below:

(1) Use a conservative problem formulation. Focus the assessment on generic species that are at highest risk of exposure in regions and for crop uses where pesticide concentrations and persistence are likely to be high.

(2) Where uncertainty is high and difficult to quantify, re-state the objective of the assessment in a conservative manner. Frequency on field, for example, is an important but difficult to quantify source of uncertainty for many bird species. To deal with this uncertainty, the assessment could estimate exposure for "birds that have a frequency on field of 90%".

(3) Once the problem formulation and objective of the assessment have been formalized in an appropriately conservative manner, conduct the assessment as a fully probabilistic assessment. This does not mean that every variable has to be treated as a distribution. Well characterized constants or variables that are of only minor importance (as determined with sensitivity and elasticity analyses) can be treated as point estimates. Remaining variables should, however, be treated as distributions. If it would be useful to separate variability and uncertainty due to lack of knowledge, then 2nd order Monte Carlo techniques or probability bounds analysis could be considered to accomplish this objective.

(4) To properly err on the side of conservatism with the outputs in Level II, risk management decision making could focus on the relatively low probability-high consequence effects (e.g., effects that occur with 5 or 10% probability). For some pesticide assessments, it may not be necessary to incorporate all of the Level II model modules. For example, if a pesticide has very low volatility, then it seems unlikely that exposure via inhalation will be significant. In these cases, it would be useful to have the option to turn off certain modules. The advantage of having this capability is that it removes the necessity to gather information and parameterize input variables in the modules that have been turned off. Therefore, as an early step in running the model it would be useful to have stopping rules for some modules (e.g., above a specified Henry's Law Constant, inhalation module turned on, otherwise the module is turned off).

Model Version 2 And Formulation Type

The Panel noted the Terrestrial assessment Model Version 2 is meant only for liquid formulations. It does not include granular, and for granular to be included, new modules should be developed because of the added compartmentalization and distribution of granular particles. The Agency mentioned that it would be a simple matter to change to granular formulations instead of liquids. This may not be true since the analysis of granular formulations requires a totally new form of model. Model Version 2 is not currently appropriate for granular formulations.

Response Surface Methods To Address Sensitivity Analyses Throughout Risk Assessment Process

Determining whether the model is good enough for a given purpose is more important than validating that it is accurate in all respects. To be good enough for risk assessment purposes, a stochastic model must be able to reproduce extreme events with realistic probabilities. With this in mind, the Panel believes there can be considerable benefit in performing sensitivity analysis at this stage of the model's development. The Panel also recognizes that the Agency has plans to carry out sensitivity analysis and definitely encourages it to do so. To provide aid in this process, the Panel suggested an approach a little different from the running of a variety of scenarios. For complex models with a large number of parameters, simplified reduced-form or response surface models are often developed to enable a more efficient representation of the original model for use in sensitivity and uncertainty analysis. A reduced-form model involves a simplification of the original model that is derived from the underlying, mechanistic principles of the parent model (Kros et al., 1993; Sinha et al., 1998; Cocca, 2001; Schultz et al., 2004). A response-surface equation provides a purely empirical, statistical representation of the input-output relationship determined from the original model, e.g., by fitting a regression model that includes each of model inputs and their pairwise cross-products as explanatory variables (Cox and Baybutt, 1981; Downing et al., 1985), or fitting a set of "stochastic response surfaces" that have the form of a multidimensional polynomial (Isukapalli et al., 1998; Cryer and Applequist, 2003a,b). Papers by Cryer and Applequist are of particular interest, because they involve studies of agricultural chemicals and ecological risk.

To fit a response-surface model, input parameters for the original model must be sampled using an appropriate experimental design, and the model executed for each sample to develop a set of input-output "data" (simulation results) that are used for the fitting procedure. The statistical-fitting procedure provides an initial screen of parameter sensitivity, because only those model parameters that have a statistically significant effect on the model output are included in the response-surface model. The simplified model can then be used for more extensive sensitivity and uncertainty analysis. Furthermore, if the response-surface or reduced-form model provides a sufficiently close match to the original model for predicting key model outputs, it may be deemed suitable for use in place of the original model for specific scientific or policy evaluations (so long as the conditions to which it is applied fall within those considered when fitting the model). The Agency should explore the development of a reduced-form or response-surface representation of their pesticide ecological risk assessment model, to determine whether this can help to identify important input parameters to the model, and serve as a simplified version of the model for future applications.

The Panel also recommended other similar sensitivity analysis tools: FAST (Fourier Amplitude Sensitivity Analysis) developed by McRae (Fontaine et al 1992) and Plackett and Burman (1946) that provide a structured, formal, statistical approach to the process. These tools essentially identify a rate of change in output per unit of input (a response surface) for all model input parameters. The procedures then rank each parameter in terms of importance relative to each other so that one can readily see which parameters are important and which are not.

For purposes of illustration, an example using the Plackett-Burman (PB) tool is provided below. In this example, the leaching of chemicals through soil is being modeled by PRZM and Table 1 below lists all the input parameters implemented by PB for analysis of sensitivity. The subsequent figure presents results from PB and shows the importance of some parameters relative to each other for the prediction of leaching by PRZM. Numbers in parenthesis for each parameter in the table serve as the key to the identity of parameters in Figure 4.

Table 1 and Figure 5 were extracted from Appendix 4, pages 105-106, of the report "FIFRA Environmental Model Validation Task Force Final Report" submitted to EPA as MRID 45433201. It is available to the public and can be reviewed and downloaded at the following web site address: www.femvtf.com/Welcome.html. It provides more detail on the workings of Plackett-Burman.

Table 1: PRZM3 Model Input Parameters Implemented by Plackett-Burman as found in Appendix B:	
1) PAN FACTOR	33) % CLAY
2) MIN DEPTH FROM WHICH EVAP. IS EXTRACTED	34) HORIZON ORGANIC CARBON
3) MAX INTERCEPT STORAGE OF CROP	35) DISSOLVED PHASE DECAY RATE (1)
4) MAX ROOTING DEPTH OF CROP	36) ADSORBED PHASE DECAY RATE(1)
5) MAX AERIAL COVERAGE OF CANOPY	37) PESTICIDE PARTITION COEFFICIENT(1)
6) R.O. CURVE # 1 OF ANTE MOIST COND II	38) DISSOLVED PHASE DECAY RATE (2)
7) R.O. CURVE # 2 OF ANTE MOIST COND II	39) ADSORBED PHASE DECAY RATE(2)
8) R.O. CURVE # 3 OF ANTE MOIST COND II	40) PESTICIDE PARTITION COEFFICIENT(2)
9) UNI SOIL LOSS COVER MGT FACTORS	41) DISSOLVED PHASE DECAY RATE (3)
10) MANNINGS N	42) ADSORBED PHASE DECAY RATE(3)
11) HYDRAULIC LENGTH	43) PESTICIDE PARTITION COEFFICIENT(3)
12) SLOPE (SLP)	44) DISSOLVED PHASE DECAY RATE (4)
13) MAX DRY WGT OF CROP FULL CANOPY	45) ADSORBED PHASE DECAY RATE(4)
14) MAX CANOPY HEIGHT	46) PESTICIDE PARTITION COEFFICIENT(4)
15) DEPTH OF PESTICIDE APPLICATION	47) DISSOLVED PHASE DECAY RATE (5)
16) TOTAL APPLICATION OF PESTICIDE	48) ADSORBED PHASE DECAY RATE(5)
17) FILTRATION PARAMETER	49) PESTICIDE PARTITION COEFFICIENT(5)
18) PEST. VOLATIL. DECAY RATE ON FOLIAGE	50) DISSOLVED PHASE DECAY RATE (6)
19) PESTICIDE DECAY RATE ON FOLIAGE	51) ADSORBED PHASE DECAY RATE(6)
20) FOLIAR EXTRACT. COEFF FOR PLANT W.O	52) PESTICIDE PARTITION COEFFICIENT(6)
21) PLANT UPTAKE FACTOR	53) DISSOLVED PHASE DECAY RATE (7)
22) DIFFUSION COEFF FOR PEST IN AIR	54) ADSORBED PHASE DECAY RATE(7)
23) HENRYs LAW CONSTANT	55) PESTICIDE PARTITION COEFFICIENT(7)
24) ENTHALPY OF VAPORIZATION	56) DISSOLVED PHASE DECAY RATE (8)
25) PESTICIDE SOLUBILITY	57) ADSORBED PHASE DECAY RATE(8)
26) BULK DENSITY/MINERAL DENSITY	58) PESTICIDE PARTITION COEFFICIENT(8)

27) INITIAL SOIL WATER CONTENT OF HORIZON	59) DISSOLVED PHASE DECAY RATE (9)
28) SOIL DRAINAGE PARAMETER	60) ADSORBED PHASE DECAY RATE(9)
29) PEST SOLUTE DISP. COEFF.	61) PESTICIDE PARTITION COEFFICIENT(9)
30) VAPOR PHASE PESTICIDE DECAY RATE	62) DISSOLVED PHASE DECAY RATE (10)
31) THICKNESS OF HORIZON COMPARTMENT	63) ADSORBED PHASE DECAY RATE(10)
32) % SAND	64) PESTICIDE PARTITION COEFFICIENT(10)

Figure 5. Example summarization of model sensitivity for PB output. E/Emax for Maximum Total Pesticide (Mg/Kg) In Compartment 150, PF =10%.

Several benefits can be achieved from the conduct of quasi-global analysis such as an analysis of sensitivity:

1. Attention is called to those parameters of greatest sensitivity, and thus to those areas where greatest effort should be made to capture uncertainty in the form of distributions. Just as importantly, it also identifies parameters of little importance that do not need distributions and can be input as single point values.

2. It can be an enlightening experience because it forces the model builders to think deeply about each input variable and to put on paper some estimate of its uncertainty and range in value. When completed, the modeler has a much deeper understanding of the characteristics of each model input.

3. It identifies the areas of experimentation where effort should be spent to develop better data.

4. It aids in model simplification. As model-building progresses there is the tendency for the model to become all-encompassing, and at some point it is necessary to go back, review what is and is not important, and simplify the model accordingly. Version 2 appears to be at such a place in its development.

Several Panel members believed that some of the uncertain parameters in the model (e.g., FOF) might benefit from treatment as scenarios rather than as uncertainty distributions. This may aid in communicating results. This particular issue came up at the New York Monte Carlo Workshop and people less familiar with the 2-D approaches requested a scenario-based approach to help them understand the model outputs. When explaining to risk managers the effects of some uncertain parameters in the model (e.g., FOF), it might be helpful to treat these as scenarios rather than as uncertainty distributions.

Additional Data Needs

The Agency has made significant progress in developing its approach to probabilistic risk assessment and is to be commended for its efforts. However, while the analyses have become more sophisticated and the data sources more varied, there appears to be little change in the amount of "field" data to support the analyses. Data gaps identified previously have not been fulfilled. Instead new ways of applying existing data/other models to estimate unavailable data have been identified and applied. Although this approach can serve to advance the development of probabilistic models in the short term, it will increase uncertainties and reduce the Agency's ability to validate/refine models in the future. At times, it appears the Agency argues that a lack of data hampers the analyses and model development, but also that additional data would not reduce uncertainty (for example, paragraph two on page six of the Agency's background document). The absence of appropriate data is noted throughout Chapter 3, and The Panel would encourage the Agency to rapidly fill these data gaps. A research thrust to quantify critical variables is necessary within the Agency's intramural or extramural research program. Avian toxicokinetic modeling would seem a reasonable thrust area, but there are also topics of exposure such as avian inhalation of pesticides and dermal exposure. Also, evaluation of processes that affect pesticide fate such as puddle formation, size, and duration need to be quantified along with pesticide concentrations in these waters. However, it is important that the Agency first define the role of the Level II modeling effort in the regulatory framework, and utilize sensitivity analyses (as described above) to identify those parameters most important to the model, before collecting additional data.

Effects assessment was mostly ignored in the Level II model. This is likely a reflection of the limited effects data that are currently required from registrants for birds. In some pesticide assessments (particularly re-registration), however, it may be feasible to develop dose-response curves for endpoints other than mortality (e.g., reproduction, growth). The current model is incapable of considering such endpoints at present. The Generalized Linear Modeling framework (Bailer and Oris 1997) should be considered if reproductive and growth endpoints are considered in the future.

Role of Level II Models

In reviewing the documentation supporting the Agency's Level II modeling efforts, the role of the Level II analyses is not clear. The role these modeling efforts play will in large part dictate whether or not the models should be conservative (i.e., protective against false negatives) similar to the quotient method in Level I. Level II models can be used to generate a regulatory decision point or they can serve as a refinement for those pesticides that do not pass Level I. The latter application should be encouraged because the Level II modeling efforts would then complement rather than duplicate Level I analyses. As a result, modeling efforts could utilize untrimmed distributions for model parameterization, i.e., absent restrictions to ensure unnecessary conservatism. In this paradigm, regulatory decisions could be made after Level I, after application of Level II models, after exposure risk mitigation, or after cost-benefit analysis, in that order.

Model refinement can then focus on identifying those parameters most important to the model, and can be used to identify those parameters governing a Level II decision for a particular product. This paradigm accommodates the development and implementation of higher-tier modeling efforts in the future that complement existing analyses, and particularly pertinent to the present discussions, reducing the need for Level II models to be all encompassing in their parameters.

Lack of Data, Uncertainty, Sensitivity Analyses, and Model Validation

The idea of model validation was discussed by the Panel. Some members suggested validating isolated components of the model but it is apparent that it is not practical to run field trials capable of validating the predictions of the model as a whole. This model has many deterministic coefficients and relationships in it and these should be made stochastic. This is perhaps a more important direction to go at this point, rather than making all details of the model more realistic and hence more complicated.

Inputs Into the Decision Making Process

If the model outputs will be used to guide decisions, thought must be given to how to establish decision criteria. Obviously, these will not be a single fixed value (e.g., 0.2 incidence) but may need set de-minimus and de-maximus bounds and considerations for making decisions in the middle range. These are policy decisions but science will play a role here. In the Monte Carlo Guidance document developed for the Agency's Superfund Program, such decision criteria were defined near the tails of the cumulative distributions of risk (e.g., the range was 90 to 99 with 95th percentiles the typical point of departure). At other sites, fractions of the exposed population have been used to judge the significance of the exposure and risk. Examples range from 5 to 25%. In the Calcasieu and Housatonic Superfund risk assessments, ranges were established for risk management decisions along the lines of de-minimus, de-maximus, and the middle ground. These were set as probabilities of particular levels of effect.

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