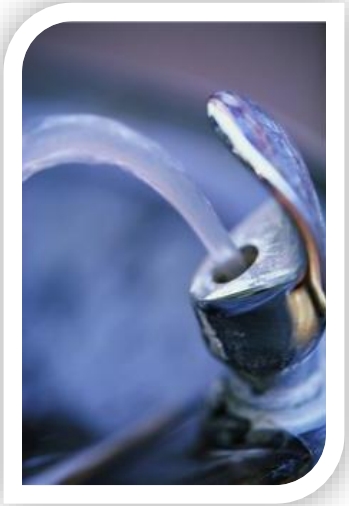
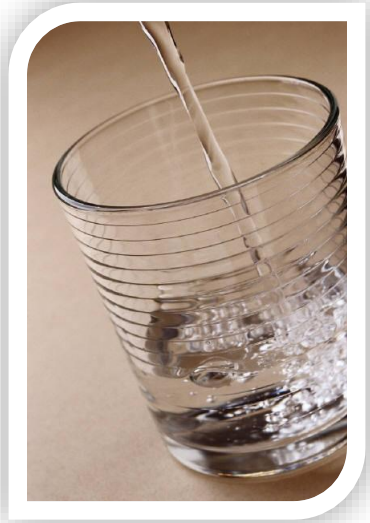
Draft Contaminant Candidate List 4





Science Advisory Board

April 29, 2015

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USEPA

Office of Ground Water and Drinking Water

Contaminant Candidate List 4 (CCL 4) Agenda

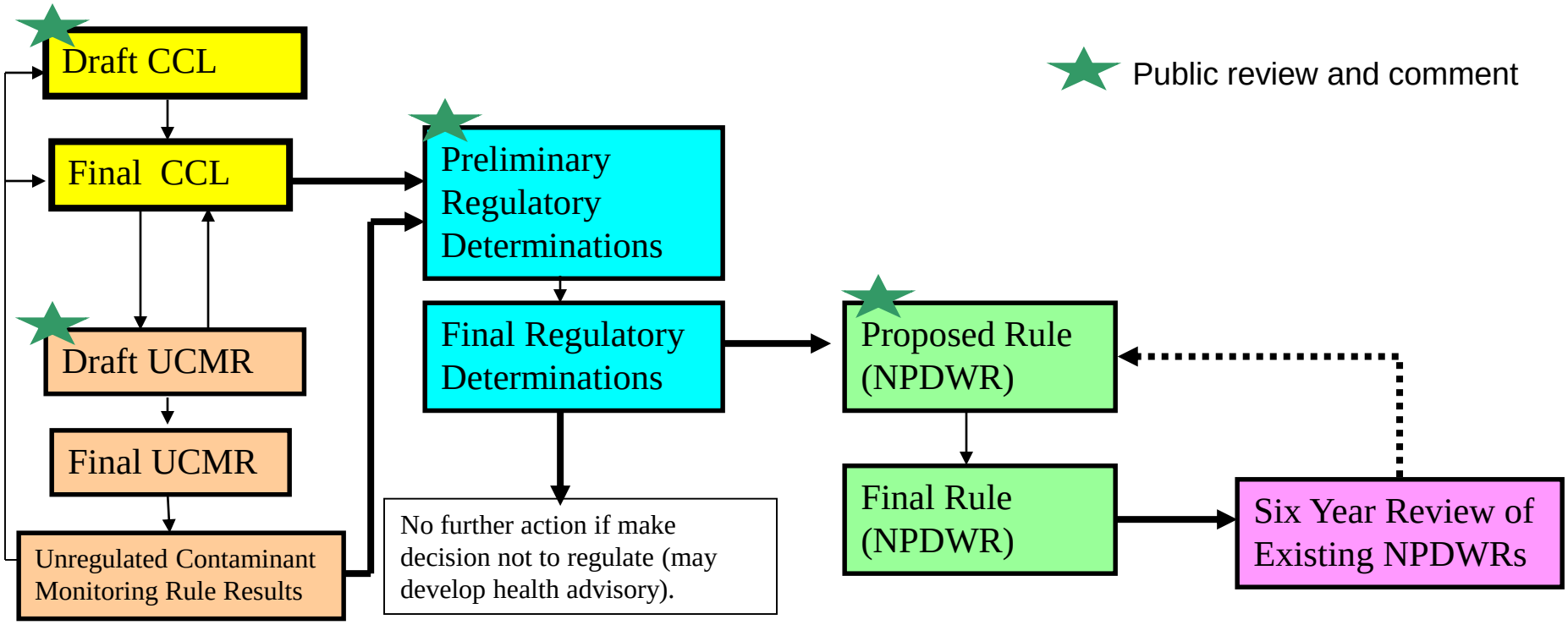
1. Provide statutory and regulatory background for the Contaminant Candidate List (CCL)
2. Provide an overview of previous CCLs
3. Provide an overview of the CCL 4 approach and the draft list
4. Discuss CCL 4 status and next steps

CCL Statutory Requirements & Background

- 1996 Safe Drinking Water Act (SDWA) Amendments require EPA to:
  - Publish a list of contaminants (the CCL) every 5 years that are not subject to any proposed or promulgated national primary drinking water regulation (NPDWR), which are known or anticipated to occur in public water supplies and may require regulation.

- In developing the list, SDWA also specifies that EPA:
  - Consider substances listed on CERCLA and FIFRA.
  - Consult with the scientific community including the Science Advisory Board (SAB).
  - Provide an opportunity for public comment.
- The decision to list a contaminant is not judicially reviewable, CCL does not impose any burden or requirements on public water systems or primacy agencies.
- EPA uses the CCL to identify priority contaminants for regulatory decision making and information collection.

SDWA Regulatory Processes

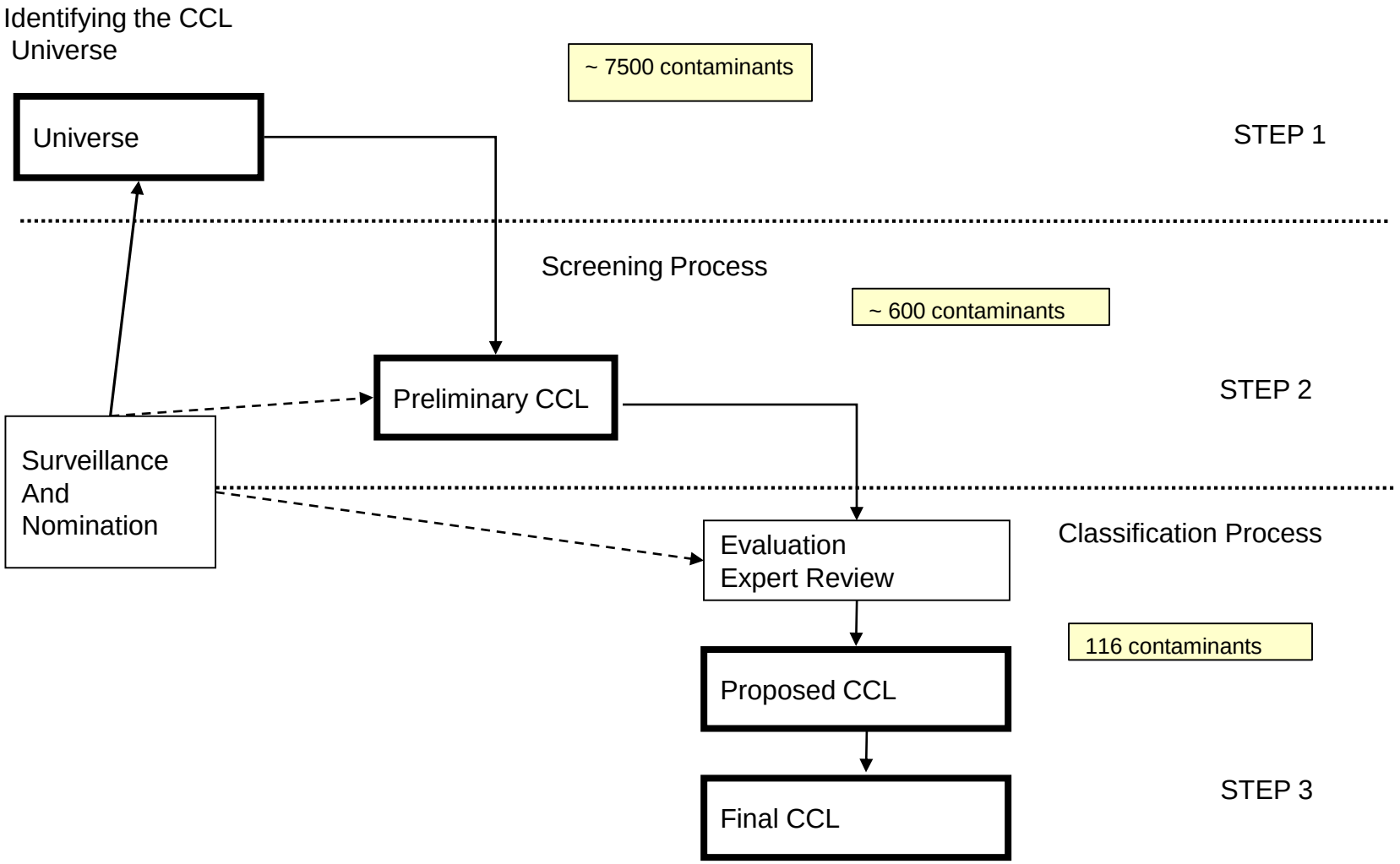


At each stage, we like to have increased specificity and confidence in the type of supporting data used (e.g., health and occurrence).

CCL 1, CCL 2 and CCL 3

- CCL 1 (March 1998) – 60 contaminants
- CCL 2 (February 2005) – 51 contaminants
  - After making negative regulatory determinations for 9 of the 60 contaminants on CCL 1, EPA carried forward the remaining 51 contaminants to CCL 2.
- CCL 3 (October 2009) – 116 contaminants
  - **New multi-step process** developed based on recommendations by the National Academy of Science's National Research Council and the National Drinking Water Advisory Council (NDWAC).

CCL 3 Process



Screening Process for CCL 3 Chemicals

Health Effects (e.g., LD_{50}, RfD, LOAEL, Cancer Classifications)	**Occurrence (finished water, ambient water, release (TRI or pesticide application), production)**					
	No Detect	**Very Low**	**Low**	**Moderate**	**High**	**Very High**
 Increasing Toxicity						

Classification Process for CCL 3 Chemicals

- Classification models used as tools to further evaluate PCCL chemicals
  - Four attributes serve as input to model
    - Occurrence – 1) magnitude and 2) prevalence
    - Health Effects – 3) potency and 4) severity
  - Scoring protocols developed for each attribute and type of data
    - Data hierarchies used if a chemical had several different types of data
  - Model results inform decision whether to list or not

- Post-model analyses (expert review) and CCL 3 chemical selection
  - Contaminants with water data were listed if Health Reference Level (HRL) / Water Concentration Ratio ≤ 10
    - HRL converts potency data to concentration in water
    - Modeled ratio serves as a benchmark that suggests level of concern
  - Chemicals with only release data were listed if model outcome was to list or potentially list

Screening Process for CCL 3 Microbes

- The microbial CCL 3 Universe was defined as microbes that are known to cause disease in humans
  - 1,425 pathogens
  - Based on literature review and public nominations
- Selection of microbes from the CCL Universe for the PCCL is based on exclusionary criteria that assess the potential of water-related transmission (occurrence) and the plausibility of causing waterborne disease by ingestion, inhalation, or dermal contact (health effects)

Classification Process for CCL 3 Microbes

- EPA devised a scoring system to assign a numerical value to each pathogen on the PCCL, those pathogens receiving high scores were considered for placement on the CCL.
- Three scoring protocols:
  - Waterborne Disease Outbreak (WBDO)
  - Occurrence in Drinking Water
  - Health Effects

$$\text{Pathogen Total Score} = \text{Highest Score b/w WBDO and Occurrence} + \left(\left(\text{General Population Score} + \text{Highest Sensitive Subpopulation Score} \right) \times 5/14 \right)$$

- Natural breaks in pathogen total scores, top 12 pathogens made final CCL 3

Draft CCL 3 SAB Review

- SAB noted that the documentation of the CCL 3 process lacked transparency.
  - EPA updated the CCL 3 technical support documents to increase transparency.
  - EPA also updated the CCL 3 web site so the support documents could be found more easily.
- SAB recommended prioritization of the list to better identify regulatory priorities.
  - In the Final CCL 3 Federal Register Notice, EPA identified data/ information needs on occurrence, health effects, and analytical methods.

CCL 4 Approach

The CCL 4 evaluation and selection process includes a three pronged approach:

1) Carrying forward CCL 3 contaminants (minus those with regulatory determinations).
2) Seeking and evaluating nominations from the public for additional contaminants to consider.
3) Evaluating any new data for those contaminants with previous negative regulatory determinations from CCL 1 or CCL 2 for potential inclusion on the CCL 4.

Carry Forward of CCL 3 Contaminants to CCL 4

EPA believes it is appropriate for the Draft CCL 4 to carry forward the CCL 3 contaminants (minus those with regulatory determinations) for the following reasons:

1) In developing the CCL 3, the agency implemented a robust process recommended by the NRC and the NDWAC to screen and score the universe of potential contaminants;
2) EPA used the best available, peer-reviewed data and information to evaluate contaminants for CCL 3; and
3) Carrying forward CCL 3 contaminants allows the agency to focus resources on evaluating contaminants nominated by the public for CCL 4 and review new data for CCL 1 or CCL 2 contaminants with previous negative regulatory determinations.

CCL 4 Nominations

- Sought public nominations on May 8, 2012, for contaminants to be considered for possible inclusion in the CCL 4.
- Received nominations for 59 unique contaminants (54 chemicals and 5 microbes).
  - Nominations from 10 different organizations or individuals.
  - Eight contaminants nominated by more than one nominator.
  - Seven nominated contaminants were on CCL 3, carried forward to Draft CCL 4.
  - Four nominated contaminants are covered under existing or proposed NPDWRs, therefore were not considered eligible for CCL 4.
- For remaining nominated contaminants:
  - EPA reviewed data provided by nominators and collected additional data, when available.
  - If new data available, EPA screened and scored the nominated contaminants utilizing the same process used for CCL 3.
- EPA added two nominated contaminants (manganese and nonylphenol) to the Draft CCL 4 based on new health information and occurrence data.

Development of the Draft CCL 4

- EPA evaluated the nominated microbial contaminants for CCL4 using the same process used in CCL 3 and determined there was no new data that would change the scores or listing decisions.
  - The 12 microbes included in CCL 4 are the same as those included in CCL 3.

- EPA evaluated the 20 contaminants from CCL 1 and CCL 2 for which the agency made negative regulatory determinations.
  - EPA included manganese on the Draft CCL 4 and determined there is not sufficient new information for any of the other 19 contaminants to justify their inclusion on the Draft CCL 4.

Draft CCL 4

- The Draft CCL 4 includes 100 chemicals and 12 microbes.
- Based on the agency's review of the best available new data, EPA made the following changes from the Final CCL 3 to the Draft CCL 4:
  - Added 2 nominated chemicals (nonylphenol and manganese) based on new or updated health effects and occurrence data.
  - Removed 5 of the CCL 3 contaminants that have preliminary regulatory determinations (1,3-dinitrobenzene, dimethoate, terbufos, terbufos sulfone, strontium), pending final determinations.
  - Removed perchlorate because EPA made a positive regulatory determination in 2011.

CCL 4 Status

- Draft CCL 4 published February 4, 2015
- 60-day comment period ends April 6, 2015
- SAB panel meeting April 29 -30, 2015
- Consider public comments and SAB recommendations in developing Final CCL 4
- Publish Final CCL 4 in 2016

CCL References

- For more information on the CCL 4:
  - http://www2.epa.gov/ccl/draft-contaminant-candidate-list-4-ccl-4
- The CCL 4 support documents can be found here:
  - http://www2.epa.gov/ccl/ccl-4-technical-support-documents
- CCL 4 Fact Sheet:
  - http://www2.epa.gov/ccl/fact-sheet-contaminant-candidate-list-4-draft
- CCL 3 technical support documents:
  - http://www2.epa.gov/ccl/contaminant-candidate-list-3-ccl-3#tech_support_docs

Appendices

Appendix 1- List of nominated contaminants

List of CCL 4 nominated chemicals

3-chloro-4-dichloromethyl-5-hydroxy-2(5H)-furanone
alpha-Hexachlorocyclohexane
Aldicarb
Alkylphenol mono- to tri-oxylates
Amoxicillin
Azinphos-methyl
Bacitracin zinc
Bentazone
Benzyl butyl phthalate
Bisphenol A
Bromoxynil
Carbaryl
Cesium 137
Chlorothalonil
Chlorpyrifos
Dibutyl phthalate
Dicamba
Dichlorvos
Dicofol
Dicyclohexyl phthalate
Diethyl phthalate
Di-isononyl phthalate
Dimethyl phthalate
Di-n-octyl phthalate
Endosulfan
Fluometuron
Linezolid
Linuron
Malathion
Manganese
Methicillin
Methyl parathion
Methyl tertiary butyl ether (MTBE)
Microcystin-LR
Nonylphenol
Nonylphenol ethoxylate
Octylphenol
Octylphenol ethoxylate
Oxacillin
Penicillin
Perfluorooctanoic acid (PFOA)
Permethrin
Phosmet
Progesterone
Radon
Spiramycin
Strontium 90
Testosterone
Trichlorfon
Triclocarban
Triclosan
Tylosin
Vancomycin
Virginiamycin

List of CCL 4 nominated microbes

Adenovirus
Heterotrophic Plate Count Bacteria (HPC)
Naegleria fowleri
Toxoplasma gondii
Vibrio cholerae

Appendix 2: Draft CCL 4 Contaminants

100 Chemicals and 12 Microbes

1,1,1,2-Tetrachloroethane
1,1-Dichloroethane
1,2,3-Trichloropropane
1,3-Butadiene
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
Disulfoton
Diuron
Equilenin
Equilin
Erythromycin
Estradiol (17-beta)
Estriol
Estrone
Ethinyl Estradiol (17-alpha)
Ethoprop
Ethylene glycol
Ethylene oxide
Ethylene thiourea
Fenamiphos
Formaldehyde
Germanium
Halon 1011 (Bromochloromethane)
HCFC-22
Hexane
Hydrazine
Manganese
Mestranol
Methanol
Methamidophos
Methyl bromide (Bromomethane)
Methyl tert-butyl ether
Metolachlor
Metolachlor ethanesulfonic acid (ESA)
Metolachlor oxanilic acid (OA)
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)
Nonylphenol
Norethindrone (19-Norethisterone)
n-Propylbenzene
o-Toluidine
Oxirane, methyl-
Oxydemeton-methyl
Oxyfluorfen
Perfluorooctane sulfonic acid (PFOS)
Perfluorooctanoic acid (PFOA)
Permethrin
Profenofos
Quinoline
RDX
sec-Butylbenzene
Tebuconazole
Tebufenozide
Tellurium
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