

# Introduction to Toxicity and Risk Assessment for Project Chemists

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# Role of Risk Assessment on Environmental Projects

- Used to determine whether site requires further study or remediation
- Used with regulatory values to determine cleanup levels
- Risk-based screening levels (aka PRGs, RBCs, RSLs)
  - ▶ Screen sites early in project lifecycle
  - ▶ Determine project quantitation limits



# Risk-Based Values Function of Toxicity and Exposure

$$\text{Risk} = \frac{\text{Intake}}{\text{Toxicity}}$$

↑ Toxicity = ↓ Criteria

- Tiered approach used to identify toxicity values for site risk assessments
- Other values: EPA provisional values, ATSDR, States
- EPA Integrated Risk Information System (IRIS) is the “gold standard”



# Integrated Risk Information System

- Values used for site risk assessment and also for regulatory determinations (MCLs)
- May derive cancer oral slope factors (SF) and inhalation unit risks (IUR) and /or oral reference dose (RfD) and reference concentration (RfC) for noncancer effects
- If insufficient information exists a value is not derived



# Definitions: Cancer Assessment

- Slope factor and Inhalation Unit Risk: A plausible upper-bound estimate of the probability of a response per unit intake of a chemical over a lifetime.
- OSF  $(\text{mg/kg-day})^{-1}$
- IUR  $(\mu\text{g/m}^3)^{-1}$



## Definitions: Non-Cancer

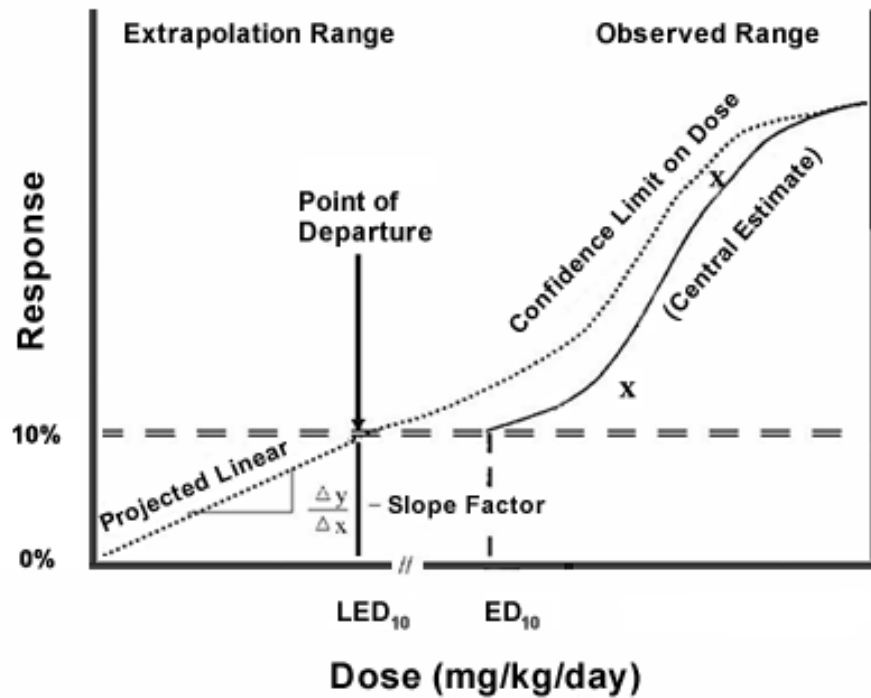
- Reference Dose (RfD) and Reference Concentration (RfC): An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure (or continuous inhalation exposure) to the human population that is likely to be without an appreciable risk of deleterious effects during a lifetime.

RfD mg-kg/day

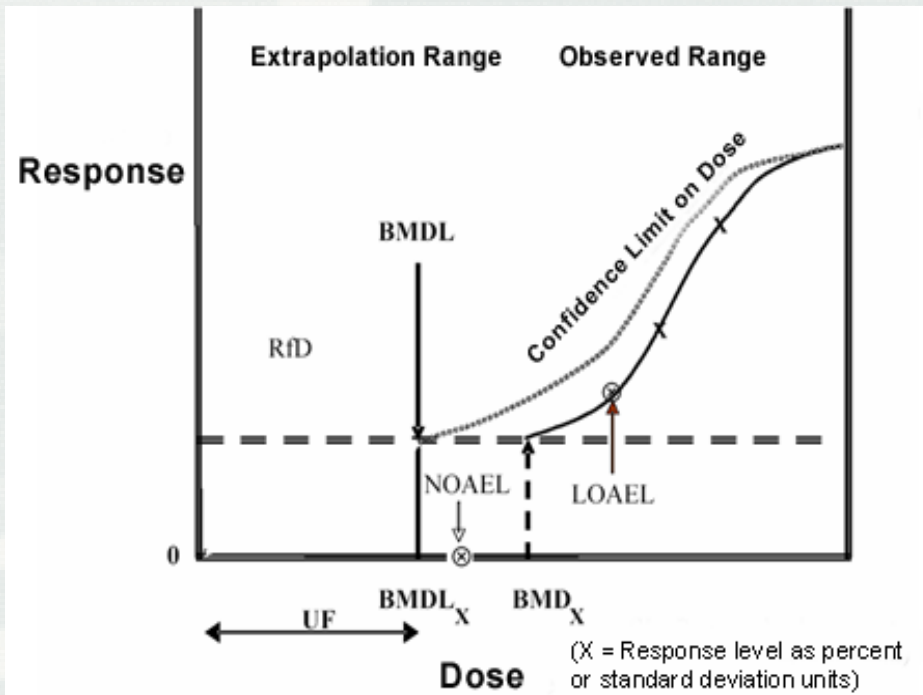
RfC mg/m<sup>3</sup>



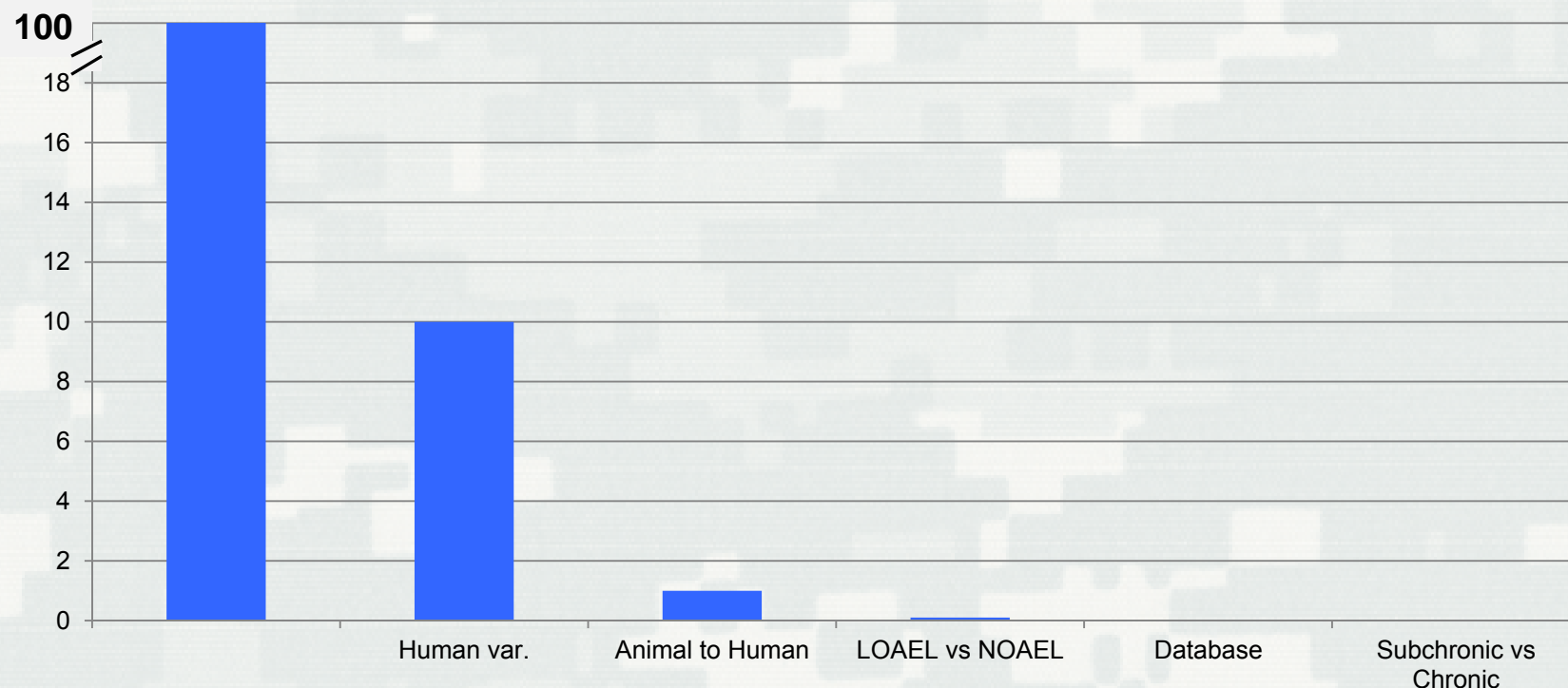
# OSF Development



# RfD Development



# Uncertainty in Toxicity Values: Multiplicative Application of Uncertainty Factors



If total of UFs exceed 3000, by policy the RfD is not published.  
Here 100 mg/kg-day adjusted to 0.03 mg/kg-day.

# IRIS Process for Deriving toxicity Values

- Study identification
  - ▶ Literature search
  - ▶ Evaluate quality of studies
- Weight of Evidence
  - ▶ Mode of action – relevance to humans



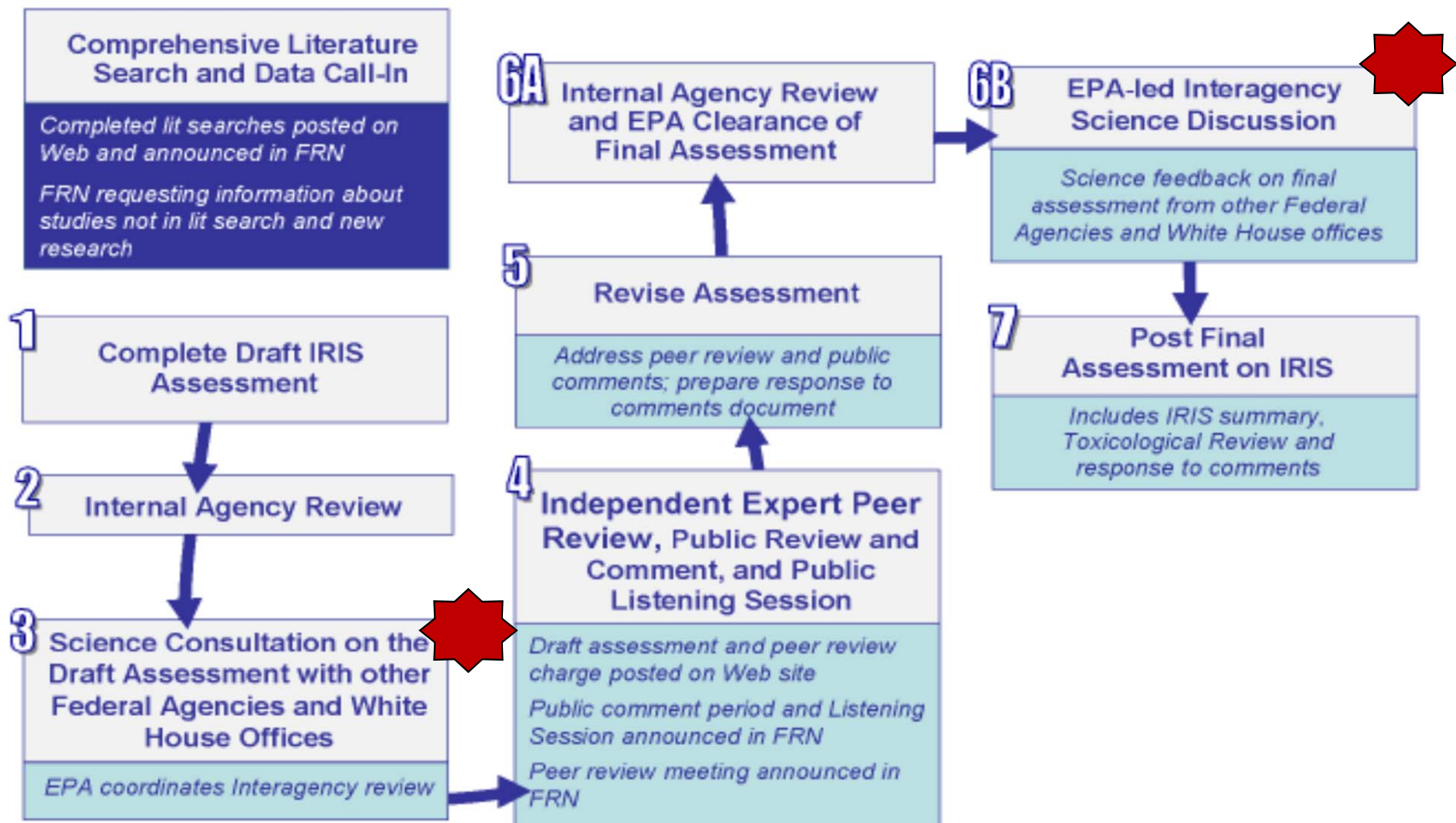
# IRIS Process for Deriving toxicity Values

- Dose – Response analysis
  - ▶ Model response in range of observation
    - Benchmark dose
  - ▶ Extrapolate to lower doses
    - Carcinogens
  - ▶ Consider sensitive populations and life stages
  - ▶ Apply uncertainty factors
    - Non-carcinogens



# IRIS Assessment Development Process

## Assessment Development Process for New IRIS



# Use of IRIS (and other) Toxicity Values

- Estimate risk associated with exposure to chemicals in environmental media at sites
- Used with estimates of exposure frequency and duration

Example:  $5 \times 10^{-5}$  excess cancer risk i.e. in addition to existing 1 in 2 or 3 cancer risk\*

Hazard Quotient of 2



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\* American Cancer Society *Cancer Facts & Figures 2011*

# Use of IRIS (and other) Toxicity Values

- Use with default exposure information to develop risk-based screening levels
- EPA harmonized regional PRGs and RBCs to the Regional Screening Levels
- **Screening levels are not cleanup levels!**

$$SL_{\text{res-sol-nc-ing}} \text{ (mg/kg)} = \frac{THQ \times AT_r \left( \frac{365 \text{ days}}{\text{year}} \times ED_c \text{ (6 years)} \right) \times BW_c \text{ (15 Kg)}}{EF_r \left( \frac{350 \text{ days}}{\text{year}} \right) \times ED_c \text{ (6 year)} \times \frac{1}{RfD_o \left( \frac{\text{mg}}{\text{Kg-day}} \right)} \times IRS_c \left( \frac{200 \text{ mg}}{\text{day}} \right) \times \frac{10^{-6} \text{ Kg}}{1 \text{ mg}}}$$



# Why Aren't Screening Levels Cleanup Levels?

- Conservative by design

- ▶ Default exposure values – not site specific
- ▶ Non-carcinogen RSLs use childhood exposure of 6 years: More dose per unit body weight
- ▶ All exposure pathways assumed to be complete
- ▶ Some RSLs utilize toxicity values that are only suitable for screening

Unsure of site-specific exposure scenarios and factors.



# Why Aren't Screening Levels Cleanup Levels or Limits?

- RSLs use  $1 \times 10^{-6}$  as the target risk; the acceptable risk range in the National Contingency Plan (NCP) is  $1 \times 10^{-4}$  -  $1 \times 10^{-6}$
- Site-specific PRGs derived at conclusion of the risk assessment and/or in the FS
- If an actionable risk is found i.e.  $> 1 \times 10^{-4}$ , analytical constraints are one factor provided by the NCP to adjust upward from  $1 \times 10^{-6}$



# IRIS Assessment of Oral Toxicity of Hexavalent Chromium

- External review complete
- EPA will wait until studies underway on carcinogenic mode of action are complete to finalize the assessment
- NJ and Cal values for hex chrome

<b>Risk-Based Screening Levels</b>		
	Resident Soil (mg/kg)	Resident Water Use (µg/L)
DRAFT		0.04
Final (Aug'10)	4.85	0.67
RSL Table (NJ OSF)	0.29	0.031



# Trichloroethylene Status: Final

- Lowest RSLs based on  $10^{-6}$  cancer risk
- 1.6 E-04 mg/kg groundwater leachability

Risk-Based Screening Levels			
	Res. Soil (mg/kg)	Res. Water Use ( $\mu\text{g/L}$ )	Indoor Air ( $\mu\text{g/m}^3$ )
Old	2.8	2	1.2
Current	0.91	0.44	0.43



# EPA's Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments

- Oral noncancer reference dose (RfD) finalized Feb. 2012; cancer values will follow
- Draft cancer slope factor uses NIOSH occupational cohort data

Risk-Based Screening Levels		
	Residential Soil Noncancer Effects	Residential Soil Cancer Effects (DRAFT)
	50 ppt	0.45 ppt
1998 OSWER Value	1000 ppt	



# Inhalation Assessment 1,4- Dioxane (Ext Review Draft)

- Oral SF and RfD finalized in 2010
- Noncancer reference concentration and inhalation unit risk

Risk-Based Screening Levels*			
	Resident Soil (mg/kg)	Resident Water Use (µg/L)	Air (µg/m <sup>3</sup> )
Final (Aug'10)	4.85	0.67	
Draft			0.49



\*Using EPA Regional Screening Level Calculator, basis  $10^{-6}$  risk goal; Current air RSL is  $0.32 \mu\text{g}/\text{m}^3$  using CalEPA tox values

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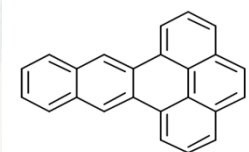
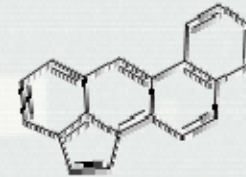
# Carcinogenic PAHs and Relative Potency Factors

	Current RPF	Draft RPF	$\Delta$
Benzo(a)pyrene	1	1	RSL 15 $\mu$ g/kg
Benz(a)anthracene	0.1	0.2	2x
Benzo(b)fluoranthene	0.1	0.8	8x
Benzo(k)Fluoranthene	0.01	0.03	3x
Chrysene	0.001	0.1	100x
Dibenz(a,h)anthracene	1	10	10x
Indeno(1,2,3-c,d)pyrene	0.1	0.07	



# Additional PAHs from 2010 RPF Assessment

- Anthanthrene
- Benzo[g,h,i]perylene
- Benzo[j]fluoranthene
- Cyclopenta[c,d]pyrene
- Dibenzo[a,e]fluoranthene
- Dibenzo[a,e]pyrene
- Dibenzo[a,h]pyrene
- Dibenzo[a,i]pyrene
- Dibenzo[a,l]pyrene
- Fluoranthene
- Benz[b,c]aceanthrylene
- Benz[e]aceanthrylene
- Benz[j]aceanthrylene (60x)
- Benz[l]aceanthrylene
- Cyclopenta[d,e,f]chrysene
- Naphtho[2,3-e]pyrene



# Vanadium Pentoxide Valence State May Matter.....

- IRIS reassessment undergoing external peer review
- Includes (new) cancer IUR which to some degree is dependent on solubility
- Current RSL table adjusts IRIS  $V_2O_5$  RfD for V compounds (RSL = 400 mg/kg)
- Use of IUR in similar way would lead to vanadium in soil RSL below natural occurring levels of 7 to 500 ppm

