October 4, 2021

DEQ and DHHS Secretaries' Science Advisory Board Meeting

DEQ Emerging Contaminants Framework

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Topics Covered

- **Components of the DEQ Framework**
- **PFAS Example: Activities/Initiatives Associated with the Framework**
- **PFAS Regulatory Path Options**
  - **Questions for the SSAB**

Emerging Contaminants Framework

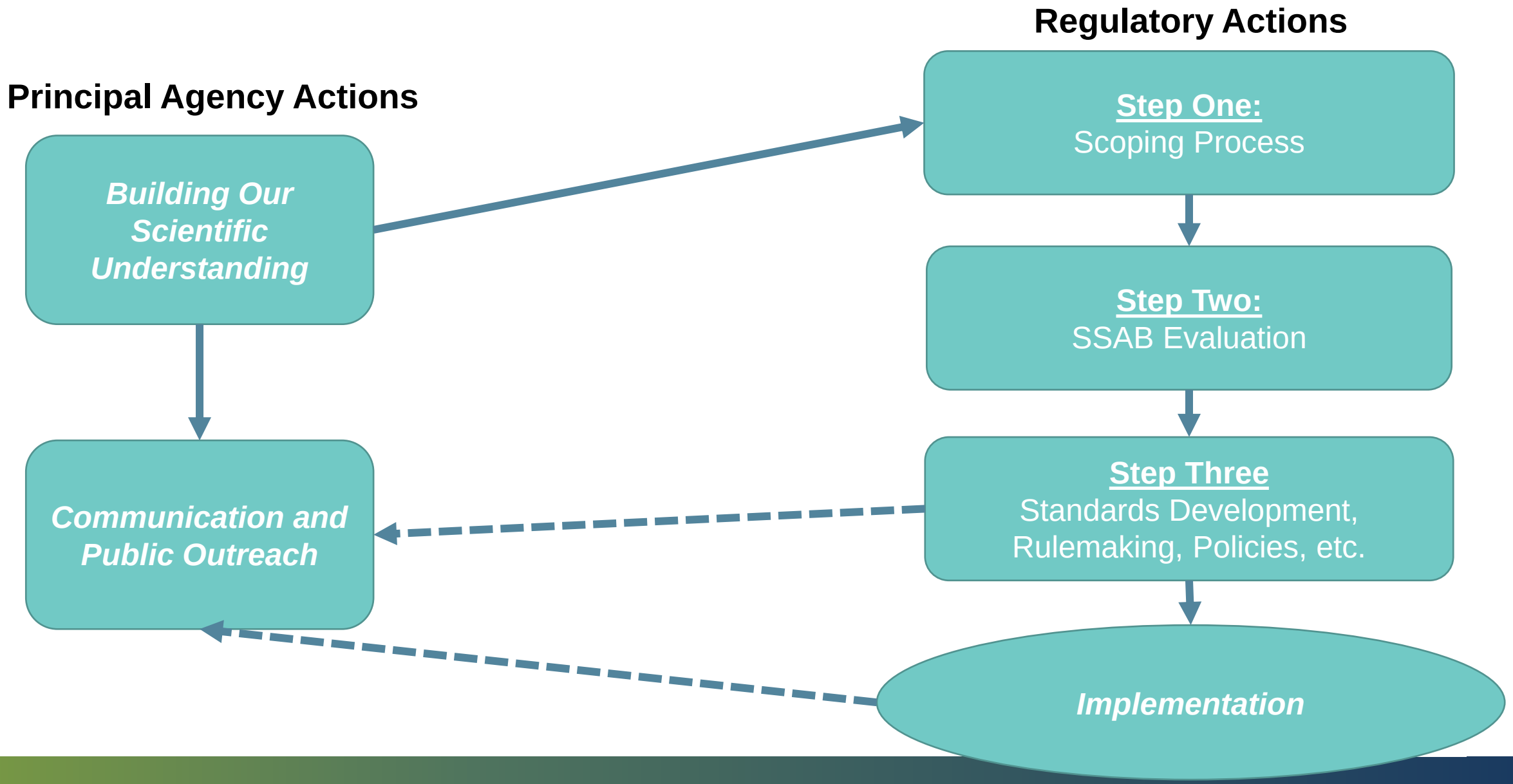
Goal Statement:

- Protect North Carolinians from sources of emerging contaminants (EC) and related exposures using an established transparent and science-based decision-making process.

Objectives:

- **One Year (2021-2022) –** Work with experts in the fields related to emerging contaminants to initiate actions within DEQ's authority to protect the environment and public health.
- **Beyond 2022 –** Utilize new and developing scientific data and other findings to address contamination from both point and non-point sources to reduce exposures and protect public health.

Key Components of the Framework



Emerging Contaminants Framework: Principal Agency Actions

A. Continuous Data Collection and Building our Scientific Understanding of ECs in NC

- DEQ formulates and implements a multimedia program to increase our understanding of the science around the Emerging Compound in question in terms of:
  - Extent of contamination,
  - Sources of pollution, and
  - Associated risk.
- Identifying/addressing unanswered questions, data gaps, and the need for additional expertise.
- Leveraging external partnerships with federal and state agencies.
- Utilizing toxicity assessments, standards development and regulatory actions taken at both the federal level and within other states for application to NC as appropriate.
- Results are synthesized and utilized in Step 1 of the regulatory framework.
- DEQ regulatory divisions use existing authority to increase monitoring and data reporting and take permitting actions that reduce emissions and/or discharges.

Emerging Contaminants Framework: Principal Agency Actions

B. Communication, Education, and Outreach

- DEQ develops streamlined risk communications protocols for engaging, communicating, and educating within state government and the regulated community in a consistent fashion.
- DEQ uses the information gleaned throughout this process to create educational and outreach materials for the public related to the ECs in their communities.
    - Central website, GIS mapping, and other resources
    - Enhanced public engagement in policy proposals and rulemaking (e.g., listening sessions, public comment periods)
    - Incorporation of environmental justice and health equity into risk communication

Emerging Contaminants Framework: Stepwise Regulatory Actions

Step 1: Scoping Process

- Use of data and information gathered from DEQ's ongoing principal actions to a path towards regulatory action(s).
    - Includes examination of existing literature, measurement data, regulatory measures from other states, and guidance from federal agencies.
- Where required, DEQ examines currently available information and builds a story to present to the Secretaries Science Advisory Board (SSAB) for guidance in synthesizing this information into public health protection measures for air, water, and land.

Emerging Contaminants Framework: Stepwise Regulatory Actions

Step 2: SSAB Evaluation (as required)

- A specific charge for the SSAB is developed based on the Scoping Process.
  - Charge is specific to each EC.
  - SSAB assists the agency by evaluating the relevant toxicological science through literature review, chemical prioritization, routes of exposure, and/or derivation of potential values for regulatory action.
- SSAB presents a recommendation that is protective of public health and the environment.

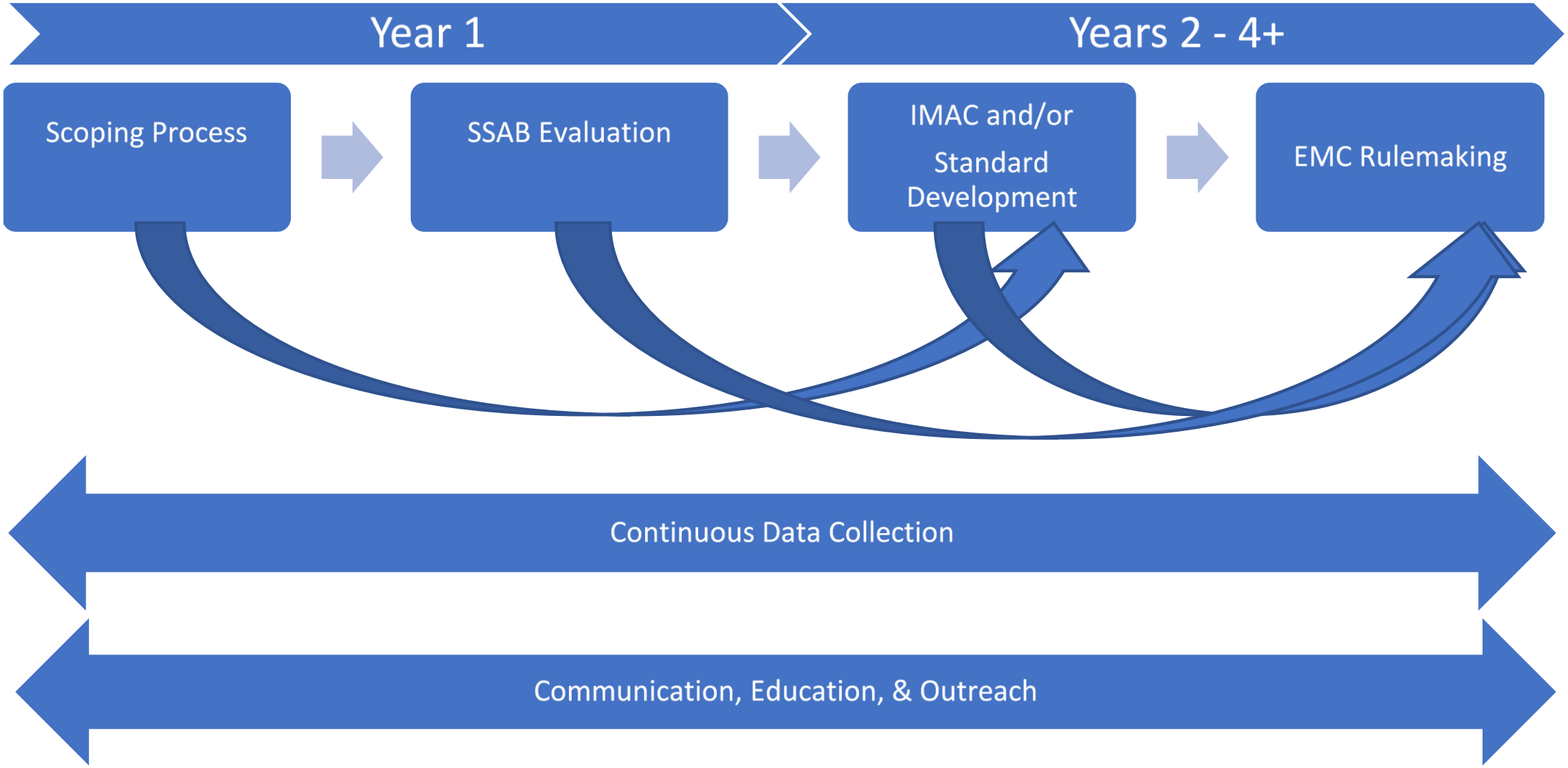
Emerging Contaminants Framework: Stepwise Regulatory Actions

Step 3: Standards Development & Rulemaking Process

- DEQ regulatory divisions develop and implement environmental quality standards for compliance and to protect public health and the environment.
  - Utilizes SSAB's recommendation.
  - Environmental Management Commission (EMC) takes action to adopt a regulatory standard
    1. DEQ division proposes a concept to the EMC for consideration
    2. DEQ division presents draft rules and a regulatory impact analysis/fiscal note to the EMC
    3. EMC votes to proceed to public notice and hearing
    4. EMC votes to adopt the rules
    5. Rules Review Commission approves/disapproves the final rules
    6. Rules go in effect right away or undergo a legislative review
  - DWR also has the authority to develop Interim Maximum Allowable Concentrations (IMAC)
    - Brought to the EMC for adoption at the next review cycle.
- DEQ divisions incorporate the standards into permits and conduct compliance assistance & enforcement activities.
- DHHS has the authority to establish provisional health goals for ECs in drinking water.

Emerging Compound Timeline

A conceptual timeline indicating the estimated times of each step in the Framework, arrows indicate concurrent activities.



Principal Agency Actions
PFAS Example

➢ Data Collection

- Standardize environmental sampling and analytical methods to ensure consistency across private and public entities
- Develop statewide, multi-media ambient sampling programs to determine PFAS levels into the air, land, and waters of NC.
  - Surface water testing
  - Groundwater testing
  - Testing of public and private water supplies
  - Testing of fish and wildlife
  - Characterization in biosolids, waste, leachate, and sediment
- Identify and prioritize likely known PFAS sources
  - Direct manufacturers of raw materials
  - Direct uses in industrial applications (e.g., fire fighting foam application at airports, military uses)
  - Materials usage in manufacturing process
  - Secondary sources (e.g., landfills, wastewater treatment plants)
  - Emergency response to prevent chemical fires
  - Site-specific investigations
  - Data to be reported to EPA under TSCA by manufacturers and importers of PFAS and PFAS-containing products
  - Data to be reported to EPA under UCMR5 on 29 PFAS compounds in drinking water intakes
- Evaluate disclosure and monitoring requirements for permit holders on PFAS discharges, emissions, and other releases.
- Evaluate control and/or treatment technology options, effectiveness, and associated Costs.

Principal Agency Actions: PFAS Example

➢ Data Mapping

- Map and prioritize locations for sampling through a documented, transparent, and reproducible process
- Build a database to house collected information on:
  - PFAS sources
  - Impacted environment and/or natural resources (e.g., waterways, well water, land parcel)
  - Extent of exposure and risk to the public
- Maintain central repository of information with public access
- Interactive GIS mapping capability

➢ Collaborative Partnerships

- Information and knowledge sharing
- Applied research related to fate and transport, toxicities, analytical methods, treatment, etc.
- Innovation hubs to bring forth remedial and treatment technology solutions
- Examples:
  - Research and university partners
  - Federal agencies
  - Firefighting groups, municipal airports, military bases
  - Private sector, local governments, volunteer groups, community advocates

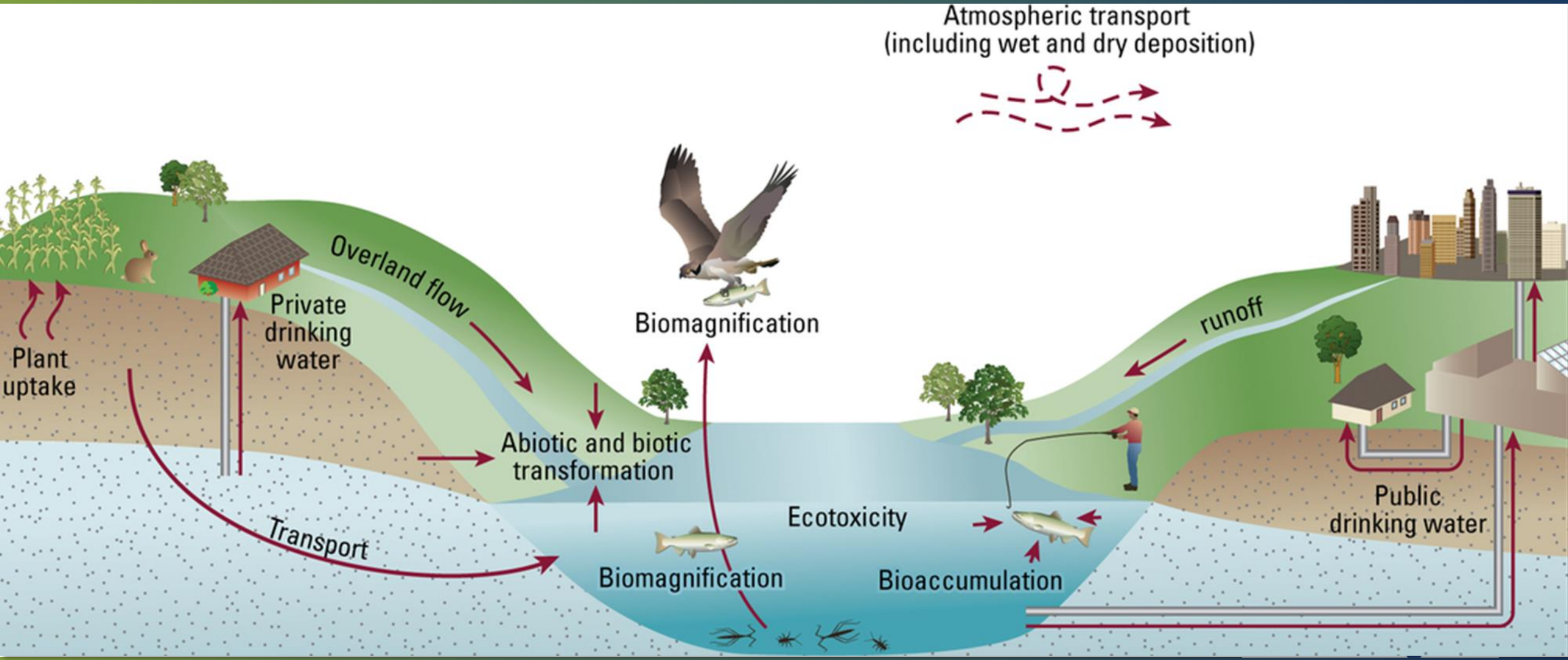
Stepwise Regulatory Actions
PFAS Example

- Science-Based Environmental Standards Development for PFAS Mitigation and Treatment
  - Groundwater quality standards
  - Surface water quality standards

The PFOS and PFOA standard is the first step in the DEQ PFAS Regulatory Strategy, and with the anticipated release of new toxicity and health data, proposals for other PFAS compounds will follow.

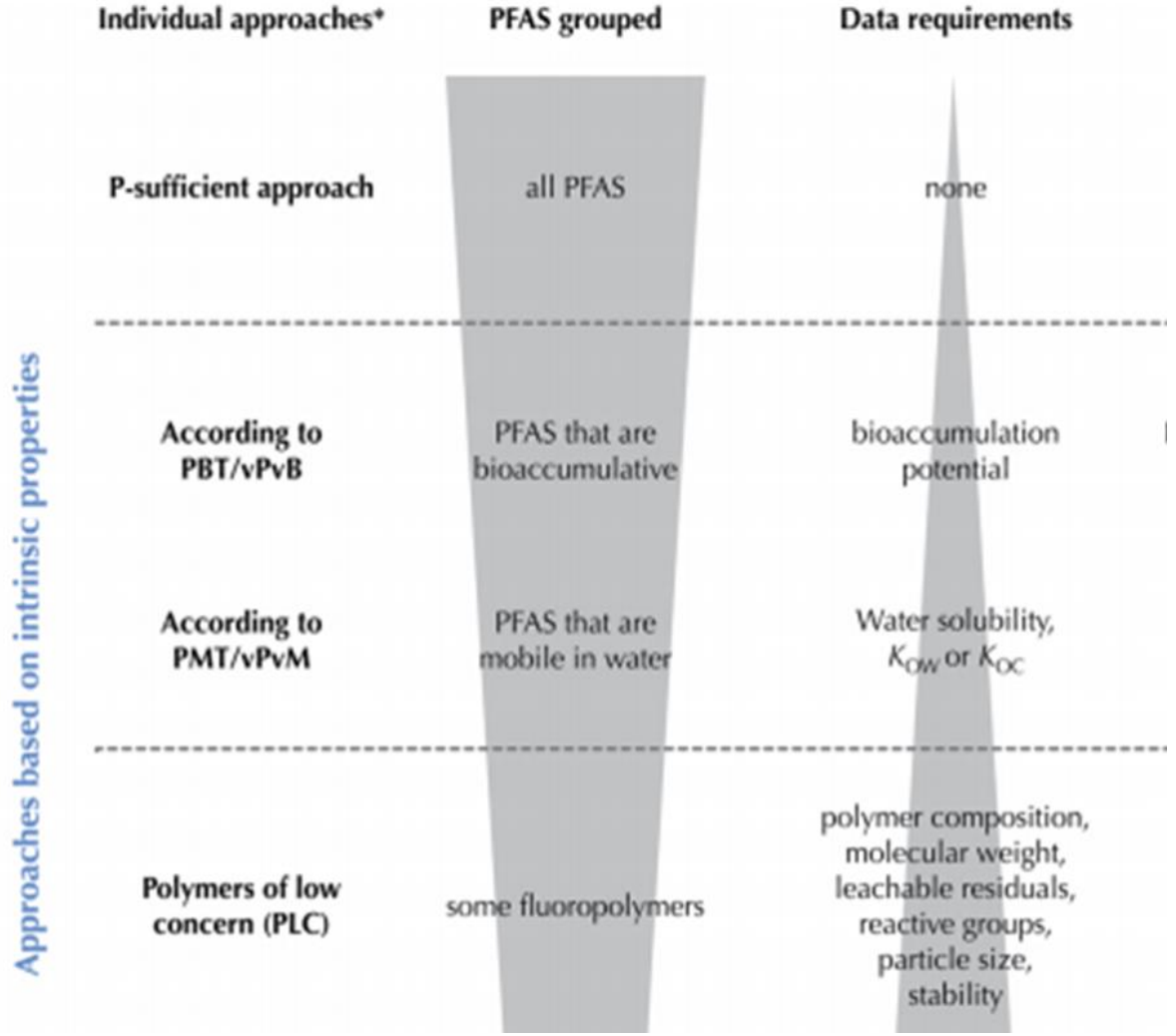
- Other Approaches
  - Provisional Health Goal in Drinking Water: Established by DHHS based on latest toxicity assessment
  - Pollution Prevention: reducing and preventing usage through alternatives, consumer choice, limiting land application of residuals, etc.
  - Federal Actions: EPA approved stack testing method and monitoring methods, federal air toxics standards, Best Available Control Technology evaluation criteria, listing as a hazardous constituent, etc.
  - Standards or Guidelines: for safely managing PFAS in leachate, solid wastes and hazardous wastes to minimize impacts to treatment plants and to drinking water wells.
  - Firefighting Foam: exploring collection, disposal and replacement program options
  - Financial Tools: promoting federal assistance options, creating local government grant and loan programs, etc.
  - Legislative Policies: reduce public health risks and impacts to NC's environment, natural resources, agriculture, wildlife, and fisheries.

DEQ's PFAS Regulatory Path Options



PFAS Regulatory Approaches

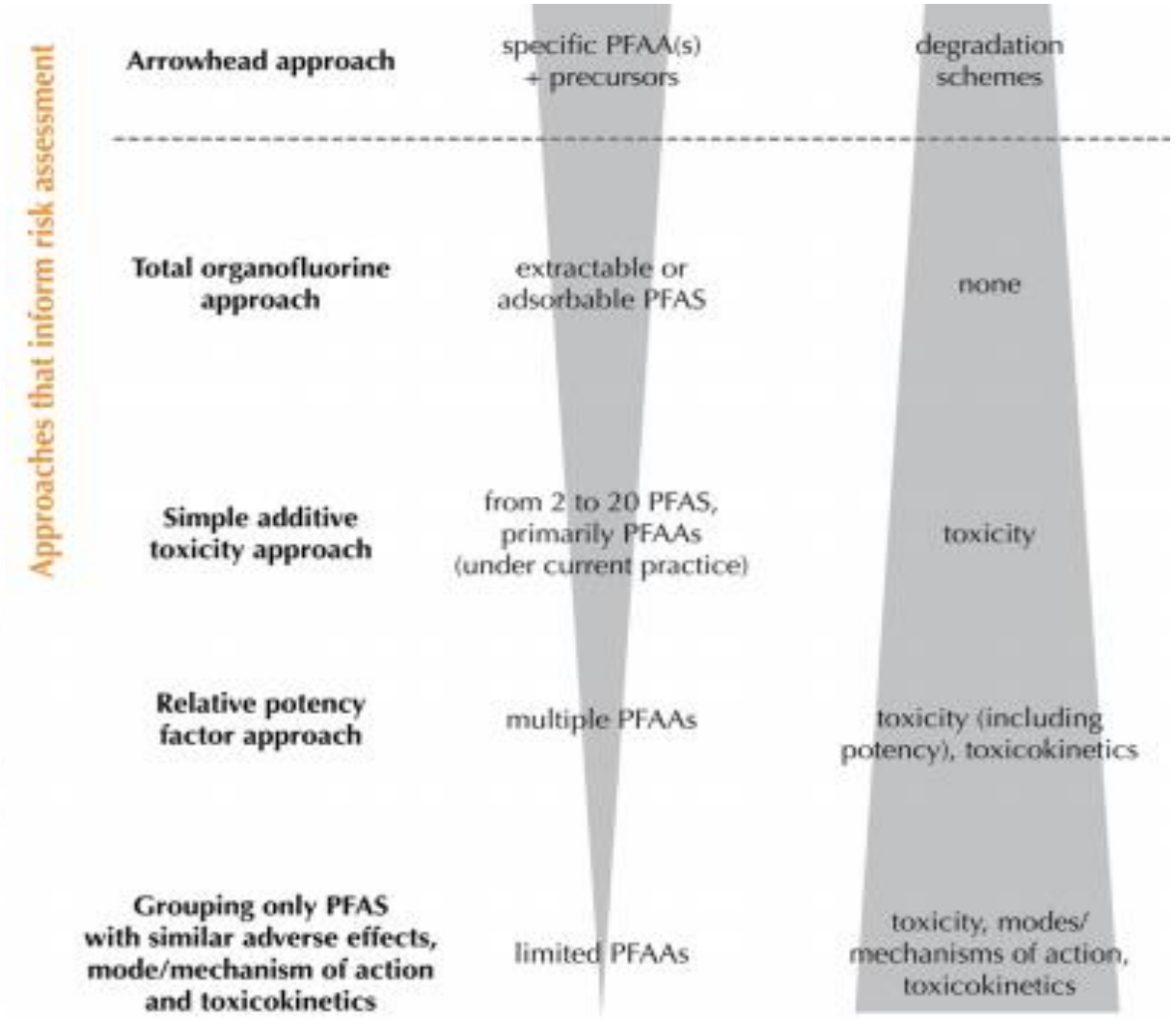
- DEQ has heard a lot of scientific support for a variety of grouping strategies.
- Grouping by class, persistence, water solubility, or physical characteristics.



Cousins et al. 2020

PFAS Regulatory Approaches

- DEQ has heard a lot of scientific support for a variety of grouping strategies.
- Grouping by class, persistence, water solubility, or physical characteristics.
- And grouping by toxicity characteristics including potency, modes of action, and toxicokinetics.



Cousins et al. 2020

DEQ's PFAS in NC Table

- Helped inform DEQ's path forward.
- Visualizing the amount of data helped evaluate each of the grouping approaches we heard for the PFAS in NC.

Most frequently detected PFAS in North Carolina ~		
PFAS Type	PFAS Group	PFAS Compound
Legacy Compounds	Sulfonic Acids	PFBS
		PFHxS
		PFOS
	Carboxylic Acids	PFBA
		PFPeA
		PFHxA
		PFOA
		PFNA
		PFDA
Consent Order Compounds		PFHpA
		PFMOPrA#
		PFMOBA#
	Ether Carboxylic Acids	PFMOAA
		PMPA#
		PFO2HxA
		PEPA#
		PFO3OA
		HFPO-DA (GenX)
		PFO4DA
		PFO5DA
		HydroEVE
	Ether Sulfonic Acids	Nafion By-prod1
		Nafion By-prod2

DEQ's Regulatory Option

- Interim Maximum Allowable Concentration (IMAC)
  - Can be implemented in weeks/months rather than years.
  - Can be updated quickly to reflect new scientific information.
  - Allows DEQ to keep regulatory values based on current information.

- Information Sources
  - EPA
    - IRIS
    - Health Advisory
    - Guidance Levels
  - ATSDR (CDC)
    - MRLs
  - CalEPA, MPART, other info

Procedure

1. Calculate systemic threshold concentration following the equation in the 2L rule: [Reference Dose (RfD) (mg/kg/day) x 70 kg (adult body weight) x Relative Source Contribution (0.10 for inorganics; 0.20 for organics)]/[2liters/day (avg. water consumption)]. Obtain the RfD from the following sources listed in priority order, (for more information on these sources of information, see section below "References for Toxicity Values"):

    1. EPA Integrated Risk Information System (IRIS)
    2. EPA Health Advisories
    3. Other health risk assessment data published by the U.S. EPA, such as, but not limited to:
        i. EPA Regional Table Toxicity Values (Regional Screening Levels for Chemical Contaminants at Superfund Sites)
        ii. EPA Provisional Peer Reviewed Toxicity Values (PPRTVs)
        iii. EPA Health Effects Assessment Summary Tables (HEAST, 1997)
    4. Other appropriate, published health risk assessment data, and scientifically valid peer-reviewed published toxicological data.
        i. Agency for Toxic Substances and Disease Registry (ATSDR) Chronic oral minimal risk levels (MRLs)
        ii. California EPA (CalEPA) Public Health Goals (PHGs)
        iii. Other published relevant toxicological data.

Agency for Toxic Substance & Disease Registry (ATSDR)

ATSDR PFAS MRLs & Example Calculations*			
PFAS compound	Oral Reference Dose (MRLs)	NC DWR GW Standard Calculation (ppt)	NC DHHS Health Assessment Calculation (ppt)
PFOA	3×10^{-6} mg/kg/day	21	4
PFOS	2×10^{-6} mg/kg/day	14	3
PFHxS	2×10^{-5} mg/kg/day	140	28
PFNA	3×10^{-6} mg/kg/day	21	4

**Values are examples calculated using equations on slide 36 and are not meant for regulatory evaluation; values displayed to demonstrate range of possible values based on different calculations*

1. ATSDR Oral exposure Intermediate Minimal Risk Level (MRL) values for PFAS finalized in May 2021 (PFOA, PFOS, PFHxS, PFNA).
   a. These are equal to, or lower than the reference dose of $2x10^{-5}$ mg/kg/day that EPA used in deriving their 2016 lifetime health advisory for drinking water value of 70ppt.
   b. In a previous meeting, the SAB supported using the EPA 2016 Drinking Water Health Advisory levels as a reasonable step to improve the current situation of having a much higher IMAC for PFOA of 2,000 ng/L and no standard for PFOS.
   c. SAB members strongly voiced a recommendation for DEQ to continue to evaluate research during the anticipated yearlong rulemaking process to determine if a lower value is warranted.
   d. States like Wisconsin have recommended an enforcement standard based on ATSDR intermediate oral MRLs for PFOS in groundwater.

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Question:

- ***Would the SSAB recommend the use of the ATSDR MRLs to set the IMAC for PFAS (PFOA & PFOS)?***

Note, on February 22, 2021,
EPA reissued final regulatory determinations for contaminants on the fourth Contaminant Candidate List (CCL 4).

- EPA is making final determinations to regulate PFOS and PFOA in drinking water.
- EPA plans to implement the national primary drinking water regulation development process for these two PFAS; however, its schedule is unknown.

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2. ATSDR has MRLs for PFHxS and PFNA, which are both prevalent in North Carolina and presented in DEQ's PFAS in NC presentation in Aug 2021.

   a. Observed in surface water, ground water, striped bass blood serum, and human blood samples from the NC population.

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Question:

- ***Would the SSAB recommend the use of the ATSDR MRLs for consideration in establishing IMACs for PFHxS & PFNA?***

Note: EPA is in Step 1 (Draft Development) of the IRIS process for PFNA and PFHxS.

US Environmental Protection Agency (EPA)

The EPA has completed and is in the process of conducting the following assessments:

- 3 complete (PFOA, PFOS, PFBS)
- 2 near completion (GenX & PFBA)
- 4 in the pipeline (PFHxS, PFHxA, PFNA, PFDA)

EPA PFAS Oral Reference Doses & Example Calculations*					
PFAS compound	Step in IRIS process	Oral Reference Dose	EPA Lifetime Health Advisory Calculation (ppt)*	NC DWR GW Standard Calculation (ppt)	NC DHHS Health Assessment Calculation (ppt)
PFOA & PFOS	Lifetime Health Advisory 2016	2×10^{-5} mg/kg/day	74	140	28
			Under revision, likely to change		
PFBS	Step 7 – Complete	3×10^{-4} mg/kg/day	1111	2100	425
GenX	Step 5 – Revising Assessment	8×10^{-5} mg/kg/day (Draft value; may change)	296	560	113
			Based on draft value; may change		
PFBA	Step 4 – Public Comment	1×10^{-3} mg/kg/day (Draft value; may change)	3704	7000	1418
			Based on draft value; may change		
PFNA	Step 1 – Draft Development				
PFHxS	Step 1 – Draft Development				
PFHxA	Step 2 – Agency Review				
PFDA	Step 1 – Draft Development				

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US Environmental Protection Agency (EPA)

EPA PFAS Oral Reference Doses & Example Calculations*		
PFAS compound	Step in IRIS process	Oral Reference Dose
PFOA & PFOS	Lifetime Health Advisory 2016	2×10^{-5} mg/kg/day
PFBS	Step 7 – Complete	3×10^{-4} mg/kg/day
GenX	Step 5 – Revising Assessment	8×10^{-5} mg/kg/day (Draft value; may change)
PFBA	Step 4 – Public Comment	1×10^{-3} mg/kg/day (Draft value; may change)
PFNA	Step 1 – Draft Development	
PFHxS	Step 1 – Draft Development	
PFHxA	Step 2 – Agency Review	
PFDA	Step 1 – Draft Development	

**Values are examples calculated using equations on slide 36 and are not meant for regulatory evaluation; values displayed to demonstrate range of possible values based on different calculations*

Questions:

- ***What action does the SSAB recommend DEQ take in regulating the PFAS compounds that have forthcoming IRIS assessments from EPA?***
  - ***Is there a preferred grouping method for these PFAS, or is regulating these PFAS individually more prudent?***
- ***PFBS reference dose is final, should this value be used for an IMAC in NC?***

DEQ's PFAS Regulatory Path

Round One:

1. **PFOA & PFOS – ATSDR, forthcoming EPA values**
2. **PFBS – EPA values final as of Jan 2021**
3. **GenX – EPA value forthcoming Oct/Nov 2021**
4. **Others?**

Round Two:

1. PFHxS & PFNA – ATSDR, EPA values forthcoming
2. PFBA – EPA values forthcoming
3. PFHxA – EPA values forthcoming
4. PFDA – EPA values forthcoming
5. Others?

Consent Order PFAS

1. This group of PFAS is prevalent in NC and has little toxicity data available
2. DEQ is working with external collaborators to acquire the toxicity data.

Question:

What kind of toxicity data is needed to confidently assign a regulatory value?

Most frequently detected PFAS in North Carolina~				
PFAS Type	PFAS Group	PFAS Compound	Environmental Data Concentration in NC water (median (range)) ng/L ppt Drinking Water Wells/ Groundwater Chemours area (n=3406)	% Detection (n)
Legacy Compounds	Sulfonic Acids	PFBS	2.9 (0.9 - 21)	1.8% (63)
		PFHxS	3.5 (1.9 - 11)	1% (37)
		PFOS	6.9 (2.2 - 39)	1.4% (49)
	Carboxylic Acids	PFBA	7.5 (2.2 - 300)	3.2% (109)
		PFPeA	6.8 (2 - 53)	3.2% (109)
		PFHxA	3.4 (1.9 - 29)	2.5% (85)
		PFOA	4.5 (1.1 -61)	2.6% (89)
		PFNA	3.5 (2.3 - 7.5)	0.2% (8)
		PFDA	3.2 (3 - 7.5)	0.1% (3)
Consent Order Compounds		PFHpA	3 (0.9 - 43)	22% (740)
		PFMOPrA#	@	@
		PFMOBA#	@	@
	Ether Carboxylic Acids	PFMOAA	13 (2 - 3500)	66% (2241)
		PMPA#	63 (2 - 8800)	92% (3117)
		PFO2HxA	13 (1.5 - 2800)	73% (2495)
		PEPA#	33 (2 - 2100)	23% (792)
		PFO3OA	4.6 (1.3 - 490)	21% (704)
		HFPO-DA (GenX)	15 (2 - 3200)	69% (2355)
		PFO4DA	3.5 (1.1 - 230)	6% (216)
		PFO5DA	5.1 (2.1 - 460)	1% (34)
		HydroEVE		
	Ether Sulfonic Acids	Nafion By-prod1	4.6 (1.5 - 20)	0.4% (14)
		Nafion By-prod2	5.5 (1.1 - 110)	51% (1748)

Reference Dose Derivation Process

- NCAC 2L.0202 states

(e) The following references, in order of preference, shall be used in establishing concentrations of substances which correspond to levels described in Paragraph (d) of this Rule.

(1) Integrated Risk Information System (U.S. EPA).

(2) Health Advisories (U.S. EPA Office of Drinking Water).

(3) Other health risk assessment data published by the U.S. EPA.

(4) Other relevant, published health risk assessment data, and scientifically valid peer-reviewed published toxicological data.

- No specific process is listed for derivation of a reference dose

Reference Dose Derivation Process

There are several derivation methods

- EPA guidance documents:
  - Reference Dose (RfD): Description and Use in Health Risk Assessments
  - A REVIEW OF THE REFERENCE DOSE AND REFERENCE CONCENTRATION PROCESSES
  - APPLICATION OF SYSTEMATIC REVIEW IN TSCA RISK EVALUATIONS
- Wisconsin:
  - Used EPA and ATSDR values alongside their own systematic review to derive their PFAS standard
    - Weighed newer science and more protective models against older studies
- PRISMA and Cochrane Systematic Review Processes

Question:

What other dose derivation methods should DEQ consider?

PFAS in NC Feedback?

Most frequently detected PFAS in North Carolina~		
PFAS Type	PFAS Group	PFAS Compound
Legacy Compounds	Sulfonic Acids	PFBS
		PFHxS
		PFOS
	Carboxylic Acids	PFBA
		PFPeA
		PFHxA
		PFOA
		PFNA
		PFDA
Consent Order Compounds		PFHpA
		PFMOPrA#
		PFMOBA#
	Ether Carboxylic Acids	PFMOAA
		PMPA#
		PFO2HxA
		PEPA#
		PFO3OA
		HFPO-DA (GenX)
		PFO4DA
		PFO5DA
		HydroEVE
	Ether Sulfonic Acids	Nafion By-prod1
		Nafion By-prod2

Question:

Based on the strategy outlined today, how does the Board recommend using the information summarized in this table?

Thank you

Frannie Nilsen, PhD
DEQ Environmental Toxicologist
Frannie.Nilsen@ncdenr.gov

Department of Environmental Quality

Questions for the Board

ATSDR MRLs

- ***Would the SSAB recommend the use of the ATSDR MRLs to set the IMAC for PFAS (PFOA & PFOS)?***
- ***Would the SSAB recommend the use of the ATSDR MRLs for consideration in establishing IMACs for PFHxS & PFNA?***

EPA IRIS Values

- ***What action does the SSAB recommend DEQ take in regulating the PFAS compounds that have forthcoming IRIS assessments from EPA?***
  - ***Is there a preferred grouping method for these PFAS, or is regulating these PFAS individually more prudent?***
  - ***PFBS reference dose is final, should this value be used for an IMAC in NC?***

Questions for the Board

Consent Order PFAS

- ***What kind of toxicity data is needed to confidently assign a regulatory value?***

Reference Dose Derivation

- ***What other dose derivation methods should DEQ consider?***

PFAS in NC

- ***Based on the strategy outlined today, how does the Board recommend using the information summarized in this table?***

Equations used in Calculations

NC 2L DW equation:

- [Reference Dose (mg/kg/day) x **70 kg (adult body weight)** x ***Relative Source Contribution (.10 for inorganics; .20 for organics)***] / **[2 liters/day (avg. water consumption)]**

EPA Lifetime Health Advisory Calculation:

- [DWEL= (RfD x bw)/DWI] x RSC = Lifetime Health Advisory Value from PFOA 2016 assessment;
  - DWEL= Drinking Water Equivalency Level; RfD = Reference Dose; bw= body weight; DWI = Drinking Water Intake; RSC = Relative Source Contribution **DWI/bw= 0.054 L/kg/day;** RSC = 20%; ***DWEL assumes 100% exposure from drinking water.*** RSC accounts for food sources, inhalation, and packaging materials

NC DHHS drinking water equivalent level (DWEL) for GenX:

- **Body Weight = 7.8 kg (bottle-fed infant); Intake = 1.1 L/day (bottle-fed infant);** ***Relative Source Contribution = 0.2;*** Unit Conversion = 106 ng/mg
- DWEL= dose (mg/kg bw/day) X body weight (kg)/intake (L/day) X RSC X Unit Conversion

ATSDR's calculations:

- Based on the guidelines published in the Public Health Assessment Guidance Manual, and the EPA 2011 Exposure Factors Handbook.
- An estimate of a child's drinking water exposure, ATSDR bases this calculation on an **infant weighing 7.8 kg & an intake rate of 1.113 liters/day**. For an adult's drinking water exposure, ATSDR bases this calculation on **adult body weight of 80 kg and an intake rate of 3.092 liters/day.**