

Guidance Document for Annex 3 Chemical Nominations

Introduction

This document is intended as a guide for organizations or individuals who wish to nominate specific chemical substances for consideration as candidate Chemicals of Mutual Concern (CMCs) under Annex 3 of the Great Lakes Water Quality Agreement (GLWQA).

This document includes the types of information that may be useful to consider and include in a nomination of a candidate CMC; however, not all categories of information described herein will be relevant in all cases. Similarly, nominators may include additional types of information, not listed below, which they consider relevant to their nomination.

Application

This application process is available to the following categories of interested parties in Canada or the U.S.:

- Environmental and/or human health-focused non-governmental organizations;
- Industry;
- Academia;
- Federal, provincial, territorial, state, tribal; Indigenous communities and organizations, and municipal governments; and
- Members of the general public.

Nomination Process

Submittal and Confirmation Process

All candidate CMC nominations must be formally submitted to the Great Lakes Executive Committee (GLEC) Co-chairs using either ec.acegl-glwqa.ec@canada.ca or glwqa@epa.gov. The GLEC Secretariat will subsequently forward each submission to the Canadian and U.S. Annex 3 Co-leads. A party who nominates a candidate CMC will be provided with an acknowledgement of receipt from the GLEC Secretariat, on behalf of the GLEC Co-chairs.

Screening with Binational Criteria

The Annex 3 Co-leads will use the information contained in an external nomination to evaluate the candidate CMC against the [*Binational Screening Criteria for Nominated Chemicals of Mutual Concern under Annex 3 of the Great Lakes Water Quality Agreement*](#). These screening criteria were developed by Environment and Climate Change Canada (ECCC) and the United States Environmental Protection Agency (U.S. EPA) to provide a consistent framework for reviewing candidate CMCs under Annex 3 of the GLWQA. Any candidate CMC will undergo an initial screening, using a weight of evidence approach that involves consideration of multiple sources of information and lines of evidence. Qualities of the data will be identified (for example: strength and relevance), along with qualitative descriptors, to help support a decision. During the initial screening, the significance of the relevant lines of evidence will be considered. Where there are multiple lines of evidence, greater weight will be placed on stronger and more relevant lines of evidence.

Once a decision is made as to whether the candidate CMC has passed the initial screening process and will be given further consideration by the Annex Sub-committee, the GLEC Co-chairs, through the GLEC Secretariat, will notify the nominating party of the screening decision.

Stakeholders who nominate candidate CMCs that do not pass the initial screening process and are not accepted for further consideration by the Annex Sub-committee by either of the Parties will be provided with the reasons why their candidate CMC did not pass the initial screening criteria.

Binational Summary Report

If the weight of evidence results in the candidate CMC passing the initial screening criteria, a more thorough evaluation of the candidate CMC will be undertaken by ECCC and U.S. EPA, taking into consideration the work of other agencies, as appropriate. This effort will involve the production of a binational summary report with detailed information on:

- the candidate CMC's environmental fate and transport;
- sources and releases to the Great lakes of the candidate CMC;
- existing policies, regulations and programs for management and control of the candidate CMC; and
- an analysis of relevant knowledge gaps pertaining to the candidate CMC.

CMC Decision

This binational summary report will recommend one of three possible options for decision by GLEC Co-Chairs:

1. **The candidate CMC is designated as a CMC** – see below.
2. **The candidate CMC is not designated as a CMC.**

**note - If a candidate CMC is not designated as a CMC, it can be re-nominated at a future date if additional monitoring data becomes available, benchmarks or guidelines for the protection of wildlife and humans have since been strengthened, or a new risk source in the Great Lakes Basin is identified; or*

3. **There is insufficient information to make a decision:** *If it is concluded that there is insufficient information to designate the candidate CMC as a CMC, the Annex 3 Sub-Committee may, as it deems appropriate, take steps to promote additional research, monitoring, or assessment, as needed.*

Binational Strategy Report

By designating a chemical substance as a CMC, Canada and the U.S. signal their intention to reduce its anthropogenic release into the environment through the development of binational strategies and actions, which may include binational or domestic actions such as research, monitoring, surveillance and pollution prevention and control provisions.

Refer to CMC Designation Process figure below.

Timelines

Nominations of candidate CMCs by interested parties will be accepted at any time throughout the year and will be given consideration in accordance with the Annex work plan.

Required Information

The nominations for candidate CMCs should be composed of the information described below. Please note that the types of information identified under each of the sections are meant to serve as guidance. In some cases, this data and/or information may not be relevant and/or available for a particular candidate chemical substance.

1. Chemical Background

- a. Chemical identity (CAS, substance name, chemical nomenclature);
- b. General physical and chemical properties;
- c. General use data

2. Existing Scientific Data

- a. TOXIC: Is the chemical substance toxic, persistent, and/or bioaccumulative?
 - i. Toxic classification:
 - Canadian Environmental Protection Act (CEPA, 1999) conclusions, U.S. hazard classifications, and applicable international assessment findings;
 - ii. Data on persistence and/or bioaccumulation:
 - Evidence of persistence in water and/or sediments;
 - Evidence of bioaccumulation and/or biomagnification;
- b. RELEASE: To what extent is the chemical substance released in the Great Lakes Basin?
 - i. Canadian and U.S. chemical data (i.e. use, release):
 - Changes in use/production over time;
 - Changes in release volumes over time;
 - Releases to water and air;
 - Identify any discernable trends in environmental concentrations and/or releases over space and time;
 - Significance of out of basin sources (via long-range atmospheric transport and deposition);
- c. LEVELS: Are levels of the chemical substance harmful, or likely to become harmful, in the Great Lakes environment?
 - i. Great Lakes monitoring data:

- Description of available environmental concentration data in all Great Lakes Basin (GLB) media (air, water, sediment, fish, and other wildlife) and of any spatial and temporal trends in these concentrations;
 - ii. Environmental and health benchmarks:
 - Description of available benchmarks* (i.e. Environmental Quality Guidelines, standards, or objectives);
 - Comparison of environmental concentrations relative to environmental benchmarks over time and geographic area;

Note – If Canadian and/ or U.S. benchmarks are available, these will be used to evaluate levels. If Canadian and U.S. benchmarks are not available, consideration will be given to benchmarks from other jurisdictions.
 - iii. Environmental health data:
 - Description of evidence or potential for harmful effects on species, populations or ecosystems;
 - Long range atmospheric transport potential (i.e. distant international sources may be of concern to the GLB);
 - Evidence of significant partitioning to dissolved phase and/or sediment;
 - Evidence of endocrine disrupting properties;
 - Evidence of carcinogenicity;
 - Evidence of cumulative effects with other chemicals of concern;
 - iv. Additional factors for consideration:
 - Chemical or structural similarity to other chemical substances known to be a concern in the GLB;
 - Reference to any external studies citing this as a chemical substance of concern for the GLB;
 - Reference to new science or information that proves important in considering the designation of chemicals, e.g. mobility of toxic chemicals.
- d. ROUTE OF EXPOSURE: Are the Great Lakes a significant route of exposure to humans or wildlife for this chemical substance?
- i. Exposure data:
 - Description of known route(s) of exposure to humans and/or wildlife;
 - Evidence of routes of exposure via Great Lakes water and food web;
- e. SCALE: Does the geographic scale of the levels of the chemical substance in the Great Lakes have binational significance?
- i. Canadian and U.S. chemical substance data as evidence of levels that are multi-lake and binational in scale. Such data should include:

- Proportion of use/production occurring within the GLB region;
 - Proportion of releases that are occurring within the GLB region;
 - Location(s) of known production and/or releases;
 - Location(s) and/or description(s) of any known sources of contamination;
- f. MANAGEMENT: To what extent are the releases of the chemical substance controlled/managed?
- i. Canadian and U.S. Federal chemical actions:
 - Risk management measures in place or proposed;
 - Research, monitoring or surveillance activities in place or proposed;
 - Relevant international agreements that Canada and/or the U.S. is party to;
 - ii. Provincial, State, Tribal or Indigenous actions:
 - Risk management, research, monitoring or surveillance activities in place or proposed;
 - iii. Stakeholder actions
 - Industry phase-outs and actions to reduce releases;
 - NGO educational campaigns or other efforts;
 - iv. Is further action benefiting the GLB warranted?
 - Identify gaps in risk management, research or monitoring for the chemical substance.

Additional Guidelines

1. Please be concise. High level bullet points are preferred over paragraphs of information.
2. Where applicable, indicate why the evidence/data being provided is relevant with respect to each criteria.
3. Provide available links to, or references for, any study cited in a nomination submission.
4. Refer to this [example nomination](#) for an example of the type and level of detail expected.

CMC Designation Process

