

**TECH** Talk



# Welcome to the Superfund Process and Risk Assessment Workshop

**GEC**  
Glynn Environmental Coalition

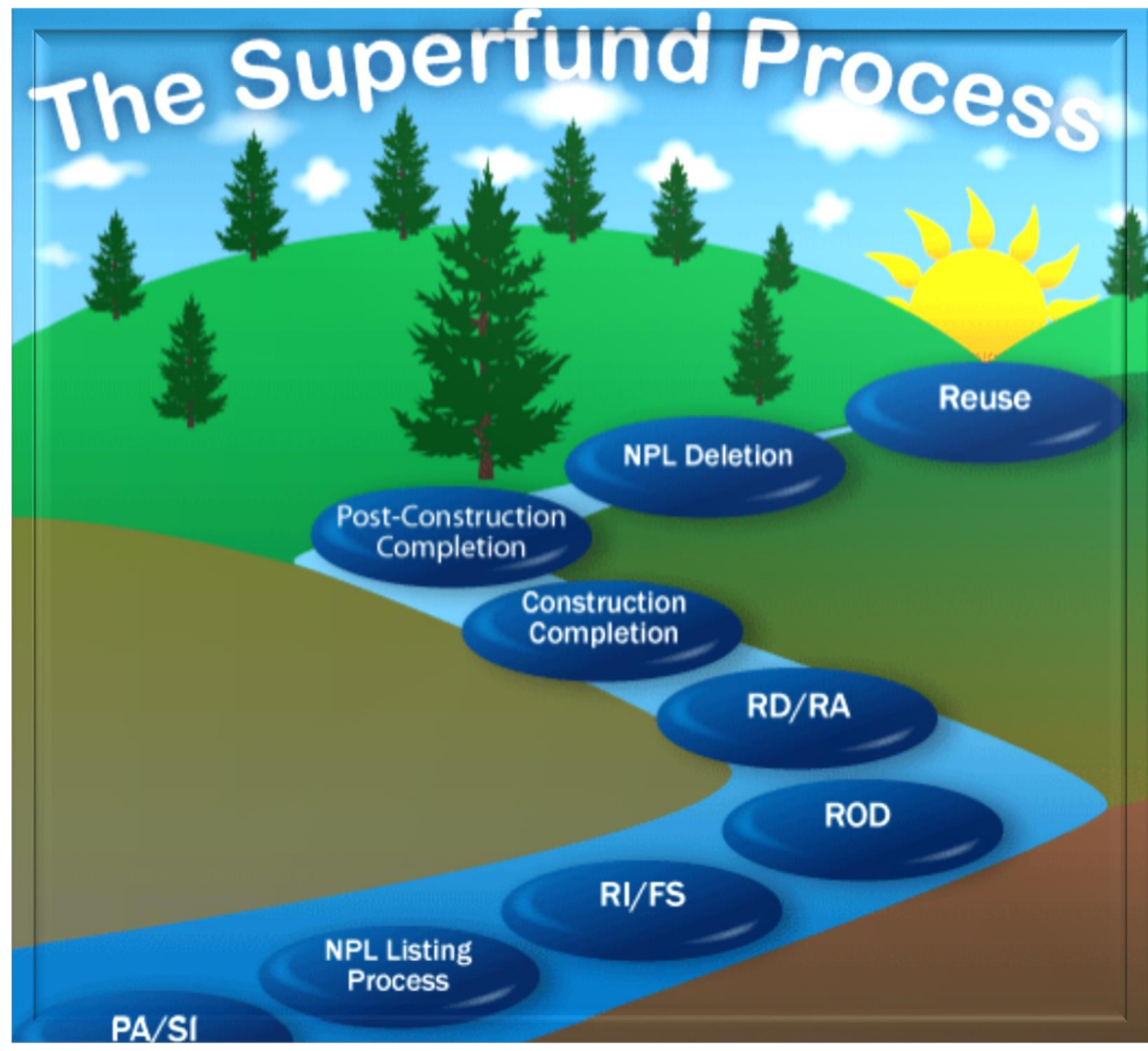
**SATURDAY, JUNE 22, 2019**

# Agenda

- Welcome – Rachael Thompson, GEC
- Introductions
- Superfund Process – Angela Miller, EPA
- Human Health Risk Assessment @ EPA: Community Basics – Tim Frederick, EPA
- GEC Fact Sheet – Frank Anastasi, Technical Advisor for GEC
- Questions/Answers
- Adjourn

# SUPERFUND PROCESS

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# HUMAN HEALTH RISK ASSESSMENT @ EPA: COMMUNITY BASICS

## EPA REGION 4

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Tim Frederick, MPH

**TECH** Talk



# WHAT IS A RISK ASSESSMENT?

## Process

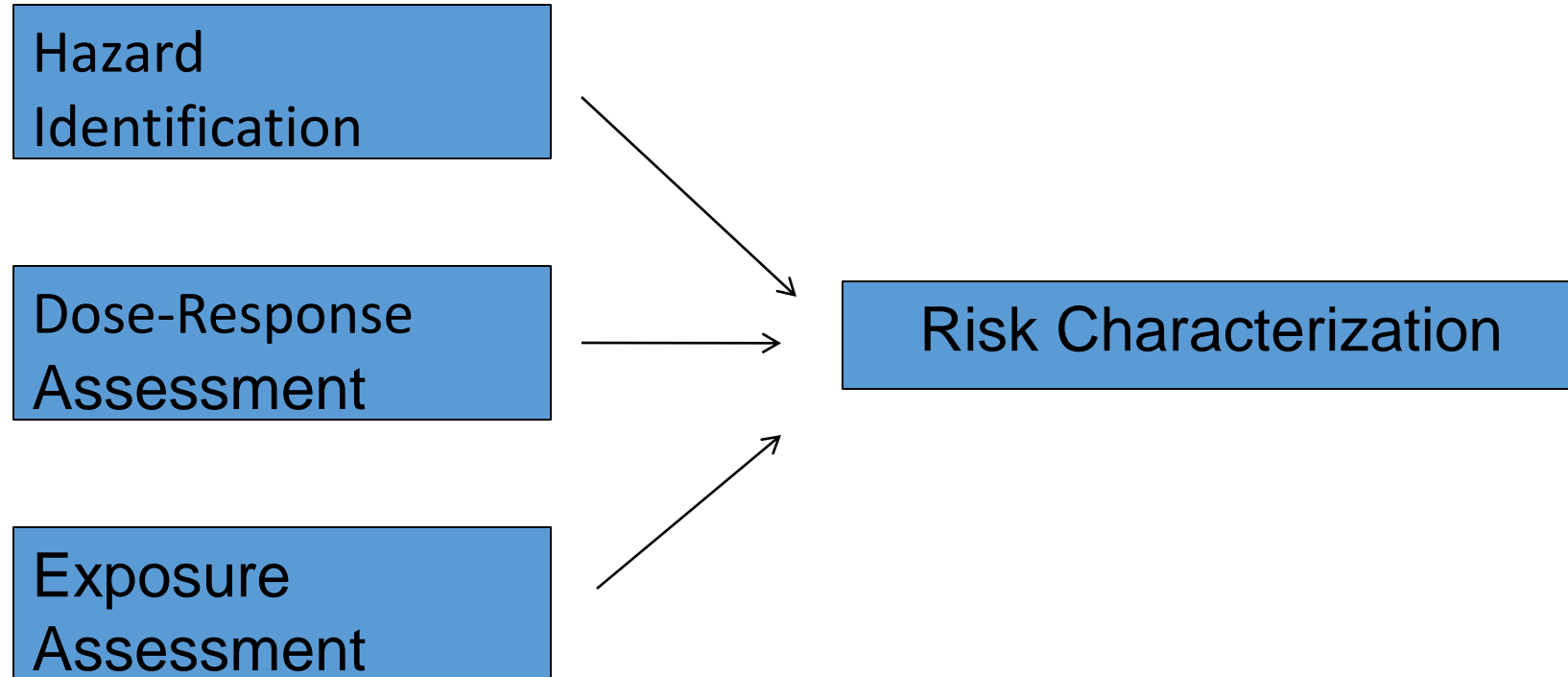
Analysis of the risks caused by hazardous substances released from a site

Informs development, evaluation, and selection of appropriate response alternatives

Site-specific and will vary in detail and scope

Separate risk assessments are conducted to evaluate human health risks and ecological risks

# Human Health Risk Assessment Process



# Hazard

A potential source of harm. Hazard identification determines whether a chemical has the potential to cause harm to humans and/or ecological systems, and if so, under what circumstances



4-2 Toxaphene - D D T  
Emulsifiable Concentrate

Each gallon contains 1 pound of 12 naphthene and 2 pounds of DDT.  
For use: dilute with 100 parts of water for most cotton insects.

ACTIVE INGREDIENT

Toxaphene	40.0%
Dichloro-diphenyl dimethyl silorane (DDT)	20.0%
Petroleum Hydrocarbons	35.0%
<b>INERT INGREDIENTS</b>	
*Technical Chlorinated Camphene	5.0%

**INERT INGREDIENTS**

Technical Chlorinated Camphene  
(Chlorine content 67% to 68%)

WARNING: KEEP OUT OF REACH OF CHILDREN. 100.0

**DIRECTION FOR USE**

...DIRECTED

... Right Hand and Cotton Headings  
... of water in ...  
... applications ...

Use the yellow plastic in its most to the right of the red plastic.

PLANTY INSEKTA  
The world of Unhappy  
at 12 Thompson Street  
NEW YORK

KIRBY'S Canada Veldman Campbell  
and do not apply law there

NOTE: Do not apply when...

to fish and wildlife. Many

TRIA

TRIANGLE C

form, Thrips, Leafworm, Green Stink Bug, Tarnished  
plumage, spray equipment.

Apply only when plants are dry at 5 to 7 day

TRIANGLE 4 lb. Methyl Parathion per

For a first noted. Repeat as needed.

more than two applications after pods form. Do not treat plants to podling stage.

... plants to poultry, dairy animals or  
... dust from crop areas treated.

Do not get in eyes or on skin or in clothing. Wear  
clean clothing daily. Wash the body.

...not feed treated foliage  
...nor apply where there may  
...be ponds and streams. Do not

ANTY

...transferred or modified, extends to the use of this  
...in any order, labels, insertions, or under abnormal  
...the buyer assumes the risk.

**PHARMACEUTICAL COMPANY**

GEORGIA COMPANY

Geol. Soc.  
No. 1842-110

# Hazard Identification



# Chemical Source: The Beginning

How is the  
contaminant  
released?

- Duration of release
- Quantity released
- Characteristics of source
- Area of contamination

Where is the  
contaminant  
discharged?

- Soil or sediment
- Surface water
- Ground water
- Biota
- Air

# Data: Soil Sampling (LCP)

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# DATA: GROUNDWATER SAMPLING





# SEDIMENT SAMPLING

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# SURFACE WATER SAMPLING



# Fish Sampling

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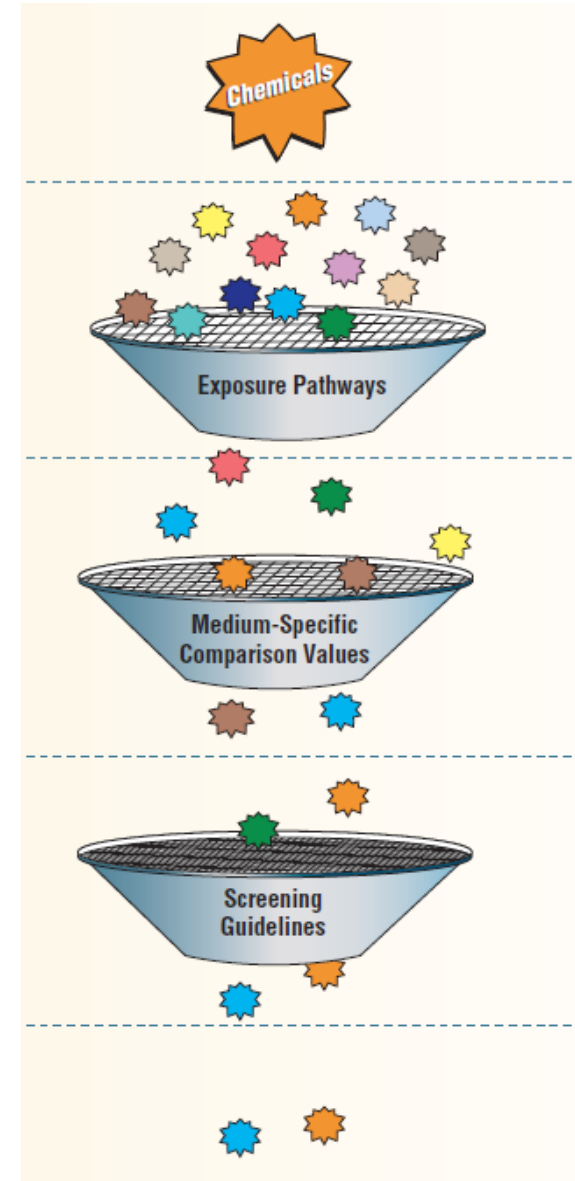


# DATA EVALUATION

Evaluate	Evaluate data quality and completeness
Compare	Compare to background where applicable
Compare	Compare to risk-based screening criteria (RSLs)
Identify	Identify Contaminants of Potential Concern

# Screening Data

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# Risk-Based Screening Levels

Calculated using:

- the latest toxicity values,
- default exposure assumptions,
- and chemical-specific physical and chemical properties
- For specific risk targets

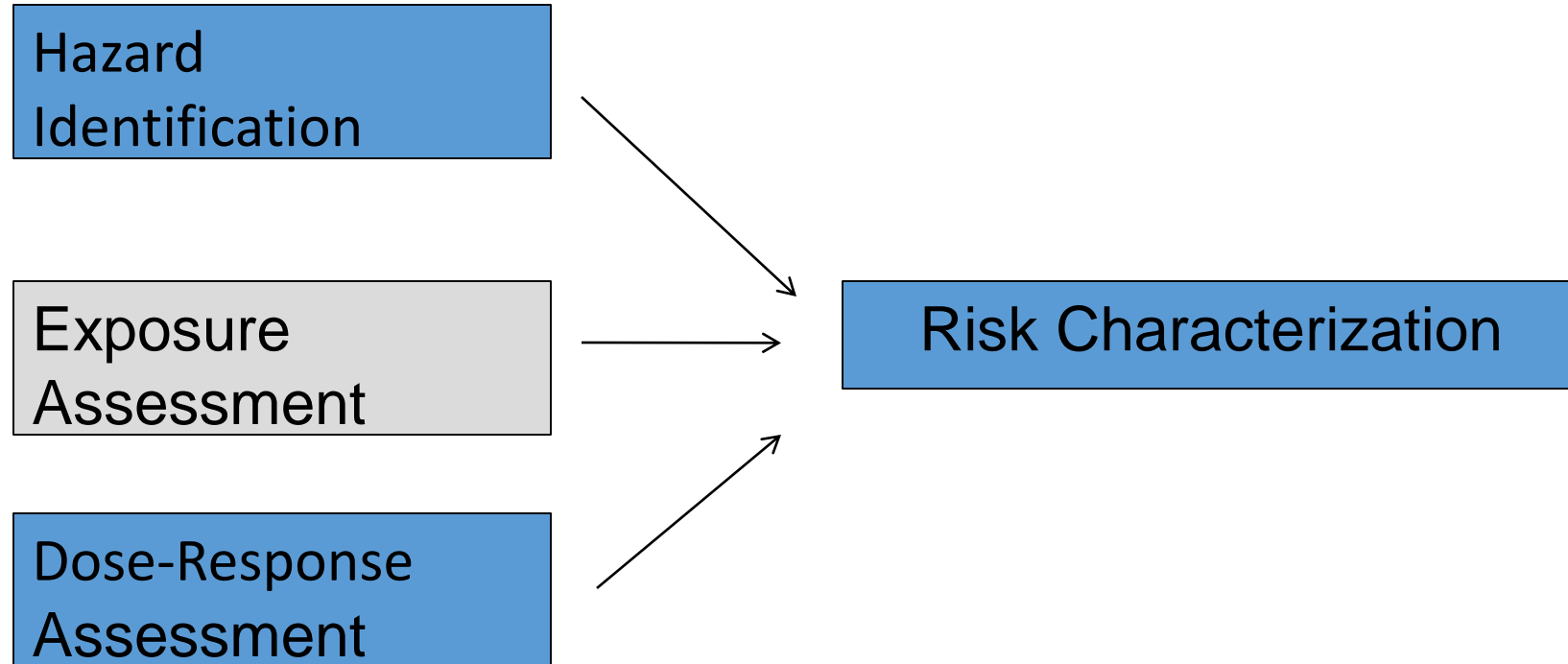
For more information: <https://www.epa.gov/risk/regional-screening-levels-rsls>

# Example: Toxaphene Screening Levels

Contaminant		Screening Levels										
Analyte	CAS No.	Resident Soil (mg/kg)	key	Industrial Soil (mg/kg)	key	Resident Air (ug/m³)	key	Industrial Air (ug/m³)	key	Tapwater (ug/L)	key	MCL (ug/L)
Toxaphene	8001-35-2	4.9E-01	c*	2.1E+00	c*	8.8E-03	c	3.8E-02	c	7.1E-02	c*	3
Toxaphene, Weathered	E1841606	1.9E+00	n	2.5E+01	n					6.0E-01	n	
Tralomethrin	66841-25-6	4.7E+02	n	6.2E+03	n					1.5E+02	n	
Tri-n-butyltin	688-73-3	2.3E+01	n	3.5E+02	n					3.7E+00	n	
Triacetin	102-76-1	5.1E+06	nm	6.6E+07	nm					1.6E+06	n	
Triadimefon	43121-43-3	2.1E+03	n	2.8E+04	n					6.3E+02	n	
Triallate	2303-17-5	9.7E+00	c	4.6E+01	c					4.7E-01	c	



# Exposure Assessment



# What is exposure?

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Exposure is contact between a chemical, biological, or physical agent and the outer boundary of an person or organism



## Routes of Exposure

- Inhalation
- Ingestion
- Contact with skin
- Ionizing radiation



## Importance of Exposure

- Exposure is a critical element of risk
- **Hazard × Exposure = Risk**
- A hazardous chemical release does not *necessarily* mean a high-risk situation

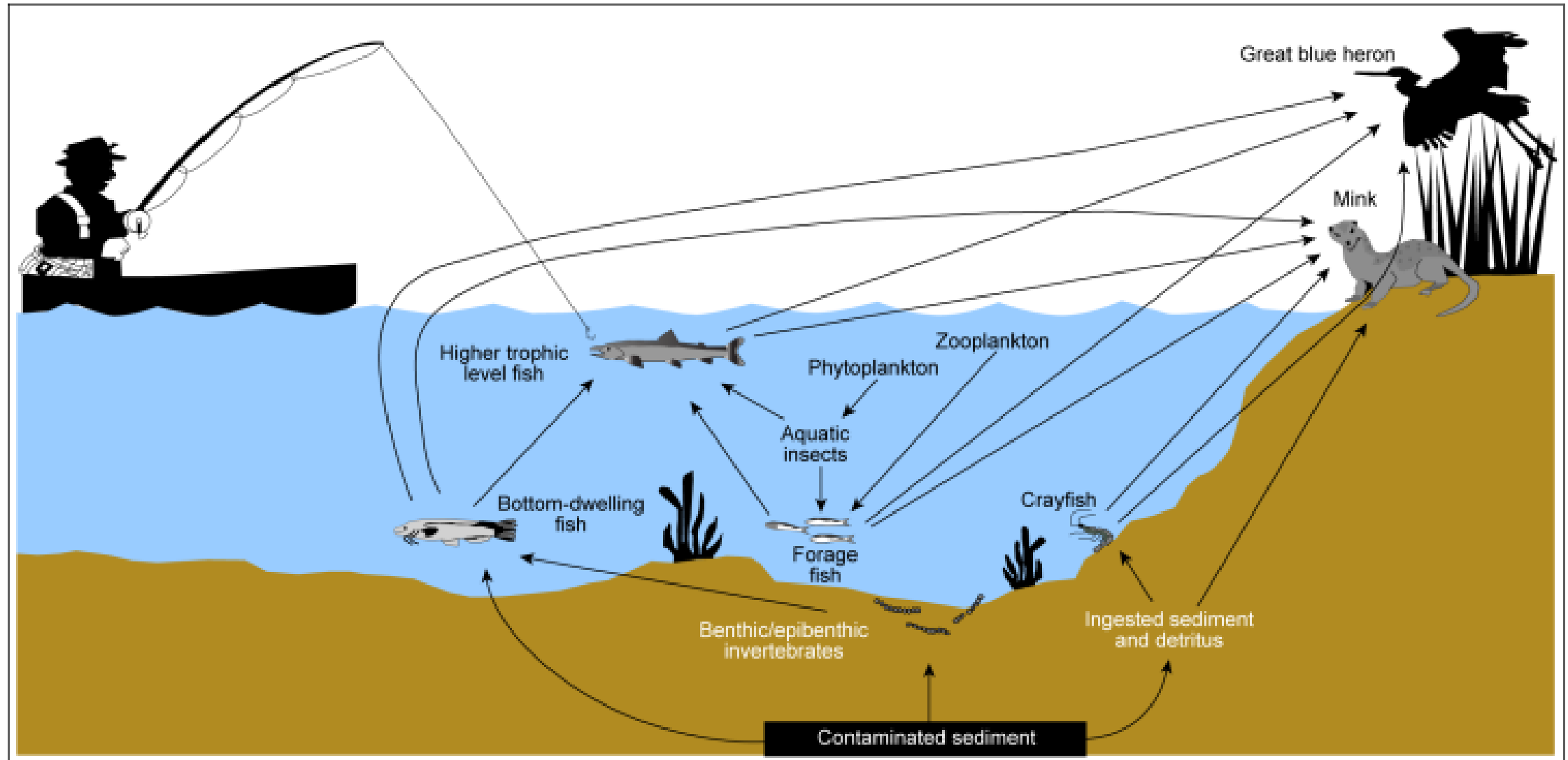
# Conceptual Model

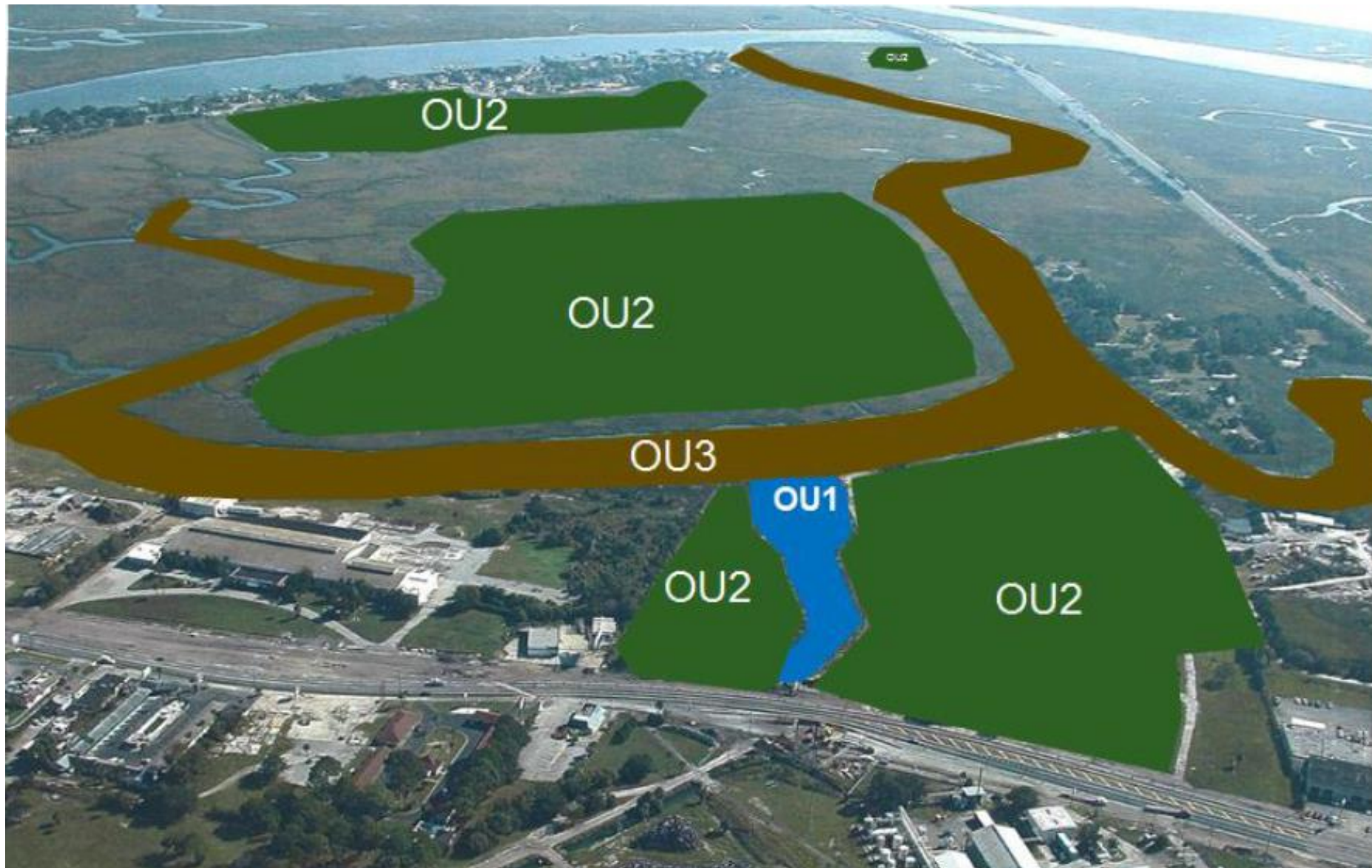
A conceptual model of exposure identifies:

- (1) the source of contamination
- (2) release/transport mechanisms,
- (3) exposure media,
- (4) exposure routes,
- (5) and potentially exposed (current and future) populations.



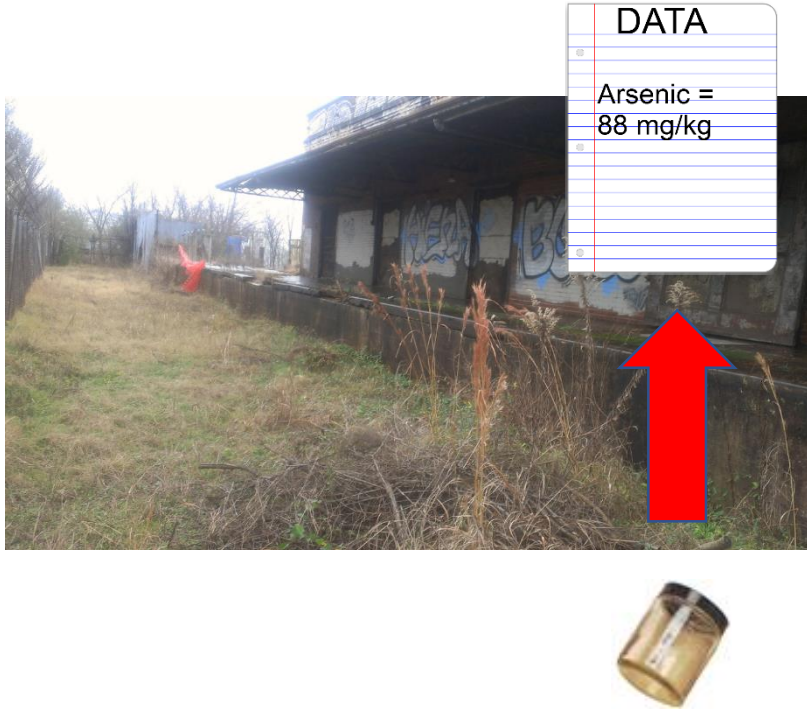
**Figure 1: Potential Sources of Exposure to Humans and the Environment at a Superfund Sediment Site**





# Concentration vs Dose

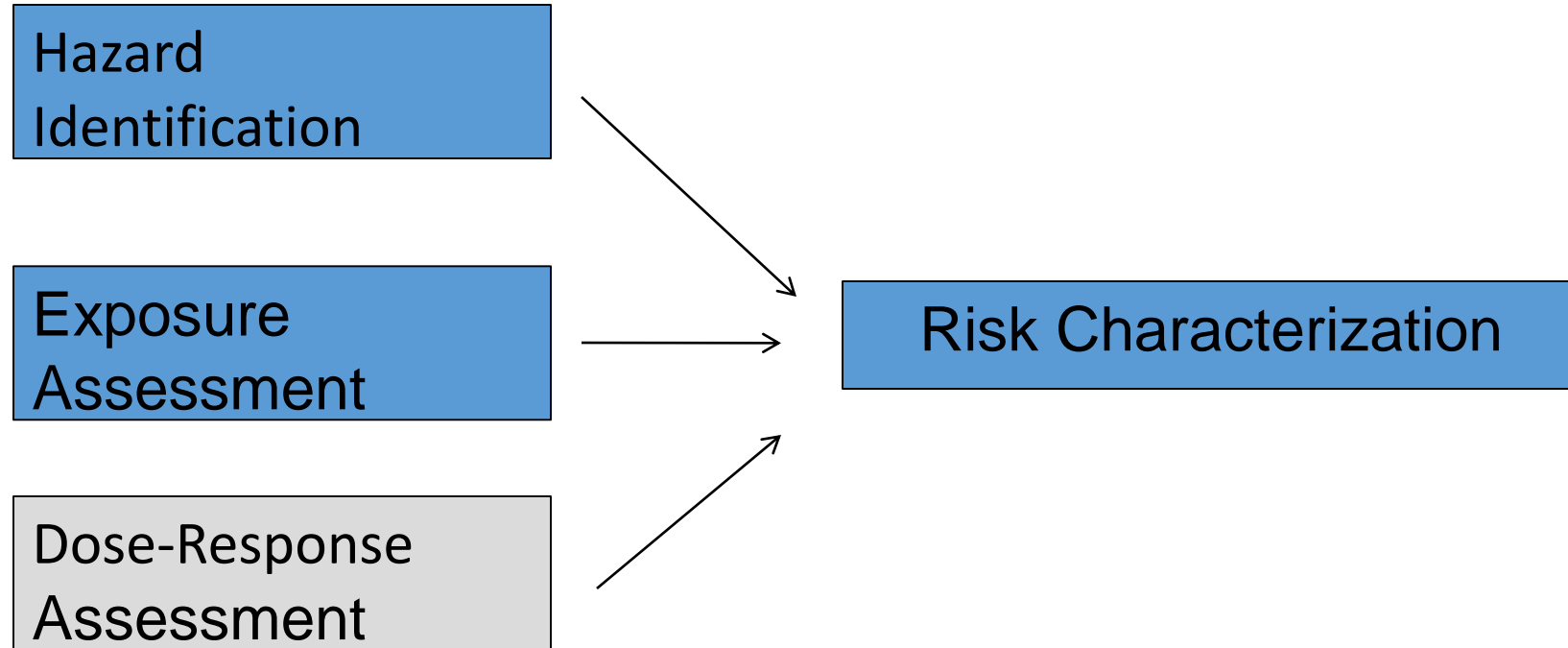
## Concentration



## Dose

The amount of the chemical in the environment that enters the body

# Dose-Response (Toxicity) Assessment



# Gather Toxicity Information

## Review

Review Contaminants of Potential Concern

## Review

Review Conceptual Site Model

## Identify

Identify Useful Sources of Toxicity Data



# Toxicity Data Selection Hierarchy

## **Tier 1- EPA's IRIS**

**Tier 2- EPA's Provisional Peer Reviewed Toxicity Values (PPRTVs)** – The Office of Research and Development/National Center for Environmental Assessment/Superfund Health Risk Technical Support Center (STSC) develops PPRTVs on a chemical specific basis when requested by EPA's Superfund program.

**Tier 3- Other Toxicity Values** – Tier 3 includes additional EPA and non-EPA sources of toxicity information. Priority should be given to those sources of information that are the most current, the basis for which is transparent and publicly available, and which have been peer reviewed.

<https://www.epa.gov/risk/human-health-toxicity-values-superfund-risk-assessments>

# Health Effects

- Contaminant can cause cancer (carcinogens)
- Contaminant can cause a health effect other than cancer (non-cancer)
- Contaminant can cause cancer and noncancer health effects

# Reference Dose (noncancer)

- A reference dose is a daily oral exposure that is likely to be without an appreciable risk of health effects
- Identify a threshold from toxicity studies at which measurable health effects begin to occur
- Identify Uncertainties and account for them with uncertainty factors

Threshold ÷ Uncertainty Factors = reference dose

# TOXICITY UNCERTAINTY

Extrapolating from high doses in experiments to lower levels expected from human exposure with chemicals in the environment

Extrapolating from short term studies to long-term exposures (or vice-versa)

Extrapolating from animal studies to predict health effects in humans

Extrapolating from genetically non-diverse animal populations to diverse human populations



## Examples (Reference Doses for Toxaphene)

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$$\begin{aligned}\text{Chronic p-RfD} &= \text{BMDL}_{10} (\text{HED}) \div \text{UF}_c \\ \text{for Technical Toxaphene} &= 0.0092 \text{ mg/kg-day} \div 100 \\ &= 9 \times 10^{-5} \text{ mg/kg-day}\end{aligned}$$

$$\begin{aligned}\text{Screening Subchronic p-RfD} &= \text{BMDL}_{10} (\text{HED}) \div \text{UF}_c \\ \text{for Weathered Toxaphene} &= 0.0092 \text{ mg/kg-day} \div 300 \\ \text{based on Technical Toxaphene} &= 3 \times 10^{-5} \text{ mg/kg-day}\end{aligned}$$

# Cancer toxicity value example

## IRIS (toxaphene)

### Cancer Assessment

[Weight of Evidence for Cancer \(PDF\)](#) (9 pp, 97 K)

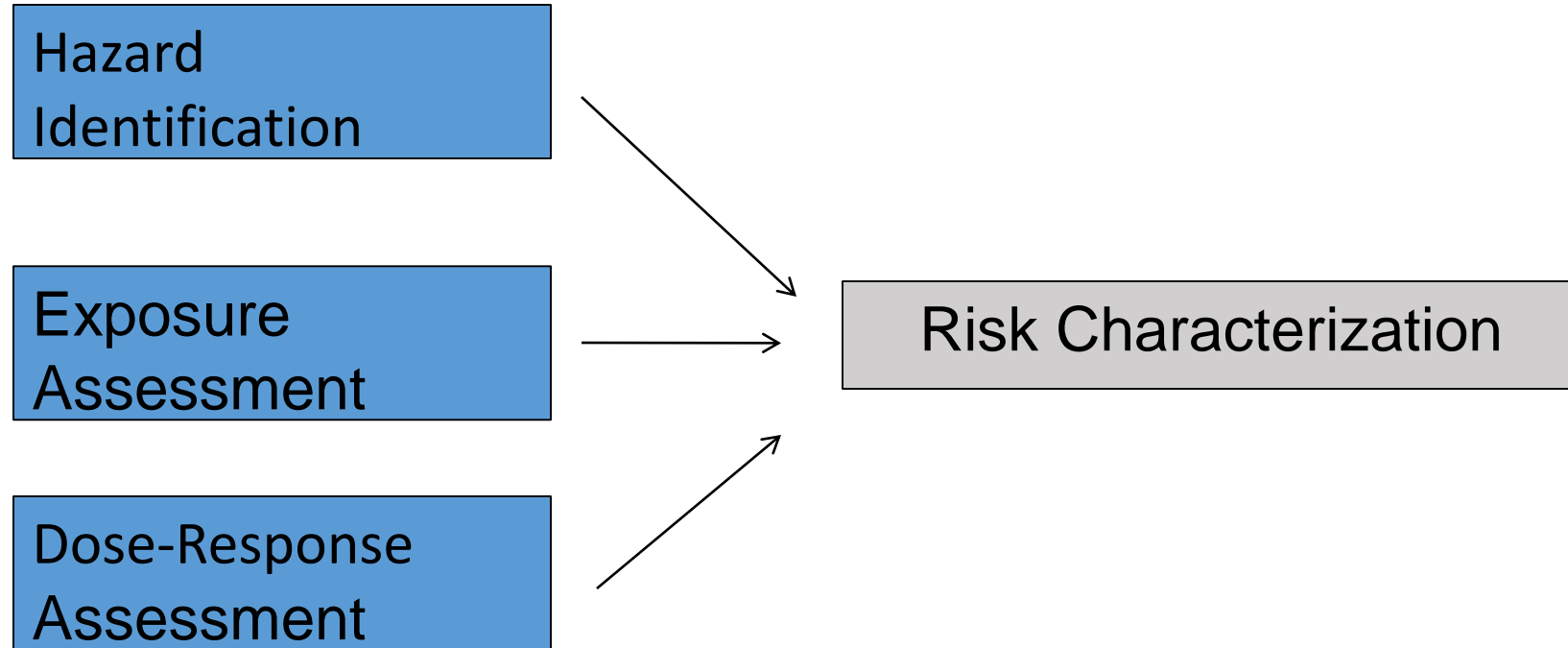
last updated: 08/22/1988

WOE Characterization	Framework for WOE Characterization
B2 (Probable human carcinogen - based on sufficient evidence of carcinogenicity in animals)	Guidelines for Carcinogen Risk Assessment (U.S. EPA, 1986)

#### Basis:

- The classification is based on increased incidence of hepatocellular tumors in mice and thyroid tumors in rats and is supported by mutagenicity in Salmonella.
  - This may be a synopsis of the full weight-of-evidence narrative.
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# Risk Characterization



# Putting it all together

Quantify	Quantify risks from individual chemicals for each pathway and scenario separately (e.g., residential inhalation, ingestion), then...
Combine	Combine risks from multiple chemicals within each pathway and scenario, then...
Combine	Combine risks across exposure pathways to give total risk for each toxicity endpoint (cancer – noncancer)

| What is  
“protective”

## Regulations

- National Contingency Plan (NCP)
- Comprehensive Environmental Response, Compensation and Liability Act (CERCLA)





# Uncertainty Evaluation

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- Data collection
- Exposure Assumptions
- Toxicity values
- Dose estimates
- Mixtures

# Reducing Uncertainty



- Understand where uncertainty exists
- Reduce uncertainty where possible
- Err on the side of protectiveness where possible

# How are risk assessment used?

- Unacceptable human health and/or ecological risks provide the scientific/regulatory basis for taking an action at a site
- Provides information to risk managers
- Information is presented in feasibility studies, proposed plan, record of decision, and other documents
- Informs decisions

# Risk Assessment & Risk Management

## Reduce Risk

- ~~Hazard~~ × Exposure = Risk
- Hazard × ~~Exposure~~ = Risk





# EPA's Peer-Reviewed Toxicity Assessment for Toxaphene

Prepared for  
Glynn Environmental Coalition

Superfund and Risk Assessment Workshop  
Brunswick, Georgia

June 22, 2019  
Frank S. Anastasi, PG



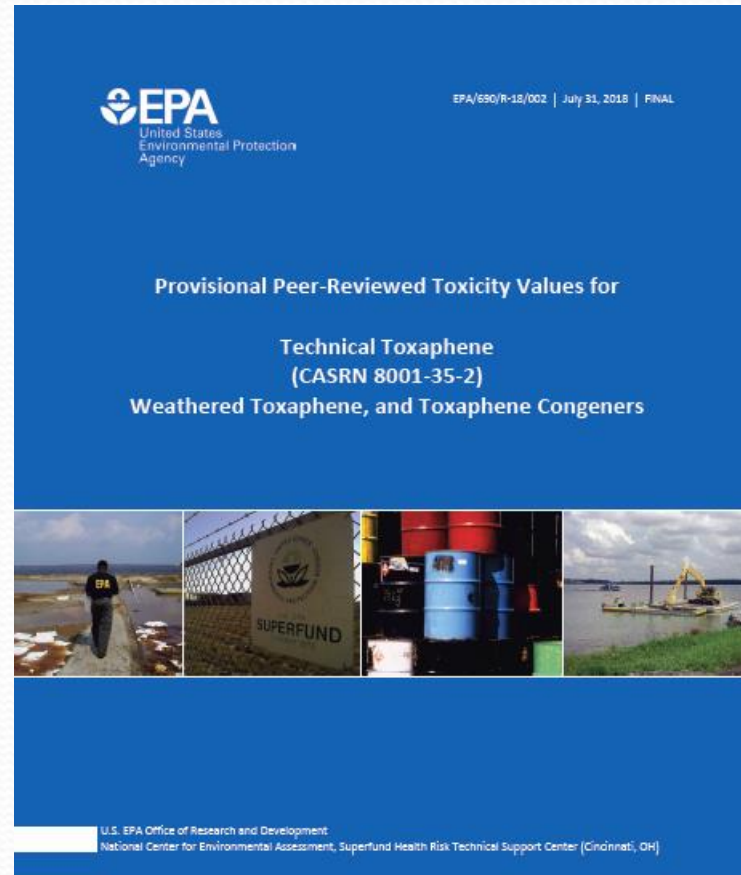


# U.S. Environmental Protection Agency Report

Provisional Peer-Reviewed Toxicity Values for Technical Toxaphene (CASRN 8001-35-2), Weathered Toxaphene, and Toxaphene Congeners

- Relatively New - Published July 2018
- One step in EPA's Superfund Risk Assessment Process
- Develop "toxicity values" used to estimate risk

# The PPRTV Report





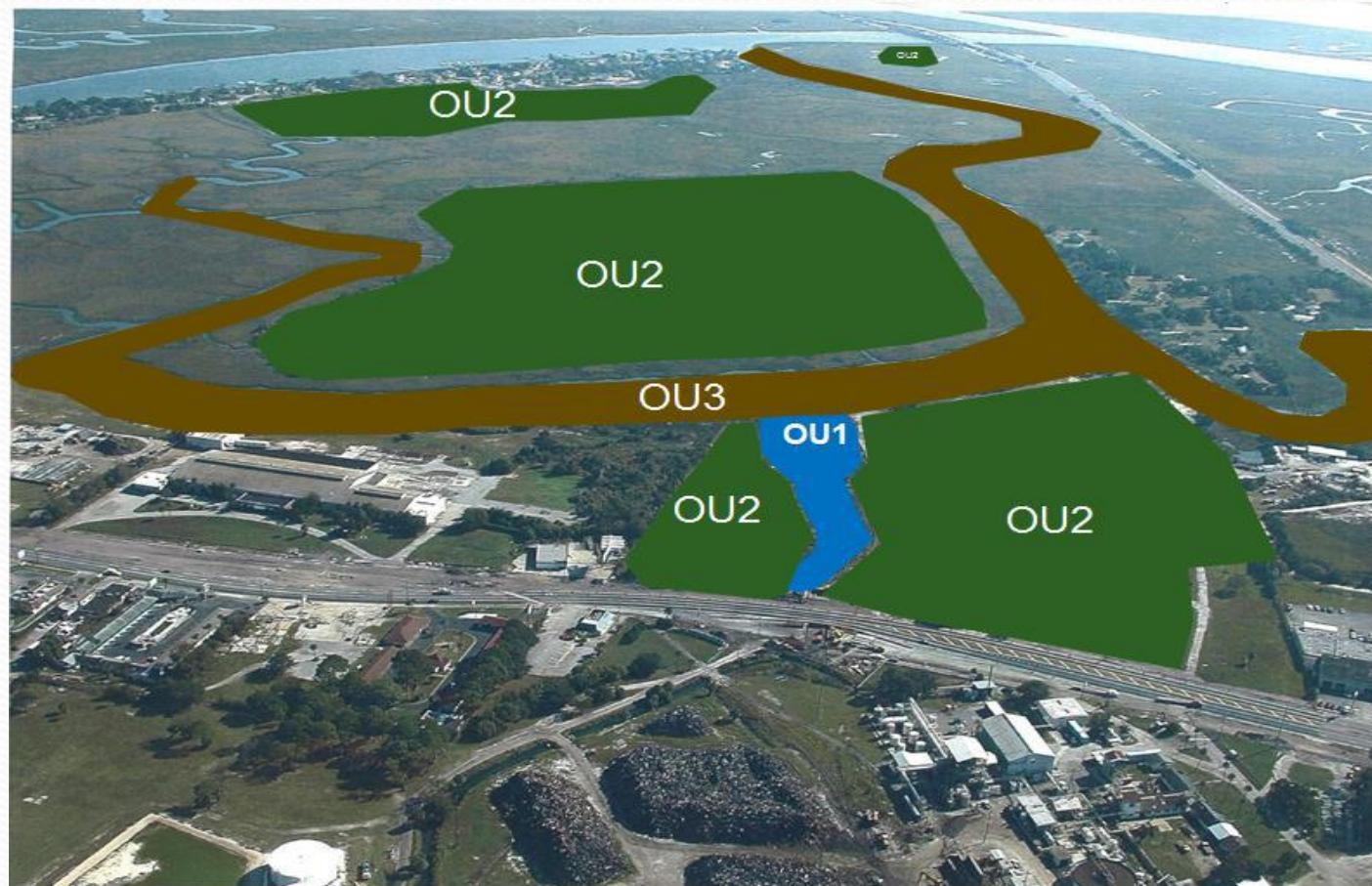
# What is Toxaphene?

Pesticide made by Hercules from 1940s to 1980

- Camphenes (natural chemical found in turpentine) mixed with chlorine gas
- Many different chemicals - “Toxaphene Congeners”
- Banned in the U.S. in 1990
- Residual Toxaphene in environment - “Weathered Toxaphene”



# Terry Creek Dedge Spoil Areas/Hercules Outfall Site





# Terry Creek Outfall Ditch

- Wastewater from toxaphene manufacturing discharged to Dupree and Terry creeks for 40 years (until 1980)
- 35,000 cubic yards contaminated sediment removed from ditch and creeks in 2000
- EPA selected Interim Remedy in 2017
  - Install new concrete-lined ditch nearby
  - Backfill and cover old ditch
  - Contain residual contamination



# Outfall Ditch





# What's in the PPRTV?

- Information from *previous scientific studies* on adverse health effects
  - Human and animal studies on exposure to substances
- *Estimated* amounts of substances that should be safe for human exposures
  - Provisional reference doses
  - Screening provisional reference doses
- *Level of Confidence* EPA has in these conclusions

# PPRTV Estimated Provisional Doses

- Provisional **oral** reference dose (p-RfDs) for Technical Toxaphene (manufactured product)
  - Daily amount for ingestion with no adverse human health effects
- **Screening** p-RfDs for Weathered Toxaphene
  - Less certainty of estimated amount so of limited use
- No toxicity values for Toxaphene Congeners
  - No appropriate studies
- No toxicity value for ecological receptors



# Uncertainties

Scientists can only *estimate* a reference dose due to uncertainties in assessing toxicity of chemicals

- Most studies are on animals in lab setting
- Apply findings to likely human health effects
- Humans may react differently than animals
- Variable health effects in different people
- Few studies = more uncertainty

# Uncertainty and Doses

## ➤ Multiple Types of Uncertainty

- A – Animals vs. Humans
- B – Extent of Toxicity Data
- C – Human variability
- Others

## ➤ Composite Uncertainty Factor

- Combine all specific factors
- $A \times B \times C \times [\text{other factors}] = \text{Composite Factor}$
- Use to calculate toxicity values

## ➤ Tables 10 (p. 75), 12 (p. 77) and A-2 (p. 86)



# Uncertainty Profiles

## Technical Toxaphene (manufactured product)

- Numerous studies and lots of data
- Composite Uncertainty
  - UFC = 100 for chronic exposure (daily, long-term ingestion)
  - UFC = 30 for subchronic exposure (less frequent ingestion)

## Weathered Toxaphene (residual in environment)

- Only one study considered valid for PPRTV
- Composite uncertainty UFC = 300
- Screening dose - Less confidence due to lack of data

# Estimated Doses for Toxaphene

## Estimated Provisional Oral Reference Doses (p-RfDs) for Technical Toxaphene and Weathered Toxaphene

<b>Substance</b>	<b>Chronic Exposure Amount</b>	<b>Subchronic Exposure Amount</b>
Technical Toxaphene	0.00009 mg/kg-day	0.0003 mg/kg-day
Weathered Toxaphene	0.00003 mg/kg-day	0.00003 mg/kg-day
Estimated Relative Difference	Estimated Amount of Weathered Toxaphene is One-Third (33.33%) of the Estimated Amount of Technical Toxaphene	Estimated Amount of Weathered Toxaphene is One-Tenth (10%) of the Estimated Amount of Technical Toxaphene

Notes: [X] mg/kg-day = amount of substance ingested per day (in milligrams per kilograms)  
EPA determined the estimated amounts for Weathered Toxaphene are considered only a “screening” value based on the lack of data, and therefore it has limited usefulness.



# Is Weathered Toxaphene more Toxic than Technical Toxaphene?

- Lower doses for Weathered Toxaphene would indicate higher toxicity compared to Technical Toxaphene, but...
- Higher degree of uncertainty about Weathered Toxaphene (only one study) prevented EPA from estimating with confidence the actual difference in toxicity



Questions?

# CONTACT INFORMATION

## EPA

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LCP OU3 – Pam Scully (404) 562-8935 [scully.pam@epa.gov](mailto:scully.pam@epa.gov)

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[martin.scott@epa.gov](mailto:martin.scott@epa.gov)

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[miller.angela@epa.gov](mailto:miller.angela@epa.gov)

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