I. Preliminary OP Cumulative Risk Assessment

G. Risk Characterization

1. Introduction

Risk characterization is the interpretation phase of the assessment process. Appropriate interpretation of results is particularly important for an assessment as complex as the preliminary OP cumulative risk assessment. Many types of data, derived from a variety of sources, have been combined to produce highly detailed estimates of risk from multiple OPs in food, drinking water or from residential use. The outputs of the assessment should be evaluated in a variety of ways. Potential biases in input parameters, the direction of the bias, and the uncertainty surrounding the inputs and the exposure model must be considered with regard to their potential impact on the results of the assessment.

OPP has attempted to reflect the ongoing risk reduction activities that have resulted from the single-chemical assessments. OPP will continue to make risk reduction decisions about individual pesticides over the next several months. Changes as a result of exposure and risk reduction measures completed through September 2001 have been included. Modifications in OP use patterns made after that date will be incorporated in the final assessment. Note that no discussion of the acceptability of any indication of potential risk is found in this section. The current document focuses only on risk assessment and does not address risk management issues.

2. Hazard and Dose-Response Assessment

The hazard and dose-response assessment is presented in detail in section I.B. That section outlines the steps in developing the dose-response relationships for each pesticide and its capacity to inhibit acetylcholinesterase in the brain of female rats. It includes a description of all of the data used in the dose-response analyses. Reasons for the selection of methamidophos as the index chemical for the OP cumulative risk assessment are also discussed. Finally, section I.B. describes the exponential dose-response model used to develop the dose response curves that provided the basis for developing the relative potency factors (RPF) for each chemical and the points of departure (POD) for the index chemical for each route of exposure (i.e., oral, dermal, and inhalation).

a. Acetylcholinesterase Inhibition: Data Quality & Common Effect

The first step in deciding that a cumulative risk assessment was needed was the determination that the OPs were toxic by a common mechanism, i.e., cholinesterase inhibition. This determination was made and subjected to peer review by the Scientific Advisory Panel in 1998 (http://www.epa.gov/scipoly/sap/1998/march/comec.htm). Once a common mechanism was identified, the next step in the process was to select an appropriate method for combining the risks from exposures to several pesticides from more than one source/route. A large body of data describing the inhibition of acetylcholinesterase in plasma, red blood cells and brain has been generated for each registered OP. OPP has elected to use the brain acetylcholinesterase data from female rats as the basis for developing RPFs and PODs for use in the assessment. The choice addressed a number of the concerns raised by the SAP and the public. Brain acetylcholinesterase inhibition is an appropriate endpoint for use as an adverse effect because it reflects a response in a target tissue of concern that is relevant to humans. Brain acetylcholinesterase inhibition is an acknowledged adverse effect in both humans and in laboratory animals. Therefore, error due to the extrapolation between the response in a surrogate tissue (i.e., red blood cell and plasma) and a target tissue itself (brain) is eliminated. In addition, the data for the brain compartment have very narrow confidence limits when compared to those from the plasma and RBC compartments, suggesting that there is much less variability in this compartment across the data base.

This assessment uses the Relative Potency Factor (RPF) approach which applies dose addition. Briefly, the RPF approach uses an index chemical as the point of reference for standardizing the common toxicity of the chemical members of the cumulative assessment group (CAG). Relative potency factors (i.e., the ratio of the toxic potency of a given chemical to that of the index chemical) are then used to convert exposures of all chemicals in the CAG into exposure equivalents of the index chemical. The RPF approach utilizes dose-response information to provide an estimate of each OP's potency for the common toxicity, and thus allows for the quantification of exposure as it relates to the joint risk of the CAG. OPP selected the relative potency factor approach based upon the relatively rich oral data base on cholinesterase inhibition available for the OPs which permitted consideration of the entire dose-response curve for each pesticide rather than only focusing on NOAELs that are an function of study design. Although a biological or pharmacokinetic modeling approach would have advantages in determining the cumulative risk for these OPs, the input parameters for such an approach are not available. Thus, the pharmacokinetic (PK) characteristics of the OPs could not be incorporated in the dose-response assessment which would allow for a more refined estimate of the combined risk to humans. Therefore, OPP has applied simple dose addition and used an empirical curve fitting model (i.e., the exponential model described below) to determine RPFs and PODs.

b. Exponential Dose-Response Model

OPP, in collaboration with ORD, developed an exponential model to describe the oral dose response curves for each OP that permitted fitting of a combination of cholinesterase (ChE) activity data from different studies. This model has been subjected to public comment and peer review by the SAP (http://www.epa.gov/scipoly/sap/2001/september/finalreport.htm). Although a PK model is the ideal approach, the SAP regarded the exponential model (with their recommended improvements) to be appropriate for the data being analyzed for derivation of relative potency factors and points of departure. OPP has responded to the SAP recommendations on the exponential model by making modifications to address the issues raised. One issue was that the original model did not appropriately reflect cholinesterase inhibition at very low doses. The revised statistical model now incorporates to the extent supported by the data, a flat region at the low dose portion of the dose response curve. Another issue raised by the SAP concerned the derivation of the factor "B". The B value is the limiting value for the maximum cholinesterase inhibition (called the horizontal asymptote). The SAP raised the issue that the weighting strategy used for calculating the "B" which assumed 100% cholinesterase inhibition (i.e., 0% ChE activity) did not adequately reflect the actual B value for each OP (the B value was often less than 100% inhibition at the asymptote). The revised approach has been modified in order to generate B values for each OP reflective of its dose-response data.

OPP assumed dose additivity by application of a single model to all of the OP's dose-response curves. There is some uncertainty surrounding the assumption of dose additivity given that the B values (horizontal asymptotes) are heterogeneous among the OPs analyzed. This heterogeneity is indicative that the dose-response curves are not parallel and, therefore the application of simple dose addition is only an approximation of joint risk and may not be precise. Dose additivity assumes that the common mechanism chemicals behave in a similar fashion (i.e., same pharmacokinetics and pharmacodynamics) and that their dose response curves will be parallel (i.e., the ratio of their relative toxic potencies remain the same throughout their dose range). The underlying biological processes that determine the toxic potency of each OP are extremely complex and involve several metabolic systems in different organs as well as re-synthesis rates of the different cholinesterases. The activation and/or deactivation rates differ for some of these OPs. However, because of insufficient data, these pesticides can not be separated into subgroups based on pharmacokinetic and pharmacodynamic characteristics. Thus, current information on OP pharmacokinetics and pharmacodynamics cannot provide a sufficient basis to depart from the assumption of dose additivity. Also, available studies on OP mixture interactions do not provide a sufficient basis for departure from dose additivity.

In summary, OPP believes that the model fitting procedure used in this assessment provides reliable estimates of relative potency and points of departure. The cholinesterase data used for the oral route of exposure was quite extensive and, in general, of good quality for dose-response modeling. The data for the inhalation and dermal routes tended to be less extensive and not as robust for dose response modeling. OPP has refined the dose response modeling for the oral dose by incorporating the SAP recommendations in its dose response assessment of these OPs. OPP has attempted to address uncertainty in extrapolating to lower human exposures by the revised model and by using a low model estimate (BMD10) to develop OP relative potency factors. OPP acknowledges that there is uncertainty that dose addition applies to all of these OPs at human exposure levels. In the absence of data to the contrary, however, dose additivity is assumed.

c. Selecting the Index Chemical

OPP selected methamidophos as the index chemical for the current assessment. Methamidophos has sufficient data for cholinesterase inhibition to support modeling of a BMD10 by all three routes of exposure. The high quality dose response data for methamidophos permits reliable estimates of PODs for all routes without resorting to the use of the less precise NOAELs. Certainty in the PODs was considered to be of great importance in as much as they will impact the outcome of the assessment to a greater extent than any other aspect of the toxicity data base.

d. Use of Steady State

During the data evaluation phase, OPP elected to use only those data points that resulted from exposure of rats for 21 days or longer. This choice was made for a number of reasons. First, because of the many agricultural uses of OPs and the resulting residues that occur in food and water, and also the application of OPs in homes across the US (as reflected in the assessment), the likelihood of encountering an exposure to OPs with no prior recent exposure was considered to be small. Therefore, the use of single-day toxicity data was considered inappropriate. Further, following exposure to an OP, regeneration of cholinesterases to pre-exposure levels occurs in the time scale of days to weeks, not a single day, making the exposed individual potentially more vulnerable to subsequent exposures during that period. Examination of the rat data suggested that for most pesticides, cholinesterase inhibition reached steady state approximately by 21 to 30 days after the start of dosing. After that point, little change occurred in the degree of inhibition resulting from continued administration of the dose for a longer period. OPP selected 21 days as a reasonable time point after which to assume that steady state had been achieved. At this point, all of the pesticides considered have very stable, reproducible levels of cholinesterase inhibition in all compartments measured.

In summary, OPP has taken steps to address the most significant methodological issues raised concerning the dose response assessment developed in support of the OP cumulative risk assessment. OPP is confident that the assessment as performed is scientifically and statistically sound and based upon a reliable data set.

3. Food Assessment

The food component of the OP cumulative risk assessment is based primarily upon two extensive, highly reliable data sets: 1) USDA's Pesticide Data Program, and 2) USDA's Continuing Survey of Food Intakes by Individuals, 1994-1996 + 1998 (CSFII). The PDP data provide a very reliable estimate of pesticide residues in the major children's foods. They also provide an indication of the co-occurrence of OPs in the same sample, alleviating much of the uncertainty about co-occurrence in foods that are monitored in the program. The CSFII provides a detailed representation of the food consumption patterns of the US public across all age groups, during all times of the year and across the 48 contiguous states. These two data components provide a firm foundation upon which to assemble other data to develop the OP cumulative risk assessment.

a. Consumption Data

Up until this time, OPP has performed its risk assessments using the 1989-91Continuing Survey of Food Intakes by Individuals (CSFII). This survey was conducted by USDA and was based on responses over three consecutive days. A more recent CSFII was performed (the 1994-96 CSFII) which was supplemented in 1998 by the Supplemental Children's Survey. This 1998 survey focused on children from birth to 9 years old and greatly expanded (by several fold) the number of birth to 4 year old children in the survey data base. Importantly, the Supplemental survey was designed in a manner such that the results from the 1998 CSFII survey could be combined with the 1994-96 survey. OPP believes that the change to the newer survey information will provide a more realistic estimate of potential risk concerns because it reflects the current eating habits of the US public. Based in part on past recommendations of the FIFRA Scientific Advisory Panel and other advisory bodies, based in part on OPP analyses of dietary and behavioral patterns, and based in part on a minimum number of individuals needed to provide a good representation of eating patterns, OPP has determined that the following age groupings are appropriate for the cumulative assessment: birth to 1 year of age (i.e., 0 -11 months); 1 to 2 year of age (i.e., 12 - 36 months); 3 through 5 years of age; 6 through 12 years of age; 13 through19 years of age; 20 through 49 years of age; and 50 years of age and greater.

For this preliminary assessment, only the following age groups were analyzed: 1 to 2 years of age; 3 through 5 years of age; 20 through 49 years of age; and 50 years of age and greater. These age groups were selected because the other age groups are rarely the most highly exposed in the single-chemical assessments. The change to the more refined age groupings should improve our ability to identify age-related differences in food consumption (especially among young children). The use of the newer CSFII and the finer age breakouts should increase the accuracy and utility of the risk assessment overall by making it more descriptive of the anticipated exposures and risks for each age group.

b. PDP Monitoring Data in the Assessment

The use of PDP as a source of residue data has a number of inherent benefits that preclude the need for the use of conservative assumptions in the assessment. PDP provides a direct measure of the occurrence of more than one OP in any sample analyzed. OPP can use these data as an indication of pesticide co-occurrence likely to be encountered in foods. OPP assumes that co-occurrence mirrors the PDP values; in fact PDP composites contain multiple individual units which may have different profiles of co-occurrence. Therefore, use of PDP data in this manner may overstate potential risk. PDP implicitly reflects the percent of a crop that has been treated with any given OP by measurement of the residues.

Samples with non-detectable residues are assumed to be "zero" values in this assessment. The impact of this assumption was tested in the OP Cumulative Risk Case Study (USEPA, 2000c) that was presented to the SAP in December 2000. In the Case Study, a similar use of PDP data as the residue data source in this assessment was demonstrated for 24 OPs. The resulting data set had very similar characteristics to the one used in the current assessment. A sample of the results of that analysis are presented in Table I.G.1. They are also presented graphically in Figures I.G.1 and I.G.2. The figures clearly demonstrate that the MOEs for analyses with non-detectable residues included as 0 and as ½ LOD converge at the upper percentiles of the distribution. The analysis performed demonstrated that the use of the "zero" values had only negligible impact on the MOEs developed at the upper percentiles of exposure.

Although the result of replacing all non-detectable residues with "zero" values would intuitively suggest an under-estimation bias, OPP has demonstrated through its case study that this change has little impact at all on the portion of the exposure curve likely to be used for regulatory purposes. This result is not surprising for a multiple chemical assessment addressing the number of chemicals under evaluation here. This assessment combines many data elements, with no single chemical or commodity dominating the exposure. The residue data used in this assessment include highly consumed foods, and several of these have large numbers of detects as well as a few high detects of OPs. There are detectable residues of at least one OP on 25% of the samples used in this assessment with a high of 66% on one commodity. Generally, the LODs for PDP data are very low (the average LOD for entire data base is about 0.01 ppm). Therefore, it seems reasonable that the effect of assumptions related to estimation of values below the LOD would not significantly influence exposures at the highest percentiles. This result may not be the case for other assessments containing fewer foods or lower levels of detectable residues and should be evaluated for each subsequent case.

c. Data Translation from PDP

Not all foods to which OPs are applied are monitored in PDP. OPP has developed a scheme by which commodities that are measured by PDP serve as surrogate data sources for commodities that are not. This approach is outlined in OPP/HED SOP 99.3 (USEPA, 1999b). It is based upon the concept that families of commodities with similar cultural practices and insect pests are likely to have similar pesticide use patterns. Although this approach is generally sound, it introduces uncertainty with regard to how similar the use patterns for a given pesticide are to those for even closely related commodities.

For example, the same OP may be applied on a similar time schedule. However, the rates of application may differ between the crops treated. The number of treatments may also differ for application to the two crops. This issue is of importance to consider when conducting sensitivity analyses of the results of the risk assessment. When the data are adapted for the use of several chemicals simultaneously, and estimates of co-occurrence are derived from that data, the likelihood of an inappropriately assigned residue becomes greater. Although the commodities may have similar cultural practices, they may differ in the number of OPs registered for these uses. In addition, the translation from one commodity to another implicitly assigns the inherent percent crop treated information from one commodity to another. The direction and magnitude of this error will differ from one commodity to another.

OPP believes that this potential source of error in its assessment will most likely result in over-estimation bias. However, the magnitude of the error is probably not great in that the commodities for which PDP data was translated represent only ~1% of a child's diet. OPP will evaluate the sensitivity of the translation as a step toward completion of the revised OP cumulative risk assessment.

d. Other Sources of Residue Data

PDP data and surrogate PDP data do not cover all commodities of interest. For meats, seafood and eggs, FDA's Total Diet Study and FDA Monitoring data provided residue estimates. These data suggest that eggs and seafood contain negligible residues. For most meats (beef, pork, sheep and goat), the maximum residue from the Total Diet Study was used. Although the use of the maximum residue as a single data point for meats is an overestimate, OPP has conducted a sensitivity analysis making all residues for meats zero and found that there was no change in the outcome of the risk assessment at the upper percentiles of exposure. This is not surprising in that the highest residue observed is itself very low. Therefore, OPP considers these factors neutral with regard to their impact on the results of the assessment.

Approximately 4% of the foods consumed still remained unaccounted for after using FDA Total Diet Study and FDA Monitoring data. Sugar, molasses and syrups were assigned a residue value of zero. These products are highly processed commodities that are unlikely to retain any significant residues following the processing steps. The limited data from the Total Diet Study found no residues in pancake syrup or sugar. No data are available for field corn or dried beans. However, these commodities are also blended and highly processed before consumption. OPP believes that omission of these foods from the assessment will not result in any change in the results of the assessment.

e. Impact of Regulatory Actions

Inherent in the use of monitoring data to estimate future residues is the concern that any changes in use patterns will not be reflected in the data. The OPs are currently undergoing use changes as a result of the individual chemical decisions. In most cases for which legal agreements have been signed, the uses have been removed from the assessment. In other cases, preharvest intervals have been extended or rates have already been reduced. These changes are not reflected in the assessment as they are not yet apparent in the monitoring data available. Decisions have not been completed for all OPs included in this assessment. This process could result in additional exposure and risk reduction measures. These changes could result in further reductions in exposure in the food portion of the assessment. The magnitude of that change is uncertain.

f. Children's Exposures

Two exposure issues unique to children are not directly addressed in the current assessment. OP exposure from breast milk is not incorporated quantitatively. However, no indication of OP transfer to breast milk has been found in the open literature. A review of the literature to identify any potential pesticide transfer from breast milk to children indicated no evidence that this is a concern (ILSI, 1998). This finding is further bolstered by the results of studies generated by the regulated community in support of pesticide registration. OPs are not found to transfer into cow's milk when cattle are fed a diet containing OPs. This finding is uniform across the entire class of OP pesticides. As a result, OPP believes that breast milk is not likely to be a contributor of OPs to the diets of infants and children. Baby formula is included in the current assessment with its consumption reflected in the FCID translation of CSFII food consumption survey, and residue data available for all of its components.

OPP is also aware that some or all baby food manufacturers have adopted policies that restrict the use of OPs on fruits and vegetables that will be used in their products. As a result, children consuming commercially prepared baby food may not be exposed to OPs in their diet. OPP does not have data on the extent of these policies or what proportion of baby food is prepared at home using fresh fruits and vegetables. Although the FCID translation of CSFII flags foods consumed as commercial baby foods, OPP does not know what proportion of those products were produced under pesticide use restrictions. Therefore, in the current assessment, OPP treated all baby food consumed as home prepared from fresh fruits and vegetables, or meats. Thus, there may be an over-estimation in the food assessment. The magnitude of that bias is uncertain.

g. Model Outputs/DEEM™

The food component of the OP cumulative risk assessment was conducted assuming that exposure to OPs in foods is uniform nationally, and that it has no significant seasonal variations. OPP has extensive experience with the two data bases that confirm this assumption as reasonable. The CSFII reflects no significant change in consumption patterns across the year. This finding is not surprising in light of the widespread distribution of foods across the United States, and the proportion of foods that are imported from abroad. Lack of seasonal consumption patterns is also not unexpected given the ability to preserve and store foods for delayed consumption, and the import of seasonal foods to bridge gaps in domestic production periods. Similarly, PDP does not suggest any significant alteration in the types of pesticides encountered or the magnitude of residues across the year. The assumption of nationally uniform distribution of foods does not reflect highly localized consumption events that may be encountered by individuals who obtain foods at road side stands and consume it closer to the time of harvest than the foods available in larger grocery stores. OPP does not have reliable data on either consumption or anticipated pesticide residues to permit evaluation of this type of exposure.

The results of the food portion of the preliminary OP cumulative risk assessment are presented in Figures I.G.3a and I.G.3b. The results are presented as a cumulative distribution function in which risk in the form of MOE varies with percentile of exposure. The percentile of exposure as used in this document indicates the percent of the population that will experience exposure less than or equal to the exposure at that point on the exposure distribution. In other words, at the 80th percentile of exposure, 80% of the population are likely to have the exposure indicated or less. Twenty percent are likely to be exposed to higher amounts of OPs. Results for four age groups are presented: children, 1 - 2 years of age; children, 3 - 5 years of age; adults, 20 - 49 years of age; and adults, 50+ years. In Figure I.C.1.a, the full range of exposure is presented. The graphic presentation of the results makes apparent that children have higher relative exposures than adults. This difference remains across the entire range of exposures including the higher percentiles (Figure I.C.1.b). In addition, children, 1 - 2 years of age, have slightly higher exposures than older children. This observation is not unexpected, given the higher relative consumption in young children during periods of rapid growth. As growth slows with age, relative consumption (and accompanying exposure to pesticides in foods) gradually decreases. Preliminary results of the assessment indicate that children, 1 - 2 years of age are the most highly exposed group consistently for all pathways and for all regions.

Initial examination of the food assessment suggests that a small number of commodities could be the source of a large percentage of the total exposure in the preliminary food assessment. OPP has begun the process of evaluating the results to determine whether they appear reasonable. OPP must re-verify the data inputs and assumptions producing this result. The OP Market Basket Survey (OPMB) provides data to verify the residue levels used in the preliminary OP cumulative risk assessment. Preliminary results obtained by comparing the use of PDP with no translation to OPMB data with no translation indicate that the OPMB data provide very similar results to those obtained with PDP. OPP will continue to evaluate these data and consider their impact on future assessments. All of the factors listed above as potential sources of error and bias will be evaluated to determine that the identification of these commodities as being major contributors to the estimated food exposure is correct and reasonable.

The consumption records occurring in the tail of the distribution will be evaluated to ensure that they reflect reasonable consumption patterns. Preliminary analysis of the tail of the distribution (>99%ile) indicates that no small subset of consumption records dominates the outcome. This observation increases OPP's confidence that the food and water components of the assessment are not unduly influenced by unusual consumption patterns. The impact of using surrogate data from foods monitored in PDP for other foods must also be evaluated to determine whether mismatches in use patterns and likely residues are an issue on commodities which are significant contributors to exposure. Finally, the contribution from each pesticide must be analyzed to determine which pesticides are indicated in the assessment to be major contributors to risk. This evaluation will include examination of the role that relative potency factors may play in determining which OPs occur in the tail of the distribution. OPP will also be seeking additional data with regard to this question during the comment period.

4. Residential Assessment

The residential component of the preliminary OP cumulative risk assessment is the most sophisticated analysis of its type that OPP has ever conducted. It is the first application of distributional analysis to residential exposure assessments. It also factors in the seasonal and regional aspects of pesticide use. Three types of data are used in the residential assessment: pesticide use; pesticide residue dissipation; and exposure contact and exposure factors. Pesticide use data are utilized to determine the percent of households using a pesticide, the timing of the pesticide treatments, frequency and duration of exposure. Use data are also important in identifying geographic regions where the pesticide will be applied. In the current assessment, use data are specific to the region under evaluation and vary according to the specific needs of that region. Pesticide residue dissipation data address the fate of the pesticides once applied to an environment (e.g., lawns). Exposure contact data are exposure specific metrics that relate human exposure to pesticide residues. Humans come in contact with the residues by contacting the product directly or by contacting the residues left after the pesticide applications are made. Human exposure factors, such as breathing rates, body weight and surface areas used in this assessment come from the Agency Exposure Factors Handbook. These will not be discussed in the risk characterization of the document because the values are established and used throughout the Agency. OPP has used all of the known available data to assess the significant residential uses of the OP pesticides. The only residential uses not covered by this assessment are pet uses - collars, shampoos and dips.

Exclusion of the pet uses are expected to underestimate the exposure to the OP pesticides from residential uses. Accurate information on use of the pet shampoos, dips and collars needs to be developed. This need for current information is especially important as product use has been declining with the introduction of the new generation of pesticidal pet products. Pet use pesticides include products applied as drops along the animal's top-line and the products which are administered orally. OPP also needs information on the number of pet owners to prepare a calendar-based probabilistic exposure assessment of these uses. Other information from the surveys conducted by the American Veterinary Medical Association and robust market share information are also needed. Very little data are available on exposure to pesticides from the use of pet shampoos, dips and collars. The Agency recently funded a study assessing adult and children's exposure to insecticides in flea collars. Preliminary results show that the use of pet collars does not result in significant exposure to pesticides (Boone et al., 2001). Further analysis of these data may lead OPP to conclude that the pet collar scenario can be eliminated from consideration.

Individual decisions for tetrachlorvinphos and DDVP that include pet uses as sources of exposure have not been completed. The screening level risk assessments for these uses are of concern and OPP will address these uses in the risk management phase of the individual RED development.

a. Exposure Contact and Pesticide Residue Dissipation Data

Exposure contact data used to assess exposures experienced by the applicator of consumer oriented pesticides are by far the most robust information used in the residential portion of this assessment. In addition, the application of pesticides is one of the more straight-forward activity patterns to measure since it represents easily defined activities. Recent data generated by the Outdoor Residential Exposure Task Force (ORETF) have been used to assess the use of hose-end sprayers (lawn care products), rotary granular spreaders (lawn care products), hand-pump sprayers (home gardens and orchards) and hand held dusters (home vegetable gardens). Another study, submitted by a registrant, was also used to assess residential applicator exposure using granular shaker cans to apply disulfoton. All studies meet or exceed current Agency guideline requirements (in particular regarding the number of replicates) and can be extrapolated to include clothing scenarios ranging from short-sleeved shirts and short pants to long-sleeved shirts and long pants. OPP has high confidence in the use of these data.

There are two post-application dermal exposure scenarios addressed in this assessment. These are: post application dermal exposure to lawn care products, and post-application exposure to vegetable and home orchard pesticide applications. Like the applicator scenarios, the post application garden and home orchard exposure scenarios are easily defined activities. For harvesting vegetables or weeding, there is a substantial amount of data based on farm worker exposure performing similar activities in crops requiring substantial hand labor. These contact values have the potential to overestimate exposure since they are based on individuals working for profit based largely on their productivity. Such workers are likely to be more efficient than most home gardeners. A uniform distribution of values representing hoeing and harvesting may overestimate early season activities that consist of potential exposure to small plants.

Dermal exposure from post-application contact with the lawn chemicals is equally varied. Contact data, representative of the range of human activities has been difficult to model. Dermal contact exposure values were identified in data described in Vaccaro et al., 1996, for adults who performed scripted activities and contact values for children performing non scripted activities on lawns treated with a non-toxic substance were described by Black in 1993. Similar rate of transfer for the surrogate compounds in the dermal contact studies was assumed with the rate of transfer observed in the chemical specific dissipation data available to the Agency at this time. Although these dermal contact values are considered to be reasonably representative of human activity on lawns, uncertainty is introduced when comparing them to stand alone residue dissipation data. Contact values developed assumed a transfer rate of 0.5 and 1%. This uncertainty is not unique to this cumulative assessment. It is present in all OPP assessments of the post-application exposure to turf chemicals. ORETF is developing dermal contact data using concurrent residue collection methods. At this time the method OPP is using in this assessment is the best available.

Turf transferable residue data are available for all turf chemicals. For malathion, these studies were conducted at multiple locations. Studies conducted in Missouri, North Carolina and Pennsylvania were used for the eastern regions and the study conducted in California was used for the western regions. Similar regional residue data were available for the use of malathion on home gardens and orchards and were used accordingly in this assessment. These data are of good quality and provide accurate estimates for this parameter.

There are no chemical specific turf residue data that address the influence of wet hands and the mouthing behavior of young children on the efficiency of residue transfer. To address this uncertainty, OPP considered a study performed by Clothier et al., 2000, in which an increased transfer efficiency of ~1.5 to 3x was observed when comparing a turf residue collection method (Poly Urethane Foam (PUF) roller), with volunteers pressing dry hands or hands wetted with saliva onto treated turf. A higher transfer rate was noted for the compound with the lowest application rate. This observation may suggest that increased loading is a function of pesticide concentration and that the hand surface may become saturated. The transfer efficiency of the PUF roller is similar to the transfer efficiency of the residue method used in the chemical specific studies. This same factor was applied to the existing data. Chemical-specific wet hand transfer efficiency data would be needed to refine the estimate for this exposure pathway. The assumption of decreased transfer with increasing loading may result in an overestimation due to the assumption that the two vary directly in the current assessment. The impact of saliva on transfer efficiency is assumed intuitively to increase the amount of transfer of a surface-borne pesticide. However, the extent of the increase that would be realized is unknown. Additional data are needed to better define this parameter.

b. Pesticide Use Data

Accurate pesticide use data are key to the residential risk assessment. Useful information include regional site/pest markets, timing of application and the percent of households using their products. In the absence of specific pesticide use information, OPP developed exposure scenarios based on timing aspects found in regional Cooperative Extension Service publications and surveys such as the National Home and Garden Pesticide Use Survey (NHGPUS), the National Garden Survey, and Doanes GolfTrak.

The Cooperative Extension Service publications were useful for establishing the timing of various turf chemicals. The survey data were used to establish the number of households that may use a given pesticide. For some regions, these application windows were expanded to account for the differences in length of growing season. This is particularly important when regions consist of several USDA Plant Hardiness Zones (e.g., Region 8). The NHGPUS delineates percent of households using pesticides based on a large national survey. These values consider users and non-users as well as homes having lawns and those that do not. The uncertainty of using this survey is the age of the survey (1989-90) which may not reflect current OP use. Doane's GolfTrak was used to identify the percent of golf courses treated with pesticides and is more timely (1998-99). OPP believes this is a robust data source. The National Garden Survey has been tracking percent of households employing lawn care applicators and is considered very robust. In addition, variables such as vegetable garden size are well characterized since these gardens are easy for survey respondents to define.

c. Use of Calendex

OPP believes using a calendar-based model is justified in order to manage the timing of pesticide applications and delineating subsequent exposures in the general population. Models that can employ distributions of the available residue and contact exposure data are needed to capture the inherent variability in the exposed population and can be used to provide justification regarding co-occurrence of pesticide exposure events. This method is preferable to relying solely on point estimates and combining "what if" scenarios which only adds uncertainty, while providing little information to risk managers regarding the potential numbers of exposed individuals and their ranges of exposure. Calendex provides the ability to evaluate route specific pathways which are defined by the model user so that appropriate residue and residue contact data can be used. In most cases, uniform distributions were used based on the advice of the Scientific Advisory Panel. Uniform distributions are a useful way to reflect the range and variability of available data when dealing with small data sets such as OPP has for the residential assessment and for those data sets for which the actual shape of the distribution is unknown. In this way, the impact of variability of the input parameters can be reflected in the resulting exposure distributions reducing reliance on point estimates and assumptions.

d. Non-dietary ingestion

Non-dietary ingestion is an important exposure pathway in the residential assessment in the southern regions. However, this exposure pathway is associated with significant uncertainty. Frequencies of hand to mouth events used in the assessment are based on real world observations of children in homes and day care centers enumerated on video tape. However, a number of issues surround the estimation of the impact of this activity. The number of hand-to-mouth events occurring in a given time frame was developed by observing children's behavior during quiet play. Video tape data are based on children situated indoors and not outdoors. Hand to mouth frequency may be higher when children are engaged in "quiet play" (e.g., listening to stories) than when engaged in active play (running, tag etc.). Children playing on lawns are likely to be engaged in active play. Therefore, the frequency of hand-to-mouth events used in the current assessment may be an overestimate.

The variety of hand-to-mouth events (such as the hand being near the mouth rather than in it) makes the enumeration of events difficult. Further, video tape values provide no information on rate of transfer from treated surfaces to hands. Transfer estimates in the assessment were based on studies measuring wet hand transfer efficiency with wet hands using surrogate compounds. No chemical specific data are available. For each hand-to-mouth event, the hand is assumed to have residue when data indicates a child may touch other things (e.g., clothing, non-treated surfaces or nothing). Chemical specific data and more research are required to get a better understanding of this exposure pathway.

e. Results

The results of the residential portion of the cumulative risk assessment are relatively straight-forward to interpret. The results of the individual regional assessments can be found in section II of this document. Inhalation exposures to DDVP from No-Pest strips and crack and crevice treatments are the major contributors to indoor residential exposures. This determination is relatively obvious because these are the only remaining indoor uses for OPs. Some of the regional assessments from the southern regions also indicate hand-to-mouth activities by children in conjunction with lawn scenarios as an important contributor to exposure. Significant uncertainty surrounds the estimate of exposure from hand-to-mouth behaviors in the assessment. Any bias from this uncertainty is anticipated to overestimate exposure. The magnitude of overestimation is uncertain. OPP is seeking better information to refine its characterization of exposures resulting from behaviors that include hand-to-mouth activities. OPP believes that the current OP cumulative risk assessment represents a reasonable, health protective estimate of likely exposure to OPs from residential uses.

5. Regional Water Exposure Assessments

The regional water exposure assessments are designed to represent exposures from typical OP usage conditions at one of the more vulnerable surface watersheds in the region. Each regional assessment focuses on areas where combined OP exposure is likely to be among the highest within the region as a result of total OP usage and vulnerability of the drinking water sources. In this manner, OPP is confident that if the regional cumulative risk assessment finds that exposure in water is not a significant contributor to the overall OP exposure in that area, it will not be a significant contributor in other areas in the region. However, because the assessment is based on typical usage, it is not a high-end estimate of pesticide exposure at that vulnerable site. A comparison of the estimated concentrations from individual OPs with available monitoring indicates that this assessment is by no means worst case or unrealistic. In each region, levels of one or more OP pesticides detected in monitoring studies exist that are greater than that estimated by the cumulative water assessment; in some cases, the estimates are off by an order of magnitude or more. However, in that same region, estimates of other OP pesticides are similar to or greater than detections found in monitoring studies.

The discussion that follows characterizes the results of the regional water exposure distributions, and identifies assumptions and approaches to the assessment that might impact the level of certainty in the results. Additional analysis and characterization of the results can be found in each of the regional assessments.

a. What Each Regional Assessment Represents

Each region in the assessment is represented by a geographic area with the highest apparent potential for cumulative exposure to OPs in drinking water. Each geographic area has a relatively high usage of multiple OP pesticides (in relation to other parts of the region) coinciding with surface and/or ground water sources of drinking water which are vulnerable to potential contamination by these OPs. Because OP usage varies within the region, the initial evaluation focused on the areas of highest use which are dependent upon the crops grown, which OP(s) are used on these crops, how much OP pesticides are applied and when they are used. Since the purpose of the assessment is to identify the impact from multiple OPs occurring in water in the same area, the area(s) selected for the assessment do not necessarily represent the highest exposure of a single chemical, but rather the highest multiple OP exposure within the region. Since OP use may vary from year to year and cropping and usage patterns may change, some areas in other parts of the region may have greater water exposure in a given year.

Because OPP considers both total OP usage and vulnerability of the drinking water sources, the site selected may not necessarily coincide with the highest OP use area in the region or the area where runoff alone is greatest. For instance, the highest OP use areas in the Northwest Fruitful Rim are in Yakima County and eastern Washington and in southeast Idaho. However, because of low rainfall, few surface-water intakes, and irrigation-dominated agriculture, OP usage in this area did not necessarily pose the greatest risk to drinking water sources. Instead, the surface-water sources of drinking water in the Willamette Valley were potentially more vulnerable, despite lower OP usage.

Comparisons of the estimated pesticide concentrations with available monitoring in each region indicate that, in almost every region, a few known detections of one or more OP pesticide occur at higher levels than are being predicted for the cumulative assessment. As noted, because the estimate focuses on the cumulative impact from multiple OP pesticides, it doesn't necessarily focus on the conditions that lead to the highest concentration of one particular OP. In addition, some of the monitoring data may come from water bodies that are not representative of drinking water sources. In some instances, the higher monitoring levels may reflect uses that are being cancelled, such as the residential uses of chlorpyrifos and diazinon. In the case of azinphos methyl, in which upper percentile regional distributions were consistently one to three orders of magnitude less than monitoring detections, the underestimates may be due to inadequate or missing data on pesticide fate and transport properties or usage.

b. What PRZM-EXAMS and the Index Reservoir Represent

OPP adapted available tools to provide daily distributions of OP levels in water for incorporation into the probabilistic cumulative exposure assessment. While these tools have provided OP distributions that are, in many cases, comparable with available monitoring data in the same or nearby locations, assumptions regarding the nature of the drinking water source and watershed influence the estimated distributions.

i. Nature of the Drinking Water Source

The Index Reservoir is based on the specific geometry (watershed and reservoir size) of an actual reservoir (Shipman City) in the Midwest. As such, it may best represent potential transport to similar drinking-water sources in high rainfall areas such as the Midwest and East. It may not so well represent reservoirs in drier parts of the West, where inflow and outflow are artificially managed. In addition, while the Index Reservoir scenario will not necessarily reflect short pulses of higher concentrations found in flowing rivers and streams, long-term average concentrations in a reservoir may be greater than in streams because of differences in the residence time for water in these water bodies.

The Index Reservoir is adapted to the runoff and stream inflow calculated from local soil and weather data. OPP used the PRZM runoff data for the cropping scenario that generated the lowest total runoff volume in the region to derive the inflow and outflow of the Index Reservoir. This introduces a small additional error into the concentrations calculated for the other chemical-crop simulations in each region.

ii. Nature of the Watershed

PRZM is not a basin-scale model, but a field-scale model which provides an edge-of-field pesticide loads in runoff to the 5.3-hectare reservoir simulated by EXAMS from a 172.8-hectare watershed. PRZM does not explicitly account for the relative contributions of each field to the Index Reservoir. OPP uses a cumulative adjustment factor (a combination of the regional percentage of the total watershed area in crops with OP uses and the percentage of acres treated by each OP on each crop) to adjust the resulting reservoir concentrations calculated by EXAMS. Further information on the assumptions involved in applying Percent Crop Area (PCA) factors for drinking water assessments of individual pesticides can be found in the science policy paper, "Applying a Percent Crop Area Adjustment to Tier 2 Surface Water Model Estimates for Pesticide Drinking Water Exposure Estimates" (USEPA, 2000e)

PRZM does not account for location in the watershed: all fields are assumed to be uniformly distributed within the watershed, with runoff going directly into the reservoir. The simulation of multiple chemicals to multiple crops grown in different soils represents a significant adaptation of PRZM-EXAMS. Ideally, the cumulative drinking-water exposure assessment for a region would allow separating the different crop-soil regions within a watershed, and could simulate the different path lengths through runoff and stream-flow to the Index Reservoir. However, since PRZM is an edge-of-field model, runoff from fields representing the application of each OP to a different crop follows the same path length in the treated field and empties directly to the reservoir. In other words, this simulation assumes that the treated fields with their individual soils are uniformly distributed throughout the watershed and essentially ring the index reservoir for direct deposition of the edge-of-field load.

Each crop use simulated in PRZM assumes that the entire area of the watershed planted in the crop consists of a single soil. In each of the regions, OPP used actual soil data from local soils on which the crops are grown. When possible, the soil selected for each scenario was a benchmark soil that was prone to runoff (classified as hydrologic group "C" or "D" soils). While OPP attempted to simulate soils that might be prone to runoff, the emphasis in developing the scenarios was to choose important local soils for which sufficient data are available, and which are know to be used to grow the crops of interest. These soils may not represent those most prone to runoff, but afford reasonable certainty that the simulation represents local soil conditions. While an assessment using a single soil assumes that each part of the watershed will be equally vulnerable to runoff, areas of higher and lower runoff vulnerability will exist in an actual watershed.

iii. Multiple Years of Local Weather Data

Because the application rates, frequencies, and timing are held constant, the PRZM/ EXAMS Index Reservoir simulations over multiple years evaluate the impact of the variability in precipitation on the amount of pesticide that reaches surface water. Because weather data spanning 24 to 36 years is available for many locations across the country, PRZM and EXAMS can account for OP runoff from a wide range of weather patterns not otherwise possible with monitoring studies that span relatively few years. The age of the data (collected through 1983) limits OPP's ability to compare of the modeling output to monitoring data.

Weather data files for PRZM are available for weather stations across the country. The weather station nearest to the county or counties used for the simulations was chosen for the cumulative assessment. To the extent that precipitation in these counties over the period of record might have been greater or less than that recorded at the nearest weather station, runoff for that area may have been over- or underestimated by PRZM.

Additional uncertainty in the modeling results is associated with application of OPs to irrigated crops. PRZM has a relatively simple irrigation subroutine, applying a user-specified amount of irrigation to the simulated field when the moisture content of the top soil layer drops to some fraction of field capacity. Actual irrigation in the field follows a more complicated formula, with irrigation timing dependent on the grower's professional judgement of crop needs. In addition, PRZM has a limited ability to distinguish between various irrigation methods.

c. What the Usage, Cropping Areas, and Acre Treatments Represent

Typical usage was generated by dividing the pounds reported as applied in a given area by acres treated in that area. This derivation of the "typical" number assumes that all applications were made at this typical or average rate and that frequencies of applications were constant year to year. The assessment considered only yearly variations in weather, and not variations in application rates. Thus, using these typical application rates and frequencies may underestimate water concentrations in years when pest pressure is higher than in our reported years and may overestimate in years when lower amounts of pesticide is used.

The regional percent crop area (PCA) factors are based on a large area: the size of the hydrologic units (average > 1000 square miles) used generally span multiple counties and may contain several watersheds that supply drinking water intakes. These regional PCAs represent the aggregation of crop areas from county-level NASS data and assume that the cropping area is uniformly distributed. However, cropping intensity is variable and smaller watersheds, including those capable of supporting drinking water supplies, may have a much higher percentage of crop land than the rest of the large basin. An example is Zollner Creek in the Willamette River Valley. This watershed had the highest concentrations and frequencies of detection of OPs among all of the NAWQA monitoring sites in the Willamette Valley. This stream drained a watershed that was 99% agriculture, much greater than the regional PCA of 60%.

The regional assessment areas generally coincided with the area with the highest PCA. However, in some regions, such as the Northwest Fruitful Rim and the Eastern Uplands, the regional assessment focused in a lower-intensity agricultural area which was otherwise more vulnerable because of OP usage and/or the nature of the drinking water source. In the case of the Eastern Uplands, the difference in the PCA accounts for a good portion of the differences between the estimated OP concentrations in water and those reported in the NAWQA study.

The typical application rates and percent acres treated are derived from state-level data (or NASS reporting districts) and assume uniform use practices across the state. Indeed, an uneven distribution of application rates and percent acres treated is expected in response to differing pest pressures. This assumption will underestimate areas where pest pressures may dictate a higher percentage of acres treated in a given year; similarly, it will overestimate areas where low pest pressures will require fewer acre treatments. In the Red River Valley (Northern Great Plains region), differences in percent acres treated and application rates between the Minnesota counties and the North Dakota counties located within the Red River Valley (see the regional assessment) are more likely due to differences in the state-level data than in actual differences between the adjacent counties.

d. Timing of Application

OPP selected the midpoint date from most active application period for the application date of the pesticide on a particular crop. A preliminary evaluation of this assumption in the Heartland region found that variations based on date of selection may result in differences of approximately two to three times in cumulative concentrations. In the case of the Heartland, the highest concentrations were found when the applications were made at the end of the most active application period rather than at the midpoint, which was used in the probabilistic exposure assessment.

In the absence of data to show otherwise, OPP assumed that all of the pesticide applied on a particular crop is done on the same date. While this may be an unreasonable assumption for a large watershed, it is not unrealistic for the size of the watershed used in this assessment. This assumption may result in higher peaks, but similar overall average concentrations than if applications are spread out over time. The resulting estimate of exposure may result in a small overestimation bias in the results that will be greater in large than in small watersheds.

e. Water Treatment Effects

Although not extensive, scientific evidence suggests that many of the parent OP pesticide residues in water are likely to be reduced during drinking water treatment, primarily by transformation by oxidation through chlorination. These oxidative transformation products, such as sulfones, sulfoxides, and oxons, are still of toxicological concern, have been detected in treated water from water treatment plants, and may be stable for at least 24 to 48 hours. The information is not sufficient to make quantitative adjustments to the cumulative exposure estimates. However, OPP assumed that any transformation due to chlorination results in the conversion to a product of toxicological concern. Where the transformation is less than complete, and where non-toxic products are also formed, the assessment will overestimate the ultimate drinking water exposure. However, if the oxon products are significantly more toxic than the parent OP, then this assessment may underestimate the risks from exposure to pesticide residues in water.

In summary, OPP believes that the estimates of OP residues in drinking water that were used in the current assessment are health protective. They were generated using the use characteristics from a high end site in each of the12 regions. They assume that all drinking water is taken from surface sites. This is a likely source of overestimation bias in as much as ground water sources of drinking water generally have lower OP residues than are found in surface water. Pesticide use patterns incorporated in the PRZM/EXAMS analyses are regionally specific, reducing overestimation bias that may be encountered if high end, national pesticide use data were used instead. In addition, the water residue data reflect the characteristics of a vulnerable site. Although the potential exists that peak water concentrations may not be captured in this approach, the impact on the contribution from water to the overall risk assessment is anticipated to be small.

6. Overall Risk Assessment Considerations

The transition from the traditional single-route, single-day risk assessment to a multi-route, calendar-based risk assessment requires the risk assessor to consider a variety of new issues in designing and interpreting a risk assessment. The issues become more complex when the assessment addresses the simultaneous exposures to more than one pesticide. In addition to addressing these new types of risk assessments, OPP has used this OP cumulative assessment as a vehicle to advance its techniques in all aspects of risk assessment. Many questions will arise regarding interpretation of data generated in a more complex, highly refined assessment than is generally found in the single-chemical RED assessments. The detailed outputs from the analysis allow in depth analysis of interactions of data sets in estimating the possible risk concerns and identifying the sources of exposures. The available data are used extensively and, as a result, the assessment provides a more refined picture of what is likely to be encountered in the real world. This assessment reduces reliance on assumptions by replacing them in most cases with distributions of data. This practice permits expression of the full range of values for each parameter in the assessment.

In designing this assessment, OPP looked at the available information regarding US population exposure to OP pesticides. There is a body of evidence that indicates a sizeable proportion of the US population has a fairly constant background exposure to OPs. This is evident from the results of the NHANES III in which 82% of people who provided urine samples for analysis were found to be positive for trichloropyridinol, a metabolite of the OPs chlorpyrifos and chlorpyrifos-methyl (Hill et al., 1995). Further examination of the NHANES III data indicate that a sizeable proportion of the population have metabolites in their urine that are not compound specific, but are associated with other OPs. Preliminary analyses of data collected under the auspices of NHEXAS also indicate that metabolites from a variety of OPs are found in urine from populations of adults and children sampled around the US.

As a result of these findings, OPP considered it reasonable to assume that the likelihood of a naive exposure to an OP is small. This is particularly important considering that the current assessment is designed to simultaneously evaluate the exposure to and risk from 29 widely used OPs. Therefore, the concept of an unexposed population suddenly encountering an OP exposure and then returning quickly to an unexposed state was determined to be unrealistic. This finding was important in determining the appropriate manner in which to incorporate the available acetylcholinesterase inhibition data into the hazard assessment. In conjunction with the understanding that the period of reversibility for OP-induced cholinesterase inhibition is on the order of several days to weeks, it provides a reasonable basis for the decision to use steady state measures of cholinesterase inhibition as the basis for OPs RPFs and the PODs for methamidophos.

The next question framed in designing the assessment was to determine the characteristics of the population of interest. OPP determined first that the assessment would be designed to reflect population risk as opposed to individual risk. This is consistent with past practice in other, single-chemical risk assessments. Use of population risk permits incorporation of the full range of behavioral and exposure considerations that could not reasonably be accommodated by an assessment focusing on individual risk. It also permits evaluation of the impact of a variety of risk reduction strategies on the population as a whole. The individual is represented in the perspective of the spectrum of many other possible outcomes. For the purposes of the OP cumulative risk assessment, the decision was made to focus on a limited number of population subgroups. They are the four age groups listed above: children, 1 - 2 years of age; children, 3 - 5 years of age; adults, 20 - 49 years of age; and adults, 50+ years.

OPP evaluated the nature of the toxic response, i.e., brain cholinesterase inhibition to determine an appropriate time frame over which to consider exposure to OPs. As mentioned in section I.B above, cholinesterase inhibition is not immediately reversible, with the effects persisting for days to weeks. Because there is a constant background exposure to OPs from food, a period two to three weeks was selected as an appropriate window over which to evaluate the pattern of exposures and resulting MOEs for the OP cumulative assessment.

The next aspect of the assessment was the decision to construct the estimated exposure of the appropriate subpopulation over a calendar year. This decision is a key determinant of how to combine the many components of exposure across the year. Considerations in this decision were to:

1. represent population estimates of risk as opposed to individual risk.
2. properly reflect the likelihood of encountering an exposure on any given day. This consideration is particularly important given the potential for multiple exposures.
3. ensure that the assessment developed is appropriately protective of the public health.
4. develop an assessment that is internally consistent and that logically reflects the patterns of exposure to which the public is actually exposed.

5. be certain that contributors to risk can be identified and subjected to detailed analysis.

Based upon these considerations, OPP decided to develop a distribution of exposure distributions generated for each day of the calendar year. This process is outlined in more detail in Section I.F. In summary, a series of population risk estimates are developed across each day of the calendar year. These estimates reflect the full range of population risk across the calendar year, capturing the seasonal and regional variability that are an important aspect of the drinking water and residential assessments. Using this approach, OPP can present a snap shot of the potential population risk from a variety of sources by cutting across the distribution at any given percentile of exposure.

OPP considered a number of other possible means of combining the data. These included averaging of population estimates across a multi-day interval, and following the exposure of individuals over multiple days. Both of these approaches are anticipated to result in the same total exposure. However, OPP believes that the presentation of the distribution of daily distributions will be more amenable to evaluating risk contributors. OPP's evaluation of the outputs is to evaluate the results graphically, looking for patterns of change across the calendar year. Because the appropriate time frame for consideration is multi-week, events of interest are those resulting in a sustained period of elevated exposure. Shorter term changes in exposure (such as a few days) are not considered to be of sufficient duration to be of concern within the hazard framework defined for the OPs in Section I.B. The likelihood of a sustained elevation in an individual exposure assessment is anticipated to be lower than an elevated population exposure at any given percentile. An example of the rationale behind this conclusion is as follows: Few individuals are likely to repeat residential applications for every day of the pest season. However, on a population basis, the upper percentiles of exposure will reflect the phenomenon of a large number of individuals encountering an increase in exposure due to performing these tasks. It is this increase in population risk that would serve as evidence of a risk contribution of concern. As a result, this approach to calculating the exposure to the population is considered to be health protective, and will reduce the likelihood that an exposure pattern would be inappropriately omitted from consideration in the risk assessment. OPP believes that this approach of developing a distribution of daily population distributions more appropriately addresses those questions raised by the implementation of FQPA. OPP will pursue a series of further analyses to evaluate the utility of alternative evaluation strategies described above.

7. Conclusions

The results of the OP cumulative assessment indicate that the contribution to OP cumulative risk from drinking water is generally at least one order of magnitude lower than the contribution from OPs in food at percentiles of exposure above 95th for all population subgroups evaluated. As the percentile of exposure increases, the difference between the food and water contributions increase. Below the 95th percentile of exposure, the water risk comes within one order of magnitude of the food contribution. This pattern is consistent for all regions in the current risk assessment. Those regions with the lowest total MOEs at the upper percentiles in the exposure distribution generally reflect the contribution of the inhalation route of exposure from residential indoor uses of DDVP. The exposures occur from the No Pest Strips and crack and crevice treatments. This observation is consistent for all regions evaluated. The same pattern of risk from each pathway is observed for all regions. At these higher percentiles of population exposure, residential uses are the major source of risk - in particular exposure from hand-to-mouth activity by children and inhalation exposure by all age groups. These patterns occur in all population sub-groups, although actual risks appear to be higher for children than for adults regardless of the population percentile considered. OPP believes that the results of the current assessment provide a highly refined, health protective estimate of the cumulative risk to the US public from the use of OPs.

Table I.G-1. Effect of Assumption that ND=0 on Exposure at Higher Percentiles (Children 1-3 yrs) (From the Case Study on 24 OPs Presented to the SAP in December 2000)

ND = 0	95th Percentile		99th Percentile		99.9th Percentile	
	Exposure (mg/kg body wt/day)	MOE	Exposure (mg/kg body wt/day)	MOE	Exposure (mg/kg body wt/day)	MOE
Yes	0.000130	153	0.000342	58	0.001057	19
No	0.000143	139	0.000355	56	0.001069	19

1. MOEs based on NOAEL of Chemical T (0.02 mg/kg body wt/day].

Figure I.G-1. Distribution of Margins of Exposure for 1 to 3-Year Old Children with Non-Detectable Residues Include as 0 and ½ LOD (From the Case Study on 24 OPs Presented to the SAP in December 2000)

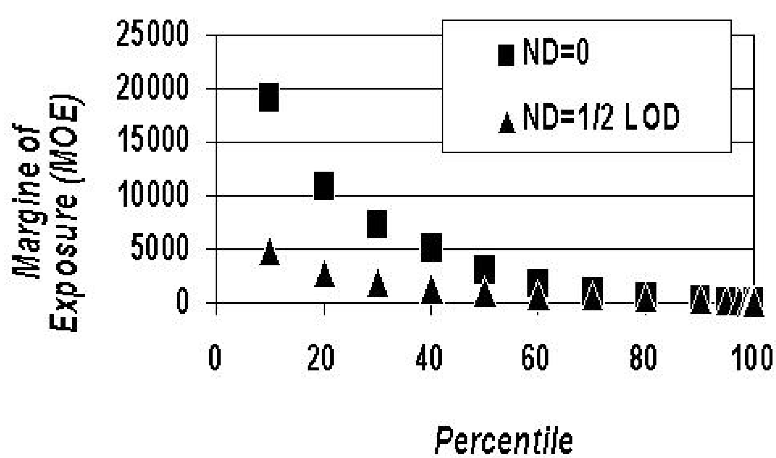

Figure I.G-2. Distributions of Margins of Exposure for Adults 18+ years with Non-Detectable Residues Included as 0 and ½ LOD (from the Case Study on 24 OPs presented to the SAP in December 2000)

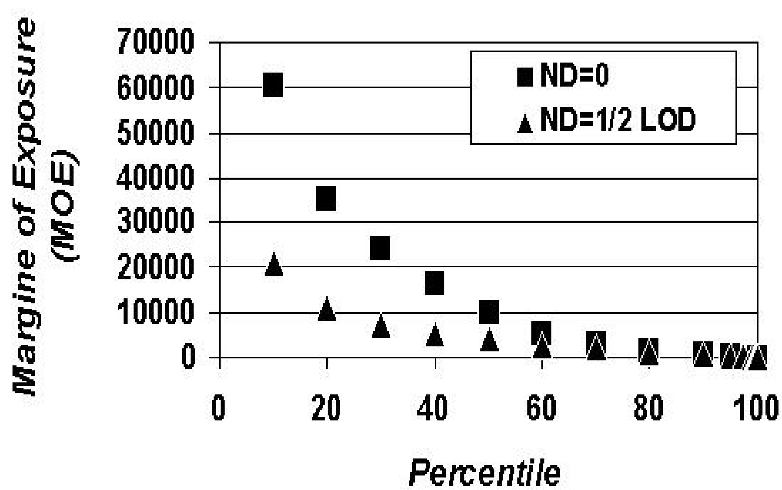

Figure 1.G-3a Margin of Exposure vs. Percentile of Exposure

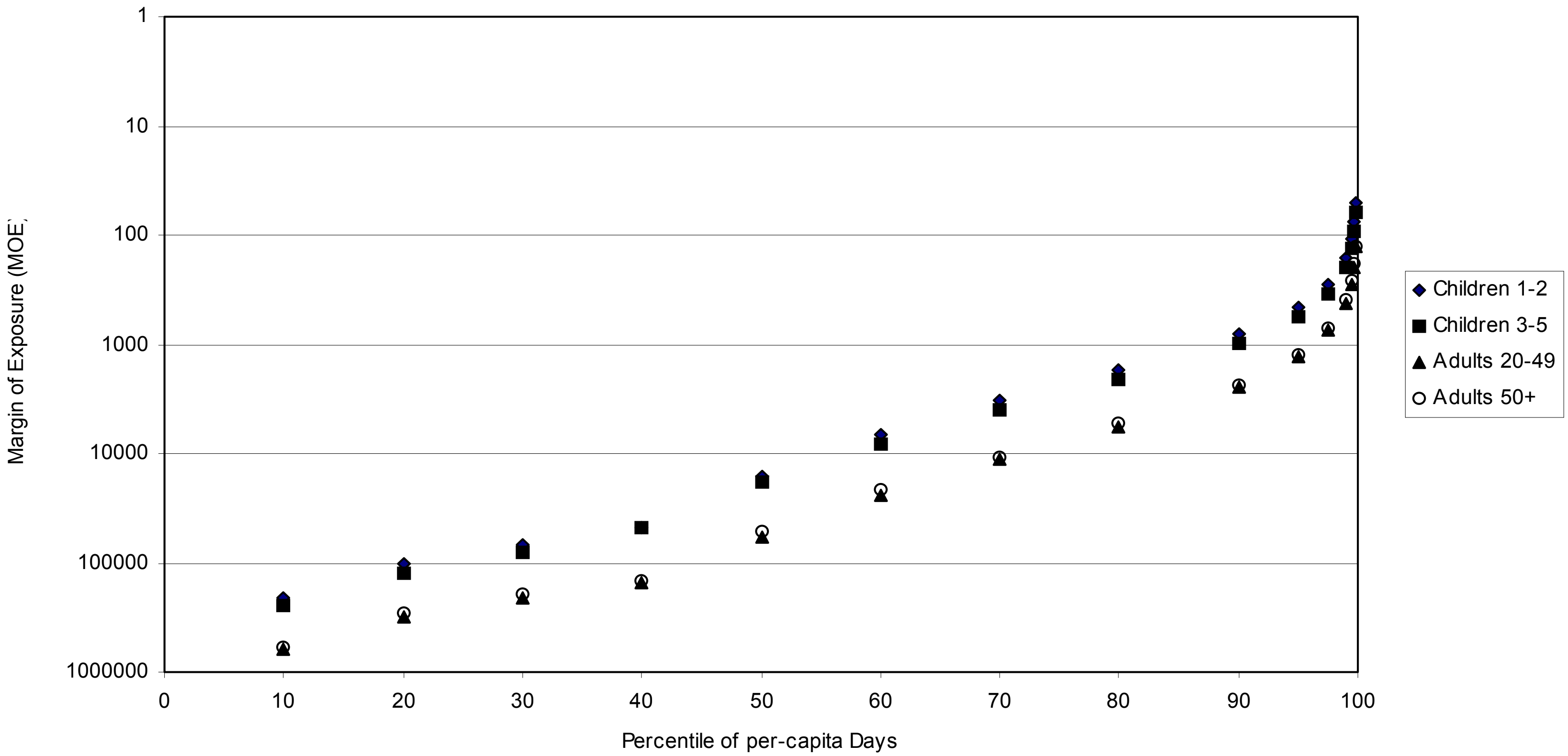

Figure 1.G-3b Margin of Exposure vs. Percentile of Exposure -upper portion of distribution