

## Considerations When Evaluating Exposure Assessments

Exposure information is critical for determining if a chemical can pose a risk to humans or the environment. OPPT follows the EPA Guidelines for Exposure Assessment and expects that assessments submitted to the Agency will follow this or other comparable and appropriate guidance. When evaluating exposure assessments for chemicals, OPPT exposure assessors look at the completeness of the overall assessment and the quality of individual exposure estimates as well as the transparency of the exposure assessment results and conclusions. Exposure information should also be presented in a consistent manner.

OPPT believes characterizing the completeness of the overall assessment is important because it will convey the scope of the assessment, what exposures were assessed, what exposures were not assessed and, for those exposures that were not assessed, why they were not included in the assessment. When trying to determine how complete the assessment is for a chemical, OPPT looks for the assessment to provide information on the total chemical volumes manufactured, imported and exported and the volume associated with each U.S. use. OPPT also looks for the assessment to provide information on the fraction of those volumes that are covered by the assessment.

In addition to looking at chemical volumes, OPPT also expects that assessments will address human and ecological exposures from manufacturing, processing and from each use of the chemical. These exposures include exposures to workers who may come in contact with the chemical in their jobs (e.g., occupational exposures during manufacture of a dye), to consumers who come in contact with the chemical when it is used in consumer products (e.g., residential exposures to emissions from paints used indoors), and exposures to people and the environment resulting from environmental releases and disposal of the chemical (e.g., fugitive emissions monitoring in a neighborhood next to a plant). In some cases there are good reasons why an exposure estimate is not provided (e.g., release to an environmental media does not occur). In these cases the assessment should provide an explanation why an estimate of exposure was not provided. OPPT believes that monitoring data of known quality that are representative of the exposed population are preferred over estimated exposure values calculated using models and these monitoring data should be submitted when available. If monitoring studies exist, they should be identified and, where appropriate, used in the assessment. If appropriate monitoring studies do not exist, models may also be used to provide estimates of exposure.

OPPT believes characterizing the quality of each exposure estimate, whether it is based on monitoring data or on models, is important because it will help inform decisions about whether the exposure estimates are of sufficient quality to adequately assess exposures and ultimately to assess risks. The level of data quality needed will vary. All readily available exposure data and information should be utilized. A conservative (i.e., protective) estimate of exposure based on a simple model may be sufficient to alleviate concerns for a particular exposure situation. However, if it does not alleviate concern or if it is a close call, the next step is to obtain better exposure data.

When characterizing the quality of an exposure estimate based on monitoring data, OPPT believes that in addition to presenting the key results of the monitoring study and explaining how they are used to estimate exposures, the assessment should address:

- What was the objective of the monitoring study (e.g. conservative estimate of exposure, an estimate of typical exposures to the population of interest, etc.)?
- Were the monitoring study objective and study design suitable for the objective of the exposure assessment?
- What are the sampling methods and analytical chemistry methods and have they been adopted by an authoritative body (e.g. NIOSH) or have they been otherwise accepted by the scientific community?
- Were quality assurance and quality control procedures were employed, and if so, what were they?
- What are the key uncertainties in the monitoring study and in the exposure estimates derived from the study?

When characterizing the quality of an exposure estimate based on models, OPPT believes that in addition to presenting exposure estimates obtained from the models, the assessment should address:

- What was the modeling objective (i.e. conservative estimate of exposure, an estimate of typical exposures to the population of interest, etc.)?
- What is the model algorithm and what are the key assumptions used in the model?
- What is the scenario that is being modeled?
- What are the key inputs to the model?
- Has the model been peer reviewed?
- Has the model been evaluated by testing it against other models or against monitoring data?
- What are the key uncertainties in the model estimate of exposure?

OPPT believes transparency in an assessment is important. When reviewing an exposure assessment, OPPT expects that the written document will be very clear in explaining to readers how complete the assessment is, what the underlying data and assumptions behind the exposure estimates are, and what the data gaps and uncertainties are in the assessment. For each exposure estimate it should be clear to whom the estimate applies (i.e., the population being assessed), the environmental media being assessed (e.g., outdoor air, surface water, etc.) the nature of the estimate (e.g., conservative, average, etc.), and whether the exposure estimate is for acute (i.e. peak or short term) or chronic (i.e., long term) exposures. OPPT follows the guidance in the EPA Risk Characterization Handbook.

OPPT also believes that it is important that exposure information be provided in a consistent format. A consistent format is important because it allows readers to easily find key pieces of information such as information on the completeness of the overall assessment, summaries of release and exposure information by activity (i.e. manufacturing, processing, uses) and characterizations of the quality of individual exposure estimates. The OECD is in the process of

developing a format for reporting summary exposure information that will hopefully serve as a vehicle for accomplishing this goal.

Below is a checklist that OPPT uses when reviewing exposure assessments.

### **Exposure Assessment Checklist**

- Does the exposure assessment provide the total volume (i.e. production + import - export) of the chemical and describe what volume is assessed? Is the data current?
- Does the exposure assessment identify the U.S. uses associated with the chemical and provide the volume of chemical associated with each use? Is the data current?
- Does the exposure assessment address the following exposures, as appropriate, for the U.S. manufacture and for each U.S. use of the chemical:
  - consumer product uses/exposures to the chemical?
  - environmental exposures from environmental releases from manufacturing, processing and use of the chemical?
  - indirect human exposures from environmental releases from manufacturing, processing and use of the chemical?
  - occupational exposures during manufacturing, processing and use?
- Does the assessment provide an adequate explanation when potential exposures are not assessed?
- Does the assessment adequately support its conclusions on who is exposed and on the likelihood, frequency and magnitude of the exposures?
- When assessing the above exposures, does the assessment use U.S. monitoring data? Is the data current? Does it also provide summary information for each key monitoring study on:
  - the objective of the monitoring study and the study design?
  - the utility and limitations for using the monitoring data to assess exposures to the chemical?
  - the sampling and analytical methods that were used?
  - the quality assurance and quality control procedures that were employed?
  - uncertainties in the monitoring data and the exposure assessment?
  - a reference where more complete information may be found?
- When assessing the above exposures, does the assessment use model estimates of exposure? Does it also provide summary information for each key assessment result on:
  - the modeling objective?
  - the status of model validation and peer review?
  - the key inputs to the model?
  - the model algorithm/assumptions?
  - the model scenario?
  - uncertainty in the model results?
  - a reference where more complete information may be found?