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To: Environment and Climate Change Canada
Via email eccc.substances.eccc@canada.ca

**Comments regarding
Canada Gazette, Part I, Volume 154, Number 27
Screening assessment of six naphthalene sulfonic acids and salts
specified on the Domestic Substances List (paragraphs 68(b) and (c) or
subsection 77(1) of the *Canadian Environmental Protection Act, 1999***

At the request of the CNHHE-RCSHE, we offer the following comments about the screening assessment of the naphthalene sulfonic acids and salts grouping, on behalf of *Prevent Cancer Now*, and Dorothy Wigmore as an individual occupational health specialist.

Based upon the data presented, and recognising the substantial data gaps, we believe that it is premature to conclude that, “the six substances in the NSAs Group do not meet any of the criteria set out in section 64 of CEPA.” Data gaps include:

- absence of health data for the highest-volume, simplest substance, and the only one that is manufactured in Canada – sodium naphthalene sulfonate (NaNSA);
- paucity of health data for another five naphthalene sulfonic acids and salts;
- exclusion of the most highly exposed people; and
- the assumption that adolescents are not exposed, when a principle source of exposure is lubricating oils.

Various naphthalene sulfonic acids and salts (both those subject to this screening assessment and others) are found in common products, such as fuels, lubricants, paints, coatings and rubber materials. In addition, they are used for oil and natural gas extraction, and in some unspecified manner for water treatment. There is uncertainty as to quantities produced and imported, but they conceivably range over a million kilograms annually in total. The majority is NaNSA, the smallest, simplest molecule, with no alkyl chains, and the only one manufactured in Canada according to the assessment.

Summary Findings

Our findings include that the screening assessment does *not*:

- assess uses, exposures or health effects for the highest-volume chemical (NaNSA). Instead, the government assessors assumed that the population is not exposed (S 8.2). This substance is the one most closely related to naphthalene, that is listed on the CEPA Schedule 1 list of toxic substances;

- assess health effects via read-across for any molecules with zero or one alkyl chain, in spite of these being the predominant substances in commerce;
- assess exposure to the same molecules in drinking water (Appendix D);
- present *measured* exposure data – environmental discharges were modelled, but not human exposures for manufacturing, use or in the environment;
- address exposure of the thousands of workers routinely using common products such as lubricating oils containing naphthalene sulfonates. It is not scientifically rigorous to consider the “general population” while excluding the most highly exposed people, who would be expected to be the first to be affected;
- flag a need to assess workplace issues under the *Hazardous Products Regulations* or occupational health in general;
- consider effects on molecular signalling such as hormone or endocrine effects, that can occur at levels much lower than represented in the animal toxicology, both for the parent compounds and metabolites;
- consider endpoints representing direct endocrine toxicity;
- consider data on reproductive, developmental or genetic toxicity for the predominant substances, although data is noted for three comparator “read across” larger molecule congeners with multiple alkyl chains;
- include measured data on discharges to the environment;
- consider the opportunity for, or alternatives for least-toxic approaches to achieve the results of use of this group of substances.

On this basis, the assessment lacks grounds to conclude that no further action is needed.

Further information needs

In lieu of presenting the evidence, the consultation document notes:

NaNSA was not identified as posing a high hazard to human health on the basis of classifications by other national or international agencies for carcinogenicity, genotoxicity, developmental toxicity, or reproductive toxicity. Further investigation into the potential health effects of NaNSA was not pursued as exposure of the Canadian general population to this substance is not expected.

The Canadian assessment should include the detailed evidence and analysis that form the basis of these conclusions, and reference the international agencies.

It is not clear how *CEPA* and precautionary approaches are consistent with setting a bar of “high hazard” before further investigations of hazards to human or environmental health. Manufacturers’ warnings about NaNSA noted by the U.S. PubChem (<https://pubchem.ncbi.nlm.nih.gov>) include:

- avoid breathing dust/fume/gas/mist/vapors/spray (P261)
- wash ... thoroughly after handling (P264)
- use only outdoors or in a well-ventilated area (P271); and
- wear protective gloves/protective clothing/eye protection/face protection (P280).

Trends in manufacture and use of NaNSA, as well as importation and use of other analogues, should also be presented and followed as indicators of exposures of

workers, their families, their communities and the general public. Instead, claims of confidentiality were accepted, and information from the highest-volume analogue is not included in Table 4-2. It is merely stated that:

The only uses reported in response to surveys issued pursuant to CEPA section 71 (Environment Canada 2013; ECCC 2018) were industrial and would not result in environmental releases or exposure for the general population (personal communication, email from a stakeholder to the Existing Substances Risk Assessment Bureau, Health Canada, dated August 2018; unreferenced) (Section 7.3.1).

NaNAS was represented by naphthalene-2-sulphonic acid (2-NAS); there are concerning warnings from the European Chemicals Agency (ECHA - <https://www.echa.europa.eu/web/guest/substance-information/-/substanceinfo/100.003.978>

*Danger! According to the classification provided by companies to ECHA in **REACH registrations** this substance causes severe skin burns and eye damage, is toxic to aquatic life with long lasting effects, is harmful if swallowed, causes serious eye damage and is suspected of causing cancer.*

Hazards such as carcinogenicity should be considered in the human health assessment. As well, use of a threshold of toxicological concern is not justifiable when assessing carcinogens or endocrine disruptors. Indeed, a zero threshold is more reasonable, and the probability of disproportionately high marginal increases in hazards at low doses is a reasonable assumption. Please see our comments regarding “chemicals of low concern”, submitted January 21, 2019, where we said “(r)elying on the Threshold of Toxicological Concern (TTC) approach for health effects of hazardous chemicals is not justified.”

The further action required, is to gather the necessary data to carry out this evaluation.

Chemical Hazards

Searching of chemical hazards databases (Table 1) identified “warning” and “danger” notices regarding skin and eye damage, irritation and sensitization, but little if any information regarding systemic toxicities. In most cases acute and chronic data is missing or very limited. In fact, the government noted in its statements about uncertainty:

Substance-specific empirical health effects data, including chronic hazard studies, for DNNSA, CaDNNSA and DNNSA, and their analogues, were limited or unavailable. .. The available health effects data for the analogues are limited and were accessible only as robust summaries submitted in REACH dossiers.

Sensitization

Sensitization to organic chemicals can be very serious, as it is the first step in development of multiple chemical sensitivities. If ignored or downplayed, it can progress to disabling and life-altering effects. Environmental sensitivities is a disability according to a policy under the *Canadian Human Rights Act*, and should be addressed and accommodated in the home and workplace, with least-toxic options.¹

Hazard statements regarding the Naphthalene Sulfonic Acids and Salts (NSAs) Group

Substance	CAS number	Pharos/Data Commons	European Chemicals Agency (ECHA)	Other
Naphthalenesulfonic acid, sodium salt (sodium naphthalenesulfonate) (NaNSA)	1321-69-3	LT-UNK : skin irritation; no other information available/known	No data to classify	Risctox : no information
Naphthalenesulfonic acid, dinonyl (dinonylnaphthalenesulfonic acid) (DNNSA)	25322-17-2	No GreenScreen. DK-EPA - Danish Advisory List : skin irritation	GHS signal: Danger . Causes serious eye damage and skin irritation. Data lacking for other hazards	Risctox : no information
Naphthalenesulfonic acid, dinonyl-, barium salt (barium dinonylnaphthalenesulfonate) (BaDNNSA)	25619-56-1	LT-UNK : EPA IRIS said not classifiable as carcinogen (because of barium). On Cradle to Cradle restricted substances lists (children and biological nutrient materials)	GHS signal: Warning . Harmful if inhaled, is harmful if swallowed, causes serious eye and skin irritation, may cause allergic skin reaction. Majority of submitters agree it's a skin sensitiser. Data lacking for chronic hazards	Risctox : Category 4 acute toxicity, warning (signal word)
Naphthalenesulfonic acid, dinonyl-, calcium salt (calcium dinonylnaphthalenesulfonate) (CaDNNSA)	57855-77-3	LT-P1 : water toxin (Germany) DK-EPA - Danish Advisory List : skin irritation	GHS signal: Warning . causes serious eye irritation, causes skin irritation and may cause an allergic skin reaction. Majority of submitters agree it's a skin sensitiser. Data lacking for chronic hazards.	Risctox : no information
Naphthalenedisulfonic acid, dinonyl- (dinonylnaphthalenedisulfonic acid) (DNNDSA)	60223-95-2	LT-UNK : CEPA bioaccumulative; REACH manufacturers submissions say skin irritant, serious eye damage, very toxic to aquatic life (with long-term effects)	GHS signal: Warning . in one site; Danger in another. Causes serious eye damage and skin irritation, harmful to aquatic life with long lasting effects. Data lacking for most hazards.	Risctox : no information
Naphthalenesulfonic acid, bis(1-methylethyl)-, compd. with cyclohexanamine (1:1) (cyclohexylammonium diisopropyl naphthalenesulfonate) (CDINSA)	68425-61-6	LT-UNK : CEPA designations	GHS signal: Warning . Causes serious eye and skin irritation. Data lacking for most hazards.	Risctox : no information

Endocrine disruption

Naphthalene is listed on CEPA Schedule 1. Its conjugated ring structure, noted as important in Appendix F, is a hallmark of endocrine disruptors. Hormones have similar structures; however, the assessors of these naphthalene derivatives emphasised analogues with multiple large alkyl groups – substances that would be expected to be less likely to exert the same effects, due to steric hindrance by the alkyl chains.

Endocrine disruption would affect the exposed individual (particularly worker) as well as his or her family, particularly offspring.

Although not noted, there is evidence accruing among regulatory authorities that substances are interfering with the chemical signalling that is central to development (physical including neurological), metabolism, reproduction and aging.^{2,3} Our submission cannot cover the entire scope of findings regarding these multiple chemicals, but we provide as an example findings from U.S. Environmental Protection Agency Tox21/ToxCast for NaNAS and metabolites, summarized in Table 2. 1- and 2-NaNAS have many fewer hits than their metabolites, which have the hallmarks of being endocrine disruptors and carcinogens.

Table 2. Numbers of “Active” findings in U.S. Environmental Protection Agency ToxCast screening, indicating binding with nuclear or cellular receptors and potential disruption of normal reproduction, development and homeostasis

Substance ID	Number of “Active” Hits	Example targets affected
Sodium 1-naphthalenesulfonate 130-14-3 DTXSID3042394	2	DNA repair, cytotoxicity
Sodium 2-naphthalenesulfonate 532-02-5 DTXSID4041442	16	DNA binding, non-steroidal nuclear receptor, cell cycle & death
Metabolite, 1-naphthol	52	Steroidal & non-steroidal nuclear receptors, mitochondrial (multiple), DNA binding & synthesis, cell viability, DNA repair, thyroid, oxidoreductase, neurotransmitter, cell adhesion, coagulation, immune modulators,
Metabolite, 2-naphthol	114	Kinase, oxidoreductase, steroidal nuclear receptor (multiple), neurotransmitter, thyroid, cytotoxicity, aromatase inhibition, mitochondrial, DNA binding & synthesis, nuclear receptor binding, cell viability, multiple developmental defects (zebrafish), cytokines, coagulation factors, immunoglobulins, inflammatory factors, multiple steroidal reporters

What is the validity of modelled data?

As outlined in Table 2, environmental and human health effects of metabolites and degradation products may dwarf the effects of the parent compounds, and there is no transparency as to the extent of these considerations. As well, other sources of naphthalene derivatives in wastewater such as azo dye degradation products, merit being considered in a cumulative assessment.

Independent peer review

Like other assessments, this was submitted for external review by individuals connected with commercial firms. There are serious concerns that the corporate connections of the individuals and companies selected to review this and other assessments are not consistent with independent peer review. Ethical, independent peer review is required, to take advantage of the knowledge and experiences of university researchers and otherwise independent specialists with no vested interest in the substances at hand.

We recommend that the government expand its list of external reviewers, in consultation with groups such as academic institutions, the Office of the Science Advisor, the CNHHE-RCSHE, the Institute for Work & Health and the Canadian Association for Research on Work and Health. Bringing in a variety of outsiders with different knowledge bases and perspectives will strengthen the programme and make its consultation process much more effective. It will avoid the current situation with external concerns and criticisms getting on the table only after the government's draft document is released, and when those who have worked on documents are, understandably, more defensive about the time and effort they have expended and the deadlines they deal with.

For us, and others, the issue is about credibility and consequences. Canada's CMP is cited by people outside this country for its results. For example, the Global Silicones Council made this statement when it approved of Canada's decision on D5:

Canada's leadership on chemical management issues continues to demonstrate that regulators can simultaneously protect the environment and human health, while promoting product innovation.

It is not unique. For example, Chemical Industry Association of Canada (CIAC) website says it is very supportive of the program and its accomplishments.¹ It is rarer to find accolades from NGOs and non-industry voices, but it still happens.

This kind of recognition brings a responsibility to ensure the government is using effective due diligence to protect human and environmental health. There can be disturbing consequences when Canada assesses a substance as not harmful to human health or the environment, and others use that information elsewhere. For example, as described in Dorothy Wigmore's comments about siloxanes (August 6, 2019), the American Chemistry Council used CMP assessments to (fairly successfully) demand at least three US states de-list siloxanes from hazardous

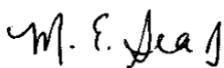
¹ <https://canadianchemistry.ca/advocacy/chemicals-management/keeping-canadians-healthy/>

chemical lists (Maine, Vermont, and Minnesota) and to add industry-favourable definitions in their regulations/rules.

In summary, with all these concerns and unknowns, we can only conclude the assessment lacks grounds to say that no further action is needed. Further action **is** required -- to gather the data required to carry out this evaluation and to delay conclusions until that is completed. It is hoped that the initial review process will include knowledgeable, non-industry views before draft documents are released.

We would be pleased to discuss our comments with CMP staff, at our mutual convenience.

Respectfully submitted,



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References

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