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Navigating the Complexities of Toxic Tort Litigation

Presented By | Adam Miller and Jen Hackman

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Introductions

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1. Toxic Torts

2. Emerging Substances / Trends

3. Risk v. Reality in Toxic Tort Litigation

4. Questions

“Toxic Torts”

What is a “Toxic Tort”

- Toxic torts are a specific kind of lawsuit.
- Plaintiffs in toxic tort cases often claim they have been harmed by ***exposure*** to certain ***substances.***
- Many toxic tort cases are handled as class actions, where a group of plaintiffs with similar claims join together in one lawsuit. Alternatively, cases may be consolidated into multidistrict litigations (MDLs) to streamline the process and handle common issues collectively.

Toxic Tort Claims/Damages

- Personal injuries (various alleged human health effects ranging from endocrine disruption to cancers).
- Damage to property or the diminution in its value.
- Medical monitoring.
- Equitable claims to compel remedial action or corrective action.

How are “Toxic Torts” Litigated?

- Toxic tort cases often involve detailed analysis of legal and scientific issues.
- Causation questions often rely upon chemistry, toxicology, epidemiology, and medical expertise.
- There are also often complex analysis of supply chains, fate and transport, and more.

Emerging Substances in Toxic Torts

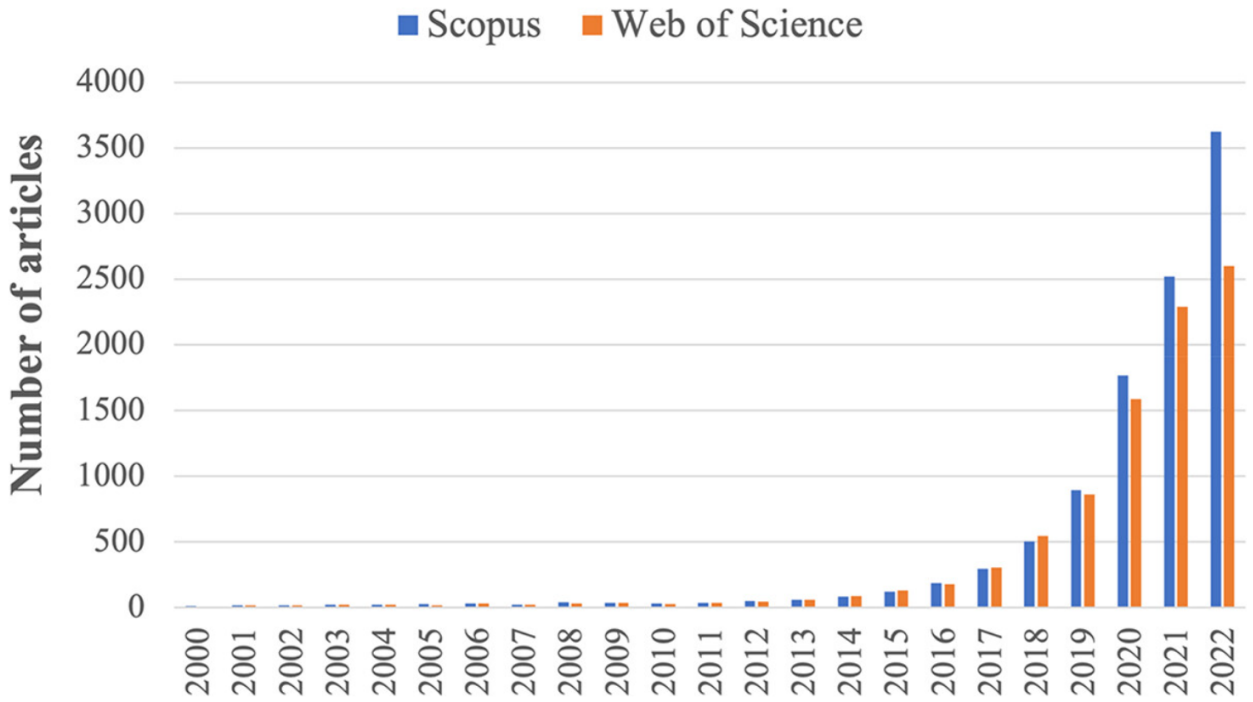
- PFAS
- Microplastics
- 1,4-Dioxane
- Pharmaceuticals in water

Microplastics

- Microplastics are micro-sized particles of plastic and related chemicals. This tiny plastic "debris," including submicron-sized particles, can come in all shapes and sizes.
- **Primary microplastics**: intentionally manufactured small particles used in consumer products (e.g., microbeads, plastic fibers, and pellets).
- **Secondary microplastics**: plastic particles that break down from larger plastic materials (e.g., food wrapping, tires, and synthetic textiles).
- Manufacturers and distributors in diverse industries, are increasingly defending microplastic-based litigation.

Microplastics

- Over the past several years, the potential health risks of microplastics have attracted much scrutiny, as they have also been found in various human foods and environmental compartments, such as drinking water, table salt, sugar, and air.
- Money is beginning to flow in steady amounts to scientists who are researching the possible medical and physiological effects of microplastics.



Recent Case Studies

- Despite the lack of clarity on the basic question of whether microplastics pose any risks to human health, the plaintiffs' bar has increasingly filed class actions based on the presence of microplastics in various products.
- These cases span jurisdictions including district courts in:
  - Connecticut
  - Massachusetts
  - Florida
  - California
  - Illinois
- These cases often allege that marketing campaigns mislead customers into believing its business practices are environmentally friendly when they are responsible for release of microplastics into the environment.

Recent Case Studies - BlueTriton Brands

- In class actions filed this year, plaintiffs in California and Illinois alleged that BlueTriton Brands **"misleadingly labels its Arrowhead-brand bottled water as '100% Mountain Spring Water,' despite the fact that it contains microplastics."** *See Perry Bruno v. BlueTriton Brands, Inc.*, 2024 WL 3993861 at *1 (C.D. Cal., Aug. 8, 2024) and *Slowinski v. BlueTriton Brands, Inc.*, 2024 WL 3757097 at *1 (N.D. Ill., Aug. 9, 2024).

Recent Case Studies - BlueTriton Brands

- These plaintiffs alleged that they **"paid a premium"** for their water because of the labeling, and that they did not receive **"the benefit of the bargain they paid for"** because of the misleading label.
- The Illinois District Court found the allegations insufficient, holding that "plaintiffs' barebones assertion that they didn't get the benefit of the bargain is not enough" because they **"fail[ed] to show that they suffered 'any observable economic consequences' from purchasing Ice Mountain water."**
- The Court held that plaintiffs failed to plead a plausible damages theory. Ultimately, it affirmed that plaintiffs failed to plead that BlueTriton created a material misrepresentation that would deceive a reasonable consumer. The Court accordingly granted defendant's motion to dismiss.

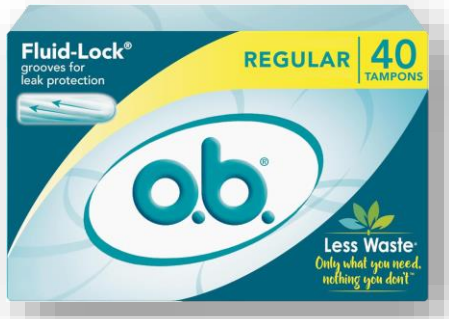
Recent Case Studies - BlueTriton Brands

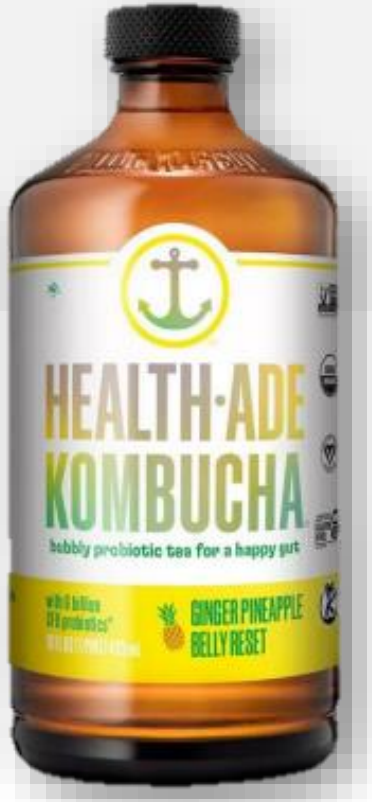
- Similarly, the court in the California case rejected theories that BlueTriton violated California false labeling or false advertising laws.
- The court explained that plaintiffs' proposed requirement to remove "100%" from its label due to the presence of microplastics, or to more accurately disclose their presence, "**would impose obligations that go beyond those provided in the FDCA**" (the Food, Drug, and Cosmetic Act). *See Bruno*, 2024 WL 3993861 at *3.

Recent Case Studies - BlueTriton Brands

- As the Illinois Northern District Court stated, "[a]t the end of the day, microplastics are in just about everything. Even the most health-conscious person among us can't escape the possibility of consuming microplastics. **When simply breathing air puts you at risk of inhaling microplastics, it's unreasonable to assume that your spring water won't have any microplastics**." *See Slowinski,* 2024 WL 3757097 at *14.

PFAS – Consumer Products





Top Industry Frustrations, Desires, and Concerns with Emerging Substances

	FRUSTRATIONS	DESIRES	CONCERNS
1.	Complex and evolving regulatory landscape	Clear and consistent regulations	Legal liabilities and lawsuits
2.	High costs of compliance and testing	Cost-effective alternatives	Negative public perception and brand damage
3.	Difficulty in finding chemical-free materials	Access to safer, effective materials	Evaluating potential health risks associated with exposure

Risk v. Reality in Toxic Tort Litigation

Understanding The Difference

- **Personal injury cases require proof of causation.**
  - General causation: Is the chemical capable of causing the type of injury alleged and at what dose.
  - Specific causation: Did the chemical cause the injury alleged at the dose the plaintiff received.
- **Nuisance/Medical Monitoring/Remediation Claims**
  - Does the presence of chemical in the environment create an unreasonable risk of harm.

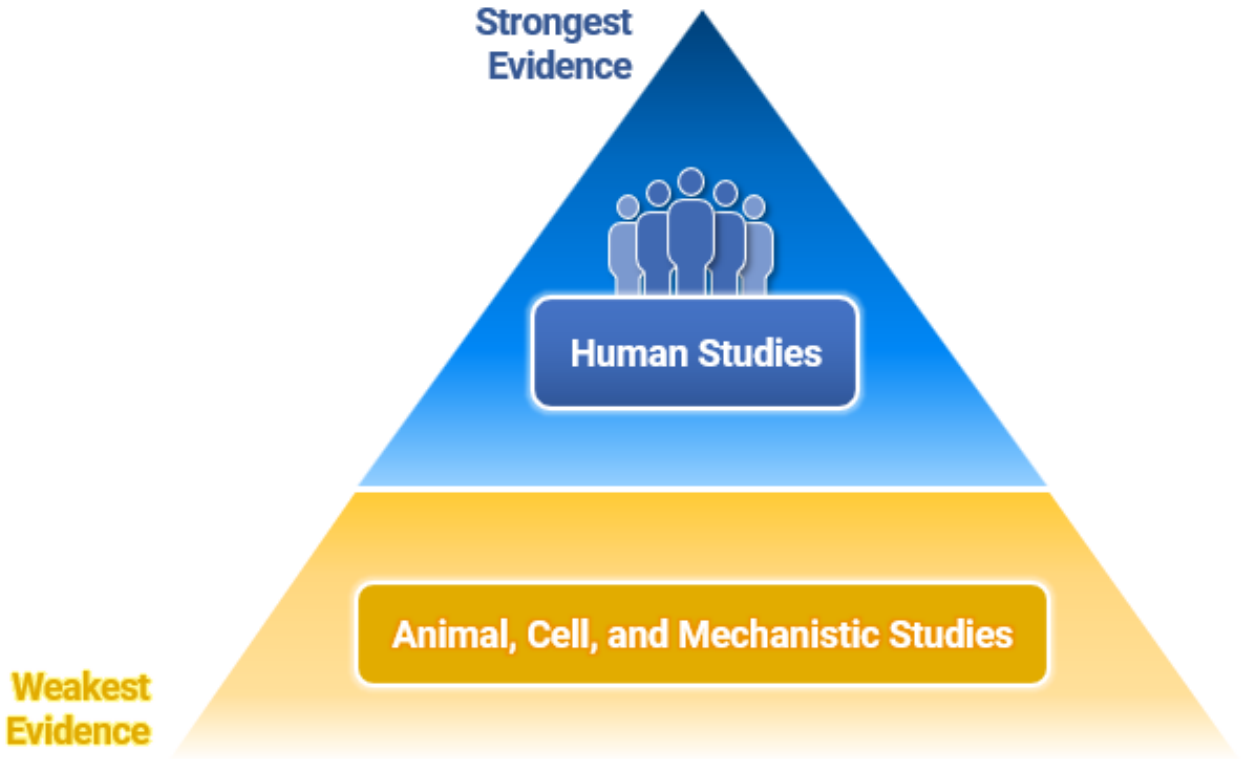
Causation Requires* Epidemiological Evidence

The study of health and disease in human populations.

Descriptive epidemiology
Describes the distribution of disease in terms of person, place and time

Analytic epidemiology
Studies **associations** between diseases and determinants (risk factors)

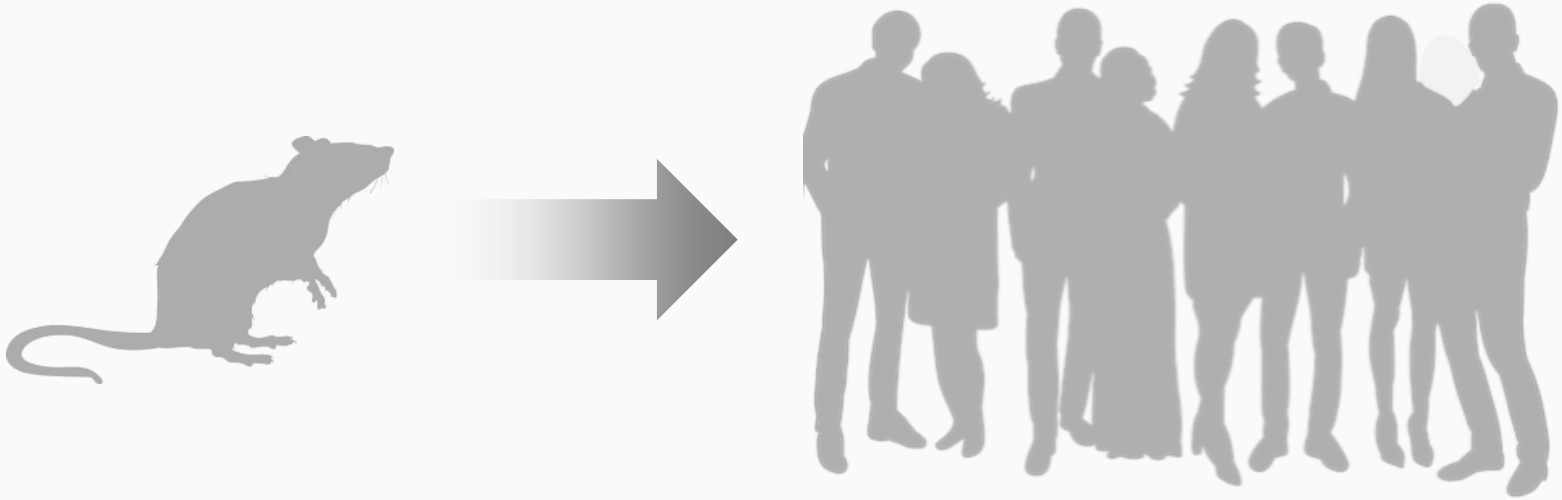
Epidemiology is Critical in Assessing Causes of Human Disease



- Causality assessment without considering epidemiologic evidence **is incomplete.**
- Toxicology experiments **cannot replicate the complexity** of human lived experience and environments.

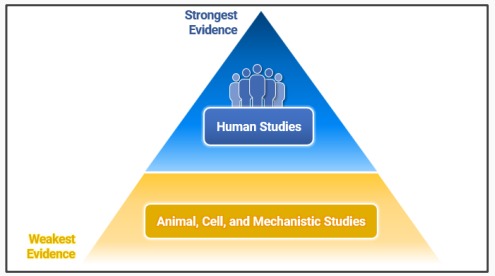
Limitations of Extrapolation from Animals to Humans

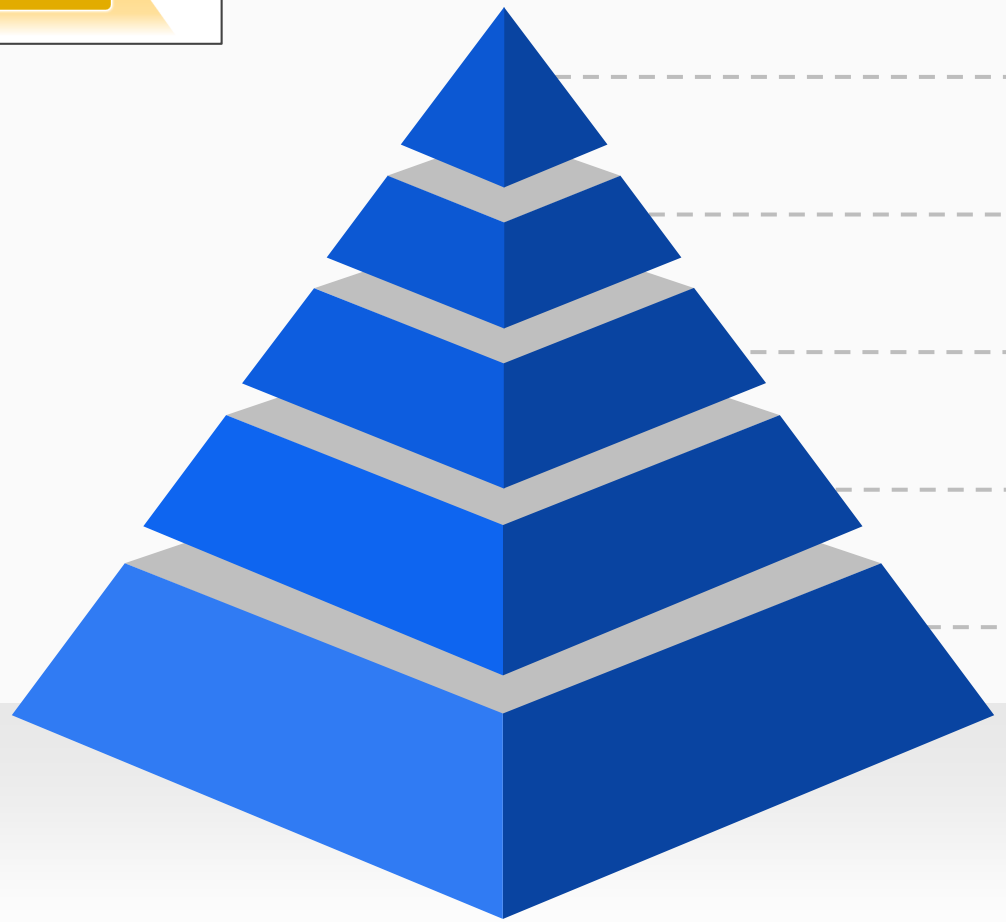
Extrapolate from animal results to predict effects in human populations



- ✗ Dose may not be relevant to human exposure experience
- ✗ Route of administration may not be relevant to exposure routes in humans
- ✗ Mechanisms and outcomes may not be relevant to human disease

Hierarchy of Human Epidemiology Study Designs





1. **Randomized Controlled Trials** (not observational)
2. **Cohort Studies**
3. **Case-Control Studies**
4. **Cross-sectional Studies**
5. **Case Reports** (not population based)

Weighing the Evidence
Interpretation of Associations In Publications

- Scope
- Chance
- Size
- Bias
- Quality
- Confounding
- Conflict of Interest and Funding Source

Bradford-Hill Guidelines, 1965

- Consistency among epidemiology studies
- Dose-response
- Timing of exposure
- Strength of Association
- Specificity
- Biologically plausible
- Coherence
- Human interventions
- Analogous similarities to other toxins

Most Important Causality Guidelines

- **Temporality**: The cause must be observed before the effect.
- **Strength**: Strong associations give support to a causal relationship between factor and disease.
- **Biological gradient**: also known as a dose-response curve; shows a (linear) trend in the association between exposure and disease.
- **Consistency**: multiple studies using various locations, populations and methods show consistent association between exposure and disease.

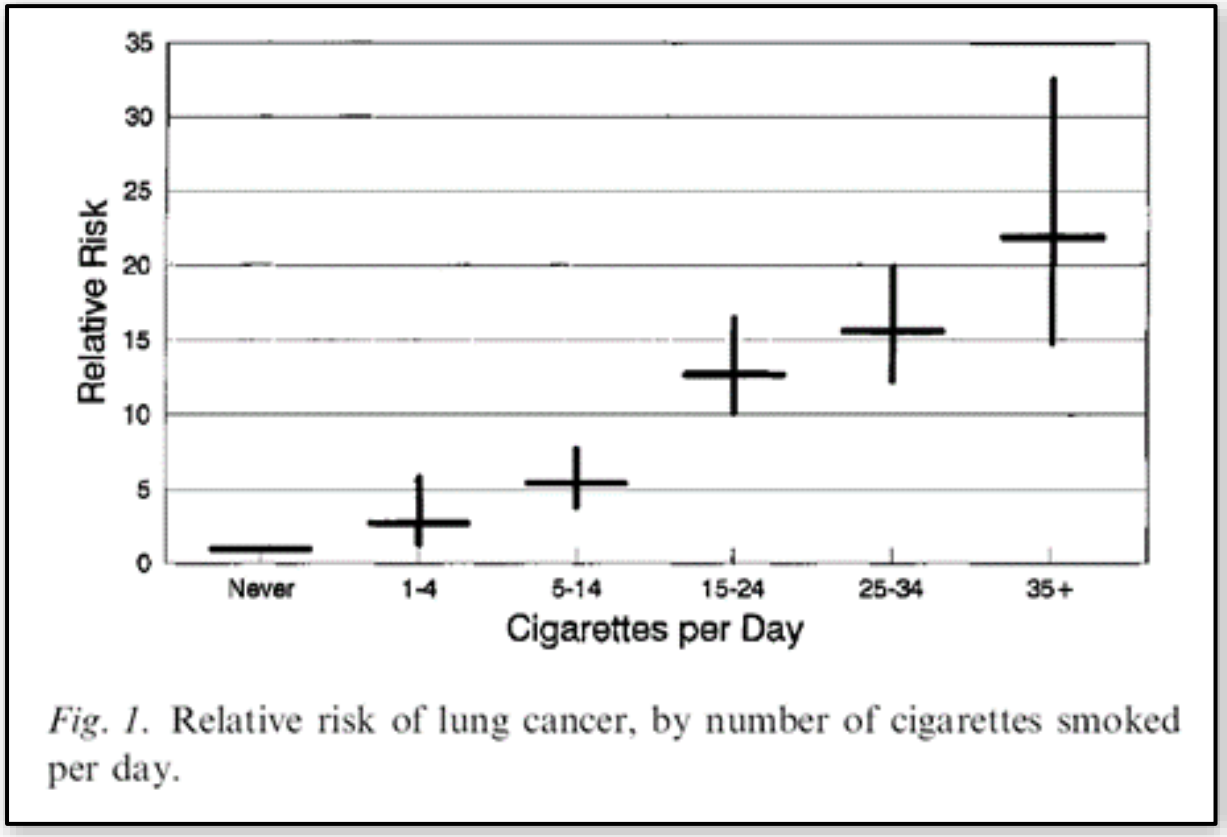
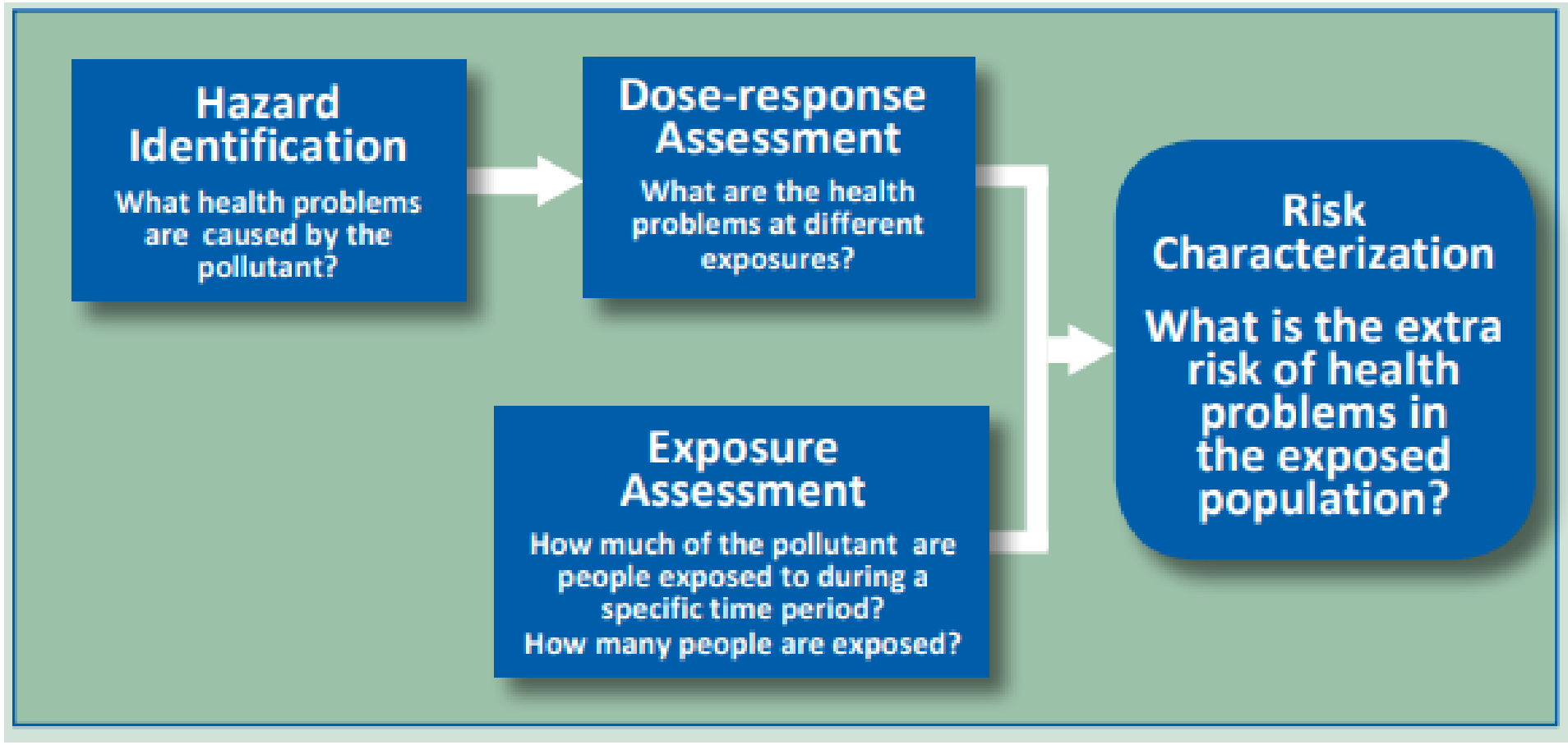


Fig. 1. Relative risk of lung cancer, by number of cigarettes smoked per day.

Assessing Risk

- **RISK**
  - The possibility that something will cause harm
- **HUMAN HEALTH RISK ASSESSMENT**
  - A systematic scientific way to evaluating potential human health effects from exposure to hazards in specific situations
- **RISK MANAGEMENT**
  - Processes put in place to control or limit exposure to hazards

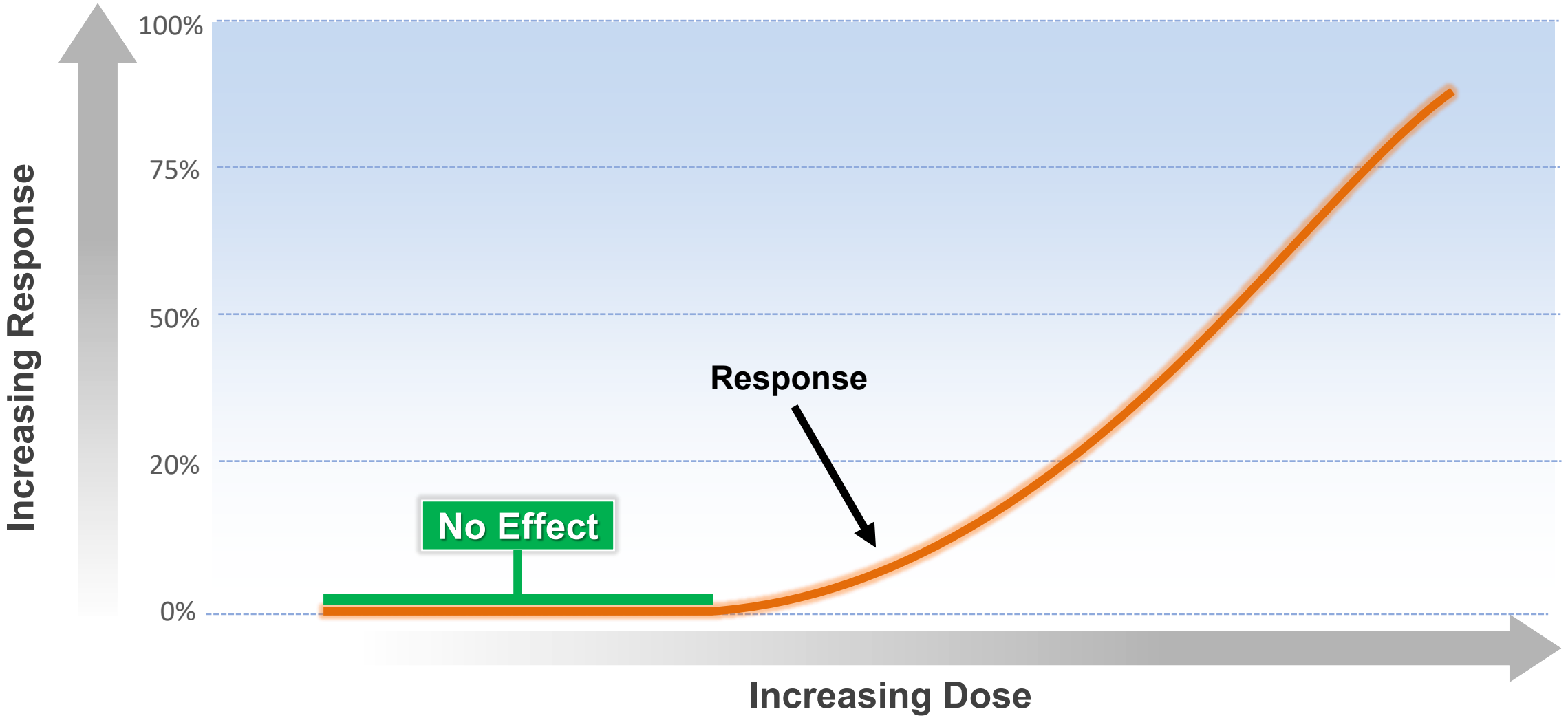
Elements of Risk Assessment



Hazard and Risk are Not the Same Thing

- Hazard: What Could Happen
- Risk: The likelihood the hazard might occur

Bradford-Hill: What Is Dose-Response?



The Dose Makes The Poison

Paracelsus (1493-1541):

“All things are poison, and nothing is without poison; only the dose permits something not to be poisonous.”

Hazard and Risk are Not the Same Thing

- Hazard Assessments:
  - International Agency for Research on Cancer.
  - National Toxicology Program
  - Environmental Protection Agency
- No consideration of dose
- No statement of likelihood of the outcome occurring

What Is the Difference Between Hazard and Risk?

IARC Identifies Hazards Even When Risks Are Very Low At Current Exposure Levels

IARC's evidence-based classification system

		Human		Animal		Additional
Group 1:	✓ *Carcinogenic* to humans	✓ Sufficient ⚠ < Sufficient	+	✓ Sufficient	+	mechanism

IARC's evidence-based classification system

		Human		Animal	Additional
Group 1:	✓ *Carcinogenic* to humans	✓ Sufficient ⚠ < Sufficient	+	✓ Sufficient	+ mechanism
Group 2A:	⚠ *Probably* carcinogenic to humans	⚠ Limited	+	✓ Sufficient	
		✗ Inadequate	+	✓ Sufficient	+ mechanism

IARC Cancer Classifications: Hazard Assessment

IARC

Group 1: ***Carcinogenic agents with sufficient evidence in humans***

- Processed Meat
- Alcoholic Beverages
- Tobacco Smoking
- Sunlight
- PCBs (malignant melanoma)
- Asbestos

Group 2A: *Agents with Limited evidence of carcinogenicity in humans*

- Salted Fish
- Very Hot Beverages
- Frying (Cooking)
- PCBs *(for NHLs)*
- Nightshift Work
- Red Meat

IARC's evidence-based classification system

		Human		Animal	Additional
Group 1:	✓ *Carcinogenic* to humans	✓ Sufficient			
		⚠ < Sufficient	+	✓ Sufficient	+ mechanism
Group 2A:	⚠ *Probably* carcinogenic to humans	⚠ Limited	+	✓ Sufficient	
		✗ Inadequate	+	✓ Sufficient	+ mechanism
Group 2B:	? *Possibly* carcinogenic to humans	⚠ Limited	+	⚠ < Sufficient	
		✗ Inadequate	+	✓ Sufficient	
		✗ Inadequate	+	⚠ < Sufficient	+ mechanism

IARC's evidence-based classification system

		Human		Animal	Additional
Group 1:	✓ *Carcinogenic* to humans	✓ Sufficient			
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Group 2A:	⚠ *Probably* carcinogenic to humans	⚠ Limited	+	✓ Sufficient	
		✗ Inadequate	+	✓ Sufficient	+ mechanism
Group 2B:	? *Possibly* carcinogenic to humans	⚠ Limited	+	⚠ < Sufficient	
		✗ Inadequate	+	✓ Sufficient	
		✗ Inadequate	+	⚠ < Sufficient	+ mechanism
Group 3:	✗ *Not classifiable* to humans	✗ Inadequate	+	✗ Inadequate	
		✗ Inadequate	+	✓ Sufficient	+ non-relevant mechanism

IARC's evidence-based classification system

		Human		Animal	Additional
Group 1:	✓ *Carcinogenic* to humans	✓ Sufficient			
		⚠ < Sufficient	+	✓ Sufficient	+ mechanism
Group 2A:	⚠ *Probably* carcinogenic to humans	⚠ Limited	+	✓ Sufficient	
		✗ Inadequate	+	✓ Sufficient	+ mechanism
Group 2B:	? *Possibly* carcinogenic to humans	⚠ Limited	+	⚠ < Sufficient	
		✗ Inadequate	+	✓ Sufficient	
		✗ Inadequate	+	⚠ < Sufficient	+ mechanism
Group 3:	✗ *Not classifiable* to humans	✗ Inadequate	+	✗ Inadequate	
		✗ Inadequate	+	✓ Sufficient	+ non-relevant mechanism

Components of Risk Assessment

- **Evaluation of Exposure Pathways**
  - Determine the relevant, complete exposure pathways (e.g., dermal contact, ingestion, or inhalation) for chemicals of potential concern (COPCs) – only complete exposure pathways can result in increased risk;
- **Evaluation of Exposure to COPCs and Exposure Point Concentrations**
  - Identification of contaminants found in media at the site and determination of appropriate exposure point concentrations
- **Evaluation of Chemical Toxicity**
- **Risk Characterization**
  - Integration of results of the hazard assessment to provide a quantitative estimation of non-carcinogenic hazard (e.g., Hazard Index) and carcinogenic risks

Assessing Risk In Regulatory Arena

Hazard Index (HI)

A comparison (calculated as a ratio) of a receptor's potential exposure to a dose at the exposure point relative to a standard exposure level and toxicological end-point

Excess Lifetime Cancer Risk

Probability that an individual will develop cancer over a lifetime because of exposure to the carcinogen

What is an acceptable risk (cancer)

- EPA acceptable cancer risk range:
  - **For populations**: One additional cancer in a population of identically situated population of between 10,000 and 1,000,000 (1E-04 to 1E-06).
  - **For individuals**, with a background lifetime cancer risk 40.0%, an added 1 in 10,000 risk increases overall risk to 40.01%

Derivation of Cancer Slope Factors

- Assume a linear, non-threshold dose response.
  - This approach assumes the agent is capable of causing cancer and other effects at every dose, no matter how small.
  - Assumes cancer causation at any dose even when thresholds are observed in animal data.
- Assumes agent is capable of causing cancers observed in experimental animals but not observed in humans;
- Assumes agent is capable of causing cancers even human evidence does not support such a conclusion.

What is an acceptable risk (non-cancer)

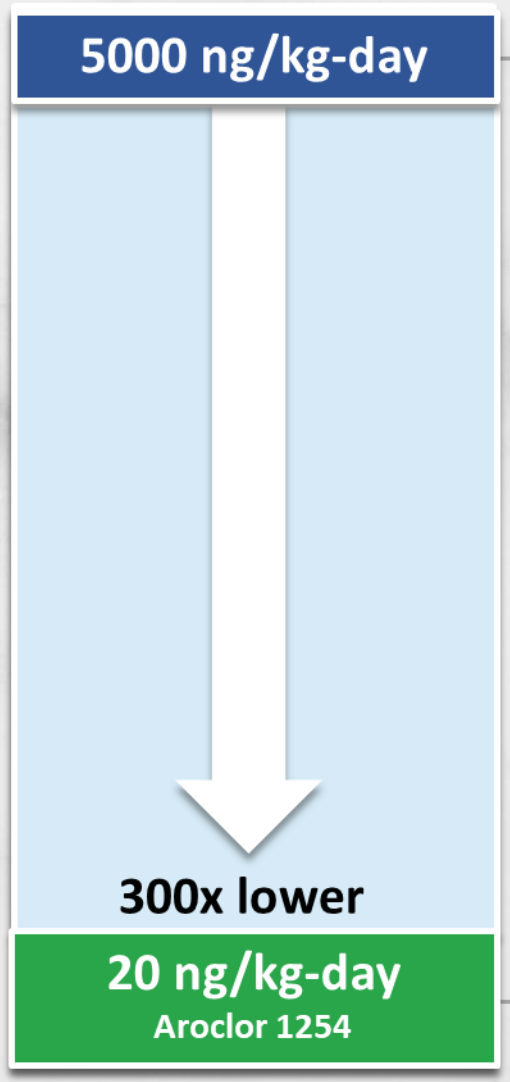
- A Hazard Index (HI) that does not exceed 1 for a toxicological outcome indicates the receptor's exposure is expected to be equal to or less than an exposure level that is hypothesized to cause adverse effects and that it is unlikely that adverse health effects will occur.
- An HI greater than 1 indicates that the receptor's exposure is greater than the allowable exposure level, and that adverse health are hypothesized to occur.

Hazard Index – The case of PCBs

- Begins with the Derivation of a Reference Dose

EPA advises that total exposure to PCBs from all sources be kept below the oral reference dose (RfD) of 20 ng PCB/kg body weight per day. This RfD is an estimate of a daily, lifelong, oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of harmful effects during a lifetime. The Exposure Levels for Evaluating PCBs in

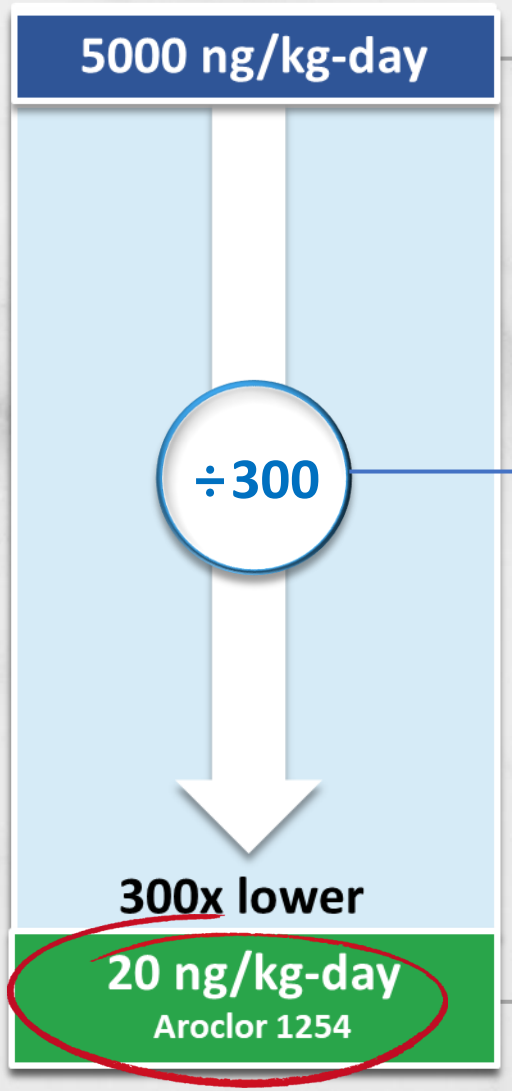
What Is the Reference Dose (RfD) Based On?



LOAEL: Lowest Observed Adverse Effect Level

EPA Reference Dose (RfD)

EPA Uncertainty Factors



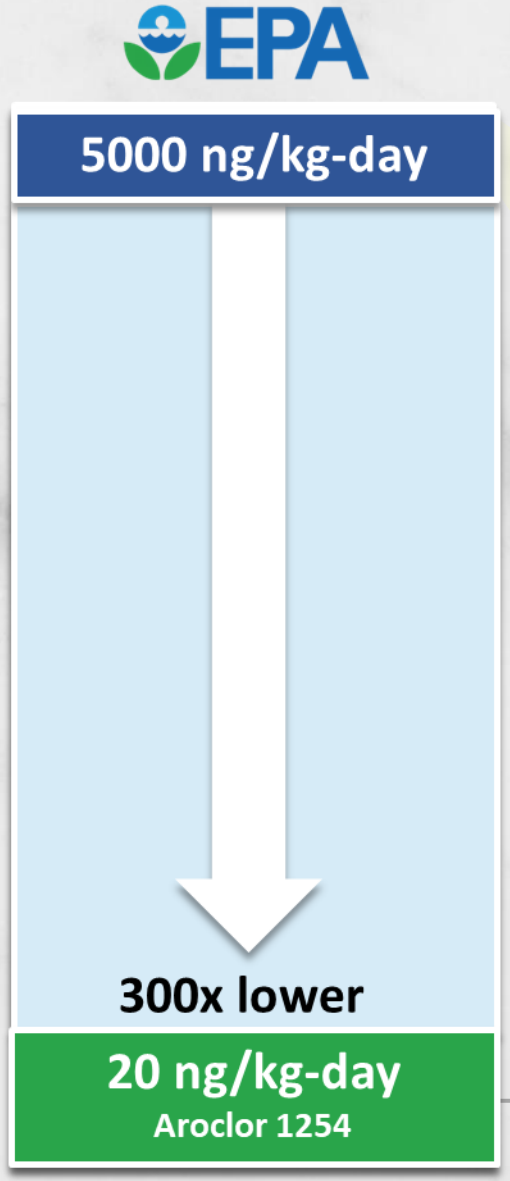
LOAEL: Lowest Observed Adverse Effect Level

Uncertainty Factors (Uncertainty between animals and humans, sensitive humans, lifetime exposure, use of LOAEL vs. NOAEL)

EPA Reference Dose (RfD)

DX_43206.0013

What Is the Reference Dose (RfD) Based On?



NOAEL or LOAEL (ng/kg-day)	Animal	Endpoint	Study
5,000 (LOAEL) No NOAEL	**Monkey**	Ocular exudate, inflamed and prominent Meibomian glands, distorted growth of finger and toenails, decreased antibody response to sheep erythrocytes	Arnold et al. 1993b; Tryphonas et al. 1989, 1991a, b

EPA Reference Dose (RfD)

What Is the Reference Dose (RfD) Based On?

NOAEL or LOAEL (ng/kg-day)	Animal	Endpoint	Study
25,000 (LOAEL) 5,000 (NOAEL)	**Monkey**	Reproductive effects (reduction in birth weight and body weight gain in offspring); Ocular and dermal signs and/or histological changes in adults and offspring	Levinskas et al. (1984)
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What Is the Reference Dose (RfD) Based On?

90,000

25,000

NOAEL or LOAEL (ng/kg-day)	Animal	Endpoint	Study
90,000 (LOAEL) No NOAEL	**Rat**	Reduction in serum T4 and T3; Decreased disappearance rate of radiolabeled T4	Byrne et al. (1987)
25,000 (LOAEL) 5,000 (NOAEL)	**Monkey**	Reproductive effects (reduction in birth weight and body weight gain in offspring); Ocular and dermal signs and/or histological changes in adults and offspring	Levinskas et al. (1984)
5,000 (LOAEL) No NOAEL	**Monkey**	Ocular exudate, inflamed and prominent Meibomian glands, distorted growth of finger and toenails, decreased antibody response to sheep erythrocytes	Arnold et al. 1993b; Tryphonas et al. 1989, 1991a, b

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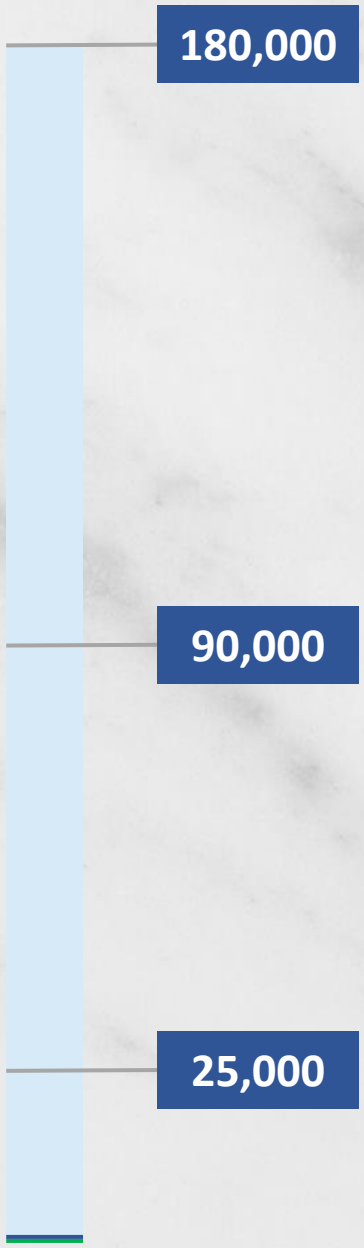

NOAEL or LOAEL (ng/kg-day)	Animal	Endpoint	Study
180,000 (LOAEL) No NOAEL	**Rabbit**	Thymic cortical atrophy	Street and Sharma (1975)
90,000 (LOAEL) No NOAEL	**Rat**	Reduction in serum T4 and T3; Decreased disappearance rate of radiolabeled T4	Byrne et al. (1987)
25,000 (LOAEL) 5,000 (NOAEL)	**Monkey**	Reproductive effects (reduction in birth weight and body weight gain in offspring); Ocular and dermal signs and/or histological changes in adults and offspring	Levinskas et al. (1984)
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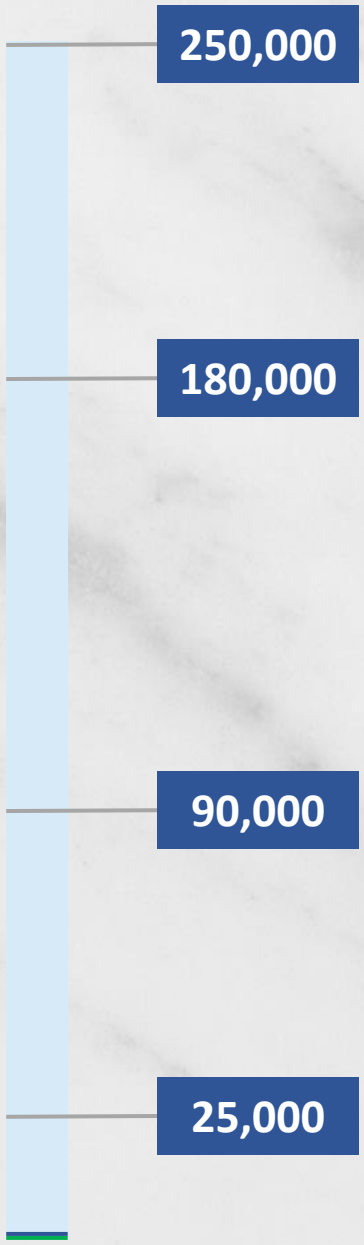

NOAEL or LOAEL (ng/kg-day)	Animal	Endpoint	Study
250,000 (LOAEL) 50,000 (NOAEL)	**Rat**	Decrease in serum corticosterone, dehydroepiandrosterone, and dehydroepiandrosterone sulfate	Byrne et al. (1988)
180,000 (LOAEL) No NOAEL	**Rabbit**	Thymic cortical atrophy	Street and Sharma (1975)
90,000 (LOAEL) No NOAEL	**Rat**	Reduction in serum T4 and T3; Decreased disappearance rate of radiolabeled T4	Byrne et al. (1987)
25,000 (LOAEL) 5,000 (NOAEL)	**Monkey**	Reproductive effects (reduction in birth weight and body weight gain in offspring); Ocular and dermal signs and/or histological changes in adults and offspring	Levinskas et al. (1984)
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What Is the Reference Dose (RfD) Based On?

NOAEL or LOAEL (ng/kg-day)	Animal	Endpoint	Study
1,300,000 (LOAEL) 130,000 (NOAEL)	**Rat**	Impaired motor coordination in developing infants (delayed auditory startle response, delayed righting ability, slower motor coordination performance)	Overman et al. (1987)
250,000 (LOAEL) 50,000 (NOAEL)	**Rat**	Decrease in serum corticosterone, dehydroepiandrosterone, and dehydroepiandrosterone sulfate	Byrne et al. (1988)
180,000 (LOAEL) No NOAEL	**Rabbit**	Thymic cortical atrophy	Street and Sharma (1975)
90,000 (LOAEL) No NOAEL	**Rat**	Reduction in serum T4 and T3; Decreased disappearance rate of radiolabeled T4	Byrne et al. (1987)
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What Is the Reference Dose (RfD) Based On?

NOAEL or LOAEL (ng/kg-day)	Animal	Endpoint	Study
7,200,000 (LOAEL) No NOAEL	**Rat**	Increased liver weight with degenerative changes; reduced survival to weaning	Linder et al. (1974)
1,300,000 (LOAEL) 130,000 (NOAEL)	**Rat**	Impaired motor coordination in developing infants (delayed auditory startle response, delayed righting ability, slower motor coordination performance)	Overman et al. (1987)
250,000 (LOAEL) 50,000 (NOAEL)	**Rat**	Decrease in serum corticosterone, dehydroepiandrosterone, and dehydroepiandrosterone sulfate	Byrne et al. (1988)
180,000 (LOAEL) No NOAEL	**Rabbit**	Thymic cortical atrophy	Street and Sharma (1975)
90,000 (LOAEL) No NOAEL	**Rat**	Reduction in serum T4 and T3; Decreased disappearance rate of radiolabeled T4	Byrne et al. (1987)
25,000 (LOAEL) 5,000 (NOAEL)	**Monkey**	Reproductive effects (reduction in birth weight and body weight gain in offspring); Ocular and dermal signs and/or histological changes in adults and offspring	Levinskas et al. (1984)
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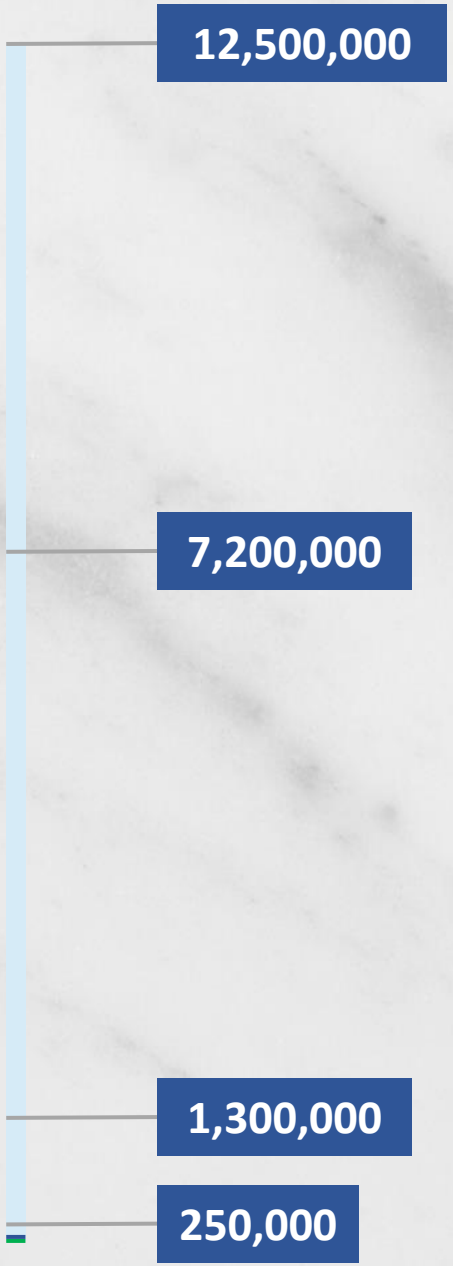
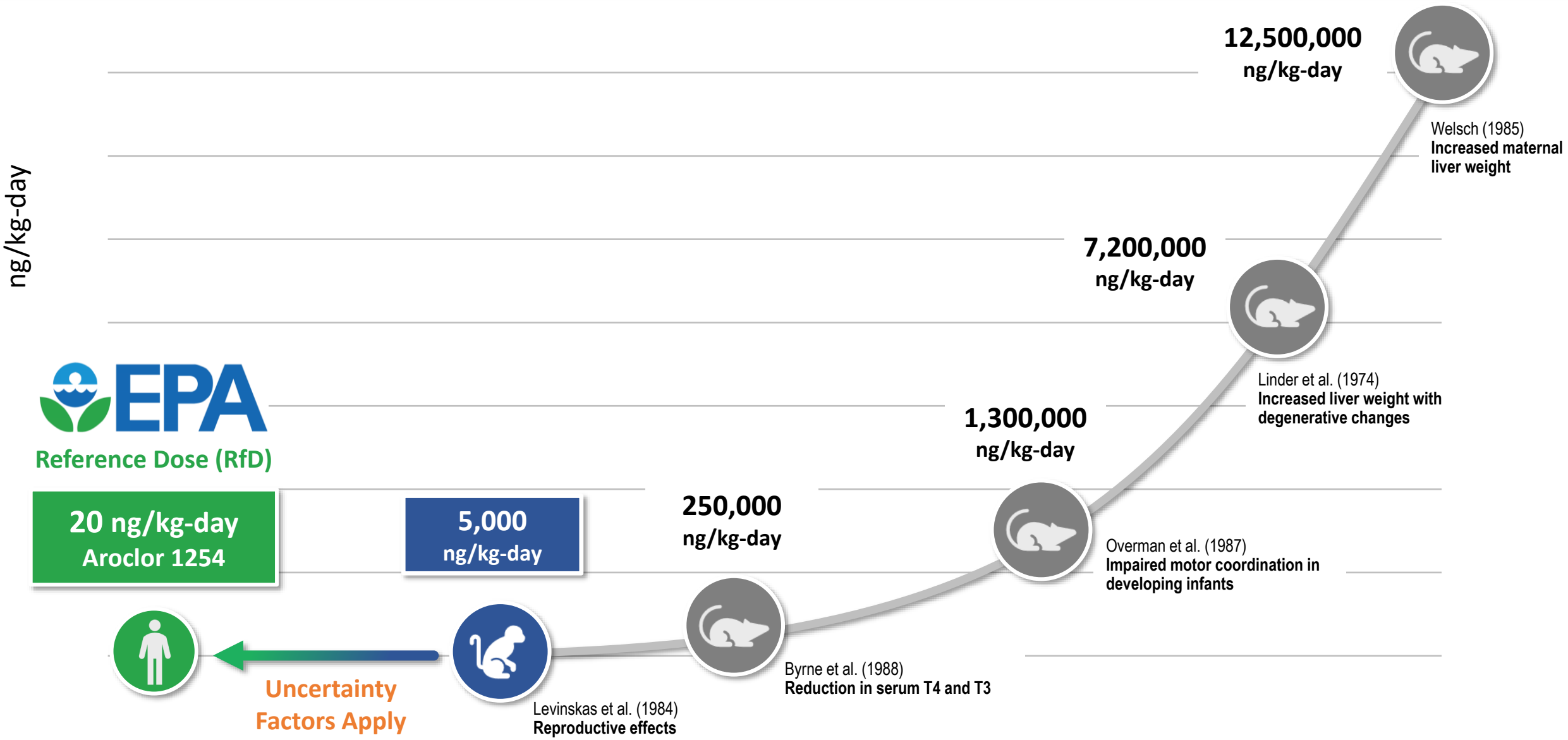


NOAEL or LOAEL (ng/kg-day)	Animal	Endpoint	Study
12,500,000 (NOAEL) highest dose tested	**Mice**	**Increased maternal liver weight but no reproductive or developmental effects**	**Welsch (1985)**
7,200,000 (LOAEL) No NOAEL	**Rat**	Increased liver weight with degenerative changes; reduced survival to weaning	Linder et al. (1974)
1,300,000 (LOAEL) 130,000 (NOAEL)	**Rat**	Impaired motor coordination in developing infants (delayed auditory startle response, delayed righting ability, slower motor coordination performance)	Overman et al. (1987)
250,000 (LOAEL) 50,000 (NOAEL)	**Rat**	Decrease in serum corticosterone, dehydroepiandrosterone, and dehydroepiandrosterone sulfate	Byrne et al. (1988)
180,000 (LOAEL) No NOAEL	**Rabbit**	Thymic cortical atrophy	Street and Sharma (1975)
90,000 (LOAEL) No NOAEL	**Rat**	Reduction in serum T4 and T3; Decreased disappearance rate of radiolabeled T4	Byrne et al. (1987)
25,000 (LOAEL) 5,000 (NOAEL)	**Monkey**	Reproductive effects (reduction in birth weight and body weight gain in offspring); Ocular and dermal signs and/or histological changes in adults and offspring	Levinskas et al. (1984)
5,000 (LOAEL) No NOAEL	**Monkey**	Ocular exudate, inflamed and prominent Meibomian glands, distorted growth of finger and toenails, decreased antibody response to sheep erythrocytes	Arnold et al. 1993b; Tryphonas et al. 1989, 1991a, b

What Is the Reference Dose (RfD) Based On?



Modelling Risk Variables

Generic Factors: target risk level, surface area of an adult and child, particulate emission factors;

Agent-Specific Factors: Inhalation unit risk, cancer slope factor, relative bioavailability factor, fraction absorbed dermally, fraction absorbed by GI tract, volatilization factors.

Site-Specific Exposure Scenarios (Reasonable Max. Exp.)

Exposure Scenario	Exposure Frequency (days/yr)	Exposure Duration (yr)	Soil Ingestion Rate (mg/day)	Exposed Skin Surface Area (cm^2)	Adherence Factor (mg/cm^2)	Body Weight (kg)
RME Outdoor Industrial Worker	190	25	100	3282	0.2	70

Regional Screening Values

Regional Screening Values

- Provides Default Screening Levels
- Generic Tables are chemical-specific concentrations for individual contaminants in air, drinking water, and soil that, if exceeded, may warrant further investigation.
- Risk-based SLs are derived from equations combining exposure assumptions with chemical-specific toxicity values.
- Generic SLs are based on default exposure parameters and factors that represent Reasonable Maximum Exposure (RME) conditions for long-term/chronic exposures and are based on the methods outlined in EPA's Risk Assessment Guidance for Superfund
- "SLs are not cleanup standards and should not be used as cleanup levels."

Questions?