Framework for the Risk Assessment of Manufactured Nanomaterials under the Canadian Environmental Protection Act, 1999

Draft

Plain Language Summary

The full version of the draft Framework for the Risk Assessment of Manufactured Nanomaterials under the *Canadian Environmental Protection Act, 1999* is available.

Introduction

Nanotechnology is the study and manipulation of matter at the nanoscale (about 1 to 100 nm[1]). It is an emerging technology with enormous innovation potential. Substances developed using this technology (manufactured nanomaterials) enter the Canadian market across a wide range of applications and industries.

Different from traditional chemical substances, those manufactured at the nanoscale can be designed to exhibit unique characteristics. For example, some nanomaterials can reflect ultra-violet light while remaining transparent, while others may reinforce mechanical structures, providing strength and durability to materials. These characteristics come from changing the size, shape and/or surface chemistry of traditional chemical substances. These characteristics can also alter the hazardous effects and environmental behaviour of a substance, and may change its potential to harm human health and the environment. As such, there is a need to assess nanomaterials in a different way to conventional chemicals.

The Government of Canada is developing a draft framework for the risk assessment of nanomaterials. This document describes how Government of Canada scientists conduct risk assessments on nanomaterials under The *Canadian Environmental Protection Act*, 1999 (CEPA) to account for the unique characteristics exhibited by these substances.

[1] A nanometer is one billionth of a meter, 0.000000001 or 10^{-9} meters. For example, a human hair is approximately 80,000-100,000 nanometers wide, and a strand of human DNA is approximately 2.5 nanometers wide.

The assessment of substances, including nanomaterials under CEPA

The assessment of nanomaterials follows the same general principles and approaches as traditional chemical substances. Under CEPA, scientists at Environment and Climate Change Canada (ECCC) and at Health Canada (HC) assess existing substances that are in commerce in Canada (substances on the Domestic Substances List) and new substances not yet on the Canadian market (not yet on the Domestic Substances List), to determine whether these substances present or may present a risk to the environment or to human health. Weight of evidence and precaution are used when concluding on substance risk assessments under CEPA.

Purpose of this framework:

The framework describes how scientists at ECCC and HC conduct risk assessments on nanomaterials. With this document, ECCC and HC can communicate to industry and the public the methods that we use to make decisions under CEPA.

Scope of the framework:

This risk assessment framework outlines approaches and considerations for informing the risk assessment of nanomaterials under CEPA, including both existing nanomaterials on the domestic substances list, and new nanomaterials notified under the *New Substances Notification Regulations (Chemicals and Polymers)*. A substance is assessed as a nanomaterial if it meets the criteria described in Health Canada's working definition for nanomaterials and particle size distribution threshold (number or mass-based), as stated in both this framework and the New Guidance Document for the notification and testing of new substances: chemicals and polymers.

Nanomaterial-specific risk assessment approaches:

Because nanomaterials can have different behaviours than traditional chemical substances, the information and test data used to assess traditional chemical substances may not be applicable to nanomaterials. This means that in some cases, ECCC and HC scientists cannot simply use this information to characterize the hazard or potential for exposure that determines environmental or human health risks for nanomaterials. This becomes more complicated because there can exist different forms of a nanomaterial (for example, a substance manufactured to have a size between 1-10 nm may have a different behaviour, or have a different use application and thus a different exposure pathway, than the same substance manufactured between 50-70 nm). Scientists and industry use the physical chemical properties of the nanomaterial to help identify and classify nanomaterials, and this in turn helps to select the appropriate data that may support a nanomaterial risk assessment.

Scientists conducting nanomaterial risk assessments rely on test data and currently available models to support risk assessments. Along with expert judgment, ECCC and

HC scientists make conservative assumptions to account for uncertainties and data quality on each nanomaterial assessed. The framework discusses in detail the nanomaterial-specific considerations for risk assessment, such as:

- the key physical and chemical properties specific for nanomaterial identification and used for grouping or classifying nanomaterials for information gathering;
- the data considerations used in a nanomaterial risk assessment such as test data or modeling;
- the behaviour of nanomaterials throughout the lifecycle of the nanomaterial (from production to disposal) and characterizing those potential effects on human health and the environment.

The framework also details the ecological and human health risk characterization of nanomaterials as summarized below:

Ecological risk characterization approach for nanomaterials

The ecological risk characterization of nanomaterials considers relevant ecological processes that may affect the potential exposure and hazardous effects of nanomaterials. This includes investigating how nanomaterials are transported in the environment, and where in the environment nanomaterials may end up (environmental fate). In addition, ECCC scientists investigate how biotic (living components of an ecosystem) and abiotic (non-living components such as sunlight, pH and temperature) can influence the bioavailability, persistence or toxicity of a nanomaterial. These investigations determine where, in what quantity and with what toxicity a nanomaterial may be present in the environment to characterize its overall risk to ecological components.

Human health risk characterization approach for nanomaterials

Human health risks of nanomaterials are characterized based on nanomaterial-specific hazards and exposures for relevant routes of exposure. Characterization of the risks to Canadians are based on, but not limited to, use of products available to consumers, exposure via food, drinking water and environmental media, and with special consideration given to the potential risks to vulnerable populations (for example, children, pregnant women).

Conclusion

The conclusions reached through the assessment process for nanomaterials under CEPA may differ between the traditional chemical form of a substance and the nanomaterial form of the same substance, and differ among different nanoscale forms of the same substance. ECCC and HC scientists use a Weight-of-Evidence approach to combine the multiple lines of evidence and their uncertainties to conclude on if a nanomaterial reaches the environment in a quantity or concentration or under conditions that meets any of the criteria for toxicity as set out under CEPA.

More information on the assessment of Nanomaterials under the Canadian Environmental Protection Act is available.

We invite you to read the draft Framework for the Risk Assessment of Manufactured Nanomaterials under the *Canadian Environmental Protection Act, 1999* and provide comment.

For more information, please contact substances@ec.gc.ca.