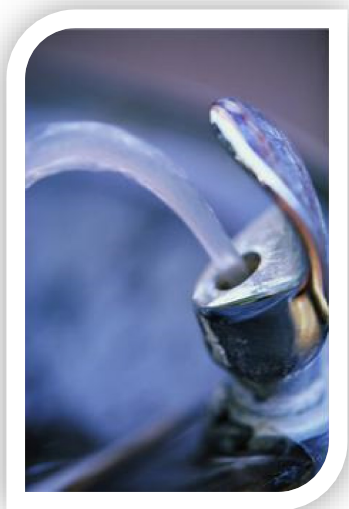
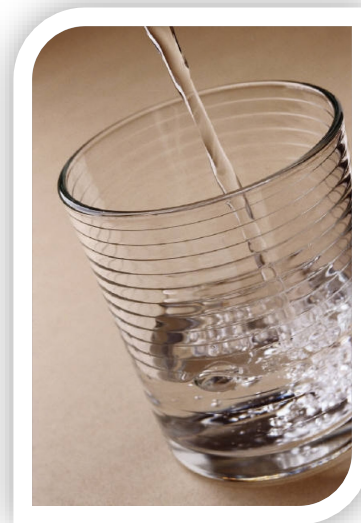


Preliminary Regulatory Determinations for the Third Drinking Water Contaminant Candidate List



**Public Meeting
December 9, 2014**



US EPA

Office of Ground Water and Drinking Water

Meeting Objectives and Agenda

1. Provide Background

- Overview of Safe Drinking Water Act (SDWA) regulatory processes
- Statutory criteria for Regulatory Determination & potential outcomes
- History and timeline for previous Contaminant Candidate Lists (CCLs) and Regulatory Determination (RD) processes
- RD3 stakeholder outreach efforts

2. Provide Overview of the Regulatory Determination 3 (RD3) Approach

- Approach to screen/identify potential contaminants for RD3
- Information and data sources considered in evaluating the three SDWA statutory criteria
- Drinking Water Strategy and evaluation of contaminant groups

3. Discuss Contents of the RD3 Notice

4. Discuss RD3 Next Steps

5. Stakeholder Questions/Feedback

Overview of the SDWA Regulatory Processes, the Contaminant Candidate List (CCL) and Regulatory Determination Process

Zeno Bain, US EPA

Statutory Requirements and the Drinking Water Regulatory Process

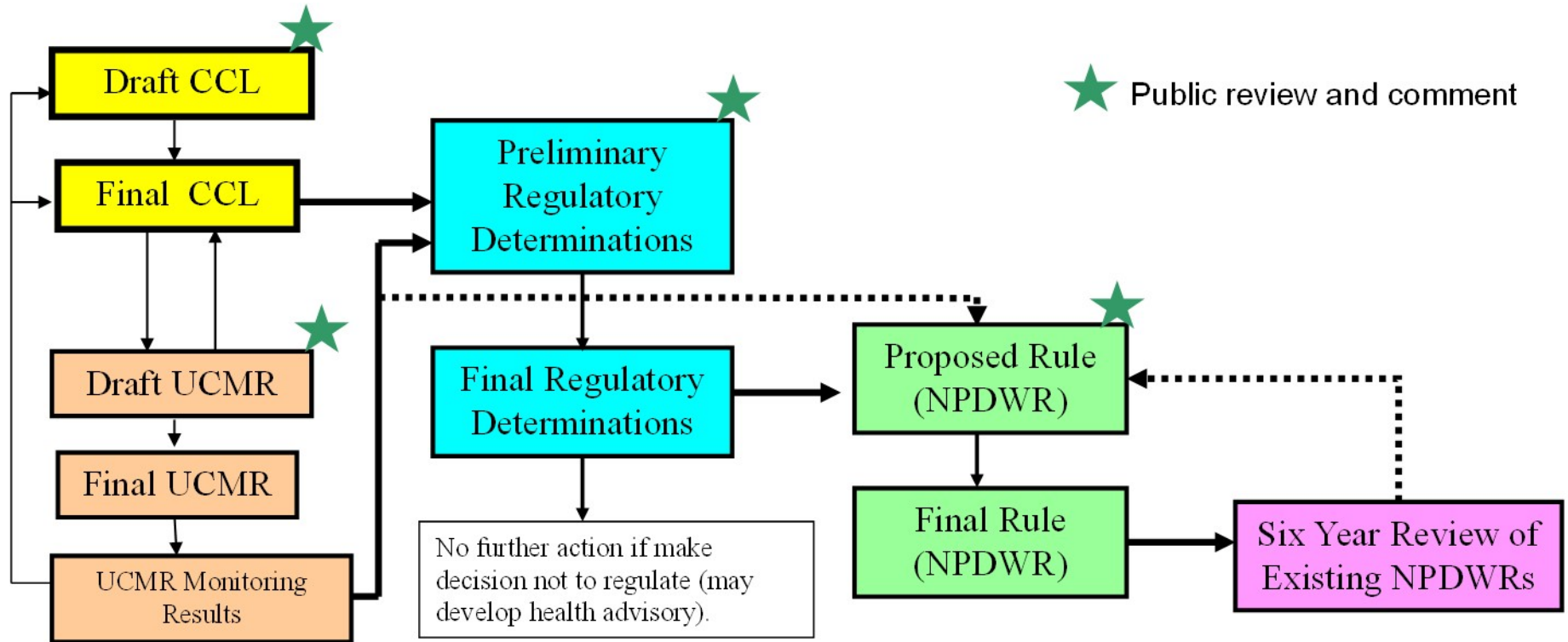
(1996 Safe Drinking Water Act Amendments*)

- **Contaminant Candidate List (CCL)** – Every five years, the Administrator shall publish a list of contaminants which, at the time of publication, are not subject to any proposed or promulgated national primary drinking water regulation (NPDWR), which are known or anticipated to occur in public water systems, and which may require regulation.
- **Regulatory Determination** – Every five years, the Administrator shall, after notice of the preliminary determination and opportunity for public comment, for not fewer than five contaminants included on the CCL, make determinations on whether or not to regulate such contaminants. A determination to regulate a contaminant shall be based on specified criteria.
- **Regulation Development** – The Administrator shall propose the Maximum Contaminant Level Goal (MCLG) and NPDWR not later than 24 months after determination and promulgate within 18** months after proposal.
- **Unregulated Contaminant Monitoring** – Process to monitor up to 30 different unregulated contaminants every 5 years.
- **Six Year Review** – Every 6 years, review and (if appropriate) revise the standard. Any revision must maintain or improve public health protection. If revise, we go through the regulation development process again and evaluate a number of factors.

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

***SDWA allows 9 month extension if needed*

General Flow of SDWA Regulatory Processes



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

Three Regulatory Determination Criteria Specified by the 1996 SDWA* Amendments

SDWA requires EPA to publish a MCLG and promulgate an NPDWR for a contaminant if the Administrator determines that:

- 1) *The contaminant may have an adverse effect on the health of persons;*
- 2) *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*
- 3) *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)

Consideration of Sensitive Populations in Regulatory Determination of Drinking Water Contaminants

In the regulation of unregulated contaminants, as directed by the 1996 Amendments to the SDWA, section 1412(b)(1)(B):

The Administrator, in making such selection, shall take into consideration, among other factors of public health concern, the effect of such contaminants upon subgroups that comprise a meaningful portion of the general population (such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations) that are identifiable as being at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population.

Regulatory Determination Outcomes

- **No Regulatory Determination**
 - Insufficient data to assess contaminant on three criteria

- **Positive Determination**
 - Affirmative determination for all three criteria
 - Begin process to develop a drinking water regulation
 - Not considered a final agency action

- **Negative Determination**
 - Negative determination for any one the three criteria
 - Considered a final agency action
 - Drinking water regulation is not developed
 - Health Advisory is a non-regulatory option

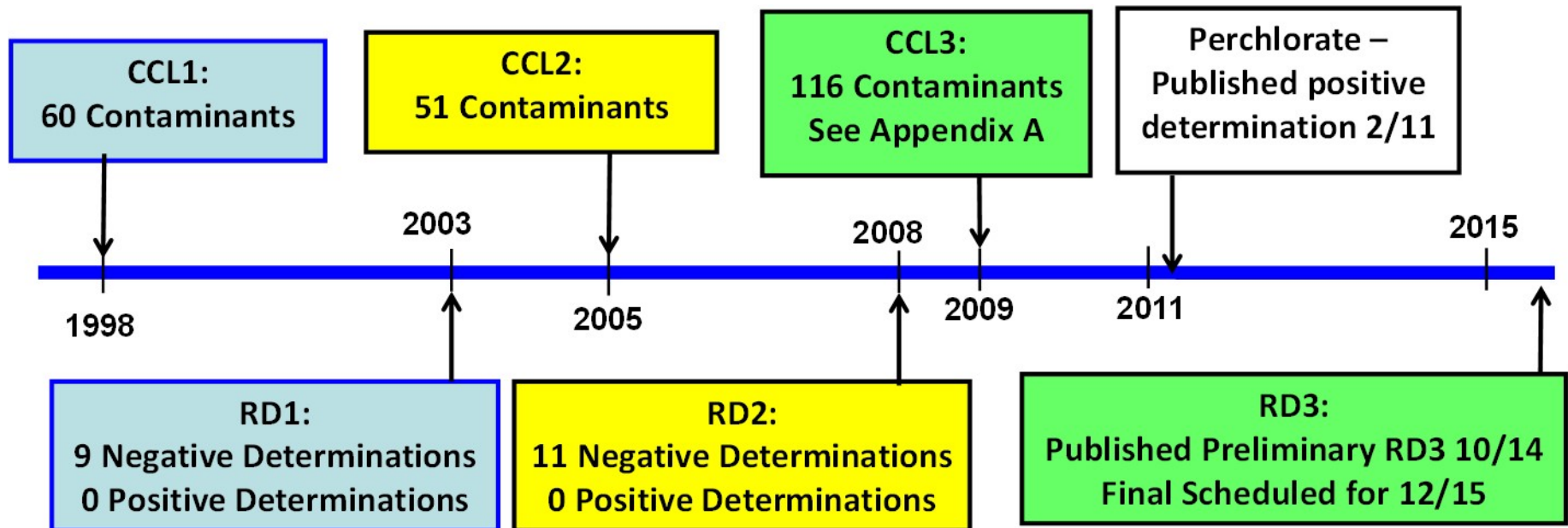
#	Outcome
1	✓
2	✓
3	✓

#	Outcome
1	✓
2	✗
3	✗

Stakeholder Outreach Efforts

- Held public stakeholder meeting – June 2011
 - EPA presented the process and available data for the 30+ contaminants on the “short list”, and requested any additional data to inform the process.
- Held expert review of the RD3 process – October 2012
 - Panel included seven experts representing a variety of expertise including health effects, occurrence, public water system experience, state perspectives, etc.
 - We convened the group for a two day meeting; Reviewers provided clarifying comments and agreed with overall approach for identifying contaminants for RD3 and the outcomes for each phase of the process.
- Published Preliminary Regulatory Determination 3 Notice with 60-day opportunity for public comment – October 2014

Contaminant Candidate List and Regulatory Determination Timeline

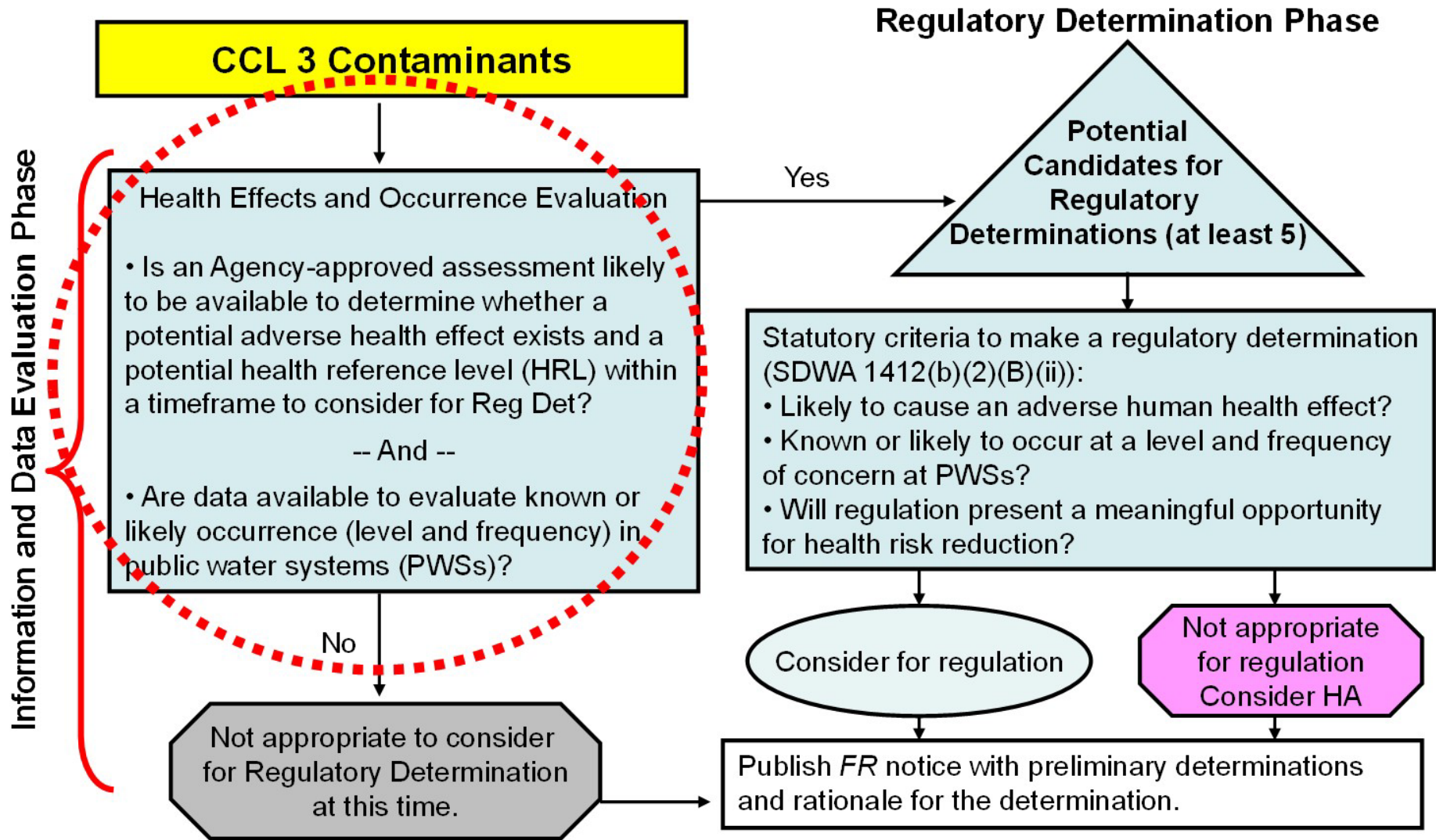


Questions?

Overview of Approach and Data Sources Used to Evaluate Potential Contaminants for Regulatory Determinations 3

Zeno Bain, US EPA

Overall Approach Used to Evaluate CCL 3 Contaminants for Regulatory Determinations



RD3 Approach – Three Main Phases

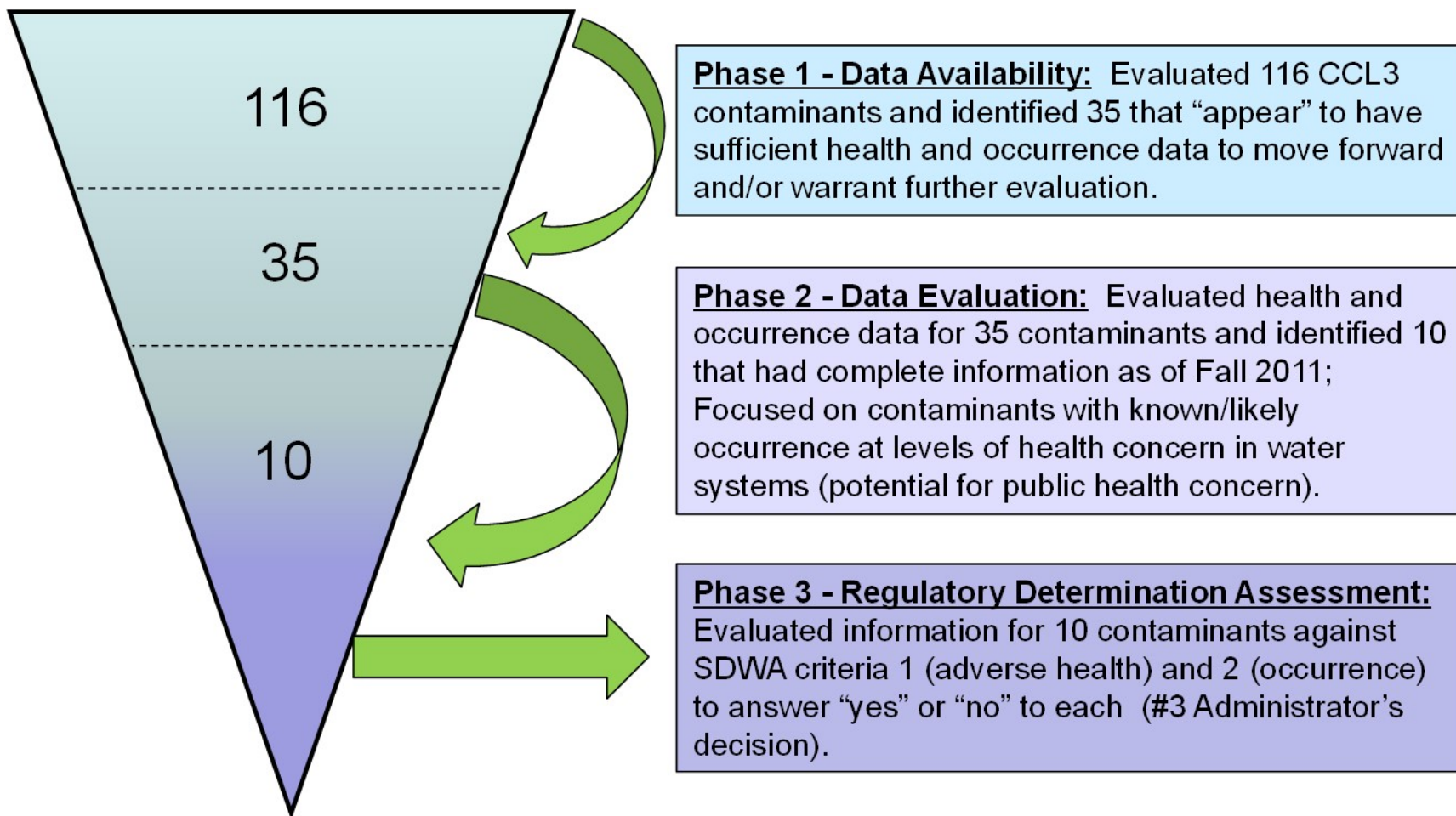


Table 1a. Phase 2 Contaminants with Data Gaps

Contaminant	Complete Health Data Available	Occurrence Data Available
1,4-Dioxane	✓	X
Acephate	✓	X
Acetochlor	X	✓
Acetochlor ethanesulfonic acid (ESA)	X	✓
Acetochlor oxanilic acid (OA)	X	✓
Alachlor ESA	X	✓
Alachlor OA	X	✓
Cobalt	X	✓
Disulfoton	✓	X
Diuron	✓	X
Methyl Bromide	X	✓
Methyl tert-butyl ether	X	✓
Metolachlor	X	✓

Table 1b. Phase 2 Contaminants with Data Gaps (continued)

Contaminant	Complete Health Data Available	Occurrence Data Available
Metolachlor ESA	X	✓
Metolachlor OA	X	✓
Molinate	X	✓
Molybdenum	X	✓
N-Nitrosodiphenylamine (NDPhA)	✓	X
Perfluorooctanesulfonic acid (PFOS)	X	X
Perfluorooctanoic acid (PFOA)	X	X
RDX	X	✓
Vanadium	X	✓
1,1,1,2-Tetrachloroethane	} Evaluated under separate process for Carcinogenic Volatile Organic Compounds Rule in 2011	
1,2,3-Trichloropropane		
Nitrobenzene		

Overall Approach Used to Evaluate CCL 3 Contaminants for Regulatory Determinations

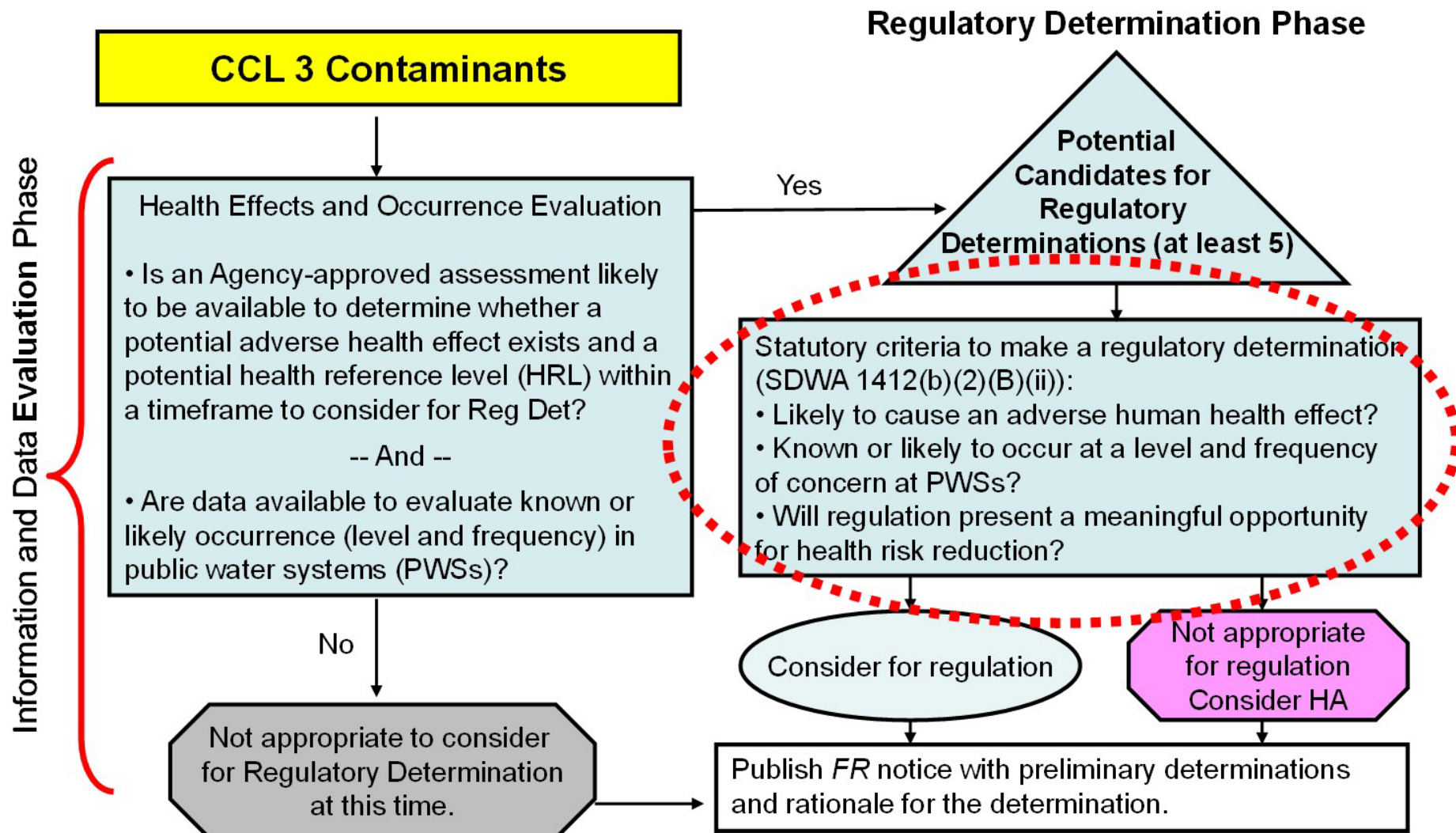


Table 2. How We Evaluate the Three SDWA Criteria?

#	Statutory Criteria	Information and Data Sources to Consider During Evaluation
1	May the contaminant cause an adverse effect on the health of humans?	<ul style="list-style-type: none"> • Identify and/or complete Agency risk assessment (i.e., IRIS, OPP, OW) or peer reviewed non-Agency assessment, which includes the potential health effects, the Reference Dose (RfD) and/or cancer slope factor • Develop the health reference level (HRL) based on the Agency risk assessment; HRL used to assess occurrence/exposure in criteria 2 and 3
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"> • Primarily evaluate “national” and “non-national” data relative to the HRL • National data: the Unregulated Contaminant Monitoring Regulations (UCMR 1 & 2), the Unregulated Monitoring Contaminant Surveys (UCM 1 & 2), and National Inorganics and Radionuclides Survey (NIRS) • Non-national data: monitoring by EPA/federal agencies, state data, etc. • Supplemental occurrence data also evaluated from sources including USGS, States, Toxic Release Inventory, and localized studies
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 • Supplemental sources of exposure information could also be considered • Other

Sources of Health Data and Information

- Identify recent or impending Agency risk assessment (i.e., IRIS, OPP, OW) and peer reviewed non-Agency risk assessment that meet Agency guidelines (e.g., ATSDR, NAS, WHO).
- Conduct literature searches (if older assessment)
- Identify the following:
 - Potential health effects
 - Reference Dose (RfD) or other non-cancer health value, and/or
 - Cancer slope factor
- Calculate benchmark value or health reference level to evaluate occurrence
 - Use ten to the negative sixth power risk level for carcinogens
 - Use lifetime health advisory value for non-carcinogens along with a 20% relative source contribution (RSC)

Sources of Occurrence Data and Information

- Unregulated Contaminant Monitoring Regulation (UCMR)
 - UCMR 1 Assessment (2001 – 2003)
 - UCMR 2 Assessment (2008 – 2010)
 - UCMR 3 Assessment (2013 – 2015)
- Unregulated Contaminant Monitoring (UCM)
 - Round 1 (1988 – 1992)
 - Round 2 (1993 – 1997)
- National Inorganics and Radionuclides Survey (NIRS) (1984 – 1986)
- Occurrence results presented as the number/percent of systems with an analytical result greater than a specified concentration (e.g., greater than MRL (detection), greater than $\frac{1}{2}$ HRL or HRL, etc.).

Sources of Occurrence Data and Information (continued)

- State Data – Available on a contaminant specific basis
- DBP Information Collection Rule (ICR) – July 1997 – Dec 1998
- US Geological Survey
 - National Water Quality Assessment Program (NAWQA)
 - National Random & Focused Source Water Surveys (with AWWARF)
 - Special reports
- USDA Pesticide Data Program (PDP)
- Community Water System Surveys
- Consumer Confidence Reports
- Environmental Working Group data
- Toxics Release Inventory (TRI)
- Production Data (e.g. Chemical Update System/Inventory Update Reporting Program (CUS/IUR))
- OPP Reregistration Eligibility Document (RED)
 - Data from pesticide registrants
- Other specialized studies and literature

Drinking Water Strategy (DWS) and Evaluation of Contaminant Groups

- Administrator announced the four principles of DWS in March 2010; one particularly relevant to RD3.
- Principle incorporated into RD3 process – *Address contaminants as groups rather than one at a time.*
- September 2010 DWS Stakeholder Meeting – Identified four factors to consider when evaluating groups:
 - Has similar health effect endpoint
 - Removed by common treatment or control processes
 - Measured by common analytical method(s)
 - [Known or likely occurrence and co-occurrence]

Questions?

Preliminary Regulatory Determination 3 Contaminants

Ali Arvanaghi, US EPA

Contents of RD3 Preliminary Notice

4 Negative Determinations

- 1,3-Dinitrobenzene
- Dimethoate
- Terbufos
- Terbufos Sulfone

1 Positive Determination

- Strontium

No Determination – Chlorate and (4) Nitrosamines

- Chlorate and the nitrosamines are disinfection byproducts
- Will consider as part of the review of the Microbial Disinfection Byproduct Regulations, as part of the third Six Year Review

Table 3. October 20, 2014 Preliminary Regulatory Determinations

#	Contaminant	1. Health Effects?	2. Occurrence?	3. Meaningful Opportunity?
1	1,3-Dinitrobenzene	Yes	No	No
2	Dimethoate	Yes	No	No
3	Terbufos	Yes	No	No
4	Terbufos Sulfone	Yes	No	No
5	Strontium	Yes	Yes	Yes

“No Determination” Contaminants Considered in Phase 3: Regulatory Determination Assessment

Ali Arvanaghi, US EPA

Chlorate and the Nitrosamine Group

- Chlorate
 - Adverse Effect – follicular cell hypertrophy
 - Occurrence – Found at health level of concern in 11% (34/296) large systems (DBP ICR)
- Nitrosamines Group
 - Adverse Effect – All are mutagenic carcinogens
 - Occurrence – At least one or more nitrosamines within the group was detected in 29% of systems
 - NDMA is the predominant nitrosamine, occurring in 27% (343/1198) of the systems (UCMR 2)
 - Occurrence of other nitrosamines (NDPA, NPYR, NMEA, NDBA, NDEA) = 0 to 2%, respectively
- Chlorate and the nitrosamines will be considered as part of the review of the Microbial Disinfection Byproduct Regulations, as part of the third Six Year Review

Preliminary Negative Regulatory Determination 3 Contaminants

Ali Arvanaghi, US EPA

Table 4. 1,3-Dinitrobenzene

#	Background → Statutory Criteria ↓	1,3-Dinitrobenzene: Used as industrial chemical and in the production of other substances.
1	Adverse Effect? Yes	<ul style="list-style-type: none"> • Increased spleen weight
2	Known or likely to occur? No	<ul style="list-style-type: none"> • No to very low occurrence in public water systems at health levels of concern based on national surveys • 0%(0 of 4137) PWSs with at least 1 detection > HRL (UCMR2)
3	Meaningful opportunity? No	<ul style="list-style-type: none"> • Individuals w/ blood disorders & sperm complications • Because no/very low national occurrence at health levels of concern in drinking water, expect no/very low population exposure

Table 5. Dimethoate

#	Background → Statutory Criteria ↓	Dimethoate: Organophosphate pesticide used on field crops.
1	Adverse Effect? Yes	<ul style="list-style-type: none"> • Cholinesterase enzyme (ChE) inhibition
2	Known or likely to occur? No	<ul style="list-style-type: none"> • No to very low occurrence in public water systems at health levels of concern based on national surveys • 0%(0 of 4138) PWSs with at least 1 detection > HRL (UCMR2)
3	Meaningful opportunity? No	<ul style="list-style-type: none"> • No sensitive populations of concern • Because no/very low national occurrence at health levels of concern in drinking water, expect no/very low population exposure

Table 6. Terbufos & Terbufos Sulfone

#	Background → Statutory Criteria ↓	Terbufos & Terbufos Sulfone: Organophosphate pesticide, primarily used on corn and beets.
1	Adverse Effect? Yes	<ul style="list-style-type: none"> • Cholinesterase (ChE) enzyme inhibition
2	Known or likely to occur? No	<ul style="list-style-type: none"> • No to very low occurrence in public water systems at health levels of concern based on national surveys • 0%(0 of 295) PWSs with at least 1 detection > HRL (Terbufos) (UCMR1) • 0%(0 of 4138) PWSs with at least 1 detection > HRL (Terbufos Sulfone) (UCMR2)
3	Meaningful opportunity? No	<ul style="list-style-type: none"> • No sensitive populations of concern • Because no/very low national occurrence at health levels of concern in drinking water, expect no/very low population exposure

Questions?

Preliminary Positive Regulatory Determination 3 Contaminant

Zeno Bain, US EPA

Strontium Background Information

- Naturally occurs and enters water through weathering of rocks and soils, from atmospheric deposition, and from wastewater discharges
- Mining in U.S. ceased in 1959. Annual imports of strontium minerals and compounds have steadily declined since 2001 to less than 10,000 metric tons
- 11 strontium-containing compounds reported as produced/imported in 2006 (CUS)
- Several radioactive isotopes (e.g., ^{90}Sr) which are regulated in drinking water under the existing radionuclides rule.

Strontium Health Effects: Critical Study and Sensitive Life Stage

- Critical studies: Marie et al., 1985; Grynepas and Marie, 1990; decreased bone calcification (critical health endpoint) in male weanling rats (i.e., comparable to sensitive time period in humans), which administered strontium chloride in drinking water for eight or nine weeks
- Children are expected to be a sensitive population, since they are actively growing and strontium can substitute for calcium in growing bone (Abrams et al., 2000; Lee et al., 1996; Matkovic et al., 2005; Storey, 1961)

Strontium: Health Reference Level

- Non-cancer HRL of 1500 micro grams per liter

HRL = [(RfD times BW) divided by DWI] times RSC

- Reference Dose (RfD) = 0.3 milligrams per kilogram-day (Marie et al., 1985)
- Relative Source Contribution (RSC) = 20%
- Drinking Water Intake to Body Weight Ratio (DWI to BWR) values from the Exposure Factors Handbook (US EPA, 2011)
 - Used Age-Specific Exposure Factors for the sensitive population of birth through 18 years to reflect the most active period of bone growth and development
 - Rationale: Critical health endpoint had dose-response data associated with exposure during a specific period of sensitivity (i.e., sensitive population)

Strontium Occurrence

- Strontium found in 7% (60/989) of water systems greater than HRL of concern (older national survey of ground water systems)
- USGS found strontium greater than HRL of concern in 12% (61/503) of ground water systems
- Preliminary UCMR 3* data - 5% of systems (ground and surface water) have found greater than HRL

* Note: Currently collecting surface and ground water occurrence data as part of UCMR 3 (2013-2015). The first 18 months of data (half) will be available for making the final determination. All of the UCMR 3 data will be available for the proposed and final regulations.

Strontium Meaningful Opportunity

- 11% of population exposed for systems with detects at health level of concern in the ground water survey.
- National extrapolation for ground water population approximately ten million.
- Sensitive populations/ life stages include:
 - Growing children (especially those with low dietary calcium and Vitamin D),
 - People with renal problems, and
 - People with Paget's disease

* Note: Currently collecting surface and ground water occurrence data as part of UCMR 3 (2013-2015). The first 18 months of data (half) will be available for making the final determination. All of the UCMR 3 data will be available for the proposed and final regulations.

Questions?

Regulatory Determination 3 Next Steps

Next Steps

- Sixty-day comment period closes December 19, 2014
- Publish final RD3 determinations in ~December 2015*
- If the agency makes a final determination to regulate strontium, then:
 - Proposed regulation 24 months after final regulatory determination notice.
 - Promulgate final regulation 18 months after proposal.



* Note: Statutory deadline is July 2013 for final determinations.

Public Comment

Appendix

Appendix: CCL 3 Contaminants

104 Chemicals and 12 Microbes

1,1,1,2-Tetrachloroethane	Cyanotoxins (3)	Molinate	Tribufos
1,1-Dichloroethane	Dicrotophos	Molybdenum	Triethylamine
1,2,3-Trichloropropane	Dimethipin	Nitrobenzene	Triphenyltin hydroxide (TPTH)
1,3-Butadiene	Dimethoate	Nitroglycerin	Urethane
1,3-Dinitrobenzene	Disulfoton	N-Methyl-2-pyrrolidone	Vanadium
1,4-Dioxane	Diuron	N-Nitrosodiethylamine (NDEA)	Vinclozolin
17 alpha-Estradiol	Equilenin	N-nitrosodimethylamine (NDMA)	Ziram
1-Butanol	Equilin	N-Nitroso-di-n-propylamine (NDPA)	
2-Methoxyethanol	Erythromycin	N-Nitrosodiphenylamine (NDPhA)	Adenovirus
2-Propen-1-ol	Estradiol (17-beta)	Norethindrone (19-Norethisterone)	Caliciviruses
3-Hydroxycarbofuran	Estrinol	n-Propylbenzene	<i>Campylobacter jejuni</i>
4,4'-Methylenedianiline	Estrone	o-Toluidine	Enterovirus
Acephate	Ethinyl Estradiol (17-alpha)	Oxirane, methyl-	<i>Escherichia coli (0157)</i>
Acetaldehyde	Ethoprop	Oxydemeton-methyl	<i>Helicobacter pylori</i>
Acetamide	Ethylene glycol	Oxyfluorfen	Hepatitis A virus
Acetochlor	Ethylene oxide	Perchlorate	<i>Legionella pneumophila</i>
Acetochlor ethanesulfonic acid (ESA)	Ethylene thiourea	Perfluorooctane sulfonic acid (PFOS)	<i>Mycobacterium avium</i>
Acetochlor oxanilic acid (OA)	Fenamiphos	Perfluorooctanoic acid (PFOA)	<i>Naegleria fowleri</i>
Acrolein	Formaldehyde	Permethrin	<i>Salmonella enterica</i>
Alachlor ethanesulfonic acid (ESA)	Germanium	Profenofos	<i>Shigella sonnei</i>
Alachlor oxanilic acid (OA)	Halon 1011 (Bromochloromethane)	Quinoline	
alpha-Hexachlorocyclohexane	HCFC-22	RDX	
Aniline	Hexane	sec-Butylbenzene	
Bensulide	Hydrazine	Strontium	
Benzyl chloride	Mestranol	Tebuconazole	
Butylated hydroxyanisole	Methanol	Tebufenozide	
Captan	Methamidophos	Tellurium	
Chlorate	Methyl bromide (Bromomethane)	Terbufos	
Chloromethane (Methyl chloride)	Methyl tert-butyl ether	Terbufos sulfone	
Clethodim	Metolachlor	Thiodicarb	
Cobalt	Metolachlor ethanesulfonic acid (ESA)	Thiophanate-methyl	
Cumene hydroperoxide	Metolachlor oxanilic acid (OA)	Toluene diisocyanate	