

New Substances Program Operational Policies Manual

Environment Canada and Health Canada

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1. FOREWORD

1. FOREWORD

This Operational Policies Manual provides the staff of the New Substances Program, stakeholders of the New Substances Program, and the public with general information on how Environment Canada and Health Canada interpret and apply the provisions of Part 5 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999) in the context of the New Substances Program. These operational policies will be updated from time to time, and additional operational policies will be added as they are developed.

Although care has been taken to ensure that these documents accurately reflect requirements prescribed in CEPA 1999 and the *New Substances Notification Regulations* (NSNR), notifiers are advised that, should any inconsistencies be found, CEPA 1999 and the NSNR will prevail.

Notifiers should also keep in mind that the operational policies described in this manual may not cover all situations. Notifiers should undertake, on their own initiative, to consult Environment Canada or Health Canada experts for specific information as necessary.

2. GENERAL

2.A. OPERATIONAL POLICY FOR ADMINISTERING THE DSL AND NDSL

PURPOSE

This document describes Environment Canada's operational policy for administering the Domestic Substances List (DSL) and Non-Domestic Substances List (NDSL) under the *Canadian Environmental Protection Act, 1999* (CEPA 1999).

APPLICATION

This document applies to all substances on the DSL as well as new substances, including those listed on the NDSL.

CONTEXT

The DSL includes all commercial substances that were identified as being in use in Canada between January 1, 1984 and December 31, 1986, as well as substances notified subsequently under the *New Substances Notification Regulations* (NSNR) that have met the listing criteria set out in CEPA 1999. Organisms were not present on the original DSL.

Substances listed on the DSL are considered to have existed in Canadian commerce and as such, do not require notification before being imported or manufactured. Substances on the original DSL are subject to scrutiny under CEPA as existing substances (e.g., categorization and screening, Priority Substances List assessment).

Under section 81 of CEPA 1999, importers and/or manufacturers of new substances (ie. Not on DSL) must provide prescribed information so that Environment Canada and Health Canada can assess the new substances to determine if they are "toxic" (in accordance with the criteria set out in section 64 of CEPA 1999) or capable of becoming "toxic." The information requirements are established in the *New Substances Notification Regulations*.

The NDSL is an inventory of substances that are not on the DSL but are accepted as being in commercial use in the United States. The NDSL is therefore based on the United States Environmental Protection Agency's (USEPA) *Toxic Substances Control Act* (TSCA) Chemical Substances Inventory, and contains more than 58 000 entries. Substances that are not on the DSL but are on the NDSL must be notified and assessed under the new substances regime. However, they are subject to lesser information requirements under the NSNR.

OPERATIONAL POLICY

Amendments to the DSL

The DSL is amended from time to time following:

- applications to add substances that were in commerce in Canada between January 1, 1984 and December 31, 1986; and
- assessments under the NSNR.

Amendments may also be made to correct printing or eligibility errors. Environment Canada publishes amendments to the DSL based on additions and deletions in the *Canada Gazette*, Part II every six to eight weeks.

Additions to the DSL

Applications for Substances in Commerce between January 1, 1984 and December 31, 1986

For substances to be added to the DSL under subsection 66(1) of CEPA 1999, the Minister of the Environment must be satisfied that these substances were manufactured in or imported into Canada between January 1, 1984 and December 31, 1986 in a quantity not less than 100 kilograms in any one calendar year or in Canadian commerce or used for commercial manufacturing purposes in Canada.

Applications to add a substance to the DSL under subsection 66(1) of CEPA 1999 must either include direct evidence or a sworn affidavit accompanied with any supporting evidence that a company's commercial activity with the substance meets the criteria set out in subsection 66(1) of CEPA 1999.

Living organisms are added to the DSL under subsection 105(1) of CEPA 1999 if the most comprehensive Schedule has been submitted and if there is no suspicion of toxicity.

New Substances Meeting Eligibility Criteria

When a new substance becomes eligible for addition to the DSL, Environment Canada must add the substance to the DSL and, if it appears on the NDSL, delete it from that list, within 120 days after the following conditions are met:

For chemicals, biochemicals, polymers, biopolymers:

- (a) the most comprehensive Schedule prescribed under the NSNR has been submitted;
- (b) the substance has been imported or manufactured by the notifier in excess of the criteria listed in subsection 87(1) (Notice of Quantity Exceedance); or manufacture or import has commenced according to paragraph 87(5)(a) (Notice of Manufacture or Notice of Import); and
- (c) no conditions have been imposed on the substance under paragraph 84(1)(a) of CEPA 1999.

For living organisms:

- (a) the most complete information package prescribed under the NSNR has been supplied (Schedule XV or XIX);
- (b) manufacture or import of the substance has commenced according to paragraph 112(1)(b) (Notice of Manufacture or Notice of Import); and
- (c) no conditions have been imposed on the substance under paragraph 109(1)(a) of CEPA 1999.

The NSNR was amended on June 18, 2003, to establish an alternative method for adding a substance to the DSL, without requiring the tracking of quantities, by prescribing requirements for the submission of a “Notice of Manufacture” or “Notice of Import” (NoMI) under paragraph 87(5)(a) of CEPA 1999. According to the requirements, if the assessment period for the most comprehensive information package has ended and no conditions have been specified for the substance, it is eligible for listing on the DSL when a NoMI has been received by the Minister indicating that the importation or manufacture of the substances has commenced. It should be noted that if the notifier exceeds the trigger quantity before the substance is added to the DSL, they would be required, under subsection 81(14) of CEPA 1999, to submit a notice of quantity exceedance to Environment Canada within 30 days of exceeding the trigger quantity.

Deletions from the DSL

If the Minister of the Environment subsequently determines that a substance on the DSL does not meet the eligibility criteria of CEPA 1999, the substance will be deleted from the DSL, and if appropriate, added to the NDSL. Such corrections may be required if, in the course of a follow-up audit, the nominator of a substance is unable to provide documentation to substantiate DSL eligibility. Deletion amendments are published in the *Canada Gazette*, Part II.

Amendments to the NDSL

The NDSL is amended from time to time as appropriate following:

- annual updates based on the USEPA TSCA inventory; and
- applications under the Four Corners Arrangement.

Amendments are also made following amendments to the DSL. Amendments to the NDSL, whether additions or deletions, are published in the *Canada Gazette*, Part I every six to eight weeks.

Updates based on the USEPA TSCA Inventory

The NDSL is based on substances that have been on the USEPA's TSCA Inventory for five years (e.g. the 2000 NDSL was based on the 1995 TSCA Inventory). Updates to the NDSL based on the TSCA Inventory are published annually in January or February in the *Canada Gazette*, Part I. It should be noted that substances for which the USEPA implemented risk management measures are not included in the updates of the NDSL.

As a result of the multistakeholder consultations on the NSNR, a two year process which ended in August 2001, the NDSL will be updated annually based on a one year time-lag once proposed amendments to the NSNR are in force (e.g. the 2006 NDSL will be based on the 2005 TSCA Inventory).

Applications under the Four-Corners Arrangement

Under the Arrangement for Sharing of Information Between the U.S. Environmental Protection Agency (USEPA), Environment Canada and Health Canada (the Four Corners Arrangement, or 4CA), notifiers may request that a substance be added to the NDSL if the substance was on the TSCA Inventory within the last five years.

In response to a request, Environment Canada may decide to add the substance to the NDSL or waive certain information requirements under the NSNR. Decisions to add a

substance to the NDSL are made on a case-by-case basis based on information received pursuant to the 4CA. The notifier will be informed of decisions.

RELATED INFORMATION

- DSL and NDSL www.ec.gc.ca/substances/nsb/eng/sub_e.htm
- *New Substances Notification Regulations*
www.ec.gc.ca/substances/nsb/eng/reg_e.htm
- Amending the *New Substances Notification Regulations*
www.ec.gc.ca/substances/nsb/eng/consul_e.htm
- The Arrangement for Sharing of Information Between the U. S. Environmental Protection Agency (USEPA), and Environment Canada (EC) and Health Canada (HC) www.ec.gc.ca/substances/nsb/html/4corners_e.htm

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3. PROCESSING NEW SUBSTANCES NOTIFICATIONS

3.A. OPERATIONAL POLICY FOR PROCESSING NEW SUBSTANCES NOTIFICATIONS

PURPOSE

This document describes Environment Canada's and Health Canada's operational policy for processing new substances notifications (NSN) under the *Canadian Environmental Protection Act, 1999* (CEPA 1999) and the *New Substances Notification Regulations* (NSNR).

APPLICATION

This document applies to all New Substances Notifications.

CONTEXT

Under section 81 and section 106 of CEPA 1999, importers and manufacturers of new substances must provide prescribed information so that Environment Canada and Health Canada can assess the new substances to determine if they are "toxic" (in accordance with the criteria set out in section 64 of CEPA 1999) or capable of becoming "toxic." A substance is considered "new" if it is not listed on the Domestic Substances List (DSL). The information requirements are established in the NSNR. Starting January 1, 2003, at present, notifiers of new chemicals and polymers are required to pay a fee according to the *New Substances Fees Regulations* (NSFR).

OPERATIONAL POLICY

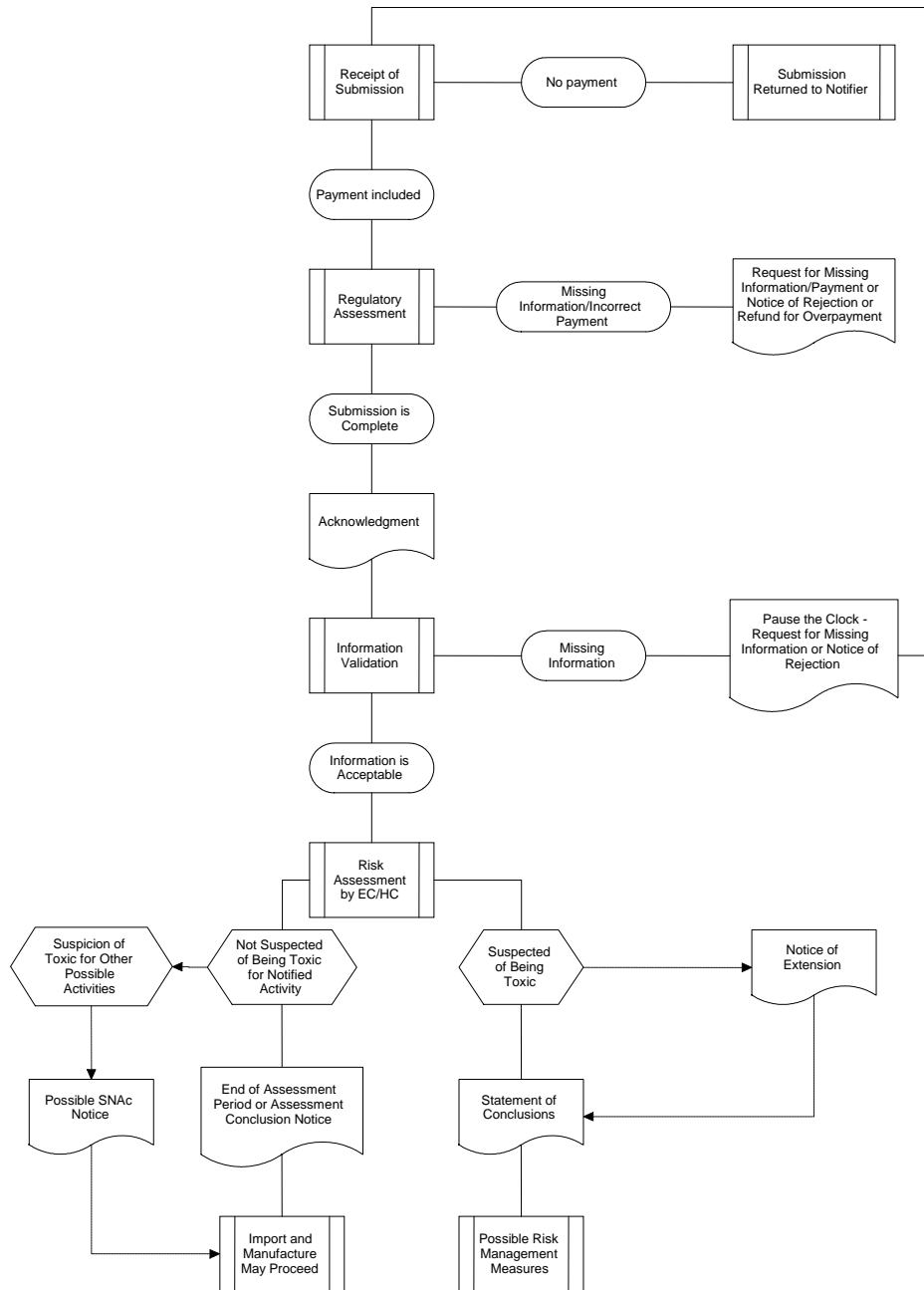
Environment Canada's and Health Canada's procedure for processing a New Substances Notification is shown in Figure 1 and described in the following steps.

Receipt of Submission

When a NSN is received by Environment Canada, any payment (applies only to chemicals and polymers only at this time) will be deposited, even if other prescribed regulatory information is found missing during the information review process described below, and a NSN reference number will be assigned. This number will appear on all correspondence issued by Environment Canada and Health Canada and should be used in any subsequent communications regarding that notification.

If the required payment is not included with a notification, the notification will be returned to the notifier (notice of rejection), requesting payment as prescribed by the NSFR. Refer to the *Operational Policy for Processing Fees and Refunds* for more information.

Processing Notifications



Note: Environment Canada and Health Canada conduct a risk assessment of the New Substance Notification during the assessment for toxicity.

Regulatory Assessment

Evaluators within Environment Canada will conduct a regulatory assessment to determine whether the:

- information required by the NSNR has been included in the notification;
- fees prescribed by the NSFR have been submitted
- substance identity and masked names are correct and acceptable; and
- claims for confidential business information have been substantiated.

If there are no deficiencies in the notification, an acknowledgment will be issued specifying the date on which the assessment period begins and concludes, and the NSN reference number. Acknowledgment indicates that the administrative information is satisfactory, and the prescribed fees and information have been received but not yet reviewed.

If deficiencies in the notification are identified there are three possible courses of action. If the deficiencies are minor in nature and could be remedied by telephone, e-mail or facsimile the evaluator will attempt to do so. If the deficiencies are more numerous or will require additional information to be generated by the notifier, then a request for missing information will be sent to the notifier specifying the deficiencies and the notification will be retained by the Notification and Client Services Division until such time as the notifier supplies the missing information (the clock does not start). Finally, if the notification is more substantially deficient, a notice of rejection will be sent outlining all of the deficiencies and, along with the notice, the notification is returned to the notifier. It should be noted that missing or insufficient fees according to the requirements of the *New Substances Fees Regulations* are considered a deficiency.

Risk Assessment

Evaluators assess the notification package to determine the acceptability of:

- test protocols and procedures;
- test data;
- rationales for requests for waivers of information; and
- exposure information.

If there are any difficulties with the notification package, evaluators will attempt to contact the notifier by telephone to resolve them before issuing a rejection or interruption notice. Deficiencies in the submitted information that cannot be easily resolved may result in the rejection of the notification or interruption of the assessment.

If the notification contains erroneous information that invalidates the assessment in progress a rejection notice will be issued. In this case, the assessment will be terminated and the assessment period will be reset at Day 1 when the correct information is received.

If the erroneous information does not invalidate the assessment, an interruption notice will be issued indicating that the assessment time clock was stopped at Day X (e.g., Day 14 of a 90-day assessment period). Upon receipt of the correct information, the assessment will continue with the time clock set at Day X + 1 (e.g., Day 15).

Assessment for Toxicity

The purpose of the assessment process is to determine whether the substance is suspected of being “toxic” or capable of becoming “toxic” in accordance with the criteria set out in section 64 of CEPA 1999. Consequently, evaluators assess the potential for exposure to humans and components of the environment, and the potential for adverse effects of the substance on humans, the environment or biological diversity.

When additional time is required to complete a risk management measure, Environment Canada will inform the notifier of an extension before the end of the initial assessment period. For example, if there is a suspicion of toxicity, the assessment period could be extended to allow for sufficient time to develop a regulatory response. An assessment period may be extended only once, for a length of time not exceeding the initial assessment period.

Actions Taken After an Assessment

If there is no suspicion that the substance is “toxic” or capable of becoming “toxic”, the notifier may proceed with import or manufacture after the assessment period has expired.

If a risk assessment is completed before the end of the assessment period, Environment Canada will inform the notifier of the early termination of the assessment period by issuing a notice of termination. For CEPA 1999 purposes, this will allow the notifier to commence import and/or manufacture of the substance before the end of the prescribed assessment period. Refer to the *Operational Policy for Early Termination of Assessment Periods* for more information.

If there is a suspicion that the substance is “toxic” or capable of becoming “toxic”, the notifier will be informed prior to the end of the assessment period of the results of the assessment and any risk management measures that may be applied.

If changes to the exposure profile may result in a suspicion of toxicity, a SNAc notice may be issued to define the new activities for which a notification and assessment are required. The SNAc provisions define when a substance needs to be renotified and reassessed.

Refer to *Operational Policy for Taking Action After an Assessment* for more information.

RELATED INFORMATION

- *Operational Policy for Processing Fees and Refunds*
- *Operational Policy for Early Termination of Assessment Periods*
- *Operational Policy for Taking Action After an Assessment*
- *Operational Policy for Issuing Significant New Activity Notices*

Last updated: April 2004

3.B. OPERATIONAL POLICY FOR PROCESSING FEES AND REFUNDS

PURPOSE

This document describes Environment Canada's operational policy for processing fees and refunds for new substances (chemicals and polymers) and other services under the *Canadian Environmental Protection Act, 1999* (CEPA 1999), the *New Substances Fees Regulations* (NSFR) and the *New Substances Notification Regulations* (NSNR).

APPLICATION

This policy applies to the assessment of new substance notifications and other services for new chemicals and polymers. Other services include

- confidential searches of substances appearing on the Domestic Substances List (DSL) or Non-Domestic Substances List (NDSL) that have been published under masked names;
- masked name applications; and
- applications for a service under the Arrangement for Sharing of Information (the "Four Corners Arrangement") between the U.S. Environmental Protection Agency (USEPA), Environment Canada and Health Canada.

At this time, the *New Substances Fees Regulations*, and therefore this policy, do not apply to:

- biochemicals, biopolymers, living organisms or animate products of biotechnology; or
- substances whose use is regulated under another Act of Parliament, whether or not it is listed in Schedules 2 or 4 of CEPA 1999.

CONTEXT

Under Section 81 and Section 106 of CEPA 1999, importers and manufacturers of new substances must provide prescribed information so that Environment Canada and Health Canada can assess the new substances to determine if they are "toxic" (in accordance with the criteria set out in section 64 of CEPA 1999) or capable of becoming "toxic." A substance is considered "new" if it is not listed on the DSL. The information requirements are established in the *New Substances Notification Regulations* (NSNR).

As of January 1, 2003, notifiers of new chemicals and polymers must pay a fee as established in the *New Substances Fees Regulations* (NSFR). The fees for a notification assessment range from \$50 to \$3,500, with reductions available for staged, matched, or consolidated notifications, and for notifiers having total annual sales in Canada of \$40 million or less. In addition to fees for notification assessments, the regulations include fees for other services, including confidential searches of the DSL or the NDSL, masked name applications, and Four Corners Arrangement submissions.

The *Financial Administration Act* and its *Repayment of Receipts Regulations, 1997* generally apply for determining when refunds are warranted.

OPERATIONAL POLICY

The fees and refund operational policy is summarized in Table 1 and described in the following sections.

Table 1: Summary of Fees and Refund Operational Policy

STATUS OF PAYMENT	EFFECT ON SERVICES	APPLICABLE REFUND
No payment with submission	Submission is returned to notifier.	Not applicable
Insufficient payment		
<ul style="list-style-type: none"> • Service(s) for the same substance 	All services are suspended until full payment is received.	Not applicable
<ul style="list-style-type: none"> • Services for different substances <ul style="list-style-type: none"> • Fees clearly identified for each service 	Services are rendered for fully paid requests; other services are suspended until payment is received.	Not applicable
<ul style="list-style-type: none"> • Fees not clearly identified for each service 	All services are suspended until payment is received.	Not applicable
Exact payment	Services are rendered.	Payments are not refundable once full services are rendered.
Overpayment	Services are rendered.	Overpayment is refunded.
Valid withdrawn requests		
<ul style="list-style-type: none"> • Services not rendered 	Services are terminated.	Full payment is refunded.
<ul style="list-style-type: none"> • Partial services rendered 	Services are terminated.	A portion of applicable fees are retained.
Unnecessary services	Submission is returned to notifier.	Full payment is refunded.
Previous notifications made before January 1, 2003	Services are rendered.	Payment corresponding to previous schedules is refunded.

Exact Payment

If the exact payment for any service has been received, the service will be rendered.

No Payment

If payment is not received with the submission, the services will not be rendered and the submission will be returned to the notifier (notice of rejection).

Insufficient Payment

Single or Multiple Services for the Same Substance

If the payment is insufficient to cover the service(s) associated with a single substance, all services, including assessments of notifications, will be suspended until full payment is received.

***Example:** A submission contains a notification, a masked name application, and a payment covering the notification only. Evaluation of the notification and masked name application will be suspended until the full payment for the masked name application is received.*

Note: Payment for a Masked Name application can be made with any notification regardless of the Schedule being submitted, and it is only required to be paid once per substance per notifier. However, it is only necessary to ensure that payment for the Masked Name application is made, or has been made, when submitting what will be the final notification for a substance, that is, a Schedule II (where the substance is on the NDSL), a Schedule III, a Schedule VI (final), a Schedule VII or a Schedule VIII.

Multiple Services for Different Substances

If the submission clearly identifies the fees associated with each substance, only the services for which full payment was received will be rendered. Other services will be suspended until full payment is received.

***Example:** A submission contains separate notifications for substances A and B, an exact payment for one notification, and a fee form clearly indicating that the payment applies to substance A. The service for substance A will be rendered. The service for substance B will be suspended until the full payment is received.*

If one payment is sent for multiple services without clearly identifying the fees associated with each substance, all services will be suspended until full payment is received.

***Example:** A submission contains separate notifications for two different substances and a payment for only one notification. Since it is not clear that the payment applies to a specific notification, all services will be suspended until the full payment is received or until receipt of the fee form indicating to which notification the fees apply.*

Overpayment

If the payment exceeds the fee prescribed by the NSFR, the service will be rendered and the overpayment will be refunded. Overpayments will not be retained "on account" as deposits for future notifications or other services.

Withdrawn Service Requests

If the notifier withdraws a notification or other service request before any service has been rendered, a full refund will be issued. If the notifier withdraws its notification or other service and partial services have been rendered, a portion of the fee prescribed by the NSFR will be retained. If the notifier withdraws a notification but full services have already been rendered, no refund will be issued.

Unnecessary Services

If a notification is not required by the NSNR (e.g. if the substance is already listed on the DSL), the service will not be rendered and the submission will be returned to the notifier along with a full refund.

Previous Notifications Made Before January 1, 2003

"Subsequent" notification fees consist of the amount set out in the applicable schedule of the NSFR, less any amount previously paid for the assessment of that substance under any previous schedules. If the previous schedules were notified before January 1, 2003 when no fees were applicable, the notifier must pay the full amount for initial fees or final fees as prescribed in the NSFR for the subsequent notification.

However, to respect the intent of the regulations, previous notifications will be considered when determining refunds. When full payment is made for a notification and previous schedules were notified before January 1, 2003, the fees corresponding to the previously notified schedules will be refunded.

In these cases, refunds will only be issued upon written request from notifiers. To allow this type of refund, notifiers should clearly identify the New Substance Notification (NSN) numbers of any previous notifications on the current submission. The NSN number is a number assigned to a specific file/notification package in order to track it through the notification, assessment and post-assessment process.

Example: A submission contains a Schedule III notification and a payment of \$3,500, along with a request for a refund associated with previous Schedule 1 and Schedule 2 notifications that were made before January 1, 2003. A total of \$2,200 will be refunded, which corresponds to the fees for the previously notified schedules (\$200 for Schedule I and \$2,000 for Schedule II).

Notifications received prior to January 1, 2003 and for which prescribed information was missing are subject to the NSFR upon submission of missing information.

RELATED INFORMATION

- *New Substances Fees Regulations* www.ec.gc.ca/substances/nsb/eng/reg_e.htm
- *Financial Administration Act* <http://www.canlii.org/ca/sta/f-11/>
- *Repayment of Receipts Regulations, 1997* <http://www.canlii.org/ca/regu/sor98-127/whole.html>
- A Guide to the New Substances Fees Regulations for the notification of chemicals and polymers, and other services www.ec.gc.ca/substances/nsb/eng/gui_e.htm

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3.C. OPERATIONAL POLICY FOR EARLY TERMINATION OF ASSESSMENT PERIODS

PURPOSE

This document describes Environment Canada's operational policy for the early termination of assessment periods under the *Canadian Environmental Protection Act, 1999* (CEPA 1999) and the *New Substances Notification Regulations* (NSNR).

APPLICATION

This document applies to all New Substances Notifications.

CONTEXT

Under section 81 and section 106 of CEPA 1999, importers and manufacturers of new substances must provide prescribed information so that Environment Canada and Health Canada can assess the new substances to determine if they are "toxic" (in accordance with the criteria set out in section 64 of CEPA 1999) or capable of becoming "toxic." A substance is considered "new" if it is not listed on the Domestic Substances List (DSL). The notification requirements are established in the NSNR.

Import or manufacture of a new substance is not allowed until the period for assessment, as established in the NSNR, has expired. However, subsection 83(6) for chemicals and polymers, and subsection 108(6) for living organisms, of CEPA 1999 allows for assessments to be terminated at an earlier time. This means that import or manufacture of a substance may commence at that time.

OPERATIONAL POLICY

All new substances and Significant New Activity Notifications (SNAN's) are eligible for consideration for early termination if the evaluation is completed by Health Canada and Environment Canada prior to the end of the assessment period.

These provisions enable the program to take advantage of opportunities which could result in early completion of notifications (e.g. when the substance has already been assessed). Administrative procedures have been implemented to identify those notifications which have been completed early, thereby facilitating the application of the provisions to these files.

It should be noted that the program will not compromise the quality of its risk assessment or its ability to deal with other notifications in a timely fashion in order to apply an early termination to a notification.

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3.D. OPERATIONAL POLICY FOR MAINTAINING CONFIDENTIALITY OF SUBSTANCE IDENTITIES

PURPOSE

This document describes Environment Canada's operational policy for maintaining confidentiality of new substance identities under the *Masked Name Regulations* of the *Canadian Environmental Protection Act, 1999* (CEPA 1999).

APPLICATION

This policy applies to all new substances notifications.

CONTEXT

Under section 81 and section 106 of CEPA 1999, importers and manufacturers of new substances must provide prescribed information so that Environment Canada and Health Canada can assess the new substances to determine if they are “toxic” (in accordance with the criteria set out in section 64 of CEPA 1999) or capable of becoming “toxic.” A substance is considered “new” if it is not listed on the Domestic Substances List (DSL). The information requirements are established in the NSNR.

According to section 313 of CEPA 1999, a notifier who provides information to the Minister of the Environment may also submit a request for the substance to be identified with a masked name to prevent disclosure of the specific identity of the substance when it is listed on the DSL or the Non-Domestic Substances List (NDSL).

When a non-confidential substance is added to the public portion of the DSL or NDSL, the substance's specific identity is revealed through publication of its:

- Chemical Abstracts Service (CAS) Registry Number (chemicals, polymers, biochemicals and biopolymers);
- Culture Collection Number (living organisms) if applicable; or
- International Union of Biochemistry and Molecular Biology Number (enzymes).

If a substance identity confidentiality request is accepted, the substance is available for publication on the confidential portion of the DSL or NDSL using an appropriate masked name. Masked names must be developed in accordance with the criteria established in the *Masked Name Regulations*.

OPERATIONAL POLICY

Information Review

Environment Canada will review each request for a masked name to determine whether it is valid. Notifiers will be advised if their request is not accepted and given an opportunity to provide additional justification in support of their request. If the

supplementary information is not supplied or is not satisfactory, the request may be rejected, or alternatively, the company may choose to withdraw the notification.

If a request for a masked name is made for a substance that is already in the public domain, it will be rejected and the substance will be added to the public portion of the DSL or NDSL. Public commercial substances inventories include, but are not limited to, the United States Environmental Protection Agency Toxic Substances Control Act Inventory, the European Inventory of Existing Commercial Chemical Substances, and the Australian Inventory of Chemical Substances.

Identification of Masked Names

If a request for a masked name is valid, the masked name proposed by the notifier will be evaluated against the criteria in the *Masked Name Regulations*. If assessed to be consistent with these regulations, the masked name will be used in publications such as the DSL. If not, inconsistencies will be communicated to the notifier and an alternative name requested. Environment Canada will try to reach a consensus with the company on a masked name. If consensus is not reached, Environment Canada will publish a masked name that, in its opinion, will respect the confidentiality claim of the company while retaining the generic molecular structure of the substance. Alternatively, the company may choose to withdraw the notification.

Reversal of Substance Identity Confidentiality Claims

If a substance was listed on the confidential portion of the DSL or NDSL and Environment Canada learns that the identity of the substance was subsequently published on another public inventory, the substance will be transferred from the confidential portion to the public portion of the DSL or NDSL. The original notifier will be informed before this is done.

Use of Masked Names in Published Notices

When a request for a masked name has been accepted following the process stated above, the Department will use this masked name when and if there is publication of a new substance condition, prohibition, or significant new activity (SNAc) notice.

RELATED INFORMATION

- *Masked Name Regulations* www.ec.gc.ca/substances/nsb/eng/reg_e.htm

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4. RISK ASSESSMENTS

4.A OPERATIONAL POLICY FOR USING THIRD-PARTY INFORMATION

PURPOSE

This document describes Environment Canada's and Health Canada's operational policy for using third-party information (information from sources not associated with the notification) in assessments of new substances under the *Canadian Environmental Protection Act, 1999* (CEPA 1999) and the *New Substances Notification Regulations* (NSNR).

APPLICATION

This operational policy applies to all new substances notifications.

CONTEXT

Under section 81 and section 106 of CEPA 1999, importers and manufacturers of new substances must provide prescribed information so that Environment Canada and Health Canada can assess the new substances to determine if they are "toxic" (in accordance with the criteria set out in section 64 of CEPA 1999) or capable of becoming "toxic." A substance is considered "new" if it is not listed on the Domestic Substances List (DSL). The notification requirements are established in the NSNR.

Notification of new substances in Canada is a tiered system, with more detailed information required for notification of higher volumes of a substance. Third-party information can be useful in supplementing required information, thus helping to build a weight of evidence during assessments.

OPERATIONAL POLICY

Use of Third-Party Information

Program evaluators may use all available information when assessing a substance, including notified information as well as third-party information. Third-party information includes information from publicly available sources and information already in possession of the Program, such as data from other new substance notifications for similar substances. Third-party information is used to augment notified information and support assessment conclusions by building a weight of evidence. Third-party information is not used to relieve notifiers of their obligations to provide information under the Act and NSNR.

Third party information can support the validity of the notified data, or in cases where data is contradictory, it can help to determine the factors that may have influenced the test results. In some cases, third-party information (e.g. chronic studies) may be preferable over notified data (e.g. acute studies).

Example: When conducting an exposure assessment, evaluators use the notified information as well as third-party information, such as emission scenarios, monitoring data, and notified information for a substance with similar use and exposure patterns. Quantitative information from a third-party may be used to help determine a predicted environmental concentration. Third-party information may also be used to assist in identifying other possible uses of the substance or to support assumptions in the exposure assessment, such as typical volumes employed in an application.

Confidentiality of Third Party Information

If third party information is protected under the Disclosure of Information provisions of the Act, it will be removed from assessment reports prior to being released to the notifier or the public. Masked names will also be maintained. Refer to the *Operational Policy for Maintaining Confidentiality of Substances Identities* for more information.

RELATED INFORMATION

- *Operational Policy for Maintaining Confidentiality of Substances Identities*

Last updated: April 2004

5. RISK MANAGEMENT

5.A. OPERATIONAL POLICY FOR TAKING ACTION AFTER A RISK ASSESSMENT

PURPOSE

This document describes Environment Canada's options for action following new substances environmental and human health risk assessments under the *Canadian Environmental Protection Act, 1999* (CEPA 1999) and the *New Substances Notification Regulations* (NSNR).

APPLICATION

This document applies to all new substances notifications.

CONTEXT

Under section 81 and section 106 of CEPA 1999, importers and manufacturers of new substances must provide prescribed information so that Environment Canada and Health Canada can assess the new substances to determine if they are “toxic” (in accordance with the criteria set out in section 64 of CEPA 1999) or capable of becoming “toxic.” A substance is considered “new” if it is not listed on the Domestic Substances List (DSL). The information requirements are established in the NSNR. Following an assessment, the Minister of the Environment and the Minister of Health may take one of several possible actions under CEPA 1999.

OPERATIONAL POLICY

No Suspicion of Toxicity

If there is no suspicion of toxicity and the assessment period has expired, the Minister of the Environment will take no further action.

When a new substance becomes eligible for addition to the DSL, the Minister must add the substance to the DSL and, if it appears on the Non-Domestic Substances List (NDSL), delete it from that list, within 120 days. Refer to the *Operational Policy for Administering the DSL and NDSL* for more information.

Suspicion of Toxicity

If Environment Canada or Health Canada suspects that a substance is “toxic” or capable of becoming “toxic”, it may be managed through risk management measures to minimize any risk to human health, the environment, or biological diversity. The Minister of the Environment may¹:

¹ Under sections 84 of CEPA 1999 for chemicals, biochemicals, polymers, biopolymers or section 109 of CEPA 1999 for living organisms.

- (a) permit the manufacture or import of the substance subject to specified conditions;
- (b) prohibit the manufacture or import of the substance for a period not exceeding two years; or
- (c) prohibit the manufacture or import of the substance until supplementary information or test results have been submitted and assessed.

These measures must be undertaken before the expiration of the assessment period.

When a risk management measure (see above) is issued or altered, Environment Canada must publish a notice in the *Canada Gazette*, Part I describing the action and the substance to which it applies. The name of the notifier is not included in the notice. If the publication of the substance name would result in the release of confidential business information, a masked name will be published. Refer to the *Operational Policy for Maintaining Confidentiality of Substance Identities* for more information.

Prohibitions on substances expire two years after they are imposed unless proposed regulations to manage the substance are published in the *Canada Gazette*. In that case, the prohibition expires on the day the regulations come into force and the substance becomes eligible for addition to the DSL.

New Activity may Result in Suspicion of Toxicity

If there is no suspicion of toxicity, but the Minister suspects that a significant new activity (SNAc) in relation to the substance may result in the substance becoming “toxic”, the substance can be made subject to a SNAc notice. SNAc notices require notification of prescribed information so that Environment Canada and Health Canada can assess the substance in relation to the new activity to determine if it is “toxic” or capable of becoming “toxic”. Refer to the *Operational Policy for Issuing Significant New Activity Notices* for more information.

RELATED INFORMATION

- *Operational Policy for Administering the DSL and NDSL*
- *Operational Policy for Issuing Significant New Activity Notices*

Last updated: April 2004

5.B OPERATIONAL POLICY FOR ISSUING SIGNIFICANT NEW ACTIVITY NOTICES

PURPOSE

This document describes Environment Canada's operational policy for issuing significant new activity (SNAc) notices under the *Canadian Environmental Protection Act, 1999* (CEPA 1999).

APPLICATION

This document applies to new and existing substances.

CONTEXT

Under section 81 and section 106 of CEPA 1999, importers and manufacturers of new substances must provide prescribed information to Environment Canada and Health Canada so that the new substances can be assessed to determine if they are “toxic” (in accordance with the criteria set out in section 64 of CEPA 1999) or capable of becoming “toxic.” A substance is considered “new” if it is not listed on the Domestic Substances List (DSL). The notification requirements are established in the *New Substances Notification Regulations* (NSNR).

A new substance assessment looks at the potential risks for other possible activities involving the substance. If there is a suspicion that a significant new activity may result in the substance becoming “toxic”, CEPA 1999 allows the Minister of the Environment to issue a SNAc notice. A SNAc is an alternative use or other activity that results or may result in:

- a significantly greater quantity or concentration of the substance in the environment; or
- a significantly different manner or circumstances of exposure to the substance.

If there is no suspicion of toxicity, but there is a suspicion that a significant new activity (SNAc) in relation to the substance may result in the substance becoming “toxic”, the substance can be subject to a SNAc notice (section 85 and section 110 of CEPA 1999). A SNAc notice communicates the criteria under which a notification will be required.

A SNAc notice defines:

- the significant new activity by inclusion (e.g. listing the new activity) or exclusion (e.g. anything other than a certain activity);
- information that must be notified;
- timelines for providing the information; and
- period for assessing the information.

If a new substance is not yet listed on the DSL, a SNAc notice is issued to the notifier and also applies to users of the substance. If a new substance has been listed on the DSL with a SNAc flag, the SNAc flag definition applies to all importers, manufacturers and users.

OPERATIONAL POLICY

SNAC Decision Process for New Substances

Following receipt of a new substance notification, an assessment of the current or proposed activities as well as other possible activities is conducted. If a risk *is* identified, a conclusion of “suspicion of toxicity” will be made and risk management measures may be taken under section 84 (chemicals, polymers, biochemicals, and biopolymers) or section 109 (living organisms) of CEPA 1999. Refer to the *Operational Policy for Taking Action After an Assessment* for more information.

Under subsection 85(1) of CEPA 1999, SNAC provisions may be applied when the Ministers of the Environment and of Health “*suspect that a significant new activity in relation to the substance may result in the substance becoming toxic.*” This also applies to living organisms under subsection 110(1) of CEPA 1999.

The decision to use these provisions is based on the potential for other activities to occur that could change the exposure scenario sufficiently to necessitate additional information and assessment to determine a suspicion of toxicity. Environment Canada will inform the notifier, prior to the end of the assessment period, of the intent to publish a SNAC notice. The notifier will be able to import or manufacture the substance as established in the SNAC notice but is still responsible, if necessary, for notifying under subsequent schedules of the NSNR for that new substance.

If the assessment of other possible activities does not indicate a risk, then no further action is taken on the substance at this time (i.e. no SNAC Notice is needed). In this case, a SNAC could be modified or rescinded. The notifier will be able to import or manufacture the substance without restriction under the new substances program, but is still responsible for notifying under subsequent schedules of the NSNR for that new substance until the substance is added to the DSL.. In the case of a new substance, if a risk is identified for other possible activities, a conclusion of “suspicion of toxicity” will be made and risk management measures will be taken under section 84 or 109 of CEPA 1999.

Publication of SNAC Notices

New Substances

SNAC notices are published in the *Canada Gazette*, Part I within 90 days after the expiry of the assessment period. Although there is no formal comment period prior to or after the publication of the SNAC notice, a notifier may submit, at any time, information that could have a bearing on the notice. Environment Canada and Health Canada will review this information and take appropriate action if required.

Once a substance, which has been subject to a SNAC notice, is eligible for addition to the DSL, the substance is published in the *Canada Gazette*, Part II with an “S” flag indicating that a SNAC notice has been issued for that substance.

RELATED INFORMATION

- *Operational Policy for Taking Action After an Assessment*

Last updated: April 2004

6. *ACRONYMS*

6. ACRONYMS

CBI	Confidential Business Information
CEPA 1999	<i>Canadian Environmental Protection Act, 1999</i>
DSL	Domestic Substances List
NDSL	Non-Domestic Substances List
NSFR	<i>New Substances Fees Regulations</i>
NSN	New substance notification
NSNR	<i>New Substances Notification Regulations</i>
SNAc	Significant new activity
TSCA	<i>Toxic Substances Control Act (USEPA)</i>
USEPA	United States Environmental Protection Agency

7. CONTACTS

7. CONTACTS

For further information on the notification of new substances contact:

New Substances Branch
Environment Canada

Tel.: (800) 567-1999 (toll-free within Canada)
(819) 953-7156 (outside Canada)

Fax: (819) 953-7155

Or visit the following websites:

- Environment Canada New Substances – www.ec.gc.ca/substances/
- CEPA Registry – www.ec.gc.ca/CEPARegistry/
- Health Canada New Substances – www.hc-sc.gc.ca/hecs-sesc/nsac/index.htm