

Explanation of ATSDR's Public Health Assessment Process

To evaluate potential exposures at a site, ATSDR follows the general public health assessment (PHA) process to find out:

- Whether people living near a hazardous waste site are being exposed to toxic substances.
- Whether that exposure is harmful.
- What must be done to stop or reduce exposure.

During the stepwise PHA process, ATSDR does the following:

- **Evaluates conditions.** Evaluates site conditions and determines the nature and extent of environmental contamination.
- **Engages communities.** Engages communities at the beginning of site activities and involves them throughout the process to respond to their health concerns.
- **Defines pathways.** Defines potential human exposure pathways related to site-specific environmental contaminants.
- **Identifies exposures.** Identifies who may be or may have been exposed to environmental contamination associated with a site (past, current, and future).
- **Evaluates and screens contaminant data.** Evaluates sampling data, screens detected contaminants to identify those that require further examination, and if appropriate, defines exposure units (EUs) for completed and potential exposure pathways before or after the screening analysis.
- **Calculates exposure estimates.** Estimates the exposure point concentrations (EPCs) and performs exposure calculations to evaluate noncancer and cancer effects to assess potential human exposures to site-specific contaminants.
- **Examines public health implications.** Examines the public health implications of site-related exposures through the examination of environmental and health effects data.
- **Communicates findings.** Clearly communicates the findings of its evaluations, while acknowledging the impact of uncertainties and limitations.
- **Provides recommendations.** Provides recommendations to site-related entities, partner agencies, and communities to prevent and minimize harmful exposures.

Scientific Evaluations Conducted During the PHA Process

ATSDR performs different types of scientific evaluations during the PHA process.

- After examining the available information and data, health assessors conduct an [exposure pathways evaluation](#).

- For completed and potential exposure pathways, health assessors will perform a [screening evaluation](#) using the available sampling data.
- Based on the screening results, you may need to conduct an [evaluation of EPCs and exposure calculations \(exposure doses, air adjusted EPCs, hazard quotients, and cancer risks\)](#).
- Then, if necessary, you would perform an [in-depth toxicological effects evaluation](#).

The sequence of steps can differ based on site-specific factors. For instance, health assessors might define an exposure unit before or after the screening analysis. Details on each of these scientific evaluations that ATSDR may conduct during the PHA process are summarized below.

Exposure Pathways

Evaluating exposure pathways involves examining available data (environmental, biological) and developing a conceptual model of the site to determine the specific ways in which people might contact site-related contamination. Note that ATSDR may define exposure units during this step.

To pinpoint the exposure pathways associated with a site, ATSDR will answer these questions:

- Are there people who were, are, or could be exposed to contaminants from the site?
- Under what conditions did, does, or could exposure occur?
- When were people exposed (past, present, future)?

ATSDR identifies human exposure pathways by examining environmental and human components that might cause exposure to contaminants in the past, present, or future. ATSDR's exposure pathway analysis considers five elements:

1. A contaminant source
2. Environmental fate and transport
3. An exposure point
4. An exposure route
5. A potentially exposed population

ATSDR examines these elements and considers three exposure categories for the past, present, and future site-specific situations:

- **Completed exposure pathways:** All five elements of a pathway are present.
- **Potential exposure pathways:** One (or more) element of a pathway is missing, but information is not sufficient to eliminate or exclude the element.
- **Eliminated exposure pathways:** One (or more) element of a pathway is not present for the timeframe of interest.

The identification of a completed or potential exposure pathway **does not mean** that the exposure will result in harmful health effects. The likelihood of health effects depends on specific exposure conditions such as the exposure duration, contaminant toxicity and concentration, and exposure frequency. Therefore, even if exposure has occurred, is now occurring, or likely will occur in the future, human health might not be affected. To determine whether health effects are possible, ATSDR will further evaluate the completed and potential exposure pathways in the next scientific evaluation – the screening analysis.

Screening Analysis

For completed and potential exposure pathways, ATSDR next conducts the screening analysis – a quick, easy mechanism for identifying contaminants that do and do not require further evaluation at a site. Conducting the screening analysis involves comparing contaminant concentrations to media-specific screening levels (ATSDR comparison values [CVs] and non-ATSDR screening levels) to identify

those that meet or exceed screening levels. It also involves pinpointing contaminants with no available screening levels and evaluating other factors (e.g., a community concern) that warrant closer examination. Note that exposure units can be determined after performing the screening evaluation and before calculating EPCs.

Important: If a contaminant level exceeds an ATSDR CV or non-ATSDR screening level, it does not mean that health effects will occur, just that more evaluation is necessary.

ATSDR Comparison Values (CVs)

CVs are developed by ATSDR. They are contaminant concentrations found in a specific medium (e.g., air, soil, water) that are not likely to cause harmful health effects to those exposed. ATSDR develops its CVs assuming that exposures occur through contact to a single medium and to a single contaminant for a specified exposure period: acute (14 days or less), intermediate (15 to 364 days), or chronic (365 days and longer). CVs are based on a default exposure scenario (i.e., they do not reflect site-specific exposures), assuming daily exposure to the chemical and a standard amount of media (e.g., air, water, soil) that a person might inhale or ingest each day. CVs are generated to be conservative and to protect the health of children and adults. CVs are not intended as environmental cleanup levels and are not indicators that health effects occur above the CV concentrations.

ATSDR develops different CVs for *noncancer* and *cancer* health effects. When developing noncancer CVs, ATSDR assumes that only noncancer health effects will occur. When developing cancer CVs, ATSDR assumes that only cancer health effects will occur. When a contaminant has both a cancer and noncancer CV, health assessors use the lowest of the two CVs for screening (except for arsenic because the CV for cancer is below background).

ATSDR develops noncancer CVs using appropriate noncancer health guidelines and standard default exposure assumptions. Health guidelines consist of oral doses (ATSDR's oral minimal risk levels [MRLs], EPA's reference doses [RfDs]) and air concentrations (ATSDR's inhalation MRLs, EPA's reference concentrations [RfCs]) developed from toxicology or epidemiology

studies (with safety factors applied) that are protective of human health. For cancer effects, ATSDR develops cancer CVs using EPA's cancer risk values to identify estimated concentrations of cancer-causing contaminants that would be predicted to cause no more than one excess cancer in a million persons exposed during their lifetime (78 years). Cancer risk values consist of EPA's oral cancer slope factors (CSFs) and inhalation unit risks (IURs).

Non-ATSDR Screening Levels

In addition to ATSDR CVs, ATSDR may use non-ATSDR screening levels when ATSDR CVs are not available, or when lower (i.e., more health protective) than ATSDR CVs used.

The screening levels described below were used in preparing this document.

- *Cancer Risk Evaluation Guides (CREGs)* are ATSDR CVs that represent estimated contaminant concentrations that are unlikely to result in no more than one excess cancer in a million persons exposure during their lifetime (78 years). CREGs for media, like water and soil, are derived using EPA's oral CSFs and default exposure assumptions. CREGs for air are derived using EPA's IURs. CREGs are calculated using age-group specific formula exposure assumptions for body weight and ingestion of soil or water. Age-dependent adjustment factors (ADAFs) are included for carcinogens with a mutagenic mode of action.
- *Environmental Media Evaluation Guides (EMEGs)* are ATSDR CVs. EMEGs are concentrations of contaminants in a specific medium (e.g., water, soil) that represent estimated contaminant concentrations below which humans exposed during a specific timeframe (acute, intermediate, or chronic) are not expected to experience noncancer health effects. EMEGs are based on ATSDR's oral and inhalation MRLs.
- *Reference Media Evaluation Guides (RMEGs)* are ATSDR CVs. RMEGs represent the concentration in a specific medium (e.g., water, soil) at which daily human exposure for a chronic duration is unlikely to result in noncarcinogenic effects. RMEGs are derived from EPA's oral RfDs for ingestion and RfCs for inhalation.
- *Regional Screening Levels (RSLs)* are concentrations of chemical contaminants used by EPA as risk-based screening levels at hazardous waste sites. RSLs are calculated using the latest toxicity values, default exposure assumptions, and physical and chemical properties.

EPCs and Exposure Calculations

Next, for all contaminants identified as requiring further evaluation during the screening analysis, ATSDR conducts the EPCs and exposure calculations evaluation. This evaluation involves calculating EPCs for each contaminant in each completed and potential exposure pathway (by exposure unit, if appropriate). During the PHA process, health assessors must use whatever environmental sampling data are available for a site to estimate human exposures to contamination levels. To specifically consider uncertainties associated with environmental sampling data, ATSDR uses robust statistical procedures to generate reasonable, health-protective EPCs. By applying [ATSDR's EPC guidance](#), health assessors should be confident

that their estimated EPCs do not understate actual exposures, despite the statistical uncertainties associated with environmental sampling data.

ATSDR's EPC calculations use default or site-specific exposure conditions to estimate:

- Exposure doses for ingestion and dermal contact, and inhalation under very specific circumstances.
- Adjusted air EPCs for inhalation.
- Hazard quotients (HQs) for evaluating noncancer effects.
- Cancer risks (CRs) for assessing risks from carcinogens.

ATSDR uses the EPCs and exposure calculations evaluation to determine the contaminants that need to be further examined in the last scientific evaluation, the in-depth toxicological effects analysis, because they exceed acceptable noncancer and cancer levels, have no health guidelines (MRLs, RfDs, RfCs) or cancer risk values (CSFs, IURs), or pose other issues (e.g., a community concern).

During the EPCs and exposure calculations step, for ingestion and dermal exposures, ATSDR uses pathway-way specific equations (e.g., drinking water ingestion, surface water dermal contact) to calculate exposure doses for standard age groups and custom groups, when appropriate. ATSDR uses site-specific exposure scenarios with assumptions of who goes on the site and how often they are potentially exposed to site contaminants. The amount of chemical that is swallowed or gets absorbed through the skin is called a dose. Exposure doses are calculated in units of milligrams per kilograms per day (mg/kg/day). For exposures via ingestion, ATSDR breaks doses out by:

- **Reasonable maximum exposure (RME)**, which refers to people who are at the high end of the exposure distribution (approximately the 95th percentile). The RME scenario is intended to assess exposures that are higher than average, but still within a realistic exposure range.
- **Central tendency exposure (CTE)**, which refers to individuals who have average or typical exposure to a contaminant.

More information on our calculation of estimated exposure doses is presented in the [Estimating Site-Specific Ingestion and Dermal Exposure Doses section in ATSDR's Public Health Assessment Guidance Manual \(PHAGM\)](#).

For evaluating inhalation exposures, ATSDR's standard approach is to adjust the air concentration (EPC) by an appropriate exposure factor (rather than calculate an exposure dose) depending on chronic, intermediate, or acute exposure. More information is in the [Estimating Site-Specific Inhalation Exposures section in ATSDR's PHAGM](#).

Some chemical exposures are associated with noncancer health effects but are not associated with cancer-related health effects. Thus, for each contaminant carried into this evaluation, we conducted separate calculations to account for noncancer and cancer health effects, as applicable, depending on the contaminant's documented health effects.

Noncancer Health Effects

Once we have our estimated exposure doses and adjusted air concentrations for each contaminant and exposure pathway, we compare them to contaminant-specific health guidelines (used to evaluate noncancer health effects), such as an MRL, RfD, or RfC, to assess whether harmful health effects are expected. Health guidelines are derived from data in the epidemiologic and toxicologic literature with appropriate uncertainty or safety factors applied to ensure they are set at levels below those that could result in harmful health effects. The values do not represent thresholds of toxicity. For reference, the common health guidelines ATSDR uses are defined in the table below.

| Health Guidelines | Definition |
|--|--|
| ATSDR-Developed Minimal Risk Levels (MRLs) | <ul style="list-style-type: none"> • Represent estimates of the daily human exposure to a contaminant that, based on ATSDR evaluations, are not expected to cause noncancer health effects during a specified exposure duration. • Are set below levels that might cause harmful health effects in most people, including sensitive populations. • Are derived for acute (1-14 days), intermediate (15-364 days), and chronic (365 days and longer) exposure durations. • Are available for oral and inhalation exposures. • A complete list of the available MRLs can be found at https://www.atsdr.cdc.gov/mrls/index.html. |
| EPA-Derived Reference Doses (RfDs) | <ul style="list-style-type: none"> • Are estimates of daily oral exposures to a contaminant not likely to have a discernible risk of deleterious effects to the general human population, including sensitive subgroups, during a lifetime of exposure. • A complete list of EPA's available RfDs can be found at https://www.epa.gov/iris. |
| EPA-Derived Reference Concentrations (RfCs) | <ul style="list-style-type: none"> • Are estimates of daily inhalation exposures to a contaminant not likely to have a discernible risk of deleterious effects to the general human population, including sensitive subgroups, during a lifetime of exposure. • A complete list of EPA's available RfCs can be found at https://www.epa.gov/iris. |

We calculate a hazard quotient (HQ) to evaluate the potential for noncancer health hazards to occur from exposure to a contaminant with available noncancer health guidelines (MRLs, RfDs, RfCs). For our exposure doses, we obtain the HQ by dividing the duration-specific (acute, intermediate, or chronic) exposure dose by the noncancer health guideline for the same

duration MRL or RfD for our exposure groups of interest. For our air concentrations, we obtain the HQ by dividing the duration-specific exposure concentration by the MRL or RfC.

Once we have our HQ, we compare it to 1. HQs less than 1 indicate a noncancer hazard should not be an issue (i.e., the exposure likely will not cause noncancer health effects). When an HQ is greater than 1, it means there is an exceedance of the noncancer health guideline, and we retain those contaminants for further evaluation in the in-depth toxicological effects analysis.

Cancer Health Effects

ATSDR conducted a separate evaluation to determine the potential risks from cancer-causing chemicals detected at this site. Information about the increased risk for cancer from exposure to these chemicals is also provided in each exposure scenario. Cancer is a complex subject, and we think providing some background information here is a good idea before discussing cancer evaluations of specific chemicals. [According to the American Cancer Society](#), the overall probability that U.S. residents will develop cancer at some point in their lifetime is 1 in 2 for men (40.14%) and 1 in 3 (38.70%) for women. This is considering the background risk of developing cancer. Stated another way, half of all men and one-third of all women will develop some type of cancer in their lifetime. This is based on medical data collected on all types of cancer, regardless of whether the cause was identified, the case was successfully treated, or the patient died (directly or indirectly) of the cancer.

Factors that play major roles in cancer development include:

- lifestyle (what we eat, drink, and smoke; where we live);
- exposures to natural light (sunlight) and medical radiation;
- workplace exposures;
- drug use;
- socioeconomic factors; and
- chemicals in our air, water, soil, or food.

Infectious diseases, aging, and individual susceptibilities such as genetic predisposition are also important factors in cancer development.

We rarely know the environmental factors or conditions responsible for cancer onset and development. We have an understanding of cancer development for some occupational exposures or for the use of specific drugs. Overall cancer risks can be reduced by eating a balanced diet, getting regular exercise, having regular medical exams, and avoiding high-risk behaviors such as tobacco use and excessive alcohol consumption. Using proper safety procedures, appropriate personal protective equipment, and medical monitoring programs can decrease workplace cancer risks.

ATSDR calculates a population's cancer risk estimate for carcinogens with available cancer risk values (EPA's CSFs and IURs). In general, we use EPA's quantitative approach for estimating a theoretical risk of cancer in the exposed population. When we have exposure doses, we obtain

the CR by multiplying a chemical-specific CSF by the estimated exposure dose. When we have air concentrations, we obtain the CR by multiplying an IUR by the chemical concentration in air. This table below describes these cancer risk values.

| EPA-Derived Cancer Risk Values | Definition |
|---|--|
| Oral Cancer Slope Factors (CSFs) | <ul style="list-style-type: none"> • Measure of the relative potency of various carcinogens from oral exposures. • Are estimates of possible increases in cancer cases in a human population. • Represent the result of EPA's quantitative evaluation of oral exposure to a suspected carcinogenic contaminant. • A complete list of the available CSFs can be found at https://www.atsdr.cdc.gov/mrls/index.html. |
| Inhalation Unit Risks (IURs) | <ul style="list-style-type: none"> • Measure of the relative potency of various carcinogens from inhalation exposures. • Are estimates of possible increases in cancer cases in a human population. • Represent the result of EPA's quantitative evaluation of inhalation exposure to a suspected carcinogenic contaminant. • A complete list of the available IURs can be found at https://www.atsdr.cdc.gov/mrls/index.html. |

ATSDR calculates CTE and RME CRs, depending on what is appropriate for the site-specific scenario, and calculates the cancer risk for children separately from the cancer risk for adults. When childhood exposure continues into adulthood or if exposure occurs for a lifetime, ATSDR combines the cancer risks for children and adults. For children, CRs are derived for a combined child: CTE (12 years) and RME (21 years) at a given residence. For the CTE child CR, the combined child is the sum of the cancer risks for each age group for the first 12 years of exposure only. The RME CR for the combined child is derived by summing all the cancer risks for each age group from birth to < 21 years. The adult CR assumes living at the residence for 12 (CTE) or 33 (RME) years.

Another important concept is carcinogens that have a *mutagenic mode of action (MOA)*. Children are more susceptible to cancer and tumor development if exposed to carcinogens with a mutagenic MOA. To account for this increased susceptibility, ATSDR applies age-dependent adjustment factors (ADAFs) to the CR equation for these contaminants.

ATSDR uses the following EPA-recommended ADAFs based on age:

- 10 for children 0 < 2 years
- 3 for children 2 to < 16 years
- 1 for children ≥16 years and adults

The resulting risk of cancer is called an estimated excess cancer risk because it is the risk of cancer greater than the background risk of cancer that already exists. Unless directly stated, ATSDR cancer risk estimates for exposure to environmental contaminants do not include the existing background cancer rate in the U.S. population. Once we have a CR, we see if it is greater than 1.0E-06 (i.e., cancer risk exceeds one extra case in a million people similarly exposed). We retain those contaminants with CRs greater than 1.0E-06 and conduct further evaluation in the in-depth toxicological effects analysis.

In-depth Toxicological Effects Analysis

At this point in the process, we have ruled out those exposure pathways and contaminants that pose no health hazards and retained those requiring more examination. During this last scientific evaluation step in the PHA process, we closely analyze toxicological information for contaminants to determine whether people could possibly have health problems from their exposure. Contaminants examined during this analysis are those that exceeded acceptable noncancer (HQ>1) and cancer (CR>1.0E-06) levels, had no available health guidelines or cancer risk levels, represented contaminants of community concern, or had other factors (e.g., multiple contaminant exposures) that warranted evaluation.

During the in-depth toxicological analysis, we review information to understand questions such as these:

- How does the contaminant get into the body?
- What happens to the contaminant after it gets into the body?
- What data were used to develop the health guidelines and/or cancer risk values?
- What health effects are associated with the contaminant and at what doses or concentrations?
- How do site-specific doses or concentrations compare to health effects doses or concentrations in published studies?

The analysis then helps us find answers about 1) what harmful effects might be expected in exposed people and 2) what public health actions are needed to prevent or reduce exposures.

We evaluate and integrate exposure data (e.g., site-specific exposure conditions, doses, concentrations) and contaminant-specific health effects data from toxicologic or epidemiologic studies. We consider the exposure assumptions used when site-specific exposure parameters are unavailable.

For noncancer effects, we compare site-specific doses and concentrations to effect levels from critical studies. Critical studies are those used to generate noncancer health guidelines as well

as studies for contaminants without noncancer health guidelines. This process helps us determine where site-specific doses and concentrations lie in relation to the observed-effect levels in the published literature. We look to see if differences between the study data and the exposure scenario we are evaluating make health effects more or less likely.

For cancer effects, we look at results quantitatively, as a theoretical risk, and qualitatively. The quantitative results describe the cancer risk numerically, such as three extra cancer cases for every 100,000 similarly exposed persons (3×10^{-5}). These theoretical risk estimates are calculated assuming people have the same exposures (e.g., the same soil concentration, soil ingestion rate, specified duration), and do not represent individual cancer risks or account for variation in exposure in people living around a site. The objective of the cancer risk estimate (quantitative) and hazard (qualitative) evaluation is to draw conclusions and make recommendations that will protect the public.

As included in the body of this document, the result of our in-depth toxicologic analysis is a **qualitative description** of whether site-specific exposures could result in harmful health effects. The findings help us determine the health conclusions and recommendations for public health actions presented herein. For more information on this in-depth analysis, refer to the [Process and Decision Logic for ATSDR's In-Depth Toxicological Effects Analysis in ATSDR's PHAGM](#).