Welcome to the Minnesota Department of Health’s Contaminants of Emerging Concern Initiative’s presentation on Nomination, Screening and Ranking Process.

This presentation provides an overview of the process for nominating, screening and ranking nominated contaminants, which is used to inform selection for guidance development.

The Contaminants of Emerging Concern initiative is funded through the Clean Water Land and Legacy amendment.
Throughout the presentation the abbreviation MDH will be used for the Minnesota Department of Health, and CEC will be used for Contaminants of Emerging Concern.

**Slide 2**

**Definition of a Contaminant of Emerging Concern**

Substances that have been released to, found in, or have the potential to enter Minnesota waters and

- Pose a real or perceived health threat,
- Do not already have Minnesota human health-based guidance, or
- Have new or changing health or exposure information that increases the level of concern

**Narrative**

Before we begin we would like to review the definition MDH uses to define a contaminant of emerging concern:

MDH identifies substances that have been released to, found in, or have the potential to enter Minnesota waters and:
Substances that meet this definition are considered to be Contaminants of Emerging Concern.

**Slide 3**

**Nomination, Screening, and Ranking Process**

**Slide Title**
Nomination, Screening, and Ranking Process

**Slide Image Description**
Jigsaw puzzle pieces

**Narrative**
On this slide, showing puzzle pieces, I will begin the background section on the nomination, screening, and ranking process used by the CEC Initiative.
Slide 4

CEC Screening Process – Ten Years of Development

- CEC Screening Criteria and Prioritization Task Group
  - MDH solicited input on the development of an efficient and effective process for screening and selecting nominated chemicals
- Diverse Stakeholders engaged from 2010-2011
  - Nonprofits, consultants, industry, federal agencies, state agencies, and academia
- Six meetings convened (August 2010 through June 2011)

Narrative

When the CEC Initiative was first formed in late 2009, MDH established a Task Group to provide input on developing a process for nominations, screening, and prioritization.

Representatives of a wide variety of stakeholders and experts from academia were invited to participate.

Ultimately the Task Group had members from:
• Several Nonprofits [Clean Water Action, Freshwater Society, IATP, American Water Works Association]
• A couple of Environmental consultants [Wenck, Ridge Road Consulting (individual)]
• Industry – MN Chamber of Commerce identified a toxicologist from Ecolab and an environmental lawyer to represent industry
• Federal agencies – United States Geological Survey (USGS)
• Several State agencies – other MDH programs, MDH Public Health Lab, MPCA and MDA
• Experts from Academia – experts from St. Cloud State, University of St Thomas, and University of Minnesota

The Task Group met six times over the course of 10 months.

**Slide 5**

CEC Screening Process – Ten Years of Development

- Task Group provided a foundation of critical stakeholder issues and recommendations
  - Open nomination process
  - Use US EPA Office of Water Contaminant Candidate prioritization methodology (Classification of the PCCL to CCL) as starting point for screening and scoring of toxicity and exposure potential
  - Supplement US EPA’s methodology to address emerging concerns such as endocrine activity, nontraditional contaminants (e.g., pharmaceuticals), and focus on Minnesota occurrence data
  - Maintain documentation of nominations and status of review
- Screening process today uses components of US EPA’s methodology and includes the Task Group recommendations

**Slide Title**

CEC Screening Process – Ten Years of Development (continued)

**Slide Text**

- Task Group provided a foundation of critical stakeholder issues and recommendations
  - Open nomination process
▪ Use US EPA Office of Water Contaminant Candidate prioritization methodology (Classification of the PCCL to CCL) as starting point for screening and scoring of toxicity and exposure potential

▪ Supplement US EPA’s methodology to address emerging concerns such as endocrine activity, nontraditional contaminants (e.g., pharmaceuticals), and focus on Minnesota occurrence data

▪ Maintain documentation of nominations and status of review

▪ Screening process today uses components of US EPA’s methodology and includes the Task Group recommendations

**Narrative**

Task Group members identified key issues of importance and made recommendations to MDH to develop an inclusive and transparent process.

Based on MDH’s suggestion, and endorsement by the Task Group, a process used by the US Environmental Protection Agency’s (EPA) Office of Water for prioritizing potential drinking water contaminants for regulatory review was identified as a starting point. In particular, an EPA document outlining a risk-based process for ranking the preliminary contaminant candidate list (PCCL) for inclusion in the final contaminant candidate list (CCL) was identified. Appendix A of this EPA document specifically contained potency and severity scoring metrics for ranking drinking water contaminants. A reference to this document is provided at the end of the presentation.

Based on recommendations and input from the Task Group, the EPA process was supplemented to address several specific areas of concern identified by Task Group members. These specific areas of concern included evidence of endocrine activity, nontraditional contaminants such as pharmaceuticals, and use of Minnesota specific water monitoring data.

MDH’s current screening, scoring and ranking process uses components of the US EPA’s Office of Water CCL methodology and incorporates the Task Group recommendations.
Slide Title
Resulting CEC Screening Criteria and Prioritization Process

Slide Text
Step 1) Nomination (open to everyone)
Step 2) Eligibility?
   - Clear Identification
   - Meets CEC Definition
   - Not addressed by other programs
Step 3) Toxicity and Exposure Screening
Step 4) Ranking and Selection
   - Risk-Based Ranking
   - Feasibility Determination
   - Stakeholder Input
Narrative

The resulting nomination, screening, scoring and ranking process is shown in this graphic and is comprised of 4 steps:

Step 1) Nomination
Step 2) Evaluation of eligibility
Step 3) Toxicity and Exposure Screening, and
Step 4) Ranking and selection for full review.

Each step will briefly be discussed in more detail in the next set of slides.

Slide 7

Slide Title
Step 1 - Nominations

Slide Text and Image Description
Image: Screen shot of the Contaminants of Emerging Concern Nominate Contaminants web page with the Get Email Updates link circled in red. Screen shot of Table 1 of Nominated Contaminant Status table behind screen shot of Contaminants of Emerging Concern Nominate Contaminants page.
Requests from agencies, organizations, and individuals
Nomination

- Document
  - All nominations
  - Date nominated
  - Status

**Contaminants of Emerging Concern**

**Narrative**

Step 1 – Nominations

MDH’s CEC homepage contains a link to an online public nomination form (the location is pointed out by the red arrow on slide). This form can be used to submit nominations at any time.

The CEC homepage also contains links to the Nominated Contaminants Status Table document, which is shown on the slide behind the image of the homepage.

This table is updated on a quarterly basis and contains two tables:

- Table 1 provides a summary of the nominated contaminants grouped by status (i.e., which step in the process is the contaminant at).
- Table 2 provides a list of all nominated chemicals to date in alphabetical order. This list includes a summary of when and who nominated the chemical as well as the supporting rationale provided by the nominator. All nominated contaminants are included in this list. If a contaminant is determined not to be eligible for the CEC Initiative it is included. If a contaminant has been nominated more than once that information is also included.

The best way to keep abreast of MDH’s CEC Initiative activities is to subscribe to our free GovDelivery service. Signing up is easy and can be done by simply clicking on “Get Email Updates” in the upper right hand corner of the webpage (see red circle on slide).
Slide Title
Step 2 - Eligibility

Slide Text
Eligibility?
- Clear contaminant identification Yes
- Meet the definition of CEC? Yes
- Addressed by other programs? No

Narrative
Step 2 is an evaluation of eligibility for the CEC Initiative. At this step several questions are asked to determine whether the nominated contaminant is eligible to be addressed through the CEC Initiative.

The first question is – does the nomination contain sufficient information to identify a contaminant? For example, a nomination of “chemicals in stormwater” would not contain sufficiently clear contaminant identification and therefore would not be eligible for further evaluation. To be considered eligible the answer to this question needs to be “Yes”.

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The second question is – does the contaminant meet the definition of a CEC?
MDH’s working definition of a CEC is: Substances that have been released to, found in, or have the potential to enter Minnesota waters and

- Pose a real or perceived health threat,
- Do not already have Minnesota human health-based guidance, or
- Have new or changing health or exposure information that increases level of concern

To be considered eligible the answer to this question needs to be “Yes”.

The final and third question is – has or is the contaminant being sufficiently addressed by other programs? Funded initiatives can supplement existing programs at MDH but can not supplant the work of other programs at MDH. For example, if a nominated chemical is on the Health Risk Limits program workplan it would not be considered eligible for review under the CEC Initiative.

To be considered eligible the answer to this question needs to be “No”.

Slide 9

Step 3 – Toxicity and Exposure Screening

- Built on existing known methods

  - US EPA Drinking Water Contaminant Candidate List (CCL) 3 process
    1) Potential for health risk (toxicity)
    2) Potential to occur in drinking water (exposure)

Slide Title

Step 3 – Toxicity and Exposure Screening (1)

Slide Text

- Built on existing known methods
US EPA Drinking Water Contaminant Candidate List (CCL) 3 process

1. Potential for health risk (toxicity)
2. Potential to occur in drinking water (exposure)

Narrative

Step 3 is Toxicity and Exposure Screening.

The Task Group endorsed the use of EPA Office of Water’s CCL prioritization process as a starting point for developing a screening and ranking process. EPA’s process has been used for many years and was developed based on recommendations from the National Academy of Sciences and the National Drinking Water Advisory Council.

The screening and prioritization process uses simple criteria to identify a contaminant’s potential for health risk (toxicity) and the potential to occur in drinking water (exposure).

More details regarding toxicity and exposure screening are provided in the next several slides.

Slide 10
Slide Text

▪ Hazard Potential (based on USEPA)
  ▪ Potency
  ▪ Type and severity of health effect(s)
▪ Additional Concerns (Task Group)
  ▪ Endocrine activity
  ▪ Indication of developmental, reproductive, genotoxicity, bioaccumulation, or commonly co-occur with related contaminants

Narrative

Toxicity screening evaluates what dose levels cause health effects as well as the type and severity of those health effects. As a starting point, MDH adopted the scoring approach used in EPA’s CCL process, which includes scoring metrics from Appendix A of the Classification of the PCCL to CCL document. Contaminants that are more potent (causing effects at low doses) or that cause more severe or long lasting effects score higher.

The Task Group recommended expanding EPA’s scoring approach to highlight specific concerns that they believed to be more relevant to CECs. As a result, MDH’s screening evaluation also specifically assesses available information regarding potential endocrine activity, developmental or reproductive toxicity, and genotoxicity as well as evidence of bioaccumulation potential and whether the contaminant typically co-occurs with other similarly structured compounds.

Please note that this is a screening level evaluation, which is meant to be a relatively quick assessment. The focus is on accessing and evaluating readily available information for the purpose of prioritizing the contaminant. An extensive in-depth search and review is not conducted at this point in the process.
Slide Title
Step 3 – Toxicity and Exposure Screening (3)

Slide Text
- Exposure Potential (framework similar to EPA)
  - Occurrence
  - Release potential
  - Persistence and Fate
- Additional Concerns (Task Group)
  - Chemical use trends
  - Identified on other lists of concern
  - Exposure potential from nonwater sources

Narrative
Exposure screening evaluation also used EPA Office of Water’s CCL screening criteria and scoring process as a starting point. Over time MDH has modified this process to be more
focused on how the contaminant will be released to water, how easily it moves through the environment, how long it might persist, how likely it is to occur in Minnesota sources of drinking water, and detection frequency and measured concentration.

The Task Group recommended expanding the EPA’s CCL scoring approach for exposure potential to include trends in chemical use (e.g. is use expanding), the presence on lists such as United States Geological Survey (USGS) Tier 1 and 2 or California’s list of biomonitored chemicals. Another expansion included determining whether there is high potential for exposure from nonwater sources (such as consumer products) so that the total exposure potential was considered in these situations.

Slide 12

Slide Title
Step 4 – Ranking, Feasibility, and Stakeholder Input

Slide Text and Image Description
Image: Graph with Exposure on the x-axis (percent of maximum total score) and Toxicity on the y-axis (percent of maximum score). Example (not real) data points are on the graph.

Selection for Full Review
- Risk-Based Ranking
- Feasibility Determination
- Stakeholder Input

Contaminants not selected remain eligible for future selection.
- Feasibility Determination
- Stakeholder Input

- Nominated contaminants ranked relative to other screened contaminants
- Feasibility of developing guidance (quality and quantity of toxicity data)
- Stakeholder Input (e.g., need and usefulness of review)

Contaminants not selected remain eligible for future selection

**Narrative**

Step 4 is a risk-based ranking of the screened and scored contaminants.

This ranking is based on the toxicity and exposure scores, represented here on the graphic as percent of the maximum possible score. These scores represent the potential health risk and exposure from drinking water. The goal of ranking is to identify contaminants of higher concern from those of lower concern. Some contaminants may have very limited or no information such that they can not be scored and ranked.

Please remember that the ranking conducted is relative only to other screened nominated contaminants, not the universe of existing chemicals.

In addition to risk-based ranking, the feasibility of developing guidance is also considered. During the screening process the quality and quantity of publically available toxicity data is noted and is used to determine whether sufficient information is available for deriving contaminant-specific guidance values. Higher ranked contaminants with adequate information are identified as the best candidates for guidance development. Contaminants not selected for full review remain eligible for future selection.

Stakeholder input is the final step in developing the review workplan. The preliminary workplan is shared with stakeholders and stakeholders are encouraged to provide input on the need and usefulness of guidance development for the identified contaminants as well as to ask questions and make suggestions for improvements to the process.
MDH CEC homepage https://www.health.state.mn.us/cec

- MDH CEC Nominate Contaminants web page https://www.health.state.mn.us/cec#cecnom
- MDH online public nomination form https://survey.vovici.com/se/56206EE31C3C546B
- MDH Human Health-Based Water Guidance Table https://www.health.state.mn.us/communities/environment/risk/guidance/gw/table.html

**Slide Title**

Resources

**Slide Text**

MDH CEC homepage: Contaminants of Emerging Concern (CEC) https://www.health.state.mn.us/cec

MDH CEC Nominate Contaminants https://www.health.state.mn.us/cec#cecnom

MDH online public nomination form: Nominate Contaminants https://survey.vovici.com/se/56206EE31C3C546B

MDH Human Health-Based Water Guidance Table https://www.health.state.mn.us/communities/environment/risk/guidance/gw/table.html


**Narrative**

This concludes the background presentation on MDH’s nomination, screening and ranking process.
Key resource mentioned during the presentation, include the MDH CEC homepage at www.health.state.mn.us/cec

Urls for individual additional CEC webpages and the EPA Office of Water CCL document that served as a starting point for the screening and ranking process are also provided in this slide.

Slide 14

Thank you.

Comments or Questions – send an email to health.risk@state.mn.us

Slide Title
Thank you

Slide Text
Comments or Questions – send an email to health.risk@state.mn.us

Narrative
We hope this presentation was informative. If you have questions or would like to discuss issues related to the nomination, screening and ranking process in more detail please send an email to health.risk@state.mn.us.

Minnesota Department of Health
Health Risk Assessment Unit
To obtain this information in a different format, call: 651-201-4899