New Substances Notification Advisory Note 2015-01

Masking substance names for New Chemicals and Polymers under the *Canadian Environmental Protection Act*, 1999, when the substance identity is claimed as confidential

This advisory note is to clarify that for masking a new substance name, it must be based on the explicit chemical name of the substance.

Background

Under section 313 of the *Canadian Environmental Protection Act, 1999* (the *Act*), any person who provides information to the government under this Act may, at the same time, submit a written request that the information be treated as confidential. This feature ensures that Confidential Business Information (CBI) is protected from public disclosure. The degree of protection given to information claimed to be confidential is consistent with sections 314–321 of the Act.

When the identity of a substance is claimed confidential, the procedures for generating a masked name are prescribed in the *Masked Name Regulations*. These procedures are further elaborated in Appendix 7 of the Guidelines for the notification and testing of New Substances: Chemicals and Polymer (the Guidelines). Note that there are fees associated with masked name application.

These procedures are in place to obtain a balance between protecting CBI while ensuring some degree of transparency. Another is to ensure that the masking process is conducted in a predictable and consistent manner.

Proposing a Masked Name

Masking may be accomplished by disguising structurally distinctive elements of the explicit chemical name of the substance, while retaining the generic identity/molecular structure of the substance. In most cases, masking a single element of the explicit chemical name of the substance would be sufficient, although masking multiple elements of the substance is also accepted when needed with supporting justification (see section 4 of Appendix 7 in the Guidelines).

The explicit chemical name of the substance is the name established in accordance with the current chemical nomenclature rules of the International Union of Pure and Applied Chemistry (IUPAC) **OR** the Chemical Abstracts Service (CAS)¹, as provided on the new substances submission form (e.g., New Substances Notification (NSN) Reporting Form, The Domestic Substances List Reporting Form for substances proposed for the Non-domestic Substances list, etc.).

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¹ CAS Nomenclature is considered to be any CAS approved names (e.g., CA Index Name, CAS Synonyms or Inventory name).



Masked Name process

Masked names will be reviewed upon submission. If the claim for confidentiality of the explicit chemical name is acceptable, the proposed masked name will be evaluated to determine whether or not it is consistent with the *Masked Name Regulations*.

Replacing components of the explicit chemical name

An acceptable masked name disguises the explicit chemical name as described above. As such, replacing components of the explicit chemical name with synonyms and then masking the synonyms will not be accepted.

Changing the order of components of the explicit chemical of a polymer

Although changing the order of monomers and reactants of the explicit chemical name of a polymer before masking, generally, may be acceptable, the first element of the name may not be moved. Furthermore, a written statement substantiating the need of moving the monomers and reactants will be required as well as a listing of the new position of each of the moved monomers and reactants.

Masking a pre-polymer

If the name of a pre-polymer is conserved in the explicit name of a polymer, then the pre-polymer name must be equally conserved in the masked name (*i.e.*, the pre-polymer that is conserved as a part of the explicit chemical name is considered as a single reactant for the purposes of naming and cannot be broken up into its elements). However, it remains that structural components of the pre-polymer name can be masked in accordance with the provisions of the masked name regulations just the same as they can be for structural elements of the polymer name as a whole.

Masked Name rejection

If a masked name is considered unacceptable, the New Substances (NS) program will communicate this decision to the notifier and an alternative name will be requested. If a consensus is not reached, the NS program will publish a masked name that, in its opinion, will respect the confidentiality claim of the company while reflecting the generic molecular structure of the substance.

Please note that a substance will not be eligible for the Domestic Substances List until an acceptable masked name is received (Eligibility requirements are described in detail in section 10 of the Guidelines)

Review of the masked name is separate from review of the New Substances Notification and will not affect the assessment period for the substance.

Masked Name fees

Notifiers of new substances (chemicals and polymers) and persons requesting other services are required to pay a fee as per the *New Substances Fees Regulations*. This includes a fee for the masked name applications.

A complete refund of the masked name application fee will be provided if the masked name is rejected or withdrawn prior to the publication of the substance in the *Canada Gazette*.

Contact Information:

If you have any questions, please contact the Substances Management Information Line:

Telephone: 1-800-567-1999 (toll-free in Canada)

1-819-938-3232 (outside Canada)

Fax: 1-819-938-5212

E-mail: <u>ec.substances.ec@ec.gc.ca</u>

You may also visit the New Substances Web site: http://www.ec.gc.ca/subsnouvelles-newsubs/.

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Signed on December 3, 2015