

PFAS and Human Health Risk Assessment, Overview of the State of the Practice

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Overview

1. Hazard Identification
2. Exposure Assessment
3. Dose-Response
4. Risk Characterization
5. Risk Management
6. Where do we go from here?

Hazard Identification

- Critical effect variations between countries:
 - EFSA
 - US EPA
 - Australia
- Carcinogenicity Classifications
 - IARC
 - USEPA

EFSA. 2008. Opinion of the Scientific Panel on Contaminants in the Food chain on Perfluorooctane acid (PFOA) and their salts, The EFSA Journal, 653, 1-131. Available at: <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2008.653>

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USEPA 2016b. Drinking Water Advisory for Perfluorooctane Sulfonate (PFOS). Retrieved from: https://www.epa.gov/sites/production/files/2016-05/documents/pfos_health_advisory_final_508.pdf

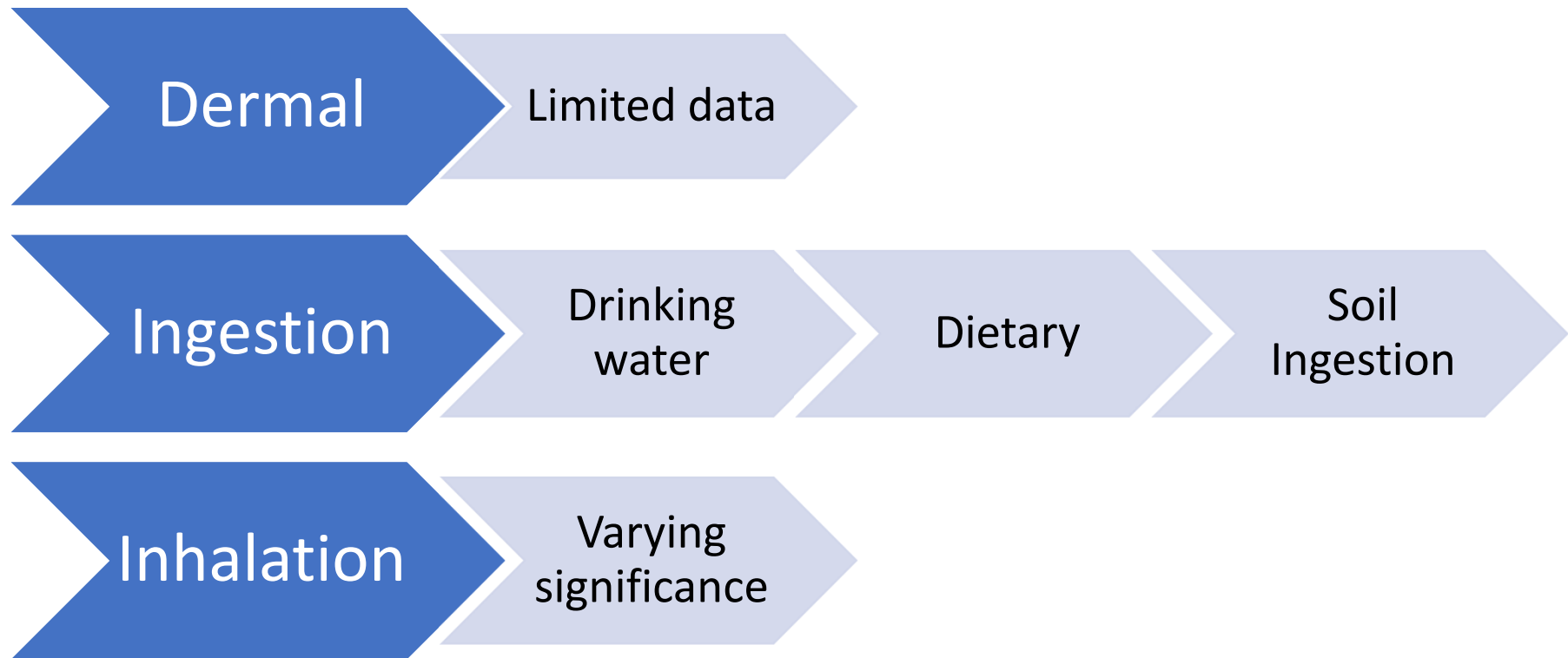
New Jersey Drinking Water Institute Health Effects Subcommittee. Health-Based Maximum Contaminant Level Support Document. Available at: <http://www.nj.gov/dep/watersupply/pdf/dwqi-pfos-mcl-draft.pdf>

Exposure Assessment

Sources of PFAS

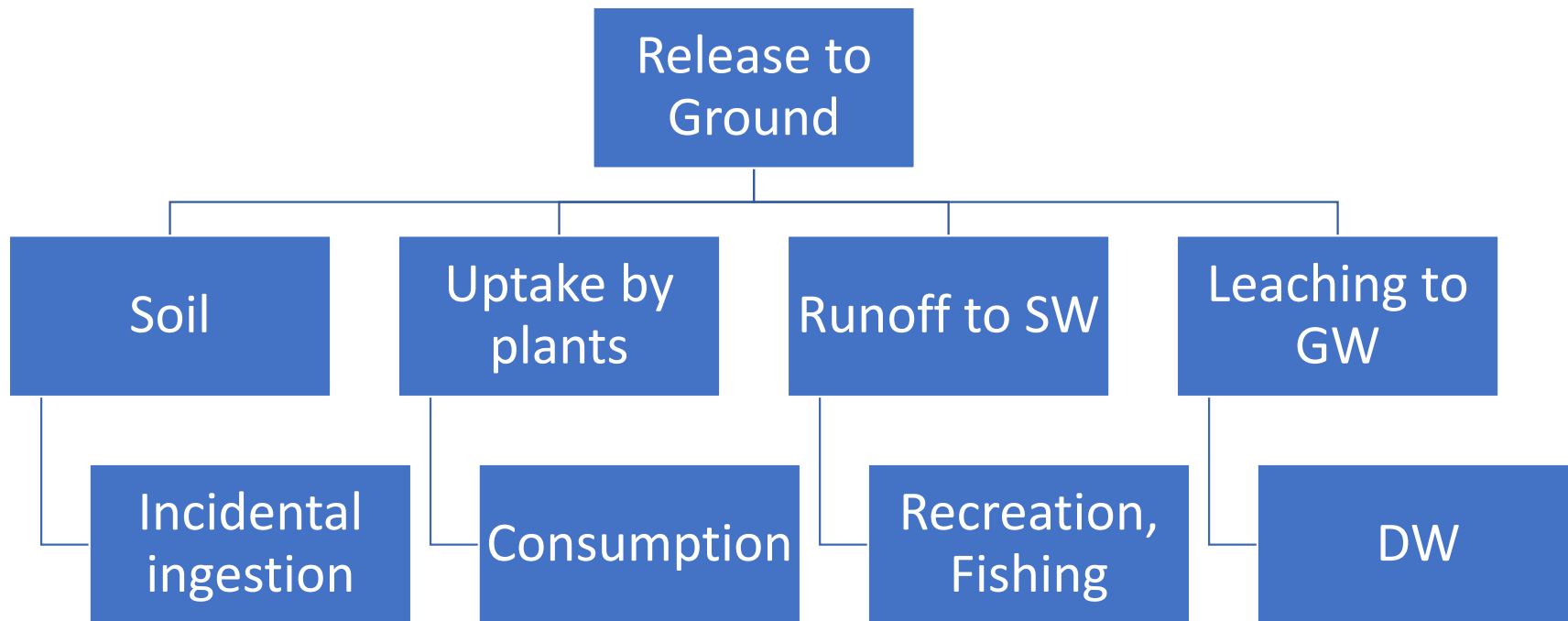
- Manufacturing source
- AFFF source
- Metal Plating
- Consumer products
- Secondary sources: landfills, WWTP

Exposure Assessment



CRC CARE. 2017. Assessment, management and remediation guidance for perfluorooctanesulfonate (PFOS) and perfluorooctanoic acid (PFOA) – Part 1: background, CRC CARE Technical Report no.38, CRC for Contamination Assessment and Remediation of the Environment, Newcastle, Australia. Available at: https://www.crccare.com/files/dmfile/CRCARETechReport38Part1_AssessmentmanagementandremediationforPFOSandPFOA_background2.pdf
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Exposure Assessment



Exposure Assessment

Uncertainties and Assumptions

- Analytical Challenges
- Bioaccumulation
- Bioavailability in soils
- Plant uptake
- Relative Source Contribution

Dose-response

State of Practice: PFOA and PFOS

- Critical Effects selected
- Uncertainty factors selected
- Calculation of toxicity reference values
- Generic or site-specific HSLs, ESLs, and PRGs can be calculated with a number of assumptions

Dose-response

Uncertainties

- Epidemiology studies
 - Inconsistent findings
 - Associations
 - Confounders
- Animal studies
 - PPAR α
 - Interspecies UFs

Dose-response

Evaluation of PFAS toxicity

- Exposure to unique mixtures of PFAS
 - Few evaluated
 - Mixture constantly changing
- Variations by regulatory agency
 - PFASs included in assessment
 - Additivity/Read Across

Risk Characterization

- Tying together uncertainties
- Reaching a defensible number
- Regulatory Agency Conclusions:
 - EFSA CONTAM: human exposure typically below TDI
 - FSANZ: “persistence gives rise to some concern, although PFOA appears to have few adverse effects” (FSANZ, 2017)
 - EPA: “studies indicate that exposure to PFOA and PFOS over certain levels may result in adverse health effects” (EPA, 2016)

Risk Management- what is it?

The process of deciding whether and how to manage risks.

Where do the challenges lie for PFASs?

What are key considerations moving forward?



Key Risk Management Considerations

Risk Management- Legal Considerations

- Establishes the basis for the risk assessment, management decisions

Challenges:

1. Lack of Federal promulgated rule (i.e. SDWA, CERCLA, RCRA)
2. Legal actions on the rise despite promulgated rule
3. Cooperative federalism approach- State-driven actions



Risk Management- Economic Considerations

- the cost of risks and the benefits of reducing them, the costs of risk mitigation or remediation options

Challenges:

1. Response action is immediate- little time to thoroughly evaluate economic impact.
2. Large population affected – high dollar cost options become only options
3. Remedial technology options are limited- feasibility studies are essentially non-existent



Risk Management- Behavioral Factors

- **Social factors**, may affect individual or a definable group to risks from a particular stressor.
- **Political factors** are based on the interactions among branches of the Federal, state, and local government entities.

Challenges:

1. Social media is driving message leading to risk amplification
2. Availability of misinformation
3. Lack of awareness of standard principles of practice
4. Lack of consistency across EPA regions
5. Scientific decisions are being influenced by political pressures
6. Variable State information leads to contradiction and mistrust—further amplifying risk



Risk Management- Human Health and Ecological Effects

- Evaluates the risk assessment outputs to determine effects on human health and the environment

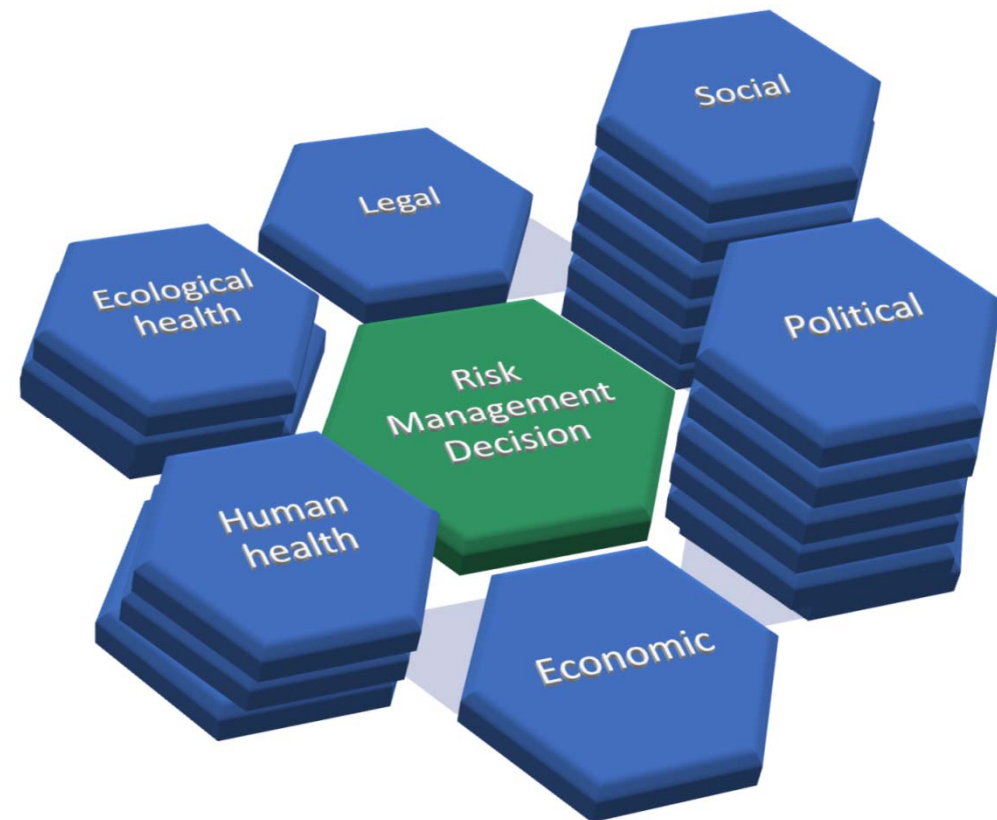
Challenges:

1. Many analytes lack peer-reviewed reviewed toxicological information
2. Reference doses are based on developmental/reproductive endpoints
3. Little to no consensus on derivation of criteria



Risk Management- How have we stacked up?

- The balance of scale for risk management decisions has been uneven
- Toxicology, by design, cannot keep up to demand
- Economic impact has been exponential compared to beneficial impact



Where do we go from here?

1. Legal
 - ✓ Federal leadership required to establish consistency across the country
2. Economic
 - ✓ Establish relative risk and economic benefit holistically
3. Social
 - ✓ Unite stakeholders to disseminate common message
4. Political
 - ✓ Educate stakeholders on standard risk assessment practice
5. Human Health and Ecological
 - ✓ Evaluation of class vs compound

Live Poll Results

- Have you and/or your employer been involved in PFAS risk assessments to date?
 - [Results](#)
- What do you think the primary drivers have been in making PFAS risk management decisions to date?
 - [Results](#)
- Do you think that PFASs should be managed as a Class or individually?
 - [Results](#)
- Do you think PFASs with no peer-reviewed toxicological information should be considered in risk assessment?
 - [Results](#)
- In your opinion, which scientific disciplines have advanced the most around the PFAS issue?
 - [Results](#)
- If willing, please provide your current employer type.
 - [Results](#)

Thank you

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