

What is Human Health Risk Assessment?

5 Step Process for CERCLA

- Planning and Scoping
- Hazard Identification
- Exposure Assessment
- Toxicity Assessment
- Risk Characterization

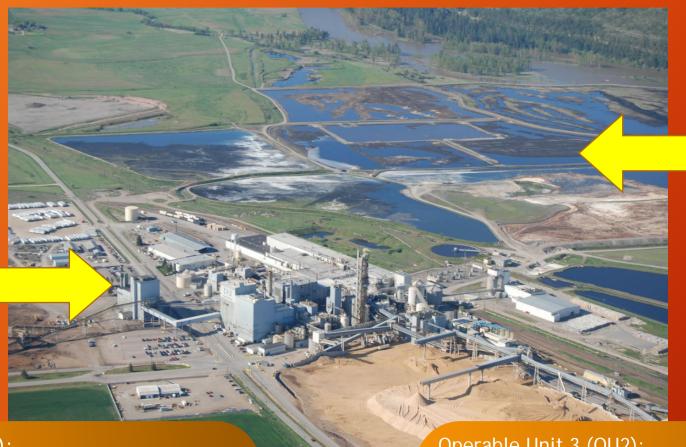
Required by CERCLA and the NCP to ensure remedial actions are protective of human health and the environment

Designed to inform the risk management process and the remedial investigation (RI)

A logical, *objective*, and *quantitative* approach to *analyzing and interpreting environmental data* with the purpose of predicting the *potential adverse health effects* at specific levels of exposure to chemical hazards

Goal of human health risk assessment is to determine if contaminants present at a site pose an *unacceptable* risk to people who may be exposed at the site

Risk assessment can be viewed as an iterative process which involves identifying and filling data gaps in order to develop a more refined assessment of risk



Operable Unit 2 (OU2):

• The 255-acre core industrial footprint of the Site. This includes the former pulp and paper mill building, the recycle plant (old corrugated container or OCC), a wood chip staging area, the hog fuel area, a chlorinated bleach plant, pulp tanks, multi-fuel and recovery boilers, lime kilns, a transformer storage building, an equipment repair building, offices, and various equipment storage areas.

Operable Unit 3 (OU2):

 1,700-acres of the Site where solid and aqueous wastes were treated and stored. This area includes the former wastewater treatment system (settling ponds, aeration basins, polishing ponds, solid waste basins, holding ponds, spoils basins, and infiltration basins), the holding ponds areas within the 100-year floodplain, and parts of the Clark Fork River where hazardous substances from historic mill operations may have come to be located.



What was sampled and analyzed for?

OU2 - Core Industrial Footprint

Media Sampled

- Soil
- Groundwater

Contaminants Analyzed

- Dioxins/Furans (TEQ)
- Polychlorinated Biphenyls (PCBs)
- Metals
- Volatile Organics (VOCs)
- Semi-volatile organics (SVOCs)

OU3 - Peripheral Waste Treatment Areas

Media Sampled

- Upland and Floodplain Soils
- Groundwater
- Sediment
- Surface Water
- Fish Tissue

Contaminants Analyzed

- Dioxins/Furans (TEQ)
- Polychlorinated Biphenyls (PCBs)
- Metals
- Volatile Organics (VOCs)
- Semi-volatile organics (SVOCs)
- Mercury and Selenium (Fish)



Who could be exposed?

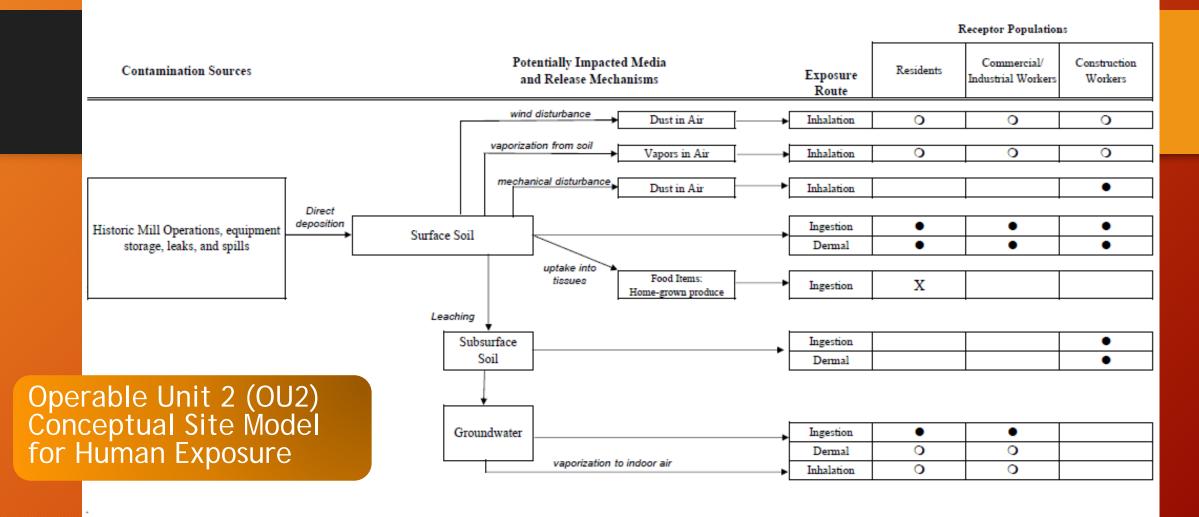
OU2 - Core Industrial Footprint

- Hypothetical Future Residents
- Commercial/Industrial Workers
- Construction Workers

OU3 - Peripheral Waste Treatment Areas

- Commercial/Industrial Workers
- Recreational Visitors & Tribal Fishers
- Hypothetical Future Residents
- Recreational Worker

Figure 3-1. Conceptual Site Model for Human Exposure at OU2

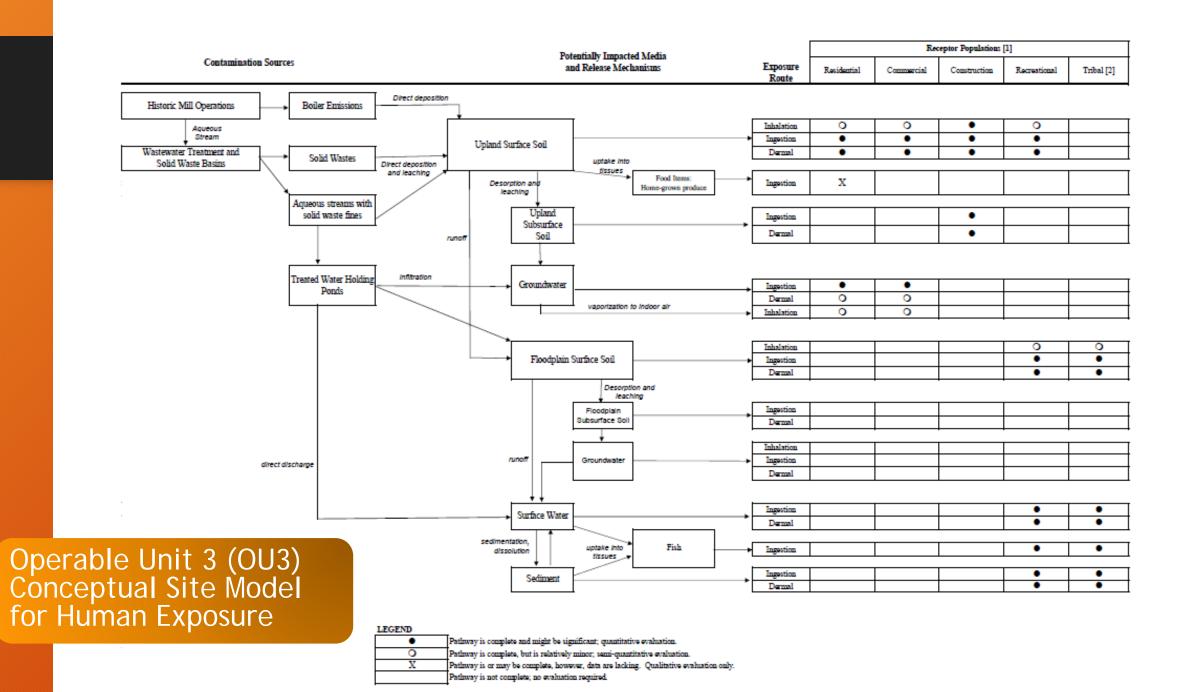


Description ■ Pathway is complete and might be significant; quantitative evaluation. ■ Pathway is complete, but is relatively minor; semi-quantitative evaluation. Pathway is not complete; no evaluation required.

Notes:

[1] Future land use is expected to be consistent with current and past use, although OU2 is currently not zoned for a specific land use.

Figure 3-1. Conceptual Site Model for Human Exposure at the OU3 Site



How are they primarily exposed?

OU2 - Core Industrial Footprint

All Populations of Concern

Ingestion and dermal exposure to soil

Hypothetical Future Residents

Ingestion of groundwater

Commercial/Industrial Workers

Ingestion of groundwater

Construction Workers

- Ingestion and dermal exposure to subsurface soil
- Inhalation of dust

OU3 - Peripheral Waste Treatment Areas

Hypothetical Future Residents & Workers

- Ingestion and dermal exposure to upland soil
- Ingestion of groundwater

Construction Workers

- Ingestion and dermal exposure to both upland surface and subsurface soils
- Inhalation of upland dust

Recreational Users & Tribal Fishers

- Ingestion and dermal exposure to floodplain soil
- Ingestion and dermal exposure to surface water
- Ingestion of fish
- Ingestion and dermal exposure to sediments

How do we estimate *risk*?



Risk = Site-specific exposure toxicity of a chemical



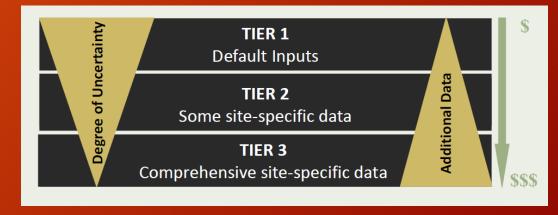
How do we estimate *exposure* to people?

 Use equations to estimate how often and how much people contact a given media to derive a site-specific estimate of exposure

- Intake = CxIRxEFxED/BWxAT
- C=concentration
- IR=intake rate
- EF=exposure frequency
- ED=exposure duration
- BW=body weight
- AT=period over which exposure is averaged

How do we estimate exposure to people?

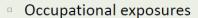
- For each land use and each pathway we estimated the upper bound of exposure that a person could reasonably receive.
- This is called the Reasonable Maximum Exposed or (RME) individual in the baseline risk assessment.
- If adequate site-specific data was available it was used in the exposure assessment
- If not, EPA recommends the use of standard RME default values based on a comprehensive national database.

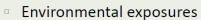


How do we estimate *toxicity* of chemicals?

- EPA evaluates toxicity data from a variety of sources, including epidemiological studies of occupational, environmental and poisoning exposures, laboratory animal studies, in vitro (petri dish) studies, and in silico (compuer modeling) studies.
- Toxicity data is extrapolated to human populations and used to develop *reference doses/concentrations* for exposures to non-carcinogens, and *slope factors/unit risks* for exposures to carcinogens over a 70-year lifetime.
- Site data are then compared to national toxicity benchmarks which are *protective of the most susceptible members of the population* (e.g., the elderly, the very young, etc.) to develop risk estimates and cleanup levels.

Epidemiologic studies





Poisonings



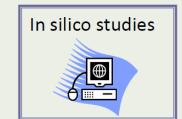


Laboratory animal (in vivo) studies

In vitro ("in glass") studies

- Metabolism
- Genotoxicity
- Gene expression
- □ Etc.





Screening for Contaminants of Concern

- The first step of the risk assessment process is a screen which identifies contaminants that may be of potential concern for human health and eliminates those that present a de minimis risk
- If analytes <u>fail</u> the screen (i.e., they are higher than the risk-based screening levels or background), they are evaluated further in a site-specific risk assessment
- If analytes <u>pass</u> the screen, they do not pose an unacceptable risk for human health and no further evaluation is needed

- Steps of the screening process:
 - Compare the maximum detected concentration in each media to a conservative risk-based screening level based on the person expected to receive the greatest exposure
 - Compare to background
 - Frequency of detection

Screening for Contaminants of Concern

OU2 - Core Industrial Footprint

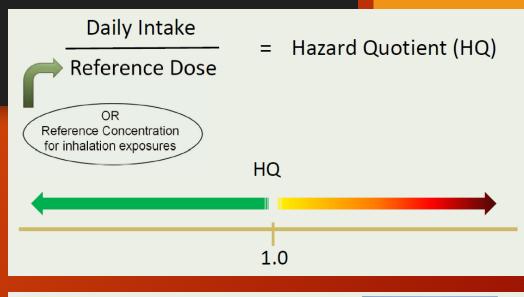
- TEQ (dioxins/furans/PCBcongeners), Total non-DL PCBs, and Aroclor-1254 in surface soil
- Manganese in groundwater

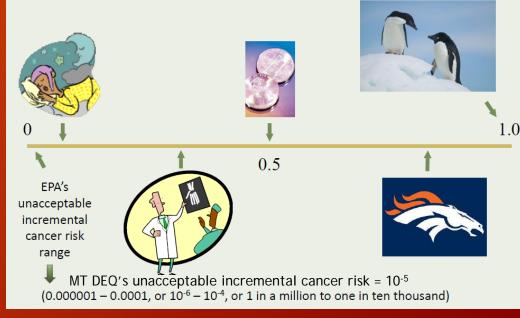
OU3 - Peripheral Waste Treatment Areas

- TEQ, antimony, cadmium and mercury in OU3 upland soil
- TEQ, barium, and mercury in OU3 floodplain soil
- TEQ, aluminum, arsenic, chromium, cobalt, iron, manganese, nickel and vanadium in groundwater
- TEQ and Aroclor-1254 in fish

How is the risk assessment conservative?

- The *maximum contaminant concentration* is used instead of the average
- Reasonable maximum exposure assumptions are used for the receptor who is expected to receive the *highest amount of exposure*
- The screen uses risk levels of 1 in a million excess cancer risk for carcinogens and a Hazard Quotient of 0.1 for systemic toxicants
 - These levels are 100 times lower than the risk levels required for cleanup of carcinogens and 10 times lower than risk levels required for cleanup of systemic toxicants

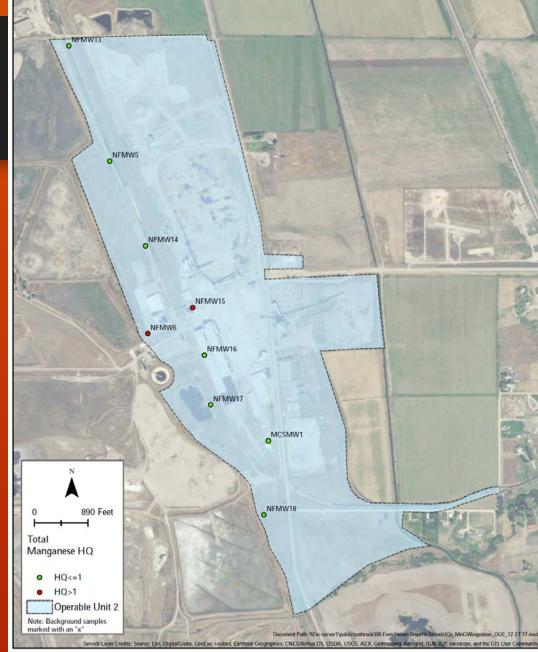




Preliminary Conclusions - OU2

- Residential, commercial/industrial workers, and construction workers were identified as current or plausible future receptors for OU 2
- The maximum contaminant concentration in each media was compared to:
 - A conservative risk-based screening level based on the site receptor expected to receive the most exposure
 - Background levels
- Nearly all contaminants analyzed in OU 2 were either:
 - Below conservative risk-based screening levels, or
 - Below background levels, or
 - Present at a level that did not pose an unacceptable risk
- Residents: risks from incidental ingestion of and dermal contact to surface soils appear to be within usual EPA guidelines across OU2, except for one exposure area
- Non-cancer hazards to a resident from the consumption of groundwater as drinking water appear to be elevated above a level of concern due primarily to manganese

Figure 5-1. Total Manganese Hazard Quotients in OU2 Groundwater: Smurfit-Stone/Frenchtown Mill Site, Montana

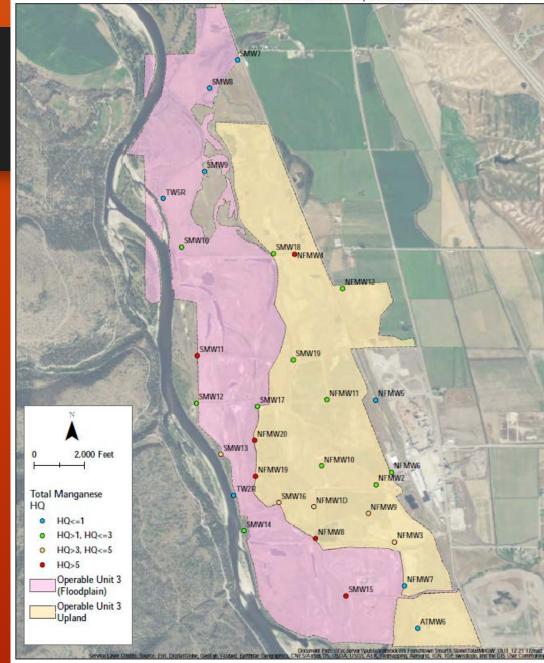




Preliminary Conclusions - OU3

- Residents: risks from incidental ingestion of and dermal contact to surface soils appear to be within usual EPA guidelines across OU3, except for one location where non-cancer hazards were slightly elevated
- Non-cancer hazards and cancer risks to a resident from the consumption of groundwater as drinking water appear to be elevated above a level of concern due primarily to manganese, cobalt and arsenic
- Workers: risks from incidental ingestion of and dermal contact to commercial/industrial workers and construction workers within OU3 upland from incidental ingestion of and dermal contact to surface soils appear to be within EPA guidelines
- Non-cancer hazards to commercial/industrial workers from consumption of groundwater as drinking water appear to be elevated above a level of concern due primarily to manganese and cobalt
- Recreational: Non-cancer hazards and cancer risks from exposures to soils appear to be within usual EPA guidelines
- General population fisher: risks from the consumption of fish are approaching, but within usual EPA guidelines

Figure 5-1. Total Manganese Hazard Quotients in OU3 Groundwater: Smurfit-Stone/Frenchtown Mill Site, Montana







How certain are we of these conclusions?

- Sediment and surface water data in the Clark Fork River
- Background TEQ data from surface water
- TEQ data from organisms and sediment and surface water in LaValle Creek, O'Keefe Creek, and the Clark Fork River
- Limited number of TEQ data points in fish tissue
- Tribal fisher subsistence consumption rates

What are the next steps?

- Draft HHRAs will be on the website by February 26, 2018
- EPA asks for public comment and stakeholder input on the HHRAs for OU2 and OU3 by March 26, 2018
- Respond to comments and revise the HHRAs by April 6, 2018
- Evaluate any new site data collected during the ecological risk assessment to reduce stated uncertainties and determine how the HHRA conclusions might change
- Revise the HHRAs as needed based upon any new data collected
- EPA and MT DEQ use HHRAs to inform risk management decisions and the implementation of the remedial investigation