The ecological risk classification of organic substances approach

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

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Ecological risk classification of organic substances

Environment and Climate Change Canada (ECCC) has produced 2 versions of an innovative science approach to classifying ecological risks of organic substances on the Canadian Domestic Substances List (DSL). This approach integrates progressive scientific and weight of evidence thinking to identify substances of higher priority for risk assessment and other regulatory activities under the Chemicals Management Plan (CMP).

Ecological risk classification of organic substances approach: version 1

In 2016, ECCC developed and published an approach known as the Ecological Risk Classification of Organic Substances (ERC) Approach. This first version of ERC (ERC1) was applied to 640 organic substances under the third phase of the CMP. These substances had met criteria for further risk assessment following the Government of Canada's categorization of the DSL in 2006, performed under CEPA.

ERC1 was a risk-based prioritization approach that used multiple chemical descriptors (multiple lines of evidence). Empirical and modeled data were used to establish hazard and exposure profiles for individual organic substances, not including polymers. The profiles were compared to hazard and exposure classification rules in order to determine an overall risk classification for each substance. ERC1 helped better define substances of higher ecological concern that merited additional risk assessment under

the CMP, and demonstrated that a weight of evidence approach was viable for organic substance prioritization.

The impact of classifying organic substances from the third phase of the CMP using ERC1 was significant. Fewer organic substances required further ecological risk assessment (approximately 80% fewer). Additional information on ERC1 can be found in the Science Approach Document: Ecological Risk Classification of Organic Substances.

Ecological risk classification of organic substances approach: version 2

The development of version 2.0 of the ERC Approach (ERC2) began in late 2017 and was completed mid-2021. ERC1 provided a proof of concept that could be used as a template to increase the sophistication of the ERC Approach, while incorporating new sources of information and tools that had become available.

ERC2 was developed to re-examine approximately 12,200 organic substances on the DSL that did not meet the categorization criteria for persistence, bioaccumulation and inherent toxicity. ERC2 is a risk-based approach for identifying candidate substances for future regulatory activities, such as further data gathering and risk assessment. ERC2 integrates many types of new approach methods (for example, computer models, cell line assays) inside a weight of evidence framework. Rule-based algorithms for several hazard and exposure descriptors are used to classify potential ecological risks (Figure 1). Consensus of data within and among ERC2 descriptors is used to classify hazard, exposure and risk as well as assign confidence and severity scores. Higher confidence scores are typically assigned when empirical studies have been performed on the organic substance, or when multiple data points agree on the outcome. Lower confidence can be assigned when no or few empirical data are available, or data give mixed results. Severity scores reflect the number of descriptors that are suggesting that an organic substance may pose ecological hazard and exposure concerns. In other words, the classification is more severe if several descriptors suggest concerns.

Hazard data in ERC2, from molecular interaction information to toxicity test results on whole organisms, are organized according to the adverse outcome pathway framework. Organizing the data this way allows for an examination of data consistency and can provide plausible mechanistic understanding of potential hazards, thereby increasing confidence in hazard classification. ERC2 data are contained in profiles for each organic substance, searchable by Chemical Abstracts Service Registry Number or substance name. These profiles are available in Excel format on the ERC2 web page.

The conceptual model of ERC2 is shown in Figure 1. First, an organic substance passes through pre-filter rules that consider substance properties related to adsorption, distribution, metabolism, and excretion (ADME). The substance then passes through a series of descriptor nodes to create a hazard profile and an exposure profile. For the hazard profile, descriptor nodes include receptor-mediated toxicity, reactivity and

genotoxicity, mode of toxic action, foodweb toxicity, and cumulative toxicity. For the exposure profile, descriptor nodes include response time, mobility, emission pattern, foodweb exposure, and margin of exposure (MOE). Using data collected from these 2 profiles, the substance then undergoes a weight of evidence-based classification routine applying confidence rules in the process. Final ADME and MOE checks are made before determining the final ecological risk classification as well as severity and confidence scores.

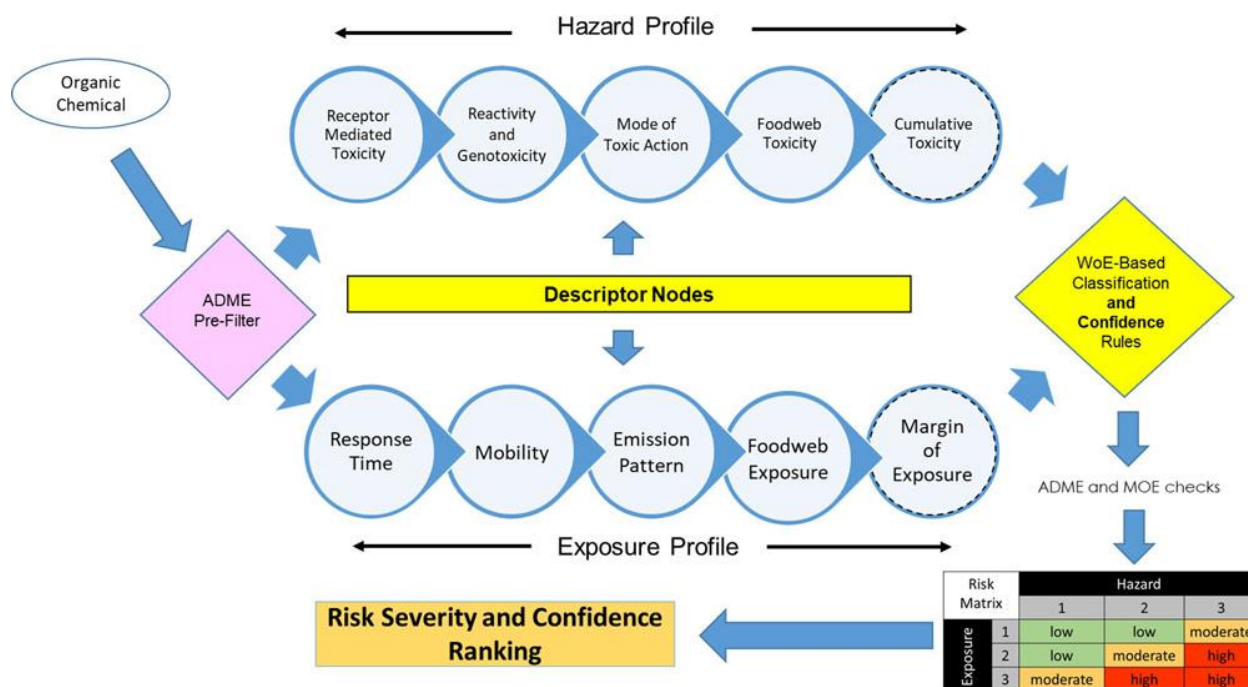**Figure 1: Conceptual model of ERC2 showing hazard and exposure descriptors**

Figure 1 - Text Description
Ecological risk classification results from ERC2 provide the Government of Canada with information for future priority setting and work planning as a major feeder into the identification of risk assessment priorities (IRAP) approach. In addition, results from ERC2 can be used to identify substances of global concern, endocrine active substances, and regrettable alternatives. The ERC2 Approach can also be applied to other organic substances beyond the 12,200 presently included. Additional information on ERC2 can be found in the science approach document (SciAD) and the spreadsheet of results for ERC2, available on the SciAD web page.