PREVENT CANCER NOW

Chemical Sensitivities Manitoba

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The Honorable Catherine McKenna
Minister of the Environment

The Honourable Jane Philpott
Minister of Health

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Submission in response to the "Proposed Approach to Promote Transparency in Chemicals Management Plan Risk Assessment Activities", Canada Gazette, Part I: Vol. 151, No. 19. May 13, 2017.

Dear Ministers McKenna and Philpott:

Prevent Cancer Now (PCN) and Chemical Sensitivities Manitoba (CSM), are responding to the consultation document "Proposed Approach to Promote Transparency in Chemicals Management Plan Risk Assessment Activities."[1] Our organizations have submitted comments and have engaged in stakeholder discussions with federal government departments that included review of claims of confidential business information (CBI). These highlighted the importance of public disclosure of CBI on substances that may impact human health and the environment. Specifically, our comments emphasized the lack of clarity and transparency as to how confidentiality requirements are currently being applied, and hence how the public may be confident in protection of human health and the environment from adverse effects of both new and existing substances.

CBI is addressed mainly in sections 51 to 53 and 314 to 321 of the *Canadian Protection Act* (CEPA 1999), with the latter sections addressing CBI in a broader context. For the domestic substances list (DSL), other substances lists and public documents, a submitter can claim confidentiality for the name of a substance, substituting a "masked name," and property ranges rather than specific values for a number of physical-chemical properties of the substance.

[1] Environment and Climate Change Canada May 2017. http://www.ec.gc.ca/ese-ees/C7C66AA6-7BAC-4C5C-AFC6-

Currently, submitters can claim confidentiality if they fulfill a number of conditions, including information that may not necessarily be considered confidential. This approach undermines the transparency of risk assessment and trivializes the process. Unnecessary and excessive confidentiality claims also require government resources to respond, and to validate (or not) such claims.

The current practice of the use of CBI in risk assessment to conclude toxicity or the potential to be harmful (any hazard) to the environment or human health, without disclosure of the evidence, remains a contentious issue. This practice is unacceptable when the substance is then used in consumer products. Also, the continued use of a masked name for an unlimited time is inappropriate.

Comments & recommendations on the government's proposed approach

The following are comments and recommendations on the various elements of the consultation document: "Proposed Approach to Promote Transparency in Chemicals Management Plan Risk Assessment Activities." We recognize that the issue of confidentiality claims under CEPA may be subject to further discussion through the current review of CEPA. The following recommendations are offered with the understanding that amendments to CEPA regarding CBI claims are required for improvement in the process of chemical assessment.

A) Claiming confidentiality

The following are the government's proposed guidelines for claiming confidentiality:

> *a) it is a trade secret of the submitter;*
> *b) it is information of a financial, commercial, scientific or technical nature that is treated consistently in a confidential manner by the submitter;*
> *c) its disclosure could reasonably be expected to result in material financial loss or gain to, or could reasonably be expected to prejudice the competitive position of, the submitter; or*
> *d) its disclosure could reasonably be expected to interfere with contractual or other negotiations of the submitter.*[2]

- The above proposal is an amendment of the current Section 52 of CEPA 1999. It should include context to the effect that the "submitter" is not the only party involved; responsibilities of the party to whom the information is provided are also

[2] Ibid

important, and including the requirement that information must be adequate to have confidence in hazard and risk assessment also broadens the scope.

- All claims for confidentiality should be accompanied by substantial, meaningful background data to justify the need for confidentiality. This should also include data that would justify any claims of potential material financial loss and any prejudice to the company's competitive position in the marketplace.
- Any substance that is already listed in another public national chemical inventory, (e.g. United States Environmental Protection Agency's Toxic Substances Control Act Chemical Substances Inventory) should be ineligible for confidentiality status in Canada' unless strong evidence to prove otherwise, is provided.
- Once publicly reviewed, all criteria to be met for a confidentiality claim should be mandatory, clearly articulated, and added to the text of CEPA; not relegated to guidance documents.

Recommendations:

- Strengthen the requirements for confidentiality claims such that any and all parties from and to whom information is provided are included in the above listed conditions, when confidentiality is being claimed.
- The government must require meaningful background data to justify the need for confidentiality for all the above listed guidelines. The absence of data should result in the disclosure of information.
- Claims for confidentiality should be rejected if the substance is already on another public government chemical inventory.
- CEPA should be amended to include mandatory criteria for a confidentiality claim in the text of CEPA.

B) Review of a confidentiality claim

Once all the supporting documents for the confidentiality claim have been received by the government, the proposed approach review process to assess applicability and accuracy of the CBI claim should be explicitly detailed.

Parameters that would warrant the decision to release confidential information publicly should also be listed in CEPA.

The government claims to take all opportunities to promote transparency in the best interest of Canadians, but it is difficult to discern this vague claim in action. The financial repercussions of impacts of chemical exposures on human health and the environment are traditionally not publicly assessed by the federal government, and are not

considered in parallel with industries' claims of economic impacts of chemical identity disclosure.

We are in general agreement that once a submitter has been requested to provide information such as additional rationale for a confidentiality claim and possible masking of the name, that process and timeline guidelines are necessary for the submitter to follow when responding. The validity of CBI should be clearly demonstrated. If this is not forthcoming, public disclosure of relevant information should take precedence.

Recommendations:

- Include in the "Review of a confidentiality claim" description explicit mention that all elements of a confidentially claim are reviewed for applicability and accuracy.
- Include parameters that would trigger the need for the government to release some CBI.
- For additional information regarding a CBI claim, strict adherence to the stipulated process and timelines should be respected by the submitter. If not, the alternative would be public disclosure of the information.

C) Information generally not expected to be confidential

The consultation document identifies examples of substance information that are likely to be excluded from confidentiality claims, although there could be exceptions. Such examples include:

a) *Trade name(s) or name(s) commonly used;*
b) *General information on uses (the uses need to be described only broadly: e.g., closed or open system, agriculture, domestic use, etc.);*
c) *Safe handling precautions to be observed in the manufacture, storage, transport and use of the substance;*
d) *Recommended methods for disposal and elimination;*
e) *Safety measures in case of an accident;*
f) *Physical and chemical information with the exception of data revealing the substance identity (e.g. spectra).*
g) *If the physical and chemical information make it possible to deduce the substance identity, non-confidential ranges of values can be identified;*
h) *Summaries of health, safety, and environmental data including precise figures and interpretations. In cases where the study is claimed confidential, the submitter of the health, safety, and environmental study has the option of preparing a non-confidential summary. If no summary is provided,*

Environment and Climate Change Canada and Health Canada will prepare one following the OECD harmonized template format.[3]

We agree that the above examples should be excluded from confidentiality claims. The following includes topics for clarification and possible further grounds for exclusion from confidentiality:

- General information on uses should include the extent of exposure of pregnant women and children to the chemical – occupationally, directly, indirectly or through the use of consumer products.
- Basic physical-chemical properties of the chemical, particularly if they are associated with physiological or environmental distribution or specific impacts to health or the environment, should be non-confidential.
- It is unclear if government approval is required for the chosen non-confidential ranges for physical and chemical information on a chemical when actual values may make the identification of the substance possible. This should be clarified, with latitude for requirements for narrower ranges.
- Summaries of health, safety and environmental data including precise figures and interpretations should include raw data in a format that would facilitate subsequent use by the government and public. All summaries should be easily understood and relate directly to the substance for which there is a confidentiality claim, and all information should be submitted in a useful format per government specifications, for database storage and mathematical manipulation. For a risk assessment, the summary should be available in the public domain. When there is a confidentiality claim for the study and the submitter has an option of preparing a non-confidential summary, the onus should be on the submitter and not the government to do so. If the submitter does not supply the non-confidential version of the study, market entrance should be denied. If the government prepares the study, it signals to the submitter that there will likely be a fall back alternative – this is inappropriate.
- Transparency dictates that a confidentiality claim should not be accepted by the government if there is evidence suggestive of potential harm to the environment or human health.
- Similarly, information used to determine hazard, and to draw conclusions on the toxicity of a substance in a risk assessment, should be in the public domain.

Recommendations:

- It is recommended that exposure data for specific vulnerable subgroups (including pregnant women, children, and all of child-bearing age) be explicitly required and released for public access.
- Confidentiality should not be granted when pregnant women or children may be exposed to a chemical.

[3] Ibid

- Physical-chemical properties should not be confidential for chemicals that have the potential to or cause harm to human health or the environment.
- Ranges for disclosure of physical and chemical properties of a substance should be subject to government approval.
- Raw data in summaries should be in an easily understood and useful format, and should relate directly to the substance. Summaries should be made public and if there is no summary, the substance should not be allowed on the Canadian market.
- Market entrance should be denied for “masked” substances until the submitter has provided a non-confidential summary that satisfies questions regarding potential hazards.
- The government should not accept a confidentiality claim for a substance if there is evidence of potential accumulation or harm to the environment or human health.
- Confidential status of information should be revoked when that information results in a conclusion of potential toxicity of the substance in a hazard and risk assessment.

D) Confidential substance identity claims

A masked name (complete or partial) should not be granted or accepted unless there is a clear and complete justification to do so. A substance that has the potential to harm human health and/or the environment, that may at any level be persistent, bioaccumulative, reprotoxic, genotoxic, neurotoxic, or endocrine disrupting, or act as a sensitizer, etc. should not have a masked name. Under those conditions, transparency, in terms of the clear identification of a substance in a risk assessment, is essential for both new and existing substances.

Recommendations:

- Clear justification is required before acceptance of masking of a substance name.
- The name of a substance should not be masked if the substance has the potential to accumulate, or to harm human health and/or the environment.

E) Duration of confidentiality claims for substance identity

A ten year period before a confidentiality claim for substance identity is reviewed could in some cases be too long. During that timeframe, similar chemicals may arise with properties indicating harm to human health and the environment, or new evidence may come to light that the chemical for which there is a confidentiality claim may actually be harmful. Triggers for earlier review of confidentiality could include new scientific information, and emergence of similar chemicals and/or possible substitutes. These caveats, possibly among others, should be taken into consideration before and at the 10 year review date, for confidentiality claims for substance identity.

Recommendations:

- The timeframe should be a maximum of 10 years to complete review of confidentiality claims regarding substance identity, unless during that time new scientific data indicates that there is potential for accumulation, or harm to human health and/or the environment, for the chemical in question or similar chemicals. As well, identification of clearly safer, more sustainable substitutes or alternative approaches should trigger reconsideration.
- Triggers for earlier review with emerging information of toxicity and/or clearly safer alternatives should be identified in CEPA.

We are grateful for the opportunity to comment on this important topic. Please do not hesitate to contact us for further information or clarification.

Respectfully submitted,

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