POLICY ON THE USE OF SIGNIFICANT NEW ACTIVITY PROVISIONS OF THE CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999

1. PURPOSE AND APPLICATION

This document describes Environment Canada (EC) and Health Canada's (HC) operational policy for applying the significant new activity (SNAc) provisions of the Canadian Environmental Protection Act, 1999 (CEPA 1999).

This policy applies to all uses of the SNAc for:

- new substances;
- substances on the Domestic Substance List (DSL) that are not on Schedule 1;
 and
- substances on the DSL that are listed on Schedule 1.

This policy applies to all types of substances covered by CEPA 1999, including chemicals, polymers and living organisms.

2. CONTEXT

The SNAc provisions trigger an obligation for industry to notify and the government to assess, information about a substance when a proponent proposes to use the substance in a significant new activity. The provisions are used to assess the risks associated with the proposed new activity before the new activity is undertaken. The Minister of the Environment and the Minister of Health assess the information provided by the notifier and other information available to them to determine whether the substance, if used in the proposed new activity, could pose a risk to the environment or human health, and if so, whether new or additional risk management is required.

3. OPERATING PRINCIPLES

3.1 When SNAcs should be considered for use

The decision to use a SNAc is risk-based. The SNAc provisions will be considered for use where there is reasonable suspicion that new activities with respect to a substance may result in new or increased risks to the environment or human health. That suspicion could be based on factors such as the specific properties of the substance, the function of the substance, the presence of the substance in markets in other jurisdictions, etc.

SNAcs are more permissive than some other instruments as they implicitly signal that some new uses of the substance may be acceptable. Where there is suspicion that no new activity would be acceptable, other instruments – such as conditions (for new substances) or prohibitions – may be used.

<u>For new substances:</u> a SNAc will be considered when there is suspicion that activities other than those that were the subject of the new substance notification may pose a risk.

<u>For DSL substances that have not been added or recommended for Schedule 1</u>: a SNAc will be considered when:

- there are no, or limited uses of the substance in Canada, but where there is suspicion that a significant new activity could pose a risk;
- the current uses of the substance in Canada present no or limited risk, but where there is a suspicion that a significant new activity could pose a risk; or
- current uses of the substance are adequately managed, but there is a suspicion that a significant new activity could pose a risk.

For DSL substances that are on, or have been proposed for addition to Schedule 1: a SNAc will be considered:

- as the sole preventive or control instrument where exposure from current uses is low but where there is a suspicion that a significant new activity could pose a risk;
- in combination with a preventive or control measure that addresses the risk posed by the current uses of the substance where there is suspicion that a significant new activity could pose a new or increased risk to the environment or human health.

3.2 Design of a SNAc Notice or Order

i. Identification of activities subject to notification

A significant new activity can include one that has not been conducted with the substance in the past or an existing one with a different quantity or in different circumstances that could affect the exposure pattern of the substance. As such, the key factor in determining whether the activity is significantly new is whether the activity may result in a significant change in exposure.

The SNAc Notice or Order will define the significant new activity either inclusively by describing those activities that will require notification or exclusively by describing those activities that will not require notification. In either case, the SNAc will be written as specifically as possible so as to target only those potential activities that are suspected of posing a risk to the environment or human health.

Notification thresholds may be described in the SNAc Notice or Order requiring notification before reaching a certain quantity, concentration or volume. Where annual quantity thresholds are used in defining a significant new activity, they will be derived in a manner relevant to possible new activities of interest, and will take into consideration relevant thresholds used under data gathering initiatives such as CEPA section 71 notices and the *New Substances Notification Regulations* (NSNR).

ii. Identification of the information to be submitted

The information requirements set out in the SNAc Notice or Order will be selected to address relevant areas of uncertainty identified during the original assessment. These may include information about inherent properties of the substance (e.g. physical-chemical properties, environmental fate, toxicity, etc.) and information related to its presence in the environment (e.g., uses, releases, processing, handling and disposal procedures).

When information requirements need to be more general, they will reflect those of the notification schedules of the NSNR (Chemicals and Polymers) or the NSNR (Organisms). In these cases, the SNAc Notice or Order will either use the relevant wording from these schedules or refer to the relevant items of the schedule.

iii. Identification of the assessment period

The SNAc Notice or Order must specify the assessment period, which is the period of time within which EC and HC will complete the assessment. It should reflect the expected complexity of the significant new activity notice (SNAN) assessment. For new substances and DSL substances not on Schedule 1, an assessment period of 90 days (120 for organisms) is typically specified in the SNAc Notice or Order. For Schedule 1 substances, the typical assessment period specified is 180 days.

3.3 Assessing information submitted based on a SNAc

The scope of each SNAN assessment will be determined by the information provided in the notification and by whatever other information is available to the Ministers.

A SNAN assessment will normally focus on the anticipated exposure resulting from the new activity. In addition, if the information submitted warrants it, the SNAN assessment may also re-visit prior assessment conclusions about the substance itself.

The Minister of the Environment and the Minister of Health assess the information provided in the SNAN to determine:

- whether the substance is toxic (as defined in section 64 of CEPA 1999) or to determine the circumstances in which it is toxic or capable of becoming toxic; and
- whether the proposed significant new activity is likely to change the exposure profile in such a way that it is expected to change the environmental or human health risk.

<u>For new substances or existing substances not on Schedule 1</u>: the conclusion of an assessment of a SNAN can be that the substance is:

- toxic or capable of becoming toxic; or
- not toxic.

<u>For existing a substances already on Schedule 1</u>: the conclusion of an assessment of a significant new activity can be that the new activity is:

- expected to increase or change the risk to human health or the environment; or
- not expected to increase or change the risk.

3.4 Action that will be taken after risk assessment

If the assessment determines that the substance is not toxic as a result of the significant new activity, or if the significant new activity is not expected to increase or change the risk, the notifier would be enabled to undertake the notified activity upon completion of the assessment period, and be informed as such. The Minister may either modify or rescind the Significant New Activity Notice or Order to reflect this decision. The Minister will endeavour to publish any amendment to a SNAc within 180 days from the end of the assessment period.

If the assessment determines that the substance is toxic or capable of becoming toxic, or if the proposed significant new activity is expected to increase the risk to human health or the environment, the Minister of the Environment will inform the notifier of this decision and proposed next steps to manage the risks identified prior to the end of the assessment period specified in the SNAC Notice or the Order.

3.5 Stakeholder input

Consultations on SNAc Notices and Orders provide potentially affected stakeholders with the opportunity to inform SNAc development and to be apprised of coming into force dates.

<u>For new substances</u>: the person responsible for the new substance notification is given an opportunity to comment on draft SNAc text and is informed when the SNAc Notice is published in *Canada Gazette*, Part 1.

For existing substances not meeting the CEPA definition of "toxic": typically, the government will signal its intent to use the SNAc provisions in the draft and/or final screening assessment report publication. The comment period following the publication of the Notice of Intent to apply the SNAc provisions gives stakeholders an opportunity to comment.

<u>For existing substances meeting the CEPA definition of "toxic":</u> stakeholders will have opportunities to provide input during the public comment periods following publication of the Risk Management Scope document, the Risk Management Approach document, and the Notice of Intent to apply the SNAc provisions.