



# PFAS: Lessons Learned During the Evolution of Global Regulations

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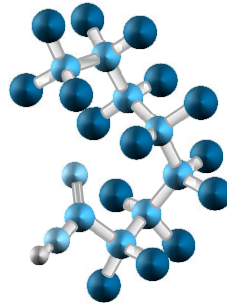
April 2019

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# Regulatory Challenges for PFAS



## State of Science

## Use in commerce

## Regulatory issues

Large and diverse group of chemicals

Persistence of perfluorinated chemicals

Used in many industries and products

Lack of federal guidance in some countries

Regulatory processes are not agile enough

Environmental behavior?

Analytical Methodologies

Not all uses of all PFAS are widely known

Insufficient resources and sharing of resources

Multiple coordinated criteria and guidelines need

Toxicology and bioaccumulation?

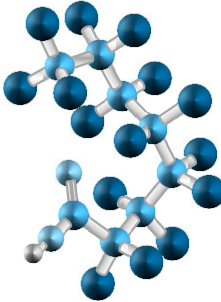
Lack of remediation technologies

Downstream users may not even be aware of PFAS

Concerns over financial impacts to municipalities

Public concern outstripping regulations and guidance

# Which PFAS to Focus on?



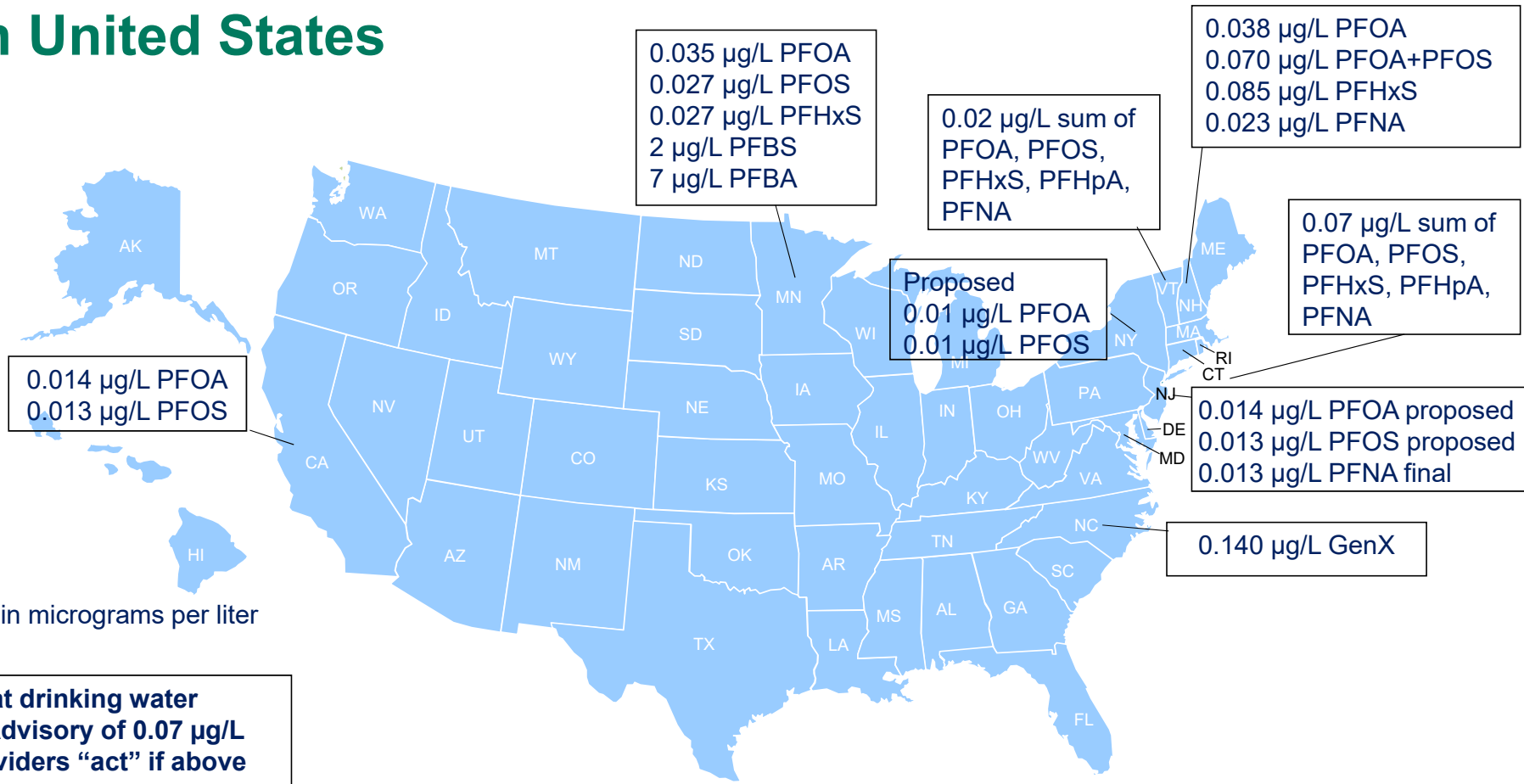
## Selection of targets among a large and diverse group of chemicals

- Widely used
- Bioaccumulation
- Detections in environmental media

## Resulting Selections

- PFOA and PFOS – primary or only focus in many regulatory jurisdictions
- PFOA, PFOS, PFNA – New Jersey USA
- PFOA, PFOS and PFHxS – primary indicators for Australia under PFAS NEMP
- PFOA, PFOS, PFNA, PFHxS, PFHpA – focus of several US States
- PFOA, PFOS, PFNA, PFHxS, PFHpA, PFBA, PFBS, PFPeA, PFHxA – Canada
- PFOA, PFOS, PFNA, PFHxS, PFHpA, PFBS, PFPeA, PFHxA + 6 more - Texas
- Replacements for PFOS and PFOA
- Expanded analyte lists (UCMR - 6, USEPA 537 -14, USEPA 537.1 – 18; NYSDEC – 21)

# Regulatory Status of PFOA & PFOS in United States

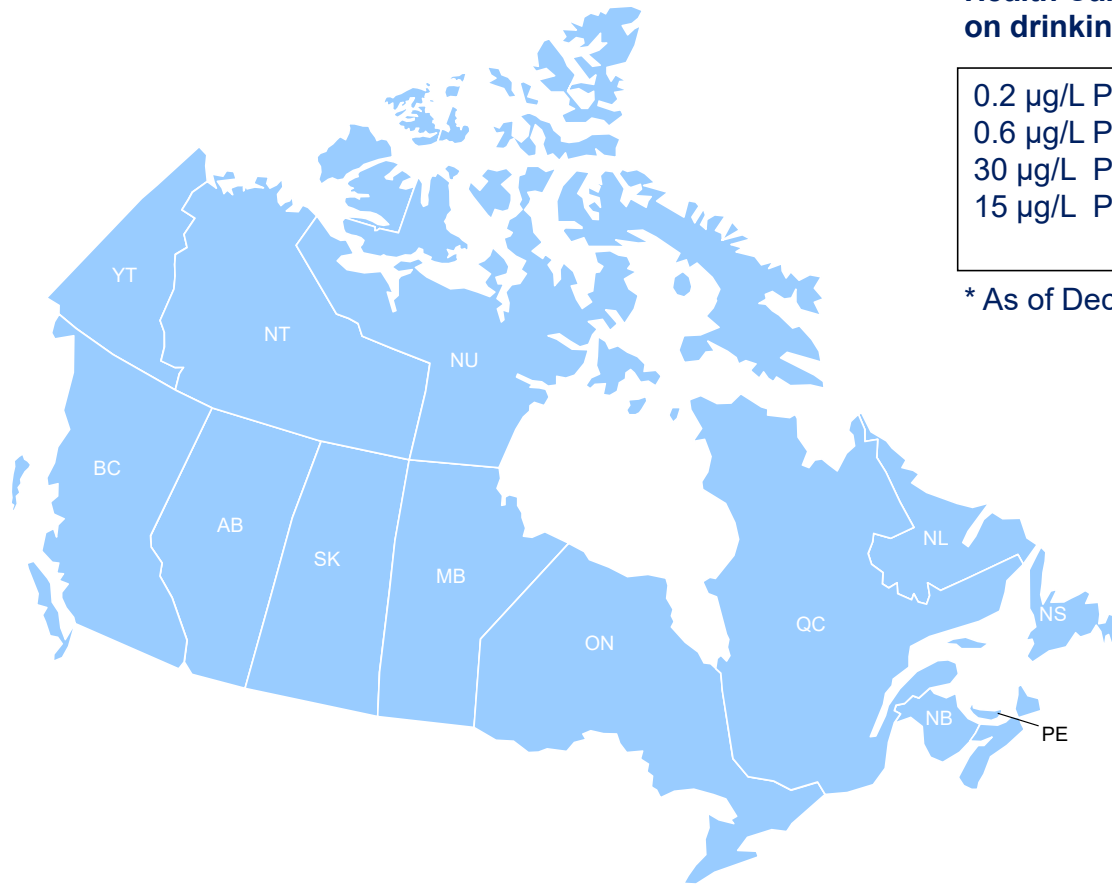


All values presented in micrograms per liter

**USEPA advises that drinking water meets the Health Advisory of 0.07 µg/L and that water providers “act” if above**

Criteria for PFAS are rapidly changing; check with local regulators to confirm current status

# Regulatory Status of PFOA & PFOS in Canada

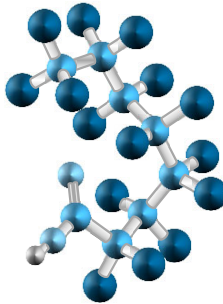


Health Canada has established guidance on drinking water screening values\*

0.2 µg/L PFOA  
0.6 µg/L PFOS  
30 µg/L PFBA  
15 µg/L PFBS

0.6 µg/L PFHxS  
0.2 µg/L PFPeA  
0.2 µg/L PFHxA  
0.2 µg/L PFHpA  
0.02 µg/L PFNA

\* As of December 2018



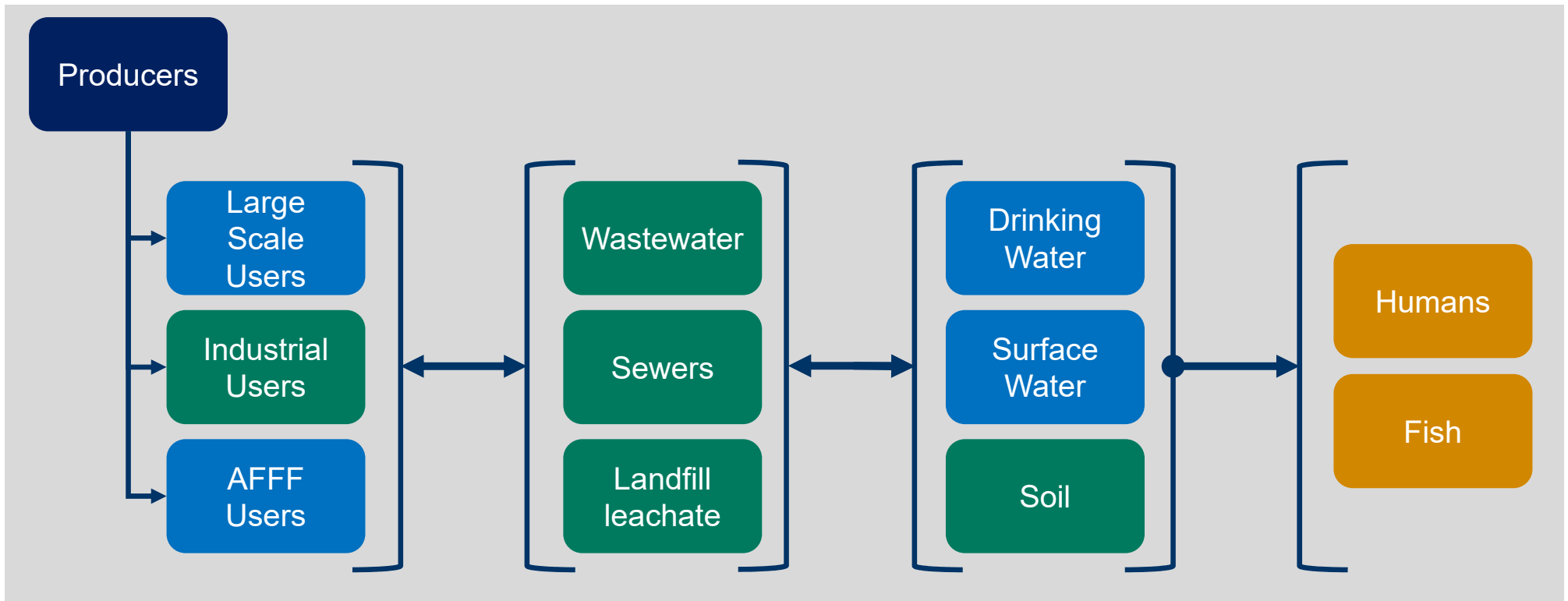
- Canadian Council of Ministers of the Environment (CCME) has developed PFOS draft soil and groundwater quality guidelines
- Government of Canada has prohibited import, manufacture, use, and sale of PFOA and LC-PFCAs (December 23, 2016)

All values presented in micrograms per liter

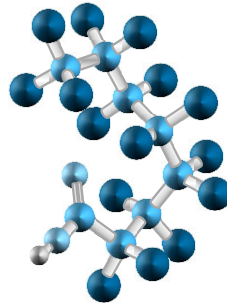
Criteria for PFAS are rapidly changing; check with local regulators to confirm current status

# How are the Potential Releases of PFAS being identified Globally?

- 1
- 2
- 3
- 4



# Has Exposure Risk Decreased as a Result of Regulatory Guidelines?



**Voluntary cessation of production of PFOA and PFOS in USA, EMEA, and Japan has reduce mass going into products and environment**

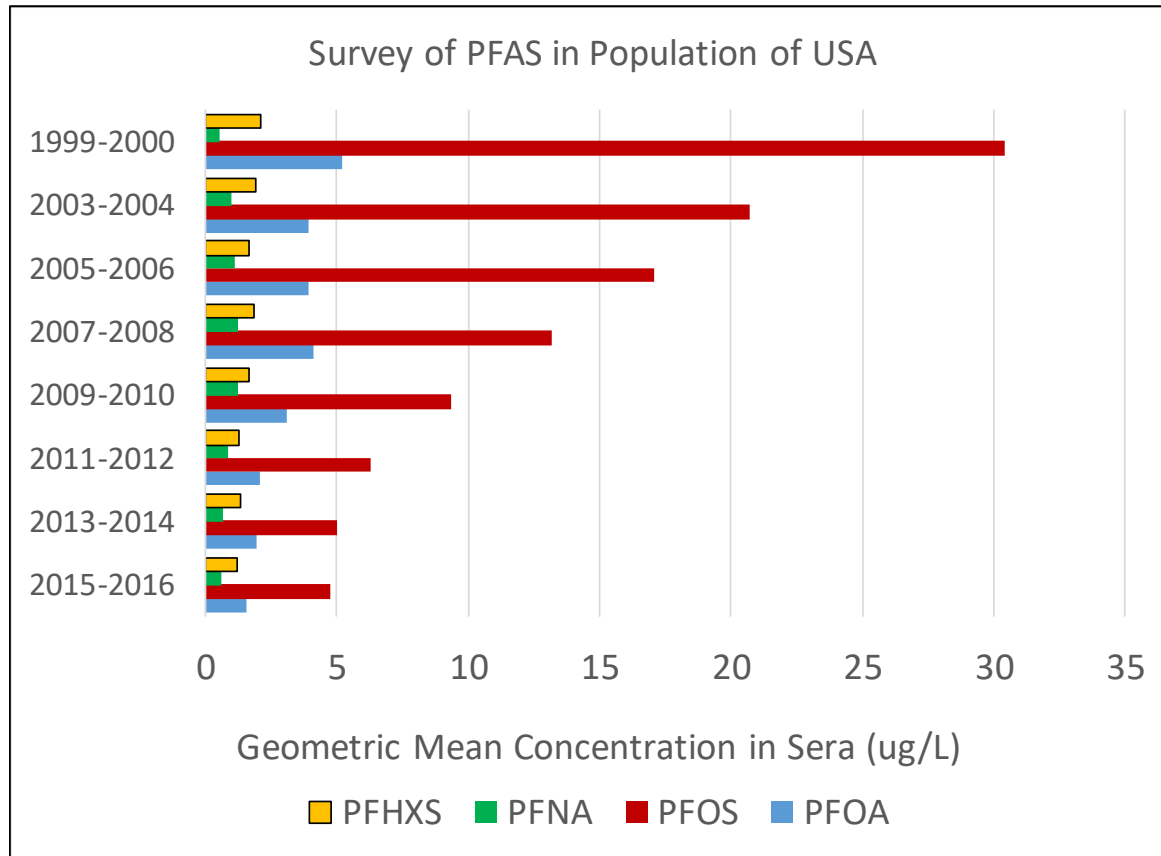
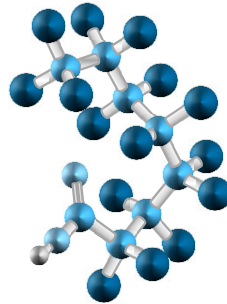
**Japan has observed in Tokyo Bay basin (Masunaga & Zushi, 2016)**

- Increases in PFHxA, PFOA and PFNA – 1977 through 2005, then decreases from 2006
- Decreases in PFOS since 1990s

**Treatment of drinking water in USA, Canada, Australia, EMEA, Japan has reduced exposure for millions of persons (>6M in US alone)**

- Arnsberg, Germany - PFOA reductions in blood plasma of 39% in children and mothers within two years of treating drinking water supplies (Brede et al, 2010)
- Reduced concentrations observed in human blood in US in NHANES

# PFAS Concentration Reductions Observed in the Blood of Population of USA



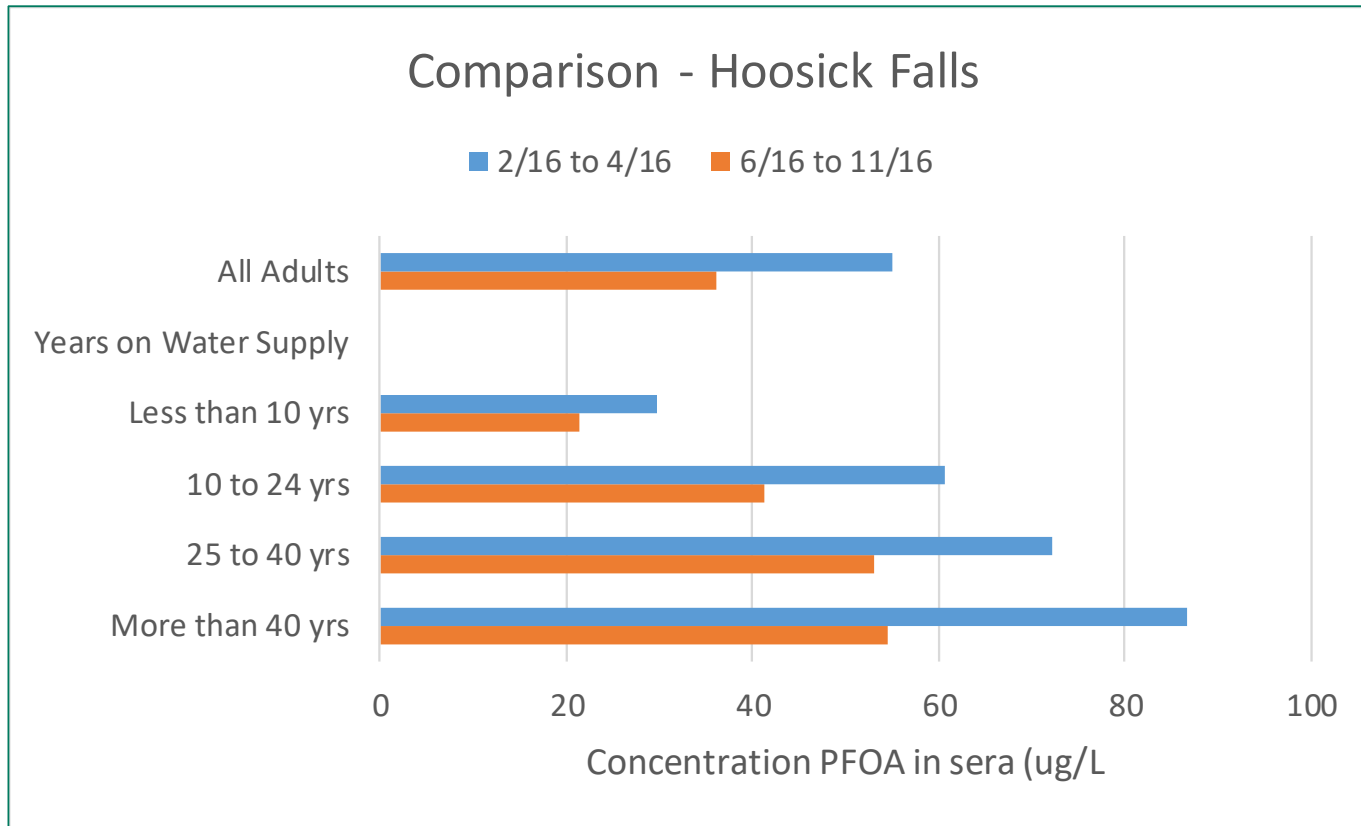
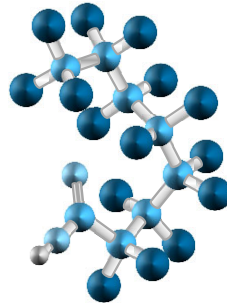
Largest percentage reductions in PFOS and PFOA

After May 2016?

2019 NHANES Results

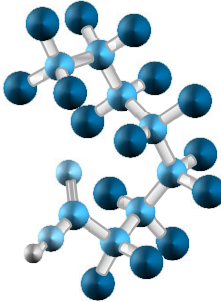


# PFAS Concentration Reductions Observed in the Blood of Residents After Implementation of GAC



2018 Presentation  
by NYSDOH

# Complications of Publishing Criteria and Regulations in Midst of Evolving Science



**Criteria and target compound list change rapidly**

**Public outrage and distrust of regulators**

**Inconsistent regulations and guidance for different media or uses and Federal/Local**

**Delays in investigation and remediation**

# USEPA – “Don’t Drinking the Water If....”

**USEPA**  
November 2015

2 months


**USEPA**  
January 2016

4 months

**USEPA**  
May 2016

2 years

**ATSDR – draft**  
June 2018



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 2  
200 BROADWAY  
NEW YORK, NY 10027-1866

NOV 25 2015

Honorable Mayor David B. Borge  
Municipal Building  
24 Main Street  
Hoosick Falls, NY 12090

Dear Mayor Borge:

I am writing regarding the perfluoroctanoic acid (PFOA) water contamination that has been discovered in groundwater and drinking water in the Village of Hoosick Falls, NY. On October 15, 2015, I was contacted about the problem with the Hoosick Falls public water supply and was asked if funding from the U.S. Environmental Protection Agency (EPA) was available to address this drinking water problem.


EPA does not have a funding stream to which the Village could apply in this situation. A more detailed response will be provided shortly. In summary, EPA provides Safe Drinking Water Act State Revolving Funds to New York State to address drinking water needs. EPA's Safe Drinking Water Act State Revolving Fund Program is implemented by the New York State Department of Health (DOH).

Because of PFOA's extreme persistence in the environment and its toxicity, mobility and bioaccumulation potential, which pose potential adverse effects to human health and the environment, EPA has been gathering information regarding the Hoosick Falls PFOA contamination and has been discussing this matter with DOH and the New York State Department of Environmental Conservation (DEC). While EPA has not, to date, promulgated an enforceable drinking water standard for PFOA under the Safe Drinking Water Act, in 2009, EPA's Office of Water established a **provisional health advisory of 400 nanograms per liter**, that is, 400 parts per trillion (ppt), for PFOA.

Provisional health advisories reflect reasonable, health-based hazard concentrations above which action should be taken to reduce exposure to unregulated contaminants in drinking water. In 2014, EPA stated that its **provisional health advisory for PFOA, if exceeded, suggests the need for discontinuing use of the water for drinking or cooking**, and that the advisory reflects an amount of PFOA that may cause adverse health effects in the short term (weeks to months).


“...greater than **100 ppt** not use that water for drinking or cooking...”

“...provisional health advisory for PFOA [**400 ppt**], if exceeded, suggests the need to discontinue the use of the water for drinking or cooking...”



EPA Statement on Private Wells in  
The Town of Hoosick and Village of Hoosick Falls, NY  
January 28, 2016

The EPA is developing a lifetime health advisory level for PFOA. While this work continues, the EPA recommends that people in the Town of Hoosick and the Village of Hoosick Falls who have private wells at which PFOA has been found to be present at a level **greater than 100 parts per trillion not use that water for drinking or cooking**, and instead take advantage of the free bottled water that is being made available at the Tops Market in Hoosick Falls. In addition, the EPA recommends that people in the Town of Hoosick and the Village of Hoosick Falls who have private wells that have not yet been tested for the presence of PFOA ask the New York State Department of Health to test their well and, in the meantime, take advantage of the bottled water available at the Tops Market in Hoosick Falls.



**FACT SHEET**  
PFOA & PFOS Drinking Water Health Advisories

**Overview**  
EPA has established health advisories for PFOA and PFOS based on the agency's assessment of the latest peer-reviewed science to provide drinking water system operators, and state, tribal and local officials who have the primary responsibility for overseeing these systems, with information on the health risks of these chemicals, so they can take the appropriate actions to protect their residents. EPA is committed to supporting states and public water systems as they determine the appropriate steps to reduce exposure to PFOA and PFOS in drinking water. As science on health effects of these chemicals evolves, EPA will continue to evaluate new evidence.

**Background on PFOA and PFOS**  
PFOA and PFOS are fluorinated organic chemicals that are part of a larger group of chemicals referred to as perfluorinated substances (PFAS). PFOA and PFOS have been the most extensively produced and studied of these chemicals. They have been used to make carpets, clothing, fluorics for furniture, paper packaging for food and other materials (e.g., cookware) that are resistant to water, grease or stains. They are also used for firefighting at airfields and in a number of industrial processes.


Because these chemicals have been used in an array of consumer products, most people have been exposed to them. Between 2000 and 2002, PFOS was voluntarily phased out of production in the U.S. by its primary manufacturer. In 2006, eight major companies voluntarily agreed to phase out their global production of PFOA and PFOA-related chemicals, although there are a limited number of ongoing uses. Scientists have found PFOA and PFOS in the blood of nearly all the people they tested, but these studies show that the levels of PFOA and PFOS in blood have been decreasing. While consumer products and food are a large source of exposure to these chemicals for most people, drinking water can be an additional source in the small percentage of communities where these chemicals have contaminated water supplies. Such contamination is typically localized and associated with a specific facility, for example, an industrial facility where these chemicals were produced or used to manufacture other products or an airfield at which they were used for firefighting.

**EPA's 2016 Lifetime Health Advisories**  
EPA develops health advisories to provide information on contaminants that can cause human health effects and are known or anticipated to occur in drinking water. EPA's health advisories are non-enforceable and non-regulatory and provide technical information to states agencies and other public health officials on health effects, analytical methodologies, and treatment technologies associated with drinking water contamination. In 2009, EPA published provisional health advisories for PFOA and PFOS based on the evidence available at that time.


“...**70 ppt** health advisory level.”

**FACT SHEET**  
PFOA & PFOS Drinking Water Health Advisories

**EPA's 2016 Lifetime Health Advisories, continued**  
To provide Americans, including the most sensitive populations, with a margin of protection from a lifetime of exposure to PFOA and PFOS from drinking water, EPA established the **health advisory levels at 70 parts per trillion**. When both PFOA and PFOS are found in drinking water, the **combined concentrations** of PFOA and PFOS should be compared with the 70 parts per trillion health advisory level. This health advisory level offers a margin of protection for all Americans throughout their life from adverse health effects resulting from exposure to PFOA and PFOS in drinking water.



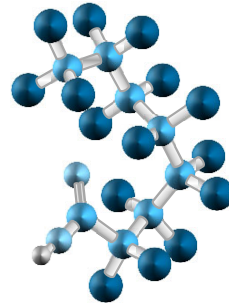
**Toxicological Profile for**  
Perfluoroalkyls  
Draft for Public Comment  
June 2018



U.S. Department of Health and Human Services  
Agency for Toxic Substances and Disease Registry

ATSDR recommendations may result in lower levels than USEPA's current HAs  
**~7 ppt for PFOS**  
**~11 ppt for PFOA**

# Australia – “Don’t Drink the Water If....+”



enHealth  
June 2016

10 months

Australian DOH  
April 2017

June 2016

**enHEALTH**  
Environmental Health Standing Committee (enHealth) of the Australian Health Protection Principal Committee

enHealth Statement: Interim national guidance on human health reference values for per- and poly-fluoroalkyl substances for use in site investigations in Australia

**Background and context:**

In March 2016, the Australian Health Protection Principal Committee (AHPPC) endorsed the Standing Committee on Environmental Health (enHealth) *Guidance Statements on Perfluorinated Chemicals* (Guidance Statements) to support jurisdictional responses to incidents of environmental contamination with per- and poly-fluoroalkyl substances (PFAS). Guidance Statement 3 concerned the development of human health reference values for perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA) for site investigations.

**“... Interim Drinking Water Quality Guidelines:  
PFOA - 5000 ppt  
PFOS / PFHxS – 500 ppt**

The recommended enHealth interim values are:

Toxicity reference value	PFOS/PFHxS	PFOA
Tolerable Daily Intake (µg/kg/d)	0.15	1.5
Drinking Water Quality Guideline (µg/L)	0.5	5
Recreational Water Quality Guideline (µg/L)	5	50

Australian Government  
Department of Health

## Health Based Guidance Values for PFAS FOR USE IN SITE INVESTIGATIONS IN AUSTRALIA

In June 2016, the Department of Health commissioned Food Standards Australia New Zealand (FSANZ) to develop final health based guidance values for perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA) and perfluorohexane sulfonate (PFHxS), which belong to a group of chemicals known as per- and poly-fluoroalkyl substances (PFAS).

The Department of Health has received FSANZ's final assessment of the health based guidance values for PFAS. The final health based guidance values are used consistently across Australia to assess the health risk of PFAS in food and drinking water. The final health based guidance values are used to provide advice to affected communities on how to minimise exposure to PFAS.

**Final health based guidance values for use in site investigations in Australia**

FSANZ has recommended final health based guidance values for PFOS and PFOA in the form of a tolerable daily intake. A tolerable daily intake is a level of daily oral exposure over a lifetime that is considered to be without significant health risk for humans.

**“... Final Drinking Water Quality Guidelines:  
PFOA - 560 ppt  
PFOS / PFHxS – 70 ppt**

The health based guidance values for use in site investigations in Australia are:

Toxicity reference value	PFOS/PFHxS		PFOA	
	ng	µg	ng	µg
<b>Tolerable daily intake (ng or µg / kg bw/day)</b>	20	0.02	160	0.16
<b>Drinking water quality value (ng or µg /L)</b>	70	0.07	560	0.56
<b>Recreational water quality values (ng or µg /L)</b>	700	0.7	5,600	5.6

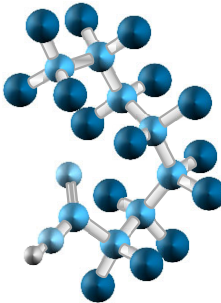
Note: bw = body weight, ng = nanograms, µg = micrograms

**What is a health based guidance value?**

Health based guidance values indicate the amount of a chemical in food or drinking water that a person can consume on a regular basis over a lifetime without any significant risk to health. Health based guidance values can be expressed as a tolerable monthly intake (TMI), a tolerable weekly intake (TWI) or a tolerable daily intake (TDI). The choice of whether a TMI, TWI or TDI is set depends on the nature of the chemical.

Health based guidance values are used by organisations and government agencies to investigate and assess potential human health risks.

# Germany– “Don’t Drink the Water If....+”



**Drinking Water Committee of  
Federal Health Ministry  
2006**

11 Years

**German  
Federal Environment Agency  
January 2017**

Statement by the Drinking Water Commission (Trinkwasserkommission) of the German Ministry of Health at the Federal Environment Agency  
**June 21, 2006 (revised July 13, 2006)**

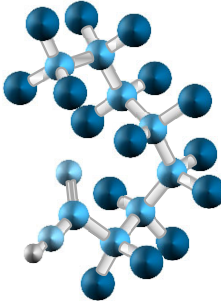
**5. Overview of the key maximum value guidance in the present report for composite PFOA and PFOS concentrations**

Type of max. value	English (German) abbreviation	Relevant value	Relevant section in the present report
Health based precautionary value (long term minimum quality goal) for non-genotoxic substances	HPV <sub>1</sub> ( <i>GOW<sub>1</sub> = Gesundheitlicher Orientierungswert</i> )	0.1 µg/L	Section 2.1; lifelong precautionary value, e.g. in case additional perfluorocarbons would be present
Strictly health based guide value for safe lifelong exposure of all population groups	GV ( <i>LW = Leitwert</i> )	0.3 µg/L	Section 3; Composite concentrations of PFOA and PFOS are (still) tolerable
Precautionary action value for infants	<i>Maßnahmewert für Säuglinge</i>		Section 3; precaution of infants, e.g. against the presence of additional perfluorocarbons
Precautionary action value for adults	PAV <sub>0</sub> ( <i>VMW<sub>0</sub> = Vorsorge-Maßnahmewert für Erwachsene</i> )	5.0 µg/L	Section 2.3 (PAV <sub>0</sub> ) and section 3 (AV <sub>10</sub> ) in conjunction with the action value guidance: drinking water inadmissible for food processing and preparation

Drinking Water  
PFOA + PFOS - 100 ppt

Drinking Water  
PFOA + PFOS - 300 ppt

# Complications of Publishing Criteria and Regulations in Midst of Evolving Science



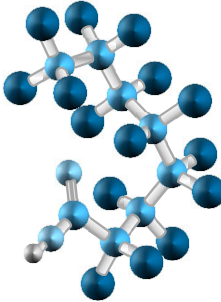
**Acceptance of criteria from one regulatory entity by another entity is complicated:**

- Human/ecological toxicological thresholds may be different
- Consumption amounts (e.g. fish) differ among different populations
- Different calculated bioaccumulation factors
- Example for PFOA:

2017 Dutch proposed Surface Water EQS for human consumption of fish = 0.048 ug/L

Using German guidelines, calculated EQS for human consumption of fish = 28 to 109 ug/L

# Inconsistent Regulations and Guidance for Different Media or Uses and Federal/State



## Germany

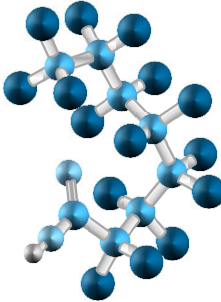
### Soil – Sludge application vs soil

- 100 µg/kg – Under German Fertilizer Ordinance [Düngemittel-Verordnung], maximum of 100 µg/kg PFOA+PFOS in sewage sludge may be used as fertilizer on agricultural land
- Local Values for Soil – e.g. Bavarian Water Management Agency
  - Preliminary Level 1 – 0.1 µg/L in soil leachate (de minimus threshold)
  - Preliminary Level 2 – 0.4 µg/L in soil leachate (remedial measures indicated)
- BBodSchV - No values for soil

### Drinking Water vs Groundwater

- Federal/state Water Working Group (LAWA) formulating a preliminary threshold value (GFS) of 0.1 µg/L for maximum concentration classified as insignificant (based on ecological and human toxicology)

# Inconsistent Regulations and Guidance for Different Media or Uses



## USA

### Groundwater vs Soil

- Protection of groundwater values for soil?

### Groundwater vs Drinking Water

- Not all groundwater is drinking water

### Discharge of Treated Water

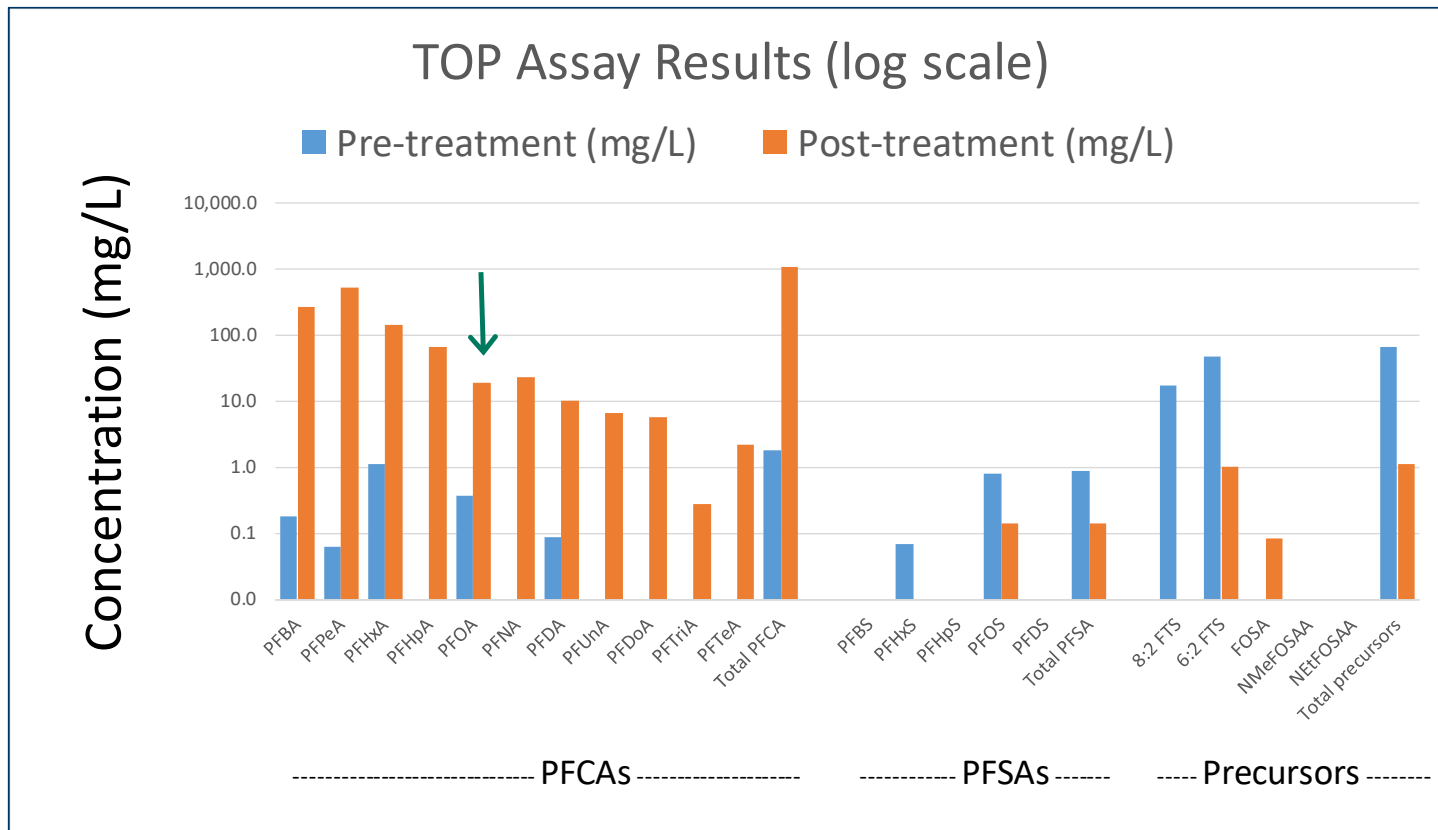
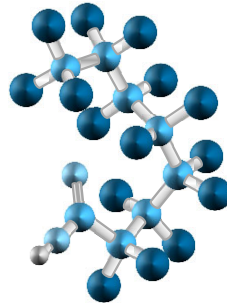
- Requirements to treat water to less than drinking water criteria or even to non-detect prior to discharge to sewers

## AFFF

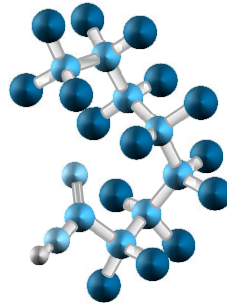
- Fluorosurfactant containing AFFF required by US Military under Mil Spec and by FAA at commercial airports (until reauthorization in October 2018)
- Implications of C6 replacement foams as regulators expand list of target PFAS



# “Non-PFOS” AFFF Concentrate – Before and After Oxidation in TOP Assay



# Effects on Businesses and Municipalities



## Businesses:

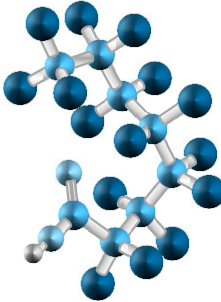
- Reformulation of products and processes
- Replacement of equipment
- Supply chain management
- Re-opening of closed environmental sites
- Hidden liabilities in portfolio and for mergers or acquisitions
- Toxic tort claims

## Municipalities:

- Wastewater treatment upgrades
- Landfill leachate treatment
- Drinking water treatment
- AFFF usage by local fire departments
- Costs to search for sources of contamination

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## Impact on Remediation Strategies



**Today's investigation and remediation may be insufficient for tomorrow's criteria**

**Changing regulatory criteria require flexible strategies**

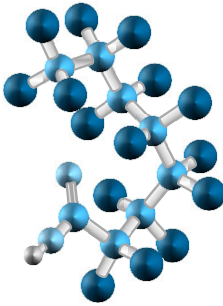
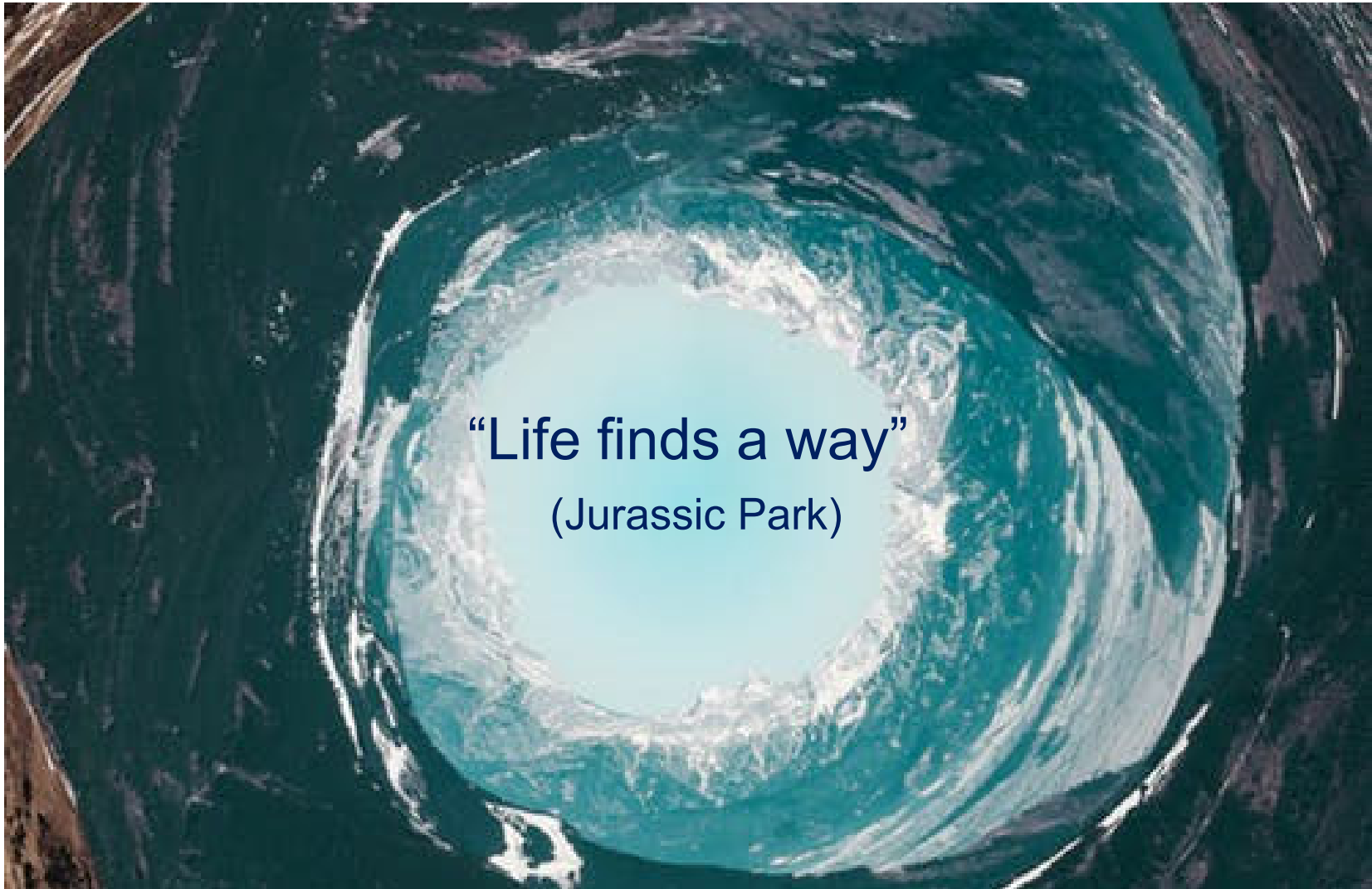
**Treatment of water to "ND" to cover all future outcomes**

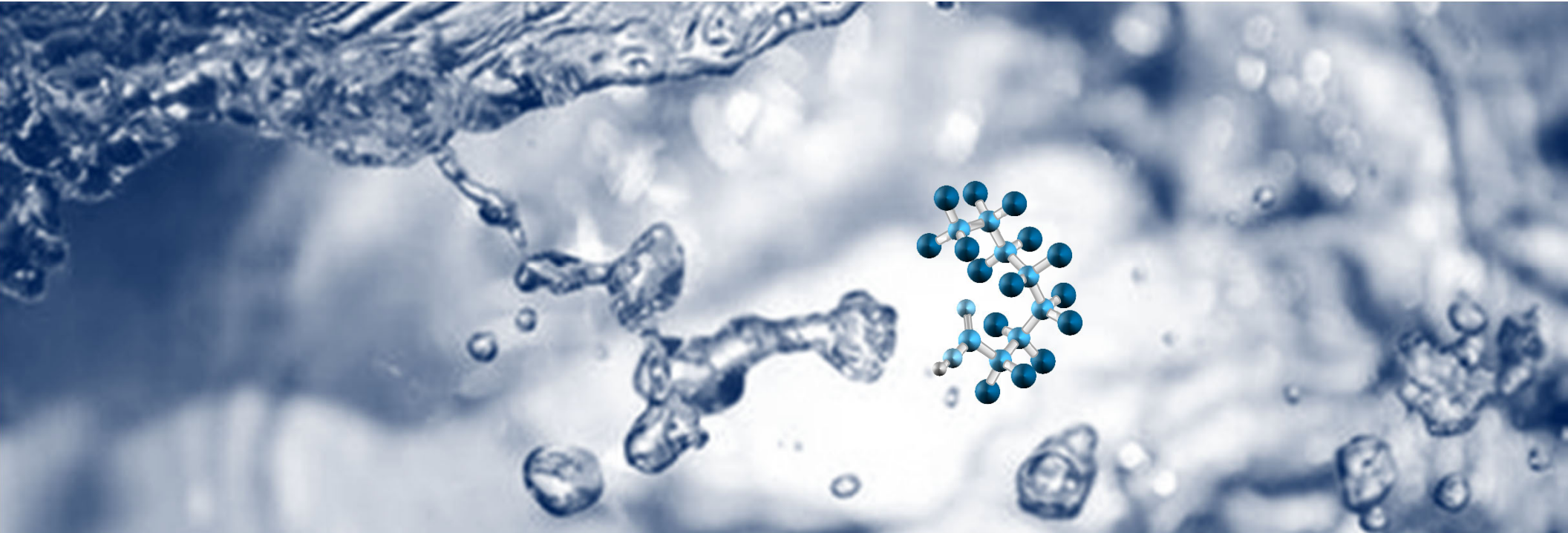
**Concern that disposal of impacted media may result in future liabilities**

**Challenge of large dilute plumes with limited attenuation**

**Return of "Pump & Treat" and other containment strategies:**

**Focus on blocking exposure pathways (e.g. treat drinking water)**





**Thank you**

**Questions?**

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