

Chemicals Management Plan Risk Assessment Toolbox

Fact sheet series: Topics in risk assessment of substances under the *Canadian Environmental Protection Act, 1999* (CEPA 1999)

Addressing substances under the Chemicals Management Plan

Since the onset of the Chemicals Management Plan (CMP), various approaches have been used to address the substances identified as priorities through the [categorization](#) of the [Domestic Substances List](#). One example is the use of the [rapid screening approach](#). As Health Canada and Environment and Climate Change Canada move forward with addressing the remaining substances and newly identified priorities, the Risk Assessment Toolbox has been developed to delineate the various types of approaches that can be considered for assessing a substance or group.

Figure 1, below, illustrates the different types of risk assessment approaches that are used to address substances under CMP and the level of complexity for each.

The Risk Assessment Toolbox

The Risk Assessment Toolbox was developed to formally identify approaches that have been used to address substances under the CMP. These approaches will be considered to address the remaining substances or groups by selecting an appropriate and fit-for-purpose approach in each case. This approach ensures the ability to focus efforts on the substances of highest concern and to engage stakeholders on substances as efficiently as possible. The toolbox underwent consultation with stakeholders through a workshop held in May 2015 and was presented to the [Chemicals Management Plan Science Committee](#) in June 2015.

As described in more detail below, the first 2 types of approaches are typically used to address multiple, dissimilar substances within a single document, thereby gaining efficiencies. In the third type of approach, substances would typically be addressed individually or in groups, based on chemical or functional similarities.

This type of approach can be further split into 3 levels based on the complexity of the assessment needed. Often, a different assessment approach will be used for ecological versus human health assessment, as a substance can have different levels of concern and evaluation needs for the environment and human health.

Type 1 approaches are used to address substances or groups of substances with a science-based policy response. These approaches are used when it is considered that a formal conclusion under section 64 of [CEPA 1999](#) is not appropriate at the time. Examples of type 1 approaches include referral of the assessment to a better-placed federal risk assessment program, or documentation of a substance or group as having been previously addressed by an existing action or initiative under CEPA 1999.

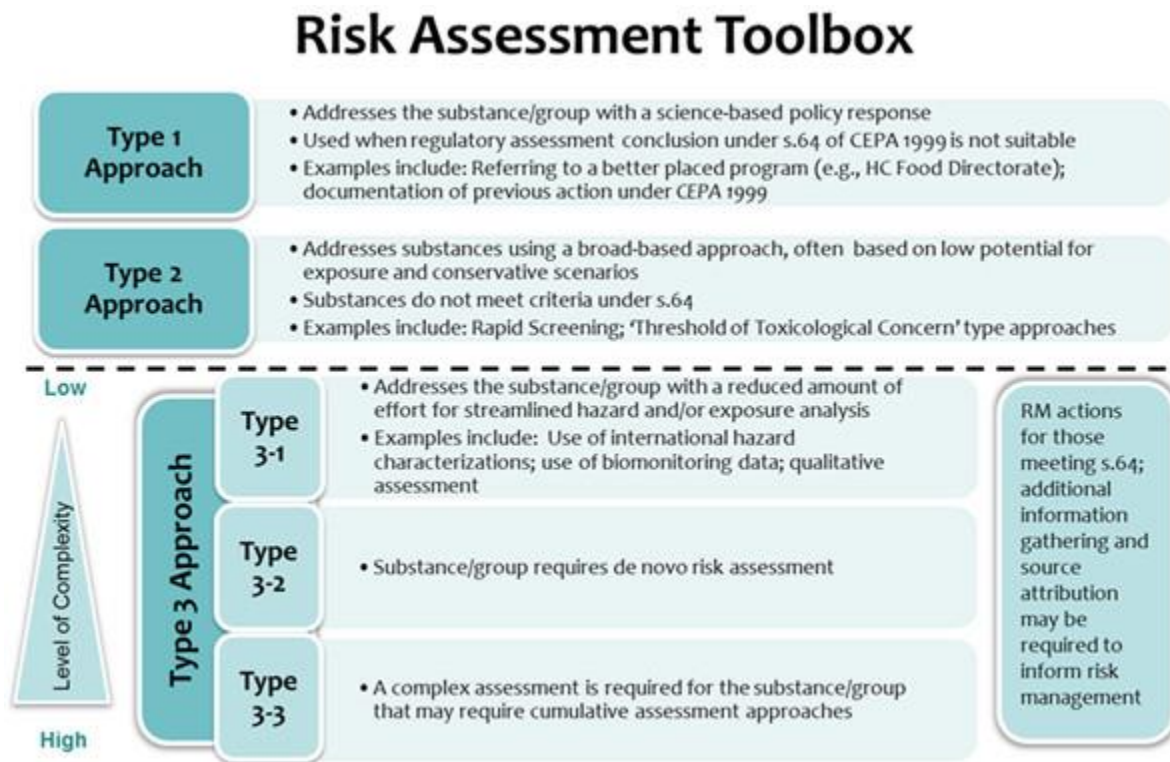
Type 2 approaches are used to address substances using a broad-based approach. These approaches are typically applied to substances that have lower potential for exposure and risk. The assessments may use either qualitative or quantitative approaches to assess the substances, applying conservative (protective) assumptions. Assessments using this approach may or may not make a formal conclusion under section 64 of CEPA 1999. The [rapid screening approach](#) and [polymer rapid screening approach](#) are past examples of type 2 approaches. In upcoming assessments, the proposed approach for ecological risk classification of organic substances (ERC) and the health approach based on threshold of toxicological concern (TTC) are 2 other examples.

Type 3 approaches are used to address substances using a standard risk assessment approach that considers both hazard and exposure, for either the ecological assessment and/or health assessment, in more detail. Documents may have a similar structure to the typical screening assessments that have been completed under the CMP to date. This type of approach can be sub-divided into 3 levels representing a continuum of increasingly complex assessment approaches. They may include consideration of a combination of qualitative and quantitative lines of evidence in determining whether a substance or group of substances meet the criteria under section 64 of CEPA 1999. Assessments will be conducted according to a fit-for-purpose approach to focus efforts.

- **Type 3-1** approaches are streamlined to allow assessment of a substance or group of substances with a reduced effort on either, or both, the hazard or exposure characterization. Examples include adoption of existing hazard characterizations from international organizations, or use of biological equivalents (BE) for substances for which biomonitoring (exposure) data are available.

- **Type 3-2** approaches are those in which *de novo* exposure and hazard characterizations are undertaken.
- **Type 3-3** approaches are used to assess substances where a more in-depth consideration of exposure and/or hazard is required than in a type 3-2 assessment. Such assessments could include, for example, consideration of cumulative risk.

Figure 1. The Risk Assessment Toolbox



Text description - Figure 1

Figure 1 illustrates the different types of risk assessment approaches that are used to address substances under CMP and the level of complexity for each.

Type 1 approaches are used to address substances or groups of substances with a science-based policy response. These approaches are used when it is considered that a formal conclusion under section 64 of CEPA 1999 is not appropriate at the time. Examples of type 1 approaches include referral of the assessment to a better-placed federal risk assessment program, or documentation of a substance or group as having been previously addressed by an existing action or initiative under CEPA 1999.

Type 2 approaches are used to address substances using a broad-based approach. These approaches are typically applied to substances that have lower potential for

exposure and risk. The assessments may use either qualitative or quantitative approaches to assess the substances, applying conservative (protective) assumptions. Assessments using this approach may or may not make a formal conclusion under section 64 of CEPA 1999. The rapid screening approach and polymer rapid screening approach are past examples of type 2 approaches. In upcoming assessments, the proposed approach for ecological risk classification of organic substances (ERC) and the health approach based on threshold of toxicological concern (TTC) are 2 other examples.

Type 3 approaches are used to address substances using a standard risk assessment approach that considers both hazard and exposure, for either the ecological assessment and/or health assessment, in more detail. Documents may have a similar structure to the typical screening assessments that have been completed under the CMP to date. This type of approach can be sub-divided into three levels representing a continuum of increasingly complex assessment approaches. They may include consideration of a combination of qualitative and quantitative lines of evidence in determining whether a substance or group of substances meet the criteria under section 64 of CEPA 1999. Assessments will be conducted according to a fit-for-purpose approach to focus efforts.

Type 3-1 approaches are streamlined to allow assessment of a substance or group of substances with a reduced effort on either, or both, the hazard or exposure characterization. Examples include adoption of existing hazard characterizations from international organizations, or use of biological equivalents (BE) for substances for which biomonitoring (exposure) data are available.

Type 3-2 approaches are those in which *de novo* exposure and hazard characterizations are undertaken.

Type 3-3 approaches are used to assess substances where a more in-depth consideration of exposure and/or hazard is required than in a type 3-2 assessment. Such assessments could include, for example, consideration of cumulative risk.