

Cumulative Risk - Food

- 1. The OP case study uses PDP monitoring data only. Data for pesticide residues in foods from market basket surveys and FDA data are of similar quality and reflect the co-occurrence of multiple OPs. OPP considers it reasonable to combine these types of data in as much as they reflect similar data quality. However, these data sets combined reflect only a limited number of crops. How might data from field trials that are designed to reflect exaggerated use rates (maximum application rates and minimum pre-harvest intervals) be adjusted to reflect a more realistic estimate of pesticide residues to which the public is likely to be exposed?
- 2. The use of surrogate data and translation of residue data between crops with similar pest pressures and agronomic practices is common across commodities in single pesticide assessments. Under what practices can this approach be applied to multi-chemical assessments?
- 3. PDP and market basket surveys implicitly reflect usage of pesticides for the crops for which they are available and the co-occurrence of pesticides in those commodities. However, for commodities for which these types of data are not available, no direct measure of co-occurrence is available. OPP has considered assuming the independence of pesticide use weighted for the percent of the crop treated. What alternatives can the Panel suggest to estimate co-occurrence when direct measures are not available?

Cumulative Risk - Residential Exposure

- 4. Current methods for estimating residential exposures to single chemicals in residential settings rely upon the use of standard values derived from the literature or from studies submitted in support of pesticide registration. This approach was applied to the current cumulative case study, relying upon use instructions to determine the frequency, period of re-treatment, rate of pesticide application and dates of onset and discontinuance of use. No information is available for estimating likelihood of co-occurrence of pesticides in a residential setting. Is the adaptation of this single chemical assessment approach to a multi-chemical assessment reasonable? What aspects of this approach are appropriate? What aspects of this approach require development of better data?
- 5. Distributions of exposure parameters were introduced into the residential assessment in this case study, but only in the form of uniform distributions due to data limitations. OPP has little experience in the use of distributional analyses for residential exposures. What guidance can the Panel provide for determining the appropriateness of using point estimates, uniform distributions and fitted distributions?
- 6. Many data types are needed to improve the accuracy and precision of residential cumulative assessments. What types of data would be the most useful to further the ability to develop reasonable estimates of cumulative risk from residential use of

pesticides?

Cumulative Risk - Drinking Water

- 7. Current modeling procedures for estimating pesticide residues in drinking water rely upon a clear understanding of pesticide use patterns for agricultural and urban uses. In the absence of these data, it may be possible to back calculate use rates in urban environments from water concentration data and urban density data. This process was used in the current case study to estimate contribution from urban use. Is this approach a reasonable method for estimating urban use for the purposes of modeling water concentrations as a function of pesticide use? What alternative methods for estimating urban use of pesticides might OPP consider?
- 8. Assuming that the WARP model is adequately developed for use in risk assessments, is the approach taken in this example of a cumulative case study to incorporate exposure through drinking water appropriate? Can the Panel make any suggestions for improving the method by which drinking water is incorporated in cumulative assessments, given the limited availability of monitoring data?
- 9. In the case study, the 95th percentile upper bound prediction interval on the 95th percentile concentration estimate was used as the basis for year round estimates of pesticide exposure in drinking water. This approach was adopted because available estimates of concentrations of pesticides in drinking water are annualized, with no indication of seasonal variation. Is this approach a reasonable, health protective approach or is it likely to provide an overestimate of exposure? If this approach produces an exceedance of essentially safe exposure levels, in what manner could a better estimate of exposure to pesticides in water be derived from existing data and modeling approaches?

Integrated Cumulative Risk Assessment

- 10. The case study demonstrates the combination of data for food, water and residential exposures that reflect differences in the quantity of available data. Does the Panel have any concerns about combining data for different exposure sources that differ in the extent to which they describe anticipated real world exposures?
- 11. In the current integrated case study, the contribution of water relative to other sources of exposure is very small. This pattern was evident from the initial single source assessment that preceded the integrated cumulative assessment. This approach could be used as a form of sensitivity analysis to simplify of the overall assessment. Can the Panel recommend any considerations in determining the extent to which minor contributors to risk can be eliminated from an integrated cumulative risk assessment? Generically, can the Panel identify any major concerns or pitfalls in this approach?

- 12. The cumulative assessment in the case study was limited in geographic scale to the Piedmont areas of Virginia, North Carolina and South Carolina in an attempt to focus the scale of the assessment on an area of consistent seasonal variation and pest pressure. In this way, OPP hopes to develop an integrated assessment within which the water and residential uses are relative constant, making the risk assessment relevant for that particular area and other areas like it. Does the Panel find the geographic scale to be appropriately limited such that the results of the risk assessment are applicable across the entire area? What considerations should OPP apply to define the appropriate geographic scale for drinking water and residential cumulative risk assessments? Does the Panel see major pitfalls to this approach?
- 13. The data used in single chemical assessments often contains many sources of overestimation bias. However, because the cumulative risk assessment is developed from combining data from many sources and describing many pesticides, concerns for compounding conservatisms is greater than for single chemical assessments. In the current case study, OPP has taken the approach of depending to the extent possible on monitoring data which most closely approximates real world exposures and has applied the value of zero where no detectable residues were available for food residues. Are these conventions reasonable given the complexities and uncertainties inherent in combining many data sets to develop an integrated, multi-chemical, multi-pathway risk assessment?