CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF TOXIC SUBSTANCES CONTROL

Updates in Risk Assessment

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Topics to be discussed

- Preliminary Endangerment Assessment Guidance Manual
- Human Health Risk Assessment (HHRA) Notes (1-6)
- Arsenic *in vitro* Bioaccessibility method (HHRA note 6)
- Polyfluoroalkyl substances (PFASs)

Preliminary Endangerment Assessment Guidance Manual

- Guidance for evaluating Hazardous substance release sites in California under DTSC oversight
- Finalized in October 2015
- Scoping, data collection and evaluation
- Screening level and baseline risk assessment

HHRA Note 1, 2 and 3

- HHRA Note 1: List of default exposure assumptions used in cancer risk and non-cancer hazard calculations (2014)
- HHRA Note 2: Dioxin cleanup goals (2009)
- HHRA Note 3: Soils, tap water and air screening values for chemicals that differ from USEPA's Regional Screening Levels (RSLs)

HHRA Notes 4, 5 and 6

- HHRA Note 4: Guidance on Screening Level Risk Assessments (Updated October 2015)
- HHRA Note 5: TCE action levels for residential and commercial/industrial scenarios. Same as USEPA.
- HHRA Note 6: *In vitro* Bioccessibility methodology for arsenic in soils

HHRA Note 6 (August 2016)

- California Arsenic Bioaccessibility (CAB): *In vitro* site-specific relative bioavailability method for arsenic (RBA) in soils

- RBA = ratio of bioavailability of arsenic in soils to that of arsenic in water.

- Toxicity values for arsenic are based on arsenic in water

- Until recently, it was assumed that arsenic RBA is 100%

- In 2012, USEPA adopted a default arsenic bioavailability from soils of 60%. This has been incorporated into USEPA's RSL table.

HHRA Note 6 (cont'd)

- In 2008, DTSC received a grant from USEPA (Brownfields Training, Research and Technical Assistance). Partnered with USGS and Universities (OSU, Chapman, U. Missouri) to develop *in vitro* method.
- Historically, regulatory agencies accepted only data based on *in vivo* methods (animal models-expensive, time consuming).
- *In vitro* RBA method – quick, reliable, cost effective.

HHRA Note 6 (August 2016)

Example Risk Equation:

$Risk_{soil} = SF_{oral} \times C_{soil} \times RBA \times IR \times EF \times ED \times 10^{-6} / BW \times AT$

Where: $Risk_{soil}$ = Risk in Soil (unitless)

SF_{oral} = Slope Factor ([mg/kg-day]-1)

C_{soil} = Concentration in Soil (mg/kg)

RBA = Relative Bioavailability (unitless, 0 to 1.00)

IR = Ingestion Rate (mg/day)

EF = Exposure Frequency (day/year)

ED = Exposure Duration (year)

BW = Body weight (kg)

AT = Averaging Time (days)

HHRA Note 6 (cont'd)

When to consider site-specific bioavailability study for arsenic

- Arsenic levels are higher than background
- Soil arsenic levels are low to moderate (100 ppm, < 1500 ppm)
- Anticipated future land use (beneficial for residential, but not necessarily for trespasser)
- Soil type; RBA is typically lower in soils rich in iron; higher in sandy soils
- Arsenic source (mining site vs. site with pesticide application)

HHRA Note 6 (cont’d)

Hypothetical Site with Soils Contaminated with Arsenic

Future Land Use: Unrestricted Residential; therefore background is clean-up goal

Background As in Soils: **30 mg/kg** (IVBA Background: 50%)

Arsenic due to contamination: **100 mg/kg** (IVBA Contaminated Soils: 30%)

Available As in Background: Csoil x IVBA= 30 mg/kg x 0.5 = **15 mg/kg**

Available As in Contaminated Soils: Csoil x IVBA= 100 mg/kg x 0.3= 30 mg/kg

Potential site-specific clean up goal for As in contaminated Soils: **50 mg/kg**

Whereas 50 mg/kg x 0.3= 15 mg/kg available Arsenic, which is comparable to the available As in background soils.

HHRA Note 6 (cont’d)

- Currently, only two labs have access to the Standard Operating Procedures (SOP) for the in vitro method
- However, once these methods are published in a peer-reviewed journal (2016-2017), other labs should be able to replicate it.
- Contact person at DTSC: Dr. Valerie Hanley

PFOS and PFOA

What is it?

- Perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS) are fully fluorinated organic compounds that are part of the polyfluoalkyl substances (PFASs).

- Widely used in consumer and industrial products to make materials stain, grease, and water resistant (carpets, leather, textiles, upholstery, non-stick cookware, paper packaging, fire/crash training sites, aviation fluid)

- Contaminated groundwater at military facilities, manufacturing sites, industrial facility, municipality waste sites

PFOS and PFOA

Why is it of concern?

- Highly resistant to degradation; bioaccumulates in environment
- Causes cancer in laboratory animals (kidney); reproductive and development (delayed ossification of bones) toxicant
- Found in 99% of people (sampled as part of biomonitoring studies); wildlife and water
- In 2012, under the Safe Drinking Water Act (SDWA's), Unregulated Contaminant Monitoring Rule 3 (UCMR3), PFOA was measured in large drinking water systems, and detected in 2% of the 5000 Public Water Systems (PWS)
- Most manufacturers in U.S. phased out production (2015)

PFOS and PFOA

Regulations/Advisories

- In May 2016, USEPA derived drinking water Health Advisory (HA) for PFOA of 0.07 ug/L (PFOS+PFOA). HA's developed for 200 chemicals.
- USEPA has not yet developed soil screening levels (RSL table).
- The Air Force is using 5 mg/kg, based on older toxicity values.
- DTSC will include residential (~1.3 mg/kg) and commercial/industrial screening levels of PFAS's in next HHRA Note 3, since it has been recently found at many military sites (Air Force Bases) under DTSC oversight.

HERO Quarterly Updates: http://www.dtsc.ca.gov/AssessingRisk/index.cfm

Questions?