I. Preliminary OP Cumulative Risk Assessment

C. Cumulative Risk From Pesticides in Foods

1. Introduction to Food

The cumulative dietary risk due to the use of Organophosphorus (OP) Chemicals on food crops was assessed using residue monitoring data collected by the United States Department of Agriculture's Pesticide Data Program (USDA-PDP) supplemented with information from the Food and Drug Administration (FDA) Surveillance Monitoring Programs. The BMD10 for brain cholinesterase inhibition in female rats was chosen as the Toxicological Point of Departure (POD) for this assessment. Methamidophos served as the index chemical. The residue values for the other OP chemicals were converted to methamidophos equivalents by a Relative Potency Factor (RPF) approach. Residue data were collected on approximately 44 food commodities monitored by PDP between the years of 1994 and 2000. Food processing factors were applied to specific chemical/commodity pairs to extend these data for use on cooked and processed food/food forms in the analysis. The PDP residue data were further extended to other commodities identified as reasonable for translation of pesticide residue data per OPP/HED SOP 99.3 (USEPA, 1999b); see Table III.C.4. Other food commodities, not included in the PDP database, were incorporated using FDA monitoring data. The residue estimates incorporated in the assessment represent approximately 96 percent of the per capita food consumption for children aged 3 to 5 years in the Continuing Survey of Food Intakes by Individuals (CSFII) for the years 1994-1998.

The residue data were compiled as distributions of cumulative residues of methamidophos equivalents and, after application of processing factors, were 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 four subpopulations in the CSFII 1994-1998 (Children 1-2, Children 3-5, Adults 20-49, and Adults 50+ years old). The results of this assessment are shown in Figure I.C.1 and Table I.C.2.

2. Sources of Residue Data

a. USDA-PDP

The PDP program has been collecting pesticide residue data since 1991, primarily for purposes of estimating dietary exposure. The program is designed to focus on foods highly consumed by children and to reflect foods typically available throughout the year. Foods are washed and inedible portions are removed before analysis. This database is the primary source for residue data used in the current assessment, and data collected between 1994 and 2000 were included. A complete description of the PDP program and all data through 1999 are available on the Internet at http://www.ams.usda.gov/science/pdp. The residue data from 2000 are not publicly available at this time but will be by the time the final version of this assessment is published. A summary of the PDP residue data on OP chemicals is shown in Table III.C.2. Table III.C.1 lists all of the food forms for which estimated residues were based on PDP data.

b. FDA Surveillance Monitoring Data

The FDA Surveillance Monitoring Program is designed primarily for enforcement of EPA pesticide tolerances on imported foods and domestic foods shipped in interstate commerce. Domestic samples are collected as close as possible to the point of production in the distribution system. Import samples are collected at the point of entry into U.S. commerce. The emphasis in sample collection is on the agricultural commodity, which is analyzed as the unwashed, whole (unpeeled), raw commodity. Processed foods are also included in the program. A description of the program and residue data for recent years can be found on the Internet at http://vm.cfsan.fda.gov/~lrd/pestadd.html. Because the emphasis of this program is not on dietary exposure, it is being used in the current assessment mostly as a semi-quantitative check on the potential for residues and as support for data from other sources. The program has extensive data available on eggs and fish and these data support the judgement that the OP residues are negligible on these foods as consumed. Table III.C.1 indicates the food forms for which exposure estimates were supported by this program.

c. FDA Total Diet Study (TDS)

The TDS has provided data on dietary intake of food contaminants for about 40 years. A program description and residue data can be found at the same Internet site listed above for FDA Surveillance Monitoring Data. Foods are purchased in grocery stores, generally 3 or 4 times a year, prepared and cooked for consumption, and analyzed by highly sensitive multiresidue methods. Between 1991 and 1999 there have been 26 market baskets collected and approximately 260 foods analyzed for, among other things, OP pesticide contamination. A disadvantage of these data is that only one sample is analyzed of each food in each market basket. For this reason these data have been used primarily as semi-quantitative support for judgements on residues in foods. An exception is made in this assessment for the estimate for residues in meats other than poultry. Multiple forms and tissues of beef, pork, lamb, and meat byproduct cold cuts have been analyzed in all of the market baskets with only limited residues of OP pesticides on a few of the meats at low levels. In an effort to include residue estimates for all highly consumed foods, a conservative estimate for meat commodities was based on the TDS Data. A maximum residue level was used for each meat based on the TDS. The meat commodities included on this basis are identified in Table III.C.1 and the residue data are summarized in Table III.C.3.

3. OP Pesticides Included in Cumulative Assessment

All of the OP analytes detected in the PDP program are included in the current assessment. See Table III.C.1 for a complete summary of the analyses for OP pesticides and metabolites on each food commodity in the database. There have been significant numbers of analyses for 67 OP active ingredients, degradates, or metabolites between 1994 and 2000. A total of 39 of these OP analytes have been detected in at least one of the foods analyzed. After exclusion of data on pesticides that have been canceled or do not have food uses, and combining data for metabolites and degradates, there are positive analytical data being used for 22 OPs. These are the following:

acephate	azinphos methyl	chlorpyrifos
chlorpyifos-methyl	disulfoton	diazinon
dichlorvos	dimethoate	ethoprop
fenamiphos	malathion	methidathion
methamidophos	mevinphos	oxydemeton-methyl
methyl-parathion	phorate	phosalone
phosmet	pirimiphos-methyl	terbuphos
tribufos		

Naled has not been separately analyzed generally and residues from this use would be reflected in the dichlorvos analyses. Bensulide is not included in the PDP data; however, negligible residues would be expected in foods based on field trial data submitted for registration purposes. Cadusafos is not represented in the PDP data but the only registered use that could potentially result in food residues is as a nematacide soil application on bananas that are imported into the United States. Field trial data submitted for registration/tolerances purposes indicate that residues will not occur in the edible portion of the banana. Chlorethoxyfos is not included in PDP data but its only food use is soil application to corn crops at a low rate; therefore, significant residues in edible portions and processed foods from corn would not be expected. Dicrotophos, not included in PDP data, has one food use on cotton. Cottonseed oil is the only food commodity of cotton and it is not included in the current assessment, but the impact of the chemical on dietary (food) exposure is expected to be low due to the extent of refining and blending of the oil. Tebupirimphos (phostebupirim) has one food use on corn, mainly to control root worm. Significant contribution to cumulative food exposure is not expected. Profenofos is used on cotton, which is not included in the current assessment for the reasons stated above. Trichlorfon has no food uses except for an overseas use as pour-on treatment of beef cattle. Tetrachlorvinphos is used only on livestock or livestock premises. Potential residues from the two latter livestock uses are anticipated to be covered by the conservative cumulative residue estimate for meat commodities.

4. Foods Included in the Cumulative Risk Assessment

The universe of foods included in the cumulative dietary exposure assessment is defined by the USDA CSFII for the years 1994-1996 with supplementary data on children obtained in 1998. The survey data, CSFII 1994-1998, is integrated into DEEM-fcid™. Table III.C.1 lists all of the foods in CSFII 1994-1998 in decreasing order of their relative per capita consumption by children 3-5 years old. Each food is assigned a percent of relative consumption which was estimated in the following manner: the per capita consumption of each food was summed for all children in the survey between 3 and 5 years old. This consumption was summed for all foods in the survey and the individual sums for each food were expressed as a percent of the total. This measure of relative consumption is used as a partial indication of the potential significance of a given food in the diet of children.

According to the above described measure of relative consumption, the available PDP data were used either directly or with processing factors to estimate cumulative residues in foods accounting for about 86% of the per capita consumption of children 3-5 years old. PDP data were used for the top 10 ranked foods and for 25 out of the top 30 foods.

Residues in other foods were estimated using translated PDP data according to HED SOP 99.3 (USEPA, 1999b). Translations included only residues for chemicals registered on the food being simulated. These foods account for about 1% of the per capita consumption of children 3-5 years old.

Surveillance monitoring data from FDA include extensive analysis of eggs and fish with the implication that OPs would not be expected to occur in significant amount on these two categories of foods. The TDS data from FDA indicate a similar situation for livestock meats. In this case a conservative estimate of residues was incorporated into the assessment, i.e., meats were assumed to always be contaminated with OP residues equal to the maximum values found in the TDS market baskets (see Table III.C.3 for a summary of TDS data used). These foods being supported by FDA data, i.e., eggs, fish, and meat, account for about 6% of the per capita consumption of children 3-5 years old.

PDP has analyzed high fructose corn syrup and found no pesticide residues but have not analyzed any other sugar or syrup sources. The FDA TDS has analyzed refined sugar and maple sugar and found no OPs in 26 market baskets. A knowledge of the highly refined nature of sugars and syrups supported by the limited residue data mentioned above is the basis for assuming that negligible residues of OPs would be expected to occur on sugars and syrups. Therefore, residues were assumed to be zero for these foods derived from sugarcane, sugar beet, and maple. These foods account for about 3% of the per capita consumption of children 3-5 years old.

The food forms not included in the current assessment account for almost 4% of the per capita consumption distributed among many food forms. Table I.C.1 summarizes the above discussion on inclusion of foods in the assessment and the information detailed in Table III.C.1.

Table I.C.1. The Proportion of the Diet of Children (3-5 years old) Covered in the Cumulative Food Assessment

Source of Residue Estimate	Percent of Per Capita Consumption
PDP	85.7
Translation of PDP	1.3
FDA Monitoring and TDS	6.3
Assumed Negligible	3.1
Not Included in Current Assessment	3.6

5. Method of Estimation of Cumulative Dietary Risk

Dietary exposure was estimated using the Dietary Exposure Evaluation Model (DEEM-fcid™) software. A joint distributional analysis was conducted by combining representative data on concentrations of OP 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 inputs were distributions or point estimates for residues, distributions for consumption, and a hazard endpoint. The output was a series of distributions of one-day dietary exposures and distributions of associated risks, i.e., margin of exposures (MOEs). The different components of the input data are discussed further in the remainder of this section.

a. 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 ($Residue_{IE}$), 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 ***RPF*** to get the equivalent residue of an index chemical. This new calculated residue is termed ***$Residue_{IE}$*** 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:

$$Exposure_{IE} = Residue_{IE} \text{ X Consumption}$$

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.

b. Generation of Cumulative Equivalent Residue ($Residue_{IE}$)

To determine a given one-day cumulative oral exposure to multiple OPs, first an $Residue_{IE}$ for each residue value is calculated. On a given PDP sample, each residue value is multiplied by any applicable processing factor (PF) for that chemical on food sample of interest and the RPF for the same chemical to express it as a $Residue_{IE}$ 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 chemicals detected 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 $Residue_{IE}$ = $\sum$ $Residue_{IE}$** (per PDP sample)

For example, given 100 samples of apples, each analyzed for 22 OPs, there will be generated 22 $Residue_{IE}$ values for each sample. In step 2, each set of 22 $Residue_{IE}$ 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. Another very important advantage of this approach is that, using appropriate record keeping (see next section), the complete history of each cumulative residue value in the exposure assessment can be potentially traced back to its origins. All of the sample collection and analytical information associated with a given PDP sample and all arithmetic adjustments incorporated in producing a $Residue_{IE}$ can be traced in the process of sensitivity analysis or critical food commodity contribution analysis.

c. 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 multiple chemicals and food commodities is problematic. The residue data used in this case study consist of approximately 1.5 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, to keep track of them, and work backward from the cumulative assessment results to determine contributors, all the data manipulations were conducted using relational database techniques. This database consists of four major data tables:

1. Residue data table; about 1.5 million records containing essentially all of PDP sample and analyses data for OP pesticides.

2. Processing factor data table; containing all relevant processing factors for specific food form/chemical combinations. Table III.C.5 in this document is extracted from these data.

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

4. Translation Table; providing bridging links between PDP commodity codes, such as *AJ* (apple juice), and all corresponding DEEM™ food forms, such as *Apple, juice cooked:canned;cook meth N/S*. This table allows the assignments of translation of data between PDP commodities also, such as cantaloupe data to watermelon food forms. Table III.C.6 summarizes the links used in this assessment.

These four tables are linked through common fields, including pesticide codes and commodity codes. Calculation queries are coded into the database so that all the pertinent residue 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.

A cumulative residue calculation query essentially performs the two-step process described earlier, extracting the various parameters needed from the four tables described above. The calculation is performed on all of the PDP samples that are of interest and the results are compiled in text files containing the cumulative distributions for each food commodity of interest.

Each text file contains 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.

Residue distributions inputs to DEEM™ are converted to single average values for those foods that are highly blended before consumption.

By maintaining all of the calculation parameters in separate tables in the database, it is possible to repeat the above process with new inputs by simply replacing or adding data to the appropriate table. For example a specific chemical can be omitted from the entire process by assigning it a value of zero in the RPF table. Specific chemical/commodity combinations can be selectively omitted by entering a zero value for that pair in the processing factor table.

d. Generation of Exposure Values

The cumulative $\text{Residue}_{\text{IE}}$ 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 $\text{Exposure}_{\text{IE}}$. This process (semi-Monte Carlo in nature and conducted by DEEM™ software) is repeated many times per each consumption record to generate a distribution of exposure values. This process has been described in public documents and proceedings of the FIFRA Science Advisory Panel (http://www.epa.gov/oscpmont/sap/2000/#february). For the food forms that 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.

e. Food Consumption Data

For this assessment, food consumption is being modeled on the USDA CSFII, 1994-1998. The consumption survey is included as an integral component of the DEEM-fcid™ software. The CSFII 1994-1998 contains survey data on 20,607 participants interviewed over two discontinuous days. It contains a supplemental children’s survey conducted in 1998 in which an additional 5,459 children, birth through 9 years old, were added to the survey. This is the first dietary exposure assessment in which OPP has used this survey.

DEEM-fcid™ also has integrated new USDA/EPA recipes for conversion of foods reported eaten in the survey to food commodities on which residue data are available. These recipes, which will be publicly available, replace proprietary recipes used in previous versions of DEEM™.

Four separate assessments were conducted on the following age groups from the CSFII 1994-1998:

Children 1-2 years old
Children 3-5 years old
Adults 20-49 years old
Adults 50+ years old

f. Hazard Data used in the Cumulative Food Assessment

Section II describes the hazard portion of this risk assessment in detail. Methamidophos was chosen as the index chemical for this assessment and relative potencies of the OPs was based on female rat brain cholinesterase inhibition. The point of departure (BMD10) was 0.08 mg/kg body weight/day.

6. Results

Figures I.C.1.a and 1.C.1.b summarize the results of a dietary exposure assessment for OP pesticides on food commodities. Results are presented for four age groups: Children 1 to 2 years, Children 3 to 5 years, Adults 20 to 49 years, and Adults 50 years and older. The results are plotted as the estimated percentile of per capita days falling below a calculated MOE versus the MOE, plotted on a log scale. The semi-logrithmic plot was used in order to graphically capture the very large range of MOEs encountered when viewing the entire distribution.

Table I.C.2 provides more complete information on the cumulative exposure distributions for the four populations. The exposures represent index chemical (methamidophos) equivalents and are based on a point of departure (BMD10) of 0.08 mg/ kg body weight/day.

Figure 1.C.1.a Margin of Exposure vs. Percentile of Exposure

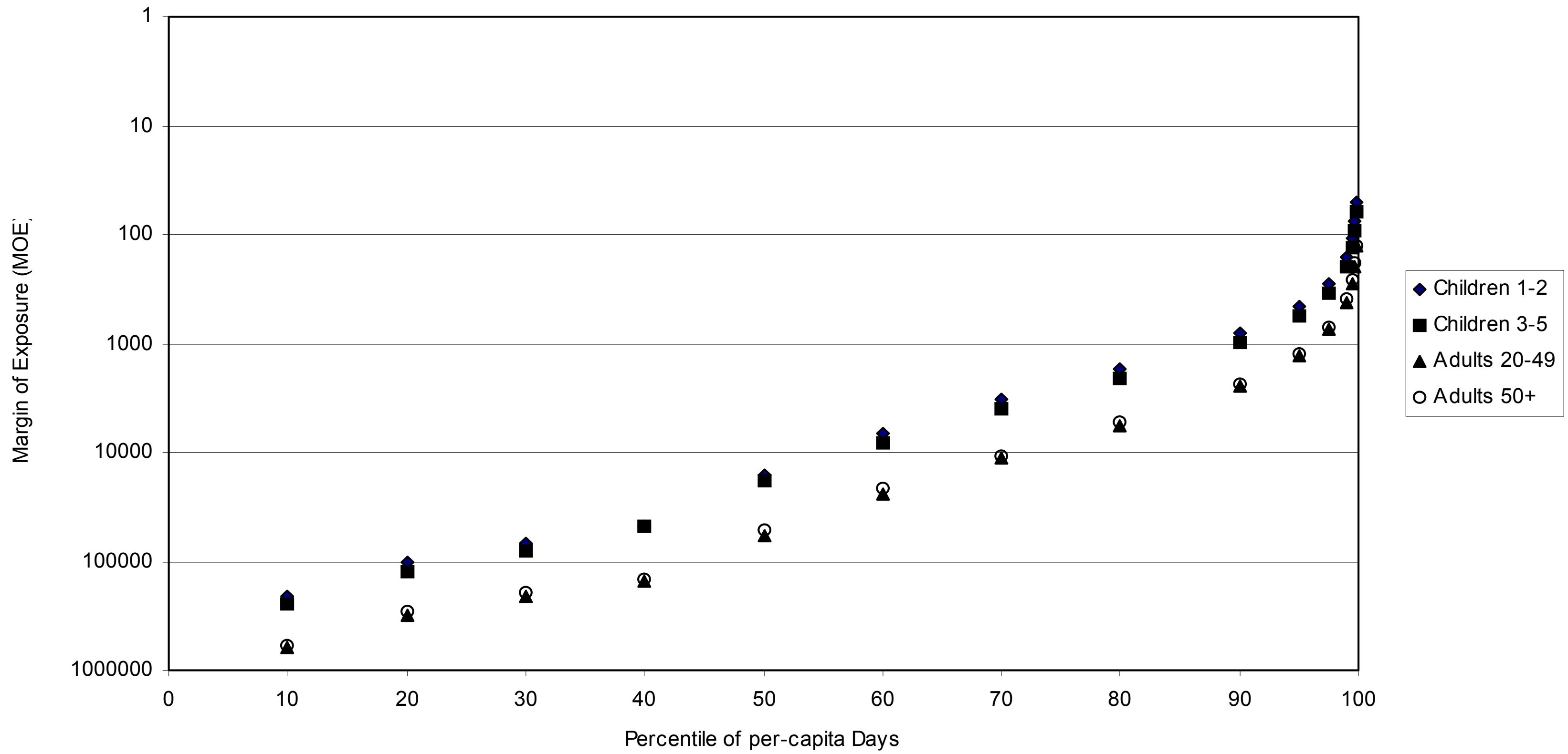

Figure 1.C.1.b Margin of Exposure vs. Percentile of Exposure - upper portion of distribution

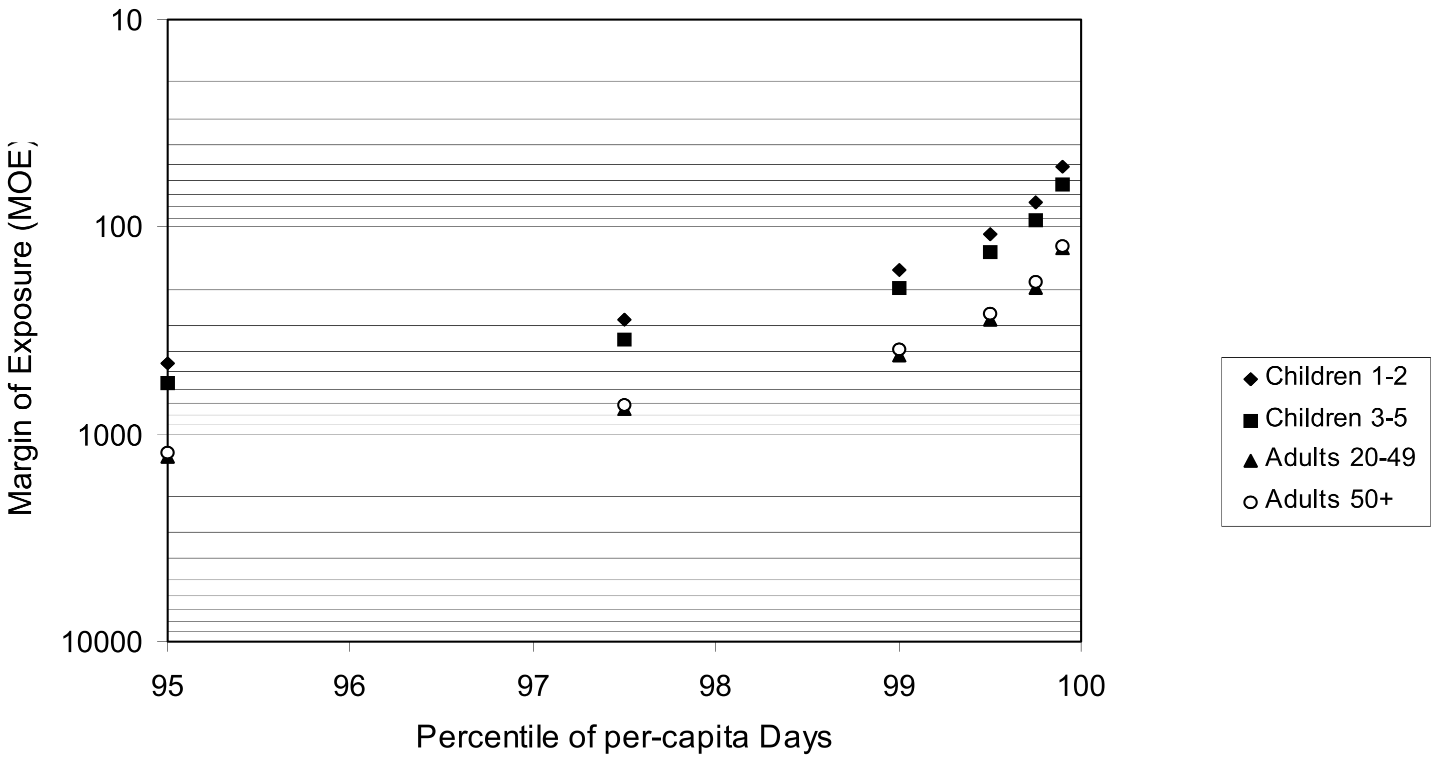

Table I.C.2. Cumulative OP Food Exposure Analysis using DEEM-fcid™ (Ver 1.05)

Children 1-2
All Seasons
All Regions
Sex: M/F-all/
All Races
Nursing and Non-Nursing

Daily Exposure Analysis /a (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000041	0.000041
Standard Deviation	0.000137	0.000137
Margin of Exposure /b,c	1,972	1,972

Estimated percentile of per capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE)

Percentile	Exposure	MOE	Percentile	Exposure	MOE
10.00	0.000000	206,281	90.00	0.000100	800
20.00	0.000001	103,063	95.00	0.000176	454
30.00	0.000001	68,691	97.50	0.000285	280
40.00	0.000002	47,258	99.00	0.000499	160
50.00	0.000005	15,879	99.50	0.000735	108
60.00	0.000012	6,641	99.75	0.001045	76
70.00	0.000024	3,293	99.90	0.001541	51
80.00	0.000047	1,715			

Children 3-5
All Seasons
All Regions
Sex: M/F-all/
All Races
Nursing and Non-Nursing (Ages <= 3)

Daily Exposure Analysis (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000033	0.000033
Standard Deviation	0.000107	0.000107
Margin of Exposure	2,433	2,433

Estimated percentile of per capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE)

Percentile	Exposure	MOE	Percentile	Exposure	MOE
10.00	0.000000	245,776	90.00	0.000080	994
20.00	0.000001	122,782	95.00	0.000142	562
30.00	0.000001	81,831	97.50	0.000230	348
40.00	0.000002	48,245	99.00	0.000407	196
50.00	0.000004	18,433	99.50	0.000600	133
60.00	0.000010	8,056	99.75	0.000855	93
70.00	0.000020	4,043	99.90	0.001280	62
80.00	0.000038	2,119			

Adults 20-49
All Seasons
All Regions
Sex: M/F-all/
All Races

	Daily Exposure Analysis (mg/kg body-weight/day) per Capita	per User
Mean	0.000014	0.000014
Standard Deviation	0.000053	0.000053
Margin of Exposure	5,659	5,653

Estimated percentile of per capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE)

Percentile	Exposure	MOE	Percentile	Exposure	MOE
10.00	0.000000	629,396	90.00	0.000033	2,415
20.00	0.000000	310,365	95.00	0.000062	1,280
30.00	0.000000	205,965	97.50	0.000106	755
40.00	0.000001	154,121	99.00	0.000193	415
50.00	0.000001	58,721	99.50	0.000285	281
60.00	0.000003	24,485	99.75	0.000408	195
70.00	0.000007	11,491	99.90	0.000627	127
80.00	0.000014	5,622			

Adults 50+ (ages 50 to 99 yrs)
All Seasons
All Regions
Sex: M/F-all/
All Races

	Daily Exposure Analysis (mg/kg body-weight/day) per Capita	per User
Mean	0.000015	0.000015
Standard Deviation	0.000052	0.000052
Margin of Exposure	5,402	5,401

Estimated percentile of per capita days falling below calculated exposure in mg/kg body-wt/day with Margin of Exposure (MOE)

Percentile	Exposure	MOE	Percentile	Exposure	MOE
10.00	0.000000	583,370	90.00	0.000034	2,321
20.00	0.000000	290,522	95.00	0.000065	1,228
30.00	0.000000	193,424	97.50	0.000111	720
40.00	0.000001	144,972	99.00	0.000203	393
50.00	0.000002	51,444	99.50	0.000302	264
60.00	0.000004	21,800	99.75	0.000429	186
70.00	0.000008	10,661	99.90	0.000637	125
80.00	0.000015	5,355			

a/ Analysis based on all two-day participant records in CSFII 1994-1998 survey.
b/ Margin of Exposure = PoD/ Dietary Exposure.
C/PoD = 0.08 mg/kg body-wt/day

Table III.C.7 contains a complete listing of the food forms in the DEEM-fcid™ software that were included in this assessment. Data inputs in this table are defined as residue distributions (rdf files) or, for highly blended commodities, a single average residue. Table III.C.8 includes a summary of the residue inputs for each food form. The actual DEEM™ input file and necessary rdf files will be available on CD ROM so that the assessment can be repeated by others. This is the first exposure assessment conducted by the Agency using DEEM-fcid™ and there are new coding and categorization of food forms. In Table III.C.9 a cross-walk is provided for relating food forms as defined in earlier versions of DEEM™ and DEEM-fcid™.

7. Discussion

The processes for exposure and risk assessment in the Office of Pesticide Programs (OPP) have been undergoing a rapid evolution. A number of choices and assumptions made in the conduct of the current assessment may differ from previous single-chemical assessments. The following discussion is intended to provide some background on the impact of choices that are unique to this assessment.

a. Some PDP residue data were excluded

The assessment includes only chemical/crop combinations currently registered in the United States or with import tolerances. Therefore, residues representing canceled and phased-out uses are excluded. Also, tolerance-exceeding residues or residues on commodities with no registered uses for the residue found, are excluded. These violative residues, which are rare in both PDP and FDA monitoring, are not considered appropriate in simulating an exposure scenario that reflects pesticide registrations and tolerances as regulated by the Agency.

b. Composite samples were used to estimate residues in single-servings as consumed

Only the residue data from composite samples were utilized in this assessment. A single composite sample may contain several individual serving of some foods. For purposes of the present assessment, 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. PDP has conducted single-unit sampling for apples, pears, and peaches since 1998. A comparison of the residue levels on these single-servings to the residues on comparable composite samples indicate that use of composite samples will not result in a significant under- or overestimation of residues.

c. PDP samples were assumed to reflect residues in foods prepared for consumption

The PDP generally collects foods at wholesale distribution centers and stores them frozen until analysis. Foods are washed and inedible portions are removed before analysis but these foods are not further cooked or processed. Processing factors (see Table III.C.5) were applied to the residue data in this assessment. These factors were taken from the most recent single-chemical dietary exposure assessments for the OPs. Information on these factors is somewhat limited; therefore, some storage or process related dissipation of residues may not be accounted for.

d. Residue data were assumed to reflect co-occurrence of OPs in single-day diets

One reason for conducting the assessment of PDP residue data on a sample-by-sample basis is to maintain the connections in multi-analyte occurrences on these samples. In other words, it is assumed that the PDP sampling and analysis protocols capture the co-occurrence of OPs. Table III.C.10 demonstrates the extent of this measured co-occurrence in the PDP program between 1994 and 1999. It can be seen in this table that a majority of PDP samples were reported as containing no detectable residues at all. For those that contained detectable residues, single residues were most prevalent but many multiresidue samples were found. The maximum number of OP analytes reported on a PDP sample is 5 (this occurred on only 5 samples during the period 1994-1999).

In addition to considering co-occurrence of different OPs on one food, the potential exists for co-occurrence from residues of one or more OPs on different foods consumed in one-day. This assessment is using residue data collected over a seven year period, 1994 through 2000. This is necessary in order 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. One may question if it is appropriate to model exposure based on bananas grown in 1994 and apples grown in 1998. On the other hand, the consistency in appearance of residues in the monitoring data over time suggest that the uncertainty in this choice is probably not more significant than those in other aspects of the model.

A related choice in selection of residue data was to include all available data for a given food. This has resulted in data sets that span time periods of less than one year to as much as four years of data. Current ongoing analysis of the importance of assumptions such as these includes comparative assessments in which the data are restricted to the most recent one or two years. This could potentially have an impact on assessments because of risk mitigation efforts that have resulted in changes of the use of pesticides on food crops.

e. It was assumed that all OPs of concern on an analyzed food sample were accounted for in the residue analysis

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 analytical method reliable limit of detection (LOD). It has been usual practice in Agency assessments on individual pesticides to assume that residues in non-detectable samples are present at ½ LOD of the analytical method in samples that were 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.

In the current assessment it is assumed that all OP residues reported as non-detectable are absent from the sample, i.e., they are assigned a value of zero. In a complex analysis such as this cumulative analysis, in which there are abundant samples with detectable residues, the assumption of zero for non-detects would not be expected to impact greatly the outcome of the exposure assessment at the highest percentiles. This was tested in an earlier stage of the assessment and reported in the case study that was presented to the SAP in December of 2000. Cumulative food exposure assessments were conducted using 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 on a given food. 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. Under the conditions of the case study the two extremes showed essentially no significant difference in exposure above the 95th percentile of exposure. At the lower percentiles of exposure the impact of input for non-detectable residues on cumulative exposure became apparent; however, the overall exposure levels were so low they would not be considered to be of regulatory concern.

f. PDP residue data were translated in some cases to foods for which no residue data were available

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 (USEPA, 1999b). 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 assessment, translations of the residue data were made using the translation scheme in HED SOP 99.3 (USEPA, 1999b) in order to ensure representation of the maximum number of commodities possible. The cross walk between foods and food forms is presented in Table III.C.6. In making these translations the only residues included were those that could occur on the simulated food from current registrations of OP pesticides. The uncertainty in this scheme is not expected to have a major impact on the assessment because the foods being translated comprise a relatively small portion of the per capita consumption by children. An analysis of critical commodities contributing to the higher percentiles of exposure in this assessment is currently under way. If any translated foods appear in this analysis then the sources of data for those specific contributors will be examined even more closely for their validity as surrogate residue estimates.

g. The food exposure portion of this cumulative assessment is considered to be constant throughout the year and across regions

It is currently assumed that the food distribution and storage systems in the United States result in essentially a national distribution of the major foods in our diet that is constant throughout the year. For some of the seasonal changes in availability of certain foods, PDP has designed its sampling program to concentrate on these time frames so that the residue data should reflect the foods as available to the consumer. This applies to imports also. For the water portion of dietary exposure it is recognized that the potential for residues is not constant nationwide. The national food estimate is combined with regional water assessments to provide 13 regional dietary assessments.

h. Some residue data are under consideration but not included in this assessment

A task force of pesticide producers has provided the Agency with an OP pesticide market basket survey. The results of this market basket survey, conducted in 1998, were submitted to the Agency in 2001. The final report is still under review in the Agency but the data are currently under preliminary examination for their impact on cumulative exposure assessment for OPs on food. In this survey 13 foods were analyzed for 29 OP analytes. Samples were taken from grocery stores and single-serving size homogenates analyzed by methods with very low limits of detection. The foods collected, all of which are also covered by PDP, were apples, broccoli, cherries, cucumbers, green beans, grapes, peaches, sweet corn, lettuce, oranges, potatoes, strawberries, and tomatoes. Preliminary examination of the data indicate that cumulative exposure assessment using market basket survey data are in general agreement with a similar assessment using PDP data. The impact of these data on the OP cumulative risk assessment will continue to be examined.

8. Work currently in progress

Work is continuing in efforts to define the limits on the uncertainty introduced in the assessment by omitting some foods. Also, the analysis of exposure contributors in the food assessment is in progress, both for food and residue contributors. In preliminary analysis the expected food contributors are appearing at the higher percentiles of exposure, i.e., highly consumed foods with significant presence of chemicals of relatively high potency. The complexity of an assessment that includes so many foods and chemicals does not allow the isolation of single high impact contributors at this time but rather points to several contributors of comparable impact. See section I.g for a discussion of the process that is being followed in analyzing the relative importance of individual foods and chemicals to the cumulative risk.