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Challenges of Regulating Chemicals of Emerging Concern

April 24, 2018

Bloomberg Environment

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Today's Presentation

I. Introduction
II. How do Chemicals of Emerging Concern (CEC) come to be identified and regulated?
III. The uncertainty and implications that accompany the identification and assessment of emerging contaminants
IV. Recent regulatory actions in New Jersey and New York
V. Conclusions

INTRODUCTION

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- Processes for identifying chemicals of concern (CECs)
- Challenges - extremely low laboratory method detection limits
- Evolution - data gathering, to public concern and demand for answers, to potential regulatory action
- Implications CECs with limited information on:
  - health effects
  - frequency of occurrence in water resources
- Need for coordinated national leadership to ensure regulatory response is appropriate and consistent across jurisdictions.

HOW DO CECS COME TO BE IDENTIFIED AND REGULATED?

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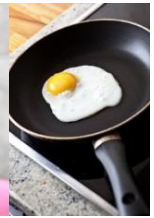
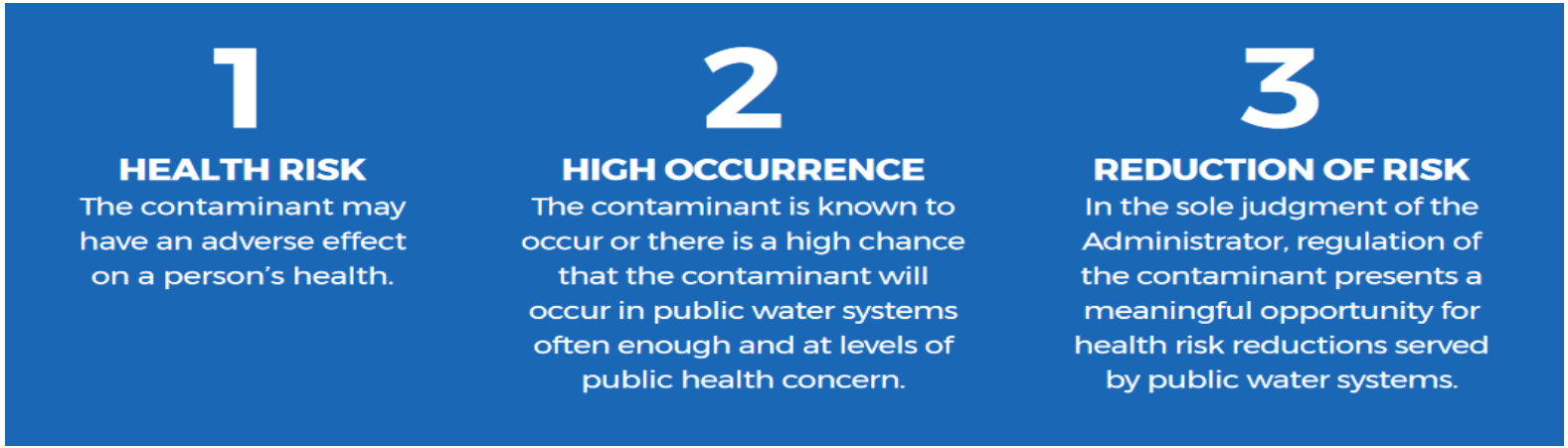
Multiple sources of federal authority:

- Safe Drinking Water Act (SDWA)
- Toxic Substances Control Act (TSCA)
- Comprehensive Environmental Response Compensation and Liability Act (CERCLA)






EPA shall establish a national primary drinking water regulation (NPDWR) for a contaminant if:



Source: SDWA §1412(b)(1)(A).
Infographic from: https://www.epa.gov/sites/production/files/2017-12/documents/epa-regulate_drinking_water_contaminants-final-508.pdf.

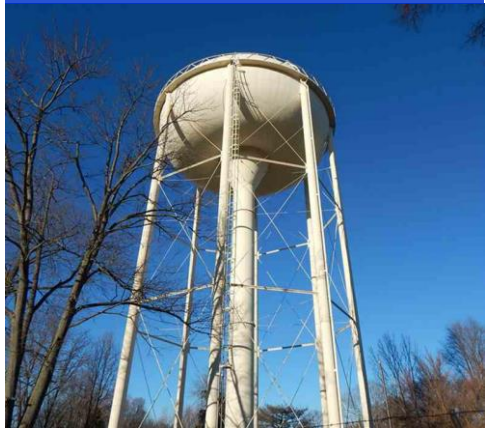
SAFE DRINKING WATER ACT - APPLICABILITY

- NPDWRs may take the form of
  - maximum contaminant levels (MCLs)
  - treatment/technology requirements
- **NPDWRs enforceable only as to public water systems (PWS) . . . .**
- But relied on as *de facto* environmental clean-up standards under other federal (e.g., CERCLA) and many state programs

"the ripple effect"

94 Current MCLs

- 60 organic chemicals
- 16 inorganic chemicals
- 7 microorganisms (and related indicators)
- 3 disinfectants
- 4 disinfection byproducts
- 4 radionuclides



SAFE DRINKING WATER ACT – REGULATORY DEVELOPMENT PROCESS

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- Contaminant Candidate List (CCL) – List of unregulated contaminants that are known to or may occur in drinking water; published every 5 years
- Unregulated Contaminant Monitoring Rule (UCMR) – Rule/process to monitor at least 30 contaminants in PWS every 5 years
- Regulatory Determinations (RD) – Decisions on whether to regulated CCL contaminants; EPA must make RDs for at least 5 every 5 years. Positive RD requires EPA to propose regulation w/in 24 months and finalize within another 18 months
- Regulatory Development – EPA must consider health, analytical/treatment feasibility, costs/benefits, etc.
- Six Year Review – Regulations reviewed and (if appropriate) revised every six years

SAFE DRINKING WATER ACT – CCL4

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- Published November 2016
- The list . . .
  - 97 chemicals
  - 12 microbial contaminants
- Derivation of the list
  - carryovers from CCL3
  - public nominations

1,1-Dichloroethane	Dicrotophos	N-Methyl-2-pyrrolidone
1,1,1,2-Tetrachloroethane	Dimethipin	N-nitrosodiethylamine (NDEA)
1,2,3-Trichloropropane	Diuron	N-nitrosodimethylamine (NDMA)
1,3-Butadiene	Equilenin	N-nitroso-di-n-propylamine (NDPA)
1,4-Dioxane	Equilin	N-Nitrosodiphenylamine
17alpha-estradiol	Erythromycin	N-nitrosopyrrolidine (NPYR)
1-Butanol	Estradiol (17-beta estradiol)	Nonylphenol
2-Methoxyethanol	Estriol	Norethindrone (19-Norethisterone)
2-Propen-1-ol	Estrone	n-Propylbenzene
3-Hydroxycarbofuran	Ethinyl estradiol	o-Toluidine
4,4'-Methylenedianiline	Ethoprop	Oxirane, methyl
Acephate	Ethylene glycol	Oxydemeton-methyl
Acetaldehyde	Ethylene oxide	Oxyfluorfen
Acetamide	Ethylene thiourea	Perfluorooctanesulfonic acid (PFOS)
Acetochlor	Formaldehyde	Perfluorooctanoic acid (PFOA)
Acetochlor ethanesulfonic acid (ESA)	Germanium	Permethrin
Acetochlor oxanilic acid (OA)	HCFC-22	Profenofos
Acrolein	Halon 1011 (bromochloromethane)	Quinoline
Alachlor ethanesulfonic acid (ESA)	Hexane	RDX
Alachlor oxanilic acid (OA)	Hydrazine	sec-Butylbenzene
alpha-Hexachlorocyclohexane	Manganese	Tebuconazole
Aniline	Mestranol	Tebufenozide
Bensulide	Methamidophos	Tellurium
Benzyl chloride	Methanol	Thiodicarb
Butylated hydroxyanisole	Methyl bromide (bromomethane)	Thiophanate-methyl
Captan	Methyl tert-butyl ether (MTBE)	Toluene diisocyanate
Chlorate	Metolachlor	Tribufos
Chloromethane (Methyl chloride)	Metolachlor ethanesulfonic acid (ESA)	Triethylamine
Clethodim	Metolachlor oxanilic acid (OA)	Triphenyltin hydroxide (TPTH)
Cobalt	Molybdenum	Urethane
Cumene hydroperoxide	Nitrobenzene	Vanadium
Cyanotoxins	Nitroglycerin	Vinclozolin
		Ziram

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SAFE DRINKING WATER ACT – REGULATORY DEVELOPMENT PROCESS

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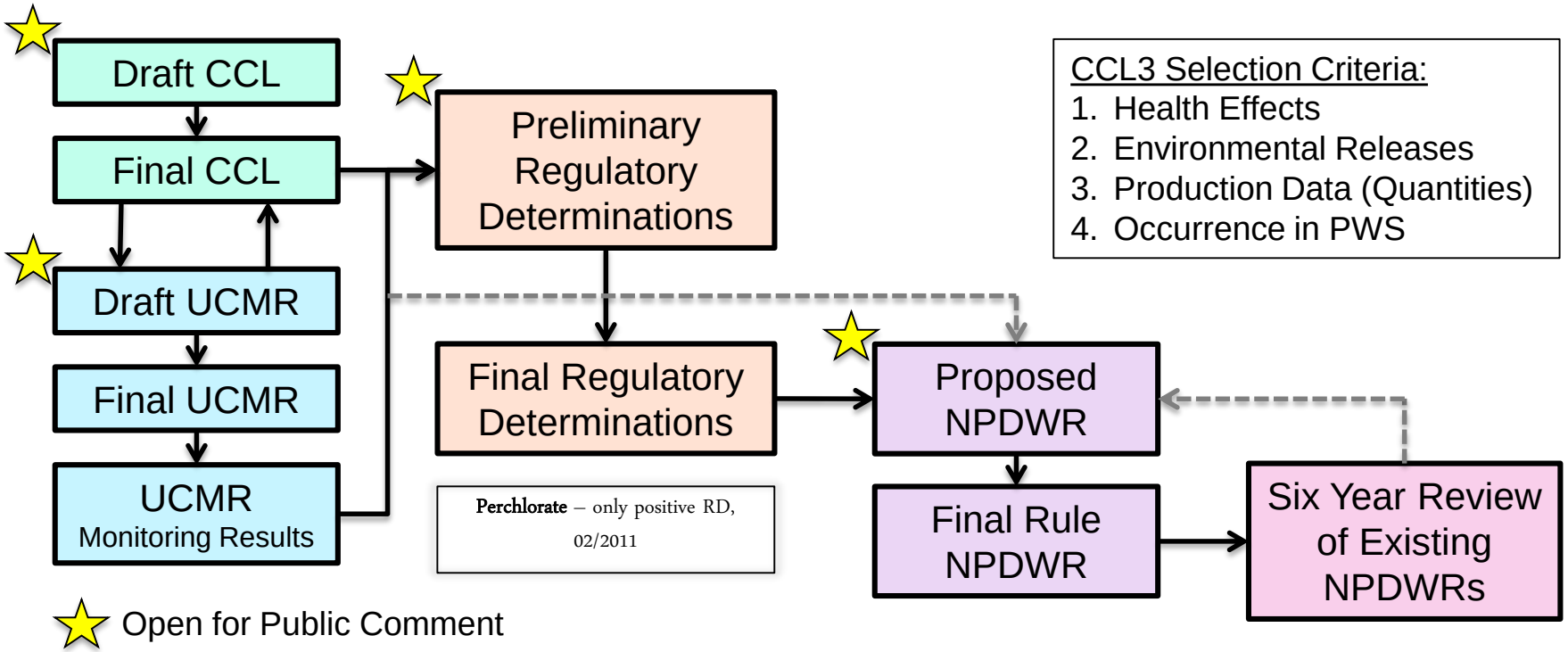

Modified from: Slides by Eric Burneson of the National Drinking Water Advisory Council, December 6, 2016

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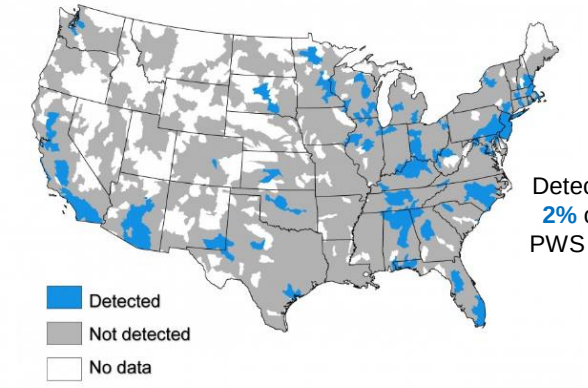
Illustrations of UCMR3 Data from the National Contaminant Occurrence Database

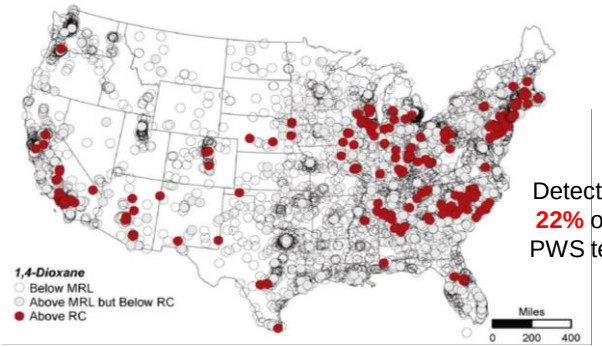
Hydrological units with detectable PFASs



Detected in **2%** of the PWS tested

Source: August 2016 Edition of Environmental Science & Technology Letters - http://pubs.acs.org/doi/pdf/10.1021/acs.estlett.6b00260

1,4-Dioxane Occurrence in 4,864 PWS Included in UCMR3



Detected in **22%** of the PWS tested

Source: D.T. Adamson et al. / Science of the Total Environment 596–597 (2017) 236–245

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- Selection criteria
  - Drawn primarily from the CCL
  - Step 1 – not on previous lists, significant occurrence nationally, available (validated) analytical method
  - Step 2 – available health assessment, public concern, critical health endpoints (e.g., likely carcinogen), on-going use, data gaps
- Chemicals to be tested (2018-20)
  - 10 cyanotoxin chemical contaminants (incl. microcystins)
  - 20 other chemicals (pesticides, metals, brominated haloacetic acids (HAA), alcohols, semi-volatiles)

SAFE DRINKING WATER ACT – PACE OF REGULATION

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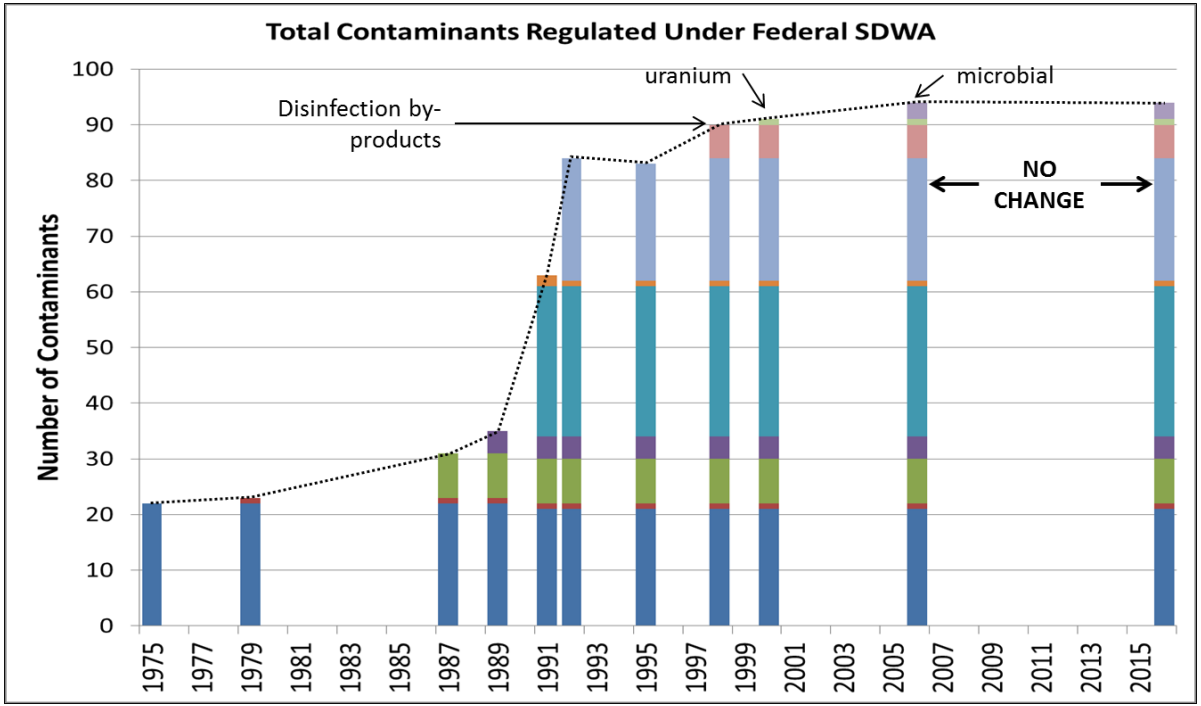

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FEDERAL VS. STATE REGULATION OF 1,4-DIAXANE AND PFAS

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1,4-dioxone

- EPA (not regulated)
  - Lifetime Health Advisory – 200 ppb
- States – proposed/established levels for GW/DW
  - **at least 18 states**
  - lowest = 0.35 ppb (Colorado)

PFAS

- EPA (not regulated)
  - Lifetime Health Advisory PFOA+PFOS – 0.07 ppb
- States – proposed/established levels for GW/DW
  - **at least 14 states**
  - lowest = 0.010 ppb (PFNA, New Jersey) (Groundwater Quality Standard)

State	1,4-dioxane	PFOA and/or PFOS
Alaska	X	X
California	X	
Colorado	X	X
Connecticut	X	X
Delaware	X	X
Florida	X	
Indiana	X	
Iowa		X
Maine	X	X
Massachusetts	X	
Michigan		X
Minnesota		X
Mississippi	X	
Nevada		X
New Hampshire	X	X
New Jersey	X	X
North Carolina	X	X
Pennsylvania	X	
Texas	X	X
Vermont	X	X
Washington	X	
West Virginia	X	

- Under §1431, when the USEPA determines there may be an imminent and substantial endangerment from a contaminant that is present in or likely to enter a public water supply, EPA may issue Emergency Administrative Orders (EAOs) to take any action necessary to protect human health if state and local authorities have not acted
- Sites where EPA has issued EAOs to address water supply wells affected by PFAS
  - Air Guard Station, Horsham, PA
  - Naval Air Warfare Center, Warminster, PA
  - Pease Air Force Base, NH

TOXIC SUBSTANCES CONTROL ACT – "SUBSTANTIAL RISK" REPORTING OBLIGATIONS, E.G., §8(e)

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- May be triggered by CEC detections in drinking water
- For example, in 2004, EPA took enforcement action against DuPont for PFOA in the environment around its Washington Works Plant in Parkersburg, WV
- That action was settled for > $10MM

TSCA §8(e) - Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.

TOXIC SUBSTANCES CONTROL ACT – FRANK R. LAUTENBERG CHEMICAL SAFETY FOR THE 21ST CENTURY ACT (2016)

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- Affirmative requirement for EPA to systematically assess and manage the safety of existing chemicals
- Gives EPA expanded authority to obtain testing information from manufacturers
- Reforms may yield data that could raise new concerns about some of the more than 86,000 chemical substances currently registered under TSCA
- EPA is reviewing 1,4-dioxane as part of the TSCA Priority Chemicals Process

- EPA has recently asserted the power to consider risks associated with “pollutants” or “contaminants” that are not listed as Superfund hazardous substances in its decision to add a site in Hoosick Falls, New York to the Superfund National Priorities List (NPL)
- Additionally, EPA has added a variety of CECs to its regional screening levels (RSLs) tables, which it uses to screen chemicals at Superfund sites.

FROM IDENTIFICATION TO POTENTIAL REGULATION

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- Detection, concern, questions, call for answers, potential regulation
  - Drive for specific values
  - Drive for low numeric values

STAKEHOLDERS AND CHALLENGES THEY FACE AFTER CECS ARE IDENTIFIED

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- Primary stakeholders:
  - Water consumers, from public and private water supplies
  - Water purveyors, including municipalities and private water utilities
  - Potentially responsible parties
  - Regulatory bodies

- Potential challenges where standards don’t exist:
  - Deciding which water resources are impaired
  - Deciding what, if any, action is appropriate
  - Communicating with residents
  - Defining the extent of responsibility

POTENTIAL GAPS IN THE SCIENCE FOR CECS

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- Gaps in the science can include:
  - Lack of health effects data and agreed upon toxicity values (e.g., reference dose from ATSDR)
  - Lack of occurrence data to evaluate the overall problem and impact of a particular regulatory response

ADVERSE CONSEQUENCES OF SETTING STANDARDS WITH INSUFFICIENT SCIENCE

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- Potential implications of setting standards on limited data:
  - Standards used or adopted may be too low or too high
  - Lack of science sometimes leads to stricter numbers
  - Implementation may not be feasible or commensurate with health risk
  - Lack of consensus among regulatory agencies
  - Decisions based on perceived certainty of specific standard may be expensive/disruptive/difficult to undo
  - Confusion, concern, lack of confidence among stakeholders
  - Communications can be difficult or suspect

NEW JERSEY SETS A GROUNDWATER CLEAN-UP STANDARD FOR PFNA

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- 2006 – NJDEP conducts occurrence study for PFOA -- detected in more than 70 percent of public water systems sampled -- establishes a guidance level of 40 ppt for PFOA
- 2009 – DEP conducts further occurrence sampling for broader range of PFAS -- PFNA detected in a public water supply well at 96 ppt
- 2013-2015 UCMR3 – Additional occurrence data collected for PFAS to 20 ppt detection limit
  - Estimated that over 75% of water resources had not been sampled to what became the proposed standard
- August 2013 – NJDEP releases 2009 PFNA data to public

NEW JERSEY SETS A GROUNDWATER CLEAN-UP STANDARD FOR PFNA

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- NJDEP January 17, 2014 letter and fact sheet to town:

What should I do?

At this time, the DEP is not aware of any studies that have directly linked consumption of water with PFNAs with human health effects. However, out of an abundance of caution, the New Jersey Department of Health advises that residents use bottled water for powdered or concentrated infant formula and all other drinking uses for children up to the age of one year until the situation is resolved. Pregnant women and nursing mothers can continue to drink the water because there is no increased risk.

- NJDEP March 2014 proposed Interim Specific Groundwater Quality Criterion (ISGWQC) of 20 ppt, later reduced to 10 ppt by applying additional uncertainty factor for “data base uncertainty”

NEW JERSEY SETS A GROUNDWATER CLEAN-UP STANDARD FOR PFNA

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- November 2015, NJDEP posts “immediately enforceable” ISGWQC of 10 ppt to website -- where exceeded, notices required within 5 days:

  . . . the Reference Dose that supports the derivation of a [groundwater] criterion of 13 ng/L is 0.74 ng/kg/day, as follows:

  $$\frac{13\ ng/L \times 2\ L/day}{70\ kg \times 0.5} = 0.74\ ng/kg/day$$

- April 3, 2017, Proposed Final Rule: December 19, 2017 -- ISGWQC Vacated by Super. Ct. App. Div.
- January 16, 2018, NJDEP publishes Final Rule:
  - PFNA 10 ppt groundwater criteria and classified as hazardous substance
  - NJDEP loosens rules on how it can calculate GWQC
  - 22 other ISGWQC converted to final GWQC, e.g., 1,4 Dioxane at 400 ppt

NEW JERSEY PROPOSES DRINKING WATER MCLS FOR PFAS

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- April 2014 – NJDEP directs DWQI to develop MCL recommendations for PFNA, PFOA and PFOS, in that order
- June 2015 – DWQI recommends PFNA MCL of 13 ppt
- February 2017 – DWQI recommends PFOA MCL of 14 ppt
- August 2017 – NJDEP publishes Proposed MCL for PFNA of 13 ppt
- November 2017 – NJDEP announces intent to issue MCL of 14 ppt, as lowest in the country:

  "The new standard, which is expected to become effective in about a year, is tougher than the DEP's current guidance level of 40 ppt, and is the strongest in the country, said DEP Commissioner Bob Martin at a press conference to announce the new measure at the Voorhees headquarters of New Jersey American Water." NJ Spotlight, Nov. 2, 2017, J. Hurdle
- November 2017 – DWQI recommends Draft PFOS MCL of 13 ppt
- January 16, 2018 -- New Governor inaugurated

NEW YORK STATE CLEAN WATER INFRASTRUCTURE ACT (2017)

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Why?

- PFOS in the City of Newburgh, PFOA in **Hoosick Falls**
- 1,4-dioxane on Long Island

What?

- Expanded testing program for CECs to all local drinking water systems servicing 25 homes or more. Initially, PFOS, PFOA and 1,4-dioxane will be monitored.
- Drinking Water Quality Council expected to establish MCLs by the Fall of 2018.
- Interim requirement to evaluate drinking water systems near facilities suspected to be frequent users of PFOA, PFOS, and 1,4-dioxane, and; all sites under the oversight of NYSDEC in a Part 375 Environmental Remediation Program.
- 1,4-dioxane found in **71 percent** of tested water supply wells on Long Island: CWIA invests up to $900,000 per supply well to meet treatment levels prior to adoption of MCLs…

Implications?

- Uncertainty, widespread occurrence, public concern and response

Conclusions

- Identification of CECs and collection of CEC data at low detection limits from drinking water….
  - Significant consequences for water purveyors and potentially responsible parties and creates concern among water users.
- Resulting impacts and concerns…
  - Unfounded actions and fears until clear, specific standards are developed based on appropriate levels of science.
- Evolving experiences with recent CECs including PFAS compounds demonstrates…
  - Rush to issue standards with insufficient scientific support can lead to unwarranted consequences.
- Coordinated leadership at a national level is needed.