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 12, 2016

Principle Investigators

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Acknowledgements

The review team expresses gratitude to the people who contributed to the quality of this project including the staff at the Water Resources Center, the staff at MDH for their time in providing information, Dr. Peter Calow for helping out beyond expectations, and the members of the Science Panel and Stakeholder Panel for their thoughtful insights.

1. Executive Summary

The University of Minnesota reviewed the process used by the Minnesota Department of Health's Contaminants of Emerging Concern (MDH CEC) program to select chemicals to develop health-based guidance values. The reviewers concluded that the CEC program staff use a process that is overall thoughtfully developed, scientifically sound, and justifiable; however it is inadequately explained to stakeholders and could be refined to be clearer. A larger group of stakeholders around the state should be engaged to help identify chemicals of concern and needs for guidance values.

The review of the CEC program was the result of a legislative mandate. MDH receives funds from the Clean Water Fund. With the funding, it conducts several activities related to chemicals of emerging concern, including a process of nominating, screening and ranking chemicals for purposes of determining which chemicals will be given full evaluations for purposes of developing Health-based values (HBVs). The program completes approximately five full evaluations per year. HBVs are the concentration of a chemical in drinking water that is likely to pose little or no health risk to people, including vulnerable subpopulations.

The University of Minnesota was designated by the Legislature to conduct the review. Personnel from the Water Resources Center and the Humphrey School of Public Affairs collaborated on the project. The review consisted of fact gathering regarding the MDH CEC program, a literature review of scientific articles related to chemicals of emerging concern and processes for screening these chemicals, analysis of similar programs in federal agencies and other jurisdictions, and evaluation of the CEC screening process by a panel of scientists and by a panel of stakeholders. Although the University of Minnesota team discussed its recommendations with the scientists and stakeholders and with MDH, the recommendations are the product of the University of Minnesota team. The overall conclusion was that the MDH CEC program is sound but that MDH needed to improve and clarify several steps in the process and expand its efforts to engage stakeholders and the public.

Following the review, the University of Minnesota project team recommends:

1. MDH should preserve and publicize the valuable services of the CEC program.
2. MDH should maintain the Internet-based tool for nominating chemicals for consideration in the CEC program. At the same time, it should engage with membership organizations, for example, the Sierra Club, Clean Water Action or the AARP, that represent individual citizens in developing a communication effort that will increase awareness of the CEC program and awareness of the nomination process.
3. MDH should build on known sources of expertise to develop new methods for systematically nominating chemicals for screening, in addition to relying on voluntary nomination and communicating closely with key agency staff.

4. MDH should publish on their CEC website the process and criteria for assigning categories, summarizing data groups, and combining scores into overall rankings.
5. For clarity in the screening worksheet, MDH should evaluate cumulative effects and reaction products separately.
6. So it is transparent to stakeholders, MDH should describe its method (if it has one) for identifying reaction products and mixtures with cumulative effects as CECs that may require full evaluations.
7. To keep up with the complexity and dynamic nature of chemical exposure science, MDH should incorporate regular consultations with exposure specialists beyond the CEC program staff.
8. MDH should calculate Hazard Quotients (HQs) for currently screened chemicals to assess how the HQ impacts the ranking of chemicals, how much time the calculation requires, the feasibility of the calculations, and whether the use of the HQ is clear to stakeholders or creates more misunderstanding of the uncertainty involved. If the trial shows the HQ is helpful for ranking or communication, it should be incorporated into the screening process.
9. MDH should consider using a "weight of evidence" approach to help streamline the interpretation of toxicological and exposure data and make the process more transparent.
10. MDH should clarify how it is defining "usefulness" of health-based guidance.
11. MDH should increase the engagement of stakeholders during the screening and selection process to help make the process more transparent and inject more information about the nature of needs for health guidance. This engagement should go beyond informal contact with state agencies to reach other stakeholders. To maintain agency accountability, the final decision on chemical selections should remain with CEC program staff.
12. To increase public and stakeholder awareness of the CEC program, MDH should consult with a variety of stakeholders to learn what information they most need, reorganize the CEC website to reflect user needs and add additional communication methods to its current communications activities.

2. Background

2.1. Legislation

This project is the product of a legislative mandate issued to the Minnesota Department of Health (MDH). 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.*" (2015 Special Session Laws, Chap 2, Article 2, Sect 8(a))

The bill in which this language was included was signed by the Governor on June 13, 2015.

2.2. Contract

MDH contacted the University of Minnesota through the Water Resources Center and Humphrey School Senior Fellow Steve Kelley to discuss arrangements for the independent review. Based on the specific terms of the legislation, MDH and the University agreed that the review would focus on the process used by MDH to rank contaminants. A contract reflecting this definition of the scope of the review was completed on December 14, 2015. The contract is Appendix A.

2.3. The Review Process

The review was carried out under the joint supervision of Ann Lewandowski of the Water Resources Center and Steve Kelley of the Humphrey School. Two graduate research assistants were recruited to assist with the review of the scientific literature on contaminant ranking processes and the processes used by the U.S. Environmental Protection Agency and other states and relevant national or European Union programs.

Lewandowski and Kelley recruited five faculty researchers from the University of Minnesota, the University of St. Thomas, and the United States Department of Agriculture to provide scientific insights regarding issues in ranking or prioritizing contaminants of emerging concern. This Science Panel met three times to help identify issues, review the progress and findings of the research and consider the draft final report. The Science Panel did not meet directly with representatives of the CEC program staff regarding the review.

Lewandowski and Kelley also recruited a Stakeholder Panel representing a range of people and organizations that are or could be stakeholders in the work of MDH's CEC program. CEC staff did not participate in the two Stakeholder Panel meetings.

The research team gathered written materials from MDH regarding the CEC program. Lewandowski and Kelley met with CEC program staff to learn more about the development and operation of the program. Lewandowski also conducted detailed interviews with all members of the CEC program staff.

The research team submitted a draft report, including draft recommendations, to the CEC program staff at MDH, after the second Science Panel meeting. The goal was to determine whether the description of the program contained errors and whether the recommendations included processes that MDH was already using. After receiving comments from MDH, the research team clarified some of the current process descriptions and clarified elements of the draft recommendations. The substance of the recommendations were not changed as a result of any of the MDH comments.

2.4. Limitations

The MDH CEC program includes activities that go beyond the screening and ranking process which is the focus of this report. The Legislature did not, for example, mandate an examination of the MDH process of a full evaluation of a chemical to develop health-based guidance. Consequently, the full evaluation process is not considered in this report. We also did not look at the rapid assessment process used by MDH to assess pharmaceuticals and pesticides. These aspects of the CEC program could be evaluated but such an evaluation would require additional financial and time resources.

3. Research Findings

3.1. The MDH CEC Program

The legislative mandate for the Drinking Water Contaminants of Emerging Concern (CEC) program is quite short. It was created in response to Minnesota laws in 2009[1] and 2011[2] that appropriated Clean Water Fund money "for addressing public health concerns related to contaminants found in Minnesota drinking water for which no health-based drinking water standard exists." MDH was required to "characterize and issue health-based guidance" for 10 chemicals in the first biennium.

The CEC program is part of the Health Risk Assessment Unit of the MDH. The program is staffed by three toxicologists, one exposure scientist, one risk assessor, and one communicator. The toxicity and exposure screening processes were originally designed in 2010-2011 in consultation with a Contaminant Selection Criteria and Prioritization Development Task Group comprised of specialists assembled by CEC staff from state agencies, universities, private business, cities, and environmental advocacy groups.

Health-based guidance is provided in the form of numerical estimates of concentrations that would be unlikely to impact human health. Several months of toxicological literature review is needed to determine guidance values, so only about five chemicals can be given a full review each year. It is important, then, that MDH staff carefully screen potential chemicals to select the most important ones to review. In addition, through other program activities, they provide alternative guidance for a greater number of chemicals based on less thorough reviews. Table 1 defines the types of guidance provided. Table 2 lists the types of information generated by the program.

Table 1: Definitions of guidance

Health Based Values (HBVs) – the concentration of chemical in drinking water (in µg/L) that is likely to pose little or no health risk to humans, including vulnerable subpopulations.
Health Risk Limits (HRLs) – an HBV that has been promulgated into Minnesota rule through a formal rulemaking process authorized in the 1989 Groundwater Protection Act. If a contaminant has been detected in groundwater, then HBVs for water may become HRLs at the time that MDH next amends the Health Risk Limits for Groundwater rule.
Risk Assessment Advice (RAA) – contains greater uncertainty than HRLs and HBVs. Not eligible for rule-making. May be in a narrative format rather than numerical.

Table 2: Information products generated by the MDH CEC Program

Information sheets • Based on full reviews • ~2-page, for a non-technical audience • Includes description of the chemical, health guidance values, occurrence in Minnesota, and how people can reduce exposure • 24 available • http://www.health.state.mn.us/divs/eh/risk/guidance/dwec/chemunderrev.html
Toxicological Summary Sheets • Based on full reviews • ~4-page, detailed description of the health guidance and basis of the values • http://www.health.state.mn.us/divs/eh/risk/guidance/gw/table.html
Screening Profiles • Based on screening results • 30 available • http://www.health.state.mn.us/divs/eh/risk/guidance/dwec/chemunderrev.html
Human Health-Based Water Guidance Table • Based on the activity of multiple programs of the MDH Health Assessment Unit, including the CEC program • Guidance values help users evaluate potential human health risks from exposures to chemicals in groundwater • 170 chemicals in the table, but fewer than 30 derive from the CEC program • http://www.health.state.mn.us/divs/eh/risk/guidance/gw/table.html
Rapid Assessments for Pesticides • A rapid method to generate conservative assessment values to aid in setting site clean-up goals. Rapid assessments generally produce more protective results than guidance values MDH would produce in a full chemical review. • 162 pesticides have values • http://www.health.state.mn.us/divs/eh/risk/guidance/dwec/rapidpest.html
Rapid Assessment of Pharmaceuticals • This program generated water screening values: the amount of a pharmaceutical in water that can be consumed daily with no expected health risk to humans. The water screening values developed are intended to be lower (i.e., more protective of health) than values that result from an in-depth assessment by MDH. • 119 active pharmaceutical ingredients have screening values • http://www.health.state.mn.us/divs/eh/risk/guidance/dwec/pharmproj.html

Who uses the work of the CEC program? The primary customers who use MDH CEC guidance are agencies that monitor water or the environment for various purposes. The most active customers and collaborators are the Minnesota Pollution Control Agency (PCA), the Minnesota Department of Agriculture (MDA), and other units within the MDH, including Site Assessment and Consultation (SAC), Drinking Water Protection (DWP) and the Toxic Free Kids Act (TFKA) program.

The main agencies that monitor for and collect data on occurrence of CECs are the PCA, MDA, and the United States Geological Survey (USGS). PCA and MDA staff have nominated numerous chemicals, but USGS staff do not nominate because they do not want to direct state level work. MDH CEC staff frequently interact with all three agencies, and USGS staff have collaborated to make USGS CEC monitoring data easily available.

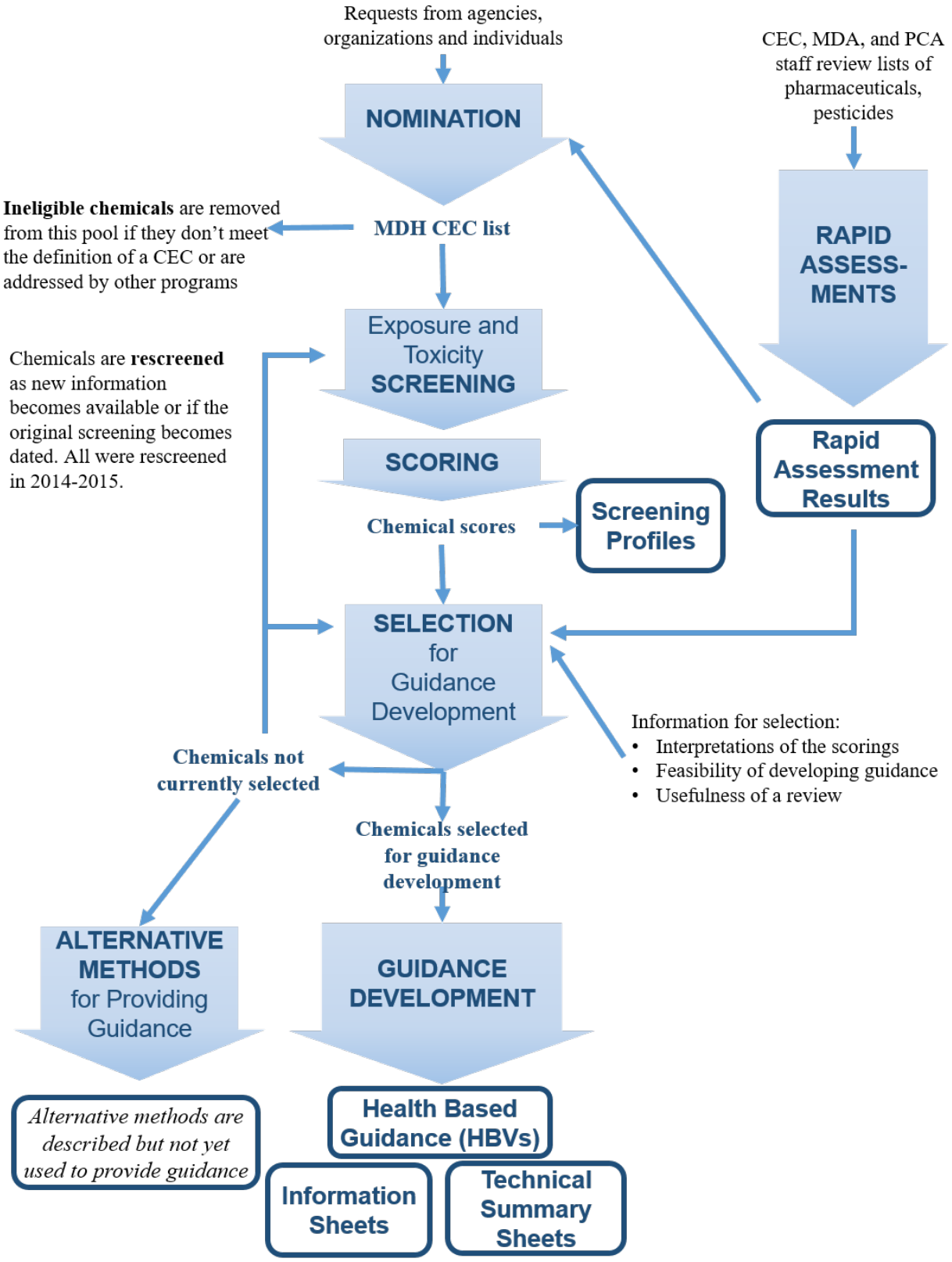
Local water utilities have used MDH CEC guidance, but they are more likely to interact with the MDH Drinking Water Protection unit than with CEC program staff. Other users include citizens, and health and environment advocacy organizations.

Based on the mission of the MDH and Clean Water Legacy funding requirements, the CEC program is charged with examining human health effects of contaminants found in drinking water. However, people are also exposed to CECs in food, air, and their environment, and CECs have ecological as well as human impacts. To a limited extent, the program addresses these other stakeholder interests in CECs.

3.1.1. The process for selecting chemicals for review

Figure 1 illustrates the CEC program workflow, including the nomination of chemicals to be considered, screening to quickly learn about the chemical, selection of chemicals for full review, and the development of health guidance values. In parallel, the program staff undertake other activities, including rapid assessments and examination of alternative methods for providing guidance.

Figure 1: MDH CEC Program Activities and Products



Nominations

The stakeholder advisers who helped develop the nominating process were concerned about ensuring that the program addressed Minnesota's needs by tapping into the knowledge and interests of the people around the state who were most familiar with CECs and recognized high priorities. In response, the CEC staff developed an easy online option allowing anyone to suggest chemicals for review. Nomination requires little information or justification. Of the chemicals nominated, a few have been deemed ineligible for the CEC program because their health guidance is addressed by other programs (Table 3).

Over the years, CEC staff have received far fewer nominations than anticipated; regular nominations come primarily from the PCA, MDA, and other units of the MDH. In response, MDH CEC program staff are beginning to take the initiative to work with other units and agencies to identify chemicals for consideration. For example, they have been working with MDA to examine lists of pesticides of concern in Minnesota, reviewing the EPA's Contaminant Candidate List (CCL), and reviewing lists of pharmaceuticals.

No list compiled for other purposes entirely serves the needs of the CEC program. In particular, few lists focus on drinking water, which is MDH's CEC mandate. The EPA's CCL does focus on drinking water, but for the purpose of regulation. Thus, the list is biased towards chemicals with the higher quality toxicity data needed to generate regulations. Other lists tend to focus on industrial contaminants rather than high volume chemicals such as those found in personal care products.

Table 3: Fate of Nominated Chemicals (as of February 2016)

	Of 91 nominations:
Ineligible for the CEC program. (Most were addressed by the HRL program.)	10
Waiting to be screened	6
Screened	43
Screened and selected for full review; review in progress	4
Screened and full review completed; health-based guidance provided	14
Screened and full review completed; guidance adopted as an HRL	14

Screening

Nominated chemicals (minus those deemed ineligible) are all screened to locate available data related to toxicity and exposure risks. The screening is a rapid process taking perhaps two days to collect all available exposure and toxicity values.

During the screening, there is little consideration of related chemicals. For example, a pesticide and its degradation product may be screened separately, or only the nominated chemical will be screened, or staff may nominate a related chemical that they learn about during screening. In contrast, the full review process may address related chemicals together, or will consider the combined impact of chemicals acting on the same target in the body.

Once chemicals are nominated, they stay in the pool of CEC chemicals for consideration. The chemicals are rescreened as new information becomes available or if the original screening becomes dated.

Toxicity Screening and Scoring

Staff use a detailed worksheet to systematically search various databases for toxicity information. They look for data that could inform health guidance values; thus, the existence of a chemical on others' lists of concerns is not helpful, except to suggest that toxicity information may be available.

The toxicity of a chemical can be characterized using many different values (Table 4). Typically, only some of these have been calculated for any particular chemical. In order to compare a list of chemicals which do not all have a comparable set of toxicity values, each potency data value is categorized as low-medium-high and given a numerical score ranging from 1 to 10. "Other concerns" (Table 5) generally do not have numerical values so those are qualitatively rated as low-medium-high and given a score of 1 to 3. A single toxicity score is calculated by adding together the score of the highest quality potency data (based on a hierarchy of data types), the corresponding severity score, and a qualitative average of the other concerns. In the view of CEC program staff, this approach ensures that chemicals with little data available can still be compared to those with more information.

Table 4: Examples of Toxicity Values

Non-cancer potency

- Reference Doses (RfD) – EPA defines the RfD as "[A]n estimate, with uncertainty spanning perhaps an order of magnitude, of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime." It may be determined by applying an uncertainty factor to a NOAEL.
- Acceptable Daily Intake (ADI) – similar to RfD
- No observed adverse effect levels (NOAEL) – Dose tested at which no observable adverse effects are seen, expressed as mg/kg-day. Data is generated through studies of laboratory animals, and occasionally humans. Studies vary in length, and whether the chemical was administered orally, through inhalation, or injection.
- Lowest observed adverse effect levels (LOAEL) – Lowest dose tested that resulted in observed adverse effects.
- Lethal doses (LD50) – the chemical dose at which half of a test population (usually rats) dies

Cancer potency

- Cancer slope factors (CSF) – an upper bound (95% confidence limit), on the increased cancer risk from a lifetime of exposure
- Doses resulting in tumors (TD50) – the dose at which 50% of the study population develops cancerous tumors
- Cancer classifications from IARC, EPA, and GHS labeling categories

Table 5: "Other Concerns" Considered in the Toxicity Screening

Qualitative categories may be used for these concerns.

- Endocrine activity
- Development/reproductive concerns
- Genotoxicity alerts
- Evidence of bioaccumulation
- Cumulative effects

Exposure Screening and Scoring

Exposure screening involves searching for values describing:

- The persistence and fate of the chemical (e.g., Koc, biodegradation half-life, solubility),
- Emissions and disposal rates (in wastewater, down-the-drain, landfills, ag chemicals release, industrial releases), and
- Measures of occurrence (in drinking water, pre-treatment source water, other surface water and groundwater).

As with the toxicity screening, the values are categorized as low, medium, or high and given a score between 1 and 10. The median of the persistence data, median of the release data, and the maximum of the occurrence data are calculated and averaged to arrive at a single exposure score, which may be adjusted to reflect exposure potential.

Selection

When staff are ready to start a toxicological review to develop health guidance values, the MDH CEC program staff meets to select one or more chemicals. The selection is not based simply on ranking the toxicity and exposure scores, but rather a discussion based on four pieces of information:

1. **Toxicity and exposure scores**
   Selection begins with a list of screened chemicals, ordered based on both their toxicity and exposure scores. Discussion focuses on the chemicals near the top of the list.
2. **Additional exposure and toxicity considerations**
   Further explanation may be useful to interpret the scores, especially when different types of chemicals are being considered side-by-side. For example, rapid assessment advice may be available in the case of pesticides and pharmaceuticals. In one case, the EPA was in the midst of a major study of a chemical, so staff did not want to start a review until they had the results of that study.
3. **Feasibility of developing guidance**
   Each chemical is given a qualitative (low-medium-high) rating of the quantity and quality of data available to form the basis of health guidance values.
4. **Need for developing guidance (termed "usefulness" in this report)**
   Shortly before the selection meeting, agency partners are given the list of screened chemicals and asked to indicate which are of particular importance to their program activities.

3.1.2. Related projects and programs

This report is narrowly focused on assessing the process for nominating and selecting chemicals for a health guidance review. At the same time, CEC program staff work on related "special projects." These are described at http://www.health.state.mn.us/divs/eh/risk/guidance/dwec/specproj.html.

- Alternative Risk Assessment Methodology – a project to examine alternative ways to arrive at risk guidance when a full review is not feasible. This project has generated reports describing and evaluating alternative methods, and providing a decision framework for using the methods.
- Rapid Assessment for Pesticides – a project in collaboration with the MDA to provide rapid assessment values for a large number of pesticides.
- Pharmaceutical Screening Project – a project to develop a method and assess a large number of pharmaceutical ingredients likely to be found in drinking water.

The Health Risk Limits (HRL) Program is not part of the CEC program. It is charged with setting health risk limit values as part of drinking water regulations. It addresses different chemicals than the CEC program, particularly ones that have already been found in groundwater.

3.2. Scientific literature

3.2.1. Risk and hazard-based approaches

The key characteristics of a chemical are its toxicity (How dangerous is it to human or ecological health?) and exposure (How much and how frequently is it in the environment and how likely are people to be exposed to it in drinking water or other sources?). The various approaches to quantifying toxicity and exposure can be summarized as either hazard-based or risk-based methods.

Hazard-Based Method

A hazard-based prioritization system attempts to calculate the damage that a chemical could cause based on its intrinsic characteristics.[3] It focuses on determining "which type of adverse effects should be expected" but does not consider site-specific exposure data.[4] Hazard-based systems may consider exposure potential in the form of accumulation or persistence data, but do not incorporate environmental concentrations.[5]

Hazard-based ranking is better suited to a program that is applicable across territorial boundaries and is independent from what water treatment options are available in each specific region.[6] It may also be an effective system for a new program that is trying to understand the risks of chemicals that are being monitored across the country.[7] In addition to toxicity (T), hazard-based systems may consider persistence (P) and bioaccumulation (B) but P and B are not site specific.[8] Site-specific information is often not necessary for PBT chemicals, which persist in the environment, accumulate in tissue, and are toxic at low doses, because there may not be a safe level.[9] A PBT approach would identify chemicals of

emerging concern that should be of high concern based on their persistence, bioaccumulation, and toxicity but have not yet been found in the water samples from the area.[10]

Risk-based Method

A risk-based prioritization system compares adverse effects with occurrence data.[11] The goal of a risk-based assessment is to determine the probability that the adverse effects will actually happen in a specific location.[12, 13] The risk-based approach is influenced by exposure data while hazard-based is not.[14]

Exposure data should not be based solely on how much of the chemical is sold or released in the region because some chemicals could be easily removed from the water supply.[15] Similarly, exposure data should consider how the chemical actually behaves in water, including degradation.[16]

From a practical level, risk-based prioritization is preferred because chemicals are often considered "chemicals of concern" because of widespread detection in a specific region, as opposed to toxicity alone.[17] Risk-based methods may be more appropriate for organizations involved in local decision making because it considers whether the chemical is actually present in the region.[18]

A ranking system does not have to be exclusively risk or hazard-based but could instead combine the two procedures or use one (e.g. hazard) for the first tier analysis and then use the other system (e.g. risk) on the smaller list of chemicals.[19] However, when risk and hazard-based systems are compared, risk-based systems of prioritization are considered a better method for monitoring a specific region, since hazard, or the potential to cause harm, is only realized if there is exposure.[20, 21, 22]

MDH's CEC screening and scoring process is considered a risk-based program because it uses data about occurrence in Minnesota waters before and after treatment in addition to toxicity and persistence data.[23]

Hazard Quotient Ranking

In the literature, the most commonly used method for ranking and selecting chemicals was to use hazard quotients (HQ), which compare the occurrence data to a threshold level at which the chemical would begin producing adverse effects. HQs can also be called "trigger levels,"[24] "benchmark quotients,"[25] or "risk quotients."[26] HQs are developed by dividing the occurrence concentration by a calculated toxicity level that represents a threshold at and below which effects are very unlikely.[27, 28, 29, 30, 31] HQs are risk-based because the score includes occurrence data. In fact, some jurisdictions refer to the HQs as risk quotients. The occurrence concentrations can be either predicted environmental concentration (PEC) or measured environmental concentration (MEC).[32, 33] Many systems used calculated or predicted rather than actual exposure data.[34]

The next step is to determine a threshold of toxicity. The threshold can come from established health guidelines from organizations like WHO or EPA.[35] If there is no established threshold, then the next option is to create a provisional threshold

based on toxicology data: predicted no-effects concentration (PNEC), no observed effect concentration (NOEC), Tolerable Daily Intake (TDI), Acceptable Daily Intake (ADI), or reference dose (RfD).[36, 37, 38]

$$Hazard\ Quotient\ =\ Exposure/Toxicity\ Threshold$$

The HQ is used to prioritize based on whether it is above a level of concern. The most common level of concern was at or above the value 1.0, i.e., where the exposure was equal to or greater than the threshold.[39, 40, 41, 42] If the HQ for a particular chemical is greater than 1.0 then it is a higher priority compared to a chemical that has a HQ less than 1.0. While 1.0 is the most common level of concern, an organization could choose a lower concern level if it was trying to protect a more sensitive interest, such as a vulnerable population or environmental health.[43]

Categorical Ranking

Categorical systems usually focus on the toxicity data and not the occurrence data, meaning that the scoring system is hazard- rather than risk-based.[44] Categorical ranking aggregates information on toxicity and then generates a qualitative score either on a number scale (1-10 or 1-100 are the most common) or another scale ("very low" to "very high" or color coding).[45]

From the scoring sheets, MDH uses the same input data (RfD, NOEC, etc.) and has exposure data but it does not then create a HQ. Instead, the exposure and toxicity data are given independent indexed scores. Although it incorporates occurrence data, the MDH system resembles a categorical approach because it translates exposure and toxicity data into a score on a numbered scale.

3.2.2. Evaluation of ranking or scoring processes

A few researchers have systematically evaluated tools for prioritizing chemicals of concern. The evaluation criteria generally focus on response to data gaps, selection of endpoints or databases, and development of the tool.[46, 47]

One of the most important criteria in the evaluation of a ranking system is how the program responds to data gaps.[48, 49] Missing data do not necessarily mean that there is no risk.[50] Lack of data is likely to be a reoccurring problem for a program like MDH's CEC program that handles chemicals of emerging concern rather than established ones. Many of the commercial tools struggle with how to respond to data gaps.[51] For example, one independent, web-based risk assessment tool, GreenSuite,[52] developed a system where there are five different levels of response to data gaps, some which do not affect the overall score and some that do. When data are missing because that particular piece cannot be measured due to particular properties then there is no penalty.[53] However, a chemical's score is penalized when data are missing due to a lack of studies.[54]

MDH's use of alternative methods and its consideration of feasibility are in line with GreenSuite's varied level of response to data gaps. When there are alternative methods, the chemical is not penalized for not having complete data available. On

the other hand, the feasibility factor will penalize chemicals that would be unreasonably difficult to review.

The best programs will include qualitative data that describe the pathway or method of the harm, "carcinogenicity, mutagenicity, genotoxicity, and developmental/reproductive toxicity." [55] Qualitative data are an important part of the prioritization system because quantitative data are often not available.[56, 57] The emphasis on qualitative data parallels MDH's concern about handling chemicals that do not have as much quantitative data. MDH does consider qualitative factors such as developmental and reproductive toxicity as well as endocrine disruption in its analysis.[58]

Exposure is an area where data gaps and qualitative data will be very important. There is often limited exposure data for CECs so any ranking system has to have a method to address exposure data gaps.[59, 60] In the absence of measured environmental concentrations, programs can and have used proxy numbers including release data, predicted environmental data and maximum observed concentrations. [61, 62, 63, 64, 65] Unfortunately, modeling involves a high degree of uncertainty.[66]

Secondly, the endpoints should be selected to further the purpose of the program, whether that be human or environmental concerns.[67, 68] In addition to site-specific environmental concentrations, exposure data should also include endpoints associated with bioaccumulation and bioavailability.[69] Bioaccumulation data is important to account for probability that the chemical could have adverse effects on a population.[70] MDH uses K_{ow} and BCF as indicators of bioaccumulation. Toxicity endpoints should also reflect the goals of the program (aquatic or terrestrial, human or environment).[71]

A secondary issue within the endpoint selection analysis is transparency.[72] It is important to know what methods are being used and what assumptions are being made.[73] The evaluation literature did not identify what programs were doing to be more transparent; however, one potential area for transparency concerns is when and where expert judgment is exercised.[74]

The final area of evaluation is the development process of the tool. The better tools were developed through a process that involved a variety of stakeholders from different organizations.[75] When prioritizations systems are developed entirely internally then it has a much higher potential to have unexamined biases.[76] Including the stakeholders in the development process can help to improve the transparency of the process.[77] MDH involved a wide range of stakeholders in developing its selection process.

3.2.3. Treatment of reaction products

One of the main problems with the exposure parameter is that it does not always effectively consider degradation products and the effects that those will have on a system.[78] In response, programs commonly evaluate chemicals together with their degradation or reaction products.[79]

A related problem is the combined impact of chemicals operating within a mix of other chemicals.

3.2.4. Weight of the evidence

Weight of the evidence (WoE) is a structured method of integrating multiple lines of evidence and professional judgment.[80] WoE began to develop in response to "concerns about the lack of sufficient objectivity, certainty, transparency, repeatability, and consistency in the approaches used to integrate lines of evidence in reaching conclusions about environmental risks."[81] Scientists have been using WoE analytical frameworks to provide guidance and transparency when combining a qualitative element like professional judgments with quantitative data.[82] Despite having a central impetus behind its development, currently, WoE does not have a procedure or meaning that is consistent across disciplines or researchers.[83,84] WoE can range from "casual and vague remarks to quantitatively well-defined analytical methods."[85]

WoE can be a metaphorical description of the general state of the evidence[86] or a theoretical framework for understanding patterns.[87] More importantly WoE can also be a methodological reference.[88] As a method WoE can have multiple meanings that range from methods that are more qualitative to ones that are more quantitative.[89,90]

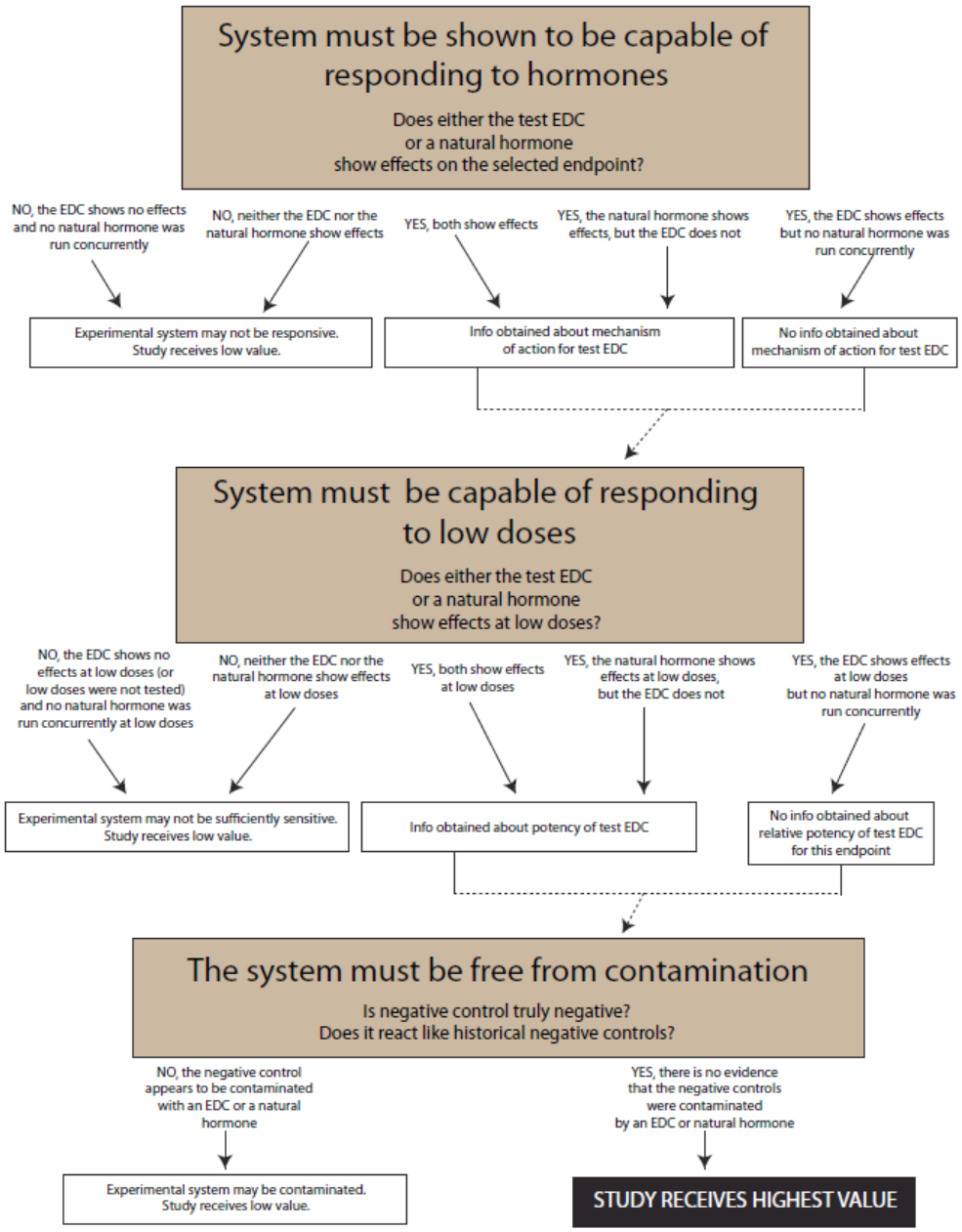
The methods that focus most on qualitative considerations are referred to as "systematic narrative review"[91] or "best professional judgment."[92] In a narrative review WoE method, the researcher integrates and weights different lines of evidence using professional judgment.[93,94] One example is the way that American courts examine scientific evidence for trial.[95] The court's analysis of the evidence is guided by the four key questions: relevance, reliability, sufficiency and standard of proof.[96] The four guiding questions give the court a structured way to frame its professional judgment.

In the realm of risk assessment, the narrative review method is the most commonly used form of WoE and is most often used to evaluate toxicity analyses.[97] One of the strengths of qualitative methods is that they can integrate critical professional judgments and stakeholder values in an explicit and organized manner.[98] However, because narrative review focuses on qualitative features the method has a tendency to lack transparency and repeatability.[99]

The next type of WoE method is causal criteria, a more quantitative method that uses criteria in evaluating lines of evidence. The integration process is guided by slightly more structured and constant set of requirements.[100] The criteria can either be a set, absolute list, where each criterion has to be met otherwise the chemical is considered not to be a risk, or a more flexible list that functions as a guideline.[101, 102] A criteria WoE scheme can provide a more systematic, transparent way to organize a discussion of the lines of evidence. However, it still relies on professional judgment in setting the criteria and determining the rule for when that criterion is met.[103] Causal criteria methods are used more often in identification of ecological hazards.[104] Figure 2 shows an example of a decision tree used to organize criteria for evaluating endocrinology studies.

The final WoE method, called scoring, indexing or quantification, focuses significantly on the quantitative data.[105] This method uses formal analytical techniques, such as statistics, empirical models, and weighing and ranking, to integrate various lines of evidence.[106, 107] Quantitative WoE methods are much more likely to be transparent and reproducible.[108] However, the emphasis on quantitation means that stakeholder values and other professional judgments are not explicitly considered and incorporated into the risk assessment.[109]

Figure 2: A decision tree used in a WoE analysis of endocrine studies[110]



3.3. Processes in Other Jurisdictions

Programs to identify and rank CECs exist in many states, at the federal level, and around the world. The purposes of these programs vary. They are commonly designed for the regulation of drinking water, but also for improving overall water quality, and for the regulation of toxics in commerce and the environment. These programs are described in detail in Appendix D, and summarized in Tables 6 and 7.

Table 6: Variations in Programs to Evaluate CECs

Program Features	MDH CEC Program characteristics
Program objectives For example, is it aimed at supporting regulations, guiding clean-up efforts, planning monitoring, or triggering notifications? Is it to protect drinking water, monitor wastewater, or track commerce and industry? Setting regulatory goals requires better toxicity and occurrence data than is needed for other goals.	MDH program's first priority is drinking water protection, but also gives attention to environmental contamination. They explicitly are not aimed at regulation, but rather at identifying and providing initial guidance on chemicals of emerging concern. An important use of their guidance is to inform monitoring activities.
Funding and authority Is there a dedicated program and a legislative mandate to address CECs, or is the work an add-on to a drinking water protection program? How much and how secure is the funding?	The dedicated CEC program is far better funded than efforts in almost any other state. Funding is from the CWL Act to the MDH for the purpose of addressing public health concerns related to drinking water.
Chemical types Is the focus on industrial chemicals, or on high-volume chemicals such as pharmaceuticals and personal care products (PPCPs)?	MDH has put more attention on PPCPs and pesticides than many jurisdictions, but also looks at industrial chemicals important to Minnesota.
Initial list of chemicals for evaluation Does the program begin with a large universe of chemicals, the EPA's CCL lists, a more targeted state-specific list, or nominations from stakeholders?	MDH begins with a nomination list, but examines the CCL and other lists for suggestions of nominations. Many other programs start with a much larger universe of chemicals.
Evaluation approach Does the program use a hazard-based or a risk-based approach, or some combination of the two at various stages in the process?	MDH uses a risk-based approach to prioritizing chemicals, considering occurrence in Minnesota along with toxicity and persistence data.

Table 7: Comparison of CEC Programs

	MDH CEC	EPA CCL	Watershed CEC monitoring programs (DE River, Columbia River, Great Lakes)	Chemicals of concern in commerce/ products (CA Safer Products, ME Toxic Free Kids, WA Toxic Free Kids, Canada CMP)	Pollutants in surface water (CA WWTP CEC, Oregon PPPL)	Regulatory drinking water standards or guidance programs (CA Notification List, MA CEC)
Nomination						
Public Submissions	X	X				
Total Universe of Chemicals		X		X	X	
Established List of High Hazard or High Risk Chemicals			X			
Ad Hoc from Specific Problems						X
Screening						
Hazard Screen	X	X		X	X	X
Human Health Effects Screen	X	X				X
Required End Points				X	X	
Exposure (Risk) Screen	X	X	X	X	X	X
Detection in Jurisdiction	X				X	X
Required/Prohibited Data Sources				X		
Not Otherwise Regulated	X	X				
Analytic Methods			X			
Selection and Ranking						
Hazard Scoring	X	X		X	X	X
Categorical Scoring and Ranking	X	X			X	X
End Point Prioritization in Ranking		X	X	X	X	
Exposure/Detection Scoring	X		X	X	X	X
Uses Actual Detection	X		X		X	X
Uses Estimated Occurrence		X		X		
Public Comment on Draft List of Selections		X		X	X (OR only)	X

The most significant program for comparison to the MDH Contaminants of Concern program is the EPA's process for identifying new pollutants for setting primary drinking water standards under the Safe Drinking Water Act (SDWA). The EPA process identifies a Contaminant Candidate List (CCL), from which Regulatory Determinations are made. Many states rely on this EPA program to identify emerging contaminants. A few state legislatures have established state programs to identify and prioritize action on contaminants of emerging concern. Some of these programs are implemented to develop additional drinking water standards for public water utilities, health-based drinking water guidelines for non-utility stakeholders in the state, general water quality, or as cleanup standards.

Where the ultimate goal is setting regulatory standards, as is the case for the EPA CCL, adequate data must be available to support a rule, and procedures for considering non-health information such as cost and benefit of regulation are often required.

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 states[111] are the delegated primary enforcement authority and must ensure that public water utilities provide safe drinking water.[112] States must adopt any federal primary drinking water standard, but are also free to adopt more stringent or additional standards. 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.

One analytic methodology for integrating and comparing disparate risk assessment information can be referred to as a Weight-of-Evidence (WoE) methodology for screening, ranking, or communicating. EPA has developed, published, and uses WoE methods in a number of risk assessment contexts. For example, when combining different types of information on carcinogenicity risk, or when combining different endocrine disrupting potentials for a chemical among different hormones and hormone regulating systems. Appendix D provides an example of EPA's use of WoE in its Endocrine Disruptor Screening Program that the agency uses to screen and rank chemicals, and then require enhanced data submissions for pesticides and industrial chemicals under FIFRA and SDWA.

3.4. Feedback from the Stakeholder and Science Panels

3.4.1. Science Panel

The Science Panel was five academic researchers with expertise in environmental toxicology, public health, chemical exposure, and public policy related to contaminants of concern. A few panel members were advisers to the early design of the MDH CEC program, so were able to provide some context for the current program. The panel met three times: once at the beginning to guide the review, a second time to discuss an early draft of the recommendations, and a third time to respond to MDH comments about the recommendations.

In all three meetings, the panel identified strengths of the existing program, including use of a comprehensive and up-to-date list of sources of toxicological data, and consideration of more components of exposure than is typical for state programs.

The panel spent a lot of time discussing how to balance qualitative and quantitative information to compare diverse chemicals. One person summarized: "the reality is there is always professional judgment. The key is to be transparent." They appreciated reading the notes from the February 10th meeting of the MDH CEC team, and seeing the components that went into their decision of which chemical to review.

Out of the discussions came several possible approaches to improving the consideration and communication of qualitative information:

- Calculate a Hazard Quotient (HQ) along with the current scoring system. This calculation might add complexity, but would add transparency. The HQ could highlight different chemicals than are highlighted by the scoring system, and would be clearer to explain.
- Staff would need to define rules for which data would be used for the threshold and exposure components of the HQ.
- Provide clear explanations of the scoring process and the rest of the selection process. In fact, provide two explanations: one for scientists and one for non-scientists. Include a Minnesota translation of what was adapted from the EPA's CCL process.
- Staff would obtain a better understanding of the transparency of their explanations if they had to regularly explain their choices to an advisory group.
- Convene the meeting of stakeholders before the selection process to get feedback on the screening results and to gather information about the need for health guidance.

Another extended discussion related to the challenges of quantifying exposure. The group concluded that it is important to ultimately base ranking decisions on discussion, because a structured discussion is easier to explain than the uncertainty of the numbers. That said, they also emphasized the importance of starting with

good measured and estimated data, and utilizing additional expertise outside of MDH staff to keep up with the changing science.

The panel raised some concern about whether the source of nominations was too narrow. The "public" is not making nominations and they are not aware of the opportunity. If public nominations are the intent, then engage the public. Leverage advocacy groups to help educate the public and solicit nominations.

The panel acknowledged the boundaries of the program, noting the routes of exposure and impacts that are overlooked because the program is focused on health-based impacts of chemicals found in drinking water.

3.4.2. Stakeholder Panel

The stakeholder panel included representatives from state agencies; business; city water utilities; regional planning; and environment, health, and citizen advocacy organizations.

During their first meeting, the group had a lot of questions about how the CEC program works. For example:

- Who is nominating chemicals and what are the biases? Are they considering all classes of chemicals?
- How are toxicity and exposure, and their subcomponents, weighted and scored?
- How are data gaps handled?
- Are alternative methods of guidance used inappropriately?

Many were concerned that the MDH "stick to science" in selecting chemicals. At the same time, they recognized the lack of science around many chemicals, and thought it was very important to only address chemicals for which there was a need for health guidance. Usefulness was raised as a concern in all stages from nomination, eligibility, screening, and selection.

The group also identified the range of users who would have an interest in the outcomes of the CEC program.

Panel members came into the second meeting with a greater understanding of the program and thus were able to provide more focused comments about the proposed recommendations.

Like the Science Panel, they generally supported the CEC program and wanted to ensure the program got credit for the good work they are currently doing.

<u>Nomination process</u>

Panel members were concerned about the bias inherent to the small pool of people who were aware of the process. So they liked the recommendations to add systems for automatic nominations while retaining the opportunity for public nominations, and suggested adding a connection to University experts as a source of nominations.

Screening and scoring

Panel members agreed with the need for a clearer scoring system and liked the HQ and Weight of Evidence approaches for their potential to provide clearer communication about the process. But they were cautious about the danger of misusing the single number in communication or as the basis for decision making without understanding the limitations of the number. One participant noted, "Sometimes discussion is better than a number for chemicals about which little is known."

One group raised concern about potential confusion around the word Hazard Quotient, which may sound more dangerous than is appropriate. They suggested using a different name for the concept, such as "risk quotient", when communicating with stakeholders.

There remained concern about whether there was enough attention during the screening process to reaction products, metabolites, and chemical mixtures. The toxicity of metabolites should impact the toxicity ranking of the original chemical.

One panel member took issue with the suggestion that a CEC is not relevant to Minnesota if it has not been detected or there are no sources: Only a fraction of chemicals can be detected, and some chemicals have been detected that do not have obvious sources in the state.

Panel members liked the idea of quantifying prospective exposure, and increasing consultation with outside exposure specialists.

Concerns were raised in both the first and second meetings about how un-reviewed chemicals are handled. Panel members wanted to ensure there was a connection between this program and researchers and monitors who could fill data gaps. They wanted clear communication about the fate of and reasoning behind chemicals that were deemed ineligible or that were not reviewed.

Communication and Stakeholder Engagement

A lot of discussion related to improving communication. The panel agreed strongly with the need to improve communications and public education. Some of the comments included:

- Can't find a straight forward list of chemicals with links to information sheets, guidance values, and updates on progress.
- Make it easier to find the great resources produced by the program.
- Use GovDelivery to announce finished reviews and screening profiles, not just to announce the start of reviews.
- Need to raise public awareness about the nominations process.
- Ensure that any stakeholder engagement efforts don't have the inadvertent effect of hijacking or slowing the process of generating health guidance.
- What is the relationship between the CEC program and other state agencies and other programs within MDH?

- What is the timeline from nomination to screening to selection to guidance? Can you show where a chemical is along this path?
- Put together a traveling road show: e.g., one presentation per month at state agencies, interest groups, Rotary clubs, League of Women voters, Minnesota-specific water conferences, etc. Hire professional help to develop effective communication materials.
- Use MPCA's NPDES compliance officers as a resource for reaching out to industry with regard to nominations, sampling data, and advice regarding treatment.
- Translate the Weight of Evidence information into an info-graphic.

At several points in the two meetings, some panel members emphasized the huge potential costs of treatment associated with any rules or guidance related to water contaminants. Panel members appreciated this burden on utilities and their customers. Near the end of the second meeting, during the discussion of communication needs, some panel members stated that the drinking water and wastewater utility community needs to hear more about the program. Better communication about the purpose of the program and the meaning of health guidance values could reduce fear about the program and fear of unwarranted costs. Plus, early involvement in the identification of concern and guidance for a chemical may help later if a utility needs to treat for the chemical.

Other Comments

Several comments were made that fell outside of the scope of this review that reflected concern about the overall impact of the program. How are the final results used to manage chemicals? Was it having an effect on reducing impacts of and exposure to chemicals of concern? Were they evaluating impact? Has MDH looked back to see if the chemicals reviewed were actually the worst? Could you tell a story of how the process has led to a reduction in contamination? Several panel members felt strongly that the mission of CEC work should be preventing contaminants from reaching drinking water in the first place.

One part of prevention is clearly communicating the process and impacts of chemicals so stakeholders who can impact exposure understand the implications of the chemical, and how they can reduce exposure. Use publications to ultimately reduce what people put in water. In addition to raising concerns, CEC materials should also work to put concerns in context, e.g., clarify when the presence of a chemical does not mean there is an effect.

4. Discussion and Recommendations

4.1. Discussion of the MDH CEC Selection Process

4.1.1. Principles

The legislative mandate for the CEC program is to issue health-based guidance "for addressing public health concerns related to contaminants found in Minnesota drinking water for which no health-based drinking water standard exists." Based on listening to MDH staff and CEC program stakeholders, the authors of this report highlighted several principles that are either explicitly or implicitly part of the mission of the CEC program:

Protect public health
: Data interpretations and chemical guidelines are focused on human health impacts of the chemicals.

Comprehensiveness
: MDH staff put a high priority on not overlooking chemicals because of lack of information. Chemicals may be a concern even if there is limited data describing toxicity, occurrence, or their impact on less-studied endpoints such as endocrine activity.

Transparency
: For accountability and to promote appropriate use of guidance values, the MDH needs to clearly communicate a scientifically defensible process for selecting chemicals to both a lay audience and a technical audience. MDH's process should be visible to and understandable by the full range of stakeholders.

Efficiency and flexibility
: The MDH CEC program can respond to changing needs, such as developing industries, new detections, or new health information. They can rapidly screen a large number of chemicals, and can generate scientifically sound health guidance values within months. The result is an efficient use of the financial resources allocated to the CEC program.

Relevance to Minnesota
: To maximize return to Minnesota taxpayers, the program focuses on Minnesota needs, i.e., chemicals that are or may be found in our environment, chemicals that have significant releases in the state, and instances where health-based guidance is not available from other authoritative sources.

4.1.2. Uses and users of the CEC program activities

The CEC staff have a close working relationship with major users of their health guidance including staff at the PCA, the MDA, and other units of the MDH. They do not have a direct connection to the community of water utility operators around the state, but instead reach them through the work of the Drinking Water Protection Unit of the MDH. They also have little connection to industry – both those that

release chemicals into the environment and those that design and distribute water treatment approaches.

Potential users and uses of guidance provided by the CEC Program include:

- Industries that manufacture chemicals have more information to help them compare alternatives
- Analytical laboratories and industries that manufacture analytical equipment
- Engineers who design water treatment equipment and water reuse systems
- Drinking water and waste water treatment utilities who need to understand potential threats and need help communicating with customers
- Regulated CEC dischargers
- State agencies that assess resources and environmental risks, and clean up contaminated sites
- Policy makers, planners, and decision-makers who craft effective rules and design healthy built environments
- Farmers who need information about the quality of their irrigation water and the potential impact of their chemical use
- Citizens and private well-owners who need information about the impact of their consumer and waste management choices

4.1.3. Balancing qualitative and quantitative criteria for comparing chemicals

As the project team for this review learned more about the CEC program, the work became more focused on a few aspects of the program: 1) the complexity of the elements considered in the screening process and the related numerical scores assigned in each element; 2) the role of exposure information; 3) the interpretations and judgments made by the staff regarding eligibility of a chemical for the program, the feasibility of doing a full evaluation and the usefulness of an evaluation; and 4) the explanations of the program to the public and the degree of stakeholder awareness of the program.

Not all the information available about a chemical can be quantified. Even when there is toxicity or exposure data available, it may be appropriate to apply an uncertainty range to those data in order to avoid placing too much reliance on a single number. Consequently, the CEC staff must be able to apply its informed judgment in the screening process. One of the risks is that external audiences may not understand how the CEC staff interpretations or judgments were applied in a particular case, or how they were applied to one chemical compared to a different chemical.

This review highlights several points in the selection process where professional interpretations and judgments play an important role in the outcome. The program would benefit from making the following points in the process more systematic and transparent.

- Adding chemicals to the nomination list. This is the most significant point in the process where stakeholders outside the CEC program can use their experience and judgment to identify a need for health guidance.

- Categorizing, scoring, and summarizing toxicity and exposure data values
- Interpreting the ranking of screening scores to account for unique characteristics of chemicals
- Determining the feasibility of generating a health guidance value
- Evaluating the usefulness of developing health guidance

4.2. Recommendations

4.2.1. Continue the strong components of the program

The MDH CEC screening process is a unique and thorough approach to rapidly examining and ranking chemicals to be considered for developing guidance on levels that are not expected to have health effects. **MDH should preserve and publicize the valuable services of the CEC program.**

The process and mission of the MDH CEC program is different from the EPA CCL process used to develop Maximum Contaminant Levels (MCL), which take a decade or more to establish, may be based on more robust datasets, and go beyond health impacts to consider cost and benefit of the standard. The MDH CEC program is effectively filling a gap and helping Minnesotans assess the risk from chemicals for which there is less national or international information. Program staff have been regularly examining and looking for ways to improve their process over the years. Although the report makes recommendations regarding changes in the process, the review did not identify instances in which the Science Panel or the Stakeholder Panel questioned the outcomes of the screening and ranking process.

4.2.2. Enhance the sources of nominations

By welcoming suggestions of chemicals from the public using an easy online form, the nominating process was designed to draw on the knowledge of people across the state who would be the first to become aware of potential contaminants of concern.

However, the success of this process depends on public awareness and engagement. In fact, few nominations have been made by individuals acting as citizens or residents of Minnesota. Few people are aware they can make nominations, and few nominations have come from beyond the state agency staff who work most closely with unregulated contaminants. Even though the public nomination process has been little used, that is not a reason to discontinue the ability or individuals to nominate chemicals.

MDH should maintain the Internet-based tool for nominating chemicals for consideration in the CEC program. At the same time, it should engage with membership organizations, for example, the Sierra Club, Clean Water Action or the AARP, that represent individual citizens in developing a communication effort that will increase awareness of the CEC program and awareness of the nomination process.

Many of the nominations of CECs have come from state agencies, including MDA, MPCA and other units of the MDH. These nominations can reflect agency awareness

of exposure or potential exposure that adds to the quality of the nomination. **MDH should build on known sources of expertise to develop new methods for systematically nominating chemicals for screening, in addition to relying on voluntary nomination and communicating closely with key agency staff.** Illustrations of criteria for systematic and automatic nominations include:

- The top ten pesticides by volume sold each year
- High volume industrial chemicals
- Top-ranked chemicals from the rapid assessment programs
- Automatic nominations based on processes at the PCA or other agencies
- Breakdown products identified during screenings or reviews

4.2.3. Clarify the current scoring system

Several points in the scoring process rely on expert judgment and interpretation, rather than simply quantitative data:

1. Scoring categories are defined for each data value. The definitions are largely, but not entirely, based on the EPA's process for generating their CCL.
2. Chemicals are placed into scoring categories. For some data types (e.g. potency, severity, persistence), the categories are defined by the numerical values of the data so no judgment is involved in putting the value into a category. However, for other data types (e.g. endocrine activity and genotoxicity), the categories are qualitative, based on judgment. For example, the literature on overall endocrine activity is categorized as showing no evidence, unknown/conflicting/limited evidence, or suspected evidence.
3. A system is established to combine scores across criteria.
   Overall Toxicity Score = Highest in the hierarchy of the potency data scores (1-10) + Severity score (1-9) + Other scores (1-3)
   Overall Exposure Score = The average of (Median of scores for persistence data, median of scores for release potential data, and maximum of scores for occurrence data). That overall score is then adjusted based on potential exposure and frequency of detections.
4. Finally, the bottom line scores are interpreted to prioritize chemicals for a full review. To equally weight exposure and toxicity, the overall exposure and toxicity scores are converted to a percentage of total possible score and averaged. The exposure and toxicity scores are also considered separately.

These points of judgment are not unwarranted. The system allows the MDH to compare chemicals that have very different behavior in the human body and in the environment, and that have different types and quality of data available. However, the lack of an accessible published explanation of this scoring system can be problematic in two ways: there can be unnecessary variations between individuals doing the scoring and stakeholders and the public cannot evaluate how CEC staff are interpreting or judging the data. **MDH should publish on their CEC website the process and criteria for assigning categories, summarizing data groups, and combining scores into overall rankings.**

4.2.4. More systematically address cumulative effects and reaction products

Early in the process, both the Science Panel and the Stakeholder Panel raised questions about how the CEC staff were considering the role of chemicals that are created by the interaction of the chemical being screened with the environment.

Cumulative effects refers to how the chemical being screened interacts with other chemicals to create a potentially more or less toxic combination. Reaction products (for this discussion) include breakdown products, reaction products, or metabolites of the chemical being screened. They can be toxic when the original chemical is not and may form in groundwater, drinking water or inside the body.

The MDH examines cumulative effects and reaction products during the full review process, but it is not possible to consider them during the much shorter screening process. However, it is helpful to acknowledge known cumulative effects and reaction products during the screening. They are both handled together in the toxicity worksheet, as explained in their draft Best Management Practices document: "if the chemical being screened is known to occur with other chemicals, degrade into other known chemicals, have degradates which are more toxic than the parent compound, or have known and serious interactions with other chemicals (mainly for pharmaceuticals), record this data in a qualitative manner." The effects of the combined chemicals are a legitimate concern in their own right. **For clarity in the screening worksheet, MDH should evaluate cumulative effects and reaction products separately.**

The other question regarding reaction products is whether the reaction product itself has been or should be subjected to screening and evaluation. How MDH handles this issue is not clear from the CEC program materials, but is important to stakeholders. **So it is transparent to stakeholders, MDH should describe its method (if it has one) for identifying reaction products and mixtures with cumulative effects as CECs that may require full evaluations.**

4.2.5. Strengthen the exposure element of the screening and ranking process

The CEC staff includes one person who focuses on exposure data and exposure-related issues; this is one of its strengths. Nonetheless, the Science Panel identified the complexity of the exposure issues related to CECs as an area requiring additional attention, and asked whether the MDH staff was in a position to keep up with the dynamic and sometimes idiosyncratic technical information about CEC exposure. For example, new science recently revealed that a CEC may be present in the environment but was hidden from detection because it had formed a complex with other chemicals that made standard detection methods ineffective. This type of highly technical information, specific to one chemical, could have a significant impact on the screening score for that chemical.

To keep up with the complexity and dynamic nature of chemical exposure science, MDH should incorporate regular consultations with exposure specialists beyond the CEC program staff. Possible consultants include the environmental and analytical chemists at MDH and MPCA, and exposure specialists with the EPA and

USGS. An additional source of current science is the abstracts from meetings of professional associations including the American Chemical Society (ACS) and Society of Environmental Toxicology and Chemistry (SETAC).

While raising this concern, the Science Panel also noted that MDH conducts much better exposure determinations than other states that merely note whether the chemical has been detected in a neighboring state.

4.2.6. Consider using the "hazard quotient" (HQ) for screening and ranking

The hazard quotient (HQ) is recognized in the scientific community as a way to characterize chemicals. It is the ratio of the estimated exposure level to a threshold level at and below which the likelihood of harm is considered to be very low. The HQ allows the comparison of the risk posed by one chemical with that posed by another. Decision rules would need to be established to choose which toxicity data (Table 4) to use as the threshold level, since data availability varies by chemical. In this way, the HQ does require professional judgment and incorporates significant uncertainty, but it would be more transparent than the current process of combining a large number of values into single scores.

Calculating and publishing the HQ for each screened chemical would not likely replace the scoring process, but would provide additional information that could highlight a concern that might not have been highlighted by the scoring system. The HQ does not incorporate all of the factors currently considered, such as bioavailability. Adding a PBT calculation (Persistence, Bioavailability, Toxicity; see "Hazard-Based Method" p. 16) would account for these other factors.

MDH should calculate Hazard Quotients (HQs) for currently screened chemicals to assess how the HQ impacts the ranking of chemicals, how much time the calculation requires, the feasibility of the calculations, and whether the use of the HQ is clear to stakeholders or creates more misunderstanding of the uncertainty involved. If the trial shows the HQ is helpful for ranking or communication, it should be incorporated into the screening process. Note, however, that stakeholders recommended against using the term "Hazard Quotient", as it sounded more dangerous than what scientific users mean. "Risk Quotient" may be a better alternative for public communications.

4.2.7. Make qualitative explanations more systematic and transparent

The current process for selecting chemicals for review appears to have an appropriate balance of quantitative and qualitative considerations, including toxicity and exposure risk data, qualifications to help interpret the risk data, and information about the usefulness or timeliness of developing health guidance. While quantitative data are important for providing objective justification for selecting chemicals, qualitative information is important to address chemicals with limited data and to provide the flexibility needed to compare the variety of types of chemicals being considered and account for the small number of chemicals being reviewed each year. We identified two areas where a more systematic narrative explanation is needed to legitimize choices based on qualitative information: a)

interpretations of the toxicological and exposure data, and b) consideration of usefulness or need for health-based guidance. These are addressed by the next two recommendations, respectively.

MDH should consider using a "weight of evidence" approach to help streamline the interpretation of toxicological and exposure data and make the process more transparent. A weight of evidence approach has several different meanings (see section 3.2.4, p. 20). The current MDH CEC scoring process might be considered a weight of evidence (WoE) approach to the extent it is a systematic method for combining multiple types of data. However, it is not a WoE approach in terms of reporting or communicating. We recommend exploring the use of narrative or graphical characterizations of chemical hazard and data quality, not as an alternative to the current chemical selection process, but a way to make the process explicit.

To illustrate: notes from the most recent chemical selection meeting reflected that the staff considered some information that was relevant but difficult to quantify. For example, the discussion addressed the prospective release of an EPA study related to one of the chemicals being considered. It would be counter-productive for MDH to conduct a review before this information was released.

Judgments such as this need to be more public and systematic. A weight of evidence approach could be used to identify standard discussion items or decision points, and then to guide a narrative response to each of these decision points. The discussion summary could follow a systematic list of questions with brief descriptions of feasibility, usefulness, timeliness, and any other standard considerations. The discussion and the public report of the discussion could be guided by a decision tree such as that shown in Figure 2, page 21. For example, the descriptions of top-ranked chemicals might include a decision tree such as the following.

1. Is the chemical present in Minnesota?
2. Could it potentially be present?
3. If present, could it persist and bioaccumulate?
4. What is its toxicity?

The questions would be answered with a description of the level of confidence in the data. The result would be a standardized narrative summary of the discussion behind the selection process, and a systematic explanation of feasibility, usefulness, and timeliness of a review. The goal would be to make the selection process and judgment factors less arbitrary in reality and in appearance, and make the decision relatively easy for an outsider to follow.

The ToxPi software[113] from the EPA is one possible tool for graphically summarizing screening data in a way that visually communicates multiple data sources. We are not necessarily recommending use of ToxPi, but we suggest this as one possible tool for improving communication of diverse sets of data.

MDH should clarify how it is defining "usefulness" of health-based guidance. Given the small number of chemicals getting a full review, an important consideration is the usefulness of or need for health-based guidance for each chemical. While usefulness is hard to quantify, MDH could be more explicit in how it is defining and comparing usefulness. Actual and potential exposure are perhaps the most important components of usefulness. Another component could be timeliness in relation to an impending permit, clean-up site, or newly-developing industry. A decision tree, as described above, could be useful for this purpose, too.

A contaminant of emerging concern is arguably not relevant to Minnesota – and a full evaluation would not be useful – if it has not been detected in Minnesota or if there are no current or potential sources in Minnesota. One of the areas where MDH could be clearer about the balance between its quantitative approach and the need for flexibility in addressing new issues is the relationship between usefulness and exposure.

For example, if a stakeholder claims that it would be useful to do a full evaluation of a chemical because a company proposes to begin producing it in Minnesota, it may be possible to develop predicted exposure values given the quantity that is proposed to be produced, its method of production and related transportation methods. The predicted exposure values could be included in MDH's worksheet with appropriate uncertainty factors. Then MDH would not have to rely on a difficult-to-quantify concept like "usefulness" in prioritizing chemicals for full evaluation. If no reasonable predicted exposure values can be identified, MDH should explain that it attempted to quantify the potential exposure. Then if MDH still believes, based on information from stakeholders or other sources, that a full evaluation would be useful, the relationship between exposure and usefulness would be clearer to outside observers and to stakeholders.

4.2.8. Engage stakeholders in the selection process

Currently, stakeholders are formally engaged at two points in the chemical selection process: (1) They are invited to nominate chemicals. (2) Shortly before a selection meeting, key contacts at other state agencies are asked to comment on their needs for health guidance on the chemicals being considered. In addition, some stakeholders may have informal conversations with staff throughout the process, and staff give occasional presentations about the process to various groups. CEC staff are in the process of reviving the Advisory Forum, which last met three years ago, and is an opportunity to engage stakeholders.

MDH should increase the engagement of stakeholders during the screening and selection process to help make the process more transparent and inject more information about the nature of needs for health guidance. This engagement should go beyond informal contact with state agencies to reach other stakeholders. To maintain agency accountability, the final decision on chemical selections should remain with CEC program staff.

Experts on risk assessment, including the National Research Council, have recognized that judgment is involved in all techniques that simplify complex

realities to inform decision making.[114] These experts have recommended that risk assessments combine expert analysis and judgment with deliberation that reaches beyond the relevant experts and includes stakeholders and members of the public who may have different perspectives on risk that should be included in the deliberation.

As an example of the type of engagement we are suggesting, a stakeholder group such as the Advisory Forum could be convened to review the screening profiles and provide additional information about the occurrence of the chemicals in Minnesota and in what context health guidance would be used. This meeting could also be an opportunity to discuss potential nominations and identify ways to promote awareness. Explaining the screening and scoring process to this group of concerned stakeholders would illuminate which aspects of the process need to be made more transparent.

The Advisory Forum would also be an opportunity to interact with utilities and industry representatives, whom the CEC program staff currently have little contact with. Building industry connections may be useful for supporting efforts to prevent releases and design solutions, as well as to leverage any industry information or resources that might support MDH work.

4.2.9. Improve communications with diverse stakeholders

The CEC staff has done an excellent job of providing concise information about health impacts of a large number of unregulated chemicals. The information is in the form of the screening profiles, information sheets, toxicological summary sheets, and rapid assessment advice -- all available on their website.

They have provided information about program activities and processes on their website and during in-person presentations. Additionally, about 3,000 people subscribe to their announcements through GovDelivery.

Despite these efforts, gaps in the desired impact of communication are still apparent. For example:

- Many stakeholders who felt they should be aware of the nomination process were not aware anyone could nominate.
- As explained earlier, a clear description of the process for screening, scoring, and selecting chemicals is not accessible.
- The goals, scope, and limits of the program are sometimes misunderstood. E.g. the chemicals considered are limited to those found in drinking water, and the program does not consider exposure from air or skin.
- The unique value of this program in contrast to the work of the EPA and other states is not clearly communicated.
- Stakeholders are not able to quickly find the items of greatest interest, for example, the list of all chemicals addressed by MDH and a link to toxicological summaries, information sheets, and screening profiles (i.e. the Guidance Table). Stakeholders are less interested in whether a particular

chemical falls under the purview of the CEC program, Drinking Water Protection, Toxic Free Kids, or the HRL program.

To increase public and stakeholder awareness of the CEC program, MDH should consult with a variety of stakeholders to learn what information they most need, reorganize the CEC website to reflect user needs, and add additional communication methods to its current communications activities.

4.3. Further research

This review was limited to examining the process for selecting chemicals, and did not look at how chemicals were reviewed or what happens after the review. Some stakeholders asked questions about how chemicals are selected to move into rule-making after Health Based Values are established, and how the entire program impacts Minnesotans' exposure to CECs. Stakeholders also raised questions about the consequences of setting HBVs: How are HBVs interpreted by the public and by utilities, what is their sense of risk, and what costs are incurred from responding to that sense of risk? These all may be issues for further research.

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6. Appendices

Appendix A: Contract

Appendix B: Stakeholder Panel Names and meeting dates

Appendix C: Science Panel Names and Meeting Dates

Appendix D: Processes in Other Jurisdictions

Appendix E: Acronyms

[1] 2009 Regular Session, Chapter 172, Article 2, Section 7b https://www.revisor.mn.gov/laws/?id=172&year=2009&type=0

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