



Review of the Minnesota Department of Health Contaminants of Emerging Concern Program Process for Selecting Chemicals

Review conducted by the University of Minnesota
Water Resources Center and Humphrey School of Public Affairs

May 2, 2016

APPENDICES

Appendix A: Contract.....	2
Appendix B: Stakeholder Panel Members and Meeting Dates.....	5
Appendix C: Science Panel Members and Meeting Dates.....	6
Appendix D: Processes in Other Jurisdictions.....	7
I. EPA - Safe Drinking Water Act.....	7
II. SDWA State Standards, and Programs for Setting Regulatory Standards.....	9
California.....	9
Massachusetts.....	10
III. Surface Water Monitoring Programs	10
Delaware, New Jersey, Pennsylvania.....	10
IV. Product Regulation and Chemicals in Commerce	11
California.....	11
Maine.....	11
Canada	11
V. State Water Quality Programs	12
Oregon	12
U.S. Geological Survey	13
VI. Use of Weight-of-Evidence Risk Methodologies.....	13
U.S. Environmental Protection Agency.....	13
Appendix E: Definition of Acronyms.....	15

Appendix A: Contract

Review of MDH Process for Ranking Contaminants of Emerging Concern Submitted by the Board of Regents of the University of Minnesota

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Prepared by the Minnesota Water Resources Center and the Humphrey School of Public Affairs

Proposal Background

During its 2015 session, the Minnesota Legislature adopted the following provision in law:

“The commissioner shall contract with the Board of Regents of the University of Minnesota to provide an independent review of the department's drinking water contaminants of emerging concern program. The review must include an assessment of the process used by the department to rank contaminants that are threats to drinking water supplies and include a comparison of efforts at the department with efforts by other states and the United States Environmental Protection Agency. The review must be submitted to the Clean Water Council and the chairs and ranking minority members of the house of representatives and senate committees and divisions with jurisdiction over environment and natural resources by June 1, 2016.”

Program Issues to Review

MDH has identified issues that the program review process should address along with responding to the specific issues identified by the legislature. These are:

Is the process balanced? Does the process meet customer needs? Does the process respond to concerns unique to Minnesota? Does the process accommodate innovative methods that could improve the CEC program's effectiveness and responsiveness? Does the program properly incorporate pragmatic or practical concerns?

Within the limits of the information sources and constraints described below, the proposed program review process will address these issues.

Scope of Work

1. Review program documents related to the operation of the Contaminants of Emerging Concern program, including all its elements.
Deliverable: List of documents reviewed and written summary of the program (Nov 30)
2. Conduct a targeted literature review of research related to effective risk assessment processes of contaminants of emerging concern, including the use of chemical groupings and quantitative structure-activity relationships.
Deliverable: Draft literature review (Feb 29)
3. Meet with and/or interview MDH staff to obtain information on the operation of the CEC program and strengths and weaknesses of the program as observed by staff. Identify appropriate staff in November, conduct interviews after meeting with panels in December, and analyze interviews in January.
Deliverable: Summary of information obtained including a list of meetings (Feb 29)
4. Review statutes, rules and operational procedures for programs similar or comparable to Minnesota's CEC program in other states and at the United States Environmental Protection Agency, including the EPA's Contaminant Candidate List and the ChAMP program.
Deliverable: Draft summary of other programs (Feb 5)
5. As needed, conduct telephone interviews regarding the operation of similar programs to obtain information that may not be represented in documents.
Deliverable: List of interviews (Jan 30)
6. Recruit and consult with a Stakeholder Panel (details described below) regarding the University's program review process, concerns about the CEC program and preliminary findings from the program review. Stakeholder consultation may include interviews with individuals not on the Panel.
Deliverables: First meeting agenda (Dec 15), Second meeting agenda (Feb 15)
7. Recruit and consult with a Science Panel (details described below) regarding the design of the University's program review process, the strengths and weaknesses of the CEC program in light of research regarding risk assessment processes, and proposed findings from the program review.
Deliverables: First meeting agenda (Dec 15), Second meeting agenda (Feb 15), Third meeting agenda (Apr 1)
8. Conduct an analysis of the information gathered, prepare a draft report that would be discussed with the Stakeholder Panel and the Science Panel, and prepare a final report of the program review process and findings. The final report would be submitted to MDH no later than May 1, 2016.
Deliverables: Preliminary report (Feb 1), Draft final report (Apr 1), Final report (May 1)
9. Communicate monthly with the MDH about progress on the project, and present a report of the project methods and findings.
Deliverables: Check-in meetings with MDH (end of each month), Presentation to MDH and guests (May 15)

Stakeholder Panel

The Stakeholder Panel would consist of knowledgeable persons who are drawn from or represent organizations or constituencies that have expressed interest in the CEC program or may be affected by the results of the CEC program. The PIs anticipate recruiting 10-15 individuals from the following groups or organizations: state agencies other than MDH, business, environmental and public health advocacy organizations, city water departments, Metropolitan Council Environmental Services, watershed districts or management organizations, and public health practitioners. The PIs propose to hold two meetings of the Stakeholder Panel. The first meeting would focus on current concerns regarding the CEC program, perceived strengths and weaknesses of the program and the proposed design of other elements of the University's program review. At the second meeting, the PIs would describe the proposed findings from the program review and obtain responses from the panel regarding gaps in the findings, the clarity of the findings and the extent to which the findings are responsive to concerns and issues identified at the first meeting.

Science Panel

The Science Panel would consist of five academically trained researchers who conduct research in chemistry, toxicology, risk assessment, public health, environmental science or related fields and who can provide objective assessments of the CEC program based on the information obtained or generated during the University's program review process. The PIs anticipate that the Science Panel would meet three times: initially to guide the design of the program review process, to review interim results of the program review process and to evaluate the findings prior to submission of the final report to MDH. One of the researchers may be asked to consult with the research team outside the panel's meetings based on that person's expertise in chemical risk assessment.

Confidentiality

The PIs recognize that there may be some degree of conflict regarding the operation of the CEC program. In order to obtain candid information, the research process would be designed to preserve the individual confidentiality of interviewees and other contributors to the program review process. At the same time, since the report will be public, there must be aggregate transparency regarding sources of information. The meetings of the Stakeholder and Science Panels will be private and confidential. Any quotations used in the final report will not be attributed to individuals and will be selected or excerpted so that the identity of the quoted individual cannot be readily identified. Members of the Stakeholder and Science Panel and persons interviewed for purposes of the program review will be identified in the report.

Appendix B: Stakeholder Panel Members and Meeting Dates

Panel Members

- Sarah Elliott (US Geological Survey)
- Mark Ferrey (PCA Water Assessment Section, Environmental Analysis & Outcomes Division)
- Rajinder Mann (MDA Pesticide and Fertilizer Management Division)
- Heidi Rantala (DNR Fisheries)
- Lloyd Grooms (Chamber of Commerce)
- Cliff Twaroski (Barr Engineering)
- James Zappia (3M)
- Matt Byrne (Growth and Justice)
- Kathleen Schuler (Conservation Minnesota, Healthy Legacy & Healthy Kids and Families Program Director)
- Deanna White, substitute: Steve Schultz (Clean Water Action and Clean Water Fund of Minnesota)
- Annika Bankston (City of Minneapolis)
- Jon Eaton (City of Eagan)
- Craig Johnson (League of Minnesota Cities)
- Pete Moulton (City of St. Peter)
- Brian Davis (Met Council, Water Supply Unit)
- Karen Jensen (Met Council, Water Resources Assessment Unit)
- Sandy Rummel (Met Council and Clean Water Council)

Meeting dates:

- January 29, 2016
- April 15, 2016

Appendix C: Science Panel Members and Meeting Dates

Panel Members:

- Bill Arnold (University of Minnesota Department of Civil Engineering)
- Peter Calow (Humphrey School of Public Affairs)
- Dalma Martinovic-Weigelt (University of St. Thomas, Department of Biology)
- Pam Rice (USDA Agricultural Research Service, St. Paul)
- Betsy Wattenberg (University of Minnesota School of Public Health, Division of Environmental Health Sciences)

Peter Calow consulted with the team throughout the process, in addition to serving on the Science Panel.

Meeting dates:

- January 25, 2016
- March 21, 2016
- April 11, 2016

Appendix D: Processes in Other Jurisdictions

Contaminants of concern ranking and identification programs exist for the regulation of drinking water, for improving overall water quality, and for the regulation of toxics in commerce and the environment. The most significant program for comparison to the Minnesota Department of Health (MDH) Contaminants of Concern program is Environmental Protection Agency (EPA)'s process for identifying new pollutants for setting primary drinking water standards under the Safe Drinking Water Act (SDWA). Many states rely on this EPA program to identify emerging contaminants. Within this scheme, a few state legislatures have established state programs to identify and prioritize action on emerging contaminants of concern. Some of these programs are implemented to develop additional drinking water standards for public water utilities, others establish health-based standards or guidelines for various stakeholders in the state for non-utility drinking water quality, general water quality, or as cleanup standards.

Some state health and environmental agencies publish additional drinking water standards and guidance for pollutants EPA has not regulated as part of general drinking water quality programs, without any specific legislatively mandated or authorized contaminants of concern program. These activities are often undertaken as part of a state's delegated SDWA enforcement program. Currently, 49 of 50 states¹ are the delegated primary enforcement authority and must ensure that public water utilities provide safe drinking water.² States must adopt any federal primary drinking water standard, but are also free to adopt more stringent or additional standards.³ Some of these activities also involve screening and ranking of emerging unregulated contaminants, others exist purely as responses to requests from stakeholders within their state and don't necessarily involve screening and prioritization.

I. EPA – Safe Drinking Water Act

In the United States, drinking water is subject to national health-based water quality standards, which are set by the Environmental Protection Agency (EPA) under the Safe Drinking Water Act (SDWA).⁴ The original act and amendments expressly list some contaminants EPA must regulate, and also create a continuing duty to assess additional unregulated contaminants for potential regulation.⁵ EPA is required to publish a Contaminant Candidate List (CCL) at least every five years.⁶ Contaminants on the CCL cannot be subject to any proposed or promulgated standard, must be "known or anticipated to occur" in public drinking water,⁷ and they must "present the greatest public health concern."⁸ EPA must publish this list for notice and comment only after consulting with "the scientific community, including the Science Advisory Board."⁹ After finalizing the CCL list, EPA must review at least five CCL contaminants every five years and determine if a water quality standard should be promulgated.¹⁰ This second review is based on human health effects, quantities found in drinking water supplies, and the level of exposure reduction that would result from regulation.¹¹ If EPA decides from this human health and exposure review that the contaminant should be regulated, the agency must conduct a cost-benefit analysis and may only proceed to standard setting if the benefits of regulation exceed implementation cost.¹² EPA has set regulatory standards for 94 contaminants under

the SDWA, most were finalized between 1975 and 1992, and only 12 have been added in the last 20 years.¹³

The most recent CCL—CCL3—was published in 2009,¹⁴ and a draft CCL4 was published in 2015.¹⁵ CCL3 was created using a more comprehensive methodology than previous lists and represented a culmination of methodological recommendations from a 2001 National Research Council report¹⁶ and 2004 recommendations from the National Drinking Water Advisory Council.¹⁷ CCL3 contains 116 contaminants, which were selected from a list of 600 substances (which EPA refers to as the “PCCL” or “potential CCL”) that had been identified as those that could occur at levels that pose a public health concern from a larger list of 7,500 substances (which EPA refers to as the “universe of potential drinking water contaminants”) that were identified from all potential contaminants that had some drinking water occurrence data and health impact data.¹⁸ Most state programs use a similar overall structure as the EPA CCL process, following this cascade from full universe, to higher risk contaminants, to final selection.

EPA’s CCL nomination process for establishing its “universe” of contaminants, and then shorter list of “potential contaminants” starts with statutory requirements in the SDWA to review substances that meet the CERCLA definition for hazardous substances,¹⁹ pesticides registered under FIFRA, and substances detected in drinking water in the National Contaminant Occurrence Database.²⁰

EPA is not limited to the Occurrence Database, CERCLA, and FIFRA substances, and can add to its “universe” of contaminants any substance “known or anticipated to occur in public water systems, and which may require regulation” under the SDWA after consultation with the scientific community.²¹ For CCL3, EPA held a stakeholder workshop to identify all possible data sources for potential contaminants, the workshop identified 284 data sources, of which 39 were used as the most relevant and complete.²² These 39 databases contained 26,000 substances, from which EPA identified 7,500 as having data on both occurrence in drinking water and human health effects.²³ EPA screened these 7,500 substances down to 600 that had the highest intersection of toxicity and occurrence data.²⁴ From this potential CCL, EPA created the CCL3 using classification models that further sorted toxicity and occurrence data and allowed comparison across diverse chemicals.²⁵ The classification model for grouping and scoring different health and occurrence data was run initially and tested on a small pool of compounds, reviewed and validated, and then modified to improve the accuracy of prioritizing contaminants.²⁶ The ranked and sorted 600 substance prioritized listing was reviewed and evaluated by agency experts to select the top contaminants for inclusion in the CCL3.²⁷ EPA had also requested public nominations for inclusion in the CCL3, and requested comment on the PCCL classification model design and parameters.²⁸ EPA received nominations of 174 unique chemical and microbial contaminants from 11 organizations, states, and individuals.²⁹ EPA added the additional information provided through public nominations to its classification models, which led to the inclusion of 8 contaminants in the CCL3 that would not have been selected.³⁰

The Occurrence Database is comprised of monitoring data from public water systems, and the list of monitored compounds is set by EPA after soliciting recommendations from the

National Academy of Sciences and the states, and allowing unsolicited recommendations from “any person.”³¹ All recommendations, from solicited or unsolicited sources, must be accompanied by “reasonable documentation that (A) the contaminant occurs or is likely to occur in drinking water; and (B) the contaminant poses a risk to public health.”³² The SDWA includes a catch-all that allows the Occurrence Database to include other monitoring data beyond that required of public utilities, when “other reliable and appropriate monitoring information on the occurrence of the contaminants in public water systems . . . is available to the Administrator.”³³ EPA has required public water systems to monitor for unregulated contaminants under three different rulemakings published in 1999, 2007, and 2012, each of which required monitoring for 25 to 30 contaminants;³⁴ and EPA published a draft fourth monitoring rule in 2015.³⁵ The contaminants required to be monitored under the unregulated contaminants monitoring rules include some from the most recent CCL, and also non-CCL contaminants “with potential health effects of concern that can be measured concurrently using the analytical methods for the CCL contaminants.”³⁶

II. SDWA State Standards, and Programs for Setting Regulatory Standards

Enforcement of drinking water standards is mostly delegated to the states, and 49 of 50 states³⁷ have been delegated primary enforcement authority to adopt and apply the federal drinking water standards to public water suppliers in their state.³⁸ States must adopt any federal primary drinking water standard, but are also free to adopt more stringent or additional standards.³⁹ A few state legislatures have established state programs to identify emerging contaminants of concern and either develop additional drinking water standards for public water utilities, or otherwise establish health-based standards or guidelines for various stakeholders in the state. Some state health and environmental agencies publish additional drinking water standards and guidance for pollutants EPA has not regulated as part of general drinking water quality programs without any specific legislatively mandated or authorized contaminants of concern program.

California

California has two programs that rank and select CECs for different reasons, one program for monitoring contaminants in California waters specifically those coming out of wastewater treatment plants due to California’s practices of using recycled water,⁴⁰ and another program setting “drinking water notification levels” of specific California contaminants of concern.⁴¹ California’s program for setting California-specific drinking water standards respond mostly to stakeholder concerns over specific pollution incidence, but is one of the most prolific standard setting state offices.⁴² California currently has eleven state MCLs establishing primary drinking water standards on utilities for chemicals that EPA has not regulated.⁴³

The California notification levels program has set numeric standards for 93 contaminants since its inception in 1981, 39 of these have then become California MCLs.⁴⁴ California generates notification levels based on specific needs in the state, the agency note that most levels “have been established in response to actual contamination of drinking water supplies” but on occasion will be developed due to severe hazard of potential

contamination at a known site.⁴⁵ Of the 54 notification levels that were not superseded by a formal MCL, 25 have been “archived” due to lack of current known issues, while 29 are still active. In the 1990s roughly one notification level was developed per year, in the 2000s roughly two levels have been developed per year.⁴⁶ The notification levels are health-based standards, and are not independently enforceable regulatory limits and don’t require monitoring. However, overriding public safety duties are triggered by the notification levels, and public water utilities generally must notify water consumers and municipal governance layers⁴⁷ when chemicals above notification levels are detected or present in finished drinking water.

Massachusetts

The Massachusetts Department of Environmental Protection (DEP) has generated and maintains a list of emerging contaminants that are otherwise unregulated as part of its general drinking water standards program without a specific legislative mandate.⁴⁸ After developing drinking water guidance and limits for perchlorate in 2006 in response to requests from towns with specific requests, the DEP subsequently convened an Emerging Contaminant Workgroup to generate a list of emerging contaminants the agency could continue to investigate and work on.⁴⁹ The Workgroup developed a definition of emerging contaminant that includes “a perceived or real threat to human health . . . or the environment; no published health standards or guidelines; insufficient or limited available toxicological information. . . ; significant new source, pathway, or detection limit information.”⁵⁰ In 2007, the Workgroup developed a list of 80 emerging contaminants, further prioritized 30 on a watch list for continued information gathering, and identified 9 for further evaluation and agency action.⁵¹ The 2007 emerging contaminants list was developed based on database searches, the workgroup’s professional expertise on exposure pathways, and an assessment of the urgency of the issue.⁵² The 80 contaminant list was screened down to 30 by removing contaminants considered to not be “generally important,” and removing contaminants undergoing existing actions at EPA or DEP, or if they had jurisdictional issues with addressing sources.⁵³ The final selection of pollutants to take action on were based on how the certainty of scientific support for action, and the identification of tangible reduction steps that could be taken.⁵⁴

III. Surface Water Monitoring Programs

Delaware, New Jersey, Pennsylvania

In the Delaware River Basin, there has been cross-jurisdictional cooperation to monitor for pharmaceuticals and personal care products (PPCPs) as part of a contaminants of emerging concern initiative.⁵⁵ Water monitoring for a number of PPCPs took place between 2007 and 2009.⁵⁶ It was not reported how the contaminants of concern were selected for monitoring, but the analytic methods used could detect 13 perfluoroalkyl and polyfluoroalkyl substances, 119 PPCPs, 27 sterols and hormones, 4 nonylphenols, BPA, and 46 polybrominated diphenyl ethers.⁵⁷ Based on occurrence data from monitoring, the report then used a risk-based method to compare detection levels with known eco-toxicity data the EPA ECOTOX and ECOSAR databases, the NOAA PEIAR database, and some additional

academic literature.⁵⁸ The study detected 57 compounds in at least one of the testing years, and based on occurrence and toxicity potential, selected 10 compounds as priority PPCPs.⁵⁹

IV. Product Regulation and Chemicals in Commerce

California

California also regulates chemicals in products under the Safer Consumer Products Regulations.⁶⁰ The California Department of Toxic Substances Control publishes a list of candidate chemicals, which is used to identify priority products which are then targets for regulation through data production and substitution. The candidate chemicals are generated by evaluating toxicity and exposure endpoints of a universe of chemicals that come from 23 lists identified in regulation.⁶¹ The lists are from California, EPA,⁶² ATSDR, CDC, NTP, European Commission, Canadian PBiT, IARC, and OSPAR. The prioritized product-chemical of concern combinations require that there is 1) potential for public or environmental exposure, 2) end of life effects, 3) not already regulated, and 4) has a safer alternative.

Maine

Maine has a statutory requirement to maintain a “Chemicals of High Concern (CHC)” list, which is developed by the Maine Center for Disease Control and Prevention and the Maine Department of Environmental Protection.⁶³ The Maine process began with a list of “Chemicals of Concern (COC),” which in 2012 contained 1384 chemicals and was generated by taking a subset of chemicals from a similar list published by the state of Washington (listing 2219 chemicals), which have both certain toxicity endpoints and exposure evidence.⁶⁴ The Maine list screened out chemicals whose toxicity information did not come from national or international health sources.⁶⁵ Both the Washington and Maine lists use exposure information that is not location specific and combine US biomonitoring data, EPA drinking water monitoring, CA indoor dust monitoring, and chemicals in products list from the Dutch and Danish governments.⁶⁶ From this larger sub-set, the Maine CDC used exposure and toxicity ranking criteria to publish a CHC list of 46 chemicals.⁶⁷

Canada

The Canadian Chemicals Management Plan (CMP) is mandated by a 1999 statute, and was first implemented in 2006.⁶⁸ Starting from an initial list of 23,000 chemicals known to be in commercial use in the previous two decades, the list was screened down to 4,300 chemicals needing further attention, of which rapid screening identified 1,200 that were considered of “low ecological concern” and 750 were identified as potentially not of concern.⁶⁹ The CMP system involves both high risk and low risk screens to identify where to focus in-depth reviews.

V. State Water Quality Programs

Oregon

The Oregon legislature tasked its Oregon Department of Environmental Quality (DEQ) to develop a list of Priority Persistent Pollutants that should be limited from entering the environment through reduction of emissions in wastewater treatment plant effluent.⁷⁰ The DEQ developed this list in consultation and oversight of a seven member expert panel Science Workgroup.⁷¹ This program is limited to “persistent pollutants,” which is defined as those that are toxic, and either persist in the environment, or accumulate in humans or the food chain (PBTs).⁷² DEQ interpreted its scope to be limited to those contaminants that may reach humans or other animals through the aquatic system, which includes contaminants present in water, sediment, or animals, but excludes pollutants reaching humans directly through consumer products or plant/vegetable consumption.⁷³ DEQ’s nomination phase identified a universe of contaminants that have been previously identified in state, national, and international assessments of PBTs.⁷⁴ When combined with lists of chemicals detected or used in Oregon and the region, the initial list contained 1,191 distinct chemicals.⁷⁵ DEQ then screened this list down to 175 chemicals by removing the lowest persistence and bioaccumulative compounds based on EPA’s PBT Profiler, and EPISuite, which are database and predictive computerized toxicology modeling tools;⁷⁶ removing chemicals that have been comprehensively sampled for in Oregon for and non-detected;⁷⁷ removing chemicals with no aquatic toxicity in EPA’s ECOSAR database, or human health toxicity under EPA IRIS, IARC, or CalEPA Prop 65;⁷⁸ and by removing chemicals that were low risk congeners in a chemical family that was already represented.⁷⁹ After publishing this procedure and draft list for notice and comment, DEQ received 200 comments, which were reviewed by the Science Workgroup, and led to adjustments of cutoff points and assumptions and led to additions and removals for an “interim final list” of 140 pollutants.⁸⁰

The Oregon statute also provides four consideration factors for developing the list, which include the toxicity, potency, magnitude of ongoing or legacy discharges, and feasibility of reducing discharges.⁸¹ In practice, DEQ implemented the technical feasibility factor by categorizing an interim final list of 140 pollutants into three tiers based on whether the pollutant had 1) known sources in the state that could be controlled, 2) no known local sources, or 3) needed more information. After public comment and information gathering, 22 pollutants were dropped because public submissions or new information led to lowered assessments of toxicity, exposure, or removal feasibility.⁸² The final list contained 118 toxic pollutants.⁸³

Under the Oregon program DEQ published “trigger levels” for these 118 pollutants, and the largest Oregon WWTPs are required to monitor their effluent for exceedances of the trigger levels.⁸⁴ For those contaminants of concern where trigger levels are exceeded, WWTPs must then develop and submit a plan to reduce effluent levels.⁸⁵ The trigger level is set as a default at the Maximum Contaminant Level promulgated by EPA as a primary drinking water standard under the Safe Drinking Water Act, if such a value exists.⁸⁶ If EPA has not promulgated an MCL, then a cascading list of other regulatory and toxicological values are used in order from EPA Ambient Water Quality Criteria,⁸⁷ EPA chronic exposure Aquatic

Life Benchmarks,⁸⁸ Canadian long-term exposure Water Quality Guidelines,⁸⁹ a lowest observed adverse effect level (LOAEL) from the peer-reviewed scientific literature,⁹⁰ the lowest estimated activity level based on chemical structure activity relationships in EPA's ECOSAR model,⁹¹ and a number of risk level calculations in EPA's IRIS database,⁹² and others,⁹³ finally in the absence of all others, with a default level at the practical quantitation limit (PQL), which is the lowest detection level of a reliable analytic methods.⁹⁴

In practice, Oregon's largest WWTPs monitored effluent for 117 of the 118 pollutants, but only five pollutants were detected above trigger levels resulting in five plants submitting pollution reduction plans for arsenic, beta-sitosterol, and pyrene.⁹⁵ Two other pollutants, cholesterol and coprostanol, were detected above trigger levels at 47 of the 52 WWTPs conducting monitoring, but DEQ issued a rule to exempt reduction plan requirements for these pollutants as no feasible pollution prevention or cost-effective treatment options could be identified, and DEQ determined the requirements would be "a disproportionate response for these types of pollutants,"⁹⁶

U.S. Geological Survey

The United States Geological Survey has a robust program that assesses water quality across the country, and as part of that USGS develops new analytical methods for detecting unregulated contaminants, and monitors for environmental occurrence of a wide variety of contaminants. USGS has an Emerging Contaminants in the Environment program that does the primary analytical methods development, and monitoring in interstate watersheds.⁹⁷ The USGS does not set regulatory standards for these contaminants, and pursues monitoring of contaminants based on detection and information from other agencies and the peer-reviewed literature.

VI. Use of Weight-of-Evidence Risk Methodologies

U.S. Environmental Protection Agency

EPA first described and published a Weight-of-Evidence (WoE) framework in 1986 for use in its human health risk assessments. The original purpose was to have a standardized method for comparing and combining studies showing a chemical's carcinogenicity and mutagenicity—two different biological endpoints that together along with others comprise a chemical's carcinogenicity risk.⁹⁸ One of the most recent and analogous uses of WoE methodology at EPA is in the Weight of Evidence Guidance Document EPA has issued for use in evaluating, ranking, and selecting Tier 2 chemicals from the universe of Tier 1 chemicals in the agency's Endocrine Disruptor Screening Program. The draft guidance was issued for comment on November 4, 2010, and the final guidance was published on September 28, 2011.⁹⁹ EPA's EDSP program has partial screening information on 1,800 chemicals, and has completed Tier 1 assessments for 52 chemicals.¹⁰⁰

The EDSP was created in response to statutory language in the 1996 amendments to the Federal Food, Drug, and Cosmetic Act that directed EPA to create "a screening program . . . to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effect."¹⁰¹ The EDSP is a two tier screening program that in Tier 1 uses 11 assays to assess the potential and reliability of a chemical to interact with the estrogen, androgen, and thyroid hormonal

pathways.¹⁰² Based on a WoE analysis of Tier 1 testing results, EPA determines if Tier 2 testing should be done to assess the endocrine disruptor effect. EPA notes that the WoE analysis “is not a simple tallying of the number of positive and negative results”¹⁰³ but rather a method for combining the results of individual studies into a cohesive assessment of biological pathways/endpoints and then integrating different lines of evidence into a single overall assessment.¹⁰⁴ The final result of an EPA WoE analysis in its EDSP program is a “Weight-of-Evidence Narrative/Characterization,” which follows a detailed analysis of the individual studies that go into the analysis. The final narrative/characterization explains the “selection of the studies or effects used as the main lines of evidence and relevant basis for conclusions” that the chemicals does or does not interact with the relevant endocrine systems, and what types of Tier 2 assays are needed or why they are not needed.¹⁰⁵

¹ Mary Tiemann, Cong. Research Service, *Safe Drinking Water Act (SDWA): A Summary of the Act and Its Major Requirements*, at 1, 6 (2014), <https://www.fas.org/sgp/crs/misc/RL31243.pdf>.

² See 42 U.S.C. § 300g-2 (2012) (outlining requirements for delegation to State for primary enforcement responsibility); 40 C.F.R. §§ 142.10-142.19 (2015) (providing regulatory requirements and procedures for state assumption of of primary authority).

³ 42 U.S.C. § 300g-2.

⁴ See generally Pub. L. No. 93-523 (1974) (codified as amended at 42 U.S.C. §§ 300f to 300j-26).

⁵ See *Id.*; Pub. L. No. 104-182, 110 Stat. 1613 (1996). See generally Thomas Richichi & Linda Tsang, *Safe Drinking Water Act*, in ENVIRONMENTAL LAW HANDBOOK 473, 474-77 (22d ed. 2014).

⁶ 42 U.S.C. § 300g-1(b)(1)(B)(i)(I).

⁷ *Id.*

⁸ *Id.* § 300g-1(b)(1)(C).

⁹ *Id.* § 300g-1(b)(1)(B)(i)(I).

¹⁰ *Id.* § 300g-1(b)(1)(B)(ii)(I).

¹¹ *Id.* § 300g-1(b)(1)(B)(ii)(II); *id.* § 300g-1(b)(1)(A)(i)-(iii).

¹² 42 U.S.C. § 300g-1(b)(1)(E); *id.* § 300g-1(b)(3)(C).

¹³ *Regulation Timeline: Contaminants Regulated Under the Safe Drinking Water Act*, U.S. ENVTL. PROTECTION AGENCY, http://www.epa.gov/sites/production/files/2015-10/documents/dw_regulation_timeline.pdf (last updated Sept. 2015).

¹⁴ See *Contaminant Candidate List 3*, U.S. ENVTL. PROTECTION AGENCY, <http://www.epa.gov/ccl/contaminant-candidate-list-3-ccl-3> (last updated Oct. 13, 2015).

¹⁵ See *Draft Contaminant Candidate List 4*, U.S. ENVTL. PROTECTION AGENCY, <http://www.epa.gov/ccl/draft-contaminant-candidate-list-4-ccl-4> (last updated Dec. 28, 2015); see also *Drinking Water Contaminant Candidate List 4—Draft*, 80 Fed. Reg. 6076 (Feb. 4, 2015).

¹⁶ Nat'l Research Council, *Classifying Drinking Water Contaminants for Regulatory Consideration* (2001), <http://www.nap.edu/read/10080/chapter/1>.

¹⁷ Nat'l Drinking Water Advisory Council, *National Drinking Water Advisory Council Report on the CCL Classification Process to the U.S. Environmental Protection Agency* (2004), http://www.epa.gov/sites/production/files/2015-11/documents/report_ccl_ndwac_07-06-04.pdf. For a longer discussion on the CCL3 methodology, see the draft rather than the final federal register notice. *Drinking Water Contaminant Candidate List 3—Draft*, 73 Fed. Reg. 9628, 9630-51 (Feb. 21, 2008).

¹⁸ *Contaminant Candidate List 3*, *supra* note 14; see also *Drinking Water Contaminant Candidate List 3—Final*, 74 Fed. Reg. 51850, 51852 (Oct. 8, 2009). A comprehensive explanation of the CCL3 methodology can be found in three EPA support documents from the rulemaking docket, U.S. ENVTL. PROTECTION AGENCY, *CONTAMINANT CANDIDATE LIST 3: IDENTIFYING THE UNIVERSE* (2008); U.S. ENVTL. PROTECTION AGENCY, *CONTAMINANT CANDIDATE LIST 3: SCREENING TO A PCCL* (2008), http://www.epa.gov/sites/production/files/2014-05/documents/ccl3chem_screening_to_pccl_08-31-09_508v2.pdf; U.S. ENVTL. PROTECTION AGENCY, *FINAL CONTAMINANT CANDIDATE LIST 3: CLASSIFICATION OF THE PCCL TO THE CCL* (2009) [hereinafter EPA,

CLASSIFICATION OF THE PCCL TO THE CCL], http://www.epa.gov/sites/production/files/2014-05/documents/ccl3_pccltoccl_08-31-09_508.pdf.

- ¹⁹ 42 U.S.C. § 300g-1(b)(1)(B)(i)(II); *see* 42 U.S.C. § 9601(14) (defining hazardous substance to include any substance expressly designated by regulation under CERCLA by 42 U.S.C. § 9602(a) because the substance “when released into the environment may present substantial danger to the public health or welfare or the environment”; any Clean Water Act toxic regulated under 33 U.S.C. § 1321(b)(2)(A) or § 1317(a); any RCRA waste with a hazardous characteristic regulated under 42 U.S.C. § 6921; any Clean Air Act hazardous air pollutant under 42 U.S.C. § 7412; or any TSCA hazardous chemical for which action has been taken under 15 U.S.C. § 2606).
- ²⁰ 42 U.S.C. § 300g-1(b)(1)(B)(i)(II). The National Contaminant Occurrence Database was created by the SDWA. *Id.* § 300j-4(g).
- ²¹ 42 U.S.C. § 300g-1(b)(1)(B)(i)(I).
- ²² Drinking Water Contaminant Candidate List 3—Draft, 73 Fed. Reg. 9628, 9633–34 (Feb. 21, 2008) (describing the stakeholder workshop process and listing the 39 data sources, which are primarily US governmental and international databases of hazardous chemicals).
- ²³ *Id.* at 9634–35.
- ²⁴ *Id.* at 9635–38 (Health effects data included quantified toxicity endpoints as well as descriptive toxicity assessments from US governmental and international sources. Occurrence data included both actual monitoring data from EPA, USGS, and USDA, as well as reported chemical releases in the TRI and high volume uses reported under TSCA).
- ²⁵ *Id.* at 9639–44.
- ²⁶ EPA, CLASSIFICATION OF THE PCCL TO THE CCL, *supra* note 18, at 2–4.
- ²⁷ 73 Fed. Reg. at 9639–44.
- ²⁸ 71 Fed. Reg. 60704 (Oct. 16, 2006); *see* EPA, CLASSIFICATION OF THE PCCL TO THE CCL, *supra* note 18, at 68.
- ²⁹ 73 Fed. Reg. at 9649–50.
- ³⁰ *Id.*; *id.* at 9644.
- ³¹ 42 U.S.C. § 300j-4(g)(4).
- ³² *Id.*
- ³³ *Id.* § 300j-4(g)(7)(C).
- ³⁴ National Contaminant Occurrence Database (NCOD), U.S. ENVTL. PROTECTION AGENCY, <http://www.epa.gov/dwucmr/national-contaminant-occurrence-database-ncod> (last updated Oct. 21, 2015); *see also* Unregulated Contaminant Monitoring Rule 1, 64 Fed. Reg. 50556 (Sept. 17, 1999); Unregulated Contaminant Monitoring Rule 2, 72 Fed. Reg. 368 (Jan. 4, 2007); Unregulated Contaminant Monitoring Rule 3, 77 Fed. Reg. 26072 (May 2, 2012).
- ³⁵ *See* Revisions to the Unregulated Contaminant Monitoring Rule (UCMR 4) for Public Water Systems and Announcement of a Public Meeting, 80 Fed. Reg. 76897 (Dec. 11, 2015).
- ³⁶ 80 Fed. Reg. at 76902.
- ³⁷ Mary Tiemann, Cong. Research Service, *Safe Drinking Water Act (SDWA): A Summary of the Act and Its Major Requirements*, at 1, 6 (2014), <https://www.fas.org/sgp/crs/misc/RL31243.pdf>.
- ³⁸ *See* 42 U.S.C. § 300g-2 (2012) (outlining requirements for delegation to State for primary enforcement responsibility); 40 C.F.R. §§ 142.10–142.19 (2015) (providing regulatory requirements and procedures for state assumption of of primary authority).
- ³⁹ 42 U.S.C. § 300g-2.
- ⁴⁰ Keith A. Maruya et al., An Adaptive, Comprehensive Monitoring Strategy for Chemicals of Emerging Concern (CECs) in California’s Aquatic Ecosystems, 10 INTEGRATED ENVTL ASSESSMENT & MGMT 69 (2013).
- ⁴¹ *Emerging Contaminants*, CALIF. ENVTL PROTECTION AGENCY STATE WATER RESOURCES CONTROL BD., http://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/EmergingContaminants.shtml (last updated Feb. 21, 2014).
- ⁴² *See generally*, Earl L. Hagstrom, Muddy Waters: The Tension Between Health-Based Standards and Nondegradation Policies Creates Uncertainty for Parties in Groundwater Litigation, L.A. LAWYER, Dec. 2007, at 29.
- ⁴³ STATE WATER RES. CONTROL BDS., MAXIMUM CONTAMINANT LEVELS AND REGULATORY DATES FOR DRINKING WATER U.S. EPA VS CALIFORNIA (2014), http://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/documents/dwdocuments/MCLsEPAvsDWP-2014-07-01.pdf.

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- ⁴⁴ STATE WATER RES. CONTROL BD., DRINKING WATER NOTIFICATION LEVELS AND RESPONSE LEVELS 3 (2015), http://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/documents/notificationlevels/notificationlevels.pdf.
- ⁴⁵ *Id.*
- ⁴⁶ *Id.*
- ⁴⁷ *See, e.g.*, Cal. Health & Safety Code § 116455 (requiring notification of any local governing body that covers residents receiving water where a notification level is exceeded).
- ⁴⁸ *See* Millie Garcia-Serrano, Deputy Reg. Dir., Mass. Dept. of Env'tl. Prot., presentation to the Ass'n of State and Territorial Solid Waste Mgrs., *The Massachusetts Emerging Contaminants Story: Coordinating Actions for Perchlorate and other Unusual Suspects* (Apr. 20, 2011), http://www.astswmo.org/Files/Meetings/2011/2011-MYM/GARCIA-SERRANO-Emerging_Contaminants.pdf (describing regulation of perchlorate as a response to request for drinking water health guidance level from towns neighboring military facilities when there was no federal or state promulgated standard).
- ⁴⁹ Mass. Dept. of Env'tl. Prot., *Emerging Contaminants*, <http://www.mass.gov/eea/agencies/massdep/toxics/sources/emerging-contaminants.html> (last visited Feb. 19, 2016).
- ⁵⁰ Mass. Dept. of Env'tl. Prot., *Emerging Contaminant Workgroup*, <http://www.mass.gov/eea/agencies/massdep/toxics/sources/emerging-contaminant-workgroup.html> (last visited Feb. 19, 2016).
- ⁵¹ *Id.*
- ⁵² Mass. Dept. of Env'tl. Prot., *Contaminant Screening Process*, <http://www.mass.gov/eea/agencies/massdep/toxics/sources/contaminant-screening-process.html> (last visited Feb. 19, 2016).
- ⁵³ *Id.*
- ⁵⁴ *Id.*
- ⁵⁵ *Contaminants of Emerging Concern*, DEL. RIVER BASIN COMM'N, <http://www.nj.gov/drbc/quality/reports/emerging/> (last modified July 23, 2015).
- ⁵⁶ <http://www.nj.gov/drbc/library/documents/contaminants-of-emerging-concernAug2013rev.pdf>
- ⁵⁷ *Id.* at 9-10.
- ⁵⁸ *Id.* at 15-16.
- ⁵⁹ *Id.* at 18, 23-25.
- ⁶⁰ Cal. Code Regs., tit. 22, §§ 69501-69510.
- ⁶¹ Candidate Chemicals Identification, Cal. Code Regs., tit. 22, § 69502.2, subd (a). *See also* "Authoritative Lists" of the California Department of Toxic Substances Control <https://www.dtsc.ca.gov/SCP/SourceLists.cfm>
- ⁶² Product-Chemical Identification and Prioritization Factors, Cal. Code Regs., tit. 22, § 69503.2.
- ⁶³ ME. STAT. tit. 38, § 1693-A(1); *see Chemicals of High Concern*, MAINE DEPT ENVTL PROTECTION, <http://www.maine.gov/dep/safechem/highconcern/> (last visited Jan. 30, 2016).
- ⁶⁴ MAINE CTR FOR DISEASE CNTL. & PREVENTION, DERIVING CHEMICALS OF HIGH CONCERN: PROCESS DOCUMENTATION 3-6 (2012), http://www.maine.gov/dep/safechem/highconcern/documents/ME_CHC_Process_Documentation2012.pdf
- ⁶⁵ *Id.* at 2, 5 (this is because the Maine statute definition of "credible scientific evidence" did not include state based resources).
- ⁶⁶ *Id.* at 4, 15.
- ⁶⁷ *Id.* at 1.
- ⁶⁸ Gov't Can., *Overview of the Chemicals Management Plan*, <http://www.chemicalsubstanceschimiques.gc.ca/fact-fait/overview-vue-eng.php> (last modified Jan. 24, 2014).
- ⁶⁹ http://www.un.org/esa/dsd/dsd_aofw_ni/ni_pdfs/NationalReports/canada/Chemicals.pdf
- ⁷⁰ *See* Oregon Dep't of Env'tl. Quality, Senate Bill 737 Development of a Priority Persistent Pollutant List (P3L) for Oregon (2009) [hereinafter OR DEQ, Development of a P3 List], <http://www.deq.state.or.us/wq/sb737/docs/P3LReportFinal.pdf>.
- ⁷¹ *Id.* at 8.
- ⁷² OR. REV. STAT. § 468B.138(4) (2015).
- ⁷³ OR DEQ, *Development of a P3 List*, *supra* note 70, at 7.

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- ⁷⁴ *Id.* at 12-14.
- ⁷⁵ *Id.* at 15.
- ⁷⁶ *Id.* at 17-20, 23; see *About the PBT Profiler*, PBT PROFILER, <http://www.pbtprofiler.net/about.asp> (last updated Sept. 4, 2012); *EPI Suite - Estimation Program Interface*, U.S. ENVTL. PROT. AGENCY, <http://www.epa.gov/tsca-screening-tools/epi-suite-estimation-program-interface> (last updated Oct. 21, 2015).
- ⁷⁷ *OR DEQ, Development of a P3 List*, *supra* note 70, at 22.
- ⁷⁸ *Id.* at 16, 25.
- ⁷⁹ *Id.* at 20-22.
- ⁸⁰ *Id.* at 23-28.
- ⁸¹ OR REV. STAT. § 468B.139(2)(a)(A)-(D) (2015).
- ⁸² *OR DEQ, Development of a P3 List*, *supra* note 70, at 28-30.
- ⁸³ *Id.*
- ⁸⁴ Oregon Dept. of Env'tl. Quality, *Senate Bill 737 Selection of Trigger Levels for Oregon's Priority Persistent Pollutants* (Sept. 30, 2009) [hereinafter *OR DEQ, Selection of Trigger Levels*], <http://www.deq.state.or.us/wq/SB737/docs/ProposalDraftF30SEP09.pdf>.
- ⁸⁵ See OR REV. STAT. § 468B.140(2)(a)-(c), (3)(a)-(m).
- ⁸⁶ *Id.* at § 468B.140(1)(a)(A); *OR DEQ, Selection of Trigger Levels*, *supra* note 84, at 3-4.
- ⁸⁷ *OR DEQ, Selection of Trigger Levels*, *supra* note 84, at 5.
- ⁸⁸ *Id.*
- ⁸⁹ *Id.* at 5-6.
- ⁹⁰ *Id.* at 6-7.
- ⁹¹ *Id.* at 7.
- ⁹² *Id.* at 7-9.
- ⁹³ *Id.* at 9-12.
- ⁹⁴ *Id.* at 4.
- ⁹⁵ Oregon Dept. of Env'tl. Quality, *Fact Sheet Implementing Senate Bill 737* (June 2011), <http://www.deq.state.or.us/wq/pubs/factsheets/programinfo/09-WQ-25SB737FS.pdf>.
- ⁹⁶ Memorandum from Dick Pedersen, Director, Oregon Dept. of Env'tl. Quality, to Env'tl. Quality Comm'n, Agenda item G, Rule adoption: Revision of Division 045 Initiation Level Rule 340-045-0100 (Sept. 26, 2011), <http://www.deq.state.or.us/about/eqc/agendas/attachments/2011oct/G-InitiationLevelRuleStaffRpt.pdf>.
- ⁹⁷ <http://toxics.usgs.gov/regional/emc/>
- ⁹⁸ See Igor Linkov et al., Weight-of-Evidence Evaluation in Environmental Assessment: Review of Qualitative and Quantitative Approaches, 407 SCI. TOTAL ENV'T. 5199, 5200 (2009).
- ⁹⁹ See U.S. Env'tl. Protection Agency, Endocrine Disruptor Screening Program, Weight-of-Evidence: Evaluating Results of EDSP Tier 1 Screening to Identify the Need for Tier 2 Testing (Sept. 14, 2011), <https://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2010-0877-0021> [hereinafter EPA, EDSP WoE Guidance]; see also Endocrine Disruptor Screening Program (EDSP); Announcing the Availability of a Draft for Weight-of-Evidence Guidance Document: Evaluating Results of EDSP Tier 1 Screening To Identify Candidate Chemicals for Tier 2 Testing, 74 Fed. Reg. 67963 (Nov. 4, 2010); Endocrine Disruptor Screening Program; Weight-of-Evidence Guidance Document; Notice of Availability, 76 Fed. Reg. 60022 (Sept. 28, 2011).
- ¹⁰⁰ U.S. Env'tl. Protection Agency, *Endocrine Disruptor Screening Program Chemical Screening and Testing Progress*, <https://www.epa.gov/endocrine-disruption/endocrine-disruptor-screening-program-chemical-screening-and-testing-progress> (last updated Apr. 19, 2016).
- ¹⁰¹ 21 U.S.C. § 346a(p) (2012); see EPA, EDSP WoE GUIDANCE, *supra* note 99, at 7.
- ¹⁰² See EPA, EDSP WoE GUIDANCE, *supra* note 99, at 8-15.
- ¹⁰³ *Id.* at 26-30.
- ¹⁰⁴ *Id.* at 33-36.
- ¹⁰⁵ *Id.* at 40-43.

Appendix E: Definition of Acronyms

AARP American Association of Retired Persons	MEC Measured Environmental Concentration
ADI Acceptable Daily Intake	NOAEL No Observed Adverse Effect Levels
ASC American Chemical Society	NOEC No Observed Effect Concentration
BCF Bioconcentration Factor	OSPAR Oslo and Paris Conventions for the Protection of the Marine Environment of the North-East Atlantic
CCL Contaminant Candidate List	PBT Persistent, Bioaccumulative and Toxic
CEC Contaminants of emerging concern	PCA Pollution Control Agency
CERCLA Comprehensive Environmental Response, Compensation, and Liability Act of 1980	PEC Predicted Environmental concentration
CHC Chemicals of High Concern	PNEC Predicted No-effects Concentration
CSF Cancer Slope Factors	PPCP Pharmaceutical and personal care products
CWL Clean Water Legacy Act	PPPL Princeton Plasma Physics Laboratory
DWP Drinking Water Protection unit of the MDH	RAA Risk Assessment Advice
EDSP Endocrine Disruptor Screening Program	RfC Inhalation Reference Concentration
EPA Environmental Protection Agency	RfD Reference Doses
FIFRA Federal Insecticide, Fungicide, and Rodenticide Act	SAC Site Assessment and Consultation unit of the MDH
GHS Globally Harmonized System (for labeling)	SETAC Society of Environmental Toxicology and Chemicals
HBV Health-based values	SDWA Safe Drinking Water Act
HQ Hazard quotient	TD50 Median toxic dose
HRLs Health Risk Limits	TDI Tolerable Daily Intake
IARC International Agency for Research on Cancer	TFKA Toxic Free Kids Act
IRIS Integrated Risk Information System	USDA United States Department of Agriculture
LD50 Lethal dose 50%	USGS United States Geological Survey
LOAEL Lowest Observed Adverse Effect Levels	WHO World Health Organization
MDA Minnesota Department of Agriculture	WoE Weight of Evidence
MDH Minnesota Department of Health	WWTP Wastewater Treatment Plant