

EPA'S RISK ASSESSMENT PROCESS AND APPLICATION TO DIOXIN

**Tittabawasse-Saginaw Rivers Contamination
Community Advisory Group**

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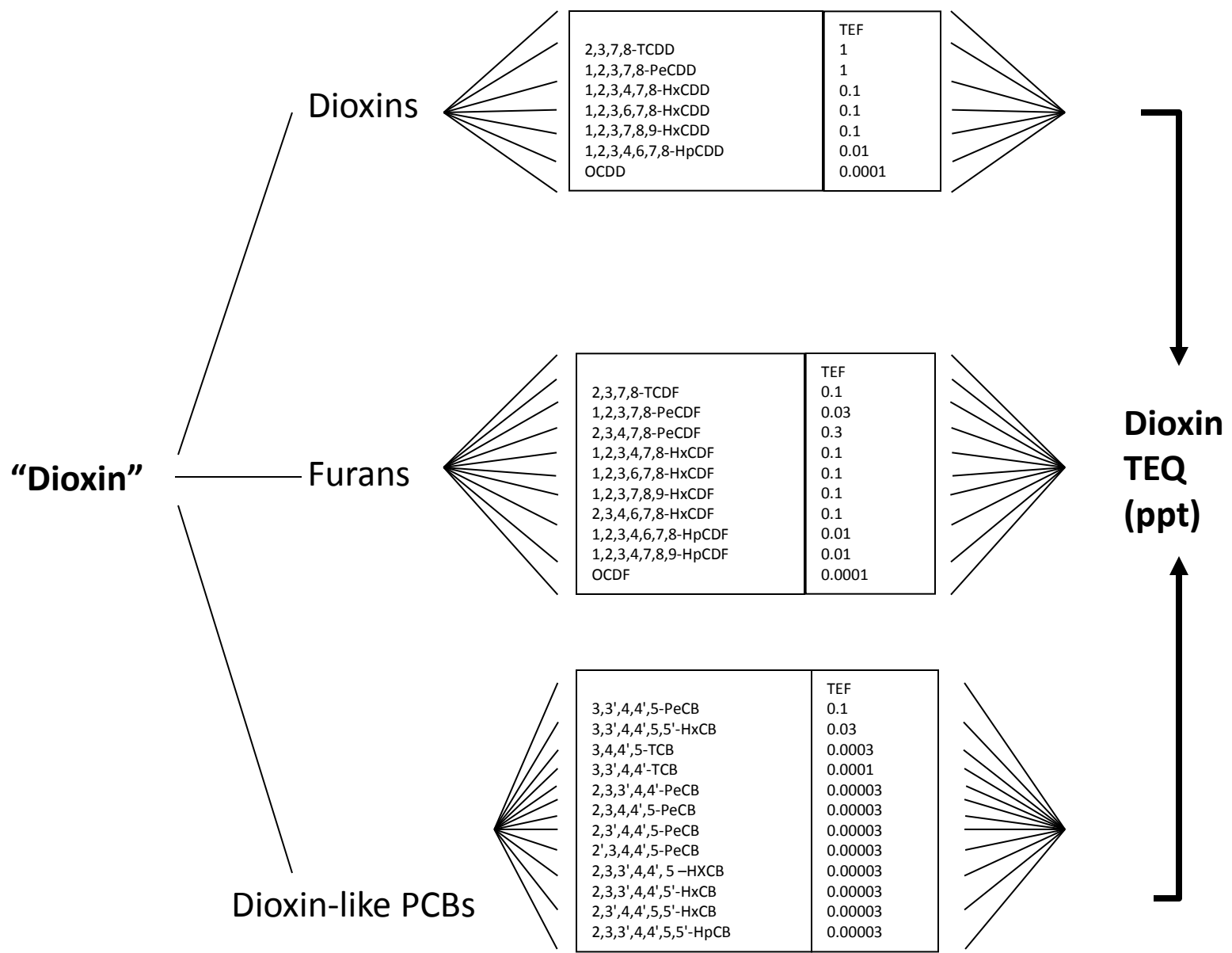
Outline

- What are dioxins?
- EPA's risk assessment process.
- What is a reference dose (RfD)?
- Use of EPA's new dioxin RfD at Superfund sites.

Dioxins

- Dioxins comprise a large group of chlorinated compounds:
 - Not all dioxins are toxic,
 - 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) is considered the most toxic of the dioxins,
 - Others toxic dioxins are compared to TCDD using the toxicity equivalence factor (TEF) approach, and
 - The total concentration of dioxins is expressed as toxicity equivalence or TEQ.
- Dioxins are produced as a by-product of chemical production or combustion (e.g., Agent Orange, wood pulp bleaching, backyard trash burning, and forest fires).
- Over the past several years, EPA, states, and industry efforts have reduced air emissions of dioxins by 90 percent so that today, most Americans have only low-level exposure to dioxins.

What Can Contribute to Dioxin TEQ?



What are the Health Impacts of Dioxin?

Cancer health effects:

- Exposure to dioxins at high enough levels may cause a number of adverse health effects, including cancer.
(http://www.epa.gov/dioxin/pdfs/EPA_Dioxin-Factsheet-2012.pdf)

Non-cancer health effects:

- The most obvious non-cancer health effect if exposed to large amounts of dioxin is chloracne (severe skin disease with acne-like lesions),
- Developmental and reproductive effects,
- Damage to the immune system, and
- Interference with hormones

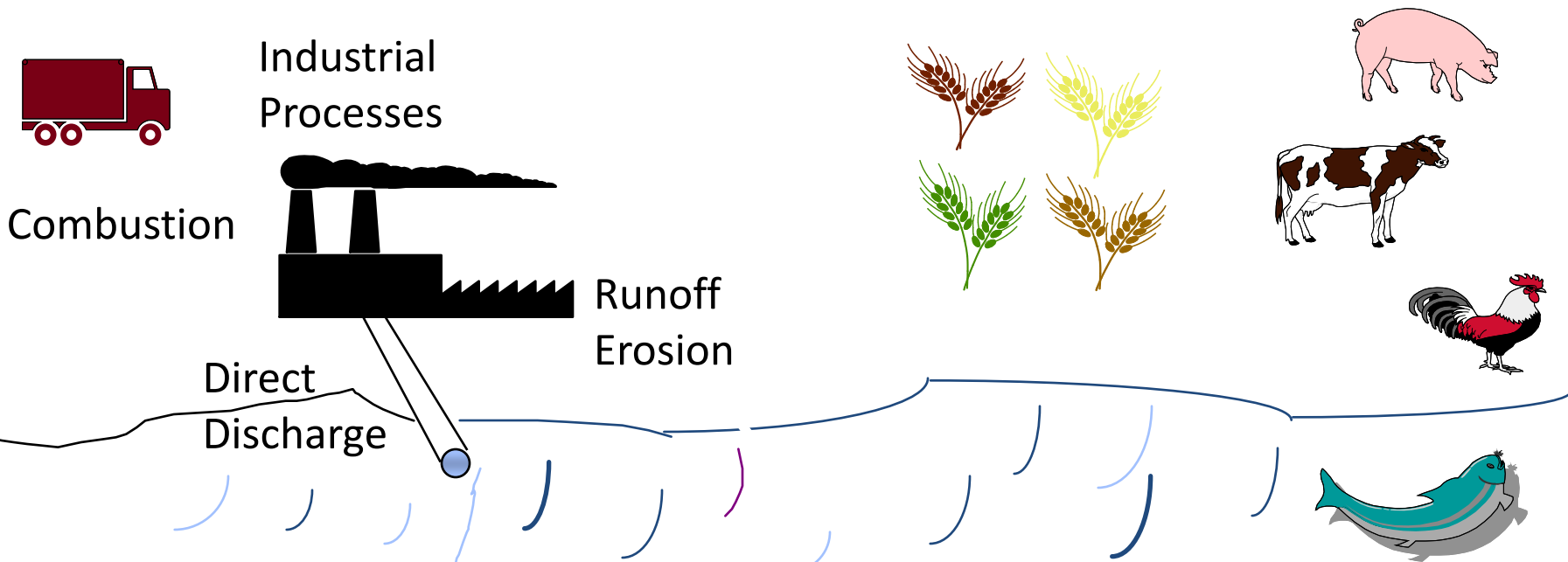
Dioxin Sources and Pathways to Human Exposures

SOURCES

TRANSPORT

DEPOSITION

FOOD SUPPLY



Potential Environmental Risk

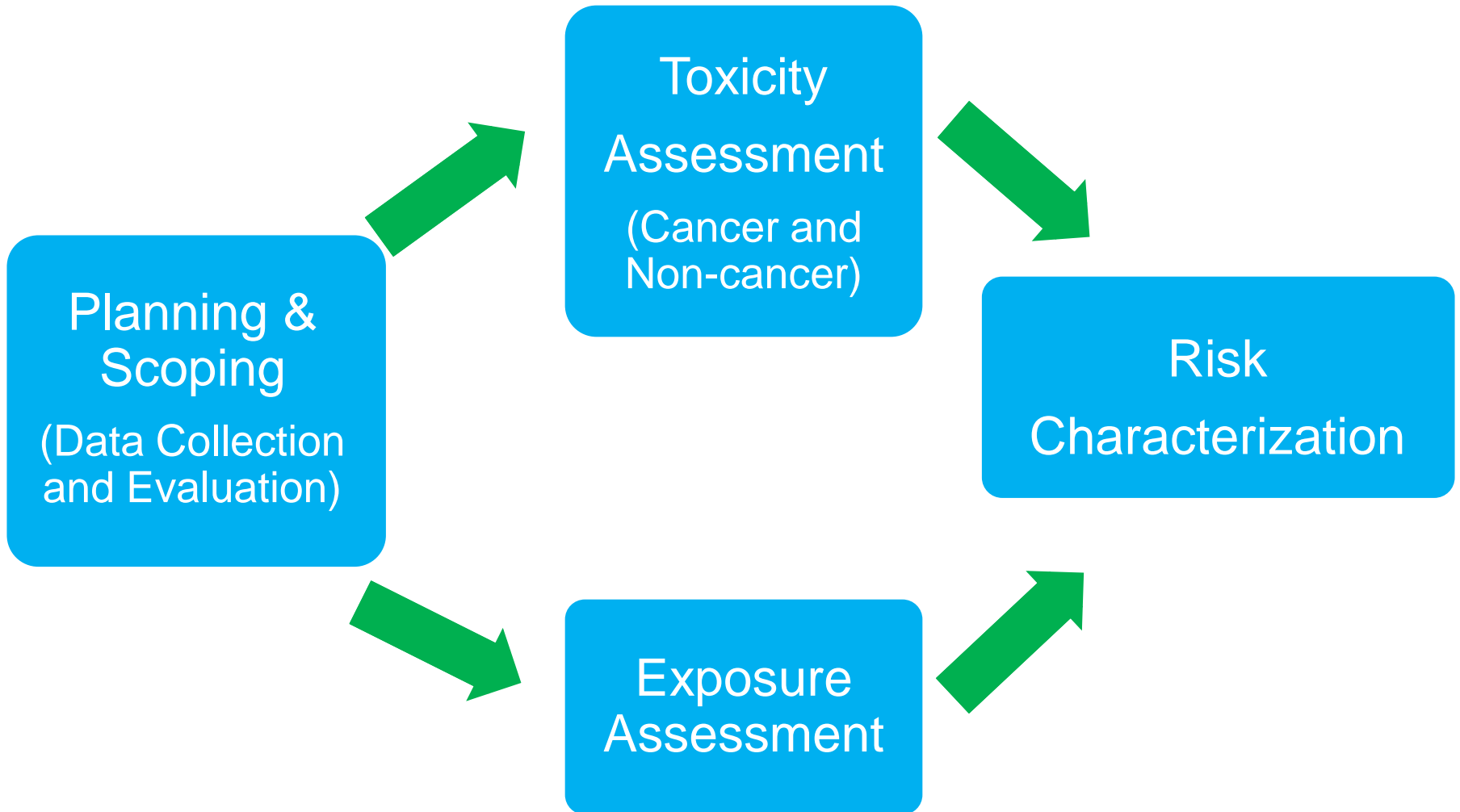
In general terms, potential risk depends on the following three factors:

- **EPA headquarters-determined values:**
 1. The toxicity of the chemical:
 - The dioxin RfD relates to non-cancer toxicity.
- **Site-specific factors:**
 2. How much of a chemical is present in an environmental medium (e.g., soil, sediment).
 3. How much exposure a person has:
 - Contact with the contaminated environmental medium, and
 - How much is “bioavailable”; that is, how much is absorbed into the body relative to how much is ingested.

EPA Risk Assessment Process

- **Planning & Scoping** entails collecting and reviewing data about the nature and extent of contamination at the site.
- **Toxicity Assessment** determines the toxicity or potency of site contaminants (i.e., how much of a contaminant causes harm).
- **Exposure Assessment** describes how people can come into contact with site contaminants and estimates current and future exposure to chemicals of concern.
- **Risk Characterization** determines the likelihood of harm to the population from site contaminants, by using the data collected in the first three steps.

Superfund Human Health Risk Assessment Framework



Toxicity Assessment

- Hazard identification: cancer, non-cancer
- Dose/response relationship

Cancer

- Expresses probability of developing cancer from a lifetime exposure to a contaminant
- Probability of risk value
 - ◆ Slope Factor
 - ◆ Unit Risk

Non-Cancer

- Level below which no appreciable risk of deleterious effects during a lifetime is anticipated.
- Protective level
 - ◆ RfD/RfC
 - ◆ MRL (Minimum Risk Level)

History of EPA Dioxin Assessment Activities

Brief History of EPA's Dioxin Reassessment Activities:

- EPA has been studying the health effects of dioxin and dioxin-like compounds for many years.
- ☑ EPA's Health Assessment Document (1985)
- ☑ Release of External Review Draft Dioxin Reassessment: 2002-2004
- ☑ National Academy of Sciences (NAS) Review of draft Dioxin Reassessment: 2004-2006
- ☑ NAS Report: July 2006
- ☑ Release of EPA's Science Plan for Activities Related to Dioxins in the Environment: May 2009
- ☑ Release External Review Draft of Dioxin Reanalysis Report: May 2010
- ☑ Public Science Advisory Board (SAB) Review Meetings: July & October 2010; public SAB teleconferences: June 2010, Feb 2011, May 2011
- ☑ Final SAB Review Report Released: August 2011
- ☑ EPA announces plan to separate dioxin reanalysis into two Volumes: August 2011
- ☑ EPA posted Volume 1 of the Dioxin Reanalysis (noncancer) on IRIS database: February 2012

What are the Non-Cancer Toxicity Values for Dioxin What do They Mean?

Non-cancer:

EPA issued the non-cancer reassessment of dioxin on February 17, 2012.

- An oral RfD of 0.7 picogram per kilogram of human body weight per day (pg/kg-day) was published in EPA's Integrated Risk Information System (IRIS) for 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD).
- A non-cancer toxicity value, or RfD, is EPA's estimate of the amount of dioxin that can be ingested on a daily basis that is likely to be without an appreciable risk of deleterious effects during a lifetime.

How did EPA develop the non-cancer toxicity value for dioxin?

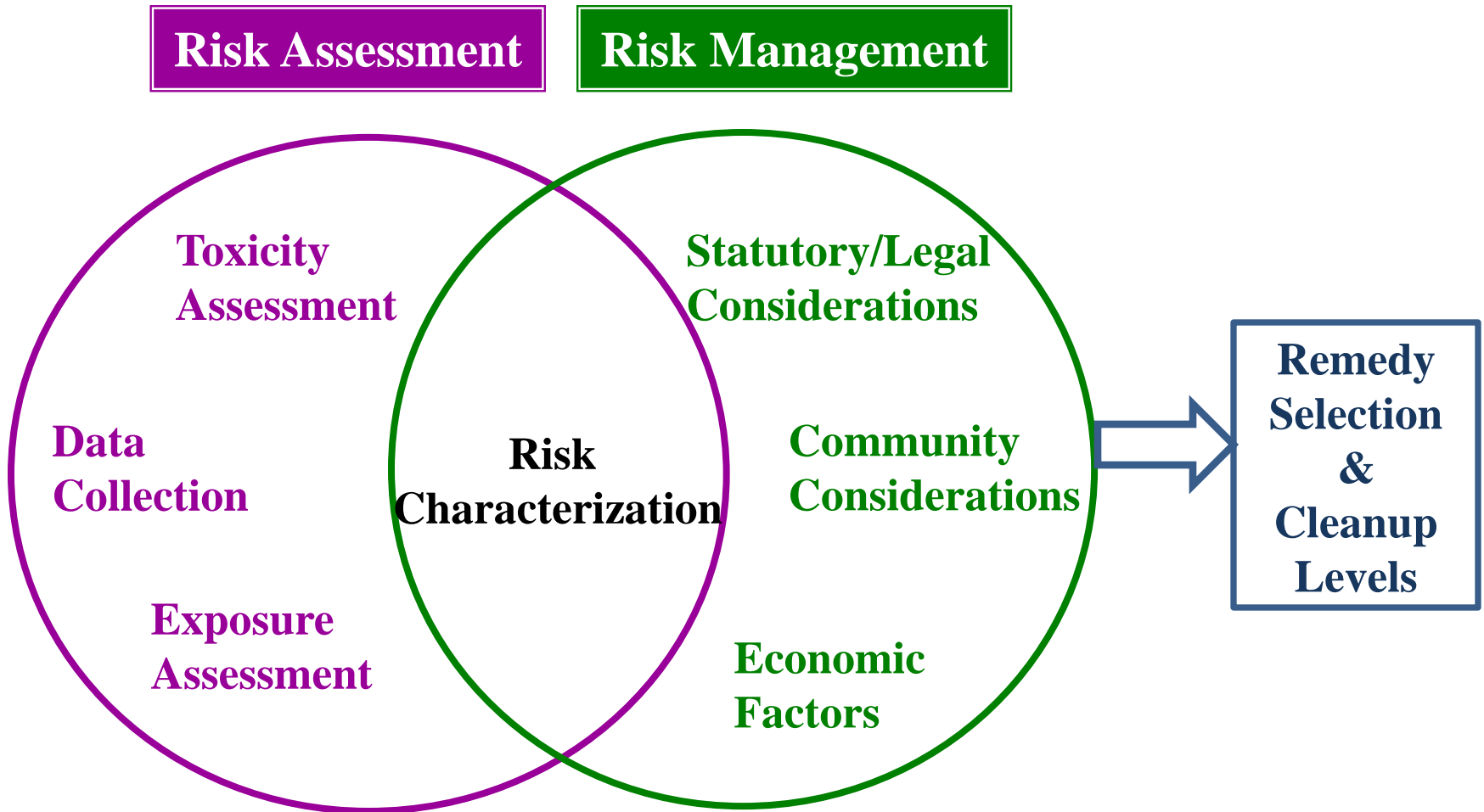
- EPA evaluated dozens of health endpoints from published animal and human epidemiological studies and developed candidate RfDs for endpoints that met EPA's rigorous study selection criteria.
- Two studies from a human population exposed to dioxin after an industrial accident in Seveso, Italy gave the most reliable information for developing an RfD. The RfD is based on two health effects observed in that population:
 - Decreased sperm concentrations and sperm motility in men exposed to dioxin in early childhood compared to a population that lived nearby but did not have the same level of exposure, and
 - Increased thyroid stimulating hormone (TSH) levels in newborns exposed to dioxin in utero.
- The peer reviewers (EPA's Science Advisory Board) agreed with EPA's approach in deriving the RfD. They noted that the changes from normal sperm counts, sperm motility, and TSH levels are of public health relevance and, therefore, appropriate for deriving an RfD.

What are the Cancer Toxicity Values for Dioxin What do They Mean?

Cancer

- EPA has not published a final IRIS Cancer Slope Factor (CSF) for dioxin.
- When there is no available IRIS value, EPA evaluates other sources of toxicity values that are peer-reviewed and publically available.
- For dioxin, the Agency has considered EPA's Health Assessment Document (1985) CSF for dioxin and California-EPA's dioxin CSF (1986, 2002).
- A cancer slope factor (CSF) is an upper-bound estimate of the increased risk (i.e., probability) of developing cancer from a lifetime exposure to a contaminant.

Risk Assessment, Risk Characterization, and Risk Management within Superfund



Setting Site-Specific Preliminary Remediation Goals and Cleanup Levels

- Preliminary remediation goals (PRGs) and cleanup levels can differ site to site:
 - Cleanup levels are calculated to be protective for cancer and non-cancer health effects, and
 - Differences in cleanup levels are primarily based on different site-specific exposures:
 - How much contact is there with the contamination?
 - How bioavailable is the contaminant?
- Cleanup levels are used for on-going and future cleanups as well as determining whether past cleanups remain protective.

How Does Superfund Use an RfD to Calculate Site-specific PRGs or Cleanup Levels?

Acceptable concentration of dioxin in soil:

$$\frac{THQ \cdot RfD_o \cdot BW \cdot AT \cdot 365 \frac{days}{yr} \cdot RSC}{EF \cdot ED \cdot [IR_{soil} \cdot RBA + (AF \cdot ABS_d \cdot EV \cdot SA) / (ABS_{GI})]}$$

RfD_o Oral reference dose

Commonly adjusted variables:

EF Exposure frequency
ED Exposure duration
RBA Relative bioavailability
EV Dermal exposure frequency

Other adjustable variables:

BW Body weight
AT Averaging time
IR Soil ingestion rate
AF Dermal adherence factor
RSC Relative source contribution
ABS_d Dermal absorption factor
SA Dermal surface area exposed
ABS_{GI} Gastrointestinal absorption fraction

What is Bioavailability?

- Bioavailability - The fraction of an ingested dose that is absorbed and becomes available for distribution to internal target tissues and organs.
- Measuring the bioavailability of dioxin in soil is complex. For example:
 - Varies for different soil types,
 - Varies in common animal models (rats and pigs) used to measure bioavailability,
 - Varies depending on the material used to dose animals, e.g., corn oil, dough ball, and
 - Varies for different forms of dioxins and different levels of chlorination.
- Generally assume 100% bioavailability unless a site-specific value is determined through testing.

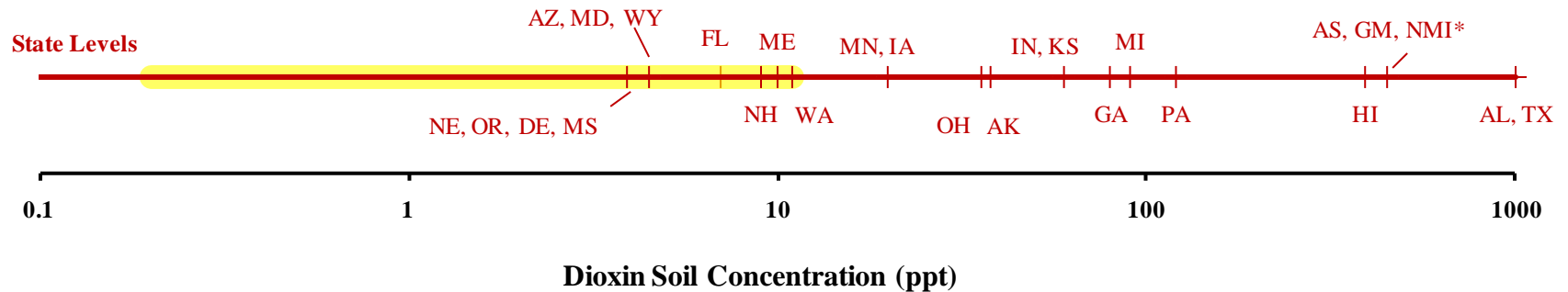
What does EPA Consider in Selecting a Remedy?

Superfund's Nine Remedy Selection Criteria:

- Protection of human health and the environment,
- Compliance with applicable or relevant and appropriate requirements (e.g., state standards),
- Long-term effectiveness and permanence,
- Toxicity, mobility, or volume reduction through treatment,
- Short-term effectiveness,
- Implementability,
- Cost,
- State agency acceptance, and
- Community acceptance.

Impact of the New Dioxin RfD on Sites

- States are not required to implement EPA's dioxin RfD.
- Many States have developed target levels for dioxin in soil.



- EPA will continue to work closely with states, particularly with states that are co-regulators managing federal cleanup programs, as EPA implements the new dioxin RfD.