

Proposed Approach to Promote Transparency in Chemicals Management Plan Risk Assessment Activities

Introduction

Transparency, clear accountability, and meaningful public involvement are among the key guiding principles of the *Canadian Environment Protection Act, 1999* (CEPA). In carrying out the mandate to assess and manage risks posed by new and existing substances, Environment and Climate Change Canada and Health Canada must ensure a high degree of public participation, openness and transparency in decision making. Moreover, transparency is the cornerstone for building and maintaining public confidence. Environment and Climate Change Canada and Health Canada also have an obligation to protect confidential business information. CEPA allows those submitting information to require that the information be treated as confidential. This feature protects Canadian commercial interests by ensuring that confidential information is protected from public disclosure.

The Government of Canada is currently proposing an approach to achieve an appropriate balance between transparency and industry's right to protect confidential information. The aim is to minimize the scope, frequency and duration of claims of confidentiality for information related to substances. This will help with publishing robust rationales for risk assessment decisions, as well as increasing transparency to Canadians with respect to substances in commerce in Canada, while protecting confidential information.

To inform this approach, Environment and Climate Change Canada examined transparency-related best practices in other domestic and international programs, as well as conducted a thorough analysis of data received and claimed as confidential.

Opportunities for alignment of the process for reviewing confidentiality claims are currently being explored with the United States Environmental Protection Agency. This document may be updated as the approach is further informed through ongoing alignment potential and considering comments received on the proposed approach.

Claiming Confidentiality

Claims for confidentiality should only be made when the submitted information is truly confidential, such as when it is a trade secret or where its disclosure could negatively impact the competitive position of the submitter. To reduce the scope of confidentiality requests and focus on what is truly confidential, a request for confidentiality must indicate which specific information or data should be treated as confidential.

In addition, a company requesting confidentiality for submitted information should provide rationale regarding the nature of the confidentiality, such as whether:

- 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.

Review of a Confidentiality Claim

There may be instances where the government would wish to release certain confidential information publicly. In these situations, a review will be done to determine whether certain information claimed as confidential could be released to promote transparency or because it is in the best interest of Canadians. In most cases, the submitter of the information will be contacted and asked to provide additional information to substantiate their original claim, which may include:

1. **Description of commercial interest:** A description of the nature and importance of the submitter's commercial interest.
2. **Description of potential competitive or financial harm:** Explanations of why release of the information claimed confidential would be likely to cause potential harm to the commercial interest and the specific nature of those harmful effects. This can include the detrimental effects to the competitive position of the submitter that would result from the release of the information; the detrimental financial effect on the submitter, or the potential financial gain for a competitor, which can be reasonably expected, resulting from the disclosure of the information. A causal link between disclosure and such harmful effects should be clearly explained.
3. **Explanation of the measures taken to ensure confidentiality:** This includes the measures the submitter has taken, and intends to continue to take, to maintain the confidentiality of the information; the measures that have been taken to prevent undesired disclosure of the information and the extent of any disclosures to date; the process the submitter is using to ensure confidentiality where a third person is obtaining the information with the consent of the submitter.

Submitters will be given an opportunity to review and provide the appropriate rationale for their claim or to recommend appropriate masking prior to any decisions regarding disclosure of the confidential information. When a submitter is contacted with respect to the review of a confidentiality claim, a process and timeline to respond is communicated at the same time.

Information Generally Not Expected To Be Confidential

Certain types of information are generally not expected to be confidential. Release of this information is seen as desirable to promote transparency.

The following list identifies the kinds of information concerning a substance that would not be expected to be confidential although it is understood that there will be exceptions. It is not restrictive and is based on the *Recommendation of the Council concerning the OECD List of Non-Confidential Data on Chemicals 26 July 1983 - C(83)98/FINAL*.

- Trade name(s) or name(s) commonly used;
- General information on uses (the uses need to be described only broadly, like: closed or open system, agriculture, domestic use, etc.);
- Safe handling precautions to be observed in the manufacture, storage, transport and use of the substance;
- Recommended methods for disposal and elimination;
- Safety measures in case of an accident;
- Physical and chemical information with the exception of data revealing the substance identity (e.g. spectra). If the physical and chemical information make it possible to deduce the substance identity, non-confidential ranges of values can be identified;
- 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](#).

Confidential Substance Identity Claims

It may be the case that the actual identity of a substance is claimed as confidential and its disclosure would result in the release of confidential information. Therefore, when claiming confidentiality for substance identity, the submitter should also provide the following:

1. a proposed masked name developed in accordance with the *Masked Name Regulations*; and
2. when proposing the masking of more than one descriptive segment of the name, the justification as to why the name with one masked segment would still qualify as confidential information.

Claims for protecting the confidentiality of substance identity will follow the procedures described in section 2.1.2 of the *Guidelines for the Notification and Testing of New Substances: Chemicals and Polymer* or in section 8.2.2 of the *Guidelines for the Notification and Testing of New Substances: Organisms*, as appropriate, as well as the New Substances Notification Advisory Note 2015-01 - *Masking substance names for New Chemicals and Polymers under the Canadian Environmental Protection Act, 1999*.

As mentioned in subsection 3(2) of the Masked Name Regulations, and in keeping with the above mentioned advisory note, the name of a substance may be masked only to the extent necessary to protect confidentiality. This means that the name should be masked at the minimum level to avoid the disclosure of information.

Duration of Confidentiality Claims for Substance Identity

To help increase awareness of the substances in the Canadian market, confidentiality claims for substance identity will be reviewed after a period of 10 years. Before this period expires, Environment and Climate Change Canada will make reasonable attempts to contact submitters once a confidentiality claim is more than 10 years old. Submitters will be asked to update their claim if they wish the substance identity to remain confidential for an additional period of 10 years. To update a claim, submitters need to follow the instructions described in the section 'Claiming Confidentiality'.

How to provide comments:

The Government of Canada is currently seeking comments on the proposed approach by June 30, 2017. To provide comments on this proposed approach, please submit via email to eccc.substances.eccc@canada.ca and indicate "Comments on proposed Approach for Confidentiality Claims" in the subject line.