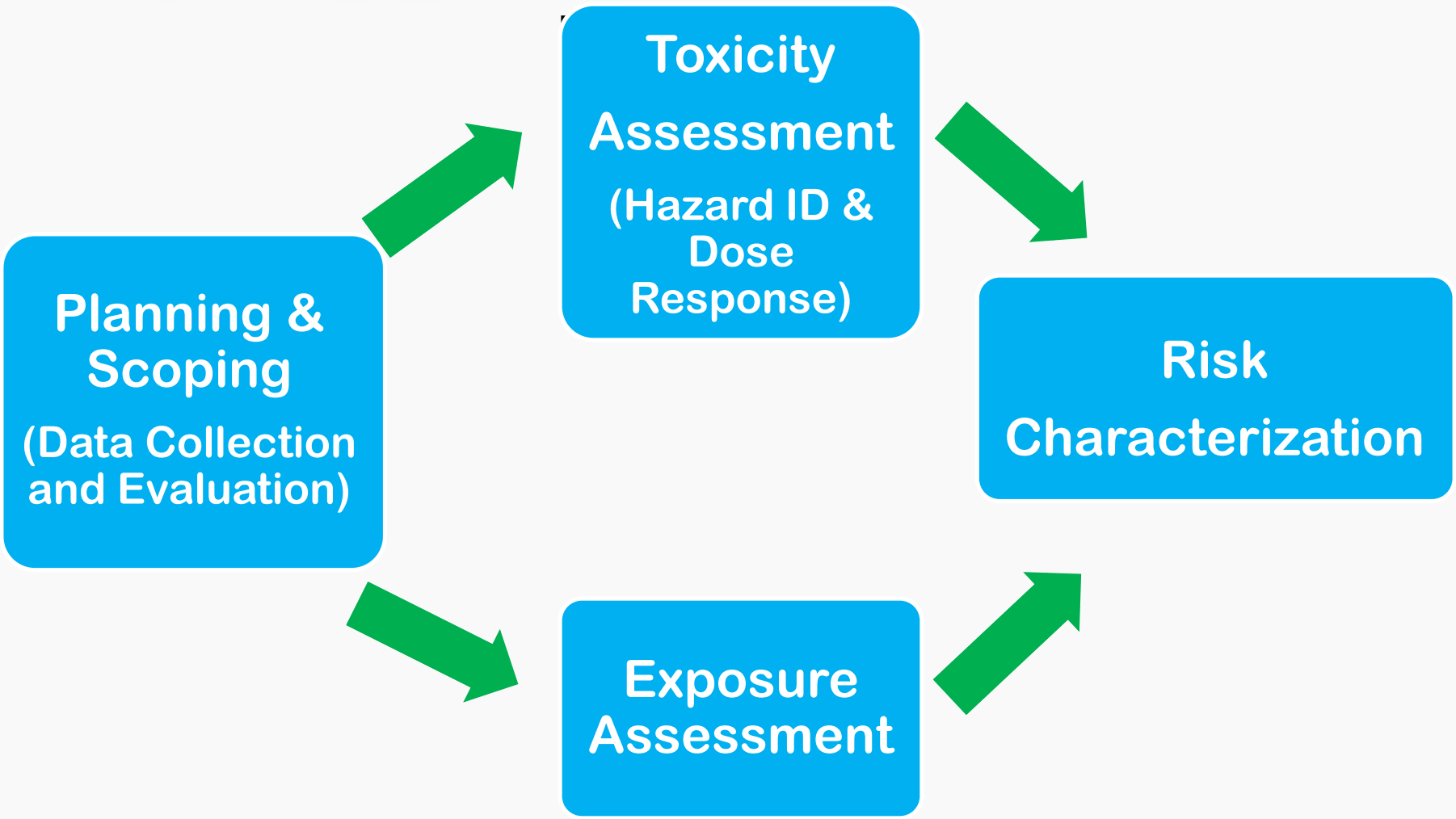
PFAS Risk Assessment Basics

U.S. Environmental Protection Agency

Superfund Human Health Risk Assessment:



http://www.epa.gov/oswer/riskassessment/risk_superfund.htm

Toxicity Assessment

Toxicity assessment is the investigation of how toxic a contaminant may be to human health (or the hazard identification and dose-response relationship)

Toxicity Assessment

Addresses the questions:

- *What kind of harm are you dealing with?*
- *What illness/health effect may occur?*
- *How much exposure causes harm?*

Toxicity Assessment

Two categories of toxic chemicals

Noncarcinogenic Chemicals

- Believed to act via a “threshold” mechanism of action. This means that there is a level of exposure (i.e., a threshold) below which it is unlikely to have an effect.

Carcinogenic Chemicals

- Believed to act via a “non-threshold” mechanism of action. There is a risk associated with any exposure level.

Exposure Assessment

Exposure Pathways

- Inhalation – air, soil, vapors
- Oral – water, soil, food
- Dermal – soil, water, food, air

Exposure Duration

- Acute
- Short-term
- Longer-term
- Chronic (continuous)

Potentially Exposed Population

- Workers
- Emergency responders or victims
- Pregnant women
- Children or the elderly

Exposure Assessment

Exposure

quantified as the amount of an agent available at the exchange boundaries of the organism (e.g., skin, lungs, gut)

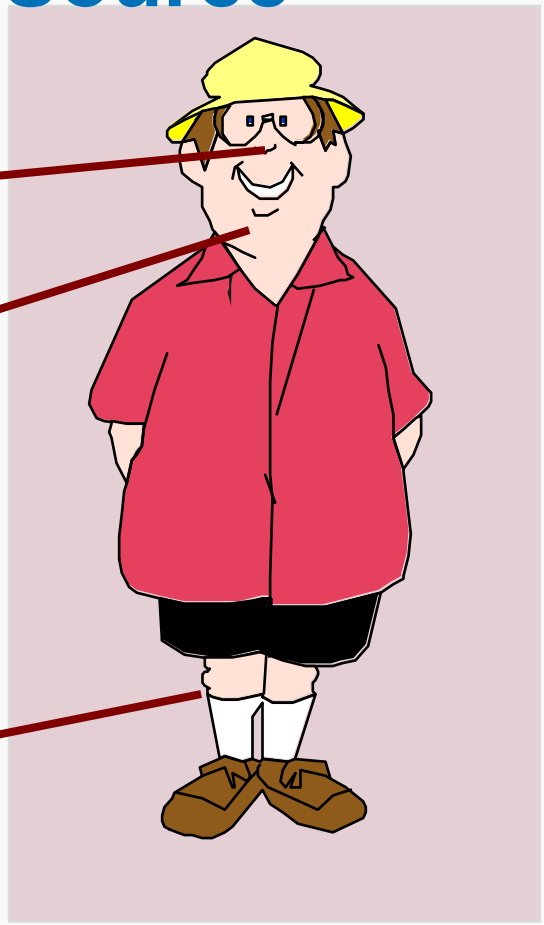
From EPA's IRIS Glossary

Addresses the questions:

- *Who is exposed? How?*
- *How much of the contaminants are they exposed to?*

Exposure Assessment

Pathways, Route, Media & Source



Exposure Assessment

Site-Specific Exposure Pathways

- Unique exposure pathways vs standard assumptions
- Current and future land use

Reasonable Maximum Exposure (RME)

- “High end” exposure values on sensitive parameters
- Protective of vulnerable groups in the community

Superfund Exposure

- Generally, default receptor is a child, more sensitive than an adult
- Default exposure assumptions:
  - Body mass 15 kg
  - Exposure duration 6 years
  - Exposure frequency 350 days/year
  - Ingests 200 mg/day soil
  - Drinks 0.78 l/day water

Risk Characterization

Risk characterization integrates the data from the previous three steps, evaluates the uncertainty in the data, and summarizes the overall health risk in a number or estimate. Different methods used for cancer vs non-cancer effects.

Addresses the questions:

- *Which exposure pathways are creating the risk?*
- *Which contaminants are causing the health risk?*

Superfund Risk Calculation

- Cancer calculated using target risk value
  - Between 10^{-6} and 10^{-4} considered acceptable depending on situation
- Non-cancer risk calculated using a hazard index
  - HI>1 indicates potential risk
- Risk calculated based on spill or release

Superfund Risk Calculation

- Risk calculated for all contaminants present and for all media they are present in that is related to spill or release
- Typically look at tap water, soil, air, surface water, etc. near site

Cancer Risk

- Total cancer risk is sum of individual chemical cancer risks
- $CR = \sum_{i=1}^{n} CR_i$
- For example, with PFAS, it would be:
  - $CR_{total} = CR_{PFOA} + CR_{PFOS}$

Hazard Index

- Hazard Quotient = Exposure/Reference Dose
- $HQ = \frac{E}{RfD}$
- Hazard Index is sum of hazard quotients
- $HI = \sum_{i=1}^{n} HQ_i = \sum_{i=1}^{n} \frac{E_i}{RfD_i}$

Hazard Index

- $HI_{PFAS} = HQ_{PFODA} + HQ_{PFTetDA} + HQ_{PFDoDA} + HQ_{PFUDA} + HQ_{PFDA} + HQ_{PFNA} + HQ_{PFOA} + HQ_{PFHxA} + HQ_{PFBA} + HQ_{PFPrA} + HQ_{PFOS} + HQ_{PFHxS} + HQ_{PFBS} + HQ_{HFPO\text{-}DA} + HQ_{BisPFMSA}$
- Other contaminants may be at a site that would also be added to the HI

CERCLA HQ

- Tap water screening level based on
  - Ingestion of tap water
  - Inhalation of tap water
  - Dermal contact with tap water
- PFAS
  - None have inhalation component because no inhalation toxicity values currently
  - Many have dermal component; dermal almost insignificant compared to ingestion

Tap Water SL

$$SL_{res\text{-}wat\text{-}totnc}\left(\frac{\mu g}{L}\right) = \frac{1}{\frac{1}{SL_{res\text{-}wat\text{-}ingnc}} + \frac{1}{SL_{res\text{-}wat\text{-}inhnc}} + \frac{1}{SL_{res\text{-}wat\text{-}dernc}}}$$

Tap Water SL ingestion

$$SL_{res\text{-}wat\text{-}ingnc}\left(\frac{\mu g}{L}\right) = \frac{THQ \times AT_{res\text{-}c}\left(\frac{365\ days}{yr}\right) \times ED_{res\text{-}c}(6\ yr) \times BW_{res\text{-}c}(15\ kg)}{\left(\frac{1}{RfD_o\left(\frac{mg}{kg-day}\right)}\right) \times \left(\frac{mg}{1000\ \mu g}\right) \times EF_{res\text{-}c}\left(\frac{350\ days}{yr}\right) \times ED_{res\text{-}c}(6\ yr) \times IRW_{res\text{-}c}\left(\frac{0.78\ L}{day}\right)}$$

Tap Water SL dermal

For Inorganics:

$$SL_{res\text{-}wat\text{-}dernc}\left(\frac{\mu g}{L}\right) = \frac{DA_{event}\left(\frac{\mu g}{cm^2\text{-}event}\right) \times \left(\frac{1000\ cm^3}{L}\right)}{K_p\left(\frac{cm}{hr}\right) \times ET_{event\text{-}res\text{-}c}\left(\frac{0.54\ hrs}{event}\right)}$$

For Organics:

IF $ET_{event\text{-}res\text{-}c}\left(\frac{0.54\ hrs}{event}\right) \leq t^*\ (hrs)$, then:

$$SL_{res\text{-}wat\text{-}dernc}\left(\frac{\mu g}{L}\right) = \frac{DA_{event}\left(\frac{\mu g}{cm^2\text{-}event}\right) \times \left(\frac{1000\ cm^3}{L}\right)}{2 \times FA \times K_p\left(\frac{cm}{hr}\right) \times \sqrt{\frac{6 \times \tau_{event}\left(\frac{hrs}{event}\right) \times ET_{event\text{-}res\text{-}c}\left(\frac{0.54\ hrs}{event}\right)}{\pi}}}$$

or:

IF $ET_{event\text{-}res\text{-}c}\left(\frac{0.54\ hrs}{event}\right) > t^*\ (hrs)$, then:

$$SL_{res\text{-}wat\text{-}dernc}\left(\frac{\mu g}{L}\right) = \frac{DA_{event}\left(\frac{\mu g}{cm^2\text{-}event}\right) \times \left(\frac{1000\ cm^3}{L}\right)}{FA \times K_p\left(\frac{cm}{hr}\right) \times \left[\frac{ET_{event\text{-}res\text{-}c}\left(\frac{0.54\ hrs}{event}\right)}{1\ +\ B} + 2 \times \tau_{event}\left(\frac{hrs}{event}\right) \times \left(\frac{1\ +\ 3B\ +\ 3B^2}{(1\ +\ B)^2}\right)\right]}$$

where:

$$DA_{event}\left(\frac{\mu g}{cm^2\text{-}event}\right) = \frac{THQ \times AT_{res\text{-}c}\left(\frac{365\ days}{yr}\right) \times ED_{res\text{-}c}(6\ yr) \times BW_{res\text{-}c}(15\ kg)}{\left(\frac{1}{RfD_o\left(\frac{mg}{kg\text{-}day}\right) \times GIABS}\right) \times \left(\frac{mg}{1000\ \mu g}\right) \times EF_{res\text{-}c}\left(\frac{350\ days}{yr}\right) \times ED_{res\text{-}c}(6\ yr) \times EV_{res\text{-}c}\left(\frac{1\ event}{day}\right) \times SA_{res\text{-}c}\left(6{,}365\ cm^2\right)}$$

CERCLA Risk calculations

- Similar concept for cancer
- Similar concept for other media like soil
- Always consider which exposure pathways are appropriate for media
  - Ex. Ingestion of soil, inhalation of volatiles in soil, dermal contact with soil

PFAS RSLs and MCLs

PFAS	RfD (mg/kg day)	SFO (mg/kg/day)-1	RSL HQ=0.1 (ng/l, ppt)	RSL HQ=1 (ng/l, ppt)	MCL (ng/l,ppt)
PFODA	4.00E-02		8.00E+04	8.00E+05	
PFTetDA	1.00E-03		2.00E+03	2.00E+04	
PFDoDA	5.00E-05		1.00E+02	1.00E+03	
PFUDA	3.00E-04		6.00E+02	6.00E+03	
PFNA	3.0E-06		5.90E+00	5.90E+01	1.00E+01
PFOA	3.00E-08	2.93E+04	2.65E-03	2.65E-03	4.00E+00
PFHxA	5.00E-04		9.90E+02	9.90E+03	
PFBA	1.00E-03		1.80E+03	1.80E+04	
PFPrA	5.00E-04		9.80E+02	9.80E+03	
PFOS	1.00E-07	3.95E+01	2.01E-01	1.97E+00	4.00E+00
PFHxS	2.0E-05		3.90E+01	3.90E+02	1.00E+01
PFBS	3.0E-04		6.00E+02	6.00E+03	
HFPO-DA	3.0E-06		1.50E+00	1.50E+01	1.00E+01
BisPFMSA	3.00E-04		5.90E+02	5.90E+03	

*PFDA will be added in fall update with finalized IRIS assessment

Hazard Index

- PFAS HI MCL for OW
- Overall concept does not differ between program offices
- SDWA HI based on SDWA regulations
- CERCLA HI based on CERCLA regulations and guidance

SDWA Hazard Index

- 4 PFAS – PFNA, PFHxS, PFBS, HFPO-DA
- Accounts for other exposure using RSC = 0.2
- Receptor (DWI/BW) varies
  - PFHxS – general population adult
  - PFNA and HFPO-DA – lactating woman
  - PFBS – woman of childbearing age
- Regulatory, so can only change with reg update

CERCLA Hazard Index

- All PFAS found at site plus other contaminants
- Only looks at exposure related to spill or release (RSC=1)
- Typically use a child receptor (BW, DWI)
- Updates with new toxicity information
  - Adds contaminant
  - Update toxicity of existing contaminant

CERCLA HI

- Risk Assessment Guidance for Superfund (RAGS) equation has been adjusted to allow for easier comparison to SDWA equation
- Ignores non-PFAS contaminants that may be present that would also be used in calculation

CERCLA HI for PFAS

- $$HI = \frac{E_{PFODA}}{SL_{PFODA}} + \frac{E_{PFTetDA}}{SL_{PFTetDA}} + \frac{E_{PFDoDA}}{SL_{PFDoDA}} + \frac{E_{PFUDA}}{SL_{PFUDA}} + \frac{E_{PFDA}}{SL_{PFDA}} + \frac{E_{PFNA}}{SL_{PFNA}} + \frac{E_{PFOA}}{SL_{PFOA}} + \frac{E_{PFHxA}}{SL_{PFHxA}} + \frac{E_{PFBA}}{SL_{PFBA}} + \frac{E_{PFPrA}}{SL_{PFPrA}} + \frac{E_{PFOS}}{SL_{PFOS}} + \frac{E_{PFHxS}}{SL_{PFHxS}} + \frac{E_{PFBS}}{SL_{PFBS}} + \frac{E_{HFPO-DA}}{SL_{HFPO-DA}} + \frac{E_{BisPFMSA}}{SL_{BisPFMSA}}$$

CERCLA Toxicity and Exposure Factors

PFAS	RfD (mg/kg/d)	DWI-BW (L/kg/d)**	RSC
PFODA	4E-2	0.050	1
PFTetDA	1E-3	0.050	1
PFDoDA	5E-5	0.050	1
PFUDA	3E-4	0.050	1
PFDA	2E-9	0.050	1
PFNA	3E-6	0.050	1
PFOA	3E-8*	0.050	1
PFHxA	5E-4	0.050	1
PFBA	1E-3	0.050	1
PFOS	1E-7*	0.050	1
PFHxS	2E-5	0.050	1
PFBS	3E-4	0.050	1
HFPO-DA	3E-6	0.050	1
BisPFMSA	3E-4	0.050	1

**DWI-BW includes ED ratio of (350 days/365 days), which is based on residents going on vacation

SDWA HI

- $$HI = \frac{E_{HFPO-DA}}{HBWC_{HFPO-DA}} + \frac{E_{PFBS}}{HBWC_{PFBS}} + \frac{E_{PFHxS}}{HBWC_{PFHxS}} + \frac{E_{PFNA}}{HBWC_{PFNA}}$$

- $$HBWC = \frac{RfD}{DWI * BW} * RSC$$

SDWA Toxicity and Exposure Factors

PFAS	RfD (mg/kg/d)	DWI-BW (L/kg/d)	RSC	HBWC (ng/l)
HFPO-DA	3E-6	0.0469	0.2	10
PFBS	3E-4	0.0354	0.2	2000
PFHxS	2E-6*	0.034	0.2	10
PFNA	3E-6	0.0469	0.2	10

*OW applied a UF_S=10 to ATSDR's MRL; OLEM does not

State Toxicity/Risk Levels

- 30 states have derived water levels (risk, screening, cleanup, MCL, etc.) for a total of 25 different PFAS
- Many states only using EPA levels
- 14 different PFAS have originally derived state toxicity values
- 9 PFAS have a state derived toxicity equivalent factor or similar
- ITRC has good summary of information
  - https://pfas-1.itrcweb.org/

*Information compiled before release of final EPA MCLs

QUESTIONS?