Supplemental Material for:
February 5-8, 2002 SAP
25 January 2002

Revision to SAP Question #1 For Food Session and Associated Background Material for "Preliminary Cumulative Risk Assessment for Organophosphorous Pesticides: Review of Methodology"

Questions on Food Assessment

1. In the Preliminary OP Cumulative Risk Assessment, OPP used all available PDP monitoring data generated since 1994 as the basis for the residue distributions of pesticides in treated foods. As a result, some foods have multiple years of data (as many as 5), while others have only a single year of data. All years of data were included to provide the most robust residue data set possible. These data were extended to cover foods and processed forms of foods for which data are not directly available. Additionally, some foods were included in the analysis based on less robust data from FDA.

   OPP is conducting a sensitivity analysis in which the residue contributions from specific foods (either one at a time or in combination with other foods) are removed from the analysis. This analysis is being conducted as part of an effort to determine the contributions of specific food commodities and chemicals to the upper tail of the exposure distribution. Some preliminary results are shown in Table 1 of the addendum to this document.

   Partly as a result of this exercise, OPP has observed that the more variables (e.g., commodities, chemicals, years of data) that are included in the exposure distribution, the more difficult it becomes to affect the tail of the distribution by removing commodity/pesticide combinations from the calculations. While removal of most exposure contributors results in a demonstrable change in the lower portion of the distribution, the exposures at the upper end of the tail (for example the 99.9^{th} percentile) are relatively unaffected by removal of a single commodity, even if it is identified by DEEM as a frequent contributor to the high end of the exposure distribution.

   Please discuss the significance of this observation and its potential impact on interpretation of the output distributions and results from highly complex distributional analyses such as the Preliminary OP Cumulative Risk Assessment.

Addendum

Background material for Revised Question #1 for OP Cumulative Food Assessment

This addendum is being provided as additional background for discussion of revised question 1 on the food assessment.

Table 1 summarizes the results of 10 separate assessments of cumulative OP exposure distributions from food consumption by children 1-2 years old. The conditions for the 10 assessments were as follows:

1. **Preliminary Cumulative Assessment** is the assessment as published for comment on Dec 3, 2001. These results were based on, among other things, all PDP residue data available on foods analyzed between 1994 and 2000.

2. **Preliminary with reduced PDP data set** was conducted as part of an evaluation of the impact of removal of older residue data from the assessment for those foods with several years of data. Only the most recent analyses were included for each food commodity with a maximum of 2 years of data for any given commodity.

3. **No Translated Commodities** represents an assessment from which all foods were removed that were not directly supported by PDP data or PDP data adjusted by a processing factor. These results are consistent with similar ones summarized in the OP Case Study presented to the SAP in December of 2000. They demonstrate that foods included by translation (for example parsnips based on carrots) or from other data sources (such as beef, pork, and other meats based on FDA TDS data) do not impact significantly at the higher end of the exposure/risk distribution. This is also supported by data summarized in the public document related to the relative per capita consumption of foods that were based on surrogate data or less robust monitoring data than those collected by PDP.

4. **Minimum Assessment (only food forms analyzed by PDP)** represents a lower boundary of the preliminary assessment as affected by residue data. The only foods included in the analysis were those that closely matched the actual commodity that PDP analyzed. Cooked and processed food forms were excluded unless they were actually analyzed

by PDP. Therefore, this assessment included no foods based on processing factors, surrogate data, or FDA data.

5. **No Baby Foods** was conducted as a check on the impact of residue assumptions related to these food commodities. In the preliminary assessment it was assumed that commercial baby foods are derived from crops with the same pesticide treatment history as adult foods. This is a conservative estimate of residue levels on these commodities; however, this assessment confirms that the impact of this assumption on the overall assessment is negligible.

6. **No Forms of Food A** excluded all of the foods derived from Food A, which was the most frequent contributor to the upper end of the exposure distribution.

7. **No Forms of Food B** excluded all of the foods derived from Food B, which was the second most frequent contributor to the upper end of the exposure distribution.

8. **No Forms of Food C** excluded all of the foods derived from Food C, which was the third most frequent contributor to the upper end of the exposure distribution.

9. **No Forms of Foods A or B** excluded food forms of both A and B.

10. **No Forms of Foods A, B, or C** excluded food forms of A, B and C.

Assessments 6 through 10 represent analyses of the relative impact of the contribution to the exposure distribution for the three foods (foods A, B and C) that were found to contribute most frequently to the extreme upper portion of the distribution (99.8th-100th percentile). Residues were removed from the assessment for <u>all food forms</u> of foods A, B, and C. It can be seen that, even for the three top contributors to the upper end of the exposure distribution, removal of the contribution of exposure from one food had very little effect at the 99.9th percentile. Similar results are observed for the other top contributors to exposure. As seen in assessment 10, all of the food forms for all three top contributors had to be removed from the analysis to obtain a two-fold reduction in risk at the 99.9th percentile.

Table 1. Sensitivity Analysis of Various Exposure Parameters in Cumulative Assessment.

Assessment	Description	MOEs for Children 1-2 at Selected Points in the Exposure Distribution [1,2]				
		Mean	95th %	99th %	99.5th %	99.9th %
1	Preliminary Cumulative Assessment	2001	457	160	110	52
2	Preliminary with Reduced PDP Data set	2205	503	181	125	58
3	No Translated Commodities	2082	470	165	114	53
4	Minimum Assessment (only food forms analyzed by PDP)	4895	988	293	188	77
5	No Baby Foods	2087	471	164	112	52
6	No Forms of Food A	2925	651	222	149	63
7	No Forms of Food B	2183	495	178	121	56
8	No Forms of Food C	2920	652	192	126	55
9	No Forms of Foods A or B	3330	727	255	174	75
10	No Forms of Foods A, B, or C	7063	1666	428	268	105

1. MOE = Point of Departure/Exposure
2. Point of Departure =BMD_{10}=0.08 mg/kg body wt./day