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By email and US Mail

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Re: ***General comments on CMC Process developed and implemented under Annex 3 of the Great Lakes Water Quality Agreement***

Dear Ms. Galatone and Ms. Wise:

The Council of Great Lakes Industries (CGLI) offers these comments and suggestions regarding the process of designating and managing chemicals of mutual concern (CMCs) under Annex 3 of the Great Lakes Water Quality Agreement (GLWQA or Agreement). CGLI is a binational non-profit organization representing the common policy interests of Canadian and US industrial organizations from the manufacturing, utilities, transportation, natural resources, and trade sectors that have investments in the Great Lakes region. The mission of CGLI is to promote the growth and vitality of the region in harmony with its human and natural resources (sustainable development).

CGLI appreciates the opportunity we have had to participate in reviewing candidate chemicals for CMC designation. As you know, representatives of CGLI have served as members of the GLWQA Annex 3 Extended Subcommittee (EC3) and the initial Identification Task Team (ITT). ITT members have helped to produce binational summary reports for certain chemicals, and EC3 members have commented on and contributed to drafts of the reports. Members of CGLI's Chemical Management Work Group (CMWG) have supported the ITT activities by collaborating to provide data and information regarding the candidate substances.

The comments and suggestions in this letter arise from these experiences. Specifically, we offer suggestions for consideration by the Annex 3 Subcommittee (C3) and the Great Lakes Executive Committee (GLEC) as they move forward to list and manage CMCs in this first phase of review and consider additional chemical substances for subsequent review.

1. We support the evaluation of chemicals on the basis of hazard, exposure and risk.

Nearly all chemical substances present identifiable hazards. For this reason, it is not accurate to designate one chemical substance as inherently “safer” than another. Chemical safety and/or potential harm depend on three factors – hazard, exposure, and risk. It is critical to note that risk is a function of hazard and exposure, highlighting the need to assess all of these factors when determining whether or not a substance should be designated as a CMC. We commend the Annex 3 chemical review process for considering risk and exposure as well as hazard when establishing and applying the binational considerations to guide the activities of the ITT.

2. More time, and more government resources are necessary to ensure that the chemical review process is consistent, reliable and balanced.

CGLI and its members were very pleased to have had the opportunity to sit on the ITT and participate in the chemical reviews. Direct stakeholder engagement is essential to a successful and balanced CMC decision making process.

We learned through the ITT chemical reviews that substantial resources were required to perform the initial chemical assessments. ITT members were asked to collate chemical effects information, monitoring data, and other information for use in binational summary reports and the group’s deliberation processes. In the end, the tasks performed by the ITTs were too involved for volunteers to undertake the work entirely on their own, without government resources or support, especially given the tight time frame established for the ITT activities.

As you know, in previous letters to you and to the GLEC Co-chairs dated August 11, 2014, CGLI recommended that ITTs include a larger contingent of government personnel from the US and Canada who are closely associated with federal chemical programs. It was extremely helpful to have knowledgeable government personnel from Environment Canada involved in the process to guide and support CMC candidate selection and assessment processes and ensure that information developed through their national chemical assessment efforts was applied. Additional benefit also could be obtained by including government personnel from other programs. For example, the ITT Summary Report for NP/NPE states

NPEs were assessed by US EPA for use as inert ingredients in pesticide products under the Food Quality Protection Act (US EPA 2006). This human health risk assessment, which also considered data on NP, was conducted as part of a reassessment of all inert ingredients as mandated by Food Quality Protection Act (FQPA).

The CMC review process would be more efficient if the ITTs are able to directly consult with and utilize the work of experienced federal government personnel from these and other programs when conducting future chemical reviews.

With the first round of chemical reviews now complete, we would like to recommend that government personnel take the lead in assembling the initial data for the chemical dossiers and preparing the dossiers for review. We appreciated that the governments edited the binational summary reports once basic information had been compiled by the ITTs, but the process might have been more streamlined and efficient if the governments had compiled the initial reports and distributed them to the ITTs for supplementation and comment.

Finally, we continue to believe that additional time is required to comprehensively evaluate candidate chemicals for CMC designation. We understand that the Parties and Annex 3 Co-leads are considering the timeline associated with nominating, proposing, evaluating, and selecting

chemicals for CMC designation. We suggest a significant extension in the time allowed for evaluating candidate chemicals in future review cycles.

- 3. CMC assessments should incorporate both data and information from national chemical assessment programs and Great Lakes-specific chemical assessment information.*

We urge the Parties to utilize data and information developed under national chemical assessment programs when identifying CMCs. As you know, Canada and the US have developed and continue to implement robust national chemical assessment programs. Pursuant to these programs, both countries invest significant resources to determine the potential human health and ecological impacts of chemicals and their use. A critical part of this effort is screening the data and information that is examined to ensure that quality data is used in these assessment processes. Utilizing data and information from the national chemical assessment programs is needed to streamline, expedite, and validate candidate CMC reviews.

We recognize that data and information developed under national chemical assessment programs should be supplemented with chemical assessment data specific to the Great Lakes region. However, the Annex does not require or contemplate that the Parties will start over and undertake entirely new chemical assessments for CMC identification purposes, the Annex calls for utilizing all available information—including that developed through national programs as well as monitoring data and other information specific to the Great Lakes--to determine which substances should be managed within the Great Lakes region pursuant to GLWQA goals and objectives.

- 4. CMC designations are appropriate only if Great Lakes-specific management action is viable for the specific chemical.*

With respect to some the chemicals reviewed in the first phase, existing national programs are sufficient to achieve the desired outcomes, while Great Lakes regional management actions likely will have little or no additional effect. The guidelines that the C3 established to guide the chemical assessment process (*Binational Considerations When Evaluating Candidate Chemicals of Mutual Concern*) require reviewers to evaluate existing management actions and determine that additional region-specific action is needed before designating a candidate chemical a CMC. Chemical assessments therefore must include an evaluation of the viability of Great Lakes-specific management actions to achieve desired Annex 3 outcomes

- 5. The C3 deliberation process must be more transparent.*

The final recommendations that were presented to the GLEC at the June 24-25, 2015 meeting do not mirror the recommendations in the final draft binational summary reports that the EC3 and ITT reviewed. Nor do they mirror the recommendations in the versions of the binational summary reports that are available on-line at binational.net. The reports regarding flame retardant compounds and chlorinated paraffins recommended that the members of these chemical classes should be characterized as “Insufficient Information on which to Base a Determination.” By contrast, the Annex 3 co-leads reported at the GLEC meeting that HCBd and short chain chlorinated paraffins should be listed as CMCs. When, how, and why did the original recommendations change? The report noted that final recommendations to the GLEC incorporated C3 and co-chair deliberations after the ITT reports were finalized, but CGLI is not aware that the difference in recommendations was announced. Nor can we find any record of this decision or its rationale. CGLI requests that these changes and the rationale for listing be made publically available before a final decision on listing these two compounds is announced by the GLEC

6. “Not a CMC” is an acceptable and justified conclusion.

After preparing and reviewing the binational summary reports in the first round of chemical reviews, we were surprised that none of the candidate chemicals were affirmatively designated “not a CMC.” No determination can be made regarding whether or not a chemical should be recommended for listing as a CMC if data is insufficient to support the designation or if Great Lakes-specific management actions will not lead to desired outcomes. However, by the same token, some of the binational summary reports supported a finding that a particular substance should be designated not a CMC but the chemicals addressed in the reports were not so designated. For example:

- **PCBs:** According to the binational summary report for PCBs, the primary source of PCBs in the Great Lakes basin is environmental cycling from PCB reservoirs that have resulted from past PCB releases. PCBs in sediments serve as sinks from which the PCBs continue to be released over a long period of time. Designating PCBs as a CMC will not address this source or contribute to the achievement of GLWQA General and Specific Objectives. Therefore, the decision to list PCBs as a CMC is questionable.
- **NP/NPEs:** According to the binational summary report for NP/NPE, a rigorous review of NP/NPE under Canada’s Chemical Management Plan resulted in a finding that the substance does not meet CMC criteria. How can NP/NPE be of “mutual concern” to the Parties if Canada has concluded that NP/NPE is not a critical concern? *See, e.g., Annex 3, Section B*, “The parties shall mutually determine those chemicals that are potentially harmful to human health or the environment” (emphasis added).

Moreover, while the binational summary report for NP/NPEs identified certain data gaps regarding these substances (e.g., surface water concentrations, especially within the US), CMC designation is not needed to attract or justify the resources needed to fill these data gaps. Both Canada and the US have regulatory measures in place (some just now coming on-line) that will require additional NP/NPE data collection. Additional management actions for these substances under Annex 3 appear unwarranted.

- **Bisphenol A:** According to the binational summary report for BPA, environmental concentrations of BPA, with a few exceptions, are below applicable benchmarks and guidelines and do not differ substantially from levels found elsewhere in North America. The report indicates that:
 - typical reported sediment concentrations of BPA are generally very low in North America;
 - Environmental levels of BPA appear to be relatively stable; and
 - the BPA market in North America is not expected to grow.

The report also concludes that current and/or pending Canadian and US management actions will be compatible with and protective of the Great Lakes.

Desires for additional data regarding BPA always will exist in this region and elsewhere. However, BPA has been well studied in North America and available information leads to the understanding that additional or Great Lakes specific management actions are unlikely to result in reduced BPA levels in the Great Lakes basin. The reports firmly support a recommendation that BPA be designated “not a CMC.”

- Perfluorinated Chemicals: According to the binational summary report for PFOA/PFCAs report, the major sources and uses of PFOA and long-chain PFCAs already have been or will be eliminated by the end of 2015 pursuant to US and Canadian chemical management programs. Moreover, levels of PFOA in key species are either not detected or do not exceed relevant guidelines, and are predicted to decline for top predators. Emissions have declined by more than 95% and levels of PFOA in human serum have declined by 60% between 1999/2000 and 2011/12. The 2015 US UCMR3 data for PFOA show none of the 22,941 results from 3,604 Public Water Systems reported exceed the Reference Concentration of 0.4µg/L for PFOA. These results demonstrate that existing programs have been and will likely continue to be successful in managing PFOA. A decision to list PFOA as “not a CMC” therefore can be supported.

7. Focus CMC listing considerations on specific chemicals, not classes of chemicals

The initial list of substances that were considered for CMC evaluation included both specific chemicals and classes of chemicals (i.e. chlorinated paraffins – short, medium, and long chain; perfluorinated chemicals – PFOS, PFOA, and long-chain PFCAs; and brominated flame retardants – PBDEs and HBCD). The ITT process demonstrated that individual substances within chemical classes can vary widely, and individual materials need to be evaluated and managed separately. CGLI was pleased to note that when the final list of substance recommendations was presented to the GLEC, the compounds were split out and identified individually. This individual assessment practice should continue during subsequent chemical reviews.

8. Focus Annex 3 activities on a short and manageable list of CMCs.

In order for Annex 3 to be successful in addressing chemicals that truly impact the health of the Great Lakes ecosystem, the list of CMCs cannot simply incorporate any substance that is perceived to have an unspecified or undefined potential for impact. The list must include only those materials that exist in the Great Lakes ecosystem at levels that must be and can be addressed by coordinated, binational, and region-specific management action that can achieve Great Lakes-specific goals and objectives.

CGLI strongly urges the Parties to resist the call to identify substances as CMCs in order to justify monitoring activities or to support research agendas. These objectives can be achieved by other Annex subcommittees, such as the Annex 1 (Areas of Concern), Annex 2 (Lakewide Action and Management), and Annex 10 (Science) subcommittees. These committees have the authority and incentive to encourage and support chemical monitoring and research. Annex 3 activities should focus on the management actions that are necessary to address CMCs, not research and monitoring.

9. Notify the EC3 when CMC candidates are proposed.

According to the provisions of Annex 3, the Parties are charged with nominating substances for potential CMC listing. CGLI appreciates that the Parties have decided to consider chemical nominations proposed by stakeholders when nominating specific substances for CMC review. Moreover, CGLI regards the process that has been proposed for stakeholder nominations (“Stakeholder Process for Proposing Chemicals for Consideration as Candidate Chemicals of Mutual Concern under Annex 3 of the *Canada-United States Great lakes Water Quality Agreement*”) as a reasonable framework for considering stakeholder nominations.

However, CGLI does request one relatively minor procedural addition to the framework. CGLI requests that the EC3 be notified when chemical substances have been proposed for nomination,

and that the EC3 be invited to comment on the proposed candidates. Engaging the EC3 will provide additional information and perspectives to inform the Parties' consideration.

CGLI appreciates the opportunity to participate in the CMC review process and looks forward to working with Environment Canada and USEPA as implementation of the Annex 3 provisions continues. Please contact us regarding any questions or need for additional information.

Very truly yours,

COUNCIL OF GREAT LAKES INDUSTRIES



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