Moiety approach

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

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Introduction

The use of a moiety approach in chemical substance assessment under CEPA involves evaluating the risk posed by a common <u>moiety</u> of potential concern. A moiety approach generally groups substances with a mutual chemical component (for example, a common element or representative structure), and assumes that all substances in the group release the same component, which leads to similar toxic effects in the exposed organisms. Examples of assessments under CEPA that use the moiety approach include the <u>benzotriazoles and benzothiazoles group</u> (specifically, the benzothiazole subgroup) and <u>zinc and its compounds</u>.

Assessments using the moiety approach can include any substance that may release and contribute to the moiety of potential concern. These assessments are therefore not limited to substances identified as a priority for assessment under CEPA. For example, the zinc and its compounds assessment focused on the zinc moiety and therefore considered zinc in its elemental form, zinc-containing substances, and zinc released to the environment in dissolved, solid, or particulate forms. Therefore, zinc substances considered in the moiety approach include elemental zinc, organic and inorganic zinc salts, organometallic, and UVCBs (unknown or variable composition, complex reaction products, or biological materials) that contain zinc. Substances included in this group are considered as having the potential to release the common zinc moiety through various transformation pathways and contribute to the exposure of living organisms (Figure 1).

Figure 1. A diagram illustrating the potential of zinc-containing substances to release the zinc moiety through various transformation pathways under environmentally relevant conditions.

[Alt-text: Figure 1 illustrates examples of zinc-containing substances, including elemental zinc, an inorganic zinc chloride salt, an organic-zinc salt, and an organometallic zinc compound which may dissolve, dissociate, or degrade to release the zinc moiety under environmentally relevant conditions.]

The following sections describe how the moiety approach is used to address such a diverse group of substances.

Assessing effects

In an assessment using the moiety approach, the ecological effects characterization focuses on the moiety of potential concern. Targeted searches are conducted in databases and the scientific literature for data on effects of the moiety in aquatic, sediment, and soil-dwelling organisms. Available effects data are evaluated for their reliability and applicability to establishing a long-term predicted no-effect concentration (PNEC) for a moiety. Depending on the type and quantity of reliable data available, PNECs may be derived for aquatic, sediment, and soil-dwelling organisms in the Canadian environment, using either a species-sensitivity distribution approach or an assessment factor approach. When there are established Canadian environmental quality guidelines (either national, federal, or provincial) these may form the basis for the PNECs. Given that the toxicity of metals in the environment often depends on factors such as pH, hardness, and dissolved organic matter, PNECs may be corrected to account for relevant toxicity-modifying factors when sufficient information is available.

The health effects assessment focuses on the moiety of potential concern. Literature searches are conducted on the moiety of potential concern, and the resulting hazard data is then used to select a level of exposure at which harm to human health is not expected to occur. In addition, in the human health assessment, a literature search on health effects and toxicokinetic data available on individual substances within the grouping is conducted to assess the potential for increased toxicity above the toxicity of

the moiety. Individual substances that have increased toxicity above the toxicity of the moiety may require individual consideration separate from the moiety approach.

Assessing exposure

Exposure of living organisms to the moiety of potential concern may occur from any substance that has the potential to release the moiety through various transformation pathways (for example, dissolution, dissociation, or degradation). The potential for adverse effects to living organisms is considered in assessments using the moiety approach by examining the combined exposures to the moiety from the broader substance group. The moiety approach also considers exposure to the moiety from both natural and anthropogenic (human-caused) sources (for example, naturally occurring elements). When feasible and relevant, contributions from background concentrations are differentiated from concentrations of anthropogenic sources in concluding whether the moiety is of potential concern. The potential ecological and human health exposure can be quantified using measured or modelled concentrations of the moiety in environmental media (for example, water, sediment, soil, and air), in biota, human tissues and fluids, food or products. In the exposure characterization, measured and modelled environmental concentration data for the moiety of potential concern is an integral component of identifying potential risk of the moiety and sources of exposure to the organisms in the Canadian environment and people in Canada. Additionally, human biomonitoring data of the moiety may be used as an integrated measure of exposures across multiple routes (for example, oral, dermal, and inhalation) and sources.

CEPA conclusions on assessments using the moiety approach

Information gathered for the exposure and effects of the moiety of potential concern are used as <u>lines of evidence</u> to determine whether the moiety has the potential to cause harm to the environment and/or human health. If data are available, the assessment also includes consideration of subpopulations who may have greater susceptibility or greater exposure and vulnerable environments.

In general, engineered nanomaterials are addressed under the <u>Framework for Manufactured Nanomaterials</u> under CEPA and are not explicitly considered in assessments using the moiety approach. However, nanomaterials may be present in environmental media or in products, therefore measured concentrations of the moiety of concern in the environment or in human biomonitoring could include nanomaterials.