I. Revised 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 Center for Food Safety and Applied Nutrition (FDA/CFSAN) monitoring data. 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 Appendix 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 97 percent of the per capita food consumption for children aged 1 to 2 years (the most highly exposed age group) in the Continuing Survey of Food Intakes by Individuals for the years 1994-1998.

The residue data were compiled as distributions of cumulative residues of methamidophos equivalents and, after application of processing factors and FQPA 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 multiple subpopulations in the CSFII 1994-1998 (Infants less than 1, Children 1-2, Children 3-5, Children 6-12, youth 13-19, Adults 20-49, and Adults 50+ years old). The most highly exposed age group was confirmed to be Children 1-2 years old.

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 2000 are available on the Internet at http://www.ams.usda.gov/science/pdp. A summary of the PDP residue data on OP chemicals is shown in Appendix III.C.2. Appendix III.C.1 lists all of the food forms for which estimated residues were based on PDP data.

b. Market Basket Study of OP Residues in Apple Sauce

The Apple Processors Association sponsored a market basket study of OP pesticide residues in apple sauce samples collected in 1999. These data are incorporated in the current assessment for residue estimates on apple sauce and baby food apple sauce. The residue data on these samples are summarized in Appendix III.C.2.

c. FDA/CFSAN 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. Appendix III.C.1 indicates the food forms for which exposure estimates were supported by this program.

d. FDA/CFSAN 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 Appendix III.C.1 and the residue data are summarized in Appendix 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 Appendix III.C.2 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 20 OP pesticides. These are the following:

acephate	azinphos methyl	chlorpyrifos
diazinon	dichlorvos	dimethoate
disulfoton	ethoprop	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 Food 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™. Appendix III.C.1 lists all of the foods in CSFII 1994-1998 in decreasing order of their relative per capita consumption by children 1-2 years old and 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 in the two age groups. These consumptions were totaled 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 88% of the per capita consumption of children 1-2 years old. PDP data were used for the top 10 ranked foods and for 24 out of the top 30 foods. Apple sauce, which was supported by special study data, account for about 1% of the consumption by children 1-2 years old.

Residues in other foods were estimated using translated PDP data according to HED SOP 99.3, (USEPA, 1999b) as summarized in Appendix III.C.4. 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 1-2 years old.

Surveillance monitoring data from FDA include extensive analysis of eggs and fish with the implication that OP residues 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 Appendix 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 5% of the per capita consumption of children 1-2 years old.

PDP has analyzed high fructose corn syrup and found no OP residues but has not analyzed any other sugar or syrup sources. The FDA TDS has analyzed refined sugar and maple sugar and found no OP residues 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 OP pesticides would be expected to occur in 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 2% of the per capita consumption of children 1-2 years old.

The food forms not included in the current assessment account for almost 3% of the per capita consumption of children 1-2, distributed among many food forms. Table I.C-1 summarizes the relative consumption of foods in the assessment for children 1-5 years old. The information is provided in detailed form in Appendix III.C.1.

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

Source of Residue Estimate	Percent of Per Capita Consumption	
	Children 1-2	Children 3-5
PDP (RACs & processed)	88.4	85.0
Apple Sauce Study	0.9	0.7
Translation of PDP	1.1	1.3
FDA Monitoring and TDS	4.9	6.3
Assumed Negligible	2.0	3.1
Not Included in Current Assessment	2.7	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:

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

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

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

To determine a given one-day cumulative oral exposure to multiple OP chemicals, 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. OPCRA Food Residue 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 assessment 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. The OPCRA food residue database currently being used for this purpose consists of, among other things, four major data tables:

1. Residue data table(s); about 1.5 million records containing essentially all of PDP sample and analyses data for OP pesticides as well as other residue data compiled from FDA and the Apple Sauce Market Basket Survey.

2. Processing factor data table; containing all relevant processing factors for specific food form/chemical combinations. Appendix III.C.5 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. Appendix 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 stored in various formats for further analysis.

A cumulative residue calculation query 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 food 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 distribution 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. These methods have been used extensively in the current assessment to adjust the inputs to reflect currently supported uses of OPs on food crops and to test the relative contributions of chemicals and commodities to the results of an assessment.

d. Generation of Exposure Values

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 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 are available to the public, replace proprietary recipes used in previous versions of DEEM™.

Separate assessments were conducted on the various segments of the population as represented in the CSFII 1994-1998. Among others, the current assessment included the following age groups:

- ❏ Infants less than 1 year old
- ❏ Children 1-2 years old
- ❏ Children 3-5 years old
- ❏ Children 6-12 years old
- ❏ Youth 13-19 years old
- ❏ Adults 20-49 years old
- ❏ Adults 50+ years old

The most highly exposed population group in this cumulative assessment is children 1-2 years old; subsequent analyses of the results reported in this document will emphasize results for this age group.

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 OP chemicals were based on female rat brain cholinesterase inhibition. The point of departure (BMD10) was 0.08 mg/kg body weight/day. The application of FQPA Safety Factors for this OP cumulative assessment is made for each individual chemical in the assessment. This is accomplished by incorporating these factors into the relative potency factors for each chemical in the assessment.

6. Results

The revised cumulative food exposure assessment for OP pesticides on food commodities was conducted for seven age groups, infants of less than one year, children 2-3 years old, children 3-5 years old, children 6-12 years old, youth 13-19 years old, adults 20-49 years old, and adults 50+years old.

Appendix III.C.7 contains a complete listing of the food forms in the DEEM-FCID™ software that were included in this assessment. This table also includes summary information on the residue distributions that were prepared from the OPCRA food residue database as input for each food form. Although most of the data inputs in this table are defined as residue distributions (rdf files), for highly blended commodities, a single average residue was estimated. The actual DEEM™ input file and necessary rdf files will be made available on CD ROM and on the internet for any interested party.

The most highly exposed age group in this assessment is Children 1-2 and the subsequent results reported in this chapter will focus on this group. Figure I.C-1a is a cumulative plot of the exposure distribution for this age group. Figure I.C-1b expands the portion of the cumulative distribution between the 99th and the 99.99th percentile. There are 4192 person-days (approximately half that many individuals with two reported days of food consumption) represented in the consumption records for this age group.

Figure I.C-1a. Cumulative Distribution of Food Exposure for Children 1-2 yrs

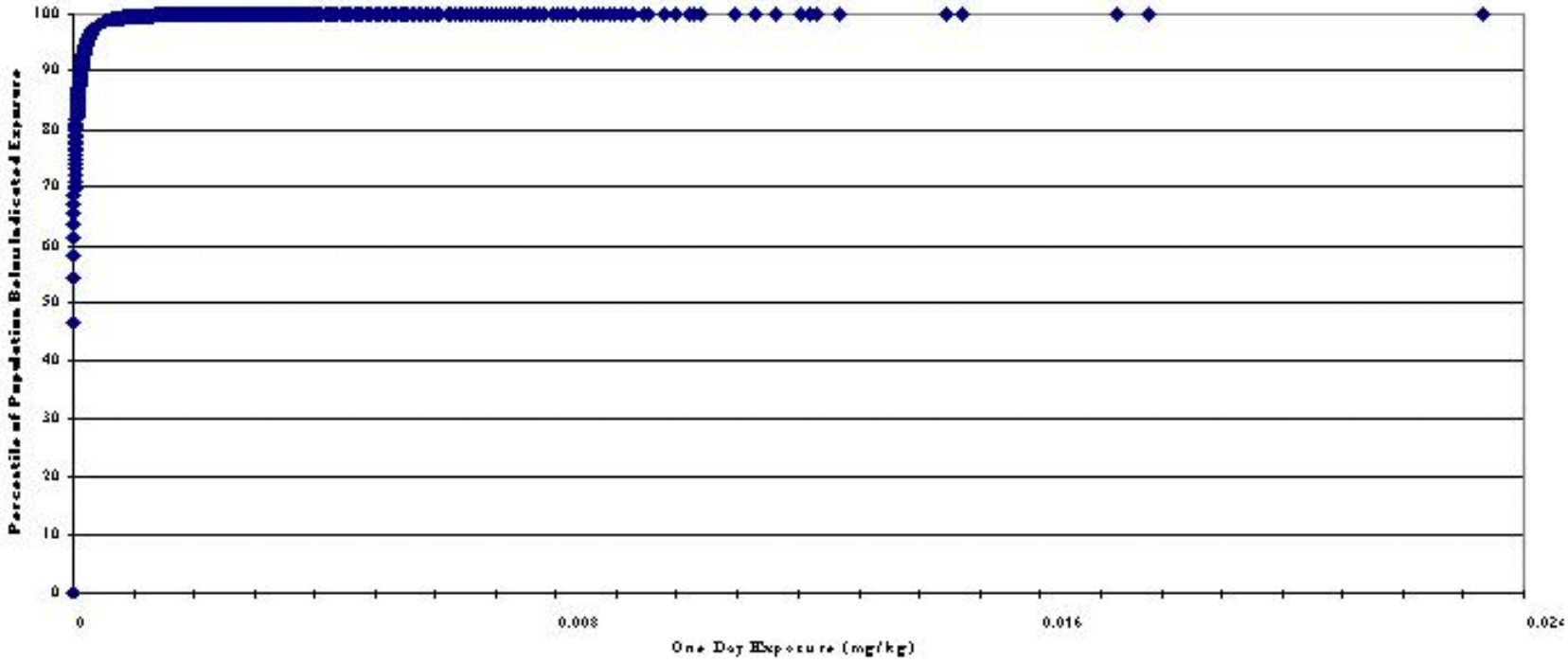
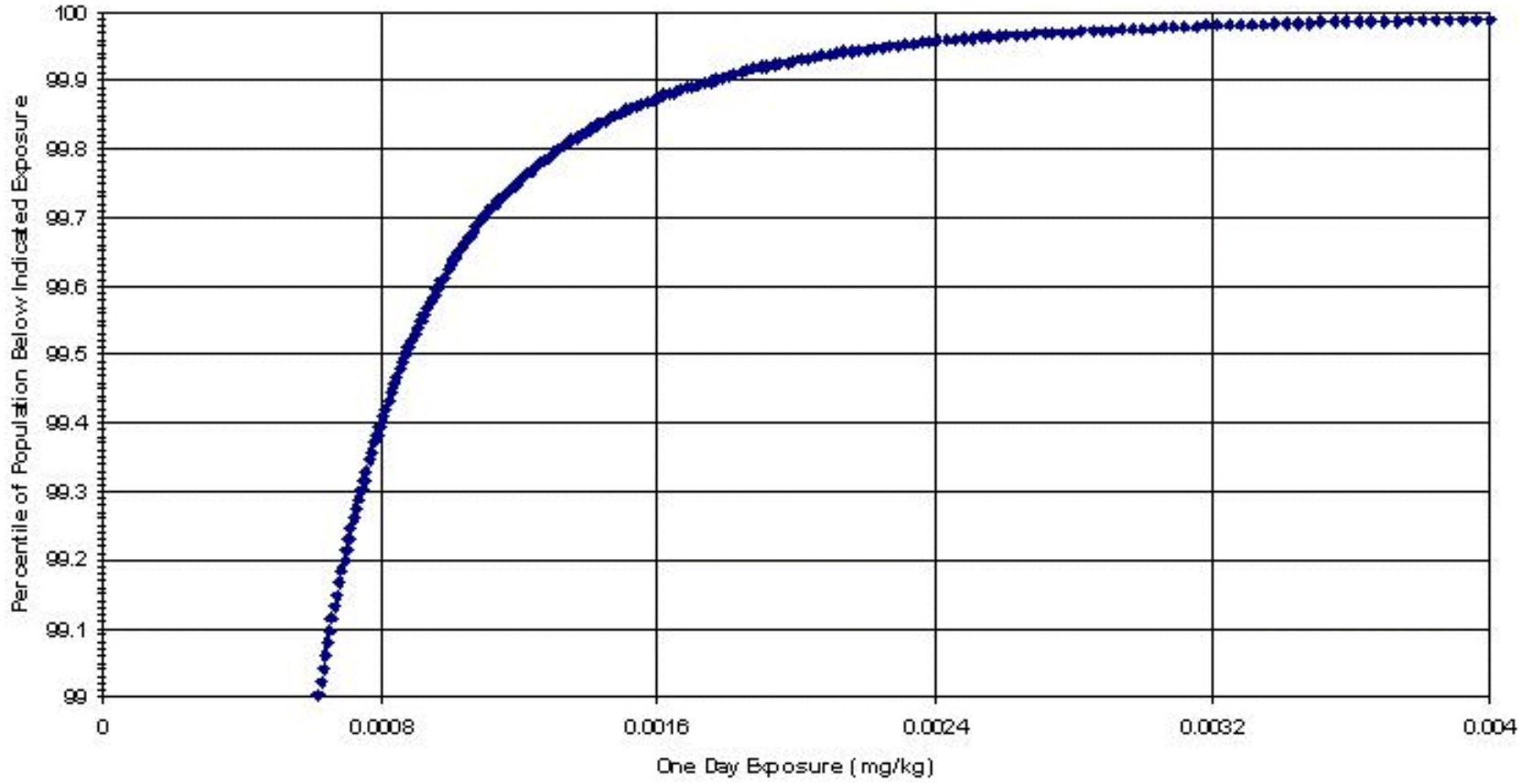


Figure I.C-1b. Cumulative Distribution of Food Exposure for Children 1-2 yrs - 99th percentile to 99.99th percentile of Exposure



a. Analysis of Significant Presence in The Upper Portion of the Distribution

The DEEM software has a provision for analyzing the foods and food forms that are contributing to the upper portions of an exposure distribution, up to a maximum interval of 5 percentile. This provision was used in the current assessment, in combination with the chemical/commodity specific information maintained in the database described above, to assess both foods and chemicals present in the tail of the distribution. The data summarized here were obtained by examination of the exposure distribution interval from the 99.8th percentile to the 100th percentile. Table I.C.2 lists all of the food forms appearing at or above the 99.8th percentile from a Monte Carlo assessment of the exposure of children 1-2 years old.

Table I.C-2. Partial Summary of Foods and Food Forms Occurring in the Top 0.2 Percentile of Exposure to an Exposed Sub-population in OP Cumulative Risk Assessment.*

[Monte Carlo Iterations =1000. Number of actual records in this interval = 8247. N=number of appearances in all records (including duplicates).]

Food	Food Form	N	Fraction of Total Exposure
Grape	Uncooked; Fresh or N/S; Cook Meth N/S	2600	0.33
Pear	Uncooked; Fresh or N/S; Cook Meth N/S	1549	0.16
Apple, fruit with peel	Uncooked; Fresh or N/S; Cook Meth N/S	2177	0.13
Apple, juice	Uncooked; Fresh or N/S; Cook Meth N/S	1510	0.10
Tomato	Uncooked; Fresh or N/S; Cook Meth N/S	584	0.05
Grape, raisin	Uncooked; Dried; Cook Meth N/S	376	0.04
Bean, snap, succulent	Cooked; Frozen; Boiled	397	0.03
Pepper, bell	Uncooked; Fresh or N/S; Cook Meth N/S	337	0.03
Bean, snap, succulent	Cooked; Canned; Boiled	383	0.02
Potato, tuber, w/o peel	Cooked; Fresh or N/S; Boiled	155	0.02
Spinach	Cooked; Frozen; Boiled	39	0.01
Bean, snap, succulent	Cooked; Fresh or N/S; Cook Meth N/S	58	0.01
Squash, summer	Cooked; Fresh or N/S; Boiled	33	0.01
Bean, lima, succulent	Cooked; Frozen; Boiled	76	0.01
Celery	Uncooked; Fresh or N/S; Cook Meth N/S	136	0.01
Cucumber	Uncooked; Fresh or N/S; Cook Meth N/S	42	0.01
Bean, lima, succulent	Cooked; Canned; Boiled	64	<0.01
Spinach	Cooked; Fresh or N/S; Baked	22	<0.01
Cucumber	Cooked; Canned; Cook Meth N/S	28	<0.01
Potato, tuber, w/peel	Cooked; Fresh or N/S; Fried	32	<0.01
Pepper, bell	Cooked; Canned; Cook Meth N/S	32	<0.01
Bean, snap, succulent	Cooked; Fresh or N/S; Boiled	110	<0.01
Bean, snap, succulent	Cooked; Fresh or N/S; Boiled/baked	31	<0.01
Potato, tuber, w/o peel	Cooked; Frozen; Fried	36	<0.01
Pepper, bell	Cooked; Fresh or N/S; Cook Meth N/S	46	<0.01
Potato, tuber, w/o peel	Cooked; Fresh or N/S; Fried	22	<0.01
Tomato	Cooked; Fresh or N/S; Boiled/baked	32	<0.01
Potato, tuber, w/o peel	Cooked; Fresh or N/S; Baked	23	<0.01
Apple, juice - babyfood	Cooked; Canned; Cook Meth N/S	37	<0.01
Apple, juice	Uncooked; Frozen; Cook Meth N/S	22	<0.01
Strawberry	Uncooked; Frozen; Cook Meth N/S	15	<0.01
Bean, lima, succulent	Cooked; Fresh or N/S; Boiled	36	<0.01
Bean, snap, succulent	Cooked; Fresh or N/S; Fried	13	<0.01
Cherry, juice	Uncooked; Fresh or N/S; Cook Meth N/S	11	<0.01
Bean, snap, succulent- babyfood	Cooked; Canned; Cook Meth N/S	19	<0.01
Tomato	Cooked; Fresh or N/S; Boiled	94	<0.01
Spinach	Uncooked; Fresh or N/S; Cook Meth N/S	7	<0.01
Peach	Uncooked; Fresh or N/S; Cook Meth N/S	42	<0.01
Grape, juice	Uncooked; Fresh or N/S; Cook Meth N/S	8	<0.01
Tomatillo	Uncooked; Fresh or N/S; Cook Meth N/S	7	<0.01
Apple, juice	Cooked; Canned; Cook Meth N/S	94	<0.01
Tomato, juice	Cooked; Canned; Cook Meth N/S	5	<0.01

Food	Food Form	N	Fraction of Total Exposure
Potato, tuber, w/peel	Cooked; Fresh or N/S; Baked	4	<0.01
Pepper, bell	Cooked; Fresh or N/S; Fried	21	<0.01
Cucumber	Uncooked; Cured etc; Cook Meth N/S	3	<0.01
Bean, snap, succulent	Cooked; Frozen; Baked	5	<0.01
Apple, peeled fruit- babyfood	Cooked; Canned; Cook Meth N/S	6	<0.01
Lettuce, head	Uncooked; Fresh or N/S; Cook Meth N/S	48	<0.01
Potato, tuber, w/peel	Cooked; Fresh or N/S; Boiled	5	<0.01
Broccoli	Cooked; Frozen; Boiled	3	<0.01
Celery	Cooked; Fresh or N/S; Boiled	64	<0.01
Potato, tuber, w/o peel	Cooked; Frozen; Baked	6	<0.01
Squash, summer	Cooked; Frozen; Boiled	2	<0.01
Squash, summer	Cooked; Fresh or N/S; Boiled/baked	1	<0.01
Tomato	Cooked; Fresh or N/S; Cook Meth N/S	11	<0.01
Spinach	Cooked; Fresh or N/S; Boiled/baked	1	<0.01
Grape	Cooked; Fresh or N/S; Cook Meth N/S	26	<0.01
Tomato	Cooked; Fresh or N/S; Baked	49	<0.01
Apple, sauce	Cooked; Fresh or N/S; Boiled	34	<0.01
Orange	Uncooked; Fresh or N/S; Cook Meth N/S	24	<0.01
Grape	Cooked; Canned; Cook Meth N/S	30	<0.01
Tomato, puree	Cooked; Canned; Cook Meth N/S	39	<0.01
Orange, juice	Uncooked; Fresh or N/S; Cook Meth N/S	17	<0.01
Strawberry	Uncooked; Fresh or N/S; Cook Meth N/S	2	<0.01
Celery	Cooked; Fresh or N/S; Cook Meth N/S	30	<0.01
Potato, chips	Cooked; Fresh or N/S; Fried	3	<0.01
Pepper, bell	Cooked; Fresh or N/S; Baked	19	<0.01
Orange, juice	Uncooked; Frozen; Cook Meth N/S	8	<0.01
Celery	Cooked; Dried; Boiled	3	<0.01
Celery	Cooked; Canned; Cook Meth N/S	17	<0.01
Pear	Cooked; Fresh or N/S; Cook Meth N/S	25	<0.01
Broccoli	Cooked; Fresh or N/S; Boiled	2	<0.01
Grape, raisin	Cooked; Dried; Cook Meth N/S	10	<0.01
Potato, tuber, w/o peel	Cooked; Fresh or N/S; Cook Meth N/S	2	<0.01
Pepper, non-bell	Uncooked; Fresh or N/S; Cook Meth N/S	8	<0.01
Celery	Cooked; Canned; Boiled	9	<0.01

*This table was prepared as part of the evaluation of the potential outliers and potential contributors and does not represent a judgement about the threshold of concern.

To evaluate the presence of chemicals in the tail of the distribution, all of the food forms in the above table were linked with the corresponding residue distributions that had been generated for the cumulative assessment. The individual chemical contributors to these distributions were extracted from the OPCRA food residue database used to generate the distributions. Thus the relative percent contributions of food forms derived from DEEM were combined with the relative percent contributions of chemicals to each food form's residue distribution to give an estimate of the relative contribution of each chemical to the interval being examined. These data were further reduced by combining all food forms to the crop level, for example, fresh grapes, raisins, and grape juice were all combined under the crop name grapes, and so on. All metabolites, degradates, and isomers were combined for each active ingredient in that assessment. The linkage of the DEEM output and the OPCRA food residue database information on chemical/food form specific contributions are summarized in Appendix III.C.8.

The most significant chemical presence in the exposure interval between the 99.8th percentile and 100th percentile is dimethoate/omethoate with a relative contribution of approximately 48% of the exposure, followed by azinphos methyl at 27%, acephate and its metabolite methamidophos at 11%, methamidophos, as active ingredient, at 5%, phosmet at 2.5%, phorate at 2.2%, and mevinphos at 1.8%. The most significant food crops are: apples, grapes, green peppers, pears, potatoes, spinach, succulent beans, and tomatoes.

7. Discussion

a. Changes Since the Preliminary Assessment

A preliminary cumulative assessment was published on December 3, 2001. Since that time a number of changes have been made in the input data, some of them as a result of public comments. All of these changes are captured in the data summaries included in the Appendices to this document. A summary of the major changes or categories of changes is provided in this section.

- ❏ Processing factors were updated. Several factors were added or changed based on public comments on the preliminary assessment. Appendix III.C.5 provides a summary of the processing factors currently being used. It should be noted that the absence of a processing factor in Appendix III.C.5 or a factor of zero indicates that the specific food form/chemical pair does not contribute to any residue distribution estimates. In some cases the absence of a factor is simply due to the fact that there are no detectable residues of that chemical in the database but in other cases it is due to the fact that a specific use is being excluded from the assessment because it is not being supported. Several commodities are not entered in the table at all because the residue

analyses conducted on these foods were uniformly below detectable levels. Therefore, one must not use this table as a means of determining the uses included in the assessment. The appropriate starting point for this determination is Appendix III.C.7, which lists every food form included in the assessment. A factor of zero in the processing factor table in some cases is due to a correction of a former entry and in some cases, such as for chlorpyrifos on apple and grape commodities, is a means of adjusting the assessment to account for mitigation negotiations. In the example of chorpyrifos, the use patterns are being altered to allow only pre-bloom applications, which are expected to yield essentially no detectable residues. The PDP data set contains many detects due to foliar applications; therefore, the processing factor was used as a use flag that was lowered to zero for this assessment. The residue data are still in the database and can be reactivated by raising the use flag.

- ❏ Apple sauce residue data have been added to the data set based on MRID 45432001: Data are from The National Food Laboratory and were sponsored by Apple Processors Association. The data have been incorporated in the PDP Data set in the OPCRA food residue database.

- ❏ Relative Potency Factors have been revised. Among the revisions, omethoate now has a factor different from that of dimethoate.

- ❏ FQPA Factors of 3 have been applied (via RPF adjustments) to all chemicals in the assessment except methamidophos, dimethoate/omethoate and chlorpyrifos, which have their FQPA factors reduced to 1.

- ❏ The bridging and translation of residue data from source to CSFII food forms have been updated. Several adjustments and corrections were made in these assignments. Among these was the changing of all tomato processed food forms to be derived from canned tomato residue data instead of fresh tomato residue data. All of the translations for the current assessment can be seen in Appendix III.C.6.

- ❏ Some inappropriate residue data were removed from the assessment. Lettuce residue data from 1994 were removed completely from the assessment because they contained residues from use patterns of methamidophos and mevinphos that are not current. Lettuce residues are now based solely on data from 1999 and 2000.

- ❏ Fenamiphos and chlorpyrifos-methyl have been removed from the assessment based on planned phase-outs. Appendix III.C.9 should be consulted for the complete summary of OP pesticide uses or import tolerances that are currently being supported in the reregistration process. It is important to note that this appendix provides the scope of use patterns that are being considered as having potential for producing OP

residues on foods. This list is based on reregistration actions up through March of 2002. If an OP use is not listed in this appendix then it is not considered in the current assessment.

- ❑ Tolerance exceeding residues were added back to the residue data as a result of discussion with SAP after release of the preliminary assessment. These violative residues are not a significant contributor to the assessment.

b. Major Assumptions in the Revised OPCRA for Foods

The following discussion of input assumptions is provided as a revision to the same discussion that was included in the preliminary assessment. The assumptions are revised to reflect their current status and thus some of the points covered in the previous section may be restated here.

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.

i. Some PDP Residue Data Were Excluded

The assessment includes only chemical/crop combinations currently being supported for registration in the United States or with import tolerances (see Appendix II.C.9). Therefore, residues representing canceled and phased-out uses are excluded. That is, residues in the OPCRA food residue database that do not represent supported section 3 registrations, SLN uses, or supported import tolerances, are excluded from the assessment. In a change from the preliminary assessment of 12/3/01, we are not excluding violative residues, i.e., tolerance exceeding residues, from the assessment. The criteria listed in this paragraph are intended to ensure that the cumulative assessment simulates the residue pattern that will result from ongoing mitigation actions in the reregistration of OP pesticides. Although this may appear to underestimate the food exposure as reflected by available residue data, it should be kept in mind that these data reflect past patterns of residue occurrence. The inclusion of violative residues in the assessment has no significant effect on the overall results of the assessment. Violative residues are rare in residue monitoring data.

ii. 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.

iii. 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 Appendix 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. In response to the preliminary assessment we have had several public comments with suggestions for improvements in the processing factors. These suggestions have been incorporated in the current assessment as appropriate. The processing factors in Appendix III.C.5 reflect these changes. The processing factors still probably result in some overestimation of residues in processed foods for which factors are not available, but the impact on this assessment of this possibility appears to be minimal according to the results reported here. Most of the food forms that appear to be significantly present in the upper ends of the exposure distribution are either uncooked food forms or are supported by residue data on food forms that have been processed in a similar manner.

iv. 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. Appendix 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. At the time of the preliminary assessment we were exploring the impact of using reduced data sets for foods with a suggested maximum of 2 years of data for any given commodity. A decision was made to continue using the complete data set in the absence of specific information that a given subset of the data were inappropriate to consider for currently supported uses or import tolerances. Therefore, the complete data set is still being used (1994-2000 PDP) with the exception of data from 1994 on lettuce. These samples contained residues of methamidophos and mevinphos that could have resulted from applications that were not representative of current use patterns. The use of the complete data set from 1994 through 2000 increases the probability that variations in climate and pest pressures may have been captured in the residue distributions.

v. 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 concern.

vi. 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 allowable translation are summarized in Appendix III.C.4. 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 (See Appendix III.C.1 for confirmation of this fact). An analysis of foods in the higher percentiles of exposure in this assessment has confirmed that translated foods do not significantly impact that portion of the distribution.

vii. 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 a series of regional dietary assessments.

viii. 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. 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 are not included in this assessment.