

San Jacinto River Waste Pits Superfund Site Technical Document Review: Toxicological and Epidemiological Studies Memorandum

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What is a Toxicological and Epidemiological Studies Memorandum?

A *Toxicological and Epidemiological Studies Memorandum* (TESM) is completed prior to the *Baseline Human Health Risk Assessment* (a document that will evaluate risks to people based on site-specific conditions, scheduled to be completed in March 2013.) The TESM report presents the toxicological and epidemiological studies that will be used to perform the toxicity assessment. The TESM is to specify the toxicological criteria that will be used in the BHHRA to evaluate potential risks and hazards associated with exposure to chemicals of potential concern (COPCs) at the Site. Toxicity criteria include cancer slope factors (CSFs) for evaluating potential cancer effects for COPCs assumed to have a linear mode of action, and reference doses (RfDs) for evaluating both noncancer health effects and cancer effects for COPCs assumed to have a nonlinear mode of action.

What are the Chemicals of potential concern (COPC)

For the area north of I-10 the main chemicals of potential concern are dioxins and furans, but there are other COPCs as well: arsenic, cadmium, chromium, copper, mercury, nickel, thallium, zinc, PCBs. Because the south impoundment is still under investigation, it is possible that additional chemicals could be added.

What are the Ways People Could be Exposed to these Chemicals?

- Ingestion of fish and shellfish
- Direct contact (ingestion and dermal) with soils and sediments
- North impoundment: Fishers, recreational visitors, trespassers
- South impoundment: workers and trespassers

What are *Toxicological Criteria*?

The effect that a chemical has on human health is dependent on how much of that chemical a person is exposed to. For example, iron is an essential nutrient, if you don't have enough it can cause anemia. But, iron can also be dangerous if too much accumulates in the body, causing problems like liver damage.

Toxicological criteria is a risk assessment term that describes how much of a chemical might cause a health concern.

There are two types of concerns that are considered, cancer and noncancer effects. Some COPCs have both cancer/non-cancer effects. For those COPCs that are considered to have the potential to cause cancer, toxicological criteria are developed using the results of the toxicological studies, where either a tumor was found in the patient or there was a potential for tumor development. For COPCs that are considered to have the potential to cause non-cancer health effects, toxicological criteria are based on the negative health effects possible at the lowest doses.

Skin contact and eating contaminated fish are the most significant exposure routes. However, there is no skin contact –specific toxicological criteria available for the COPCs of interest, so the risk assessment will use oral criteria for both oral and dermal routes with adjustments for absorption efficiency by dermal route according to EPA’s guidelines.

How Does the EPA Evaluate Cancer Effects?

Based on rates from 2007-2009, 41.24% of people born today will be diagnosed with some type of cancer at some time during their lifetime.¹ USEPA evaluates the potential for individual chemicals to cause cancer in humans. To assess the potential, USEPA typically develops *Cancer Slope Factors* (CSFs). CSFs are used to estimate the risk of developing cancer, corresponding to a lifetime of exposure at the levels estimated in the exposure assessment. The CSF is often used to calculate what dose would result in a one-in-a-million extra risk (10⁻⁶ risk) or a one-in-a-hundred-thousand extra risk (10⁻⁵ risk).

How does the EPA Evaluate Non-Cancer Effects

For long term exposures (over 7 years), EPA creates a *chronic reference dose* (RfD), which is a concentration where an individual could be exposed daily exposure without an appreciable risk of adverse effects during a lifetime. For shorter term exposures, (between 2 weeks and 7 years), EPA creates a *subchronic RfD*, which is an average daily exposure at which no adverse health effects occur. EPA also has data for acute (short-term) exposures.

Challenges with Risk Assessment

Risk assessments are challenging because of the uncertainty involved. Most data is based on using animal studies to predict human effects; it might involve interpretation to approximate long term to medium term exposure, and the need to estimating exposure levels, among other challenges. When a risk assessment is done, the risk assessors should be aware of these limitations, and clearly state them in the documentation. Taking these limitations into account, the risk assessment for the San Jacinto Waste Pits site should use conservative estimations to make sure that any recommended site-specific clean-up levels are appropriately protective of human health and the environment.

¹ National Cancer Institute <http://seer.cancer.gov/statfacts/html/all.html> (accessed October 31, 2012)