EXPOSURE DATA REQUIREMENTS FOR ASSESSING RISKS FROM PESTICIDE EXPOSURE OF CHILDREN

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Guidance Document:
EXPOSURE ASSESSMENTS IN SUPPORT OF FQPA

I. INTRODUCTION

EPA is committed to protecting the health of infants and children by ensuring that sound evaluations and practices are used for the risk assessments conducted in support of FQPA. As part of this process, the EPA Administrator has requested an evaluation of the current approaches for establishing the FQPA Safety Factor. This document was prepared in response to the Administrator's request and describes the evaluations and conclusions of the Exposure Group. Specifically, this document:

- gives background information on conducting exposure assessments, especially as they relate to infants and children;
- defines what would constitute a complete and reliable data set for exposure assessments;
- describes the approaches that are used for estimating pesticide exposures from food, drinking water, and nonoccupational sources;
- identifies uncertainties and information gaps that currently exist;
- describes ongoing work to improve the assessment procedures;
- provides recommendations to improve the assessment procedures; and
- describes approaches for aggregating exposures from all sources and pathways.

II. DEFINITIONS AND GENERAL PRINCIPLES FOR EXPOSURE ASSESSMENT

Exposure is defined as the contact of an individual (at visible external boundaries) with a pollutant for specific durations of time. In order for exposure to occur, an individual must be present and must come into contact with a contaminated medium. As described in the *Guidelines for Exposure Assessment* (U.S. EPA, 1992), exposure is dependent upon the intensity, frequency, and duration of contact. The intensity of contact is typically expressed in terms of the concentration of contaminant per unit mass or volume in the medium to which humans are exposed. Exposure assessments seek to characterize "real-life" situations whereby (1) potentially exposed populations are identified, (2) potential pathways of exposure are identified, and (3) the magnitude, frequency, and duration of chemical intakes/potential doses are quantified.

In conducting exposure assessments for children, it is important to understand the fundamental concept that children are not little adults. Children's exposures to environmental contaminants are expected to be different and, in many cases, much higher than adults. These differences are due to differences in physiological function and surface-to-volume ratio. However, differences in their behavior and the way in which children interact with their environment may also have a profound effect on the magnitude of exposures to pesticides. Children will crawl, roll, and climb over contaminated surfaces resulting in higher dermal contact and hence, absorption. Children eat different foods which may result in higher dietary ingestion.

Increased dietary ingestion may also occur when children handle and eat foods that have come in contact with the floor or other contaminated surfaces. Finally, children's mouthing activities (hand-to-mouth and object-to-mouth) will result in nondietary ingestion of pesticides if the hands or objects are contaminated. It is important to understand that the activities listed above will not only result in differences in exposures between children and adults, but they will also result in differences in exposures among children of different developmental stages. Thus, exposure assessments should be required for children in each age group, with age group being defined by the developmental stage of the child. Example age groups for young children would include: prenatal, 0 to 6 months of age (infants), 6 to 12 months of age (crawlers), 12 to 24 months of age (young toddlers), 24 to 36 months of age (older toddlers), and 3 to 5 years of age (preschoolers). In addition, a special category should be included for children who are teething because they are expected to have very high hand-to-mouth and object-to-mouth activities during this period.

Children's exposure to pesticides is a complex process that may occur from several sources through a number of different pathways and routes. For example, Figure 1 is a schematic that depicts the potential sources, pathways, and routes of pesticide exposures that could occur. **Sources** include all pesticide uses that could result in children's exposure. Within this document, only nonoccupational exposures to pesticides will be considered. **Route** of exposure (i.e., dermal, oral, inhalation) is defined as the portal of entry. **Pathway** is defined as the course that the pesticide takes from its source to the portal of entry. Exposure pathways will include those that occur indoors and outdoors at the home, as well as at other institutional and non-residential settings (e.g., schools and daycare centers).

Risk assessments must take into account the frequency and duration of exposure, as well as its magnitude. In pesticide risk assessments, four exposure durations generally are considered. **Acute** exposure is defined as an exposure period of less than one day. Exposures through food and drinking water have been included in acute exposure assessments. **Short-term** exposure is defined as an exposure lasting from one to seven days. Possible short-term exposures to pesticides in and around the home could come from uses such as on lawns, ornaments, and home gardens, as a crack and crevice treatment for insects, as a treatment for carpets or other surfaces, and as a flea treatment for pets. Other short-term exposures could occur in public places such as parks, school playgrounds, and playing fields. Data indicate that postapplication exposures from these uses typically last from a day to several weeks.

Short-term risk results from exposure to the pesticide for a period of 1 to 7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of the FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses of pesticides when reliable data are available. Historically, In this assessment, risks from average food and water exposure, and high-end residential exposure, were aggregated. High-end exposures from all three sources were not

typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks may be aggregated and presented as part of the comprehensive risk assessment/characterization. In the draft document "Guidance for Performing Aggregate Exposure and Risk Assessments, the Agency is proposing to select the most appropriate techniques (deterministic or probabilistic) for each exposure scenario on a case-by-case basis. Selection would be driven by the amount and nature of the available data. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least seven days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1 to 7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least seven days of exposure. (Toxicity results at lower levels when the dosing duration is increased.).

Intermediate-term exposure is defined from one week to several months. Possible intermediate-term exposures to pesticides in and around the home could occur due to use of rodenticides as well as some of the exposure scenarios described above in the acute and short-term categories. **Chronic** exposure is presumed to occur over a substantial portion of the individual's lifetime. Although chronic exposure can occur via all routes and pathways, dietary is considered to be the largest component. Pesticides that are used as termite control could also result in chronic exposures.

An important component of FQPA is the concept of aggregate exposures. Thus when setting a food tolerance, EPA should aggregate exposure information from all potential sources to include:

- residues in the food in question (i.e., the commodity for which a tolerance is being sought),
- residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and
- residues from other nondietary, nonoccupational uses of the pesticide (e.g., residential and other indoor/outdoor uses).

Given this requirement to aggregate exposures, all of the potential sources and pathways shown in Figure 1 must be considered in the exposure assessment process, as well as any others that may be identified for a particular pesticide. As examples, a child may be exposed to a specific pesticide in his/her food as it comes from a store, in the food as a result of contact with a contaminated floor, in the air, in a glass of water, in fruit juice reconstituted with contaminated

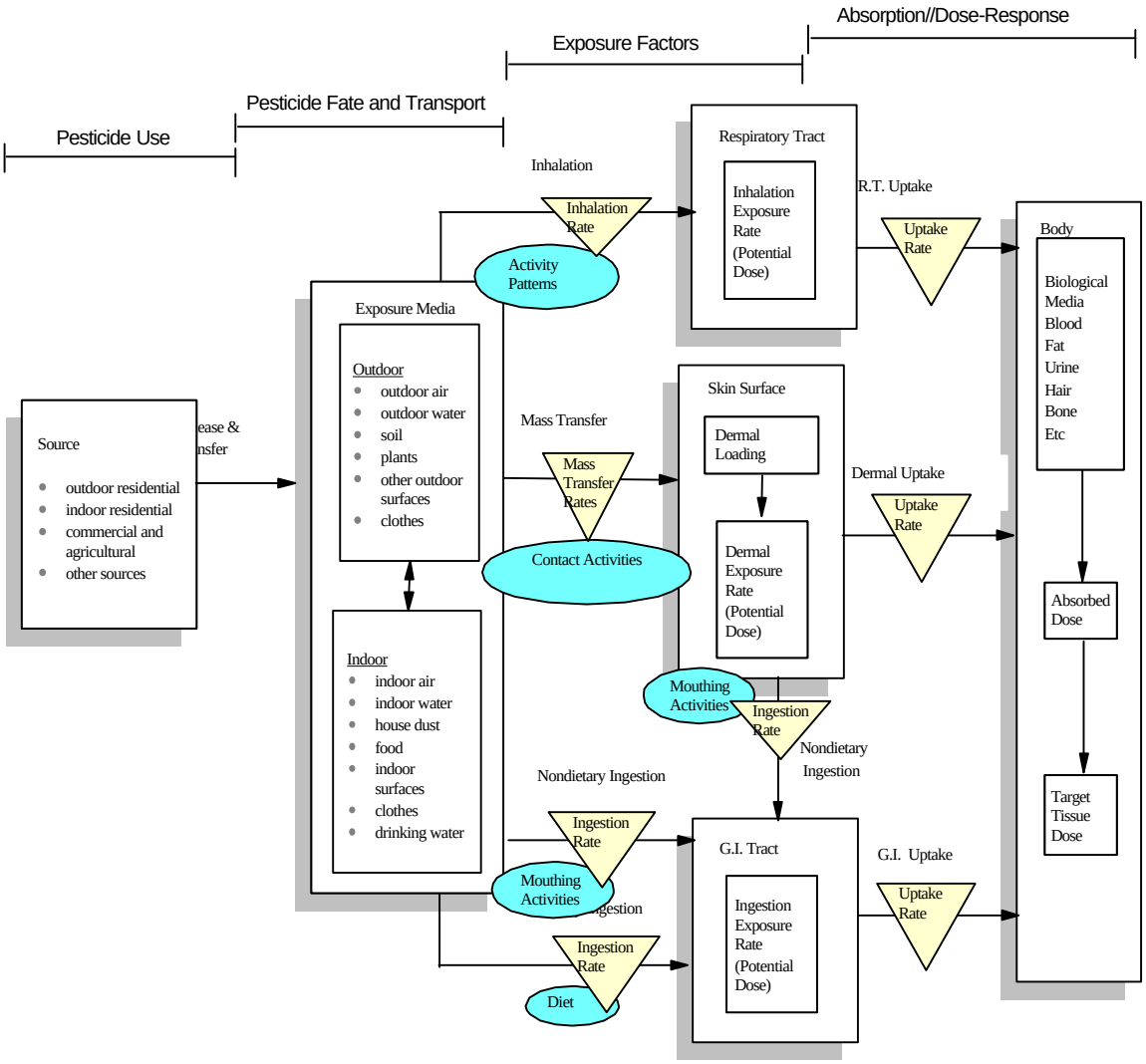

Figure 1. Children's Exposure to Pesticides

water, from placing his/her hands on a contaminated surfaces, from placing contaminated hands in his/her mouth, mouthing contaminated toys, from contaminated hands, etc.

Exposure assessments may be conducted using either direct or indirect approaches. **Direct assessments** measure the contact of the person with the chemical concentration in the exposure media over an identified period of time. There are very few cases where methods exist and are used to make direct exposure assessments. Personal monitoring techniques such as the collection of personal air or duplicate diet samples are used to directly measure exposure to an individual during a point in time. **Indirect assessments** use available information on concentrations of chemicals in exposure media, along with information about when, where, and how individuals might contact the exposure media. The indirect approach then uses models and a series of

exposure factors (i.e., pollutant concentration, contact duration, contact frequency) to estimate exposure.

For a few pesticides, biomarkers can serve as a useful measure of direct exposure aggregated over all sources and pathways. It should be understood that biomarkers will measure integrated exposure from all routes. However, to use biomarkers for this purpose, several important criteria must be met. Biomarkers that can accurately quantitate the concentration of a pesticide or its metabolite(s) in easily accessible biological media (blood, urine, breath) must be identified and available. The pharmacokinetics of absorption, metabolism, and excretion must be known. Finally, the time between pesticide exposure and biomarker sample collection must be known. Although there are a number of biomarkers that meet these criteria, very few studies using biomarkers have collected all of the information required to accurately estimate exposure.

Exposure assessments can use models that are either deterministic or probabilistic. A **deterministic model** provides a point estimate of exposure. A **probabilistic model** considers the range of estimates and provides a probability distribution of exposures. As an example, a deterministic dietary exposure would assume that a typical child eats an assumed mass of food per day with a given concentration of a pesticide residue. A probabilistic exposure model would calculate the range of mass of food and the range of food types (with each food type having a given concentration of a pesticide residue) eaten by a particular class of child (e.g., of a certain age and gender). The result would be identification of the age and gender of children likely to be in the upper percentile of the exposure distribution. Probabilistic models can also be used to identify the number of children likely to be at risk.

Finally, even when a complete exposure assessment can be conducted, a full risk characterization requires knowledge of the delivered dose (or an indicator of this) because it is the dose at the target that ultimately causes health effects. For example, suppose there is extensive exposure to a child's hands, but his/her hands are washed before dermal absorption or oral transfer occurs. Furthermore, route-specific pharmacokinetics can impart a significant influence on target-site dose.

III. DESCRIPTION OF THE EXPOSURE EVALUATION PROCESS

III. A. Definition of a Complete, Reliable Data Set

The definition of a complete and reliable data set for pesticide exposures of children is a primary consideration relative to the FQPA safety factor. An exposure assessment should include the following four elements:

1. An initial exposure assessment that includes all elements in Figure 1 to identify all important sources and pathways of exposure for the pesticide. The assessment should also include the expected exposure duration for each pesticide’s use and pathway of

exposure.

2. An initial assessment to identify the age groups that are at the greatest risk from aggregrate pesticide exposures. This should include identifying those age groups with the potentially highest exposure as well as the greatest susceptibility to the exposure.
3. Protocols for conducting exposure assessments for all relevant pathways and age groups. Protocols should include:
   - a description of the environmental media that should be measured;
   - standard methods for measuring pesticides in those environmental media;
   - a description of the activity patterns and exposure factors required;
   - available distributional data or methods to collect same for all of the relevant activity pattern and exposure factors;
   - the algorithms for combining the environmental monitoring data with the exposure factors to estimate an exposure or a dose.
4. An aggregate exposure assessment using probabilistic multimedia, multipathway models to develop population exposure distributions.

For the data base to be considered reliable, the following three criteria should be met:

1. Protocols for estimating exposure should be reliable. The methods for measuring pesticide concentrations in environmental media should be accurate. The uncertainty associated with models for combining measurement data with exposure factors should be known.
2. Exposure factors should be accurate. Uncertainty associated with these factors should be defined.
3. Validity of the protocols should be demonstrated through field studies.

The state-of-the-science of exposure analysis is evolving; thus, all of the elements of an exposure data set do not exist. Exposure protocols are not established to the same degree as toxicology protocols. Accurate measurements of pesticides in environmental media can be made, but validated models are not available combining the data on environmental concentrations with activity patters to estimate exposure. For dermal absorption and nondietary ingestion (two very important routes for children), new research has identified additional important exposures for which we have not yet developed methods and models. Further, there are new methodological issues that are important. For example, some researchers support the use of macroactivity models that lump children's behavior into several very general categories and then develop transfer coefficients for pesticide uptake based on these activities. Other researchers feel that the microactivities of each child must be defined and then exposures estimated for each individual microactivity. These estimates are then summed. The two approaches require different measurements, exposure factors, and models for estimating exposure. In addition to the uncertainties associated with the measurements and the models, the available exposure factors have varying degrees of robustness for children (see subsequent sections for their discussion). Most of the exposure factors have been developed for broad age categories of children. In particular, refinements of the exposure factors are needed that take into account changes in

activity patterns with changes in age. The process of developing and verifying exposure factors such as pesticide uptake rates and transfer rates for young children has not taken place. Methods for collecting activity pattern data for children are uncertain. Finally, children engage in a wider range of contact activities than adults. Thus, there is a much wider distribution of activities that must be accounted for.

The current approach for aggregating exposures is to sum the single point exposure estimates for each source and pathway. This approach can substantially overestimate the aggregate exposure beyond any reasonable value. The optimal approach for conducting aggregate exposure assessments is through the development of probabilistic, multimedia, multipathway models that have a solid foundation in theory and measurements. These models should produce distributions of total exposure for risk characterization, along with distributions for each pathway that will enable decisions on which pathway(s) contribute most to risks and must be integrated. Unfortunately, advanced models of this type will not be available for some time. In the interim, the currently available measurement methods, exposure factors, and models are the only feasible approach for conducting exposure assessments for children. It is, therefore, mandatory to understand the assumptions that are used in the models and the degree to which the underlying assumptions are conservative and based on existing, reliable data.

It should be recognized that the exposure assessment procedures used by EPA are dynamic. At present, the draft SOPs for Residential Exposure are being revised. A few new studies on multimedia pesticide exposures are nearing completion. This evaluation by the Exposure Group covers the present situation (as of early December, 1998). Revisions should reflect progress on these fronts as they become available. In addition, to evaluate the need for the FQPA Safety Factor, all improvements should be incorporated into the exposure assessment process as the state-of-the-science progresses.

III. B. Procedures for Evaluating the Exposure Assessment

To evaluate the FQPA Safety Factor, the Exposure Group used the criteria March 1998 policy paper presented to the Scientific Advisory Panel regarding the assessment of exposure data and needs specific to infants and children. Based on these criteria, the FQPA Safety Factor can be reduced or eliminated if:

- infants and children are not expected to receive any exposure to the pesticide;
- the available exposure data are of high quality and high quantity (direct assessment approach); or
- exposure models use factors that are judged to use conservative assumptions based on existing, reliable data (indirect assessment approach).

Of the three criteria, the first is the most straightforward. For example, exposures unique to pesticide applicators need not be considered for young children. Currently, OPP and ORD are defining those residential exposure scenarios (sources, pathways, and routes) that are of high importance to children of different age groups (using the 1997 *Standard Operating Procedures*

for Residential Exposure Guidelines as a starting point). Initially, scenarios for the most important short-term exposures will be defined. Additional work will be required to identify intermediate-term and chronic scenarios. When finalized, these draft scenarios will be peer-reviewed again for completeness and accuracy. They will then be used to define those residential scenarios that are relevant to children's exposures.

The second criterion which focuses on the direct approach is evolving particularly for residential exposure assessment, as the state-of-the-science of exposure analysis advances. Although high *quality* data exist for some pesticides and some pathways, high *quantity* data are rare. To date:

- few pesticide residential exposure studies have been conducted;
- fewer studies have been conducted with children;
- none of the studies have considered short-term residential exposure;
- only a limited suite of pesticides have been measured;
- only one pilot study has been conducted in important nonresidential settings such as day care centers; and
- some exposure routes, such as dermal absorption and nondietary ingestion, cannot be measured with the direct approach.

The third criterion that focuses on the indirect modeling approach is the most important and generally will provide the basis for conducting exposure assessments, as well as for evaluating the need for the FQPA Safety Factor. The critical feature in evaluating models against this criterion is to determine if the models use sufficiently conservative exposure factors that will be adequately protective of infants and children. The approach that we have used in this document mirrors the strategy for creating reasonable high-end scenarios as indicated in the U.S. EPA's 1992 Dermal Exposure Assessment: Principles and Application (EPA/600/8-9/01 1F), namely:

- use of all central values for each parameter should produce a central value;
- use of all high-end values for each parameter produces a bounding estimate that is usually above the high end of the distribution; and
- a mix of high-end and central values is probably the best way to create a reasonable high-end value.
- All exposure estimates that are high-end or bounding will be defined as conservative.

The single most important part of the exposure assessment is analyzing the full range of potential exposures as well as the databases and models that may be applicable. This will determine the completeness of the information. This analysis can also be used to identify missing elements and to provide directions for obtaining the needed information. Knowing whether the information from data/models is sufficient for the intended purpose is another essential feature. Such decisions are made in conjunction with a preliminary risk characterization. For example, if the integration of the exposure and health information show that exposures are low when compared to the health risk level, then uncertainties in the data may not be important. If, on the other hand, the exposure is at or higher than the health-risk level, then the uncertainties associated with the exposure assessments are important and more information and reevaluation may be

required.

In the remaining sections in this document, the monitoring data, models, and model factors that are used for exposure assessments to pesticides are given for Dietary (Section IV. A.), Drinking Water (Section IV. B.) and Residential/Non-Occupational (Section IV.C.) exposure. Information on procedures for aggregating exposures is provided separately in Section V because it is a compilation of the information from the individual pathways. In each section, available information will be judged against the criteria for high quality and high quantity data or the use of accepted models that incorporate conservative exposure factors. Uncertainties and gaps associated with the available data are described. Finally, recommendations on how the available exposure information should be considered when determining the need for the FQPA safety factor and how to improve the exposure assessment process are given.

IV. SINGLE-PATHWAY EXPOSURE ASSESSMENTS

IV.A. Dietary Exposure Assessment

1. Assessment Procedures

Direct dietary exposure assessments may be performed by collecting "duplicate diet" samples from individuals and analyzing pesticide content. This approach is more of a research tool, than a testing tool. Therefore, for regulatory purposes, acute and chronic dietary exposure to pesticides in foods are estimated using indirect modeling approaches that consider pesticide residues in the food and the amount of food consumed. Initially, EPA uses deterministic assessments based on various assumptions about the concentration of pesticide residue in the food. For more refined acute dietary assessments, the Agency uses probabilistic exposure assessments (FIFRA Scientific Advisory Committee, March 1998). A science policy for probabilistic exposure assessments is currently out for public notice and comment, which addresses the use of such tools currently for acute assessments, and potentially, for chronic assessments, in the future.

In an attempt to conserve limited resources, EPA assesses dietary exposure using a tiered approach, proceeding from conservative to more refined assumptions as the overall risk assessment situation requires, when the data exist. This approach is outlined in Table 1.

Tier 1 assessments begin with "worst-case" or bounding assumptions about pesticide residue levels in food (for example, residues on foods are assumed to be at tolerance levels and 100% of the crop is treated). They are refined in Tier 2 using more realistic values for pesticide residues (for example, the use of average residues from field trials and the actual percentage of crop treated). In Tiers 3 and 4, pesticide residue data are combined with assumptions on actual pesticide application rates, stability, etc., to refine further residue estimates in foods as they are consumed.

TABLE 1. Tiered Approach to Estimating Dietary Risk from Pesticides in Foods

Dietary Assessment (Food)		
	Acute	Chronic
Tier 1	Non-probabilistic Tolerance 100% CT	Non-probabilistic Tolerance 100% CT
Tier 2	Non-probabilistic Tolerance for single serving size items Average residue from field trials or monitoring data for blended commodities 100% CT	Non-probabilistic Tolerance %CT
Tier 3	Probabilistic EDF from field trials for single serving size items Average residue from field trials or from monitoring data for blended commodities % CT Processing factors	Non-probabilistic Average residue from field trials or monitoring data for blended and single-serving commodities %CT Processing factors
Tier 4	Probabilistic Market basket survey (single serving sized samples) Cooking, residue decline, residue degradation, etc %CT	Non-probabilistic Market basket survey Cooking, residue decline, residue degradation, etc. %CT

Tolerance: maximum legal pesticide residue allowed resulting from registered use (40 CFR 180)[14]
%CT: percent crop treated
EDF: empirical distribution frequency

2. Data, Factors, Models, and Key Assumptions Used in the Assessment Procedures

Pesticide Residue Data.

Data from many sources can be used to estimate residue levels at successive tiers in the exposure assessment process. The reliability of the estimated pesticide residue levels "at the plate" depends upon the reliability of the available data sets as well as the assumptions used when calculating residue levels. Tolerance levels for residues used in Tier 1 dietary exposure estimates are not expected to accurately reflect actual residues in ready-to-eat foods; rather, as the highest residue levels that are legally permitted, they are intended to provide inputs for "worst-case" exposure estimates. Residue data for Tier 1 assessments meet the criterion for conservative exposure factors because they assume that all crops are treated with the pesticide and that the pesticide residues in all foods prepared from that crop are present at the tolerance or highest legal level when eaten.

More accurate (and less conservative) exposure assessments of higher level tiers require refinements in the predictions for pesticide residues in foods as they are consumed. To this end, anticipated residues and information on percent crop treated are used. An anticipated residue is simply the best estimate (developed from all available residue data) of the pesticide residue concentration in treated foods from treated crops as they are consumed. OPP has a large database of pesticide residue data on foods. Because the data have been collected for a variety of purposes, considerable judgment is required for their use in dietary exposure assessments. The main data sources include field studies of residues on commodities in their raw state at the farm gate, monitoring studies conducted by the federal agencies (USDA Pesticide Data Program, FDA Surveillance Monitoring, FDA Total Diet Study), states, pesticide manufacturers, and food processors. In addition, the EPA has a variety of studies on the fate and the level of pesticides as a given commodity is processed into ready-to-eat food forms. This may include washing, cooking, drying, and other processing studies. An overview of the available data is given in Table 2. The limitations of the data and an evaluation of whether the data meet the conservative criterion for exposure factors has also been included in Table 2. A more thorough characterization of the available data and guidance documents for developing and using these data are given in Appendix A.

Data from many sources can be used to estimate residue levels at successive tiers in the exposure assessment process. The reliability of the estimated pesticide residue levels "at the dinner plate" depends upon the reliability of the available data sets as well as the assumptions used when calculating residue levels.

TABLE 2. Pesticide Residue Data Available for Calculating " Residue Levels"

Available Data	Description	Uncertainties
Crop Field Trials	-Conducted under use conditions to produce highest residues (highest application rate, maximum number of applications, shortest harvest time). -Residues determined at normal harvesting times. -Data used to establish a tolerance for each food/feed crop.	-Overestimates dietary exposure
Animal Feeding Studies	-Pesticide residue levels determined in meat, milk, poultry, and eggs after livestock ingesting pesticide treated feeds. -Maximum application rates, shortest post-harvest interval	-Overestimates dietary exposure
FDA, USDA Compliance Monitoring	-Designed for tolerance enforcement -Samples unwashed, whole, raw commodity with peel or skin intact -About 10,000 samples collected per year -Residues generally measured at below tolerance levels -Not specifically designed for children's foods, but many collected	-Not all pesticides monitored -Samples collected close to point of production, so residues may overestimate foods as eaten -High detection level, nondetects may reflect unacceptable risk if toxic health effect level is low. -Few meat and poultry samples.
FDA Total Diet Study	-Designed to estimate dietary exposure to selected pesticides by various U.S. age-sex groups -Residues measured in foods purchased at supermarkets, prepared ready to eat -Large number of pesticides tested -Very low detection limits for pesticides -234 foods collected that represent 90% of American diet. -Samples collected 4X per year at 12 locations	-Very few samples of each commodity – best used to develop central tendency, rather than high-end exposure

Available Data	Description	Uncertainties
USDA Pesticide Data Program	-Statistically based monitoring for dietary risk assessment -Sampling commodity/pesticide combinations -- includes foods consumed by infants and children -Foods collected close to time of consumption -700 samples per year per commodity -Approximately 7000 analyzed per year -Detection limit is usually 10X lower than most enforcement programs -Random sampling procedures and rigorous QA	-Not all pesticides monitored
Pesticide Manufacturer's Data	-Commodities collected at the farm gate -Known treatment history -Low detection limits for residues -Food processing studies -Market basket surveys	-Specially designed studies to answer specific questions. -Use of data for exposure assessment must be evaluated on a case-by-case basis.

Food Consumption Data

Surveys currently accepted by the EPA as sources for estimating food consumption by individuals are the USDA Nationwide Food Consumption Survey (NFCS) 1977-78, the Continuing Survey of Food Intakes by Individuals (CSFII) 1989-91, and the CSFII 1994-96. These surveys were designed to provide a multistage, stratified, probability sample that was representative of the 48 contiguous states. These surveys consist of food consumption data obtained over two or three days based on questionnaires completed by consumers. OPP considers these data adequate to determine average chronic consumption patterns and to model acute consumption patterns as distributions. However, OPP does *not* consider these data adequate to model *chronic* consumption patterns as distributions across the population. Respondents provided the recall information on their children. Demographic information collected as part of the surveys allows classification of food consumption information by categories, such as children. Even though the populations surveyed were large, certain demographic categories, including infants and children, contain too few people to develop meaningful consumption distributions for certain food items that have a low probability of being consumed during a two- or three-day period. This was recognized in 1993 in the NAS/NRC report, "Pesticides in the Diets of Infants and Children". Since then, work has been underway to

plan and fund a supplementary surveys that will provide more robust data for young children. This survey is now underway.

For acute consumption for children, the NSCF and CFSII surveys should provide adequate, high quality data to model distributional patterns. Using these data, the Agency currently addresses total population and subpopulation risk for a variety of age groups, such as infants, children 1-6 years of age, and children 7-12 years of age. Such age clustering is needed because of the limited number of observations for each year of age. The next round of CFSII survey data will allow EPA to further disaggregate these age groups.

Several limitations have been identified with the available data sets:

- Since these were 2- or 3-day surveys, data from the NSCF and CFSII can not be used for probabilistic modeling of *chronic* food consumption patterns. Frequently, foods are not consumed repeatedly by an individual sampled during the survey. Also seasonality and demographics make it unlikely that 2-3 day surveys can generate surrogate chronic consumption data of sufficient validity in most instances.
- Only a very small number of infants and nursing infants were included in the survey, so there is low statistical power for infrequently eaten foods.
- Dietary exposure assessments should be conducted for the age groups given in Section II. The ability to conduct assessments for these age groups is limited by the number of participants in each age category that were in the surveys.

3. Evaluation of the Assessment Procedures

The dietary exposure assessment procedure is based on the indirect modeling approach. Hence, to have a high level of confidence that the exposure assessment is protective of infants and children, exposure factors and models that are conservative must be used. The Tier 1 and 2 assessment procedures meet this criterion but, in many cases, the data on anticipated pesticide residue levels on food and percent crop treated information may not be available for Tier 3 and 4 analyses.

- Residue data used to estimate dietary exposure to pesticides come from numerous sources. As noted above, Tier 1 and Tier 2 assessments can be considered high-end residue estimates. In Tiers 3 and 4 use data which may or may not be sufficiently conservative to provide high-end exposure estimates, depending on which data are used in the exposure assessment.
- The food consumption data can be used to provide probability distributions for acute consumption estimates. Thus, reasonable high-end consumption patterns can be estimated for children in two age groups, 1- to 6-year olds and 7- to 12-year olds. If the age groups are further subdivided, the error associated with distribution estimates at the high-end becomes large. When these data are combined with the very conservative Tier 1 and 2 residue data, exposure assessments should still be sufficiently conservative to protect infants and children. When used with Tier 3 and Tier 4 data, these assessments may not be sufficiently conservative unless the Tier 3 and Tier 4 data can plausibly be interpreted to provide a “high end” estimate of residue levels. However, in most cases, sufficient

information is available to demonstrate that these assessments do not underestimate exposure.

- Food consumption data can be used to estimate deterministically chronic dietary consumption and exposure with conservatism. However, they cannot be used to conduct a probabilistic chronic dietary exposure analysis at this time.

4. Recommendations to Improve the Assessment Procedures

Exposure assessments that are protective of infants and children must be **certain** or **conservative**. The more uncertain the models or the data in the assessment, the more conservative they must be. Currently, the screening level assessments that are used have a high degree of uncertainty but they are also very conservative. To make less conservative estimates that are still protective of infants and children, work must be conducted that reduces the uncertainty associated with the methods, exposure factors, and models. Recommendations for improving the dietary exposure assessment process are consistent with those delineated by The National Research Council, in the document *Pesticides in the Diets of Infants and Children* (NRC, 1993).

- A simple, uniform method needs to be developed for conversion of a product as consumed to its components in terms of raw agricultural commodities.
- Those foods most frequently consumed by infants and children need to be identified. Distributions of amounts consumed and pesticide residue levels on these foods need to be quantitated more specifically (See 5d below).
- Because of the changing nature of children's diets, food consumption surveys should include adequate sample sizes of children aged 0 to 6 months, 6 to 12 months, 12 to 24 months, 24 to 36 months, 3 to 5 years, 5 to 10 years, and 11 to 18 years (See 5d below).
- Food residue monitoring programs should target a special market basket survey designed around the diet of infants and children (See 5a and b below).
- Methods for residue analysis need to be standardized, as should reporting requirements, and QA/QC procedures. This would allow residue data from different monitoring programs to be combined when estimating exposures (See 5a below).
- More effort is required to define changes in pesticide/metabolite residues during processing (See 5a below).

5. Ongoing Work to Improve the Assessment Procedures

a. EPA and USDA are involved in efforts to obtain additional pesticide residue data for children's foods. These include identifying target pesticide/food combinations for monitoring by the Pesticide Data Program and negotiating with grower and food processor groups to obtain residue data developed during food production. Additional emphasis is being placed upon registrant submission of post-harvest processing factors that demonstrate the impact of washing, peeling, and cooking on residue levels.

b. OPP is in the process of creating a pesticide residue data repository (National Pesticide Residue Data Base) that will enable the Agency to pool residue data from a variety of

sources and make it more available for use by risk assessors.

c. OPP is evaluating the quality and quantity of the residue data for each of the commodities measured in key food surveys.

d. OPP has worked with USDA to develop a survey for collecting additional food consumption data that will approximately double the number of children's observations in the most recent CSFII. The data collection has been completed. The protocol design was such that the data can be directly combined with the data from CSFII 1994-1996. In addition, the Agency has negotiated an agreement to obtain a privately developed consumption data set that can be used to verify and supplement the CSFII data. However, these data can not be directly incorporated into the CSFII data set because of differences in protocol.

e. Until recently, OPP has been limited to conducting its acute dietary risk assessments with the Dietary Risk Evaluation System (DRES). DRES was used for Tier 1 assessments. OPP is replacing the DRES with the Dietary Exposure Evaluation Model (DEEM) which has the capability to conduct both acute and chronic risk assessments, as well as probabilistic (Monte-Carlo techniques) and deterministic risk assessments and uses more recent food consumption data (1989-91 and 94-96). DEEM can therefore be used to conduct Tier 3 and 4 assessments. These assessments also use ranges or distributions of residue levels from field trials and use data on percent crop treated for monitoring for estimating exposure.

IV.B. Drinking Water Exposure

1. Assessment Procedures

Prior to the enactment of the FQPA, human exposure through the drinking water route was not routinely factored into decisions about acceptable levels of pesticide residues on food (i.e., the FIFRA registration decision and the setting of FFDCA tolerances). OPP's approach to managing pesticides which had the potential to contaminate water was to emphasize prevention; OPP required mitigation measures such as geographic restrictions on use (to protect groundwater) and buffer zones (to protect surface water) to reduce the likelihood of contamination.

OPP's latest interim approach for addressing the "FQPA drinking water issue" was formulated in November 1998 (see Appendix B). Exposure estimates for drinking water are generated by combining default consumption factors with modeling estimates of pesticide residues in source waters. The model estimates represent upper bounds on concentrations of pesticides that might be expected in surface and ground water. It is then assumed that the same concentration will be found in drinking water. This policy is currently out for public notice and comment.

OPP takes the assessment a step further by comparing this exposure estimate to a health threshold termed the theoretical upper limit (TUL) of a pesticide in drinking water. The TUL is

determined based on the concept of aggregate exposures from food, residential pesticide use, and drinking water. The TUL may be expressed mathematically as

$$AHT = E_{diet} + E_{res} + TUL$$

or

$$TUL = AHT - (E_{diet} + E_{res})$$

where

AHT is the aggregate health threshold level,
E_{diet} is dietary exposure, and
E_{res} is exposure from residential use of pesticides

As a screening-level risk assessment, the TUL is then compared to the estimates of pesticide concentrations in drinking water that are generated using environmental fate models. If the pesticide concentration estimated from the model is less than the TUL, then drinking water residues (when considered along with other sources of exposure for which OPP has reliable data) should not result in a human health risk..

The next generation of this approach will need to incorporate the estimation of dermal and inhalation exposure from the use of drinking water for non-drinking purposes, such as bathing or doing the dishes, and for incorporating non-occupational, non-residential exposures, if they occur for the specific pesticide(s) under evaluation.

2. Data, Factors, Models, and Key Assumptions Used in the Assessment Procedures

Pesticide Residue Data

Currently, the validity of the measurement databases for pesticide residues in surface water, ground water, or drinking water has not been fully established. Models, including GENEEC, PRZM-EXAMS, and SCI-GRO are used in the interim approach. These models use pesticide residue concentrations in ground water and surface water to estimate drinking water concentrations. OPP views the output estimates of these models to be upper-bound estimates of potential pesticide concentrations in drinking water.

Drinking Water Consumption Data

Because few direct measurements of water consumption for consumers are currently available, the Agency has been using the consumption factors and body weights shown in Table 3 as part of its interim approach. These factors are based on reliable data and are considered to be conservative, high-end values for water consumption.

Table 3. Water Consumption Factors and Body Weights

Population	Consumption Volume (liters)	Body Weight (kg)
General U.S. population	2	70
Females 13+	2	60
Other adult populations	2	70
All infant/children populations	1	10

The use of these values is consistent with the risk assessment methods used by the Office of Water to establish Maximum Contaminant Levels (MCLs) and Health Advisory Levels (HALs) and can be found in the Agency's Exposure Factors Handbook.

3. Evaluation of the Assessment Procedures.

The current drinking water exposure assessment procedure is based on the indirect modeling approach. Hence, to have a high level of confidence that the exposure assessment is protective of infants and children, exposure factors and models that are conservative must be used. The current procedures for estimating exposures in drinking water meet this criterion. Key elements of this conclusion follow.

- The models used to estimate pesticide concentrations in ground and surface waters provide bounding estimates. Although the models do not estimate drinking water concentrations, the estimates for ground and surface waters can be used as conservative surrogates for drinking water.
- The factors used for drinking water consumption are high-end for the population because they are based on data for humans who are very active at elevated temperatures and assume that all water intake for a day is from the tap (as opposed to other sources, e.g., juice, milk, bottled water, water consumed outside of the home, etc.).

4. Recommendations to Improve the Assessment Procedures

Exposure assessments that are protective of infants and children must be **certain** or **conservative**. The more uncertain the models or the data in the assessment, the more conservative they must be. Currently, the screening level assessments that are used have a high degree of uncertainty but they are also very conservative. To make less conservative estimates that are still protective of infants and children, work must be conducted that reduces the uncertainty associated with the methods, exposure factors, and models. For drinking water assessments the following recommendations are made.

- The uncertainties in current residue databases for source waters, ground water, and drinking water should be evaluated. Information should be collected to characterize the inherent degree of conservatism in the existing models and/or databases.
- The uncertainties associated with current exposure assessment models/frameworks used to

evaluate drinking water exposures to pesticides for infants and children should be evaluated and reduced where needed.

- The OW evaluation of water consumption data needs to be concluded, evaluated, and decisions made as to the adequacy of the current default values used for infants and children. If the evaluation points to continued uncertainty about whether they are protective, then more accurate data will need to be collected.

5. Ongoing Work to Improve the Assessment Procedures

- OPP is continuing to refine its interim drinking water assessment approach based on experience gained with its early-generation procedures, the work of an International Life Sciences Institute expert workgroup and the recommendations of the FIFRA Scientific Advisory Panel (SAP).
- Both the ODW and OPP are working to provide an assessment of the reliability and adequacy of current pesticide residue databases for surface and ground water information.
- Efforts are underway in OPP to improve existing databases, to collect available data on pesticides in drinking water, and to generate data on pesticides in drinking water.
- OW will generate estimates of tap and bottled water intake based on the USDA's 1994, 1995, and 1996 Continuing Survey of Food Intake by Individuals (CSFII). Information and data provided through this investigation will include: the CSFII, 1994, 1995, and 1996 data; methods used to calculate the amount of indirect tap water in specific foods; data on daily average water consumption for individual respondents; data on subpopulations of interest; and statistical methodologies used to generate point estimates of empirical distributions of long-term average daily tap water intake.

IV. C. Nonoccupational Exposure Assessment Procedures

1. Assessment Procedures

"Nonoccupational" refers to all pesticide exposures in a range of microenvironments including homes, schools, day care centers, etc. It covers a very wide-range of scenarios that can result in exposure through all three routes – oral, dermal, and inhalation. Figure 1 (Section II) depicts the complexity associated with residential and other exposures and shows all of the known potential sources, pathways, and routes of exposure. Exposure pathways include those that occur indoors and outdoors at the home as well as at other institutional and residential settings, such as schools and daycare centers. A complete exposure assessment should consider all of the important exposure routes and pathways (e.g. crack and crevice application indoors, pesticide residues on hard surfaces, transfer to skin via dermal contact, exposure not resulting directly as a consequence of use as a pesticide) for infants and children.

Given the great difficulties with direct methods, an indirect deterministic modeling approach is currently being used. This approach is documented in the draft *Standard Operating*

Procedures (SOPs) for Residential Exposure Assessments (relevant SOPs are listed in Table 4).[2] The objective of these SOPs is to provide high-end screening level methods (models and exposure factors) for developing Tier 1 residential assessments for both handler and postapplication exposures and, thus, are considered to be conservative estimates. Additionally, this SOP document was intended to identify the important residential exposure scenarios for young children. Each SOP provides procedures for estimating short- and intermediate-term or acute daily doses for a single route and pathway of exposure. These residential SOPs do not cover other nonoccupational settings, such as schools, parks, and day care centers. However, they may be applicable to these settings. Exposures from each residential and other nonoccupational setting must then be aggregated to estimate total exposure. Each SOP includes: a description of the exposure scenario, the recommended methods (i.e., algorithms/models and exposure factors) for quantifying doses, example calculations, limitations and uncertainties associated with the use of the SOP, and references. These draft SOPs have been reviewed by the SAP (September, 1997) and are currently receiving public notice and comment review.

2. Data, Factors, Models, and Key Assumptions Used in the Assessment Procedures

Monitoring Data

Although often data are not available for directly assessing residential exposure to infants and children, when available, they can be used as inputs to and development of models for assessing exposure. Several field monitoring studies have been conducted to evaluate personal exposures to pesticides in residential settings (Appendix C.1). The Nonoccupational Pesticide Exposure Study (NOPES)[7] was the largest, with over 600 participants; however, adults were the primary participants and inhalation was the principal exposure pathway studied. The National Human Exposure Assessment Survey (NHEXAS) involved multimedia, multipathway measurements of over 500 people of all ages, selected as a probability sample. Only a small number of children were involved in the main study and an even smaller portion had pesticide monitoring. A correlated study enriched for children measured multimedia, multipathway exposures to Chlorpyrifos and several other common pesticides. Several pilot studies (less than 9 participants) have been conducted with children to evaluate multimedia, multipathway exposures to pesticides in homes or daycare settings. These existing studies cannot meet the criterion of providing high quantity data on children's exposure to pesticides, even for the pesticides that have been monitored.

Some biomonitoring data are available with which to assess exposure. The recent work of Fenske[10] on organophosphate exposure among children of agricultural workers and recent NHANES data on Chlorpyrifos in urine[11] suggest relatively low pesticide exposures. Although Fenske studied preschool children, monitoring was not conducted after a residential pesticide application. These data, therefore, do not reflect the elevated short-term exposures modeled in the SOPs. NHANES did not include young children and again results are not expected to reflect short-term exposures resulting from recent pesticide applications. In addition, the state-of-the-art of biomonitoring for pesticides is still under development. Currently, biomarker data may be

useful to show correlations between pesticide concentrations in exposure media and biological samples to suggest an exposure. However, the quantitative relationship between a measurement of a metabolite in one urine sample to an exposure level of the parent compound is not well established for most pesticides, especially for children.

Activity Pattern Data

Many of the same field studies identified above collected time/activity pattern data for children that could be used as part of an indirect modeling approach for exposure assessments to pesticides. A summary of these studies is also given in Appendix C.1. As shown, most of the databases include information on time spent at a given location or conducting a given activity. There is very little information available on specific indoor locations where children spend their time, what type of surface they contacted, what they were wearing (i.e., how much surface was exposed), and what was their hand-to-mouth or object-to-mouth activity. The National Human Activity Pattern Survey (NHAPS)[8 a,b,c] is the largest probability activity survey ever conducted in the U.S., but it has few children in the 0 to 4 age group (approx. 500), thereby creating uncertainty in the distribution of activities. Most of the data can be used for estimating inhalation exposures, but they are not useful for developing input variables for estimating dermal uptake and absorption, nondietary ingestion, or dietary ingestion of home-contaminated foods. Most studies that have collected data on hand-to-mouth activities, etc., are small and data have not been thoroughly evaluated. Pica behavior and the amount of soil, dust, or pesticide pellets consumed is also an area of high uncertainty. The NHAPS does not provide information on the age or season-dependent changing of activities.

Exposure Scenarios/Exposure Factors

Each Residential Exposure SOP addresses a single exposure scenario. Overall, the SOPs cover more than 40 scenarios (Appendix C.2.). There are 25 SOPs relevant to children's exposure (Table 4). Each of the scenarios vary significantly in terms of their scientific foundation. For example, many of the approaches and exposure factors used in the scenarios are supported by a substantial pool of empirical data. In other cases, exposure factors and algorithms have been developed in lieu of data or use preliminary data in order to address obvious exposure scenarios. Appendix C.2 provides a preliminary evaluation of all of the assumptions and exposure factors in the SOPs. Table 5 evaluates the critical assumptions and factors that are used to assess children's exposure.

TABLE 4. SOPs Relevant to Exposures for Infants and Children[a]

SOP No.	SOP Title	Children Included
2.2	Postapplication Dermal Potential Dose from Pesticide Residues on Turf	toddler (1 to 4 years)
2.3.1	Postapplication Potential Dose Among Toddlers from the Ingestion of Pesticide Pellets or Granules from Treated Areas	toddler
2.3.2	Postapplication Potential Dose Among Toddlers from Incidental Nondietary Hand-to-mouth Transfer	toddler
2.3.3	Postapplication Potential Dose Among Toddlers from the Ingestion of Pesticide-Treated Turf Grass	toddler
2.3.4	Postapplication Potential Dose Among Toddlers from Incidental Ingestion of Soil from Pesticide-Treated Residential Areas	toddler
3.2	Postapplication Dermal Potential Doses from Pesticide Residues on Gardens	toddler
3.3.1	Postapplication Incidental Nondietary Ingestion – Eating Pellets or Granules	toddler
3.3.2	Postapplication Incidental Nondietary Ingestion – Hand-to-Mouth Transfer	toddler
3.3.4	Postapplication Incidental Nondietary Ingestion – Soil Ingestion	toddler
4.2	Postapplication Dermal Potential Doses from Pesticide Residues While Harvesting Fruit from Trees	youth (10 to 14)
5.2.1	Postapplication Potential Doses from Incidental Nondietary Ingestion of Pesticide Residues While Swimming	6 years
5.2.2	Postapplication Dermally Absorbed Dose from Swimming in Pesticide-Treated residential Swimming Pools	6 years
5.2.3	Postapplication Potential Dose from Inhalation of Pesticide Residues in Swimming Pools	6 years
6.3	Postapplication Potential Dose Among Children from the Ingestion of Paint Chips Containing Pesticide Residues	infants (6 to 18 months

SOP No.	SOP Title	Children Included
7.1	Inhalation Doses Among Adults and Children after Pesticide Applications (e.g., Foggers) Outside of a Residence for the Purposes of Short-Term Pest Control	toddler
8.2.1	Postapplication Dermal dose from Pesticide Residues on Carpets	toddler, infants
8.2.2	Postapplication Dermal Dose from Pesticide Residues on Hard Surfaces	toddler, infants
8.3	Postapplication – Inhalation	toddler
8.4	Postapplication Doses Among Toddlers from Incidental Nondietary Ingestion of Pesticide Residues on Indoor Surfaces from Hand-to-mouth Transfer	toddler
9.2.1	Postapplication Dermal Dose from Pesticide Residues on Pets	toddler
9.2.2	Postapplication Potential Dose Among toddlers from Incidental Nondietary Ingestion of Pesticide Residues on Pets from Hand-to-mouth Transfer	toddler
11.2	Postapplication Pesticide Residue Dermal and Inhalation Dose from Material Impregnated with Pesticides	toddler
11.3	Postapplication Doses Among Toddlers from Incidental Nondietary Ingestion of Pesticide Residues Contained in Impregnated Materials	toddler
12.2	Postapplication Inhalation from Termiticides	toddler
13.2	Inhalation Bystanders and Postapplication Dose Among Adults and Children From Pesticide Applications in and Around a Residence	toddler

[a] Handler SOPs not included; all handler SOPs included youth ages 10 to 12 years.

TABLE 5. Important Exposure Factors in the Residential SOPs used to Estimate Children's Exposure to Pesticides

Parameter	Assumption	Relative Uncertainty
Dermal Adsorption	100% or data provided by manufacturer or others	May greatly overestimate uptake. This may be especially important when pesticide is bound to particles. When data are provided by manufacturer or others, then the assumption is not conservative

Parameter	Assumption	Relative Uncertainty
Dislodgeable Residues	20% from carpets, 50% from hard surfaces	Based on OPP's review of chemical-specific data. This term is the % of pesticide that is applied that has reached the surface and is extractable with an aqueous extracting solution. It is based on experimental data for freshly applied pesticides to carpets. Reported values from carpet were 50%. This may not be a conservative assumption.
Transfer Coefficient	8700 cm^2/h	This term takes into account the fraction of the dislodgeable residues transferred during contact and the surface area of contact. This is probably a conservative number when contact is made with a carpeted surface because data were generated based on a jazzersize routine, which would have a high surface contact area relative to many children's activities. The magnitude of how conservative this value is unknown. This may not be a conservative number when contact is made with a hard surface. Data have shown that 10 times more residues are transferred from a hard surface to the hand than from carpet to the hand.
Contact Area-Child Hand Surface Area	350 cm^2	Surface area for the hand is reasonable. This is conservative in that it assumes that the entire hand contacts the surface and then is put in the mouth. There is an additional conservative assumption that all of the pesticide is removed from the hand into the mouth during contact. There are no data available on this. Hand-to-mouth is the only mouthing activity defined, but small children may also mouth toes, hair, arms, etc.
Hand-to-Mouth Activity	1.56 times per hour	This is not conservative; other data by Freeman and Zartarian suggest that 10 is a better value.
Exposure Times	Turf - 2h/day garden- 0.33h/day trees-0.33h/day swim-5h/day (6 to 12 years) outdoor-3h/day carpets- 8h/day hard surfaces-4h/day	Relatively high; in the absence of data many assumptions made.

Parameter	Assumption	Relative Uncertainty
	pets-2h/day mattress-8h/day	
Impregnated Materials, Object-to-Mouth	once per day	High uncertainty– this is an assumed value. Whether this is a conservative value for young children depends on the object. The scenario of children mouthing contaminated objects has not been included. Because this could result in substantial exposure, it is not overly conservative. There are no data on potential exposures from this route.
Turf Ingestion	25 cm^2/day	Assumed as the amount of grass a child can grasp. Assumes they will eat grass and that they eat one handful. This is probably a conservative assumption.
Soil/Dust Ingestion	100 mg/day	Derived from the Exposure Factors Handbook where this is given as a mean daily intake, this appears reasonable and not conservative based on measurement data.
Water Ingestion During Swimming	0.05 L/h for 6 year old	Stated as mean from the Exposure Factors Handbook.
Swimming-Inhalation Rate	1.2 m^3/hr	Based on data for moderate physical activity

The draft SOPs are considered to be a good start for conducting residential exposure assessments for FQPA. However, there are several major uncertainties and limitations with respect to both the exposure scenarios and the exposure factors. There are a number of important exposure scenarios that are not included in the current version of the SOPs.

- Only residential scenarios are included in the SOPs. Pesticide exposure can occur in other nonoccupational settings. Exposure scenarios specific to microenvironments where children spend a substantial portion of their time (i.e., day care centers and schools) may provide important exposure pathways that are different from those in the home.
- Exposure to pesticides from turf application is considered in the SOPs. Secondary exposure resulting from lawn or other outdoor pesticides being tracked into the home should also be addressed. When this happens, children can be exposed to outdoor pesticides within their home. Within the home, pesticide dissipation rates are often much slower than outdoors, so there is a potential for much longer exposures, both per day (8 hours on a carpet vs. 2 hours on the grass) and over time (weeks vs. days for dissipation).
- Very recent studies suggest that for residential pesticide applications, all objects (not just the floor or carpet) within the home must be considered as potential sinks for pesticides.

These objects should then be considered secondary exposure sources for residential pesticide exposure, much like the track-in scenarios. The most important objects would be those that the child puts in his/her mouth, including body parts other than hands, clothing, toys, blankets, bottles, pacifiers, teething rings, and food.

- Foods can become contaminated with pesticides in the home if they are stored, handled, or eaten in an area with pesticide residues. Foods contaminated in this way may be an important source of dietary exposure to pesticides. This is especially true for young children who eat with their hands and eat food off of floors and other surfaces that may be contaminated with pesticide residues.
- Most scenarios consider only one group, toddlers (1- to 4- year olds). Exposure scenarios and models for infants (0 to 6 months), crawlers (6 to 12 months), and young toddlers (12 to 24 months) should be included as separate groups.

In some cases, the exposure factors that are currently used in the SOPs are based on literature reports and on professional judgement. In other cases, exposure factors are the same as those in the EPA *Exposure Factors Handbook*[3]. It should be recognized that the factors in this document have varying degrees of scientific foundation. They have received peer review by the SAP. Because the adequacy of the underlying data is described in the document, this element must also be considered in the exposure evaluation. As shown in Table 5, some of the factors (i.e., transfer coefficients) may overestimate exposure. On the other hand, other factors (i.e., a rate of 1.56 contacts/hour for hand-to-mouth activity) may underestimate exposure.

3. Evaluation of the Assessment Procedures

The nonoccupational exposure assessment procedure is based on the indirect modeling approach. Hence, to have a high level of confidence that the exposure assessment is protective of infants and children, exposure factors and models that are conservative must be used. Residential exposure assessments are based an the indirect modeling approach. The Tier 1 residential exposure assessments for short-term exposures generated by the SOPs generally appear to meet this requirement.

It should be understood, however, that because not all exposure scenarios are included in the SOPs, the exposure assessment must be evaluated on a case-by-case basis. This will ensure that those scenarios that produce the highest exposure and dose estimates have been included and the assessment is sufficiently conservative to protect infants and children.

In spite of the fact that there is uncertainty for many of the exposure factors, the overall exposure estimates being used are probably conservative. Essentially, the draft Residential SOPs for short-term exposures mirror the strategy for creating reasonable high-end scenarios as indicated in the EPA's *Dermal Exposure Assessment: Principles and Applications* (EPA/600/8-9/011F)[9]. The specific guidance from this document is as follows:

"The strategy for selecting default values is to express them as a range from a central

value to a high end value of their distribution. Where statistical distributions are known, the central value corresponds to the mean and the high end value corresponds to the 90 or 95th percentile. Where statistical data are not available, judgement is used to select central and high end values. This strategy corresponds to the default selection strategy used in the Exposure Factors Handbook (EPA, 1989a)[3]. [Note: These principles are also used in the 1997 version.] Note that the range of values is intended to represent variations that occur across a population. Ideally, assessors should also consider uncertainty in the actual value due to measurement error or other factors. The combination of these factors to derive an exposure estimate can create scenarios of varying severity. Ideally, these combinations would be made via statistical techniques such as Monte Carlo Analysis. However, this requires detailed knowledge of the distributions of each input variable, which is rarely available. Lacking such data, some general guidance can be offered as follows: use of all central values for each parameter should produce a central value scenario; use of all high end values for each parameter, produces a bounding estimate that is usually above the high end of the distribution; and a mix of high end and central values is probably the best way to create a reasonable high end scenario."

4. Recommendations to Improve the Assessment Procedures

Exposure assessments that are protective of infants and children must be **certain** or **conservative**. The more uncertain the models or the data in the assessment, the more conservative they must be. Currently, the screening level assessments that are used have a high degree of uncertainty but they are also very conservative. To make less conservative estimates that are still protective of infants and children, work must be conducted that reduces the uncertainty associated with the methods, exposure factors, and models. Recommendations relative to non-occupational exposure assessment follow.

- ORD and OPP should strive to obtain empirical data, as well as develop probabilistic modeling to allow calculation of more realistic exposure assessments.
- OPP and ORD should lead the development of the next generation of methods and approaches for making measurements for direct assessments of major residential exposure pathways. Guidelines should follow. Several exist, but data becoming available now and over the next several years will enable improvements/expansions of guidelines.
- OPP should proceed with its reevaluation of some of the exposure scenarios/factors in the SOPs (some overestimate and some may underestimate) and include distributional data, where possible and appropriate. Modeled exposure estimates should be judged against available monitoring data for validation purposes. Significant exposure scenarios that are missing (e.g., daycare centers, etc.) should be studied, evaluated, and included in the SOPs by OPP and ORD.
- New data should be collected for those variables with the greatest uncertainty and the highest potential impact on the resulting exposure estimate. Data could be generated by the registrant as part of the registration package, by the research community at large, or by ORD. Only those exposure variables that are chemical specific and that have a standard

protocol for testing should be provided by the registrant. Possible candidates include measurement of absorption rates and permeability coefficients, measurements of transfer coefficients, concentrations in soil after application, dissipation rates, leaching from consumer products, etc. Other issues are more generic and would provide the basis of reduced uncertainties associated with dermal methods and exposure. ORD is designing research to evaluate a few of these fundamental exposure variables.

- The nature of the science of exposure analysis is that the optimal assessment will be a blend of measurement data and modeling. Therefore, scientifically robust probabilistic multimedia, multipathway exposure models for nonoccupational exposure scenarios should be developed by ORD. This will require an extensive program that includes measurements to provide the scientific foundation for the models and the means to verify their accuracy. Improved exposure factors that follow from the recommendations above will be an asset to these models. The models should also have a high quality estimate of uncertainty.

5. Ongoing Work to Improve the Assessment Procedures

- OPP is reevaluating the draft SOPs for adequacy to assess residential exposure to infants and children, as per FQPA mandates. Revisions are being submitted to the Scientific Advisory Panel for expert review. They are currently undergoing public notice and comment review. Revised SOPs will be available in mid-1999. However, even if all the SOPs were founded on high quality and quantity of data, they would provide a highly quantitative assessment only if they encompass the full range of nonoccupational exposure scenarios.
- The exposure factors that are used for estimating exposure for each scenario should be based on reliable data. To ensure this, each factor should be carefully evaluated against this criterion and revised if necessary. As a first step, ORD is in the process of collecting, reviewing, and summarizing the available data.
- Several large studies to be funded or conducted by ORD are now in the planning stages or underway. These studies will evaluate children's exposure to selected pesticides, including several organophosphate pesticides. This research should provide important information on the magnitude of pesticide exposures in children and the factors that affect exposures under the study conditions. Most of these studies will evaluate chronic pesticide exposures, as compared to short-term exposures that can occur immediately after pesticide application. These studies should therefore be useful in improving the state-of-the-science of exposure analysis measurements and defining the important scenarios and pathways of chronic exposure to consider when using a modeling approach.

V. AGGREGATE (MULTIPATHWAY) EXPOSURE ASSESSMENTS

Traditionally, OPP's exposure assessments have focused on a single chemical and single route of exposure. Currently, there are several OPP groups actively working on aggregate exposure/risk issues. The first workgroup is evaluating drinking water issues and identifying long term goals, one of which is to develop a database of groundwater and surface water residue information. The Agency continues to examine multiple pathways of exposure in addition to food (e.g., drinking water and other residential sources). Historically, these exposures and resultant risks have been expressed individually, not as combined exposures or risks.

FQPA mandates consideration of aggregate exposures to pesticides from food, drinking water and all other non-occupational sources. Currently, the approach is to sum the single point estimates for each exposure source. This is very conservative for two reasons. First, the estimate for each source is conservative because it is based on high-end exposure assumptions. The aggregate or summed exposure should, therefore, be conservative. Second, the approach to sum the single point estimates for each source assumes that an individual will not only receive an exposure from all sources, but a high-end exposure from all sources. Based on this very conservative approach, there should be a high level of confidence in these exposure assessments that they are protective of infants and children.

The Agency will be developing new data and exposure models for estimating specific pesticide exposures from non-food sources. Until this information can be generated and validated, the Agency will estimate aggregate risk/exposure using an interim approach which relies on health protective scientific judgements for estimating relative contributions from food and other nonoccupational sources.

The document entitled *Interim Guidance for Conducting Aggregate Exposure and Risk Assessments* (November 26, 1998)[13] provides an initial foundation for combining risks by route, but this needs considerable work on refining exposure and characterizing important exposure information and pathways specific to infants and children. This proposed guidance document is currently undergoing public notice and comment review. Major uncertainties exist in a comprehensive assessment of exposures to pesticides and development of realistic/appropriate scenarios for combining, assessing, and assigning levels of risk to combined pathways of exposure (food, drinking water, and nonoccupational). As pointed out in the *Interim Guidance for Conducting Aggregate Exposure and Risk Assessments*, current methods for aggregating exposures use simple addition and do not account for the distribution of exposure and risk across the population; they only provide bounding point estimates. Methods more clearly demonstrating the range of risks across the population and population subgroups, such as probabilistic Monte-Carlo simulation models, are needed.

ORD is conducting research to develop probabilistic exposure and dose models for children's exposure to pesticides. A two-stage Monte-Carlo simulation system will be used in the probabilistic pesticide exposure /dose model. Both the uncertainty in each model parameter and

the variability in the concentrations or exposure factors will be explicitly simulated with this new procedure. Acute, as well as short-term, intermediate-term, and chronic average exposures/dose to selected pesticides will be predicted based on various scenarios of pesticide use. The model outputs will provide information on estimates of both inter-individual variability in the population exposure/dose, as well as uncertainty in the predicted percentiles of the age and gender-specific empirical pesticide exposure/dose distributions.

Efforts are underway in OPP to develop an appropriate policy for aggregate risk and exposure assessments. Draft guidance is anticipated to be developed in March, 1999, with final guidance submitted in June, 1999. Until this time, the interim guidance will be used, and new methods and data will be incorporated into assessments as they become available.

The Exposure Group recommends continued development of the aggregate risk/exposure approaches used by the Agency. Until this guidance is more completely developed and incorporates existing and newly developing exposure measurements and models specific to infants and children, an appropriate set of recommendations regarding use of the current guidance would be premature.

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12. Vaccaro, J.R.; Nolan, R.J.; Murphy, P.G., and Berbich, D.B.; The use of unique study design to estimate exposure of adults and children to surface and airborne

chemicals; American Society for Testing and Materials, Standard Technical Publication 1287, ASTM, West Conshohocken, PA, 1996.

13. Interim Guidance for Conducting Aggregate Exposure and Risk Assessments" (November 26, 1998)

14. 40 CFR 180.240 Residue Chemistry Data Requirements for Pesticide Tolerance Setting.(Appendix A.)

15. OPPTS Test Guidelines Series 860–40 CFR 180.240.(Appendix A.)

16. OPPTS Test Guideline 860.1540–Anticipated Residues.(Appendix A.)

17. 40 CFR Parts 141, 142 and 143- National Primary and Secondary Drinking Water Regulations; Proposed Rule.(Appendix A.)

APPENDIX A. CHARACTERIZATION OF AVAILABLE DATA AND GUIDANCE DOCUMENTS FOR DIETARY EXPOSURE ASSESSMENTS

Pesticide tolerances are listed in 40 CFR 180. A pesticide tolerance is the maximum legal residue allowed on a crop/feed item resulting from registered uses. Pesticide tolerances are used to regulate raw agricultural commodities as they travel in interstate commerce. Residue chemistry data requirements and associated guidance documents for the establishment of pesticide tolerances include:

Data Requirement	OPPTS Guideline	EPA Pub. No.
Background	860.1000	712-C-96-169
Chemical Identification	860.1100	712-C-96-170
Direction for use	860.1200	712-C-96-171
Nature of the residue Plants Livestock	860.1300	712-C-96-172
Residue analytical method	860.1340	712-C-96-174
Multi residue method	860.1360	712-C-96-176
Storage stability data	860.1380	712-C-96-177
Water, fish, and irrigated crops	860.1400	712-C-96-178
Food handling	860.1460	712-C-96-181
Meat/milk/poultry/egg	860.1480	712-C-96-182
Crop field trials	860.1500	712-C-96-183
Processed food/feed	860.1520	712-C-96-184
Proposed tolerance	860.1550	712-C-96-186
Reasonable grounds in support of the petition	860.1560	712-C-96-187
Submittal of analytical reference standards	860.1650	712-C-96-016
Confined accumulation in rotational crops	860.1650	712-C-96-188
Field accumulation in rotational crops	860.1900	712-C-96-189

Pesticide residue monitoring data, to assure compliance with established tolerances and for assessing dietary risk assessments, are collected by:

- Food and Drug Administration, Center for Food Safety and Applied Nutrition (FDA/CFSAN).
- United States Department of Agriculture, Agriculture Marketing Service (USDA/AMS).
- United States Department of Agriculture, Food Safety Inspection Service (USDA/FSIS).
- State Monitoring Programs (primarily CA and FL)

Guidance documents, describing how dietary exposure assessments are derived, include:

- Policy for Anticipated Residues in Chronic Dietary Exposure Assessments (OPPTS 860.1540).
- Policy for Generating Acute Dietary Exposure Assessments (D. Edwards, 6/13/96).
- Guidance for Submission of Probabilistic Exposure Assessments to the Office of Pesticide Programs' Health Effects Division (presented to SAP 3/24/98).

Types of Residue Data

Available residue data (see above) generated to establish and reassess pesticide tolerances, and assure compliance with established tolerances are also used to estimate dietary exposure. These data are briefly described below:

Nature of the Residue in Plants and Animals (OPPTS 860.1300).

Plant and animal metabolism studies are designed to characterize the chemical composition of the pesticide residue in plants and animals. In plant metabolism studies, the plant is treated with the pesticide, usually radiolabelled with ^{14}C, in a manner similar to the proposed use. For example, if corn were to be treated with a pesticide using foliar spray applications, foliar applications of the radiolabelled pesticide would be made to corn in the metabolism study. Following pesticide treatment, the plant is managed as closely as possible to the way the plant would be managed in the field and samples of important plant commodities are obtained (e.g. corn grain, forage, silage and fodder). The samples usually are collected at times which correspond to normal harvest times. The samples then are analyzed to determine the chemical structures and quantities of metabolites present in the total residue.

Two types of animal metabolism studies normally are conducted. If an animal is to receive dermal pesticide treatments (sprays, dips, etc.), the radiolabelled pesticide must be applied to the animal dermally. If the animal will consume the pesticide or pesticide residue orally, oral administration is required. Following pesticide treatment for a sufficient length of time, animal tissue, milk, and egg samples are obtained and analyzed to determine the chemical structures and quantities of metabolites present in the total pesticide residue.

The tolerance expression which is published in 40 CFR Part 180 for each pesticide,

describes which chemical components of the pesticide must be regulated. Metabolites are included in the tolerance expression depending on their toxicological significance, their percentage of the total residue, and whether analytical methodology can be developed to measure residues of the metabolite in agricultural commodities. Methodology is essential for metabolites which are both toxicologically significant and present at significant levels. The active ingredient and significant metabolites are called the total toxic residue. If one component of the residue is significantly more toxic than the other components, two levels may be necessary in the tolerance expression.

Analytical Methodology (OPPTS 860.1340, 860.1360)

Chemical components of the pesticide residue which must be included in the total toxic residue are determined in metabolism studies. Once the total toxic residue has been determined, analytical methods must be developed to allow determination of residues of these components in agricultural commodities (raw, processed or animal) for which tolerances are required. These analytical methods are necessary to provide residue data in residue field trials and as a means of enforcement of the tolerances.

Crop Field Trials (OPPTS 860.1500)

After the metabolism studies have indicated what to look for and analytical methods have been developed to measure the total toxic residue, the actual residue field trials are carried out. These are studies in which the pesticide is applied to crops in a manner similar to the directions for use which will eventually appear on the label; then, samples are obtained and analyzed for total residues. The purpose of residue field trial studies is to determine the appropriate tolerance level which is the maximum legally allowable pesticide residue and is used to regulate the commodity as it travels in interstate commerce. Data normally are required for each crop (or for representative commodities in a crop group as defined in 40 CFR 180.34(f)(9)) for which a tolerance and registration is requested. Data also are required for each raw agricultural commodity (rac) derived from the plant (for example, corn residue data would be required for the grain and the forage, silage, and fodder). Samples generally are placed in frozen storage immediately after collection to minimize loss or dissipation of the pesticide residue prior to analysis. The field trial data must reflect the use conditions that could lead to the highest residues and must represent the highest application rate, the maximum number of applications, and the shortest time intervals between applications and between the last application and harvest to be included on the label. The residue data also must be representative of major growing areas and seasons, major types or varieties of the rac, the general types of pesticide formulations for which registration is requested, and the types of applications to be made (e.g. ground applications, aerial applications, ultra-low volume aerial applications.)

Processed Food/Feed (OPPTS 860.1520).

Processing studies are designed to determine the concentration (or reduction) of residues when the raw agricultural commodity is processed commercially. Typically, a raw agricultural commodity containing weathered residues, frequently resulting from field applications at exaggerated (higher than maximum label) pesticide application rates to assure obtaining detectable residues, is processed using a method which closely simulates commercial processing. Important processed fractions are obtained at various points in the process and analyzed for the total toxic residue. The ratio of the residue in the processed commodity to the residue in the raw commodity is the concentration (or reduction) factor. If the ratio is greater than 1, the residue is said to concentrate upon processing. If the ratio is equal to or less than 1, there is no concentration of residues. These ratios, if greater than 1, are then multiplied by the tolerance for the raw agricultural commodity to obtain the tolerances for the processed commodities. Tolerances are not required for processed commodities unless the residue concentrates (concentration factor > 1) upon processing.

Meat/Milk/Poultry/Eggs (860.1480)

In animal feeding studies, pesticide residue levels are determined which are likely to be found in meat, milk, poultry, and eggs as a result of ingestion of treated feeds by animals. The maximum residue levels in animal commodities likely to result from ingestion of animal feeds treated at the maximum application rates (and shortest PHIs) are used to determine tolerances for animal commodities (except in cases where dermal applications are also made to the animal in which cases residues from dermal applications also would have to be incorporated into the tolerance level).

In general, animals are dosed with the pesticide for a period of time, and the resultant residues in eggs, milk, and animal tissues are measured (the total toxic residue as determined in the animal metabolism studies). If metabolism studies show that there are plant metabolites which are not also animal metabolites, the animal must be dosed with the metabolites which are plant metabolites and not animal metabolites, as well as with the parent compound.

The livestock dietary burden (residue intake from treated feeds) is determined by multiplying the tolerance level for livestock feed items by the maximum fraction of each feed item in the livestock diet (Table 1, OPPTS 860.1000). Then the residue contributions from each commodity are summed to obtain the total dietary burden of the animal. The feeding levels to be used in the livestock feeding studies are based on the estimated dietary burden of the pesticide in the livestock feed. The levels used should be approximately 1x, 3x, and 10x of the estimated dietary burden, where 1x is the worst case estimate of potential livestock dietary exposure based on the assumption that all components of the feed contain tolerance level residues. The exaggerated feeding levels are particularly important if non-detectable residues are reported at the 1x feeding level; they help show whether residues in tissues vary linearly with the feeding level. Additionally, exaggerated feeding levels will allow for future tolerance requests (the animal dietary residue burden must be less than the maximum feeding level used in the feeding studies or additional feeding studies may be required).

The dietary burden is compared to the levels fed in the livestock feeding study, and the residue in each tissue, in milk, and in eggs is determined from a graph or linear regression analysis. Sometimes a simple ratio is used if the estimated dietary burden is close to one of the levels in the livestock feeding study or is significantly lower than the lowest level in the feeding study. The residue estimated in this manner for meat and poultry tissues, milk, and eggs is rounded upward and becomes the tolerance level. However, the tolerance level is not set at a level lower than the limit of quantification of the analytical method.

Monitoring Data

In a pesticide residue monitoring study, samples of agricultural commodities are obtained at various times and from various locations and analyzed for pesticide residues. The specific commodities sampled, sampling locations and times, numbers of samples, sample sizes, and many other sampling parameters depend on the purpose of the study. Purposes for which pesticide residues are commonly monitored in foods include enforcement of tolerances and effluent discharges, trend analyses, assessment of environmental contamination and dietary exposure assessment. Although our focus here is on dietary exposure assessment, monitoring data obtained specifically for this purpose are not always available for many commodities and pesticides. Therefore, monitoring data designed for other purposes commonly are used taking into account the uncertainties or bias introduced because of the different purposes for which the data were generated. Below we discuss some of the major existing monitoring programs and the factors which determine their usefulness in dietary exposure assessment.

The most widely available monitoring data are those from the FDA and USDA. The Food and Drug Administration (FDA), as part of their enforcement program for pesticides, collects four types of monitoring data: domestic surveillance, domestic compliance, import surveillance, and import compliance. Compliance data generally are the result of targeting collection towards commodities suspected of containing illegal residues, while surveillance samples are collected without any suspicion that a particular shipment contains illegal residues. They are, however, selected partly on the basis of volume of production of a commodity and partly on the basis of prior residue problems with a certain food commodity and growing region. In their surveillance monitoring program, FDA monitors a wide variety of agricultural and processed commodities for numerous contaminants, including pesticides, using primarily multiresidue methods of analysis which are capable of determining a variety of contaminants from a single sample analysis. In its surveillance monitoring program, FDA also conducts incidence/level monitoring to acquire information on specific pesticides, commodities, or pesticide/commodity/country combinations. Among recent incidence/level monitoring conducted by FDA are monitoring for residues of aldicarb (potatoes), captan (cherries), benomyl (apples, grapes, peaches), captafol (apples, cherries, rice), an aquaculture survey, a milk survey, and a processed food survey. Although routine monitoring and incidence/level monitoring provide data for many pesticides, other pesticides are not monitored by FDA or only limited data are available. Domestic samples are collected as close as possible to the point of production in the food distribution chain since the prime objective is to monitor fresh food being shipped in interstate commerce for compliance with

EPA tolerances. Therefore, additional degradation which could occur between the collection point and the "dinner plate" is possible. Information which would allow determination of the location at which a sample was grown is not readily available. Import samples are collected at the point of entry into U.S. commerce (12, 13, 14).

A major objective of the FDA monitoring program is to prevent foods that contain illegal residues from entering interstate commerce. Although the overall program is not designed to provide truly representative sampling of commodities for the purpose of dietary exposure assessment, FDA's FY'92 program includes a trial effort to provide statistically based monitoring data in pears and tomatoes. Bias may enter if the compound of concern was targeted for FDA monitoring and higher than typical levels were seen. If the compound being assessed were not given priority in sample collection, and monitoring were directed towards other competing compounds, the FDA surveillance data for the first compound may show infrequent "detects" and artificially low average residue levels.

FDA also conducts the Total Diet Study, also called the Market Basket Survey, in which pesticide residues are determined in food prepared for consumption. The Total Diet Study is designed to estimate dietary intake of selected pesticides by various U.S. age-sex groups. Foods are collected four times per year in retail markets at 12 locations throughout the U.S. and are prepared as table-ready (cooked) before analysis. Each market basket consists of 234 foods that represent at least 90% of the items in the American diet (14). These data are useful to the FDA for making trend analyses; however, since so few samples of each commodity are obtained, these data have limited use for risk assessment.

FDA includes few samples of meat and poultry (these commodities commonly are included only in the Total Diet Study). Monitoring data may be available for animal commodities from USDA for chemicals included in their routine monitoring programs. Pesticide monitoring data from USDA's Food Safety and Inspection Service (FSIS) primarily include analyses for chlorinated pesticides in animal fat, and other selected pesticides in liver samples. USDA's Agricultural Marketing Service (AMS) monitors shelled eggs and egg products for pesticides, while FDA monitors for pesticide residues in-shell eggs.

The USDA, in cooperation with the EPA and FDA, has recently (1991) initiated the Pesticide Data Program (PDP). This new program is designed to provide actual residue monitoring and usage data to help form the basis for conducting more realistic risk assessments. Briefly, EPA provides USDA with pesticide/commodity combinations for which the EPA desires data; and USDA generates these data (including residue monitoring and usage data). These data are then provided to EPA. The PDP measures residues in fresh fruits and vegetables. An important aspect of this program is that it is designed to meet the data quality and random sampling criteria required for data used for risk assessment.

Monitoring data also may be generated by other sources including states, registrants, and other interested parties such as food processors and consumer or environmental groups.

Monitoring data generated by the states (CA, FL, NJ and others) are available; some of these data are incorporated into a data base acquired through an FDA contract. FDA is working currently with several states to coordinate data collection and compile the data to increase their availability and usefulness (FOODCONTAM project).

EPA has the authority to require pesticide registrants to generate market level surveys of pesticide residues and recently has exercised this authority in issuing "Data Call-Ins" requiring statistically based national surveys for residues of specific pesticides.

Residue Degradation-Reduction Studies (Required only as a result of a specific DCI).

Residue degradation/reduction describes any change in the amount and composition of the total toxic residue from harvest to the point of consumption. Therefore, many types of processes are grouped under degradation-reduction studies including storage, commercial processing, washing, peeling, trimming, cooking, and others. In the case of post-harvest pesticide applications, degradation/reduction describes the changes from pesticide application to consumption. The pesticide may degrade to form less toxic products or to form more toxic products.

Two general mechanisms are responsible for the degradation/reduction of pesticide residues in a commodity: physical processes and chemical processes. Physical processes include washing, volatilization, and removal of parts of a commodity such as peels, hulls or outer leaves. The pesticide also may react chemically in the presence of moisture, heat, light, acids, bases, enzymes, oxidizing or reducing agents, metal ions, or under other conditions which may decrease or modify the residue. The major chemical degradation pathways are oxidation and hydrolysis, both of which can occur by enzymatic or non-enzymatic mechanisms. Most enzymes responsible for pesticide degradation would lose their activity permanently after being heated to 100^{o}C or above.

The kinetics of pesticide degradation generally are assumed to be pseudo first order for a particular degradation process depending only on the pesticide residue level (which would be very low relative to other chemicals involved in the degradation process such as water). However, many degradation processes can occur at the same time. Therefore, in order to determine the overall kinetics of degradation, a mean half-life value (obtained by averaging half-lives calculated from a series of sets of points along the curve of log (residue concentration vs. time) may be used cautiously as an estimate of the half-life of the composite degradation process.

After harvest, commodities can be stored (sometimes for extended periods of time), transported, commercially processed, waxed, washed, peeled, cooked, and treated in other commodity-specific ways. Time and temperature considerations are important when examining the effects of storage, transportation, commercial processing, and cooking. Humidity may be important when examining storage and transportation. The point at which wax (with or without pesticides) is applied to some commodities must be considered (e.g. apples, cucumbers). The

typical way(s) commodities are washed, peeled, and cooked (e.g., boiled, fried, roasted, etc.) are important considerations. Other processes also may be important for specific commodities (e.g., shelling nuts, removal of the outer leaves from lettuce and cabbage, removal of the thick part of the stem from broccoli and asparagus). Residue degradation/reduction studies for representative commodities within a crop group may be sufficient to characterize residue degradation/reduction within the entire crop group if commercial and home preparation practices are similar for the different commodities.

A residue degradation/reduction study should take a treated sample through all of the processes from harvest to consumption and should simulate typical commercial and home practices as closely as possible. Subsamples should be removed at each important point for residue determination in the edible portion of the commodity. In all cases, but particularly when degradation products are more toxic than the parent, application rates should be chosen which are close to the maximum registered rates so that metabolite ratios which approximate those likely to result from typical applications can be determined. Residues in the raw commodities should be well above the analytical method limit of detection at the beginning of the study so that the decline in residues can be measured accurately. Analytical methods must have sufficiently low limits of detection (LODs) so that an acceptable risk can be estimated using the LOD, considering combined risk from all foods.

EPA is working with the National Food Processors Association (NFPA) to develop protocols for commercial processing studies for some commodities. These protocols are not yet available for distribution.

Directions for Use (OPPTS 860.1200)

Pesticide usage data describe the amount of pesticide applied per unit time (lbs.a.i.(active ingredient) per year, for example), the number of acres of each crop treated (or the percentage of the crop treated), and similar information. This is to be distinguished from **use** data which describe the specific way the pesticide is used on a crop such as the type of application ("in-furrow", for example) or the timing of applications. Pesticide usage data are collected by the Agency for use in human risk/benefit analyses, environmental exposure/risk analyses, and serve as an input for design and planning activities for monitoring and enforcement efforts (25).

Usage data are available from many sources. Proprietary sources of usage information include those from Doane Marketing Research, Inc., Maritz Marketing Research, Inc. and Technomic Consultants. Doane and Maritz provide current estimated use and usage data for major crops and some small acreage crops. Doane also provides livestock usage data. Estimates generally are based on surveys/panels and may include some expert opinion, especially Technomic. Survey data are available from USDA covering major field crops, and more recently other crops. Usage information are available from many states, but the usefulness of these data frequently are limited for many reasons including pesticide usage not being reported by crop, sporadic collection of data, the availability of only older data (5-10 years old), and collection of

data only for "major crops". The Census Bureau estimates usage by pesticide classes, not specific pesticide, and can conduct special surveys for selected states when funds are available. Battelle provides primarily foreign pesticide usage data. Information sometimes is obtained through phone calls to cooperative extension personnel, but the information usually is based on opinion rather than on hard data. Finally, registrants provide data under Section 7 of FIFRA giving the amounts of pesticide that are produced and distributed, but the amounts used on specific crops are not provided.

These data are most useful for estimating ranges of percent of crop treated on a national and regional basis for major chemicals on major crops (major crops as defined here include field corn, wheat, soybeans, peanuts, cotton, sorghum, barley, oats/rye, alfalfa, and perhaps rice, plus a few specialty crops such as potatoes, tobacco, and citrus as a group.) Data are limited for specialty (minor) crops, postharvest applications (except apples, oranges, grapes, and some grain fumigants), and livestock (while there are data on percent of crop treated for feed, there is little information on which animals are fed the treated feed.)

The usefulness of pesticide usage data for dietary exposure assessment has been limited to national estimates of percent crop treated because of the reasons discussed above, and because there has been no information connecting the treated crop to its distribution in commerce and processing.

Appendix B. Background Paper: Factoring drinking water exposure into tolerance decisions.

I. Introduction

Pesticides are found in both groundwater and surface water throughout the United States. The overall picture emerging from the USGS's initial look at 20 major watersheds in the National Water Quality Assessment Program (NAWQA) is of a mixture of pesticides that typically occur at low levels, punctuated by seasonal pulses of higher concentrations. Ninety-five percent of streams and 50 percent of wells near agricultural and urban areas in the initial 20 study units (spread throughout the United States) contain at least one pesticide and often contain detectable levels of 2 or more. Most groundwater aquifers investigated by NAWQA and about half the streams are sources of drinking water.

Unlike food, which is part of a national distribution system, the water that comes from the tap in a home is for the most part locally derived; if the source of a family's water is contaminated with a pesticide, avoiding exposure can be expensive and difficult. If pesticide levels in a family's drinking water are high, the combined risks from residues on food and residues in water could be significant and could cause health effects. In the United States, roughly ½ of the population derives its drinking water from surface water and ½ from groundwater, with approximately 15 million households in the United States deriving their drinking water from private wells.

Prior to the enactment of FQPA, OPP's approach to managing pesticides which had the potential to contaminate water was to emphasize prevention; OPP required mitigation measures such as geographic restrictions on use (to protect groundwater) and buffer zones (to protect surface water) to reduce the likelihood of contamination. However, prior to FQPA, human exposure through the drinking water route was not routinely factored into decisions about acceptable levels of pesticide residues on food (i.e., registering the pesticide under FIFRA and the setting of tolerances under FFDCA).

With the passage of the FQPA, EPA was directed to factor into its human health risk assessment for purposes of setting tolerances, "all anticipated dietary exposures and all other exposures for which there is reliable information". EPA has interpreted this provision as requiring it to factor into its human health risk assessment anticipated exposures to pesticides in drinking water.

Fortunately, not all pesticides have a potential to reach drinking water in concentrations of concern from a human health perspective. The extent to which this pathway of exposure is significant depends on the inherent physical/chemical properties of a pesticide (i.e, properties which are the underlying basis for conclusions about a pesticide's mobility and persistence in soil and water), where and how the pesticide is used, and whether effective treatment of source water occurs prior to ingestion. Some pesticides bind tightly to certain soils, are not very soluble in water, and degrade slowly; others are more soluble but degrade much more rapidly. Still others

are not only very soluble in water, but they persist for much longer periods of time. The amount of pesticide used (and where it is used) along with pesticide-specific properties such as its soil binding coefficient(s) and soil degradation ½ life are key factors in determining the likelihood of significant contamination of water.

Although there is much that we do not fully understand about the fate and transport of pesticides in the environment, we have learned a great deal over the past 20 years. The state of the science is such that we are able in most cases to accurately identify (based on use rates, use locations, and fate and transport data and properties) those pesticides which are more or less likely to migrate to and persist in groundwater and surface water. Further, methods developed over the past 5-8 years for estimating pesticide concentrations in surface water for purposes of ecological risk assessment (PRZM/EXAMS and GENEEC) have allowed us to produce some quantitative estimates of pesticide concentrations in small bodies of water. Although OPP has not conducted extensive analyses of the relationship between what these methods predict and what is observed in the real world, the analyses that have been done suggest that these estimates are reasonably accurate for the scenarios simulated (i.e., vulnerable surface water) and function reliably for purposes of an initial screen for ecological risk assessment purposes.

II. OPP's Approaches to Addressing the FQPA Water Issue

With the FQPA requirement to factor drinking water exposure into tolerance decisions, and OPP's recognition that "not all pesticides are created equal" with regard to the potential to reach and persist in water, OPP realized that it needed either to have adequate temporal measurements (i.e., measurements over time in a single body of water) and spatial measurements (i.e., measurements throughout entire use areas) of pesticide levels in drinking water or that it needed to be able to estimate pesticide levels in drinking water. OPP knew that targeted, statistically designed and well conducted drinking water monitoring studies (which could be used to produce probability distributions of contaminant levels) were not generally available, and would never be available in advance of registration for new pesticides. Further, OPP also knew that gathering the kind of data needed to really "nail down" pesticide levels in drinking water nationally was a resource intensive and time-consuming venture. Because of this, OPP came to the realization that in order to comply with the FQPA it would need to develop methods for estimating pesticide levels in drinking water and methods for analyzing and interpreting available water monitoring data. OPP also realized that developing scientifically sound approaches for accurately estimating human exposure to different pesticides in drinking water would take substantial time and effort.

Interim Approach

In the initial months after the enactment of FQPA (while OPP quickly worked to develop

a science-based approach for estimating drinking water exposure) OPP adopted an interim approach which assumed that 10% of what it considered acceptable exposure to a pesticide would occur via the drinking water route (PRN 97-1). That is, OPP reserved 10% of the "risk cup" for water-related risks and allowed food residues to take up to 90% of the "acceptable" risk (80% if the pesticide also had indoor or outdoor residential uses). This 10% value for drinking water was a "default" assumption that OPP knew was likely to over-estimate actual exposure in many cases, while potentially underestimating actual exposures in some others.

Further evaluation of the "10% default" assumption in light of available information on the measured values of certain pesticides in water revealed that there would be some cases/pesticides where assuming 10% would not be enough to cover actual exposures in drinking water. This fact, combined with the recognition that the Office of Water practice is to assume that as much as 20% of exposure to a pesticide can come from drinking water, led OPP to reconsider its approach. Raising the default to 20% or some other value could be unnecessarily restrictive for many pesticides while still underestimating the drinking water exposure in some cases. Most critically, OPP did not have actual data or scientific principles on which to base such a default assumption.

Current Approach

Based on our experience with the 10% default assumption and our further analysis of available information, OPP adopted the following approach for addressing the "FQPA drinking water issue" in November 1997. This approach, which OPP is continuing to refine, has undergone external scientific peer review by the FIFRA Scientific Advisory Panel.

1. OPP scientists review substantial amounts of registrant-submitted data for each pesticide which describe how the pesticide behaves in the environment. These data tell us whether the pesticide will easily move to groundwater or surface water and whether it will degrade quickly or persist. Based on these data and pesticide use-related information, OPP scientists draw conclusions about the mobility, persistence, and degradation pathways of the pesticide in soil and water.

2. OPP scientists use these pesticide-specific data as inputs to "screening level" models (GENEEC and PRZM/EXAMS for surface water and SCI-GROW for groundwater). The data used in these models include pesticide-specific data on whether the pesticide has a tendency to bind to soil or move into water, its vapor pressure, how quickly it breaks down in water and soil, and how much is applied. These models allow OPP to develop rough estimates of pesticide concentrations in surface water and groundwater. The models are based on 20 plus years of experience in studying how pesticides move in the environment and are based on a good understanding of the key characteristics of pesticides which determine where they are likely to move in the environment. OPP views the estimates coming out of these models as upper bound estimates of potential pesticide concentrations in drinking water. (*During this stage of the process, OPP also conducts an initial review of in-house water monitoring data to check to be*

sure that the screening level estimates are in fact "upper bound" estimates. If OPP finds that readily accessible monitoring data suggest the possibility of higher concentrations in surface or groundwater than what these models indicate, then OPP immediately moves to a more thorough analysis of available monitoring data.)

3. OPP compares the model estimates (i.e., levels which OPP views as upper bound estimates of potential pesticide levels in drinking water) to human health-based "drinking water levels of concern" (which are arrived at *after* having first considered all food-related exposures). Based on this comparison, OPP either clears the pesticide from a drinking water perspective OR it attempts to refine its estimates of pesticide concentrations in order to make them less worst case and more realistic.

4. If OPP determines that it needs to refine its estimates, OPP gathers available water monitoring data and begins its analyses of these data. Typically, OPP consults the United States Geological Survey's (USGS's) National Water-Quality Assessment Program (NAWQA Program) and the National Stream Quality Accounting Network (NASQAN), Office of Water's STORET data base, the data from the USGS's Mid-Continent Group, OPP's Pesticides in Groundwater Data Base, and the National Pesticide Survey to identify monitoring data. In some cases, OPP has also done open literature searches or has contacted state agencies to obtain additional water monitoring data. (*OPP generally defers doing an intensive analysis of available monitoring data until after it completes its comparison of the upper bound drinking water estimates to the human health levels of concern because locating, analyzing and interpreting water monitoring data, for purposes of developing a refined estimate of drinking water levels can be very time consuming. In many cases thus far (at least 50% of the cases), OPP's model estimates have been sufficient to clear pesticides from concern and further refinement has not been necessary*.)

5. If there are no monitoring data available (or if the available water monitoring data are not adequate for purposes of refining the screening level estimates), OPP makes a risk management decision as to the need for groundwater and/or surface water monitoring and/or risk mitigation.

6. If monitoring data are available and reliable, the scientists in OPP review the data and gather as much information as is readily available on how the samples were collected and analyzed, where they were collected, when they were collected, and why they were collected. OPP attempts to fully characterize the range of values reported, the highest values reported, the 95th percentile value, and the mean value. If the data are adequate to produce some regional-based picture of the distribution of measurements, this is completed as well.

7. After EFED discusses with HED and the risk managers the exposure characterization and how it fits with the specific risk endpoints being addressed by HED, appropriate short-term (for acute effects) and/or longer-term average (for chronic effects or cancer) drinking water concentrations are selected. OPP's analysis and characterization of

monitoring data is then incorporated into the food and residential exposure analyses to complete the aggregate exposure assessment.

More on GENEEC (and PRZM/EXAMS) Surface Water Estimates

OPP's decision to use GENEEC and PRZM/EXAMS for purposes of generating conservative upper bound values for purposes of ruling out drinking water (from surface water) as a concern has been the subject of much discussion and misunderstanding. Since November of 1997, OPP has maintained that GENEEC and PRZM/EXAMS are very useful for purposes of rapidly identifying pesticides that are unlikely to occur at significant levels in drinking water derived from surface water. Although OPP views these models and the scenarios it is using as very effective initial screens, it does not believe that it is appropriate to incorporate these values directly into the human health risk assessment for purposes of tolerance reassessment as representative values for the large majority of the U.S. population. OPP believes that further refinement of these values (or confirmation of these estimates through monitoring) is necessary before they should be used in making final decisions in the tolerance reassessment context.

OPP uses GENEEC (which is a meta model of PRZM/EXAMS) to perform an initial screening level assessment of pesticide concentrations in surface water. GENEEC and PRZM/EXAMS were initially used by OPP for purposes of completing ecological risk assessments. These were the only mechanistic models available to OPP for estimating pesticide levels in surface water when FQPA was enacted. GENEEC provides estimates of peak, 96 hour, 21 day and 56 day average pesticide concentrations in a small body of water (20 million liters) at the edge of a 10 hectare treated cotton field under reasonable worst case conditions. Reasonable worst-case means that the compound is assumed to be applied at the maximum label rate, in an environmentally vulnerable setting which is conducive to maximizing the movement of dissolved pesticides to surface water.

Using a pesticide's soil/water partition coefficient and degradation ½ life, GENEEC produces conservative estimates of annual peak and maximum 96-hour, 21-day, and 56-day average dissolved concentrations in a 20 million liter pond, which is assumed to be completely mixed. GENEEC assumes a static, edge-of-field pond (i.e., no buffer) in which inflow from runoff is exactly equal to outflow from evaporation. OPP believes that concentrations estimated in this small pond also represent concentrations which would be likely in a small upland stream in a high use area as well. GENEEC assumes either a single or a series of pesticide applications to bare soil. It simulates a single rainfall event 2 days after the final application and assumes that this single storm washes off into the pond, from 1-10% of the pesticide remaining in the top 1 inch of soil at the time of the storm, depending upon the Koc of the pesticide (i.e., its propensity to move to water or stay with the soil).

PRZM/EXAMS modeling produces slightly refined estimates of potential pesticide levels

in surface water, because multiple years are modeled to reflect climatic variations and this modeling is done on a crop specific basis. The advantage of PRZM/EXAMS over GENEEC is that it allows inclusion of more site-specific information in the scenario details regarding application method, temporal distribution with weather, and in general it is better at accommodating the peculiarities of individual chemicals. However, it still represents a small pond or stream from which few people would derive their drinking water.

More on SCI-GROW Groundwater Estimates

OPP developed SCI-GROW as an initial screening level model for estimating pesticide concentrations in ground water under reasonable worst-case conditions, specifically for FQPA purposes. SCI-GROW is an empirical model that links measured field data with measured fate and transport properties of pesticides. It represents a regression of 10 prospective groundwater monitoring studies conducted for OPP by pesticide registrants. The studies were conducted at extremely vulnerable areas (i.e., shallow aquifers, coarse permeable soils, maximum label application rates, with substantial rainfall and/or irrigation to maximize leaching). In each of these 10 prospective studies, the highest 3 consecutive monthly data points from a selected well were averaged to represent 90-day peak average pesticide concentrations. These 90-day peak averages were then regressed against the Relative Intrinsic Leaching Potential (RILP) for 10 pesticides to predict 90-day peak average pesticide concentrations in vulnerable groundwater. The RILPs represent environmental fate properties of the particular pesticides, and are derived from studies which established the degradation ½ lives in soil and soil/water partition coefficients. The monitoring data are normalized by the rate of application.

With data on a pesticides' aerobic soil ½ life and its Koc along with the application rate, OPP is able, using SCI-GROW, to fairly accurately estimate the concentration of a pesticide in shallow groundwater (average depth 15 feet) beneath highly permeable soils (average % sand was 89; average % clay was 4).

More on the Collection, Evaluation, and Interpretation of Available Monitoring Data

In those cases where OPP determines that further refinement is necessary of either the groundwater estimate (from SCI-GROW) or the surface water estimate (from GENEEC and/or PRZM/EXAMS), OPP gathers available water monitoring data and analyzes, characterizes and interprets the data relative to the question being asked by FQPA. That question being, "What are the anticipated human exposures to the pesticide under review via the drinking water route?" By the time a pesticide reaches this stage of OPP's review, OPP scientists are operating under the assumption (based on their review of the battery of fate and transport studies as well as the model results) that the pesticide has some potential to reach surface water and/or groundwater and that it has some potential to be present at levels of concern to human health.

The availability of adequate temporal and spatial monitoring data can reduce much of the uncertainty associated with models, and can provide a more accurate estimate of the distribution

of drinking water concentrations in areas of use. In some limited cases, EPA will have "considerable" water monitoring data available to it for a particular pesticide, including small-scale prospective groundwater monitoring studies, state data, USGS data, and data from the National Pesticide Survey. Nevertheless, even when available, there are choices to be made over the best use and interpretation of these data, and how to interpret exposures and risk estimates calculated from them. This is particularly true when trying to characterize exposures from a region where there may be more than one source of water monitoring data.

Monitoring studies are often designed for different purposes, and are often performed under different sampling and analysis protocols, yielding variable detection limits and quality control. Sometimes, the reported limits of detection are significantly above what OPP consider to be levels of concern. Sometimes, there is no clear association between locations sampled and actual areas of use of a pesticide. Such considerations can make filtering and combining data collected under different studies particularly challenging and time consuming.

Sample collection can also be biased in various ways; there are relatively few pesticide samples collected from reservoirs, and alternative data are often collected from sites that are not known drinking water sources. Sampling can also be biased temporally (e.g., samples may be purposefully taken only during certain periods of the month or year), spatially (e.g., samples may be purposely taken only in certain areas involving certain uses/crops), and by chemical (e.g., samples may only be analyzed for certain pesticides and toxicologically important degradates may not be looked for at all). With flowing water, the timing of sampling can be very critical. Concentrations a few hours or days out of the year can be multiple orders of magnitude higher than during the rest of the year. Without a very intense sampling effort, the maximum concentration can be severely underestimated--which can have significant ramifications if the end point of concern is an acute end point. Over time there can also be a bias in well monitoring towards better quality water since highly contaminated wells may be shut down.

In evaluating, characterizing, and interpreting water monitoring data, EFED attempts to collect as much information as is readily available on the design of the studies. That is, EFED tries to determine (within the very real constraints of time and available resources) how the samples were collected and analyzed, why they were collected and where they were collected. For purposes of completing the FQPA assessment, EFED reviews the reliability/validity of the monitoring data and presents the range of values reported, the highest values reported, the 95th percentile value, and the mean/median values. If EFED has adequate data to produce a regional "picture" of the distribution of reported values, this is completed as well. EFED's characterization of available monitoring data is then sent to HED and to the risk managers.

The next step in the process, OPP's "selection" of a value or values to be incorporated into the human health risk assessment, is heavily laden with policy and, over the past year, has been heavily influenced by the judgement of risk managers in OPP and OPPTS. As is clear from a review of the available monitoring data, choices need to be made in the selection of drinking water residue estimate(s) from EFED's report on the analysis of available water monitoring data.

Sometimes valid reported values vary from one region to another by several orders of magnitude. Without having very specific information on the history of the use of the pesticide in the sampled area, it is very difficult to fully understand the reasons for these differences. In many cases, the number of "non detects" greatly exceeds the number of measurements above the limits of detection--suggesting that generally the pesticide does not move to water and persist. However, this may or may not be true. Because EPA lacks data to verify that reported "non detects" were in actual areas of use, it is often difficult to conclude that the pesticide when used is not, in fact, reaching water. Further, it is not always known whether samples were taken from potable water-that is or could be a drinking water source. Much of the monitoring data are not, in fact, from potable water.

Despite the challenge of analyzing and interpreting these data, and in order to make needed decisions, OPP has felt that it was appropriate to choose a value or values from these data for use in the human health risk assessment. To assume "zero" in the human health risk assessment simply because available, valid monitoring data are variable (making it difficult to select a number or numbers) appears counter to OPP's objective to use the best science available in its decisions. Over the past several months, as OPP has gained experience in reviewing and incorporating monitoring data into tolerance decision making, it has generally chosen "reasonable high end" monitoring values for use in the human health risk assessment. That is, OPP has not selected the highest measured value; but, rather has chosen a value that is "on the high end". Although OPP has developed some crude estimates of the total number of people using different types of source water for drinking water in areas of use, because of data limitations, OPP has not yet been able to develop credible estimates of the number of people expected to be exposed to different concentrations of a pesticide under review to incorporate into its assessment.

IV. Results of Peer Review and External Scientific Review of Our Interim Approach

OPP has sought and obtained external scientific review of its interim approach and of the fundamental aspects of the models it is using for purposes of completing screening level assessments. Most of the external review to date has focused on evaluating the tools and methods OPP is using to estimate pesticide concentrations in drinking water (in the context of these methods serving as initial screens).

ILSI Working Group

In October 1997, ILSI convened a working group of scientists with expertise in the fate, transport, and occurrence of pesticides in surface water and groundwater to assist OPP in developing tools and methods for estimating potential concentrations of pesticides in drinking water. The ILSI working group focused on OPP's current methods and models for screening and offered what they believed would be improvements which could be implemented in the short term to improve the accuracy of its estimates. How to go about refining screening level model estimates and the use and interpretation of monitoring data were also addressed.

Regarding the types of information on drinking water that are needed for completing aggregate exposure assessments for FQPA, the ILSI working group concluded in its April 2, 1998 report to EPA that Agency should work toward developing probability distributions (as frequency of exceedance) for peak and long term average drinking water concentrations within a pesticide's use region(s). Ideally, the estimates of peak and chronic concentrations should be derived from full temporal distributions in actual drinking water. These are the kind of residue data which are needed for inclusion with the more refined, probabilistic, food-related exposure assessments performed using Monte Carlo methods.

The ILSI working group also concluded that:

1. Screening tools are needed to quickly identify pesticides and pesticide uses that are unlikely to contaminate drinking water AND that, in general, the screening models being used by OPP (i.e., GENEEC and SCI-GROW) are of the appropriate type and level of detail to enable the rapid identification of pesticides that are unlikely to be a water problem;

2. Preliminary evaluations indicate that these models may be adequately reliable for screening purposes (although further comparisons of model outputs to measured values is needed to confirm the preliminary evaluations); and

3. The screening models should be improved so that a higher percent of non-problem pesticides (from a drinking water perspective) can be identified in the initial screen.

FIFRA SAP Review

In December 1997 OPP presented for SAP review, its interim methods for estimating exposure to pesticide contaminated drinking water. The FIFRA SAP complimented OPP on the work it had done to develop screening tools while under the severe time pressure to make FQPA decisions. The SAP encouraged OPP to commit to develop a longer term plan to develop improved tools and methods for producing more refined, more accurate estimates of drinking water concentrations. The SAP, responding to specific questions from OPP, provided the following important comments:

1. Many SAP panel members agreed that SCI-GROW generates appropriately conservative estimates of pesticide concentrations in drinking water for use in an initial screen. Most members believed that the estimates needed to be further tested against monitoring data and verified.

2. Nearly all panel members agreed that the pesticide estimates produced by GENEEC are most likely overly conservative and that some adjustments should be made to account for the % cropped area around a water body and the % of that crop treated with the pesticide.

3. OPP needs to develop databases and methods for effectively using monitoring both in assessments and to "validate" model estimates; it needs to invest time and resources in the development of GIS tools related to soil type, crop coverages and water monitoring sampling points; it needs to describe and document all variables in its models and methods and be able to better articulate the relative impact of these variables on its drinking water assessment; and it needs to compare model predictions from its screening models with monitoring data to better understand how these relate.

V. Next Steps to Improve OPP's Drinking Water Assessments

As of December 1998, ILSI had convened a second workshop to attempt to develop appropriate methods to estimate distributions of pesticide concentrations in drinking water. Ultimately, OPP would like to use these kinds of data in distributional (probabilistic) analyses comparable to food. Preliminary results of the workshop indicate a strong need to develop / obtain actual monitoring data for pesticides in drinking water. An important early action item is the development of a drinking water reservoir scenario to replace the small pond scenario currently being used in the running of GENEEC and PRZM/EXAMS. OPP presented this modification to the FIFRA SAP at the end of July 1998. Modification to existing models is still ongoing. Finally, OPP needs to develop interim policy guidance on how it "selects" drinking water residue levels based on monitoring data for use in its human health risk assessments.

APPENDIX C.1. Summary of Available Pesticide Exposure Data and Child Time/Activity Pattern Data

Study	Participants	Exposure Data	Activity/Pattern Data
Nonoccupational Pesticide Exposure Study (NOPES)[7a,b,c]	>600, probability survey in Florida and Massachusetts, adult participants	Indoor, outdoor, and personal exposure measurements for pesticides; limited housedust measurements	Pesticides inventory, time/location for selected activities, limited set of dietary information.
Children's Exposure to Persistent Organic Pollutants [*]	9 preschoolers; pilot study	Indoor air, outdoor air, housedust, soil, dislodgeable residue, handwipe, duplicate diet, and urine samples collected and analyzed for selected pesticides	Same as HIPES; additional information on chewing nails, hand washing, toys and objects in mouth, feet in mouth.
House dust/Infant Pesticide Exposure Study (HIPES)[7b]	9 toddlers, pilot study	Indoor air, outdoor air, personal air, housedust, soil, handwipe, dislodgeable residue samples collected and analyzed for 31 pesticides	Next day diaries. Information on locations (indoor/outdoors), surface contacted, skin exposure, hand-to-mouth, and movement (walking, crawling, not mobile).
Total OP pesticide Exposure Among Children in Rural and Urban Environments[*]	Children 1 to 5. Number unknown	Indoor air, outdoor air, housedust, and urine samples collected and analyzed for selected pesticides.	Same questionnaire as HIPES.
NHEXAS[14]	Children older than 8.	Indoor air, outdoor air, housedust, soil, dislodgeable residue, duplicate diet, and urine samples collected and analyzed for selected pesticides	Time/location of activities; not specific to dermal adsorption or non dietary ingestion
Children's Pesticide Exposure Study[*]	Children 3 to 12	Indoor air, outdoor air, housedust, soil, dislodgeable residue, handwipe, duplicate diet, and urine samples collected and analyzed for selected pesticides	Same as NHEXAS; videotapes on 19 kids; data review not complete

Study	Participants	Exposure Data	Activity/Pattern Data
Agricultural Health Pilot Study(*)	Farm workers, spouses, and children. Six farms in NC and Iowa study	Indoor air, outdoor air, housedust, soil, dislodgeable residue, handwipe, duplicate diet, blood, and urine samples collected and analyzed for selected pesticides	Time/location of activities; not specific to dermal adsorption or non dietary ingestion
Child Lead Study(*)	9 toddlers, pilot study	No exposure data for pesticides	Same as HIPES; additional information collected on paint chips, toys, and other objects.
Child Dietary Lead Study (*)	50 toddlers	No exposure data for pesticides.	Information on location, eating activities (off floor or surfaces), hand size, hand wash.
Activity Patterns Survey for California Children(*)	1200 children;	No exposure data	Next day diaries on activity locations, presence of smokers, housing and SES characteristics
National Human Activity Pattern Survey (NHAPS)(8 a,b,c,d)	9386 Participants-all age groups; 48 states	No exposure data	Next day interview of time/location activities
Farm Labor Children in Salinas CA(*)	four 2- to 4- year old	No exposure data	Video taping and recording of hand-to-mouth activities, etc.
Children's Hand to Mouth Activities(*)	20 day care and 10 residential preschool children	No exposure data	Video taping and recording of hand -to-mouth activities
CHAD (Consolidated Human Activity Database(*)	Relational data from existing human activity pattern surveys(questionnaire and diary data) either national in scope or are site limited.	No exposure data	Queries can be made of original survey data or the modified CHAD data, to query or select a single variable (e.g. respondents age) and apply to all studies in CHAD.

*** ORD Sponsored Exposure Studies**

APPENDIX C.2. PRELIMINARY ASSESSMENT OF EXPOSURE SCENARIOS IN RESIDENTIAL SOPs – ASSESSMENT CONDUCTED BY OPP

Exposure Scenario	Assumptions To Be Updated	Relative Uncertainty	Comments
Overall-Body Weights	**No**	**The median or mean body weights are selected and the variability across the population is likely to be low -- low uncertainty.**	**The body weight is in the denominator of the exposure/dose equation (i.e., the lower the body weight the more conservative the estimate). Body weight values are from the Exposure Factors Handbook and are deemed reliable.**
Overall-Dermal Absorption	**Chemical Specific**	**100% assumed if no data are available, otherwise peer reviewed chemical-specific data are used -- the upper bound default assumption provides more than a "reasonable" certainty of no harm to children.**	**If a NOEL from dermal study is used, dermal absorption is not necessary.**
2.1 Turf Handlers	**Body weight–None**	**The SOPs qualify the data confidence for each PHED (Pesticide Handlers Exposure Database) estimates as "High, Medium, and Low confidence" based on the Pesticide Assessment Guideline criteria for analytical recovery and number of replicates. FQPA is assumed not to include children as handlers.** **Although PHED data are "central tendency" values, it is believed that combining PHED estimates with other "upper percentile" assumptions (e.g., acres treated and application rates) will create a "central tendency to high end" exposure assessment.**	**FQPA is assumed to cover residential handlers.**
2.2 Turf Postapplication	**Exposure duration of 2 hrs/day is the 95th percentile for playing on grass, however, this is an unreasonable duration for doing a jazzercise routine. HED is *considering* either reducing this duration (maybe ~20 minutes) as per CalEPA (1996) protocol or using a reasonable activity that can be performed for a 2 hour duration.**	**The 20% of the application rate being available as dislodgeable residue is based on HED's review of chemical-specific data and is believed to represent the "high-end" of the distribution -- high end default assumption provides reasonable uncertainty of no harm to children.** **Jazzercise activity is assumed to represent a "high end" activity for playing on turf. The adult transfer coefficient (Tc) of 43,000 cm^2/hr is relatively high and was reduced using the ratio of body surface area of adults to children to calculate a Tc of 8,700 cm^2/hr for toddlers -- Although uncertainty exists in using adult jazzercise routines to represent children playing, this activity provides a reasonable certainty of no harm to children.** **Exposure duration of 2 hrs/day represents the 95th percentile -- selecting the upper percentile provides a reasonable certainty of no harm to children.**	**If a different activity is selected by HED, the uncertainty will need to be readdressed.**

Exposure Scenario	Assumptions To Be Updated	Relative Uncertainty	Comments
2.3.1 Ingestion of Pellets	**Toddlers age -- should a different age group be selected as most prone to eat pellets? What is the justification for including this scenario as a major exposure route?**	**The 0.3 grams/day ingested is based on assuming 150 lbs of product is applied to ½ acre lawn (i.e., 3 g/ft^2) and that a child would eat 1/10th of the pellets in this area. Since 150 lbs product per ½ acre lawn is the highest application rate HED could find, this is assumed to represent the high end of the distribution–the uncertainty in this scenario lies in ???? It as part of the aggregate exposure estimate.**	**This is not considered a pica issue, rather the sometimes colorful turf pellets may be attractive (as in candy) to children. The 0.3 gram value was also similar to that HED estimated by selecting a small handful of pellets to weigh.**
2.3.2 Turf -- Hand-to-mouth	**The 3 yr old age group needs to be revised. Select the age group with the highest frequency of hand-to-mouth activity.** **The surface area of the hand that goes into the mouth could be revised; the SOP currently assumes that both hands are entirely put into the mouth -- seems excessively high.** **Replenishment of residues on the hand is assumed to be 100 % for each hand-to-mouth activity -- seems excessively high.**	**The assumed 20 % of the application rate available as dislodgeable residue is not from a reference article, however, it is believed to represent the high end of the distribution.** **High uncertainty for age group and value selected for hand-to-mouth frequency.** **If 100 % of hand surface area is assumed as the default there is more than a reasonable certainty of no harm to children.** **If 100 % replenishment of residues is assumed as the default there is more than a reasonable certainty of no harm to children.** **Hand-to-mouth rate of 1.56 events per hour is too low, even for toddlers playing outdoors -- high uncertainty.** **Toddlers exposed 2 hrs/day as the 95th percentile for playing on grass (1 to 4 yr olds) provides reasonable certainty of no harm to children.**	**It would be difficult to incorporate, but indoor exposure to lawn-applied pesticides is, in one opinion, more important than outdoor.** **A matrix of hand-to-mouth activity will be provided by ORD (e.g., frequency for each age group and sex).**
2.3.3 Non-dietary Ingestion -- Eating Turf	**Is it reasonable to include this route as a child specific exposure scenario?**	**This entire exposure scenario seems to be a conservative assumption for regulating a pesticide.** **The assumed 20 % of the application rate available as dislodgeable residue is not from a reference article, however, it is believed to represent the high-end of the distribution.** **The 25 cm^2/day ingestion rate is derived by HED and is intended to represent an area a child may grasp (2 in x 2 in = 4 sq in.). Insufficient information to determine if this would provide an under- or-overestimate.**	**SOPs were reviewed by the SAP and they did not specifically suggest that this scenario be deleted.**
2.3.4 Ingestion of Soil	**Should this scenario become part of the Hand-to-Mouth activity so that double counting does not occur?**	**The 100 mg/day of soil/dust is an average value and children can ingest over 1,000 mg/day without deliberately ingesting soil. The use of 100 mg/day provides reasonable certainty of no harm to children.**	**This not a Pica issue. The values used represent the incidental ingestion of soil through hand-to-mouth activities without deliberately ingesting soil.**

Exposure Scenario	Assumptions To Be Updated	Relative Uncertainty	Comments
3.1 Garden -- Handlers	**Body weight–None**	**The SOPs qualify the data confidence for each PHED estimates as "High, Medium, and Low Confidence" based on the Pesticide Assessment Guideline criteria for analytical recovery and number of replicates. FQPA is assumed not to include children as handlers.** **Although PHED data are "central tendency" values, it is believed that combining PHED estimates with other "upper percentile" assumptions (e.g., acres treated and application rates) will create a "central tendency to high end" exposure assessment.**	**At this point in time, the Exposure Group will assume that no youths (i.e., under 12 years old) will mix/load and apply pesticides in and around the home. FQPA is assumed to cover residential handlers.**
3.2 Gardens -- Postapplication	**No changes**		
4.1 Trees -- Handlers	**Body weight–None**	**The SOPs qualify the data confidence for each PHED estimate as "High, Medium, and Low confidence" based on the Pesticide Assessment Guideline criteria for analytical recovery and number of replicates. FQPA is assumed not to include children as handlers.** **Although PHED data are "central tendency" values, it is believed that combining PHED estimates with other "upper percentile" assumptions (e.g., acres treated and application rates) will create a "central tendency to high end" exposure assessment.**	**At this point in time, the Exposure Group will assume that no youths (i.e.,under 12 years old) will mix/load and apply pesticides in and around the home. FQPA is assumed to cover residential handlers.**
4.2 Trees -- Postapplication	**None, but this should probably be condensed into Section 3.2 for Gardens (same assumptions used)**		**Information is currently not available to draw conclusions specific to the FQPA Safety Factor.**
5.1 Pools -- Handlers	**See above handler comments.**	**See above handler comments**	**see above handler comments**

Exposure Scenario	Assumptions To Be Updated	Relative Uncertainty	Comments
5.2.1 Pools -- Ingestion	None. 100 percent of application concentration are available for ingestion and no dissipation. --- None. The overall water ingested for each event is approximately 50 ml/hr ingestion rate for adult and children non-competitor --- None. Exposure duration is 5 hrs/day for children (6 yrs) and adults (18 to 64 yrs) --- None. Body weights for adults male (71.8 kg), female (60 kg), and child (6yrs, 22 kg) are from EPA EFH and are deemed reliable --- The SWIMODEL had been validated by using PB-PK model and available swimmer exposure data sets. The SWIMODEL usually overestimated the exposure value calculated by PB-PK model at a factor of less than two.	If no dissipation of chemical, 100 percent of application concentration is assumed, there is no uncertainty. It is believed to be a reasonable assumption because a.i.(active ingredient) is maintained at specific level --- Based on EPA SEAM (Superfund Exposure Assessment Manual, 1988) low uncertainty for age group and high uncertainty for competitor vs. non-competitor --- The assumed 5 hrs/day for children and adults is based on 90th percentile from EPA Exposure Factor Handbook. The default may be conservative but there is no uncertainty --- The median or mean body weights are selected to be conservative -- low uncertainty --- Based on EPA SEAM (Superfund Exposure Assessment Manual, 1988) low uncertainty for age group and high uncertainty for competitor vs. non-competitor	The concentration of a.i. (active ingredient) in pool water can be estimated based on the amount of water input and output, the frequency of treatment, application rates, temperature and evaporative rates, and physical properties of the active ingredient. --- The ingestion rate can be much less than 50 ml/hr for competitor swimmer, and will be more than 50 ml/hr for young child playing in water and accidentally ingesting a remarkable quantity of water --- If used the data based on the estimates by Olympic coaches and YMCA swimming instructors for 5-9 year old competitive swimmers, the average is 2.6 hrs/event (approximate 50th percentile for 5-11 old children in EPA EFH) --- Body weights for adults male (71.8 kg), female (60 kg), and child (6yrs, 22 kg) are from EPA EFH and are deemed reliable

Exposure Scenario	Assumptions To Be Updated	Relative Uncertainty	Comments
5.2.2 Pools -- Absorbed Dose	None. Surface area 20,900 cm^2 for adults and 9,000 cm^2 for children (6 yrs) --- None. Permeability coefficient (K_p) is chemical specific --- None. Body weights for adults and children (see above comments on body weights) --- None. The SWIMODEL had been validated by using PB-PK model and available swimmer exposure data sets. The SWIMODEL usually overestimated the exposure value calculated by PB-PK model at a factor of less than two.	Surface area is based on 90th percentiles for females and males of adult and children --- K_p is estimated by measuring the loss of compound from the skin surface. Low uncertainty if it depends on the chemical transport process --- Same as left. --- Same as left.	Surface area values are from EPA EFH and are deemed reliable --- K_p is a key parameter in estimating dermal absorption. The effective use of K_p values in dermal exposure assessments requires understanding of the processes that affect the transport of compounds across the skin (including some factors, such as vehicles, temperatures, etc) --- Same as left.
5.2.3 Pools -- Inhalation	None. Inhalation rate of 1.7 m^3/hr for adults (over 18 yrs) and 1.2 m^3/hr for children (under 18 yrs) --- None. Gas phase concentration based on the Ideal gas and Raoult's Law --- The SWIMODEL had been validated by using PB-PK model and available swimmer exposure data sets. The SWIMODEL usually overestimated the exposure value calculated by PB-PK model at a factor of less than two.	Mean based on moderate activity from EPA EFH. There is low uncertainty. --- There is a very low uncertainty if the Ideal gas model and Raoult's Law were applied in this model. --- Same as left	For competitor and non-competitor at the same sex and age group, there are remarkable differences at the inhalation rates when the swimmer is at the stage of rest in contrast to high performance activities.. --- Use of either Raoult's Law or Henry's Law to estimate swimmer's breathing zone air values, C_{vp} from pool water concentration values, C_w , was validated. ---

Exposure Scenario	Assumptions To Be Updated	Relative Uncertainty	Comments
6.1.1 Painting -- Handlers	**None. The assumptions for the application rates by using brush, roller, airless sprayer, and low-pressure hand pump deck-type stain sprayer are from central tendency to high-end (90th percentile) based on EPA EFH.**	**There is a low uncertainty for painting with brush and roller. Median uncertainty for sprayer painting due to the types of equipment and the pressure of nozzles used and also what kind of materials in the products are used to paint.**	**Three 5-gallon cans with an airless sprayer derived based on coverage rate of 200 ft^2 per gallon of latex -paint and house size of 20x30x40 ft (a total of surface area 2,800 ft^2). The exposure scenarios are reasonably conservative.**
6.3 Ingestion of Paint Chips	**20% active ingredient remaining in the paint by the time it "chips" off of the wall maybe too high.**	**This entire exposure scenario seems to be a conservative assumption for regulating a pesticide.** **20% of active ingredient remaining in the paint by the time it "chips" off of a wall seems to be very conservative -- if not too high.**	
7.1 Foggers -- Inhalation	_____	_____	**Information is currently not available to draw conclusions specific to the FQPA Safety Factor.**
8.1 Indoor Crack & Crevice Handler	**See above handler comments**	**See other comments**	**See other comments**
8.2.1 Carpets-Post application	_____	_____	**Information is currently not available to draw conclusions specific to the FQPA Safety Factor.**
8.2.2 Hard Surfaces-Post Dermal	_____	_____	**Information is currently not available to draw conclusions specific to the FQPA Safety Factor.**

Exposure Scenario	Assumptions To Be Updated	Relative Uncertainty	Comments
8.4 Indoor Surfaces-Hand to Mouth Toddlers	_____	**Here it is implied that hand-to-mouth exposure to surface dislodgeable residues occurs only in the bathroom and kitchen. Carpeted floors and other living areas have been omitted, probably by oversight, and should be restored.** **Again, the hand-to-mouth rate of 1.56 events per hour is too low. Children under two constitute the population at greatest risk and mouthing activities are much higher. Older children are prone to mouth more when inactive, e.g., when watching TV or being read to or reading on their own. To be safe, estimates of 10 events per hour for 8 hours a day in contact with carpets or hard floors in living areas and 4 hr/day in contact with hard surfaces in bathrooms and kitchens appear more reasonable.**	
9.1.1 Pet-Handlers (Dips/shampoos/Dust/Flea Collar)	_____	_____	**Information is currently not available to draw conclusions specific to the FQPA Safety Factor.**
9.1.2 Pets -Handlers (spray)	_____	_____	**Information is currently not available to draw conclusions specific to the FQPA Safety Factor.**
9.2.1 Pets-Post-Residues Dermal	_____	_____	**Information is currently not available to draw conclusions specific to the FQPA Safety Factor.**
9.2.2 Pets-Post-Hand to mouth	_____	_____	**Information is currently not available to draw conclusions specific to the FQPA Safety Factor.**
11.2 Impregnated Materials-Post	**None. 90th percentile body surface area for vinyl mattresses is one-half the total surface area for adult (1 m^2) and children (0.35 m^2).**	**Using 10% of the body as the portion that may come into contact with the product, lower skin surface areas may be reasonable central tendency estimates (i.e., 0.2 m^2 for adults and 0.07 m^2 for toddlers age 3) to low uncertainty.**	**The migration (flux rate) of pesticides from the impreganated material to outside media (air or liquid) can be estimated by models and migration cells test methods extracted with simulated solvents (artificial sweat, saliva, 10% ethanol).**
11.3 Impregnated materials-Toddler ingestion	**The frequency, duration of exposure, and the quantity of pesticides flux to the surface of products, the transfer of pesticide residues needed to be upgraded.**	**The dose estimates are considered to be based on some central tendency (e.g., surface area of the impregnated material mouthed and body weight) and some upper-percentile assumptions (e.g., 100 percent of chemical flux transferred and entire surface of an impregnated object mouthed on a daily basis). The dose estimates are believed to be reasonable high-end assumptions.**	**The migration (flux rate) of pesticides from the impreganated material to outside media (air or liquid) can be estimated by models and migration cells test methods extracted with simulated solvents (artificial sweat, saliva, 10% ethanol).**
13.1 Crack & Crevice-Inhalation Handler Indoors	_____	_____	**Information is currently not available to draw conclusions specific to the FQPA Safety Factor.**

Exposure Scenario	Assumptions To Be Updated	Relative Uncertainty	Comments
13.2Inhalation bystanders and post application dose among adults and children from pesticide applications in and around the residence	———	**The post-application exposure scenario here is confined to inhalation exposure as a result of soil off-gassing. While this is certainly important, we are missing other important routes of exposure; e.g., hand-to-mouth exposure to tracked-in residues in house dust and non-dietary ingestion of foundation soil.**	**Information is currently not available to draw conclusions specific to the FQPA Safety Factor.**
15.0 Pick Your Own Fruits/Vegetable	**Current assumptions appear adequate**	**Exposure duration, frequency, and other important dermal contact/transfer should be built in to this scenario.**	**Information is currently not available to draw conclusions specific to the FQPA Safety Factor.**

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