EXPOSURE ASSESSMENT

OVERVIEW: An exposure assessment is the quantitative or qualitative evaluation of the contact an organism (human or environmental) may have with a chemical or physical agent, which describes the magnitude, frequency, duration, and route of contact.

GOALS:

- Estimate occupational exposure to workers.
- Estimate consumer exposure from product use (if applicable).
- Estimate exposure to humans and aquatic organisms from releases to the ambient environment.

PEOPLE SKILLS: The following lists the types of skills or knowledge that are needed to complete this module.

- Knowledge of exposure assessment guidance and methodology, including in the context of an occupational setting.
- Understanding of chemical fate, transport modeling and exposure modeling.
- Background in chemistry and environmental science.
- Background in occupational health or industrial hygiene.

Within a business or a DfE project team, the people who might supply these skills include a chemist, environmental scientist, industrial hygienist, and/or chemical engineer.

Note: The analysis presented in this module should only be undertaken by someone with expertise in exposure assessment. Because of the complexity and multidisciplinary nature of exposure assessments, it may be necessary even for the experienced exposure assessor to seek assistance from others with expertise in certain areas of the assessment. Furthermore, peer-review of the completed exposure assessment is recommended.

DEFINITION OF TERMS:

Acute Exposure: Exposure occurring over a short period of time (e.g., 14 days or less for fish). The specific time period varies depending on the test method and test organism or the receptor of interest.

Acute Potential Dose Rate (APDR): The dose, usually expressed on a per day basis, averaged over a period of time corresponding to an acute exposure period.

Averaging Time (AT): The time period, usually expressed in units of days, over which exposure is averaged when calculating an average dose rate.

Bioconcentration Factor (BCF): The equilibrium ratio of the concentration of a chemical in an exposed organism to the concentration of the chemical in the surrounding water.

Chronic Exposure: Continuous or intermittent exposure occurring over an extended period of time, or a significant fraction of the animal's or the individual's lifetime (e.g., > 20 days for daphnids).

Contact Rate (CR): The amount of contaminated medium contacted per unit time or event (e.g., m^3 per day of air inhaled, liters per day of water ingested).

Dose: See Potential Dose Rate.

Exposure: The contact of an organism (human or environmental) with a chemical or physical agent, expressed in terms of concentration and time.

Exposure Concentration, Exposure Point Concentration: The chemical concentration, in its transport or carrier medium, at the location of contact with an organism. Also defined, typically for exological risk, as the *Expected Environmental Concentration* (EEC) or *Predicted Environmental Concentration* (PEC).

Exposure Descriptor: A term used to characterize the position an exposure estimate has in the distribution of possible exposures (e.g., high-end, central tendency) for the population of interest.

Exposure Duration (ED): The duration of exposure, typically expressed in terms of days or years.

Exposure Frequency (EF): The frequency of exposure, expressed in units of days per year, events per year, events per lifetime, etc.

Exposure Level: In general, a measure of the magnitude of exposure, or the amount of an agent available at the exchange boundaries (i.e., lungs, gastrointestinal tract, or skin), during some specified time. In the Exposure Assessment and Risk Characterization modules, "exposure level" is used specifically as a measure of exposure expressed as a concentration rather than as a potential dose rate.

Exposure Pathway: The physical course a chemical takes from the source to the organism exposed. An example of an exposure pathway might be inhalation by a worker of volatile organic compounds (VOCs) that have evaporated from a solvent to the air.

Exposure Point: The location of potential contact between an organism and a chemical or physical agent.

Exposure Route: The route by which a chemical (or physical agent) comes in contact with the body of a receptor (e.g., by inhalation, ingestion, or dermal contact).

Exposure Scenario: A description of the specific circumstances under which exposure might occur, consisting of facts, assumptions, and inferences about how exposure takes place. An exposure scenario may comprise one or more exposure pathways.

Exposure Setting: The time frame and location, including a facility and its surrounding environment, where exposure might occur.

Lifetime Average Daily Concentration (LADC): The estimated daily concentration (usually in air) during the exposure duration, averaged over a lifetime.

Lifetime Average Daily Dose (LADD): The estimated potential daily dose rate received during the exposure duration, averaged over a lifetime. LADD is typically expressed in units of mg/kg-day.

Peak Exposure Level or Dose: The maximum exposure level or maximum potential dose rate.

Potential Dose Rate (PDR): The amount of a chemical ingested, inhaled, or applied to the skin per unit time (e.g., in units of mg/day). PDR may also be expressed per unit body weight per unit time (e.g., in mg/kg-day). PDR is the amount of a chemical that is available at the body's exchange boundaries and potentially could be absorbed into the body. (Related terms used elsewhere include "intake" or simply "dose," although the term dose implies that absorption is taken into account while PDR does not. The concepts of intake, dose and potential dose are described in detail in "Guidelines for Exposure Assessment" [EPA, 1992a].)

Receptor: The organism of interest (human or non-human) involved in a particular exposure pathway.

APPROACH/METHODOLOGY: The following presents a summary of the approach or methodology for conducting an exposure assessment. Further details on Steps 2, 3, 5, 6, 7, 8, and 9 are presented in the next section of this module. It should be noted that this is intended as a simplified overview of the exposure assessment process, which will vary on a case-by-case basis. The reader is referred to guidance documents (see Table 6-8) for further information. The guidance documents alone, however, do not substitute for experience; professional judgement plays an important role in the exposure assessment process, as stated in "Guidelines for Exposure Assessment" (EPA, 1992a)*:*

> *"Exposure assessments are done for a variety of purposes and for that reason, cannot easily be regimented into a set format or protocol." ... "Professional judgement comes*

into play in virtually every aspect of the exposure assessment process, from defining the appropriate exposures scenarios, to selecting the proper environmental fate models, to determining representative environmental conditions, etc."

With these caveats, the steps involved in exposure assessment are summarized below.

Step 1: Identify the potentially exposed population(s), including any sensitive or highly exposed subpopulation(s). For example, populations may include workers in a facility and residents living near a facility; special subpopulations may include children, the elderly, or residents living especially close to a facility. Occupational and population exposures are evaluated separately.

Step 2: Characterize the exposure setting. This includes characterizing the physical environment, all waste streams, and defining the exposure scenarios to be evaluated for the identified population(s). Collect information on the exposure setting from the Chemistry of Use & Process Description and the Workplace Practices & Source Release Assessment modules, and the Industry and Use Cluster Profile (see Chapter 2).

Step 3: Based on the characterization from Step 2, evaluate any possible exposure pathways and select complete exposure pathways to evaluate. Collect information pertaining to exposure pathways from the Workplace Practices & Source Release Assessment and Environmental Fate Summary modules. The potential for population exposures should be evaluated for releases to water, releases to air, and releases to land.

Step 4: Perform a literature search for available chemical concentration data, such as chemical concentrations in indoor air.

Step 5: Estimate concentrations in all media where exposure could occur. (For the aquatic exposure assessment, estimate concentrations in water where exposure to aquatic organisms could occur.) Concentrations can be from measured data and/or estimated using chemical fate and transport models. Use information from the previous steps, the Industry and Use Cluster Profile, and the following modules to estimate concentrations: Chemical Properties, Environmental Fate Summary, Workplace Practices & Source Release Assessment, Performance Assessment, and Control Technologies Assessment.

Step 6: Select values for exposure parameters used to estimate PDR for the population(s) of interest, clearly documenting the data sources and any assumptions made. Collect information pertaining to occupational exposure parameters from the Workplace Practices & Source Release Assessment module.

Step 7: Quantify exposure either in terms of PDR or exposure level.

Step 8: Evaluate uncertainties.

Step 9: Provide exposure information to the Human Health Hazards Summary, Risk Characterization, and Risk, Competitiveness & Conservation Data Summary modules.

METHODOLOGY DETAILS: This section presents methodology details for completing Steps 2, 3, 5, 6, 7, 8, and 9. Additional information on these and other steps can be found in the previously published guidance (see Table 6-8: Published Guidance on Exposure Assessment). In addition, detailed examples of occupational exposure assessment and population exposure assessment are presented in Appendix B and C, respectively, from the Screen Reclamation CTSA (EPA, 1994c).

Details: Step 2, Characterizing the Exposure Setting

This involves characterizing the physical setting with regard to actual or potential exposure for the population(s) of interest (e.g., workers, consumers, persons exposed through releases to the ambient environment, and aquatic organisms). In a CTSA, some of this characterization is performed in other modules. An evaluation of the process flow or the unit operations involved in the use cluster is performed in the Chemistry of Use & Process Description module. The Workplace Practices & Source Release Assessment module provides information on the occupational setting and worker activities required to characterize worker population exposure (e.g., number of workers, job descriptions), the chemical release/emission points, and the quantity of chemical released for a "model" or "sample" facility, as well as the media to which the chemical is released.

Information on product use by consumers, and land use and demographic data for areas surrounding the facilities and other release points could be used to assess potential exposures to other human populations. Additional information on the location of aquatic environments might be used to assess exposure to aquatic organisms, and to humans through the food chain.

Characterizing the exposure setting leads to defining exposure scenarios to be evaluated. Some example scenarios include:

- Nearby residents using groundwater in their homes that has been contaminated by releases from a landfill.
- Consumers bringing dry-cleaned clothes into their homes, potentially exposing themselves to perchloroethylene.
- Workers in a facility using a specific piece of equipment or performing a specific process.

Many other exposure scenarios are possible, and are very case-specific. The definition of exposure scenarios leads to selection of the exposure pathways to be evaluated. An exposure scenario may comprise one or several pathways.

Example data elements that may be used to characterize the exposure setting and define the exposure scenarios are listed below, along with sources of those data.

- *Sizes for small and medium facilities:* from the Workplace Practices & Source Release Assessment module.
- *Average number of workers at a facility*: from the Workplace Practices & Source Release Assessment module.
- *Total population of workers in the industry*: from the Workplace Practices & Source Release Assessment module, the Industry and Use Cluster Profile, and other sources (e.g., industry sources, census data, National Institute for Occupational Safety and Health [NIOSH], Health Hazard Evaluations [HHE]).
- *Operations/activities in handling the chemicals*: from the Workplace Practices & Source Release Assessment module, professional judgement, and other sources (e.g., NIOSH HHE, industry sources).
- *Chemical fate in the environment*: from the Environmental Fate Summary module.

Details: Step 3, Selecting Exposure Pathways

Selection of exposure pathways involves professional judgement and is based on the characterization of the physical setting, potentially exposed populations, and exposure scenarios from Steps 1 and 2. All of the pathways considered should be documented, with reasons for selection or exclusion of each pathway. A complete exposure pathway consists of:

- A source of chemical and mechanism for release.
- An exposure point.
- A transport medium (if the exposure point differs from the source).
- An exposure route.

For example, an occupational exposure pathway in a printing shop could consist of volitization of lacquer thinner from an open container as the source and mechanism of release; a worker's breathing zone as the exposure point; air as the transport medium (transport from the container to the worker's breathing zone); and inhalation as the exposure route.

Typical exposure pathways evaluated for occupational exposure are inhalation of airborne chemicals and dermal contact. Typical exposure pathways evaluated for human exposures in the ambient environment are:

- Inhalation of chemicals in air.
- Ingestion of chemicals in drinking water, from either groundwater or surface water.
- Ingestion of fish that have been exposed to bioaccumulative chemicals. EPA's Exposure Assessment Branch generally assumes that chemicals with a BCF of > 100 will bioaccumulate. (BCF values come from the Environmental Fate Summary module.)

Other pathways are possible, and will vary on a case-by-case basis. Other possible pathways might include:

- Ingestion of mother's milk by an infant, where the mother has been exposed to the chemical(s) of interest.

- Incidental ingestion of soil by nearby residents where the soil has been contaminated by releases from a nearby facility.
- Inhalation of VOCs from household water use.

Additional data elements that may be used to select occupational exposure pathways, and sources of those data, are listed below.

- *Personal protective equipment used*: from the Workplace Practices & Source Release Assessment module, using professional judgement, and checked against other sources of information.
- *Types of engineering controls used to reduce exposures (e.g., ventilation)*: from the Workplace Practices and Source Release Assessment module, professional judgement, and other sources of information (e.g., NIOSH HHE, Material Safety Data Sheets [MSDSs]).

Details: Step 5, Estimating Concentrations

Exposure concentrations can be determined by measurements or by fate and transport models (see Table 6-7: Analytical Models Used in Exposure Assessment). Selection of fate and transport models depends in part on the available data and on the data needs for the exposure assessment. Typical data sources for exposure assessment, listed in order of preference, include:

- Actual monitoring data for the compound of interest at the location where exposure could occur.
- Monitoring data for a similar process.
- Models to estimate worker exposures and environmental releases.
- Administrative controls and permit requirements to roughly estimate exposure and/or releases.

Additional data elements that may be used to estimate exposure concentrations, and sources of those data, are listed below.

- *Chemical formulations*: from the Performance Assessment module.
- *Amount of chemical used per day*: from the Workplace Practices & Source Release Assessment module and professional judgement.
- *Media of release*: from the Workplace Practices & Source Release Assessment module and types of control technologies used to reduce releases/exposures.
- *Amount of releases per site-day*: data for waste streams that can be quantified are obtained from the Workplace Practices & Source Release Assessment module; other release rates are modeled in the exposure assessment using information on conditions for potential releases from the Workplace Practices & Source Release Assessment module.
- *Number of shifts run per day and number of operating days*: from the Workplace Practices & Source Release Assessment module.
- *Number of facilities in the industry*: from the Workplace Practices & Source Release Assessment module, the Industry and Use Cluster Profile, and other sources (e.g., industry sources, census data, NIOSH HHE).

- *Total industry releases per year*: determined from amount of releases per site-day, number of facilities in the industry, number of shifts run per day, and number of operating days.
- *Pretreatment standards and discharge permits*: from the Workplace Practices & Source Release Assessment module or other sources.
- *Types of control technologies used to reduce releases and subsequent exposures*: from the Control Technologies Assessment and Workplace Practices & Source Release Assessment modules.
- *Frequency and duration of releases*: determined from number of shifts run per day, number of operating days, and duration of potential exposures.
- *Chemical fate in the environment* (specifically, chemical/physical parameter values used for transport modeling/exposure determination): from the Chemical Properties and Environmental Fate Summary modules.

Below is an example format for documenting the point-of-contact concentrations used in the exposure assessment.

Population(s) of Interest/Pathways	Chemical	Exposure Concentration	Comments (e.g., Details, Assumptions)
Workers, inhalation of VOCs in air.	chemical *a* . . . chemical *z*	conc. *a* (mg/m^3) . . . conc. *z* (mg/m^3)	Concentrations estimated using a volatilization model and average measured concentrations in solution x.

Table 6-3 is an example of calculating and presenting surface water concentrations from releases to water from a single facility.

TABLE 6-3: EXAMPLE - ESTIMATED RELEASES TO WATER FROM TRADITIONAL FORMULATIONS FROM SCREEN RECLAMATION AT A SINGLE FACILITY[a]

Substance	Amount Released to Water From Facility (g/day)	Waste Water Treatment Removal Efficiency	Amount to Water After Waste Water Treatment (g/day)	Daily Stream Concentration, for 1,000 MLD Receiving Water (µg/l)[b]
Methyl ethyl ketone	363	84%	58	0.06
n-Butyl acetate	191	97%	5.7	0.006
Methanol	37	97%	1.1	0.001
Naptha, light aliphatic	257	94%	15.4	0.02
Toluene	251	92%	20	0.02
Isobutyl isobutyrate	132	98%	2.6	0.003

a) Example taken from Screen Reclamation CTSA (EPA, 1994c).
b) µg/l is micrograms per liter, which is parts per billion for a substance in water. MLD is million liters per day.

In some areas there may be several facilities connected to the same waste water treatment plant. The concentration in the stream would be the combined amounts of all the releases in the stream.

As an example, the combined effects of multiple screen printing facilities in St. Louis County, Missouri, were demonstrated in the Screen Reclamation CTSA. Dun and Bradstreet data showed 135 screen printing facilities in St. Louis County. It was assumed that the waste water from all of these facilities goes to the St. Louis County Sewer Company, which releases into the Meramec River. Table 6-4 presents the surface water concentrations for the combined facilities' releases.

TABLE 6-4: EXAMPLE - ESTIMATED CUMULATIVE RELEASES FOR ST. LOUIS COUNTY, MISSOURI, FROM 135 SCREEN PRINTING FACILITIES[a]

Substance	Total Amount Released to Water From All Facilities (kg/day)	Waste Water Treatment Removal Efficiency	Amount to Water After Waste Water Treatment (g/day)	Average Concentration in Meramec River, (µg/l)[b]
Methyl ethyl ketone	49	84%	7,800	1
n-Butyl acetate	26	97%	800	0.1
Methanol	5	97%	150	0.02
Naptha, light aliphatic	35	94%	2,100	0.3
Toluene	34	92%	2,700	0.3
Isobutyl isobutyrate	18	98%	360	0.04

a) Example taken from Screen Reclamation CTSA (EPA, 1994c).
b) µg/l is micrograms per liter, which is parts per billion for a substance in water. The mean flow of the river is 7,895 MLD (million liters per day).

Table 6-5 is an example of calculating and presenting air concentrations from releases to air.

TABLE 6-5: EXAMPLE - AIR RELEASES AND CONCENTRATIONS FROM A SINGLE MODEL SCREEN PRINTING FACILITY[a]

Substance	Amount of Releases per Day (g/day)	Highest Average Concentration at 100 Meters[b] (µg/m^3)
Methyl ethyl ketone	403	0.8
n-Butyl acetate	107	0.2
Methanol	101	0.2
Naptha, light aliphatic	222	0.4
Toluene	255	0.5
Isobutyl isobutyrate	19.7	0.04

a) Example taken from Screen Reclamation CTSA (EPA, 1994c).
b) This estimates air concentrations at 100 meters from a hypothetical facility. The actual number of people who would fall into this range can be determined from census data, if the facility location is known. The model used to calculate concentrations is explained in the Screen Reclamation CTSA, Overview by Media - Air Section in Appendix C.

Details: Step 6, Selecting Values for Exposure Parameters for the Population(s) of Interest

Typical required parameters include:

- Contact rate (CR) (e.g., water ingestion, inhalation, or dermal contact rates).
- Exposure frequency (EF).
- Exposure duration (ED).
- Body weight (BW).
- Averaging time (AT).

Additional data elements that may be used to determine parameter values for quantifying worker exposure are listed below, along with the appropriate sources.

- *Duration of potential exposures*: from the Workplace Practices & Source Release Assessment module.
- *Frequency of exposures*: from the Workplace Practices & Source Release Assessment module, with professional judgement required to interpret the applicability of survey information.
- *Number of shifts run per day and number of operating days:* from the Workplace Practices & Source Release Assessment module.

If data are not available, professional judgement may be used to select default parameter values. See Table 6-9: Sources of Data for Exposure Assessment, for documents containing measured or default values for exposure parameters.

Following is an example format for documenting the parameters and assumptions used in the exposure assessment.

Population/ Pathways	Parameter	Value, Units	Reference, Rationale
Workers in Ocupational Setting			
Inhalation of VOCs	inhalation rate exposure frequency exposure duration body weight averaging time	__ m^3/day __ days/year __ years __ kg __ days	Information from the Workplace Practices & Source Release Assessment module or default values from EPA guidance (e.g., EPA, 1990a; EPA, 1991f).
Adults in a Residential Setting			
Inhalation of VOCs Released from Site	inhalation rate exposure frequency exposure duration body weight averaging time	__ m^3/day __ days/year __ years __ kg __ days	Information from the Workplace Practices & Source Release Assessment module or default values from EPA guidance (e.g., EPA, 1990a; EPA, 1991f).

Note: Default values are not presented. Exposure frequency and exposure duration for workers are typically determined from the Workplace Practices & Source Release Assessment module.

Details: Step 7, Quantifying Exposure

The concentration and other parameter values selected in Steps 5 and 6 are used to quantify exposure in pathway-specific exposure equations. Equations for several pathways can be found in "Guidelines for Exposure Assessment" (EPA, 1992a), *Risk Assessment Guidance for Superfund* (EPA, 1989a), and in *Dermal Exposure Assessment: Principles and Applications* (EPA, 1992d). A generic equation for quantifying exposure is:

$$PDR = (C)(CR)(EF)(ED)/[(BW)(AT)]$$

where:

- PDR = potential dose rate (mg/kg-day) (LADD, APDR or other dose rate)
- C = chemical concentration in exposure medium (average or peak concentration contacted during the exposure period)
- CR = contact rate; the amount of contaminated medium contacted per unit time or exposure event (i.e., m^3/day of air inhaled, L/day of water ingested, etc.)
- EF = exposure frequency (days/year)
- ED = exposure duration (years); exposure frequency and duration may also be combined into one term, also called exposure frequency but expressed in units of days
- BW = body weight; the average body weight over the exposure period (kg)
- AT = averaging time; the time period, in days, over which exposure is averaged

For example:

For a chemical concentration of 5 mg/L in water, 2 liters of water ingested per day, an exposure frequency of 365 days per year, an exposure duration of 9 years, a body weight for an adult of 70 kg, and an averaging time of 25,550 days (for a 70-year lifetime), the LADD for ingestion of drinking water is typically calculated as follows:

$$LADD = (5\ mg/L)(2\ L/day)(365\ days/year)(9\ years)/[(70\ kg)(25{,}550\ days)]$$
$$= 0.018\ mg/kg\text{-}day$$

An acute PDR can also be calculated using an exposure frequency and duration, and an averaging time of one day:

$$APDR = (5\ mg/L)(2\ L/day)(1\ day)/[(70\ kg)(1\ day)]$$
$$= 0.14\ mg/kg\text{-}day$$

An example of occupational exposure results is shown in Table 6-6.

TABLE 6-6: EXAMPLE - OCCUPATIONAL EXPOSURE ESTIMATES FOR SCREEN RECLAMATION, INK REMOVER SYSTEM[a]

Substance	Inhalation (mg/day)[b]				Dermal (mg/day)	
	I	II	III	IV	Routine	Immersion
Methyl ethyl ketone	165	5.3	3	20	468	2,180
n-Butyl acetate	44	1.3	1	5.3	234	1,090
Methanol	27	4.7	2	15	78	364
Naptha, light aliphatic	98	1.6	1	6.2	312	1,460
Toluene	110	2.3	1	9.2	312	1,460
Isobutyl isobutyrate	7	0.4	0	1.7	156	728

a) Example taken from Screen Reclamation CTSA (EPA, 1994c).
b) Scenario I = reclaiming 6 screens per day; each screen is approximately 2100 in^2; Scenario II = pouring 1 ounce of fluid for sampling; Scenario III = transferring chemicals from a 55 gallon drum to a 5 gallon pail; Scenario IV = storing waste rags in a drum and transferring them to a laundry.

Details: Step 8, Evaluating Uncertainties

A discussion of uncertainties in the overall risk assessment process is presented in the Risk Characterization module. Sources of uncertainty in the exposure assessment could include:

- Description of exposure setting - how well the typical facility used in the assessment represents the facilities included in the CTSA; the likelihood of the exposure pathways actually occurring.
- Possible effect of any chemicals that may not have been evaluated, including minor ingredients in a formulation.
- Chemical fate and transport model applicability and assumptions - how well the models and assumptions that are required for fate and transport modeling represent the situation being assessed and the extent to which the models have been verified or validated.
- Parameter value uncertainty, including measurement error, sampling error, parameter variability, and professional judgement.
- Uncertainty in combining pathways for an individual.

In a CTSA, uncertainty is typically addressed qualitatively. Because of the uncertainty inherent in the parameters and assumptions used in estimating exposure, and the variability that is possible within a population, there is no one number that can be used to describe exposure. Using exposure (or risk) descriptors is a method typically used to provide information about the position an exposure estimate has in the distribution of possible outcomes for a particular population. "Guidelines for Exposure Assessment" (EPA, 1992a), Habicht (1992), and others provide guidance on the use of risk descriptors, which include the following:

- *Central tendency*: represents either an *average estimate* (based on average values for the exposure parameters) or a *median estimate* (based on 50th percentile or geometric mean values) of the actual distribution.

- *High-end*: represents approximately the upper 10th percentile of the actual (measured or estimated) distribution. The high-end descriptor is a plausible estimate of individual risk for those persons at the upper end of the exposure distribution (i.e., a person exposed to an amount higher than 90 percent of the people who are exposed to the substance). It is also no higher than the individual in the population who has the highest exposure.
- *Bounding estimate*: an intentional overestimate of exposure used for screening purposes. Bounding estimates are useful in developing statements that exposures, doses, or risks are "not greater than" the estimated value.
- *Worst case*: a combination of events and conditions such that, taken together, produces the highest conceivable risk.
- *What-if*: represents an exposure estimate based on postulated questions (e.g., what if the worker is exposed to the concentration predicted by a particular air dispersion model). The estimates based on these what-if scenarios do not give any indication as to the likelihood of the exposure actually occurring, but may be useful for decision-making or to add perspective to the risk assessment.

Two types of quantitative uncertainty analysis (discussed in EPA, 1990a and EPA, 1992a) are sensitivity analysis and probability analysis. Sensitivity analysis requires data on the range of exposure parameter values, and gives information on how the results are impacted by variation within the different parameters. Sensitivity analysis can be used to determine the percent contribution to the overall uncertainty and/or variability from specific exposure parameters. Probability analysis (e.g., Monte Carlo simulation) requires data on the range and probability function, or distribution, of the exposure parameters and yields a probability function that describes the range of possible results. (Although not generally recommended for a CTSA, the increasing use of Monte Carlo simulation and availability of software for performing this type of analysis warrants mention of the technique.)

Details: Step 9, Transferring Information

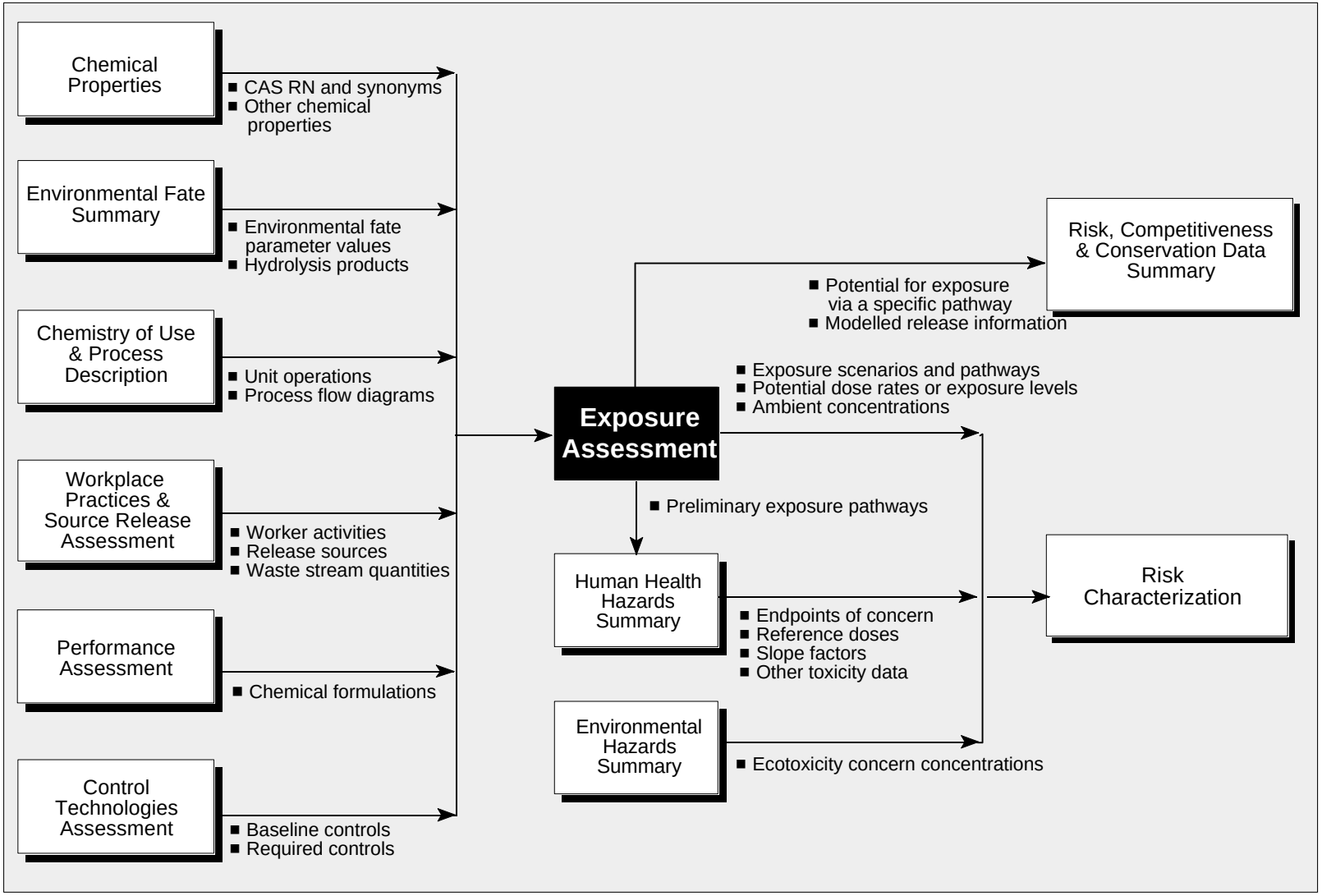
Data elements that are transferred from the Exposure Assessment module are listed below:

- *Preliminary exposure pathways*: to the Human Health Hazards Summary module.
- *Exposure scenarios and pathways, ambient aquatic exposure concentrations, PDR, human exposure levels, and uncertainty information*: to the Risk Characterization module.
- *Modeled release information (i.e., releases not quantified in the Workplace Practices & Source Release Assessment module but modeled in the Exposure Assessment module instead, such as releases of VOCs from containers of solvent left open during operating hours) and potential for exposure (e.g., high, medium, low) via a particular pathway (e.g., inhalation, ingestion, dermal):* to the Risk, Competitiveness & Conservation Data Summary module.

To the extent possible, include "unit of production" information with the exposure assessment results. For example, report the square feet of printed wiring board produced during the time period corresponding to the PDR. This can be determined by multiplying ED (in years) by the production rate (in ft^2/year). This may not be possible in all cases, depending on the available

data. This information is used in the Risk Characterization module to express risk on a "per unit of production" basis.

FLOW OF INFORMATION: The Exposure Assessment module receives information from the Chemical Properties, Environmental Fate Summary, Chemistry of Use & Process Description, Workplace Practices & Source Release Assessment, Performance Assessment, and Control Technologies Assessment modules. It transfers information to the Human Health Hazards Summary, Risk Characterization, and Risk, Competitiveness & Conservation Data Summary modules. Examples of information flows are shown in Figure 6-4.


Chemical Properties
■ CAS RN and synonyms
■ Other chemical properties
Environmental Fate Summary
■ Environmental fate parameter values
■ Hydrolysis products
Chemistry of Use & Process Description
■ Unit operations
■ Process flow diagrams
Workplace Practices & Source Release Assessment
■ Worker activities
■ Release sources
■ Waste stream quantities
Performance Assessment
■ Chemical formulations
Control Technologies Assessment
■ Baseline controls
■ Required controls
Exposure Assessment
■ Potential for exposure via a specific pathway
■ Modelled release information
Risk, Competitiveness & Conservation Data Summary
■ Exposure scenarios and pathways
■ Potential dose rates or exposure levels
■ Ambient concentrations
■ Preliminary exposure pathways
Human Health Hazards Summary
■ Endpoints of concern
■ Reference doses
■ Slope factors
■ Other toxicity data
Environmental Hazards Summary
■ Ecotoxicity concern concentrations
Risk Characterization

ANALYTICAL MODELS: Table 6-7 presents references for analytical models that can be used to estimate exposure concentrations. This list contains the major models used by the U.S. EPA Office of Pollution Prevention and Toxics, in the Exposure Assessment Branch, for their work, and is not all-inclusive.

Note: Chemical fate and transport modeling is a highly technical undertaking, and should be performed only by someone with the appropriate technical background and experience with the particular models to be used. Additional sources of information on models includes the Integrated Model Evaluation System (IMES), developed by the Office of Research and Development within the U.S. EPA. IMES is currently undergoing review by EPA and is available to assist in the selection of appropriate fate models.

TABLE 6-7: ANALYTICAL MODELS USED IN EXPOSURE ASSESSMENT

Reference	Type of Model
AMEM (A.D. Little Migration Estimation Model): A.D. Little, Inc. Lastest version, 1993.	Multimedia environmental fate; models migration of additives, monomers, and oligomers from polymeric material.
AT123D[a,b] (Analytical Transient One-, Two-, and Three-Dimensional Simulation model): Yeh, G.T. 1981. *AT123D: Analytical Transient One-, Two-, and Three-Dimensional Simulation of Waste Transport in an AQUIFER System.*	Groundwater model; estimates spread of contaminant plume through saturated zone, considers adsorption and degradation.
BOXMOD[a]: General Sciences Corporation. 1991a. *GEMS User's Guide.*	Air model; estimates exposure in urban areas with diffuse emissions. BOXMOD is implemented in the Graphical Exposure Modeling System (GEMS).
DERMAL: Versar, Inc. 1995a. *DERMAL User's Manual.*	Estimates consumer dermal exposure for a variety of product categories.
ENPART[a,b]: General Sciences Corporation. 1985a. *A User's Guide to Environmental Partitioning Model.*	Multimedia environmental fate model to screen for chemical partitioning in the environment.

TABLE 6-7: ANALYTICAL MODELS USED IN EXPOSURE ASSESSMENT

Reference	Type of Model
EXAMS-II[a,b] (Exposure Analysis Modeling System): Burns, L.A., et al. 1982. *Exposure Analysis Modeling System (EXAMS) User Manual and System Documentation*. Burns, L.A., et. al. 1985. *Exposure Analysis Modeling System: User's Guide for EXAMS II*.	Surface water model; simulates fate, transport, and persistence of organic chemicals in surface water.
FLUSH: Versar, Inc. 1995b. *FLUSH User's Manual*.	Surface water model; estimates surface water concentrations from disposal of household products.
Fugacity models: For example: Mackay, D. 1993. *Multimedia Environmental Models, The Fugacity Approach*.	Multimedia fate and transport models.
GAMS[a] (GEMS Atmospheric Modeling Subsystem): General Sciences Corporation. 1990a. *Draft GAMS Version 3.0 User's Guide*.	Air exposure model; estimates average annual concentrations, LADD and risks; incorporates ISCLT and TOXBOX as the air fate and transport models.
GEMS/PCGEMS (Graphical Exposure Modeling System): General Sciences Corporation. 1988a. *PCGEMS User's Guide Release 1.0*. General Sciences Corporation. 1991b. *Graphical Exposure Modeling System, GEMS User's Guide*. Harrigan, P. and A. Battin. 1989. *Training Materials for GEMS and PCGEMS: Estimating Chemical Concentrations in Surface Waters*. Harrigan, P. and A. Nold. 1989. *Training Materials for GEMS and PCGEMS: Estimating Chemical Concentrations in Unsaturated Soil and Groundwater*. Harrigan, P. and S. Rheingrover. 1989. *Training Materials for GEMS and PCGEMS: Estimating Chemical Concentrations in the Atmosphere*.	Modeling system for general population exposure assessment. Includes fate and transport models along with some relevant data needed to run those models, and where possible applies results to assess the population exposed. Includes many of the models listed below, as well as population data.

TABLE 6-7: ANALYTICAL MODELS USED IN EXPOSURE ASSESSMENT	
Reference	**Type of Model**
INPUFF[a]: General Sciences Corporation. 1986. *INPUFF User's Guide*.	Air model; estimates air exposure from short term releases or continuous plume.
ISCLT[a,b] (Industrial Source Complex Long-Term), and ISCST[a] (Industrial Source Complex Short-Term): U.S. Environmental Protection Agency. 1992e. *Industrial Source Complex (ISC2) Dispersion Models User's Guide*.	Air model; ISCLT calculates average annual air concentrations and exposures. Air model; ISCST calculates short term air concentrations and exposures.
MCCEM (Multi-Chamber Concentration and Exposure Model): Geomet Technologies, Inc. 1991a. *MCCEM User's Manual, Version 2.3*. Geomet Technologies, Inc. 1991b. *MCCEM Documentation Model, Version 2.3*.	Air model; estimates consumer inhalation exposure.
PDM 3.1 (Probabilistic Dilution Model): Versar, Inc. UNDATED. *User's Guide to PDM 3.1*.	Surface water model; estimates frequency that concentration of concern is exceeded.
PRZM[a,c] (Pesticide Root Zone Model): Carsel, R.F., et. al. 1984. *Users Manual for the Pesticide Root Zone Model (PRZM) Release 1*.	Soil model; simulates vertical transport in the vadose zone, plant uptake, runoff, etc.
PTPLU[a,b] (Point Plume): General Sciences Corporation. 1988b. *User's Guide for PTPLU in GEMS*. Pierce, T.E. and D.B. Turner. 1982. *PTPLU - A Single Source Gaussian Dispersion Algorithm User's Guide*.	Air model; calculates maximum short term air concentrations.
ReachScan: Versar, Inc. 1992a. *ReachScan User's Manual*.	Surface water model; estimates downriver concentrations and exposures.

TABLE 6-7: ANALYTICAL MODELS USED IN EXPOSURE ASSESSMENT

Reference	Type of Model
ReachScan/PDM: Versar, Inc. 1992b. *ReachScan/PDM User's Manual*.	Surface water model; combines downriver concentration estimates from REACHSCAN with the concentration of concern (COC) exceedance information from PDM.
SCIES (Screening Consumer Inhalation Exposure Software): Versar, Inc. 1994. *SCIES User's Manual, Version 3.0*.	Air model; estimates consumer inhalation exposure for a variety of product categories.
SEAS (Screening Exposure Assessment Software): U.S. Environmental Protection Agency. 1995e.	Surface water concentration estimation; simple dilution calculations from flow data. Calculates by single facility or by groupings of Standard Industrial Classifications (SICs). SIC-based stream information used to calculated mean and low flows for the industry.
SESOIL[a,b] (Seasonal Soil Compartment Model): Bonazountas, M. and J. Wagner. 1981. *SESOIL, a Seasonal Soil Compartment Model*.	Soil/vadose zone model; long-term fate simulations for organic and inorganic chemicals.
STP (Sewage Treatment Plant fugacity model): Clark, B., et al. 1995. "Fugacity Analysis and Model of Organic Chemical Fate in a Sewage Treatment Plant."	Estimates chemical fate in sewage treatment plants.
SWIP[a] (Survey Waste Injection Program): General Sciences Corporation. 1985b. *User's Guide to SWIP Model Execution Using Data Management Supporting System*. U.S. Geological Survey. UNDATEDa. "Detailed Model Description and Capabilities." U.S. Geological Survey. UNDATEDb. "Revised Documentation for the Enhanced Model."	Groundwater model; estimates chemical or thermal pollutant transport and transformation in groundwater systems.
TOXBOX[a]: General Sciences Corporation. 1990a. *Draft GAMS Version 3.0 User's Guide*.	Air model; estimates air exposure levels over large areas from diffuse sources. Available only within the GEMS Atmospheric Modeling Subsection.

TABLE 6-7: ANALYTICAL MODELS USED IN EXPOSURE ASSESSMENT	
Reference	**Type of Model**
TOXSCREEN[a,b]: Hetrick, D.M. and L.M. McDowell-Boyer. 1983. *User's Manual for TOX-SCREEN: A MultiMedia Screening-Level Program for Assessing the Potential of Chemicals Released to the Environment.*	Multimedia environmental fate; models fate of chemicals released to air, water, soil, or a combination.
TRIAIR[a]: General Sciences Corporation. 1990b. *Draft TRIAIR User's Guide.*	Air model; models dose and air concentrations using TRI data and ISCLT model. Must be run by OPPT personnel.
TRIWATER: General Sciences Corporation. 1990c. *Implementation of the T.R.I. Regional Surface Water Modeling System in GEMS.* General Sciences Corporation. 1993. *Final Report, GEMS and RGDS Linkage III, EPA Contract 68-d0-0080, Work Assignment No. 3-4.*	Surface water model; estimates surface water concentrations and risks from point source releases. Must be run by OPPT personnel.
UTM-TOX[a] (Unified Transport Model for Toxicants): Browman, M.G., et. al. 1982. *Formulations of the Physicochemical Processes in the ORNL Unified Transport Model for Toxicants (UTM-TOX), Interim Report.* General Sciences Corporation. 1985c. *Characterization of Data Base Requirements for Implementation of UTM-TOX Under GEMS: Parameter Sensitivity Study.* Patterson, M.R., et. al. 1984. *A User's Manual for UTM-TOX, the Unified Transport Model.*	Multimedia environmental fate; simulates dispersion of chemicals in soil, air, and water.
Valley[a]: Burt, E. 1977. *VALLEY Model User's Guide.* General Sciences Corporation. 1989. *User's Guide for Valley in GEMS.*	Air model; estimates 24-hour average air concentrations in complex terrain.

TABLE 6-7: ANALYTICAL MODELS USED IN EXPOSURE ASSESSMENT	
Reference	**Type of Model**
Other models as required; from various sources, for example: U.S. Environmental Protection Agency. 1988c. *Superfund Exposure Assessment Manual*.	

a) Model is implemented in GEMS.
b) Model is implemented in PCGEMS.
c) Model is available from other sources in a more recent version than the version implemented in GEMS.
Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

PUBLISHED GUIDANCE: Table 6-8 presents references for published guidance on exposure assessment. **Some of these documents may not have been published outside of EPA**.

TABLE 6-8: PUBLISHED GUIDANCE ON EXPOSURE ASSESSMENT	
Reference	**Type of Guidance**
Gilbert, R.O. 1987. *Statistical Methods for Environmental Pollution Monitoring*.	Guidance on statistical methods for summarizing and using environmental monitoring data.
Habicht, F.H. II. 1992. *Guidance on Risk Characterization for Risk Managers and Risk Assessors*.	Guidance for risk assessors on describing risk assessment results in EPA reports, presentations and decision packages; includes guidance on use of exposure descriptors.
Harrigan, P. 1994. *Guidelines for Completing the Initial Review Exposure Report*.	Information on models, assessing releases to various media, and environmental fate default values as well as guidance on assessing exposure to consumers from use of various products.
U.S. Environmental Protection Agency. 1989a. *Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A)*.	Detailed guidance for developing health risk information at Superfund sites; may also be applicable to other assessments of hazardous wastes and hazardous materials.
U.S. Environmental Protection Agency. 1989b. *Toxic Chemical Release Inventory Risk Screening Guide*.	Guidance for risk screening for ranking and further evaluation.
U.S. Environmental Protection Agency. 1991e. *Chemical Engineering Branch Manual for the Preparation of Engineering Assessments.*	Describes various approaches and data sources for occupational exposure estimation.

TABLE 6-8: PUBLISHED GUIDANCE ON EXPOSURE ASSESSMENT	
Reference	**Type of Guidance**
U.S. Environmental Protection Agency. 1991f. *Human Health Evaluation Manual, Supplemental Guidance:* "Standard Default Exposure Factors."	Standard default values for exposure parameter to be used in the Superfund remedial investigation/feasibility study process; may also apply to exposure assessments in general.
U.S. Environmental Protection Agency. 1992a. "Guidelines for Exposure Assessment."	EPA guidance on exposure assessment.
U.S. Environmental Protection Agency. 1992d. *Dermal Exposure Assessment: Principles and Applications. Interim Report*.	Guidance on procedures for assessment of dermal exposure pathways.
U.S. Environmental Protection Agency. 1992f. *EPA Supplemental Guidance to RAGS: Calculating the Concentration Term.*	Calculating exposure point concentrations from environmental sample data.
U.S. Environmental Protection Agency. 1992g. *RM1/RM2 Process Manual, Version 1.0*.	Guidance for exposure assessors on performing RM1 and RM2 exposure assessments.
U.S. Environmental Protection Agency. 1994g. *Guidelines for Completing the Initial Review Exposure Report - Final Draft.*	Guidance for preparation of initial exposure assessments for substances submitted under the Pre-manufacture Notification Program.
U.S. Environmental Protection Agency. 1994h. *Guidelines for Statistical Analysis of Occupational Exposure Data*.	Guidance on using occupational exposure data.
Versar, Inc. 1988. *The Nonexposure Aspects of Risk Assessment, An Introduction for the Exposure Assessor*, Final Draft.	Guidance on interpreting results.
Wood, P. 1991. *Existing Chemical Assignment/RM1 Exposure Report*.	Information on chemical properties, production and use information, and consumer uses (if applicable).

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

DATA SOURCES: Table 6-9 lists sources of data for exposure assessment.

TABLE 6-9: SOURCES OF DATA FOR EXPOSURE ASSESSMENT	
Reference	**Type of Data**
American Industrial Health Council. 1994. *Exposure Factors Sourcebook.*	Summary and evaluation of current scientific documentation and statistical data for various exposure factors used in risk assessments.

TABLE 6-9: SOURCES OF DATA FOR EXPOSURE ASSESSMENT

Reference	Type of Data
Chambers of Commerce.	Number of businesses of interest within a specified area.
Dun and Bradstreet, various sources.	Business census information.
Eastern Research Group, Inc. 1992. *Inventory of Exposure-Related Data Systems Sponsored by Federal Agencies*.	Description of and contacts for other sources of exposure data.
Environmental monitoring data from various sources.	Air, water, other environmental concentrations.
GEMS/PCGEMS models.	Contains census data, chemical properties for SARA Title III chemicals, and default model parameters (chemical, environmental, population, and site property data).
Industry, trade associations.	Chemical release information, controls used.
National Institute for Occupational Safety and Health (NIOSH). UNDATEDb. *Health Hazard Evaluations.*	Occupational exposure data.
Open literature.	Other exposure parameter data, other fate and transport models, etc.
U.S. Census Bureau.	Population, demographic data, some information on activity patterns (e.g., average time in a residence, average tenure for different occupations, etc.).
U.S. Environmental Protection Agency. 1989a. *Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A).*	Detailed guidance for developing health risk information at Superfund sites, including values for exposure parameters; may also be applicable to other assessments of hazardous wastes and hazardous materials.
U.S. Environmental Protection Agency. 1990a. *Exposure Factors Handbook.*	Data on human physiological and behavioral parameters.
U.S. Environmental Protection Agency. 1991f. *Human Health Evaluation Manual, Supplemental Guidance:* "Standard Default Exposure Factors."	Standard default values for exposure parameter to be used in the Superfund remedial investigation/feasibility study process; may also apply to exposure assessments in general.
U.S. Environmental Protection Agency. 1992d. *Dermal Exposure Assessment: Principles and Applications. Interim Report*.	Guidance on assessment of dermal exposure.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.