CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF TOXIC SUBSTANCES CONTROL

Highlights Of Toxicity Criteria And Risk Assessment Methodologies Recommended By DTSC

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Topics to be discussed

- California Human Health Screening Levels (CHHSLs)
- Human Health Risk Assessment (HHRA) Notes (1-5)
- Chemicals with unique toxicity values or risk evaluations (cadmium, beryllium, TCE, PCE, lead)
- Vapor intrusion
- Guidance documents – Updates and Revisions

California Human Health Screening Levels (CHHSLs)

- DTSC does not recommend CHHSLs as screening levels
  - outdated toxicity values for some chemicals
  - outdated exposure assumptions (still based on 1989 exposure assumptions)
  - CHHSLs available for only a handful of chemicals

HHRA Note 3

- Recommended screening values are provided in HHRA note 3 (http://www.dtsc.ca.gov/assessingrisk/humanrisk2.cfm)
  - USEPA's Regional Screening Levels (RSLs): used for majority of chemicals
    - Except for 217 of the ~800 chemicals
  - DTSC modified screening levels for contaminants in soils, tap water and air
  - Residential and commercial/industrial scenario
  - Used USEPA updated default exposure assumptions (see HHRA note 1) (USEPA 2014, Human Health Evaluation Manual, Supplemental Guidance: Update of Standard Default Exposure Factors, OSWER 9200.1-120)

HHRA Note 3 (Cont'd)

- Differences between USEPA's RSLs and DTSC's screening values
  - different toxicity values (derive by CalEPA's Office of Human Health Screening Levels (OEHHA)
  - route-to-route extrapolation for VOCs with no inhalation toxicity values (67 compounds)

HHRA Note 3 (Cont'd)

- How were they derived
  - Used USEPA's RSL calculator, along with appropriate toxicity value, exposure assumptions
  - Compared these values to RSLs
  - If calculated screening level was at least 3 times more stringent than the RSL, that value was adopted and is presented in the HHRA note 3:

Table 1 (soils); Table 2 (water); Table 3 (air)

HHRA Note 3 (Cont'd)

- Recommendations for conducting screening level vapor intrusion (VI) evaluation using air screening levels and default attenuation factors

- Specific chemicals with more stringent screening levels
  - Trichloroethylene (TCE)
  - Tetrachloroethylene (PCE)
  - Lead
  - Cadmium
  - Beryllium

TCE Update

- Integrated Risk Information System (IRIS) released new toxicity criteria for TCE in Sept 2011.
  - USEPA reviewed the most recent literature of TCE
  - The IRIS toxicity criteria are more health protective than OEHHA values.
- DTSC adopted USEPA's toxicity criteria for TCE
- OEHHA has not updated the Toxicity Criteria Database with this values
- However OEHHA revised the No Significant Risk Levels (used under Prop 65) for TCE using USEPA's values.

Toxic Endpoint	IRIS (9/2011)	OEHHA	Ratio of IRIS to OEHHA (Relative Conservativeness)
Carcinogenicity			
Inhalation Unit Risk (IUR) risk per µg/m^3	**4.1×10^{-6}** Kidney, Liver & non-Hodgkin lymphoma	**2.0×10^{-6}** (2004) Liver/Lung tumors	**2** **(2-fold more health protective)**
Oral Cancer Slope Factor (CSF) risk per mg/kg-day	**4.6×10^{-2}** Kidney, Liver & non-Hodgkin lymphoma	**5.9×10^{-3}** (2009) Liver/Lung Tumors	**7.8** **(8-fold more health protective)**
Chronic Toxicity (Noncarcinogenic effects)			
Inhalation Reference Concentration (RfC) µg/m^3	**2** Cardiac malformations, developmental immunotoxicity, adult immunological effects	**600** (REL) Neurological effects in workers	**300-fold more health protective**
Oral Reference Dose (RfD) mg/kg-day	**5×10^{-4}** Cardiac malformations, adult immunological effects	**5×10^{-1}** (2009 PHG) Neurological effects in workers	**1000-fold more health protective**

TCE Update

- Significance/Impact
  - Noncancer threshold (i.e., Hazard Index) may exceed 1 at sites when the cancer risk is at the lower end of the risk management range or point of departure (1×10^{-6}).
  - Noncancer threshold may play more of a role in risk management decisions and must be discussed and considered.
  - When reviewing the risk assessment during the Five Year Review process, there is a potential that the original proposed remediation, land use controls, and/or institutional controls will have to be revised.

HHRA Note 5

EPA Region 9 Interim TCE Indoor Air Response Action Levels - Residential and Commercial TCE Inhalation Exposure from Vapor Intrusion		
Exposure Scenario	***Accelerated Response Action Level*** *(HQ=1)*	***Urgent Response Action Level*** *(HQ=3)*[4]
Residential *	**2 µg/m^3**	**6 µg/m^3**
Commercial/Industrial ** (8-hour workday)	**8 µg/m^3**	**24 µg/m^3**
Commercial/Industrial ** (10-hour workday)	**7 µg/m^3**	**21 µg/m^3**

* The residential HQ=1 accelerated response action level is equivalent to the inhalation reference concentration (RfC) since exposure is assumed to occur continuously.

** Commercial/Industrial accelerated response action levels are calculated as a time-weighted average from the RfC, based on the length of a workday and rounding to one significant digit (e.g., for an 8-hour workday: Accelerated Response Action Level = (168 hours per week/40 hours per week) x 2 µg/m^3 = 8 µg/m^3). Time-weighted adjustments can be made as needed for workplaces with longer work schedules.

Note: Indoor air TCE exposures corresponding to these accelerated response action levels would pose cancer risks near the lower end of the Superfund target cancer risk range, considering the IRIS toxicity assessment; thus, the health protective risk range for both accelerated response actions and long-term exposures becomes truncated to: 0.5 – 2 µg/m^3 for residential exposures and 3 –8 µg/m^3 for 8-hour/day commercial/industrial exposures.

HHRA Note 1, 2 and 4

- HHRA Note 1: List of default exposure assumptions used in cancer risk and non-cancer hazard calculations (September 2014)
- HHRA Note 2: Dioxin cleanup goals (2009)
- HHRA Note 4: Guidance on Screening level risk assessments (Updated October 2015)

PCE Update

- DTSC adopted OEHHA toxicity criteria (2009)
  - USEPA's IRIS – Released new toxicity criteria in February 2012
- Same toxic endpoints were used to derive toxicity values by both OEHHA and IRIS
  - Noncarcinogenic effects: Neurotoxicity, kidney, liver, immune and hematologic systems, development and reproduction
  - Carcinogenicity: Liver Cancer
- However, the selected studies used different mouse strains

Toxic Endpoint	IRIS (2/2012)	OEHHA	Relative Conservativeness
Carcinogenicity			
Inhalation Unit Risk (IUR) risk per $\mu g/m^3$	**2.6×10^{-7}** Liver Cancer	**5.9×10^{-6}** (2009) Liver Cancer	**22** (22-fold less health protective)
Oral Cancer Slope Factor (CSF) risk per mg/kg-day	**2.1×10^{-3}** Liver Cancer	**5.4×10^{-1}** (2001) Liver Cancer	**250** (250-fold less health protective)
Chronic Toxicity (Noncarcinogenic effects)			
Inhalation Reference Concentration (RfC) $\mu g/m^3$	**40** Neurotoxicity - occupational exposure	**35** (2001) Neurotoxicity – occupational exposure	**Similar value**
Oral Reference Dose (RfD) mg/kg-day	**6×10^{-3}** Neurotoxicity - occupational exposure	**3.2×10^{-2}** (2001 PHG) Neurotoxicity	IRIS value is 5x more conservative

Potential Impacts from Differences in Toxicity Criteria

PCE			
Indoor Air Screening Levels (µg/m^3)			
Scenario	OEHHA Toxicity Criteria (based on 10^{-6})	IRIS Toxicity Criteria (based on 10^{-6})	Fold difference between OEHHA and IRIS
Future Residential	0.48	11	23
Current Commercial/Industrial	2.1	47	22

Cadmium

- DTSC adopted OEHHA's toxicity criteria

  based on an RfD of 0.0063 ug/kg/d derived by OEHHA (vs. 1.0 ug/kg/d for RSL)

  the same RfC as that in the RSL table.

- The RfDs derived by OEHHA and RSL are based on the same toxic endpoint; kidney toxicity.
- However, OEHHA assumes that cadmium rapidly accumulates in the kidney (derivation of PHG)
  - assumes an exposure duration of 50 years, rather than the typical 6 year period for a child to a non-carcinogen
    - adverse effects continue into adulthood.

Cadmium

Chronic Toxicity (Non-carcinogenic effects)		
	RSL	**DTSC**
Oral Reference Dose (RfD) mg/kg-day	**1×10^{-3}** (IRIS) Kidney toxicity	**6.3×10^{-6}** (2006 PHG) Kidney toxicity
Inhalation Reference Concentration (RfC) mg/m^3	**1×10^{-5}** (ATSDR) Kidney toxicity	**1×10^{-5}** (OEHHA) Kidney toxicity Respiratory system
Soil Screening Level		
Residential (mg/kg)	**71**	**4.5**
Commercial/Industrial (mg/kg)	**980**	**5.7**

Beryllium

- DTSC adopted OEHHA's toxicity criteria for Beryllium which are more stringent than USEPA's values
- OEHHA derived toxicity values are more conservative due to differences in dose response modeling and uncertainty analysis
- OEHHA's RfD for beryllium is 10x more conservative that that derived by IRIS
- OEHHA RfC for beryllium is approximately 3x more conservative than that derived by IRIS

Beryllium

Chronic Toxicity (Non-carcinogenic effects)		
	RSL	**DTSC**
Oral Reference Dose (RfD) mg/kg-day	**2×10^{-3}** (IRIS) Small Intestinal lesions	**2×10^{-4}** (2003 PHG) Small Intestinal lesions
Inhalation Reference Concentration (RfC) mg/m^3	**2×10^{-5}** (IRIS) Sensitization and progression to chronic beryllium disease	**7×10^{-6}** (OEHHA) Sensitization and progression to chronic beryllium disease
Soil Screening Level		
Residential (mg/kg)	**160**	**3.0**
Commercial/Industrial (mg/kg)	**2300**	**21**

Lead

- DTSCs residential (80 ppm) and commercial /industrial (320 ppm) are more stringent than USEPAs values of 400 ppm (residential) and 800 ppm (commercial/industrial), respectively
- Differences in acceptable blood lead levels between CalEPA and USEPA
- For cleanup levels, the 95%UCL of the mean for lead should not exceed the appropriate soil screening level. The maximum concentration allowed onsite is dependent of distribution of the dataset

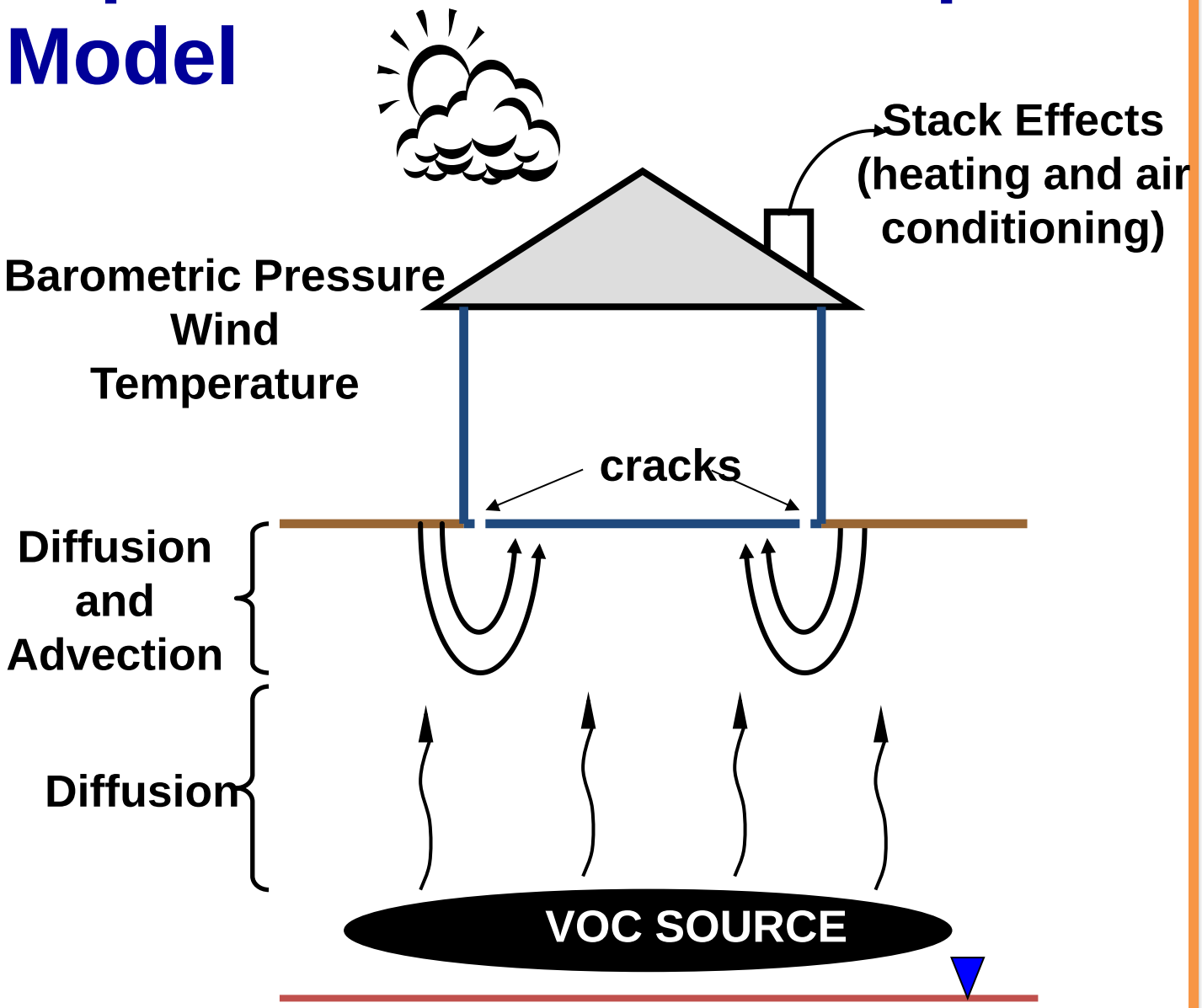
Lead

Modeling of Blood lead levels (µg/dL)		
	RSL	**DTSC**
Blood lead Modeling	**IEUBK (residential)** **Adult Lead Model (ALM) (commercial/industrial)**	**Leadspread (residential)** **DTSC modified ALM (commercial/industrial)**
Blood lead level of concern	**Threshold PbB of 10 µg/dl**	**∆ PbB of 1µg/dl**
Soil Screening Level		
Residential (mg/kg)	**400**	**80**
Commercial/Industrial (mg/kg)	**800**	**320**

Lead (cont'd)

- For cleanup goals, the 95%UCL of the mean for lead should not exceed the appropriate soil screening level.
- The maximum concentration allowed onsite is dependent of distribution of the dataset

Vapor Intrusion – Conceptual Model



Predicting Indoor Air from Subsurface Concentrations

Attenuation Factor (α, AF) is a term used to denote the ratio of concentrations in indoor air (C_{air}) to the concentrations in soil vapor (C_{sv}) or groundwater (C_{gw}).

$$\alpha = \frac{C_{air}}{C_{sv}} \qquad \alpha = \frac{C_{air}}{C_{gw}\ x\ H'}$$

where H' is the unitless Henry's law constant for the chemical of concern

Preliminary Screening Attenuation Factors

Building Scenario	Building Type	Sample Location	Attenuation Factor
Existing	Residential	Contaminant Source	0.002
		Crawl Space	1.0
		Subslab	0.05
	Commercial	Contaminant Source	0.001
		Subslab	0.05
Future	Residential	Contaminant Source	0.001
	Commercial	Contaminant Source	0.0005

USEPA SG-SCREEN
Version 2.0, 04/2003

DTSC Modification
December 2014

Department of Toxic Substances Control
Vapor Intrusion Screening Model - Soil Gas

Scenario: Residential
Chemical: Trichloroethylene

DATA ENTRY SHEET

Results Summary				
Soil Gas Conc. ($\mu g/m^3$)	Attenuation Factor (unitless)	Indoor Air Conc. ($\mu g/m^3$)	Cancer Risk	Noncancer Hazard
1.72E+03	1.2E-03	2.1E+00	3.0E-06	1.0E+00

Reset to

Soil Gas Concentration Data

ENTER Chemical CAS No. (numbers only, no dashes)	ENTER Soil gas conc., C_g ($\mu g/m^3$)	OR	ENTER Soil gas conc., C_g (ppmv)	Chemical
79016	1.72E+03			Trichloroethylene

MESSAGE: See VLOOKUP table comments on chemical properties and/or toxicity criteria for this chemical.

MORE ↓

ENTER Depth below grade to bottom of enclosed space floor, L_F (15 or 200 cm)	ENTER Soil gas sampling depth below grade, L_s (cm)	ENTER Average soil temperature, T_S (°C)	ENTER Vadose zone SCS soil type (used to estimate soil vapor permeability)	OR	ENTER User-defined vadose zone soil vapor permeability, k_v (cm^2)
15	152	24	S		

MORE ↓

Lookup Soil

ENTER Vandose zone SCS soil type	ENTER Vadose zone soil dry bulk density, ρ_b^A (g/cm^3)	ENTER Vadose zone soil total porosity, n^V (unitless)	ENTER Vadose zone soil water-filled porosity, θ_w^V (cm^3/cm^3)	ENTER Average vapor flow rate into bldg. (Leave blank to calculate) Q_{soil} (L/m)
S	1.66	0.375	0.054	5

MORE ↓

Lookup Receptor

	ENTER Averaging time for carcinogens, AT_C (yrs)	ENTER Averaging time for noncarcinogens, AT_{NC} (yrs)	ENTER Exposure duration, ED (yrs)	ENTER Exposure frequency, EF (days/yr)	ENTER Exposure Time ET (hrs/day)	ENTER Air Exchange Rate ACH $(hour)^{-1}$
NEW=> Residential	70	26	26	350	24 (NEW)	0.5 (NEW)

END

DTSC Guidance Updates

- Guidance documents revised
  - Preliminary Endangerment Assessment Manual
  - DTSC J&E Model (December 2014)
  - Active Soil Gas Advisory (July 2015)

  Revision in process…
  - Updated Vapor Intrusion Guidance
  - Petroleum Risk Assessment Guidance