CUMULATIVE RISK:

A CASE STUDY OF THE ESTIMATION OF RISK FROM 24 ORGANOPHOSPHATE PESTICIDES

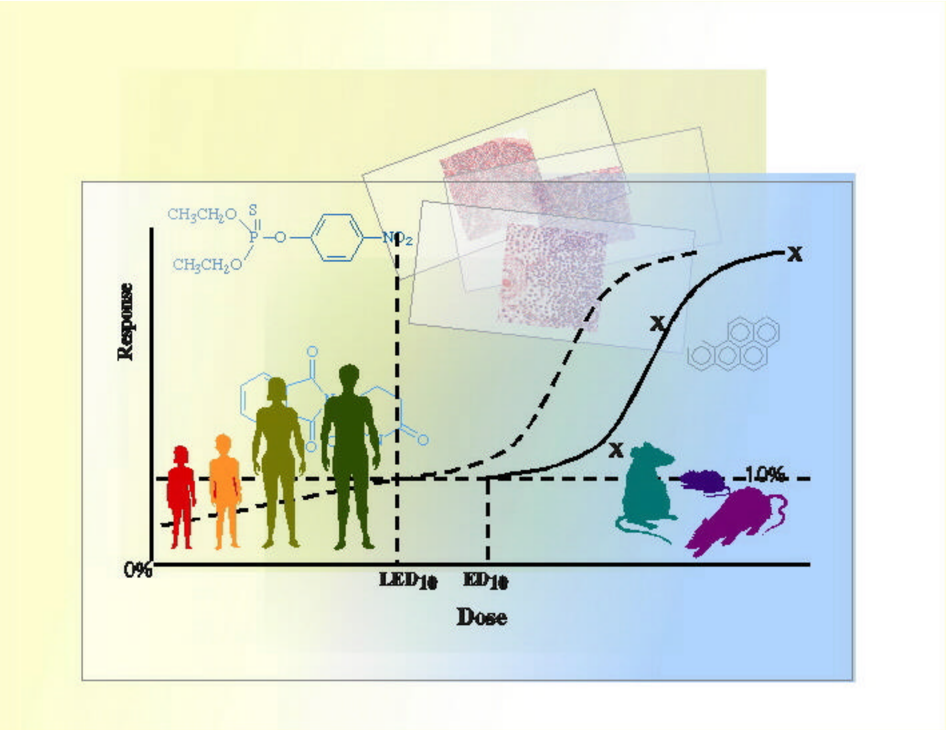

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Table of Contents

I. Introduction 1

II. Background 2

III. Methods for Developing a Time Weighted Cumulative Risk Assessment . 5

IV. Cumulative Risk From Pesticides in Foods 8
- **A. Method of Estimation of Cumulative Dietary Risk** 8
- **B. Selection of Oral Relative Potency Factors and Points of Departure** 8
- **C. Dietary (Food) Residue Input Data for Dietary Risk Assessment** . . . 9
- **D. Manipulation of Residue Data for Exposure Assessment** 10
  - **1. Generation of Cumulative Equivalent Residue (Residue$_{IE}$)** . . 10
- **E. Food Consumption Data** 16
- **F. Estimation of Acute Exposure Using DEEM™ Software** 16
- **G. Results** 16
- **H. Summary** 17

V. Cumulative Risk from Pesticides Used in a Residential Setting 42
- **A. Calendex Aggregate/Cumulative Software** 42
- **B. Development of Residential Aspects of Case Study Example** 43
- **C. Application Scenarios** 44
  - **1. Applicator Exposure to Consumer Applied Pesticide Treatments** 44
  - **2. Post Application Exposure to Consumer Applied Pesticide Treatments or Treatments Made by Professional Lawn Care Operators (LCOs)** 46
- **D. Other Data and Assumptions** 49
- **E. Detailed Data File Descriptions** 52
- **F. Results** 57
  - **1. Oral ED10 = 0.175 mg/kg/day** 57
  - **2. Uncertainties in Residential Assessment** 63
- **G. References** 66

VI. Cumulative Risk from Pesticides in Drinking Water 71
- **A. USGS Regression Approach** 71
- **B. Development of WAtershed Regression for Pesticides (WARP) Approach Applied to Cumulative Case Study for Chemicals T and P** 73
- **C. Combining Chemical T and Chemical P Concentration for Use in a Cumulative Assessment** 78

D. HED Incorporation of USGS predicted 95th Percentile Concentrations for Chemical T and P into a Cumulative Exposure Estimate 79
E. Generation of Water Concentration Values for Use in Exposure Assessment through DEEM 80
F. DEEM Model Output 81
G. Sources of Uncertainty in Estimating Pesticide Concentrations in Water 81

VII. The Mulit-Pathway Cumulative Assessment 97
A. Attributes of the Case Study 97
B. Results 98
1. Children, 1-3 years 99
2. Adults, 18+ years 104

VIII. Conclusions 108

List of Appendix Figures

Appendix A

Appendix B

Appendix C

Appendix D

I. Introduction

The passage of the Food Quality Protection Act (FQPA) in August 1996 imposed upon the Office of Pesticide Programs (OPP) the requirement to develop methodology to evaluate the risk from exposure to more than one pesticide acting through a common mechanism of toxicity. The exposures of concern were to include all relevant routes and sources based upon the use patterns of the pesticides in question. This multi-chemical, multi-pathway risk is referred to as cumulative risk.

In September 1999 and December 1999, OPP presented guidance documents and early case studies to the Scientific Advisory Panel (SAP) for discussion of the hazard and exposure aspects of cumulative risk, respectively. At those meetings, the SAP requested that OPP develop more complex case studies to better demonstrate the concepts in the guidance, and present those to the Panel when they were completed. To this end, a hazard evaluation of 24 organophosphate pesticides (OPs) was presented to the SAP in September 2000. This paper continues the development of the cumulative risk assessment, building the exposure assessment on the hazard presentation in September. Its focus is on the appropriate use of available data and the limitations imposed upon the assessment process by the available data. This analysis explores the impact of different points of departure (NOAEL vs ED10) on the interpretation of the risk results. In addition, the implications of the handling of non-detectable residues is discussed. Finally, no consideration was given to the application of a child-specific or other safety factors.

Ultimately, OPP must develop an assessment consider all of the OPs. This case study presents a possible method for combining a number of data sets including the incorporation of data use policies and science-based assumptions to permit evaluation of potential risk to 24 OPs that act by a common mechanism of toxicity. It is presented to help elicit and focus discussion and, as such, is not intended necessarily to reflect any final regulatory judgements or future regulatory decisions. Future regulatory actions may not reflect this exact combination of data use conventions.

II. Background

This case study continues the evaluation of the cumulative risk from 24 OPs. These OPs were selected based upon the occurrence of levels of each pesticide above the limit of detection in the USDA's Pesticide Data Program (PDP). Pesticides for which no detectable residues were identified were not included in the assessment. This approach and a number of other decisions regarding the use of data in this case study were designed to reduce the amount of uncertainty in the assessment and rely to the extent possible on data collected in a manner reflective of likely exposure to the population. OPP believes that this approach is reasonable given the goals and purpose of the cumulative risk assessment. The cumulative assessment is intended to serve as a pointer toward major sources of risk likely to accrue due to the use of a variety of pesticides with a common mechanism of toxicity, with regulatory decision making based upon the many detailed aspects of the single-chemical, aggregate risk assessment. Because of the coalescing of many data sets into a single assessment, reducing the likelihood of compounding conservative assumptions and over-estimation bias becomes very important in constructing the cumulative risk assessment. As a result, OPP has chosen to work with those data which most closely reflect likely exposures and not to incorporate those data which are inherently conservative by their nature.

Bearing in mind the comments above, the following overarching decisions were made regarding the scope of the assessment:

- Only those foods monitored by PDP and those foods for which PDP data could reasonably serve as surrogate were included. No attempt was made to adapt field trial data for use in the assessment because the field trial samples reflect highest label rates, shortest allowable pre-harvest interval and are taken at the farm gate. PDP implicitly reflects actual application rates, time in the chain of commerce, proportion of the crop imported and proportion of the crop treated. In addition, PDP was specifically designed to monitor foods disproportionately consumed by children.

- The cumulative assessment consists of the food contribution of each of the 24 OPs as they occur in PDP. The residential component of the assessment reflects crack and crevice, lawn, and rose uses for seven of the 24 OPs. These uses are common to the geographic area of consideration. The contribution to exposure from water was limited to those OPs for which a sufficient body of monitoring data from the United States Geological Survey (USGS) National Water Quality Assessment program were available to permit chemical specific modeling of the relationship of OPs to use in the area.

- The geographic scale was limited to reflect a coherent area likely to have common pesticide use patterns based upon pest pressure and climate. This limitation is important in that OPP is assuming that potential water residues within this area reflect a constant pattern of use both in the urban and agricultural setting. Similarly, OPP is assuming that this geographic area is sufficiently restricted such that residential uses of pesticides will reflect common pest pressure with similar climatic conditions such that the outcome of the assessment should be relevant across the entire area.

- With respect to drinking water, the extent to which the pesticides of interest co-occurred in drinking water sources is not known. The analyses conducted here used the sum (accounting for the Relative Potency Factor) of the estimated concentrations for each pesticide to produce an estimated total concentrations. If the pesticides tend to be used at different times or be used in different places, this is likely to be a conservative estimate.

- Since longitudinal estimates (i.e., a time series of daily water concentrations at a given site) of pesticide concentrations in water are not available, it was assumed that all individuals are exposed to a population weighted 95th percentile concentration in drinking water. That is, it was assumed that the upper end concentration in drinking water predicted by the regression model for each drinking water system was repeated every day throughout the year. This, too, is a conservative assumption and is likely to significantly overstate exposures through drinking water.

- The assessment reflects a 365-day series of single-day distributions of exposures, using a calendar-based approach to look for patterns of exposure that are seasonal in nature. Each aspect of the assessment -- food, water and residential -- was conducted separately as well as in an integrated cumulative assessment.

- Two age-groups were evaluated to consider the impact of behavior on exposure. They were Children 1-3 years of age, reflecting a high rate of contact with the floor and ground, and Adults, 18+ years, reflecting homeowners who may apply pesticides in a residential setting as well as other occupants.

- The relative potency factor (RPF) approach outlined in the September 27, 2000 SAP document entitled *Endpoint Selection and Determination of Relative Potency in Cumulative Hazard and Dose-Response Assessment: A Pilot Study of Organophosphorus Pesticide Chemicals* was used in this assessment. The RPFs from that document are reflected in this case study. They were based upon comparison of inhibition of plasma cholinesterase in male rats following a multi-day exposure. Careful attention was paid to ensure that inhibition had stabilized in the studies used for developing the RPFs.

- The index compound used in the September 2000 hazard assessment was retained for this case study. The points of departure (PoDs) used in this study were taken from the index chemical and are route specific. For the purposes of this case study, oral exposures were compared to two PoDs: an ED_{10} of 0.175 mg/kg/day and a NOAEL of 0.02 mg/kg/day. The dermal and inhalation exposures were compared to NOAELs of 1 mg/kg/day and 0.026 mg/kg/day for dermal and inhalation exposures, respectively. Data for the latter two routes were not considered sufficient to be used for estimating an effective dose. All of the endpoints reflect plasma cholinesterase inhibition in male rats. They are taken from the body of data used to generate the RPFs.

- The assessment was compiled using the Calendex software. This software package and its component, DEEM, have been the subject of previous SAP discussions.

III. Methods for Developing a Time Weighted Cumulative Risk Assessment

OPP has defined the parameters that should be considered in estimating the cumulative exposure to a group of pesticides. As defined in FQPA, only those pesticides that induce adverse effects by a common mechanism of toxicity must be considered together. Guidance on determining whether two or more chemicals have a common mechanism of toxicity was published by EPA in 1999. The reader is referred to the *Guidance for Identifying Pesticide Chemicals and Other Substances that Have a Common Mechanism of Toxicity* (1/29/99). Further discussion on considerations for the hazard portion of the assessment were set forth in the *Proposed Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity* 6/22/00 Science Policy Paper Public Comment Draft released for public comment in June 2000. The application of the principles set out in the *Proposed Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity* (6/22/00) is demonstrated in a hazard assessment case study presented to the Scientific Advisory Panel on September 27, 2000 entitled *Endpoint Selection and Determination of Relative Potency in Cumulative Hazard and Dose-Response Assessment: A Pilot Study of Organophosphorus Pesticide Chemicals*. Relative Potency Factors used in this case study are those developed for the September 27 presentation.

The *Proposed Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity* (6/22/00) and its precursor paper *Guidance for Performing Aggregate Exposure and Risk Assessments* (10/29/99) also describe those aspects of the exposure assessment that must be accounted for in developing an integrated cumulative risk assessment. The assessment must account for temporal aspects of exposure such as those related to the time of year during which applications resulting in exposures are likely to occur, the frequency of application and period of re-application. To perform this case study, OPP has used the Calendex model. Calendex is a proprietary software package licensed from Novigen Sciences, Inc. The Calendex model and its component DEEM have been the subject of review at two previous SAP meetings. The reader is directed to the materials provided from those SAP meetings for a detailed description of the Calendex and DEEM models.

As used in this example, it employs the approach of estimating sequential daily exposures, with a series of user defined variables available to define the temporal component of the exposure assessment. For each day's exposure estimate, a distribution of exposures is generated, permitting determination of the distribution of exposures across time on a percentile basis. This approach is demonstrated in the case study below. Demographics for each individual whose exposure is modeled by Calendex are taken from the Continuing Survey of Food Intakes by Individuals (1994-1996)(CSFII). Based upon knowledge of the use pattern for pesticides in specific use scenarios, the risk assessor can define the period of the year during which a pesticide will be used for a given pest pressure. In addition, the risk assessor can indicate that during the months or weeks of the use period, the pesticide will be assumed to be reapplied weekly. A period of decline can be incorporated for dissipation of the exposure following application. Several scenarios can be included in the same assessment. The residential assessment below demonstrates this approach. Similar limitations can be placed on the introduction of water data into the assessment if adequate data are available to estimate seasonal variation.

Other important factors in developing an integrated cumulative assessment are an understanding of the application rates and methods as they impact the residues likely to result. The types of residue data most useful in estimating exposure are those that result from direct measurement of the medium of concern, that is, food, water or surfaces and air in the residence. This is particularly true if the measurements are made in such a manner that they reflect real world concentrations, the changing patterns of residue levels as they relate to differences in location and time, and the likelihood of the co-occurrence of multiple pesticides. OPP depends upon the PDP monitoring data for measurements of residues of pesticides on foods close to the point of consumption, and for direct indication of co-occurrence in sampled foods. OPP also anticipates the receipt of market basket data for OP residues. However, for most classes of pesticides, the available data will not be as extensive as currently exists for OPs. In particular, measurement of co-occurrence may not be available. OPP is considering implementation of estimation methods assuming that residues from different pesticides are independent and weighting their occurrence based upon frequency of use for a given crop.

Barring access to detailed monitoring data, OPP depends upon the use of data driven modeling approaches to estimate the magnitude of residues resulting from a variety of use patterns. Models currently are used for both drinking water and residential assessments. The success of modeling approaches is largely driven by availability of data to support development of highly refined predictive models. In the case study presented, sufficient monitoring data was available to permit USGS to develop chemical specific regression models relating pesticide concentrations in surface water to the use of pesticides in the region. In the discussion of the water portion of the case study below, a less definitive alternative currently under consideration by OPP is also presented. This approach may be used for chemicals with lesser amounts of available monitoring data. For residential exposures, OPP depends largely upon modeled estimates of exposure based upon widely accepted relationships between pesticide residues, use rates and human behavior patterns. The Calendex model permits the introduction data inputs as distributions as an alternative to point estimates used in the past.

The case study is presented with a focus on each of the major pathways including a discussion of assumptions, data inputs and inter-relationships of data. Each pathway has unique issues relating to availability of data, scale and interpretation of results. Results of each aspect of the assessment are discussed with particular attention to how they reflect potential exposures to the population and what might be inferred with regard to the greatest sources of risk resulting from the exposures. The final section of the document examines the results of combining estimates of risk from all sources of exposure and discusses further the interpretation of the outputs with regard to potential to identify the most significant sources of risk.

IV. Cumulative Risk From Pesticides in Foods

The exposure assumptions for these assessments, which are described in the following discussion, differ in many ways from those commonly used by the Agency in estimating dietary risk for single chemicals. The input assumptions used in this example preserve few of the conservative assumptions commonly encountered in dietary assessments. These assessments are intended as a conceptual basis for deliberations and are not to be interpreted as representing the Agency's recommended procedure for conducting cumulative assessments or as demonstrating a dietary risk assessment intended for regulatory purposes.

A. Method of Estimation of Cumulative Dietary Risk

Dietary exposure was estimated using the Dietary Exposure Evaluation Model (DEEM™) software. A joint distributional analysis was conducted by combining representative data on concentrations of 24 organophosphorus pesticides on foods with distributions of anticipated consumption of these foods by different segments of the U.S. population. The primary advantage of a joint distribution analysis is that the results are in the form of a simultaneous analysis (i.e., a distribution) of exposures that demonstrate both best-case and worst-case scenarios of exposure. The typical level of regulation for single chemical dietary exposures has been at the 99.9th percentile of exposure.

B. Selection of Oral Relative Potency Factors and Points of Departure

Twenty-four chemicals were included in this organophosphorus cumulative assessment group. These chemicals were selected based on their occurrence in the PDP monitoring data collected between the years 1994 and 1999. A process for hazard assessment of the organophosphorus cumulative assessment group was described at the September 2000 meeting of the FIFRA Scientific Advisory Panel in a session entitled *End Point Selection and Determination of Relative Potency in Cumulative Hazard Assessment: A Pilot Study of Organophosphorus Pesticide Chemicals*. Table 4-1 lists the estimated relative potency factors for these 24 organophosphorus pesticides, A through Y (please note that although we refer to the group as Chemicals A through Y, there is no chemical K in the group) . These factors were chosen by comparison of dose response curves for plasma cholinesterase inhibition by the 24 chemicals in male rats. The dose response curves were transformed to approximate linear forms and compared at their ED_{50}. Chemical T was selected as an Index Chemical (RPF=1) and the RPFs for the other 23 chemicals were estimated as;

$$RPF_{[\text{chemical } n]} = ED50_{[\text{chemical } T]}/ED50_{[\text{chemical } n]}$$

Where chemical n is a member of the cumulative assessment group.

Two points of departure were selected for use in this case study: the ED10 = 0.175 mg/kg body wt/day and the NOAEL = 0.02 mg/kg body wt/day for the inhibition of plasma cholinesterase in male rats by Chemical T.

C. Dietary (Food) Residue Input Data for Dietary Risk Assessment

Anticipated concentrations of Chemicals A through Y in foods were based on residue monitoring data collected by the PDP. These data are available for downloading from the PDP internet site (http://www.ams.usda.gov/science/pdp/). For this case study we used data collected from 1994 through 1999. The selection of commodities and chemicals analyzed by PDP varies from one year to the next but most of the organophosphorus pesticides of concern were analyzed throughout this period and the foods selected for analysis generally reflect high consumption items for children.

The analyses of the 24 OPs on 44 food commodities between 1994 and 1999 are summarized in Table 4-2. The data are summarized by parent OP although in some cases multiple metabolites were included in the database. The 44 food forms in the PDP data were used as the source of residue data for their matching food forms in the DEEM software (CSFII consumption data). Food processing factors were applied to specific chemical/commodity pairs to extend these data to a total of 319 DEEM food forms. Table 4-3 shows all of the food forms for commodities monitored by PDP included in the food exposure assessment along with chemical specific processing factors to convert these residue values to food forms not included in PDP. The factors are intended to adjust residues in foods for changes that can occur in food preparation procedures such as cooking, canning, curing, and drying. The processing factors in Table 4-3 were taken from the most recent single-chemical dietary risk assessments, which are available on the Agency internet site (http://www.epa.gov/pesticides/op/status.htm). The absence of a processing factor in Table 4-3 indicates that no residues were detected in that chemical/food form combination.

Processing factors are based on the submitted processing studies, published data, or logical calculations in the absence of submitted studies (e.g., estimates based on loss of water in drying fruits). Consequently, in some instances there were rather large ranges for factors of certain food forms of some commodities among the 24 OPs.

An additional 73 food forms were implicit in the exposure assessment as making a negligible contribution because there were no detects in PDP monitoring data. This included food forms of banana, sweet corn, corn syrup, and milk.

For single chemical assessments, OPP commonly extends the use of pesticide residue data from one commodity to represent another commodity if pesticide uses and cultural practices are sufficiently similar. This practice, referred to as data surrogation, is outlined in HED SOP 99.3. Table 4-5 summarizes the surrogation scheme. Based on the scheme in Table 4-5 the available PDP data were extended to an additional 172 food forms.

D. Manipulation of Residue Data for Exposure Assessment

Commonly, the following two equations are used for estimating exposure and risk from a single chemical:

1) Exposure = Residue X Consumption

2) Risk = Hazard X Exposure

In the case of cumulative exposure assessment, the residue term in the first equation is changed to Index Equivalent Residue, and the hazard end point in the second equation is based on the index chemical.

The calculated cumulative residue is a simple arithmetic addition of residues of different chemicals that have different toxicities (potency) and therefore simple addition of their residues is not appropriate. For that reason, the amount of residue of each chemical is adjusted by multiplying by a ***Relative Potency Factor (RPF)*** to get the equivalent residue of an index chemical. This new calculated residue is termed ***Index Equivalent Residue (Residue$_{IE}$***) and the exposure value resulting from combining Residue$_{IE}$ and consumption is termed ***Index Equivalent Exposure (Exposure$_{IE}$***). The new central equation for exposure will then become:

$$\text{Exposure}_{IE} = \text{Residue}_{IE} \text{ X Consumption}$$

and in the risk equation (second equation) the toxic end point of the index chemical is going to be used. The following discussion explains in more detail how this was accomplished for this case study.

1. Generation of Cumulative Equivalent Residue (Residue$_{IE}$)

To determine a given one-day cumulative oral exposure to the 24 OPs, first an Index Equivalent Residue for each residue value is calculated. Each residue value (ideally, there are at least 24 or more values coming from each PDP sample), is multiplied by the processing factor (PF) for that chemical and the Relative Potency Factor for the same chemical (RPF) to express it as an Index Equivalent residue for that chemical; this is step 1.

Step 1: **Residue$_{IE}$ (per chemical n) = Residue X PF$_n$ X RPF$_n$**

The cumulative Residue$_{IE}$ for all 24 chemicals on one PDP sample will then be the sum of all the Residue$_{IE}$ for all the chemicals on that sample; this is step 2.

Step 2: **Cumulative Residue$_{IE}$ = S Residue$_{IE}$** (per PDP sample)

For example, given 100 samples of apples and 24 OPs, there will be generated 24 Residue$_{IE}$ values for each sample; hence a total of 100 * 24 = 2400 Residue$_{IE}$ values from step 1. In step 2, each set of 24 Residue$_{IE}$ for a sample is summed to generate a cumulative Residue$_{IE}$ per one sample; hence 100 cumulative Residue$_{IE}$ points for 100 samples of apples are generated.

By summing on a sample-by-sample basis, the potential for capturing any co-occurrence on the same commodity is enhanced. See Table 4-4 for a summary of the actual reporting of co-occurrence of OPs in the data used in this assessment

a. Relational Database

The data manipulations necessary to prepare the PDP residue data for input into the risk equation are in principle very simple; however, the task of performing these calculations for 24 chemicals and 44 commodities is problematic. The residue data used in this case study consist of over one million records of analytical data and sample information. The processing factors account for several thousand additional records of information. For this reason, and in anticipation of the need to make multiple uses of the data and keep track of them, all the data manipulation were conducted using relational database techniques. This database consists of four major data tables:

1 Residue data table; over one million records containing essentially all of PDP sample and analyses data for organophosphorus pesticides.

2 Processing factor data table; containing all relevant processing factors for specific food form/chemical combinations. (Table 4-3 in this document is extracted from these data).

3 RPF Table; containing the relative potency factors for all chemicals of interest.

4 Code-Bridging Table; providing bridging links between PDP commodity codes, such as *AP* for apple products, and all corresponding DEEM food forms, such as *Apples-uncooked*.

These four tables are linked through common fields, such as pesticide codes, or commodity codes. With modern relational database design, it is relatively simple to design queries so that all the pertinent PDP samples records can be extracted, each calculation outlined above can be performed, and the results can be sorted and output in various formats for further analysis. For this assessment the final output consisted of 243 separate text files formatted for input into DEEM. Each text file contained a header with sample information (number of values, number of detects, number of zeros, average of residues) and all of the cumulative residue values for a single food form, sorted in descending order. An additional 76 residue distrbutions were estimated as single average values for those foods that are highly blended before consumption.

By maintaining the factors and bridging codes in separate tables in the database, it is relatively easy to repeat the above process with new inputs by simply replacing or adding data to the appropriate table. Specific chemicals, commodities, or combinations can also be excluded conveniently with this database.

b. Generation of Exposures

The cumulative Residue_{IE} values (text files described in the previous section) are treated as distributions of representative residues and linked to all appropriate food forms; cumulative residue values are then randomly picked and combined with a consumption record to generate a single exposure value which is termed Exposure_{IE}. This process (semi-Monte Carlo in nature and conducted by DEEM software) is repeated many times per each consumption record for each individual to generate a distribution of exposure values. This process has been described in previous meeting of the panel (*Dietary Exposure Evaluation Model (DEEM^{TM}) and DEEM^{TM} Decompositing Procedure and Software*). For the food forms, which are highly blended before consumption, the residue input consisted of the average of all the cumulative residues, i.e., a single average residue value was entered into the DEEM calculation. The risk for a population group of choice is estimated by choosing an exposure value from the generated exposure distribution for that population and dividing the value by the toxicological end point of the index chemical.

c. Assumptions

The input residue data were solely drawn from PDP data base. The PDP program tests different commodities for various pesticides in 10 states throughout U.S. The residue data of 1994 to 1999 were used in this assessment. Following assumptions were made in the process:

1) Although PDP has been conducting single-unit sampling for limited crops (apples and pears) since 1998, only the residue data from composite samples were utilized in this assessment for the sake of simplicity. A single composite sample may contain several individual servings of some foods; it is implicitly assumed that all these single servings in a composite sample have residues no more or less than the composite residue (average value). For purposes of the present example, it is assumed that residues reported on composite homogenates adequately reflect the residues in any given single serving contained in that homogenate. Therefore, no attempt was made to "decomposite" residue values to simulate residues that might be present in the single servings contained in the PDP composite sample.

2) Although PDP uses multi-residue methods to simultaneously analyze various pesticides on a crop sample, occasionally, for various reasons, there are no entries for some pesticides on some samples. In such instances, it was assumed that those pesticides with no entries had zero residues.

3) All residue analyses are subject to the limitations of the sensitivity of the analytical methods. Many of the samples analyzed are reported as being below the limit of reliable detection of the analytical method. It is usual practice in Agency assessments to assume that residues in non-detectable samples are present at ½ the limit of detection (LOD) of the analytical method in samples that were potentially harvested from treated fields. Thus, for purposes of estimating residues in samples reported as <LOD, a proportion of the samples equal to the estimated percent crop treated is assigned a residue level of ½ LOD and the remaining samples, which are assumed to come from untreated crops, are assigned a residue value of zero. This procedure becomes problematic for a cumulative assessment. It is not enough to simply estimate the percent crop treated for each of the pesticides in the cumulative assessment; it is also important to consider the potential for

co-occurrence of residues of multiple residues on the same crop. A strength of the present example is that it accounts for co-occurrences in single samples if they are detectable. In order to assess the impact of incorporating ½ the LOD for non-detects in the current assessment, the food portion of the assessment was conducted using the two extreme default assumptions: all non-detects = 0, and all non-detects = ½ LOD for the chemical with the greatest number of detectable residue findings. The most prevalent detected chemical was chosen because it is reasonable to assume that chemical would also have the greatest number of residues below the limit of detection. The database utility being used in this analysis allows one to quickly select individual residue values that DEEM shows to be contributing to high exposure and examine them for chemical specific contributions to the exposure.

4) The sample-by-sample method of summing of residues relied on the PDP sampling procedures to adequately capture the temporal and geographic variations in uses of pesticides. This procedure assumed that the PDP sampling protocols were designed in such a way as to reflect the foods available to the public for consumption in different regions of the country and throughout the year.

5) This assessment is using residue data collected over a six year period, 1994 through 1999. The primary reason for this is to maximize the number of food commodities in the assessment but this raises issues of lack of co-occurrence. Co-occurrence in the food is important from the standpoint of all the food consumed in the same time period. It is not readily obvious if it is appropriate to model exposure based on bananas grown in 1994 and apples grown in 1998. A related choice in selection of residue data was to include all available data for a given commodity from this time period. This includes data sets that span a time period of at least one year to 4 years data. Future assessments could readily restrict these data to the most recent one or two years.

6) In chemical specific dietary exposure assessments the Agency routinely translates residue data from one food commodity to related ones if the pesticide use patterns are similar on these commodities (HED SOP 99.3, Margaret Stasikowski, 3/26/99). For example, data on cantaloupes is often used as surrogate data for watermelons and other melons. For a cumulative assessment, in which a grower

has a choice of several chemicals from the cumulative assessment group, these translations of data become more difficult to make. In the current case study, translations of the residue data were made using the surrogation scheme in HED SOP 99.3 in order to ensure representation of the maximum number of commodities possible. The cross walk between crops is presented in Table 4-5.

E. Food Consumption Data

Food consumption data were taken from the CSFII conducted by USDA between 1994 to 1996. These data were based on 2-day surveys collected from households throughout the contiguous 48 states, and represents information provided by 15,303 individuals of all ages. The food consumption data are translated into ingredients within the DEEM™ software using a proprietary ingredient translation database. In this example assessments were based on the consumption patterns representative of children one to three years old, and all adults above eighteen years old.

F. Estimation of Acute Expsoure Using DEEM™ Software

Residue distribution files, or average residue values for highly blended commodities, were input in the DEEM™ software for a Monte Carlo analysis.

The Monte Carlo analysis was conducted by an iterative process of multiplication of residue concentrations on foods, expressed in Chemical T equivalents, by one-day consumption of these foods, as reported by all individuals in CSFII. This process used all individuals reporting in the consumption survey for both days of the survey and the exposures were calculated as mg/kg body wt./day.

The use of DEEM for dietary exposure analysis was briefly described in the presentation of our previous dietary case study to the panel in December of 1999. The functioning of the program has also been described in a previous SAP presentation (*Dietary Exposure Evaluation Model (DEEM™) and DEEM™ Decompositing Procedure and Software*). Two PoDs of 0.175 mg/kg/day and 0.02 mg/kg/day were used and 1000 iterations of the algorithm were run.

G. Results

Tables 4-6 and 4-7 summarize the results of a dietary exposure assessment for 24 Chemicals on food commodities. Results are presented for two age groups: Adults, 18+ years, and children, 1 to 3 years. The summary results are provided for three points in the distribution of exposures estimated, i.e., at the 95th percentile, 99th percentile, and 99.9th percentile of exposure. These exposure values are expressed in terms of Chemical T equivalents and any evaluation of the risk from these levels of exposure should be compared to the PoD for Chemical T. Insertion of the ½ LOD values in place of zeroes resulted in little change in exposures at the higher percentiles. However, exposures were increased at the lower percentiles of exposure. This observation suggests that the impact of the assumption of ½ LOD as used in single chemical assessments will not be necessary for cumulative assessments because the upper portion of the exposure distribution at which regulatory decisions are made are largely unaffected by their inclusion. Further investigation of exposure reduction scenarios are being conducted.

H. Summary

The cumulative dietary risk due to the use of 24 Organophosphorus Chemicals on food crops was assessed using residue monitoring data collected by PDP. The ED10 and NOAEL for plasma cholinesterase inhibition in rats were chosen as the Toxicological Points of Departure (PoD) for this assessment. Chemical T served as the index chemical. The residue values for the other 23 chemicals were converted to Chemical T equivalents by a Relative Potency Factor ($RPF=ED50_{[\text{index chemical}]}/ED50_{[\text{chemical } n]}$) approach. Residue data were collected on approximately 44 food commodities monitored by PDP between the years of 1994 and 1999. Food processing factors were applied to specific chemical/commodity pairs to extend these data for use on a total of 319 food/food forms in the analysis. An additional 73 food forms were implicit in the exposure assessment as making a negligible contribution because there were no detects in PDP monitoring data. The PDP residue data were further extended to other commodities identified as reasonable for surrogation of pesticide residue data per HED SOP 99.3. A total of 564 food forms were thus included in this case study.

The residue data were compiled as distributions of cumulative residues of Chemical T equivalents that were, after adjustment for processing, summed on a sample-by-sample basis. These residue distributions were combined with a distribution of daily food consumption values *via* a probabilistic procedure to produce a distribution of potential exposures for two subpopulations in the CSFII (children, 1 to 3 years of age, and adults, 18+ years). The results of this assessment are shown in Table 4-6 with all non-detects included as zero values. A similar analysis was conducted with all non-detects replaced with ½ LOD values (Table 4-7). The results of these analyses suggest that the treatment of non-detects as zeroes is an appropriate simplification of the cumulative assessment process.

Table 4-1. Relative Potency Factors for Exposure Assessment

Chemical Pseudonym	Oral	Inhalation	Dermal
Chemical A	0.47	----	----
Chemical B	0.02	0.52	10

Chemical C	0.01	0.09	0.0033
Chemical D	1.86	----	----
Chemical E	0.50	—	----
Chemical F	0.37	----	----
Chemical G	0.02	----	----
Chemical H	0.009	----	----
Chemical I	0.85	0.65	2.5
Chemical J	0.30	----	----
Chemical L	0.19	----	----
Chemical M	0.10	----	----
Chemical N	0.11	----	----
Chemical O	0.006	----	----
Chemical P	0.10	0.26	0.2
Chemical Q	0.01	----	----
Chemical R	0.08	----	----
Chemical S	0.70	----	----
Chemical T (Index Chemical)	**1**	**1**	**1**
Chemical U	0.0005	0.0002	0.2
Chemical V	0.02	0.08	0.067
Chemical W	0.61	----	----
Chemical X	0.19	----	----
Chemical Y	0.17	----	----

Table 4-2. A summary of PDP Monitoring Data on Organophosphorus Pesticides, 1994-1999

	Chemical A			Chemical B			Chemical C			Chemical D		
Commodity	**Analy**	**Dete**	**%**	**Analy**	**Dete**	**%**	**Analy**	**Dete**	**%**	**Analy**	**Dete**	**%**
Apple Juice	1554	40	2.6	1553		0.0	1554	14	0.9	1554		0.0
Apples	2289		0.0	2289		0.0	2288	1	0.0	2091		0.0
Bananas	1126		0.0	1126		0.0	1124		0.0	915		0.0
Broccoli	630	3	0.5	630		0.0	610		0.0	456		0.0
Cantaloupe	1234	65	5.3	1234		0.0	1234	23	1.9	1234		0.0
Carrots	1888	1	0.1	1888		0.0	1888	5	0.3	1646	1	0.1
Celery	176	45	25.6	176		0.0	176	73	41.5	53		0.0
Corn Syrup	47		0.0	408		0.0	49		0.0	454		0.0
Cucumbers	730	95	13.0	730	1	0.1	730	2	0.3	730		0.0
Grape Juice	1377		0.0	1377		0.0	1378		0.0	1379		0.0
Grapes	1884	2	0.1	1884	1	0.1	1884	2	0.1	1684		0.0
Green Beans	1178	239	20.3	1178	1	0.1	1178	252	21.4	1021		0.0
Green Beans,	835	357	42.8	854		0.0	840	356	42.4	854		0.0
Green Beans,	715	283	39.6	743		0.0	706	293	41.5	743		0.0
Lettuce	876	55	6.3	876		0.0	876	117	13.4	690		0.0
Milk	692		0.0	1892	1	0.1	1892		0.0	692		0.0
Oats, Bran				45		0.0						
Oats, Rolled				287		0.0						
Orange Juice	1377		0.0	1392		0.0	1377		0.0	1392		0.0
Oranges	1892		0.0	1892		0.0	1892		0.0	1599		0.0
Peaches	1087	1	0.1	1087		0.0	1087		0.0	973		0.0
Peaches,	756	7	0.9	756		0.0	754	3	0.4	756		0.0
Pears	1779	2	0.1	1779	1	0.1	1779	1	0.1	1779		0.0
Pears, canned	371		0.0	371		0.0	371		0.0	371		0.0
Potatoes	1401	19	1.4	1401		0.0	1401	1	0.1	1203		0.0
Soybean Grain	490		0.0									
Spinach	1638	44	2.7	1638		0.0	1638	58	3.5	1638		0.0
Spinach,	863		0.0	863		0.0	863		0.0	863		0.0
Spinach,	715	1	0.1	702		0.0	715	3	0.4	715		0.0
Strawberries	1250	3	0.2	1250	24	1.9	1250	2	0.2	1250		0.0
Strawberries,	117		0.0	118	1	0.8	118		0.0	118		0.0
Sweet Bell	704	254	36.1	701		0.0	704	180	25.6	701		0.0
Sweet Corn	19		0.0	19		0.0	19		0.0	19		0.0
Sweet Corn,	652		0.0	652		0.0	652		0.0	627		0.0
Sweet Corn,	635		0.0	635		0.0	635		0.0	618		0.0
Sweet Peas	9		0.0	9		0.0	9		0.0	9		0.0
Sweet Peas,	746		0.0	746		0.0	746		0.0	720		0.0
Sweet Peas,	703	1	0.1	703		0.0	703		0.0	691		0.0
Sweet	1559	3	0.2	1559		0.0	1544	3	0.2	1559	1	0.1
Tomatoes	1965	543	27.6	1977		0.0	1962	10	0.5	1962		0.0
Tomatoes,	368	58	15.8	368		0.0	368	2	0.5	368		0.0
W Squash	1216	28	2.3	1216		0.0	1216	16	1.3	1216		0.0
W Squash,	470	1	0.2	370		0.0	470	1	0.2	470		0.0
Wheat Grain				1333		0.0						

Table 4-2 continued next page

Table 4-2 continued

	Chemical E			Chemical F			Chemical G			Chemical H		
Commodity	**Analyze**	**Dete**	**%**	**Analyz**	**Dete**	**%**	**An**	**Dete**	**%**	**An**	**Dete**	**%**
Apple Juice	623		0.0	1554		0.0	627		0.0	239		0.0
Apples	406		0.0	2289		0.0	155	5	0.3	468		0.0
Bananas				1126		0.0	530		0.0			
Broccoli				679		0.0	362		0.0			
Cantaloupe	1198		0.0	1234		0.0	409		0.0	62		0.0
Carrots	9		0.0	1888		0.0	802		0.0	72		0.0
Celery				176		0.0	78		0.0			
Corn Syrup				454		0.0	453		0.0	454		0.0
Cucumbers	730	3	0.4	730	1	0.1	551		0.0			
Grape Juice	1223		0.0	1379		0.0	457		0.0	108		0.0
Grapes	27		0.0	1884	2	0.1	945		0.0	89		0.0
Green Beans				1178		0.0	503		0.0			
Green Beans,	164		0.0	854		0.0	344		0.0	126		0.0
Green Beans,	138		0.0	743		0.0	302		0.0	117		0.0
Lettuce	185		0.0	876		0.0	397		0.0			
Milk	533		0.0	1892		0.0	692		0.0	189		0.0
Oats, Bran										45	1	2.2
Oats, Rolled										287		0.0
Orange Juice	671		0.0	1392		0.0	121		0.0	216		0.0
Oranges	18		0.0	1892		0.0	143		0.0	79		0.0
Peaches	9		0.0	1087		0.0	800		0.0	52		0.0
Peaches,	115		0.0	756		0.0	654		0.0	115		0.0
Pears	1018		0.0	1779		0.0	913		0.0	216		0.0
Pears, canned	371		0.0	371		0.0	191		0.0			
Potatoes				1401		0.0	805		0.0			
Soybean Grain				749	2	0.3						
Spinach	99		0.0	1638		0.0	130		0.0	160		0.0
Spinach,	549		0.0	863		0.0	749		0.0	135		0.0
Spinach, frozen	715		0.0	715		0.0	715		0.0	178		0.0
Strawberries	1097		0.0	1250		0.0	125		0.0	437		0.0
Strawberries,	116		0.0	118		0.0	118		0.0	7		0.0
Sweet Bell	701		0.0	716		0.0	566		0.0	177		0.0
Sweet Corn				19		0.0	1		0.0			
Sweet Corn,				652		0.0	439		0.0	15		0.0
Sweet Corn,				635		0.0	428		0.0	30		0.0
Sweet Peas				9		0.0						
Sweet Peas,				746		0.0	456		0.0	44		0.0
Sweet Peas,				703		0.0	450		0.0	46		0.0
Sweet Potatoes	385		0.0	1559		0.0	780		0.0	362		0.0
Tomatoes	1018		0.0	1977	4	0.2	136		0.0	332		0.0
Tomatoes,	368		0.0	368		0.0	287		0.0	90		0.0
W Squash	680		0.0	1216		0.0	507		0.0	110		0.0
W Squash,	286		0.0	470		0.0	125		0.0	106		0.0
Wheat Grain										156	920	58.9

Table 4-2 continued next page

Table 4-2 continued

	Chemical I			Chemical J			Chemical L			Chemical M		
Commodity	**Analy**	**Dete**	**%**	**Analy**	**Dete**	**%**	**Analy**	**Dete**	**%**	**Analy**	**Dete**	**%**
Apple Juice	1554		0.0	1554	3	0.2	160		0.0	1554	81	5.2
Apples	2289	1	0.0	2289	128	5.6	379		0.0	2287	1150	50.3
Bananas	1126		0.0	1125		0.0				1126		0.0
Broccoli	673		0.0	637		0.0				678		0.0
Cantaloupe	1234		0.0	1234		0.0	62		0.0	1234		0.0
Carrots	1888	1	0.1	1888	8	0.4				1888		0.0
Celery	176		0.0	176	1	0.6				176		0.0
Corn Syrup	416		0.0	454		0.0				423		0.0
Cucumbers	730		0.0	730		0.0				730		0.0
Grape Juice	1379		0.0	1379	7	0.5	108		0.0	1379		0.0
Grapes	1884		0.0	1884	16	0.8				1884	36	1.9
Green Beans	1178	4	0.3	1178		0.0				1177	8	0.7
Green Beans,	854	5	0.6	854	1	0.1	63		0.0	853		0.0
Green Beans,	743	16	2.2	743	65	8.7	45		0.0	729	3	0.4
Lettuce	876		0.0	876		0.0				876		0.0
Milk	1606		0.0	1366		0.0	842		0.0	1892		0.0
Oats, Bran	45		0.0	45		0.0				45		0.0
Oats, Rolled	287		0.0	287		0.0				287		0.0
Orange Juice	1379		0.0	1392		0.0	162		0.0	1392		0.0
Oranges	1892		0.0	1892	1	0.1				1892	2	0.1
Peaches	1087		0.0	1087	303	27.9				1087	289	26.6
Peaches,	756		0.0	756		0.0	54		0.0	754	1	0.1
Pears	1778		0.0	1779	121	6.8	162		0.0	1773	1039	58.6
Pears, canned	371		0.0	371		0.0				371		0.0
Potatoes	1401	3	0.2	1401		0.0				1401		0.0
Soybean Grain	748	1	0.1	748		0.0				748		0.0
Spinach	1638	2	0.1	1637	1	0.1	27		0.0	1639	4	0.2
Spinach,	863		0.0	863		0.0	135	1	0.7	863		0.0
Spinach,	715		0.0	715		0.0	178		0.0	714	1	0.1
Strawberries	1250		0.0	1250	3	0.2	352		0.0	1250	2	0.2
Strawberries,	118		0.0	118		0.0	3		0.0	118	2	1.7
Sweet Bell	701		0.0	716	6	0.8	177		0.0	716	6	0.8
Sweet Corn	19		0.0	19		0.0				19		0.0
Sweet Corn,	652		0.0	652		0.0				652		0.0
Sweet Corn,	635		0.0	635		0.0				635		0.0
Sweet Peas	9		0.0	9		0.0				9		0.0
Sweet Peas,	746		0.0	746		0.0				746		0.0
Sweet Peas,	703		0.0	703	12	1.7				703		0.0
Sweet	1559		0.0	1559	3	0.2	132		0.0	1559		0.0
Tomatoes	1962	1	0.1	1962	1	0.1	251		0.0	1960	31	1.6
Tomatoes,	368		0.0	368		0.0	90		0.0	368	2	0.5
W Squash	1216		0.0	1216		0.0	82		0.0	1216		0.0
W Squash,	470		0.0	470		0.0	80		0.0	470		0.0
Wheat Grain	1563	1	0.1	1563	2	0.1				940	3	0.3

Table 4-2 continued next page

Table 4-2 continued

	Chemical N			Chemical O			Chemical P			Chemical Q		
Commodity	Analy	Dete	%	Analy	Dete	%	Analy	Dete	%	Analy	Dete	%
Apple Juice	1554	1	0.1	1554		0.0	1554	1	0.1	368		0.0
Apples	2289	9	0.4	2289		0.0	2288	516	22.6	379		0.0
Bananas	1126		0.0	1126		0.0	1126		0.0			
Broccoli	679		0.0	679		0.0	679	11	1.6			
Cantaloupe	1234		0.0	1234		0.0	1234	19	1.5	332		0.0
Carrots	1887	4	0.2	1888		0.0	1888	15	0.8			
Celery	176		0.0	176		0.0	176	4	2.3			
Corn Syrup	454		0.0	454		0.0	454		0.0	408		0.0
Cucumbers	729		0.0	730		0.0	730	9	1.2	180		0.0
Grape Juice	1379	1	0.1	1379		0.0	1379		0.0	407		0.0
Grapes	1884		0.0	1884		0.0	1884	162	8.6			
Green Beans	1178		0.0	1178	1	0.1	1178		0.0			
Green Beans,	854		0.0	854		0.0	854		0.0	132		0.0
Green Beans,	743		0.0	743		0.0	743		0.0	104		0.0
Lettuce	876		0.0	876		0.0	876	1	0.1			
Milk	1892		0.0	1890		0.0	1890		0.0	844		0.0
Oats, Bran												
Oats, Rolled												
Orange Juice	1392	139	10.0	1392	15	1.1	1392	2	0.1	327		0.0
Oranges	1892	33	1.7	1892	86	4.5	1892	144	7.6			
Peaches	1087		0.0	1087		0.0	1087	130	12.0			
Peaches,	754		0.0	756		0.0	754		0.0	54		0.0
Pears	1779		0.0	1779	6	0.3	1779	35	2.0	232		0.0
Pears, canned	371		0.0	371		0.0	371		0.0			
Potatoes	1401		0.0	1401		0.0	1401	1	0.1			
Soybean Grain							747	182	24.4			
Spinach	1639		0.0	1639		0.0	1639	83	5.1	27		0.0
Spinach,	863		0.0	863		0.0	863		0.0	299		0.0
Spinach,	715		0.0	715		0.0	715	47	6.6	353		0.0
Strawberries	1250		0.0	1250	1	0.1	1250	12	1.0	607		0.0
Strawberries,	118	1	0.8	118		0.0	118		0.0	55		0.0
Sweet Bell	701	21	3.0	716		0.0	716	105	14.7	506		0.0
Sweet Corn	19		0.0	19		0.0	19		0.0			
Sweet Corn,	652		0.0	652		0.0	652		0.0			
Sweet Corn,	635		0.0	635		0.0	635		0.0			
Sweet Peas	9		0.0	9		0.0	9		0.0			
Sweet Peas,	746		0.0	746		0.0	746		0.0			
Sweet Peas,	703		0.0	703		0.0	703	1	0.1			
Sweet	1547	2	0.1	1559		0.0	1559	163	10.5	272		0.0
Tomatoes	1962	8	0.4	1962		0.0	1962	261	13.3	787		0.0
Tomatoes,	368		0.0	368		0.0	368	6	1.6	261		0.0
W Squash	1216	3	0.2	1216		0.0	1216	6	0.5	232		0.0
W Squash,	470	6	1.3	470		0.0	470	4	0.9	198	1	0.5
Wheat Grain							1563	206	13.2	623	23	3.7

Table 4-2 continued next page

Table 4-2 continued

	Chemical R			Chemical S			Chemical T			Chemical U		
Commodity	Analy	Dete	%	Analy	Dete	%	Analy	Dete	%	Analy	Dete	%
Apple Juice	1554	324	20.8	1344		0.0	1554		0.0	1554	1	0.1
Apples	2289	136	5.9	2079	5	0.2	2289	19	0.8	2289		0.0
Bananas	1126		0.0	1036		0.0	1126		0.0	1117		0.0
Broccoli	679	11	1.6	635		0.0	634		0.0	679		0.0
Cantaloupe	1234	13	1.1	980	1	0.1	1234	4	0.3	1234		0.0
Carrots	1888		0.0	1639	24	1.5	1887	68	3.6	1865	1	0.1
Celery	176		0.0	143		0.0	176	8	4.5	176		0.0
Corn Syrup	430		0.0	430		0.0	454		0.0	454		0.0
Cucumbers	730	5	0.7	551		0.0	730	3	0.4	730		0.0
Grape Juice	1379	7	0.5	1114	2	0.2	1378		0.0	1379	4	0.3
Grapes	1883	300	15.9	1746	16	0.9	1884	29	1.5	1884		0.0
Green Beans	1178	75	6.4	1038		0.0	1178	5	0.4	1178		0.0
Green Beans,	854	7	0.8	730		0.0	854		0.0	854		0.0
Green Beans,	743	27	3.6	639		0.0	743	11	1.5	743		0.0
Lettuce	876	102	11.6	840		0.0	876	29	3.3	876	3	0.3
Milk	1892		0.0	1364		0.0	1366		0.0	1892		0.0
Oats, Bran				45		0.0				45	2	4.4
Oats, Rolled				287		0.0				287	16	5.6
Orange Juice	1392		0.0	1212		0.0	1392		0.0	1392		0.0
Oranges	1892	22	1.2	1716	1	0.1	1892		0.0	1892		0.0
Peaches	1087	5	0.5	976	1	0.1	1087	65	6.0	1087	2	0.2
Peaches,	756	1	0.1	654		0.0	754		0.0	756		0.0
Pears	1779	9	0.5	1505	4	0.3	1779	39	2.2	1779	3	0.2
Pears, canned	371		0.0	281		0.0	371	2	0.5	371		0.0
Potatoes	1401	1	0.1	1377		0.0	1401		0.0	1401		0.0
Soybean Grain	749		0.0	748		0.0	748	8	1.1	749	295	39.4
Spinach	1638	238	14.5	1385		0.0	1638	40	2.4	1639	5	0.3
Spinach,	863		0.0	749	12	1.6	863		0.0	863		0.0
Spinach,	715	51	7.1	715	1	0.1	715	8	1.1	715	14	2.0
Strawberries	1250		0.0	1250		0.0	1250	16	1.3	1250	165	13.2
Strawberries,	118		0.0	118		0.0	118		0.0	118	26	22.0
Sweet Bell	702	75	10.7	716		0.0	716	7	1.0	701	5	0.7
Sweet Corn	19		0.0	19		0.0	19		0.0	19		0.0
Sweet Corn,	652		0.0	652		0.0	652		0.0	652		0.0
Sweet Corn,	635		0.0	635		0.0	635		0.0	635		0.0
Sweet Peas	9	1	11.1	9		0.0	9		0.0	9		0.0
Sweet Peas,	746		0.0	746		0.0	746		0.0	746		0.0
Sweet Peas,	703	158	22.5	703	1	0.1	703	10	1.4	703		0.0
Sweet	1559		0.0	1487		0.0	1559	3	0.2	1559	9	0.6
Tomatoes	1962	71	3.6	1766		0.0	1962	12	0.6	1962		0.0
Tomatoes,	368		0.0	368		0.0	368	1	0.3	368	1	0.3
W Squash	1216	1	0.1	1078	5	0.5	1216	3	0.2	1216		0.0
W Squash,	470		0.0	343	2	0.6	470	1	0.2	470		0.0
Wheat Grain	1563		0.0	1563	1	0.1	1563	24	1.5	1563	1090	69.7

Table 4-2 continued next page

Table 4-2 continued

	Chemical V			Chemical W			Chemical X			Chemical Y		
Commodity	**Analy**	**Dete**	**%**	**Analy**	**Dete**	**%**	**Analy**	**Dete**	**%**	**Analy**	**Dete**	**%**
Apple Juice	1344	333	24.8	1554		0.0	1554		0.0	1554		0.0
Apples	2104	128	6.1	2289	6	0.3	2155		0.0	2090	43	2.1
Bananas	1062		0.0	1126		0.0	972		0.0	915		0.0
Broccoli	663		0.0	675	1	0.1	512		0.0	459		0.0
Cantaloupe	973		0.0	1234		0.0	1234		0.0	1234		0.0
Carrots	1662	3	0.2	1888		0.0	1699		0.0	1648	1	0.1
Celery	176		0.0	176	4	2.3	77		0.0	53		0.0
Corn Syrup	442		0.0	454		0.0	392		0.0	454		0.0
Cucumbers	551		0.0	730	1	0.1	730		0.0	730	1	0.1
Grape Juice	1114	1	0.1	1377		0.0	1379		0.0	1379		0.0
Grapes	1770	20	1.1	1884	8	0.4	1748		0.0	1684		0.0
Green Beans	1059		0.0	1178		0.0	1050		0.0	1015		0.0
Green Beans,	730		0.0	854		0.0	854		0.0	854		0.0
Green Beans,	639		0.0	743		0.0	743		0.0	743		0.0
Lettuce	876		0.0	876	77	8.8	734		0.0	689		0.0
Milk	692		0.0	692		0.0	1892		0.0	690		0.0
Oats, Bran												
Oats, Rolled												
Orange Juice	1212		0.0	1392		0.0	1392		0.0	1392		0.0
Oranges	1740		0.0	1892		0.0	1684		0.0	1585		0.0
Peaches	990	194	19.6	1087	1	0.1	996		0.0	963		0.0
Peaches,	654		0.0	756		0.0	756		0.0	756		0.0
Pears	1504	315	20.9	1779		0.0	1779		0.0	1779		0.0
Pears, canned	281		0.0	371		0.0	371		0.0	371		0.0
Potatoes	1401		0.0	1401		0.0	1253	20	1.6	1201	1	0.1
Soybean Grain							746		0.0			
Spinach	1385		0.0	1638	17	1.0	1639		0.0	1639		0.0
Spinach,	749		0.0	863		0.0	863		0.0	863		0.0
Spinach,	715		0.0	715	2	0.3	715		0.0	715		0.0
Strawberries	1250		0.0	1250		0.0	1250		0.0	1250		0.0
Strawberries,	118		0.0	118	3	2.5	118		0.0	118		0.0
Sweet Bell	716		0.0	701		0.0	701		0.0	701		0.0
Sweet Corn	19		0.0	19		0.0	19		0.0	19		0.0
Sweet Corn,	652		0.0	652		0.0	627		0.0	627		0.0
Sweet Corn,	635		0.0	635		0.0	618		0.0	618		0.0
Sweet Peas	9		0.0	9		0.0	9		0.0	9		0.0
Sweet Peas,	746		0.0	746		0.0	720		0.0	720		0.0
Sweet Peas,	703		0.0	703		0.0	691		0.0	691		0.0
Sweet	1487	77	5.2	1559		0.0	1559		0.0	1559		0.0
Tomatoes	1766	1	0.1	1977		0.0	1962		0.0	1969		0.0
Tomatoes,	368		0.0	368	1	0.3	368		0.0	368		0.0
W Squash	1078		0.0	1216		0.0	1216		0.0	1216		0.0
W Squash,	343		0.0	470		0.0	470		0.0	470		0.0
Wheat Grain							1563	3	0.2			

end Table 4-2.

Table 4-3. Processing Factors Used in Cumulative Dietary Exposure Assessment

Code (com+ff)	Commodity	Foodform	Chemical																							
			A	B	C	D	E	F	G	H	I	J	L	M	N	O	P	Q	R	S	T	U	V	W	X	Y
5211	Apples	Uncooked							1		1	1		1	1		1		1	1	1		1	1		1
5212	Apples	Cooked: NFS							1		0.9	0.05		1	1		0.15		0.7	1	1		0.1	1		1
5213	Apples	Baked							1		0.9	1		1	1		0.15		0.7	1	1		1	1		1
5214	Apples	Boiled							1		0.9	0.05		0.36	1		1		0.7	1	1		0.1	1		1
5215	Apples	Fried							1		0.9	1		1	1		0.15		0.7	1	1		0.1	1		1
5218	Apples	Dried							1		1	1		1	1		1		1	1	1		1	1		1
5231	Apples	Canned: NFS							0		0.2	0.05		0.36	1		1		1	1	1		0.1	1		1
5232	Apples	Canned: Cooked							0		0.2	0.05		0.36	1		1		0.7	1	1		0.1	1		1
5233	Apples	Canned: Baked							0		0.2	0.05		0.36	1		1		0.7	1	1		0.1	1		1
5234	Apples	Canned: Boiled							0		0.2	0.05		0.36	1		1		0.7	1	1		0.1	1		1
5242	Apples	Frozen: Cooked							1		1	0.05		0.36	1		1		0.7	1	1		0.1	1		1
5313	Apples-dried	Baked							8		7.4	8		5.84	8		1.2		5.6	8	8		0.1	8		8
5314	Apples-dried	Boiled							8		7.4	0.4		5.84	8		1.2		5.6	8	8		0.1	8		8
5318	Apples-dried	Dried							8		8	8		5.84	8		1.2		8	8	8		0.1	8		8
5342	Apples-dried	Frozen: Cooked							8		7.4	0.4		5.84	8		1.2		5.6	8	8		0.1	8		8
5411	Apples-juice/cider	Uncooked	1		1							1		1	1		1		1			1	1			
5412	Apples-juice/cider	Cooked: NFS	1		1							0.05		1	1		1		0.7			1	1			
5414	Apples-juice/cider	Boiled	1		1							0.05		1	1		1		0.7			1	1			
5431	Apples-juice/cider	Canned: NFS	1		1							0.05		1	1		1		1			1	1			
5441	Apples-juice/cider	Frozen: NFS	1		1							1		1	1		1		1			1	1			
37712	Apples-juice-concentrate	Cooked: NFS	3		3							0.15		3	3		3		2.1			3	3			
37713	Apples-juice-concentrate	Baked	3		3							3		3	3		3		2.1			3	3			
37731	Apples-juice-concentrate	Canned: NFS	3		3							0.15		3	3		3		3			3	3			
37741	Apples-juice-concentrate	Frozen: NFS	3		3							3		3	3		3		3			3	3			
23411	Beans-succulent-green	Uncooked	1	1	1						1	1		1		1			1		1					
23412	Beans-succulent-green	Cooked: NFS	0.64	1	0.5						0.9	0.05		1		1			0.7		1					
23414	Beans-succulent-green	Boiled	0.64	1	0.5						0.9	0.05		1		1			0.7		1					
23431	Beans-succulent-green	Canned: NFS	1	1	1						1	1		1		1			1		1					

Code (com+ff)	Commodity	Foodform	Chemical																							
			A	B	C	D	E	F	G	H	I	J	L	M	N	O	P	Q	R	S	T	U	V	W	X	Y
23432	Beans-succulent-green	Canned: Cooked	1	1	1						1	1		1		1			1		1					
23434	Beans-succulent-green	Canned: Boiled	1	1	1						1	1		1		1			1		1					
23442	Beans-succulent-green	Frozen: Cooked	1	1	1						1	1		1		1			1		1					
23444	Beans-succulent-green	Frozen: Boiled	1	1	1						1	1		1		1			1		1					
23451	Beans-succulent-green	Cured: NFS(smoked/pickled/	0.64	1	0.5						1	1		1		1			1		1					
23311	Beans-succulent-lima	Uncooked	1	1	1						1	1		1		1			1		1					
23312	Beans-succulent-lima	Cooked: NFS	0.64	1	0.5						0.9	0.05		1		1			0.7		1					
23314	Beans-succulent-lima	Boiled	0.64	1	0.5						0.9	0.05		1		1			0.7		1					
23332	Beans-succulent-lima	Canned: Cooked	1	1	1						1	1		1		1			1		1					
23342	Beans-succulent-lima	Frozen: Cooked	1	1	1						1	1		1		1			1		1					
23344	Beans-succulent-lima	Frozen: Boiled	1	1	1						1	1		1		1			1		1					
23534	Beans-succulent-other	Canned: Boiled	1	1	1						1	1		1		1			1		1					
23614	Beans-succulent-yellow/wax	Boiled	0.64	1	0.5						0.9	0.05		1		1			0.7		1					
23632	Beans-succulent-yellow/wax	Canned: Cooked	1	1	1						1	1		1		1			1		1					
23642	Beans-succulent-yellow/wax	Frozen: Cooked	1	1	1						1	1		1		1			1		1					
16811	Broccoli	Uncooked	1														1		1					1		
16812	Broccoli	Cooked: NFS	1														1		0.7					1		
16813	Broccoli	Baked	1														1		0.7					1		
16814	Broccoli	Boiled	1														1		0.7					1		
16815	Broccoli	Fried	1														1		0.7					1		
16832	Broccoli	Canned: Cooked	1														1		0.7					1		
16842	Broccoli	Frozen: Cooked	1														1		0.7					1		
16844	Broccoli	Frozen: Boiled	1														1		0.7					1		
19811	Carrots	Uncooked	1		1	1					1	1			1		1			1	1	1	1			1
19812	Carrots	Cooked: NFS	1		1	1					0.9	0.05			1		1			1	1	1	1			1
19813	Carrots	Baked	1		1	1					0.9	1			1		1			1	1	1	1			1
19814	Carrots	Boiled	1		1	1					0.9	0.05			1		1			1	1	1	1			1
19831	Carrots	Canned: NFS	1		1	1					0.2	0.05			1		1			1	1	1	1			1

Code (com+ff)	Commodity	Foodform	Chemical																							
			A	B	C	D	E	F	G	H	I	J	L	M	N	O	P	Q	R	S	T	U	V	W	X	Y
19832	Carrots	Canned: Cooked	1		1	1					0.2	0.05			1		1			1	1	1	1			1
19834	Carrots	Canned: Boiled	1		1	1					0.2	0.05			1		1			1	1	1	1			1
19842	Carrots	Frozen: Cooked	1		1	1					1	0.05			1		1			1	1	1	1			1
19844	Carrots	Frozen: Boiled	1		1	1					1	0.05			1		1			1	1	1	1			1
16611	Celery	Uncooked	1		1							1					1				1			1		
16612	Celery	Cooked: NFS	0.54		1							0.05					1				1			1		
16613	Celery	Baked	0.54		1							1					1				1			1		
16614	Celery	Boiled	0.54		1							0.05					1				1			1		
16615	Celery	Fried	0.54		1							1					1				1			1		
16631	Celery	Canned: NFS	0.54		1							0.05					1				1			1		
16632	Celery	Canned: Cooked	0.54		1							0.05					1				1			1		
16634	Celery	Canned: Boiled	0.54		1							0.05					1				1			1		
16642	Celery	Frozen: Cooked	0.54		1							0.05					1				1			1		
38431	Celery juice	Canned: NFS	1		1							1					1				1			1		
14811	Cucumbers	Uncooked	1	1	1		1	1									1		1		1			1		1
14834	Cucumbers	Canned: Boiled	1	1	1		1	1									1		0.7		1			1		1
14860	Cucumbers	Canned: Cured	1	1	1		1	1									1		1		1			1		1
1311	Grapes	Uncooked	1	1	1			1				1		1			1		1	1	1		1	1		
1312	Grapes	Cooked: NFS	1	1	1			1				0.05		1			1		0.7	1	1		1	1		
1331	Grapes	Canned: NFS	1	1	1			1				0.05		0.38			1		1	1	1		1	1		
1341	Grapes	Frozen: NFS	1	1	1			1				1		0.86			1		1	1	1		1	1		
1511	Grapes-juice	Uncooked													1				1	1		1				
1512	Grapes-juice	Cooked: NFS													1				0.7	1		1				
1514	Grapes-juice	Boiled													1				0.7	1		1				
1531	Grapes-juice	Canned: NFS													1				1	1		1				
1534	Grapes-juice	Canned: Boiled													1				0.7	1		1				
1541	Grapes-juice	Frozen: NFS													1				1	1		1				
39212	Grapes-juice-concentrate	Cooked: NFS													3				2.1	3		3				
39213	Grapes-juice-concentrate	Baked													3				2.1	3		3				

Code (com+ff)	Commodity	Foodform	Chemical																							
			A	B	C	D	E	F	G	H	I	J	L	M	N	O	P	Q	R	S	T	U	V	W	X	Y
39214	Grapes-juice-concentrate	Boiled													3				2.1	3		3				
39231	Grapes-juice-concentrate	Canned: NFS													3				3	3		3				
39241	Grapes-juice-concentrate	Frozen: NFS													3				3	3		3				
1411	Grapes-raisins	Uncooked	4.3	4.3	4.3			4.3				1		4.3			0.17		4	4.3	0.1		0.9	4		
1412	Grapes-raisins	Cooked: NFS	4.3	4.3	4.3			4.3				0.05		4.3			0.17		3	4.3	0.1		0.9	4		
1413	Grapes-raisins	Baked	4.3	4.3	4.3			4.3				1		4.3			0.17		3	4.3	0.1		0.9	4		
1414	Grapes-raisins	Boiled	4.3	4.3	4.3			4.3				0.05		4.3			0.17		3	4.3	0.1		0.9	4		
1418	Grapes-raisins	Dried	4.3	4.3	4.3			4.3				1		4.3			0.17		4.3	4.3	0.1		0.9	4		
1442	Grapes-raisins	Frozen: Cooked	4.3	4.3	4.3			4.3				0.05		4.3			0.17		3	4.3	0.1		0.9	4		
19211	Lettuce-head varieties	Uncooked	1		1												1		1		1	1		1		
17611	Lettuce-leafy varieties	Uncooked	1		1												1		1		1	1		1		
18231	Lettuce-unspecified	Canned: NFS	1		1												1		1		1	1		1		
14211	Melons-cantaloupes-pulp	Uncooked	1		1												1		1	1	1					
26911	Oats	Uncooked								1												1				
26912	Oats	Cooked: NFS								0.36												1				
26913	Oats	Baked								0.36												1				
26914	Oats	Boiled								0.03												1				
26915	Oats	Fried								0.36												1				
26931	Oats	Canned: NFS								0.03												1				
39911	Oats-bran	Uncooked								1												1				
39912	Oats-bran	Cooked: NFS								0.36												1				
39913	Oats-bran	Baked								0.36												1				
39914	Oats-bran	Boiled								0.03												1				
39915	Oats-bran	Fried								0.36												1				
3611	Oranges-juice	Uncooked													1	1	1									
3612	Oranges-juice	Cooked: NFS													1	1	1									
3631	Oranges-juice	Canned: NFS													1	1	1									
3641	Oranges-juice	Frozen: NFS													1	1	1									
3311	Oranges-juice-concentrate	Uncooked													4	4	3.72									

Code (com+ff)	Commodity	Foodform	Chemical																					
			A	B	C	D	E	F	G	H	I	J	L	M	N	O	P	Q	R	S	T	U	V	W	X	Y
3312	Oranges-juice-concentrate	Cooked: NFS													4	4	3.72									
3313	Oranges-juice-concentrate	Baked													4	4	3.72									
3314	Oranges-juice-concentrate	Boiled													4	4	3.72									
3331	Oranges-juice-concentrate	Canned: NFS													4	4	3.72									
3341	Oranges-juice-concentrate	Frozen: NFS													4	4	3.72									
3342	Oranges-juice-concentrate	Frozen: Cooked													4	4	3.72									
3511	Oranges-peel	Uncooked										1		1	100	46	15		46	1		1				
3512	Oranges-peel	Cooked: NFS										0.05		1	100	46	15		32	1		1				
3531	Oranges-peel	Canned: NFS										0.05		1	100	46	15		46	1		1				
3541	Oranges-peel	Frozen: NFS										1		1	100	46	15		46	1		1				
3411	Oranges-peeled fruit	Uncooked										1		1	1	1	1		1	1		1				
3412	Oranges-peeled fruit	Cooked: NFS										0.05		1	1	1	1		0.7	1		1				
3431	Oranges-peeled fruit	Canned: NFS										0.05		1	1	1	1		1	1		1				
6511	Peaches	Uncooked	1		1							1		1			1		1	1	1	1	1	1		
6512	Peaches	Cooked: NFS	1		1							0.05		1			1		0.7	0.1	1	1	0	1		
6513	Peaches	Baked	1		1							1		1			1		0.7	1	1	1	1	1		
6514	Peaches	Boiled	1		1							0.05		0.36			1		0.7	0.1	1	1	0	1		
6531	Peaches	Canned: NFS	1		1							1		1			1		1	1	1	1	1	1		
6541	Peaches	Frozen: NFS	1		1							1		0.36			1		1	1	1	1	1	1		
6614	Peaches-dried	Boiled	7		7							0.35		7			7		4.9	0.4	7	7	0	7		
6618	Peaches-dried	Dried	7		7							7		7			7		7	7	7	7	0	7		
40211	Peaches-juice	Uncooked	1		1							1		0.81			0.3		1	1	1	1	0	1		
40231	Peaches-juice	Canned: NFS	1		1							0.05		0.81			0.3		1	0.1	1	1	0	1		
5611	Pears	Uncooked		1	1							1		1		1	1		1	1	1	1	1			
5612	Pears	Cooked: NFS		1	1							0.05		1		1	0.15		1	1	1	1	0.1			
5613	Pears	Baked		1	1							1		1		1	0.15		1	1	1	1	1			
5614	Pears	Boiled		1	1							0.05		1		1	0.15		1	1	1	1	0.1			
5631	Pears	Canned: NFS		1	1							0.05		0.36		1	0.15		1	1	1	1	0.1			
5713	Pears-dried	Baked		6.3	6.3							6.25		5.8		1	0.94		6.3	6.3	6.3	6.3	0.1			

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			A	B	C	D	E	F	G	H	I	J	L	M	N	O	P	Q	R	S	T	U	V	W	X	Y
5714	Pears-dried	Boiled		6.3	6.3							0.313		5.8		1	0.94		6.3	6.3	6.3	6.3	0.1			
5718	Pears-dried	Dried		6.3	6.3							6.25		1		1	0.94		6.3	6.3	6.3	6.3	0.1			
40411	Pears-juice	Uncooked		1	1							1		1		1	1		1	1	1	1	0.1			
40412	Pears-juice	Cooked: NFS		1	1							0.05		1		1	1		1	1	1	1	0.1			
40413	Pears-juice	Baked		1	1							1		1		1	1		1	1	1	1	0.1			
40431	Pears-juice	Canned: NFS		1	1							0.05		1		1	1		1	1	1	1	0.1			
40433	Pears-juice	Canned: Baked		1	1							0.05		1		1	1		1	1	1	1	0.1			
40441	Pears-juice	Frozen: NFS		1	1							1		1		1	1		1	1	1	1	0.1			
40442	Pears-juice	Frozen: Cooked		1	1							0.05		1		1	1		1	1	1	1	0.1			
24111	Peas (garden)-green	Uncooked	1									1					1		1	1	1					
24112	Peas (garden)-green	Cooked: NFS	0.64									0.05					1		0.7	1	1					
24113	Peas (garden)-green	Baked	0.64									1					1		0.7	1	1					
24114	Peas (garden)-green	Boiled	0.64									0.05					1		0.7	1	1					
24115	Peas (garden)-green	Fried	0.64									1					1		0.7	1	1					
24131	Peas (garden)-green	Canned: NFS	1									1					1		1	1	1					
24132	Peas (garden)-green	Canned: Cooked	1									1					1		1	1	1					
24134	Peas (garden)-green	Canned: Boiled	1									1					1		1	1	1					
24142	Peas (garden)-green	Frozen: Cooked	1									1					1		1	1	1					
24144	Peas (garden)-green	Frozen: Boiled	1									1					1		1	1	1					
24145	Peas (garden)-green	Frozen: Fried	1									1					1		1	1	1					
40512	Peas-succulent/blackeye/cowpea	Cooked: NFS	0.64									0.05					1		0.7	1	1					
40514	Peas-succulent/blackeye/cowpea	Boiled	0.64									0.05					1		0.7	1	1					
40532	Peas-succulent/blackeye/cowpea	Canned: Cooked	1									1					1		1	1	1					
40542	Peas-succulent/blackeye/cowpea	Frozen: Cooked	1									1					1		1	1	1					
15511	Peppers-sweet(garden)	Uncooked	1		1							1		1	1		1		1		1	1				
15512	Peppers-sweet(garden)	Cooked: NFS	0.6		1							0.05		1	1		1		0.7		1	1				
15513	Peppers-sweet(garden)	Baked	0.6		1							0.05		1	1		1		0.7		1	1				

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			A	B	C	D	E	F	G	H	I	J	L	M	N	O	P	Q	R	S	T	U	V	W	X	Y
15514	Peppers-sweet(garden)	Boiled	0.6		1							0.05		1	1		1		0.7		1	1				
15531	Peppers-sweet(garden)	Canned: NFS	0.6		1							0.05		1	1		1		1		1	1				
15532	Peppers-sweet(garden)	Canned: Cooked	0.6		1							0.05		1	1		1		0.7		1	1				
15534	Peppers-sweet(garden)	Canned: Boiled	0.6		1							0.05		1	1		1		0.7		1	1				
15542	Peppers-sweet(garden)	Frozen: Cooked	0.6		1							0.05		1	1		1		0.7		1	1				
15551	Peppers-sweet(garden)	Cured: NFS(smoked/pickled/	0.6		1							1		1	1		1		1		1	1				
21012	Potatoes/white-dry	Cooked: NFS	6.5		6.5						1.3						6.5		0.2						1.2	7
21014	Potatoes/white-dry	Boiled	6.5		6.5						1.3						6.5		0.2						1.2	7
21015	Potatoes/white-dry	Fried	6.5		6.5						1.3						6.5		0.2						0.5	7
21031	Potatoes/white-dry	Canned: NFS	6.5		6.5						1.3						6.5		0.2						1.2	7
21034	Potatoes/white-dry	Canned: Boiled	6.5		6.5						1.3						6.5		0.2						1.2	7
21042	Potatoes/white-dry	Frozen: Cooked	6.5		6.5						1.3						6.5		0.2						1.2	7
21113	Potatoes/white-peel only	Baked	1		1						0.9						1		0.6						0.4	1
21115	Potatoes/white-peel only	Fried	1		1						0.9						1		0.6						0.5	1
20912	Potatoes/white-peeled	Cooked: NFS	0.2		1						0.6						1		0.2						0.3	1
20913	Potatoes/white-peeled	Baked	0.2		1						0.6						1		0.2						0.4	1
20914	Potatoes/white-peeled	Boiled	0.2		1						0.6						1		0.2						0.5	1
20915	Potatoes/white-peeled	Fried	0.2		1						0.2						1		0.2						0.5	1
20932	Potatoes/white-peeled	Canned: Cooked	0.2		1						0.6						1		0.2						0.3	1
20934	Potatoes/white-peeled	Canned: Boiled	0.2		1						0.6						1		0.2						0.3	1
20942	Potatoes/white-peeled	Frozen: Cooked	0.2		1						0.6						1		0.2						0.3	1
20943	Potatoes/white-peeled	Frozen: Baked	0.2		1						0.6						1		0.2						0.4	1
20945	Potatoes/white-peeled	Frozen: Fried	0.2		1						0.2						1		0.2						0.5	1
20831	Potatoes/white-unspecified	Canned: NFS	0.2		1						0.6						1		1						1	1
20711	Potatoes/white-whole	Uncooked	0.2		1						1						1		1						1	2
20712	Potatoes/white-whole	Cooked: NFS	0.2		1						0.6						1		0.7						1	3
20713	Potatoes/white-whole	Baked	0.2		1						0.6						1		0.7						0.5	4
20714	Potatoes/white-whole	Boiled	0.2		1						0.6						1		0.7						1	5

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			A	B	C	D	E	F	G	H	I	J	L	M	N	O	P	Q	R	S	T	U	V	W	X	Y
20715	Potatoes/white-whole	Fried	10		1						0.2						1		0.7						0.5	6
20731	Potatoes/white-whole	Canned: NFS	0.2		1						0.6						1		1						1	7
30712	Soybeans-flour (defatted)	Cooked: NFS						1			0.5						1				1	1				
30713	Soybeans-flour (defatted)	Baked						1			0.5						1				1	1				
30714	Soybeans-flour (defatted)	Boiled						1			0.5						1				1	1				
30715	Soybeans-flour (defatted)	Fried						1			0.5						1				1	1				
30731	Soybeans-flour (defatted)	Canned: NFS						1			0.1						1				1	1				
30734	Soybeans-flour (defatted)	Canned: Boiled						1			0.1						1				1	1				
30742	Soybeans-flour (defatted)	Frozen: Cooked						1			0.5						1				1	1				
30798	Soybeans-flour (defatted)	Refined						1			0.5						1				1	1				
30512	Soybeans-flour (full fat)	Cooked: NFS						1			0.5						1				1	1				
30513	Soybeans-flour (full fat)	Baked						1			0.5						1				1	1				
30514	Soybeans-flour (full fat)	Boiled						1			0.5						1				1	1				
30534	Soybeans-flour (full fat)	Canned: Boiled						1			0.1						1				1	1				
30542	Soybeans-flour (full fat)	Frozen: Cooked						1			0.5						1				1	1				
30612	Soybeans-flour (low fat)	Cooked: NFS						1			0.5						1				1	1				
30613	Soybeans-flour (low fat)	Baked						1			0.5						1				1	1				
30615	Soybeans-flour (low fat)	Fried						1			0.5						1				1	1				
30631	Soybeans-flour (low fat)	Canned: NFS						1			0.1						1				1	1				
30412	Soybeans-mature seeds dry	Cooked: NFS						1			0.9						1				1	1				
30413	Soybeans-mature seeds dry	Baked						1			0.9						1				1	1				
30414	Soybeans-mature seeds dry	Boiled						1			0.9						1				1	1				
30415	Soybeans-mature seeds dry	Fried						1			0.9						1				1	1				
30441	Soybeans-mature seeds dry	Frozen: NFS						1			1						1				1	1				
29798	Soybeans-oil	Refined						1			0.5						0.14				1	1				
48212	Soybeans-protein isolate	Cooked: NFS						1			0.9						1				1	1				
48213	Soybeans-protein isolate	Baked						1			0.9						1				1	1				
48214	Soybeans-protein isolate	Boiled						1			0.9						1				1	1				
48215	Soybeans-protein isolate	Fried						1			0.9						1				1	1				

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48231	Soybeans-protein isolate	Canned: NFS						1			0.2						1				1	1				
48232	Soybeans-protein isolate	Canned: Cooked						1			0.2						1				1	1				
48233	Soybeans-protein isolate	Canned: Baked						1			0.2						1				1	1				
48234	Soybeans-protein isolate	Canned: Boiled						1			0.2						1				1	1				
48241	Soybeans-protein isolate	Frozen: NFS						1			1						1				1	1				
48242	Soybeans-protein isolate	Frozen: Cooked						1			0.9						1				1	1				
48251	Soybeans-protein isolate	Cured: NFS(smoked/pickled/						1			1						1				1	1				
25514	Soybeans-sprouted seeds	Boiled						0.3			0.3						0.33				0.3	0.3				
18611	Spinach	Uncooked	1		1						1	1	1	1			1		1	1	1	1		1		
18612	Spinach	Cooked: NFS	1		1						0.9	0.05	1	1			1		0.7	1	1	1		1		
18614	Spinach	Boiled	1		1						0.9	0.05	1	1			1		0.7	1	1	1		1		
18631	Spinach	Canned: NFS	1		1						1	1	1	1			1		1	1	1	1		1		
18632	Spinach	Canned: Cooked	1		1						1	1	1	1			1		1	1	1	1		1		
18634	Spinach	Canned: Boiled	1		1						1	1	1	1			1		1	1	1	1		1		
18642	Spinach	Frozen: Cooked	1		1						0.9	0.05	1	1			1		0.7	1	1	1		1		
18644	Spinach	Frozen: Boiled	1		1						0.9	0.05	1	1			1		0.7	1	1	1		1		
15111	Squash-winter	Uncooked	1		1										1		1		1	1	1					
15112	Squash-winter	Cooked: NFS	0.77		1										1		1		0.7	1	1					
15113	Squash-winter	Baked	0.77		1										1		1		0.7	1	1					
15114	Squash-winter	Boiled	0.77		1										1		1		0.7	1	1					
1711	Strawberries	Uncooked	1	1													1				1	1				
1712	Strawberries	Cooked: NFS	1	1													1				1	1				
1713	Strawberries	Baked	1	1													1				1	1				
1714	Strawberries	Boiled	1	1													1				1	1				
1731	Strawberries	Canned: NFS	1	1													1				1	1				
1734	Strawberries	Canned: Boiled	1	1													1				1	1				
1741	Strawberries	Frozen: NFS	1	1										1	1		1				1	1		1		
41611	Strawberries-juice	Uncooked	1	1													0.3				1	1				

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41612	Strawberries-juice	Cooked: NFS	1	1													0.3				1	1				
41613	Strawberries-juice	Baked	1	1													0.3				1	1				
41614	Strawberries-juice	Boiled	1	1													0.3				1	1				
41631	Strawberries-juice	Canned: NFS	1	1													0.3				1	1				
21812	Sweet potatoes (incl yams)	Cooked: NFS	1		1	1						0.05			1		1				1	1	1			
21813	Sweet potatoes (incl yams)	Baked	1		1	1						1			1		1				1	1	1			
21814	Sweet potatoes (incl yams)	Boiled	1		1	1						0.05			1		1				1	1	1			
21815	Sweet potatoes (incl yams)	Fried	1		1	1						1			1		1				1	1	1			
21832	Sweet potatoes (incl yams)	Canned: Cooked	1		1	1						0.05			1		0.15				1	1	1			
21834	Sweet potatoes (incl yams)	Canned: Boiled	1		1	1						0.05			1		0.15				1	1	1			
16334	Tomatoes-catsup	Canned: Boiled	0.7		2.5			2.5			1.6	0.06		0.02	2.5		0.1		1.1	2.5	0.3		2.5			
42312	Tomatoes-dried	Cooked: NFS	14.3		14			14			13	0.715		7.45	14		14.3		10	14	14		14			
42315	Tomatoes-dried	Fried	14.3		14			14			13	14.3		7.45	14		14.3		10	14	14		14			
16031	Tomatoes-juice	Canned: NFS	0.9		1.5			1.5			0.3	0.003		0.004	1.5		0.03		0.1	1.5	0.1		1.5			
16032	Tomatoes-juice	Canned: Cooked	0.9		1.5			1.5			0.3	0.003		0.004	1.5		0.03		0.1	1.5	0.1		1.5			
16034	Tomatoes-juice	Canned: Boiled	0.9		1.5			1.5			0.3	0.003		0.004	1.5		0.03		0.1	1.5	0.1		1.5			
16042	Tomatoes-juice	Frozen: Cooked	0.9		1.5			1.5			0.3	0.003		0.316	1.5		0.03		0.1	1.5	0.1		1.5			
16214	Tomatoes-paste	Boiled	5.4		5.4			5.4			1.6	0.006		0.01	5.4		0.1		1.8	5.4	0.6		5.4			
16231	Tomatoes-paste	Canned: NFS	0.7		5.4			5.4			1.7	0.006		1E-04	5.4		0.1		2.6	5.4	0.6		5.4			
16232	Tomatoes-paste	Canned: Cooked	0.7		5.4			5.4			1.6	0.006		1E-04	5.4		0.1		1.8	5.4	0.6		5.4			
16233	Tomatoes-paste	Canned: Baked	0.7		5.4			5.4			1.6	0.006		1E-04	5.4		0.1		1.8	5.4	0.6		5.4			
16234	Tomatoes-paste	Canned: Boiled	0.7		5.4			5.4			1.6	0.006		1E-04	5.4		0.1		1.8	5.4	0.6		5.4			
16242	Tomatoes-paste	Frozen: Cooked	5.4		5.4			5.4			1.6	0.006		0.007	5.4		0.1		1.8	5.4	0.6		5.4			
16112	Tomatoes-puree	Cooked: NFS	3.3		3.3			3.3			1.1	0.006		0.02	3.3		0.1		1	3.3	0.7		3.3			
16114	Tomatoes-puree	Boiled	3.3		3.3			3.3			1.1	0.006		0.02	3.3		0.1		1	3.3	0.7		3.3			
16131	Tomatoes-puree	Canned: NFS	0.7		3.3			3.3			1.2	0.006		2E-04	3.3		0.1		1.5	3.3	0.7		3.3			
16132	Tomatoes-puree	Canned: Cooked	0.7		3.3			3.3			1.1	0.006		2E-04	3.3		0.1		1	3.3	0.7		3.3			
16133	Tomatoes-puree	Canned: Baked	0.7		3.3			3.3			1.1	0.006		2E-04	3.3		0.1		1	3.3	0.7		3.3			
16134	Tomatoes-puree	Canned: Boiled	0.7		3.3			3.3			1.1	0.006		2E-04	3.3		0.1		1	3.3	0.7		3.3			

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16142	Tomatoes-puree	Frozen: Cooked	3.3		3.3			3.3			1.1	0.006		0.014	3.3		0.1		1	3.3	0.7		3.3			
15911	Tomatoes-whole	Uncooked	1		1			1			1	1		1	1		1		1	1	1		1			
15912	Tomatoes-whole	Cooked: NFS	1		1			1			0.9	0.05		1	1		1		0.7	1	1		1			
15913	Tomatoes-whole	Baked	1		1			1			0.9	1		1	1		1		0.7	1	1		1			
15914	Tomatoes-whole	Boiled	1		1			1			0.9	0.05		1	1		1		0.7	1	1		1			
15915	Tomatoes-whole	Fried	1		1			1			0.9	1		1	1		1		0.7	1	1		1			
15931	Tomatoes-whole	Canned: NFS	1		1			1			0.2	0.05		1	1		1		1	1	1	1	1	1		
15932	Tomatoes-whole	Canned: Cooked	1		1			1			0.2	0.05		1	1		1		0.7	1	1	1	1	1		
15933	Tomatoes-whole	Canned: Baked	1		1			1			0.2	0.05		1	1		1		0.7	1	1	1	1	1		
15934	Tomatoes-whole	Canned: Boiled	1		1			1			0.2	0.05		1	1		1		0.7	1	1	1	1	1		
15942	Tomatoes-whole	Frozen: Cooked	0.7		1			1			0.9	0.05		1	1		1		0.7	1	1		1			
27811	Wheat-bran	Uncooked								1	0.4	1		1			3	1		4.6	1	1			1	
27812	Wheat-bran	Cooked: NFS								0.36	0.3	0.05		1			3	1		4.6	1	1			1	
27813	Wheat-bran	Baked								0.36	0.3	1		1			3	1		4.6	1	1			1	
27911	Wheat-flour	Uncooked								1	0.1	0.4		1			0.15	1		0.4	1	1			1	
27912	Wheat-flour	Cooked: NFS								0.36	0.1	0.02		1			0.15	1		0.4	1	1			1	
27913	Wheat-flour	Baked								0.36	0.1	0.4		1			0.15	1		0.4	1	1			1	
27914	Wheat-flour	Boiled								0.03	0.1	0.02		1			0.03	1		0.4	1	1			1	
27915	Wheat-flour	Fried								0.36	0.1	0.4		1			0.15	1		0.4	1	1			1	
27931	Wheat-flour	Canned: NFS								0.03	0	0.02		1			0.15	1		0.4	1	1			1	
27932	Wheat-flour	Canned: Cooked								0.03	0	0.02		1			0.15	1		0.4	1	1			1	
27933	Wheat-flour	Canned: Baked								0.03	0	0.02		1			0.15	1		0.4	1	1			1	
27934	Wheat-flour	Canned: Boiled								0.03	0	0.02		1			0.03	1		0.4	1	1			1	
27941	Wheat-flour	Frozen: NFS								0.36	0.1	0.4		1			0.15	1		0.4	1	1			1	
27942	Wheat-flour	Frozen: Cooked								0.36	0.1	0.02		1			0.15	1		0.4	1	1			1	
27943	Wheat-flour	Frozen: Baked								0.36	0.1	0.4		1			0.15	1		0.4	1	1			1	
27945	Wheat-flour	Frozen: Fried								0.36	0.1	0.4		1			0.15	1		0.4	1	1			1	
27952	Wheat-flour	Cured: Cooked(smokd/								0.36	0.1	0.4		1			0.15	1		0.4	1	1			1	
27712	Wheat-germ	Cooked: NFS								0.36	0.4	0.01		1			2.7	1		1	1	1			1	

Code (com+ff)	Commodity	Foodform	Chemical																							
			A	B	C	D	E	F	G	H	I	J	L	M	N	O	P	Q	R	S	T	U	V	W	X	Y
27713	Wheat-germ	Baked								0.36	0.4	2		1			2.7	1		1	1	1			1	
27714	Wheat-germ	Boiled								0.03	0.4	0.1		1			0.03	1		1	1	1			1	
27611	Wheat-rough	Uncooked								0.84	1	1		1			0.86	1		1	1	1			1	
27612	Wheat-rough	Cooked: NFS								0.36	0.9	0.05		1			0.86	1		1	1	1			1	
27613	Wheat-rough	Baked								0.36	0.9	1		1			0.86	1		1	1	1			1	
27614	Wheat-rough	Boiled								0.03	0.9	0.05		1			0.86	1		1	1	1			1	

Table 4-4. Co-Occurrence of Organophosphorus Pesticides on PDP Samples, 1994-1996

Commodity	Samples Analyzed	% Samples w/one or more OPs	Number of Samples with indicated Detects per Sample							
			0	1	2	3	4	5	>5	total
Apple Juice	1554	28.1	1117	405	28	4	0	0	0	437
Apples	2289	43.6	1290	506	419	67	7	0	0	999
Bananas	1126	0.0	1126	0	0	0	0	0	0	0
Broccoli	679	3.7	654	24	1	0	0	0	0	25
Cantaloupe	1234	9.3	1119	105	10	0	0	0	0	115
Carrots	1888	6.1	1772	101	14	1	0	0	0	116
Corn Syrup	454	0.0	454	0	0	0	0	0	0	0
Celery	176	52.3	84	51	39	2	0	0	0	92
Cucumbers	730	15.2	619	102	8	1	0	0	0	111
Grape Juice	1379	1.5	1358	20	1	0	0	0	0	21
Grapes	1884	24.3	1427	329	120	7	1	0	0	457
Green Beans	1178	26.7	863	84	194	35	2	0	0	315
Green Beans, canned	854	44.3	476	36	336	6	0	0	0	378
Green Beans, frozen	743	45.1	408	51	208	73	3	0	0	335
Lettuce	876	31.5	600	186	72	18	0	0	0	276
Milk	1892	0.1	1891	1	0	0	0	0	0	1
Oats, Bran	45	4.4	43	1	1	0	0	0	0	2
Oats, Rolled	287	5.6	271	16	0	0	0	0	0	16
Orange Juice	1392	10.6	1245	138	9	0	0	0	0	147
Oranges	1892	14.4	1619	252	20	1	0	0	0	273
Peaches	1087	66.2	367	492	188	37	3	0	0	720
Peaches, canned	756	1.3	746	8	2	0	0	0	0	10
Pears	1779	56.2	780	721	244	28	5	1	0	999
Pears, canned	371	0.5	369	2	0	0	0	0	0	2
Potatoes	1401	3.1	1358	40	3	0	0	0	0	43
Soybean Grain	749	55.0	337	337	74	1	0	0	0	412
Spinach	1639	23.2	1259	301	56	14	8	1	0	380
Spinach, canned	863	2.0	846	17	0	0	0	0	0	17
Spinach, frozen	715	16.1	600	102	13	0	0	0	0	115
Strawberries	1250	17.1	1036	201	12	1	0	0	0	214
Strawberries, frozen	118	24.6	89	25	4	0	0	0	0	29
Sweet Bell Peppers	716	44.8	395	72	179	54	13	3	0	321

Commodity	Samples Analyzed	% Samples w/one or more OPs	Number of Samples with indicated Detects per Sample							
			0	1	2	3	4	5	>5	total
Sweet Corn	19	0.0	19	0	0	0	0	0	0	0
Sweet Corn, canned	652	0.0	652	0	0	0	0	0	0	0
Sweet Corn, frozen	635	0.0	635	0	0	0	0	0	0	0
Sweet Peas	9	11.1	8	1	0	0	0	0	0	1
Sweet Peas, canned	746	0.0	746	0	0	0	0	0	0	0
Sweet Peas, frozen	703	24.8	529	165	9	0	0	0	0	174
Sweet Potatoes	1559	16.2	1307	241	10	1	0	0	0	252
Tomatoes	1977	37.7	1231	571	149	25	1	0	0	746
Tomatoes, canned	368	17.7	303	59	6	0	0	0	0	65
W Squash	1216	4.1	1166	38	12	0	0	0	0	50
W Squash, frozen	470	2.6	458	9	2	1	0	0	0	12
Wheat Grain	1563	63.9	564	192	619	177	11	0	0	999

Table 4-5 Permissible Crop Translations for Pesticide Monitoring Data[1]

Commodity Analyzed	Commodity translated to...	Comments
Potato	Subgroup 1-C	
Carrot	Subgroup 1-A or 1-C	
Head Lettuce	Cabbage, Chinese cabbage napa (tight headed varieties), Brussels sprouts, radicchio	All have a head morphology best represented by lettuce. All are in Subgroup 5-A except radicchio (4-A).
Broccoli	Cauliflower, Chinese broccoli, Chinese cabbage bok choy, Chinese mustard, kohlrabi	Broccoli better represents these heading, thickly stemmed and/or more branching cole crops than spinach does.
Spinach	Subgroup 4-A, Subgroup 5-B and Subgroup 4-B (except celery and fennel unless a strong case can be made)	Celery and fennel typically are excluded since residues may be higher in these crops due to the whorled, overlapping petioles which may retain spray residues.
Green Bean	Subgroups 6-A and 6-B	
Soybean	Subgroup 6-C	
Tomato or bell pepper	Group 8	All are fruiting vegetables[2].
Cucumber	Subgroup 9-B	All are cucurbit vegetables; residues in melon and pumpkin expected to be lower because of removal of rind
Cantaloupe or Winter squash	Subgroup 9-A and pumpkin	
Orange	Group 10	Fruit will be peeled before analysis by PDP.
Apple or Pear	Group 11	All are pome fruits.
Peach	Group 12, except cherries (sweet and tart)	All are stone fruits.
Grape	Kiwifruit	Based on similar cultural practices.
Wheat	Group 15, except corn, rice, or wild rice	All are small grain crops or closely related thereto
Milk	Meat	Metabolism study must indicate that residues in meat, fat, and meat-by-products will likely be equal to or lower than residues in milk. If dermal use is allowed on beef cattle, then it must be permitted and used on dairy cattle as well.

[1] The reviewer should take special note of the requirement that the use scenarios be similar among translatable commodities. The mode of application (e.g., foliar, preplant) should be the same. The label application rates and preharvest intervals should be similar. The percent of crop treated also should be similar (or lower for the crop in the "translated to" column). All residues of concern should be measured or accounted for including conjugates. Tolerances and field trial residues are to be similar, as well. The reviewer should also check with the Biological and Economic Analysis Division (BEAD) to insure that use scenarios are similar, and that agricultural practices do not differ substantially.

[2] The reviewer should be careful in checking for comparable residue levels because of weight differences in tomatoes and peppers.

Table 4-6. Summary of Probabilistic Analysis of Distribution of the Cumulative Dietary Exposures In Two Populations from Use of 24 Organophosphorus Chemicals on Food Crops with Non-Detectable Residues = 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**
Children (1-3 years)	0.000130	1347 [153]	0.000342	510 [58]	0.001057	165 [19]
Adults (18 yrs +)	0.000048	3629 [412]	0.000135	1294 [147]	0.000412	424 [48]

1. MOEs based on ED10 [NOAEL] of Chemical T (0.175 mg/kg body wt/day [0.02 mg/kg body wt/day])

Table 4-7. Summary of Probabilistic Analysis of Distribution of the Cumulative Dietary Exposures In Two Populations from Use of 24 Organophosphorus Chemicals on Food Crops with Non-Detectable Residues = ½ LOD of the Predominant Chemical for Each Commodity

	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**
Children (1-3 years)	0.000143	1219 [139]	0.000355	492 [56]	0.001069	163 [19]
Adults (18 yrs +)	0.000051	3411 [388]	0.000138	1264 [144]	0.000416	420 [48]

1. MOEs based on ED10 [NOAEL] of Chemical T (0.175 mg/kg body-wt/day [0.02 mg/kg body wt/day]).

V. Cumulative Risk from Pesticides Used in a Residential Setting

Prior to the passage of FQPA, non-dietary risk assessments were conducted under the auspices of FIFRA. As a result, the emphasis of non-dietary assessment in OPP was on occupational exposure to workers encountering pesticides on the job. The passage of FQPA placed increased emphasis on the residential exposure from pesticide uses in and around the home and required OPP to refocus its efforts on understanding household exposures to pesticides. As a result, OPP has worked to adapt existing data and techniques to permit a reasonable estimation of residential risk while developing new approaches and identifying data needs to improve the exposure assessment process for estimating risks from home and garden-type pesticides. One result of this effort was the development of screening level tools such as the *Standard Operating Procedures for Residential Exposure Assessment (12/97)* (SOPs), which were an attempt to standardize exposure calculations for residential exposures. Such procedures were not originally intended for use in aggregate or cumulative exposures.

Because of the need to provide appropriate risk estimates for inclusion in aggregate and cumulative risk assessments, proposed refinements to these initial SOPs were developed and outlined in the *Overview of Issues Related to the Standard Operating Procedures for Residential Exposure Assessment* (8/99). This document was presented to the Scientific Advisory Panel on September 21, 1999. The revised SOPs serve as a starting point for scenario development, with data from the literature and registrant submissions serving as initial surrogates for developing risk estimates in the absence of chemical-specific data. In those cases where better data are available, particularly data in the form of distributions, those more refined data may be substituted for the base-line defaults in the SOPs to improve the accuracy of the assessment. These documents along with proprietary data and other published data will be used to develop the approaches which were used in this cumulative case study.

A. Calendex Aggregate/Cumulative Software

With the FQPA requirement that aggregate exposures and cumulative risks be evaluated and the development of SOPs more amenable to application to probabilistic assessments, OPP has begun to use the software program Calendex from Novigen Sciences. Calendex was previously presented to the SAP in September 2000 and is a proprietary software program that permits estimation of exposure to single or multiple compounds for a wide variety of time periods. It is designed to allow the user to combine (i.e., aggregate and cumulate) exposure to pesticides in a probabilistic manner that incorporates information relating to both the temporal and spatial aspects of exposure.

The Calendex program is based on a general exposure model of the form

Contact x Residue = Exposure

For example, for a dermal exposure calculation, the contact might be expressed in cm^2/hour and residue might be expressed in mg pesticide/cm^2 of surface contacted. The product of these would be an exposure estimate expressed in mg/hr. The Calendex program requires the user to enter formulae (in a spreadsheet-style format) based on the above general exposure model, which produce numerical estimates of exposure, effectively building the exposure scenarios from a variety of information sources. Importantly, the input parameters can be expressed as point estimates, distributional estimates, or a combination of both. In addition, inputs for the residue component of the general equation can consist of a time series of residue concentrations (e.g., Application Day residues, Day 1 residues, Day 2 residues, etc), which will be considered *as a time series* by the Calendex software. Currently, the Calendex model can accommodate 25 scenario-specific data files. This example case-study assessment uses 22.

In the current case study, the estimated exposures to each pesticide were converted to Chemical T equivalents using route specific RPFs (Table 4-1). Exposures were compared to route specific PoDs to develop the resulting route specific and total MOEs. PoDs for this assessment were taken from the data set for Chemical T and reflect plasma cholinesterase inhibition in male rats: oral ED10 = 0.175 mg/kg body wt/day or NOAEL = 0.02 mg/kg body wt/day; dermal NOAEL = 1 mg/kg body wt/day; inhalation NOAEL = 0.026 mg/kg body wt/day.

B. Development of Residential Aspects of Case Study Example

In developing this case study, the residential exposure component of Calendex was used to evaluate predicted exposures from residential uses. The data inputs to the residential exposure assessment come from a variety of sources including the published, peer reviewed literature and proprietary data submitted to the Agency to support registration and re-registration of pesticides. The use of data is consistent with OPP's current risk assessment policy for single chemical assessments. The purpose of this case study is to explore approaches which may be common to all scenarios, identify strengths and weaknesses of those approaches, and to help identify the types of data needed to refine future cumulative assessments. The case study should not be considered as an indication of any Agency findings with respect to the pesticides examined or of any future actions by OPP. This assessment is limited to the home as are most current single chemical assessments. Additional work is needed to account for an individual’s time spent in areas outside of the home (e.g., schools, workplace, etc.).

As stated earlier, the geographic region associated with the estimates presented in this case study is the Piedmont region of North Carolina and was assumed to apply to the Mid-Atlantic region (VA, NC, SC) for which this case study is presented. The residential component of the case study will incorporate dermal, inhalation, and non-dietary ingestion exposure routes which result from applications made to residential lawns (dermal and non-dietary ingestion), indoor crack and crevice sprays (inhalation) and exposure from self-applied treatments to shrubs (dermal and inhalation). These scenarios were selected because these uses are common among the compounds selected for this exercise, and because there are data available for assessing potential exposures. This approach also allows the inclusion of both indoor and outdoor uses and exploration of seasonal changes in exposure levels. Not all of the seven compounds have registered uses on turf. Therefore, a shrub use was selected to include the two pesticides that did not have turf grass use patterns. OPP recognizes that there are several other exposure scenarios that have not been addressed for this example and that will be included in future cumulative exposure assessments.

A number of application scenarios for each of the seven OP pesticides are modeled. In many of the cases (described below), surrogate data were critical to developing the OP cumulative case study. For example, some of the surrogate data is obtained from PHED (Pesticide Handler Exposure Database), an OPP database which links unit exposure to a pesticide (in mg/lb a.i. handled) to the type of application which is performed (e.g., application of granular formulations by hand, liquid concentrate application by low pressure handwand, etc.). The PHED database takes advantage of the fact that, for many pesticides, the physical parameters of pesticide application methods and formulations have a greater impact on potential human exposure than the characteristics of the chemical itself. PHED extrapolates likely exposures to pesticide formulations from existing data on other, similar formulations with similar application practices. This approach has a long history of use in the evaluation of agricultural chemicals and has been extended to the arena of home use products. Exposure values from PHED are normalized by mg per pound of pesticide active ingredient (a.i.) handled during the mixing, loading, or application activity. Unit exposures are available for the dermal and inhalation routes. OPP anticipates that these types of data will be important components of future cumulative assessments developed for regulatory purposes. The use scenarios reflected in the case study are broken out below with the types and sources of surrogate data used for each described. Similar data generated by the Outdoor Residential Exposure Task Force (ORETF) were used to estimate exposures while applying pesticides using hose-end sprayers and granular spreaders.

C. Application Scenarios

A major portion of the data inputs into the model estimate for residential exposure is specific to the characteristics of the applications scenarios, but common across all chemicals used within that scenario. These scenario-specific issues are discussed below.

1. Applicator Exposure to Consumer Applied Pesticide Treatments

Granular Dispersal by Hand - The data used in this assessment are based on values from PHED. It reflects the results from volunteers applying granular bait formulations by hand around driveways in residential settings. There are 16 replicates in this surrogate data set, but the hand values were collected based on individuals wearing protective gloves., hand exposure was estimated for bare hands using residues measured on the hands beneath the gloves by assuming a 90% protection factor afforded by gloves.

Low Pressure Handwands - The dermal unit exposure value for low pressure hand-wands represents individuals spraying mid-level shrubs and ornamentals on greenhouse benches. These data were obtained from PHED. Exposure values from these data sources are normalized by mg per pound of pesticide active ingredient (a.i.) handled during the mixing, loading, or applying activity. Unit exposures are available for the dermal and inhalation routes. In PHED, there are 70 replicates for the hands and 8 to 90 replicates for other parts of the body. The dermal data represent an individual wearing short pants, a short sleeved shirt, and shoes. Hand exposure represents ~99% of the total dermal exposure.

Granular Formulations Using Push-Type Rotary Spreaders - Data from the Outdoor Residential Exposure Task Force (ORETF) was used to represent exposure while applying pesticides in granular forms to lawns using a push-type rotary spreader. These application systems represent the most likely methods of applying pesticides to turf grass by consumers. The granular study consists of 30 volunteers applying 50 pounds of product to treat 10,000 square feet of turf grass. Volunteers participating in these exposure studies were adult non-professionals that use pesticides on their own lawns and gardens. Many of the volunteers selected as subjects in these studies are members of garden clubs. For reasons of simplicity for this case study example only, the data from this study were used to develop a uniform distribution of measured exposures bounded by the high and low values. In the future, OPP would anticipate using distribution fitting techniques to better approximate actual exposure distributions.

Spray Formulations Using Garden Hose-end Sprayers **-** For the hose-end uses in this case study, a PHED study involving 30 volunteers applying pesticides using a hose-end sprayer that required pouring the pesticide into the hose-end device was used. These same volunteers also used a hose-end device that was "pre-loaded" with pesticide. This product is referred to as "ready to use". For reasons of simplicity for this case study example only, the data from this study were used to develop a uniform distribution of measured exposures bounded by the high and low values. In the future, OPP would anticipate using distribution fitting techniques to better approximate actual exposure distributions.

2. Post Application Exposure to Consumer Applied Pesticide Treatments or Treatments Made by Professional Lawn Care Operators (LCOs)

Dermal Exposure to Residues on Lawns - There are three exposure studies used to assess post application dermal exposure to children reentering treated lawns. These studies represent dermal exposure values of young children exposed to a nontoxic substance performing unscripted activities and exposure values of adults exposed to pesticides while performing structured activities designed to mimic the activities of young children.

In the first study, children performed unscripted activities on turf grass treated with a non-toxic substance used as a whitening agent in fabrics and a set of transfer coefficients were derived (Black 1993). The subjects of the study were 14 children aged 4 to 9 years old. The children performing the unstructured activities were provided toys and observed in the treated area for a period of one half hour. Recorded activities were classified as follows: upright (standing, walking, jumping and running); sitting (straight-up, cross legged, kneeling, crouching and crawling); and lying (prone or supine). In this study, dermal exposure was measured by fluorescent measurement technology described in Fenske et al. (1986). Measurements of various body parts were expressed as µg/body part (e.g., concentration on hand or face (µg/cm^2)). These concentrations were normalized to represent the surface area of children 3 to 4 years of age for use with a standardized body weight of 15 kg. Standard surface area values were taken from the Agency's *Exposure Factors Handbook*. Turf transferable residue (TTR) measurements from Black (1993) were not adjusted since the wipe method used by the investigator had a similar transfer efficiency as the methods used in the proprietary TTR data.

In the second set of studies, adults performed structured activities of picnicking, sunbathing, weeding, playing frisbee and touch football for a period of four hours. These proprietary studies were performed by volunteers exposed to lawns treated with granular and liquid formulations of a pesticide and reported in the literature as Vaccaro et al. (1996) *The Use of Unique Study Design to Estimate Exposure of Adults and Children to Surface and Airborne Chemicals*. In these structured activity studies, dermal exposure values and/or internal doses were obtained via biological monitoring of urinary metabolites of pesticides.

These studies were used to assess adult post application exposure to lawn chemicals and (following appropriate scaling for body weights) children's post application exposure to lawn chemicals. Internal doses were estimated assuming specific dermal absorption values and standard body surface areas and were normalized as hourly exposures (µg/hr). The hourly exposures were used to develop transfer coefficients (TCs) as per the following formula:

Transfer Coefficient (cm^2/hr) = hourly dermal exposure (µg/hr) ÷ TTR ($\mu g/cm^2$)

TTRs were estimated based on the application rates used in the studies and transfer efficiency rates commensurate with the residue collection methodology observed in the chemical specific TTR dissipation studies used in this case study. The TC s were adjusted to the surface area of a 3-4 year old child based on values in EPA's *Exposure Factors Handbook*. For a more detailed discussion of transfer coefficients and TTRs please refer to the *Overview of Issues Related to the Standard Operating Procedures for Residential Exposure Assessment* presented to the FIFRA Scientific Advisory Panel on September 21, 1999. It should be noted that TC s based on the choreographed activity Jazzercise™ are not being used in this assessment. The Agency believes Jazzercise™ is a valuable tool for assessing single route exposures in screening level assessments but of limited value for addressing more realistic exposures useful in aggregate and cumulative assessments.

Both the Black and Vaccaro data were combined and, for purposes of this case study example, a uniform distribution of TTR developed (bounded by the high and low TTR estimates obtained from the Black and Vaccaro data). A uniform distribution was selected, in part, due to the uncertainty of the types of activities that may be representative of exposure experienced by the general population after a lawn treatment. In the future, OPP anticipates using more formal distribution fitting techniques.

Non-dietary Exposure Through Hand-to-mouth Behavior - Surrogate data to evaluate non-dietary ingestion through hand-to-mouth behavior in young children consists of observations reported in Reed et al. (1998). This study addressed mouthing behavior and other observations of children, ages 3-6 at day care (n=20) and children ages 2-5 at home (n=10). The frequencies of the hand-to-mouth events reported were a mean of 9.5 events per hour, a 90th percentile of 20 events per hour and a range of 0 to 70 events per hour. The children were video taped and the frequency of hand-to-mouth events was enumerated after the taping.

The observations reported by Reed are based on children in real world settings. However, they provide little information regarding the characterization of the hand-to-mouth event, residue transfer efficiency or extraction efficiency by saliva during the mouthing event. For these values, additional assumptions and studies are discussed as follows:

- Based on previous interactions with the SAP, each hand-to-mouth event equals 1 to 3 fingers (6.7 - 20 cm^2) per event. To account for the fact that a child may touch nothing between successive events, and the fact that the event may not result in insertion of fingers at all (Kissel et al., 1998), a range of 0 to 20 cm^2 per event was assigned. These distributions were entered into Calendex as uniform distributions.

- Hands wet from saliva are reportedly more efficient at residue transfer than dry hands. A range of transfer efficiencies of 0.1 to 5% was used for this variable based on a study evaluating the transfer efficiency of three pesticides by saliva wetted palms (Clothier 1999). This range was entered into Calendex as a uniform distribution.

- Studies of the removal of residues on hands by saliva and other substances (e.g., ethanol) suggests a range of removal efficiencies from 10% to 50% (Geno et al., 1995; Fenske and Lu 1994; Wester and Maibach 1989; Kissel et al., 1998). This range was entered into Calendex as a uniform distribution.

The contribution to total exposure via non-dietary ingestion continues to be difficult to quantify. This includes the variables discussed above as well as issues regarding the utility of using children's frequencies based on indoor activities for outdoor exposure scenarios and the limited data on very young children (e.g., under 2 years). Limited data evaluated by Groot et al. (1998) suggest longer durations of mouthing activities for children aged 6 to 12 months (exceeding 160 minutes per day) than children 18 to 36 months (up to 30 minutes per day) There are also issues regarding the frequency of mouthing events based on active or quiet play. The incorporation of object to mouth activity also needs to be addressed and will be explored in future assessments. However, modeling this behavior has the same problems as the hand-to-mouth behavior model. More research is needed is evaluating the distribution of behaviors across different age ranges with a view towards the influence of factors such as socio-economic status.

D. Other Data and Assumptions

A variety of additional ancillary data was required for this assessment. An overview of these data is detailed below.

Turf Residue Dissipation Data - The fate of pesticides applied to turf is a key variable for assessing post application exposure. TTR data are available for the five compounds selected for this case study that have or have had registrations on residential lawns. These data are based on the highest use rate permitted on the label. Dissipation data are available for Chemical U, Chemical T, Chemical C, Chemical B, and Chemical P. Data is either proprietary or available in the published literature (Goh et al., 1986 and Black 1993).

Indoor Air Concentration Data - Indoor air concentration data are available for two of the three compounds representing the crack and crevice uses presented in this case study. Proprietary data or data from the published literature are available for Chemical P or Chemical T (Leidy et al., 1982). Data were not readily available for Chemical C. However, air concentration from a study evaluating air concentrations of bendiocarb in offices following broadcast applications was used as a surrogate for Chemical C (Currie et al., 1990). Bendiocarb has a similar yet slightly higher vapor pressure than Chemical C. Although the use of data from a broadcast application may overstate the magnitude of the air concentration from a crack and crevice use, the similarity in vapor pressure was deemed a more significant factor in selecting a surrogate for Chemical C than matching the use pattern. The use of a surrogate compound having a low vapor pressure may be more appropriate for estimating inhalation exposures for Chemical C than using data from moderately volatile compounds such as Chemical P and Chemical T which have much higher vapor pressures than both bendiocarb and Chemical C.

Duration of Exposure - Distributions of time spent outdoors and time spent in kitchens were used in the assessments for lawn treatments and indoor crack and crevice treatments. These values were taken from EPA's *Exposure Factors Handbook*. Specific values and sources are delineated in the documentation in the scenario-specific data files.

Lawn Sizes - For the lawn scenario, a number of estimation processes were used. Values presented in Vinlove and Torla (1995) for the average and median lawn sizes for North Carolina were considered: 13,092 and 12,991 square feet, respectively. Although limited data are available to estimate this variable, the authors relied on statistics regarding lot sizes available from the U.S. Department of Housing and Urban Development. The data are from a collection of appraisal forms for FHA loans. An approach to using this data is to adjust the lot size to the "footprint" of any structures found on the lot. The authors also noted additional uncertainties regarding these estimates, including the fact that FHA loans typically represent the lower spectrum of the housing market and don't consider additional reductions in lawn size by paving and other green space such as shrubs, trees, ground cover and gardens. According to the authors, these items can reduce lawn size up to 50 percent as observed in surveys conducted in the northeastern United States. Additional survey data are needed to address this variable since assumptions regarding lawn sizes play a key role in estimating the amount of pesticide a consumer may apply. For the purposes of this assessment, lawn sizes will be bound at a minimum of 500 square feet (e.g., townhouses) and a maximum of 15,000 square feet, which is similar to the mean and median values minus the assumptions regarding additional paving, structures such as decks, and other green space. A uniform distribution between the low bound of 500 square feet and the high bound of 15,000 square feet was used in this assessment.

Pesticide Use Data - This data category broadly addresses information needed to predict what kind of pesticide will be used, the amount of pesticide used, by whom, at what time, how many times and for how long. All of these factors, coupled with exposure and chemical fate data, are needed to predict the potential for co-occurrences of exposure events in aggregate and cumulative risk assessments. Proprietary survey data that are being developed are anticipated to be helpful in future assessments. For the case study, an estimation approach using professional judgement was used to gain an understanding of model function and illustrate how use information can be employed in refining cumulative assessments.

National Gardening Survey (1996-97) - This is a study conducted by the Gallup Organization for the National Gardening Association. This source indicated that 46 percent of households in the South participated in do-it-yourself lawn care, without specific mention of the use (or non-use) of pesticides. For this assessment it was assumed that all of the households participating in do-it-yourself lawn care do apply pesticides. The survey makes a distinction between the deep South (e.g., Florida) which has a higher participation rate (50%) than the rest of the South (44%). Detailed survey information will likely play an important role for this aspect of identifying potentially exposed populations.

To determine what proportion of applications are made by consumers versus professional lawn care operators (LCO), information from the Professional Lawn Care Association of America regarding the percentage of applications of herbicides made by do-it-yourself applicators and professionals indicated that the split was approximately 60% and 40%, respectively. To facilitate the use of this model, the 60/40 split for consumer/professional applications reported for herbicide use was assumed to apply to insecticide uses as well, although the Calendex used does permit differentiation and separation of these two uses.

There are several pesticides available to control pests in lawns. To determine the identity of the specific pesticides used and the percentage of pesticide users making applications of these specific pesticides, several sources were used.

The primary source was the 1993 Certified/Commercial Pesticide Applicators Survey, Volume 1. This document contains several categories of pesticide use including distinctions made by application site (e.g., lawns) and pest to be controlled (e.g., fleas). The survey primarily reported the number of pounds sold by site and pest. This survey did not address specific aspects of amount of a.i. per treated area or frequency of use. In addition, the amount of a.i. needed to control a given pest differs by compound (e.g., the difference in amount needed to treat a pest with cypermethrin versus chlorpyrifos.). The survey data also did not address multiple active ingredients, which is key to appropriately identifying typical co-occurrences of active ingredients. Regardless, percent use values were assigned to the various pesticides in the case study to explore the use of the model. Another source of information considered (but not necessarily used) to assign percent use was the North Carolina State Pesticide Recommendations indicating a wide range of pesticide and non-pesticide options and efficacy data, which would more likely influence pesticide selections made by professional applicators.

For the other uses (shrub care, crack and crevice use), a similar approach was followed. For example, the *National Garden Survey* suggested 21% of households in the South participate in do it yourself shrub maintenance. A higher participation in the deep South was also seen in this category. Since the *National Garden Survey* does not track crack and crevice uses, it was assumed in this case study that half of the households used treatments by a professional pest control operator (PCO). This selection of 50/50 was selected as a default in the absence of specific data. Survey data are also needed to identify populations of exposed individuals. Assumptions regarding the PCOs use of certain pesticides for the crack and crevice treatment were based on pounds of a.i. sold as reported in the Certified/Commercial Pesticide Applicator Survey.

Pesticide Application Timing - Professional applications by either lawn care companies (by LCOs) or exterminators (by PCO) were assumed to occur exclusively during weekdays, with application on each weekday assumed to occur with equal probability. Self-applications were assumed to occur during the weekend with Saturday and Sunday applications occurring with equal frequency (or probability).

Seasonal Use Patterns - The seasonal use of pesticides in turf grass is primarily keyed to the appearance of pests. In cool season turf grasses (e.g., Kentucky blue grass) white grubs are a major pest whereas mole crickets are a major pest in warm season grasses (e.g., Bahia grass). Although both are grown in North Carolina, cool season grasses were selected for this case study. Warm season turf grasses appear to be more likely grown along the coastal areas of North Carolina.

It is assumed that the window of pest appearance dictates the potential for a pesticide treatment. To identify potential pest treatment periods, the North

Carolina State recommendations delineating time periods for scouting turf grass pests were used. This impacts handler assessments and post-application assessments. Due to the limitation on scenario-specific data files, one site-pest combination was assessed per chemical.

Other Exposures - There are no post application exposure scenarios for individuals mowing grass and golfing included in this case study example. However, the range of transfer coefficient developed from Black (1993) and Vaccaro (1996) bracket the transfer coefficients observed in other studies measuring those exposures. OPP is exploring ways to allocate time at the home and other locations to address these potential exposures.

E. Detailed Data File Descriptions

Specific assumptions for the following pesticides are presented as follows:

Chemical C - Pesticide C is used to control chinch bugs on residential lawns which may appear from June to September. The application is via a hose-end sprayer and, for this mode of application, label instructions provide for an application rate of between 1 and 2.5 lbs a.i/acre. Chemical C can also be used for in home crack and crevice treatments via a PCO.

For the lawn treatment scenario, three modes of exposure (oral, inhalation, and dermal, as appropriate) by Chemical C were considered. Application could be made by either a PCO (40% of the time) or by the homeowner (60% of the time). Chemical C was assumed to be applied to lawns to control chinch bugs during a randomly selected weekday (in the case of professional applicators) or a randomly selected weekend day (in the case of self-application) during the month of June. No re-application was assumed to occur. Per the *National Gardening Survey* discussed above, a total of 46% of households participate in lawn care activities, and Chemical C was assumed to be applied to 20% of those lawns. The application rate (via hose-end sprayer) was assumed to be at the maximum label rate, or 2.5 lbs ai/acre. A proprietary residue dissipation study was conducted on Bahia grass in Florida with multiple residue measurements collected for 10 days after treatment (Days 0, 1, 2, 3, 5, 7, and 10 days). No half-life value or other degradation parameter was used, with the current assessment based instead on the time-series distribution of actual residue measurements. Residues measured at Day 10 in the proprietary study were assumed to be available and persist through Day 14 (i.e., the residue concentrations measured at 10 days was assumed to persist unchanged until 14 days post-application). An active exposure period of 14 days was entered into the Calendex software.

Chemical C was also assumed to be used for crack-and-crevice treatment by PCOs as part of a regularly scheduled monthly maintenance treatment throughout the year (no self-application was assumed) with this being applied to

3.5% of households. Only post-application inhalation exposure to occupants was assessed. Post-application inhalation exposure was assessed using surrogate data for Day 0, 1, 2, and 3 air concentrations from a pesticide having a similar vapor pressure and applied as a broadcast treatment (Curry, 1990). This study resulted in a Day 0 air concentration of 0.003 mg/cubic meter which was presumed to persist unchanged for three subsequent days. This post-application inhalation exposure was entered into Calendex as a point estimate (i.e., concentrations of 0.003 mg/cubic meter on Days 0, 1, 2, and 3) with an active exposure period of 3 days (implying concentrations of zero on subsequent days until reapplication)

Chemical U - Chemical U is not recommended for major turf pests in North Carolina and thus in this case study was assumed to be used only to control fleas on turf. In future assessments, this scenario should be tied to population of pet owners such that use is limited to only the pet-owning subpopulation. The application is via a spray and, for this mode of application, label instructions provide for an application rate up to 5 lbs a.i/acre.

For the current cumulative assessment, three modes of exposure (oral, inhalation, and dermal, as appropriate) by Chemical U were considered. Chemical U was assumed to be applied once during the months of March and April by either a LCO (40% of applications) or home-owner (60% of applications), with a re-application 30 weeks later during the months of October and November. Per the *National Gardening Survey*, a total of 46% of households participate in lawn care activities, and Chemical C was in this case study assumed to be applied via hose-end sprayer to 2% of those lawns at the maximum label application rate of 5 lbs ai/acre. A residue degradation study was based on a 3-day study conducted on a cool-season grass in Pennsylvania (application rate of 5 lb ai/acre). These measured residue values were entered into the Calendex software as a time series distribution of 4 values (Days 0, 1, 2, and 3). Measured Day 3 residues were assumed to be available and persist for 7 days post application before declining to zero on Day 8 and subsequent days (i.e., an active exposure period of 7 days was entered into Calendex).

Chemical T - Chemical T is used to control white grubs on residential lawns with spray or granular treatments. The label instructions provide for an application rate of up to 4 lbs a.i/acre. Chemical T can also be used for in home crack and crevice treatments via a PCO as monthly maintenance.

For the lawn treatment application, three modes of exposure (oral, inhalation, and dermal, as appropriate) by Chemical T were considered. Chemical T was assumed to be applied once during the month of March through May. As described in the *National Gardening Survey* discussed above, a total of 46% of households participate in lawn care activities, and Chemical T was assumed to be applied to 30% of those lawns. The application rate (via granules) was assumed to be 4 lbs a.i./acre. The residue dissipation characteristics used in this case study were based on a study in which a spray application rate of 4 pounds per acre was used in North Carolina. Although no residues were detected in the North Carolina dissipation study after the day of application, Day 0 measured residues in the North Carolina dissipation study were assumed for this case study to be available and persist for 7 days following application. A value of 7 days was therefore entered into Calendex as the maximum active exposure period.

Chemical T was also assumed to be used for crack and crevice treatment by PCOs as part of a regularly scheduled monthly maintenance treatment throughout the year. It was assumed to be applied to 1.9% of households. Post application inhalation exposure was assessed using data available in the published literature for applications made to dormitory rooms and not kitchens as is the scenario for this case study (Leidy, 1992). Air concentration measurements were made up to 21 days after application. These residues were entered into the Calendex program as a time series distribution of measurements. The measured residues on Day 21 were assumed to be available for the remaining days of the month. For Chemical T, an active exposure period of 30 days was assumed.

Chemical P - Chemical P is used to control white grubs on residential lawns with spray or granular treatments. The application is via a hose-end sprayer and, for this mode of application, label instructions provide for an application rate of up to 4 lbs a.i./acre. Chemical P can also be used for in-home crack and crevice treatments via a PCO as monthly maintenance.

For the lawn treatment scenario, three modes of exposure (oral, inhalation, and dermal, as appropriate) by Chemical P were considered. Chemical P was assumed to be applied by a LCO (40% of applications) or homeowner (60% of applications) once during the month of March, April, May or June. As before, the *National Gardening Survey* estimates that a total of 46% of households participate in lawn care activities, and Chemical P was assumed to be applied to 10% of those lawns. The application rate (via hose-end sprayer) was assumed to be 4 lbs a.i./acre, the label-specified maximum application rate. The residue dissipation study used in this case study was based on a spray application rate of 4 lbs a.i./acre in a study conducted in New Jersey (Black 1993) in which residue measurements were collected on Days 0, 1, and 2. These residues were entered into Calendex as an time series distribution. Although no residues were measured in the New Jersey study after the second day of the application, Day 2 residues as measured by Black were assumed to be available and extend to 7 days post application in the current case study example. A value of 7 days was thus entered into Calendex as the active exposure period.

Chemical P was also assumed to be used for crack and crevice treatment by PCOs as part of a regularly scheduled monthly maintenance treatment throughout the year. It was assumed to be applied to 12.5% of households.

Post application inhalation exposure was assessed using proprietary data for pesticide applications made to kitchens. Measurements were made up to 10 days after application. These measured residue values were entered into Calendex as a time series distribution, with the Day 10 measured values assumed to be available, and persist, for one month. An active exposure period of 30 days was entered into Calendex.

Chemical B - Chemical B is not recommended for major turf pests in North Carolina and thus in this case study was assumed to be used only to control fleas. In future assessments (as with Chemical U) this scenario should be limited to only the pet owning subpopulation. The application is via hose-end sprayer and, for this mode of application, label instructions provide for an application rate of up to 2 lbs a.i/acre.

For the current cumulative assessment example, three modes of exposure (oral, inhalation, and dermal, as appropriate) were considered. Applications were assumed to occur on turf during March and April and again thirty weeks later during October or November. A total of 46% of all households participate in lawn care activities with Chemical B being applied to 2 percent of those lawns. This chemical was assumed to be applied by either LCOs (40% probability) or by the homeowner (60% probability). The application rate assumed in this case study is the maximum label rate, or 2 lbs a.i./acre via spray treatment. The residue dissipation used here was based on an a study available in the published literature (Goh et al., 1986). In this dissipation study, no material was detected after 24 hours. For this case study, however, it was assumed that the Day 0 (application day) measured residues were available for one week and a time series distribution of residue data were entered into Calendex with an active exposure period of 7 days.

Chemical I - Chemical I is used for shrub care. The application is via a granular dispersion applied by hand. The label indicates that treatment can be repeated after 6 weeks.

For the current cumulative assessment, the dermal and inhalation modes of exposure by Chemical I were considered for applicators only (no post-application exposures were assumed). Chemical I was assumed to be applied during the months of April through May by the homeowner (no professional applications) with a re-application 6 weeks later during the months of May, June, or July. Per the *National Gardening Survey*, a total of 21% of households participate in do-it-yourself shrub maintenance, and Chemical I was assumed to be applied in 25% of these households. The hand application was assumed to be at a rate of 0.001250 lbs a.i./bush and treatment was assumed to be of between one and 20 bushes per day (uniform distribution between 1 and 20)

Chemical V - Chemical V is also used for shrub care. The application is via spray treatment.

For the current cumulative assessment, the dermal and inhalation modes of exposure by Chemical V was considered for applicators only (no post-application exposures were assumed). Chemical V was assumed to be applied during the months of April through May with a re-application six weeks later during the months of May, June, or July. A total of 21% of households participate in do-it-yourself shrub care activities, and Chemical V was assumed to be applied to 25% of those lawns (no professional application was assumed). The hand application rate was assumed to occur at a rate of 0.001250 lbs per bush with between one and twenty bushed being treated (uniform distribution between 1 and 20).

F. Results

The Gaant chart shown in Figure 5-1 displays and summarizes the various residential applications and their timing (including repeated applications) over the course of a year.

Figures A-1 through A-10 in Appendix present the results of this cumulative risk analysis for Children, 1-3 years and Adults, 18+ years under the scenario in which the oral ED10 is used to estimate exposures through the oral route. Appendix C presents these same figures (labeled Figures B-1 through B-10) except use the oral NOAEL to estimate risk (instead of the ED10). The following paragraphs describe, in additional detail, the exposure profiles for Children, 1-3 years and Adults, 18+ years for a variety of percentiles (50th, 90th, 95th, 99th, and 99.9th percentiles) and each of the individual plots which have been produced in this case-study example. This discussion represents the unmitigated exposures (i.e., exposures which have not been attempted to be reduced by discontinuing specific uses of pesticides). Section VII of this document presents additional scenarios in which various uses are removed in an effort to estimate the effect on total cumulative exposure of potential mitigation actions.

1. Oral ED10 = 0.175 mg/kg/day

<u>Children, 1-3 years, MOEs at 50th percentile (Figure A-1)</u>: This figure presents the 50th percentile time course of exposure (expressed as MOEs) for Children, 1-3 years. That is, the median (or 50th percentile) exposure (by each pathway or route) is estimated for each of the 365 days of the year, with each of these median exposures plotted. The result is a "time course" of exposures representing exposures throughout the year. As can be seen, exposures at this percentile are exclusively from dietary (food + water) exposure. No exposures from lawn treatment applications or crack and crevice treatments (exclusively inhalation) are apparent at this percentile.

<u>Children, 1-3 years, MOEs at 90th percentile (Figure A-2)</u>: This figure presents the 90th percentile time course of exposure (expressed as MOEs) for Children, 1-3 years. Here, inhalation exposures from the crack and crevice treatment begin to enter into the assessment, and are substantially greater (or MOEs are substantially lower) than exposures from dietary exposure. As indicated previously, a substantial number of homes (50%) are assumed in this assessment to receive crack and crevice treatment by a PCO. The total (through all pathways) cumulative exposures at this percentile produce an MOE of approximately 500 and varies little throughout the year. This is consistent with the assumption that retreatment occurs monthly.

<u>Children, 1-3 years, MOEs at 95th percentile (Figure A-3)</u>: This figure presents the 95th percentile time course of exposure for Children, 1-3 years. The exposure profile and relative contributions have changed little: inhalation exposures are still the major contributor to the total, with total cumulative exposures at this percentile producing an MOE of approximately 300. The magnitude of exposure varies little throughout the year. At this percentile, exposure from non-dietary oral ingestion begins to be apparent during the time period from March to May (i.e., Julian days 80 to 169). This corresponds to lawn treatment applications for grubs.

<u>Children, 1-3 years, MOEs at 99th percentile (Figure A-4)</u>: Shown here is the 99th percentile time course of exposure for Children, 1-3 years. Dramatic changes in the exposure profile and relative contributions begin to appear here. The total MOE here now is less than 100 throughout the entire year and is reasonably constant at about 40-50. Predicted dietary exposures (as measured by the MOE) at the 99th percentile increase approximately three-fold compared to dietary exposures at the 95th percentile, and inhalation exposures increase by about six-fold at this percentile. While dietary and inhalation exposures vary little throughout the year, a dramatic shift in the exposure profile occurs in that dermal and

non-dietary oral exposures during the months of March to May (Julian Days 72 through 156). These months correspond to treatment by Chemical B and U for fleas and Chemicals T and P for grubs. In this time period, dermal MOEs are as high as approximately 170 and oral non-dietary MOEs are as high as 1800, but in both cases these MOEs (even when summed) are less than 100. The appearance of these exposures via these pathways (and only at higher percentiles) is expected since children, as per OPP Residential SOP's and the formulae entered into Calendex, are assumed to play on the lawn (dermal exposure), engage in hand-to-mouth activities, and eat grass (non-dietary oral).

The major contributor to total cumulative exposure at this percentile, however, remains inhalation. MOEs from this pathway range from 50 to 70 and are below 100 throughout the year[1]. There are three products in use for in-home PCO crack and crevice treatment: Chemical C (applied to 3.5% of households); Chemical T (used in 1.9% of households); and Chemical P (12.5% of households). It is not apparent from these time profiles, at this stage of the analysis, which of these pesticide uses, if any, is a significant contributor to these inhalation exposures, although as noted above, Chemical C has a substantially lower vapor pressure than Chemicals P and T.

Children, 1-3 years, MOEs at 99.9th percentile (Figure A-5): Shown here is the 99.9th percentile time course of exposure for Children, 1-3 years. Here, too, dramatic changes in the exposure profile and relative contributions are apparent. Predicted dietary exposures (as measured by the MOE) at the 99.9th percentile increase approximately two to three-fold compared to dietary exposures at the 99th percentile, and inhalation exposures increase approximately five-fold to 5-10 at this percentile (and remain at this level throughout the year). As at previous percentiles, dietary and inhalation exposures vary little throughout the year. Dermal exposures, which were considerably lower than inhalation exposures at the 99th percentile, are now increased by more than an order of magnitude and are on a par with (and often exceed) inhalation exposures during the months of March to May (Julian days 71-160). This time period corresponds to grub and flea treatment season treatment by Chemicals B, T, and P. These exposures fall off dramatically as this time window of treatment closes.

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[1] It is important to note that the phrase "MOEs [remain] below 100 throughout the year" does NOT mean that any specific individual or collection of individuals will experience MOEs of this magnitude over the long term (e.g., throughout the month, treatment season, or year), but rather that the *99th percentile individual* on any given day receives exposures that reflect MOEs of less than 100.

Additional dermal and non-dietary oral exposures are seen to occur during the month of October and November (Julian Days 286 to 336), although these are at MOE's that are two or three orders of magnitude higher than the first exposures during the spring season at the beginning of the year. These exposures correspond to a second treatment for fleas that occurs 30 weeks after the first treatment. It is notable, too, that these exposures did not occur at the 99th or lower percentiles and that they show significant oscillation and variation (more than an order of magnitude). Overall, however, these exposures are still low compared to the inhalation and dietary routes.

Adults, 18+ years, MOEs at 50th percentile (Figure A-6): This figure presents the 50th percentile time course of exposure (expressed as MOEs) for Adults, 18+ years. As can be seen (and as was true with children 1-3), exposures at this percentile are exclusively from dietary (food + water) exposure. No exposures from lawn treatment applications or crack and crevice treatments are apparent at this percentile. The MOE associated with this exposure route is approximately 3400, and varies little.

Adults, 18+ years, MOEs at 90th percentile (Figure A-7): This figure presents the 90th percentile time course of exposure (expressed as MOEs) for Adults, 18+ years. Here, inhalation exposures from the crack and crevice treatment begin to enter into the assessment, and are substantially higher than exposures from dietary exposure. No exposures through the dermal route are apparent. As indicated earlier in this document, 50% of homes are assumed in this assessment to receive crack and crevice treatment by a PCO. The total cumulative exposures at this percentile represent MOEs of approximately 500 and remain essentially constant throughout the year.

Adults, 18+ years, MOEs at 95th percentile (Figure A-8): This figure presents the 95th percentile time course of exposure for Adults, 18+ years. The exposure profile and relative contributions have changed little from those observed at the 90th percentile: inhalation exposures are still the major contributor to the total, with total cumulative exposures at this percentile represented by MOEs of approximately 300. Dietary exposure represents a still smaller fraction of this total, with MOEs of approximately 1800. Exposures through the dermal route are not reflected in the assessment. The total cumulative MOE of approximately 300 varies little throughout the year.

Adults, 18+ years, MOEs at 99th percentile (Figure A-9): Shown here is the 99th percentile time course of exposure for Adults, 18+ years. Dramatic changes in the exposure profile and relative source contributions begin to appear here. The total MOE drops below 100, but only during the grub/flea/chinch season. This is in contrast to the MOEs for Children, 1-3 years at this percentile which are below 100 throughout the entire year. During the remainder of the year, MOEs for adults at this percentile hover at just below 100. MOEs associated with predicted inhalation exposures decrease from about 350 at the 95th percentile to the range of 120 to 160 at this percentile. While dietary and inhalation exposures vary little throughout the year (i.e., are essentially constant), a significant dermal exposure appears during the months of March to May (Julian Days 72 through 156), corresponding to treatment by Chemicals B and U for fleas and Chemicals T and P for grubs. It is this dermal exposure which is responsible for the incursion of MOEs below 100. Considered alone, however, dermal MOEs themselves never decrease to levels below 100. A second dermal exposure (of much lower magnitude) appears during the months of June to August (Julian days 171 to 247) due to application of Chemical C for chinch bugs and shrub treatments.

As with children, the major contributor to total cumulative exposure at this percentile remains as inhalation. MOEs associated with inhalation range from 120 to 140, remain relatively stable through the year, and are responsible for the bulk of the total cumulative MOE during most of the year. As discussed earlier under Children, 1-3 years, there are three products in use for in-home PCO crack and crevice treatment, but it is not apparent from these time profiles at this stage of the analysis which of these pesticide uses, if any, is the most significant contributor to exposures.

Adults, 18+ years, MOEs at 99.9th percentile (Figure A-10): Shown here is the 99.9th percentile time course of exposure for Adults, 18+ years. Here, too, dramatic changes in the exposure profile and relative contributions are apparent. Predicted dietary exposures (as measured by the MOE) at the 99.9th percentile increase approximately three-fold compared to dietary exposures at the 99th percentile, and inhalation exposures increase almost an order of magnitude to MOEs of approximately 20 at this percentile compared to those exposures at the 99th percentile. Total cumulative MOEs are now below 10 during the flea/grub/chinch treatment season in the spring (chiefly through dermal exposures during this time) and are now equal in magnitude to the inhalation exposures due to crack and crevice treatments by PCOs. As before, dermal exposures fall off dramatically after this window of treatment. As at previous percentiles, dietary and inhalation exposures vary little throughout the year, with MOEs of 400-550 and 20, respectively.

The additional dermal exposures from lawn treatments are seen to occur during the months of March to August and October to November (JDs 71 to 255 and JD 286-336). These exposures correspond to a second treatment for fleas in the fall. It is notable, too, that this latter exposure did not occur at the 99th or lower percentiles and that oscillation of a significant magnitude is seen. In all probability, this observation reflects the very small number of individuals involved in fall fleas treatments.

Oral NOAEL = 0.02 mg/kg/day

The above discussion and associated time profiles of exposures used an oral ED10 to estimate MOEs associated with various pathways and the total cumulative MOE which would be associated with all pathways, considered together. To provide an alternate, but equally plausible set of outcomes, the above exposure profiles were duplicated, except for the assumption that for the oral route of exposure an NOAEL was appropriate to use instead of an oral ED10 (as used above). This use of the NOAEL is more in keeping with OPP's traditional methods of risk assessment and represents a parallel approach to the dermal and inhalation exposure routes in which only NOAELs (and not ED10s) were available. The issue of whether and ED10 or NOAEL approach is more appropriate (and the advantages and disadvantages of each) was discussed in an SAP meeting conducted in September 2000, but the SAP final report on this meeting has not yet been issued.

The risk profiles for this alternate assumption are presented in Appendix B in Figures B-1 to B-10. It is important to note that this use of an alternate measure of toxicity does not change the estimated *exposures*, but rather affects only the estimated *risk* which is associated with these exposures. As can be seen, MOEs associated with any oral pathway (i.e., dietary and the smaller non-dietary oral) decrease (representing increased risk) when the oral NOAEL is used in place of the oral ED10. Thus, dietary exposures represent a larger portion of the total cumulative risk.

2. Uncertainties in Residential Assessment

In any risk assessment, there will be numerous identified and unidentified uncertainties. Assessment of residential exposures to pesticides is no exception. The risk assessor must be aware of and communicate these uncertainties to the risk manager. Sensitivity analyses will provide direction as to where best to focus resources and efforts to improve the quality and quantity of data to inform the risk assessment process. Some of the sources of uncertainty in the residential portion of the case study are summarized below:

- For some pesticides and behavior patterns, experimental and other propriety data as well as data from the literature (including US EPA's *Exposure Factors Handbook*) were available and used. OPP expects this data base to continue to expand in the future as a result of cooperative efforts between OPP and various industry task forces. For the case study presented here, data distribution fitting or further distribution analysis was not performed and instead, a uniform distribution bounded by the low and high measured values was assumed in many instances. For example, uniform distributions were established for such factors as transfer coefficients; exposure to granular formulations using push-type rotary spreaders and spray formulations using hose end sprayers; turf transferable residues (TTR); various aspects and components of hand-to-mouth behavior of toddlers; and lawn sizes. The uniform distribution (bounded by low and high values with a uniform probability density) was used in this case study because much of the task force data is currently under review and curve fitting efforts, although ongoing, are not yet complete.

- Uncertainties exist in modeling human behaviors. Where possible, distributions of behavioral patterns (e.g, hand to mouth activity of toddlers) and durations of exposure (e.g., time spent on lawn) were obtained from the *Exposure Factors Handbook* or the open literature, but significant uncertainties still remain due in part to a paucity of studies. Uncertainties exist in the practice of using adult volunteers to mimicking children's behavior, and then mathematically adjusting the measured exposures to account for differing body sizes and other factors between adults and children.

- A substantial portion of the information used in this case-study example was obtained from survey information which was made as specific to the region of interest (i.e., mid-Atlantic) as possible. Specifically, information from the National Garden Survey (1996 - 1997) and the Certified/Commercial Pest Applicator Survey (1993) was used, and supplemented by professional judgement and estimation by OPP staff. Information obtained from these surveys included percent of households performing lawn care activities themselves or using LCOs; percent of households performing shrub maintenance; percent of households treating for specific pests; and percent of household receiving professional in-home crack and crevice treatments. Use practices (including rate and timing), common pests, and re-application practices were also obtained from these surveys and professional judgement. A further assumption was professional crack-and-crevice treatment occurred in 50% of homes. Additional information in these areas is critical to a cumulative risk assessment, and the pesticide industry and others are encouraged to submit such information to supplement that which is available.

- Substantial uncertainties exist in PHED, which was used to estimate exposures to pesticide active ingredients based on amount handled. PHED data are limited, and any uncertainties and limitations in these data would extend to the current analysis. A major tenet of the use of this data is that physical form and application method are primary determinants of exposure to a pesticide, and physico-chemical properties of the pesticide are of lesser importance. In some areas, PHED data are rich with many replicates available for situations close to those being modeled. In other areas, PHED data are minimal with few replicates available which must be extrapolated to cover situations for which exposure information is desired. OPP is aware of these uncertainties, and used PHED data sparingly, with all data concerning lawn applications obtained from ORETF studies.

- In a variety of instances, surrogate chemicals or formulations for which concentration and other measurements were available were used in this assessment.

- A limited number (10) of iterations were used in this case study. This limited number of iterations may affect the stability of the results and estimated exposures. The limited number of iterations was due, in part, to the substantial computing requirements that an analysis such as the one performed here requires. In the future, OPP would ensure that adequate stability was achieved by performing additional iterations and verifying that computed exposures were not significantly affected.

- The current analysis does not control for the probability of concurrent uses (e.g., flea treatment on lawn and crack and crevice treatment) or for competitive uses (e.g., if Chemical T is used one time in the March to May time frame to treat lawns for grubs it is unlikely that Chemical P will be used on that same lawn during its March 1 to June 30 application window; if Chemical U is used to treat a lawn for fleas, in is unlikely that Chemical B will be used during this time frame too). The ability to include conditions of product use overlap or exclusion will greatly increase the accuracy of risk estimates produced.

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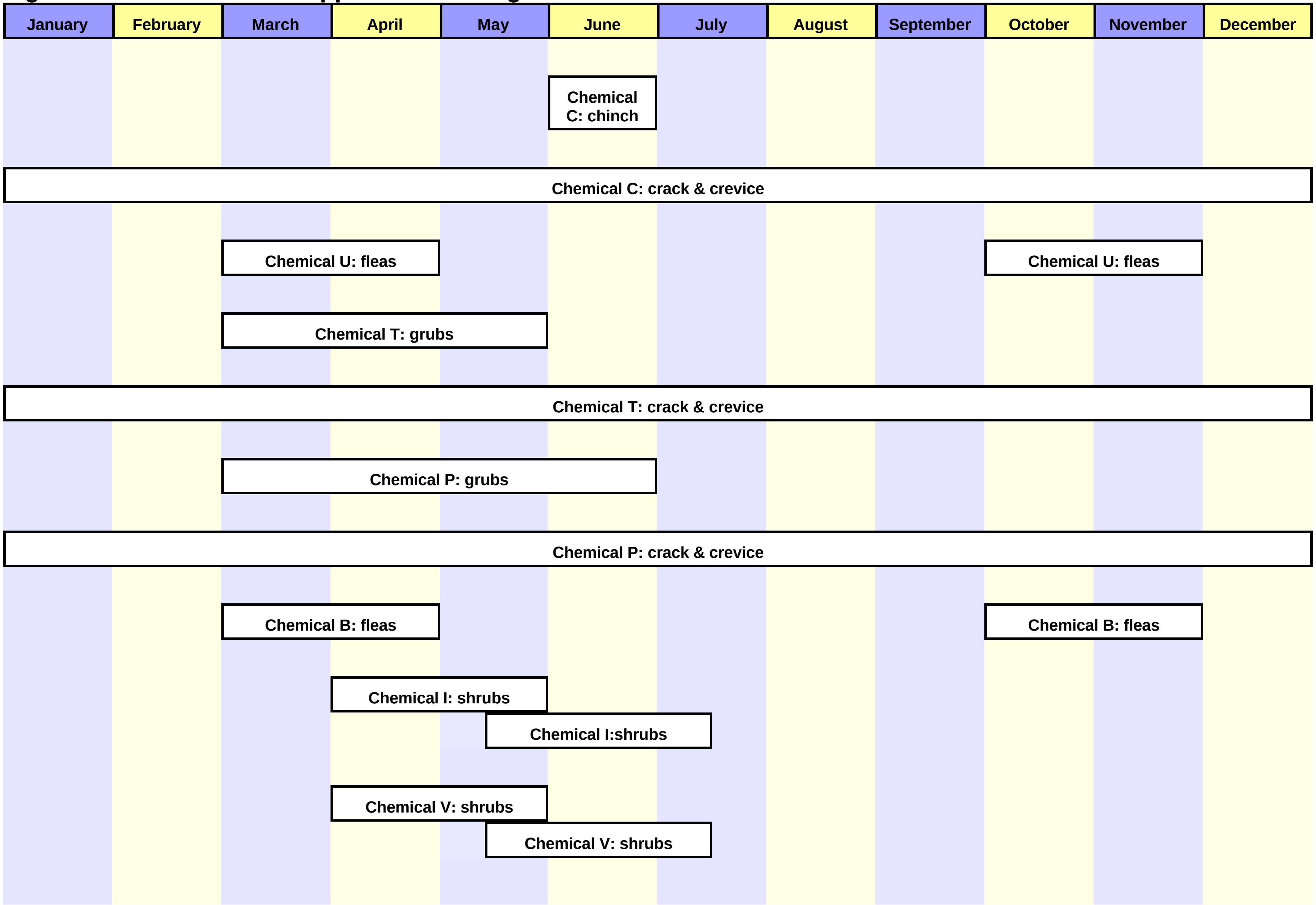
Figure 5-1 Gaant Chart of Application Timing of Pesticide Chemicals



VI. Cumulative Risk from Pesticides in Drinking Water

OPP has been estimating pesticide concentrations in surface water through a combination of modeling and monitoring for the purposes of ecological risk assessment since the mid-1980's. FQPA, passed in 1996, imposed a greater emphasis on estimating risk from pesticides in drinking water and the need to integrate risk from pesticides in drinking water with risk from pesticide exposure through other routes. Ideally, data to support the water side of this exposure calculation would consist of extensive multi-analyte, longitudinally collected monitoring data from drinking water sources collected throughout the U.S. However, due to the great diversity of geographic, climatic, and time dependent factors impacting surface water contamination with pesticides, this approach is not practical. OPP continues to acquire additional monitoring data and is working to develop a national multi-pesticide monitoring effort. However, much of this effort is focused upon developing sufficient data to permit the modeling of pesticide concentrations in surface water.

In mid 1999, OPP began exploring a United States Geological Survey (USGS) project aimed at estimating distributions of contaminants at the locations of drinking water intakes based on concentrations measured at other locations. The USGS methods are based on the premise that pesticide concentrations found in drinking water are not randomly determined, but are in large part determined by the amount, method, and location of pesticide application, as well as by the physical characteristics of the watersheds in which the community water systems (CWS) are located and other environmental factors (such as rainfall) which cause the pesticide to move from the location where it was applied. USGS scientists have investigated the importance of these factors in estimating pesticide concentrations in the watersheds where monitoring data have been collected. They have developed regression equations that use pesticide and environmental variables to predict concentrations of a specific pesticide at sites at which measurements of pesticide concentrations have not been made. This approach appears to be very promising in broadly extrapolating from existing monitoring data to the general case of pesticide residues in surface water. The outputs of the USGS WAtershed Regression for Pesticides (WARP) model was used in this case study to provide reasonable, health protective estimates of pesticide concentrations in drinking water for the two most prevalent OPs in the geographic area of the case study.

A. USGS Regression Approach

UGSG began this modeling approach by looking at nutrient concentrations. Figure 6-1 shows the results of USGS's first attempts to use regression-like equations to predict total nitrogen in 567 drinking water systems serving 60 million people. This type of data and output can be used to assess the magnitude of the exposure across the country on an exposed population basis and identify regions deserving special attention. To date, OPP has been able to estimate only the high end concentrations which would be represented in the upper right hand corner of Figure 6-1 and concentrations can not be *linked* with a specific intake location, a specific site or region, or with a specific number of individuals. By developing regression procedures which permit estimating the concentration separately at each intake location, the population link which is critical for aggregate and cumulative assessments can to be established.

Following USGS's initial efforts to predict total nitrogen concentration in flowing water, OPP requested that USGS extend its regression procedure and attempt to estimate the concentrations of the widely used corn herbicide atrazine at the same drinking water intake locations. The approach proposed by USGS for estimating pesticide concentrations in streams uses regression equations based upon a large quantity of monitoring data, as well as pesticide usage and nationally available soils, hydrologic and hydrographic data, and other drainage-basin characteristics. Specifically, concentration data on herbicides from 45 streams sampled as part of USGS's NAtional Water Quality Assessment (NAWQA) Program during 1993-1995 were used to develop individual regression models for stream concentrations of the herbicides alachlor, atrazine, cyanazine, metolachlor, and trifluralin. USGS used measured concentrations of the herbicides as the response variable and nationally available agricultural use data and physiographic basin characteristics as predictor variables. Separate equations were developed for each of six percentiles (10th, 25th, 50th, 90th, and 95th) of the annual distribution of stream concentrations, and for the annual time-weighted mean concentration for each pesticide individually. This work was completed in late 1999 and the results were presented to the SAP in March 2000. Figure 6-2 shows the results of this work for atrazine. The March 2000 SAP concluded that the Agency, with substantial assistance from USGS, had made significant progress toward estimating pesticide exposure to the U.S. population with its increased sophistication and its move from deterministic to stochastic methods. The Panel stated that the approaches involving the use of regression-type models based on real world monitoring data were a significant step forward in providing estimated concentrations of pesticides in drinking water that could be used in quantitative aggregate risk assessments.

Since the March SAP presentation, additional work has been undertaken to investigate the regression approach to predicting site-specific pesticide concentrations in flowing water. The results of this development work were presented to another SAP meeting in late September. Development work has included checking the model against two new verification data sets of measured pesticide concentration values: 38 NAWQA stream sites sampled primarily during 1996-1997 and 23 NASQAN (NAational Stream Quality Assessment Network) sites on larger rivers sampled primarily during 1996-1997. Based on these results and feedback from the latest SAP, it appears reasonable to expect to be within an order of magnitude for the upper percentiles (e.g., 95th) and annual average concentrations most of the time for single sites and much more accurate for the overall distribution of concentration values across all CWS locations.

USGS's recent work in developing regression models based on monitoring holds promise for providing the Agency a needed tool to extend the value of limited data in completing quantitative aggregate and cumulative risk assessments for pesticides under FQPA. Further development of modeling approaches is ongoing. Availability of new data, collected specifically to enhance these models, will greatly improve the scope and accuracy of the model predictions. To this end, OPP has initiated a workgroup composed of US EPA, USGS, USDA, and ACPA representatives to discuss methods and design an institutional structure to work on the further advancement of the regression modeling approach and support the collection of the additional monitoring data needed for model development. Initial plans call for a government planning and oversight group and formation of two technical committees that will address such issues as monitoring design and development of pesticide usage estimates. Future development of this and related modeling efforts will depend upon the continued collection of monitoring data to permit enhancement of the existing models and to extend them to other groups of pesticides.

B. Development of WAtershed Regression for Pesticides (WARP) Approach Applied to Cumulative Case Study for Chemicals T and P

As a step toward developing methodologies for assessing cumulative and aggregate exposure, USGS work on the WARP model has continued and been expanded to include both old and new monitoring data for two selected OP insecticides which are being presented to the December, 2000 FIFRA SAP. Specifically, the WARP model was applied to 71 identified water system intakes in the mid-Atlantic/Piedmont region of the U.S. in an attempt to develop preliminary data for a pilot cumulative assessment for the organophosphate pesticides for presentation to the SAP. For the purpose of this case study, the contribution to aggregate/cumulative assessment has been limited to the two OP insecticides most commonly detected in water. These pesticides are identified as T and P and correspond to the designations provided earlier in this document.

The following paragraphs describe the steps followed by USGS in developing estimates of concentrations of these two pesticides in drinking water at 71 sites in the mid-Atlantic/Piedmont region of the U.S.:

> Briefly, USGS NAWQA studies of pesticides in streams are available for 101 selected sites nationwide (collecting during the period 1993-1998), including 55 agricultural basins, 21 urban basins, and 25 mixed land use basins. The agricultural and urban streams were selected to be examples of agricultural and urban areas typical of the NAWQA study areas, which are distributed throughout the coterminous U.S. The sampling sites consisted only of streams; the sites were not randomly selected, and location with respect to drinking water intakes was not a site selection factor. A subset of these streams was selected (see below) and used to

estimate (separate) regression equations for Chemicals T and P relating NAWQA-measured stream concentrations in agricultural and urban basins with various pesticide application parameters and hydro-geomorphic properties which were characteristic of those watersheds. Since no information was available on urban uses of the two pesticides, USGS derived a relationship between known use in agricultural areas and concentrations in agricultural streams that was used to estimate usage in urban areas where only stream concentrations were known.

STEP 1: Estimation of Contribution of Agricultural Uses to Stream Concentrations USGS first selected 19 agricultural sites (for Chemical T) or 28 sites (for Chemical P) from across the U.S. at which measured flowing water concentrations would be expected to reflect predominantly agricultural uses. These agricultural sites were distributed throughout the coterminous U.S. and watersheds with predominantly agricultural uses for which pesticide application rates were known. In situations where monitoring data for multiple years were available for a given site, the year with the most data was used in the regression. The sites were not randomly selected and did not represent ponds, lakes, reservoirs, or other impoundments. In addition, the location with respect to CWS intakes (or indeed the ability of stream flow to even support a CWS) was not a site selection factor. Specifically, to be designated as reflecting primarily agricultural uses the selected sites had low population density (<50 persons/km^2), low percentage of urban land (<5%), and high use of the selected pesticide[2] (>0.2 kg/km^2 for Chemical T and >1 kg km^2 for Chemical P). From this data, a regression equation which was believed to accurately reflect stream concentrations resulting from runoff associated with agricultural uses was developed for the mean and 95th percentile concentrations for Chemical T and 95th percentile concentration (only) for Chemical P (since no mean concentration could be calculated) using log (use/basin area) as a regressor (regressions were also developed for the mean concentration but were not used in this case study example). The 95th percentile equation was developed by taking, by site, the 95th percentile of the 15-40 pesticide concentration measurements per site and using each site's 95th percentile concentration

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[2] Agricultural usage of pesticides is reported on a county-basis and average rates are derived by dividing county-wide sales, in lbs of active ingredient (a.i.) by total county acreage. Agricultural pesticide use data was based on crop data from the 1992 Agricultural Census and application rates were estimated for the years 1992-1994. However, actual single applications can range from a minimum efficacious rate to maximum application rates; applications may be intensive in areas of high pest pressure and nonexistent where the pest does not occur. Such variations are not captured in averaging data based on sales and total county acreage.

value in the regression. These regression equations had R^2 values of 0.75 and 0.14 for the 95th percentile for Chemicals T and P, respectively.

STEP 2: Estimation of Contribution of Urban Uses to Stream Concentrations Although USGS work and other studies have shown that Chemicals T and P are being detected in urban settings, no information is available to estimate urban uses of these two pesticides and USGS was thus required to estimate these uses. This was done by applying the above developed "ag equation" (separately for each pesticide) to urban sites (i.e., sites with low agricultural uses, high population density, and high percent urban area) in an attempt to back calculate urban uses (i.e., the "ag equation" was used to back calculate urban use assuming that the measured concentrations at the selected urban sites were totally due to urban uses). For Chemical T, 15 sites with <0.01 kg/km^2 agricultural uses, 40-100% urban land, and population densities of 330-1700 persons/km^2 were selected and predicted Chemical T use (mean and 95th percentile, in kg/km^2 drainage area) was back calculated from stream concentrations assuming that all use occurred in urban areas of the basin. For each of the 15 primarily urban basins for Chemical T(or 23 primarily urban basins for Chemical P) for which this back calculation was performed, the mean and 95th percentile urban use estimate (kg/km^2 drainage area) calculated in STEP 1 for each site were arithmetically averaged to obtain an estimate for the site; the median value of these fifteen averages was selected as a regional estimate of the use per unit area of urban land. For Chemical T this number was estimated to be 24.8 kg applied/km^2 urban land. This was similarly done for Chemical P in which 23 primarily urban sites with <5.3 kg/km^2 Chemical P use, 21-100% urban land, and population densities of 145-1700 persons/km^2 were used for this back calculation. Here the median of the 23 back calculated urban use rates was calculated and likewise assumed to apply to all urban land while for Chemical P this was estimated to be 78.8 kg applied/km^2 urban land. This urban use estimate was added to the agricultural use estimate for the basin to obtain an estimate for total use of Chemical T or P in the basin. The log(total use/drainage area) was used as the use intensity variable in the subsequent regression analysis (see below).

STEP 3: Development of Overall Regression Equation With total (agricultural and urban uses) on a watershed basis now estimated, USGS developed separate equations for the 95th percentile Chemical T or Chemical P concentration (by water system) using stream concentration measurements from the 1991 and 1994 NAWQA survey. Use intensity (i.e., log(total use/drainage area)) and other basin parameters were used as predictor variables. Predictor variables were added to the regression equation if they significantly improved the regression ($p < 0.05$), with residuals examined and other diagnostics performed at each step in the equation development. Specifically, the 95th percentile concentrations from 101 sites on streams throughout the U.S. were used to develop the regression equations for the site-specific 95th percentile concentrations. The regression equations for the 95th percentile values for Chemicals T and P are as follows:

For Chemical T:

$$\log(95^{\text{th}}\text{\%ile concentration}) = -2.42 + 0.762\log\left(\frac{\text{total use}}{\text{basin area}}\right) + 0.010\,(\text{HGC} + \text{HGD})$$

where :

total use = total use of pesticide in the basin area
basin area = area of contributing basin area (square km)
HGC = percentage of basin area comprised of soil hydrologic group C
HGD = percentage of basin area comprised of soil hydrologic group D

and

R-SQU = 0.63

For Chemical P:

$$\log(95^{\text{th}}\text{\%ile concentration}) = -3.354 + 0.600\log\left(\frac{\text{total use}}{\text{basin area}}\right) + 0.013\,(\text{SILT}) - 0.425\log(\text{OM}) - 0.0089(\text{ppt} - \text{evap})$$

where:

total use = total use of pesticide in basin area
basin area = area of contributing drainage basin (square km)
SILT = average silt content of soil in the drainage area (%)
OM = average organic matter content of soils in basin area (%)
ppt = mean annual precipitation for drainage basin (inches)
evap = mean annual potential evaporation of drainage basin (inches)

R-SQU = 0.43

STEP 4: Application of Regression Equations to Mid-Atlantic/Piedmont Area Drinking Water Intake Locations For each of the two case study pesticides, the above developed regression equations for the 95th percentile pesticide concentrations were applied to 71 sites on streams in the mid-Atlantic/Piedmont region (VA, NC, and SC) of the U.S. that serve as sources of drinking water in order to estimate concentrations of Chemical T and P in these streams. For each of the 71 sites, data was required on agricultural uses of Chemical T or P[3], land use in the basin, and values for each of the ancillary parameters in the regression equations. Predictions were obtained for 95th percentile concentrations of each pesticide for each site; for each predicted value, a 95% prediction interval about the median 95th percentile concentration estimate were also calculated. These are shown in Tables 6-1 and 6-2 for Chemicals P and T, respectively.

C. Combining Chemical T and Chemical P Concentration for Use in a Cumulative Assessment

The above described USGS regression model was used to produce *separate* estimates for 95th percentile concentrations of Chemical T and Chemical P, but since these two pesticides belong to a Common Mechanism Group, a cumulative risk assessment conducted as per OPP Cumulative guidance requires that these two pesticides be <u>combined</u> and expressed in terms of an index (or reference) chemical (here, Chemical T). As described in Section IV of this document, this can be done relatively easily by means of the Relative Potency Factor, with the combined residues expressed in terms of Chemical T equivalents. However, in order to appropriately combine these two pesticides and express them in terms of Chemical T equivalents, it is necessary to consider the degree to which they *co-occur* in drinking water. That is, it is clearly <u>not</u> appropriate to add Chemical P (expressed in Chemical T equivalents) to Chemical T for each of the 71 water system for which prediction is desired, since it is not known to what degree, if any, these pesticides are used or occur together. We note that this was <u>not</u> a problem with USDA PDP derived concentrations in produce used in Section IV of this document to estimate exposures through food since the PDP program *simultaneously* measured all pesticides in *each* sample using multi-analyte methods and co-occurrence is then implicitly accounted for. For example, if Chemical T was never found in water samples together with Chemical P because of differences in use practices or application timing/patterns between the two pesticides, then it would be entirely inappropriate to add these together as part of a cumulative assessment. However, the extent of co-occurrence, or lack thereof, is ***not*** considered in the USGS model <u>since the regression equations were developed separately for Chemical T and Chemical P</u>. *In short, the nature of the USGS regression model at this stage of development precludes incorporation of this information into water concentration data*.

It is also important to note that the regression estimates reflect *site-specific* (i.e. by-site) distributions of estimated single-day 95th percentile concentrations for 71 drinking water intake sites in the Mid-Atlantic/Piedmont area of the U.S. <u>There is</u>

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[3] Use data for urban uses was, as described in the text, not available and a nationwide estimate of 24.8 kg/km^2 was used for Chemical “D” and 78.8 kg/km^2 was used for Chemical “C”

<u>no time-component or time-series associated with the USGS regression output and thus any incorporation of "subsequent-day" exposures to a specific individual is not possible at this time</u>. That is, it is not possible to use the regression equations developed by USGS to estimate subsequent day concentrations in water. Since concentrations in water are likely to display significant auto-correlation (i.e., high concentrations on the first day are likely to be followed by high concentrations on the second day) and can change substantially from one day to the next, it is not possible to use the USGS regression model to concatenate exposures through drinking water to estimate average exposures of periods of time longer than one-day (e.g., 3-day, 7-day, 28-day or seasonal exposures)[4] nor is it possible to mathematically predict next-day or subsequent day exposures[5].

For purposes of this case study, then, the following two simplifying assumptions were made to develop a series of water concentrations for use in this cumulative risk assessment:

- Since it was not known to what degree Chemical T and Chemical P co-occurred in drinking water sources, the analyses conducted here used the sum (accounting for the Relative Potency Factor) of the regression-predicted estimates for each pesticide to produce estimated total concentrations expressed in Chemical T equivalents. If Chemical T and Chemical P tend to be used at different times or be used in different places, this is likely to be a conservative estimate.

- Since the USGS regression based model does not produce longitudinal estimates (i.e., a time-series of daily water concentrations at a given site) of pesticide concentrations in water, it was assumed that all individuals are exposed to (a population-weighted) 95th percentile concentration in drinking water. That is, it was assumed that the upper end concentration in drinking water predicted by the regression model for each drinking water system were repeated every day throughout the year. This, too, is

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[4] Sampling was designed to be more intense in the high use and runoff seasons and it may be possible to develop separate regression models for seasonal (or any other time period) statistics if frequency of sampling during runoff or the high use season is adequate.

[5] This is in marked contrast to the residential component of the aggregate assessment in which Day 2 and subsequent day exposures <u>*can*</u> be calculated since a defined mathematical relationship (for example, first order decay with a defined half-life or straight line decay) is assumed for relating Day 0 (application day) to Day 1 and subsequent exposures. Alternatively, actual post-application day measurements can be made and inserted into the Calendex program.

a conservative assumption and is likely to significantly overstate exposures through drinking water.

D. HED Incorporation of USGS predicted 95th Percentile Concentrations for Chemical T and P into a Cumulative Exposure Estimate

As described above, the USGS WARP equation was used to estimate the 95th percentile concentration at 71 sites on streams in the mid-Atlantic/Piedmont region of the U.S. that serve as sources of drinking water. Information was also provided by USGS on the population associated with the drinking water intake associated with each of these 71 sites, thereby allowing the estimation of a *population weighted* cumulative distribution[6] (i.e., graph showing the fraction of the population exposed at or below any given 95th percentile concentration of T or P). This population weighting is necessary since it is important that any given predicted concentration be probabilistically associated with an appropriate size of population. This is shown in Figure 6-3 for Chemical T, Chemical P, and combined Chemicals T and P (which is estimated in Chemical T equivalent units). It is the information displayed in the bottom panel of Figure 6-3 (combined Chemical T and P) that is of interest for use in a cumulative assessment and was used to generate the input data for the cumulative assessment. It should be noted that for purposes of this case study, the 95th percentile upper prediction limit on the predicted 95th percentile concentration was used. This is expected to over-estimate pesticide concentrations in drinking water by an order of magnitude or more.

DEEM, however, does not currently permit cumulative distributions to be used in its input RDF files (and, as indicated previously, it is NOT appropriate to simply draw from an unweighted USGS collection of annual mean or 95th percentile concentrations as predicted by the regression model since this data does not, by itself, appropriately reflect associated probabilities of an individual consuming that water). Thus, it was necessary to generate from this population weighted cumulative distribution curve a series of possible water concentrations for insertion into DEEM. This was done by using Crystal Ball software and its cumulative distribution function to generate 1000 individual potential water concentration values which follow the defined cumulative distribution function and inserting these (now appropriately weighted) 1000 values into a DEEM data input file. In this way, DEEM draws from this population-weighted distribution of values, and concentrations associated with a larger fraction of the population will appropriately have a greater proportionate probability of being selected and combined with an individual reported water consumption.

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[6] There is an unfortunate conflict of phraseology between standard statistical terms such as “cumulative” distribution vs. language of FQPA referring to “cumulative” exposure. It is hoped that in this document the contextual meanings of these two terms are clear.

E. Generation of Water Concentration Values for Use in Exposure Assessment through DEEM

The collection of site-specific 95th percentile concentrations in drinking water (or, more accurately, a distribution of individual water concentrations generated in Crystal Ball's Cumulative Distribution Function which is derived from and matches the cumulative distribution function implied by the USGS regression model for Chemical T and Chemical P) can then be used in the DEEM (Dietary Exposure Evaluation Model) software. DEEM will randomly assign a water concentration to each individual in the CSFII who reported consuming water, with the resulting estimated pesticide exposure from water (i.e., calculated as the product of reported water consumption and the selected 95th percentile water concentration) added to DEEM's estimated pesticide exposure from food. Since the random assignments of water concentration will be *population weighted* (i.e., as defined by the cumulative frequency distribution), DEEM's estimated exposures through water will accurately reflect the exposure picture of the population through water.

F. DEEM Model Output

As described earlie, this water-only assessment makes a variety of assumptions which are, by their nature, designed to produce conservative, high-end estimates. For example, it assumes that Chemical T and P co-occur in every water sample and each individual is exposed to the 95% upper prediction limit of the 95th percentile concentration of the combined T and P pesticide concentration. The DEEM outputs presented in each of these two figures use as input values the distribution of upper 95% prediction intervals about the 95th percentile water concentration as input values. As can be seen in the bottom panel of Figure 6-3, these upper prediction intervals are in many cases several-fold to an order-of-magnitude higher than the median 95th percentile values, and were assumed to occur every day of the year. Even so, we note that exposures to Children, 1-3 years and Adults, 18+ years are small compared to exposures from food even at percentiles of exposure as high as the 99.9th. For example, considering exposures from water alone at the 99.9th percentile, MOEs for Children, 1-3 years and Adults, 18+ years are 1973 and 3385, respectively, using the upper prediction limit for water concentrations. These MOEs reflect exposures of 0.000089 and 0.000052 mg/kg-day for Children, 1-3 years and Adults,18+ years, respectively. This compares to 99.9th percentile MOEs for food of 165 (0.001057 mg/kg-day) and 424 (0.000412 mg/kg-day) for food alone for Children, 1-3 years and Adults,18+ years, respectively. MOEs at the 99.9th percentile for residential exposure are ~7-10 for Children, 1-3 years and ~7-10 for Adults, 18+ years. From this information, we can conclude that exposures through water are likely to be a negligible fraction of total cumulative exposures.

G. Sources of Uncertainty in Estimating Pesticide Concentrations in Water

As with all attempts to estimate exposures, there are a number of specific uncertainties associated with OPP's estimation of water exposures in this case study. Overall, however, OPP has attempted to produce estimates of exposure through drinking water which are health protective but use the available data to the greatest extent possible. That is, the assumptions made by OPP in performing this assessment for pesticide exposure through water specifically erred on the side of *overestimating* concentrations in drinking water and therefore *overestimating* exposures through drinking water. For example, it was assumed that Chemicals T and P occur simultaneously in drinking water, that each of these pesticides are present in drinking water at concentrations representative of the 95% upper prediction limit of the 95th percentile, and that these concentrations occur every day throughout the year. In addition, no treatment (or, more precisely, no effect of water treatment) was assumed. Even in light of these conservative assumptions, it can be seen that estimated exposures through the drinking water are relatively small when compared to not only total cumulative exposure, but also to those exposures occurring via the food pathway.

Nevertheless, it is important to consider the uncertainties that may be present in the estimated drinking water concentrations as modeled by the USGS WARP model and, if possible, evaluate the effects that these uncertainties might have on both the estimated exposure through the drinking water pathway and total cumulative exposure through all routes and pathways. It is only when the uncertainties about exposure estimates can be adequately evaluated and conveyed to risk managers, interested parties, and the general public that productive dialogue on potential refinements, responses, and mitigation actions can take place.

The following paragraphs discuss some specific uncertainties that may influence our estimate of exposure through the drinking water pathway.

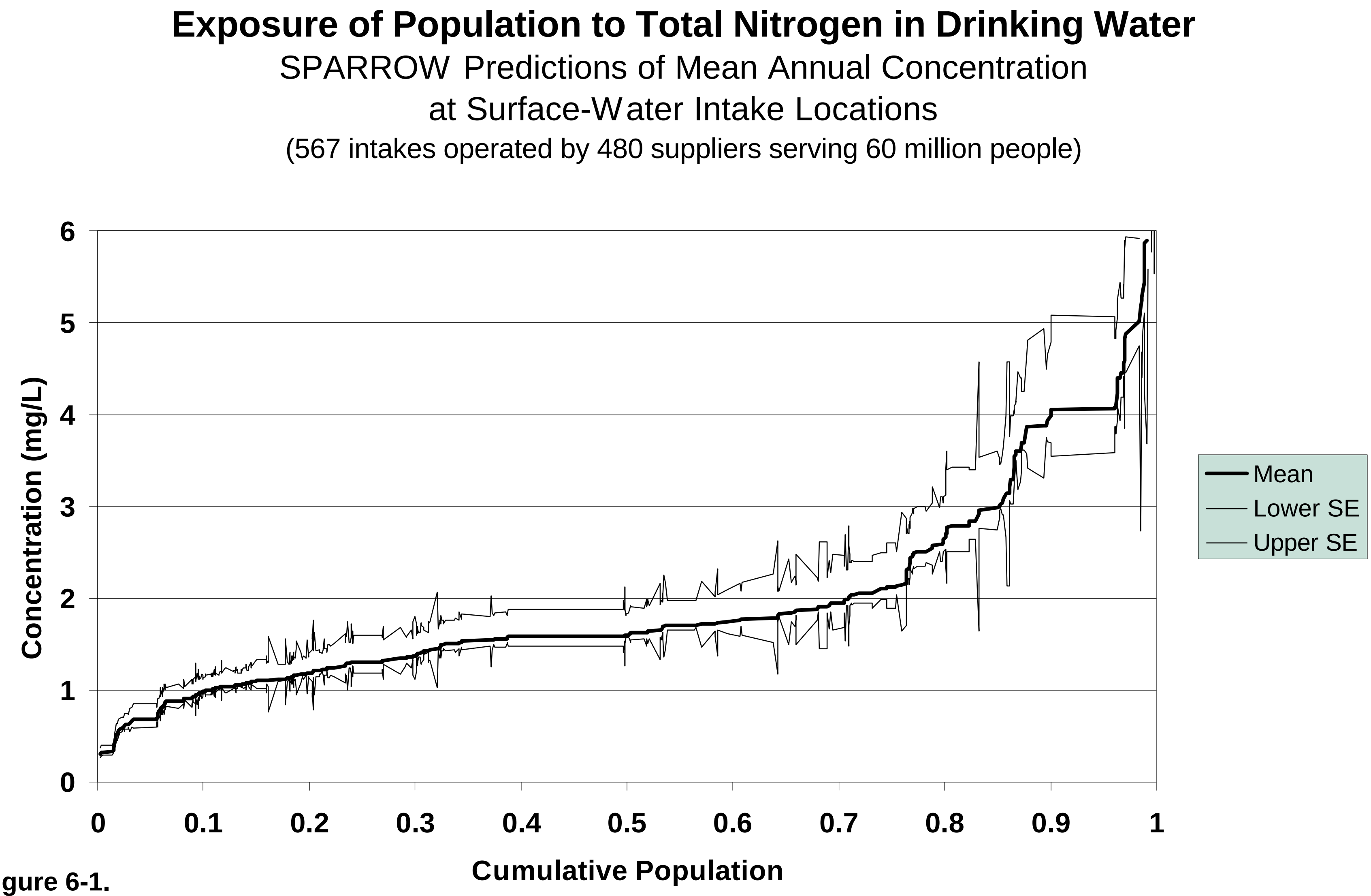
There are a number of uncertainties associated in applying a regression model developed with nationwide data to water bodies serving drinking water treatment plants in the mid-Atlantic/Piedmont region of the U.S. simulated here in this case study. First, the data used to develop the regression model were based on streams across the entire coterminous U.S. and were not randomly selected. In addition, the location of the sites with respect to drinking water intakes was not a site selection factor in NAWQA survey design nor was the ability of the stream to support a drinking water facility considered or the location of sites in relation to pesticide use area. Finally, the data obtained from this regression relationship were applied not only to streams (the NAWQA sampled water bodies which served as the basis in development of the regression model), but also to rivers, lakes, reservoirs, and other surface impoundments which serve as drinking water sources for the 71 mid-Atlantic/Piedmont drinking water intake sites which were modeled in this cumulative assessment example. The fact that the regression model was based only on stream measurements, and that the highest concentrations of these pesticides in the 71 water systems were predicted by the regression model to occur in water systems drawing from reservoirs, adds a further degree of uncertainty to the high end exposure estimates from water. Thus, there are potential uncertainty issues associated with the *representativeness* or *validity* of the study sites which were used to develop the WARP regression model with respect to application of this model to sites at which drinking water intakes are located.

Temporal factors associated with sample collection are a major consideration in evaluating the quality and representation of monitoring data on which the regression is based. The data used to develop the model were limited to data collected during the period from 1993 to 1998 and are relatively short term, limited in the number of samples collected per site, limited in frequency of collection, and limited in its ability to detect peak concentrations.

Little information is available to permit estimation of urban pesticide use. The USGS regression model relied on a back calculation of urban uses based on the measured concentration in urban streams, the regression relationship for agricultural streams, and an assumption that the estimated usage rate for urban areas is reasonably uniform across the region of interest. Estimated usage as calculated based on the regression equation was highly variable by site and a median value was selected for application across all sites.

There are uncertainties associated with input parameters to each of the regression equations. For example, use rates of pesticides in agricultural watersheds were obtained from estimated county averages which may or may not accurately reflect the pesticide inputs or correspond to the time of sampling. Agricultural pesticide use was based on crop data from the 1992 Agricultural Census and application rates were estimated for the period 1992-1994. There is uncertainty associated with applying this use data to other years. In addition, such factors as soil characteristics, precipitation, and evapo-transpiration were, of necessity, averaged across a watershed and uncertainty would be associated with any such spatial homogenization.

The method of combining exposures to Chemicals T and P was highly simplified. It was assumed that these chemicals co-occur in drinking water bodies and that high concentrations of one (e.g., the 95th percentile) simultaneously occur with high concentrations of the other (again, the 95th percentile). In particular, attempting to estimate upper percentiles of exposure increases the uncertainty in concentration estimates. Regression procedures are inherently more uncertain as on moves away from the mean. For the purposes of this assessment, the USGS regression model was used to predict the 95th percentile and 95% upper prediction limit on the 95th percentile concentration at 71 water intakes in the mid-Atlantic/Piedmont area.

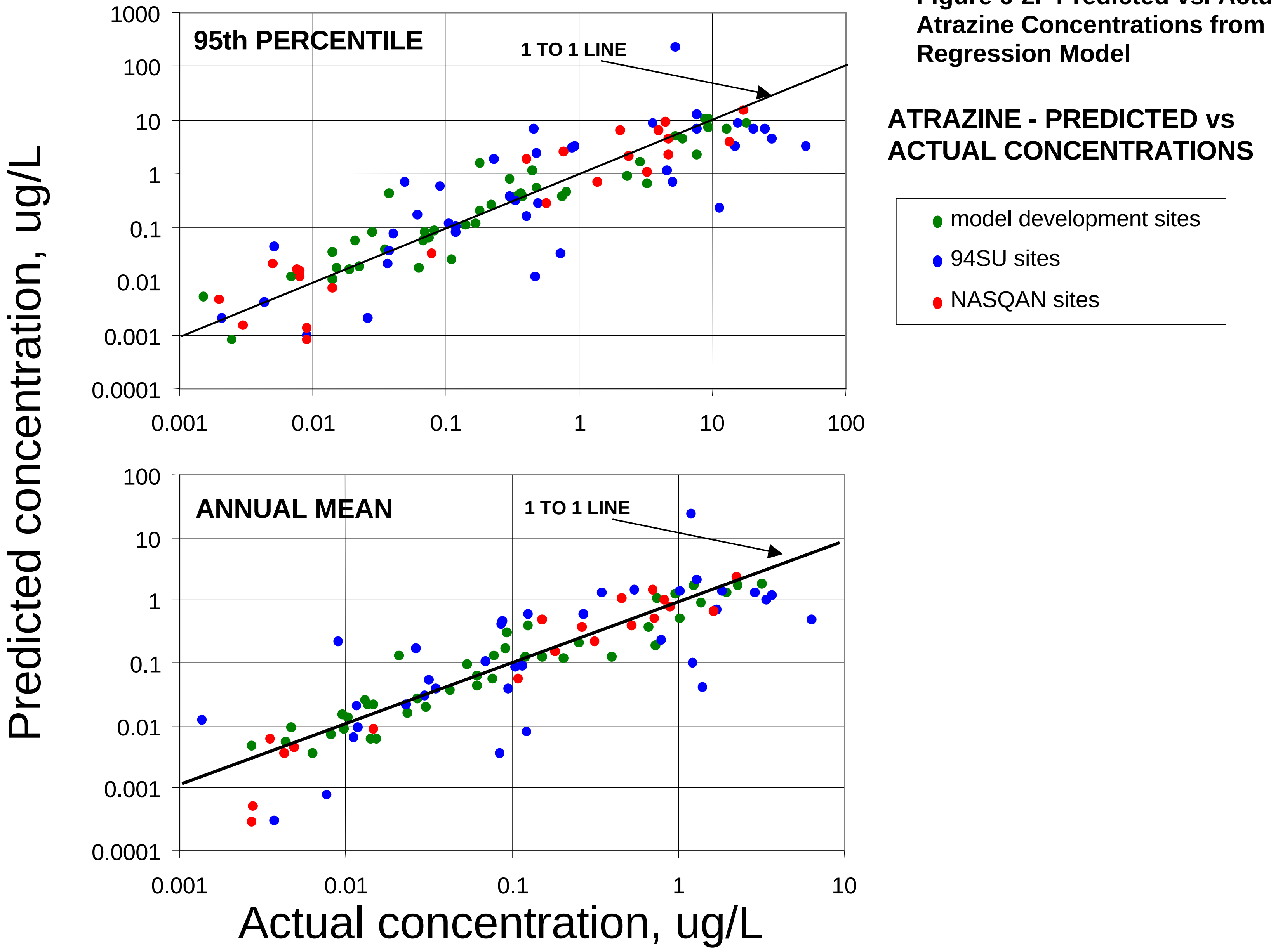


Exposure of Population to Total Nitrogen in Drinking Water

SPARROW Predictions of Mean Annual Concentration
at Surface-Water Intake Locations
(567 intakes operated by 480 suppliers serving 60 million people)

Figure 6-1.

Figure 6-2. Predicted vs. Actual Atrazine Concentrations from Regression Model



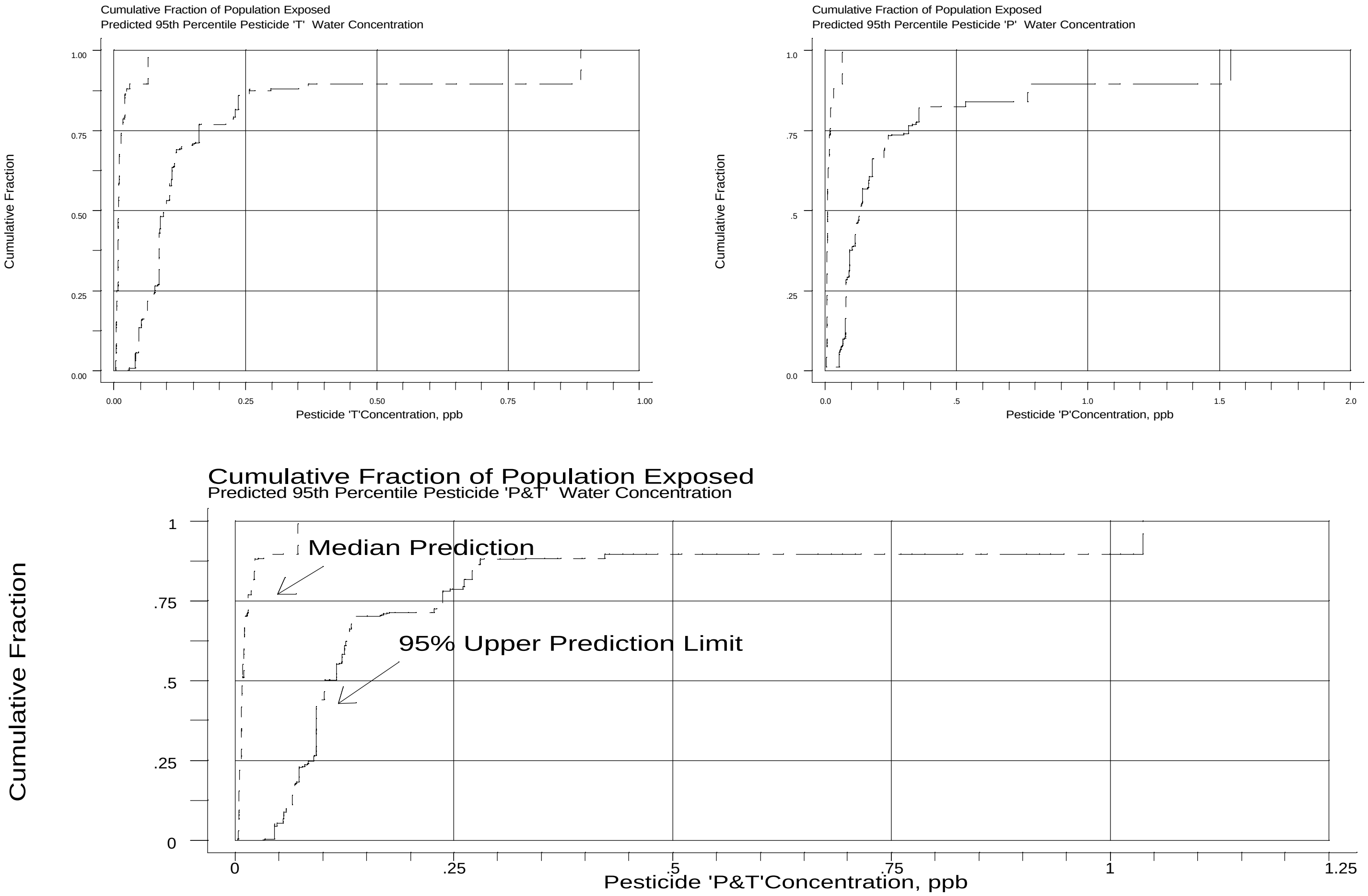


Figure 6-3. Population-Weighted Cumulative Distribution of 95th Percentile Exposures to Chemical T (Alone), Chemical P (Alone), and Chemicals T & P (Combined)

Table 6-1. Predicted 95th Percentile Concentrations of Chemical P by WaRP Regression

PWS_SRCE_ID	STATE	SRCENAME	Type Code	HUC	SYSTEM_NAME	CITY	POPULATION SERVED	predicted 95th%ile Chemical P	lo Prediction Interval Chemical P	hi Prediction Interval Chemical P
	NC	CATAWBA RIVER	1	3050101	MORGANTON, CITY OF	MORGANTON	20550	0.004509	0.000307	0.05832
1752969	NC	LAKE RHODHISS	2	3050101	LENOIR, CITY OF	GRANITE FALLS	15700	0.005191	0.000356	0.0673
1753921	NC	CATAWBA RIVER	1	3050101	HICKORY, CITY OF	HICKORY	35300	0.005238	0.00036	0.06783
1776685	NC	YADKIN RIVER	1	3040101	DAVIDSON WATER INC	LEXINGTON	113441	0.009263	0.000626	0.12753
1787587	NC	CAPE FEAR RIVER	1	3030004	FAYETTEVILLE PUBLIC WORKS COMM	FAYETTEVILLE	128000	0.017257	0.00092	0.31528
1799202	NC	BLEWITT FALLS LAKE	3	3040104	RICHMOND COUNTY WATER SYSTEM	ROCKINGHAM	15317	0.010858	0.000697	0.15965
1799969	NC	LUMBER RIVER	1	3040203	LUMBERTON, CITY OF	LUMBERTON	21000	0.006638	0.000334	0.12394
1803356	NC	FALLS LAKE	3	3020201	RALEIGH, CITY OF	RALEIGH	225000	0.020403	0.001146	0.35572
1803365	NC	B EVERETT JORDON LAKE	3	3030002	CARY, TOWN OF	APEX	77030	0.026919	0.001345	0.53475
1809276	NC	CAPE FEAR RIVER	6	3030005	BRUNSWICK COUNTY WATER SYSTEM	LELAND	20000	0.012938	0.000706	0.2278
1819133	NC	CAPE FEAR RIVER	6	3030005	WILMINGTON WATER SYSTEM	WILMINGTON	60906	0.012938	0.000706	0.2278
1829838	SC	EDISTO RIVER	1	3050205	CHARLESTON CPW	CHARLESTON	197343	0.002808	0.000137	0.0524
1830683	SC	BROAD RIVER	1	3050105	GAFFNEY BPW	GAFFNEY	21925	0.00447	0.000292	0.06105
1832362	SC	EDISTO RIVER	1	3050205	SUMMERVILLE TOWN OF	SUMMERVILLE	42502	0.002808	0.000137	0.0524
1842206	SC	RAW WATER RESERVOIR	3	3050106	UNION CITY OF	UNION	14300	0.006379	0.000414	0.08993
1842410	SC	CATAWBA RIVER	1	3050101	ROCK HILL CITY OF	ROCK HILL	60988	0.007445	0.000504	0.10082
2498081	NC	SOUTH FORK CATAWBA RIVER	1	3050102	GASTONIA, CITY OF	GASTONIA	64000	0.006511	0.00043	0.09022
2498083	NC	CATAWBA RIVER	1	3050101	BELMONT CITY OF	BELMONT	10117	0.006579	0.000446	0.08825

PWS_SRCE_ID	STATE	SRCENAME	Type Code	HUC	SYSTEM_NAME	CITY	POPULATION SERVED	predicted 95th%ile Chemical P	lo Prediction Interval Chemical P	hi Prediction Interval Chemical P
2500079	NC	LAKE NORMAN	3	3050101	MOORESVILLE WTR TRTMT PLT	MOORESVILLE	10190	0.005787	0.000393	0.07663
2500711	NC	LAKE NORMAN	3	3050101	LINCOLN COUNTY WTP	DENVER	10734	0.005787	0.000393	0.07663
2513303	NC	CAPE FEAR RIVER	1	3030004	HARNETT CO DEPT OF PUBLIC UTIL	LILLINGTON	31560	0.018989	0.001019	0.34573
2513851	NC	NEUSE RIVER	1	3020201	SMITHFIELD, TOWN OF	SMITHFIELD	11750	0.020873	0.001228	0.348
2523518	NC	TAR RIVER	1	3020103	TARBORO WATER SYSTEM	TARBORO	11000	0.010097	0.000606	0.15928
2525136	NC	CAPE FEAR RIVER	1	3030005	WILMINGTON WATER SYSTEM	WILMINGTON	60906	0.009461	0.000516	0.16427
2637767	VA	NEW RIVER	1	5050001	B'BURG-C'BURG-VPI WATER AUTH.	BLACKSBURG	49594	0.005512	0.000346	0.07948
2639627	VA	SOUTH HOLSTON RIVER	1	6010102	BRISTOL VA FILTER PLANT	ABINGDON	20000	0.008273	0.000488	0.13067
2639661	VA	NEW RIVER	1	5050001	CITY OF RADFORD WTP	RADFORD	15940	0.005049	0.000314	0.07338
2642974	VA	SOUTH FORK SHENANDOAH	1	2070005	TOWN OF FRONT ROYAL	FRONT ROYAL	10900	0.01507	0.000868	0.25183
2643138	VA	ROANOKE RIVER	1	3010101	CITY OF SALEM WATER DEPT.	SALEM	23900	0.016426	0.000794	0.33031
2645548	VA	NORTHWEST RIVER	1	3010205	CITY OF CHESAPEAKE GR BR NW	CHESAPEAKE	136600	0.012989	0.000718	0.22473
2645931	VA	APPOMATTOX RIVER	1	2080207	VIRGINIA-AMERICAN WATER CO	HOPEWELL	40331	0.005207	0.000329	0.07465
2645971	VA	BLACKWATER RIVER	1	3010202	NORFOLK CITY MOORES BRIDGES	NORFOLK	295000	0.031009	0.001245	0.77025
2645973	VA	NOTTOWAY RIVER	1	3010201	NORFOLK CITY MOORES BRIDGES	NORFOLK	295000	0.010582	0.000588	0.18134
2649771	VA	JAMES RIVER	1	2080205	CITY OF RICHMOND WTP	RICHMOND	209000	0.008998	0.000532	0.1425

PWS_SRCE_ID	STATE	SRCENAME	Type Code	HUC	SYSTEM_NAME	CITY	POPULATION SERVED	predicted 95th%ile Chemical P	lo Prediction Interval Chemical P	hi Prediction Interval Chemical P
2652524	VA	SMITH RIVER	1	3010103	Henry County Public Supply Authorit	MARTINSVILLE	11590	0.00367	0.000221	0.05442
2653767	VA	DAN RIVER	1	3010103	CITY OF DANVILLE-WATER TREAT P	DANVILLE	53056	0.008315	0.000544	0.11804
2653786	VA	JAMES RIVER	1	2080203	CITY OF LYNCHBURG	LYNCHBURG	76000	0.005286	0.00028	0.09179
2653788	VA	JAMES RIVER	1	2080203	CITY OF LYNCHBURG	LYNCHBURG	76000	0.007858	0.000446	0.12927
2654499	VA	OCCOQUAN RIVER RESERVOIR	3	2070010	FAIRFAX CO WTR AUTH HENRY GAY	OCCOQUAN	550000	0.064345	0.002734	1.54431
2654507	VA	POTOMAC RIVER	1	2070008	FAIRFAX CO WTR AUTH JJCORBALIS	HERNDON	150000	0.014177	0.000801	0.24084
2655449	VA	POTOMAC RIVER	1	2070008	TOWN OF LEESBURG	LEESBURG	16700	0.013439	0.000753	0.22953
2656716	VA	RAPPAHANOCK RV	1	2080104	CITY WATERWORKS	FREDERICKSBURG	20750	0.016109	0.000842	0.29836
2797426	NC	CAPE FEAR RIVER	1	3030004	SANFORD, CITY OF	SANFORD	21585	0.020401	0.001087	0.37518
2803017	NC	ROANOKE RAPIDS LAKE	3	3010106	ROANOKE RAPIDS SANITARY DIST	ROANOKE RAPIDS	21421	0.009215	0.000588	0.13519
2887559	NC	TAR RIVER	1	3020101	ROCKY MOUNT WATER SYSTEM	ROCKY MOUNT	55285	0.01088	0.000668	0.16789
2888752	NC	TAR RIVER	1	3020103	GREENVILLE UTILITIES COMM	GREENVILLE	60928	0.010356	0.000611	0.16645
3045996	NC	SOUTH YADKIN RIVER	1	3040102	DAVIE COUNTY WATER SYSTEM	MOCKSVILLE	19439	0.00382	0.000238	0.0548
3045998	NC	YADKIN RIVER	1	3040101	DAVIE COUNTY WATER SYSTEM	MOCKSVILLE	19439	0.006873	0.000459	0.09413
3385897	NC	BADIN LAKE	3	3040103	ALBEMARLE, CITY OF	ALBEMARLE	17079	0.009419	0.000625	0.13257
3385902	NC	TUCKERTOWN LAKE	3	3040103	ALBEMARLE, CITY OF	ALBEMARLE	17079	0.009282	0.000617	0.13013
3489943	SC	SAVANNAH RIVER	1	3060106	NORTH AUGUSTA CITY OF	N AUGUSTA	27775	0.004462	0.000273	0.06578
3490506	SC	SAVANNAH RIVER	1	3060109	BJW&SA	BEAUFORT	18858	0.004206	0.000252	0.06342

PWS_SRCE_ID	STATE	SRCENAME	Type Code	HUC	SYSTEM_NAME	CITY	POPULATION SERVED	predicted 95th%ile Chemical P	lo Prediction Interval Chemical P	hi Prediction Interval Chemical P
3491255	SC	CATAWBA RIVER	1	3050103	CHESTER METRO	CHESTER	15128	0.009992	0.000672	0.13913
3491793	SC	SAVANNAH RIVER	1	3060106	EDGEFIELD CO W&SA	EDGEFIELD	20712	0.004462	0.000273	0.06578
3492113	SC	BLACK RIVER	1	3040205	GEORGETOWN CITY OF	GEORGETOWN	10195	0.004808	0.000233	0.09205
3492320	SC	LAKE GREENWOOD	2	3050109	GREENWOOD CPW	GREENWOOD	39660	0.007869	0.000514	0.11184
3492887	SC	LAKE WATEREE	2	3050104	LUGOFF ELGIN WATER AUTH	LUGOFF	11453	0.009898	0.000647	0.14192
3493018	SC	ENOREE RIVER	1	3050108	CLINTON CITY OF	CLINTON	10265	0.00941	0.000597	0.13997
3493102	SC	CONGAREE RIVER	1	3050110	CAYCE CITY OF	CAYCE	17790	0.00346	0.000178	0.06171
3493104	SC	SALADA RIVER	1	3050109	WEST COLUMBIA CITY OF	WEST COLUMBIA	34331	0.008439	0.000542	0.12257
3493105	SC	LAKE MURRAY	2	3050109	WEST COLUMBIA CITY OF	WEST COLUMBIA	34331	0.007885	0.000505	0.1143
3493855	SC	SALADA RIVER	1	3050109	NEWBERRY CITY OF	NEWBERRY	10548	0.007908	0.000506	0.11498
3494030	SC	NORTH EDISTO RIVER	1	3050203	ORANGEBURG DPU	ORANGEBURG	57795	0.00227	0.000113	0.04119
3494230	SC	LAKE MURRAY	2	3050109	COLUMBIA CITY OF	COLUMBIA	225831	0.007885	0.000505	0.1143
3706040	NC	MOUNTAIN ISLAND RESERVOIR	3	3050101	CHARLOTTE-MECKLENBURG UTILITY	CHARLOTTE	413500	0.005833	0.000395	0.07771
3706041	NC	LAKE NORMAN	3	3050101	CHARLOTTE-MECKLENBURG UTILITY	CHARLOTTE	413500	0.005787	0.000393	0.07663
3707882	NC	YADKIN RIVER	1	3040101	SALISBURY, CITY OF	SALISBURY	26545	0.005339	0.00034	0.0759
3712792	NC	YADKIN RIVER	1	3040101	WINSTON-SALEM, CITY OF	WINSTON SALEM	225000	0.006873	0.000459	0.09413
3715630	NC	DAN RIVER	1	3030103	EDEN, TOWN OF	EDEN	15600	0.007487	0.000487	0.10625
3716492	NC	YADKIN RIVER	1	3040101	KING, CITY OF	TOBACCOVILLE	18000	0.006681	0.000446	0.09137
3856248	SC	SALADA RIVER	1	3050109	GREENWOOD CPW	GREENWOOD	39660	0.006026	0.000395	0.08377

Table 6-2. Predicted 95th Percentile Concentrations of Chemical T by WaRP Regression

PWS_SRCE_ID	STATE	SRCENAME	Type Code	HUC	SYSTEM_NAME	CITY	POPULATION SERVED	predicted 95th%ile Chemical T	lo Prediction Interval Chemical T	hi Prediction Interval Chemical T
1751115	NC	CATAWBA RIVER	1	3050101	MORGANTON, CITY OF	MORGANTON	20550	0.0048927	0.0003212	0.062841
1752969	NC	LAKE RHODHISS	2	3050101	LENOIR, CITY OF	GRANITE FALLS	15700	0.0059282	0.0003928	0.07616
1753921	NC	CATAWBA RIVER	1	3050101	HICKORY, CITY OF	HICKORY	35300	0.0060199	0.000399	0.077369
1776685	NC	YADKIN RIVER	1	3040101	DAVIDSON WATER INC	LEXINGTON	113441	0.009039	0.0006183	0.114697
1787587	NC	CAPE FEAR RIVER	1	3030004	FAYETTEVILLE PUBLIC WORKS COMM	FAYETTEVILLE	128000	0.0192247	0.0014451	0.230995
1799202	NC	BLEWITT FALLS LAKE	3	3040104	RICHMOND COUNTY WATER SYSTEM	ROCKINGHAM	15317	0.0095884	0.0006801	0.116848
1799969	NC	LUMBER RIVER	1	3040203	LUMBERTON, CITY OF	LUMBERTON	21000	0.0094516	0.0006825	0.112758
1803356	NC	FALLS LAKE	3	3020201	RALEIGH, CITY OF	RALEIGH	225000	0.0196646	0.0014782	0.236534
1803365	NC	B EVERETT JORDON LAKE	3	3030002	CARY, TOWN OF	APEX	77030	0.0299476	0.0022657	0.370372
1809276	NC	CAPE FEAR RIVER	6	3030005	BRUNSWICK COUNTY WATER SYSTEM	LELAND	20000	0.021327	0.0016054	0.257658
1819133	NC	CAPE FEAR RIVER	6	3030005	WILMINGTON WATER SYSTEM	WILMINGTON	60906	0.021327	0.0016054	0.257658
1829838	SC	EDISTO RIVER	1	3050205	CHARLESTON CPW	CHARLESTON	197343	0.0031186	0.0002012	0.039974
1830683	SC	BROAD RIVER	1	3050105	GAFFNEY BPW	GAFFNEY	21925	0.0039798	0.0002502	0.053332
1832362	SC	EDISTO RIVER	1	3050205	SUMMERVILLE TOWN OF	SUMMERVILLE	42502	0.0031186	0.0002012	0.039974
1842206	SC	RAW WATER RESERVOIR	3	3050106	UNION CITY OF	UNION	14300	0.005738	0.0003829	0.072896
1842410	SC	CATAWBA RIVER	1	3050101	ROCK HILL CITY OF	ROCK HILL	60988	0.0089456	0.0006073	0.114508
2498081	NC	SOUTH FORK CATAWBA RIVER	1	3050102	GASTONIA, CITY OF	GASTONIA	64000	0.0071713	0.0004704	0.094404
2498083	NC	CATAWBA RIVER	1	3050101	BELMONT CITY OF	BELMONT	10117	0.0077598	0.0005246	0.098906
2500079	NC	LAKE NORMAN	3	3050101	MOORESVILLE WTR TRTMT PLT	MOORESVILLE	10190	0.0065995	0.0004397	0.084763

PWS_SRCE_ID	STATE	SRCENAME	Type Code	HUC	SYSTEM_NAME	CITY	POPULATION SERVED	predicted 95th%ile Chemical T	lo Prediction Interval Chemical T	hi Prediction Interval Chemical T
2500711	NC	LAKE NORMAN	3	3050101	LINCOLN COUNTY WTP	DENVER	10734	0.0065995	0.0004397	0.084763
2513303	NC	CAPE FEAR RIVER	1	3030004	HARNETT CO DEPT OF PUBLIC UTIL	LILLINGTON	31560	0.0188711	0.0014174	0.226784
2513851	NC	NEUSE RIVER	1	3020201	SMITHFIELD, TOWN OF	SMITHFIELD	11750	0.0242267	0.0018055	0.298458
2523518	NC	TAR RIVER	1	3020103	TARBORO WATER SYSTEM	TARBORO	11000	0.0085029	0.0005997	0.10348
2525136	NC	CAPE FEAR RIVER	1	3030005	WILMINGTON WATER SYSTEM	WILMINGTON	60906	0.0176138	0.0013173	0.211165
2637767	VA	NEW RIVER	1	5050001	B'BURG-C'BURG-VPI WATER AUTH.	BLACKSBURG	49594	0.0037866	0.0002491	0.0478
2639627	VA	SOUTH HOLSTON RIVER	1	6010102	BRISTOL VA FILTER PLANT	ABINGDON	20000	0.0054444	0.000374	0.066706
2639661	VA	NEW RIVER	1	5050001	CITY OF RADFORD WTP	RADFORD	15940	0.0031879	0.0002057	0.040853
2642974	VA	SOUTH FORK SHENANDOAH	1	2070005	TOWN OF FRONT ROYAL	FRONT ROYAL	10900	0.0124921	0.0009201	0.148753
2643138	VA	ROANOKE RIVER	1	3010101	CITY OF SALEM WATER DEPT.	SALEM	23900	0.0173747	0.0012773	0.213949
2645548	VA	NORTHWEST RIVER	1	3010205	CITY OF CHESAPEAKE GR BR NW	CHESAPEAKE	136600	0.0082726	0.0005876	0.10025
2645931	VA	APPOMATTOX RIVER	1	2080207	VIRGINIA-AMERICAN WATER CO	HOPEWELL	40331	0.0047513	0.0003123	0.060815
2645971	VA	BLACKWATER RIVER	1	3010202	NORFOLK CITY MOORES BRIDGES	NORFOLK	295000	0.0122467	0.0008344	0.162098
2645973	VA	NOTTOWAY RIVER	1	3010201	NORFOLK CITY MOORES BRIDGES	NORFOLK	295000	0.0037872	0.0002497	0.04786
2649771	VA	JAMES RIVER	1	2080205	CITY OF RICHMOND WTP	RICHMOND	209000	0.007356	0.0005205	0.088445
2652524	VA	SMITH RIVER	1	3010103	Henry County Public Supply Authorit	MARTINSVILLE	11590	0.001911	0.0001149	0.026079
2653767	VA	DAN RIVER	1	3010103	CITY OF DANVILLE-WATER TREAT P	DANVILLE	53056	0.0068417	0.0004632	0.086335
2653786	VA	JAMES RIVER	1	2080203	CITY OF LYNCHBURG	LYNCHBURG	76000	0.0035596	0.0002317	0.045648
2653788	VA	JAMES RIVER	1	2080203	CITY OF LYNCHBURG	LYNCHBURG	76000	0.0063787	0.0004451	0.077444
2654499	VA	OCCOQUAN RIVER RESERVOIR	3	2070010	FAIRFAX CO WTR AUTH HENRY GAY	OCCOQUAN	550000	0.0654228	0.0047866	0.887917

PWS_SRCE_ID	STATE	SRCENAME	Type Code	HUC	SYSTEM_NAME	CITY	POPULATION SERVED	predicted 95th%ile Chemical T	lo Prediction Interval Chemical T	hi Prediction Interval Chemical T
2654507	VA	POTOMAC RIVER	1	2070008	FAIRFAX CO WTR AUTH JJCORBALIS	HERNDON	150000	0.0090806	0.0006516	0.109279
2655449	VA	POTOMAC RIVER	1	2070008	TOWN OF LEESBURG	LEESBURG	16700	0.0081594	0.0005793	0.098813
2656716	VA	RAPPAHANOCK RV	1	2080104	CITY WATERWORKS	FREDERICKSBURG	20750	0.0114328	0.0008283	0.138606
2797426	NC	CAPE FEAR RIVER	1	3030004	SANFORD, CITY OF	SANFORD	21585	0.0200867	0.0015115	0.242106
2803017	NC	ROANOKE RAPIDS LAKE	3	3010106	ROANOKE RAPIDS SANITARY DIST	ROANOKE RAPIDS	21421	0.0068446	0.000472	0.084415
2887559	NC	TAR RIVER	1	3020101	ROCKY MOUNT WATER SYSTEM	ROCKY MOUNT	55285	0.009068	0.0006432	0.110075
2888752	NC	TAR RIVER	1	3020103	GREENVILLE UTILITIES COMM	GREENVILLE	60928	0.008974	0.0006375	0.108671
3045996	NC	SOUTH YADKIN RIVER	1	3040102	DAVIE COUNTY WATER SYSTEM	MOCKSVILLE	19439	0.0020807	0.0001247	0.028605
3045998	NC	YADKIN RIVER	1	3040101	DAVIE COUNTY WATER SYSTEM	MOCKSVILLE	19439	0.0049973	0.0003301	0.063757
3385897	NC	BADIN LAKE	3	3040103	ALBEMARLE, CITY OF	ALBEMARLE	17079	0.0092064	0.0006368	0.115381
3385902	NC	TUCKERTOWN LAKE	3	3040103	ALBEMARLE, CITY OF	ALBEMARLE	17079	0.0091975	0.0006355	0.115417
3489943	SC	SAVANNAH RIVER	1	3060106	NORTH AUGUSTA CITY OF	N AUGUSTA	27775	0.0039199	0.0002494	0.05169
3490506	SC	SAVANNAH RIVER	1	3060109	BJW&SA	BEAUFORT	18858	0.004525	0.000297	0.057858
3491255	SC	CATAWBA RIVER	1	3050103	CHESTER METRO	CHESTER	15128	0.0127276	0.0008845	0.162147
3491793	SC	SAVANNAH RIVER	1	3060106	EDGEFIELD CO W&SA	EDGEFIELD	20712	0.0039199	0.0002494	0.05169
3492113	SC	BLACK RIVER	1	3040205	GEORGETOWN CITY OF	GEORGETOWN	10195	0.0067495	0.0004733	0.081767
3492320	SC	LAKE GREENWOOD	2	3050109	GREENWOOD CPW	GREENWOOD	39660	0.0095738	0.0006322	0.127285
3492887	SC	LAKE WATEREE	2	3050104	LUGOFF ELGIN WATER AUTH	LUGOFF	11453	0.0121985	0.0008613	0.152052
3493018	SC	ENOREE RIVER	1	3050108	CLINTON CITY OF	CLINTON	10265	0.0111883	0.0007173	0.155475
3493102	SC	CONGAREE RIVER	1	3050110	CAYCE CITY OF	CAYCE	17790	0.0093599	0.0006176	0.124382
3493104	SC	SALADA RIVER	1	3050109	WEST COLUMBIA CITY OF	WEST COLUMBIA	34331	0.0093524	0.0006385	0.119233

PWS_SRCE_ID	STATE	SRCENAME	Type Code	HUC	SYSTEM_NAME	CITY	POPULATION SERVED	predicted 95th%ile Chemical T	lo Prediction Interval Chemical T	hi Prediction Interval Chemical T
3493105	SC	LAKE MURRAY	2	3050109	WEST COLUMBIA CITY OF	WEST COLUMBIA	34331	0.0082799	0.0005632	0.105181
3493855	SC	SALADA RIVER	1	3050109	NEWBERRY CITY OF	NEWBERRY	10548	0.0091438	0.0006178	0.117889
3494030	SC	NORTH EDISTO RIVER	1	3050203	ORANGEBURG DPU	ORANGEBURG	57795	0.0039863	0.0002551	0.052225
3494230	SC	LAKE MURRAY	2	3050109	COLUMBIA CITY OF	COLUMBIA	225831	0.0082799	0.0005632	0.105181
3706040	NC	MOUNTAIN ISLAND RESERVOIR	3	3050101	CHARLOTTE-MECKLENBURG UTILITY	CHARLOTTE	413500	0.0066556	0.0004453	0.085094
3706041	NC	LAKE NORMAN	3	3050101	CHARLOTTE-MECKLENBURG UTILITY	CHARLOTTE	413500	0.0065995	0.0004397	0.084763
3707882	NC	YADKIN RIVER	1	3040101	SALISBURY, CITY OF	SALISBURY	26545	0.0044443	0.0002895	0.057303
3712792	NC	YADKIN RIVER	1	3040101	WINSTON-SALEM, CITY OF	WINSTON SALEM	225000	0.0049973	0.0003301	0.063757
3715630	NC	DAN RIVER	1	3030103	EDEN, TOWN OF	EDEN	15600	0.005222	0.0003464	0.066452
3716492	NC	YADKIN RIVER	1	3040101	KING, CITY OF	TOBACCOVILLE	18000	0.0048297	0.0003181	0.061712
3856248	SC	SALADA RIVER	1	3050109	GREENWOOD CPW	GREENWOOD	39660	0.0070856	0.0004573	0.095071

VII. The Multi-Pathway Cumulative Assessment

As demonstrated above, sufficient data and methods exist to produce detailed, time-dependent estimates of risk from exposure to more than one pesticide from the same source. In addition, exposure can be calculated on a route specific basis within a source as demonstrated for the residential scenarios which incorporate inhalation, dermal and oral components of exposure, comparing them to route specific toxicity endpoints to estimate total cumulative risk. Using the same calendar based approach, it is possible to combine the exposures from the food, water and dietary pathways. To develop a cumulative risk assessment that is highly descriptive of the likely interactions of the three pathways of exposure -- food, drinking water and residential -- the contributions from each pathway must be calculated simultaneously for every exposed by individual for every day reflected during the time frame of the exposure estimate. In other words, the dietary (food + drinking water) estimate for all pesticides likely to be encountered by an individual on a particular day must be calculated. The exposures from residential uses must also be calculated and the combination of these sources of exposure combined for each individual in the assessment. Then, another individual's exposure estimate is calculated. This process is repeated for each individual’s exposure estimate on each simulated day in the cumulative risk assessment. Maintaining the relationship between the residential and dietary portions of the pesticide exposure is an important aspect of the assessment in order to ensure that all estimated sources for a given individual are normalized for the same gender, body weight and time of year.

A. Attributes of the Case Study

The current case study focuses on estimating the potential risk from exposure to 24 organophosphorus pesticides in food, drinking water and from residential uses. The assessment is limited in geographic scope to the Piedmont area of Virginia, North Carolina and South Carolina. This limitation was placed on the assessment to ensure that the water and residential components of the assessment would reflect a coherent set of pesticide uses likely to be encountered from both urban and agricultural uses. Understanding the likelihood of co-occurrence of pesticide uses is critical to developing a reasonable estimate of total cumulative risk. In the absence of direct measures of co-occurrence, overlapping exposures must be extrapolated from use data.

As indicated for the food and residential components of the cumulative risk assessment, two PoDs were used for the oral component of the total cumulative risk assessment. The estimated ED10 (0.175 mg/kg body wt/day) and the NOAEL (0.02 mg/kg body wt/day) for plasma cholinesterase inhibition by the index compound, Chemical T, were each used. The inhalation and dermal components of the assessment were compared to NOAELs of 0.026 and 1 mg/kg body wt/day, respectively.

Integrated cumulated risk assessments were conducted for the age groups of Children,1-3 years of age and Adults,18+ years. These two groups were chosen to emphasize the effects of differences in behavior and food consumption patterns on estimating the risk from exposure to pesticides. The assessments reflect the same assumptions about use scenarios, timing of exposures and exposures to pesticides in food and water as used in the previous pathway specific assessments. An entire year of exposure is simulated.

The food component of the cumulative risk assessment contains as many commodities as could reasonably be extrapolated from the available PDP monitoring data. This component of the assessment is regarded as highly refined and reflective of exposures likely to be encountered by the U.S. population. The water component of the assessment has been conducted such that the exposure component is conservative in nature. That is, the pesticide residue concentrations used in the assessment were likely to underestimate exposure no more than 18-20 days per year. Overestimation was much more likely. The residential component of the assessment was also designed to reflect an overestimation bias to ensure that risk from these sources of exposure were not likely to be underestimated.

One of the most significant uses of a cumulative risk assessment is the ability to identify the pathways and chemicals that reflect the greatest contribution to risk. One possible approach to identifying risk sources is demonstrated in the scenarios presented below. The results of three mitigation strategies are presented including the removal of the use of OPs for treating grubs and fleas in lawns, and the discontinuation of crack and crevice treatments inside of the house.

B. Results

Analyses of the outputs of a cumulative distribution rely heavily upon examination of the results for changing patterns of exposure. To this end, graphical presentation of the data provides a useful method of examining the outputs for patterns. Abrupt changes in the slope of an exposure or MOE curve may indicate some combination of exposure conditions resulting in an altered risk profile due to a variety of factors. Factors may include increased pest pressure and subsequent home pesticide use, or increased use in an agricultural setting that may result in increased concentrations in water. Alternatively, a relatively stable slope indicates that exposures from a given source or combination of sources is stable across time and the sources of risk may be less obvious.

Because multiple calculations for each individual in the CSFII population panel are conducted for each day of the year, a distribution of daily exposures is available for each route and source of exposure throughout the entire year. In addition, a simultaneous calculation of MOEs for the combined risk from all routes is calculated, permitting the estimation distributions of the various percentiles of total risk across the year. As a result, the risk estimates can be displayed as a time series of exposure percentiles. As demonstrated in the graphical presentations of analytical outputs for this section, results are displayed as MOEs with the various pathways, routes and the total exposures arrayed across the year. Estimates are displayed as MOEs for this case study because the exposures from each route are compared to route specific endpoints delivered to the body. As such, an estimate of total delivered dose would not be meaningful for this case study.

Estimates of cumulative risk from 24 OPs in foods and their associated residential uses and concentrations of two OPs in drinking water are presented in Appendices A for Children, 1-3 years, and for Adults, 18+ years in Appendix B. The contributions of each of the major routes of exposure and the likely sources of those exposures is discussed in Section V above. The impact of removing specific pesticide uses on the total cumulative risk is demonstrated graphically for Children, 1-3 years in Appendix C and for Adults, 18+ years in Appendix D. Graphical presentations are limited to the 95th, 99th, and 99.9th percentiles because of the results of lower percentiles are unaffected by mitigation strategies.

1. Children, 1-3 years

The results of the total cumulative assessment for Children, 1-3 years using an estimated ED10 as the oral PoD are presented in Appendix A in Figures A-3, A-4 and A-5. Results using the NOAEL for the PoD are presented in Appendix B in Figures B-3, B-4 and B-5.

95th Percentile - The significant source of pesticidal risk from exposure to pesticides at this percentile of exposure was via the inhalation route when the oral component was compared to the ED10 (Figure A-3). This pattern of exposure is consistent with exposure from the crack and crevice use of pesticides in the home, with a stable level of exposure across the entire year and no apparent seasonal component. MOEs for the inhalation route were approximately 350. The dietary component of the assessment was also stable across time with an MOE of 1300-1400 across the year. When the oral component of the cumulative risk was compared to the NOAEL, the MOEs (~150) were shifted such that the dietary source of exposure became the most important contributor to risk (Figure B-3).

99th Percentile - Comparing to the oral ED10, the total cumulative risk was reflected in MOEs of 40-50 (Figure A-4). The contribution from the inhalation component became even more prominent as a source of risk with MOEs between 40-65, with no apparent time dependent variation. Noteworthy dermal and non-dietary oral components of exposure appeared abruptly during the months of March to May (Julian Days 72 though 156). During this period, the dermal MOEs were between 175 and 565. Although visible within the framework of the risk assessment, the dermal and non-dietary oral components had little effect on the total risk against the background of the inhalation exposure and the lower level dietary exposures. When the oral PoD was changed to reflect the NOAEL, the MOE for dietary sources of exposure became ~60, essentially equivalent to the risk from the inhalation exposure (Figure B-4). The total cumulative risk was increased as indicated by a total MOE of 25-30.

<u>99.9th Percentile</u> - The same pattern for relative source contribution continued at this exposure percentile. Using the oral ED10 for the oral PoD, the inhalation component of the exposure remained the most significant source of risk with a relatively constant year round MOE between 6-12 (Figure A-5). With the exception of the one period (the March to May grub, flea and shrub treatment period), the total cumulative risk was equivalent to the cumulative inhalation risk. From March to May, significant non-dietary oral and dermal components of exposure were obvious, with the dermal component causing a noticeable impact on the total cumulative risk. MOEs for this period were ~4. A second window of dermal and non-dietary exposure is also apparent during October and November (Julian Days 286-336). This period corresponds to a second application period for fleas using Chemicals U and B. The impact on the total risk picture is negligible, with MOEs below both those for dietary and inhalation. When the NOAEL is substituted as the oral PoD (Figure B-5), the total cumulative risk is shifted to lower MOEs of 5-7 for all but ther periods from March to May during which the totals were 2-3. At this percentile of exposure, the relative contribution to risk from the oral component of exposure becomes approximately equal to that from the inhalation exposure with MOEs for dietary exposure alone of 9. With this additional burden from the dietary component, the relative contributions from the non-dietary oral and dermal exposures become much less noticeable in light of the total.

<u>No flea use</u> - The results of the total cumulative assessment for Children, 1-3 years with flea treatments removed from the scenario, and using an estimated ED10 as the oral PoD are presented in Appendix C in Figures C-1, C-2 and C-3. Results using the NOAEL for the PoD are presented in Appendix D in Figures D-1, D-2 and D-3.

<u>95th Percentile</u> - Comparing Figure C-1 to A-3 and Figure D-1 to B-3, it is apparent that there has been little impact on the total cumulative risk. In the first instance, the inhalation is still the overriding source of risk, resulting from indoor crack and crevice uses. In the second case)PoD = NOAEL), the dietary exposure remains the most important source of risk.

<u>99th Percentile</u> - At this exposure percentile with oral PoD = ED10, little change has occurred relative to the unmitigated scenario (Figures C-2 and A-4). The dermal and non-dietary oral components of the risk from the March to May applications can be observed in the background against a dominant inhalation source of risk. Substituting the NOAEL for the oral PoD further reduces the significance of the risk mitigation by increasing the relative importance of the dietary oral component (Figures D-2 and B-2).

<u>99.9th Percentile</u> - The profile at this percentile is essentially the same as observed for the 99th percentile. The significant impact of the dermal source of exposure and the non-dietary oral exposures at this percentile during March to May are greatly reduced by removing the flea use (Figures C-3 and A-5). In addition, no dermal or non-dietary oral component of exposure is evident in the fall months. Use of the NOAEL for estimating oral risk greatly reduces the impact of this effort at risk mitigation (D-3 and B-5).

<u>No grub use</u> - The results of the total cumulative assessment for Children, 1-3 years removing grub uses on lawns from the scenario, using an estimated ED10 as the oral PoD are presented in Appendix C in Figures C-4, C-5 and C-6. Results using the NOAEL for the PoD are presented in Appendix D in Figures D-4, D-5 and D-6.

<u>95th Percentile</u> - As for the flea scenario above, no noteworthy impact on the total cumulative risk is obtained by removing the flea use at this percentile of exposure using either PoD (Figures C-4, D-4, A-3 and B-3).

<u>99th Percentile</u> - In Figure C-5 (PoD = ED10), the inhalation component of exposure remains the driving force in the total risk picture. Compared to the unmitigated case (Figure A-4), the relative contribution of the dermal and non-dietary components of the exposure are greatly reduced. The graphing of the exposure curves results in a series of discontinuities, suggesting that very few individuals are experiencing significant exposure from these sources during the March to May season. Changing to the comparison to the NOAEL (Figures D-5 and B-4) results in the previously noted shift to reflect greater contribution to risk from the dietary pathway.

<u>99.9th Percentile</u> - In Figure C-6 (PoD = ED10), the very pronounced excursions from dermal and non-dietary sources are noted as was true for the unmitigated case (Figure A-5). In addition, the October-November occurrence of the dermal and non-dietary components of risk are also evident. This observation confirms that the source of these excursions is the flea treatments and not the lawn grub treatment. Removing this use has little impact on the total cumulative risk at any percentile of exposure. When compared to the oral PoD of NOAEL =0.02 mg/kg body wt/day, the

impact of the dermal exposure is lessened as the prominence of the dietary pathway increases (Figure D-6). However, even within this high background, the contributions from non-dietary and dermal components of exposure are noteworthy.

No crack and crevice use - The results of the total cumulative assessment for Children, 1-3 years following removal of the crack and crevice uses, and using an estimated ED10 as the oral PoD are presented in Appendix C in Figures C-7, C-8 and C-9. Results using the NOAEL for the PoD are presented in Appendix D in Figures D-7, D-8 and D-9.

95th Percentile - Comparing the results in Figure C-7 with those in Figure A-3, a great reduction in the total cumulative risk is apparent. The inhalation component of the exposure has largely disappeared in this revised scenario. Total MOEs are reduced from the previous 270 to between 1280 and 1380. The impact of this mitigation activity is much less when the oral component of the exposure is compared to the NOAEL. In this case, the total risk is reduced to an MOE of ~150, a much smaller reduction due to the overriding dietary risk contribution.

99th Percentile - In Figure C-8, the March to May period of overlapping exposures become the key period of consideration in identifying sources of risk. When compared to Figure A-4, the inhalation exposure from the crack and crevice use has disappeared as a risk driver. The dermal component of the exposure causes a drop in the total MOE from the background level of 475-540 to the 130-240. When the comparison of oral exposure is made to the NOAEL (Figure D-8), the contribution from the dietary pathway becomes dominant across the entire year (total MOE ~ 60), with little impact from the dermal component on the total risk. The non-dietary oral component increases in prominence to MOEs of ~200-235, with a resulting decrease in the final MOEs for the period (~40).

99.9th Percentile - At this percentile of exposure and using the PoD = ED10 (Figure C-9), dietary oral and inhalation components of the exposure were reflected in a background level of risk with an MOE of ~170. As at the lower percentiles of exposure, a marked reduction in the contribution from inhalation is apparent relative to the unmitigated use scenario (Figure A-5). The MOEs for inhalation in Figure A-5 are ~10, compared to inhalation MOEs indicative of essentially no inhalation exposure in Figure C-9. During the periods from March to May, notable contributions from dermal and non-dietary oral exposures are evident, with total MOEs for this period decreasing to 5-7. These increased exposures appear to correlate with the spring flea treatment. A second period of fleas treated can be observed in the months of October to November, but there is little impact on the total MOE from this treatment. When oral exposures are compared to the NOAEL (Figure D-9), the change in the total risk from the spring flea treatment is reflected by an decrease in MOE to 2-3 from a background level of 18-20.

2. Adults, 18+ years

The results of the total cumulative assessment for Adults, 18+ years using an estimated ED10 as the oral PoD are presented in Appendix A in Figures A-8, A-9 and A-10. Results using the NOAEL for the PoD are presented in Appendix B in Figures B-8, B-9 and B-10.

<u>95th Percentile</u> - Adult patterns of risk contributions were similar to those for children although less pronounced (Figures A-8 and B-8). When oral exposure was compared to the ED10, the oral and inhalations sources of exposure resulted in constant levels of risk throughout the year, with MOEs of ~350 for inhalation and ~1750 for dietary oral exposure. No other sources of exposure are evident. When the oral exposure is compared to the NOAEL, the contribution from the dietary oral sources is increased as indicated by an MOE of ~310. The shift in oral PoDs from the ED10 to the NOAEL results in a change in the total MOE from 295 to165.

<u>99th Percentile</u> - In Figure A-9, the inhalation component remains the most significant source of risk, with MOEs for inhalation of ~145 throughout most of the year, probably resulting from indoor crack and crevice use. The total MOEs for the background period are 120-130. During the months of March to May, a noteworthy increase in dermal exposure occurs, causing an decrease in the total MOEs for this period to the range of 85-100. A second period of dermal exposure is observed during the period from June to August, but this exposure had no apparent impact on the total MOE. The increase in dermal exposure for adults reflects the application of do-it-yourself residential pesticides as opposed to the large impact of post-application exposures seen in children. This pattern of exposures and risk contributions also differs from that seen in children in that there is no evidence of non-dietary oral exposure. When the oral component of exposure is compared to the NOAEL for risk estimation (Figure B-9), the contribution from the dietary component of exposure increases in significance to parity with the inhalation source. Both of these exposures have MOEs of ~145 throughout the year. The total MOE declined to ~70. The magnitude of the perturbation of the total MOE by the dermal exposure in the March to May time frame was greatly decreased, with total MOEs decreasing to 55-60.

<u>99.9th Percentile</u> - At this percentile of exposure, inhalation exposure remained the most significant contributor to the total risk. This was true whether using the ED10 or NOAEL for the oral PoD (Figures A-10 and B-10). The apparent source of the inhalation exposure appears to be the crack and crevice use. In addition, dermal exposures were apparent during three time periods of the year: March to May, June to August and October to November, corresponding to three major periods of treatment.

No non-dietary oral component was apparent in either Figure. The dermal component during the March to May treatment season cause a decrease in the total MOE in both risk calculations, although the magnitude of the decrease was greater when oral risk was calculated using the ED10. Total risk from all scenarios combined resulted in MOEs in the range of 15-20, dropping to about 9 during March to May. When the oral risk was calculated using the NOAEL, the background total MOEs were12-15, dropping to 7-8 in the March to May season.

No flea use - The results of the total cumulative assessment for Adults, 18+ years with fleas uses eliminated using an estimated ED10 as the oral PoD are presented in Appendix C in Figures C-10, C-11 and C-12. Results using the NOAEL for the PoD are presented in Appendix D in Figures D-10, D-11 and D-12.

95th Percentile - The removal of the flea use resulted in essentially no change in the estimated risks relative to the risk estimates with all scenarios included. This was true when compared to the ED10 (Figures A-8 and C-10) or the NOAEL (Figures B-8 and D-10).

99th Percentile - At this percentile of exposure, estimating the oral risk contribution using the ED10 and NOAEL, the major change in the estimated risk profile was a marked reduction in the magnitude of the dermal component of the total risk (Figures A-9, B-9, C-11 and D-11). The MOEs for dermal exposure decreased from 230-270 to 3600-3900 during the months of March to May. The impact of the dermal component on the total risk was completely eliminated by removing the flea use regardless of the point of departure used.

99.9th Percentile - Changes in the results at this percentile of exposure from the removal of the flea uses were consistent with those seen at the 99th percentile of exposure with the exception that the MOEs for all pathways were lower (Figures C-12 and D-12).

No grub use - The results of the total cumulative assessment for Adults, 18+ years with lawn treatments for grubs removed and using an estimated ED10 as the oral PoD are presented in Appendix C in Figures C-13, C-14 and C-15. Results using the NOAEL for the PoD are presented in Appendix D in Figures D-13, D-14 and D-15.

95th Percentile - At this percentile of exposure, the results of the cumulative risk assessment were identical to those seen with all scenarios included (Figures C-13 and D-13). There were no apparent impacts from the remaining residential scenarios on the total cumulative risk.

99th Percentile - At this exposure percentile, a small proportion of the population exhibited dermal exposure (Figures C-14 and D-14). When compared with the exposure profiles from all scenarios combined (Figures A-9 and B-9), the relative magnitude of the exposures indicated are comparable. However, the exposure profile appears as a series of discontinuous lines, suggesting that only a few individuals are experiencing dermal exposures. This observation suggests that a substantial portion of the dermal exposure for adults at this exposure percentile that was observed in the combination of all scenarios was due do-it-yourself lawn treatments for grubs.

99.9th Percentile - The impact of removal of the grub uses on the risk profile is essentially the same as observed at the 99th percentile of exposure (Figures C-15 and D-15). Generally, the risk profile, total and component contributions, is unchanged except for the period of lawn treatment for grubs in March to May. As at the 99th percentile, the dermal exposure signature is discontinuous, suggesting that it reflects relatively few exposed individuals.

No crack and crevice use - The results of the total cumulative assessment for Adults, 18+ years with removal of the crack and crevice use and using an estimated ED10 as the oral PoD are presented in Appendix C in Figures C-16, C-17 and C-18. Results using the NOAEL for the PoD are presented in Appendix D in Figures D-16, D-17 and D-18.

95th Percentile - Removal of the crack and crevice use resulted in the disappearance of essentially all of the inhalation component of exposure (Figures C-16 and D-16). At this percentile of exposure, the total risk is reflective of the dietary component of exposure only. As such, the exposure is constant throughout the year, with an MOE = 1790 when compared to the ED10, and an MOE = 204 when compared to the NOAEL.

99th Percentile - At this level of exposure, the only deviation from the background of dietary exposure is the occurrence of a marked dermal exposure signature during the period from March to May, consistent with the previously noted grub and flea treatments (Figures C-17 and D-17). As at 95th percentile of exposure, no inhalation exposure is apparent. When compared to the ED10, the dietary contribution reflects MOEs of ~1300, with a dermal MOE of ~200-400 superimposed. Total MOEs in this assessment for the period from March to May decrease to ~200-300. When comparing the oral component of the exposure to the NOAEL, the background MOE becomes ~150. The dermal contribution of MOE = 200-400 causes a decrease in the total MOE to between 90-120 for the period fro March to May.

99.9th Percentile - Figures C-18 and D-18 reflect the dramatic increase in the importance of dermal exposure in this use scenario at high exposure percentiles. Background risks from dietary exposure are reflected by MOEs of 405-450 and ~50 when compare to the ED10 and NOAEL, respectively. However, during the March to May treatment season, dermal exposures reflected by MOEs of 15-20 cause the total risks to increase as reflected by MOEs decreased to 13-22 and 11-15, respectively. As would be anticipated, the magnitude of the change is greater when comparing the oral exposure to the ED10 than the NOAEL. A second period of dermal exposure in the October to November time frame reflecting a fall flea treatment causes a slight decrease in the total MOE (270-300) when compared to ED10. However, the magnitude of this exposure is too small to impact the total risk estimate when compared to a dietary risk background calculated using the NOAEL.

VIII. Conclusions

The passage of the FQPA imposed upon OPP the requirement to evaluate risk on a "cumulative" basis. Prior to FQPA, OPP assessed exposures to pesticides on a chemical and pathway specific basis. That is, exposures had been evaluated on a single chemical/single pathway paradigm. With the cumulative assessment requirement of FQPA, OPP began to investigate methodologies that would permit exposures to a single pesticide to be appropriately summed across pathways and routes (e.g., food/oral, water/oral, residential/dermal) and then permit exposures to pesticides with a common mechanism to be summed across chemicals.

This document is OPP's first case study developed to demonstrate one possible approach to conducting a cumulative risk assessment that combines exposures to OP pesticides across pathways, routes, and chemicals. It incorporates ideas, processes, and thoughts provided during and subsequent to previous SAP meetings dealing with a variety of related issues. It is presented to help elicit and focus discussion on the detailed techniques of and mechanics behind a cumulative risk assessment.

This case study uses Relative Potency Factors (RPFs) for the OP pesticides which were generated and presented to the SAP in September 2000. These RPFs are based on a selected Index Chemical (here, Pesticide T) and relate the toxicity of Cumulative Assessment Group (CAG) pesticides which are to be accumulated to this index chemical such that all CAG members can be expressed in a common Pesticide T equivalent unit. The Calendex software (and its DEEM component) is then used to probabilistically combine these exposures (now expressed in common toxicity units through use of the RPF) across pathways and generate a *cumulative* risk assessment by simultaneously estimating – on an individual-by-individual basis and for each day in the assessment – a route- and pathway-specific exposure. The resulting cumulative assessment is intended to serve as a pointer toward major sources of risk likely to accrue due to the use of a variety of pesticides with a common mechanism of toxicity.

This case study has demonstrated that available data can be combined to conduct a cumulative risk assessment for the OP pesticides. The assessment was geographically limited to the mid-Atlantic/Piedmont area of the U.S. so as to permit a regional assessment in which use practices, patterns, and customs share a common basis and are specific to this region. The food component of the assessment consists of the contribution of each of the 24 OP pesticides as they occur in USDA's PDP pesticide monitoring database. The residential component of the assessment reflects estimated crack and crevice, lawn, and rose uses for seven of the 24 OP's which are common to the geographic area under consideration. The water component of the assessment uses population weighted 95% upper prediction limits on 95th percentile water concentrations generated by USGS's WARP regression based model to predict water concentrations in raw drinking water at each of 71 drinking water treatment sites in the geographic region for which the assessment was performed. This component of the assessment was limited to two OP pesticides for which WARP data was available to permit chemical specific modeling of the relationship of OP's to use in the area.

The output from the Calendex/DEEM software is presented in figures in Appendices A through D of this document and illustrate, at various selected percentiles, estimated daily cumulated risks (expressed in terms of MOE) over the course of a year. As can be seen, the display is route/pathway specific, thereby permitting the exposure analyst and risk manager to effectively evaluate and assess the various specific significant contributors to total cumulative risk. Conclusions reached from analyzing the results from the case study illustrated here, for example, are as follows:

- The results of the cumulative risk assessment are sensitive to the quality and quantity of data used to generate exposure estimates. Major consideration in the current case study have been highlighted but bear repeating. A detailed estimate of exposure to pesticides in foods was possible because of the availability of a large body of data reflecting pesticide residues in foods close to the point of consumption, and with a direct measure of co-occurrence of OPs in foods. However, not all classes of pesticides are likely to such well developed data sets. The anticipated uncertainty in the food component of the assessment will be greatly increased to the extent that assumptions regarding use patterns must be used to estimate co-occurrence. The impact of the inclusion of ½ LOD values for non-detectable values did not result in any notable change in the risk from exposure to pesticides in foods at the upper percentiles of exposure. This observation is an important indicator that this convention may not be useful in improving the precision or accuracy of the risk estimates in the upper percentiles where regulatory decisions are made.

- Detailed examination of the inputs into the residential exposure scenarios revealed that the quality and quantity of data available for estimating exposure contributions by chemical greatly impacted the apparent importance of each combination. In all cases, the understanding of the likely patterns of use were critical to understanding the likely risk from each pesticide. In particular, those scenario-chemical combinations for which distributions of residues were available were estimated to contributed less to the total risk than those for which only conservative, point estimates of residues were available. Although OPP believes that the total exposure estimates from the residential scenarios are reasonable in magnitude, their accuracy and precision could be greatly improved with more information concerning residues resulting from the various patterns of use and their associate probabilities.

- The current case study demonstrates a situation in which the assessment was very insensitive to the water residue concentrations estimated using the WARP model. The ability of the WARP model to provide accurate estimates of surface water pesticides is highly dependent upon accurate information on regarding the agricultural and urban use patterns of pesticides in the geographic area of the assessment. In addition, developing pesticide-specific regression equations, the most accurate application of the WARP process, is dependent on the availability of sufficient monitoring data to support modeling efforts. The application of the WARP output was intentionally conservative. In situations where estimated water concentrations are likely to impact the outcome of the assessment because they are greater in magnitude, the importance of developing highly descriptive predictive models will increased and reliable information regarding co-occurrence of the pesticides of interest in water samples, and a method for incorporationg this information, will become of increasing importance.

- The selection of an appropriate point of departure for each route of exposure is critical to identifying the most important sources of risk and the relative magnitude of their contribution to the total cumulative risk. As was evident in Section VII, the use of the oral NOAEL greatly changed the relative risk contribution from both dietary and non-dietary sources of oral exposure. This choice, compared to the use of the ED10, greatly affected the apparent impact of alteration of the residential use patterns on the total risk. This observation underscores the need to carefully evaluate the nature of the toxic effect upon which the estimation of risk is based. Specifically, different types of effects may more appropriately be evaluated by ED10s, estimated NOAELs or other endpoints. This selection will vary depending upon the relationship between exposure to the pesticide and the onset of effects. Important factors for consideration would include the shape of the dose response curve, latency and the sensitivity of the method for measuring response, i.e., the ability to determine the point in the dose range at which the adverse effect becomes operative.

The above conclusions will permit the risk manager to evaluate and assess the major contributors to cumulative risk and to target follow-up risk mitigation strategies toward those pesticide uses which most contribute to high end exposures. Information such as that provided by a comprehensive cumulative assessment can be critical toward ensuring that the specific mitigation activities selected by the risk managers are reasoned, sound, and effective.

In addition to identifying the significant drivers of cumulative risk and suggesting appropriate mitigation measures for consideration, a cumulative risk assessment can also serve as a useful tool to evaluate risk-risk trade-offs. OPP is keenly aware of issues associated with risk offsets in which one toxic pesticide is used to replace another (perhaps less toxic, but less effective). It is not necessarily axiomatic that total cumulative risks will be reduced in this situation if the replacement pesticide is used at greater rates or greater frequencies by the public than the pesticide it is replacing. The cumulative assessment paradigm presented to the SAP for review can provide a valuable additional tool in risk management activities which can permit a fuller accounting and more explicit, quantitative consideration of the multitude of relevant factors which should be appropriately considered and weighed in any valid decision making process.

With this document, OPP has demonstrated an approach to combining the available data to conduct such a cumulative risk assessment for the OP pesticides. It should be remembered that this case study is intended to demonstrate the concepts put forth in the cumulative risk assessment document and to provide a conceptual basis for deliberations; it should not be interpreted as representing OPP’s recommended procedure for conducting cumulative risk assessment, as demonstrating a cumulative assessment intended for regulatory purposes, or as portending any final regulatory decisions or judgements or future regulatory actions.