Overview of Site-specific Baseline Risk Assessments: What Are the Key Variables & Uncertainties for Characterizing PFAS Risk to Receptors

Janet Anderson, PhD, DABT

Principal Toxicologist

GSI Environmental Inc.

April 5, 2022

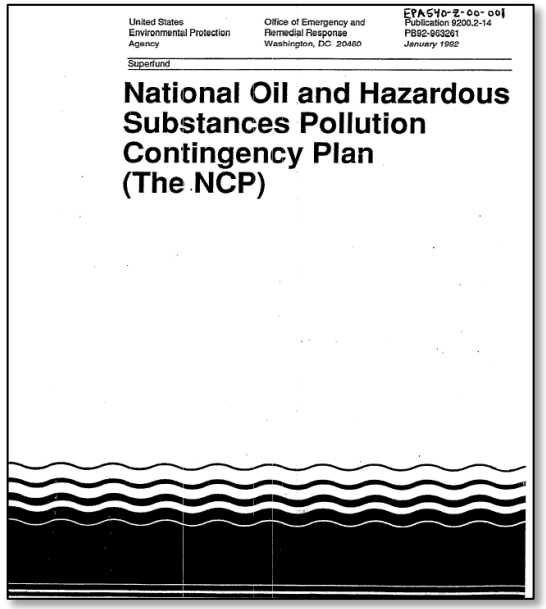
NEWMOA:

The Science of PFAS Conference

Outline

- What and why baseline line risk assessments
- Special issues and challenges for PFAS
- What to implement for successful baseline risk assessments

CERCLA Baseline Risk Assessments


United States Environmental Protection Agency
Office of Emergency and Remedial Response Washington, DC 20460
EPA540-Z-00-001
Publication 9200.2-14
PB92-963201
January 1992
Superfund
National Oil and Hazardous Substances Pollution Contingency Plan (The NCP)

National Contingency Plan (NCP, 1990):

"the lead agency shall conduct a site-specific baseline risk assessment to characterize the current and potential threats to human health and the environment…"

CERCLA Baseline Risk Assessments are RISK BASED to inform future remedial decisions

The Purpose of Baseline Risk Assessments

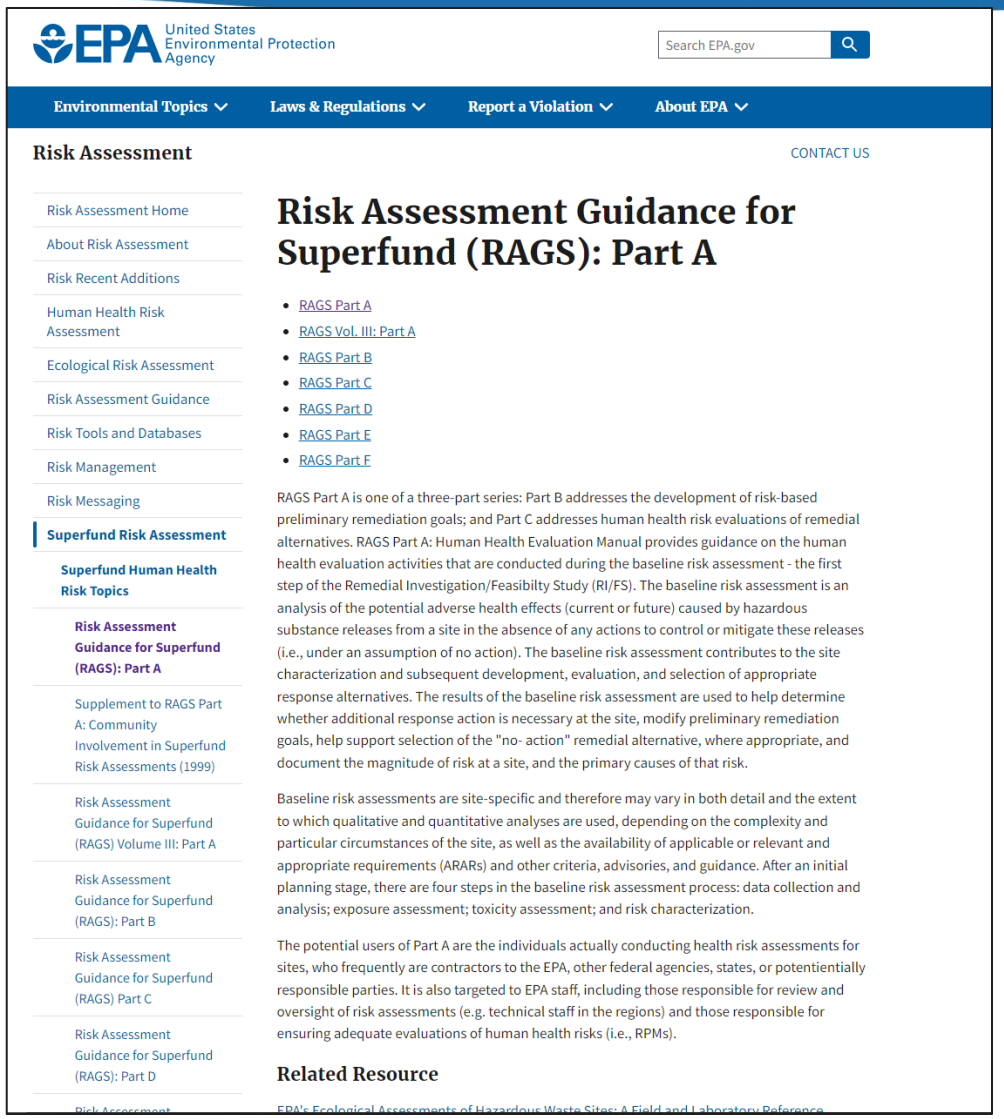
What risk assessments DO:

- Estimate site-specific exposures
- Characterize the probability of potential adverse effects
- Focus evaluation on key chemicals and receptor scenarios
- Guide risk management decisions

What risk assessments DON'T DO:

- Estimate risks to individuals
- Provide firm conclusions about disease, causation or health status
- Represent final remedial decisions
- Define cleanup levels

Plethora of Guidance for Risk Assessments



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Risk Assessment

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- Risk Assessment Home
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- Risk Recent Additions
- Human Health Risk Assessment
- Ecological Risk Assessment
- Risk Assessment Guidance
- Risk Tools and Databases
- Risk Management
- Risk Messaging
- **Superfund Risk Assessment**
  - **Superfund Human Health Risk Topics**
    - **Risk Assessment Guidance for Superfund (RAGS): Part A**
    - Supplement to RAGS Part A: Community Involvement in Superfund Risk Assessments (1999)
    - Risk Assessment Guidance for Superfund (RAGS) Volume III: Part A
    - Risk Assessment Guidance for Superfund (RAGS): Part B
    - Risk Assessment Guidance for Superfund (RAGS) Part C
    - Risk Assessment Guidance for Superfund (RAGS): Part D

Risk Assessment Guidance for Superfund (RAGS): Part A

- RAGS Part A
- RAGS Vol. III: Part A
- RAGS Part B
- RAGS Part C
- RAGS Part D
- RAGS Part E
- RAGS Part F

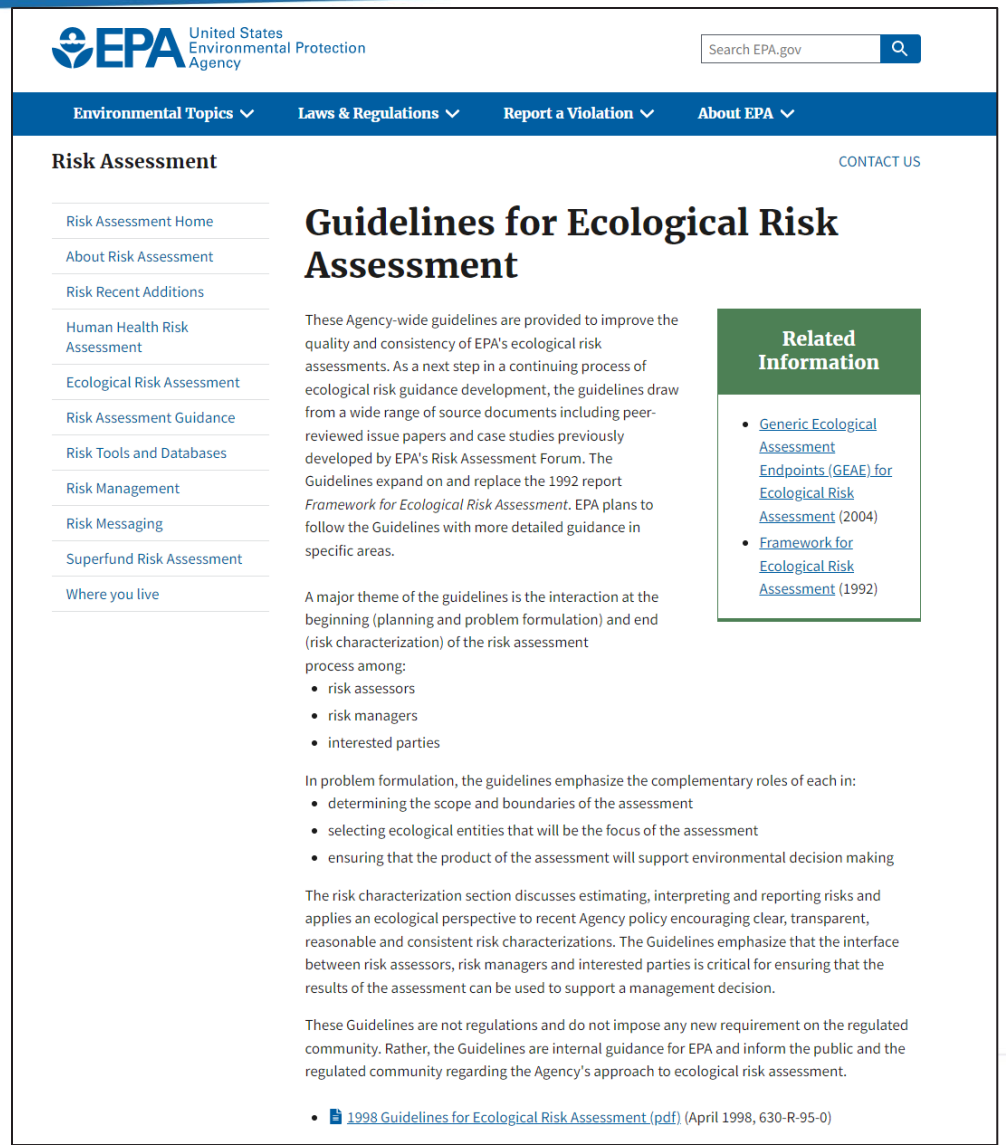
RAGS Part A is one of a three-part series: Part B addresses the development of risk-based preliminary remediation goals; and Part C addresses human health risk evaluations of remedial alternatives. RAGS Part A: Human Health Evaluation Manual provides guidance on the human health evaluation activities that are conducted during the baseline risk assessment - the first step of the Remedial Investigation/Feasibilty Study (RI/FS). The baseline risk assessment is an analysis of the potential adverse health effects (current or future) caused by hazardous substance releases from a site in the absence of any actions to control or mitigate these releases (i.e., under an assumption of no action). The baseline risk assessment contributes to the site characterization and subsequent development, evaluation, and selection of appropriate response alternatives. The results of the baseline risk assessment are used to help determine whether additional response action is necessary at the site, modify preliminary remediation goals, help support selection of the "no- action" remedial alternative, where appropriate, and document the magnitude of risk at a site, and the primary causes of that risk.

Baseline risk assessments are site-specific and therefore may vary in both detail and the extent to which qualitative and quantitative analyses are used, depending on the complexity and particular circumstances of the site, as well as the availability of applicable or relevant and appropriate requirements (ARARs) and other criteria, advisories, and guidance. After an initial planning stage, there are four steps in the baseline risk assessment process: data collection and analysis; exposure assessment; toxicity assessment; and risk characterization.

The potential users of Part A are the individuals actually conducting health risk assessments for sites, who frequently are contractors to the EPA, other federal agencies, states, or potentiently responsible parties. It is also targeted to EPA staff, including those responsible for review and oversight of risk assessments (e.g. technical staff in the regions) and those responsible for ensuring adequate evaluations of human health risks (i.e., RPMs).

Related Resource

EPA's Ecological Assessments of Hazardous Waste Sites: A Field and Laboratory Reference



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- Risk Management
- Risk Messaging
- Superfund Risk Assessment
- Where you live

Guidelines for Ecological Risk Assessment

These Agency-wide guidelines are provided to improve the quality and consistency of EPA's ecological risk assessments. As a next step in a continuing process of ecological risk guidance development, the guidelines draw from a wide range of source documents including peer-reviewed issue papers and case studies previously developed by EPA's Risk Assessment Forum. The Guidelines expand on and replace the 1992 report *Framework for Ecological Risk Assessment*. EPA plans to follow the Guidelines with more detailed guidance in specific areas.

Related Information

- Generic Ecological Assessment Endpoints (GEAE) for Ecological Risk Assessment (2004)
- Framework for Ecological Risk Assessment (1992)

A major theme of the guidelines is the interaction at the beginning (planning and problem formulation) and end (risk characterization) of the risk assessment process among:

- risk assessors
- risk managers
- interested parties

In problem formulation, the guidelines emphasize the complementary roles of each in:

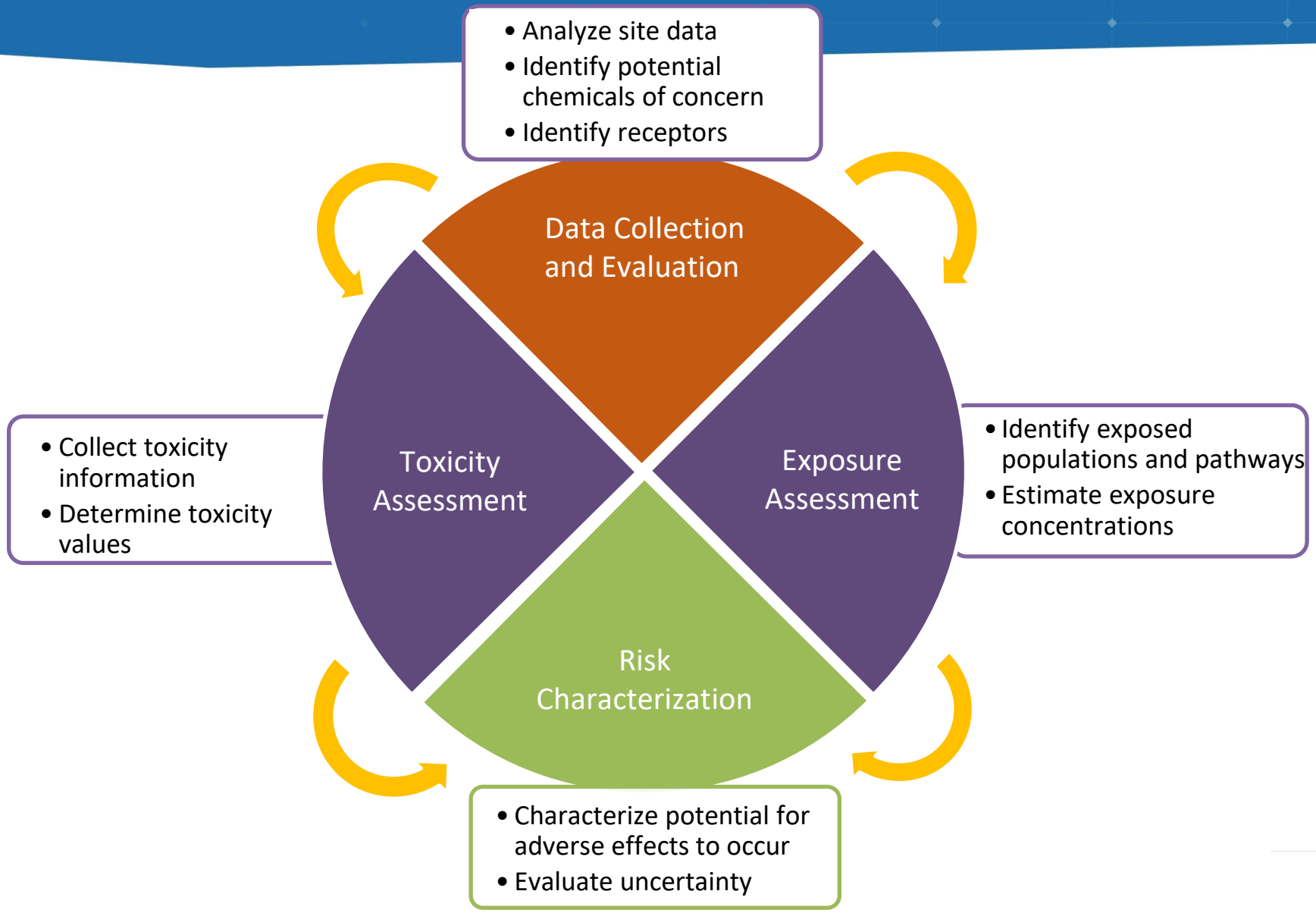
- determining the scope and boundaries of the assessment
- selecting ecological entities that will be the focus of the assessment
- ensuring that the product of the assessment will support environmental decision making

The risk characterization section discusses estimating, interpreting and reporting risks and applies an ecological perspective to recent Agency policy encouraging clear, transparent, reasonable and consistent risk characterizations. The Guidelines emphasize that the interface between risk assessors, risk managers and interested parties is critical for ensuring that the results of the assessment can be used to support a management decision.

These Guidelines are not regulations and do not impose any new requirement on the regulated community. Rather, the Guidelines are internal guidance for EPA and inform the public and the regulated community regarding the Agency's approach to ecological risk assessment.

- 1998 Guidelines for Ecological Risk Assessment (pdf) (April 1998, 630-R-95-0)

General Steps of a Risk Assessment



Challenges with PFAS Risk Assessments

- Dynamic science and regulatory guidance/policies
- Which PFAS and why?
- Which regulation/screening value and why?
- Low ppt detection levels – what is background?
- Complex conceptual site models
- Consideration of mixtures effects and if so, how?
- Precedent-setting decisions
- Risk communication and public perception

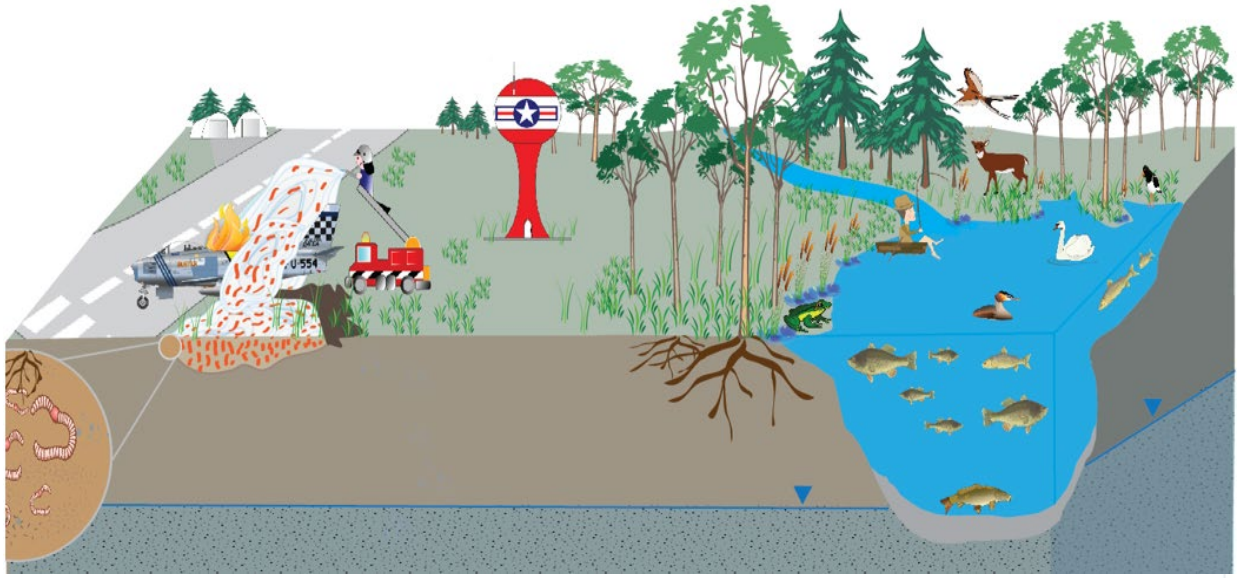
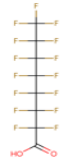


Image courtesy of H. Anderson, AFCEC

Which PFAS and Why?

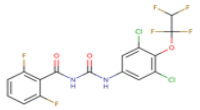
PFAS List	#
EPA's Chemical Dashboard "PFAS Master List"	6,648
Found in industry/commercial products (per EPA)	~600
Academic labs' analyte list	~500
Commercial labs – environmental samples analyte list	~40-70
Standardized method for environmental samples & DW	29 - 40
Toxicity value	~6

Perfluorooctanesulfonic acid
DTXSID:DTXSID3031864
CASRN:1763-23-1
TOXCAST:211/1007



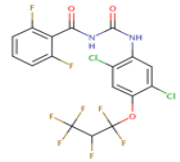
Perfluorooctanoic acid
DTXSID:DTXSID8031865
CASRN:335-67-1
TOXCAST:53/918

Lithium perfluorooctanesulfonate
DTXSID:DTXSID2032421
CASRN:29457-72-5
TOXCAST:33/237

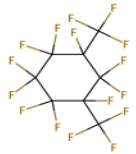


Hexaflumuron
DTXSID:DTXSID3032620
CASRN:86479-06-3
TOXCAST:27/696

N-Ethylperfluorooctanesulfonamide
DTXSID:DTXSID1032646
CASRN:4151-50-2
TOXCAST:125/795



Lufenuron
DTXSID:DTXSID5034357
CASRN:103055-07-8
TOXCAST:46/427



Perfluoro-1,3-dimethylcyclohexane
DTXSID:DTXSID0036926
CASRN:335-27-3
TOXCAST:-

Perfluoroheptanoic acid
DTXSID:DTXSID1037303
CASRN:375-85-9
TOXCAST:30/675

Potassium perfluorooctanesulfonate
DTXSID:DTXSID8037706
CASRN:2795-39-3
TOXCAST:123/707

Potassium perfluorobutanesulfonate
DTXSID:DTXSID3037707
CASRN:29420-49-3
TOXCAST:1/666

Ammonium perfluorooctanoate
DTXSID:DTXSID8037708
CASRN:3825-26-1
TOXCAST:32/676

Potassium perfluorohexanesulfonate
DTXSID:DTXSID3037709
CASRN:3871-99-6
TOXCAST:34/743

Which PFAS and Why?

https://www.apacone.com/environmental-investigations.html

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Data Collection and Evaluation

METHOD (examples)	Date Published	Matrix	Strengths	Limitations
In-house "modified 531/537"	--	Potable & Non-Potable Water, Soil, Sediment, Biosolids, Other	Performance based	· Not an established method
Method 8327	July 2021	Non-Potable Water, Soil, Sediment, Biosolids, Other	None	· Will not meet DoD requirements and is not recommended
Method 1633	**Draft Sept 2021**	**Non-Potable Water, Soil, Sediment, Wastewater, Biosolids, Tissue**	**· Isotope dilution · Expanded suite of analytes (40) · MDLs of 1 – 10 ppt for water · MDLs of 10 – 500 ppt for soil**	**· 40 PFAS only · Isotopically labelled internal standards are only available for 24 of the 40 PFAS**

Which Screening Levels? – Human Health

Data Collection and Evaluation

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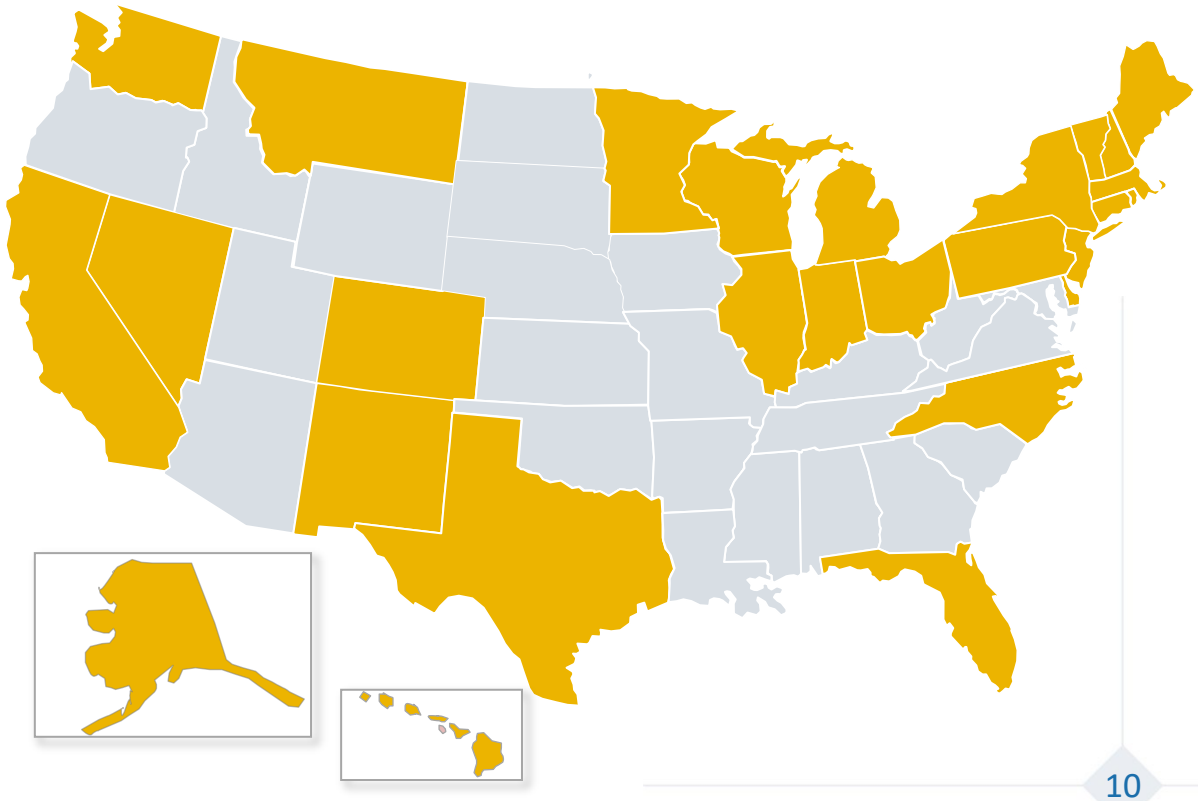
USEPA Regional Screening Levels as of November 2021

	Toxicity Criteria Source	Residential Scenario RBSL			
		Tap Water (µg/L)		Soil (mg/kg)	
		THQ = 0.1	LCR = 1E-06	THQ = 0.1	LCR = 1E-06
PFOA	USEPA (2016)	**0.040**	1.100	**0.130**	7.800
PFOS	USEPA (2016)	**0.040**	NA	**0.130**	NA
PFBS	USEPA (2021)	**0.600**	NA	**1.900**	NA

ATSDR: Groundwater Child Environmental Media Evaluation Guides (EMEGs) (µg/L)	
PFOA	**0.021**
PFOS	**0.014**
PFHxS	**0.140**
PFNA	**0.021**

States with Groundwater and/or Drinking Water PFAS Values



Full list of numbers can be found: https://pfas-1.itrcweb.org/fact-sheets/

Which Screening Levels? – Human Health

Data Collection and Evaluation

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USEPA Regional Screening Levels as of November 2021

Coming soon:
GenX
PFBA
PFHxA …

	ty Criteria ource	Residential Scenario RBSL			
		Tap Water (µg/L)		Soil (mg/kg)	
		THQ = 0.1	LCR = 1E-06	THQ = 0.1	LCR = 1E-06
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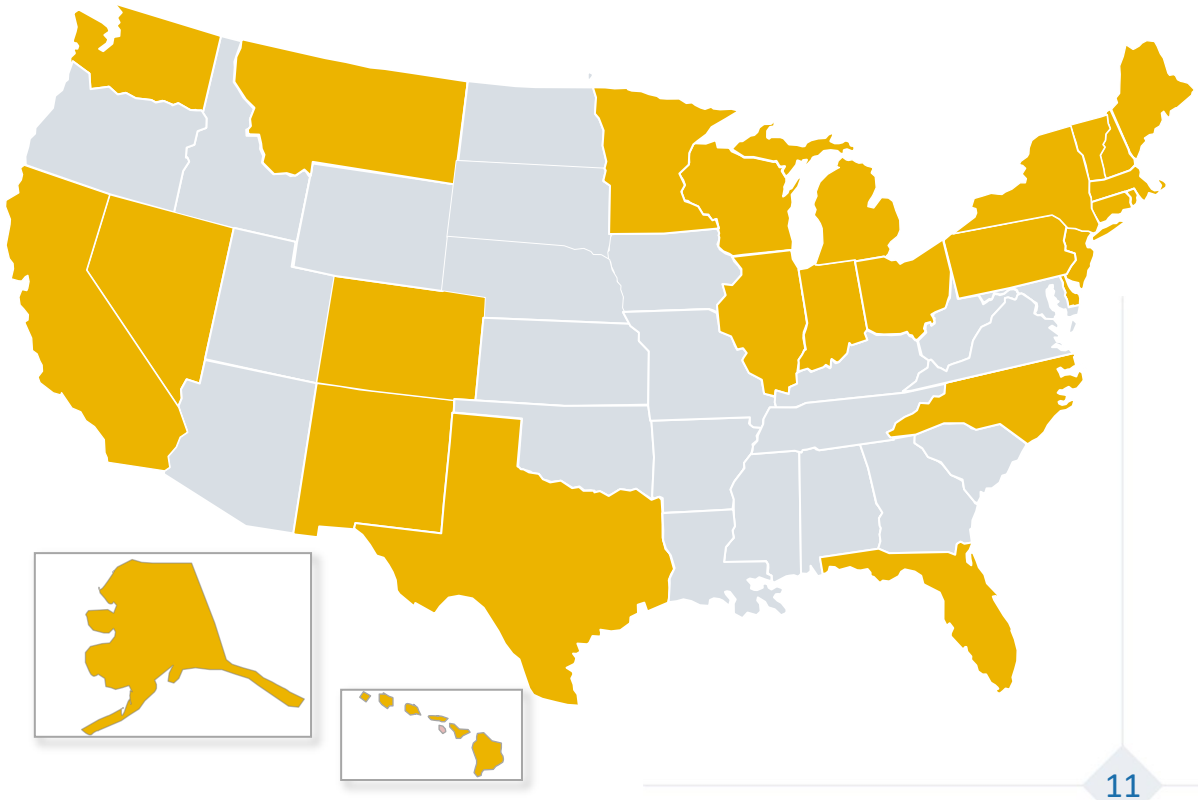


Full list of numbers can be found: https://pfas-1.itrcweb.org/fact-sheets/

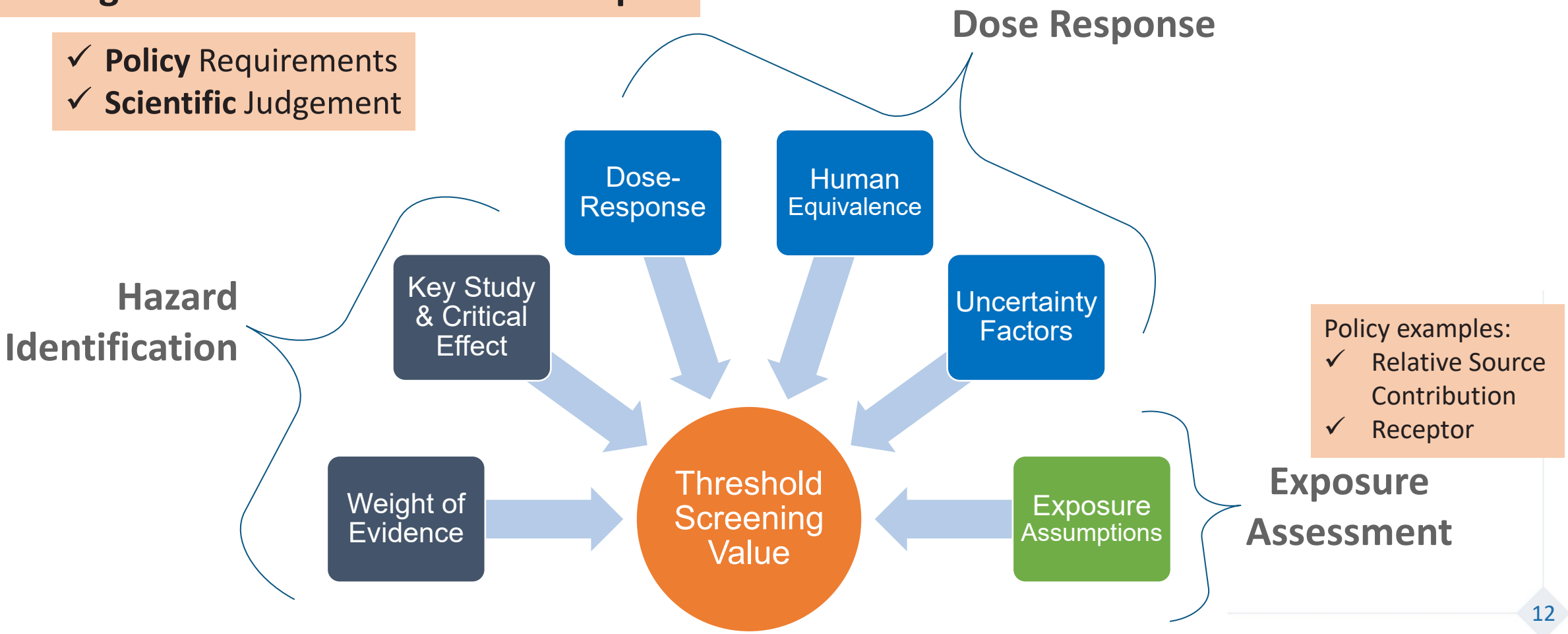
Which Screening Levels? – Human Health

Data Collection and Evaluation

GSI ENVIRONMENTAL

Screening Levels are Not all Created Equal

- ✓ **Policy** Requirements
- ✓ **Scientific** Judgement



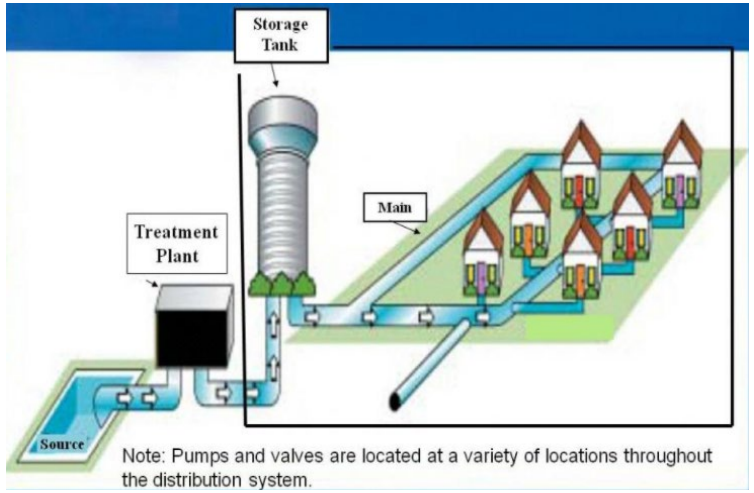
Policy examples:
- ✓ Relative Source Contribution
- ✓ Receptor

When Does the EPA Health Advisory Apply?

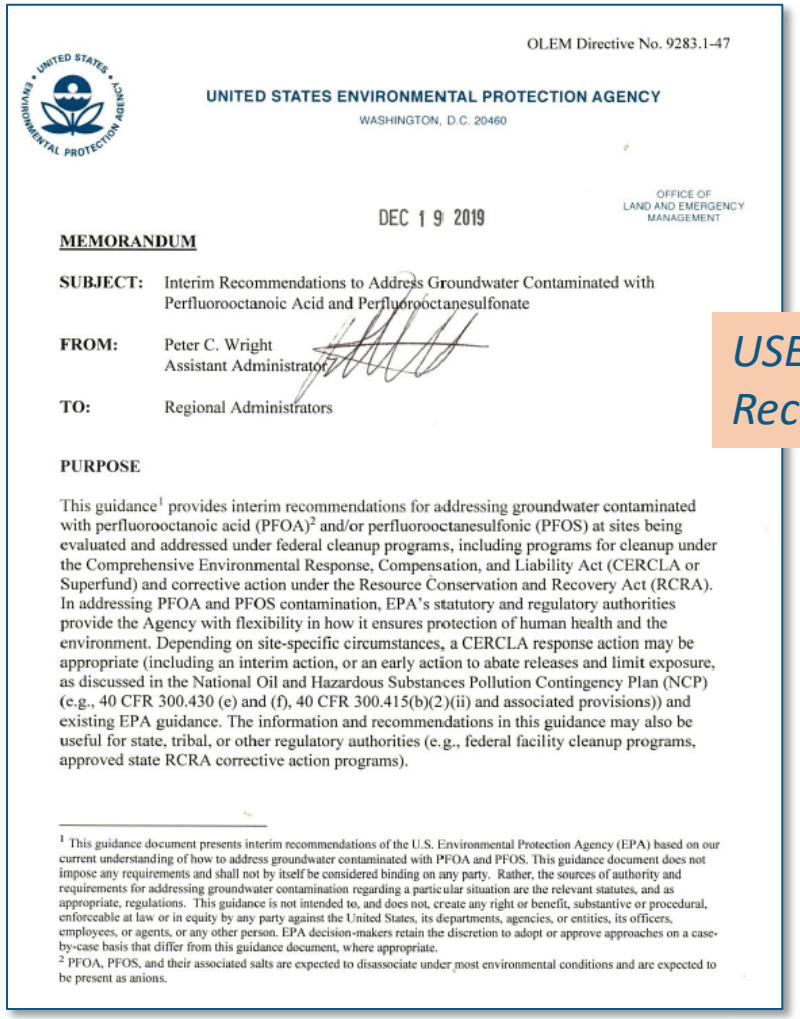
Drinking Water

70 ppt

Municipal Water Distribution System



https://19january2017snapshot.epa.gov/dwsixyearreview/drinking-water-distribution-systems_.html



OLEM Directive No. 9283.1-47

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF LAND AND EMERGENCY MANAGEMENT

DEC 19 2019

MEMORANDUM

SUBJECT: Interim Recommendations to Address Groundwater Contaminated with Perfluorooctanoic Acid and Perfluorooctanesulfonate

FROM: Peter C. Wright
Assistant Administrator

TO: Regional Administrators

PURPOSE

This guidance[1] provides interim recommendations for addressing groundwater contaminated with perfluorooctanoic acid (PFOA)[2] and/or perfluorooctanesulfonic (PFOS) at sites being evaluated and addressed under federal cleanup programs, including programs for cleanup under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund) and corrective action under the Resource Conservation and Recovery Act (RCRA). In addressing PFOA and PFOS contamination, EPA's statutory and regulatory authorities provide the Agency with flexibility in how it ensures protection of human health and the environment. Depending on site-specific circumstances, a CERCLA response action may be appropriate (including an interim action, or an early action to abate releases and limit exposure, as discussed in the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) (e.g., 40 CFR 300.430 (e) and (f), 40 CFR 300.415(b)(2)(ii) and associated provisions)) and existing EPA guidance. The information and recommendations in this guidance may also be useful for state, tribal, or other regulatory authorities (e.g., federal facility cleanup programs, approved state RCRA corrective action programs).

[1] This guidance document presents interim recommendations of the U.S. Environmental Protection Agency (EPA) based on our current understanding of how to address groundwater contaminated with PFOA and PFOS. This guidance document does not impose any requirements and shall not by itself be considered binding on any party. Rather, the sources of authority and requirements for addressing groundwater contamination regarding a particular situation are the relevant statutes, and as appropriate, regulations. This guidance is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person. EPA decision-makers retain the discretion to adopt or approve approaches on a case-by-case basis that differ from this guidance document, where appropriate.

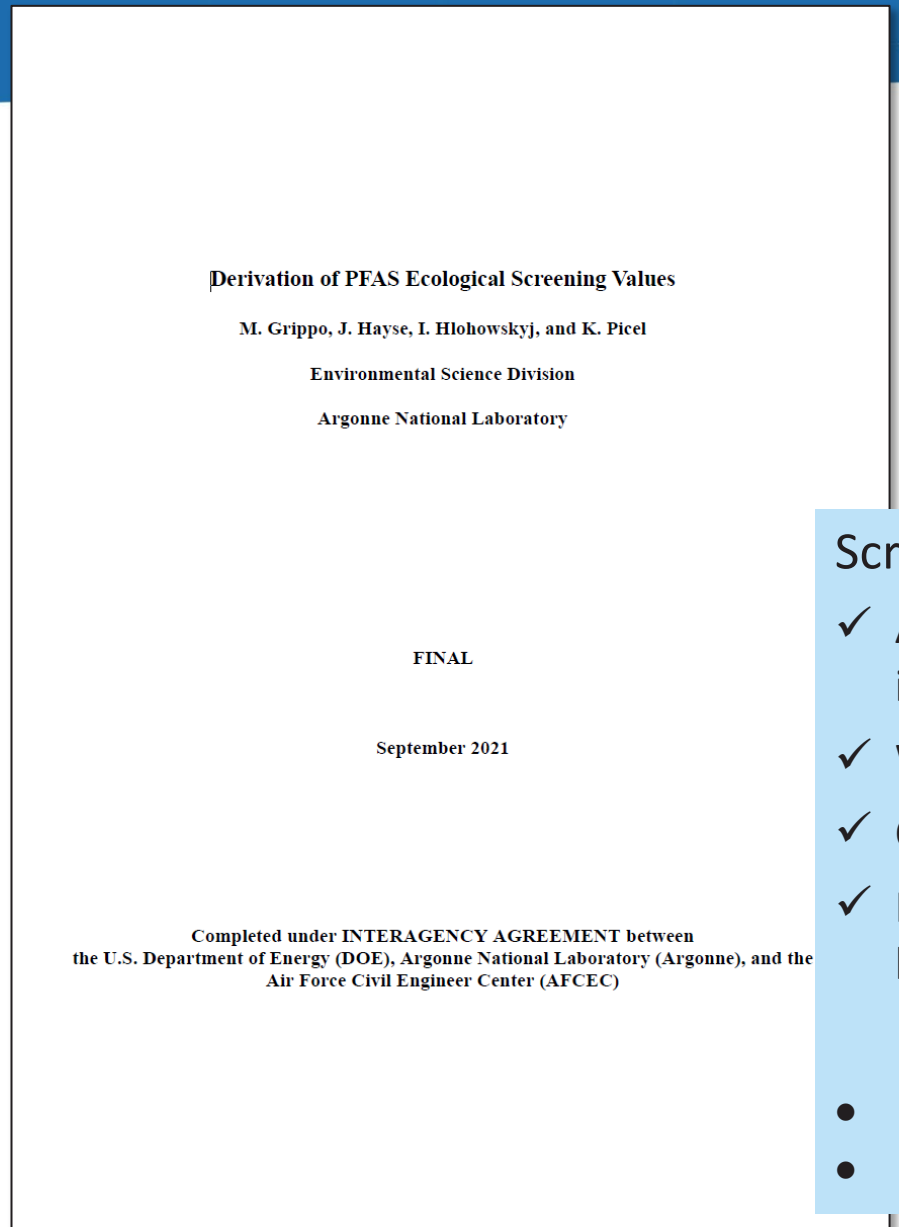
[2] PFOA, PFOS, and their associated salts are expected to disassociate under most environmental conditions and are expected to be present as anions.

USEPA. 2019. Interim Recommendations.

Which Screening Levels? - Eco

Data Collection and Evaluation

1. Literature
   - Conder et al., 2019 (SERDP)
   - Divine et al., 2020 (SERDP)
2. Argonne National Lab (2021)
3. SFRWQCB Environmental Screening Levels
4. U.S. EPA (2023?)



Derivation of PFAS Ecological Screening Values

M. Grippo, J. Hayse, I. Hlohowskyj, and K. Picel

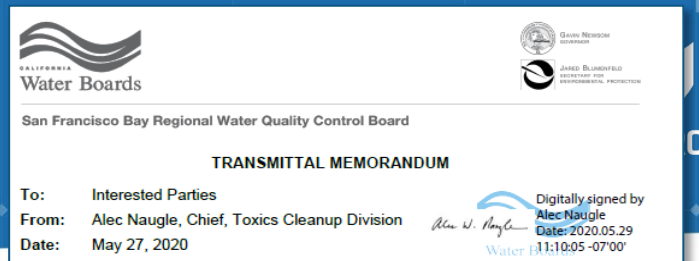
Environmental Science Division

Argonne National Laboratory

FINAL

September 2021

Completed under INTERAGENCY AGREEMENT between
the U.S. Department of Energy (DOE), Argonne National Laboratory (Argonne), and the
Air Force Civil Engineer Center (AFCEC)



Water Boards

San Francisco Bay Regional Water Quality Control Board

TRANSMITTAL MEMORANDUM

To: Interested Parties

From: Alec Naugle, Chief, Toxics Cleanup Division

Date: May 27, 2020

Digitally signed by Alec Naugle Date: 2020.05.29 11:10:05 -07'00'

Subject: Transmittal of Interim Final Environmental Screening Levels (ESLs) for Two Per- and Polyfluoroalkyl Substances (PFAS): Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoate (PFOA)

Introduction

The State Water B
Water (DDW), in c
approach to evalu
throughout Califor
commercial airport
plan to send simila
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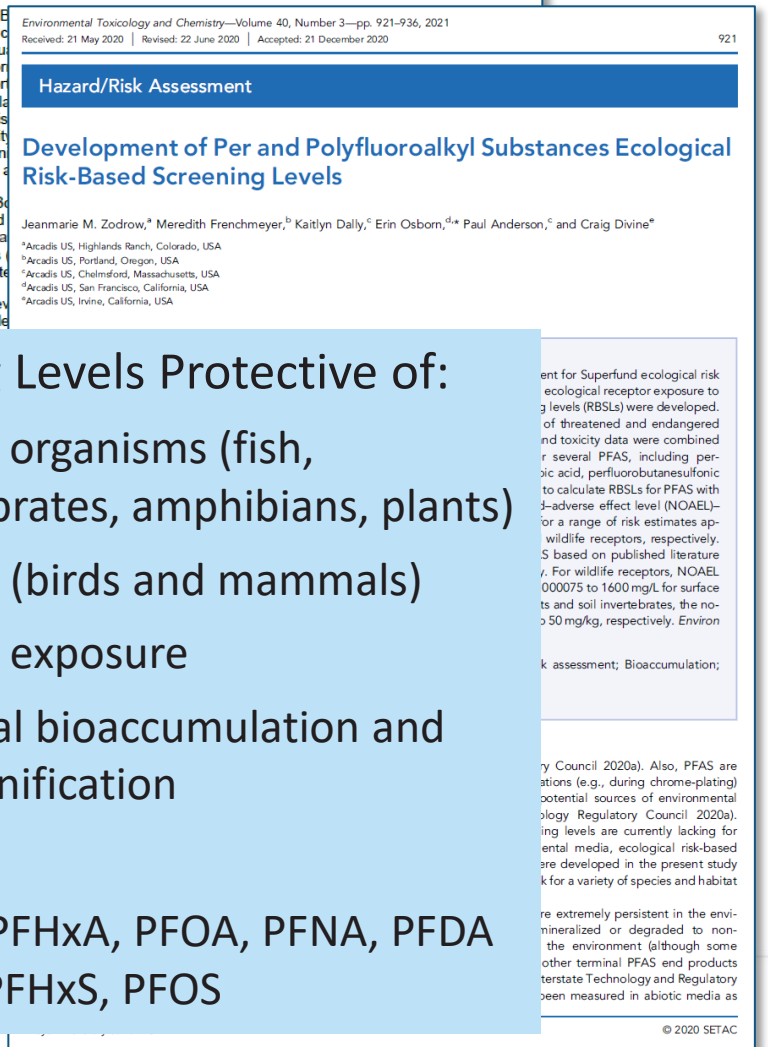
for continued mon
grows and PFAS a

Regional Water Bo
levels are needed
environment. To a
Screening Levels
perfluorooctanoate

Our ESL team dev
review of available



Environmental Toxicology and Chemistry—Volume 40, Number 3—pp. 921–936, 2021

Received: 21 May 2020 | Revised: 22 June 2020 | Accepted: 21 December 2020 921

Hazard/Risk Assessment

Development of Per and Polyfluoroalkyl Substances Ecological Risk-Based Screening Levels

Jeanmarie M. Zodrow,[a] Meredith Frenchmeyer,[b] Kaitlyn Dally,[c] Erin Osborn,[d,*] Paul Anderson,[c] and Craig Divine[e]

[a]Arcadis US, Highlands Ranch, Colorado, USA
[b]Arcadis US, Portland, Oregon, USA
[c]Arcadis US, Chelmsford, Massachusetts, USA
[d]Arcadis US, San Francisco, California, USA
[e]Arcadis US, Irvine, California, USA

ent for Superfund ecological risk
ecological receptor exposure to
g levels (RBSLs) were developed.
of threatened and endangered
nd toxicity data were combined
r several PFAS, including per-
ic acid, perfluorobutanesulfonic
to calculate RBSLs for PFAS with
l–adverse effect level (NOAEL)–
or a range of risk estimates ap-
wildlife receptors, respectively.
S based on published literature
. For wildlife receptors, NOAEL
000075 to 1600 mg/L for surface
ts and soil invertebrates, the no-
50 mg/kg, respectively. *Environ*

k assessment; Bioaccumulation;

y Council 2020a). Also, PFAS are
ations (e.g., during chrome-plating)
potential sources of environmental
ology Regulatory Council 2020a).
ing levels are currently lacking for
ental media, ecological risk-based
re developed in the present study
k for a variety of species and habitat

re extremely persistent in the envi-
nineralized or degraded to non-
the environment (although some
other terminal PFAS end products
terstate Technology and Regulatory
been measured in abiotic media as

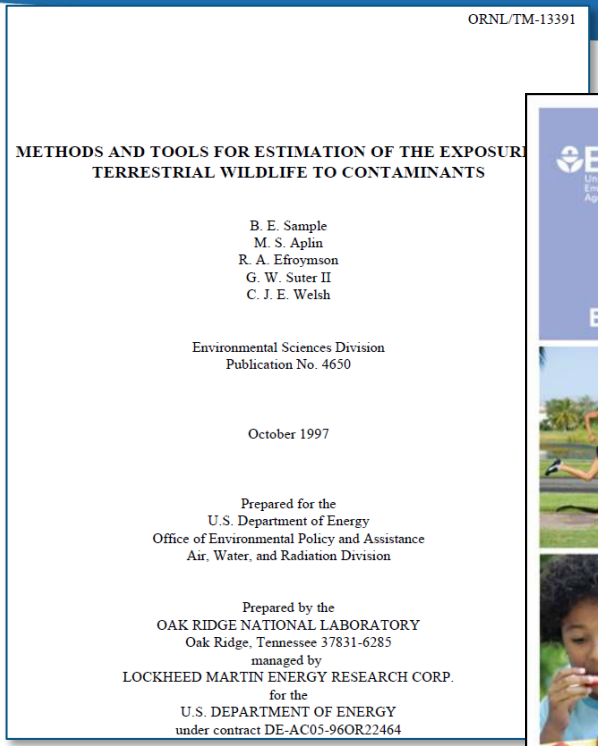
© 2020 SETAC

Screening Levels Protective of:

- ✓ Aquatic organisms (fish, invertebrates, amphibians, plants)
- ✓ Wildlife (birds and mammals)
- ✓ Chronic exposure
- ✓ Potential bioaccumulation and biomagnification

- PFBA, PFHxA, PFOA, PFNA, PFDA
- PFBS, PFHxS, PFOS

Exposure Assessment


ORNL/TM-13391

METHODS AND TOOLS FOR ESTIMATION OF THE EXPOSURE
TERRESTRIAL WILDLIFE TO CONTAMINANTS

B. E. Sample
M. S. Aplin
R. A. Efroymson
G. W. Suter II
C. J. E. Welsh

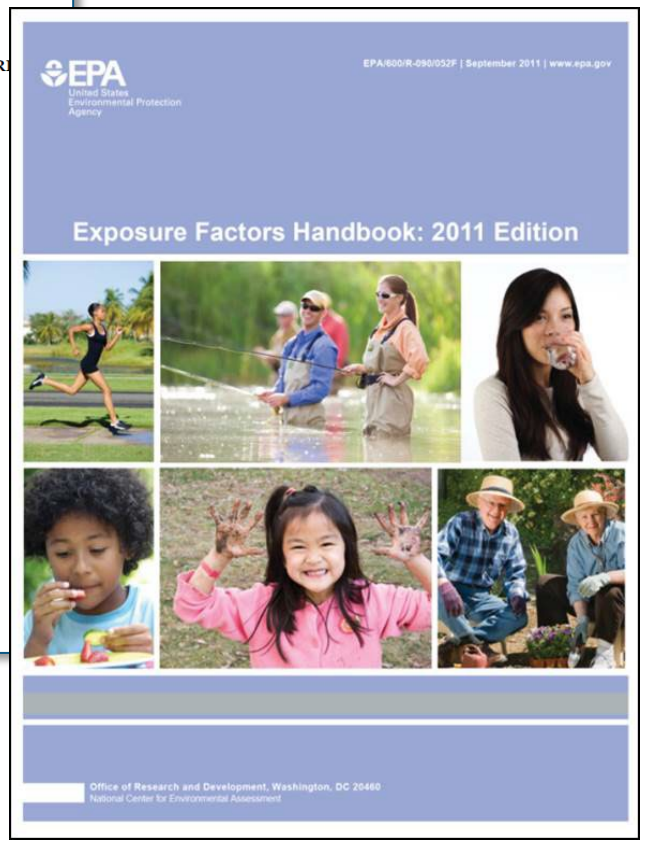
Environmental Sciences Division
Publication No. 4650

October 1997

Prepared for the
U.S. Department of Energy
Office of Environmental Policy and Assistance
Air, Water, and Radiation Division

Prepared by the
OAK RIDGE NATIONAL LABORATORY
Oak Ridge, Tennessee 37831-6285
managed by
LOCKHEED MARTIN ENERGY RESEARCH CORP.
for the
U.S. DEPARTMENT OF ENERGY
under contract DE-AC05-96OR22464

Oak Ridge National Laboratory 1997



USEPA 2011 (and updates)

- Human health

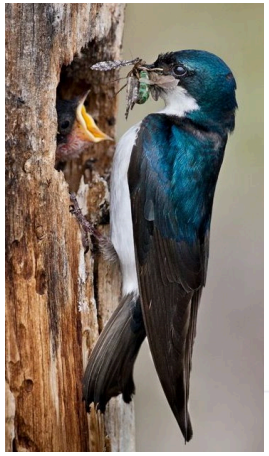
  2 L /day = 6.5 glasses of water …

  …everyday for 30 years

- Avian insectivore

Diet: 20 g insects/day

Water: 0.004 L/day



Human Health Exposure Pathways for PFAS

Exposure Assessment

GSI ENVIRONMENTAL

Residential use of groundwater as “tapwater”

Backyard garden and chickens

In utero exposure

Recreation use of surface water

Consumption of fish

Direct contact with soil

Consumption of wild game

Human Health Conceptual Site Model

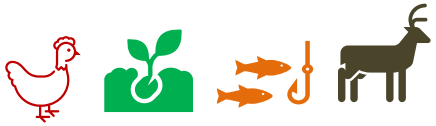
Contaminant Source → Environmental Media → Exposure Routes → Human Health Receptors

PFAS release area

Groundwater

Surface water/Sediment

Soil



Plants and Wildlife

Ingestion

Dermal

Inhalation

- Commercial/industrial workers
- Construction workers
- Trespasser/visitor
- Resident (adult + child)
- Hunter
- Angler
- Recreator

Human Health Conceptual Site Model

GSI ENVIRONMENTAL

Contaminant Source → Environmental Media → Exposure Routes → Human Health Receptors

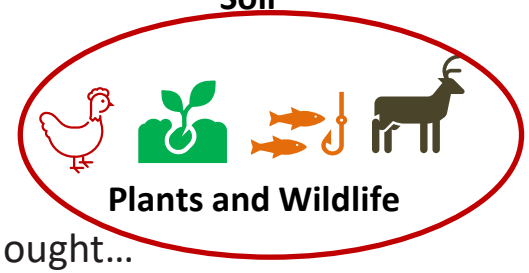
PFAS release area

Environmental Media

Groundwater

Surface water/Sediment

Soil



Plants and Wildlife

Exposure Routes

Ingestion

Dermal

Inhalation

Human Health Receptors

- Commercial/industrial workers
- Construction workers
- Trespasser/visitor
- Resident (adult + child)
- Hunter
- Angler
- Recreator

Hold this thought…

Ecological Conceptual Site Model

Contaminant Source → Environmental Media → Exposure Routes → Representative Ecological Receptors

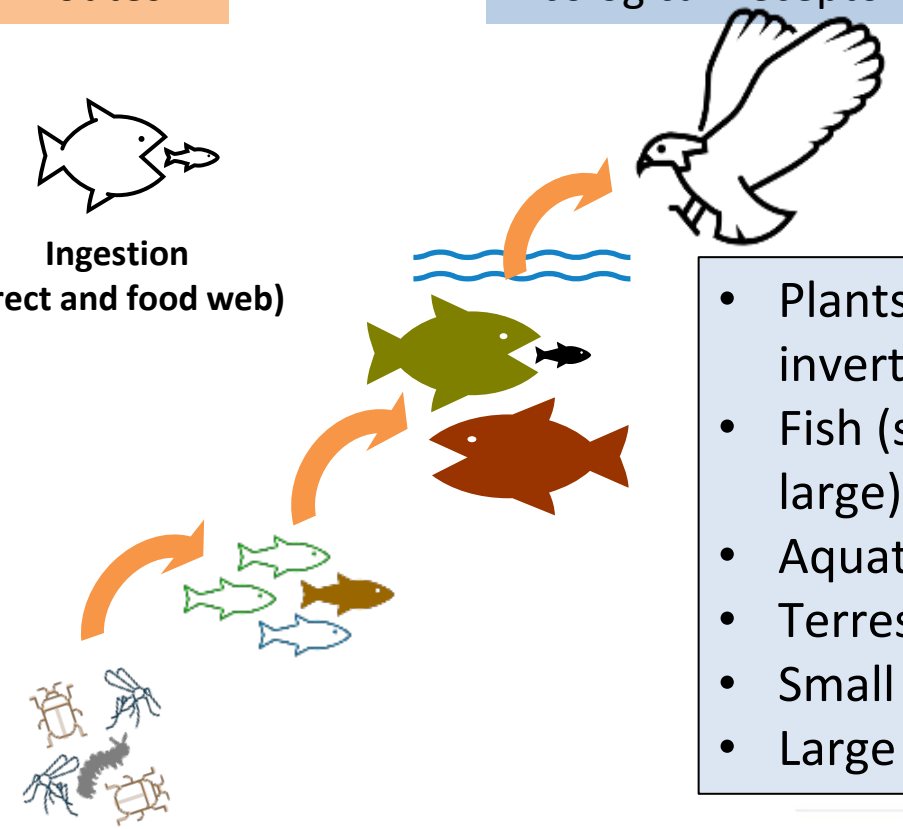
Project area: PFAS releases

Surface water / Sediment

Soil

Food Web

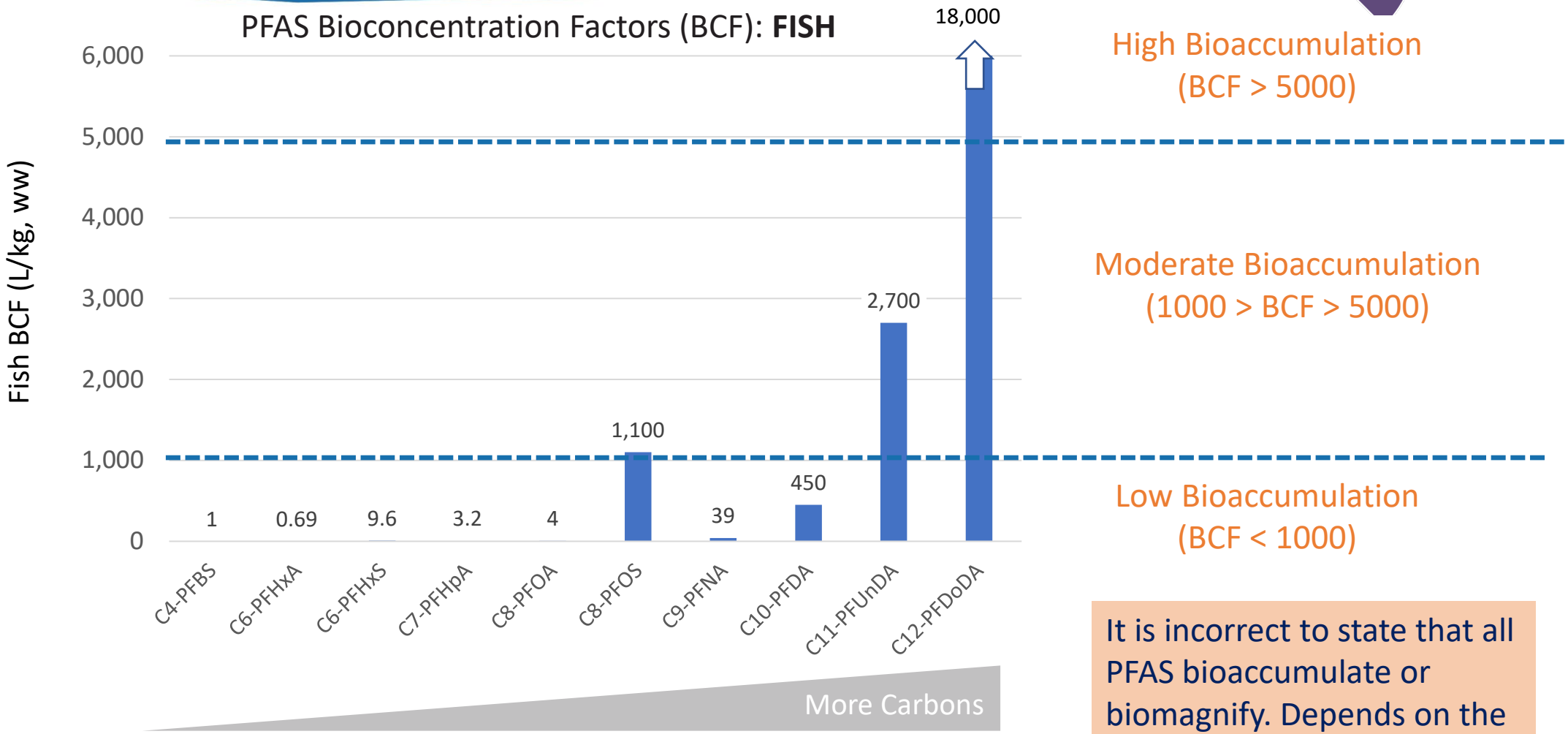
Ingestion (direct and food web)



- Plants and invertebrates
- Fish (small, medium, large)
- Aquatic birds
- Terrestrial birds
- Small mammals
- Large mammals

PFAS Uptake into Plants/Animals

GSI ENVIRONMENTAL



High Bioaccumulation
(BCF > 5000)

Moderate Bioaccumulation
(1000 > BCF > 5000)

Low Bioaccumulation
(BCF < 1000)

It is incorrect to state that all PFAS bioaccumulate or biomagnify. Depends on the PFAS and the biotic media.

Source:
1. U.S Department of Defense (DoD) Strategic Environmental Research and Development Program (SERDP). **2019.** Guidance for Assessing Ecological Risks of PFAS to Threatened and Endangered Species at Aqueous Film Forming Foam-Impacted Sites. SERDP Project ER18-1614.

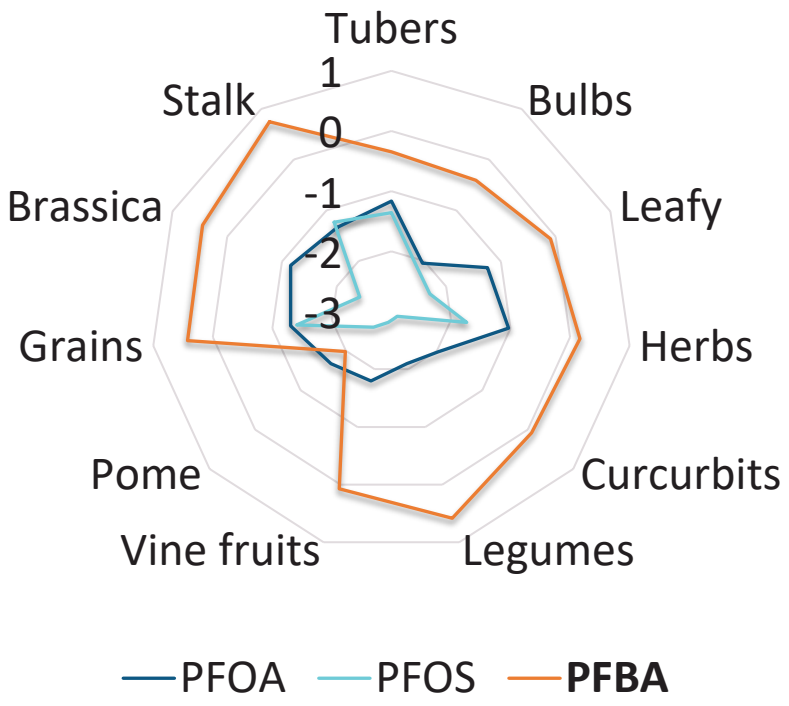
Variability for PFAS Uptake – Site-specific Information Will Be Key

Exposure Assessment

GSI ENVIRONMENTAL

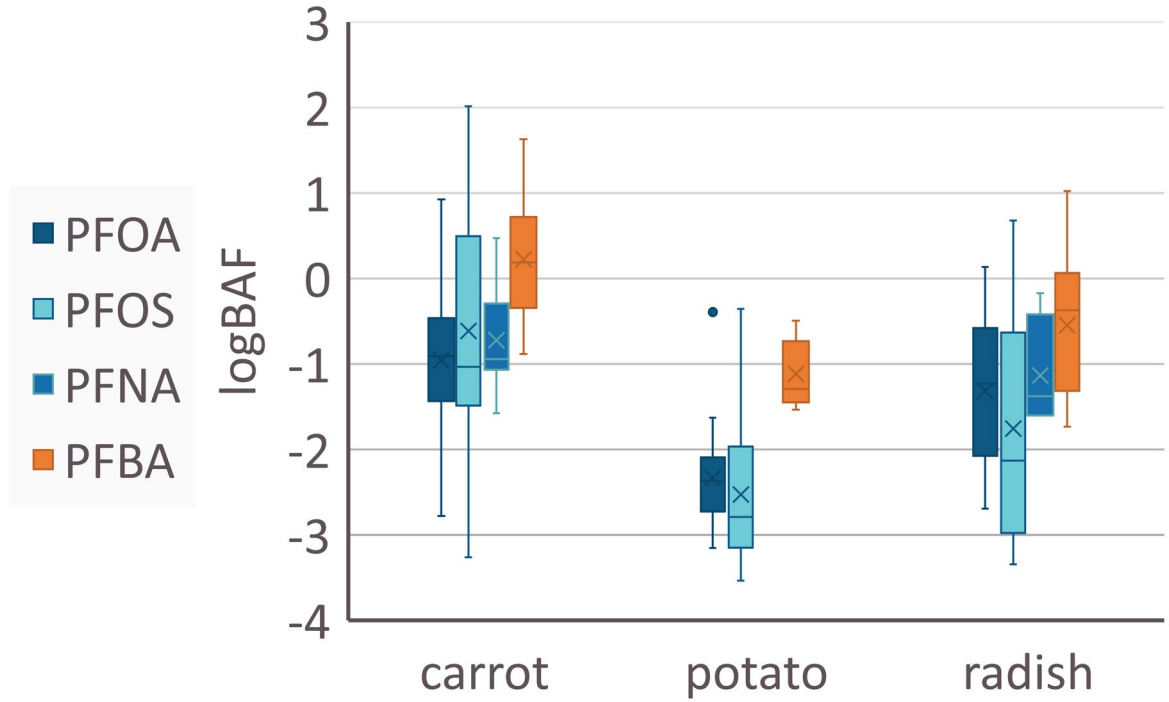
It is incorrect to state that all PFAS bioaccumulate or biomagnify. **Depends on the PFAS and the biotic media.**

Median logBAF per Food Commodity



Spider plot of median logBAF for PFOA, PFOS, and PFBA. BAF is highest for PFBA for most crops. Lowest BAF for PFBA is for tree fruits (apples).

BAFs for FCID Group 1 – Roots/Tubers



Within-group comparisons using box-and-whisker plots.

Toxicity Assessment – Selection of Tox Criteria

SERDP ESTCP
DOD • EPA • DOE
DoD's Environmental Research Programs

EPA's REQUIREMENTS

- ☑ State-of-science methods, consistent with EPA guidance
- ☑ Transparent derivation
- ☑ Most current science
- ☑ Peer-reviewed
- ☑ Comprehensive, not cherry-picked

Human Health Hierarchy of Tox Value Sources

*Rapidly changing – consult an expert!

Tier 1

EPA Integrated Risk Information System (IRIS)

Tier 2

EPA Peer-Reviewed Provisional Toxicity Values

Tier 3

- Agency for Toxic Substances and Disease Registry
- Other EPA offices (e.g., Office of Water)
- States, International Agencies

PFBA GenX
PFHxA PFNA
PFHxS PFDA

PFBS

PFOA PFOS
PFHxS PFHxA

Quantify Risks and Identify Uncertainties

Risk Characterization

$$\text{Average Daily Dose} = \frac{\text{Concentration} \times \text{Ingestion Rate} \times \text{Bioavailable Fraction} \times \text{Exposure Frequency} \times \text{Exposure Duration}}{\text{Body Weight} \times \text{Averaging Time}}$$

Toxicity Factor (in amount per day)

Taking into account:

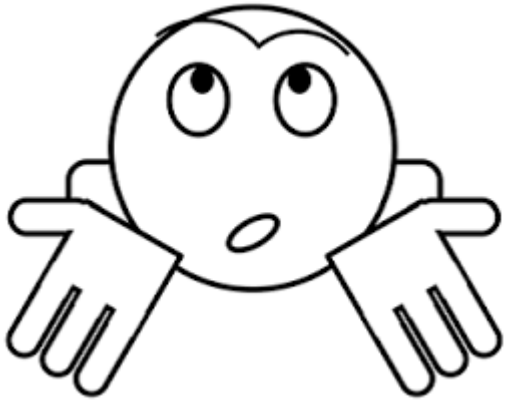
- Chemical concentration
- Chemical characteristics (such as bioavailability: how much reaches the target organs)
- Exposure:
  - What pathways/routes?
  - How frequent? – Exposure frequency
  - How long? – Exposure duration

Quantify Risks and Identify Uncertainties

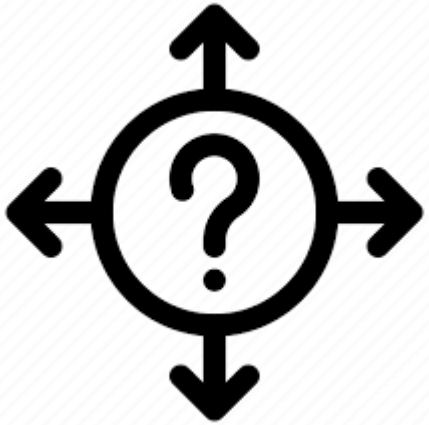
Risk Characterization

GSI ENVIRONMENTAL

Qualitative



PFAS without tox values
Sampling design
Receptor evaluation



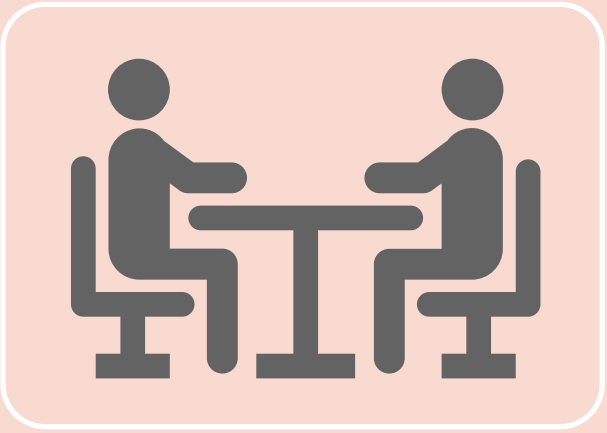
Uncertainties are inherent in RAs and cannot be eliminated;

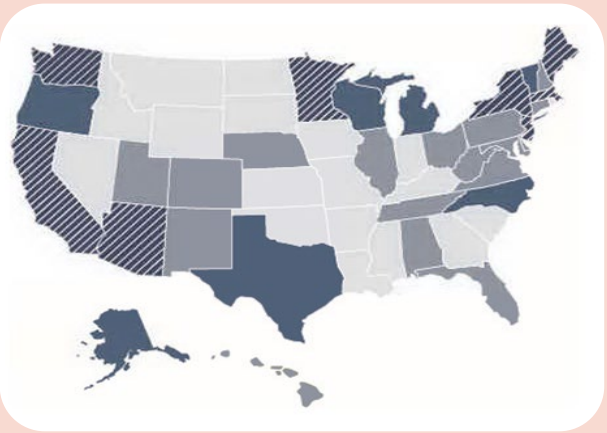
however, the magnitude and impact of some uncertainties can be estimated by using upper and lower bound point estimates and/or by the use of probabilistic methods.

Quantitative

Choice of tox value
Exposure assumptions

Wrap Up





Scope and Methods

- Risk assessors need to be involved in data DQOs (target analytes, MDLs, media sampled)
- Work Plan: Need to develop transparent decision logic

Dynamic Science and Regulations

- Must stay on top of literature
- Regulatory information to watch: CA, EPA
- Consult with experts

Food Web Risk Drivers

- Understanding site-specific exposures and trophic transfer will be key