



Contaminant Candidate List and Cyanobacteria

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Statutory Requirements and the Drinking Water Regulatory Process (1996 SDWA Amendments*)

- 1) Contaminant Candidate List (CCL)** – SDWA requires EPA to develop a list of contaminants that are known or anticipated to occur in drinking water and to publish the list every five years.
- 2) Regulatory Determination** – EPA must decide whether or not to regulate at least five CCL contaminants with a national primary drinking water regulation (NPDWR) after evaluating criteria specified under the 1996 SDWA; Publish determinations on a five year cycle.
- 3) Regulation Development** - If EPA decides to regulate a contaminant, the Agency has 24 months to propose and 18 months to finalize the health goal and the NPDWR.

**SDWA Section 1412(b)(1)*



Guiding Principle of CCL3 Development

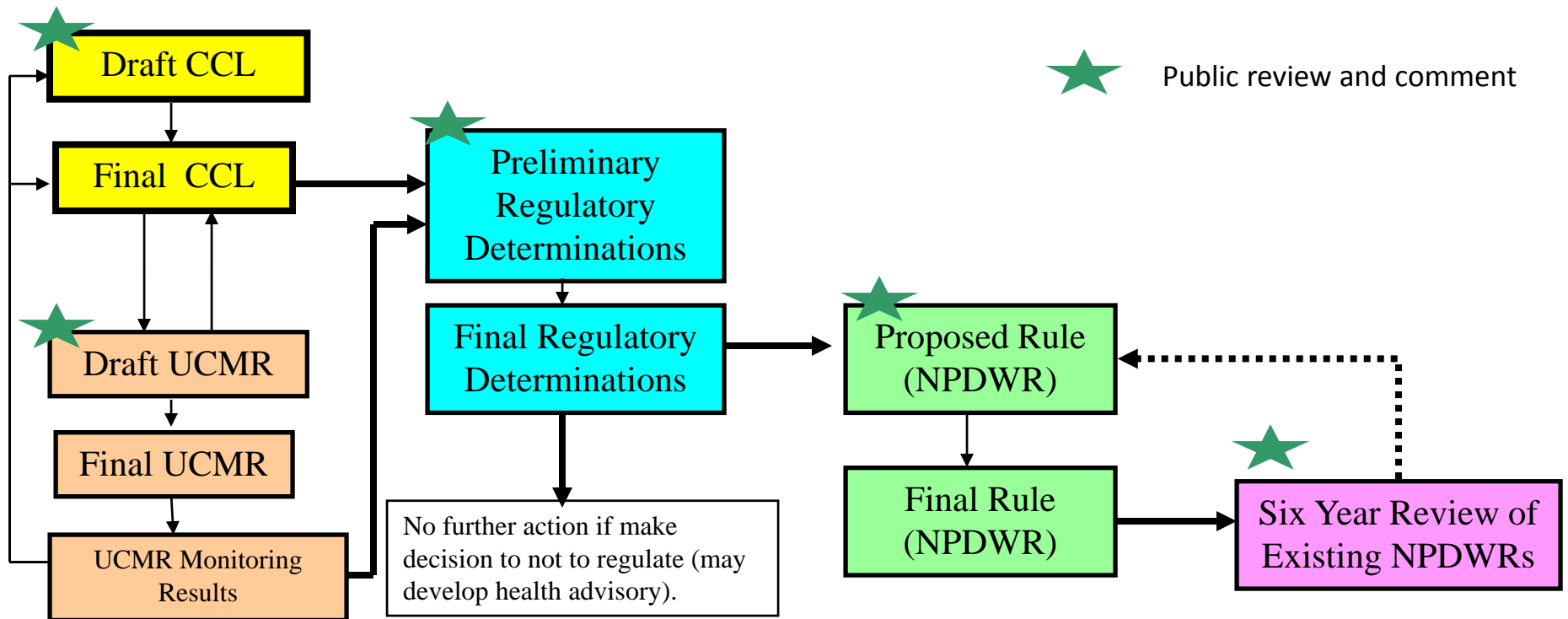
Occurrence in public water systems at frequency and levels of public health concern

Health Effects



Occurrence

Generalized Flow of Regulatory Processes



At each stage, need increased specificity and confidence in the type of supporting data used (e.g. health and occurrence).



Safe Drinking Water Act - Making Regulatory Determinations

SDWA requires EPA to publish a Maximum Contaminant Level Goal (MCLG) and promulgate an NPDWR for a contaminant if the Administrator determines that -

- *The contaminant may have an adverse effect on the health of persons;*
- *The contaminant is known to occur or there is substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and*
- *In the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.*



SDWA Section 1412(b)(1)



Regulatory Determination Outcomes

- **Positive Determination**

- Affirmative determination for all three criteria.
- Propose a drinking water regulation within 2 years and promulgate within 3 and a half years of determination.

#	Outcome
1	✓
2	✓
3	✓

- **Negative Determination**

- Negative determination for any one the three criteria.
- No action taken to develop a drinking water regulation.
- May publish a health advisory* or take other appropriate action.

#	Outcome
1	✓
2	✗
3	✗

*Health Advisory (HA) - an estimate of the acceptable drinking water levels for a chemical substance based on health effects information; an HA is not a Federal legally enforceable standard, but serves as technical guidance for Federal, State, and local officials.



Status of CCL 3

- Published in the FR on October 12, 2009
 - Lists 116 contaminants (104 chemicals & 12 microbials; Appendix C)
- Beginning Regulatory Determinations Process



Types of Contaminants on the Final CCL 3

- 11 Disinfection byproducts
 - i.e., NDMA, aldehydes, halogenated compounds
- Perfluorinated contaminants (PFOA & PFOS)
- 9 Hormones and an antibiotic
 - Considered occurrence in water
- 43 Pesticides and/or degradates
 - Detected occurrence, modeled concentrations and application considered
- 12 Pathogens
 - Identified 12 waterborne pathogens that have known or anticipated occurrence in PWS
- **3 Cyanotoxins**



Appendix A - CCL 3

104 Chemicals and 12 Microbes

1,1,1,2-Tetrachloroethane
1,1-Dichloroethane
1,2,3-Trichloropropane
1,3-Butadiene
1,3-Dinitrobenzene
1,4-Dioxane
17 alpha-Estradiol
1-Butanol
2-Methoxyethanol
2-Propen-1-ol
3-Hydroxycarbofuran
4,4'-Methylenedianiline
Acephate
Acetaldehyde
Acetamide
Acetochlor
Acetochlor ethanesulfonic acid (ESA)
Acetochlor oxanilic acid (OA)
Acrolein
Alachlor ethanesulfonic acid (ESA)
Alachlor oxanilic acid (OA)

alpha-Hexachlorocyclohexane
Aniline
Bensulide
Benzyl chloride
Butylated hydroxyanisole
Captan
Chlorate
Chloromethane (Methyl chloride)
Clethodim
Cobalt
Cumene hydroperoxide
Cyanotoxins (3)
Dicrotophos
Dimethipin
Dimethoate
Disulfoton
Diuron
Equilenin
Equilin
Erythromycin
Estradiol (17-beta estradiol)
Estriol

Estrone
Ethynyl Estradiol (17-alpha Ethynyl Estradiol)
Ethoprop
Ethylene glycol
Ethylene oxide
Ethylene thiourea
Fenamiphos
Formaldehyde
Germanium
Halon 1011 (Bromochloromethane)
HCFC-22
Hexane
Hydrazine
Mestranol
Methamidophos
Methyl bromide (Bromomethane)
Methyl tert-butyl ether
Metolachlor
Metolachlor ethanesulfonic acid (ESA)
Metolachlor oxanilic acid (OA)



Appendix A - CCL 3

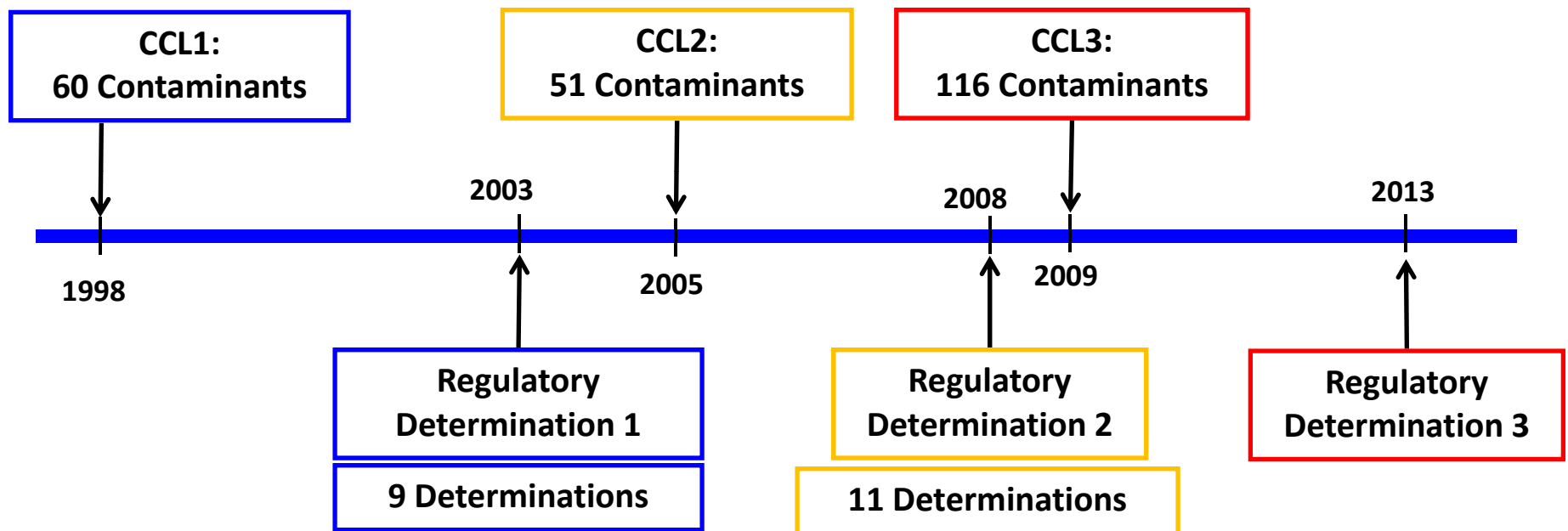
104 Chemicals and 12 Microbes

Molinate
Molybdenum
Nitrobenzene
Nitroglycerin
N-Methyl-2-pyrrolidone
N-Nitrosodiethylamine (NDEA)
N-nitrosodimethylamine (NDMA)
N-Nitroso-di-n-propylamine (NDPA)
N-Nitrosodiphenylamine
N-nitrosopyrrolidine (NPYR)
Norethindrone (19-Norethisterone)
n-Propylbenzene
o-Toluidine
Oxirane, methyl-
Oxydemeton-methyl
Oxyfluorfen
Perchlorate
Perfluorooctane sulfonic acid (PFOS)
Perfluorooctanoic acid (PFOA)
Permethrin

Profenofos
Quinoline
RDX
sec-Butylbenzene
Strontium
Tebuconazole
Tebufenozide
Tellurium
Terbufos
Terbufos sulfone
Thiodicarb
Thiophanate-methyl
Toluene diisocyanate
Tribufos
Triethylamine
Triphenyltin hydroxide (TPTH)
Urethane
Vanadium
Vinclozolin
Ziram

Adenovirus
Caliciviruses
Campylobacter jejuni
Enterovirus
Escherichia coli (0157)
Helicobacter pylori
Hepatitis A virus
Legionella pneumophila
Mycobacterium avium
Naegleria fowleri
Salmonella enterica
Shigella sonnei

Timeline of CCL and Regulatory Determinations





CCL 3 Regulatory Determinations

- **Final Regulatory Determinations for CCL 3 due mid-2013**
 - **Currently gathering available health and occurrence information**



Cyanobacteria

- Freshwater cyanobacteria that produces toxins: three toxins of high interest in US:
 - Microcystins
 - Cylindropermopsin
 - Anatoxin-A
- Toxin selection was base on four criteria:
 - Health effects
 - Occurrence in the US
 - Susceptibility to drinking water treatment and
 - Toxin stability



Occurrence

- AWWARF microcystin study of 677 source & finished water samples.
 - 80% source waters had detectable microcystin levels
 - 4.3% > WHO guideline (1 ug/L in drinking water)
 - 2 finished water samples >WHO guideline

Little occurrence information on cylindrospermopsin, anatoxin-a



Work in Progress to Fill Gaps

- Development of cyanotoxin methods;
Analytical standards: microcystins, cylindrospermopsin, anatoxin-a.
- Once methods available, planning to monitor raw & finished water (UCMR)
- Health effects research for cyanotoxins, consider risk assessment and guideline levels for drinking water.
- Develop plain language information document for public water utilities that discusses algal blooms (prevention, treatment, potential health effects).

General Approach for Evaluating the Statutory Criteria

#	Statutory Criteria	Information To Consider During Evaluation
1	Is the contaminant likely to cause an adverse effect on the health of humans?	<ul style="list-style-type: none"> • Identify most recent Agency risk assessment (IRIS,OPP,OW), the potential health effects, and the Reference Dose (RfD) and/or cancer slope factor. • Use health information to derive a health reference level (HRL)
2	Is the contaminant known or likely to occur in public water systems (PWSs) at a frequency and level of concern?	<ul style="list-style-type: none"> • Evaluate drinking water occurrence data at the HRL. • Primary source for drinking water occurrence data is the Unregulated Contaminant Monitoring Regulation (UCMR). • If available, review supplemental information (e.g. USGS, State data).
3	In the sole judgment of the Administrator, does regulation of the contaminant present a meaningful opportunity for health risk reduction for persons served by PWSs?	<p>Consider variety of factors which include:</p> <ul style="list-style-type: none"> • Population exposure (typically based on drinking water occurrence information; for non-carcinogens, consider relative exposure from drinking water and other sources. • Sensitive populations • National distribution of occurrence



More Information Available at:

www.epa.gov/safewater/

www.regulations.gov

The image displays two overlapping web browser windows. The left window is titled 'CCL and Regulatory Determinations Home' and shows the EPA website page for 'Drinking Water Contaminant Candidate List and Regulatory Determinations'. The right window is titled 'Regulations.gov - Microsoft Internet Explorer' and shows search results for the term '2007-1189'. The search results include 'Announcement of Preliminary Regulatory Determinations for Priority Contaminants on the Drinking Water Contaminant Candidate List' and 'Announcement of Regulatory Determinations for Priority Contaminants on the Drinking Water Contaminant Candidate List; Notice'.



For More Information

- Tox profiles:

<http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=161263>

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Questions ?