



Government  
of Canada

Gouvernement  
du Canada

**New**  
**Substances**

# Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers

Pursuant to Section 69 of the  
*Canadian Environmental Protection Act, 1999*

Version  
**2005**

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Canada

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# Contact Information for the New Substances Program

## Comments and Inquiries

Comments regarding the *New Substances Notification Regulations (Chemicals and Polymers)* (the Regulations) as well as technical questions or requests for additional information on procedures for New Substances Notification (NSN) packages or on the status of submitted NSN packages should be directed to:

New Substances Notification Information Line  
New Substances Division  
Science and Technology Branch  
Environment Canada  
14<sup>th</sup> Floor, Place Vincent Massey  
Gatineau QC K1A 0H3

Telephone: 1-800-567-1999 (toll-free in Canada)  
819-953-7156 (outside Canada)

Facsimile: 819-953-7155

E-mail: NSN-info@ec.gc.ca

Individuals may also visit the New Substances (NS) program web site at: [www.ec.gc.ca/substances/](http://www.ec.gc.ca/substances/) or the CEPA Environmental Registry online at: [www.ec.gc.ca/CEPARRegistry/](http://www.ec.gc.ca/CEPARRegistry/)

## NSN Reporting Forms and Guidelines

Copies of the NSN reporting forms (Appendix 2 of these Guidelines) may be obtained electronically from the NS program web site indicated above or by contacting the NSN Information Line or one of the regional offices (Appendix 11 of these Guidelines). NSN reporting forms may be reproduced without permission.

Additional copies of the Guidelines may be obtained electronically from the NS program web site indicated above or, for a fee, from Environment Canada by contacting:

Communications Services – Publications  
Environment Canada  
Ottawa, Ontario K1A 0H3

Telephone: 1-800-734-3232 (toll free within North America)  
819-953-5750 (outside North America)

Facsimile: 819-994-5629

E-mail: epspubs@ec.gc.ca

## **Cette publication est aussi disponible en français. Pour l'obtenir, s'adresser à :**

Services des communications – Publications  
Environnement Canada  
Ottawa, Ontario  
K1A 0H3

Although care has been taken to ensure that these Guidelines accurately reflect requirements prescribed in the *Canadian Environmental Protection Act, 1999* (the Act) and the *New Substances Notification Regulations (Chemicals and Polymers)* (the Regulations), notifiers are advised that should any inconsistencies be found, the Act and the Regulations will prevail.

# Abstract

This document has been prepared to assist notifiers responsible for complying with the *New Substances Notification Regulations (Chemicals and Polymers)* (the Regulations) of the *Canadian Environmental Protection Act, 1999* (the Act).

These Guidelines are meant to help notifiers determine whether a substance is subject to notification under the Regulations and identify the information requirements. In addition, these Guidelines provide step-by-step instructions for the completion of a New Substances Notification (NSN) package; user-friendly flow charts to aid in determining the appropriate Schedule to file (see Appendix 1 of these Guidelines); elaborate technical considerations of the information requirements; detailed instructions on how to complete the NSN reporting form; identification of appropriate test procedures and practices to use; and an outline of how confidential information should be submitted. These Guidelines conclude with an explanation of how the New Substances (NS) program assesses the information submitted in an NSN package and the implications of the assessment decisions for notifiers.

## Résumé

Le présent document a été préparé pour aider les administrés à observer le *Règlement sur les renseignements concernant les substances nouvelles (substances chimiques et polymères)* (le Règlement) de la *Loi canadienne sur la protection de l'environnement (1999)* (la Loi).

Les directives ont été développées pour aider les déclarants à établir si une substance doit être déclarée en vertu du Règlement, ainsi qu'à identifier les exigences en matière de renseignements. Elles renferment aussi des instructions étape par étape pour compléter un dossier de Déclaration de substance nouvelle (DSN), des diagrammes de décision faciles à consulter, destinés à faciliter le choix de l'annexe appropriée (voir l'Appendice 1 ci-dessous), des précisions techniques élaborées sur les exigences en matière de renseignements, des instructions détaillées sur la façon de remplir le formulaire de déclaration, des informations permettant de choisir les processus et les méthodes d'essai appropriés, ainsi qu'un aperçu du mode de présentation des renseignements confidentiels. Finalement, on explique comment les responsables du Programme des substances nouvelles (SN) évaluent les renseignements fournis dans le dossier de DSN, ainsi que les tenants et aboutissants des décisions d'évaluation pour les déclarants.

Publié aussi en français sous le titre : Directives pour la déclaration et les essais de substances nouvelles : substances chimiques et polymères. En application de l'article 69 de la *Loi canadienne sur la protection de l'environnement (1999)*.

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# How to Use these Guidelines

These Guidelines have been prepared for the benefit of notifiers responsible for complying with the provisions of the *New Substances Notification Regulations (Chemicals and Polymers)* (the Regulations) of the *Canadian Environmental Protection Act, 1999* (the Act). A sequential review of the sections will allow the reader to focus on requirements specific to his or her circumstances. The key to avoiding unnecessary delays or expenses when preparing an NSN package is to thoroughly understand the New Substances (NS) program.

## These Guidelines are organized into 10 sections:

- 1) **Introduction and Overview** — explains the purpose, statutory powers and features of the NS program.
- 2) **The Inventories** — explains the Domestic Substances List (DSL) and the Non-domestic Substances List (NDSL), how these are amended and how to locate a substance specified on them.
- 3) **Substances** — helps to determine whether the substance to be manufactured, imported or used must be notified; provides definitions of special categories, substances not subject to notification and substances subject to notification.
- 4) **Notification Information Requirements** — if the substance is subject to notification, this section helps identify the appropriate Schedule to be provided and determine when the NSN package must be provided to the Minister or in the case of this Guideline the NS program (the Minister and the NS program is used interchangeably throughout this Guideline).
- 5) **New Substances Notification (NSN) Packages** — provides instructions for completing the information required for an NSN package.
- 6) **The New Substances Notification (NSN) Reporting Form** — describes the process to complete the NSN reporting form and the meaning and intent of each information requirement; also elaborates when data requirements are not required.
- 7) **Confidential Information** — describes issues pertaining to confidential business information, such as confidentiality claims, masking of substance identities and determining the presence of confidential substances listed on the DSL and NDSL.
- 8) **Recommended Test Protocols and Alternative Approaches** — provides guidance on acceptable test methods and “alternative” information and describes features of subsection 81(8) of the Act, which provides for the waiver of information requirements when one of several criteria is met. The NS program provides the opportunity for notifiers to submit a Pre-notification Consultation (PNC) submission (see section 8.8 of these Guidelines) to resolve notification issues while the NSN package is being prepared.
- 9) **Processing a New Substances Notification** — explains what happens after an NSN package is received, including how the NSN package is processed and reviewed and the types of correspondence that could be issued by the NS program.
- 10) **Post-notification Responsibilities** — reviews obligations of notifiers and the NS program after an NSN package has been submitted.

Further clarification and updates on any topic covered by these Guidelines can be obtained from the NS program web site at [www.ec.gc.ca/substances/](http://www.ec.gc.ca/substances/) or by contacting the NSN Information Line by telephone at 1-800-567-1999 (within Canada) or 819-953-7156 (outside Canada), by facsimile at 819-953-7155 or by e-mail: [NSN-infoline@ec.gc.ca](mailto:NSN-infoline@ec.gc.ca).



# SECTION 1 — Introduction and Overview

## 1.1 Purpose of these Guidelines

These Guidelines provide assistance for complying with the *New Substances Notification Regulations (Chemicals and Polymers)* (the Regulations). They explain the information that a “person”<sup>1</sup> manufacturing or importing a new substance into Canada (the notifier) must provide to the Minister of the Environment (the NS program) under subsection 81(1) of the *Canadian Environmental Protection Act, 1999* (the Act) before manufacturing or importing a chemical/biochemical<sup>2</sup> or polymer/biopolymer<sup>3</sup> that is not on the Domestic Substances List (DSL)<sup>4</sup>. This information is required so that the NS program may determine whether the substance is toxic or capable of becoming toxic within the meaning of section 64 of the Act. These Guidelines also discuss the obligations of the Minister of the Environment and the Minister of Health respecting assessment periods and those of the Minister of the Environment to add a chemical or polymer to the DSL under section 87 of the Act.

Please note that these Guidelines do not address the *New Substances Notification Regulations (Organisms)*. Information pertaining to these can be found in the Guidelines for the Notification and Testing of New Substances: Organisms.

The New Substances (NS) program consists of officials from both Environment Canada and Health Canada. Each department conducts an assessment of the information provided to the Minister of the Environment in the New Substances Notification (NSN) package.

## 1.2 The *Canadian Environmental Protection Act, 1999*

The Act is a statute about sustainable development and pollution prevention. These purposes are achieved or furthered through many mechanisms, among them the new substances notification regime, a regime requiring that the Ministers of the Environment and of Health must assess substances that are not on the DSL in order to determine whether they should be subject to risk management measures. The assessment is based on the criteria set out in section 64 of the Act.

## 1.3 Overview of the New Substances Provisions under the Act

Notification is required if the substance proposed for manufacture or import is subject to sections 80–89 of the Act. Substances that require notification are:

- a) substances new to Canada (e.g. those not on the DSL);
- b) substances undertaking a significant new activity that are listed on the DSL with an “S” or “S’ ” flag (see section 2.1.4 of these Guidelines);
- c) polymers being manufactured or imported that do not meet the conditions of a Reduced Regulatory Requirement (RRR) polymer (see section 3.4.1.3 of these Guidelines) that are listed on the DSL with a “P” flag (see section 2.1.4.1 of these Guidelines); and
- d) substances regulated under any other Act of Parliament or regulations not listed on Schedule 2 to the Act (e.g. substances regulated under the *Food and Drugs Act* (F&DA)) and for which a) applies.

<sup>1</sup> The term “person” includes legal and natural persons.

<sup>2</sup> When the term chemical(s) is used in these Guidelines, it refers to both chemicals and biochemicals.

<sup>3</sup> When the term polymer(s) is used in these Guidelines, it refers to both polymers and biopolymers.

<sup>4</sup> The term Domestic Substances List (DSL) is used inclusively in these Guidelines to specify substances listed on either the public or confidential portions of the inventory.

## 1.0 Introduction and Overview

### 1.3 Overview of the New Substances Provisions under the Act

The Act features a number of provisions, including criteria for identifying substances requiring notification; notification obligations for manufacturers and importers; a detailed assessment mechanism; and enabling authorities for the implementation of risk management measures.

In the Act, the approach to the management of new substances is both proactive and preventative, employing a pre-manufacture or pre-import notification and assessment process. When this process identifies a new substance that may pose a risk to human health or the environment, the Act empowers the Government to intervene prior to or during the earliest stages of its introduction to Canada. This ability to act early makes the NS program a unique and essential component of the federal management of toxic substances.

The Regulations specify the information that must be provided to meet the notification obligations. The main regulatory features of the NS program are:

- establishment of categories of substances;
- identification of administrative and other information requirements;
- specification of conditions, test procedures and laboratory practices to be followed when developing test data;
- timing of notification before manufacture or import or a significant new activity that is defined in a Significant New Activity (SNAc) Notice; and
- requirements for the NS program to assess information within a set time.

To meet the need for evaluating different categories of substances, information requirements are determined by separating substances into categories and notification groups. Substances are first generically categorized by substance type (*e.g.* chemicals and polymers), and then each substance type is further separated into notification groups based on factors such as volume of manufacture or import or proposed use (*e.g.* research and development). This system of notification groups allows the NS program to match information requirements with anticipated concerns about quantities and characteristics of specific groups of substances.

The assessment process begins when the NS program receives an NSN package for a new substance proposed to be manufactured or imported. NSN packages must contain all required administrative and technical information prescribed in the Regulations, including the appropriate fee (if applicable), and must be provided to the NS program prior to the number of calendar days prescribed for the assessment of the notified Schedule and in advance of the prescribed trigger quantity for the same Schedule being exceeded.

Significant New Activity Notifications (SNANs) must contain all prescribed information specified in the SNAc Notice and must be provided within the prescribed time and prior to undertaking a significant new activity.

Environmental and human health assessments are conducted on the information provided and any other information that is available to the NS program to determine whether the substance is suspected of being toxic or capable of being toxic (see section 9.4.2 of these Guidelines). This assessment is required to be completed within the prescribed assessment period and may result in any of the following:

- a) a determination that the substance is not suspected of being toxic or capable of becoming toxic;
- b) a suspicion that the substance is toxic or capable of becoming toxic, which may require:
  - i) the establishment of controls on the manufacture import, use or disposal of the substance;
  - ii) prohibition of manufacture and import of the substance; or
  - iii) prohibition pending submission and assessment of additional information determined to be required by the NS program; or
- c) a suspicion that a significant new activity in relation to the substance may result in the substance becoming toxic. In such instances, a SNAc Notice will be issued for the substance.

## 1.4 Who Is Required to Notify?

Under the Regulations and Section 81 of the Act, any “person” manufacturing a new substance in or importing a new substance into Canada (notifier) must provide an NSN package to the NS program. This NSN package must contain all information specified in the Regulations.

### 1.4.1 Transfer of Notification Status — Interpretation of “Person”

Subsection 81(5) of the Act provides a rule of succession in the case of the transfer of certain rights in respect to substances subject to section 81 of the Act.

Successors to which subsection 81(5) applies are requested to sign a Certification Form prior to change of ownership if they wish to take advantage of the current notification status of a substance. This form indicates the transfer of rights or privileges, in relation to information provided for the substance, from the original notifier to the successor. The transfer of rights or privileges includes the responsibility of any risk management actions taken or SNAc Notices issued on the substance. This form can be obtained by contacting the NSN Information Line. The Certification Form must be signed by an officer of the successor and must be completed for each NSN package to which the change of ownership applies.

This provision reduces duplication of work for industry as well as the NS program, since it allows successors to continue manufacturing or importing a new substance without having to “renotify” and wait for the assessment period to expire. ([www.ec.gc.ca/substances/nsb/eng/advisory\\_e.htm](http://www.ec.gc.ca/substances/nsb/eng/advisory_e.htm)).

### 1.4.2 Canadian Agent — Subsection 14(3) of the Regulations

If the notifier providing the NSN package is not a Canadian resident they must identify, under paragraph 14(1)(b) of the Regulations a Canadian resident who is authorized to act on their behalf as the “Canadian Agent”. All notices and correspondence from the NS program will be sent to the “Canadian Agent” and he or she will be required to keep the information and any supporting data for a period of five years as per section 13 of the Regulations.

As an example, a notifier who is not a Canadian resident but, for the substance being imported, possesses “Canadian Importer Status” and is listed as the “Importer of Record” on the Canadian Customs coding form (Form B3-3) as issued by the Canada Border Services Agency, must identify a person resident in Canada who is authorized to act on their behalf as the “Canadian Agent”.

### 1.4.3 Toll Manufacturer

Toll manufacturing occurs when a company contracts a manufacturer to process its raw materials and create a new substance. Ownership of the raw materials and resulting substance remains with the contracting company throughout the activity. For new substances that are manufactured on toll, the contracting company is: designated as the notifier; is responsible for complying with the Regulations; and must submit the appropriate NSN package corresponding to the quantities of the substance being manufactured. The notifier is also required to provide the information indicated in section 6.2.1.6 of these Guidelines and all required information on the manufacturing facility as described in section 6.6.1 of these Guidelines.

By signing the certification statement (block A.1) on the NSN reporting form, the notifier accepts all other compliance responsibilities, including filing any subsequent schedules that may be required and providing the appropriate fee. Furthermore, if any risk management actions are taken as a result of the NSN review, the notifier must inform the toll manufacturer of these actions and the toll manufacturer will be responsible for complying with these risk management actions, if necessary.

## 1.5 When to Submit an NSN Package to the NS Program

The timing of an NSN package depends on the Schedule of information required, the time needed by the notifier to develop the information specific to the Schedule and when the trigger quantity specified by the Schedule is likely to be exceeded.

### 1.5.1 New Substances Notification Assessment Periods

Assessment periods range from 5 to 75 calendar days, depending on the type and amount of substance being manufactured or imported (see section 4 of these Guidelines). NSN packages must be provided prior to the number of calendar days prescribed and in advance of the prescribed trigger quantity being exceeded. These are shown in Table 1-1.

**Table 1-1 Schedule Numbers, Assessment Periods and Quantities Triggering the Requirement for New Substances Notification for Chemicals and Polymers**

Schedule <sup>a</sup>	Explanation	Time (days)	Annual quantities (kg)
<b>Chemicals</b>			
1	Special category <sup>b</sup> chemicals — NDSL <sup>c</sup> and not on NDSL	30	1 000
	Update of information	30	10 000
4	Not on NDSL	5	100
4	NDSL	30	1 000
5	Not on NDSL	60	1 000
5	NDSL	60	10 000
	NDSL — high release/exposure <sup>d</sup>	75	50 000
6	Not on NDSL	75	10 000
<b>Polymers</b>			
3	Special category <sup>b</sup> polymers — NDSL and not on NDSL	30	10 000
9	All polymers	30	1 000
10	Non-RRR polymers <sup>e</sup> either on NDSL or all reactants on DSL/NDSL	60	10 000
	Non-RRR polymers <sup>e</sup> either on NDSL or all reactants on DSL/NDSL — high release/exposure <sup>e</sup>	60	50 000
11	Non-RRR polymers <sup>e</sup> not on NDSL and not all reactants on DSL/NDSL	60	10 000

<sup>a</sup> Additional information is required from Schedule 2 if the substance is a biochemical or biopolymer for all notified substances (see sections 4.2 through 4.9 of these Guidelines).

<sup>b</sup> Special categories include research and development, contained site-limited intermediate and contained export-only substances (see section 4.2 of these Guidelines).

<sup>c</sup> NDSL — Non-domestic Substances List.

<sup>d</sup> There may be an additional assessment period for those substances that exceed 50 000 kg/year if they meet one of the following criteria: releases anticipated to exceed 3 kg/day into the aquatic environment after wastewater treatment; or significant public exposure (see section 4.4.3 or 4.9.2 of these Guidelines). If these criteria are not met, then Schedule 5 or 10 is the final requirement.

<sup>e</sup> Non-RRR polymers — Non-reduced Regulatory Requirement Polymers (see section 3.4.1.4 of these Guidelines).

### 1.5.2 New Substances Notification Fees

The *New Substances Fees Regulations* (NSFR) were developed to incorporate service fees; these fees must be provided with each NSN package submitted under the Regulations. The amount of fees required is dependent on the annual sales in Canada for the notifier, the specific Schedule being submitted and other services being requested (e.g. confidential search on the DSL or Non-domestic Substances List [NDSL] or masked name application). A fee schedule, for different levels of service, is provided in Appendix 3 of these Guidelines. Additional information can also be found in the NSFR and the *Regulations Amending the New Substances Fees Regulations*. Table 1-2 shows the maximum amount payable for each Schedule, excluding any other services.

Table 1-2: Maximum New Substances Notification Fees

Schedule (chemicals)	Maximum fee required with notification <sup>a</sup>	Schedule (polymers)	Maximum fee required with notification <sup>a</sup>
1	\$2000	3	\$2000
4	\$200	9	\$1500
5	\$3000	10	\$3500
6	\$3500	11	\$3500

<sup>a</sup> See Appendix 3 for fee reductions, graduated fees and other service fees.

### 1.5.3 Substances Not Subject to the Notification Fees

In general, all substances subject to the Regulations require fees. However, at this time, the NSFR do not apply to biochemicals, biopolymers, research and development substances and substances that are regulated under any other Act of Parliament (*e.g.* F&DA).

The fees also do not apply to SNANs (see sections 1.3 and 9.5.2 of these Guidelines) or to the submission of additional information required for special category Schedule 1 notifications (at 10 000 kg/yr) and for high release to the aquatic environment or significant public exposure to the substance (at 50 000 kg/yr) (see sections 4.2.2, 4.4.3 and 4.9.2 of these Guidelines, respectively).

## 1.6 Enforcement

For information on the enforcement of the Act and the Regulations notifiers should consult The Compliance and Enforcement Policy ([www.ec.gc.ca/ele-ale/default.asp?lang=En&n=462A94EB-1](http://www.ec.gc.ca/ele-ale/default.asp?lang=En&n=462A94EB-1)). This policy was established to ensure that the Act is applied throughout Canada in a manner that is fair, predictable and consistent.





## SECTION 2 — The Inventories

### 2.1 Role of the Domestic Substances List (DSL)

#### 2.1.1 The DSL — Definition of a “New” Substance

The DSL is a comprehensive compilation of all known substances that have been or continue to be in Canadian commerce. The DSL is the sole basis for determining whether a substance is new for the purposes of the Act and the Regulations. Substances are added to the DSL using a unique substance identifier (*e.g.* Chemical Abstracts Service [CAS] registry number, Enzyme Commission number).

Substances listed on the DSL do not require notification unless they are subject to a SNAc Notice, as indicated by the “S” or “S’” flag (see section 2.1.4.1 of these Guidelines), or they no longer qualify as an RRR polymer (see section 3.4.1.3 of these Guidelines), as indicated by the “P” flag (see section 2.1.4.1 of these Guidelines). The DSL includes the original list, published in the *Canada Gazette*, Part II, on May 4, 1994; and all additions or deletions subsequently published in the *Canada Gazette*, Part II.

#### 2.1.2 Confidential Portion of the DSL

A notifier may request that the substance they are notifying be added to the confidential portion of the DSL using a masked name submitted under the *Masked Name Regulations*. Substances eligible for addition on the confidential portion of the DSL are assigned a confidential DSL Accession Number even when a CAS registry number is available. This accession number will be provided to the notifier by the NS program only once the substance is eligible for addition on the DSL. Then, the confidential DSL Accession Number and acceptable masked name for the substance will be published in the *Canada Gazette*, Part II. Substances listed on the confidential portion of the DSL are treated the same as substances listed on the public portion of the DSL.

The NS program conducts a search for all substances that have been notified as confidential to verify whether these substances are on any public chemical inventory, such as the United States Environmental Protection Agency’s (USEPA) *Toxic Substances Control Act* (TSCA) Chemical Substances Inventory, the Australian Inventory of Chemical Substances (AICS), the Korean Existing Chemicals List (ECL) and the European Inventory of Existing Commercial Substances (EINECS). If the substance is listed on any one of these public inventories, the notifier will be informed of this fact and will be required to provide, within 20 calendar days, further justification for their request for confidentiality (see section 2.1.2.1 of these Guidelines). If the supporting documentation is deemed to be inadequate, the notifier will be informed that the NS program intends to publish the appropriate CAS registry number (see section 6.2.2.1 of these Guidelines) on the DSL. The notifier will have the opportunity to appeal this decision before the information is published.

##### 2.1.2.1 Justification for Masking a Substance that is Listed on a Public Inventory

If the NS program finds that the substance is listed on at least one public inventory in the world, such as the ones mentioned above, the notifier will be asked to provide a written justification, setting out a reason that the information should be treated as confidential. This information should provide substantive detail and be based on the following criteria:

- the information constitutes a trade secret;
- financial, commercial, scientific or technical information that is confidential information supplied to the NS program by the notifier and is treated consistently in a confidential manner by the notifier;
- disclosure of the information could reasonably be expected to result in material financial loss or gain to, or could reasonably be expected to prejudice the competitive position of the notifier; or
- disclosure of the information could reasonably be expected to interfere with contractual or other negotiations of the notifier.

## 2.0 The Inventories

## 2.1 Role of the Domestic Substances List (DSL)

The information to be provided for one of these claims must include the required information laid out in section 7.2.2 of these Guidelines for claiming a substance confidential.

Subsection 315(1) of the Act states that the Minister may, however, disclose information where:

- a) the disclosure is in the interest of public health, public safety or the protection of the environment; and
- b) the public interest in the disclosure clearly outweighs in importance:
  - i) any material financial loss or prejudice to the competitive position of the person who provided the information or on whose behalf it was provided, and
  - ii) any damage to the privacy, reputation or human dignity of any individual that may result from the disclosure.

### 2.1.3 Amendments to the DSL

As a result of statutory requirements, the DSL is amended from time to time for the following reasons:

- a) nomination of a substance to the DSL that were manufactured in or imported into Canada between January 1, 1984, and December 31, 1986 (subsection 66(1) of the Act); or
- b) all prescribed information has been received under section 81 of the Act; an assessment has determined that no risk management measures should be imposed; and the manufacture or import has commenced after the most comprehensive NSN package was assessed or the prescribed volumes have been exceeded (section 87 of the Act).

Updates to the DSL are published in the *Canada Gazette*, Part II, within 120 days following the determination that a substance is eligible. Amendments may also be made to correct printing or eligibility errors.

Amendments to the DSL are published in the *Canada Gazette*, Part II, approximately every six to eight weeks.

Eligibility requirements are described in detail in section 10 of these Guidelines.

### 2.1.4 DSL Flags

The DSL contains five different flags for substances, however, depending on different situations some flags can be combined together (*e.g.* T-S, N-S, T-P, N-P, T-P-S, etc.). Some of the flags are used for governmental tracking purposes, and others are used to indicate to notifiers that additional notification requirements may be necessary for the substance being manufactured or imported. The onus is on the notifier to search for flags and for any regulations that may be imposed on a substance to determine if additional notification requirements are necessary. The notifier may also contact the NSN Information Line (see Comments and Inquiries Section of these Guidelines) to determine if additional notification requirements are necessary.

#### 2.1.4.1 Regulatory Flags

The following three regulatory flags indicate to notifiers that additional notification requirements may be necessary prior to manufacturing or importing a specific substance:

- **The “S” flag:** The letter “S” after a substance identifier indicates that the substance is subject to subsection 81(3) of the Act. This flag is used for a substance that was assessed under section 83 of the Act, and the assessment concluded that a significant new activity, in relation to the substance, may result in the substance becoming toxic according to the Act. The substance is therefore subject to a SNAC Notice under subsection 85(1) of the Act.
- **The “S’ (prime)” flag:** The letter “S’ ” after a substance identifier indicates that the substance is subject to subsection 81(3) of the Act. This flag is used for a substance that was already listed on the DSL, but was subsequently assessed, and the assessment concluded that a significant new activity, in relation to the substance, may result in the substance becoming toxic according to the Act. The substance therefore had not previously been subject to a SNAC Notice under subsection 85(1) of the Act.

The purpose of the “S” and “S’” flags is to indicate that relevant information respecting the flagged substance must be notified if the substance is proposed for a significant new activity that is defined in the SNAc Notice which was published in the *Canada Gazette*, Part I. Anyone proposing a new activity must provide the prescribed information in the prescribed time prior to the commencement of the proposed new activity. This new information will permit the NS program to assess the environmental and human health risks associated with the new activities, modify the notices or implement risk management measures, if deemed necessary (see section 9.5.2 of these Guidelines).

- **The “P” flag:** The letter “P” after a substance identifier indicates that the substance, which was subject to subsection 81(1) or 81(2) of the Act, was assessed and added to the DSL on the basis that it met the RRR polymer criteria (see section 3.4.1.3 of these Guidelines) and that there was no suspicion of toxicity with this form of the substance.

The purpose of the “P” flag is to indicate that relevant information respecting the flagged polymer must be renotified if anyone, including the original notifier, manufactures or imports the polymer, in Canada, in a form that no longer meets the RRR polymer criteria.

In the case where the NS program assesses the renotified substance and concludes that there is no suspicion of toxicity for the non-RRR polymer and it is again eligible for the DSL, the DSL will be updated accordingly, and the “P” flag will be repealed. In the case where the NS program assesses the non-RRR form of the polymer and concludes that there is a suspicion of toxicity, appropriate risk management measures will be imposed.

#### 2.1.4.2 Administrative Flags

The following two administrative flags are used by the NS program to track the number of substances added to the DSL under specific scenarios:

- **The “T” flag:** The letter “T” after a substance identifier indicates that the substance was manufactured or imported during the transitional period (*e.g.* between January 1, 1987, and July 1, 1994) and the prescribed information was provided to and assessed by the NS program in accordance with subsection 81(2) and section 83 of the Act, respectively. The assessment concluded that there was no suspicion of toxicity in relation to the substance and it was subsequently added to the DSL.
- **The “N” flag:** The letter “N” after a substance identifier indicates that the substance was manufactured or imported after July 1, 1994, and the prescribed information was provided to and assessed by the Minister in accordance with subsection 81(1) and section 83 of the Act, respectively. The assessment concluded that there was no suspicion of toxicity in relation to the substance, and it was subsequently added to the DSL.

When there is no flag associated with a substance that is listed on the DSL, the substance was added to the list via a nomination of the substance under section 66 of the Act (see section 2.1.3 of these Guidelines).

## 2.2 Role of the Non-domestic Substances List (NDSL)

### 2.2.1 The NDSL

The NDSL<sup>5</sup> is an inventory of substances that are not on the DSL but are accepted as being in use internationally. The NDSL is based on the USEPA’s TSCA Chemical Substances Inventory. Substances that are not on the DSL but are listed on the NDSL are subject to the Regulations. However, they are subject to fewer information requirements.

<sup>5</sup> The term Non-domestic Substances List (NDSL) is used inclusively in these Guidelines to specify substances listed on either the public or confidential portions of the inventory.

### 2.2.2 Confidential Portion of the NDSL

A notifier may request that the substance they are notifying be added to the confidential portion of the NDSL using a masked name submitted under the *Masked Name Regulations*. Substances eligible for addition on the confidential portion of the NDSL (see section 2.2.3.2 of these Guidelines) are assigned a confidential NDSL Accession Number, even when a CAS registry number is available. This accession number will be provided to the notifier by the NS program only once the substance is eligible for addition on the NDSL. Then, the confidential NDSL Accession Number and acceptable masked name for the substance will be published in the *Canada Gazette*, Part I. Substances listed on the confidential portion of the NDSL, are treated the same as substances listed on the public portion of the NDSL and as such are subject to fewer information requirements. The confidential NDSL Accession Number should be used to identify the substance for all future notification purposes.

The NS program conducts a search for all substances that have been notified as confidential to verify whether these substances are on any public chemical inventory. If the substance is found to be listed on the public TSCA inventory, the masked name and confidentiality request will be rejected, and the full name and appropriate CAS registry number (see section 6.2.2.1 of these Guidelines) will be published on the NDSL. If the substance is located on any other public inventory in the world but is not located on the public TSCA inventory and if the masked name is acceptable, the confidentiality request will be accepted.

### 2.2.3 Amendments to the NDSL

As a result of statutory requirements, the NDSL is amended from time to time for the following reasons:

- a) annual updates based on the USEPA TSCA inventory;
- b) nomination of a substance to the NDSL or confidential portion of the NDSL through submission of a Domestic Substances List Reporting Form C (Form C);
- c) applications under the Four Corners Arrangement (4CA) ([www.ec.gc.ca/substances/nsb/eng/ip\\_e.htm](http://www.ec.gc.ca/substances/nsb/eng/ip_e.htm)); and
- d) DSL amendments (substances are deleted from the NDSL when they are added to the DSL).

Amendments may also be made to correct printing or eligibility errors. Amendments to the NDSL are published in the *Canada Gazette*, Part I, each time there is an amendment to the DSL published in the *Canada Gazette*, Part II. Amendments to the NDSL, based on the USEPA TSCA inventory, are published in the *Canada Gazette*, Part I bi-annually. Amendments to the NDSL due to nominations or applications under the 4CA are published in the *Canada Gazette*, Part I, two to three times per year under subsection 66(2) of the Act. There are no deadlines for publishing substances that become eligible for the NDSL through the annual update, the 4CA or submittal of a Form C.

#### 2.2.3.1 Updates Based on the USEPA TSCA Inventory

The NDSL is based on substances that have been on the public portion of the USEPA's TSCA inventory for a minimum period of one year (*e.g.* the 2005 NDSL will be based on the 2004 TSCA inventory). It should be noted that substances for which the USEPA or the NS program has implemented risk management measures are not included in the updates of the NDSL.

#### 2.2.3.2 Nominating a Substance to the NDSL or the Confidential Portion of the NDSL

Substances on the confidential portion of the TSCA inventory are not automatically added to the confidential portion of the NDSL in the annual update process. Substances will be added to the confidential portion of the NDSL or to the NDSL (if the notifier requests to remove the confidentiality request from the substance) only after a company provides the appropriate information required in a Form C including documentation

demonstrating that the substance has existed on the confidential portion of the TSCA inventory for at least one year. In the case where a notifier wishes to have the substance added to the public portion of the NDSL a Form C is still required with a statement indicating that they wish to remove the confidentiality claim from their substance. Instructions for nominating substances to the NDSL can be found on the back of the Form C. This form can be obtained through the NSN Information Line (see Comments and Inquiries Section of these Guidelines) or on the NS program web site at ([www.ec.gc.ca/substances/nsb/download/formc\\_en.pdf](http://www.ec.gc.ca/substances/nsb/download/formc_en.pdf)).

Although there are no fees associated with nominating a substance to the confidential portion of the NDSL, please note that there is a fee for the “Masked Name Application” (see Appendix 3 of these Guidelines).

### 2.2.3.3 Applications Under the Four Corners Arrangement (4CA)

The 4CA is a bilateral information-sharing arrangement that provides the NS program and the USEPA an opportunity to review the assessment results of a substance in another jurisdiction.

In response to a 4CA application and after an assessment of the substance there are three possible outcomes. These possible outcomes are:

- a) the NS program may decide to add the substance to the NDSL early with a Four Corners “FC” flag;
- b) the NS program may decide not to add the substance to the NDSL but will accept waivers for certain information requirements that are required when the higher Schedule NSN package is submitted; or
- c) the NS program may decide not to add the substance to the NDSL and not accept any waivers for any information requirements.

These decisions are made on a case-by-case basis based on information received pursuant to the 4CA. The notifier will be informed of the decision usually within 90 days of receipt of the complete 4CA package (see Appendix 9 of these Guidelines).

## 2.2.4 NDSL Flags

### 2.2.4.1 Administrative Flags

The following flag is used for government purposes to track the number of substances added to the NDSL through the 4CA:

- The “FC” flag: The letters “FC” after a substance identifier indicates that the substance was accepted for addition to the NDSL after it was assessed under the 4CA (see section 2.2.3.3 and Appendix 9 of these Guidelines).

## 2.3 Determining the Presence of Substances on Inventories

To find out whether a substance is on the DSL or on the NDSL, the CAS registry number, the confidential accession number (if available) or the Enzyme Commission number can be entered into one of the search engines located on the NS program’s web site at [www.ec.gc.ca/substances/nsb/eng/sub\\_e.htm](http://www.ec.gc.ca/substances/nsb/eng/sub_e.htm). If the confidential accession number is unknown and the notifier wishes to determine if the substance is listed on the confidential portion of either the DSL or the NDSL, a Notice of *Bona Fide* Intent to Manufacture or Import the substance (see section 2.3.1 of these Guidelines) must be filed to the NS program. The CAS registry number or confidential accession number can also be provided directly to CAS, which will, for a fee, search all inventories for that substance. For more information on CAS, see Appendix 6 of these Guidelines.

It is important to note that the search engine does not show any flags. The onus is on the notifier to consult the *Canada Gazette* publication to ensure that there are no flags associated with a particular substance (see section 2.1.4 of these Guidelines). The NS program is working on having these flags added to the search engine.

## 2.0 The Inventories

### 2.3 Determining the Presence of Substances on Inventories

#### 2.3.1 Notice of *Bona Fide* Intent to Manufacture or Import

Substances listed on the confidential portion of the DSL or NDSL are published with confidential accession numbers using masked identities that are named in a manner prescribed by the *Masked Name Regulations*. Any notifier who intends to manufacture or import a substance that he or she believes to be listed on the confidential portion of either of these lists may seek confirmation to that effect from the NS program by providing a Notice of *Bona Fide* Intent to Manufacture or Import the substance.

A Notice of *Bona Fide* Intent to Manufacture or Import must include the following information and must be provided to the NS program at the address provided in the Comments and Inquiries Section at the beginning of these Guidelines:

- a) the specific chemical identity of the substance established in accordance with the nomenclature rules of the International Union of Pure and Applied Chemistry (IUPAC), CAS or International Union of Biochemistry and Molecular Biology (IUBMB);
- b) the CAS registry or Enzyme Commission number (if one exists);
- c) a statement, signed by a person residing in Canada, declaring that the notifier intends to manufacture or import the substance and that the substance would be subject to the Regulations if it is not on the DSL;
- d) if the manufacture of the substance occurs in Canada, a description of the research and development activities conducted to date (*e.g.* information such as manufacturing procedures, quantities manufactured, types of data generated on the substance and manufacturing history in international commerce) and the intended use of the substance;
- e) if the substance is imported, a description of the manufacturing history of the substance in international commerce (if known);
- f) an elemental analysis;
- g) valid spectral analysis or analyses that confirm(s) the identity of the substance; and
- h) the applicable fee (see Appendix 3 of these Guidelines).

If a notifier who wants to manufacture or import a substance is unable to supply all of the required information because a foreign supplier considers this information confidential, the notifier is required to ensure that the foreign supplier submits the confidential information directly to the NS program.

After the notifier has provided a Notice of *Bona Fide* Intent to Manufacture or Import the substance, the NS program will search the confidential portion of the DSL and NDSL, and will respond within 30 days of receipt of the complete documentation indicating whether or not the substance is on either of the lists.

#### 2.3.2 Copies of the DSL and NDSL

The DSL and the NDSL are available for download in plain text (html) and Adobe Acrobat® pdf format at the NS program web site: [www.ec.gc.ca/substances/](http://www.ec.gc.ca/substances/). Chemicals, biochemicals, polymers and biopolymers are listed by their respective CAS registry numbers, while biochemicals that are enzymes are listed by Enzyme Commission numbers designated by the IUBMB. Confidential substances are listed by their respective confidential accession numbers and also published using masked identities that are named in a manner prescribed by the *Masked Name Regulations* (see section 7 and appendix 7 of these Guidelines).

The *Canada Gazette* is available in subscribing libraries and institutions as well as in the regional offices of Environment Canada (see Appendix 11 of these Guidelines). Published formats of the lists may be downloaded from the *Canada Gazette* web site at [www.canadagazette.gc.ca](http://www.canadagazette.gc.ca) or purchased through the following suppliers:

**In Canada:** Publishing and Depository Group  
Ottawa, Ontario  
Canada K1A 0S9

Telephone: 1-800-661-2868; or  
613-941-5995

Facsimile: 1-800-565-7757; or  
613-954-5779

**In the United States:** International Specialized Book Services Inc.  
5602 NE Hassalo Street  
Portland, OR 97213  
U.S.A.

Telephone: 1-800-944-6190

Facsimile: 503-280-8832

**In Europe:** Books Express  
P.O. Box 10  
Saffron Walden  
Essex CB11 4EW  
England

Telephone: (0799) 513726

Facsimile: (0799) 513248

Amendments to the DSL or NDSL must be ordered by date of publication.





## SECTION 3 — Substances

### 3.1 Definition of “Substance”

For the purposes of the new substances notification regime, section 3 of the Act defines a “substance” as:

any distinguishable kind of organic or inorganic matter, whether animate or inanimate, and includes

- (a) any matter that is capable of being dispersed in the environment or of being transformed in the environment into matter that is capable of being so dispersed or that is capable of causing such transformations in the environment;
- (b) any element or free radical;
- (c) any combination of elements of a particular molecular identity that occurs in nature or as a result of a chemical reaction; and
- (d) complex combinations of different molecules that originate in nature or are the result of chemical reactions but that could not practicably be formed by simply combining individual constituents.

In some instances, materials derived from natural sources and complex reactions cannot be characterized in terms of constituent chemical compounds because their composition is too complex or variable. These materials are commonly referred to as **Unknown or Variable composition Complex reaction products and Biological materials (UVCB)** and are considered a single substance for notification purposes.

### 3.2 Exclusions from the Regulations

For the purposes of the portion of the Act dealing with Substances and Activities New to Canada (sections 80 to 89 of the Act) limitations on the statutory definition of “substance” are stated under section 3 of the Act. Substances described by the following circumstances (see sections 3.2.1 through 3.2.6 of these Guidelines) are not subject to the Regulations and are therefore excluded from notification.

#### 3.2.1 Mixtures (Section 3 of the Act)

Any mixture that is a combination of substances and does not itself produce a substance that is different from the substances that were combined.

Mixtures that are prepared formulations or reaction mixtures that are fully characterized in terms of constituent substances are not considered substances for the purpose of the Regulations and, consequently, do not require notification. However, if any constituent of a mixture, is a new substance, that constituent is subject to the Regulations. An example of a mixture is a solvent mixture.

Some mixtures, such as those derived from natural sources or complex reactions that cannot be characterized because their composition is too complex or variable (*e.g.* UVCB substances), are considered single substances and are subject to notification.

Other types of mixtures are:

- a) **Hydrates:** Hydrates of a substance or hydrated ions formed by association of a substance with water are considered to be a mixture of that substance and water. Therefore, if the anhydrous form is listed on the DSL, all hydrated forms are not notifiable substances. An example of an anhydrous substance that is listed on the DSL is Carbonic acid, magnesium salt (1:1) (CAS No. 546-93-0), and therefore the hydrated form  $\text{MgCO}_3 \cdot n\text{H}_2\text{O}$  is not notifiable. Metallic hydroxides, often termed metal hydrates, do not contain water of hydration and are *not* considered hydrates for notification purposes. Such substances must be notified if not on the DSL. An example of a metal hydroxide is copper hydroxide,  $\text{Cu}(\text{OH})_2$ .

- b) **Homogeneous and Heterogeneous Alloys:** Homogeneous and heterogeneous alloys are considered mixtures and should not be notified. Alloys that are solid or liquid mixtures of two or more metals or are mixtures of one or more metals with certain non-metallic elements (*e.g.* certain carbon steels) are considered mixtures and are not notifiable. An example of a homogeneous alloy is CuZn; an example of a heterogeneous alloy is CuCo. Intermetallic compounds of well-defined stoichiometry are not considered alloys and should be notified. An example of an intermetallic compound is In-<sup>49</sup>Sn.

### 3.2.2 Manufactured Items (Section 3 of the Act)

Any manufactured item that is formed into a specific physical shape or design during manufacture and has, for its final use, a function or functions dependent in whole or in part on its shape or design.

A material that meets the above criteria for a manufactured item will possess a definite shape or design necessary to its final use.

Shape describes the macrostructure (*e.g.* the physical three-dimensional structure) of the final item. Examples of items whose end use depends on final manufactured shape are clothing, storage containers, furniture, tiles, electrical wire, etc. However, solid substances formed into a particular shape to meet subsequent processing and manufacturing requirements, rather than final use (*e.g.* metal ingots and polymer pellets), are not considered to meet this definition of manufactured item and must be notified.

Design refers to the organization or arrangement of the solid components within the macrostructure (*e.g.* the weave of fabric and carpeting, layering of plywood or binding of paper fibres) that is not altered in any subsequent processing. For example, fabric retains its final physical design regardless of whether it is a bolt of cloth or an article of clothing, because the manufacture of the clothing does not alter the design (weave) of the cloth.

Manufactured items that undergo subsequent chemical reactions may still be excluded from the definition of a substance if they:

- undergo surface chemical reactions only to increase stiffness, strength or flame resistance, to alter colour or to improve resilience or bacterial resistance, while maintaining their bulk structure (*e.g.* brake linings, fibres, leather, paper, yarns and dyed fabrics); or
- undergo a change in chemical composition that is intrinsic to the intended end use (*e.g.* matches, flares, photographic films and batteries).

Fluids (*e.g.* gases, liquids, waxes, solutions and suspensions) and particles (*e.g.* dusts, powders, dispersions, granules, lumps, flakes and aggregates of unspecified size) are not considered items, even if the usefulness of the product depends on the particle's shape. However, a fluid or particulate matter that remains contained within a manufactured item during normal use is considered an integral part of that item and is thus not notifiable. Furthermore, a fluid or particulate matter is considered an integral part of the item if the normal release of the fluid or particulate matter is controlled and non-dispersive and is specific to the end use of the item (*e.g.* lubricants in motor vehicles, ink in pens and stamp pads).

### 3.2.3 Wastes (Section 3 of the Act)

Any animate matter that is, or any complex mixtures of different molecules that are, contained in effluents, emissions or wastes that result from any work, undertaking or activity.

Material contained in effluents, emissions and wastes is excluded from the statutory definition of a new substance. However, if a material in this category is isolated and used in commerce and is not on the DSL, it is considered a notifiable substance, subject to the Regulations. An example of a waste is slags.

### 3.2.4 Substances Carried through Canada (Subsection 3(2) of the Regulations)

Subsection 3(2) of the Regulations states that notification is not required if a substance is loaded on a carrier outside Canada and moved through Canada to a location outside Canada, whether or not there is a change of carrier during transit. However, if a substance is brought into Canada and stored for subsequent distribution, the substance is subject to the Regulations.

### 3.2.5 Polymers Subject to the "Two Percent Rule"

A polymer listed on the DSL that is modified by adding reactants, none of which constitutes more than 2% by weight of the polymer, does not require the specific substance name to be changed and is therefore not subject to the Regulations. Note that the term modifying refers to the amount of additional reactant that has been incorporated into the structure of the polymer or the amount charged to the vessel. The specific substance name and CAS registry number identify a specific substance, and therefore a name or CAS registry number change may result in the substance being subject to the Regulations.

For biopolymers, monomer units and reactants are considered to be the repeating units within the polymeric substance, which are produced *in situ* by the microorganism or are added to the reaction vessel.

### 3.2.6 Proteins Subject to the "Two Percent Rule"

A protein that is manufactured by modifying a protein that is listed on the DSL may not be subject to the Regulations if:

- a) the function of the new protein has not been changed from the protein listed on the DSL; and
- b)
  - i) the new protein has 98% amino acid sequence homology with the listed protein, based on amino acid or DNA sequence; or
  - ii) the new protein is 98% identical to the listed protein based on all of the following analytical endpoints: molecular weight, isoelectric point, amino acid composition, peptide map and N-terminal sequence. This does not apply to enzymes.

Any proposed alternatives to those in the list of analytical endpoints described in item b) ii) above should be discussed with the NS program through a Pre-notification Consultation (PNC) submission (see section 8.8 of these Guidelines) to ensure acceptability.

In certain circumstances, other modified proteins could also be exempt from notification beyond the established 2% limit. A scientifically defensible rationale for exemption above the 2% limit must be presented to the NS program, which will determine whether it is applicable in those circumstances.

## 3.3 Substances Not Subject to the Regulations

The Regulations do not apply to substances described by the following circumstances (see sections 3.3.1 through 3.3.5 of these Guidelines). However, outside these descriptions, substances are still subject to the Regulations.

### 3.3.1 Other Acts of Parliament

A substance that is manufactured or imported for a use that is regulated under any other Act of Parliament that provides for notice to be given before the manufacture, import or sale of the substance and for an assessment of whether it is toxic or capable of becoming toxic [paragraph 81(6)(a) of the Act and subsection 3(1) of the Regulations].

Subsection 3(1) of the Regulations states that these Regulations do not apply in respect of a substance that is manufactured or imported for a use that is regulated under any other Act of Parliament or regulation listed in Schedule 2 to the Act.

## 3.0 Substances

## 3.3 Substances Not Subject to the Regulations

Precursor materials excluded from the scope of other Acts of Parliament or regulations are subject to the Regulations. This includes isolated reaction intermediates, feedstocks and other starting materials used in the manufacture of any new substance.

Under subsection 81(7) of the Act, the Governor in Council has the exclusive responsibility for determining whether these criteria are met by another federal Act of Parliament or regulations and, if so, adding them to Schedule 2 to the Act. Once added to Schedule 2 to the Act, substances regulated by the listed Acts are exempt from the “Substances New to Canada” reporting requirements of the Act.

Notifiers of new substances regulated under other Acts of Parliament or regulations should monitor federal government web sites ([www.ec.gc.ca/ceparegistry/](http://www.ec.gc.ca/ceparegistry/)) and/or the *Canada Gazette* to determine whether the use for the substance remains under the jurisdiction of other Acts of Parliament or regulations or if it is subject to the Regulations.

Substances that are subject to more than one Act of Parliament or regulation must be in compliance with the requirements of those Acts of Parliament or regulations. For example, a pesticide substance that is regulated under the *Pest Control Products Act* may also have non-pesticidal applications that could be subject to the Regulations.

### 3.3.2 Transient Reaction Intermediates

Transient reaction intermediates that are not isolated and are not likely to be released into the environment [paragraph 81(6)(b) of the Act].

Transient reaction intermediates are substances produced within a sequence of chemical reactions between the starting materials and the end product and are:

- a) contained in a reaction vessel or a closed manufacturing system (including process holding tanks) located within a single building or single process area;
- b) intended to be fully consumed in the course of the chemical reaction;
- c) part of an uninterrupted manufacturing process (*e.g.* at any one time, starting materials or intermediates within the reaction sequence are being processed, except in the event of an unscheduled shutdown); and
- d) not likely to be released into the environment during normal operations, and measures are in place to minimize releases during accidental breaches of the closed manufacturing system.

Notifiers are advised to maintain technical data (process and environmental release information) to support their exemption on the basis of the statements “reaction vessel or closed manufacturing system,” “single process area,” “fully consumed,” “uninterrupted manufacturing process” and “not likely to be released”.

### 3.3.3 Impurities

Impurities, contaminants and partially unreacted materials, the formation of which is related to the preparation of a substance [paragraph 81(6)(c) of the Act].

Impurities and contaminants are substances that are normally found in minimal concentration in the starting materials or are the result of secondary reactions that occur during the manufacturing process. These substances and partially unreacted starting materials that are present in the final product are the direct result of the preparation; are not necessary to the end use of the product; have not been intentionally added to the substance; and do not enhance the value of the substance.

### 3.3.4 Incidental Reaction Products

Substances produced when a substance undergoes a chemical reaction that is incidental to the use to which the substance is put or that results from storage or from environmental factors [paragraph 81(6)(d) of the Act].

Examples of incidental reaction products include substances formed from chemical reactions during:

- exposure to environmental factors such as air, moisture, microbial organisms and sunlight (substances produced from deliberate reactions with water are subject to the Regulations, *e.g.* metal hydroxides formed from a metal oxide and water);
- storage (*e.g.* partial polymerization of drying oils);
- the intended use of a substance or mixture (*e.g.* adhesives, paints, cleansers, combustion products from fuels, fuel additives and water softeners); and
- the blending of a formulation when there is no intention to produce new substances and any ensuing chemical reactions do not enhance the value of the formulation (*e.g.* blending monomers to a precise ratio for customer convenience would not result in a notifiable substance even if some reactions occurred; however, intentional manufacture of a pre-polymer to satisfy a customer's processing specifications would produce a notifiable substance).

### 3.3.5 Low-Volume Exemptions

A substance that is manufactured or imported in a quantity that does not exceed the maximum quantity prescribed as exempt from this section [paragraph 81(6)(e) of the Act and section 4 of the Regulations].

The Regulations do not apply to substances manufactured or imported in a quantity less than the lowest amount that first triggers a requirement to provide information under the Regulations. The specific quantities and Schedules that trigger notification requirements under the Regulations can be found in Table 1-1 of these Guidelines.

### 3.3.6 Substances Occurring in Nature

As specified in the *Canada Gazette*, Part I Supplement dated January 26, 1991, the NS program considers that substances occurring in nature are not subject to the Regulations. These substances are defined as naturally occurring and must be unprocessed; processed only by manual, gravitational or mechanical means, by dissolution in water, by flotation or by heating solely to remove water; or extracted from air by any means.

Further guidance is provided in Chapter 3 of "Reporting for the Domestic Substances List" ([www.ec.gc.ca/substances/nsb/cpds/eng/CPDSLGuide\\_e.htm](http://www.ec.gc.ca/substances/nsb/cpds/eng/CPDSLGuide_e.htm)).

## 3.4 Substances Subject to the Regulations

Notification is required if the substance proposed for manufacture or import is subject to sections 80 to 89 of the Act for Substances and Activities New to Canada. Materials that require notification are:

- substances new to Canada (*e.g.* those not on the DSL);
- substances proposed for a significant new activity, defined in the SNAc Notice, that are listed on the DSL with a "S" or "S'" flag (see section 2.1.4.1 of these Guidelines);
- polymers being manufactured or imported that do not meet the conditions of an RRR polymer (see section 3.4.1.3 of these Guidelines) that are listed on the DSL with a "P" flag (see section 2.1.4.1 of these Guidelines); and
- substances regulated under any other Act of Parliament or regulations not listed on Schedule 2 to the Act (*e.g.* substances regulated under F&DA) and for which a) applies.<sup>6</sup>

<sup>6</sup> NSN packages for substances intended for use in both industrial and F&DA products (dual use) must be submitted to the NS program and are subject to the appropriate fees. NSN packages for substances intended solely for use in F&DA products are not subject to the NSFR and should be submitted directly to Health Canada. For more information regarding the notification of substances in products regulated by the F&DA contact the Environmental Assessment Unit of Health Canada by phone at 1-866-996-9913 or (613) 948-3591 or by email at [eau-uee@hc-sc.gc.ca](mailto:eau-uee@hc-sc.gc.ca).

### 3.4.1 Classification of Substances

For the purposes of the Regulations, new substances are grouped into two major classes, each subject to its own specific information requirements. These classes are non-polymeric substances (referred to in these Guidelines as chemicals and biochemicals) and polymeric substances (referred to in these Guidelines as polymers and biopolymers). These Guidelines describe the notification requirements and processes for chemicals, biochemicals, polymers and biopolymers.

#### 3.4.1.1 Chemicals and Biochemicals

The information requirements for chemicals and biochemicals (substances produced by microorganisms as defined in subsection 1(1) of the Regulations) are prescribed in the Regulations and apply to all substances subject to the Regulations that are neither polymers nor organisms. Note that chemicals derived from a whole plant or animal or from parts of a whole plant or animal are not biochemicals for the purpose of the Regulations. An example of a biochemical is the enzyme subtilisin produced by *Bacillus subtilis*.

#### 3.4.1.2 Polymers and Biopolymers

Polymers are defined in subsection 1(1) of the Regulations as substances that consist of:

- a) molecules characterized by the sequence of one or more types of monomer units;
- b) greater than 50% by weight of molecules having three or more monomer units that are covalently bound to one or more other monomer units or reactants;
- c) less than 50% by weight of molecules of the same molecular weight; and
- d) molecules distributed over a range of molecular weights whose differences in molecular weights are primarily attributable to differences in the number of monomer units.

For biopolymers, monomer units and reactants are considered to be the repeating units within the polymeric substance, which are either produced *in situ* by the organism or added to the reaction vessel. An example of a biopolymer is the polysaccharide xanthan gum, produced by *Xanthomonas campestris*.

Note that polymers derived from a whole plant or animal or from parts of a whole plant or animal are not biopolymers for the purpose of the Regulations and must be notified as polymers.

#### 3.4.1.3 Reduced Regulatory Requirement (RRR) Polymers

RRR polymers are polymers with a high number average molecular weight ( $M_n$ ) that have a limited percentage of low-molecular-weight components (<1000 daltons), are chemically stable and do not contain certain reactive or cationic moieties.

An RRR polymer is one of the following:

- a) a polymer that is not one of the types listed in items 1 to 4 of Schedule 7 (see section 3.4.1.5 of these Guidelines) and that has a number average molecular weight greater than 10 000 daltons, with less than 2% of its components having molecular weights less than 500 daltons and less than 5% of its components having molecular weights less than 1000 daltons;
- b) a polymer that is not one of the types listed in Schedule 7 (see section 3.4.1.5 of these Guidelines) and that has a number average molecular weight greater than 1000 daltons and equal to or less than 10 000 daltons, with less than 10% of its components having molecular weights less than 500 daltons and less than 25% of its components having molecular weights less than 1000 daltons; or
- c) a polymer that is a polyester manufactured solely from reactants listed in Schedule 8 or an anhydrous form of those reactants, other than the reactants or their anhydrous forms that include both 1-butanol and fumaric or maleic acid.

Polymers that meet the RRR polymer criteria above require only one notification to be submitted (see section 4.8.1 of these Guidelines).

### 3.4.1.4 Non-reduced Regulatory Requirement (non-RRR) Polymers

Polymers that do not meet the above-mentioned criteria are referred to as non-RRR polymers. Non-RRR polymers require additional notification requirements at higher manufacture and import volumes (see Table 1-1 of these Guidelines).

### 3.4.1.5 Polymers Described in Schedule 7 of the Regulations

Schedule 7 of the Regulations outlines some of the criteria used to determine whether a polymer meets the RRR polymer criteria. In particular, items 1 and 5 of Schedule 7 describe circumstances where cationic or reactive polymers fail to meet the criteria. Part of this determination involves calculating the functional group equivalent weight (FGEW) of resident cationic or reactive functional groups.

The FGEW is the weight of the polymer that contains one equivalent weight (one mole) of a particular functional group. Consequently, large FGEW values represent polymers having relatively few functional groups. Before the FGEW can be calculated, it is useful to establish the type of distribution of functional groups within the polymer. This includes determining if the polymer is linear or branched. Functional groups can be located at terminal positions, randomly distributed throughout the polymer or equally distributed within the repeating unit.

Table 3-1 lists various types of functional group distributions within a polymer and provides equations to calculate FGEW for each type.

**Table 3-1: Equations for Different Functional Group Calculations**

Type of functional group distribution	Throughout polymer		At terminal ends	
	Randomly distributed	Within structural repeating unit	Linear polymer	Branched polymer
FGEW equations	$FGEW_n = \frac{mw_{mon} \times 100}{wt\%_{mon} \times nFG_{mon}}$	$\frac{eq.wt.RU}{nFG_{RU}}$	$\frac{M_n}{2}$	$\frac{M_n}{nEG}$
Combined FGEW equation	$FGEW_{comb} = \frac{1}{\frac{1}{FGEW_1} + \frac{1}{FGEW_2} + \dots + \frac{1}{FGEW_n}}$			
Branched FGEW equation	$FGEW_{BR} = \frac{M_n}{\left( \frac{M_n \times wt\%_{BR}}{mw_{BR} \times 100} \times (nRS - 2) \right) + 2}$			
Number of moles of a substance	$\# \text{ moles} = \frac{wt\%_{mon}}{mw_{mon}}$			

$mw_{mon}$	= molecular weight of monomer
$wt\%_{mon}$	= weight percent of monomer
$nFG_{mon}$	= number of functional groups within monomer
$eq.wt.RU$	= equivalent weight of repeating unit
$nFG_{RU}$	= number of functional groups within repeating unit
$M_n$	= number average molecular weight
$nEG$	= number of end groups
$nRS$	= number of reactive sites within branching reagent
$wt\%_{BR}$	= weight percent of branching reagent
$mw_{BR}$	= molecular weight of branching reagent
$FGEW_n$	= functional group equivalent weight calculation ( $n = 1, 2, 3, \dots$ )
$FGEW_{comb}$	= combined functional group equivalent weight calculation
$FGEW_{BR}$	= branched functional group equivalent weight calculation

## 1. End-Group Analysis for Linear Polymers

An end-group analysis applies to linear polymers containing functional groups only at chain ends. The FGEW for these polymers depends on the  $M_n$  of the polymer.

<b>One end:</b> $FGEW = \frac{M_n}{1}$	<b>Two ends:</b> $FGEW = \frac{M_n}{2}$
$FG - \left( A - B \right)_n - A$	$FG - \left( A - B \right)_n - FG$

$M_n$  = number average molecular weight  
 FG = functional group of concern  
 A, B = arbitrary monomer units

An example of a linear polymer is described below:

**Example 1:** A linear polyurethane polymer contains aliphatic isocyanate groups only at the chain ends. The polymer is potentially cationic, since aliphatic isocyanates can hydrolyze to aliphatic amines. The  $M_n$  of the polymer is 100 000 daltons. In a linear polymer, there are only two end groups, and therefore:

$$FGEW = \frac{M_n}{2} = \frac{100\,000}{2} = 50\,000$$

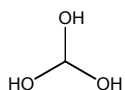
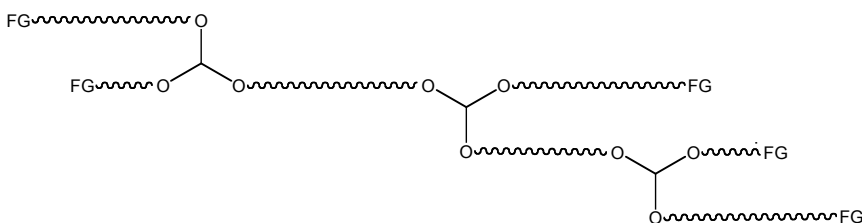
Given that this polymer contains aliphatic isocyanate groups (a functional group of concern) and is therefore potentially cationic, it falls under items 1 and 5 of Schedule 7. Since the FGEW was determined to be greater than 5000, this polymer would meet the RRR polymer criteria based on this criterion.

## 2. End-Group Analysis for Branched Structures

An end-group analysis is performed for branched polymers containing functional groups only at chain ends. An appropriate calculation and illustration of such a polymer are provided below:

$$FGEW = \frac{M_n}{\left( \frac{M_n \times wt\%_{BR}}{mw_{BR} \times 100} \times (nRS - 2) \right) + 2}$$

$M_n$  = number average molecular weight  
 nRS = number of reactive sites within branching reagent  
 wt%<sub>BR</sub> = weight percent of branching reagent  
 mw<sub>BR</sub> = molecular weight of branching reagent



representation of branching reagent



representation of polyurethane backbone



The following example demonstrates the determination of the FGEW for a branched polymer containing a cationic functional group.

**Example 2:** A branched polyurethane polymer contains isocyanate groups at chain ends that are derived solely from hydrogenated methylene diisocyanate (molecular weight = 262). The branching reagent is trimethylolpropane ( $C_2H_5C(CH_2OH)_3$ , molecular weight = 134), which accounts for 10% by weight of the polymer and has three reactive sites. The  $M_n$  of the polymer is 20 000 daltons.

$$FGEW = \frac{20\,000}{\left(\frac{20\,000 \times 10}{134 \times 100} \times (3 - 2)\right) + 2} = \frac{20\,000}{14.93 + 2} = 1182$$

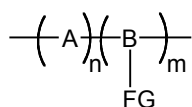
Given that this polymer contains isocyanate groups (a functional group of concern) and is therefore potentially cationic, it falls under items 1 and 5 of Schedule 7. Since the FGEW was determined to be less than 5000, this polymer would not meet the RRR polymer criteria based on this criterion.

### 3. Groups Throughout Polymer

3a. The following example demonstrates the determination of the FGEW for a polymer containing one type of cationic functional group throughout the structure.

$$FGEW = \frac{mw_{mon} \times 100}{wt\%_{mon} \times nFG_{mon}}$$

$mw_{mon}$  = molecular weight of monomer  
 $wt\%_{mon}$  = weight percent of monomer  
 $nFG_{mon}$  = number of functional groups in monomer



**Example 3a:** An acrylic polymer contains aliphatic amines that are derived solely from 2-aminoethyl acrylate ( $H_2C=CHCO_2CH_2CH_2NH_2$ , molecular weight = 115), which accounts for 2% by weight of the polymer.

$$FGEW = \frac{115 \times 100}{2 \times 1} = 5750$$

Given that this polymer contains aliphatic amines and is therefore potentially cationic, it falls under item 1 of Schedule 7. Since the FGEW was determined to be greater than 5000, this polymer would meet the RRR polymer criteria based on this criterion.

3b. The following example demonstrates the determination of the FGEW for a polymer containing one type of functional group that is not considered cationic throughout the structure.

**Example 3b:** A polymer that contains aliphatic acrylates has an  $M_n = 2500$ . There is a maximum amount of 28.9% by weight of the acrylate monomer (molecular weight = 72). Therefore, we can determine the FGEW of the acrylate functional group to be:

$$FGEW_{acrylate} = \frac{72 \times 100}{28.9 \times 1} = 249$$

Given that this polymer contains aliphatic acrylates, which are considered a functional group of concern, it falls under subitem 5(a) of Schedule 7. Since the FGEW of the acrylate was determined to be less than 5000, this polymer would not meet the RRR polymer criteria based on this criterion.

## 3.0 Substances

## 3.4 Substances Subject to the Regulations

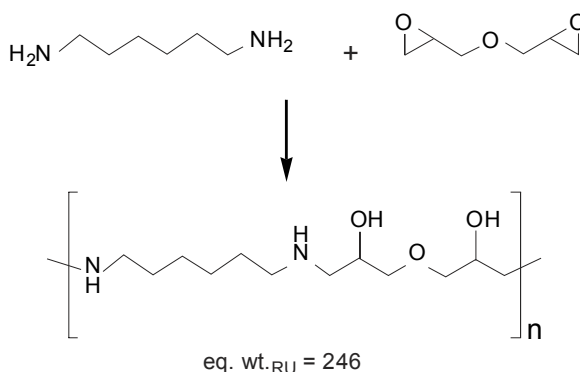
## 4. Functional Groups within Structural Repeating Units

The following example demonstrates the determination of the FGEW for a polymer with functional groups within structural repeating units.

Example 4: An addition polymer is made by reacting an excess of hexamethylene diamine with diglycidyl ether. A linear polymer is formed with a simple repeating unit of 246 daltons. There are two potentially cationic nitrogen atoms per unit, as illustrated below:

$$\text{FGEW} = \frac{\text{eq.wt.}_{\text{RU}}}{n\text{FG}_{\text{RU}}}$$

eq.wt.<sub>RU</sub> = equivalent weight of repeating unit  
nFG<sub>RU</sub> = number of functional groups within repeating unit



$$\text{Therefore, FGEW} = \frac{\text{eq.wt.}_{\text{RU}}}{n\text{FG}_{\text{RU}}} = \frac{246}{2} = 123$$

The FGEW here is independent of the amount of diamine monomer or the  $M_n$  of the polymer, as long as there is a molar excess of the diamine. If diglycidyl ether is used in excess, the polymer will be epoxy terminated, and the FGEW will require more complex calculations.

Given that this polymer contains diamines and is therefore potentially cationic, it falls under item 1 of Schedule 7. Since the FGEW was determined to be less than 5000, this polymer would not meet the RRR polymer criteria based on this criterion.

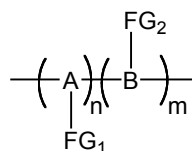
## 5. FGEW Combined

If there is more than one functional group of concern in the polymer, the FGEW must be calculated for each monomer separately, and then the combined FGEW is calculated.

$$\text{FGEW}_n = \frac{\text{mw}_{\text{mon}} \times 100}{\text{wt}\%_{\text{mon}} \times n\text{FG}_{\text{mon}}}$$

$$\text{FGEW}_{\text{comb}} = \frac{1}{\frac{1}{\text{FGEW}_1} + \frac{1}{\text{FGEW}_2} + \dots + \frac{1}{\text{FGEW}_n}}$$

FGEW<sub>1,2,...n</sub> = FGEW for each particular functional group  
mw<sub>mon</sub> = molecular weight of monomer  
wt%<sub>mon</sub> = weight percent of monomer  
nFG<sub>mon</sub> = number of functional groups within monomer



The following example demonstrates how the equation should be used to determine the FGEW of a polymer containing more than one cationic functional group of concern.

Example 5: An acrylic polymer contains aliphatic amines from 1% of 2-aminoethyl acrylate ( $\text{H}_2\text{C}=\text{CHCO}_2\text{CH}_2\text{CH}_2\text{NH}_2$ , molecular weight = 115) and 2% of dimethylaminoethyl methacrylate ( $\text{H}_2\text{C}=\text{C}(\text{CH}_3)\text{CO}_2\text{CH}_2\text{CH}_2\text{N}(\text{CH}_3)_2$ , molecular weight = 157)

$$\text{FGEW}_1 = \frac{115 \times 100}{1 \times 1} = 11\,500$$

$$\text{FGEW}_2 = \frac{157 \times 100}{2 \times 1} = 7850$$

$$\text{FGEW}_{\text{comb}} = \frac{1}{\frac{1}{11\,500} + \frac{1}{7850}} = 4665$$

Given that this polymer contains two different amine groups and is therefore potentially cationic, it falls under item 1 of Schedule 7. Since the  $\text{FGEW}_{\text{comb}}$  was determined to be less than 5000, this polymer would not meet the RRR polymer criteria based on this criterion.

### 3.5 Special Category Substances

A special category substance is defined as any substance that is manufactured or imported as:

- a research and development substance;
- a contained site-limited intermediate substance; or
- a contained export-only substance.

#### 3.5.1 Research and Development Substances

Section 1(1) of the Regulations defines a research and development substance as one that is undergoing systematic investigation or research, by means of experimentation or analysis other than test marketing, whose primary objective is any of the following:

- to create or improve a product or process;
- to determine the technical viability or performance characteristics of a product or process; or
- to evaluate a substance prior to its commercialization, by pilot plant trials, production trials (including scale-up) or customer plant trials, so that technical specifications can be modified in response to the performance requirements of potential customers.

This category includes chemicals or polymers being manufactured on toll for domestic or foreign customers that are conducting research (see section 1.4.3 of these Guidelines, Toll Manufacturer).

The Regulations also define “Test marketing,” in respect of a product as referred to above, as “the exploration of its market capability in a competitive situation where the creation or improvement of the product is not the primary objective.”

#### 3.5.2 Contained Site-Limited Intermediate Substances

Subsection 1(1) of the Regulations defines a contained site-limited intermediate substance as one that is consumed in a chemical reaction used for the manufacture of another substance and that is:

- manufactured and consumed at the site of manufacture;
- manufactured at one site and transported to a second site where it is consumed; or
- imported and transported directly to the site where it is consumed.

## 3.0 Substances

### 3.5 Special Category Substances

The Regulations also define:

- “contained” as “an absolute release limit of the substance of 1 kg per day per site to the aquatic environment after wastewater treatment”; and
- “consumed” as “destroyed or completely converted to another substance”.

If a substance is classified as a site-limited intermediate, it must, at all times during its existence (manufacture, importation, storage, transport, handling, use and disposal) be contained, as defined above, to prevent any significant environmental release.

A substance that is a direct precursor in the manufacture of an item defined in section 3.2.2 is not considered a site-limited intermediate and would be subject to the regular notification requirements. However, if the direct precursor of the item meets the criteria of a “transient reaction intermediate” (see section 3.3.2 of these Guidelines), it would not be subject to notification.

#### 3.5.3 Contained Export-Only Substances

Contained export-only substances are limited to new substances manufactured in or imported into Canada that are destined solely for foreign markets and that are contained.

Contained is defined in subsection 1(1) of the Regulations as an absolute release limit of the substance of 1 kg/day per site to the aquatic environment after wastewater treatment.

# SECTION 4 — Notification Information Requirements

## 4.1 How to Identify the Required Notification Information

The Regulations prescribe information requirements tailored to the use and quantity of the chemical or polymer being manufactured or imported. These requirements are listed in the “Schedules” of the Regulations which are presented in Appendix 4 of these Guidelines. To help select the appropriate Schedule, decision flowcharts are provided in this section and also in Appendix 1.

It is important to note that although the Regulations provide a tiered approach to notification, which links information requirements to factors such as quantity, use, intrinsic properties and class, it is not a requirement to follow this tiered notification approach. A notifier may, if he or she wishes, opt to immediately submit the highest notification Schedule required, as long as the lowest prescribed trigger quantities for the lowest Schedule are respected and the NSN package is submitted within the timeframe prescribed for the highest Schedule.

As indicated in the decision diagrams presented in this section and in Appendix 1, there are a number of factors that must be considered when identifying the nature of information to be submitted and when this information should be submitted. These factors include:

- a) whether the new substance meets the definition of a chemical or a polymer (see section 3.4 of these Guidelines);
- b) whether the new substance falls within any of the prescribed special categories (*e.g.* research and development, contained site-limited intermediate or contained export-only; see section 3.5 of these Guidelines);
- c) whether the new substance is listed on the NDSL (see section 2.2 of these Guidelines);
- d) the annual quantities of the new substance that will be manufactured in or imported into Canada (see Table 1-1 and sections 4.2, 4.4, 4.5, 4.8 and 4.9 of these Guidelines);
- e) if the new substance is a polymer, whether it meets the definition of an RRR polymer (see section 3.4.1.3 of these Guidelines);
- f) if the new substance is a polymer, whether it is manufactured solely from monomers and reactants that are listed on the DSL or the NDSL (see section 4.7.1 of these Guidelines); and
- g) whether the new substance will be released to the aquatic environment in significant quantities and/or if the public may be significantly exposed to the substance in a product (see sections 4.4.3 and 4.9.2 of these Guidelines).

### 4.1.1 Annual Quantities

The Regulations prescribe a pre-manufacture/pre-import notification scheme. As such, the notifier must develop an accurate estimate of the annual (calendar year) quantities of the new substance to be manufactured or imported in Canada and submit an NSN package before each of the prescribed “trigger” quantities are exceeded.

The prescribed “trigger” quantities relate to the actual amount of new substance manufactured or imported, not to the quantity of the formulation containing the substance. For example, if 10 000 kg of Formulation A are to be imported during a calendar year and this formulation contains 13% of new substance X, then the annual import quantity of substance X would be 1300 kg.

The following sections will help identify both the Schedule requirements necessary to comply with the Regulations and the date before which NSN packages must be submitted to the NS program.

## 4.2 Notification of Special Category Substances (see Figure 4-1)

Substances being manufactured or imported for activities defined under the special categories umbrella (see section 3.5 of these Guidelines) must be notified as indicated below. Once the special category activities have concluded, the substance is subject to notification under the appropriate Schedules based on the type of substance and its volumes (see sections 4.3 to 4.9 of these Guidelines). These requirements are specified in the Schedules in Appendix 4 of these Guidelines

### 4.2.1 Lower-Volume Special Category Notifications for Chemicals

Every notifier who manufactures or imports a chemical for research and development purposes, as a contained site-limited intermediate substance or as a contained export-only substance must provide to the NS program the information prescribed in Schedule 1 of the Regulations at least 30 days prior to the quantity of the chemical exceeding **1000 kg** in a calendar year.

#### 4.2.1.1 Lower-Volume Research and Development Biochemicals

If the substance is a research and development biochemical, the notifier is required to provide, in addition to the Schedule 1 information, items 1 and 2 of Schedule 2 of the Regulations.

#### 4.2.1.2 Lower-Volume Contained Site-Limited Intermediate Biochemicals

If the substance is a contained site-limited intermediate biochemical that is not manufactured and consumed at the site of manufacture, the notifier is required to provide, in addition to the Schedule 1 information, items 1–4 of Schedule 2 of the Regulations; and

- a) if the biochemical is a nucleic acid, the information specified in items 5 and 6 of Schedule 2 of the Regulations; and
- b) if the biochemical possesses enzymatic capability, the information specified in items 7–13 of Schedule 2 of the Regulations.

If the substance is a contained site-limited intermediate biochemical that is manufactured and consumed at the site of manufacture, the notifier is required to provide, in addition to the Schedule 1 information, items 1, 2 and 4 of Schedule 2 of the Regulations.

#### 4.2.1.3 Lower-Volume Contained Export-Only Biochemicals

If the substance is a contained export-only biochemical, the notifier is required to provide, in addition to the Schedule 1 information, items 1–4 of Schedule 2 of the Regulations; and

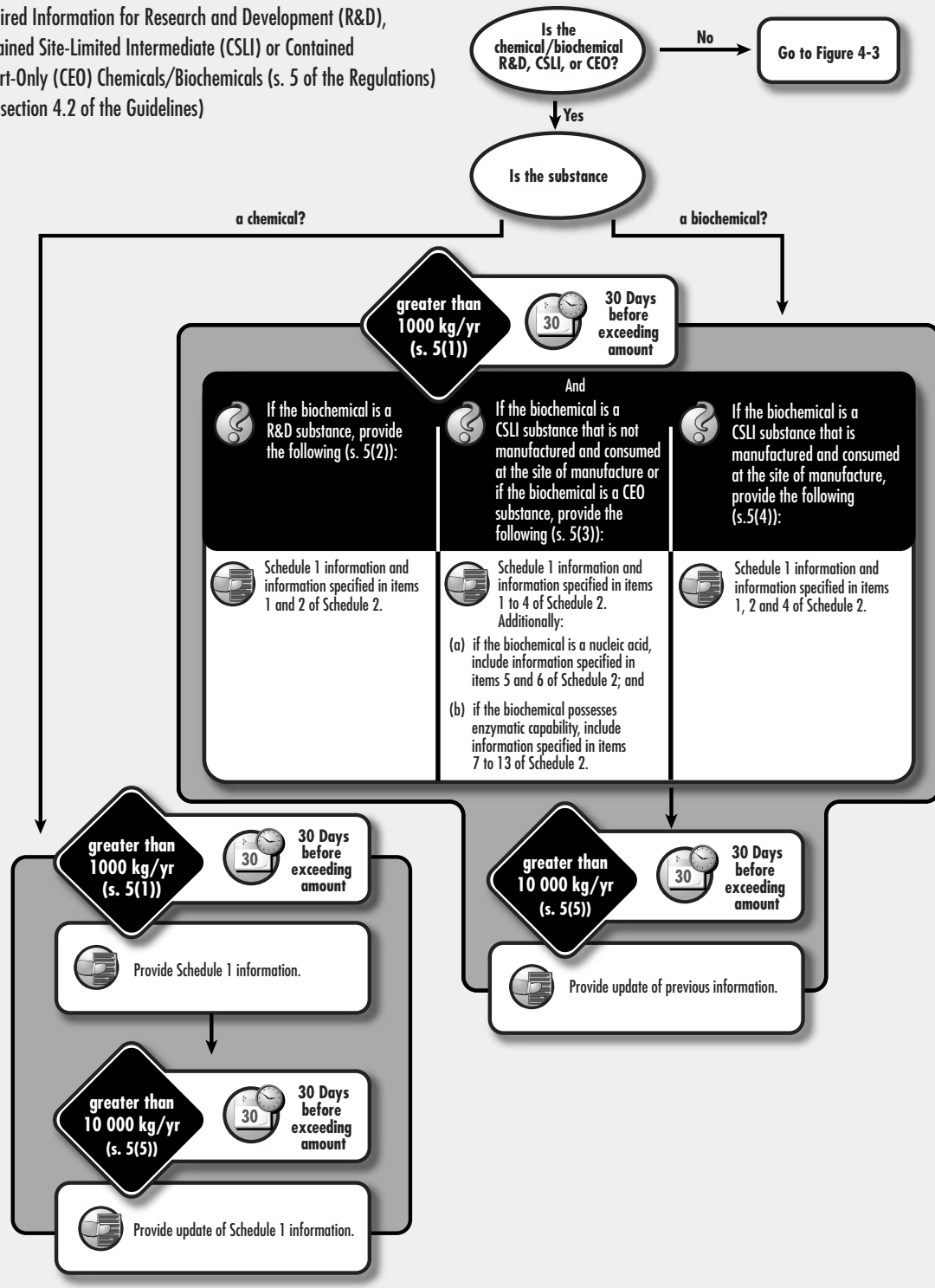
- a) if the biochemical is a nucleic acid, the information specified in items 5 and 6 of Schedule 2 of the Regulations; and
- b) if the biochemical possesses enzymatic capability, the information specified in items 7–13 of Schedule 2 of the Regulations.

### 4.2.2 Higher-Volume Special Category Notifications for Chemicals

In addition, the notifier must update all of the information that was previously provided at least 30 days prior to exceeding **10 000 kg** in a calendar year. If there is no change in the information, this must also be indicated at this time.

**Figure 4-1**

Required Information for Research and Development (R&D),  
Contained Site-Limited Intermediate (CSLI) or Contained  
Export-Only (CEO) Chemicals/Biochemicals (s. 5 of the Regulations)  
(See section 4.2 of the Guidelines)



**Figure 4-1**  
Required  
Information for  
Research and  
Development  
(R&D), Contained  
Site-Limited  
Intermediate  
(CSLI) or  
Contained  
Export-Only  
(CEO) Chemicals/  
Biochemicals

This flow chart can be found in a larger full-page version in Appendix 1 of these Guidelines.

### 4.2.3 Higher-Volume Special Category Notifications for Polymers (see Figure 4-2)

Every notifier that manufactures or imports a polymer for research and development purposes, as a contained site-limited intermediate substance or as a contained export-only substance must provide the NS program the information prescribed in Schedule 3 of the Regulations at least 30 days prior to the quantity of the polymer exceeding **10 000 kg** in a calendar year.

#### 4.2.3.1 Higher-Volume Research and Development Biopolymers

If the substance is a research and development biopolymer, the notifier is required to provide, in addition to the Schedule 3 information, items 1 and 2 of Schedule 2 of the Regulations.

#### 4.2.3.2 Higher-Volume Contained Site-Limited Intermediate Biopolymers

If the substance is a contained site-limited intermediate biopolymer that is not manufactured and consumed at the site of manufacture, the notifier is required to provide, in addition to the Schedule 3 information, items 1–4 of Schedule 2 of the Regulations; and

- a) if the biopolymer is a nucleic acid, the information specified in items 5 and 6 of Schedule 2 of the Regulations.

If the substance is a contained site-limited intermediate biopolymer that is manufactured and consumed at the site of manufacture, the notifier is required to provide, in addition to the Schedule 3 information, items 1, 2 and 4 of Schedule 2 of the Regulations.

#### 4.2.3.3 Higher-Volume Contained Export-Only Biopolymers

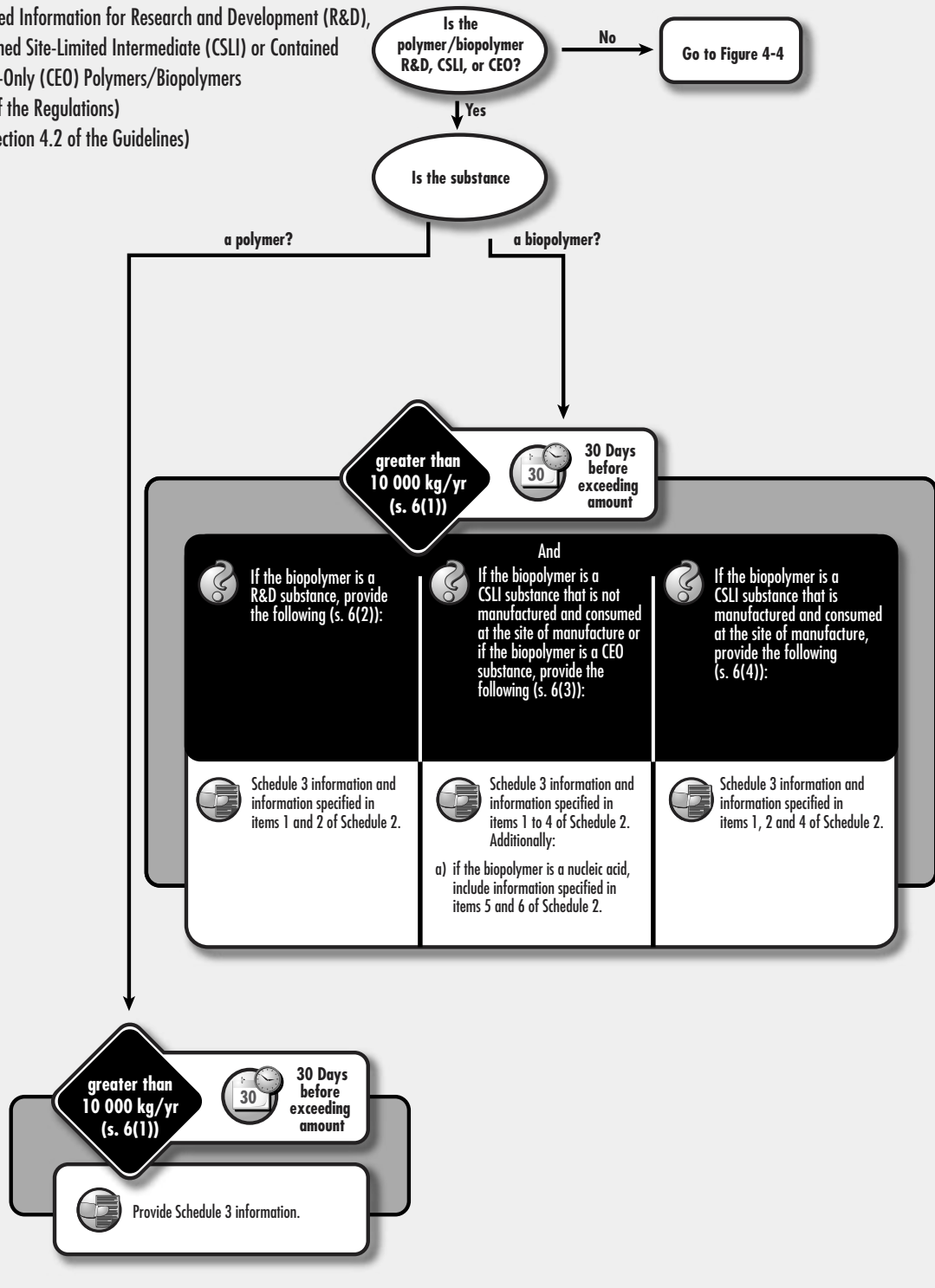
If the substance is a contained export-only biopolymer, the notifier is required to provide, in addition to the Schedule 3 information, items 1–4 of Schedule 2 of the Regulations; and

- a) if the biopolymer is a nucleic acid, the information specified in items 5 and 6 of Schedule 2 of the Regulations.



**Figure 4-2**

Required Information for Research and Development (R&D), Contained Site-Limited Intermediate (CSLI) or Contained Export-Only (CEO) Polymers/Biopolymers (s. 6 of the Regulations) (See section 4.2 of the Guidelines)



**Figure 4-2**  
Required Information for Research and Development (R&D), Contained Site-Limited Intermediate (CSLI) or Contained Export-Only (CEO) Polymers/Biopolymers

This flow chart can be found in a larger full-page version in Appendix 1 of these Guidelines.

4.0 Notification  
Information  
Requirements4.3 Notification of  
Chemicals4.4 Information  
Requirements for  
Chemicals Listed  
on the NDSL

### 4.3 Notification of Chemicals

As indicated in section 4.1 of these Guidelines, the Regulations prescribe information requirements tailored to the use and quantity of the chemical. These requirements are listed in the “Schedules” of the Regulations which are presented in Appendix 4 of these Guidelines. Decision flowcharts are provided in this section and in Appendix 1 of these Guidelines to help select the appropriate notification Schedule.

Before using the flowcharts, Table 1-1 and sections 2.2, 3.4, 3.5, 4.2.1, 4.2.2, 4.4 and 4.5 of these Guidelines should be reviewed to determine:

- a) whether the new substance meets the definition of a chemical given in the Regulations (see section 3.4.1.1 of these Guidelines);
- b) whether the new chemical falls within any of the prescribed special categories (*e.g.* research and development, contained site-limited intermediate or contained export-only; see section 3.5 of these Guidelines);
- c) whether the new chemical is listed on the NDSL (see section 2.2 of these Guidelines);
- d) the annual quantities of the new chemical that will be manufactured in or imported into Canada (see Table 1-1 and sections 4.2.1, 4.2.2, 4.4 and 4.5 of these Guidelines); and
- e) whether the NDSL-listed chemical will be released to the aquatic environment in significant quantities and/or if the public may be significantly exposed to the substance in a product (see section 4.4.3 of these Guidelines).

The following sections apply only to chemicals that are manufactured or imported for a purpose other than as a special category listed in section 3.5 of these Guidelines.

### 4.4 Information Requirements for Chemicals Listed on the NDSL (see Figures 4-3(a) and 4-3(b))

#### 4.4.1 Lower-Volume Chemicals

Every notifier who manufactures or imports a chemical that is listed on the NDSL must provide the NS program the information prescribed in Schedule 4 of the Regulations at least 30 days prior to the quantity of the chemical exceeding **1000 kg** in a calendar year.

If the substance is a biochemical, the notifier is required to provide, in addition to the Schedule 4 information, items 1–3 of Schedule 2 of the Regulations.

#### 4.4.2 Higher-Volume Chemicals

Every notifier who manufactures or imports a chemical that is listed on the NDSL must provide the NS program the information prescribed in Schedule 5 of the Regulations at least 60 days prior to the quantity of the chemical exceeding **10 000 kg** in a calendar year.

If the substance is a biochemical, the notifier is required to provide, in addition to the Schedule 5 information, items 1–4 of Schedule 2 of the Regulations; and

- a) if the biochemical is a nucleic acid, the information specified in items 5 and 6 of Schedule 2 of the Regulations; and
- b) if the biochemical possesses enzymatic capability, the information specified in items 7–13 of Schedule 2 of the Regulations.

#### 4.4.3 NDSL Chemicals with High Release and/or Significant Exposure

Every notifier who manufactures or imports a chemical that is listed on the NDSL and:

- a) that is released to the aquatic environment in a quantity exceeding 3 kg/day, per site, averaged monthly and after wastewater treatment; and/or

b) where the public may be significantly exposed to the chemical in a product must provide the NS program additional test information as prescribed in subsections 7(2) and 7(3) of the Regulations at least 75 days prior to the quantity of the chemical exceeding **50 000 kg** in a calendar year. The additional required information is indicated in the following sections.

#### 4.4.3.1 Chemicals Released to the Aquatic Environment

It is the notifier's responsibility to submit evidence in item 10(c) of the Schedule 5 NSN package to support a claim of the substance not being released to the aquatic environment in the quantity indicated above. This information should include any envisioned future use by multiple customers and/or a variety of applications. To calculate daily release to the aquatic component, the estimated daily release should be determined, per site, as follows:

$$\text{EDR} = (\text{AV}/\text{NPD}) \times \text{L} \times (1-\text{T})$$

where:

EDR	= estimated daily release (kg/day)
AV	= anticipated annual manufacture or import volume (kg) per site
NPD	= anticipated number of production days per year
L	= anticipated total loss of substance to wastewater (%)
T	= anticipated removal in wastewater treatment plant (%)

The NS program will assess this information and will perform an additional calculation based on information available to the program. If it is determined that the substance is released to the aquatic environment in quantities greater than indicated above or where the information provided is not acceptable, the additional information prescribed in subsection 7(2) of the Regulations must be provided. The NS program's determination of whether the substance is subject to all or some of the additional information requirements given below will be indicated in the final assessment outcome letter. The notifier may submit additional information to support his or her claim and request a re-evaluation of the decision made by the NS program. The NS program will review and consider this information.

The additional information required, as prescribed in subsection 7(2) of the Regulations, must include the following:

- a) for chemicals having a water solubility of greater than or equal to 200 µg/L:
  - i) adsorption-desorption screening test data; and
  - ii) the hydrolysis rate as a function of pH and, if known, an identification of the products of the hydrolysis; and
- b) the data from a repeated-dose mammalian toxicity test of the chemical of at least 28 days duration, using the most significant route of potential human exposure to the chemical, namely, oral, dermal or inhalation, plus:
  - i) the age, sex, number, species, strain and source of the animals tested;
  - ii) the route by which the chemical is administered and the conditions under which the test is conducted; and
  - iii) the dose of the chemical, the vehicle by means of which the chemical is administered and its concentration in that vehicle.

#### 4.4.3.2 Where the Public May Be Significantly Exposed to the Chemical in a Product

It is the notifier's responsibility to submit evidence in item 10(d) of the Schedule 5 NSN package to support a claim of the public not being significantly exposed to the substance in a product. The NS program will assess this information and determine if it is acceptable. If it is determined that the public may be significantly exposed to the chemical in a product or where the information provided is not acceptable, the additional information prescribed in subsection 7(3) of the Regulations must be provided. The NS program's determination of whether the substance is subject to all or some of the additional information requirements given below will be indicated

#### 4.0 Notification Information Requirements

#### 4.4 Information Requirements for Chemicals Listed on the NDSL

#### 4.5 Information Requirements for Chemicals Not on the NDSL

in the final assessment outcome letter. The notifier may submit additional information to support his or her claim and request a re-evaluation of the decision made by the NS program. The NS program will review and consider this information.

Since public exposure is dependent on many factors, it is difficult to give a calculation to determine what is “significant” without being extremely conservative. Therefore, the definition of “significantly exposed” will be assessed, by the NS program, on a case-by-case basis. This assessment will take into consideration such factors as type of use, duration and frequency of use, concentration of the chemical in the product and circumstances of exposure that may limit direct human exposure (*e.g.* whether the chemical is consumed during use or is able to migrate from the product). To determine if the public may be significantly exposed to the chemical in a product, the NS program provides the opportunity for notifiers to submit a PNC request (see section 8.8 of these Guidelines).

Some examples of consumer applications where significant exposure of a substance may occur include, but are not limited to, dishwashing detergent, laundry products, soaps, toilet paper, cleaning solutions, waxes, polishes, air fresheners, paints, oils, greases and ink.

The additional information required, as prescribed in subsection 7(3) of the Regulations, must include the following:

- a) the data from a repeated-dose mammalian toxicity test of the chemical of at least 28 days duration, using the most significant route of potential human exposure to the chemical, namely, oral, dermal or inhalation, plus:
  - i) the age, sex, number, species, strain and source of the animals tested;
  - ii) the route by which the chemical is administered and the conditions under which the test is conducted; and
  - iii) the dose of the chemical, the vehicle by means of which the chemical is administered and its concentration in that vehicle; and
- b) the data obtained from an *in vitro* test, with and without metabolic activation, for chromosomal aberrations in mammalian cells or the data from a previously existing *in vivo* mammalian test for chromosomal aberrations that, together with data substantiating that the tissue investigated was exposed to the chemical or its metabolites, permits an assessment of *in vivo* clastogenicity.

### 4.5 Information Requirements for Chemicals Not on the NDSL (see Figures 4-3(a) and 4-3(b))

#### 4.5.1 Lower-Volume Chemicals

- a) Every notifier who manufactures or imports a chemical that is not on the NDSL must provide the NS program the information prescribed in Schedule 4 of the Regulations at least five days prior to the quantity of the chemical exceeding **100 kg** in a calendar year.

If the substance is a biochemical, the notifier is required to provide, in addition to the Schedule 4 information, items 1–3 of Schedule 2 of the Regulations.

- b) Every notifier who manufactures or imports a chemical that is not on the NDSL must provide the NS program the information prescribed in Schedule 5 of the Regulations at least 60 days prior to the quantity of the chemical exceeding **1000 kg** in a calendar year.

If the substance is a biochemical, the notifier is required to provide, in addition to the Schedule 5 information, items 1–4 of Schedule 2 of the Regulations; and

- i) if the biochemical is a nucleic acid, the information specified in items 5 and 6 of Schedule 2 of the Regulations; and
- ii) if the biochemical possesses enzymatic capability, the information specified in items 7–13 of Schedule 2 of the Regulations.

### 4.5.2 Higher-Volume Chemicals

Every notifier who manufactures or imports a chemical that is not on the NDSL must provide the NS program the information prescribed in Schedule 6 of the Regulations at least 75 days prior to the quantity of the chemical exceeding **10 000 kg** in a calendar year.

If the substance is a biochemical, the notifier is required to provide, in addition to the Schedule 6 information, items 1–4 of Schedule 2 of the Regulations; and

- a) if the biochemical is a nucleic acid, the information specified in items 5 and 6 of Schedule 2 of the Regulations; and
- b) if the biochemical possesses enzymatic capability, the information specified in items 7–13 of Schedule 2 of the Regulations.

### 4.6 Information Requirements for Chemicals that are Subsequently Added to the NDSL

It is important to note that, should a chemical be added to the NDSL after a complete Schedule 4 and 5 NSN package has been submitted (including item 10 of Schedule 5) but prior to a Schedule 6 being submitted, the notifier is obligated, under subsection 8(2) of the Regulations, to inform the NS program, in writing, that the chemical is now listed on the NDSL. Once the appropriate fee has been submitted (see Appendix 3 of these Guidelines), a 60-day assessment period will commence to re-assess the substance as a final NSN package.

Alternatively, in the case where a chemical is added to the NDSL after a complete Schedule 4 and 5 NSN package has been submitted (without item 10 of Schedule 5) but prior to a Schedule 6 being submitted, the NS program will inform the notifier that the chemical was added to the NDSL and that subsection 16(3) of the Regulations applies. Subsection 16(3) of the Regulations states that the notifier must ensure that all prescribed data requirements (item 10 of Schedule 5) and fees, as prescribed for NDSL substances, are provided to the NS program. Once all the required information and appropriate fee have been submitted and accepted, a 60-day assessment period will commence to re-evaluate the final NSN package in consideration of the new information.

In addition, once the chemical is added to the NDSL, it may require the additional data prescribed in subsection 7(2) or 7(3) to be submitted if the chemical is released to the aquatic environment in a quantity exceeding 3 kg/day, per site, averaged monthly and after wastewater treatment; and/or where the public may be significantly exposed to the chemical in a product (see section 4.4.3 of these Guidelines).

For example, a complete Schedule 4 and 5 NSN package is submitted for a chemical not on the NDSL. Subsequently, the substance is added to the NDSL. The NS program will inform the notifier that the substance is now listed on the NDSL and that the notifier is required to provide item 10 of Schedule 5 and the appropriate fee (see Appendix 3 of these Guidelines). Once this information is received and accepted, the NS program then has an additional 60 days to assess the new information and take action, if necessary.

4.0 Notification Information Requirements

4.6 Information Requirements for Chemicals that are Subsequently Added to the NDSL

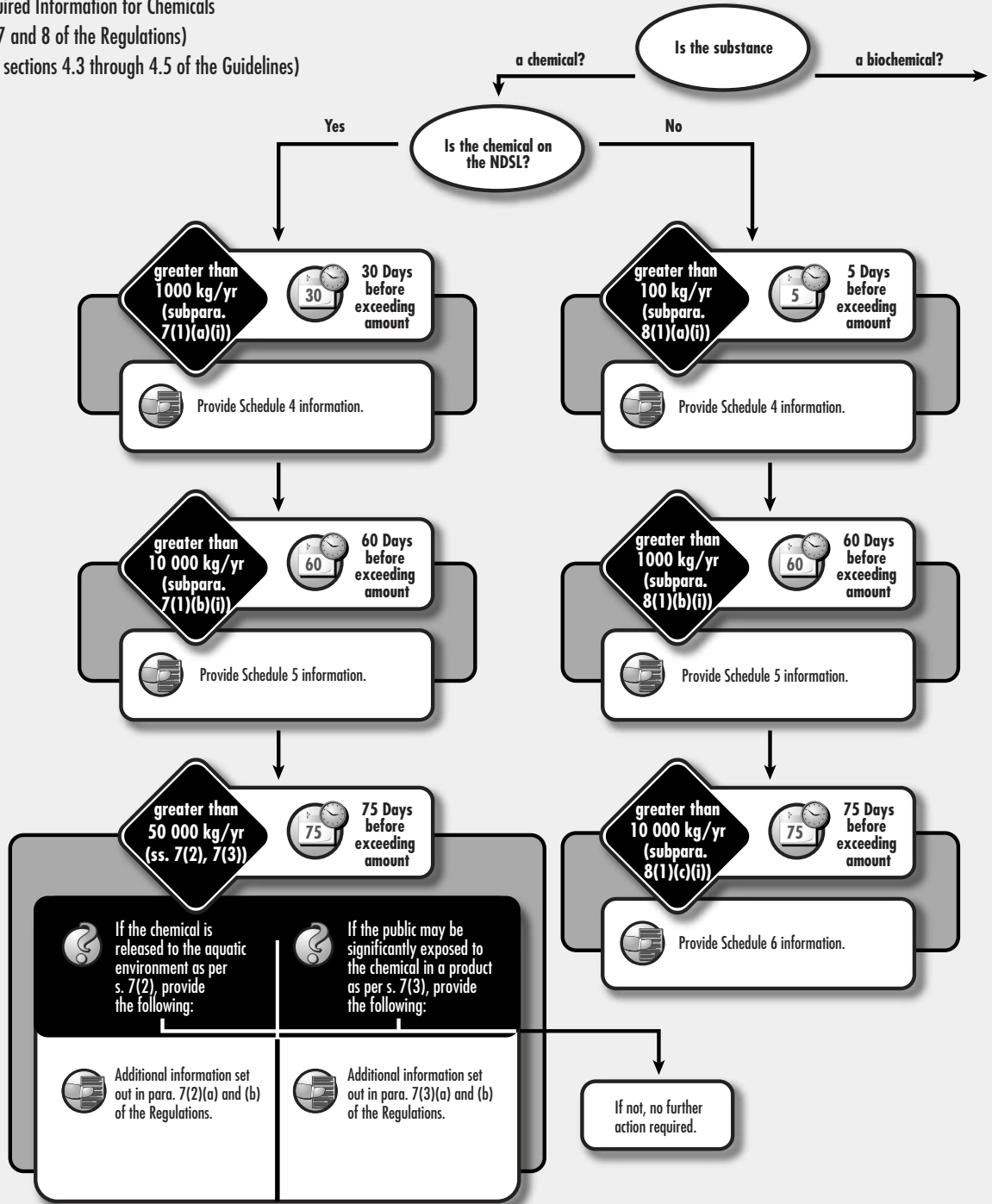
Figure 4-3(a)  
Required Information for Chemicals

**Figure 4-3(a)**

**Required Information for Chemicals**

(ss. 7 and 8 of the Regulations)

(See sections 4.3 through 4.5 of the Guidelines)



This flow chart can be found in a larger full-page version in Appendix 1 of these Guidelines.

**Figure 4-3(b)**

Required Information for Biochemicals (ss. 7 and 8 of the Regulations)  
(See sections 4.3 through 4.5 of the Guidelines)

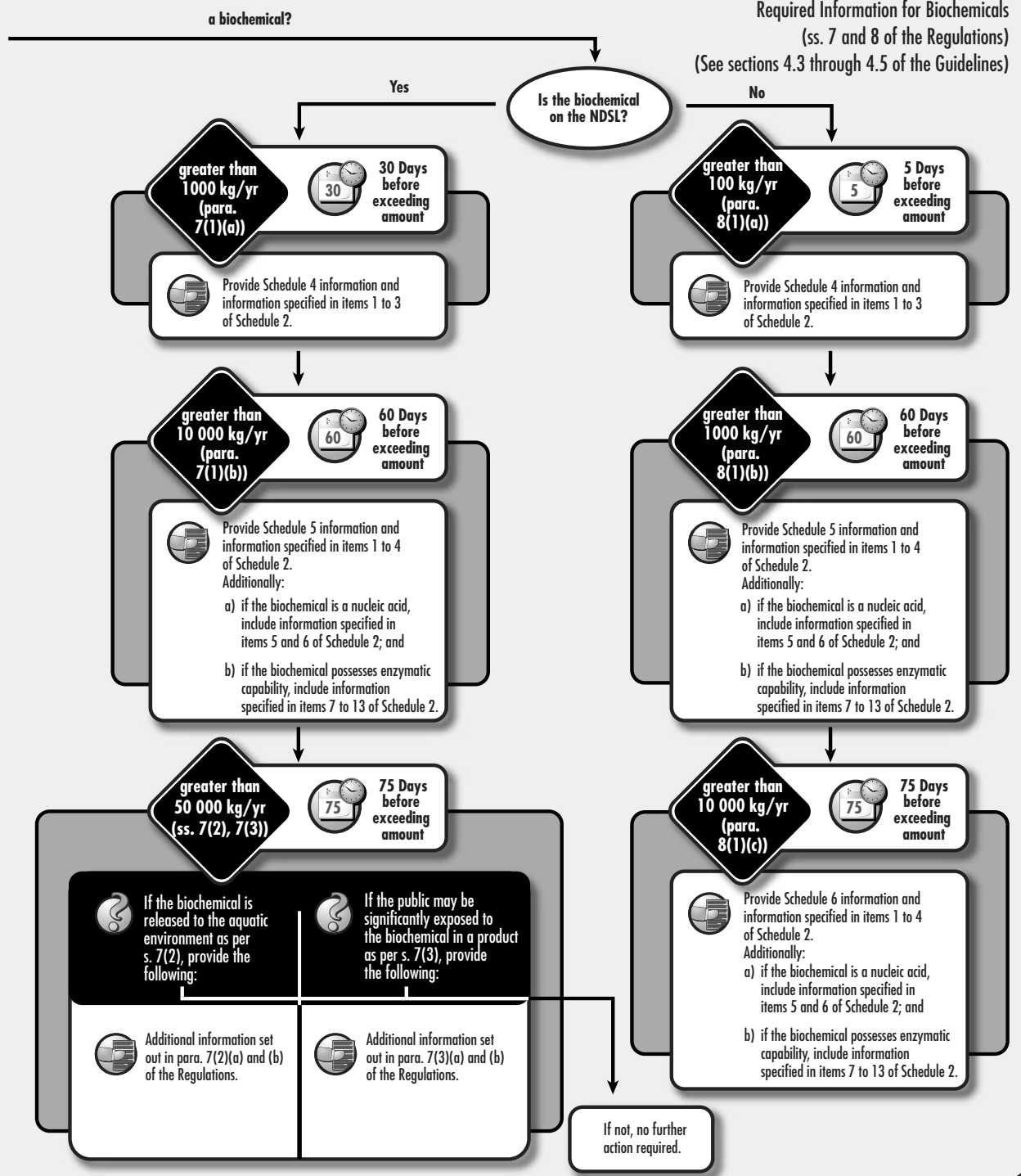


Figure 4-3(b)  
Required Information for Biochemicals

This flow chart can be found in a larger full-page version in Appendix 1 of these Guidelines.

**4.0** Notification Information Requirements**4.7** Notification of Polymers**4.8** Information Requirements for Polymers**4.7 Notification of Polymers**

Similar to the notification of chemicals and biochemicals, the Regulations prescribe information requirements tailored to the use and quantity of the polymer. These requirements are listed in the “Schedules” of the Regulations which are presented in Appendix 4 of these Guidelines. Decision flowcharts are provided at the end of this section and in Appendix 1 of these Guidelines to help select the appropriate notification Schedule.

Before using the flowcharts, Table 1-1 and sections 2.2, 3.4, 3.5, 4.2.3, and 4.7 through 4.9 of these Guidelines should be reviewed to determine:

- a) whether the new substance meets the definition of a polymer given in the Regulations (see section 3.4.1.2 of these Guidelines);
- b) whether the new polymer falls within any of the prescribed special categories (*e.g.* research and development, contained site-limited intermediate or contained export-only; see section 3.5 of these Guidelines);
- c) whether the new polymer is listed on the NDSL (see section 2.2 of these Guidelines);
- d) the annual quantities of the new polymer that will be manufactured in or imported into Canada (see Table 1-1 and sections 4.2.3, 4.8 and 4.9 of these Guidelines);
- e) whether the new polymer meets the definition of an RRR polymer (see section 3.4.1.3 of these Guidelines);
- f) whether the new polymer is manufactured solely from monomers and reactants that are listed on the DSL or NDSL (see section 4.7.1 of these Guidelines); and
- g) whether the NDSL-listed polymer or polymer manufactured solely from monomers and reactants that are listed on the DSL or NDSL will be released to the aquatic environment in significant quantities and/or if the public may be significantly exposed to the substance in a product (see section 4.9.2 of these Guidelines).

The following sections apply only to polymers that are manufactured or imported for a purpose other than as a special category listed in section 3.5 of these Guidelines.

**4.7.1 Monomers and Reactants Listed on the DSL or the NDSL**

To determine whether a polymer notification is eligible for reduced information requirements, it is necessary to find out if the monomers and reactants of the substance are listed on the DSL or NDSL.

To determine the presence of monomer and reactants on the confidential or public portions of the DSL and NDSL, the CAS registry number or Enzyme Commission number can be entered into a search engine located on the NS program web site at [www.ec.gc.ca/substances/nsb/eng/sub\\_e.htm](http://www.ec.gc.ca/substances/nsb/eng/sub_e.htm).

Alternatively, a Notice of *Bona Fide* Intent to Manufacture or Import can be sent to the NS program (see section 2.3.1 of these Guidelines).

It is important to note that if a substance is listed on the DSL, the onus is on the notifier to look at the *Canada Gazette* publication to ensure that there are no flags associated with the substance (see section 2.1.4 of these Guidelines) and therefore no further notification responsibilities. The NS program is working on having these flags added to the search engine.

**4.8 Information Requirements for Polymers (See Figures 4-4(a) and 4-4(b))****4.8.1 Lower-Volume Polymers**

Every notifier who manufactures or imports any polymer must provide the NS program the information prescribed in Schedule 9 of the Regulations at least 30 days prior to the quantity of the polymer exceeding **1000 kg** in a calendar year. If the substance meets the RRR polymer criteria (see section 3.4.1.3 of these Guidelines), the Schedule 9 NSN package is the final notification requirement.

If the substance is a biopolymer, the notifier is also required to provide, in addition to the Schedule 9 information, items 1–3 of Schedule 2 of the Regulations.



## 4.9 Information Requirements for Non-reduced Regulatory Requirement (non-RRR) Polymers (see Figures 4-4(a) and 4-4(b))

The following sections do not apply to polymers that meet the RRR polymer criteria.

### 4.9.1 Higher-Volume Non-RRR Polymers Either Listed on the NDSL or Manufactured from Reactants Listed on the DSL or NDSL

Every notifier who manufactures or imports a non-RRR polymer (see section 3.4.1.4 of these Guidelines) that is either listed on the NDSL or manufactured solely from monomers or reactants listed on the DSL or NDSL must provide the NS program the information prescribed in Schedule 10 of the Regulations at least 60 days prior to the quantity of the polymer exceeding **10 000 kg** in a calendar year.

If the substance is a biopolymer, the notifier is also required to provide, in addition to the Schedule 10 information, the information specified in items 1–4 of Schedule 2 of the Regulations. If the biopolymer is a nucleic acid, the notifier is also required to provide the information specified in items 5 and 6 of Schedule 2 of the Regulations.

The health toxicity endpoint referred to in item 4 of Schedule 10 is not required if the polymer is a non-RRR polymer solely due to the presence of any of the following functional groups:

- aldehydes whose FGEW is less than or equal to 1000 daltons;
- vinyl ethers whose FGEW is less than or equal to 5000 daltons; or
- sulphonic acids whose FGEW is less than or equal to 5000 daltons.

### 4.9.2 Polymers with High Release and/or Significant Exposure

Every notifier who manufactures or imports a polymer that is either listed on the NDSL or manufactured solely from monomers or reactants listed on the DSL or NDSL and:

- that is released to the aquatic environment in a quantity exceeding 3 kg/day, per site, averaged monthly and after wastewater treatment; and/or
- where the public may be significantly exposed to the polymer in a product

must provide the NS program additional test information as prescribed in subsections 11(2) and 11(3) of the Regulations at least 60 days prior to the quantity of the polymer exceeding **50 000 kg** in a calendar year. The additional information required is indicated in the following sections.

This additional information is not required if the polymer is a non-RRR polymer solely due to the presence of any of the following functional groups:

- aldehydes whose FGEW is less than or equal to 1000 daltons;
- vinyl ethers whose FGEW is less than or equal to 5000 daltons; or
- sulphonic acids whose FGEW is less than or equal to 5000 daltons.

#### 4.9.2.1 Polymers Released to the Aquatic Environment

It is the notifier's responsibility to submit evidence in item 5(g) of the Schedule 10 NSN package to support a claim of the substance not being released to the aquatic environment in the quantity indicated above. This information should include any envisioned future use by multiple customers and/or a variety of applications. To calculate daily release to the aquatic component, the estimated daily release should be determined, per site, as follows:

$$\text{EDR} = (\text{AV}/\text{NPD}) \times \text{L} \times (1-\text{T})$$

where:

- |     |   |
|-----|---|
| EDR | = estimated daily release (kg/day)                              |
| AV  | = anticipated annual manufacture or import volume (kg) per site |
| NPD | = anticipated number of production days per year                |
| L   | = anticipated total loss of substance to wastewater (%)         |
| T   | = anticipated removal in wastewater treatment plant (%)         |

The NS program will assess this information and will also perform an additional calculation based on information available to the program. If it is determined that the substance is released to the aquatic environment in quantities greater than indicated above or where the information provided is not acceptable, the additional information prescribed in subsection 11(2) of the Regulations must be provided. The NS program's determination of whether the substance is subject to all or some of the additional information requirements given below will be indicated in the final assessment outcome letter. The notifier may submit additional information to support his or her claim and request a re-evaluation of the decision made by the NS program. The NS program will review and consider this information.

The additional information required, as prescribed in subsection 11(2) of the Regulations, must include the following:

- a) data from a repeated-dose mammalian toxicity test of the polymer of at least 28 days duration, using the most significant route of potential human exposure to the polymer, namely, oral, dermal or inhalation, plus:
  - i) the age, sex, number, species, strain and source of the animals tested;
  - ii) the route by which the polymer is administered and the conditions under which the test is conducted; and
  - iii) the dose of the polymer, the vehicle by means of which the polymer is administered and its concentration in that vehicle; and
- b) mutagenicity data obtained from an *in vitro* test, with and without metabolic activation, for gene mutations or chromosomal aberrations in mammalian cells.

#### 4.9.2.2 Where the Public May Be Significantly Exposed to the Polymer in a Product

It is the notifier's responsibility to submit evidence in item 5(h) of the Schedule 10 NSN package to support a claim of the public not being significantly exposed to the substance. The NS program will assess this information and determine if it is acceptable. If it is determined that the public may be significantly exposed to the polymer in a product or where the information provided is not acceptable, the additional information prescribed in subsection 11(3) of the Regulations must be provided. The NS program's determination of whether the substance is subject to all, or some, of the additional information requirements given below will be indicated in the final assessment outcome letter. The notifier may submit additional information to support his or her claim and request a re-evaluation of the decision made by the NS program. The NS program will review and consider this information.

Since public exposure is dependent on many factors, it is difficult to give a calculation to determine what is "significant" without being extremely conservative. Therefore, the definition of "significantly exposed" will be assessed, by the NS program, on a case-by-case basis. This assessment will take into consideration such factors as type of use, duration and frequency of use, concentration of the substance in the product and circumstances of exposure that may limit direct human exposure (*e.g.* whether the substance is chemically consumed during use or is able to migrate from the product). To determine if the public may be significantly exposed to the polymer in a product, the NS program provides the opportunity for notifiers to submit a PNC request (see section 8.8 of these Guidelines).

Some examples of consumer applications where significant exposure of a substance may occur include, but are not limited to, dishwashing detergent, laundry products, soaps, toilet paper, cleaning solutions, waxes, polishes, air fresheners, paints, oils, greases and ink.

The additional information required, as prescribed in subsection 11(3) of the Regulations, must include the following:

- a) data from a repeated-dose mammalian toxicity test of the polymer of at least 28 days duration, using the most significant route of potential human exposure to the polymer, namely, oral, dermal or inhalation, plus:

- i) the age, sex, number, species, strain and source of the animals tested;
  - ii) the route by which the polymer is administered and the conditions under which the test is conducted; and
  - iii) the dose of the polymer, the vehicle by means of which the polymer is administered and its concentration in that vehicle;
- b) mutagenicity data obtained from an *in vitro* test, with and without metabolic activation, for gene mutations; and
- c) data obtained from an *in vitro* test, with and without metabolic activation, for chromosomal aberrations in mammalian cells or the data from a previously existing *in vivo* mammalian test for chromosomal aberrations that, together with data substantiating that the tissue investigated was exposed to the polymer or its metabolites, permits an assessment of *in vivo* clastogenicity.

#### 4.9.3 Higher-Volume Non-RRR Polymers Not on the NDSL and Not Manufactured Solely from Reactants Listed on the DSL or NDSL

Every notifier who manufactures or imports a non-RRR polymer (see section 3.4.1.4 of these Guidelines) not on the NDSL and that contains one or more reactants not on either the DSL or the NDSL must provide the NS program the information prescribed in Schedule 11 of the Regulations at least 60 days prior to the quantity of the polymer exceeding **10 000 kg** in a calendar year.

If the substance is a biopolymer, the notifier is also required to provide, in addition to the Schedule 11 information, items 1–4 of Schedule 2 of the Regulations. If the biopolymer is a nucleic acid, the notifier must also provide the information specified in items 5 and 6 of Schedule 2 of the Regulations.

Health toxicity endpoints referred to in items 5–10 of Schedule 11 are not required if the polymer is a non-RRR polymer solely due to the presence of any of the following functional groups:

- a) aldehydes whose FGEW is less than or equal to 1000 daltons;
- b) vinyl ethers whose FGEW is less than or equal to 5000 daltons; or
- c) sulphonic acids whose FGEW is less than or equal to 5000 daltons.

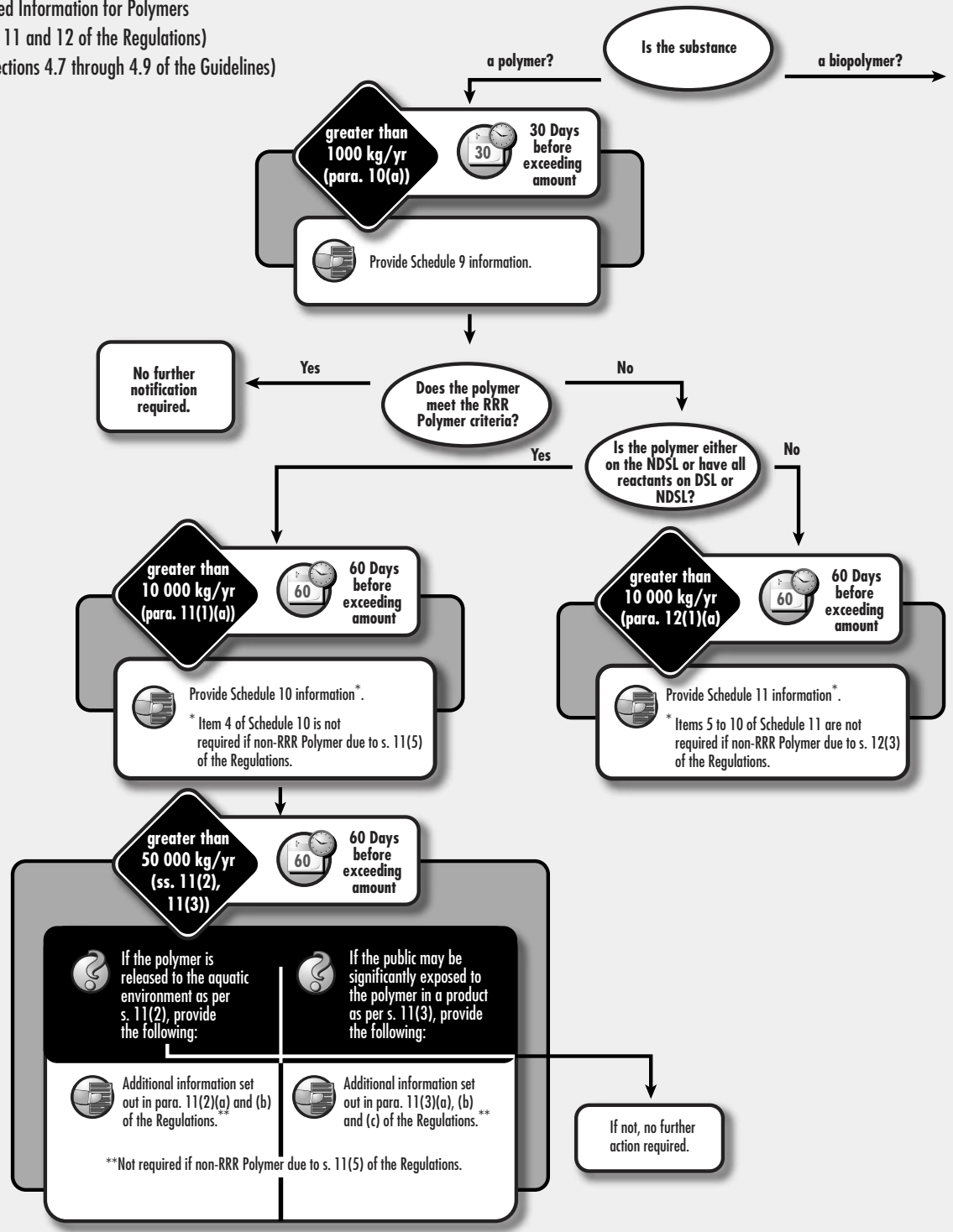
4.0 Notification Information Requirements

4.9 Information Requirements for Non-reduced Regulatory Requirement (non-RRR) Polymers

Figure 4-4(a) Required Information for Polymers

**Figure 4-4(a)**

Required Information for Polymers  
(ss.10, 11 and 12 of the Regulations)  
(See sections 4.7 through 4.9 of the Guidelines)



This flow chart can be found in a larger full-page version in Appendix 1 of these Guidelines.

**Figure 4-4(b)**  
 Required Information for Biopolymers  
 (ss.10, 11 and 12 of the Regulations)  
 (See sections 4.7 through 4.9 of the Guidelines)

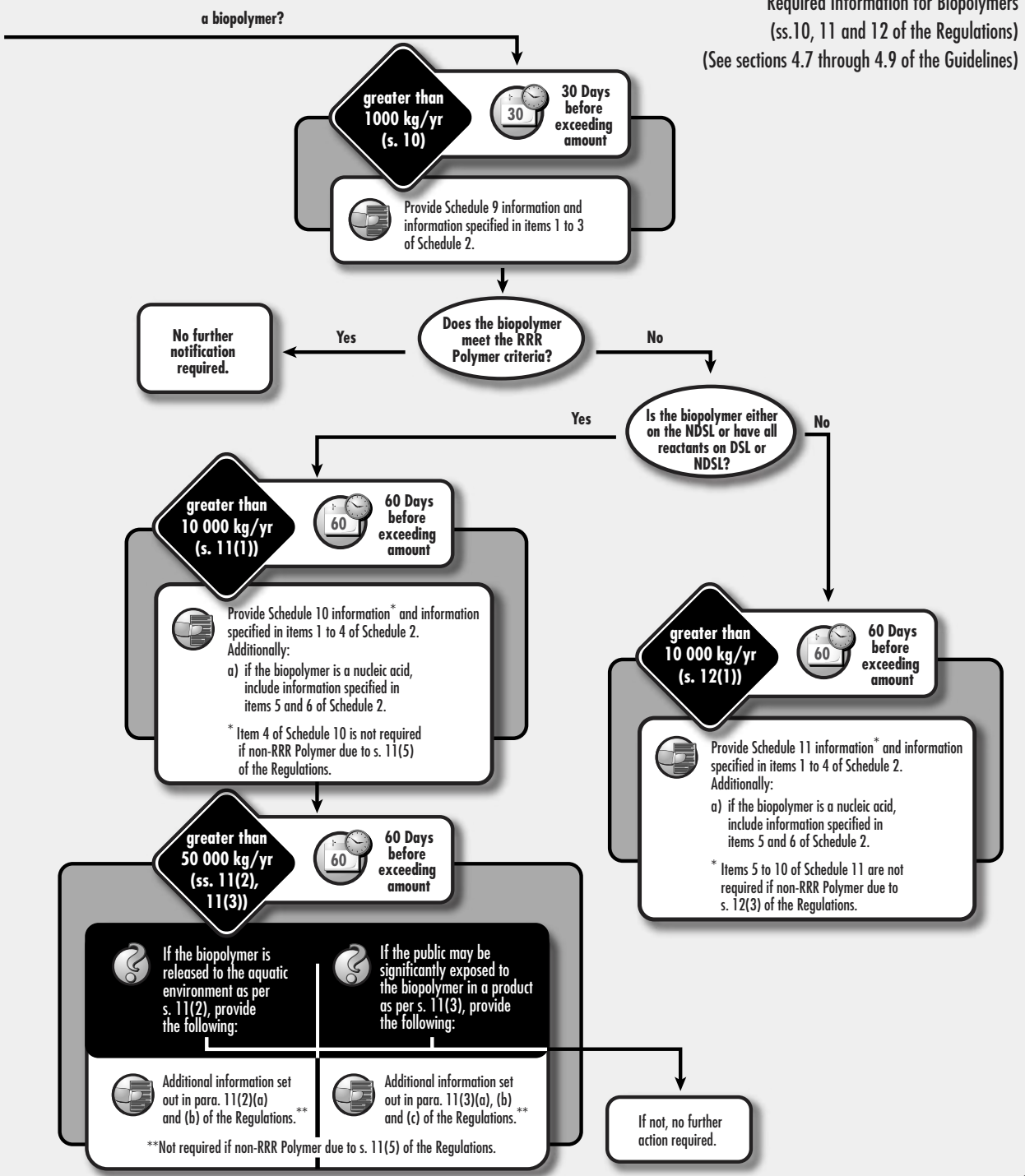


Figure 4-4(b)  
 Required Information for Biopolymers

This flow chart can be found in a larger full-page version in Appendix 1 of these Guidelines.



## SECTION 5 — New Substances Notification (NSN) Packages

Subsection 81(1) of the Act prohibits the manufacture or import of any substance that is not on the DSL or the confidential portion of the DSL unless the notifier manufacturing or importing the substance has provided the prescribed information within the prescribed time and with the prescribed fee (see Appendix 3 of these Guidelines); and the period for assessing the information has expired or has been terminated early (see section 9.3.5 of these Guidelines). The prescribed information specified in the Regulations (see Appendix 4 of these Guidelines) consists of both administrative and technical information (described in sections 6.2 through 6.7 of these Guidelines).

Fees are required to be provided with each NSN package submitted under the Regulations. The amount of fees required is dependent on the amount of annual sales in Canada for the notifier; the specific Schedule being submitted; and other services being requested (*e.g.* confidential searches on the DSL or NDSL or masked name application). A fee schedule, for different levels of service, and examples are provided in Appendix 3 of these Guidelines. Additional information can also be found in the NSFR and the *Regulations Amending the New Substances Fees Regulations*.

Fee reductions are available for notifiers meeting the criteria for small- or medium-sized enterprises (SMEs) (see Appendix 3 of these Guidelines) and for matched or consolidated notifications, as described below in sections 5.1 and 5.3, of these Guidelines.

At this time, the fees do not apply to NSN packages submitted for biochemicals or biopolymers, research and development substances or substances that are regulated under any other Act of Parliament (*e.g.* F&DA).

### 5.1 Matched Notifications

A Matched Notification takes place when a notifier requests that the NS program use information that was previously provided by another notifier for the same substance. Such information may include test requirements or additional information. The notifier who is providing the information must submit a letter of authorization to the NS program indicating his or her NSN reference number as well as the name of the notifier whom he or she is supporting, together with the latter notifier's NSN reference number, if known. When files are matched, there may be a price reduction in the required fees (see Appendix 3 of these Guidelines). This is different from a Foreign Supplier Submission (see section 5.2 of these Guidelines).

### 5.2 Foreign Supplier Submissions (Confidential Information Provided by a Foreign Supplier)

Any information submitted to the NS program may be claimed as confidential (see section 7 of these Guidelines). In cases where the notifier is not given access to information that is considered confidential by the foreign supplier, the confidential information to support the NSN package must be supplied directly to the NS program by the foreign supplier and will be identified as a "Foreign Supplier Submission".

The procedure for submitting a Foreign Supplier Submission is as follows: The notifier must initiate the NSN process by providing all the administrative information (blocks A.1 to A.16 of the NSN reporting form; see section 6.2.1 of these Guidelines); all exposure information, including manufacture, importation, use, transport, exposure, release and disposal information requirements (Appendix I of the NSN reporting form); and any other information the notifier has in his or her possession pertaining to the substance.

**5.0 New Substances Notification (NSN) Packages****5.2 Foreign Supplier Submissions (Confidential Information Provided by a Foreign Supplier)****5.3 Consolidated Notifications****5.4 Test Data**

The NSN package must also include reference to the pending Foreign Supplier Submission. Once the notifier has initiated the NSN process and has been provided with an NSN reference number, the confidential information required to complete the NSN package must be submitted directly to the NS program by the foreign supplier, referencing the appropriate NSN reference number to which the information is being provided.

If several companies are manufacturing or importing the same substance from the same foreign supplier, each notifier must submit individual NSN packages to the NS program, and each notifier is responsible for tracking their own manufacture or import volumes. Each NSN package will be assigned a different NSN reference number.

If the foreign supplier has already submitted the confidential information on a substance for one notifier, the same information does not need to be resubmitted for other notifiers. However, a letter of authorization from the foreign supplier must be sent to the NS program allowing the cross-referencing and use of the information within the original Foreign Supplier Submission to complete each subsequent NSN package by other notifiers for the same substance. Fee reductions may be applicable (see Appendix 3 of these Guidelines).

### 5.3 Consolidated Notifications

Consolidated Notifications take place when a notifier simultaneously provides two to six NSN packages for substances of the same class and where the technical information provided for one substance is used to address the technical information requirements for the remaining substances. Although not required, it is recommended that notifiers who wish to notify a number of very similar substances at one time as Consolidated Notifications do so after consultation with the NS program, through a PNC request (see section 8.8 of these Guidelines), to ensure that the technical information is sufficient to address the NSN requirements for all substances in question. In these cases, a separate NSN reference number is issued for each of the substances captured by the consolidated NSN, but the NSN packages are grouped together for the purposes of a common risk assessment. Consolidated Notifications are subject to reduced fees (see Appendix 3 of these Guidelines).

### 5.4 Test Data

Test data developed must be consistent with the conditions and procedures set out in the Organisation for Economic Co-operation and Development (OECD) Test Guidelines (TGs) that are current at the time the test data are developed (see section 8.1.1 of these Guidelines).

In addition, the development of certain test data must comply with the practices set out in the “Principles of Good Laboratory Practice” (GLP) that are current at the time the test data are developed (see section 8.3 of these Guidelines).

Protocols and laboratory practices that are recommended by the NS program for the generation of experimental data are described in section 8 of these Guidelines.

Explanations of the conditions under which waivers of prescribed information may be granted are described in section 8.7 of these Guidelines, and examples are given in Appendix 8 of these Guidelines.

Full test reports must be provided for all prescribed test data; summaries will not be accepted. It is important to ensure that the name and/or trade name of the substance indicated in the test report provided correspond to the name and/or trade name in the NSN package. Although the values for the test data will be included in the test reports, values and conditions should also be provided in sections B.1, B.2 and B.3 of the NSN reporting form (see section 6.3 of the Guidelines).

If literature papers are referenced, a copy of each paper must be provided. If software estimates/models are being used, information on the model (*e.g.* version of software, etc.), the input data and model output must be provided to allow for an assessment of the data by the NS program (see section 8.4.3 of these Guidelines).



Test data submitted in a previous NSN package, PNC request or notice under section 70 of the Act need not be resubmitted; however, the appropriate reference number must be supplied (see “P” code in section 6.1.2 of these Guidelines).

For polymers, two information requirements, “whether the substance is formulated for dispersal in water” and “physical state” do not require quantitative determinations. The requirement for dispersibility in water will be satisfied by indicating “yes” or “no”, whereas the requirement for physical state will be satisfied with an appropriate term (*e.g.* “solid,” “wax” or “liquid”). These responses are to be provided in the appropriate value column of the NSN reporting form.

## 5.5 Record-Keeping Requirements

Pursuant to section 13 of the Regulations, a notifier who is required to provide information to the Minister or the NS program under the Regulations must keep a copy of that information and any supporting data at the notifier’s principal place of business in Canada or at the principal place of business in Canada of a representative of that notifier. The information and the supporting data must be kept for a period of five years after the year in which the information is provided.

5.0 New Substances  
Notification (NSN)  
Packages

5.4 Test Data

5.5 Record-Keeping  
Requirements



## SECTION 6 — The New Substances Notification (NSN) Reporting Form

The NSN reporting form is intended to serve as an aid for complying with the Regulations. The NSN reporting form is divided into four sections: Part A — Administrative and Substance Identity Information Requirements; Part B — Technical Information Requirements; Part C — Biochemical or Biopolymer Information Requirements; and Part D — Additional Information Requirements. In addition, two Appendices are included in the NSN reporting form: Appendix I — Manufacture, Import, Use, Exposure and Release Information (Known and Anticipated), which includes all manufacture/import, use and disposal information; and Appendix II — New Substances Fee Payment Form.

Please note that a complete NSN package must contain the specific information requirements of Part A, Part B, Part C and Appendix I, including all test data, laboratory reports, waiver justifications and other attachments necessary to fulfil the requirements set by the Regulations. Additional information must be listed in Part D. Appendix II is provided as an aid in determining the fee required for each specific NSN package.

If the NSN reporting form is incomplete or is filled out incorrectly, the submission may be returned to the notifier, which will lead to delays in the assessment period.

Information that will not fit in the appropriate block on the NSN reporting form should be included in an attachment.

Subsection 14(3) of the Regulations states that all information (except for “Additional Information”, as described in section 6.5 of these Guidelines) must be provided in English or French; and two copies of any information provided under the Regulations must be submitted to:

### **Mailing Address:**

Director, New Substances Division  
Science and Technology Branch  
Department of the Environment  
Ottawa, Ontario K1A 0H3

### **Courier Deliveries:**

Director, New Substances Division  
Science and Technology Branch  
Department of the Environment  
14<sup>th</sup> Floor, Place Vincent Massey  
351 St. Joseph Blvd.  
Gatineau, Québec J8Y 3Y5

The NS program will confirm receipt of the NSN package and provide an NSN reference number (see section 9.2.3 of these Guidelines) that is to be used in all further correspondence concerning that NSN package.

The NSN reporting form or sections of the NSN reporting form may be reproduced as often as required without permission. An electronic version of the NSN reporting form can be obtained from the NS program web site at [www.ec.gc.ca/substances/](http://www.ec.gc.ca/substances/) or by contacting the NSN Information Line (see the Comments and Inquiries section of these Guidelines).

## 6.1 Data Codes, Attachments and Confidential Information

In addition to the list of information requirements, Part B of the NSN reporting form contains five columns: Submit with Schedule; Data Codes; Value and Conditions; Attachment Number; and Confidential Information. The following explains the use for each of these columns. Explanations also appear on page 2 of the NSN reporting form.

### 6.1.1 Submit with Schedule

This is a quick reference column that allows notifiers to determine, at a glance, which Schedule requires the information to be provided. Footnotes also provide additional guidance for certain exceptions and conditions associated with certain data elements. It is important to note that if lower Schedule notifications are not submitted, the information prescribed in them is still required to be submitted with the higher Schedule notifications.

### 6.1.2 Data Codes

A Data Code is a reference to indicate whether data are provided; the type of data being submitted; or whether a request for waiver of information is being submitted. The Data Codes with explanatory notes are:

- **D = test data on notified substance**  
This code is used when the data provided were generated on the notified substance using protocols consistent with those listed in Tables 8-1 to 8-4 of these Guidelines. This code is to be used even if the information is provided under the Additional Information requirements of the Schedules (see section 6.5 of these Guidelines).
- **A = alternative procedures**  
This code is used when the data provided were generated using 1) an alternative test protocol; 2) structure–activity relationships (SARs), including surrogate data and quantitative structure–activity relationships (QSARs); or 3) other calculation methods (see section 8.4.3 of these Guidelines). This code is to be used even if the information is provided under the Additional Information requirements of the Schedules (see section 6.5 of these Guidelines).
- **W = waiver requested**  
This code is used when prescribed information is being requested to be waived under subsection 81(8) of the Act. Requests for waiver(s) of prescribed information must be accompanied by justifications that satisfy any of the waiver criteria listed in the aforementioned subsection of the Act (see section 8.7 of these Guidelines).
- **N/A = not applicable**  
This code is used when the Regulations specify that the provision of information is not required under certain conditions. For example, the adsorption–desorption screening test data is not required when water solubility is less than 200 µg/L. This code cannot be used as an abbreviation for “not available”.
- **NR = not required**  
This code is used when the information has not been provided and is not required for that specific Schedule of the Regulations.
- **P = previous NSN reference number, PNC reference number or notice under section 70 of the Act**  
This code is used when the notifier has already provided the information to the NS program in a previous NSN package; PNC request; and/or a notice under section 70 of the Act. The applicable NSN, PNC or notice under section 70 reference number must be entered in the Attachment column.

### 6.1.3 Value and Conditions

Although complete physical-chemical data must be submitted in test reports (physical state and whether the notified substance is formulated for dispersal in water excepted), the notifier must enter the value and conditions in the appropriate space provided. This information will assist the notifier in organizing data for

use; in requesting waivers of information; in justifying cases when data are not applicable; and in discussing notifications with NS program officials. Physical-chemical values and corresponding conditions may be expressed in units cited within the laboratory report. In the event that the data are available, for example, only in degrees Fahrenheit, the notifier must strike the °C symbol printed in the entry and replace it with the °F symbol.

#### 6.1.4 Attachment Number

Notifiers must clearly indicate a reference for accompanying documents (*e.g.* Attachment 6) so they may be readily located within the NSN package. Attachments include: justifications for waivers of information; reports of experimental procedures; reports of test results; rationale for alternative data; results and validation of modeling studies; rationales for why information is considered “not applicable”; and information supplemental to a request for confidentiality.

#### 6.1.5 Confidential Information

Notifiers must check the appropriate box to indicate that the information provided is considered confidential (*e.g.* check “Y” to indicate that the information provided is considered confidential or check “N” to indicate that the information provided is not confidential). If the information provided is considered confidential, the notifier must provide, in the NSN package, the supplementary information detailed in section 7.2 of these Guidelines.

### 6.2 Part A: Administrative and Substance Identity Information Requirements

To assist in completing the NSN reporting form, explanations of the various administrative and substance identity information requirements are provided. Subsection 14(1) of the Regulations states the information required for the administrative requirements of the NSN package.

Blocks A.1 to A.20 of the NSN reporting form must be completed for all substances that are subject to any Schedule in the Regulations.

#### 6.2.1 Administrative Information

The alpha-numeric character associated with the following explanations corresponds with the appropriate block on the NSN reporting form.

##### 6.2.1.1 A.1 Certification Statement

The person named in this block is the person who is manufacturing the notified substance in or importing the notified substance into Canada or, when the importer is not a Canadian resident, a person authorized to act on behalf of the “Non-resident Importer” as the “Canadian Agent” (see section 6.2.1.4 of these Guidelines). The person named in this block is the notifier. The Certification Statement includes the following phrase:

I hereby certify to the best of my information, knowledge and belief that all information provided in this form, as well as any attachments to the form, is accurate and complete; and the information for which confidentiality is claimed meets the criteria for determining confidentiality as outlined in section 7 of the *Guidelines for the Notification and Testing of New Substances (Chemicals and Polymers)*.

The notifier must sign and date this Certification Statement. The signature is a certification that the information provided in the NSN package is accurate and complete to the best of his or her knowledge.

This block also allows the notifier to indicate the preferred language of correspondence and preferred mode of communication for correspondence. It is important to note that the Government of Canada does not consider facsimile a secure mode of communication; if facsimile is chosen, the notifier accepts the potential risks associated with this. If a preference for facsimile is indicated, no originals of the transmitted correspondence will be sent to the addressee unless the correspondence is from the Minister (see sections 9.5.2 and 9.5.3 of these Guidelines).

6.0 The New Substances Notification (NSN) Reporting Form

6.1 Data Codes, Attachments and Confidential Information

6.2 Part A: Administrative and Substance Identity Information Requirements

**6.2.1.2 A.2 Corporate Headquarters of the Canadian Manufacturer or Importer (Principal Place of Business in Canada): (if the importer is not located in Canada skip to block A.3)**

A notifier who is a Canadian resident and is manufacturing a substance in or importing a substance into Canada must provide:

- a) the name and address of the manufacturer or importer; and
- b) the civic and postal addresses, telephone and fax numbers (including area code) and e-mail address, if any, of the manufacturer or importer of the notified substance.

If the importer is not located in Canada, block A.2 must be left blank and blocks A.3 and A.4 must be completed, as described below.

**6.2.1.3 A.3 Corporate Headquarters of the Non-resident Importer (if applicable, also complete block A.4)**

When a foreign company or “Non-resident Importer” is the “Importer of Record,” as shown on the Canadian Customs coding form (Form B3-3) as issued by the Canada Border Services Agency, and:

- a) possesses a “Canadian Importer” status;
- b) has “Importer of Record” status; and
- c) is importing the notified substance into Canada

the foreign company or “Non-resident Importer” must leave block A.2 blank and provide the following information in block A.3:

- a) the name and address of the “Non-resident Importer”;
- b) the civic and postal addresses, telephone and fax numbers (including area code) and e-mail address, if any, of the “Non-resident Importer” of the notified substance; and
- c) the name and address of a “Canadian Agent” (see block A.4 below).

**6.2.1.4 A.4 Canadian Agent (only needed if block A.3 is applicable)**

Subsection 14(3) of the Regulations states that if the notifier who provides the information under the Regulations is not a resident of Canada, the notifier must identify, under paragraph 14(1)(b) of the Regulations, a person resident in Canada who is authorized to act on the notifier’s behalf as the “Canadian Agent”.

Therefore, when a “Non-resident Importer” (see section 6.2.1.3 of these Guidelines) is the “Importer of Record” on the Canadian Customs documentation for the notified substance being imported, information on the “Canadian Agent” must be provided.

When a “Canadian Agent” is required, the following information must be provided:

- a) the signatures of both the “Non-resident Importer” and the “Canadian Agent” in block A.1;
- b) the name, title, company, civic and postal addresses, telephone and fax numbers (including area code) and e-mail address, if any, of the “Non-resident Importer” in block A.3; and
- c) the name, title, company, civic and postal addresses, telephone and fax numbers (including area code) and e-mail address, if any, of the person authorized to act on behalf of the “Non-resident Importer” of the notified substance as the “Canadian Agent” in block A.4.

If a “Non-resident Importer” provides the information under the Regulations and does not provide the required information on the “Canadian Agent”, the NSN package will be considered incomplete and will be returned.

If the “Non-resident Importer” has more than one Canadian customer for the same notified substance, NSN packages are not required for each customer as long as the “Non-resident Importer” is recognized as the “Importer of Record” for all shipments going to his or her customers. Yearly import volumes should be tracked by both the “Canadian Agent” and the “Non-resident Importer” to ensure that subsequent higher-volume notification obligations are met.

The “Non-resident Importer” may request to be copied on all correspondence, however the “Canadian Agent” is required to receive all notices or correspondence that may be sent in relation to the NSN package and keep a copy of the complete NSN package including the confidential information (except in the case where a foreign

supplier is used) and all correspondence and supporting data with respect to the NSN package, for the period of five years after the end of the year in which the information is provided (see section 13 of the Regulations). The “Canadian Agent” is legally responsible for complying with the Regulations.

#### **6.2.1.5 A.5 Foreign Supplier (only needed if the technical information in Part B is provided by a third party)**

If any, or all, of the confidential technical information from Part B of the NSN reporting form is being provided by a third party or foreign supplier, the name and address of the third party or foreign supplier must be provided in block A.5. This information should include the civic and postal addresses, telephone and fax numbers (including area code) and e-mail address, if any.

#### **6.2.1.6 A.6 Proposed Site of Manufacture in Canada / Proposed Port of Entry into Canada / Toll Manufacturer Information**

For notified substances that are manufactured in Canada, the notifier must provide the civic address of the site of manufacture of the notified substance in Canada. If there is more than one site of manufacture, all must be provided in an attachment.

For notified substances that are manufactured in Canada on toll the notifier must provide the following information:

- a) the name of the toll manufacturer, including a contact name;
- b) the civic and postal addresses, telephone and fax numbers (including area code) and e-mail address, if any, of the toll manufacturer of the notified substance;
- c) a statement, signed by the toll manufacturer, indicating that they accept all compliance responsibilities with respect to: the manufacture of the notified substance; and any accidental release of the notified substance; and
- d) all required information on the manufacturing facility as described in section 6.6.1 of these Guidelines.

For notified substances that are imported into Canada, the notifier must provide the port of entry into Canada of the notified substance; this should include at least the city and province. If there is more than one port of entry, all must be provided in an attachment. Recognized ports of entry are listed at [www.cbsa-asfc.gc.ca/contact/listing/indexpages/index-e.html](http://www.cbsa-asfc.gc.ca/contact/listing/indexpages/index-e.html).

#### **6.2.1.7 A.7 Technical Contact**

The name of a person who is familiar with the content of the NSN package and can assist in the resolution of issues pertaining to ambiguous, incomplete or missing information must be provided. This person must be identified by his or her name, title, civic and postal addresses, telephone and fax numbers (including area code) and e-mail address, if any. The technical contact need not be a resident of Canada but must be familiar with the nature and content of the NSN package.

#### **6.2.1.8 A.8 Previous NSN Reference Number / PNC Reference Number**

All Schedules require the notifier to provide any previous NSN reference number(s) or PNC reference number(s), if one has been assigned, and the date (YYYY-MM-DD) of the submission of that information.

#### **6.2.1.9 A.9 Fee Provided (if applicable)**

The notifier should indicate the amount of the fee provided as per the NSFR (see Appendix 3 of these Guidelines). Appendix II of the NSN reporting form should also be completed and accompany the NSN package.

#### **6.2.1.10 A.10 Manufacture / Import**

An indication of whether the notified substance will be manufactured in and/or imported into Canada must be provided.

#### **6.2.1.11 A.11 Amount**

The notifier must indicate the prescribed annual quantity that triggers the requirement to notify.

## 6.0 The New Substances Notification (NSN) Reporting Form

## 6.2 Part A: Administrative and Substance Identity Information Requirements

**6.2.1.12 A.12 Date that the Amount in Block A.11 Is Expected to Be Exceeded**

The notifier must provide the date on which the trigger quantity noted in block A.10 is anticipated to be exceeded. This date should be entered in the form of YYYY-MM-DD.

**6.2.1.13 A.13 Substance Information (check all that apply)**

The notifier must mark the appropriate box(es) with an “X” to indicate substance type (chemical, biochemical, polymer, biopolymer, special categories, on NDSL). If the notified substance is a polymer, additional boxes must be marked with an “X” for information pertaining to reactants and RRR polymer criteria (see section 3.4.1.3 of these Guidelines). If the notified substance is on the confidential portion of the NDSL, the notifier must also provide the confidential NDSL accession number.

If the notified substance is intended for use in both industrial and F&DA products (dual use) the notifier must leave the box “Solely for F&DA use” blank and submit the NSN package with the appropriate fees to the NS program.

The “solely for F&DA use” box must be checked only if the notified substance is solely for an F&DA use. Substances intended solely for an F&DA use are not subject to the NSFR. For more information regarding the notification of substances in products regulated by the F&DA contact the Environmental Assessment Unit of Health Canada by phone at 1-866-996-9913 or 613-948-3591 or by email at eau-uee@hc-sc.gc.ca.

**6.2.1.14 A.14 Schedule Number**

The appropriate Schedule being provided must be circled for the type of substance that is being notified. NSN packages for notified substances that are biochemicals or biopolymers must also contain specific items from Schedule 2 of the Regulations. In these cases both the notified Schedule and Schedule 2 should be circled.

**6.2.1.15 A.15 Anticipated, Historical and Other Likely Uses of the Substance**

Any anticipated, historical or other likely uses of the notified substance should be entered here. Additional information is also required for certain Schedules and should be provided in Part B1. of Appendix I of the NSN reporting form (see section 6.6.2.1 of these Guidelines).

**6.2.1.16 A.16 Anticipated Annual Quantity to Be Manufactured and/or Imported**

An estimate of the annual manufacture or import quantities during the first 12 months after notification must be provided. Additional information should also be provided in Part A of Appendix I of the NSN reporting form (see section 6.6.1 of these Guidelines).

**6.2.1.17 A.17 Confidentiality Requests**

Notifiers must check the appropriate box to indicate whether the information provided is confidential or not (e.g., “Y” or “N”, respectively). If the information is considered confidential, the notifier must provide, in the NSN package, the supplementary information detailed in section 7.2 of these Guidelines.

Marking the “Y” box infers the following:

- **Corporation:** The link of the substance identity to the corporation or persons in any or all of blocks A.2–A.5 is confidential.
- **Manufacture:** The fact that the corporation identified in block A.2 or A.3 manufactures the substance at the site identified in A.6, or at any site indicated on any attachment provided with this NSN reporting form, is confidential.
- **Import:** The fact that the corporation identified in block A.2 or A.3 imports the substance at the port of entry identified in A.6, or at any port of entry indicated on any attachment provided with this NSN reporting form, is confidential.
- **Amount:** The amount of substance the notifier anticipates exceeding, as indicated in block A.11, as well as the expected date of the exceedence, as indicated in block A.12, are confidential.



- **Substance Identity:** The identity of this substance as indicated in block A.20 is confidential. The supplemental information described in section 7.2 and Appendix 7 of these Guidelines (Masking of Substance Names) must accompany a confidential substance identity claim.

#### 6.2.1.18 A.18 Information-Sharing Agreement Authorization

Instances may occur where a substance has been notified but has not been added to the DSL, because: the notified substance did not meet all of the criteria in section 87 of the Act; risk management measures were taken on the notified substance; or the assessment or processing of the NSN package is still in progress. In such cases, any other notifier intending to manufacture or import that substance will be required to provide a complete NSN package. To reduce both duplicate testing and the expense of developing information for an NSN package, the NS program provides an opportunity for notifiers of a common substance to exchange data through the use of an Information-Sharing Agreement (ISA). There are no additional fees required for using the ISA.

An ISA starts when a notifier provides the NS program with 1) documentation of intent to manufacture or import a particular substance; and 2) authorization to release the name of the technical contact within the company to any other company that also meets these two criteria for that substance.

Documentation of intent to manufacture or import a substance may be either an NSN package or a Notice of *Bona Fide* Intent to Manufacture or Import (see section 2.3.1 of these Guidelines). After receipt and acceptance of this documentation, the NS program will conduct a search for ISA candidates and, if any exist, will simultaneously provide each notifier with the name of the other company or companies and the name, address and phone number of the technical contact for each company. The NS program's contribution to the process will end at this point, and the notifiers may then proceed to negotiate an ISA.

If a notifier is willing to enter into an ISA, the ISA Authorization box (Box A.18) must be signed and dated (YYYY-MM-DD).

### 6.2.2 Substance Identity Information

The NS program must receive complete and unambiguous identification of the new substance (see section 3.4 of these Guidelines). If the notified substance is not adequately identified, the submission will be declared incomplete and returned. This block must be completed even if the substance identity is claimed as confidential.

#### 6.2.2.1 A.19 CAS Registry Number and/or Enzyme Commission Number

All Schedules of the Regulations require that the CAS registry number be provided, if such a number can be assigned to identify the notified substance. Schedule 2 of the Regulations requires an Enzyme Commission number to be provided for biochemicals that possess enzymatic capability, if it is available.

##### 1. CAS Registry Number

The most precise CAS registry number available for the notified substance must be obtained. For example, CAS registry number 68527-02-6 (chlorinated olefins (C<sub>12</sub>-C<sub>24</sub>)) would not be acceptable for (Z)-1-chloro-5-dodecene; the acceptable CAS registry number for this substance is 71673-24-0.

Sources of existing CAS registry numbers are described in Appendix 6 of these Guidelines. To obtain information on CAS registry numbers, contact:

**Chemical Abstracts Service**  
**2540 Olentangy River Road**  
**P.O. Box 3012**  
**Columbus, OH 43210**  
**U.S.A.**

**Telephone: 614-447-3600**  
**1-800-848-6538 Ext. 3731 (Canada and United States)**

**Facsimile: 614-447-3713**

**Internet: [www.cas.org](http://www.cas.org)**

**2. Enzyme Commission Number Designated by the IUBMB**

Enzyme Commission numbers, as designated by the nomenclature committee of the IUBMB, are also commonly referred to as IUBMB numbers. The Enzyme Commission number is the source for internationally accepted enzyme nomenclature and classification systems.

The Enzyme Commission number is a four-figure set in which the first figure denotes one of the six main classes of catalytic substances based on the reaction catalyzed; the second and third figures indicate subclasses; and the fourth figure is the serial number of the catalytic substance in its subclass. The four-digit Enzyme Commission number is a unique number assigned to substances with catalytic activity. When biochemicals that are enzymes are being notified, the most precise fourth-level Enzyme Commission number available must be obtained and submitted.

For example, Enzyme Commission number 1.1.2 would not be acceptable for Mannitol dehydrogenase (cytochrome); the acceptable Enzyme Commission number for this substance is 1.1.2.2.

Enzyme Commission numbers can be obtained from a publication made for the IUBMB by Academic Press, Inc.

To obtain a copy from the United States, contact:

**Academic Press, Inc.**  
**1250 Sixth Avenue**  
**San Diego, CA 92101-4311**  
**U.S.A.**

To obtain a copy from the United Kingdom, contact:

**Academic Press, Inc.**  
**24-28 Oval Road**  
**London NW1 7DX**  
**England**

Enzyme Commission numbers can also be obtained from the following web site:

**[www.chem.qmw.ac.uk/iubmb/enzyme](http://www.chem.qmw.ac.uk/iubmb/enzyme)**

**6.2.2.2 A.20 Chemical Name of the Substance**

All Schedules require that the exact name, established in accordance with the nomenclature rules of IUPAC, CAS or IUBMB, be used to identify substances. The name should enable an unambiguous chemical structural diagram to be drawn, unless the notified substance is considered a UVCB.

For UVCB substances, the terms “reaction product of” “compounds with” or other acceptable nomenclature may be used. Examples of UVCB substances are:

- a) carbonic acid disodium salt, reaction products with aniline, *p*-phenylenediamine, sodium sulphide ( $\text{Na}_2(\text{S}_x)$ ), sulphur and *p*-toluidine;
- b) amines, rosin, compounds with 6'-(diethylamino)-3'-hydroxy-3-oxo-spiro[isobenzofuran-1(3H),9'-[9H]xanthene]-2'-carboxylic acid and sodium bis[2-hydroxy-benzoato(2-)-O<sup>1</sup>,O<sup>2</sup>]chromate(1-); and
- c) oils, mint, *Mentha arvensis* var. *piperascens*, terpene-free.

Additional information on the naming of well-defined and UVCB chemicals can be found in Appendix 5 of these Guidelines.

Biochemicals that are enzymes should be named in accordance with the IUBMB nomenclature conventions. Group terms such as protease are not acceptable. The name must uniquely identify a single enzyme (*e.g.* subtilisin produced by *Bacillus subtilis*).

Polymer and biopolymer nomenclature, including pre-polymers, incorporates the identity of monomers and reactants used in the manufacture of the polymer or biopolymer. The name of the polymer may or may not include monomers or other reactants that are either incorporated into the polymer or charged to the reaction vessel at 2% or less by weight. However, these substances must be included in the description of the polymer composition (see section 6.2.2.8 of these Guidelines). Examples of polymer nomenclature are:

- a) benzene, ethenyl-, polymer with 1,2-ethanediol, butyl 2-propenoate, (chloromethyl)oxirane, 2,5-furanedione and methyl 2-methylpropenoate; and
- b) formaldehyde, polymer with (chloromethyl)oxirane, 4-(1,1-dimethylethyl)phenol, 4,4'-(1-methylethylidene)bis[phenol], methyloxirane polymer with oxirane ether with 1,2,3-propanetriol [(3:1)] and oxirane.

#### 6.2.2.3 A.21 Proposed Masked Name (if the Chemical Name is Claimed Confidential)

If the chemical name of the notified substance is claimed as confidential, a masked name must be provided in accordance with the *Masked Name Regulations*. Procedures for generating masked names are described in section 7.2 and Appendix 7 of these Guidelines. If the masked name includes multiple masking, then acceptable justification must also be provided in the NSN package. There is an additional fee required for a masked name application (see Appendix 3 of these Guidelines).

#### 6.2.2.4 A.22 Known Trade Names or Synonyms of the Chemical Name of the Substance

All Schedules of the Regulations require that all known trade names or internal company codes must be provided, especially any such names or code numbers used in the test reports provided for the data requirements. Synonyms of the chemical name, if known, should also be provided.

#### 6.2.2.5 A.23 Structural Formula of the Substance

The structural formula diagram must be provided for chemicals subject to Schedule 1, 5 or 6 of the Regulations.

The structural formula diagram, if possible, or else a partial structural formula must be provided for polymers subject to Schedule 3, 9, 10 or 11 of the Regulations.

In both cases, these diagrams must be made large enough to clearly indicate the identity of all atoms, types of bonds, ionic charges and relevant stereochemistry. If the structure is too large for this box, an attachment where the structure can be found should be indicated.

Carbon atoms in ring systems and their attached hydrogen atoms need not be explicitly shown. Where applicable, proportions of isomers or tautomeric forms must be indicated.

Additional information and examples of structural formulae are provided in Appendix 5 of these Guidelines.

In addition, a reaction scheme showing a detailed description of the process for which the notified substance is made is required for polymers that meet the RRR polymer criteria (see section 3.4.1.3 of these Guidelines) and are subject to Schedule 9 of the Regulations, unless the polymers are polyesters manufactured solely from reactants listed in Schedule 8 of the Regulations (see subparagraph 9(c) of the Regulations). Additional information can be found on the NS program web site at [www.ec.gc.ca/substances/](http://www.ec.gc.ca/substances/).

For UVCB substances, the name and, if known, the CAS registry number of immediate precursors must be provided. UVCB substance names may include a description of the synthesis (*e.g.* acetylation, alkaline hydrolysis) and, where applicable, the range of possible compositions (*e.g.* paraffins [petroleum], normal C<sub>5-20</sub>).

**6.2.2.6 A.24 Molecular Formula**

The molecular formula is required for chemicals that are subject to Schedule 1, 5 or 6 of the Regulations and for polymers that are subject to Schedule 3, 9, 10 or 11 of the Regulations. The empirical formula must be provided and should identify each of the monomer units. Examples are:

- methyl methacrylate, polymer with ethyl acrylate  $(C_5H_8O_2 \times C_3H_8O_2)_x$ ; and
- polyoxyethylene sorbitol tetraoleate

**6.2.2.7 A.25 Gram Molecular Weight**

This information is required for chemicals that are subject to Schedule 1, 5 or 6 of the Regulations. The gram molecular weight should be provided for chemicals with a definite structural formula. For UVCB substances, an estimate or range of molecular weights must be provided, if known.

The number average molecular weight for polymers is discussed in section 6.3.1.14 of these Guidelines and should be entered into section B.1 of the NSN reporting form and not in block A.25.

**6.2.2.8 A.26 Monomers and Reactants with their Concentration**

This information is required for polymers that are subject to Schedule 3, 9, 10 or 11 of the Regulations. Reactants include compounds such as free radical initiators, cross-linking agents, chain-terminating agents, neutralizing agents and chain-transfer agents that become part of the polymer. The name, CAS registry number and percentage by weight of each reactant must be given. Reactants, either incorporated into the polymer or charged to the reaction vessel at 2% or less by weight in the manufacture of the polymer, must also be reported, even if they were not included in the name of the polymer. The percentage by weight of the reactants must add up to 100%.

**1. Pre-Polymer Rule**

The Regulations allow for reduced information requirements if the polymer is manufactured solely from reactants listed on the DSL or NDSL. The term “reactant” is defined in subsection 1(1) of the Regulations as follows:

in respect of a polymer, means a substance that is used in the manufacture of the polymer and becomes part of its chemical composition, and includes a monomer.

For the purpose of deciding whether or not a polymer will be eligible for the regulatory relief provided in section 11 of the Regulations (see section 4.7.1 of these Guidelines), the term “reactant” includes ultimate precursors of pre-polymers.

If a pre-polymer is used in the manufacture of the notified substance and the pre-polymer rule is being used to reduce information requirements, the composition data for the pre-polymer must be provided and must include the names and CAS registry numbers for each component. This is necessary to determine if the pre-polymer exemption applies.

For example, when a notified substance contains a pre-polymer that is not on the DSL or NDSL but all of the pre-polymer’s reactants are listed on the DSL or NDSL, the notified substance would be considered for reduced information requirements. Polymer ABCDE contains reactants A and E which are listed on the DSL and pre-polymer BCD which is not on the DSL or NDSL. Pre-polymer BCD contains reactants B, C and D; pre-polymer reactants B and D are listed on the DSL; pre-polymer reactant C is listed on the NDSL. Therefore, in this case, the pre-polymer rule applies and the notified substance, Polymer ABCDE would be considered for reduced information requirements.

The percentage by weight of the composition of the pre-polymer is also required if a group of concern is present in the pre-polymer. This is necessary to determine if the notified substance meets the RRR polymer criteria.

#### 6.2.2.9 A.27 Additives, Stabilizers and Solvents with their Concentration

This information is required for chemicals that are subject to Schedule 1, 5 or 6 of the Regulations and polymers that are subject to Schedule 3, 9, 10 or 11 of the Regulations. Additives are substances that are deliberately introduced into a product and include, for example, stabilizers, emulsifiers, solvents and anti-oxidants that are present when the chemical is tested. The name, CAS registry number and concentration by weight of each must be provided.

#### 6.2.2.10 A.28 Impurities with their Concentration

This information is required for chemicals that are subject to Schedule 1, 5 or 6 of the Regulations and polymers that are subject to Schedule 3, 9, 10 or 11 of the Regulations. Impurities are substances that are present but are not necessary for the intended use of the product. Impurities are usually present in the final product in low concentrations and may include unreacted starting materials and reaction by-products. The name, CAS registry number and percentage by weight of each impurity must be given, if known.

#### 6.2.2.11 A.29 Degree of Purity in its Technical Grade Composition

This information is required for chemicals that are subject to Schedule 1, 5 or 6 of the Regulations. The degree of purity in its technical grade composition must be provided here, if applicable.

#### 6.2.2.12 A.30 Material Safety Data Sheet (MSDS)

All Schedules of the Regulations require that a Material Safety Data Sheet (MSDS) be provided if available. An MSDS, as defined in subsection 11(1) of the *Hazardous Products Act* and detailed in the *Controlled Products Regulations*, must be provided if one has been prepared. If any of the information specified in section 6.6 of these Guidelines is described in sufficient detail on the MSDS, the appropriate section of the MSDS can be referred to in sections E1. and E2. of Appendix I of the NSN reporting form.

## 6.3 Part B: Technical Information Requirements

All prescribed technical information must be addressed by submitting test data, alternative data or waivers (see section 8 of these Guidelines). The onus is on the notifier to provide acceptable information. Explanations of the information requirements, prescribed in the various Schedules of the Regulations, are provided to assist with the generation and compilation of the technical data prescribed in the Regulations. These explanatory notes elaborate details such as under which Schedules the information is required; the conditions under which various tests are required; and what constitutes complete and adequate information in the opinion of the NS program.

Part B of the NSN reporting form contains four sections:

- B.1 Physical-Chemical Information Requirements;
- B.2 Ecotoxicity Information Requirements;
- B.3 Health Toxicity Information Requirements; and
- B.4 Genotoxicity Information Requirements.

Explanatory notes for the technical information requirements are given in the following sections of these Guidelines.

6.0 The New  
Substances  
Notification (NSN)  
Reporting Form

6.2 Part A:  
Administrative and  
Substance Identity  
Information  
Requirements

6.3 Part B: Technical  
Information  
Requirements

### 6.3.1 B.1 Physical-Chemical Information Requirements

#### 6.3.1.1 Melting Point

This test is required for chemicals that are subject to Schedule 5 or 6 of the Regulations. A melting point between  $-25^{\circ}\text{C}$  and  $300^{\circ}\text{C}$  must be provided as a single value or a range of values. However, if the value is outside this temperature range, the information may be indicated as " $<-25^{\circ}\text{C}$ " or " $>300^{\circ}\text{C}$ ". In cases where the notified substance undergoes a chemical reaction (*e.g.* degradation, decomposition, rearrangement) other than melting, then the temperature at which the reaction occurs must be reported. As alternative data, a pour point, softening point or sublimation point should be provided instead of a melting point, when this is appropriate.

#### 6.3.1.2 Boiling Point

This test is required for chemicals that are subject to Schedule 5 or 6 of the Regulations. A boiling point between  $-50^{\circ}\text{C}$  and  $300^{\circ}\text{C}$  must be provided as a single value or a range of values. However, if the value is outside this temperature range, the information may be indicated as " $<-50^{\circ}\text{C}$ " or " $>300^{\circ}\text{C}$ ". In cases where the notified substance undergoes a chemical reaction (*e.g.* degradation, decomposition, rearrangement) other than boiling, then the temperature at which the reaction occurs must be reported.

#### 6.3.1.3 Density

Density is required for chemicals that are subject to Schedule 5 or 6 of the Regulations.

#### 6.3.1.4 Vapour Pressure

This test is required for chemicals that are subject to Schedule 5 or 6 of the Regulations. However, the vapour pressure is not required if the chemical has a standard boiling point less than  $0^{\circ}\text{C}$ .

#### 6.3.1.5 Water Solubility

Water solubility is required for chemicals that are subject to Schedule 5 or 6 of the Regulations.

#### 6.3.1.6 Octanol–Water Partition Coefficient

The octanol–water partition coefficient is required for chemicals having a water solubility of less than or equal to 5 g/L that are subject to Schedule 5 or 6 of the Regulations. However, there is no water extractability cut-off for polymers; therefore, the octanol–water partition coefficient is required for all substances that are subject to Schedule 10 or 11 of the Regulations.

#### 6.3.1.7 Ready Biodegradation<sup>7</sup>

A ready biodegradation test is required for chemicals that are subject to Schedule 5 or 6 of the Regulations. The identity of any known products of biodegradation must also be provided.

This test is also required for polymers that are subject to Schedule 11 of the Regulations. The ready biodegradation test is required on the water-soluble portion of the polymer unless the polymer has a water extractability (see section 6.3.1.13 of these Guidelines) at pH 7 of less than or equal to 2% or is a branched silicone or siloxane polymer. In these cases, a waiver should be requested.

#### 6.3.1.8 Spectroscopy

This test is required for chemicals that are subject to Schedule 6 of the Regulations. At least one spectrum suitable for characterization of the chemical is required (*e.g.* infrared [IR], ultraviolet [UV], nuclear magnetic resonance [NMR], etc.). Details of the methodology used (*e.g.* solvent, ionization technique, field strength, band width, instrumentation) must also be provided. UV spectra should include the range down to 290 nm.

<sup>7</sup> Must comply with GLP (see section 8.3 of these Guidelines).

### 6.3.1.9 Adsorption–Desorption

This test is required for chemicals having a water solubility of greater than or equal to 200 µg/L and that are subject to Schedule 6 of the Regulations.

This test is also required for chemicals having a water solubility of greater than or equal to 200 µg/L, that are listed on the NDSL and that are released into the aquatic environment in a quantity greater than 3 kg/day, per site, averaged monthly and after wastewater treatment (subsection 7(2) of the Regulations) (see section 4.4.3.1 of these Guidelines).

### 6.3.1.10 Hydrolysis as a Function of pH

This test is required for chemicals having a water solubility of greater than or equal to 200 µg/L, that are subject to Schedule 6 of the Regulations. The identity of any known hydrolysis products must also be provided.

This test is also required for chemicals having a water solubility of greater than or equal to 200 µg/L, that are listed on the NDSL and that are released into the aquatic environment in a quantity exceeding 3 kg/day, per site, averaged monthly and after wastewater treatment (subsection 7(2) of the Regulations) (see section 4.4.3.1 of these Guidelines). The identity of any known hydrolysis products must also be provided.

This test is also required for polymers that are subject to Schedule 10 or 11 of the Regulations and have a water extractability (see section 6.3.1.13 of these Guidelines) determined to be greater than 2%. The identity of any known hydrolysis products must also be provided.

### 6.3.1.11 Physical State

The physical state of the polymer is required for polymers subject to Schedule 3, 10 or 11 of the Regulations. The requirement for physical state will be satisfied with an appropriate term (*e.g.* “solid,” “wax” or “liquid”).

### 6.3.1.12 Formulated for Dispersal in Water

This information is required for polymers subject to Schedule 3, 10 or 11 of the Regulations. The degree of dispersibility need not be determined; however, if the polymer is formulated for dispersal in water, this must be stated. The requirement for this data point will be satisfied by indicating “yes” or “no”.

### 6.3.1.13 Water Extractability

Water extractability is required for polymers that are subject to Schedule 10 or 11 of the Regulations. Water extractability at pH 7 is required for anionic and neutral polymers; water extractability at pH 2 and 7 is required for cationic polymers; and water extractability at pH 2, 7 and 9 is required for amphoteric polymers. If the water extractability is <2%, the result must be reported as <2%. Note: For notified substances that are highly dispersed in water, a water extractability study will not be feasible; however, ecotoxicity studies would still be required, as the substance would be bioavailable in the aquatic environment. Additional information will be made available on the NS program web site at [www.ec.gc.ca/substances/](http://www.ec.gc.ca/substances/).

### 6.3.1.14 Number Average Molecular Weight ( $M_n$ )

This test is required for polymers that are subject to Schedule 3, 9, 10 or 11 of the Regulations. Generally, if the polymer is available in a series of different molecular weight compositions, information must be developed using the lowest  $M_n$  composition. However, pre-existing information developed on higher-molecular-weight compositions should also be submitted. The  $M_n$  must be determined on the composition having the lowest number average molecular weight of any composition intended for manufacture or import. The  $M_n$  information must include the test procedures used and the chromatogram, calibration curve and slice tables produced during the test.

If the notified substance has low water extractability (<2%), the  $M_n$  does not need to be submitted however the water extractability data must be provided as alternative data for the molecular weight requirements.

If the notified substance has a water extractability of greater than or equal to 2%, the  $M_n$  must be determined on the extractable portion of the notified substance (e.g. if 5% of the polymer is soluble then the  $M_n$  must be determined on this 5% portion).

Only a target  $M_n$  is required for polymers that are manufactured or imported as research and development substances and that are subject to Schedule 3 of the Regulations.

#### 6.3.1.15 Residual Constituents with Molecular Weights Less than 500 Daltons and Less than 1000 Daltons

This information is required for polymers that are subject to Schedule 3, 9, 10 or 11 of the Regulations, except for research and development substances.

The percentage of residual constituents must be determined on the composition that has the lowest number average molecular weight of any composition intended for manufacture or import.

### 6.3.2 B.2 Ecotoxicity Information Requirements

The actual number and type of ecotoxicity tests that must be performed on a substance depend on Schedule number and/or the most sensitive species with regard to the substance. Full test reports must be provided; summaries will not be accepted.

#### 6.3.2.1 Acute Fish, *Daphnia* and Algal Toxicity<sup>8</sup>

One or more of these tests are required for chemicals subject to Schedule 5 or 6 of the Regulations and for polymers subject to Schedule 10 or 11 of the Regulations.

For chemicals subject to Schedule 5 of the Regulations, data from one acute fish, *daphnia* or algal toxicity test are required.

For chemicals subject to Schedule 6 of the Regulations, data from the remaining two ecotoxicity tests (that were not completed for the submission of Schedule 5) are required.

For polymers subject to Schedule 10 of the Regulations, data from an acute toxicity test for the most sensitive species (fish, *daphnia* or algae) or, if the sensitivity of these three species is unknown, an acute algal toxicity test are required, unless the polymer has a water extractability at pH 7 of less than or equal to 2%.

For polymers subject to Schedule 11 of the Regulations and that have a water extractability at pH 7 of greater than 2%, data from the following tests are required:

- a) if the sensitivity of the three species is known, an acute toxicity test of the polymer for each of the two most sensitive species: fish, *daphnia* or algae;
- b) if the sensitivity of only one species is known and that species is not algae, an acute algal toxicity test and either a fish or *daphnia* acute toxicity test selected on the basis of the most sensitive of these species; or
- c) if the sensitivity of only one species is known and that species is algae or if the sensitivity of the three species is unknown, an acute algal toxicity test and either a fish or *daphnia* acute toxicity test.

#### 6.3.2.2 Acute Algal Toxicity<sup>8</sup>

An acute algal toxicity test, performed on regular growth medium, may be required for chemicals subject to Schedule 5 or 6 of the Regulations and for polymers subject to Schedule 10 or 11 of the Regulations (see section 6.3.2.1 of these Guidelines). Since the toxicity of polycarboxylic acids may be mitigated by the presence of  $Ca^{2+}$  or  $Mg^{2+}$  ions, algal toxicity of polycarboxylic acids can also be conducted using a modified algal growth medium (Ca, or Ca and Mg, added to attain a measured hardness of 150.0 mg/L as  $CaCO_3$ ).

<sup>8</sup> Must comply with GLP (see section 8.3 of these Guidelines).



### 6.3.3 B.3 Health Toxicity Information Requirements

For all health toxicity information requirements, the following test information must also be provided:

- the age, sex, number, species, strain and source of the animals tested;
- the route by which the substance is administered and the conditions under which the test is conducted; and
- the dose of the substance, the vehicle by means of which the substance is administered and the concentration of the polymer in the vehicle.

#### 6.3.3.1 Acute Mammalian Toxicity<sup>9</sup>

This information is required for chemicals subject to Schedule 5 or 6 of the Regulations and for polymers subject to Schedule 10 or 11 of the Regulations. For polymers subject to Schedule 10 or 11 of the Regulations the test animals must be dosed by the oral route. For chemicals subject to Schedule 5 or 6 of the Regulations, test animals must be dosed using the same route or routes of exposure that are anticipated to be the most significant route or routes for potential human exposure (e.g. oral, dermal and/or inhalation). The most significant route of potential human exposure for the Regulations refers to exposure of the general population in Canada. To select the most appropriate route or routes for testing, the expected concentration of the notified substance in the various environmental media and consumer products and the bioavailability of the substance through ingestion, inhalation and dermal absorption must be considered. The most significant route of exposure to a substance for the general population may be different from exposures for workers in an occupational setting. Consequently, data generated for occupational exposures may not meet the requirement for “the most significant route of potential human exposure” specified in the Regulations. If it is not evident which route or routes would be the most appropriate for testing under the Act, the NS program (see section 8.8 of these Guidelines) should be consulted.

**Note:** Acute toxicity test data generated after December 16, 2002, utilizing OECD TG 401 will not be considered acceptable to fulfil the regulatory requirements for this endpoint.

#### 6.3.3.2 Information Sufficient to Assess Skin Irritation<sup>9</sup>

Information sufficient to assess skin irritation is required for chemicals subject to Schedule 6 of the Regulations and for polymers subject to Schedule 11 of the Regulations. This information could be obtained from data from validated test methods for the following endpoints:

- skin irritation (e.g. OECD TG 404);
- dermal sensitization (e.g. OECD TG 406) in which the results of adequate grading of dermal responses are provided;
- dermal toxicity (e.g. OECD TGs 402, 410, 411) in which the results of adequate grading of dermal responses are provided; and
- in vitro* skin corrosion (positive response only) (e.g. OECD TGs 430, 431).

The above is not intended to be an exhaustive list. As new methods are developed and validated, the NS program will assess whether they provide sufficient information to permit an assessment of skin irritation.

Properly conducted human patch tests (positive or negative response) may be an acceptable alternative to animal testing. The concentration of notified substance to which individuals were exposed will be a critical factor regarding the acceptability of human patch tests. Human use experience may also be an acceptable alternative (positive response only), provided the human use experience is well described, including quantifying the exposure and dermal response as accurately as possible. Anecdotal information from persons handling or exposed to the substance is not an acceptable alternative.

<sup>9</sup> Must comply with GLP (see section 8.3 of these Guidelines).

In addition, information for the assessment of skin irritation may be obtained from (Q)SARs, with adequate scientific justification provided by the notifier regarding the validation and applicability domain of the model.

#### 6.3.3.3 Skin Sensitization<sup>10</sup>

This information is required for chemicals subject to Schedule 6 of the Regulations and for polymers subject to Schedule 11 of the Regulations. Properly conducted human patch tests (positive or negative response) may be an acceptable alternative to animal testing. The concentration of notified substance to which individuals were exposed will be a critical factor regarding the acceptability of human patch tests. Human use experience may also be an acceptable alternative (positive response only), provided the human use experience is well described, including quantifying the exposure and dermal response as accurately as possible. Anecdotal information from persons handling or exposed to the substance is not an acceptable alternative.

#### 6.3.3.4 Repeated-Dose Mammalian Toxicity<sup>10</sup>

This information is required for chemicals subject to Schedule 6 of the Regulations and for polymers subject to Schedule 11 of the Regulations. A test report from a study of at least 28 days duration must be submitted unless a 14-day test was performed before publication of the original Regulations in the *Canada Gazette*, Part II, on April 6, 1994. In that case, data from the 14-day test would be acceptable. As described in section 6.3.3.1 of these Guidelines, “Acute Mammalian Toxicity”, test animals must be dosed using the most significant route of potential exposure for the general population in Canada.

This test is also required for a chemical that is listed on the NDSL and for a polymer that is listed on the NDSL or all of whose reactants are listed on the DSL or NDSL and where the substance is released into the aquatic environment in a quantity greater than 3 kg/day, per site, averaged monthly and after wastewater treatment; and/or the public may be significantly exposed to the substance in a product (subsections 7(2), 7(3), 11(2) or 11(3) of the Regulations). For additional information on these data points, see sections 4.4.3 and 4.9.2 of these Guidelines.

### 6.3.4 B.4 Genotoxicity Information Requirements<sup>10</sup>

The actual number and type of genotoxicity tests that must be performed on a substance depend on the results of other genotoxicity tests; the structural similarity of the substance to known mutagens or carcinogens (or non-mutagens and non-carcinogens); and the anticipated human exposure to the substance. If it can be demonstrated that the information from a genotoxicity test is not needed for the assessment or that the test is not technically feasible, a waiver of that information will be granted (see section 8.7 of these Guidelines). Examples of conditions under which waivers may be granted for genotoxicity tests are given in Appendix 8 of these Guidelines.

#### 6.3.4.1 *In Vitro* Test for Gene Mutations

An *in vitro* test, with and without metabolic activation, for gene mutation is required for chemicals subject to Schedule 5 or 6 of the Regulations and for polymers subject to Schedule 11 of the Regulations.

This test is also required for a polymer that is listed on the NDSL or all of whose reactants are listed on the DSL or NDSL and where the substance is released into the aquatic environment in a quantity greater than 3 kg/day, per site, averaged monthly and after wastewater treatment; and/or the public may be significantly exposed to the polymer in a product (subsections 11(2) and 11(3) of the Regulations). For additional information on the determination of these data points, see section 4.9.2 of these Guidelines.

<sup>10</sup> Must comply with GLP (see section 8.3 of these Guidelines).

When this information is required under subsection 11(2) of the Regulations, the notifier may provide, in lieu of this test, an *in vitro* test, with and without metabolic activation, for chromosomal aberrations (see next section).

#### 6.3.4.2 *In Vitro* Mammalian Test for Chromosomal Aberrations

An *in vitro* test, with and without metabolic activation, for chromosomal aberrations in mammalian cells is required for chemicals subject to Schedule 6 of the Regulations and for polymers subject to Schedule 11 of the Regulations.

This test is also required for a chemical that is listed on the NDSL and for a polymer that is listed on the NDSL or all of whose reactants are listed on the DSL or NDSL and where the public may be significantly exposed to the substance in a product (subsections 7(3) and 11(3) of the Regulations). For additional information on these data points, see sections 4.4.3.2 and 4.9.2.2 of these Guidelines.

When this information is required under subsections 7(3) or 11(3) of the Regulations, the notifier may, in lieu of an *in vitro* test for chromosomal aberrations, submit data from a previously existing *in vivo* mammalian test for chromosomal aberrations, together with data substantiating that the tissue investigated was exposed to the notified substance or its metabolites.

#### 6.3.4.3 *In Vivo* Mammalian Test for Chromosomal Aberrations or Gene Mutations

An *in vivo* mammalian test for chromosomal aberrations or gene mutations or another indicator of mutagenicity that, together with data substantiating that the tissue investigated was exposed to the substance or its metabolites, permits an assessment of *in vivo* mutagenicity acceptable to the NS program is required for chemicals subject to Schedule 6 of the Regulations and for polymers subject to Schedule 11 of the Regulations.

Criteria for “evidence that the tissue investigated was exposed to the substance or its metabolites” and for what constitutes an “indicator of mutagenicity” and an assessment “acceptable to the NS program” are described in Appendix 10 of these Guidelines.

Some flexibility is given in the choice of *in vivo* test to permit the most appropriate test to be chosen for the substance. The choice of *in vivo* test should be based on results from *in vitro* genotoxicity tests; the structure and mechanism of action of the substance; and developments in the field of genotoxicity.

### 6.3.5 Regulatory Exemptions: Health Toxicity Tests Not Required for Certain Polymers

The information required for polymers with significant exposure and high release (see section 4.9.2 of these Guidelines) that is prescribed in subsections 11(2) and 11(3) of the Regulations as well as the health toxicity tests described in section 6.3.3 and 6.3.4 of these Guidelines is not required for polymers that fall under one of the classes listed in Table 6-1.

**Table 6-1: Exceptions from Health Toxicity Tests for Polymers**

Polymer class	Definition
RRR polymers	As defined in section 3.4.1.3 of these Guidelines.
Aldehyde	Polymers that do not meet the RRR polymer criteria solely due to the presence of aldehydes whose FGEW is less than or equal to 1000 daltons.
Vinyl ether	Polymers that do not meet the RRR polymer criteria solely due to the presence of vinyl ethers whose FGEW is less than or equal to 5000 daltons.
Sulphonic acid	Polymers that do not meet the RRR polymer criteria solely due to the presence of sulphonic acids whose FGEW is less than or equal to 5000 daltons.

Additions to this list may be made through regulatory amendments.

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## 6.3 Part B: Technical Information Requirements

## 6.4 Part C: Biochemical or Biopolymer Information Requirements

## 6.3.6 Waivers for Health Hazard Toxicity Data for Polymers

Table 6-2 lists some examples of polymers for which waivers will likely or will not be granted for health toxicity tests. This table is subject to change as more information becomes available. These updates will be provided through the NS program web site at [www.ec.gc.ca/substances/](http://www.ec.gc.ca/substances/). These waivers are evaluated on a case-by-case basis; although not required, the NS program provides the opportunity for notifiers to submit a PNC request (see section 8.8 of these Guidelines), while the NSN package is being prepared, to determine if the waivers are acceptable.

Table 6-2: Waivers for Health Hazard Toxicity Data for Polymers

Polymers for which waivers for health toxicity tests will likely be granted	Polymers for which waivers for health toxicity will not be granted
Polymers that do not meet the RRR polymer criteria solely due to the presence of the following cationic or potentially cationic groups: primary, secondary or tertiary amine groups; carbodiimides; or sulphoniums.	<ol style="list-style-type: none"> <li>1) Polymers containing other cationic groups (such as quaternary amines, hindered amines, azides, isocyanates [free and blocked] and phosphoniums) (see section 8.7.2 of these Guidelines).</li> <li>2) Acute and repeated-dose toxicity tests will not be waived for cationic polymers with a <math>M_n</math> greater than 10 000 daltons if inhalation is expected to be the most significant route of exposure to the general population based on expected use.</li> </ol>
<p>Polymers with insignificant amounts of low-molecular-weight species below 1000 daltons (e.g. &lt;0.1%) and information on hydrolysis, biodegradation potential or toxicity supports the rationale that the polymer will not be broken down and will not be biologically absorbed.</p> <p>Requests to waive the acute toxicity test should be accompanied by information that supports the rationale that the polymer is not biologically absorbed.</p>	Polymers with insignificant amounts of low-molecular-weight species below 1000 daltons (e.g. <0.1%) and information on hydrolysis, biodegradation potential or toxicity does not support the rationale that the polymer will not be broken down and will not be biologically absorbed.

Polymers with insignificant amounts of low-molecular-weight species (e.g. <0.1% species <1000 daltons) and that are not expected to break down, for which waivers for health data have been granted, on that basis, will only be eligible for listing on the DSL if there is a SNAc Notice issued. This will ensure that health hazard toxicity data are provided for polymers that do not meet the cut-off criteria for low-molecular-weight species.

## 6.4 Part C: Biochemical or Biopolymer Information Requirements

Additional information is required for biochemicals and biopolymers manufactured or imported, including substances being manufactured or imported under one of the special categories indicated in section 3.5 of these Guidelines. The following information is required to address the nature of the production process (e.g. living organism) and the potentially unique biological activity of enzymes and nucleic acids.

## 6.4.1 Identification, Source and History

The identification of the production organism and the organ, if applicable, from which the substance is isolated is information required for biochemicals and biopolymers subject to any Schedules of the Regulations. An accurate identification of the organism used to produce the biochemical or biopolymer must be provided. The identification should include a taxonomic designation to at least the species level. Taxonomic designations should follow International Codes of Nomenclature and standard taxonomic sources. Where the organism is genetically modified, the host organism and all organisms that were sources of genetic material must be identified.

In addition this information should include:

- a) any synonyms and common and superseded names, if known;
- b) its original source and history;

- c) any strain bank and accession number (e.g. American Type Culture Collection, or ATCC); and
- d) information describing any genetic modifications.

Where the substance's name is claimed as confidential, an acceptable masked name must be provided in accordance with the *Masked Name Regulations*. Guidance for masking microorganism names is given in section 8 of the *Guidelines for Notification of New Substances (Organisms)*.

#### 6.4.2 Adverse Environmental or Human Health Effects

This information is required for biochemicals and biopolymers subject to any Schedules of the Regulations. This information should include a description of any known adverse environmental or human health effects associated with exposure to the production organism.

#### 6.4.3 Concentration of the Viable Production Organism

This information is required for biochemicals and biopolymers subject to any Schedules of the Regulations. The concentration of the viable production organism in the biochemical or biopolymer and, if known, in end-use products must be provided.

Production organisms that are present in the notified substance are considered impurities, and the level of these organisms should therefore be determined and provided, together with a description of the assay method. The presence of viable organisms in a substance is of potential concern because of the potential health hazard that may result from exposure to an organism or its metabolic products.

During the research and development stage of manufacturing, the number of persons exposed to a substance is usually limited, and the pilot-scale manufacturing process is not necessarily representative of the conditions that will pertain during full-scale production. For these reasons, determination of the level of production organism(s) in the notified substance is not required for research and development substances or contained site-limited intermediates that are manufactured and consumed at the site of manufacture.

#### 6.4.4 Method Used to Separate the Production Organism

This information is required for biochemicals subject to Schedule 1, 5 or 6 of the Regulations and biopolymers subject to Schedule 3, 10 or 11 of the Regulations. This information must include a description of the method(s) used to separate the production organism from the biochemical or biopolymer.

This information is not required for research and development substances.

#### 6.4.5 Identification of Encoded Products

This information is required for biochemicals that are nucleic acids (repeating units of deoxyribonucleotides or ribonucleotides) and are subject to Schedule 1, 5 or 6 of the Regulations and for biopolymers that are nucleic acids and are subject to Schedule 3, 10 or 11 of the Regulations. This information must include the identification of the encoded products, if known.

This information is not required for research and development substances or contained site-limited intermediates that are manufactured and consumed at the site of manufacture.

#### 6.4.6 Description of Biological Activity

This information is required for biochemicals that are nucleic acids (repeating units of deoxyribonucleotides or ribonucleotides) and are subject to Schedule 1, 5 or 6 of the Regulations and for biopolymers that are nucleic acids and are subject to Schedule 3, 10 or 11 of the Regulations. This information must include a description of any known biological activity (e.g. antibiotic resistance) or adverse environmental or human health effects associated with the nucleic acid or with the encoded products, specified under item 5 of Schedule 2 of the Regulations.

This information is not required for research and development substances or contained site-limited intermediates that are manufactured and consumed at the site of manufacture.

#### 6.4.7 Catalytic Functions

A description of all known catalytic functions is required for biochemicals that possess enzymatic capability and that are subject to Schedule 1, 5 or 6 of the Regulations.

This information is not required for research and development substances or contained site-limited intermediates that are manufactured and consumed at the site of manufacture.

#### 6.4.8 Enzyme Commission Number

The four-digit Enzyme Commission number, if available, is required for biochemicals that possess enzymatic capability and that are subject to Schedule 1, 5 or 6 of the Regulations. Additional information on Enzyme Commission numbers can be found in section 6.2.2.1 of these Guidelines.

This information is not required for research and development substances or contained site-limited intermediates that are manufactured and consumed at the site of manufacture.

#### 6.4.9 Substrate Specificity

This information is required for biochemicals that possess enzymatic capability and that are subject to Schedule 1, 5 or 6 of the Regulations. This information must include the known substrate specificity for each known catalytic function specified under item 7 of Schedule 2 of the Regulations.

This information is not required for research and development substances or contained site-limited intermediates that are manufactured and consumed at the site of manufacture.

#### 6.4.10 Optimum pH and Temperature

This information is required for biochemicals that possess enzymatic capability and that are subject to Schedule 1, 5 or 6 of the Regulations. This information must include the optimum pH and temperature for the substrates specified under item 9 of Schedule 2 of the Regulations.

This information is not required for research and development substances or contained site-limited intermediates that are manufactured and consumed at the site of manufacture.

#### 6.4.11 Catalytic Constants $K_M$ and $K_{cat}$

This information is required for biochemicals that possess enzymatic capability and that are subject to Schedule 1, 5 or 6 of the Regulations. This information must include the catalytic constants  $K_M$  (Michaelis-Menten constant) and  $K_{cat}$  and the conditions under which they were measured.

This information is not required for research and development substances or contained site-limited intermediates that are manufactured and consumed at the site of manufacture.

#### 6.4.12 Cofactors

This information is required for biochemicals that possess enzymatic capability and that are subject to Schedule 1, 5 or 6 of the Regulations. This information must include the known cofactors necessary for enzymatic activity (*e.g.* NADPH, coenzyme Q).

This information is not required for research and development substances or contained site-limited intermediates that are manufactured and consumed at the site of manufacture.

#### 6.4.13 Enzymatic Activity

This information is required for biochemicals that possess enzymatic capability and that are subject to Schedule 1, 5 or 6 of the Regulations. This information must include the activity per unit weight of products and, if known, of end-use products.

This information is not required for research and development substances or contained site-limited intermediates that are manufactured and consumed at the site of manufacture.

## 6.5 Part D: Additional Information Requirements

### 6.5.1 D.1 Other Requirements

#### 6.5.1.1 Other Agencies Notified, the Agency's File Number and the Outcome

This information is required for all substances subject to any Schedules of the Regulations. This information must include:

- any known instances where the manufacture or importation of the substance has been notified to other government agencies, either outside or within Canada, and the purpose of such notification;
- if known, the identity of the agency, including the complete name, city and country where the agency is located; and
- if known, the agency's file number, the outcome of the assessment and the risk management measures imposed by the agency.

For example, the Ontario Ministry of Labour may have been notified of the import of a new substance for use in an occupational setting, or an American supplier may have notified the USEPA under the Pre-Manufacture Notification provisions of the TSCA.

#### 6.5.1.2 Other Information and Test Data in the Possession of the Manufacturer or Importer

This information is required for substances subject to any Schedule of the Regulations. This information must include a summary of all other information and test data in respect of the substance that are in the possession of the manufacturer or importer or to which they ought to have access and that are relevant to identifying hazards to the environment and human health and the degree of environmental and public exposure to the substance. Summaries must provide sufficient detail regarding methodology and results to permit the NS program to determine the relevance of the information. The NS program may ask to see the full report after reviewing the summaries provided.

"In the possession of the manufacturer or importer" means the information in the company's offices in Canada if the NSN package was submitted by a Canadian company or the information in the offices in the country where the notification originated if the NSN package was submitted by a foreign company through a "Canadian Agent". The phrase "to which they ought to have access" means information in any of the company's offices worldwide or other locations where the notifier can access the information.

### 6.5.2 D.2 Additional Information and Attachments

Additional information requirements refer to any information and data relevant to environmental and health hazard identification, such as:

- experimental data (including negative results);
- summaries of literature reviews;
- results of searches from databases conducted by the notifier;
- Structural-Activity Relationships (SAR) analyses performed on the substance or structurally related substances;
- reports of adverse effects identified as a result of the use of the notified substance in an occupational setting; and
- results of studies of the risk to employees, customers, public or the environment (e.g. environmental fate modelling) that may result from the use of the substance.

Information on possible environmental benefits resulting from the manufacture or use of the notified substance may also be provided. Examples of such benefits include:

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6.4 Part C: Biochemical or Biopolymer Information Requirements

6.5 Part D: Additional Information Requirements

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### 6.5 Part D: Additional Information Requirements

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- a) the substance is a “less toxic” substitute for an existing substance or technology;
- b) the substance is recovered from a waste stream;
- c) the manufacture or use of the substance will generate less waste than an existing substance; or
- d) the substance may be recycled.

Any information provided as “Additional Information” may be provided in the language in which the information was originally prepared. The NS program requests that at least a summary of any additional information be provided in English or French.

#### 6.5.2.1 Other Technical Information

During the 1999–2001 multistakeholder consultation on the 1994 Regulations and the NS program, revisions were recommended to the technical information requirements that are reflected in the 2005 Regulations. It was agreed that information elements that have wide applicability in assessing substances and have internationally accepted test protocols should be included in the Regulations.

It was also recognized that in certain cases, information in addition to the required technical information may be needed by the NS program to conduct an assessment. Since these other information elements apply to a small subset of notified substances, they have not been included in the Regulations. Instead, the NS program’s web site lists additional data elements and the types of substances where this information may be needed. For example, data on ozone-depleting potential would be needed to conduct the risk assessment for a new substance that is a member of a class of compounds known to be associated with ozone depletion (*e.g.* halons, as defined in the Montreal Protocol).

It is intended that these descriptions will alert notifiers to the potential need for generating additional data. Additional data that may be needed under certain circumstances include:

- ozone depletion potential;
- global warming potential;
- mitigation of toxicity to fish by humic acid;
- benthic toxicity data;
- chronic aquatic toxicity data;
- bioconcentration/bioaccumulation factor;
- particle size;
- chronic mammalian toxicity data; and
- fish early life stages toxicity data with determination of residues.

The NS program provides the opportunity for and encourages notifiers to submit a PNC request (see section 8.8 of these Guidelines), while the NSN package is being prepared, to discuss these data elements prior to generating the information.

### 6.6 NSN Reporting Form — Appendix I — Manufacture, Import, Use, Exposure and Release Information (Known and Anticipated)

Appendix I of the NSN reporting form lists all of the manufacture, import, use, exposure and release information (known and anticipated) that is necessary for an evaluation and that is prescribed by the Regulations.

#### 6.6.1 Part A — Manufacture and/or Importation Information Requirements

Information submitted for the following sections is required for substances subject to any of the Schedules prescribed in the Regulations and should provide sufficient detail to help predict releases into the environment and potential human exposures.



**6.6.1.1 A1. Canadian Manufacture and Processing Information**

The following information, if known, is required for substances manufactured in Canada that are subject to any Schedule of the Regulations:

- a brief description of the manufacturing process that details precursors, reaction conditions (*e.g.* temperature, pressure, catalysts and reaction stoichiometry) and the nature (batch or continuous) and scale of the process;
- a flow diagram of the manufacturing process that includes such features as process tanks, holding tanks and distillation towers; and
- the major steps in operations, the chemical conversions, the points of entry of all feedstocks and the points of release of substances.

**6.6.1.2 A2. Anticipated Annual Production / Import Quantities of Notified Substance**

The following information is required for substances that are subject to any Schedule of the Regulations:

- an estimate of the annual quantity to be manufactured in Canada, if applicable. This information should include the amounts during the first 12 months and, if known, the expected maximum amount to be manufactured during the first three years in kg/year;
- an estimate of the annual quantity to be imported into Canada, if applicable. This information should include the amounts during the first 12 months and, if known, the expected maximum amount to be imported during the first three years in kg/year; and
- an estimate of the annual quantities to be manufactured in or imported into Canada for export, if applicable. This information should include the amounts during the first 12 months and, if known, the expected maximum amount to be exported during the first three years in kg/year.

The following information is required for chemicals that are subject to Schedule 5 or 6 of the Regulations and non-RRR polymers subject to Schedule 9, 10 or 11 of the Regulations:

- if known, the three sites in Canada where the greatest quantity of the substance, manufactured or imported by the notifier, is anticipated to be used or processed, and the estimated quantity by site.

**6.6.2 Part B — Uses of the Substance****6.6.2.1 B1. Anticipated, Historical and Other Likely Uses of the Substance**

Information on the anticipated uses of the substance is required for substances subject to any Schedule of the Regulations.

Information on the historical and other likely uses of the substance is required for substances subject to Schedule 6, 10 or 11 of the Regulations and for NDSL chemicals subject to Schedule 5 of the Regulations.

The location of use is required for substances that are contained site-limited intermediates subject to Schedule 1 or 3 of the Regulations.

In addition, the following information should be submitted, for each use, for all Schedules:

- the uses (*e.g.* component of paint, component of cleaning agent); the function of the notified substance in the product (*e.g.* pigment, surfactant); and the specific application of the notified substance (*e.g.* automotive coatings, household hard surface cleaner);
- whether the use is industrial (*e.g.* reaction intermediate); commercial (*e.g.* dry cleaning solvent); or consumer (*e.g.* household cleaners, polish). A substance may have uses in more than one category;
- an indication of whether the use is highly dispersive (*e.g.* paint solvents, aerosol); dispersive (*e.g.* soaps, fabric softeners); non-dispersive (*e.g.* inks, dyes); contained (*e.g.* capacitor fluids, catalysts); consumed (*e.g.* fuels, reaction intermediates); or “other”; and
- the maximum annual quantity of the notified substance for each use (kg/year).

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6.6 NSN Reporting Form — Appendix I — Manufacture, Import, Use, Exposure and Release Information (Known and Anticipated)

**6.6.2.2 B2. Concentration in Products**

Information must be provided on the anticipated concentration of the notified substance in products; and, if known, the concentration or range of concentrations of the notified substance as manufactured or imported and the anticipated concentration in end-use products. This information is required for substances subject to Schedule 1, 3, 4, 5 or 6 of the Regulations and non-RRR polymers subject to Schedule 9, 10 or 11 of the Regulations.

**6.6.2.3 B3. Anticipated to be Used in Products Intended for Use by or for Children**

This information is required for chemicals subject to Schedule 5 or 6 of the Regulations and non-RRR polymers subject to Schedule 9, 10 or 11 of the Regulations. This can be answered by indicating either yes or no; however, if the answer is yes the types of products that these may be should also be indicated.

**6.6.3 Part C — Human Exposure Information Requirements**

**6.6.3.1 C1. Whether the Public Is Anticipated to Be Significantly Exposed to the Substance**

This information is required for substances subject to Schedule 1, 3 or 10 of the Regulations or for NDSL chemicals subject to Schedule 5 of the Regulations. This information should include whether the public is anticipated to be significantly exposed to the substance in a product (see sections 4.4.3.2 and 4.9.2.2 of these Guidelines) and should take into consideration such factors as type of use, duration and frequency of use, concentration of the substance in the product and circumstances of exposure that may limit direct human exposure (*e.g.* whether the substance is chemically consumed during use or is able to migrate from the product). Conversely, information substantiating that the public is not anticipated to be significantly exposed must, likewise, be submitted. Additional data may be required at higher manufacture or import volumes, depending on the outcome of the assessment of this information (see subsections 7(3) and 11(3) of the Regulations).

**6.6.3.2 C2. Anticipated Degree of Direct Human Exposure**

This information is required for chemicals subject to Schedule 5 or 6 and non-RRR polymers subject to Schedule 9, 10 or 11 of the Regulations and must include:

- a) the anticipated degree of direct human exposure to the notified substance (especially for the general public) including concentration, duration, frequency and circumstances of exposure; and
- b) factors that may limit direct human exposure.

The following additional information should also be provided, if known:

- a) the possible routes of exposure, at each stage, described as quantitatively as possible (when not all individuals in a population may be equally exposed); and
- b) estimates of the number of persons (in the general public and in occupational settings) who may be exposed to the substance (if known). This estimate should include information obtained from studies on the level of exposure of employees, customers and the public from the use of the substance at each of the stages in the life cycle of the substance:
  - i) manufacturing (including research and development, pilot plant and production);
  - ii) transportation and handling;
  - iii) processing;
  - iv) storage;
  - v) intended use; and
  - vi) disposal, destruction and recycling.

## 6.6.4 Part D — Environmental Exposure Information

### 6.6.4.1 D1. Components of the Environment into which Release Is Anticipated

This information is required for chemicals subject to Schedule 1, 5 or 6 of the Regulations and for polymers subject to Schedule 3 or 11 of the Regulations. This information must include an identification of the components of the environment into which the substance is anticipated to be released. The following additional information should also be provided, where applicable:

- information that indicates the stages in the manufacture or import process where emissions or discharges to the environment may occur, and the likely quantities and concentrations of these releases;
- an indication, for each release location, of the physical form of the substance (*e.g.* powder, dust, solution, mist, vapour), the nature of any carrier medium (*e.g.* process water or air), the media (air, land or water) into which the substance will be released and the anticipated frequency, duration and rate of release;
- an estimate of fugitive emissions (if known);
- a description of the waste management practices (*e.g.* scrubbers, precipitators, biological treatment) designed to prevent or minimize the release of the substance in effluents and emissions;
- an indication, for effluents and emissions, of the amount of substance expected to be released to the environment (as kg/day for continuous operations and kg/batch for batch operations), as well as the average and peak concentrations;
- a contingency plan to deal with unintended releases from the manufacturing processes, including any engineering controls (*e.g.* recovery trench or dike) in place to prevent widespread release; and
- potential releases during processing by domestic customers, if known. Potential releases from commercial or consumer products should also be provided, if known.

### 6.6.4.2 D2. Anticipated Releases of the Substance into Municipal Wastewater Systems

Whether the substance will be released directly to the Municipal Wastewater Treatment Facility or directly to surface waters must be indicated. This information is required for chemicals subject to Schedule 1, 5 or 6 of the Regulations and for polymers subject to Schedule 3, 10 or 11 of the Regulations. This information must include:

- the total amount (kg/day) anticipated to be discharged;
- an indication of whether the effluent will enter municipal waste treatment facilities or go directly into surface waters (and identification of those facilities or water bodies, as applicable);
- the name and address of the municipal treatment facility; and
- the name of the receiving water/location of discharge.

### 6.6.4.3 D3. Factors that May Limit Environmental Exposure

This information is required for substances subject to Schedule 6, 10 or 11 or NDSL chemicals subject to Schedule 5 of the Regulations. This information must describe conditions during the life cycle of the substance that may limit environmental exposure.

### 6.6.4.4 D4. Releases of the Substance to the Aquatic Environment

This information is required for NDSL chemicals subject to Schedule 5 of the Regulations and for polymers subject to Schedule 10 of the Regulations. This information must include:

- whether the substance is released to the aquatic environment in a quantity exceeding 3 kg/day, per site, averaged monthly and after wastewater treatment and, if the release is less than or equal to 3 kg/day, per site, the data substantiating the quantity released (see sections 4.4.3.1 and 4.9.2.1 of these Guidelines). Additional test requirements may be required at higher manufacture or import volumes, depending on the outcome of this information (see subsections 7(2) and 11(2) of the Regulations).

## 6.6 NSN Reporting Form — Appendix I — Manufacture, Import, Use, Exposure and Release Information (Known and Anticipated)

6.0 The New Substances Notification (NSN) Reporting Form

6.6 NSN Reporting Form — Appendix I — Manufacture, Import, Use, Exposure and Release Information (Known and Anticipated)

6.7 NSN Reporting Form — Appendix II — New Substances Fee Payment Form with Credit Card Authorization

The following additional information must also be provided:

- a) the total amount (kg/day) of releases or anticipated releases directly to surface water;
- b) the amount (kg/year) of discharges, if any, from on-site treatment and data substantiating the quantity of such releases (kg/year);
- c) the name of the receiving water/location of discharge; and if known
- d) a description of any on-site treatment system(s), including percentage of the notified substance removed, if known;

### 6.6.5 Part E — Transportation, Storage and Disposal Information Requirements

The information in sections 6.6.5.1 to 6.6.5.2 of these Guidelines is required for chemicals subject to Schedule 1, 5 or 6 of the Regulations and for polymers subject to Schedule 3, 10 or 11 of the Regulations.

#### 6.6.5.1 E1. Transport and Storage Containers

Information on the transport and storage containers for the substance must include the following:

##### 1. Transport

- a) a description of the expected modes of transport and storage; and
- b) the UN Number,<sup>11</sup> if known.

##### 2. Storage

- a) a description of the size and type of container used for transportation and storage of the notified substance and/or product containing the notified substance; and
- b) the amount (kg/year) of substance shipped in this type of container, if known.

#### 6.6.5.2 E2. Anticipated Disposal of the Substance

Information on the recommended disposal procedures for the substance must include the following:

- a) a description of the methods recommended for its destruction or disposal for consumer, commercial and industrial applications (*e.g.* lined landfill site, high-temperature incineration or recycling).

The following additional information should also be provided, if known:

- a) the expected amount (kg/year) of the substance that will be disposed of by each method;
- b) a description of the types and expected amount (kg/year) of waste from the substance for each type of waste;
- c) provincial waste classification(s); and
- d) the site(s) of disposal.

### 6.7 NSN Reporting Form — Appendix II — New Substances Fee Payment Form with Credit Card Authorization

Appendix II is a form that has been provided to aid in determining the fee amount required for a specific NSN package. It also contains a credit card authorization form if this is the chosen method of payment by the notifier. Additional information on the fees required and methods of payment available can be found in Appendix 3 of these Guidelines.

<sup>11</sup> The United Nations (UN) Number is a four-digit code used to describe materials being transported in Canada. These codes are in "Dangerous Goods: Guide to Initial Emergency Response," available through the Canada Communication Group Publishing.

## SECTION 7 — Confidential Information

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

### 7.1 Claiming Confidentiality

The confidentiality privileges described in section 313 of the Act can be satisfied by:

- a) indicating which particular information is confidential using the appropriate column in the NSN reporting form; and
- b) providing the information described in section 7.2 of these Guidelines.

### 7.2 Information Supplemental to a Confidentiality Claim

Each claim for confidentiality in an NSN package must be accompanied by the supplementary information detailed in sections 7.2.1 and 7.2.2 of these Guidelines. The NS program will review each confidentiality claim to determine whether or not it is valid. Notifiers will be advised if their request for confidentiality is unacceptable and given an opportunity to review and provide additional substantiation for their claim. If the supplementary information is not supplied, the confidentiality claim may be rejected, or, alternatively, the notifier may choose to withdraw the confidentiality claim on the substance.

#### 7.2.1 General Confidentiality Claims

Information supplemental to any request for confidentiality includes a substantiation that the information meets each of the following criteria:

- a) the information is confidential to the notifier;
- b) the notifier has taken, and intends to continue to take, measures that are reasonable in the circumstances to maintain the confidentiality of the information;
- c) the information is not, and has not been, reasonably obtainable by third persons by use of legitimate means except with the consent of the company;
- d) the information is not available to the public;
- e) disclosure of the information may reasonably be expected to cause substantial harm to the competitive position of the notifier; and
- f) disclosure of the information may reasonably be expected to result in a material financial loss to the company or a material financial gain to its competitors.

If these six criteria are met, a claim may be indicated in the appropriate column of the NSN reporting form, and the Certification Statement appearing on the front of the NSN reporting form must be signed (see section 6.2.1.1 of these Guidelines).

#### 7.2.2 Confidential Substance Identity Claims

Publication of an acceptable masked name is required under section 88 of the Act if publication of the actual identity of a substance would result in the release of CBI. Therefore, when claiming confidentiality for substance identity, the notifier must, in addition to the certification described in sections 7.2.1 and 7.2.2c) of these Guidelines, provide the information per the *Masked Name Regulations*, described in a) and b):

- a) a proposed masked name developed in accordance with the prescribed masking procedure (see Appendix 7 of these Guidelines);
- b) justification for masking more than one descriptive segment (see Appendix 7 of these Guidelines); and
- c) the following information:
  - i) the detrimental effects to the competitive position of the notifier's company that would result from the identity of the substance appearing on the DSL or in any other publication;
  - ii) the manner in which a competitor could use the identity of the substance;
  - iii) an indication of whether the identity of the substance has been kept confidential to the extent that competitors do not know it is being manufactured, imported or used;
  - iv) an indication of whether the substance has been patented and, consequently, disclosed through the patent;
  - v) an indication of whether it is public knowledge (e.g. publications in technical journals or trade publications) that the substance is being manufactured, imported or used;
  - vi) the measures that have been taken to prevent undesired disclosure of the substance identity and the extent of any disclosures to date;
  - vii) an indication of whether the substance is, or will be, in an effluent, emission or waste entering the environment;
  - viii) an indication of whether the substance is, or will be, in a product available to the public, and whether the substance can be identified by analysis of the product;
  - ix) the purpose for which the substance is being, or will be, manufactured, imported or used; and
  - x) an indication, to the best of the notifier's knowledge, of whether the NS program, another federal agency, a provincial or territorial agency or the agency of a foreign government has ever made a determination that this substance 1) has an immediate or long-term effect on the environment; 2) constitutes, or may constitute, a danger to the environment; or 3) constitutes, or may constitute, a danger to human life or health (if such a determination has been made, provide details).

#### 7.2.2.1 Masking Substance Identity

The procedures for generating a masked name are also prescribed in the *Masked Name Regulations*. These procedures are the same as those used in developing the DSL and are described in Appendix 7 of these Guidelines.

Masking a substance name will be acceptable only to the extent necessary to disguise the identity of the substance, while retaining the generic molecular structure. In most cases, masking a single structural feature should be sufficient, although multiple masking will be acceptable if it can be justified (see section 4 of Appendix 7 of these Guidelines).

If the claim for confidentiality of substance identity is acceptable, the proposed masked name will be evaluated to determine whether or not it is consistent with the *Masked Name Regulations*. If judged consistent with the *Masked Name Regulations*, the masked name will be available for use in publications such as the DSL. If not, inconsistencies will be indicated to the notifier and an alternative name requested. The NS program will try to reach a consensus with the company on a masked name. 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 retaining the generic molecular structure of the substance. Once a masked name has been accepted by the NS program, a confidential accession number will be assigned to the substance and given to the notifier only once the substance is eligible for addition on the confidential portion of the DSL or the NDSL.

There are additional fees associated with masked name applications, although the fee needs to be paid only once for a specific substance, not for each notification Schedule (see Appendix 3 of these Guidelines).

### 7.3 Determining Presence of Confidential Substances on Lists

Substances listed on the confidential portion of the DSL or NDSL are published with confidential accession numbers using masked identities that are named in a manner prescribed by the *Masked Name Regulations* as specified above. Any notifier who intends to manufacture or import a substance that he or she believes to be listed on the confidential portion of either of these lists may seek confirmation from the NS program. The NS program will respond to such an inquiry only if the notifier provides the NS program with a Notice of *Bona Fide* Intent to Manufacture or Import the substance. For more information on this, see section 2.3.1 of these Guidelines.





# SECTION 8 — Recommended Test Protocols and Alternative Approaches

## 8.1 Test Protocols

### 8.1.1 Organisation for Economic Co-operation and Development (OECD) Test Guidelines (TG)

Subsection 15(1) of the Regulations states that the conditions to be met and the test procedures to be followed in developing the required test data for a substance must be consistent with the conditions and procedures set out in the OECD TG that are current at the time the test data are developed. The OECD TG are set out in Annex 1 of the OECD Decision of the *Council Concerning the Mutual Acceptance of Data in the Assessment of Chemicals*, adopted by the OECD on May 12, 1981.

The appropriateness of the OECD TG method for the substance must be determined, and any necessary deviations must be reported and explained. The OECD TG are not intended to serve as rigid test procedures appropriate for all substances; rather, they allow flexibility for expert judgement and adjustments to new developments.

## 8.2 Accepted Test Methods

Examples of test methods recommended by the NS program for the generation of physical-chemical, toxicity and ecotoxicity data are provided in Tables 8-1 to 8-4 below. The acceptability of these test methods depends on the applicability of the methods to the substance under investigation. Sources of test methods listed in Tables 8-1 to 8-4 are given in section 8.6 of these Guidelines.

**Table 8-1: Physical-Chemical Test Methods (Chemicals)**

Data requirement	Schedules	Test method
Melting point	5, 6	OECD TG 102
Boiling point	5, 6	OECD TG 103
Density	5, 6	OECD TG 109
Vapour pressure	5, 6	OECD TG 104
Water solubility	5, 6	OECD TG 105
Octanol–water partition coefficient	5, 6	OECD TG 107 or 117
IR, UV, mass or NMR spectrum	6	As appropriate
Adsorption–desorption	6 and high release (s. 7(2) of the Regulations)	OECD TG 106, 121 as appropriate
Hydrolysis as a function of pH	6 and high release (s. 7(2) of the Regulations)	OECD TG 111

## 8.0 Recommended Test Protocols and Alternative Approaches

## 8.2 Accepted Test Methods

## 8.3 Good Laboratory Practice (GLP)

Table 8-2: Physical-Chemical Test Methods (Polymers)

Data requirement	Schedules	Test method
Number average molecular weight	3, 9, 10, 11	As appropriate (e.g. OECD TG 118)
Residual constituents with molecular weight <500 daltons and <1 000 daltons	3, 9, 10, 11	As appropriate (e.g. OECD TG 119)
Water extractability	10, 11	OECD TG 120
Hydrolysis as a function of pH	10, 11	OECD TG 111
Octanol–water partition coefficient	10, 11	OECD TG 117

Table 8-3: Toxicological Test Methods (Chemicals and Polymers)

Data requirement	Schedules	Test method
Acute mammalian toxicity	5, 6, 10, 11	OECD TG 402, 403, 420, 423, 425
Skin irritation	6, 11	OECD TG 404; see also section 6.3.3.2
Skin sensitization	6, 11	OECD TG 406, 429
Repeated-dose toxicity	6, 11 and high release/exposure (ss. 7(2), 7(3), 11(2) and 11(3) of the Regulations)	OECD TG 407, 410, 412
Mutagenicity	5, 6, 11 and high release/exposure (ss. 7(3), 11(2) and 11(3) of the Regulations)	OECD TG 471, 473, 474, 475

Table 8-4: Ecotoxicological Test Methods (Chemicals and Polymers)

Data requirement	Schedules	Test method
Acute fish toxicity	5, 6, 10, 11	OECD TG 203, Environment Canada Biological Test Methods EPS1/RM/9 and EPS1/RM/13
Acute <i>daphnia</i> toxicity	5, 6, 10, 11	OECD TG 202, Environment Canada Biological Test Method EPS1/RM/11
Algal toxicity	5, 6, 10, 11	OECD TG 201, USEPA Protocol, Environment Canada Biological Test Method EPS1/RM/25
Ready biodegradability	5, 11	OECD TG 301

### 8.3 Good Laboratory Practice (GLP)

Subsection 15(2) of the Regulations states that the laboratory practices to be followed in developing data for the following tests must comply with the practices set out in the “Principles of Good Laboratory Practice” that are current at the time the test data are developed. The principles are set out in Annex 2 of the OECD Decision of the *Council Concerning the Mutual Acceptance of Data in the Assessment of Chemicals*, adopted by the OECD on May 12, 1981 ([www.oecd.org](http://www.oecd.org)):

- a) acute mammalian toxicity tests;
- b) repeated-dose mammalian toxicity tests;
- c) genotoxicity tests;
- d) tests to assess skin irritation;
- e) skin sensitization tests;
- f) acute fish, *daphnia* or algal toxicity tests; and
- g) biodegradation tests.

If any of the tests mentioned above were commenced or completed before the day on which the Regulations came into force, the laboratory practices used must be consistent with the practices set out in the “Principles of Good Laboratory Practice”.

The “Principles of Good Laboratory Practice” are intended to promote the quality and validity of test data and to establish a basis for mutual acceptance of data among jurisdictions at the international level. They cover the organizational processes and conditions under which studies are planned, performed, monitored, recorded and reported.

The OECD has developed a series of decisions and guidelines relating to GLP. Documents are available via the OECD web site at [www.oecd.org](http://www.oecd.org).

To be GLP compliant, the final test report must include the CAS registry number (if applicable), name or trade name and the purity of the tested substance. The following information must also be provided:

- a) the name, title and dated signature of the Study Director;
- b) a GLP Compliance Statement from the Study Director;
- c) the name, title and dated signature of the Principal Investigator;
- d) the name, title and dated signature of the Quality Assurance Program;
- e) Quality Assurance Statements from the Quality Assurance Program; and
- f) dates and explanations of Quality Assurance Audits, including in-life audits.

Required studies submitted that are not compliant with GLP or do not contain the above-mentioned items will not be accepted, and the assessment period will not start until the appropriate and/or acceptable information has been provided.

For studies of physical-chemical properties, GLP compliance is not mandatory. However, the notifier is obliged to submit a test report with sufficient information to allow the NS program to assess the quality of these studies and their results. This information should include:

- identification of the test guideline and methodology employed;
- identification of the test substance and its purity;
- reference methods, standards and controls employed;
- name and address of the test facility and the name of the person responsible for the study;
- dates on which the study was initiated and completed;
- raw data;
- deviations from the test protocol;
- analytical details, including sample preparation and instrument settings; and
- a presentation of results, calculations and statistical methods employed.

### 8.3.1 Accreditation of Laboratories

If the test data submitted are from an accredited facility, then the accreditation should be stated and identified.

## 8.4 Alternative Approaches

Information in support of an NSN package may also be obtained from alternative test protocols or from calculation or estimation methods. These alternative approaches will be acceptable when, in the opinion of the NS program, they are equally or better suited to measure the endpoint under investigation. Requests for waivers of information are not required when submitting information from an acceptable alternative procedure.

Although it is not required, notifiers are encouraged to contact the NS program by submitting a PNC request (see section 8.8 of these Guidelines) while the NSN package is being prepared, to ensure that the procedure would be acceptable and to obtain answers to any questions regarding the use of alternative test procedures. This includes, but is not limited to:

- determining if the data that were generated prior to establishment of current standards of laboratory practice and method sensitivity are acceptable; and
- determining if alternative protocols or modifications to OECD protocols are acceptable.

Modifications or additions to the test protocol or the use of another protocol may be recommended by the NS program.

If an NSN package contains alternative data and a PNC was not requested, then the alternative data will be assessed, during the assessment period, by the NS program to determine whether it is acceptable. If during the assessment period it is determined that the alternative data is not acceptable, the submission will be considered incomplete, and the assessment period will be restarted on day 1 once a complete NSN package has been submitted.

#### 8.4.1 Alternative Test Protocols

Alternative protocols include other domestic or internationally recognized protocols — *e.g.* test methods developed by the NS program, International Organization for Standardization (ISO), American Society for Testing and Materials (ASTM), the United States *Federal Insecticide, Fungicide, and Rodenticide Act* (FIFRA) and the United States TSCA. In addition, protocols developed by individual companies or associations may also be acceptable. The method used by the notifier must be clearly referenced and described in sufficient detail to permit evaluation.

The alternative protocol must provide the desired data to a degree of accuracy acceptable to the NS program and must be described by the notifier in sufficient detail to allow an evaluation of the procedure and results.

The description of the alternative protocol should include, but not be limited to, a detailed description of the test principles and design, the methodology and controls used, validation studies of the accuracy and variability of the test method in comparison with the prescribed method and any references to the protocol in the scientific or technical literature. Descriptions of internationally recognized methods (*e.g.* ASTM, USEPA, Environment Canada, ISO) may not need to be provided, but must be referenced.

Properly conducted human patch tests (positive or negative response) may be an acceptable alternative to animal testing for skin irritation or skin sensitization. The concentration of notified substance used in the test will be a critical factor in determining the acceptability of this information. Well-documented human use experience may also be an acceptable alternative to the prescribed test protocols for toxicological endpoints, especially skin irritation or skin sensitization tests (positive response only). The human use experience must be well-described and give particular emphasis to quantifying the exposure (concentration, duration, frequency) as accurately as possible. Anecdotal information from persons handling or exposed to the substance is not an acceptable substitute for performing a prescribed test.

#### 8.4.2 Reduction, Refinement and Replacement

The NS program supports the principles of the Three R's (Reduction, Refinement and Replacement) approach to the use of alternative test methods for minimizing unnecessary and avoidable animal use and suffering, where the quality of the information generated to conduct a risk assessment is not compromised. The method must have been satisfactorily validated in terms of scientific rigour, reproducibility and predictability.

An alternative that would reflect the reduction approach is one in which the number of animals needed to assess a particular endpoint can be decreased without affecting the scientific value of the test. Examples of reduction alternatives already in acceptance by international regulatory agencies include the updated OECD TG for acute toxicity (OECD TG 420, 423 and 425) and skin sensitization (OECD TG 429).

Refinement alternatives are aimed at reducing the distress or discomfort experienced by laboratory animals, during and following testing, by improving the design and/or efficiency of the test. Some examples of this include eliminating unnecessary handling and restraint of animals, availability of veterinary assistance, provisions for continual monitoring of health status and early termination of animals suffering undue pain or discomfort.

A replacement alternative is one that does not involve the use of a living animal. These include the use of validated computer-based models, physical-chemical information (*e.g.* information on pH to assess irritation potential), lower (*e.g.* invertebrate) organisms and *in vitro* tests on mammalian tissues and cell cultures.

### 8.4.3 Structure–Activity Relationships (SARs)

Relationships exist between the structure of a substance and its physical properties and toxicity. Knowledge of these relationships, particularly within certain chemical groups, can be used to predict the physical, chemical, toxicological and ecotoxicological properties of a substance.

Data generated using SARs fall into two main categories:

- a) estimates based on qualitative SARs; and
- b) estimates based on Quantitative Structure-Activity Relationships (QSARs).

Calculation or estimation methods will be acceptable if the validity of the provided data is demonstrated.

#### 8.4.3.1 Qualitative Structure–Activity Relationships

Qualitative SARs, often referred to as “read-across” data or surrogate data, provide a qualitative estimate of a particular property through the submission of experimental data on a similar substance(s) (*e.g.* substances with a chemical structure closely related to that of the notified substance). Surrogate data submitted in lieu of experimental data on the notified substance must be supported with the following information:

- a) a rationale justifying the use of the surrogate data comprising a comparison of the structural features of the notified and surrogate substance(s);
- b) a comparison of the notified substance and surrogate substance(s) physical and chemical properties to help validate the estimate for the test under consideration;
- c) test report(s) for the surrogate substance(s), containing information sufficient to assess the test under consideration;
- d) a description of the test method used to generate the data on the surrogate substance(s) in order to determine the appropriateness of the method, if it is an alternative protocol; and
- e) test data on the notified substance from a range finding test, if applicable (*e.g.* a limit test).

#### 8.4.3.2 Acceptance of Surrogate Data

The validity of surrogate data will largely depend on the structural similarity between the notified and surrogate substance(s). Surrogate data is applicable when:

- a) the notified substance possesses a “trivial” structural difference from the surrogate substance(s); or
- b) the structural difference between the notified substance and the surrogate substance(s) is not considered “trivial” but will affect the property in a manner that can be accurately predicted.

A “trivial” structural difference between two substances is any change from the notified substance that is not reasonably expected to markedly alter the physical-chemical, biological or toxicological properties of the substance.

**8.4.3.3 Examples of Surrogate Data**

Examples of what may constitute a trivial structural change are:

- a change in a counter ion of a large charged organic chemical (*e.g.* sodium dodecyl sulphonate to potassium dodecyl sulphonate); or
- the addition or subtraction of a single methylene group in a long alkyl chain (*e.g.* C<sub>10</sub>H<sub>22</sub> to C<sub>11</sub>H<sub>24</sub>).

Examples of possible surrogate data applications include:

- if an ester was shown to hydrolyze rapidly, toxicity data (except dermal toxicity, irritation and sensitization) for the alcohol and the acid might be acceptable;
- if a high-molecular-weight substance had repeating units, an estimate of the physical-chemical properties or toxicity of surrogate substances that possess fewer or more units might be acceptable;
- the water solubility of an ionizable substance might be estimated to be greater than that of an appropriate similar substance that possessed fewer ionizable functional groups and exhibited very high water solubility; and
- if complex mixtures had similar carbon ranges, boiling ranges, percentage aromatics, olefinics and heteroatom content, an estimate of the physical-chemical properties or toxicity of surrogate substances might be acceptable.

Confidence in surrogate data will be strengthened if the notified substance lies within a series of substances that have similar structural features and for which reliable data are provided. It is important to note that one surrogate may not be appropriate for all data endpoints. Although it is not required, notifiers are encouraged to submit a PNC request (see section 8.8 of these Guidelines), while the NSN package is being prepared, to determine the acceptability of information resulting from alternative methods.

**8.4.3.4 Quantitative Structure–Activity Relationship (QSAR) Estimates**

QSARs provide quantitative estimates of particular properties and are often generated by computer programs that use regression analysis or molecular descriptors that mathematically represent the structural components of a molecule. Linear or multiple regression of a particular property against another property (*e.g.* octanol–water partition coefficient versus water solubility, or vapour pressure versus boiling point) can be used to derive an empirical relationship for one or several classes of chemicals. An estimate calculated using molecular descriptors can be based either on experimental values for each molecular descriptor or on experimental values for several molecules containing a common molecular descriptor.

The validity of the QSAR estimate must be explained in the NSN package, in terms of whether the estimate is reasonable in comparison with measured data, taking into account the structural features of the notified substance in comparison with the substances used to develop the estimate. The appropriateness of the QSAR must be discussed in terms of the ability of the model to correctly predict the behaviour of the notified substance.

Information to support the acceptance of data based on QSARs should include:

- a validation of the estimate (this may include the reporting of chemicals and/or structures used to generate the estimate and the experimental data for these chemicals); and
- the level of confidence associated with the estimate.

The NS program assesses a wide variety of substances, many of which are considered “model difficult” due to the substance falling outside the applicability domain of a model, with features of the molecule not represented in the training set. Consequently, the NS program advocates the judicious use of modelled data, predicting properties of well-understood classes of chemicals using robust models with strong training sets.

### 8.4.3.5 Other Calculation Methods

Other methods used to calculate data for an NSN package (*e.g.* extrapolation of data generated at different temperatures to provide a value at ambient temperature) will be assessed on a case by-case basis. The NS program provides the opportunity for notifiers to submit a PNC request (see section 8.8 of these Guidelines) to determine if the other methods will be acceptable for the NSN package.

## 8.5 Test Data on UVCBs and Impure Substances

UVCB substances are defined as substances that are of unknown or variable composition, complex reaction products or of biological origin. These materials are derived from natural sources or complex reactions and cannot be characterized in terms of constituent chemical compounds because their composition is too complex or variable. These substances are considered a single substance under the New Substances provisions of the Act; therefore, all tests should be performed on the entire UVCB substance. Where a prescribed test is not appropriate (*e.g.* melting point), the use of alternative methods should be considered (*e.g.* softening point). Also, the provision of information on any of the known components of the UVCB substance will assist in the interpretation of data generated on the UVCB substance.

Difficulties may also occur when substances are tested that contain high levels of impurities (*e.g.* residual starting materials, solvent and by-products), because impurities can confound the interpretation of test data. Consequently, tests should be performed on a high-purity sample of the substance. However, if further purification of the substance is neither technically feasible nor practical, tests on the crude product may be acceptable. In all cases, the purity of the tested material must be stated and information documenting efforts to isolate the substance must be provided. Information on the physical-chemical or toxicological properties of any of the impurities will assist in the interpretation of the data generated on the impure substance. In cases where information generated on the mixture would not be meaningful for the assessment of the notified substance (*e.g.* the notified substance comprises only a very small proportion of the mixture and further purification is not feasible), a request for a waiver on the grounds of technical infeasibility will be considered.

## 8.6 Sources of Test Methods

### 8.6.1 Organisation for Economic Co-operation and Development (OECD)

[www.oecd.org/publications/0,2743,en\\_2649\\_201185\\_1\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/publications/0,2743,en_2649_201185_1_1_1_1_1,00.html)

- a) "Guidelines for Testing of Chemicals" (November 2004)
- b) "Principles of Good Laboratory Practice" (July 2001)

#### Available in Canada from:

Renouf Publishing Company 1294 Algoma Road Ottawa, Ontario K1B 3W8	Les Éditions La Liberté 3020, chemin Sainte-Foy Sainte-Foy (Québec) G1X 3V6
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Federal Publications Ltd.  
165 University Avenue  
Toronto, Ontario  
M5H 3B8

#### Available internationally from:

OECD Bookshop  
2, rue André Pascal  
F-75775 Paris Cedex 16  
France  
[www.oecd.org/publications/0,2743,en\\_2649\\_201185\\_1\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/publications/0,2743,en_2649_201185_1_1_1_1_1,00.html)

8.0 Recommended Test Protocols and Alternative Approaches

8.4 Alternative Approaches

8.5 Test Data on UVCBs and Impure Substances

8.6 Sources of Test Methods

## 8.0 Recommended Test Protocols and Alternative Approaches

## 8.6 Sources of Test Methods

## 8.7 Waiver Requests for Information Requirements

### 8.6.2 Environment Canada Biological Test Methods

- a) Environment Canada. “Biological Test Methods: Acute Lethality Test — Rainbow Trout” (July 1990, amended May 1996). Report EPS1/RM/9.
- b) Environment Canada. “Biological Test Methods: Acute Lethality Testing — *Daphnia magna*” (July 1990, amended May 1996). Report EPS1/RM/11.
- c) Environment Canada. “Biological Test Methods: Growth Inhibition Test Using the Freshwater Algae — *Selenastrum capricornutum*” (September 1992, amended November 1997). Report EPS1/RM/25.
- d) Environment Canada. “Biological Test Method: Reference Method for Determining Acute Lethality of Effluents to Rainbow Trout” (December 2000). Report EPS1/RM/13.

#### Available from:

[www.etc-cte.ec.gc.ca/organization/bmd/bmd\\_publist\\_e.html](http://www.etc-cte.ec.gc.ca/organization/bmd/bmd_publist_e.html)

Communications Services – Publications  
Environment Canada  
Ottawa, Ontario K1A 0H3

Telephone: 1-800-734-3232 (toll free within North America)  
819-953-5750 (outside North America)

Facsimile: 819-994-5629

E-mail: [epspubs@ec.gc.ca](mailto:epspubs@ec.gc.ca)

### 8.6.3 U.S. Environmental Protection Agency

- a) “Algal Acute Toxicity Test U.S. Environmental Protection Agency Environmental Effects Testing Guidelines” (August 1982). EPA 560/6-82-002, PB 82-232992.

#### Available from:

National Technical Information Service  
United States Department of Commerce  
5285 Port Royal Road  
Springfield, VA 87007  
U.S.A.

## 8.7 Waiver Requests for Information Requirements

### 8.7.1 Introduction

Under subsection 81(8) of the Act, a request to waive the requirement for any of the prescribed information may be made to the NS program. The decision to grant a waiver will be made, on a case-by-case basis based on whether at least one of three criteria has been met. The statutory criteria for a waiver of information that are identified in subsection 81(8) of the Act are:

- (a) in the opinion of the Ministers, the information is not needed in order to determine whether the substance is toxic or capable of becoming toxic;
- (b) a substance is to be used for a prescribed purpose or manufactured at a location where, in the opinion of the Ministers, the notifier requesting the waiver is able to contain the substance so as to satisfactorily protect the environment and human life; or
- (c) it is not, in the opinion of the Ministers, practicable or feasible to obtain the test data necessary to generate the information.



Waiver requests must be submitted in writing as part of the NSN package and should include a well-documented rationale to support the request. Rejection of a waiver request may result in a delay in the assessment (see section 9.3.4 of these Guidelines). To determine if waivers are acceptable and to avoid unnecessary delays in the assessment, the NS program provides the opportunity for and encourages notifiers to submit a PNC request (see section 8.8 of these Guidelines), while the NSN package is being prepared, to determine if the waivers are acceptable.

Appendix 8 of these Guidelines provides examples of conditions under which waivers may be granted. This list is not intended to be exhaustive, but describes some independent conditions that, in most cases, would be considered to be sufficient justification to grant a waiver. Waiver requests may also be based on a combination of factors (*e.g.* physical properties, inherent toxicity and potential for exposure to the substance).

Once an assessment is complete and the waiver has been recommended for acceptance by the NS program, the substance name, company name, use of the substance and specific waiver request are sent to the Assistant Deputy Minister for approval. Once the waiver of information is granted, then the particulars of the waiver will be published in the *Canada Gazette*, Part I, in accordance with subsection 81(5) of the Act. The published waiver notice will contain only a) the name of the notifier (or company) to whom the waiver is granted; and b) the type of information to which it relates (*e.g.* Company X, biodegradability information). The notice will not specify the substance to which the waiver applies or the NSN reference number.

Substances for which waivers have been granted under paragraphs 81(8)(a) or 81(8)(c) of the Act will generally be eligible for entry onto the DSL if the criteria under subsection 87(1) of the Act have been satisfied. An exception to this would be for polymers with insignificant amounts of low-molecular-weight species (*e.g.* <0.1% species <1000 daltons) and that are not expected to break down, for which waivers for health data have been granted on that basis. These substances will only be eligible for listing on the DSL if there is a SNAc Notice issued. This will ensure that health hazard toxicity data are provided for polymers that do not meet the cut-off criteria for low-molecular-weight species and therefore would not satisfy the RRR polymer criteria.

When waivers have been granted, the notifier must provide any corrections to the information used to justify and assess the waivers as per subsection 81(11) of the Act (see section 10.1.1 of these Guidelines). The Minister may then, if necessary, request the notifier to provide the information item that was waived or take appropriate control measures.

A waiver should not be requested when information to address the data element is provided on a surrogate substance or using alternative methods. Waivers should also not be requested on the basis that another data element was waived (*e.g.* a waiver on a waiver). Furthermore, predictions should not be used based on another data element being predicted (*e.g.* a prediction on a prediction). If the NSN package contains any of these, noted above, it will be deemed incomplete and the assessment period will be terminated.

#### 8.7.1.1 Waivers Requested under Paragraph 81(8)(a) of the Act

Waiver requests may be granted if it can be established that the test is unnecessary to determine whether the substance is toxic. In cases where the requirement for one part of a prescribed test depends on the result of a previous part (*e.g.* mutagenicity test data), it is suggested that the tests be completed based on a self-evaluation of test results or a consultation with the NS program through a PNC request (see section 8.8 of these Guidelines). After receipt of the PNC request or the NSN package, the NS program will assess the submitted information to determine if the information provided is acceptable.

Examples of situations in which information may be waived under paragraph 81(8)(a) of the Act are as follows:

- a) the hydrolysis test may be waived if the substance contains only functional groups that are known to not hydrolyze; therefore, it can be assumed that the rate of hydrolysis of the substance will be very slow, and any data generated would not provide additional insight into the environmental effects of the substance; or
- b) if an *in vivo* mammalian genotoxicity test gave a positive result, the *in vitro* mutagenicity tests may be waived because the substance would be classified as an *in vivo* mutagen and the results of *in vitro* tests would not change this assessment.

#### 8.7.1.2 Waivers Requested under Paragraph 81(8)(b) of the Act

Regulations must be developed before these waivers can be granted which would delay the assessment and approval of these substances. No regulations have been made for the purposes of paragraph 81(8)(b) of the Act.

#### 8.7.1.3 Waivers Requested under Paragraph 81(8)(c) of the Act

Many of the potential waivers that can be requested under paragraph 81(8)(c) relate to instances where it is technically arduous or impossible to perform the required tests using conventional technology because of the physical or chemical properties of the substance. Examples of such waivers include:

- a) water solubility determinations for substances that react dangerously with water; and
- b) skin irritation tests using substances for which topical administration is not technically feasible.

The use of alternative protocols or surrogate data to fulfil the information requirement should be considered before it is judged to be infeasible or impractical to provide certain information. In these cases, a waiver should not be requested. The cost of obtaining data cannot alone be used as a reason for the infeasibility or impracticability of providing the prescribed information.

### 8.7.2 Class Considerations of Waivers

As a result of the NS program's experience in assessing new substances, a body of knowledge now exists on classes of substances that can be applied to newly notified substances in those classes. A systematic review of the properties of a class, corresponding to regulatory requirements, can reveal established trends in its properties. In such cases, information for specified endpoints for notified members of the class will likely not be needed to determine whether the substance is toxic or capable of becoming toxic.

Notifiers who are preparing NSN packages for substances that meet the definition of such a class are encouraged to request waivers for the specified endpoints using paragraph 81(8)(a) of the Act. Waivers will be recommended when the NS program concurs that the substance meets the eligibility criteria and no reason has been identified to decline the request.

Notifiers are encouraged to nominate new classes of substances for consideration of class waivers. They are asked to contact the NS program through the NSN Information Line to discuss the information needed to prepare a nomination.

The NS program web site will be updated as definitions of classes are developed. The NS program web site at [www.ec.gc.ca/substances/](http://www.ec.gc.ca/substances/) should be checked for any new information on available classes.

#### 8.7.2.1 Cationic Class Waivers

Available information is considered sufficient to indicate that a class comprising certain cationic polymers is expected to have low toxicity in the toxicological tests prescribed in the Regulations. Thus, notifiers are encouraged to request waivers for all the toxicological test requirements for polymers that meet this class definition.

At this time, this class is defined as polymers that do not meet the criteria for an RRR polymer solely due to the presence of the following cationic or potentially cationic groups:

- primary, secondary or tertiary amine groups;
- carbodiimides; or
- sulphoniums.

Polymers containing other cationic polymers (such as quaternary amines, hindered amines, azides, isocyanates [free and blocked] and phosphoniums) are not included in the above class definition, either because there is currently insufficient information available regarding their toxicity to warrant their inclusion or because available information indicates that there are adverse effects associated with them. For cationic polymers that do not meet the above definition and therefore are not eligible for a class waiver, notifiers may still request waivers with sufficient rationale for specific tests or submit surrogate information for consideration by the NS program on a case-by-case basis. As well, polymers with a number average molecular weight greater than 10 000 daltons will generally not be eligible for waivers for acute and repeated-dose toxicity tests if inhalation is expected to be the most significant route of exposure for the general population based on expected use.

## 8.8 Pre-notification Consultation (PNC)

A PNC is an option for notifiers who wish to consult with the NS program during the planning or preparation of their NSN package to discuss any questions or concerns they have about the required prescribed information. The notifier may submit his or her request for a PNC through the NSN Information Line (see contact information in these Guidelines). Although not required, a PNC request is recommended when clarification is needed on the notification procedures or information requirements and assistance is needed in determining the acceptability of:

- waiver requests;
- test protocols; or
- data based on calculation or estimation methods (*e.g.* Structural-Activity Relationships).

PNC requests can be addressed in writing (by mail, facsimile or electronic mail) or through a meeting or conference call.

For meeting and conference call PNC requests, the NS program will make every effort to respond to the proposed queries during the meeting. The NS program requests a minimum of two weeks between receiving the preliminary PNC request, that contains sufficient information, and conducting the meeting. This allows time for the NS program to make an informed response to the question(s) at hand during the meeting. A written response to the queries will be communicated within a period equivalent to the appropriate assessment period for that substance (see below).

For all PNC requests the NS program will make every effort to respond to the queries within a period equivalent to the appropriate assessment period for that substance. This period will start after sufficient information has been provided for the PNC request to proceed.

The information required to begin a PNC includes: information on the substance (*e.g.* the name, CAS registry number, the structure, reactants etc.); what information needs to be addressed or questions to be answered; and for meetings, a brief agenda.

For example, a PNC request is submitted with sufficient information for a substance that will be subject to Schedule 10 requirements of the Regulations, a response to the PNC request should be issued within 60 days.

The NS program will give opinions based on the information received within the PNC request. The professional opinions of the NS program, expressed during the PNC are not an official commitment, since technical conclusions may differ after a more in-depth assessment has been conducted on the complete NSN package.

In addition to PNC requests, the NS program encourages discussions to clarify any other issues related to the NS program.



# SECTION 9 — Processing a New Substances Notification (NSN)

This section describes the administrative procedures and responsibilities of the NS program when an NSN package is received.

## 9.1 Overview of the New Substances Notification (NSN) Assessment Process

The attached flow chart (Figure 9-1) gives an overview of the assessment process from the day the NSN package is received by the NS program to the day the substance is added to the DSL or risk management measures are taken on the substance.

## 9.2 Receipt of a New Substances Notification (NSN) Package

### 9.2.1 Assessment Period

The assessment period refers to the allotted time in calendar days that the NS program has to assess an NSN package. The number of days for an assessment period is indicated in Table 1-1.

Day 1 of an assessment period is the day on which the complete NSN package is received by the NS program. The starting day of the assessment period may be affected by missing or incomplete information. For example:

- if an NSN package is submitted without the required fees or with an unacceptable method of payment for the fees (see Appendix 3 of these Guidelines), the entire package will be returned, and the assessment period will not begin until a corrected package is received;
- if an NSN package is grossly inadequate or incomplete, the entire package will be returned, and the assessment period will not begin until a complete package is received;
- if proprietary information is being sent directly to the NS program by a foreign supplier, the assessment period will not start until all the required information has been received;
- if an NSN package is missing minor information, the notifier will be contacted to provide this information. The assessment period will not begin until a complete package is received;
- if, during the assessment period, minor information is found to be missing or erroneous, the assessment period will continue, provided the correct information is supplied by a date specified by the program (usually within a couple of working days); or
- if during the assessment period, the information within the NSN package is found to be incomplete or erroneous the NSN package will be deemed incomplete and the assessment period will be restarted on day 1 once a complete NSN package has been submitted.

### 9.2.2 Mail Log Number

When an NSN package is received by the NS program and where no fee is provided or where an incorrect method of payment is used, the package is stamped with a mail log number and is immediately returned to the notifier with a letter indicating the error. This mail log number must be referenced when resubmitting the NSN package to the NS program.

### 9.2.3 NSN Reference Number

When an NSN package is received by the NS program including the appropriate fee (see Appendix 3 of these Guidelines), an NSN reference number will be assigned. This number will appear on all correspondence issued by the NS program concerning that NSN package and should be used in any subsequent communication regarding that NSN package. It is important to note that the NSN reference number is not an approval by the NS program, nor can it be used by notifiers as proof of compliance for customers.

9.0 Processing a New Substances Notification (NSN)

9.1 Overview of the New Substances Notification (NSN) Assessment Process

9.2 Receipt of a New Substances Notification (NSN) Package

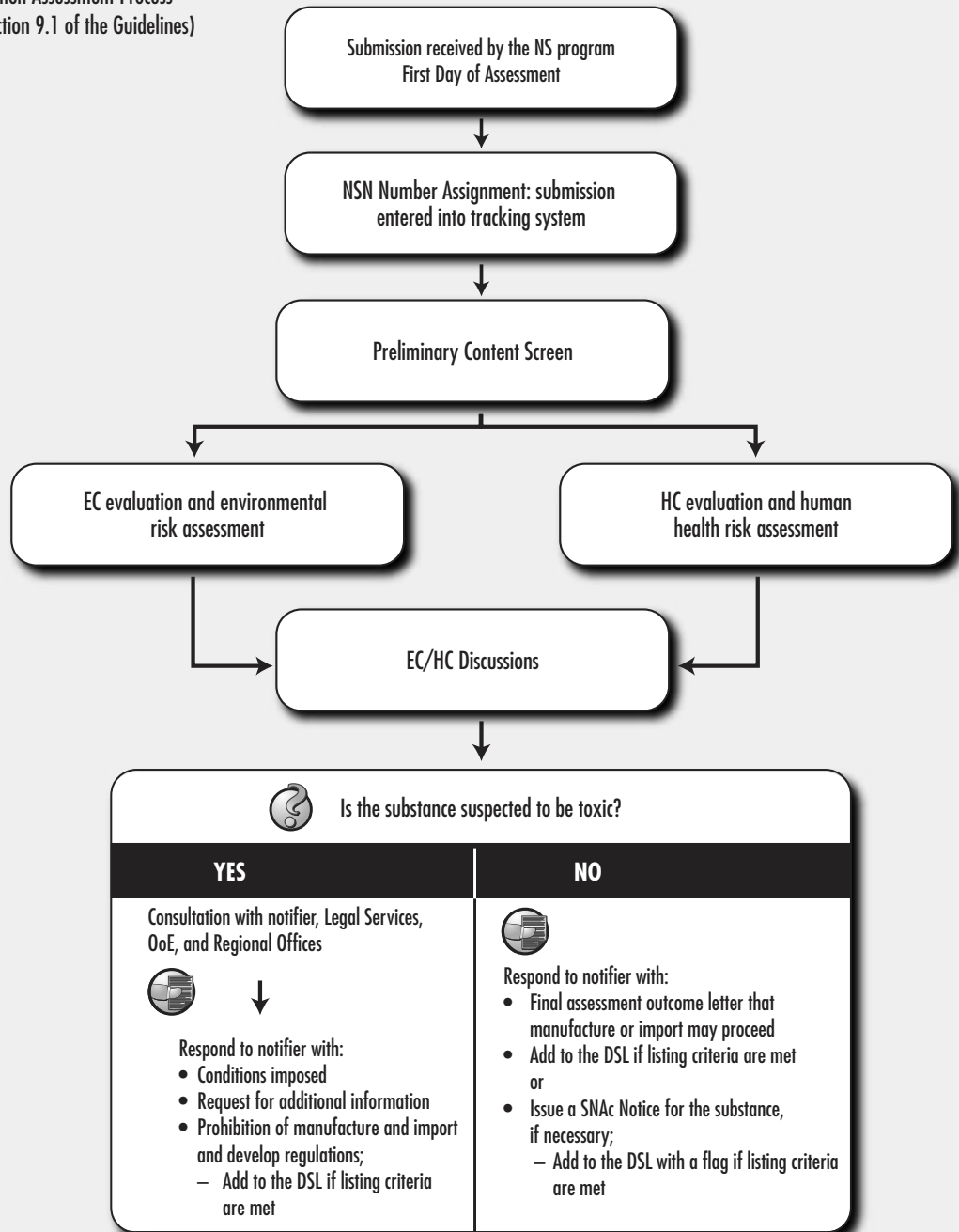
9.0 Processing a New Substances Notification (NSN)

9.2 Receipt of a New Substances Notification (NSN) Package

Figure 9-1  
Overview of the New Substances Notification Assessment Process

**Figure 9-1**

Overview of the New Substances Notification Assessment Process  
(See section 9.1 of the Guidelines)



OoE = Office of Enforcement EC = Environment Canada HC = Health Canada

This flow chart can be found in a larger full-page version in Appendix 1 of these Guidelines.

## 9.3 Correspondence

Official correspondence between the NS program and the notifier or the “Canadian Agent” will occur throughout the assessment process. When speed of communication is important, facsimile transmission will be used, with the original following by mail. Notifiers may also request to have all correspondence sent only by facsimile; in these cases, originals will not be sent by mail. The NS program will not send CBI by facsimile transmission unless consent has been given by the notifier either verbally or by marking the appropriate box in block A.1 of the NSN reporting form. The NS program also advises notifiers not to send CBI by facsimile transmission. The following are types of correspondence a notifier may receive.

### 9.3.1 Notice of Initiation

When a Foreign Supplier (see section 5.2 of these Guidelines) is involved in an NSN package the notifier must submit a partial NSN package to initiate the process. Initiation letters are issued to the notifier to acknowledge receipt of this partial information that is required to complete the NSN package. They are also issued to acknowledge receipt of an initial package for 4CA requests (see section 2.2.3.3 and Appendix 9 of these Guidelines). The assessment period does not start until all of the prescribed information has been provided by the foreign supplier or the international agency. Once the complete package of information has been received, a notice of acknowledgement of the complete package is issued (see section 9.3.2 of these Guidelines), and the assessment period will start.

### 9.3.2 Notice of Acknowledgement of Complete Package

After receipt and acceptance of the information provided in the NSN package, an acknowledgement letter will be issued specifying the starting date of the assessment period and the NSN reference number. An acknowledgement letter indicates that the administrative information is satisfactory and that all prescribed information including the prescribed fees have been received, but the file has not yet been assessed. The acknowledgement letter also provides the expected end date of the assessment period. Acknowledgement letters are also issued once all the information has been received for international sharing of information packages (*e.g.* 4CA request and Canada-Australia sharing request, see section 2.2.3.3 and Appendix 9 of these Guidelines).

A notifier may, either at the time of filing or after an NSN package has been filed, request an early termination of the assessment period (subsection 83(6) of the Act) specified for that specific Schedule in the Regulations. If such a request is received, the acknowledgement letter would indicate that the NS program will consider the request during the assessment period. However, a request made for early termination by the notifier does not automatically guarantee accommodation (see section 9.3.5 of these Guidelines).

### 9.3.3 Notice of Missing Information

A missing information notice will be issued if the NSN package contains omissions or errors in the mandatory prescribed information requirements. This notice will describe all deficiencies in the NSN package. When minor information is missing or incorrect, the notifier will be contacted by telephone to resolve the problems before a missing information notice is issued. The assessment period does not start until all the required information has been received and accepted.

### 9.3.4 Notice of Rejection

A rejection notice will be issued if the NSN package contains significant omissions or errors in the mandatory information requirements. This notice will describe all deficiencies in the NSN package. Original documentation may be returned. If the erroneous information is determined during the assessment period, the

evaluators will attempt to contact the notifier by telephone to resolve the difficulties before a rejection notice is issued. If the file is rejected during the assessment period, the assessment period will be restarted on day 1 when the additional or corrected information is received.

### 9.3.5 Notice of Early Termination of Assessment Period

Manufacture or import of a new substance is not allowed until the period for assessment, as established in the Regulations, has expired. However, subsection 83(6) of the Act, for chemicals and polymers, allows for assessment periods to be terminated at an earlier time; as a result, manufacture or importation of a substance may commence on the date indicated in the letter.

All NSN packages and SNANs are eligible for consideration for early termination if the evaluations are completed by the NS program prior to the end of the assessment period. The notifier will be informed by telephone that the assessment period will be ending early, and a final assessment outcome letter (see section 9.3.6 of these Guidelines) indicating the day on which the assessment period ends will be sent to the notifier.

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

### 9.3.6 Final Assessment Outcome Letter

If the assessment period for the notified substance concludes or is terminated early, as indicated above, and the assessment of the substance determined that there is no suspicion that the substance is toxic or capable of becoming toxic, no action will be taken. A final assessment outcome letter will be sent to the notifier, once the environmental and human health assessment reports have been completed. This letter also provides information on any additional notification requirements that are necessary for the substance to become eligible for listing on the DSL. The notifier may begin manufacturing or importing the substance in amounts exceeding the quantity that triggered the notification after the end of the assessment period, even without receipt of the final assessment outcome letter.

### 9.3.7 Notice of Extension of Assessment Period

All NSN packages and SNANs are eligible to have their assessment periods extended when additional time is required to complete an assessment. The notifier will be advised by telephone and facsimile of the extension of the assessment period before the end of the initial assessment period. The original extension letter will be sent to the notifier via courier. The Ministers may extend the assessment period *only once*, for a length of time not exceeding the time prescribed for the initial assessment period.

### 9.3.8 Withdrawing an NSN Package

A notifier may request to withdraw an NSN package if it is determined that:

- a) the substance has been previously notified by the same company;
- b) the substance is already listed on the DSL; or
- c) the notifier no longer intends to continue manufacturing or importing the substance and the notifier did not exceed the trigger volumes for the specified Schedule of the Regulations to which the NSN package refers.

Withdrawal requests for NSN packages can be mailed or faxed to the NS program. Withdrawal requests will not be accepted if the notifier has been informed of a proposed decision to take risk management measures or issue a SNAc Notice for the substance. Fees will be refunded for withdrawn NSN packages only if the request for withdrawal is received prior to the assessment period commencing. The notifier will be advised in writing if the withdrawal request has been accepted or rejected.



## 9.4 Assessment of the NSN Package

The purpose of the assessment and risk management process is to ensure that, either because of the inherent properties of the substance or because of measures taken to mitigate exposure to the substance, the use of the substance will not pose a significant risk to human health or the environment.

### 9.4.1 Information Review

Evaluators within the NS program will assess the NSN package to determine the acceptability of:

- the substance identity and masked names;
- claims for CBI;
- test protocols and procedures;
- test data;
- rationales for requests for waivers of information;
- rationales for use of alternative test protocols or surrogate information; and
- exposure information.

Deficiencies in the submitted information that cannot be easily resolved may result in the rejection of the NSN package and termination of the assessment period (see section 9.3.4 of these Guidelines).

### 9.4.2 Determination of Toxicity

The purpose of the NSN assessment process is to determine whether or not the substance is, or is suspected of being, “toxic” or capable of becoming “toxic” as per any of the criteria set out in section 64 of the Act and stated below:

64. A substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions
- (a) having or that may have an immediate or long-term harmful effect on the environment or its biological diversity;
  - (b) constitute or may constitute a danger to the environment on which life depends; or
  - (c) constitute or may constitute a danger in Canada to human life or health.

Consequently, the determination of whether a substance is, or is suspected of being, toxic or capable of becoming toxic involves assessment of the potential for exposure of humans and components of the environment and of the adverse effects of the substance on humans or the environment (including other living organisms, interacting natural systems and the abiotic components of the environment).

The potential for exposure to a substance depends on the quantity, rate, frequency and conditions of release of the substance into the environment at all points in its life cycle, as well as the mobility, environmental compartmentalization and persistence of the substance. The exposure assessment considers the use of the substance identified by the notifier, as well as other possible ways in which the substance might be used if it were listed on the DSL without restrictions.

The assessment of adverse effects on humans and other living organisms considers endpoints such as lethality, mutagenicity, reproductive effects and organ toxicity, whereas adverse effects on the abiotic components of the environment include consequences such as depletion of the ozone layer, global warming and production of acid rain.

A substance may be “suspected” of being toxic if either the adverse effects of a substance or the potential exposure to a substance is of concern. For example, substances with considerable potential for exposure because of continuous release of high quantities or persistence in the environment may be suspected of

## 9.0 Processing a New Substances Notification (NSN)

### 9.4 Assessment of the NSN Package

### 9.5 Assessment Conclusions

being toxic, although there may be uncertainty regarding any biological or environmental hazard from the information available for the initial assessment. When an assessment has led to a “suspicion of toxicity”, the Act has a unique provision, under subsection 84(1), which permits the Minister to undertake one of several risk management measures (see section 9.5 of these Guidelines).

#### 9.5 Assessment Conclusions

There are three possible outcomes of an assessment:

- 1) There is no suspicion of toxicity, and no action is taken.
- 2) There is no suspicion of toxicity for the current activities associated with the substance, and a SNAc Notice is published for the substance (see section 9.5.2 of these Guidelines).
- 3) There is a suspicion of toxicity, and risk management measures are imposed (see section 9.5.3 of these Guidelines).

The notifier will be advised in writing, before the end of the assessment period or extended assessment period, if the NS program suspects that the substance is toxic or capable of becoming toxic, and what action will be taken. The notifier will also be advised in writing, before the end of the assessment period, if the NS program intends to develop a SNAc Notice in relation to the substance (see section 9.5.2 of these Guidelines).

##### 9.5.1 No Suspicion of Toxicity and No Action Taken

If the completed environmental and human health assessment reports on the notified substance determine that there is no suspicion that the substance is toxic or capable of becoming toxic, no action is taken. If no action is taken prior to the end of the assessment period, the notifier may, after the assessment period has expired, begin manufacturing or importing the substance in amounts exceeding the quantity that triggered the notification. A final assessment outcome letter will be sent to the notifier (see section 9.3.6 of these Guidelines).

##### 9.5.2 Significant New Activity (SNAc) Notices

If the assessment for the notified substance determines that there is no suspicion that the substance is toxic or capable of becoming toxic for the notified activities but there is a suspicion that a significant new activity in relation to the substance may result in the substance becoming “toxic”, the substance can be subject to a SNAc Notice (see section 85 of the Act). A SNAc Notice defines what is considered a significant new activity for the substance which communicates the criteria under which a notification will or will not be required. Generally, the notifier will be informed, prior to the end of the assessment period, that a SNAc Notice is being developed for the notified substance.

A new substance assessment looks at the potential risks for the notified activities and any other possible activities involving the substance. If there is a suspicion that a significant new activity may result in the substance becoming “toxic”, the Act allows the Minister to issue a SNAc Notice within 90 days after the end of the assessment period. A SNAc Notice is a notice describing, by inclusion or exclusion, a significant new 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.

The Ministerial correspondence includes the SNAc Notice, which defines:

- the substance (by specific substance name or masked name, if claimed confidential);
- the significant new activity by inclusions (*e.g.* listing the new activity) or exclusions (*e.g.* anything other than a certain activity);
- the information that must be notified;
- the timelines for providing the information; and
- the period for assessing the information.

If a new substance is not yet on the DSL, the SNAc Notice issued to the notifier also applies to users of the substance. Once a new substance has been added to the DSL with an “S” flag (see section 2.1.4.1 of these Guidelines), the flag definition applies to all manufacturers, importers and users of that substance.

SNAc Notices oblige renotification and assessment of prescribed additional information prior to any of these parties undertaking a significant new activity which is defined in the notice.

If a SNAc Notice has been issued for a new substance, the notifier still remains responsible for submitting:

- the subsequent Schedules of information under the Regulations, if necessary;
- the prescribed additional information in subsection 7(2), 7(3), 11(2) or 11(3) of the Regulations in the case of significant exposure or high release; and
- the appropriate notice to fulfil the DSL listing criteria.

The substance will not be eligible for listing on the DSL until all of the above-mentioned information has been received, accepted and assessed as “no suspicion of toxicity”. Until the substance has been added to the DSL, no other notifier may manufacture or import the new substance for any activity prior to submitting an NSN package under the Regulations. A substance subject to a SNAc Notice can still become eligible for listing on the DSL, with a specified “S” flag (see section 2.1.4.1 of these Guidelines).

When information is submitted in compliance of a SNAc Notice, it is called a SNAN (see section 1.3 of these Guidelines). The NS program must assess the SNAN within the time period specified by the SNAc Notice. From the assessment of this additional information, the SNAc Notice may be modified or rescinded, or other risk management measures can be imposed, if necessary (see below). The original SNAc Notice stands unless a notice is published in the *Canada Gazette* to amend or rescind the SNAc Notice based on the additional information.

### 9.5.3 Risk Management Measures

When a substance is suspected to be toxic or capable of becoming toxic,<sup>12</sup> risk management measures may be applied to minimize any risk to human health or the environment. Notifiers will be advised, prior to the end of the assessment period, that there are concerns with the substance. Usually the assessment period is extended (see section 9.3.7 of these Guidelines), which provides time to prepare the risk management measure and obtain Ministerial approval. The notifier will be advised of the extension of the assessment period and proposed risk management measures prior to the end of the initial assessment period.

Section 84 of the Act states that when the Ministers suspect that a substance may be toxic or capable of becoming toxic, the following measures may be taken:

- 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 (this prohibition lapses at the end of this two-year period unless, before the end of this period, a notice of proposed regulation under section 93 of the Act is published in the *Canada Gazette*); or
- c) prohibit the manufacture or import of the substance until additional information or test results have been submitted to the Minister (subsection 84(2) of the Act) and assessed (the assessment period for this supplementary information expires 90 days after receipt of the information or at the end of the original assessment period, whichever is the later date).

These measures must be taken by the Minister before the expiration of the assessment period. A copy of the Ministerial correspondence and notice will be faxed to the notifier, and the originals will follow by mail. The name of the notifier is not included in the Ministerial notice. When a condition or prohibition is issued or altered, the notice must be published in the *Canada Gazette*, Part I, describing the action and the substance to which it applies. Notifiers who have a substance that is subject to risk management measures under section 84 of the Act are not required to submit a notice of excess quantity or a notice of manufacture or import, since the substance cannot be published on the DSL unless the risk management action has been rescinded or a regulation has been developed.

<sup>12</sup> The term “toxic” refers to the interpretation in section 64 of the Act and is described in section 9.4.2 of these Guidelines.

**9.5.3.1 Conditions under Paragraph 84(1)(a) of the Act**

When a substance is suspected to be toxic or capable of becoming toxic, conditions may be imposed to mitigate any risk to human health or the environment. Conditions under paragraph 84(1)(a) of the Act allow the manufacture or importation of a substance with restrictions. Types of restrictions on the substance include, but are not limited to:

- the volume allowed;
- the physical form (*e.g.* must be imported as a plastic pellet);
- the use; or
- the disposal of the substance or containers that held the substance.

The notifier and, if prescribed, the notifier's customers are obliged to abide by the conditions imposed on the substance in the Ministerial correspondence and keep records as indicated. Ministerial conditions are published in the *Canada Gazette*, Part I, after they have been issued to the notifier. Substances that have conditions imposed on them are not eligible for addition to the DSL. Therefore, any new notifier who wishes to manufacture or import the same substance must submit an NSN package, as prescribed by the Regulations. This may result in the same or similar conditions being imposed.

A notifier may submit additional information and request a re-evaluation of the decision made by the NS program. The NS program will review and consider this additional information and may amend or rescind the conditions. The conditions stand unless a notice is published in the *Canada Gazette* to amend or rescind the conditions based on the additional information.

**9.5.3.2 Prohibitions under Paragraph 84(1)(b) of the Act**

When a substance is suspected to be toxic or capable of becoming toxic, a prohibition may be imposed to mitigate any risk to human health or the environment. Prohibitions imposed under paragraph 84(1)(b) of the Act prohibit any person from manufacturing or importing the substance in any amounts. Ministerial prohibitions are published in the *Canada Gazette*, Part I, after they have been issued to the notifier. Subsection 84(4) of the Act states that this prohibition expires two years after it is imposed unless, before the expiry of the two years, the Governor in Council publishes in the *Canada Gazette* a notice of proposed regulations under section 93 of the Act in respect of the substance, in which case the prohibition expires on the day the regulations come into force. The substance may be added to the DSL after regulations have been developed and published in the *Canada Gazette*.

The notifier may submit additional information and request a re-evaluation of the decision made by the NS program. The NS program will review and consider this additional information and may amend or rescind the prohibition or take alternative risk management measures. The prohibition stands unless a notice is published in the *Canada Gazette* to amend or rescind the prohibition based on the additional information.

**9.5.3.3 Request for Additional Information under Paragraph 84(1)(c) of the Act**

When the NS program requires additional information to be provided to determine whether the substance is toxic or capable of becoming toxic, a request for additional information with a prohibition of manufacture or import pending this testing may be imposed to mitigate any risk to human health or the environment. The request for additional information is imposed under paragraph 84(1)(c) of the Act, and the prohibition of manufacture or import is imposed under subsection 84(2) of the Act. Subsection 84(2) of the Act states that the person who is required to submit the information is prohibited from manufacturing or importing the substance unless the information is provided and the regular assessment period has expired or a period of 90 days after the additional information was provided has expired, whichever is later. Once the required additional information has been submitted it will be assessed to determine if the substance is toxic or capable of becoming toxic and if it is appropriate to take alternative risk management measures.

# SECTION 10 — Post-notification Responsibilities

## 10.1 Notifier's Responsibilities

The onus is on the notifier to ensure that all information provided to the NS program is accurate and complete.

### 10.1.1 Correction of Information

Under subsection 81(11) of the Act, any notifier who has submitted information in support of an NSN package and later finds that the information is erroneous must immediately notify the NS program, via correspondence, of that fact and submit the necessary correction to his or her NSN package.

This requirement relates only to information that existed at the time the NSN package was submitted.

### 10.1.2 Section 70 of the Act

Information generated after an NSN package was submitted that reasonably supports the conclusion that the substance is toxic<sup>13</sup> or is capable of becoming toxic must be provided to the NS program under the provisions of section 70 of the Act. This information must be provided unless the notifier has actual knowledge that the NS program already has the information.

To get information on the procedures and criteria for submitting a section 70 notice, contact the Existing Substances Division via their DSL Surveys Coordinator by phone at 888-228-0530, or 819-956-9313 or by fax at 819-953-4936 or by email at [DSL.surveyco@ec.gc.ca](mailto:DSL.surveyco@ec.gc.ca)

### 10.1.3 Notice of Excess Quantity (NOEQ)

Under subsection 81(14) of the Act, a notifier who has met the requirements to manufacture or import a substance, other than research and development, contained site-limited intermediate and contained export-only substances, is required to submit a "Notice of Excess Quantity" (NOEQ) within 30 days of exceeding the manufacture or import trigger quantities (see below). The information required in a NOEQ is indicated in section 10.1.5 of these Guidelines.

#### 10.1.3.1 Trigger Quantities

As prescribed in sections 17 and 18 of the Regulations and subsection 81(14) of the Act, any notifier who chooses to submit a NOEQ must provide a notice within 30 days of meeting one of the following trigger quantities:

- a) in the case of a chemical or a biochemical not on the NDSL, a quantity that exceeds 10 000 kg in any calendar year; or
- b) in the case of a chemical or a biochemical that is listed on the NDSL, a quantity that exceeds in any calendar year:
  - i) 50 000 kg if:
    - A) the chemical or biochemical is released to the aquatic environment in a quantity exceeding 3 kg/day, per site, averaged monthly and after wastewater treatment, or
    - B) the public may be significantly exposed to the chemical or biochemical in a product,  
or
  - ii) 10 000 kg, in any other case.

<sup>13</sup> The term "toxic" refers to the interpretation in section 64 of the Act and is described in section 9.4.2 of these Guidelines.

- c) in the case of an RRR polymer, a quantity that exceeds 1000 kg in any calendar year; and
- d) in the case of any other polymer or biopolymer, a quantity that exceeds in any calendar year:
  - i) 50 000 kg if the polymer or biopolymer is listed on the NDSL or the polymer or biopolymer is not on the NDSL but all of its reactants are listed on the DSL or the NDSL and:
    - A) that polymer or biopolymer is released to the aquatic environment in a quantity exceeding 3 kg/day, per site, averaged monthly and after wastewater treatment, or
    - B) the public may be significantly exposed to that polymer or biopolymer in a product, or
  - ii) 10 000 kg, in any other case.

#### 10.1.4 Notice of Manufacture or Import (NOMI)

Alternatively, paragraphs 17(2)(a) and 18(2)(a) of the Regulations prescribe the requirement for a “Notice of Manufacture or Import” (NOMI) for chemicals and polymers. This type of notice is an additional option to the requirement for the submission of a NOEQ so that a substance may be eligible for listing on the DSL under paragraph 87(5)(a) of the Act without requiring the tracking of manufacture or import quantities. The information required in a NOMI is indicated below.

#### 10.1.5 Content and Submission of the Notices

Any notifier who has submitted the full complement of information<sup>14</sup> for a substance and has begun to manufacture or import the substance may submit a NOMI at any time prior to reaching the trigger quantities specified in section 17 or 18 of the Regulations (see section 10.1.3.1 of these Guidelines). Those who have previously notified a substance for which the full complement of information<sup>14</sup> was not provided and who has begun to manufacture or import the substance in limited quantities may submit the NOMI at the same time as submitting the full complement of information<sup>14</sup> for that substance.

Any notifier who has submitted the full complement of information<sup>14</sup> for a substance and chooses not to submit a NOMI is required to submit a NOEQ within 30 days of meeting the trigger quantities, as indicated in section 10.1.3.1 of these Guidelines.

The NOEQ or NOMI notice must be signed by the Canadian notifier manufacturing or importing the substance or the person authorized to act on behalf of the non-resident manufacturer or importer of the substance as the “Canadian Agent”. The notice should state the following:

- the person’s name and company name;
- the name of the substance and its approved masked name (if applicable);
- the NSN reference number of the NSN package for which the full complement of information<sup>14</sup> was submitted for that substance; and
- a statement indicating the trigger quantity (see section 10.1.3.1 of these Guidelines) that was exceeded (this information is required only for a NOEQ); or
- a statement indicating that the substance has been manufactured or imported (this information is required only for a NOMI; see section 10.1.4 of these Guidelines).

The above information must be sent by mail to:

New Substances Division  
Science and Technology Branch  
Department of the Environment  
Ottawa, Ontario  
Canada K1A 0H3

<sup>14</sup> The Regulations provide a tiered approach to notification. Depending on the properties, quantity and use of the substance, a full complement of information may be provided in Schedule 5, 6, 9, 10 or 11 of the Regulations.

or by courier to:

New Substances Division  
Science and Technology Branch  
Department of the Environment  
14<sup>th</sup> floor, Place Vincent Massey  
351 St. Joseph Blvd.  
Gatineau, QC  
Canada J8Y 3Y5

Once either notice is received by the NS program, the substance may be eligible for listing on the DSL if all other requirements described in subsection 87(1) of the Act have been met (see section 10.2.1 of these Guidelines).

## 10.2 The NS Program's Responsibilities

### 10.2.1 Additions to the DSL

Pursuant to section 87 of the Act, a substance must be added to the DSL and, if it is listed on the NDSL, delete it from that list within 120 days after the following conditions are met:

- the information prescribed in section 81 or 82 of the Act and any additional information or test results required under subsection 84(1)<sup>15</sup> of the Act have been provided;
- the period for assessing the information under section 83 of the Act has expired;
- no conditions have been imposed on the substance under paragraph 84(1)(a) of the Act;
- justification has been provided to warrant confidentiality requests, if applicable (see sections 2.1.2.1 and 7.2 of these Guidelines); and
- a NOMI has been received which satisfies that the substance has been manufactured or imported as specified in section 10.1.4 of these Guidelines; or
- a NOEQ has been received within 30 days of exceeding manufacture or import trigger quantities as specified in section 10.1.3.1 of these Guidelines.

Substances that are not anticipated to pose a risk to the environment and human health, regardless of their current use, quantity or any other anticipated activity, will be listed on the DSL without restrictions. Substances that could have a significant new activity that may change the outcome of the assessment will be added to the DSL with a flag requiring additional notification requirements (see sections 2.1.4.1 and 9.5.2 of these Guidelines). Polymers that are not anticipated to pose a risk to the environment and human health and life when manufactured or imported as an RRR polymer will be added to the DSL with a flag requiring renotification if they are subsequently manufactured in or imported into Canada in a form that no longer meets the RRR polymer criteria. Substances that were suspected of being toxic or capable of becoming toxic in the assessment can be listed on the DSL only if they are controlled under section 93 of the Act (see section 9.5.3.2 of these Guidelines).

When a DSL-eligible substance has been submitted as confidential with an acceptable masked name and for which the full complement of information requirements has been provided (*e.g.* Schedule 5, 6, 9, 10 or 11 of the Regulations), a confidential accession number is assigned to that substance and will be provided to the notifier only once the substance is eligible for addition to the DSL. This accession number and acceptable masked name are then published on the confidential portion of the DSL.

<sup>15</sup> Since inclusion of a substance on the DSL may permit unrestricted use if there is not a SNAc Notice, any substance for which the full complement of information requirements (*e.g.* Schedule 5, 6, 9, 10 or 11) was reduced as a result of limited use or exposure or for which waivers were granted under class waivers may not have satisfied this criterion.





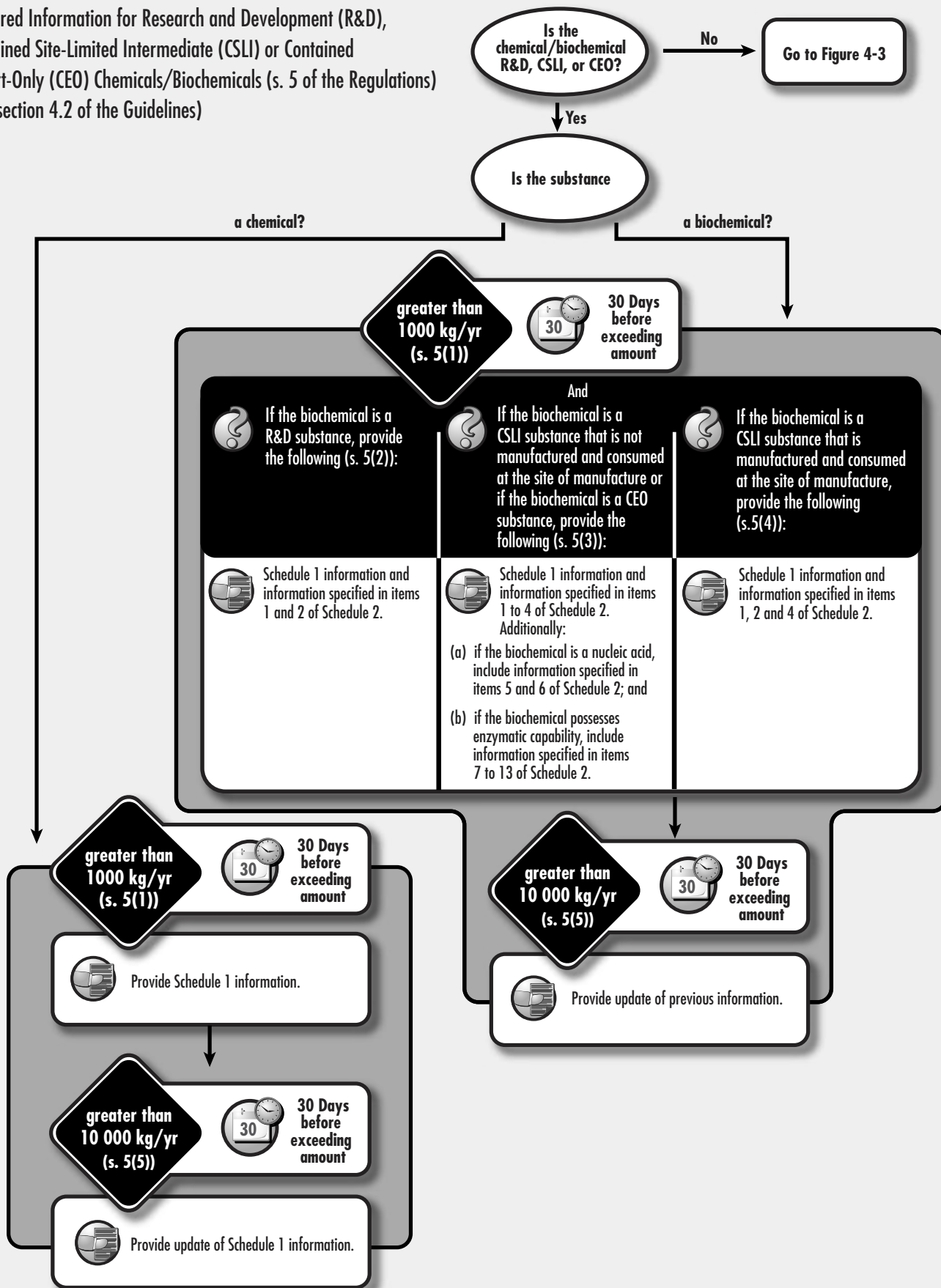
# APPENDIX 1 — Flowcharts

The decision schemes shown in this appendix can be used to determine the required Schedule of information for a substance notified under the Regulations. The information requirements for each subdivision are cumulative. When consulting the flowcharts, the user should first choose the appropriate flowchart by examining the box appearing at the top of the flowchart as it sets out the type of substance as well as the applicable section of the Regulations. The flowcharts will guide the user in identifying what information and when the information is to be provided based upon the quantity that triggers the requirement to provide the information.

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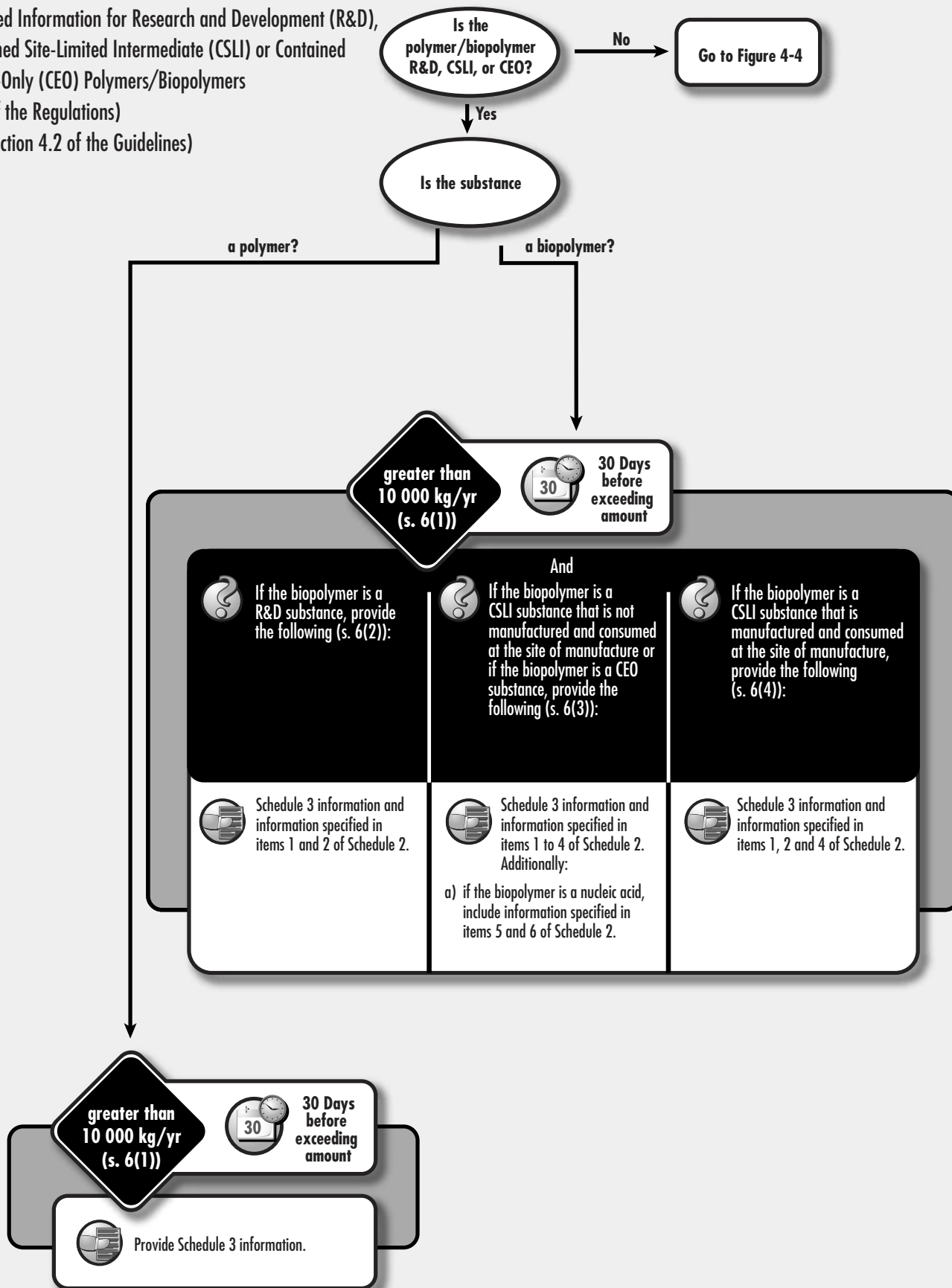
**Figure 4-1**

Required Information for Research and Development (R&D), Contained Site-Limited Intermediate (CSLI) or Contained Export-Only (CEO) Chemicals/Biochemicals (s. 5 of the Regulations) (See section 4.2 of the Guidelines)



## Figure 4-2

Required Information for Research and Development (R&D),  
 Contained Site-Limited Intermediate (CSLI) or Contained  
 Export-Only (CEO) Polymers/Biopolymers  
 (s. 6 of the Regulations)  
 (See section 4.2 of the Guidelines)

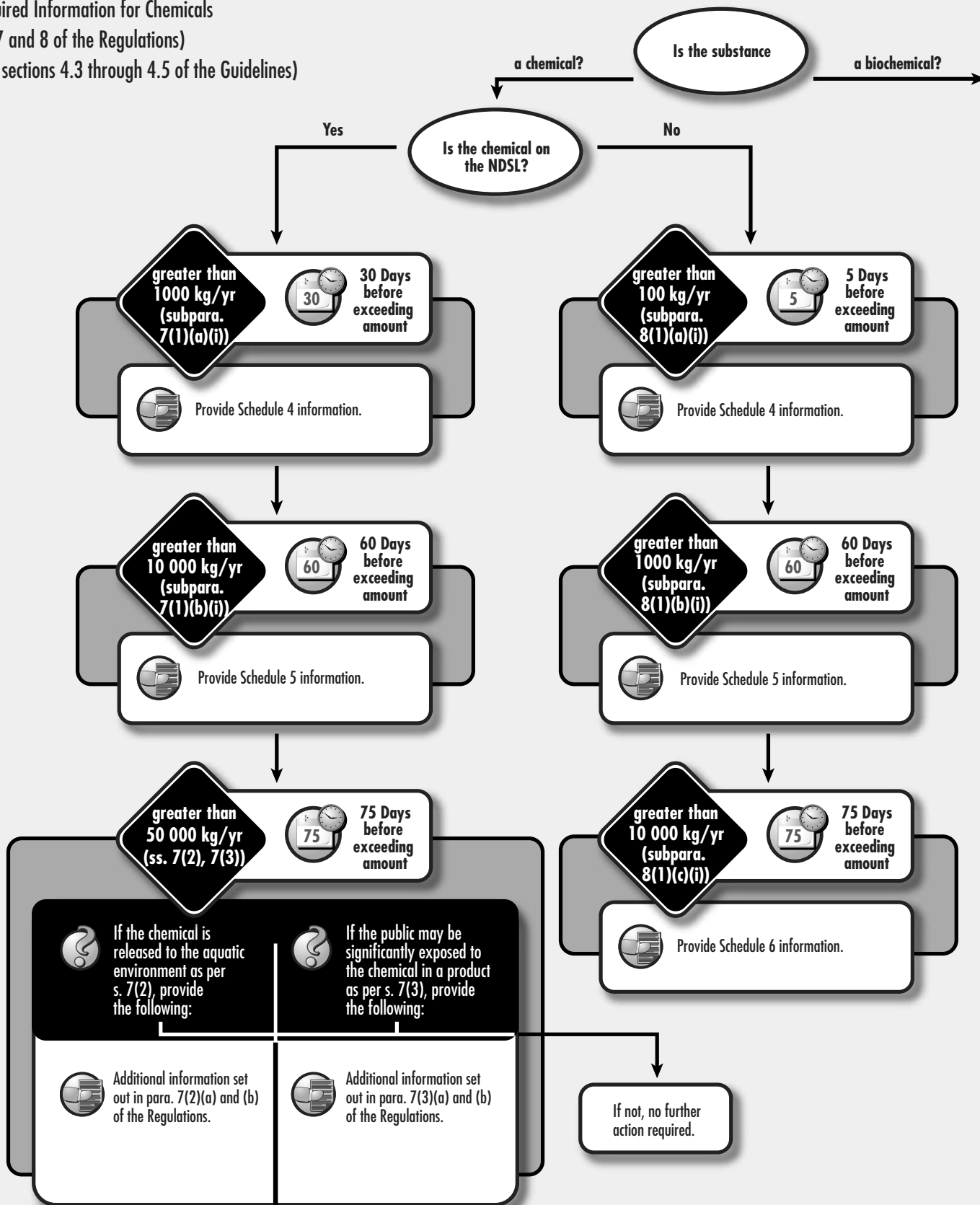


### Figure 4-3(a)

#### Required Information for Chemicals

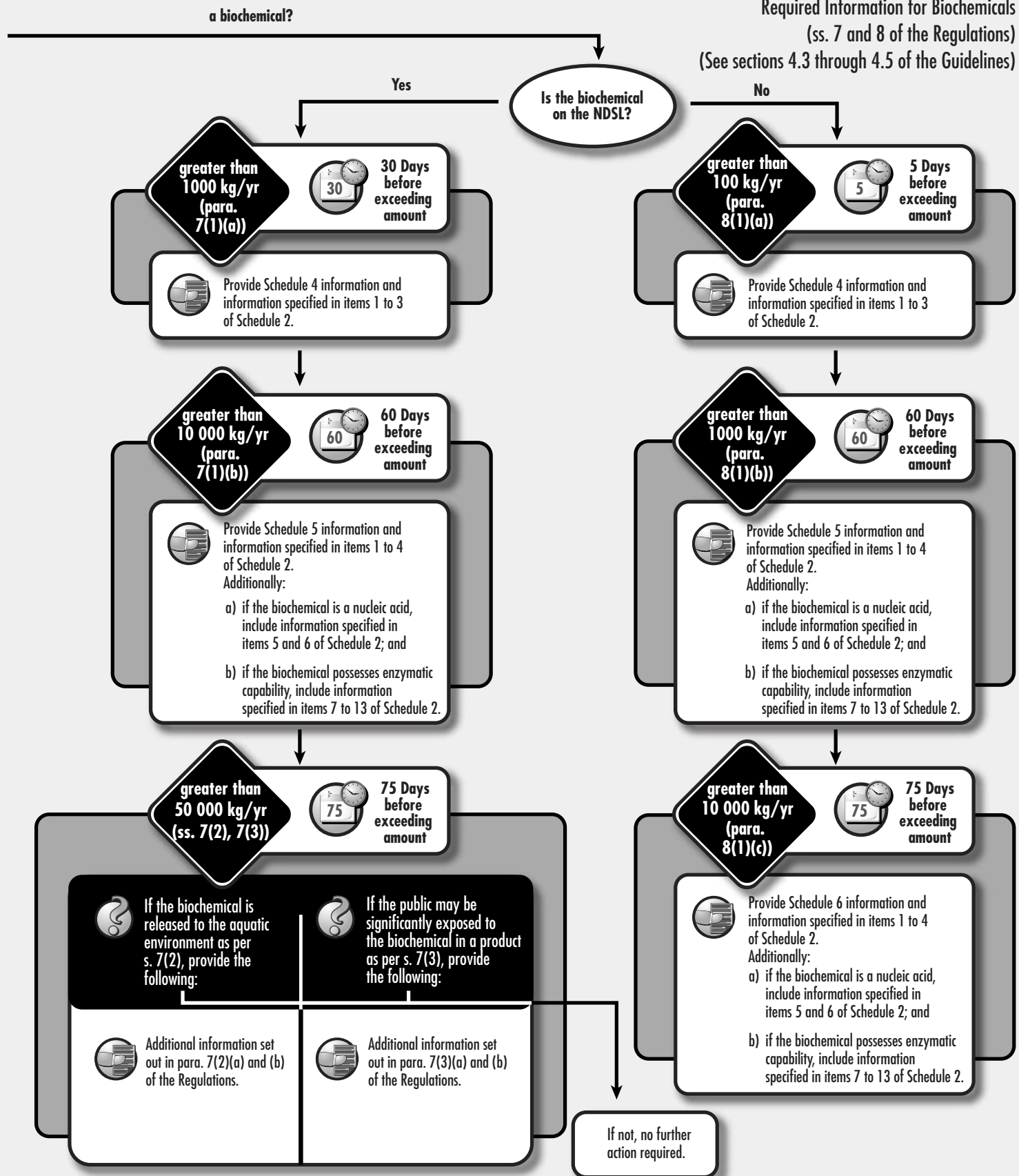
(ss. 7 and 8 of the Regulations)

(See sections 4.3 through 4.5 of the Guidelines)



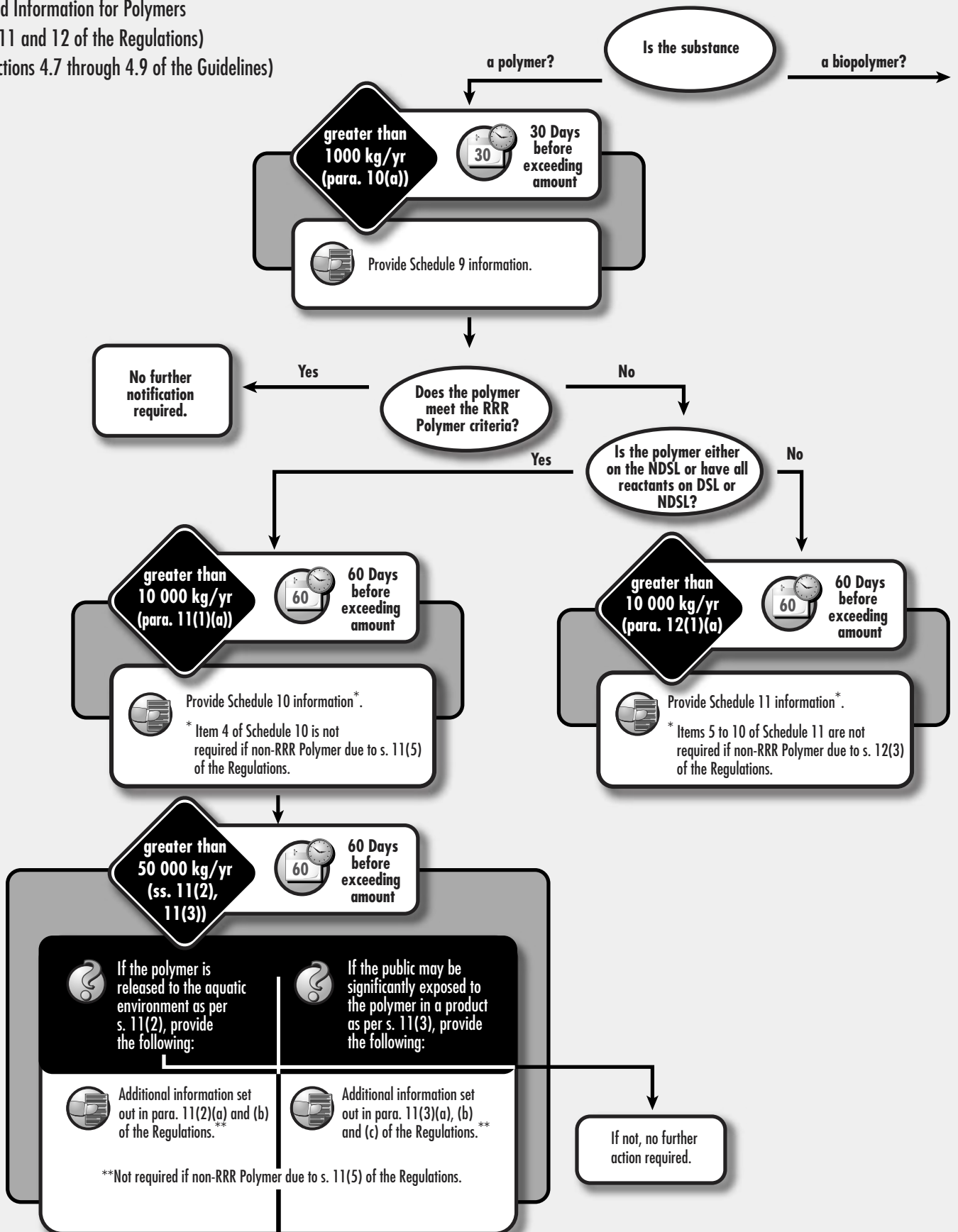
**Figure 4-3(b)**

Required Information for Biochemicals  
(ss. 7 and 8 of the Regulations)  
(See sections 4.3 through 4.5 of the Guidelines)



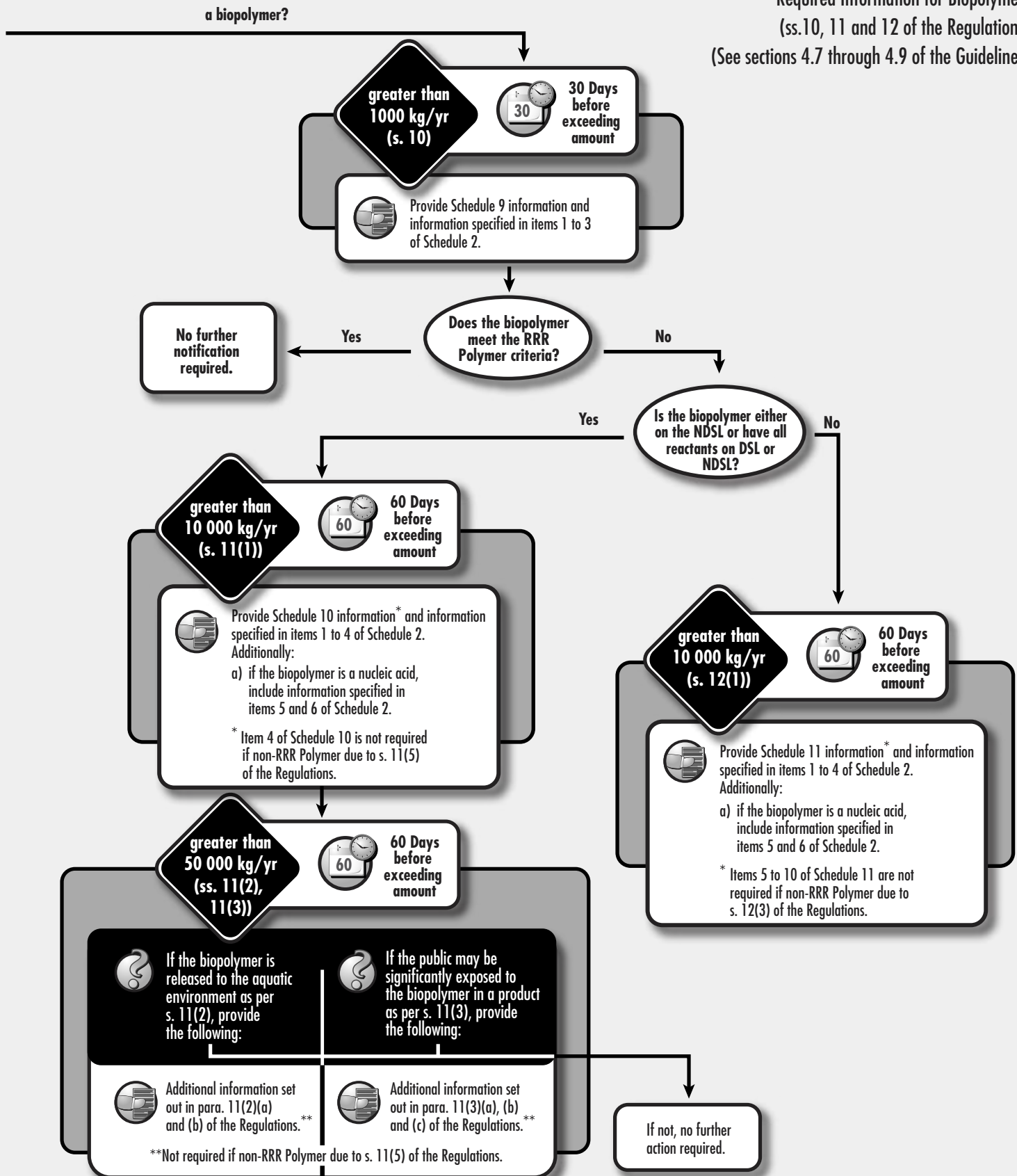
### Figure 4-4(a)

Required Information for Polymers  
(ss.10, 11 and 12 of the Regulations)  
(See sections 4.7 through 4.9 of the Guidelines)



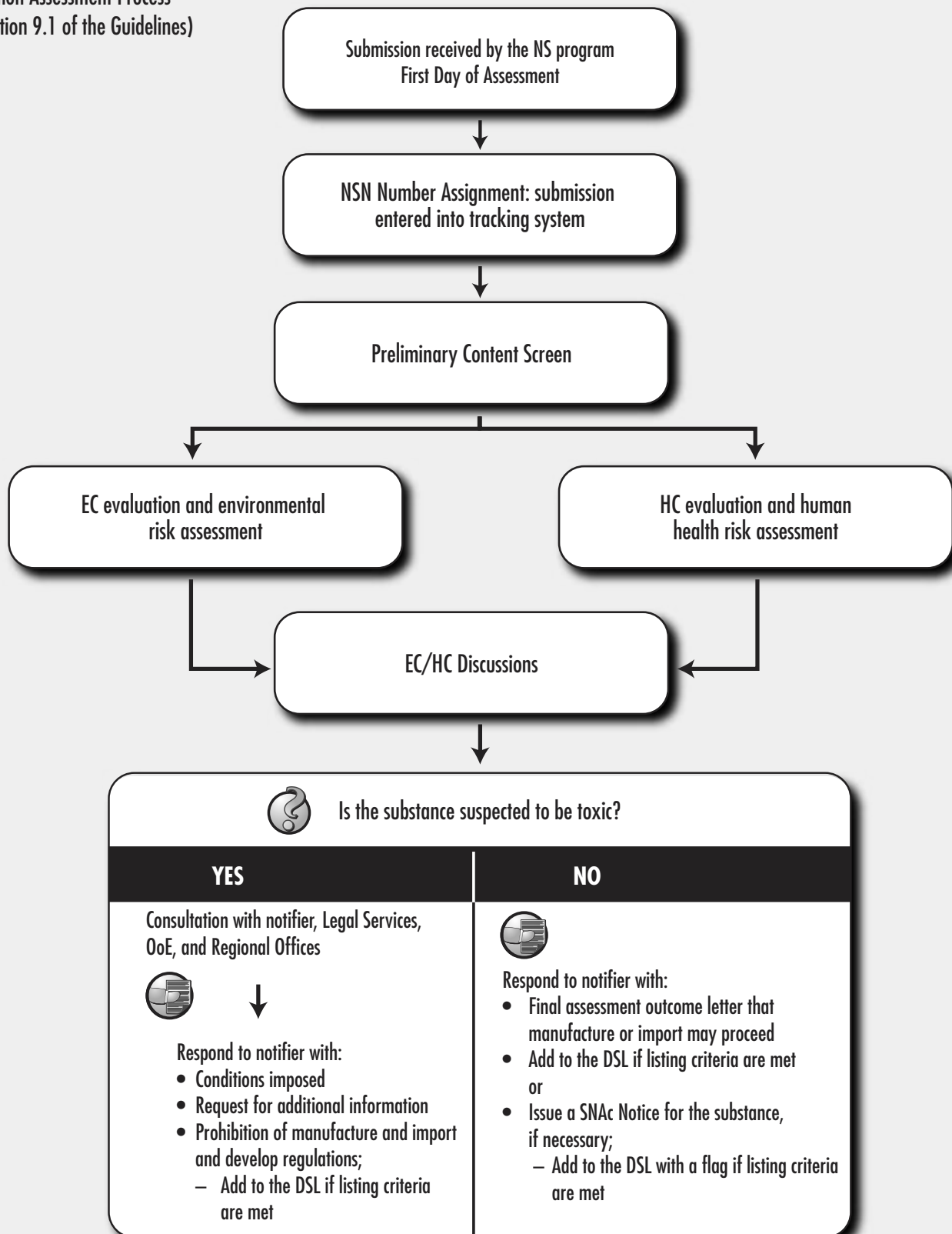
**Figure 4-4(b)**

Required Information for Biopolymers  
(ss.10, 11 and 12 of the Regulations)  
(See sections 4.7 through 4.9 of the Guidelines)



### Figure 9-1

Overview of the New Substances Notification Assessment Process  
(See section 9.1 of the Guidelines)



OoE = Office of Enforcement    EC = Environment Canada    HC = Health Canada



# APPENDIX 2 — NSN Reporting Form



Government of Canada  
Gouvernement du Canada

Environment Canada  
Environnement Canada

Health Canada  
Santé Canada

## NEW SUBSTANCES NOTIFICATION REPORTING FORM

This form is to be used for fulfilling the information requirements prescribed in the *New Substances Notification Regulations (Chemicals and Polymers)* of the *Canadian Environmental Protection Act, 1999*.

The New Substances Notification (NSN) package must be submitted to:

**Mailing Address:**

Director, New Substances Division  
Department of the Environment  
Ottawa ON K1A 0H3

**Courier Deliveries:**

Director, New Substances Division  
Department of the Environment  
14th Floor, Place Vincent Massey  
351 St. Joseph Blvd.  
Gatineau QC J8Y 3Y5

**Department Use Only**

NSN Reference No.

Date Received:

Total number of pages:

### INSTRUCTIONS FOR COMPLETING THE NOTIFICATION FORM

The New Substances Notification (NSN) Reporting Form serves as an aid for complying with the *New Substances Notification Regulations (Chemicals and Polymers)* (NSNR) of the *Canadian Environmental Protection Act, 1999*. Notifiers may reproduce this form, or portions thereof, for notification purposes. The form is also available electronically from the New Substances Web site (<http://www.ec.gc.ca/substances>).

Additional explanations necessary for fulfilling prescribed information requirements and completing this notification form are included in the *Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers* (Guidelines). Hard copies of the Guidelines may be obtained, for a fee, from Environment Canada by contacting the Environmental Protection Publications at (800) 734-3232 or for callers outside Canada, (819) 953-5750 or by e-mail at [epspubs@ec.gc.ca](mailto:epspubs@ec.gc.ca). The Guidelines are also available electronically on the New Substances (NS) program web site (<http://www.ec.gc.ca/substances>).

This form is divided into four sections: Part A to D. Part A is used for administrative and substance identity information while Part B and Part C are for technical information. Part D is used for any additional information that may be provided with the notification.

Before completing Part B or Part C of the form, you should ensure that you are providing information appropriate for the quantity and category of substance you intend to manufacture or import (refer to Section 3.4 of the Guidelines). Part B contains four sections: (1) Physical and Chemical Information requirements; (2) Ecotoxicity Information requirements; (3) Health Toxicity Information requirements; and (4) Genotoxicity Information requirements. Part C contains one section: Biochemical or Biopolymer Information Requirements. Part B contains five columns and Part C contains four columns of which consist of: Submit with Schedule; Data Codes; Value & Conditions; Attachment Number; and Confidential Information. Explanations of the use of these columns are provided on page 2 of this form. Part D contains two sections: (1) Other Requirements; and (2) Additional Information and Attachments.

Also included are two appendices. Appendix I is for Manufacture, Import, Use, Exposure and Release Information (Known and Anticipated) and Appendix II is the New Substances Fee Payment Form.

Ce formulaire est disponible en français, sur demande, en communiquant avec La ligne d'information des déclarations de substances nouvelles au 1-800-567-1999 (sans frais au Canada) ou au (819) 953-7156 (de l'étranger). Le formulaire est aussi disponible en ligne au <http://www.ec.gc.ca/substances>.

### Data Codes, Attachments and Confidential Information

In addition to the list of information requirements, Part B contains five columns and Part C contains four columns of which consist of: Submit with Schedule; Data Codes; Value & Conditions; Attachment Number; and Confidential Information. The following explains the use for each of these columns.

**Submit with Schedule:** This is a quick reference column that allows you to determine, at a glance, which Schedule requires the information to be provided. Take note of the footnotes for certain exceptions and conditions associated with certain data elements. It is important to note that if lower Schedule notifications are not submitted, the information prescribed in them is still required to be submitted with the higher Schedule notification.

**Data Codes:** A Data Code is a reference to indicate: whether data are provided; the type of data being submitted; or whether a request for waiver of information is being submitted. The Data Codes with explanatory notes are:

**D = test data on notified substance**

This code is used when the data provided were generated on the notified substance using protocols consistent with these listed in Tables 8-1 to 8-4 of the Guidelines. This code is to be used even if the information is provided under the Additional Information requirements of the Schedules (refer to section 6.5 of the Guidelines).

**A = alternative procedures**

This code is used when the data provided were generated using: (1) an alternative test protocol; (2) structure–activity relationships (SARs) including surrogate data and quantitative structure–activity relationships (QSARs); or (3) other calculation methods (refer to section 8.4.3 of the Guidelines). This code is to be used even if the information is provided under the Additional Information requirements of the Schedules (refer to section 6.5 of the Guidelines).

**W = waiver requested**

This code is used when the data required is being requested to be waived. Requests for a waiver of prescribed information must be accompanied by justifications that satisfy any of the waiver criteria listed in subsection 81(8) of the Act (refer to section 8.7 of the Guidelines).

**N/A = not applicable**

This code is used if the NSNR specify that the provision of information is not required under certain conditions. For example, the adsorption-desorption screening test data is not required when water solubility is less than 200 µg/L. This code cannot be used as an abbreviation for "not available".

**NR = not required**

This code is used when the information has not been provided and is not required for that specific Schedule of the NSNR.

**P = previous New Substances Notification (NSN) reference number / Pre-notification Consultation (PNC) reference number or notice under section 70 of the Act**

This code is to be used when the notifier has already provided the information to the NS program in a previous NSN package, a previous PNC request and/or a notice under section 70 of the Act. The applicable NSN, PNC or notice under section 70 reference number must be entered in the Attachment column.

**Value and Conditions:** Although complete physical-chemical data must be submitted in test reports (physical state and whether the notified substance is formulated for dispersal in water excepted) the notifier must enter the value and conditions in the appropriate space provided. This information will assist the notifier in organizing data for use; in requesting waivers of information; in justifying cases when data are not applicable; and in discussing notifications with NS program officials. Physical-chemical values and corresponding conditions may be expressed in units cited within the laboratory report. In the event that the data are only available in degrees Fahrenheit, the notifier must strike out the °C symbol printed in the entry and replace it with the °F symbol.

**Attachment Number:** Notifiers must clearly indicate a reference for accompanying documents (e.g., Attachment 6) so they may be readily located within the NSN package. Attachments include: justifications for waivers of information; reports of experimental procedures; reports of test results; rationale for alternative data; results and validation of modeling studies; rationale for why information is considered "not applicable"; and information supplemental to a request for confidentiality.

**Confidential Information:** Notifiers must check the appropriate box to indicate that the information provided is considered confidential (e.g., check "Y" to indicate that the information is considered confidential or check "N" to indicate that the information is not confidential). If the information provided is considered confidential, the notifier must provide, in the NSN package, the supplementary information detailed in section 7.2 of the Guidelines.

**Part A — Administrative and Substance Identity Information** (refer to sections 6.2.1.1 to 6.2.1.6 of the Guidelines)

<b>A.1. Certification Statement:</b>			
I hereby certify to the best of my information, knowledge and belief that all information provided in this form, as well as any attachments to the form, is accurate and complete; and the information for which confidentiality is claimed, meets the criteria for determining confidentiality as outlined in section 7 of the <i>Guidelines for the Notification and Testing of New Substances (Chemicals and Polymers)</i> .			
Name and Title of the Person authorized to act on behalf of the corporation of block A.2 or A.3		Signature	
		Date YYYY   MM   DD	
Name and Title of the Person in Canada authorized to act on behalf of the corporation of block A.4		Signature	
		Date YYYY   MM   DD	
<b>Preferred Language of Correspondence:</b>		English <input type="checkbox"/> French <input type="checkbox"/>	
<b>Preferred Mode of Communication for Correspondence:</b>		Mail <input type="checkbox"/> Facsimile <input type="checkbox"/> (non secure)	
<b>A.2. Corporate Headquarters of the Canadian Manufacturer or Importer (Principal Place of Business in Canada):</b> (if the importer is not located in Canada, skip to block A.3)			
Company Name:		E-Mail:	
Street:		City:	Province:
Postal Code:	Telephone No: (    )	Facsimile No: (    )	
<b>A.3. Corporate Headquarters of the Non-resident Importer</b> (if applicable, also complete block A.4):			
Company Name:		E-Mail:	
Street:		City:	State / Country:
Zip / Postal Code:	Telephone No: (    )	Facsimile No: (    )	
<b>A.4. Canadian Agent</b> (only needed if block A.3 is applicable):			
Company Name:		E-Mail:	
Street:		City:	Province:
Postal Code:	Telephone No: (    )	Facsimile No: (    )	
<b>A.5. Foreign Supplier</b> (only needed if the technical information in Part B is provided by a third party):			
Company Name:		E-Mail:	
Street:		City:	State / Country:
Zip / Postal Code:	Telephone No: (    )	Facsimile No: (    )	
<b>A.6. Proposed Site of Manufacture in Canada / Proposed Port of Entry into Canada / Toll Manufacturer Information :</b>			
Company Name/Port of Entry:		Toll Manufacturer Contact Name:	
Street:		City:	Province:
Postal Code:	Telephone No: (    )	Facsimile No: (    )	
Toll Manufacturer E-Mail:		Toll Manufacturer Statement of Responsibilities: <input type="checkbox"/> Enclosed      Attachment Number: _____	

**Part A — Administrative and Substance Identity Information** (refer to sections 6.2.1.7 to 6.2.1.18 of the Guidelines)

<b>A.7. Technical Contact</b> (Name of a person who can assist in the resolution of issues pertaining to the information provided):											
Person's Name/Title:					E-Mail:						
Street:					City:			Province / State Country:			
Zip / Postal Code:			Telephone No: ( )			Facsimile No: ( )					
<b>A.8 Previous NSN Reference Number / PNC Reference Number:</b>								Date Submitted:	YYYY	MM	DD
<b>A.9 Fee Provided (if applicable):</b> \$ _____ (Please complete Appendix II – New Substances Fee Payment Form)											
<b>A.10 Manufacture/Import:</b> Manufacture <input type="checkbox"/> Import <input type="checkbox"/> Manufacture and Import <input type="checkbox"/>											
<b>A.11 Amount</b> (Indicate the quantity that triggered this notification): 100 Kg <input type="checkbox"/> 1 000 Kg <input type="checkbox"/> 10 000 Kg <input type="checkbox"/> 50 000 Kg <input type="checkbox"/>											
<b>A.12 Date that the Amount in Block A.11 is Expected to be Exceeded:</b>								YYYY	MM	DD	
<b>A.13 Substance Information:</b> (check all that apply) Present on the NDSL or Confidential NDSL <input type="checkbox"/> NDSL Accession Number: _____ <input type="checkbox"/> Solely for F&DA <sup>1</sup> use <input type="checkbox"/> Chemical <input type="checkbox"/> Polymer <input type="checkbox"/> <input type="checkbox"/> All reactants specified on the DSL or NDSL Biochemical <input type="checkbox"/> Biopolymer <input type="checkbox"/> <input type="checkbox"/> Meets the RRR polymer criteria <b>Special Category:</b> Research & Development <input type="checkbox"/> Contained Export Only <input type="checkbox"/> Contained Site Limited Intermediate <input type="checkbox"/>											
<b>A.14 Schedule Number:</b>											
Special Category:			1	2	3						
Chemical / Biochemical:			2	4	5	6					
Polymer / Biopolymer:			2	9	10	11					
<b>A.15 Anticipated, Historical and Other Likely Uses of the Substance:</b>											
<b>A.16 Anticipated Annual Quantity to be Manufactured and/or Imported:</b>											
<b>A.17 Confidentiality Requests:</b>											
Corporation <b>Y</b> <input type="checkbox"/>		Manufacture <b>Y</b> <input type="checkbox"/>		Import <b>Y</b> <input type="checkbox"/>		Amount <b>Y</b> <input type="checkbox"/>		Substance Identity <b>Y</b> <input type="checkbox"/>			
<b>N</b> <input type="checkbox"/>		<b>N</b> <input type="checkbox"/>		<b>N</b> <input type="checkbox"/>		<b>N</b> <input type="checkbox"/>		<b>N</b> <input type="checkbox"/>			
<b>A.18 Information Sharing Agreement Authorization:</b>											
I hereby grant the Minister of the Environment permission to release the name, address and phone number of the technical contact indicated in block A.7 of this form to any person who has provided the Minister of the Environment with: (1) documentation of intent to manufacture or import the substance described in block A.20 of this form; and, (2) a statement granting the Minister of the Environment permission to release the name, address and phone number of their technical contact.											
Name and Title:					Signature:						
					Date YYYY   MM   DD						

<sup>1</sup> Food and Drugs Act  
36-2622E (09/2005)

**Part A — Administrative and Substance Identity Information** (refer to sections 6.2.2.1 to 6.2.2.8 of the Guidelines)

<b>A.19 CAS Registry Number and/or Enzyme Commission Number:</b>		
<b>A.20 Chemical Name of the Substance:</b> Nomenclature:    IUPAC <input type="checkbox"/> CAS <input type="checkbox"/> IUBMB <input type="checkbox"/>		
<b>A.21 Proposed Masked Name</b> (If the Chemical Name of the Substance is Claimed Confidential):		
Multiple Masking: <input type="checkbox"/> Justification Enclosed                      Attachment Number: _____		
<b>A.22 Known Trade Name or Synonyms of the Chemical Name of the Substance:</b>		
<b>A.23 Structural Formula of the Substance:</b>		
RRR Polymer: <input type="checkbox"/> Reaction Scheme Enclosed                      Attachment Number: _____		
<b>A.24 Molecular Formula:</b>		
<b>A.25 Gram Molecular Weight:</b>		
<b>A.26 Monomers and Reactants with their Concentration:</b>		
Substance Name	CAS Registry Number	% by weight
		_____
		<b>100 %</b>

**Part A — Administrative and Substance Identity Information** (refer to sections 6.2.2.9 to 6.2.2.12 of the Guidelines)**A.27 Additives, Stabilizers and Solvents with their Concentration:**

Substance Name	CAS Registry Number	% by weight

**A.28 Impurities with their Concentration:**

Substance Name	CAS Registry Number	% by weight

**A.29 Degree of Purity in its Technical Grade Composition:****A.30 Material Safety Data Sheet (MSDS):**  Enclosed Attachment Number: \_\_\_\_\_**Part B — Technical Information** (refer to sections 6.3.1.1 to 6.3.1.15 of the Guidelines)

B.1 Physical & Chemical Information Requirements	Submit with Schedule	Data Code	Value & Conditions	Attachment Number	Confidential Information
Melting Point	5, 6		°C		Y <input type="checkbox"/> N <input type="checkbox"/>
Boiling Point	5, 6		°C		Y <input type="checkbox"/> N <input type="checkbox"/>
Density	5, 6		g/cm @ °C		Y <input type="checkbox"/> N <input type="checkbox"/>
Vapour Pressure	5, 6		@ °C		Y <input type="checkbox"/> N <input type="checkbox"/>
Water Solubility	5, 6		g/L @ °C		Y <input type="checkbox"/> N <input type="checkbox"/>
Octanol/Water Partition Coefficient	5, 6, 10, 11				Y <input type="checkbox"/> N <input type="checkbox"/>
Ready Biodegradation	5, 6, 11				Y <input type="checkbox"/> N <input type="checkbox"/>
Spectroscopy IR <input type="checkbox"/> UV <input type="checkbox"/> NMR <input type="checkbox"/> Mass <input type="checkbox"/>	6				Y <input type="checkbox"/> N <input type="checkbox"/>
Adsorption-Desorption <sup>2</sup>	6				Y <input type="checkbox"/> N <input type="checkbox"/>
Hydrolysis as a Function of pH <sup>2</sup>	6, 10, 11				Y <input type="checkbox"/> N <input type="checkbox"/>
Physical State	3, 10, 11				Y <input type="checkbox"/> N <input type="checkbox"/>
Formulated for Dispersal in Water	3, 10, 11		Yes <input type="checkbox"/> No <input type="checkbox"/>		Y <input type="checkbox"/> N <input type="checkbox"/>
Water Extractability	10, 11		%		Y <input type="checkbox"/> N <input type="checkbox"/>
Number average Molecular Weight (M <sub>n</sub> )	3, 9, 10, 11				Y <input type="checkbox"/> N <input type="checkbox"/>
Weight Percent < 1 000 Daltons	3 <sup>a</sup> , 9, 10, 11				Y <input type="checkbox"/> N <input type="checkbox"/>
Weight Percent < 500 Daltons	3 <sup>a</sup> , 9, 10, 11				Y <input type="checkbox"/> N <input type="checkbox"/>

<sup>2</sup> Please review subsection 7(2) of the NSNR to determine if these test data are required prior to exceeding 50 000 kg per year.<sup>a</sup> Not required for Research and Development polymers.

**Part B — Technical Information** (refer to sections 6.3.2.1 to 6.3.4.3 of the Guidelines)

<b>B.2 Ecotoxicity Information Requirements<sup>3</sup></b>	<b>Submit with Schedule</b>	<b>Data Code</b>	<b>Value &amp; Conditions</b>	<b>Attachment Number</b>	<b>Confidential Information</b>
Acute Toxicity Fish <input type="checkbox"/> <i>Daphnia</i> <input type="checkbox"/> Algal <input type="checkbox"/>	5, 10				Y <input type="checkbox"/> N <input type="checkbox"/>
Other Acute Toxicity (check two that apply) Fish <input type="checkbox"/> <i>Daphnia</i> <input type="checkbox"/> Algal <input type="checkbox"/>	6, 11				Y <input type="checkbox"/> N <input type="checkbox"/>
<b>B.3 Health Toxicity Information Requirements</b>	<b>Submit with Schedule</b>	<b>Data Code</b>	<b>Value &amp; Conditions</b>	<b>Attachment Number</b>	<b>Confidential Information</b>
Acute Mammalian Toxicity Oral <input type="checkbox"/> Dermal <input type="checkbox"/> Inhalation <input type="checkbox"/>	5, 10, 11				Y <input type="checkbox"/> N <input type="checkbox"/>
Other Acute Mammalian Toxicity Oral <input type="checkbox"/> Dermal <input type="checkbox"/> Inhalation <input type="checkbox"/>	6				Y <input type="checkbox"/> N <input type="checkbox"/>
Information Sufficient to Assess Skin Irritation	6, 11				Y <input type="checkbox"/> N <input type="checkbox"/>
Skin Sensitization	6, 11				Y <input type="checkbox"/> N <input type="checkbox"/>
Repeated Dose Mammalian Toxicity <sup>4</sup> Oral <input type="checkbox"/> Dermal <input type="checkbox"/> Inhalation <input type="checkbox"/>	6, 11				Y <input type="checkbox"/> N <input type="checkbox"/>
<b>B.4 Genotoxicity Information Requirements</b>	<b>Submit with Schedule</b>	<b>Data Code</b>	<b>Value &amp; Conditions</b>	<b>Attachment Number</b>	<b>Confidential Information</b>
<i>In Vitro</i> Test for Gene Mutations <sup>4</sup>	5, 6, 11				Y <input type="checkbox"/> N <input type="checkbox"/>
<i>In Vitro</i> Mammalian Test for Chromosomal Aberrations <sup>4</sup>	6, 11				Y <input type="checkbox"/> N <input type="checkbox"/>
<i>In Vivo</i> Mammalian Test for Chromosomal Aberration <b>OR</b> Gene Mutations <sup>4</sup>	6, 11				Y <input type="checkbox"/> N <input type="checkbox"/>

**Part C — Biochemical or Biopolymer Information Requirements** (refer to sections 6.4.1 to 6.4.5 of the Guidelines)

<b>C.1 Additional Information Required for Biochemicals or Biopolymers</b>	<b>Submit with Schedule</b>	<b>Data Code</b>	<b>Attachment Number</b>	<b>Confidential Information</b>
Identification	1, 3, 4, 5, 6, 9, 10, 11			Y <input type="checkbox"/> N <input type="checkbox"/>
Source and History	1, 3, 4, 5, 6, 9, 10, 11			Y <input type="checkbox"/> N <input type="checkbox"/>
Adverse Environmental or Human Health Effects	1, 3, 4, 5, 6, 9, 10, 11			Y <input type="checkbox"/> N <input type="checkbox"/>
Concentration of the Viable Production Organism	1 <sup>b</sup> , 3 <sup>b</sup> , 4, 5, 6, 9, 10, 11			Y <input type="checkbox"/> N <input type="checkbox"/>
Methods Used to Separate the Production Organism	1 <sup>c</sup> , 3 <sup>c</sup> , 5, 6, 10, 11			Y <input type="checkbox"/> N <input type="checkbox"/>

<sup>3</sup> Please review section 6.3.2 of the Guidelines to determine the most appropriate test to provide at each Schedule.

<sup>4</sup> Please review subsections 7(2), 7(3), 11(2) and 11(3) of the NSNR to determine if these test data are required prior to exceeding 50 000 kg per year.

<sup>b</sup> Not required for Research and Development substances; and Contained Site-Limited Intermediate substances that are manufactured and consumed at the site of manufacture.

<sup>c</sup> Not required for Research and Development substances.

**Part C — Biochemical**

C.1 Additional Information Required for Biochemicals or Biopolymers	Submit with Schedule	Data Code	Attachment Number	Confidential Information
Identification of Encoded Products <sup>5</sup>	1 <sup>d</sup> , 3 <sup>d</sup> , 5, 6, 10, 11			Y <input type="checkbox"/> N <input type="checkbox"/>
Description of Biological Activity <sup>5</sup>	1 <sup>d</sup> , 3 <sup>d</sup> , 5, 6, 10, 11			Y <input type="checkbox"/> N <input type="checkbox"/>
Catalytic Functions <sup>6</sup>	1 <sup>d</sup> , 5, 6			Y <input type="checkbox"/> N <input type="checkbox"/>
Substrate Specificity <sup>6</sup>	1 <sup>d</sup> , 5, 6			Y <input type="checkbox"/> N <input type="checkbox"/>
Optimum pH and Temperature <sup>6</sup>	1 <sup>d</sup> , 5, 6			Y <input type="checkbox"/> N <input type="checkbox"/>
Catalytic Constants $K_M$ and $K_{cat}$ <sup>6</sup>	1 <sup>d</sup> , 5, 6			Y <input type="checkbox"/> N <input type="checkbox"/>
Cofactors <sup>6</sup>	1 <sup>d</sup> , 5, 6			Y <input type="checkbox"/> N <input type="checkbox"/>
Enzymatic Activity <sup>6</sup>	1 <sup>d</sup> , 5, 6			Y <input type="checkbox"/> N <input type="checkbox"/>

**Part D — Additional Information Requirements** (refer to sections 6.5.1.1 to 6.5.2.1 of the Guidelines)

D.1 Other Requirements	Submit with Schedule	Attachment Number
Other agencies notified, the agency's file number and the outcome	1, 3, 4, 5, 6, 9, 10, 11	
Other information and test data in the possession of the manufacturer or importer	1, 3, 4, 5, 6, 9, 10, 11	
D.2 Additional Information and Attachments		
Attachment Name	Attachment Number	Confidential Information
		Y <input type="checkbox"/> N <input type="checkbox"/>
		Y <input type="checkbox"/> N <input type="checkbox"/>
		Y <input type="checkbox"/> N <input type="checkbox"/>
		Y <input type="checkbox"/> N <input type="checkbox"/>
		Y <input type="checkbox"/> N <input type="checkbox"/>
		Y <input type="checkbox"/> N <input type="checkbox"/>
		Y <input type="checkbox"/> N <input type="checkbox"/>
		Y <input type="checkbox"/> N <input type="checkbox"/>
		Y <input type="checkbox"/> N <input type="checkbox"/>
		Y <input type="checkbox"/> N <input type="checkbox"/>
		Y <input type="checkbox"/> N <input type="checkbox"/>

<sup>5</sup> This information is only required for a substance that is a nucleic acid.

<sup>6</sup> This information is only required for a biochemical that possesses enzymatic capability.

<sup>d</sup> Not required for Research and Development substances; and Contained Site-Limited Intermediate substances that are manufactured and consumed at the site of manufacture.





**Appendix I — Manufacture, Import, Use, Exposure and Release Information (Known and Anticipated)**

**A. Manufacture and/or Importation Information** (See section 6.6.1 of the Guidelines)

**A1. Canadian Manufacture and Processing Information\*** (section 6.6.1.1)

Confidential? Yes  No

Manufacturing process description:

Flow diagram of process (provide attachment):

Enclosed

Attachment Number: \_\_\_\_\_

Steps in operations:

\*This information is required for substances manufactured in Canada that are subject to any of the Schedules prescribed in the NSNR.

**A2. Anticipated Annual Production/Import Quantities of Notified Substance\*** (section 6.6.1.2)

Confidential? Yes  No

	Quantity during first 12 months (kg/yr)	Maximum quantity in any 12 month period during first 3 years (kg/yr)
Amount manufactured within Canada (if any):		
Amount imported into Canada (if any):		
Amount for export (if any):		
List the three sites in Canada where the greatest quantity of the substance to be manufactured or imported by the notifier, is anticipated to be used or processed, if known <sup>a</sup> :	Estimated quantity for each site	
1)		
2)		
3)		

\*This information is required for substances subject to any of the Schedules prescribed in the NSNR.

<sup>a</sup>This information is required for chemicals subject to Schedule 5 or 6 or non-RRR polymers subject to Schedule 9, 10 or 11 of the NSNR.

**B. Uses of the Substance** (See section 6.6.2 of the Guidelines)

**B1. Anticipated<sup>a</sup>, Historical<sup>a</sup> and Other Likely Uses<sup>a</sup> for the Substance** (section 6.6.2.1)

Confidential? Yes  No

Provide anticipated, historical or any other likely use of the notified substance or type of product containing the notified substance:

1)

And to the degree known : a) The function/application for this use:

b) The industrial / commercial / consumer application for this use:

c) If the use is highly dispersive, non-dispersive, contained, consumed or other:

d) The maximum annual quantity of notified substance for this use (kg/yr):

e) For contained site-limited intermediate substances the location of use<sup>b</sup>:

## Appendix I — Manufacture, Import, Use, Exposure and Release Information (Known and Anticipated)

Provide anticipated, historical or any other likely use of the notified substance or type of product containing the notified substance: 2)
And to the degree known : a) The function/application for this use:
b) The industrial / commercial / consumer application for this use:
c) If the use is highly dispersive, non-dispersive, contained, consumed or other:
d) The maximum annual quantity of notified substance for this use (kg/yr):
e) For contained site-limited intermediate substances the location of use <sup>b</sup> :

Provide anticipated, historical or any other likely use of the notified substance or type of product containing the notified substance: 3)
And to the degree known : a) The function/application for this use:
b) The industrial / commercial / consumer application for this use:
c) If the use is highly dispersive, non-dispersive, contained, consumed or other:
d) The maximum annual quantity of notified substance for this use (kg/yr):
e) For contained site-limited intermediate substances the location of use <sup>b</sup> :

\*This information is required for substances subject to any of the Schedules prescribed in the NSNR.

<sup>a</sup> This information is required for substances subject to Schedule 6, 10 or 11 or NDSL chemicals subject to Schedule 5 of the NSNR.

<sup>b</sup> This information is required for site-limited intermediate substances subject to Schedules 1 or 3 of the NSNR.

## B2. Concentration in Products (section 6.6.2.2)

Confidential? Yes  No 

Anticipated concentration of notified substance in notifier's product (specify units)* :
Concentration (or range of concentrations) of notified substance as manufactured or imported, if known:
Anticipated concentration of notified substance in end-use products, if known (specify units)* :

\*This information is required for substances subject to Schedule 1, 3, 4, 5 or 6, or non-RRR polymers subject to Schedule 9, 10, or 11 of the NSNR.

**Appendix I — Manufacture, Import, Use, Exposure and Release Information (Known and Anticipated)**

**B3. Anticipated to be Used in Products Intended for Use by or for Children\*** (section 6.6.2.3)

Confidential? Yes  No

Check one: Yes  (See below) No

If yes, describe what types of products these may be:

\* This information is required for chemicals subject to Schedule 5 or 6 or non-RRR polymers subject to Schedule 9, 10, or 11 of the NSNR.

**C. Human Exposure Information Requirements** (See section 6.6.3 of the Guidelines)

**C1. Whether the Public is Anticipated to be Significantly Exposed to the Substance\*** (section 6.6.3.1)

Confidential? Yes  No

If yes, describe whether the substance is present in products to which the public is anticipated to be significantly exposed to the substance taking into consideration factors including the use, duration, frequency of use, concentration of the substance in the product and circumstances of exposure that may limit direct human exposure:

If not, provide below, the information substantiating that the public is not anticipated to be significantly exposed:

\* This information is required for substances subject to Schedule 1, 3 or 10 or NDSDL chemicals subject to Schedule 5 of the NSNR. Please review subsections 7(2), 7(3), 11(2) and 11(3) of the NSNR to determine if additional test data are required prior to exceeding 50 000 kg/yr.

**C2. Anticipated Degree of Direct Human Exposure\*** (section 6.6.3.2)

Confidential? Yes  No

Describe anticipated degree of direct human exposure to the notified substance, especially for the general public, including concentration, duration, frequency, and circumstances of exposure. Describe conditions of use that may limit direct human exposure:

Routes of exposure at each stage, if known:

Estimates of number of persons that may be exposed, if known:

\* This information is required for chemicals subject to Schedule 5 or 6 or non-RRR polymers subject to Schedule 9, 10 or 11 of the NSNR.

**Appendix I — Manufacture, Import, Use, Exposure and Release Information (Known and Anticipated)****D. Environmental Exposure Information (See section 6.6.4 of the Guidelines)**

D1. Components of the Environment into which Release is Anticipated\* (section 6.6.4.1)

Confidential? Yes  No 

Provide an identification of the components of the environment into which the substance is anticipated to be released:

Stages in the manufacture or import process where emissions or discharges to the environment may occur, if applicable:

Quantities and Concentration of Release:

Physical form of the substance for each location into which the substance will be released and the anticipated frequency, duration and rate of release, if applicable:

Estimate of the fugitive emissions, if known:

Description of the waste management practices designed to prevent or minimize the release of the substance in effluents and emissions, if applicable:

Amount of substance, in effluents and emissions, expected to be released to the environment, including average and peak concentrations, if applicable:

Describe the contingency plan to deal with unintended releases from the manufacturing processes; if applicable:

Provide information on any potential releases from commercial or consumer products or potential releases during processing by domestic customers, if known:

\* This information is required for substances subject to Schedule 1, 3, 5, 6 or 11 of the NSNR.

**Appendix I — Manufacture, Import, Use, Exposure and Release Information (Known and Anticipated)**

**D2. Anticipated Releases of the Substance into Municipal Wastewater Systems\*** (section 6.6.4.2)

Confidential? Yes  No

**Check one:**  Direct to the Municipal Wastewater Treatment Facility      OR       Go directly into surface waters.

Total amount (kg/day) anticipated to be discharged:

Name of municipal treatment facility:

Address of municipal wastewater treatment facility, if applicable:

Name of receiving water/location of discharge, if applicable:

\* This information is required for substances subject to Schedule 1, 3, 5, 6, 10 or 11 of the NSNR.

**D3. Factors that may Limit Environmental Exposure** (section 6.6.4.3)

Confidential? Yes  No

Describe conditions during the life cycle of the substance that may limit environmental exposure:

\* This information is required for substances subject to Schedule 6, 10 or 11 or for NDSL chemicals subject to Schedule 5 of the NSNR.

**D4. Releases of the Substance to the Aquatic Environment\*** (section 6.6.4.4)

Confidential? Yes  No

Whether the substance is anticipated to be released to the aquatic environment in a quantity less than or equal to 3 kg per day, per site, the data substantiating the quantity released is required:

Total amount (kg/day) of releases or anticipated release directly to surface water:

Amount (kg/year) of discharges, if any, from on-site treatment and data substantiating the quantity of such releases:

Name of receiving water/location of discharge:

Description of any on-site treatment system(s), including percentage of notified substance removed, if known:

\* This information is required for polymers subject to Schedule 10 or NDSL chemicals subject to Schedule 5 of the NSNR. Review subsections 7(2), 7(3), 11(2) and 11(3) of the NSNR to determine if this test data are required prior to exceeding 50 000 kg/yr.

**Appendix I — Manufacture, Import, Use, Exposure and Release Information (Known and Anticipated)****E. Transportation, Storage and Disposal Information Requirements (See section 6.6.5 of the Guidelines)****E1. Transport and Storage Containers\*** (section 6.6.5.1)Confidential? Yes  No 

Description of the expected modes for its transportation and storage :	UN Number, if known:
Description of the size and type of container(s) used for transportation and storage of the notified substance and/or product containing the notified substance :	Amount (kg/year) of substance shipped in each type of container, if known:

\* This information is required for substances subject to Schedule 1, 3, 5, 6, 10 or 11 of the NSNR.

**E2. Anticipated Disposal of the Substance \*** (section 6.6.5.2)Confidential? Yes  No 

Description of the methods recommended for its destruction or disposal for industrial, commercial and consumer applications:
Total amount (kg/year) of the substance disposed of by each method, if known:
Describe types and expected amounts (kg/year) of wastes from the substance for each type of waste, if known:
Treatment and disposal method of containers including those off-site, if known:
Provincial waste classification(s), if known:
Site(s) of disposal:

\* This information is required for substances subject to Schedule 1, 3, 5, 6, 10 or 11 of the NSNR.



Government of Canada  
Gouvernement du Canada

Environment Canada  
Environnement Canada

Health Canada  
Santé Canada

**Appendix II – New Substances Fee Payment Form**

This form is to be used for fulfilling the information requirements prescribed in the *New Substances Fees Regulations* of the *Canadian Environmental Protection Act, 1999*.

This form must be submitted to:  <b>Mailing Address:</b>  Director, New Substances Division Department of the Environment Ottawa ON K1A 0H3  <b>Courier Deliveries:</b>  Director, New Substances Division Department of the Environment 14th Floor, Place Vincent Massey 351 St. Joseph Blvd. Gatineau QC J8Y 3Y5	<b>Department Use Only</b>
	Mail Log No.
	NSN Reference No.
	Date Received
	Amount paid
	Reference No.

Please refer to Appendix 3 of the Guidelines for instructions for completing this Fee Form. A separate Fee Form must be submitted for each New Substances Notification (NSN) package except for consolidated notifications.

**Assessment Fees (Schedule 1 of Fees)**

Please circle the appropriate fee and report in box **A** below

NSNR Schedule	Company's Annual Sales in Canada (million) in Canadian dollars			
	≤\$13	>\$13 - ≤\$26	>\$26 - ≤\$40	>\$40
Schedule 1 (except R&D)	\$500	\$1 000	\$1 500	\$2 000
Schedule 3 (except R&D)	\$500	\$1 000	\$1 500	\$2 000
Schedule 4	\$50	\$100	\$150	\$200
Schedule 5	\$500	\$1 000	\$1 500	\$2 000
Schedule 6	\$875	\$1 750	\$2 625	\$3 500
Schedule 9	\$125	\$250	\$375	\$500
Schedule 10	\$875	\$1 750	\$2 625	\$3 500
Schedule 11	\$875	\$1 750	\$2 625	\$3 500

**Assessment Fees (Schedule 2 of Fees)**

Please circle the appropriate fee and report in box **A** below

NSNR Schedule	Company's Annual Sales in Canada (million) in Canadian dollars			
	≤\$13	>\$13 - ≤\$26	>\$26 - ≤\$40	>\$40
Schedule 5 final <sup>1</sup>	\$750	\$1 500	\$2 250	\$3 000
Schedule 9 final <sup>2</sup>	\$375	\$750	\$1 125	\$1 500
Fee required for any Schedule indicated above				<b>A</b>
Less any amount paid for the assessment of that substance as referenced below:				
Schedule:	NSN No:	Assessment Fee Paid	<b>B</b>	
Schedule:	NSN No:	Assessment Fee Paid	<b>C</b>	
<b>Sub-total D (A - B - C, enter 0 if negative)</b>				

<sup>1</sup> Chemical listed on the NDSL.

<sup>2</sup> Polymer that meets the Reduced Regulatory Requirement polymer criteria.



## Appendix II – New Substances Fee Payment Form

## Assessment Fees for Matched Notifications or Consolidated Notifications

Please check appropriate box and enter appropriate information. Report in Sub-total E.

Type of Notification	Fee (CDN \$)
Matched <sup>3</sup> with NSN No. _____ <input type="checkbox"/>	\$200
Consolidated <sup>4</sup> (please indicate number of notification, up to 5) Please reference master notification below: Schedule: _____ Trade Name: _____ <input type="checkbox"/>	____ X \$250
<b>Sub-total E</b>	

<sup>3</sup> A matched notification takes place when a notifier requests to use information that has been previously provided by another notifier for the same substance (see section 5.1 and Appendix 3 of the Guidelines).

<sup>4</sup> A consolidated notification takes place when a notifier provides two to six substances of the same class at one time (see section 5.3 and Appendix 3 of the Guidelines).

## Fees for Other Services (Schedule 3 of Fees)

Please circle the appropriate fee and report in Sub-total F.

Services	Company's Annual Sales in Canada (million) in Canadian dollars			
	≤\$13	>\$13 - ≤\$26	>\$26 - ≤\$40	>\$40
Confidential search of DSL and NDSL	\$62.50	\$125	\$187.50	\$250
Masked name application <sup>5</sup>	\$150	\$300	\$450	\$600
Application under Four Corners Arrangement	\$500	\$1 000	\$1 500	\$2 000
<b>Sub-total F</b>				

<sup>5</sup> If fee has been previously paid for the masked name application, please reference it below:

Schedule: _____	NSN No: _____	Service Fee Paid for Masked Name Application
-----------------	---------------	--

<b>Sub-total D</b>	
<b>Sub-total E</b>	
<b>Sub-total F</b>	
<b>Total Fees Payable (D + E + F)</b>	

**Note:** When fees are based on your company's annual Canadian sales of less than C\$40 million, you must provide sales reports for your company's most recent fiscal period with all notifications.

Payment must be made by certified cheque or money order (payable to the Receiver General for Canada), Visa, MasterCard or American Express (complete page 3 of Appendix II of this form) at the time the service is requested. If the payment is not provided with the service request, the documentation will be returned and the service will not be rendered.

**Disclaimer:** Although care has been taken to ensure that the information accurately reflects the requirements prescribed, you are advised that, should any inconsistencies be found, the legal documents, printed in the *Canada Gazette*, will prevail.



**CREDIT CARD AUTHORIZATION FORM**

**This form is protected  
when completed**

I authorize payment of the New Substances fee to the Receiver General for Canada in the amount of:

→ C\$

Please indicate your method of payment:

- Visa                       MasterCard                       American Express

Card No.: \_\_\_\_\_

Expiry Date: \_\_\_\_\_

Card holder name: \_\_\_\_\_  
(Please print)

Company Name: \_\_\_\_\_  
(As found in Box A.1 of the Notification form or Service Requester)

Telephone Number: \_\_\_\_\_

Signature: \_\_\_\_\_

Department Use Only
Mail Log No.
NSN Reference No.
Date Received
Amount debited
Authorization No.
Deposit Receipt No.

# APPENDIX 3 — Guide To Paying Fees Associated With The Regulations

## Disclaimer

Notifiers of new substances (chemicals and polymers) and persons requesting other services (see section 2 of this Appendix) are required to pay a fee as per the *New Substances Fees Regulations* (NSFR) and the *Regulations Amending the New Substances Fees Regulations*, which were made under section 328 of the Act. The information in this Appendix, however, is intended to provide general guidance to notifiers in understanding the NSFR and to assist in determining the applicable fees for: notifying a new substance; and other services. Notifiers and persons requesting other services should keep in mind that the examples provided in this Appendix do not cover all situations. In some cases, notifiers or persons requesting other services may be required to consult with the NS program through the NSN Information Line for specific individual cases.

Please note, at this time the fees do not apply to biochemicals, biopolymers, research and development substances and substances that are manufactured or imported that are regulated under any other Act of Parliament or regulations not listed on Schedule 2 to the Act. This includes substances whose use is regulated by the *Food and Drugs Act*, the *Fisheries Act* and the *Health of Animals Act*.

The fees also do not apply to SNANs (see sections 1.3 and 9.5.2 of these Guidelines) or to the submission of additional information required for special category Schedule 1 notifications (at 10 000 kg/yr) and for high release to the aquatic environment or significant public exposure to the substance (at 50 000 kg/yr) (see sections 4.2.2, 4.4.3 and 4.9.2 of these Guidelines, respectively).

## 1.0 Assessment Fees

This section explains the NSFR, including how they may apply to a particular situation. Examples are provided to help the notifier determine the applicable fees for the notification and assessment of a new substance.

The maximum fees payable for the assessment of a single new substance on the basis of the information required under the Schedules of the Regulations are \$3500 where the notifier's annual Canadian sales are greater than \$40 million. The fees are broken down into three Tables:

- Table A3.1 provides a list of initial and subsequent assessment fees for all Schedules of the Regulations (see below);
- Table A3.2 provides a list of fees for final Schedules 5 and 9 of the Regulations (see section 1.3 of this Appendix); and
- Table A3.3 provides a list of fees for other services offered by the NS program and that are covered under the NSFR (see section 2 of this Appendix).

When fees are based on the notifying company's annual Canadian sales being <\$40 million, the notifier must provide sales reports for their most recent fiscal period (refer to section 5, "Proof of Annual Canadian Sales", of this Appendix for more information).

Table A3.1: NSFR Schedule 1, Assessment Fees

Column 1		Column 2 Fee (\$Cdn)			
Row	NSNR* Schedule	Company's Annual Sales in Canada (million) in Canadian Dollars			
		≤\$13	>\$13≤\$26	>\$26≤\$40	>\$40
1.	1**	500	1000	1500	2000
2.	3**	500	1000	1500	2000
3.	4	50	100	150	200
4.	5	500	1000	1500	2000
5.	6	875	1750	2625	3500
6.	9	125	250	375	500
7.	10	875	1750	2625	3500
8.	11	875	1750	2625	3500

\* NSNR [*New Substances Notification Regulations (Chemicals and Polymers)*] Schedule as per the Regulations.

\*\* Fees do not apply to R&D NSN packages

## 1.1 Initial Fees

Scenario: A notifier provides an NSN package for a new chemical or polymer, which they are notifying to the NS program for the first time. It is not a final NSN package, and there will not be any matched notifications (see sections 1.3 and 1.4 of this Appendix for details on final and matched notifications, respectively). The fee required for their NSN package is:

- the amount set out in Column 2 of Table A3.1, under the heading corresponding to the notifying company's annual Canadian sales for the last fiscal year.

Initial fees are required for all Schedules of the Regulations.

### 1.1.1 Examples of Initial Fees

#### *Example 1*

A notifier's annual Canadian sales totaled \$21.3 million in the last fiscal year and the notifier wants to import Chemical X into Canada. Chemical X has not been previously submitted by the notifier under any Schedule of the Regulations.

After determining that Chemical X is not on the NDSL and that it requires a non-final Schedule 5 NSN package, the notifier:

- consults Table A3.1;
- refers to Row 4 for "Schedule 5";
- moves across Row 4 to the column for annual sales of ">\$13≤26 million"; and
- finds that a fee of \$1000 is required for the assessment of the non-final Schedule 5 NSN package.

#### *Example 2*

A notifier's annual Canadian sales totaled \$45 million in the last fiscal year and the notifier wants to manufacture Polymer Y in Canada. Polymer Y has not been previously submitted by the notifier under any Schedule of the Regulations.

After determining that Polymer Y does not meet the RRR polymer criteria and that it requires a Schedule 10 NSN package, the notifier:

- consults Table A3.1;
- refers to Row 7 for "Schedule 10";
- moves across Row 7 to the column for annual sales of ">\$40 million"; and
- finds that a fee of \$3500 is required for the assessment of the Schedule 10 NSN package.

**Example 3**

A notifier's annual Canadian sales totaled \$12 million in the last fiscal year and the notifier wants to manufacture Polymer Y in Canada. Polymer Y has not been previously submitted by the notifier under any Schedule of the Regulations.

After determining that Polymer Y does not meet the RRR polymer criteria and that it requires a non-final Schedule 9 NSN package, the notifier:

- consults Table A3.1;
- refers to Row 6 for "Schedule 9";
- moves across Row 6 to the column for annual sales of "≤\$13 million"; and
- finds that a fee of \$125 is required for the assessment of the non-final Schedule 9 NSN package.

**1.2 Subsequent Fees**

Scenario: A notifier provides an NSN package for a new chemical or polymer, which they have previously notified to the NS program under another Schedule of the Regulations. It is not a final NSN package, and there will not be any matched notifications (see sections 1.3 and 1.4 of this Appendix for details on final and matched notifications, respectively). The fee required for their subsequent NSN package is:

- the amount set out in Column 2 of Table A3.1, under the heading corresponding to the notifying company's annual Canadian sales for the last fiscal year; less
- the amount that the notifier paid for the previous Schedule(s) NSN package(s), if any.

The same process is used to determine the fees required for subsequent NSN packages that are submitted after the revised Regulations come into force (see examples 6 through 8).

Note that if NSN packages were submitted prior to the NSFR coming into force; the notifier is required to pay initial fees for any subsequent NSN packages for that substance. For example, if a Schedule I and a Schedule II NSN package were submitted, under the previous Regulations and prior to the NSFR coming into force and a Schedule 6 NSN package is currently being submitted, under the revised Regulations, the fee required for the Schedule 6 is the full amount of \$3500 since there are no previous Schedule payments to be deducted (see example 9).

If the subsequent fee results in a negative amount (*e.g.* the current fee is less than the fees previously paid by the same company for the same substance) the fee shall be deemed to be \$0 (see example 10). This may occur, for example, if a notifier's annual Canadian sales figures have dropped between previous and subsequent NSN packages (see example 11). Note that the negative amount does not become a credit towards other services, such as notification of another substance or a request for a search on the confidential portion of the DSL/NDSL.

In order to facilitate the processing of an NSN package, we request that the notifier clearly identify the NSN reference number(s) of any previous NSN package(s) with the submission. The NSN reference number is the number assigned to a specific file/NSN package in order to track it through the notification, assessment and post-assessment process (see section 9.2.3 of these Guidelines).

**1.2.1 Examples of Subsequent Fees****Example 4**

A notifier's annual Canadian sales totaled \$31.2 million in the last fiscal year and the notifier wants to import Chemical X into Canada. A Schedule 4 NSN package for this substance was previously submitted by the notifier in the same fiscal year.

After determining that Chemical X is not on the NDSL and that it requires a non-final Schedule 5 NSN package, the notifier:

- consults Table A3.1;
- refers to Row 4 for “Schedule 5”;
- moves across Row 4 to the column for annual sales of “>\$26≤40 million”; and
- calculates that a subsequent fee of \$1350 is required (\$1500 for the assessment of the non-final Schedule 5 NSN package, **less** \$150 that the notifier paid for the assessment of the previous Schedule 4 NSN package).

**Example 5**

A notifier’s annual Canadian sales totaled \$8 million in the last fiscal year and the notifier wants to manufacture Polymer Y in Canada. A non-final Schedule 9 NSN package for this substance was previously submitted by the notifier in a different fiscal year but with the same total annual Canadian sales.

After determining that Polymer Y does not meet the RRR polymer criteria and that it requires a Schedule 11 NSN package, the notifier:

- consults Table A3.1;
- refers to Row 8 for “Schedule 11”;
- moves across Row 8 to the column for annual sales of “≤\$13 million”; and
- calculates that a subsequent fee of \$750 is required (\$875 for the assessment of the Schedule 11 NSN package, **less** \$125 that the notifier paid for the assessment of the previous non-final Schedule 9 NSN package).

**Example 6**

A notifier’s annual Canadian sales totaled \$45 million in the last fiscal year and the notifier wants to import Polymer Y into Canada. A Schedule VI NSN package for this substance was previously submitted by the notifier, in a different fiscal year under the previous Regulations but with the same total annual Canadian sales.

After determining that Polymer Y does not meet the RRR polymer criteria and that it requires a Schedule 10 NSN package, the notifier:

- consults Table A3.1;
- refers to Row 7 for “Schedule 10”;
- moves across Row 7 to the column for annual sales of “>40 million”; and
- calculates that a subsequent fee of \$3000 is required (\$3500 for the assessment of the Schedule 10 NSN package, **less** \$500 that the notifier paid for the assessment of the previous Schedule VI NSN package).

**Example 7**

A notifier’s annual Canadian sales totaled \$33.2 million in the last fiscal year and the notifier wants to import Chemical C into Canada. A Schedule I and II NSN package for this substance was previously submitted by the notifier, in a different fiscal year under the previous Regulations but with the same total annual Canadian sales.

After determining that Chemical C requires a Schedule 6 NSN package, the notifier:

- consults Table A3.1;
- refers to Row 5 for “Schedule 6”;
- moves across Row 5 to the column for annual sales of “>\$26≤40 million”; and
- calculates that a subsequent fee of \$1125 is required (\$2625 for the assessment of the Schedule 6 NSN package, **less** \$1350 that the notifier paid for the assessment of the previous Schedule II NSN package and **less** \$150 that the notifier paid for the assessment of the previous Schedule I NSN package).

**Example 8**

A notifier’s annual Canadian sales totaled \$34 million in the last fiscal year and the notifier wants to manufacture Chemical T in Canada. A Schedule II NSN package for this substance was previously submitted

by the notifier, in a different fiscal year under the previous Regulations but with the same total annual Canadian sales. At the time of submitting the Schedule II the substance was not on the NDSL and therefore a Schedule III was required. After the revised Regulations came into force Chemical T was added to the NDSL prior to the submission of any subsequent Schedule.

After determining that Chemical T now requires a final Schedule 5 NSN package (e.g. any required information prescribed in the final Schedule 5 that was not previously provided in the Schedule II NSN package), the notifier:

- consults Table A3.2 ;
- refers to Row 1 for a final “Schedule 5”;
- moves across Row 1 to the column for annual sales of “>\$26≤40 million”; and
- calculates that a subsequent fee of \$750 is required (\$2250 for the assessment of the final Schedule 5 NSN package, **less** \$1500 that the notifier paid for the assessment of the previous Schedule II NSN package).

#### **Example 9**

A notifier’s annual Canadian sales totaled \$48 million in the last fiscal year and the notifier wants to import Polymer Q into Canada. A Schedule VI NSN package for this substance was previously submitted by the notifier prior to the NSFR coming into force.

After determining that Polymer Q does not meet the RRR polymer criteria and that it requires a Schedule 11, the notifier:

- consults Table A3.1;
- refers to Row 8 for “Schedule 11”;
- moves across Row 8 to the column for annual sales of “>\$40 million”; and
- calculates that a subsequent fee of \$3500 is required (since there was no fee provided when the notifier submitted the Schedule VI NSN package, there are therefore no previous Schedule payments to be deducted).

### **1.2.2 Examples of Varying Annual Canadian Sales**

#### **Example 10**

A notifier’s annual Canadian sales totaled \$20 million in the last fiscal year and the notifier wants to manufacture Chemical B in Canada. A Schedule 4 and 5 NSN package for this substance was previously submitted by the notifier, in a different fiscal year where the total annual Canadian sales totaled \$44 million.

After determining that Chemical B requires a Schedule 6 NSN package, the notifier:

- consults Table A3.1;
- refers to Row 5 for “Schedule 6”;
- moves across Row 5 to the column for annual sales of “>\$13≤26 million”; and
- calculates that a subsequent fee of \$0 is required since the fee that was previously paid for the assessment of the Schedule 4 and 5 NSN packages is greater than the fee required for the assessment of the Schedule 6 NSN package (\$1750 for the assessment of the Schedule 6 NSN package, **less** \$1800 that the notifier paid for the assessment of the previous non-final Schedule 5 NSN package and **less** \$200 that the notifier paid for the assessment of the previous Schedule 4 NSN package). Note that the \$250 difference does not become a credit towards other services, such as notification of another substance or a confidential search.

#### **Example 11**

A notifier’s annual Canadian sales totaled \$25 million in the last fiscal year and the notifier wants to import Chemical X into Canada. A Schedule 4 NSN package was previously submitted by the notifier, in a different fiscal year where the total annual Canadian sales totaled \$8 million.

After determining that Chemical X is not on the NDSL and that it requires a non-final Schedule 5 NSN package, the notifier:

- consults Table A3.1;
- refers to Row 4 for “Schedule 5”;
- moves across Row 4 to the column for annual sales of “>\$13≤26 million”; and
- calculates that a subsequent fee of \$950 is required (\$1000 for the assessment of the non-final Schedule 5 NSN package, less \$50 that the notifier paid for the assessment of the previous Schedule 4 NSN package).

### 1.3 Fees for Final Schedule 5 and Final Schedule 9

Different fees are required for new substances that are destined for listing on the DSL after a final Schedule 5 NSN package for NDSL chemicals or a final Schedule 9 NSN package for polymers meeting the RRR polymer criteria has been submitted and assessed. Table A3.2 below provides the fee requirements for these NSN packages.

**Table A3.2: NSFR Schedule 2, Assessment Fees**

Column 1		Column 2 Fee (\$Cdn)			
Row	NSNR* Schedule	Company's Annual Sales in Canada (million) in Canadian Dollars			
		≤\$13	>\$13≤26	>26≤40	>40
1.	5	750	1500	2250	3000
2.	9	375	750	1125	1500

\* NSNR (*New Substances Notification Regulations*) Schedule as per the Regulations.

Scenario 1: A notifier provides a final Schedule 5 NSN package for a new chemical that is listed on the NDSL. The notifier is not required to provide subsequent NSN packages for this substance and it is not a matched notification (see section 1.4 of this Appendix for details on matched notifications). The fee required for their final Schedule 5 NSN package is:

- the amount set out in Column 2 of Table A3.2, under the heading corresponding to the notifying company's annual Canadian sales for the last fiscal year; less
- the amount that the notifier paid for the assessment of the previous Schedule NSN package, if any.

Scenario 2: A notifier provides a final Schedule 9 NSN package for a new polymer that meets the RRR polymer criteria. The notifier is not required to provide subsequent NSN packages for this substance and it is not a matched notification (see section 1.4 of this Appendix for details on matched notifications). The fee required for their final Schedule 9 NSN package is:

- the amount set out in Column 2 of Table A3.2, under the heading corresponding to the notifying company's annual Canadian sales for the last fiscal year.

#### 1.3.1 Examples of Fees for Final Schedule 5 and Final Schedule 9 NSN Packages

##### *Example 12*

A notifier's annual Canadian sales totaled \$39 million in the last fiscal year and the notifier wants to manufacture Chemical X in Canada. A Schedule 4 NSN package for this substance was previously submitted by the notifier in the same fiscal year.



After determining that Chemical X is listed on the NDSL and that it requires a final Schedule 5 NSN package, the notifier:

- consults Table A3.2;
- refers to Row 1 for a final “Schedule 5”;
- moves across Row 1 to the column for annual sales of “>\$26≤40 million”; and
- calculates that a final fee of \$2100 is required (\$2250 for the assessment of the final Schedule 5 NSN package, less \$150 that the notifier paid for the assessment of the previous Schedule 4 NSN package).

#### **Example 13**

A notifier’s annual Canadian sales totaled \$13.5 million in the last fiscal year and the notifier wants to import Polymer Y into Canada. Polymer Y has not been previously submitted by the notifier under any Schedule of the Regulations.

After determining that Polymer Y meets the RRR polymer criteria and that it requires a final Schedule 9 NSN package, the notifier:

- consults Table A3.2;
- refers to Row 2 for a final “Schedule 9”;
- moves across Row 2 to the column for annual sales of “>\$13≤26 million”; and
- finds that a fee of \$750 is required for the assessment of the final Schedule 9 NSN package.

## **1.4 Matched Notification**

Scenario: A notifier requests to use information that was previously provided by another company for the same substance (see section 5.1 of these Guidelines). The notifier must obtain a letter of authorization from the initial company, who submitted the information, permitting the use of this information. After the NS program receives the letter of authorization the two NSN packages are “matched” together (see section 5.1 of these Guidelines). In this case, the notifier is required to pay a matched fee of \$200. This fee is the same regardless of the notifier’s annual Canadian sales. When using the matched notification option, there is no fee reductions for amounts previously paid when the notifier submitted a previous Schedule for assessment.

### **1.4.1 Example of Matched Notification**

#### **Example 14**

A notifier wants to manufacture Polymer Y in Canada. The notifier is aware that another company, Company B, previously submitted an NSN package for this same substance. The NS program must receive permission from Company B to use its information for the assessment of the notifier’s NSN package. If this permission is obtained and submitted to the NS program, the NSN package is then considered a matched notification, and the notifier pays a flat assessment fee of \$200.

## **1.5 Consolidated Notification**

Scenario: A consolidated notification takes place when two to six substances of the same class and Schedule are notified together but as separate NSN packages and where the information provided for one substance is acceptable for the assessment of the other(s) (see section 5.3 of these Guidelines). The notifier must pay the amount required for an initial, subsequent or final assessment (whichever applies) for one of the notified substances (as explained earlier in this section), plus a consolidated fee of \$250 for the assessment of each of the other NSN packages in the consolidation. This fee is the same regardless of the notifier’s annual Canadian sales. When using the consolidated notification option, the notifier can only deduct the fee from the previous Schedules of one of the consolidated substances.

### 1.5.1 Examples of Consolidated Notification

#### *Example 15*

A notifier's annual Canadian sales totaled \$42 million in the last fiscal year and the notifier wants to import five new polymers into Canada. None of the five polymers have been previously submitted by the notifier under any Schedule of the Regulations.

The notifier determines that the five polymers are of the same class, do not meet the RRR polymer criteria and all require non-final Schedule 9 NSN packages. Since the information required for one of the polymers would be acceptable to be submitted for the assessment of the other four polymers, the notifier:

- consults Table A3.1;
- refers to Row 6 for “Schedule 9”;
- moves across Row 6 to the column for annual sales of “>\$40 million”; and
- calculates that a fee of \$1500 is required (\$500 for the assessment of the first non-final Schedule 9 NSN package in the consolidation (master file), **plus** \$1000 for the assessment of the other four non-final Schedule 9 NSN packages in the consolidation (4x250)).

#### *Example 16*

A notifier's annual Canadian sales totaled \$30 million in the last fiscal year and the notifier wants to manufacture four new chemicals in Canada. Chemical A was previously submitted under a Schedule 4 NSN package by the notifier in the same fiscal year and Chemical B was previously submitted under both a Schedule 4 and 5 NSN packages by the notifier, in a different fiscal year but with the same total annual Canadian sales.

The notifier determines that the four chemicals are of the same class and all require Schedule 6 NSN packages. Since the information required for one of the chemicals would be acceptable to be submitted for the assessment of the other three chemicals, the notifier:

- consults Table A3.1;
- refers to Row 5 for “Schedule 6”;
- moves across Row 5 to the column for annual sales of “>\$26≤40 million”; and
- calculates that a fee of \$1875 is required (\$2625 for the assessment of the first Schedule 6 NSN package in the consolidation (master file), **plus** \$750 for the assessment of each of the other three Schedule 6 NSN packages in the consolidation (3x250), **less** \$1350 for the assessment of the previous non-final Schedule 5 NSN package of Chemical B, **less** \$150 for the assessment of the previous Schedule 4 NSN package of Chemical B).

Note: In this example, a higher required fee could have been calculated if Chemical A was the master file instead of Chemical B since only a Schedule 4 NSN package was previously submitted. The notifier must ensure that the fee required is calculated based on the master file substance which contains the test data. The notifier can only deduct the fees paid for previous Schedules submitted for the master file.

## 2.0 Fees for Other Services

In addition to the assessment of new substances, the NS program provides other services on a cost recovery basis, including:

- (a) confidential search (*bona fide* intent to manufacture or import, see section 2.3.1 of these Guidelines);
- (b) masked name applications (see section 7.2 of these Guidelines); and
- (c) applications under the Four Corners Arrangement (see section 2.2.3.3 and Appendix 9 of these Guidelines).

Note that these services may be requested at anytime and they do not necessarily have to be requested with the submission of an NSN package. Also note that notifiers need only to submit and pay for a masked name request once per substance. For example, if a masked name request was submitted for a substance and the fee was included with the non-final Schedule 5 NSN package, then it does not have to be re-submitted with the Schedule 6 NSN package.

Fees for other services can not be deducted from the fees required in Tables A3.1 and A3.2 for the assessment of NSN packages. Table A3.3 below provides the fee requirements for other services.

**Table A3.3: NSFR Schedule 3, Fees for Other Services**

Column 1		Column 2 Fee (\$Cdn)			
Row	Service	Company's Annual Sales in Canada (million) in Canadian Dollars			
		≤\$13	>\$13≤\$26	>\$26≤\$40	>\$40
1.	Confidential search*	62.50	125	187.50	250
2.	Masked name application**	150	300	450	600
3.	Application under Four Corners Arrangement***	500	1000	1500	2000

\* Search of substances appearing on the DSL or NDSL that have been published under masked names.  
Note: This requires a *bona fide* intent to manufacture or import (see section 2.3.1 of these Guidelines).

\*\* Application for a masked name, as defined in the *Masked Name Regulations*, for a new substance (see section 7.2 of these Guidelines).

\*\*\* Application for a service under the Arrangement for Sharing of Information Between the U.S. Environmental Protection Agency (USEPA) and Environment Canada and Health Canada (the "Four Corners Arrangement") (see section 2.2.3.3 and Appendix 9 of these Guidelines).

## 2.1 Examples of Fees for Other Services

### Example 17

A notifier's annual Canadian sales totaled \$35 million in the last fiscal year and the notifier wants to import Polymer Y into Canada. The notifier also wants to request a search of the confidential portion of the DSL and the NDSL to determine if the polymer is new to Canada, the notifier:

- consults Table A3.3;
- refers to Row 1 for "Confidential search";
- moves across Row 1 to the column for annual sales of ">\$26≤40 million"; and
- finds that a fee of \$187.50 is required for the Confidential search service.

### Example 18

A notifier's annual Canadian sales totaled \$56 million in the last fiscal year and the notifier wants to manufacture Chemical X in Canada. Chemical X has not been previously submitted by the notifier under any Schedule of the Regulations. The notifier wants to submit an NSN package as well as a masked name application for this substance.

After determining that Chemical X requires a Schedule 4 NSN package, the notifier:

- a)
  - consults Table A3.1;
  - refers to Row 3 for "Schedule 4";
  - moves across Row 3 to the column for annual sales of ">\$40 million"; and
  - finds that a fee of \$200 is required for the assessment of the Schedule 4 NSN package.

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- b)
  - consults Table A3.3;
  - refers to Row 2 for “Masked name application”;
  - moves across Row 2 to the column for annual sales of “>\$40 million”; and
  - finds that a fee of \$600 is required for the Masked name application service; and
- c)
  - calculates that a total fee of \$800 is required (\$200 for the assessment of the Schedule 4 NSN package, **plus** \$600 for the Masked name application service).

**Example 19**

A notifier’s annual Canadian sales totaled \$18 million in the last fiscal year and the notifier wants to import Polymer Y into Canada. Polymer Y has not been previously submitted by the notifier under any Schedule of the Regulations. The notifier also wants to submit an application under the Four Corners Arrangement for this substance, in an attempt to add the substance to the NDSL early.

After determining that Polymer Y does not meet the RRR polymer criteria and that it requires a non-final Schedule 9 NSN package the notifier:

- a)
  - consults Table A3.1;
  - refers to Row 6 for “Schedule 9”;
  - moves across Row 6 to the column for annual sales of “>\$13≤26 million”; and
  - finds that a fee of \$250 is required for the assessment of the non-final Schedule 9 NSN package.
- b)
  - consults Table A3.3;
  - refers to Row 3 for “Application under Four Corners Arrangement”;
  - moves across Row 3 to the column for annual sales of “>\$13≤26 million”; and
  - finds that a fee of \$1000 is required for the Four Corners Arrangement service; and
- c)
  - calculates that a total fee of \$1250 is required (\$250 for the assessment of the non-final Schedule 9 NSN package, **plus** \$1000 for the Four Corners Arrangement application service).

**2.2 Examples of Varying Annual Canadian Sales and Fees for Other Services****Example 20**

A notifier’s annual Canadian sales totaled \$25 million in the last fiscal year and the notifier wants to import Chemical X into Canada. A Schedule 4 NSN package for this substance was previously submitted by the notifier in a different fiscal year when the notifier’s annual Canadian sales totaled \$8 million. The notifier wants to submit a higher Schedule NSN package for Chemical X, plus they would like to request a search of the confidential portion of the DSL and the NDSL for another substance.

After determining that Chemical X is not on the NDSL and that it requires a non-final Schedule 5 NSN package, the notifier:

- a)
  - consults Table A3.1;
  - refers to Row 4 for “Schedule 5”;
  - moves across Row 4 to the column for annual sales of “>\$13≤26 million”; and

- calculates that a subsequent fee of \$950 is required (\$1000 is required for the assessment of the non-final Schedule 5 NSN package, **less** \$50 that the notifier paid for the assessment of the previous Schedule 4 NSN package).
- b)
- consults Table A3.3;
  - refers to Row 1 for “Confidential search”;
  - moves across Row 1 to the column for annual sales of “>\$13≤26 million”; and
  - finds that a fee of \$125 is required for the Confidential search service; and
- c)
- calculates that a total fee of \$1075 is required (\$950 for the assessment of the non-final Schedule 5 NSN package, **plus** \$125 for the Confidential search service).

**Example 21**

A notifier’s annual Canadian sales totaled \$13 million in the last fiscal year and the notifier wants to manufacture Polymer Y in Canada. A non-final Schedule 9 NSN package for this substance was previously submitted by the notifier in a different fiscal year when the notifier’s annual Canadian sales totaled \$39 million. The notifier wants to submit a higher Schedule NSN package for Polymer Y, plus they would like to submit a masked name application for this substance.

After determining that Polymer Y requires a Schedule 10 NSN package, the notifier:

- a)
- consults Table A3.1;
  - refers to Row 7 for “Schedule 10”;
  - moves across Row 7 to the column for annual sales of “≤\$13 million”; and
  - calculates that a subsequent fee of \$500 is required (\$875 for the assessment of the Schedule 10 NSN package, **less** \$375 that the notifier paid for the assessment of the previous non-final Schedule 9 NSN package).
- b)
- consults Table A3.3;
  - refers to Row 3 for “Masked name application”;
  - moves across Row 3 to the column for annual sales of “≤\$13 million”; and
  - finds that a fee of \$150 is required for the Masked name application service; and
- c)
- calculates that a total fee of \$650 is required (\$500 for the assessment of the Schedule 10 NSN package, **plus** \$150 for the Masked name application service).

**Example 22**

A notifier’s annual Canadian sales totaled \$11 million in the last fiscal year and the notifier wants to import Chemical X into Canada. A non-final Schedule 5 NSN package for this substance was previously submitted by the notifier in a different fiscal year when the notifier’s annual Canadian sales totaled \$14 million. The notifier wants to submit a higher Schedule NSN package for Chemical X, plus they would like to request a confidential search for another substance.

After determining that Chemical X requires a Schedule 6 NSN package, the notifier:

- a)
- consults Table A3.1;
  - refers to Row 5 for “Schedule 6”;
  - moves across Row 5 to the column for annual sales of “≤\$13 million”; and

- calculates that a subsequent fee of \$0 is required (\$875 for the assessment of the Schedule 6 NSN package, **less** \$1000 that the notifier paid for the assessment of the previous non-final Schedule 5 NSN package for assessment). Note that the \$125 difference does not become a credit towards other services, such as notification of another substance or a confidential search.
- b)
- consults Table A3.3;
  - refers to Row 1 for “Confidential search”;
  - moves across Row 1 to the column for annual sales of “≤\$13 million”; and
  - finds that a fee of \$62.50 is required for the Confidential search service; and
- c)
- calculates that a total fee of \$62.50 is required (\$0 for the assessment of the Schedule 6 NSN package, **plus** \$62.50 for the confidential search service).

### 3.0 How to Pay

The fees payable under sections 3 to 9 of the NSFR must be paid at the time the service is requested and must be provided by one of the following methods:

- (a) certified cheque or money order, made payable, in Canadian dollars, to the Receiver General for Canada; or
- (b) credit card (MasterCard, Visa, or American Express) in respect of which the notifier is either the cardholder or an authorized user, if the issuer of the credit card has entered into an agreement with the Government of Canada establishing the conditions of its acceptance and use.

Payment for the assessment of a substance must be delivered to the NS program, along with the NSN package. Non-resident Importers (see section 6.2.1.3 of these Guidelines) must pay the required fees either directly to the NS program or through their “Canadian Agent”. Notifiers who require data to be provided by a foreign supplier (see section 5.2 of these Guidelines) are still responsible for providing the fees required for the assessment of the NSN package. In these cases, additional fees may apply for a masked name application prior to the substance being eligible for listing on the DSL, if the foreign supplier wishes the name of the substance to be kept confidential.

Refunds will be made in accordance with the *Financial Administration Act* and the *Repayment of Receipts Regulations*, 1997 in the appropriate circumstances (e.g., overestimation of applicable fee).

A fee form has been developed to help notifiers determine the total fee applicable to their NSN package (see Appendix II of the NSN reporting form). A copy of this form should accompany the payment and assessment information.

### 4.0 Invalid Fees and Refunds

The payment and the NSN package will be immediately returned to the notifier and the assessment period will not commence if:

- a) the cheque or money order is not made payable to the Receiver General for Canada; or
- b) the cheque is not certified; or
- c) the cheque or money order is not in Canadian funds.

If a cheque or money order is provided but it is determined that the fee is not required, the payment will be returned to the notifier or, if already processed, a refund cheque will be issued to the notifier as soon as possible. If a payment is provided but it is determined that the fee is in excess of NSFR requirements, a refund cheque will be issued to the notifier as soon as possible.

If a credit card is used to submit the fees and the amount authorized is insufficient; or the credit card is denied, a request for additional information letter for the missing fee amount will be written and the assessment period will not start until the correct amount of fees have been paid. If sufficient funds are authorized for and charged on the credit card, the assessment period will start and the amount charged to the credit card will be indicated in the acknowledgment letter.

If a request for withdrawal of a NSN package is submitted prior to the assessment period starting, a complete refund of the fees will be provided. If the request is submitted after the assessment period has started no fees will be refunded.

## 5.0 Proof of Annual Canadian Sales

When fees are based on the notifier's annual Canadian sales the notifier must provide sales reports for the notifier's most recent fiscal period with all NSN packages. Sales reports must be prepared in accordance with generally accepted accounting principles and must be certified by the notifier, or by the company's president, or chief financial officer. Statements indicating the notifier's annual Canadian sales, signed by the company's president, are also acceptable.

In the absence of proof of annual Canadian sales, fees will be based on annual Canadian sales greater than \$40 million.

### 5.1 Annual Canadian Sales

Annual Canadian sales refer to sales of any type (not just sales of the substance being notified) to Canadian merchants and sales from the Canadian affiliates, of the Corporate Headquarters of the company, to other merchants or countries. For example, Company A's headquarters is in the United States but they have subsidiaries in Canada. The total Canadian sales for Company A include those made by Company A to Canada and those made by the subsidiaries in Canada.





# APPENDIX 4 — Schedules Under the Regulations

## Schedule 1

(Subsections 2(2) and 5(1) to (4))

INFORMATION RESPECTING CHEMICALS AND BIOCHEMICALS THAT ARE RESEARCH AND DEVELOPMENT SUBSTANCES, CONTAINED SITE-LIMITED INTERMEDIATE SUBSTANCES OR CONTAINED EXPORT-ONLY SUBSTANCES\*

1. The type of substance: research and development substance, contained site-limited intermediate substance or contained export-only substance.
2. The new substances pre-notification consultation number if it has been assigned and if known.
3. The chemical name of the chemical, established in accordance with the chemical nomenclature rules of the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service.
4. The trade names of the chemical and the synonyms of its chemical name, if known.
5. The CAS registry number of the chemical, if such a number can be assigned.
6. The following identification information in respect of the chemical:
  - (a) its molecular formula;
  - (b) its structural formula;
  - (c) its gram molecular weight;
  - (d) the degree of purity in its technical grade composition, if applicable;
  - (e) known impurities present and their concentration by weight; and
  - (f) any additives, stabilizers and solvents present when the chemical is tested and their concentration by weight.
7. A material safety data sheet in respect of the chemical, if available.
8. The following exposure information respecting the chemical:
  - (a) the anticipated annual quantity to be manufactured, if applicable;
  - (b) the anticipated annual quantity to be imported, if applicable;
  - (c) the anticipated uses;
  - (d) its anticipated concentration in products and, if known, in end-use products;
  - (e) a description of the expected modes for its transportation and storage;
  - (f) a description of the size and type of container used for its transportation and storage;
  - (g) an identification of the components of the environment into which it is anticipated to be released;
  - (h) its anticipated releases into municipal wastewater systems;
  - (i) a description of the methods recommended for its destruction or disposal;
  - (j) whether the public is anticipated to be significantly exposed to the chemical in a product taking into account factors including its concentration, duration, frequency and circumstances of exposure and factors that may limit direct human exposure and, if not, information substantiating that the public is not anticipated to be significantly exposed; and
  - (k) for site-limited intermediate substances, the location of use.

9. A summary of all other information and test data in respect of the chemical that are in the possession of the manufacturer or importer or to which they ought to have access and that are relevant to identifying hazards to the environment and human health and the degree of environmental and public exposure to the chemical.
10. The identification of the other government agencies, either outside or within Canada, that the person has notified of the manufacture or importation of the chemical and, if known, the agency's file number, the outcome of the assessment and the risk management actions imposed by those agencies.

*\*See section 4.2 of these Guidelines for definition of these special categories.*

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**Schedule 2**

(Subsections 2(2), 5(2) to (4) and 6(2) to (4), subparagraphs 7(1)(a)(ii) and (b)(ii) and 8(1)(a)(ii), (b)(ii) and (c)(ii) and paragraphs 10(b), 11(1)(b), 12(1)(b), 17(2)(b) and 18(2)(b) and (c))

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**Schedule 2**

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**INFORMATION RESPECTING BIOCHEMICALS AND BIOPOLYMERS**

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1. The identification of the organism, hereinafter referred to as “production organism”, and the organ, if applicable, from which the biochemical or biopolymer is isolated, including:
  - (a) synonyms and common and superseded names, if known; and
  - (b) its source and history.
2. A description of any known adverse environmental or human health effects associated with exposure to the production organism.
3. The concentration of the viable production organism in the biochemical or biopolymer and, if known, in end-use products.
4. A description of the method used to separate the production organism from the biochemical or biopolymer.
5. The identification of the encoded products, if known.
6. A description of any known biological activity or adverse environmental or human health effects associated with the nucleic acid or with the encoded products specified under item 5.
7. A description of all known catalytic functions.
8. The Enzyme Commission (EC) number as designated by the nomenclature committee of the International Union of Biochemistry and Molecular Biology (IUBMB), if available.
9. The known substrate specificity for each of the catalytic functions specified under item 7.
10. The optimum pH and temperature for the substrates specified under item 9.
11. The catalytic constants  $K_m$  and  $K_{cat}$  and the conditions under which they were measured.
12. The known cofactors necessary for enzymatic activity.
13. The enzymatic activity per unit of weight of products and, if known, of end-use products.

## Schedule 3

### (Subsection 2(2) and section 6)

INFORMATION RESPECTING POLYMERS AND BIOPOLYMERS THAT ARE RESEARCH AND DEVELOPMENT SUBSTANCES, CONTAINED SITE-LIMITED INTERMEDIATE SUBSTANCES OR CONTAINED EXPORT-ONLY SUBSTANCES\*

1. The type of substance: research and development substance, contained site-limited intermediate substance or contained export-only substance.
2. The new substances pre-notification consultation number if it has been assigned, and if known.
3. The chemical name of the polymer, established in accordance with the chemical nomenclature rules of the International Union of Pure and Applied Chemistry or the Chemical Abstract Service.
4. The trade names of the polymer and the synonyms of its chemical name, if known.
5. The CAS registry number of the polymer, if such a number can be assigned.
6. The molecular formula of the polymer.
7. The structural formula of the polymer, if possible, or else a partial structural formula.
8. For contained site-limited intermediate substances and contained export-only substances:
  - (a) its number average molecular weight ( $M_n$ ); and
  - (b) the maximum concentrations, expressed as a percentage, of all residual constituents having molecular weights of less than 500 daltons and of all residual constituents having molecular weights of less than 1 000 daltons.
9. For research and development substances, the target number average molecular weight ( $M_n$ ) of the polymer.
10. The known impurities present and their concentration by weight.
11. The composition of the polymer including constituents – such as monomers and other reactants, additives, stabilizers and solvents – which constituents are present when the polymer is tested, and their concentration by weight.
12. A material safety data sheet in respect of the polymer, if available.
13. The physical state of the polymer.
14. Whether the polymer is formulated for dispersal in water.
15. The following exposure information respecting the polymer:
  - (a) the anticipated annual quantity to be manufactured, if applicable;
  - (b) the anticipated annual quantity to be imported, if applicable;
  - (c) the anticipated uses;
  - (d) its anticipated concentration in products and, if known, in end-use products;
  - (e) a description of the expected modes for its transportation and storage;
  - (f) a description of the size and type of container used for its transportation and storage;
  - (g) an identification of the components of the environment into which it is anticipated to be released;
  - (h) its anticipated releases into municipal wastewater systems;
  - (i) a description of the methods recommended for its destruction or disposal;
  - (j) whether the public is anticipated to be significantly exposed to the polymer in a product taking into account factors including its concentration, duration, frequency and circumstances of exposure and factors that may limit direct human exposure and, if not, information substantiating that the public is not anticipated to be significantly exposed; and
  - (k) for site-limited intermediate substances, the location of use.

16. A summary of all other information and test data in respect of the polymer that are in the possession of the manufacturer or importer or to which they ought to have access and that are relevant to identifying hazards to the environment and human health and the degree of environmental and public exposure to the polymer.
17. The identification of the other government agencies, either outside or within Canada, that the person has notified of the manufacture or importation of the polymer and, if known, the agency's file number, the outcome of the assessment and the risk management actions imposed by those agencies.

*\*See section 4.2 of these Guidelines for definition of these special categories.*

## Schedule 4

(Subsection 2(2), subparagraphs 7(1)(a)(i), 8(1)(a)(i) and 17(2)(c)(i) and paragraph 17(2)(d))

INFORMATION RESPECTING OTHER CHEMICALS AND BIOCHEMICALS NOT ON THE NDSL  
(100 KG) OR ON THE NDSL (1 000 KG)

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1. Whether the chemical is on the NDSL.
2. The new substances pre-notification consultation number if it has been assigned and if known.
3. The chemical name of the chemical, established in accordance with the chemical nomenclature rules of the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service.
4. The trade names of the chemical and the synonyms of its chemical name, if known.
5. The CAS registry number of the chemical if such a number can be assigned.
6. A material safety data sheet in respect of the chemical, if available.
7. The following exposure information respecting the chemical:
  - (a) the anticipated annual quantity to be manufactured, if applicable;
  - (b) the anticipated annual quantity to be imported, if applicable;
  - (c) the anticipated uses within Canada; and
  - (d) its anticipated concentration in products and, if known, in end-use products.
8. A summary of all other information and test data in respect of the chemical that are in the possession of the manufacturer or importer and that are relevant to identifying hazards to the environment and human health and the degree of environmental and public exposure to the chemical.
9. The identification of the other government agencies, either outside or within Canada, that the person has notified of the manufacture or importation of the chemical and, if known, the agency's file number, the outcome of the assessment and the risk management actions imposed by those agencies.

## Schedule 5

(Subsection 2(2), subparagraphs 7(1)(b)(i), 8(1)(b)(i), subsections 8(2) and 16(3), subparagraph 17(2)(c)(i) and paragraph 17(2)(d))

INFORMATION RESPECTING OTHER CHEMICALS AND BIOCHEMICALS NOT ON THE NDSL  
(1 000 KG) OR ON THE NDSL (10 000 KG)

1. The information specified in Schedule 4 or, if that information has been previously provided, the date (year, month, day) of the submission of that information and, if they are known, the new substances pre-notification consultation number, if it has been assigned, and the new substances notification number.
2. The following identification information in respect of the chemical:
  - (a) its molecular formula;
  - (b) its structural formula;
  - (c) its gram molecular weight;
  - (d) the degree of purity in its technical grade composition, if applicable;
  - (e) known impurities present and their concentration by weight; and
  - (f) any additives, stabilizers and solvents present when the chemical is tested and their concentration by weight.
3. The following physical and chemical data<sup>1</sup> in respect of the chemical:
  - (a) its melting point or the temperature at which the chemical decomposes
    - (i) expressed in degrees Celsius if its melting point or the temperature at which it decomposes is  $-25\text{ }^{\circ}\text{C}$  or greater but not greater than  $300\text{ }^{\circ}\text{C}$ , and
    - (ii) in any other case, expressed as “less than  $-25\text{ }^{\circ}\text{C}$ ” or “greater than  $300\text{ }^{\circ}\text{C}$ ”, as appropriate;
  - (b) its boiling point or the temperature at which the chemical decomposes
    - (i) expressed in degrees Celsius if its boiling point or the temperature at which it decomposes is  $-50\text{ }^{\circ}\text{C}$  or greater but not greater than  $300\text{ }^{\circ}\text{C}$ , and
    - (ii) in any other case, expressed as “less than  $-50\text{ }^{\circ}\text{C}$ ” or “greater than  $300\text{ }^{\circ}\text{C}$ ”, as appropriate;
  - (c) its density;
  - (d) its vapour pressure if it has a standard boiling point of  $0\text{ }^{\circ}\text{C}$  or greater;
  - (e) its water solubility; and
  - (f) for chemicals having a water solubility of less than or equal to  $5\text{ g/L}$ , its octanol-water partition coefficient.
4. Ready biodegradation test data in respect of the chemical and, if known, identification of the products of biodegradation.\*
5. Data from one acute fish, daphnia or algae toxicity test in respect of the chemical.\*
6. Data from an oral, dermal or inhalation type of acute mammalian toxicity test in respect of the chemical, selected on the basis of the most significant route of potential human exposure to the chemical and the following information:
  - (a) the age, sex, number, species, strain and source of the animals tested;
  - (b) the route by which the chemical is administered and the conditions under which the test is conducted; and
  - (c) the dose of the chemical, the vehicle by means of which the chemical is administered and the concentration of the chemical in the vehicle.\*

Schedule 5

7. Mutagenicity data obtained from one *in vitro* test in respect of the chemical, with and without metabolic activation, for gene mutations.\*
8. The following exposure information respecting the chemical:
  - (a) a description of the expected modes for its transportation and storage;
  - (b) a description of the size and type of container used for its transportation and storage;
  - (c) an identification of the components of the environment into which it is anticipated to be released;
  - (d) its anticipated releases into municipal wastewater systems;
  - (e) a description of the methods recommended for its destruction or disposal;
  - (f) whether it is anticipated to be used in products intended for use by or for children;
  - (g) the anticipated degree of direct human exposure to the chemical, including concentration, duration, frequency and circumstances of exposure and factors that may limit direct human exposure; and
  - (h) if known, the three sites in Canada where the greatest quantity of the chemical, manufactured or imported by the person, is anticipated to be used or processed and the estimated quantity by site.
9. A summary of all other information and test data in respect of the chemical that are in the possession of the manufacturer or importer or to which they ought to have access and that are relevant to identifying hazards to the environment and human health and the degree of environmental and public exposure to the chemical.
10. If the chemical is on the NDSL, the following additional exposure information respecting the chemical:
  - (a) its historical and other likely uses;
  - (b) any factors that may limit environmental exposure;
  - (c) whether it is released to the aquatic environment in a quantity exceeding 3 kg per day, per site, averaged monthly and after wastewater treatment and, if the release is less than or equal to 3 kg per day, per site, the data substantiating the quantity released; and
  - (d) whether the public is anticipated to be significantly exposed to the chemical in a product taking into account factors including the concentration of the chemical, duration, frequency and circumstances of exposure and factors that may limit direct human exposure and, if not, information substantiating that the public is not anticipated to be significantly exposed.

*Note: The asterisks (\*) appearing at the end of certain provisions indicate that laboratory practices to be followed in developing data for the test referred to in that provision must comply with those practices set out in the "Principles of Good Laboratory Practice". See subsection 15(2) of the Regulations.*

<sup>1</sup> Additional test requirements prescribed in subsection 7(2) and 7(3) of the Regulations must be submitted if the quantity of the chemical exceeds 50 000 kg in a calendar year and is released to the aquatic environment in a quantity exceeding 3 kg per day, per site, averaged monthly and after wastewater treatment and/or if the public is anticipated to be significantly exposed to the chemical in a product.



## Schedule 6

(Subsection 2(2), subparagraph 8(1)(c)(i) and paragraph 17(2)(d))

INFORMATION RESPECTING OTHER CHEMICALS AND BIOCHEMICALS NOT ON THE NDSL  
(10 000 KG)

Schedule 6

1. The information specified in Schedules 4 and 5 or, if that information has been previously provided, the date (year, month, day) of the submission of that information and, if they are known, the new substances pre-notification consultation number, if it has been assigned, and the new substances notification number.
2. The following physical and chemical data in respect of the chemical:
  - (a) one of an infra-red, ultra-violet, mass or nuclear magnetic resonance spectrum suitable for characterization of the chemical;
  - (b) for chemicals having a water solubility of greater than or equal to 200 µg/L, adsorption-desorption screening test data; and
  - (c) for chemicals having a water solubility of greater than or equal to 200 µg/L, its hydrolysis rate as a function of pH and, if known, an identification of the products of the hydrolysis.
3. Data from the two tests mentioned in item 5 of Schedule 5 for which data was not submitted under that item, namely, the remaining two out of the following three tests: acute fish, daphnia and algae toxicity tests.\*
4. Unless the chemical boils below 0 °C and has been tested for acute inhalation toxicity under item 6 of Schedule 5, data from one of the remaining types of acute mammalian toxicity test of the chemical, namely, oral, dermal or inhalation, that was not completed for the submission of item 6 of Schedule 5 and that is selected on the basis of the most significant route of potential human exposure to the chemical.\*
5. Information sufficient to assess skin irritation in respect of the chemical.\*
6. Data from a skin sensitization test in respect of the chemical.\*
7. Data from one repeated-dose mammalian toxicity test in respect of the chemical, of at least 28 days duration, which test is selected on the basis of the most significant route of potential human exposure to the chemical, namely, oral, dermal or inhalation.\*
8. For the tests referred to in items 4 to 7, the following additional information:
  - (a) the age, sex, number, species, strain and source of the animals tested;
  - (b) the route by which the chemical is administered and the conditions under which the test is conducted; and
  - (c) the dose of the chemical, the vehicle by means of which the chemical is administered and the concentration of the chemical in the vehicle.\*
9. Mutagenicity data obtained from one *in vitro* test in respect of the chemical, with and without metabolic activation, for chromosomal aberrations in mammalian cells.\*
10. Mutagenicity data obtained from one *in vivo* mammalian test of the chemical for chromosomal aberrations or gene mutations or another indicator of mutagenicity that, together with data substantiating that the tissue investigated was exposed to the chemical or its metabolites, permits an assessment of *in vivo* mutagenicity.\*
11. The following exposure information respecting the chemical:
  - (a) its historical and other likely uses; and
  - (b) any factors that may limit environmental exposure.

*Note: The asterisks (\*) appearing at the end of certain provisions indicate that laboratory practices to be followed in developing data for the test referred to in that provision must comply with those practices set out in the "Principles of Good Laboratory Practice". See subsection 15(2) of the Regulations.*

## Schedule 7

(Subsection 2(2) and paragraphs 9(a) and (b))

### TYPES OF POLYMERS

1. A cationic polymer or a polymer that is reasonably expected to become cationic in a natural environment, except
  - (a) a polymer whose cationic group has a combined equivalent weight greater than 5 000 daltons; or
  - (b) a polymer that is a solid material, that is not soluble or dispersible in water and that will be used only in the solid phase, such as polymers that can be used as ion exchange beads.
2. A polymer that is designed, or can be expected, to substantially degrade, decompose or depolymerize, including polymers that could substantially degrade, decompose or depolymerize after manufacture and use, even though they are not intended to do so. Degradation, decomposition and depolymerization refer to the types of changes that convert a polymeric substance into simpler, smaller substances, through processes including but not limited to oxidation, hydrolysis, attack by solvents, heat, light and microbial action.
3. A polymer that has, as an integral part of its composition, only one or none of the following atomic elements: carbon, hydrogen, nitrogen, oxygen, silicon and sulphur.
4. A polymer that has
  - (a) any atomic elements other than carbon, hydrogen, nitrogen, oxygen, silicon, sulphur, fluorine, chlorine, bromine or iodine covalently bound to carbon;
  - (b) any monoatomic counterions other than chlorine ion, bromine ion, iodine ion, sodium ion, divalent magnesium, trivalent aluminum, potassium ion or divalent calcium; or
  - (c) 0.2% or more by weight of any atomic element or combination of the following atomic elements: lithium, boron, phosphorus, titanium, manganese, iron, nickel, copper, zinc, tin or zirconium.
5. A polymer
  - (a) that has reactive functional groups other than carboxylic acid groups, aliphatic hydroxyl groups, unconjugated olefinic groups that are considered “ordinary”\*, butenedioic acid groups, blocked isocyanates including ketoxime-blocked isocyanates, thiols, unconjugated nitrile groups, halogens excluding reactive halogen groups such as benzylic or allylic halides, and conjugated olefinic groups present in naturally occurring fats, oils and carboxylic acids, in combined equivalent weights of less than 5 000 daltons; or
  - (b) in which the only reactive functional groups present are part of acid halides, acid anhydrides, aldehydes, hemiacetals, methylol-amides, methylol-amines, methylol-ureas, alkoxy silanes with alkoxy greater than C<sub>2</sub>-alkoxy silanes, allyl ethers, conjugated olefins, cyanates, epoxides, imines, unsubstituted positions ortho or para to phenolic hydroxyl, in combined equivalent weights of less than 1 000 daltons.

*\*Not specially activated either by being part of a larger functional group, such as a vinyl ether, or by other activation influences, for example, strongly electron-withdrawing sulfone group with which the olefinic groups interact.*

## Schedule 8

(Subsection 2(2) and paragraph 9(c))

Schedule 8

## LIST OF REACTANTS AND THEIR CAS REGISTRY NUMBER

## 1. Monobasic Acids and Natural Oils

CAS RegistryNumber	Name of Substance
65-85-0	Benzoic acid
111-14-8	Heptanoic acid
112-05-0	Nonanoic acid
142-62-1	Hexanoic acid
143-07-7	Dodecanoic acid
3302-10-1	Hexanoic acid, 3,3,5-trimethyl-
8001-20-5	Tung oil*
8001-21-6	Sunflower oil*
8001-22-7	Soybean oil*
8001-23-8	Safflower oil*
8001-26-1	Linseed oil*
8001-29-4	Cottonseed oil*
8001-30-7	Corn oil*
8001-31-8	Coconut oil*
8002-50-4	Oils, menhaden*
8016-35-1	Oils, oiticica*
8023-79-8	Oils, palm kernel*
8024-09-7	Oils, walnut*
61788-47-4	Fatty acids, coco*
61788-66-7	Fatty acids, vegetable oil*
61789-44-4	Fatty acids, castor oil*
61789-45-5	Fatty acids, dehydrated castor oil*
61790-12-3	Fatty acids, tall-oil*
67701-08-0	Fatty acids, C <sub>16-18</sub> and C <sub>18</sub> -unsaturated*
67701-30-8	Glycerides, C <sub>16-18</sub> and C <sub>18</sub> -unsaturated*
68132-21-8	Oils, perilla*
68153-06-0	Oils, herring*
68308-53-2	Fatty acids, soybean oil*
68424-45-3	Fatty acids, linseed oil*
68649-95-6	Linseed oil, oxidized*
68953-27-5	Fatty acids, sunflower oil, conjugated*
84625-38-7	Fatty acids, sunflower oil*
91078-92-1	Oils, babassu palm*
93165-34-5	Fatty acids, safflower oil*
93334-41-9	Oils, sardine*
120962-03-0	Oils, glyceridic, canola*
128952-11-4	Oils, anchovy*
N/A	Fatty acids, tall-oil, conjugated*
N/A	Oils, cannabis*

## 2. Dibasic and Tribasic Acids and Esters

CAS RegistryNumber	Name of Substance
88-99-3	1,2-Benzenedicarboxylic acid
100-21-0	1,4-Benzenedicarboxylic acid
106-65-0	Butanedioic acid, dimethyl ester
106-79-6	Decanedioic acid, dimethyl ester
110-15-6	Butanedioic acid
110-17-8	Fumaric acid
110-40-7	Decanedioic acid, diethyl ester
110-94-1	Pentanedioic acid
111-16-0	Heptanedioic acid
111-20-6	Decanedioic acid

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120-61-6	1,4-Benzenedicarboxylic acid, dimethyl ester
121-91-5	1,3-Benzenedicarboxylic acid
123-25-1	Butanedioic acid, diethyl ester
123-99-9	Nonanedioic acid
124-04-9	Hexanedioic acid
141-28-6	Hexanedioic acid, diethyl ester
505-48-6	Octanedioic acid
528-44-9	1,2,4-Benzenetricarboxylic acid
624-17-9	Nonanedioic acid, diethyl ester
627-93-0	Hexanedioic acid, dimethyl ester
636-09-9	1,4-Benzenedicarboxylic acid, diethyl ester
693-23-2	Dodecanedioic acid
818-38-2	Pentanedioic acid, diethyl ester
1119-40-0	Pentanedioic acid, dimethyl ester
1459-93-4	1,3-Benzenedicarboxylic acid, dimethyl ester
1732-08-7	Heptanedioic acid, dimethyl ester
1732-09-8	Octanedioic acid, dimethyl ester
1732-10-1	Nonanedioic acid, dimethyl ester
1852-04-6	Undecanedioic acid
61788-89-4	Fatty acids, C <sub>18</sub> -unsaturated, dimers*

## 3. Polyols

CAS RegistryNumber	Name of Substance
56-81-5	1,2,3-Propanetriol
57-55-6	1,2-Propanediol
77-85-0	1,3-Propanediol, 2-(hydroxymethyl)-2-methyl-
77-99-6	1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)-
105-08-8	1,4-Cyclohexanedimethanol
107-21-1	1,2-Ethandiol
107-88-0	1,3-Butanediol
110-63-4	1,4-Butanediol
111-46-6	Ethanol, 2,2'-oxybis-
115-77-5	1,3-Propanediol, 2,2-bis(hydroxymethyl)-
126-30-7	1,3-Propanediol, 2,2-dimethyl-
144-19-4	1,3-Pentanediol, 2,2,4-trimethyl-
629-11-8	1,6-Hexanediol
2163-42-0	1,3-Propanediol, 2-methyl-
25119-62-4	2-Propen-1-ol, polymer with ethenylbenzene
25618-55-7	1,2,3-Propanetriol, homopolymer

## 4. Modifiers

CAS RegistryNumber	Name of Substance
71-36-3	1-Butanol**
80-04-6	Cyclohexanol, 4,4'-(1-methylethylidene)bis-
108-93-0	Cyclohexanol
110-99-6	Acetic acid, 2,2'-oxybis-
111-27-3	1-Hexanol
112-34-5	Ethanol, 2-(2-butoxyethoxy)-
13393-93-6	1-Phenanthrenemethanol, tetradecahydro-1,4-dimethyl-7-(1-methylethyl)-
25036-25-3	Phenol, 4,4'-(1-methylethylidene)bis-, polymer with 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bis[oxirane]
68037-90-1	Silsesquioxanes, phenyl propyl*
68440-65-3	Siloxanes and silicones, dimethyl, diphenyl, polymers with phenyl silsesquioxanes, methoxy-terminated*
68957-04-0	Siloxanes and silicones, dimethyl, methoxy phenyl, polymers with phenyl silsesquioxanes, methoxy-terminated*
68957-06-2	Siloxanes and silicones, methyl phenyl, methoxy phenyl, polymers with phenyl silsesquioxanes, methoxy- and phenyl-terminated*
72318-84-4	Methanol, hydrolysis products with trichlorohexylsilane and trichlorophenylsilane*

\* Chemical substance of unknown or variable composition, complex reaction products and biological materials (UVCB).

\*\* This substance may not be used in a substance manufactured from fumaric or maleic acid because of potential risks associated with esters, which may be formed by reaction of those reactants.

**Schedule 9**

(Subsection 2(2), paragraphs 10(a) and 18(2)(b), subparagraph 18(2)(d)(i) and paragraph 18(2)(e))

**INFORMATION RESPECTING REDUCED REGULATORY REQUIREMENT POLYMERS AND OTHER POLYMERS AND BIOPOLYMERS (1 000 KG)**

## Schedule 9

1. The type of polymer:
  - (a) a reduced regulatory requirement polymer;
  - (b) a polymer on the NDSL;
  - (c) a polymer with all of its reactants on the DSL or the NDSL; or
  - (d) a polymer with one or more reactants not on either the DSL or NDSL.
2. The new substances pre-notification consultation number if it has been assigned and if known.
3. The chemical name of the polymer, established in accordance with the chemical nomenclature rules of the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service.
4. The trade names of the polymer and the synonyms of its chemical name, if known.
5. The CAS registry number of the polymer, if such a number can be assigned.
6. The molecular formula of the polymer.
7. The structural formula of the polymer, if possible, or else a partial structural formula.
8. The reaction scheme if the polymer is a reduced regulatory requirement polymer, unless it is a polymer referred in paragraph 9(c) of the Regulations.
9. The following physical and chemical data in respect of the polymer:
  - (a) its number average molecular weight ( $M_n$ ); and
  - (b) the maximum concentrations, expressed as a percentage, of all residual constituents having molecular weights of less than 500 daltons and of all residual constituents having molecular weights of less than 1 000 daltons.
10. The known impurities present and their concentration by weight.
11. The composition of the polymer including constituents – such as monomers and other reactants, additives, stabilizers and solvents – which constituents are present when the polymer is tested, and their concentration by weight.
12. A material safety data sheet in respect of the polymer, if available.
13. The following exposure information respecting the polymer:
  - (a) the anticipated annual quantity to be manufactured, if applicable;
  - (b) the anticipated annual quantity to be imported, if applicable;
  - (c) the anticipated uses within Canada; and
  - (d) if the polymer is not a reduced regulatory requirement polymer,
    - (i) the anticipated concentration of the polymer in products and, if known, in end-use products,
    - (ii) the anticipated degree of direct human exposure to the polymer, including concentration, duration, frequency and circumstances of exposure and factors that may limit direct human exposure,
    - (iii) whether the polymer is anticipated to be used in products intended for use by or for children, and
    - (iv) if known, the three sites in Canada where the greatest quantity of the polymer, manufactured or imported by the person, is anticipated to be used or processed and the estimated quantity by site.
14. A summary of all other information and test data in respect of the polymer that are in the possession of the manufacturer or importer and that are relevant to identifying hazards to the environment and human health and the degree of environmental and public exposure to the polymer.
15. The identification of the other government agencies, either outside or within Canada, that the person has notified of the manufacture or importation of the polymer and, if known, the agency's file number, the outcome of the assessment and the risk management actions imposed by those agencies.

**Schedule 10****(Subsection 2(2), paragraph 11(1)(a), subsection 11(5), subparagraph 18(2)(d)(i))**

INFORMATION RESPECTING OTHER POLYMERS AND BIOPOLYMERS ON THE NDSL OR ALL OF WHOSE REACTANTS ARE ON THE DSL OR NDSL (10 000 KG)

1. The information specified in Schedule 9 or, if that information has been previously provided, the date (year, month, day) of the submission of that information and, if they are known, the new substances pre-notification consultation number, if it has been assigned, and the new substances notification number.
2. The following physical and chemical data<sup>1</sup> in respect of the polymer:
  - (a) its physical state;
  - (b) whether it is formulated for dispersal in water;
  - (c) its water extractability measured at:
    - (i) pH 7 for anionic and neutral polymers,
    - (ii) pH 2 and 7 for cationic polymers, or
    - (iii) pH 2, 7 and 9 for amphoteric polymers;
  - (d) its octanol-water partition coefficient; and
  - (e) if water extractability is determined to be greater than 2%, its hydrolysis rate as a function of pH and, if known, an identification of the products of the hydrolysis.
3. Unless the polymer has a water extractability at pH 7 of less than or equal to 2%, an acute toxicity test of the polymer for the most sensitive species: fish, daphnia or algae or, if the sensitivity of these three species is unknown, an acute algae toxicity test.\*
4. Data from one acute mammalian oral toxicity test of the polymer and the following information:
  - (a) the age, sex, number, species, strain and source of the animals tested;
  - (b) the route by which the polymer is administered and the conditions under which the test is conducted; and
  - (c) the dose of the polymer, the vehicle by means of which the polymer is administered and the concentration of the polymer in the vehicle.\*<sup>2</sup>
5. The following exposure information respecting the polymer:
  - (a) a description of the expected modes for its transportation and storage;
  - (b) a description of the size and type of container used for its transportation and storage;
  - (c) its anticipated releases into municipal wastewater systems;
  - (d) a description of the methods recommended for its destruction or disposal;
  - (e) its historical and other likely uses;
  - (f) any factors that may limit environmental exposure;
  - (g) whether it is released to the aquatic environment in a quantity exceeding 3 kg per day, per site, averaged monthly and after wastewater treatment and, if the release is less than or equal to 3 kg per day, per site, the data substantiating the quantity released; and
  - (h) whether the public is anticipated to be significantly exposed to the polymer in a product taking into account factors including the concentration of the polymer, duration, frequency and circumstances of exposure and factors that may limit direct human exposure and, if not, information substantiating that the public is not anticipated to be significantly exposed.

6. A summary of all other information and test data in respect of the polymer that are in the possession of the manufacturer or importer or to which they ought to have access and that are relevant to identifying hazards to the environment and human health and the degree of environmental and public exposure to the polymer.

*Note: The asterisks (\*) appearing at the end of certain provisions indicate that laboratory practices to be followed in developing data for the test referred to in that provision must comply with those practices set out in the “Principles of Good Laboratory Practice”. See subsection 15(2) of the Regulations.*

- <sup>1</sup> Additional test requirements prescribed in subsections 11(2) and 11(3) of the Regulations must be submitted if the quantity of the polymer exceeds 50 000 kg in a calendar year and is released to the aquatic environment in a quantity exceeding 3 kg per day, per site, averaged monthly and after wastewater treatment and/or if the public is anticipated to be significantly exposed to the polymer in a product.<sup>2</sup>
- <sup>2</sup> Information referred to in item 4 of Schedule 10 and the additional data requirements prescribed in subsections 11(2) and 11(3) of the Regulations is not required for polymers that do not meet the criteria for RRR polymer as per subsection 11(5) of the Regulations.

**Schedule 11****(Subsection 2(2), paragraph 12(1)(a), subsection 12(3) and paragraph 18(2)(e))**INFORMATION RESPECTING OTHER POLYMERS AND BIOPOLYMERS NOT ON THE NDSL  
(10 000 KG)

1. The information specified in Schedule 9 or, if that information has been previously provided, the date (year, month, day) of the submission of that information and, if they are known, the new substances pre-notification consultation number, if it has been assigned, and the new substances notification number.
2. The following physical and chemical data in respect of the polymer:
  - (a) its physical state;
  - (b) whether it is formulated for dispersal in water;
  - (c) its water extractability measured at:
    - (i) pH 7 for anionic and neutral polymers,
    - (ii) pH 2 and 7 for cationic polymers, or
    - (iii) pH 2, 7 and 9 for amphoteric polymers;
  - (d) its octanol-water partition coefficient; and
  - (e) if water extractability is determined to be greater than 2%, its hydrolysis rate as a function of pH and, if known, an identification of the products of the hydrolysis.
3. Data from a ready biodegradation test on the water-soluble portion of the polymer, unless the polymer has a water extractability at pH 7 of less than or equal to 2% or is a branched silicone or siloxane polymer.\*
4. Unless the polymer has a water extractability at pH 7 of less than or equal to 2%, the following tests:
  - (a) if the sensitivity of the three species is known, an acute toxicity test of the polymer for each of the two most sensitive species: fish, daphnia or algae;
  - (b) if the sensitivity of only one species is known and that species is not algae, an acute algae toxicity test and either a fish or daphnia acute toxicity test selected on the basis of the most sensitive of these species; or
  - (c) if the sensitivity of only one species is known and that species is algae or if the sensitivity of the three species is unknown, an acute algae toxicity test and either a fish or daphnia acute toxicity test.\*
5. Data from one acute mammalian oral toxicity test of the polymer.\*<sup>1</sup>
6. Information sufficient to assess skin irritation in respect of the polymer.\*<sup>1</sup>
7. Data from a skin sensitization test in respect of the polymer.\*<sup>1</sup>
8. Data from one repeated-dose mammalian toxicity test in respect of the polymer, of at least 28 days duration, which test is selected on the basis of the most significant route of potential human exposure to the polymer, namely, oral, dermal or inhalation.\*<sup>1</sup>
9. For the tests referred to in items 5 to 8, the following additional information:
  - (a) the age, sex, number, species, strain and source of the animals tested;
  - (b) the route by which the polymer is administered and the conditions under which the test is conducted; and
  - (c) the dose of the polymer, the vehicle by means of which the polymer is administered and the concentration of the polymer in the vehicle.\*<sup>1</sup>
10. Mutagenicity data obtained from each of the following tests of the polymer:
  - (a) one *in vitro* test, with and without metabolic activation, for gene mutations;
  - (b) one *in vitro* test, with and without metabolic activation, for chromosomal aberrations in mammalian cells; and



- (c) one *in vivo* mammalian test, for chromosomal aberrations or gene mutations or another indicator of mutagenicity that, together with data substantiating that the tissue investigated was exposed to the polymer or its metabolites, permits an assessment of *in vivo* mutagenicity.\*<sup>1</sup>
11. The following exposure information respecting the polymer:
- (a) a description of the expected modes for its transportation and storage;
  - (b) a description of the size and type of container used for its transportation and storage;
  - (c) an identification of the components of the environment into which it is anticipated to be released;
  - (d) its anticipated releases into municipal wastewater systems;
  - (e) a description of the methods recommended for its destruction or disposal;
  - (f) its historical and other likely uses; and
  - (g) any factors that may limit environmental exposure.
12. A summary of all other information and test data in respect of the polymer that are in the possession of the manufacturer or importer or to which they ought to have access and that are relevant to identifying hazards to the environment and human health and the degree of environmental and public exposure to the polymer.

*Note: The asterisks (\*) appearing at the end of certain provisions indicate that laboratory practices to be followed in developing data for the test referred to in that provision must comply with those practices set out in the "Principles of Good Laboratory Practice". See subsection 15(2) of the Regulations*

<sup>1</sup> Information referred to in items 5 to 10 of Schedule 11 are not required for polymers that do not meet the criteria for RRR polymer as per subsection 12(3) of the Regulations.

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## Schedule 12

### (Subsection 2(2))

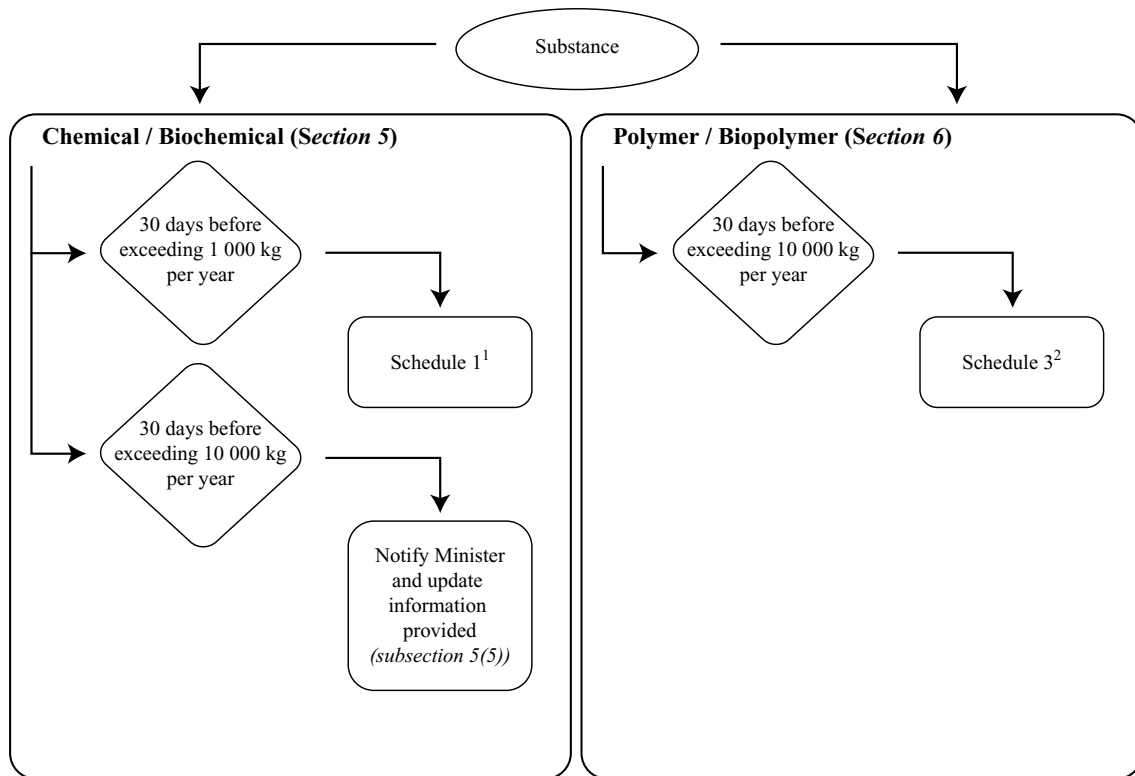
#### OVERVIEW OF INFORMATION REQUIREMENTS

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1. The information required under the *New Substances Notification Regulations (Chemicals and Polymers)* is divided into three flowcharts according to the type of substance:
  - (a) research and development, contained site-limited intermediate and contained export-only substances – Flowchart 1;
  - (b) chemicals and biochemicals other than research and development, contained site-limited intermediate and contained export-only substances – Flowchart 2; and
  - (c) polymers and biopolymers other than research and development, contained site-limited intermediate and contained export-only substances – Flowchart 3.
2. Choose the appropriate flowchart according to the type of substance. Each flowchart identifies the information to be provided and the quantity that triggers the regulatory obligation to provide it.
3. References in the flowcharts are to provisions of the Regulations, in italics, and to Schedules to the Regulations. Note that certain words and expressions used in the flowcharts are defined in section 1 of the Regulations.
4. The shapes used in the flowcharts distinguish their contents as follows:
  - (a) the ovals identify the type of substance referred to in the flowchart, as more particularly described in the flowchart's title;
  - (b) the diamonds identify the timeline and quantity trigger; and
  - (c) the rectangles identify the required information.
5. Shapes outlined with a broken line signal that information is required only in certain circumstances.
6. Additional information is set out in footnotes to each flowchart.
7. The Minister of the Environment and the Minister of Health must assess the information within the same number of days as are afforded to the manufacturer or importer for provision of that information – see section 16 of the Regulations. For example, if a manufacturer or importer is required to provide information at least 30 days before the day on which a certain quantity is exceeded, then the Ministers must assess that information within 30 days after receiving it.

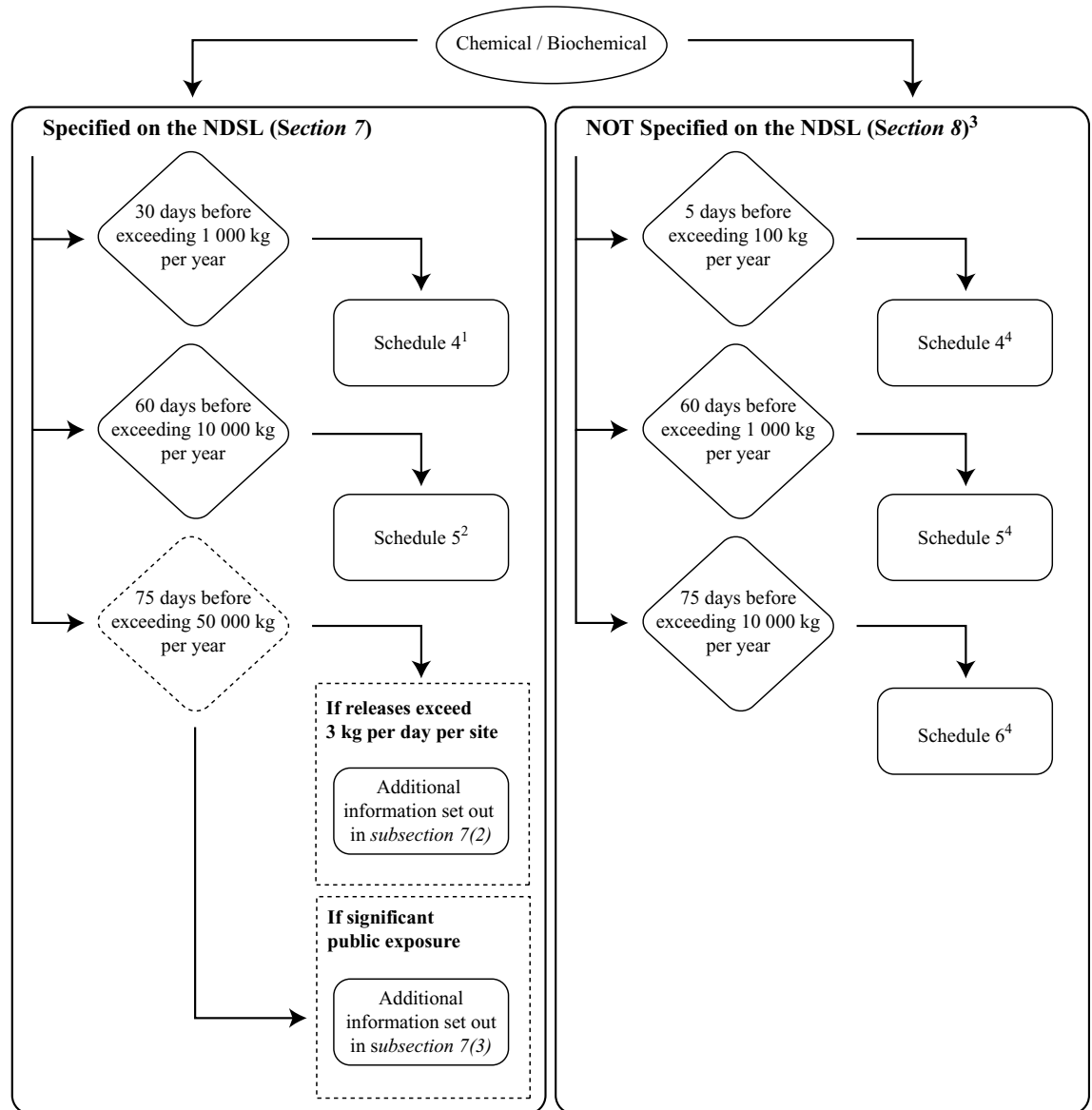
Flowchart 1

Flowchart 1  
**RESEARCH AND DEVELOPMENT, CONTAINED SITE-LIMITED  
INTERMEDIATE OR CONTAINED EXPORT-ONLY SUBSTANCES**



<sup>1</sup> Additional information specified in Schedule 2 is also required if the chemical is a biochemical – see subsections 5(2), (3) and (4).

<sup>2</sup> Additional information specified in Schedule 2 is also required if the polymer is a biopolymer – see subsections 6(2), (3) and (4).

CHEMICALS / BIOCHEMICALS  
OTHER THAN THOSE IN FLOWCHART 1

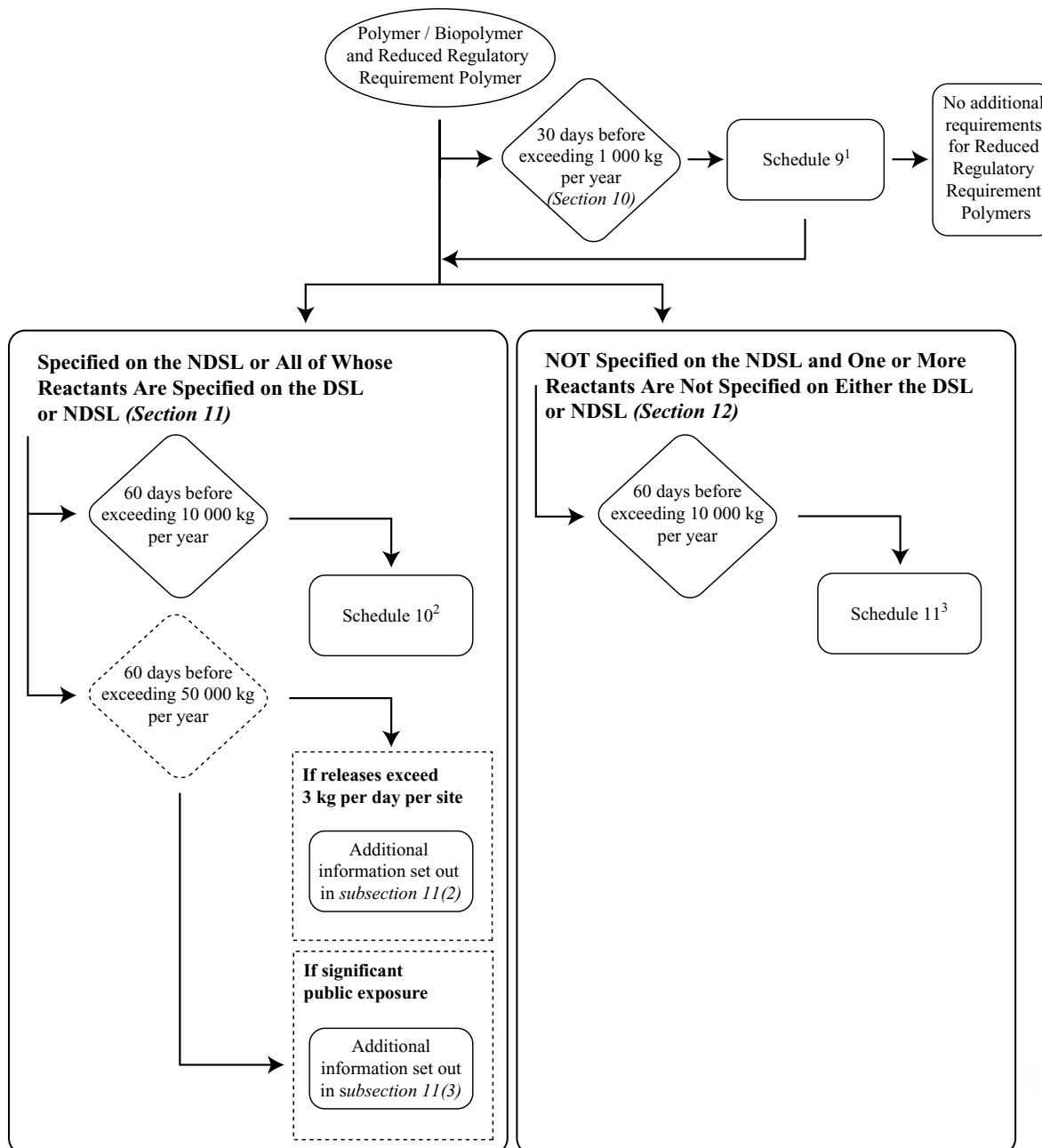
<sup>1</sup> Additional information specified in Schedule 2 is also required if the chemical is a biochemical – see *subparagraph 7(1)(a)(ii)*.

<sup>2</sup> Additional information specified in Schedule 2 is also required if the chemical is a biochemical – see *subparagraph 7(1)(b)(ii)*. No further information will be required unless: (a) the chemical is released to the aquatic environment in a quantity exceeding 3 kg per day, per site, averaged monthly and after wastewater treatment – see *subsection 7(2)* – or (b) the public may be significantly exposed to the chemical in a product – see *subsection 7(3)*.

<sup>3</sup> Notification must be sent to the Minister if: the chemical or biochemical is specified on the NDSL following submission of the information referred to in *subparagraph 8(1)(b)(i)* and item 10 of Schedule 5 – see *subsection 8(2)*.

<sup>4</sup> Additional information specified in Schedule 2 is also required if the chemical is a biochemical – see *subparagraphs 8(1)(a)(ii), (b)(ii) and (c)(ii)*.

Flowchart 3  
**POLYMERS / BIOPOLYMERS**  
**OTHER THAN THOSE IN FLOWCHART 1**



<sup>1</sup> Required for polymers/biopolymers including reduced regulatory requirement polymers. Additional information specified in Schedule 2 is also required if the polymer is a biopolymer – see *paragraph 10(b)*.

<sup>2</sup> Not required for reduced regulatory requirement polymers. Also subject to certain exceptions – see *subsection 11(5)*. Additional information specified in Schedule 2 is also required if the polymer is a biopolymer – see *paragraph 11(1)(b)*. No further information will be required unless: (a) the polymer is released to the aquatic environment in a quantity exceeding 3 kg per day, per site, averaged monthly and after wastewater treatment – see *subsection 11(2)* – or (b) the public may be significantly exposed to the polymer in a product – see *subsection 11(3)*.

<sup>3</sup> Not required for reduced regulatory requirement polymers. Also subject to certain exceptions – see *subsection 12(3)*. Additional information specified in Schedule 2 is also required if the polymer is a biopolymer – see *paragraph 12(1)(b)*.



# APPENDIX 5 — Naming Substances

## 1.0 Representing Substances with Well-defined Structures

### 1.1 Chemical Name of the Substance

A name must be provided that unambiguously describes the substance using CAS or IUPAC nomenclature. Ambiguous or incomplete names are not appropriate for substance identification or for subsequent publication on the DSL. Abbreviations, acronyms, laboratory designations, trade names, trademarks, or trivial names that are not chemically descriptive should not be provided as part of the chemical name. Further clarification of the level of specificity required is provided in Table A5.1 of these Guidelines.

Do not assume that an ambiguous name is adequate simply because there is only one isomer used in a particular industry or because the structural diagram has been provided with the notification.

Commercial dye names should not be used unless they are cross-referenced to a *Colour Index* Name in Volume 5 of the *Colour Index*. The *Colour Index* is a reference publication for manufacturers and users of dyes. It is published by the Society of Dyers and Colourists with assistance from the American Association of Textile Chemists and Colourists. This index can be found at [www.colour-index.org/](http://www.colour-index.org/).

Inorganic substance names must identify all the elements and specify the element ratios. The use of empirical formulae or Stock Numbers is encouraged. (Stock Numbers are Roman numerals added parenthetically to indicate the state or states of oxidation).

### 1.2 Molecular Formula

The molecular formula is a summation of the actual numbers and kinds of atoms present in a molecule of a substance. In the case of salts or addition compounds, the molecular formula may be presented as a single summation formula or in the “dot-disconnect” format used by CAS.

**Example:** Succinic acid, dilithium salt

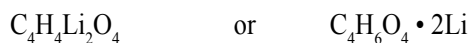
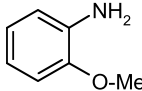
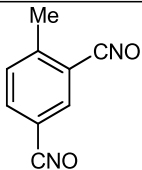
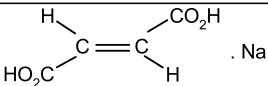
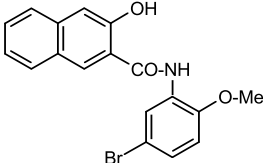


Table A5.1: Chemical Names for Well-Defined Substances

Substance	Unacceptable Name	Acceptable Name
	Anisidine	<i>o</i> -Anisidine or 2-Methoxyaniline
	Toluene diisocyanate or TDI	Toluene 2,4-diisocyanate
	Sodium fumarate or Monosodium butenedioate	Monosodium fumarate or Monosodium <i>trans</i> -butenedioate or Monosodium <i>E</i> -butenedioate
$\text{H}_3\text{C}(\text{CH}_2)_3\underset{\text{Et}}{\text{CH}}\text{CH}_2\text{O.CO}(\text{CH}_2)_2\text{CO}_2\text{H}$	Octyl succinate or Ethylhexyl succinate	Mono(2-ethylhexyl) succinate
$\begin{array}{c} \text{CH}_2\text{-O-CO-Ph} \\   \\ \text{CH-OH} \\   \\ \text{CH}_2\text{-O-CO-Ph} \end{array}$	Glycerol benzoate or Glycerol dibenzoate	Glycerol 1,3-dibenzoate
$\text{HO}(\text{CH}_2)_2\text{NH} \cdot \text{H}_3\text{C-CO}_2\text{H} \\   \\ (\text{CH}_2)_2\text{OH}$	Diethanolamine acetate	Diethanolamine acetate salt
$\text{Ac-O}-(\text{CH}_2)_2\text{NH}(\text{CH}_2)_2\text{O-Ac}$	Diethanolamine acetate or Diethanolamine acetate ester	Diethanolamine diacetate ester
$\text{Ac-O}-(\text{CH}_2)_2\text{NH}(\text{CH}_2)_2\text{OH}$	Diethanolamine acetate or Diethanolamine acetate ester	Diethanolamine monoacetate ester
	Blue APM or EMS 17	Brenthol BA or C.I. 37532 or C.I. Azoic Coupling Component 6 or 5'-Bromo-3-hydroxy-2-naphth- <i>o</i> -anisidine or <i>N</i> -(5-bromo-2-methoxyphenyl)-3-hydroxy-2-naphthalenecarboxamide
$\text{O}=\text{Ti-O-Ti}=\text{O}$	Titanium oxide	Titanium oxide ( $\text{Ti}_2\text{O}_3$ )

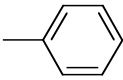


### 1.3 Structural Information

The structural diagram must clearly indicate the identity of the atoms and the nature of the bonds joining them. Guidelines for preparing these diagrams are included in section 2.3 of this Appendix.

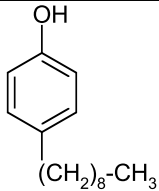
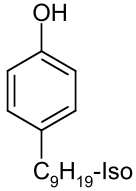
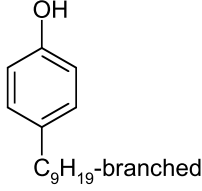
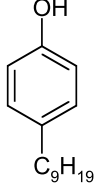
Common abbreviations are acceptable in structural diagrams as long as they are unambiguous. Table A5.2 below provides some examples of acceptable abbreviations.

**Table A5.2: Common Abbreviations that Are Acceptable in Structural Information**

Structure	Abbreviation	Structure	Abbreviation
-CH <sub>3</sub>	Me-	-C=O   OH	-CO <sub>2</sub> H
-CH <sub>2</sub> CH <sub>3</sub>	Et-	-C-    O	-CO-
-(CH <sub>2</sub> ) <sub>2</sub> CH <sub>3</sub>	Pr-	-CH=O	-CHO
-CHCH <sub>3</sub>   CH <sub>3</sub>	-Pr- <i>i</i> or -Pr- <i>iso</i>	-C=O   CH <sub>3</sub>	-Ac
-(CH <sub>2</sub> ) <sub>3</sub> CH <sub>3</sub>	-Bu	O    -S-OH    O	-SO <sub>3</sub> H
-CH <sub>2</sub> CHCH <sub>3</sub>   CH <sub>3</sub>	-Bu- <i>i</i> or -Bu- <i>iso</i>	O    -S-    O	-SO <sub>2</sub> -
-CHCH <sub>2</sub> CH <sub>3</sub>   CH <sub>3</sub>	-Bu- <i>s</i> or -Bu- <i>sec</i>	-N=O	-NO
CH <sub>3</sub>   -C-CH <sub>3</sub>   CH <sub>3</sub>	-Bu- <i>t</i> or -Bu- <i>tert</i>		-Ph

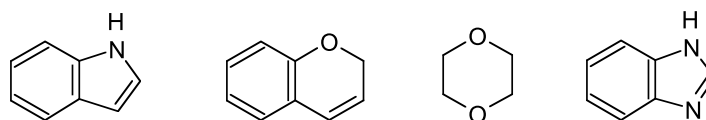
Alkyl groups will be assumed to be normal (linear) unless otherwise designated. If a substance has alkyl groups that are not linear, then the nature of the branching must be described as specifically as possible. Table A5.3 below illustrates examples of several different representations for the substance nonylphenol.

Table A5.3: Representations for Nonylphenol

Submitted Name	Structural Representation	CAS Registry Number	CA Index Name
<i>p</i> -Nonylphenol		104-40-5	Phenol, 4-nonyl-
<i>p</i> -Isononylphenol		26543-97-5	Phenol, 4-isononyl-
Branched, 4-nonylphenol		84852-15-3*	Phenol, 4-nonyl-, branched
<i>p</i> -Tripropylene phenol		87247-00-5	Phenol, 4-tripropylene-

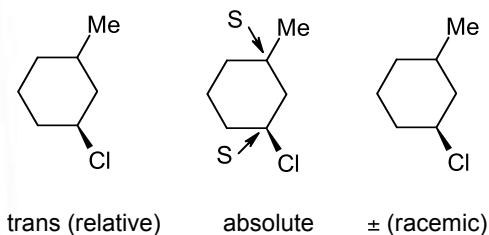
Carbon atoms in ring systems and their attached hydrogen atoms need not be explicitly shown.

For example:



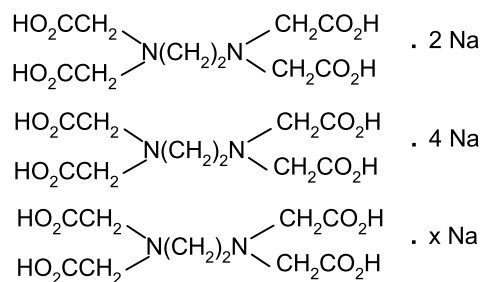
All known stereochemical details must be provided. Indicate whether the stereochemistry is absolute or relative.

For example:



The ratio of the components of an addition compound or salt must be clearly indicated if more than one form is theoretically possible. It must also be noted if the ratio is unknown.

For example:



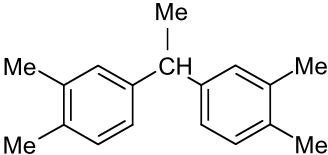
### 1.3.1 Examples of Well-defined Substances

The following examples, illustrate the information necessary to uniquely identify and represent substances with a well-defined structure.

#### Example 1

Chemical Name of the Substance: N-(s-Butoxymethyl)acrylamide
Molecular Formula: $\text{C}_8\text{H}_{15}\text{NO}_2$
Structural Information:  $\text{H}_2\text{C}=\text{CH}-\text{CO}-\text{NH}-\text{CH}_2-\text{O}-\text{Bu}-\text{sec}$ <p><b>COMMENT:</b> Branching of alkyl groups must be indicated or the group will be assumed to be linear. For example, the Bu group on the following diagram would be represented linearly as <math>-\text{CH}_2\text{CH}_2\text{CH}_2\text{CH}_3</math></p> $\text{H}_2\text{C}=\text{CH}-\text{CO}-\text{NH}-\text{CH}_2-\text{O}-\text{Bu}$

### Example 2

Chemical Name of the Substance: 1,1-Di-3,4-xylylethane; 1,1-Bis(3,4-dimethylphenyl)ethane
Molecular Formula: $C_{18}H_{22}$
Structural Information:  
<b>COMMENT:</b> The semicolon is used to separate the two names. Both names cite locants. Di-xylylethane would not be an appropriate name for this substance.

### Example 3

Chemical Name of the Substance: Sodium sebacate; Sodium decanedioate
Molecular Formula: $C_{10}H_{18}O_4 \cdot x Na$
Structural Information:  $HO_2C-(CH_2)_8-CO_2H \cdot x Na$
<b>COMMENT:</b> Use of "x" in the molecular formula and structure diagram clearly indicates the ratio of the salt is unknown.

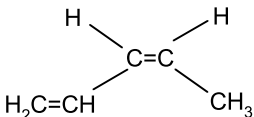
### Example 4

Chemical Name of the Substance: Disodium sebacate; Disodium decanedioate
Molecular Formula: $C_{10}H_{18}O_4 \cdot 2 Na$
Structural Information:  $HO_2C-(CH_2)_8-CO_2H \cdot 2 Na$
<b>COMMENT:</b> When known, ratios must be cited in the name, formula, and structure. The formula could also be given as $C_{10}H_{16}Na_2O_4$ . The structure could also be shown as:  $NaO_2C-(CH_2)_8-CO_2Na$

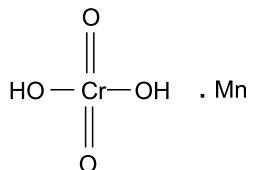
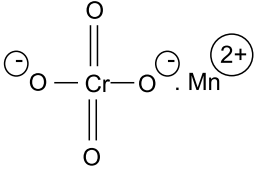
## Example 5

Chemical Name of the Substance: 1,3-Pentadiene; Piperylene
Molecular Formula: $C_5H_8$
Structural Information:  $H_2C=CH-CH=CH-CH_3$  <b>COMMENT:</b> Stereochemistry is not cited in the name or structure. See EXAMPLE 6 for a specific stereoisomer.

## Example 6

Chemical Name of the Substance: cis-1,3-Pentadiene; Z-1,3-Pentadiene; cis-Piperylene
Molecular Formula: $C_5H_8$
Structural Information:    <b>COMMENT:</b> Stereochemistry is cited in both the name and structure. See EXAMPLE 5 for an example of a non-stereo-specific substance.

## Example 7

Chemical Name of the Substance: Manganese (II) chromate (IV); Manganese chromate ( $MnCrO_4$ ); Chromium manganese oxide ( $MnCrO_4$ )
Molecular Formula: $H_2CrO_4Mn$
Structural Information:    <b>COMMENT:</b> Stock numbers or empirical formulae must be included in the name when known. The following diagram is also acceptable:  

## Example 8

Chemical Name of the Substance: PVC; Polyvinyl chloride
Molecular Formula: (C <sub>2</sub> H <sub>3</sub> Cl) <sub>x</sub>
Structural Information:  $\text{ClCH}=\text{CH}_2 + \text{ABIN} \longrightarrow \text{Polyvinyl chloride}$ <p><b>COMMENT:</b> Polymeric substances are to be described in terms of their starting reactants. Starting reactants are defined as those that become part of the polymer composition. If the role of the reactant ABIN is an initiator, it should not be included in the polymer description appearing on the DSL. ABIN, if placed in commerce, must be reported separately.</p>

## Example 9

Chemical Name of the Substance: Maleic acid-dimethyl phthalate-ethylene glycol copolymer; cis-2-Butenedioic acid-dimethyl phthalate-ethylene glycol polymer
Molecular Formula: (C <sub>2</sub> H <sub>6</sub> O <sub>2</sub> -C <sub>4</sub> H <sub>4</sub> O <sub>4</sub> -C <sub>10</sub> H <sub>10</sub> O <sub>4</sub> ) <sub>x</sub>
Structural Information:  

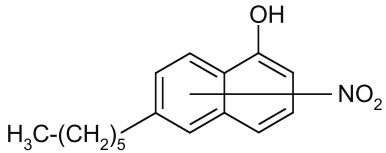
## Example 10

Chemical Name of the Substance: Styrene-polyethyleneglycol monoallylether
Molecular Formula: ((C <sub>2</sub> H <sub>4</sub> O) <sub>n</sub> C <sub>3</sub> H <sub>6</sub> O.C <sub>8</sub> H <sub>8</sub> ) <sub>x</sub>
Structural Information:  
<b>COMMENT:</b> Names and CAS registry numbers, rather than structure diagrams, may be used to describe reactants. Polyglycol derivatives must be represented on the basis of their polymeric structure.

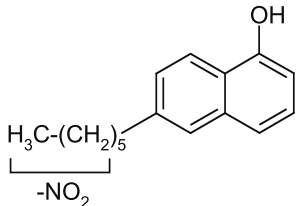
## Example 11

Chemical Name of the Substance: 2,4,4-Trimethyl-2-pentene
Molecular Formula: $C_8H_{16}$
Structural Information:  $  \begin{array}{c}  \text{CH}_3 \quad \text{CH}_3 \\    \quad   \\  \text{H}_3\text{C}-\text{C}=\text{CH}-\text{C}-\text{CH}_3 \\    \\  \text{CH}_3  \end{array}  $
<b>COMMENT:</b> Isobutylene dimer would not be an appropriate chemical name for this structure. Designations such as dimer and trimer are appropriate only when the degree of polymerization is a specific value from two through ten but the specific structure is unknown.

## Example 12

Chemical Name of the Substance: ar-Nitro-6-hexyl-1-naphthol; ar-Nitro-6-hexyl-1-hydroxynaphthalene
Molecular Formula: $C_{16}H_{19}NO_3$
Structural Information:  
<b>COMMENT:</b> Compare to EXAMPLES 13 and 14. The structural representation must represent all known specificity.

## Example 13

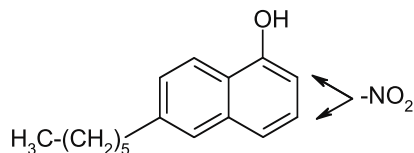
Chemical Name of the Substance: 6-(Nitrohexyl)-1-naphthol; 6-(Nitrohexyl)-1-hydroxynaphthalene
Molecular Formula: $C_{16}H_{19}NO_3$
Structural Information:  
<b>COMMENT:</b> Compare to EXAMPLES 12 and 14. The structural representation must represent all known specificity.

### Example 14

Chemical Name of the Substance: 2 or 3-Nitro-6-hexyl-1-naphthol;  
2 or 3-Nitro-6-hexyl-1-hydroxynaphthalene

Molecular Formula:  
 $C_{16}H_{19}NO_3$

Structural Information:



**COMMENT:** Compare to EXAMPLES 12 and 13. The structural representation must represent all known specificity.

### Example 15

Chemical Name of the Substance: Aluminum nickel

Molecular Formula:  
 $Ni_3Al$

Structural Information:



**COMMENT:** Known stoichiometry must be indicated. Ni-Al would be unacceptable.

### Example 16

Chemical Name of the Substance: Synthetic geikielite

Molecular Formula:  
 $Mg-O_3Ti$

Structural Information:

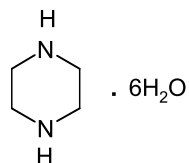
**COMMENT:** Minerals that are synthetic must be indicated as such in the Chemical Name of the Substance.

### Example 17

Chemical Name of the Substance: Piperazine hexahydrate;  
Arpezine

Molecular Formula:  
 $C_4H_{10}N_2 \cdot 6H_2O$

Structural Information:



**COMMENT:** Substances that are described as hydrates must be represented as the anhydrous form.



## 2.0 Representing Substances that are Complex and Variable

Substances that cannot be represented by a complete structure diagram and specific molecular formula are known as UVCB substances.

### 2.1 Chemical Name of the Substance

The Guidelines for naming UVCB substances are similar to the instructions given in section 1.3.1 of this Appendix for Well-Defined Substances and should be reviewed for additional information. Table A5.4 below provides further clarification of the level of specificity required.

Table A5.4: Chemical Names for Complex and Variable Substances

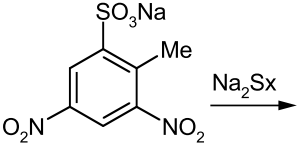
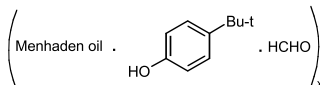
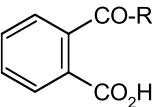
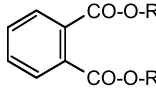
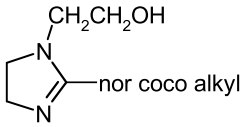
Substance	Unacceptable Name	Acceptable Name
 <p>Reaction: <chem>CC1=CC(=C(C=C1)[N+](=O)[O-])[S](=O)(=O)[O-].[Na+] + Na2Sx -&gt; [C]Sx</chem></p>	RGP Brown or Sodium dinitrotoluenesulfonic acid polysulfide	C.I. Sulphur Brown 42 or C.I. 53030 or Thionone Brown R0 or Sodium 3,5-dinitro- <i>o</i> -toluenesulfonic acid reaction product with sodium polysulfide
$H_2C=CH-R$ bromination chlorination $R = C_{10-28}$ Alkyl	Halogenated $C_{12-30}$ $\alpha$ -alkenes or Bromo and chloroalkenes	$C_{12-30}$ $\alpha$ -alkenes bromo and chloro derivs. or $C_{12-30}$ $\alpha$ -(alkenes, brominated and chlorinated) or Alkenes, $C_{12-30}$ $\alpha$ -brominated and chlorinated
 <p>Reaction: <chem>CC(C)(C)c1ccc(O)cc1.C=O -&gt; [C]</chem></p>	Fish oil-butyl phenol-formaldehyde resin or Marine oil, <i>p-tert</i> -butylphenol, formaldehyde resin or Menhaden oil, 4-butylphenol, formaldehyde resin	Menhaden oil, <i>p-tert</i> -butylphenol, formaldehyde resin
Linseed oil fatty acids . xNa	Vegetable fatty acids sodium salts or Linseed sodium salts or Linseed oil sodium salts	Linseed oil fatty acids sodium salts or Fatty acids, linseed-oil, sodium salts
 <p><math>R = C_{8-10}</math> branched alkyl</p>	Nonyl phthalate or Isononyl phthalate or Mono- $C_{8-10}$ -alkyl phthalate	Mono- $C_{8-10}$ -branched alkyl phthalate or 1,2-Benzenedicarboxylic acid, mono- $C_{8-10}$ -branched alkyl esters
 <p><math>R = C_{8-10}</math> branched alkyl</p>	Dinonyl phthalate or Diisononyl phthalate or Di- $C_{8-10}$ -alkyl phthalate	Di- $C_{8-10}$ -branched alkyl phthalate or 1,2-Benzenedicarboxylic acid, di- $C_{8-10}$ -branched alkyl esters

Table A5.4: Chemical Names for Complex and Variable Substances (continued)

Substance	Unacceptable Name	Acceptable Name
Coconut oil fatty acids + $\xrightarrow[\text{formation}]{\text{salt}}$ HOCH <sub>2</sub> CH <sub>2</sub> NHCH <sub>2</sub> CH <sub>2</sub> OH	Coconut oil fatty acids reaction product with diethanolamine	Coconut oil fatty acids-diethanolamine salt or Coconut oil fatty acids, compound with diethanolamine or Fatty acids, coco, compds. with diethanolamine
HOCH <sub>2</sub> CH <sub>2</sub> NHCH <sub>2</sub> CH <sub>2</sub> O-CO-R -CO-R = coco fatty acyl	Coconut oil fatty acids reaction product with diethanolamine	Coconut oil fatty acids diethanolamine monoester or Fatty acids, coco, 2-[[[(2-hydroxyethyl)amino]ethyl] esters
	Coconut oil reaction product with aminoethyl ethanolamine or Coco alkyimidazolineethanol	Coconut oil and <i>N</i> -(2-aminoethyl)ethanolamine cyclization product or 1 <i>H</i> -Imidazole-ethanol, 4,5-dihydro-2-norcoco alkyl derivs.

## 2.2 Molecular Formula

Most UVCB substances cannot be represented by a specific molecular formula. However, in some cases, it may be possible to provide a molecular formula that is a summation of the range of numbers and specific kinds of atoms present in a molecule of a substance. Hypothetical or idealized molecular formulae must not be cited.

Molecular formulae for salts and addition compounds, if provided, may be presented as a single summation formula or in the dot-disconnect format used by CAS.

### Example:

C<sub>6-12</sub>-alkyldicarboxylic acid, disodium salt

NaO<sub>2</sub>C-C<sub>6-12</sub>alkyl-CO<sub>2</sub>Na      HO<sub>2</sub>C-C<sub>6-12</sub>alkyl-CO<sub>2</sub>H · 2Na

C<sub>8-14</sub>H<sub>12-24</sub>Na<sub>2</sub>O<sub>4</sub>      or      C<sub>8-14</sub>H<sub>14-26</sub>O<sub>4</sub> · 2Na

## 2.3 Structure Diagram Guidelines

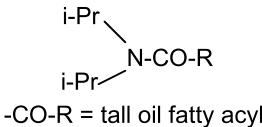
Since, in most cases, a unique structure diagram cannot be provided, descriptive information for the substance, components, or precursors must be given.

If a partial structural diagram can be provided, this diagram must clearly indicate the identity of the atoms and the nature of the bonds joining them. Common abbreviations for substituents and functional groups are acceptable if they are unambiguous. Alkyl groups will be assumed to be normal (linear) unless otherwise designated.

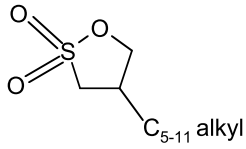
Substance representations must describe all known specificity, such as salt ratios and stereochemical details.

The following examples are intended to illustrate the level of specificity that must be provided. It is strongly recommended that the notifier follow the style of the examples.

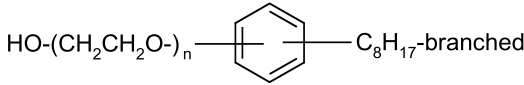
## Example 18

Chemical Name of the Substance: <i>N,N</i> -Diisopropyl tall oil fatty amides
Molecular Formula:
Structural Information:
 <p style="text-align: center;">-CO-R = tall oil fatty acyl</p>
<b>COMMENT:</b> A substance can be described in terms of a partial structure diagram.

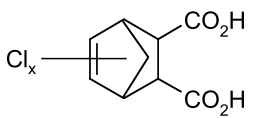
## Example 19

Chemical Name of the Substance: 4-(C <sub>5-11</sub> -alkyl)-1,2-oxathiolane, S,S-dioxide
Molecular Formula:
Structural Information:

<b>COMMENT:</b> Carbon ranges of alkyl groups must be defined.

## Example 20

Chemical Name of the Substance: C <sub>8</sub> branched alkylphenol ethoxylate
Molecular Formula:
Structural Information:

<b>COMMENT:</b> Representations must describe all known specificity, including structural information for alkyl groups.

## Example 21

Chemical Name of the Substance: Chlorinated 5-norbornene-2,3-dicarboxylic acid; Bicyclo[2.2.1]hept-5-ene-2,3-dicarboxylic acid, chloro derivs.
Molecular Formula:
Structural Information:


**Example 22**

Chemical Name of the Substance: Safflower oil, polymer with adipic acid, glycerol and phthalic anhydride
Molecular Formula:
Structural Information:

**Example 23**

Chemical Name of the Substance: Phosphoric acid, mono(branched nonyl) phenyl ester, disodium salt
Molecular Formula: $C_{15}H_{25}O_4P \cdot 2 Na$
Structural Information:

**2.4 Plant and Animal Products**

Complex and variable substances, which are produced by chemical modification of naturally occurring products or are separated from them by physical processing<sup>1</sup>, must be identified by specifying the genus and species as well as other unambiguous common names of the source.

Do not assume that a common name is adequate simply because there is only one source used in a particular industry. For example, mint oil should not be used to identify Japanese mint oil, Bergamot oil, Spearmint oil, or Peppermint oil. Vegetable oil should not be used to identify corn oil, soybean oil, or linseed oil.

The following examples are intended to illustrate the level of specificity that must be provided.

<sup>1</sup> Physical processing includes such methods as: distillation; steam distillation; crystallization; sublimation; salting-out; ion-exchange; and heating for reasons other than to remove water.

**Example 24**

Chemical Name of the Substance: Soybean fatty acids, diethylenetriamine salt
Molecular Formula:
Structural Information:
Soya fatty acids . x H <sub>2</sub> NCH <sub>2</sub> CH <sub>2</sub> NHCH <sub>2</sub> CH <sub>2</sub> NH <sub>2</sub>

**Example 25**

Chemical Name of the Substance: Mixed vegetable oils fatty acids methyl esters
Molecular Formula:
Structural Information:
Methyl esters of mixed vegetable oils fatty acids
<b>COMMENT:</b> <i>If the substance is obtained from a manufacturing process that uses different types of plants to produce the oil then the term, "mixed vegetable", must be used in the name.</i>

**Example 26**

Chemical Name of the Substance: Japanese mint oil; Japanese peppermint oil
Molecular Formula:
Structural Information:
Oil extracted from <i>Mentha arvensis</i> var. <i>piperascens</i>
<b>COMMENT:</b> <i>The genus and species of the plant that was processed to produce the oil must be identified.</i>

**Example 27**

Chemical Name of the Substance: <i>Mentha citrata</i> oil; Bergamot mint oil
Molecular Formula:
Structural Information:
Oil extracted from <i>Mentha citrata</i>
<b>COMMENT:</b> <i>Bergamot oil would not be an appropriate chemical name of the substance because bergamot oil is also extracted from Citrus bergamia.</i>

**Example 28**

Chemical Name of the Substance: Acetylated lemongrass oils
Molecular Formula:
Structural Information:
Lemongrass oil      acetylation 8007-02-1* $\xrightarrow{\hspace{1cm}}$
<p><b>COMMENT:</b> The genus and species, <i>Cymbopogon citratus</i>, is associated with CAS registry number 8007-02-1* in the Chemical Definition Section of TSCA.</p>

**Example 29**

Chemical Name of the Substance: Terpene-free bergamot oil fraction
Molecular Formula:
Structural Information:
Terpene-free fraction distilled from oil extracted from <i>Citrus bergamia</i> .

**Example 30**

Chemical Name of the Substance: Corn oil deodorizer distillate
Molecular Formula:
Structural Information:
A complex mixture of fatty acids, sterols, aldehydes, ketones, and other materials prepared by the steam distillation of corn oil followed by condensation of the steam containing these materials.

**2.5 Reaction Products**

The reaction scheme must include the chemical identity of the immediate precursors; the nature of the reaction; and the reactants, whether or not they are implied by the reaction term. Reaction terms must be as specific as possible (*e.g.*, acetylation, alkaline hydrolysis, chlorination, diazotization, epoxidation). General reaction terms such as addition, condensation, and reaction should not be used.

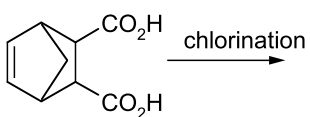
Although the substance itself may be a UVCB substance, the precursors or components may be well-defined substances. Any descriptions provided for well-defined precursors or components must meet the specifications discussed previously.

The following examples are intended to illustrate the level of specificity that must be provided.

## Example 31

Chemical Name of the Substance: Polymer of methyl methacrylate, methacrylic and bromotrichloromethane
Molecular Formula: $(C_4H_6O_2 \cdot C_5H_8O_2)_x \cdot xCBrCl_3$
Structural Information:  $  \begin{array}{c}  HO_2C-C=CH_2 \\    \\  CH_3  \end{array}  +   \begin{array}{c}  Me-O-CO-C=CH_2 \\    \\  CH_3  \end{array}  \xrightarrow[\text{telomerization (BrCCl}_3\text{)}]{\text{polymd.}}  $

## Example 32

Chemical Name of the Substance: Chlorinated 5-norbornene-2,3-dicarboxylic acid; Bicyclo[2.2.1]hept-5-ene-2,3-dicarboxylic acid, chloro derivs.
Molecular Formula:
Structural Information:  
<b>COMMENT:</b> Compare to EXAMPLE 21. Either method is acceptable. Both depict the same degree of specificity.

## Example 33

Chemical Name of the Substance: Phosphoric acid, mono(branched nonyl) phenyl ester, disodium salt
Molecular Formula:
Structural Information:  $  \begin{array}{c}  O \\     \\  HO-P-OH \\    \\  OH  \end{array}  +   \begin{array}{c}  HO \\    \\  \text{C}_6\text{H}_4 \\    \\  \text{C}_9\text{H}_{19}\text{-branched}  \end{array}  \xrightarrow{\text{esterification}} \text{monoester} \xrightarrow[\text{NaOH}]{\text{neut.}} \text{disodium salt}  $
<b>COMMENT:</b> Compare to EXAMPLE 23. Either method is acceptable. Both depict the same degree of specificity.

**Example 34**

Chemical Name of the Substance: Phthalic anhydride-trimethylolpropane copolymer, pelargonate
Molecular Formula:
Structural Information:

**Example 35**

Chemical Name of the Substance: C.I. Acid Black 47; C.I. 56055; Sulfonine Grey G
Molecular Formula:
Structural Information:

**Example 36**

Chemical Name of the Substance: Tallow fatty acid ethanolamine amides salt
Molecular Formula:
Structural Information:

Tallow fatty acids +  $\text{H}_2\text{NCH}_2\text{CH}_2\text{OH} \rightarrow$  amides

**COMMENT:** Because tallow fatty acids and ethanolamine may react to form a variety of different products (e.g., salts, esters, cyclization products), the product description must be as specific as possible and include the typical composition.



## 2.6 Products from Industrial Processes

Some Complex and Variable substances are most conveniently described by text rather than structural diagrams or reaction schemes.

The description must include precursors, method of preparation, process terms (low-boiling, catalytic reformed), physical properties (if known), and typical chemical composition. Specifically, the substance information must describe the substance as uniquely as possible and include (if known):

- (a) process description (*e.g.* catalytic cracking, dewaxed, destructive distillation);
- (b) carbon (alkyl) range (*e.g.* C<sub>4</sub> through C<sub>12</sub>);
- (c) physical properties (*e.g.* boiling range, viscosity, solid, slag, and softening point);
- (d) principal chemical composition (*e.g.* hydrocarbons, sulfides, terpenes);
- (e) source (*e.g.*, petroleum, coal)

It is recommended that, whenever appropriate, schematic diagrams (depicting the industrial process and the point where the notified substance is isolated) be provided.

The description should not include process terms that are unqualified or broadly descriptive or undefined trade jargon.

The following examples are intended to illustrate the level of specificity that must be provided. Additional examples of the type of descriptive information required can be found in the Chemical Substance Definitions sections of TSCA.

### Example 37

Chemical Name of the Substance: C <sub>9-13</sub> Alkylbenzene distillation residues
Molecular Formula:
Structural Information:  Complex residue from the distillation of C <sub>9-13</sub> alkylbenzenes having a boiling point >600 °F. Composed primarily of diphenylalkanes, dialkylbenzenes, and diphenyldialkanes. The alkyl groups are linear C <sub>9-13</sub> .

### Example 38

Chemical Name of the Substance: Ferrous metals blast furnace slag
Molecular Formula:
Structural Information:  Fused substance formed by the action of a flux on the gangue of iron-bearing materials charged to the blast furnace and on oxidized impurities in the iron produced. Composed primarily of sulfur and oxides of Al, Ca, Mg, and Si.

**Example 39**

Chemical Name of the Substance: Oxidized black liquor;  
Spent pulping liquor, oxidized

Molecular Formula:

Structural Information:

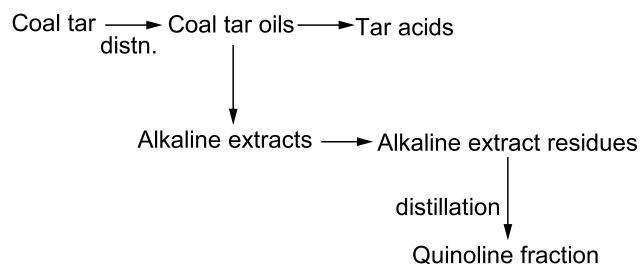
Substance produced by the oxidation of black liquor with pulping chemicals used in Kraft, sulfite, semichemical, or other pulping processes. Composed primarily of partially oxidized lignosulfonates, sugars, and hemicelluloses.

**Example 40**

Chemical Name of the Substance: Quinoline fraction of coal tar alkaline extract residues

Molecular Formula:

Structural Information:



Quinoline fraction consists primarily of quinoline, isoquinoline, methylquinolines, and dimethylquinolines.

**Example 41**

Chemical Name of the Substance: Coal coke

Molecular Formula:

Structural Information:

Carbonaceous residue from the high temperature (> 700 °C) destructive distillation of coal. Composed primarily of carbon but may contain sulfur and ash.

**Example 42**

Chemical Name of the Substance: Petroleum coke

Molecular Formula:

Structural Information:

Carbonaceous residue from the high temperature destructive distillation of petroleum fractions. Composed primarily of carbon but may contain some hydrocarbons with high carbon to hydrogen ratios.

**Example 43**

Chemical Name of the Substance: Naphtha, petroleum, hydrodesulfurized full-range
Molecular Formula:
Structural Information:  A complex combination of hydrocarbons obtained from a catalytic hydrodesulfurization process. It consists of hydrocarbons having carbon numbers predominantly in the range of C <sub>4</sub> through C <sub>12</sub> and in the boiling range of approximately 30 to 250 °C.

**Example 44**

Chemical Name of the Substance: Copper smelting slag
Molecular Formula:
Structural Information:  Substance resulting from the smelting of copper and precious metals obtained from primary and secondary sources and plant reverts. Composed primarily of iron oxides and SiO <sub>2</sub> . May contain Cu, Pb, Ni, and other non-ferrous metals and oxides.

**Example 45**

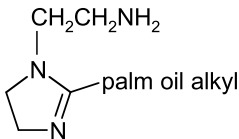
Chemical Name of the Substance: Olivine vanadium blue
Molecular Formula:
Structural Information:  An inorganic pigment formed by the high temperature calcination of vanadium (IV) oxide and silicon oxide in varying amounts. Ionic diffusion occurs to form a crystalline matrix. Alkali or alkaline earth halides may be included as modifiers.

**2.7 Combinations of UVCB Substances**

Due to their complexity, it is necessary to describe the precursors, reactants, reaction scheme, and nominated substance as specifically as possible when notifying substances produced by the combination of UVCB substances. It is strongly recommended that before reporting these types of substances all sections of this appendix be carefully reviewed.

The following examples are intended to illustrate the level of specificity that must be provided.

**Example 46**

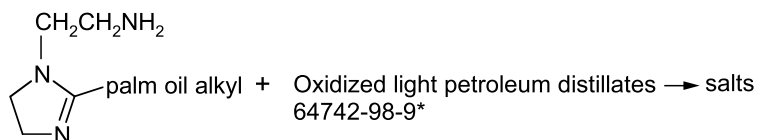
Chemical Name of the Substance: Palm oil and diethylenetriamine cyclization product, compound with distillation residue
Molecular Formula:
Structural Information:   <p>Residue from distillation of C<sub>6-18</sub> saturated and unsaturated monobasic acids and C<sub>8-15</sub> dibasic acids. Consists of ---- Salts C<sub>9-18</sub> saturated dibasic acids. May also contain polymers, anhydrides, and polyesters.</p>

**Example 47**

Chemical Name of the Substance: Palm oil and diethylenetriamine cyclization product, compound with oxidized light petroleum distillates
---

Molecular Formula:
--------------------

Structural Information:
-------------------------



**COMMENT:** The use of CAS registry number 64742-98-9\* eliminates the need for the inclusion of a lengthy description of the starting material.

**Example 48**

Chemical Name of the Substance: Oxidized sesquiterpene fraction of Cedarwood oil
--

Molecular Formula:
--------------------

Structural Information:
-------------------------

Sesquiterpene fraction distilled from oil  
 extracted from *Cedrus atlantica*, Pinaceae.  $\xrightarrow{\text{oxidation}}$

\* indicates UVCB substances.

# APPENDIX 6 — Locating Chemical Abstracts Service (CAS) Registry Numbers

To assist notifiers in their efforts to locate CAS registry numbers, sources that may be used to identify CAS registry numbers are described.

## 1.0 Chemical Abstracts (CA)

Chemical Abstracts (CA) contains abstracts and index entries selected from scientific and technical literature. The weekly issues and volume indexes provide access to the world literature for chemical substances. At present, CA publishes two complete volumes of abstracts and their corresponding indexes for each calendar year. The indexes to each volume include a Formula Index, a Chemical Substance Index, and a General Subject Index. The Formula Index provides CA Index Names, CAS registry numbers, and abstract numbers for chemical substances identified by molecular formula. Entries are arranged according to the Hill System. The Chemical Substance Index links the CA Index Name, which identifies a specific chemical substance, with an abstract number. CA Index names are listed in alphabetical order and CAS registry numbers are given. The General Subject Index links subject terms, such as reactions, classes of substances, and plant and animal species, with their corresponding CAS registry numbers ([www.cas.org/](http://www.cas.org/)).

### 1.1 Chemical Abstracts Services (CAS)

Using CAS, notifiers can obtain CAS registry numbers for their substances or CA Index Names for confidential substances. This service furnishes CAS registry numbers to customers either by retrieving existing CAS registry numbers and/or assigning new CAS registry numbers for chemical substances that meet CAS criteria for registration ([www.cas.org/](http://www.cas.org/)).

### 1.2 CA Index Guide

To help users of CA Indices locate substances and other information, CAS publishes the CA Index Guide. The CA Index Guide details the major points of CA indexing policy and provides cross-references, from various subject terms and substance names used in the literature, to the controlled CA indexing terminology and CAS registry numbers, if applicable. For substance identification, this publication provides many cross-references to common names and the CA Index Name and CAS registry number ([www.cas.org/PRINTED/caissues.html](http://www.cas.org/PRINTED/caissues.html)).

### 1.3 Registry Handbook — Common Names

A microform publication, this handbook is an alphabetical list of common names, CA Index Names, and other related names; associated with each name is the corresponding CAS registry number and molecular formula. There are over 1 250 000 names and 500 000 CAS registry numbers in this publication ([www.lib.utexas.edu/chem/info/ca.html](http://www.lib.utexas.edu/chem/info/ca.html)).

### 1.4 Registry Handbook — Number Section

This publication, in ascending CAS registry number order, provides CA Index Names and molecular formulas for over seven million substances. The “base book” covers 1965 to 1971. Additions are provided in annual supplements based on specific registry number ranges ([www.lib.utexas.edu/chem/info/ca.html](http://www.lib.utexas.edu/chem/info/ca.html)).

## 1.5 Chemical Abstracts Service ONLINE

The CAS ONLINE is a comprehensive chemical information database that offers substance-oriented and subject-oriented searching. This database makes information on chemical and related disciplines available through three related files – the Registry File for substance identification, the CA File for bibliographic searching, and the CAOLD File for reference to pre-1967 literature. CAS ONLINE is available on Scientific and Technical Information Service (STN) International by direct telephone link through most telecommunications networks. The Registry File contains information on over nine million substances reported in the literature, with over 10 000 new entries added every week. CAS registry numbers for chemical substances can be identified by searching this File using molecular formulas, substructures, or a variety of chemical dictionary terms such as chemical names or name fragments ([www.cas.org](http://www.cas.org)).

## 2.0 Toxic Substances Control Act (TSCA) Chemical Substance Inventory

The TSCA Inventory of 1985 published by the USEPA is an inventory of over 75 000 chemical substances manufactured, imported, or processed in the United States of America. The inventory consists of five volumes that can be used to identify CAS registry numbers ([www.epa.gov/region5/defs/html/tsc.htm](http://www.epa.gov/region5/defs/html/tsc.htm)).

Volume I is the list, in ascending CAS registry number, of chemical substances submitted in compliance with TSCA. It can be used if the CAS registry number for a substance is known, and the notifier wishes to verify that it represents the substance that is being reported. This verification is done by reviewing the Chemical Abstracts (CA) Index or Preferred Name associated with the CAS registry number. It must describe the substance in question precisely. A dagger (†) after the CAS registry number indicates that additional descriptive information necessary for unambiguous identification of the substance is provided in the Chemical Substance Definitions section found in Volume I; this information must be reviewed by the notifier to ensure accurate verification.

Volumes II and III are the Substance Name section of TSCA and must be used if a substance name is available. This section is an alphabetical listing of chemical names including CA Index or Preferred Names, TSCA submitted chemical names, and CAS synonyms that are associated with the corresponding CAS registry number. The notifier can examine the adjacent entries or search for a permutation of the name when a particular name is not found. Numeric and alphabetic prefixes, Roman or Greek letters or numbers used as locants, and alternate spellings (*e.g.*, sulfur and sulphur) and punctuation may affect the alphabetic sequence. The abbreviation C.I. is alphabetized as if it were expanded to *Colour Index*.

It is not uncommon for a single nonsystematic name to be associated with two or more different substances. Trademarks, trade names, and names that do not specify locants or ratios are ambiguous. When such a name is located, the notifier should look for the CAS registry number in Volume I, and review the specific CA Index or Preferred Name associated with that CAS registry number to ensure that the CAS registry number represents the substance that is to be notified.

Volume IV is the Molecular Formula section of TSCA and should be used by the notifier if the molecular formula of a substance is known. This section lists TSCA substances of known chemical constitution according to the Hill System. The notifier can review the name(s) cited below the molecular formula to find the CAS registry number for the substance to be notified. Note that when using the Molecular Formula Index, names of chemical salts and molecular addition compounds will, in most cases, be found under the molecular formula of the acid. For example, the substance name trisodium salt of phosphoric acid would be found under the molecular formula of the substance name for phosphoric acid ( $H_3PO_4$ ).

Volume V, which is the UVCB section, should be used by the notifier if a molecular formula cannot be calculated and an appropriate entry for the substance has not been located in the Name section. This Index is an alphabetic list of Subset Headings with associated CAS registry numbers and CA Preferred Names for UVCB substances. Subset Headings identify categories of closely related UVCB substances and provide a method of organizing UVCB substances into subsets containing a relatively small number of entries.

### 3.0 European Inventory of Existing Commercial Chemical Substances (EINECS)

EINECS (the Advance Edition) published by the Commission of the European Communities is an inventory of over 100 000 chemical substances that includes substances from the European Core Inventory (ECOIN) and that were declared to be on the European Community market between January 1, 1971 and September 18, 1981. This Advance Edition is divided into a Master Inventory and five supplementary Indexes (a Name Index, a Molecular Formula Index, a UVCB Index, a Definition Index, and a Plant Name Index). The Master Inventory is a list of the chemical substances in ascending order according to their EINECS Number and their CAS registry number. It also provides the chemical name, molecular formula, and substance definition, if appropriate (<http://ecb.jrc.it/existing-chemicals/>). The Name Index, the Molecular Formula Index, and the UVCB Index are similar to the corresponding indexes that were described for the TSCA Inventory.

### 4.0 The Cosmetic, Toiletry and Fragrance Association Cosmetic Ingredient Dictionary

This book, published by The Cosmetic, Toiletry and Fragrance Association, Inc. (CTFA), provides nomenclature recommendations for ingredients of formulations used by the cosmetic industry. It is an alphabetical listing of CTFA Adopted Names with associated substance information; this information includes CAS registry numbers, CTFA Recognized Disclosure Numbers, definitions, structures, and related chemical or trade names. CAS registry numbers have been included in the monographs for many of the CTFA Adopted Names and are included in a numerical listing in section VIII of this dictionary ([www.ctfa.org/](http://www.ctfa.org/)).

### 5.0 International Nonproprietary Names for Pharmaceutical Substances

This publication is a computer printout of several lists of international non-proprietary names (INN) that are published regularly in the EHO Chronicle. It includes the INN in Latin, English, French, Russian, and Spanish and references to the numbers of proposed and recommended lists in which they have been published; it also includes other data such as references to national nonproprietary names, pharmacopoeia monographs, molecular formulae, and CAS registry numbers ([www.who.int/medicines/services/inn/en](http://www.who.int/medicines/services/inn/en)).

### 6.0 Registry of Toxic Effects of Chemical Substances (RTECS)

This publication from the U.S. Department of Health and Human Services is a compendium of toxicity data extracted from the scientific literature and is prepared in compliance with the *Occupational Safety and Health Act* of 1970. The RTECS contains names of different chemicals with their associated toxicity data, synonyms, molecular formula, RTECS Number, and CAS registry number. There is a CAS registry number – RTECS Number Index that permits the reader to look up the RTECS data record of a substance when only its CAS registry number is known ([www.cdc.gov/niosh/rtecs/default.html](http://www.cdc.gov/niosh/rtecs/default.html)).

## 7.0 The Merck Index

The Merck Index published by Merck and Company Inc., is an alphabetical listing of chemicals, drugs, pesticides, and biologically active substances. The monograph for each listing contains substance data such as chemical names, drugs code numbers, literature references, toxicity data, CAS registry numbers, and generic names (<http://chemfinder.cambridgesoft.com/reference/TheMerckIndex.asp>).

## 8.0 United States Adopted Names and the United States Pharmacopeial Convention Dictionary of Drug Names

This publication by the United States Pharmacopeial Convention, Inc. is a dictionary of nonproprietary names, brand names, code designations, and CAS registry numbers for drugs. The names are listed in alphabetical order by INN ([www.usp.org/](http://www.usp.org/)).



# APPENDIX 7 — Masking of Substance Names

The procedures presented below are based on guidelines developed by the USEPA for purposes of the TSCA Inventory. They have been modified for Canadian use and are included to provide guidance to notifiers submitting an NSN package in which they wish to claim the specific substance identity as confidential. For confidentiality requests, an acceptable masked name must be submitted for publication purposes on the confidential portion of the NDSL or the DSL. The intent of masking is to disguise, only to the extent necessary, the identity of the substance. Although this appendix illustrates the masking of only a single structural feature, multiple masking is permitted if the notifier can provide justification (see section 4 below of this Appendix).

There are inherent differences between naming substances with a definite chemical structure and naming substances that cannot be depicted by a structural diagram. Each of these possibilities is addressed separately below.

## 1.0 Substances Having a Definite Chemical Structure

Substances having a definite chemical structure can be represented by a unique structure diagram. The names of substances with a distinct chemical identity normally disclose the following structural information:

- identity of parent structure (*i.e.*, a chain of carbon atoms, a ring system, or a coordinated metal);
- identity, number, and position of chemical group(s) that are attached to the parent structure(s) or to other chemical groups;
- identity and number of counter ions (for salts); and
- stereochemical relationships.

Masked names may be created for substances with a distinct chemical identity by disguising structurally descriptive segments of the specific chemical name. Masking may be accomplished by substituting non-descriptive terms for distinctive parts of the name. Proposed masked names created by eliminating stereochemical indicators (if appropriate) from the specific chemical name and by masking one other structure detail will, in most cases, be acceptable to Environment Canada.

The structurally descriptive parts of a chemical name that could be masked when creating a proposed name are:

- a locant that specifies the placement of a single chemical group;
- the locant and multiplicative prefixes (*e.g.*, di-, tri-, and tetra-) that together specify the number and placement of a given chemical group;
- the identity (but not placement and number) of a given chemical group;
- the identity of a given parent structure, and locants of a substituent chemical group; and
- the identity and multiplicative prefixes (specifying the number) of a given simple cation or anion of a salt.

Table A.7.1 lists the type of chemical groups that can be masked by name and molecular formula. The groups of atoms found in Table A7.1 are common structural units; a given group may be listed under more than one name. Each group includes at least one atom other than carbon or hydrogen.

A chemical group that includes a carbon atom having more than one single free valence (*e.g.*, carbonyl -CO-) cannot be masked if the carbon is directly attached to an acyclic carbon atom or is included within a ring system; in this circumstance, only the atom or group of atoms attached to the carbon atom can be masked (see Example 2, where the oxo group is masked).

Certain chemical groups in Table A7.1 include hydrogen atoms that are often additionally substituted, e.g., an ethyl group may be substituted for hydrogen of the sulfamyl group ( $\text{H}_2\text{NSO}_2^-$ ) to give  $\text{C}_2\text{H}_5\text{NHSO}_2^-$ . In the case of a chemical group being additionally substituted, **only** the chemical group listed in Table A7.1 should be masked, **not** the substituent.

Table A7.1 lists most of the common chemical functional groups that contain oxygen, e.g.,  $\text{H}_2\text{NCO}^-$ . Although not always listed, the Group VIa element (sulfur, selenium, and tellurium) analogs of these functional groups, e.g.,  $\text{H}_2\text{NCSe}^-$ , are considered included within Table A7.1 and, accordingly, may be used in masking.

**Table A7.1: List of Common Chemical Structural Units**

<p><b>A:</b> aldo O= amidino <math>\text{H}_2\text{NC}(=\text{NH})-</math> amino <math>\text{H}_2\text{N}-</math> (aminoamidino) <math>\text{H}_2\text{NC}(=\text{NNH}_2)-</math> or <math>\text{H}_2\text{NNHC}(=\text{NH})-</math> (aminocarbonyl) <math>\text{H}_2\text{NCO}-</math> [(aminocarbonyl)amino] <math>\text{H}_2\text{NCONH}-</math> [2-(aminocarbonyl)hydrazino] <math>\text{H}_2\text{NCONHNH}-</math> [(aminocarbonyl)hydrazono] <math>\text{H}_2\text{NCONHN}=\text{H}-</math> (aminohydrazonomethyl) <math>\text{H}_2\text{NC}(=\text{NNH}_2)-</math> [(aminohydroxymethylene) hydrazino] <math>\text{H}_2\text{NC}(\text{OH})=\text{NNH}-</math> (aminoiminomethyl) <math>\text{H}_2\text{NC}(=\text{NH})-</math> (aminoiminophosphoranyl) <math>\text{H}_2\text{NPH}(=\text{NH})-</math> (P-aminophosphinimyl) <math>\text{H}_2\text{NPH}(=\text{NH})-</math> (aminosulfinyl) <math>\text{H}_2\text{NSO}-</math> (aminosulfonyl) <math>\text{H}_2\text{NSO}_2-</math> (aminothio) <math>\text{H}_2\text{NS}-</math> (aminothioxomethyl) <math>\text{H}_2\text{NCS}-</math> ammonio <math>\text{H}_3\text{N}-</math> antimono <math>-\text{Sb}=\text{Sb}-</math> arseno <math>-\text{As}=\text{As}-</math> arsenoso OAs- arsinico HOAs(O)= arsinidene AsH= arsinidyne As= arsinimyl <math>\text{AsH}_2(=\text{NH})-</math> arsino <math>\text{AsH}_2-</math> arsinothioyl <math>\text{AsH}_2(\text{S})-</math> arsinyl <math>\text{AsH}_2(\text{O})-</math> arsinylidene <math>\text{AsH}(\text{O})=</math> arso <math>\text{O}_2\text{As}-</math> arsono <math>(\text{HO})_2\text{As}(\text{O})-</math> (arsonoxy) <math>(\text{HO})_2\text{As}(\text{O})\text{O}-</math> arsononitridyl <math>\text{AsH}(=\text{N})-</math> arsoranyl <math>\text{AsH}_4-</math> arsoranylidyne <math>\text{AsH}_2=</math> arsylene AsH= arsylidyne As= astato At- astatoxy <math>\text{O}_2\text{At}-</math> astatyl <math>\text{O}_2\text{At}-</math></p>	<p>azi <math>-\text{N}=\text{N}-</math> azido <math>\text{N}_3-</math> (azidocarbonyl) <math>\text{N}_3\text{CO}-</math> (azidofurmyl) <math>\text{N}_3\text{CO}-</math> (azidosulfonyl) <math>\text{N}_3\text{SO}_2-</math> azino <math>=\text{NN}=\text{H}-</math> azo <math>-\text{N}=\text{N}-</math> azoxy <math>-\text{N}(\text{O})=\text{N}-</math></p> <hr/> <p><b>B :</b> bismuthino <math>\text{BiH}_2-</math> bismuthylene <math>\text{BiH}=\text{H}-</math> bismuthylidyne <math>\text{Bi}=\text{H}-</math> borono <math>(\text{HO})_2\text{B}-</math> (boronoxy) <math>(\text{HO})_2\text{BO}-</math> boryl <math>\text{BH}_2-</math> borylene <math>\text{BH}=\text{H}-</math> borylidyne <math>\text{B}=\text{H}-</math> bromo Br- (bromocarbonyl) <math>\text{BrCO}-</math> (bromoiminomethyl) <math>\text{BrC}(=\text{NH})-</math> (bromosulfonyl) <math>\text{BrSO}_2-</math></p> <hr/> <p><b>C:</b> carbamido <math>\text{H}_2\text{NCONH}-</math> carbamoyl <math>\text{H}_2\text{NCO}-</math> carbamyl <math>\text{H}_2\text{NCO}-</math> carbonimidoyl <math>-\text{C}(=\text{NH})=</math> (carbonimidoylamino) <math>\text{H}_2\text{N}=\text{C}=\text{N}-</math> carbonothioyl <math>-\text{CS}-</math> carbonyl <math>-\text{CO}-</math> (carbonylidiimino) <math>-\text{NHCONH}-</math> (carbonyldioxy) <math>-\text{OC}(\text{O})\text{O}-</math> carboxy <math>\text{HO}_2\text{C}-</math> chloro Cl- (chlorocarbonyl) <math>\text{ClCO}-</math> (chloroformyl) <math>\text{ClCO}-</math> (chloroiminomethyl) <math>\text{ClC}(=\text{NH})-</math> (chlorosulfinyl) <math>\text{ClSO}-</math> (chlorosulfonyl) <math>\text{ClSO}_2-</math></p>
--	--

chlorosyl OCl-  
(chlorothio) ClS-  
chloryl O<sub>2</sub>Cl-  
cyanato NCO-  
cyano NC-

**D:**

1,2-diarsenediyl -As=As-  
diarsenyl HAS=As-  
diarsinetetrayl =AsAs=  
diarsinyl H<sub>2</sub>AsAsH-  
1,2-diazenediyl -N=N-  
diazeno HN=N-  
dialo N<sub>2</sub>=  
diazamino -NHN=N-  
diazonio N<sub>2</sub><sup>+</sup>-  
1,2-diborane(4)diylidene =BB=  
diborane(4)tetrayl =BB=  
digermanylene -GeH<sub>2</sub>GeH<sub>2</sub>-  
digermathianyl H<sub>3</sub>GeSGeH<sub>2</sub>-  
dioxy -OO-  
1,2-diphosphenediyl -P=P-  
1,2-diphosphinediyl -PPH-  
1,2-diphosphinediylidene =PP=  
diphosphinetetrayl =PP=  
diphosphinyl H<sub>2</sub>PPH-  
diselene -SeSe-  
1,2-disilanedyl -SiH<sub>2</sub>SiH<sub>2</sub>-  
disilanoxy H<sub>3</sub>SiSiH<sub>2</sub>O-  
disilanyl H<sub>3</sub>SiSiH<sub>2</sub>-  
disilanylene -SiH<sub>2</sub>SiH<sub>2</sub>-  
(disilanyloxy) H<sub>3</sub>SiSiH<sub>2</sub>O-  
(disilathianyloxy) H<sub>3</sub>SiSiH<sub>2</sub>O-  
disilazanoxy H<sub>3</sub>SiNHSiH<sub>2</sub>O-  
disilazanyl H<sub>3</sub>SiNHSiH<sub>2</sub>-  
2-disilazanyl (H<sub>3</sub>Si)<sub>2</sub>N-  
(disilazanyloxy) H<sub>3</sub>SiNHSiH<sub>2</sub>O-  
1,3-disiloxanedyl -SiH<sub>2</sub>OSiH<sub>2</sub>-  
1,3-disiloxanedylidene =SiHOSiH=  
disiloxanoxy H<sub>3</sub>SiOSiH<sub>2</sub>O-  
disiloxanylene -SiH<sub>2</sub>OSiH<sub>2</sub>-  
(disiloxanyloxy) H<sub>3</sub>SiOSiH<sub>2</sub>O-  
disilthianoxy H<sub>3</sub>SiSSiH<sub>2</sub>O-  
1,2-distannenedyl -SnH<sub>2</sub>SnH<sub>2</sub>-  
distannanylene -SnH<sub>2</sub>SnH<sub>2</sub>-  
1,3-distannathianediylidene =SnHSSnH=  
1,2-distibenedyl -Sb=Sb-  
disulfanyl -S(O)S(O)-  
dithio -SS-  
(dithiocarboxy) HSCS-  
(dithiohydroperoxy) HSS-

**E:**

epidioxy -OO-  
epidiselene -SeSe-  
epidithio -SS-  
epioxy -O-  
episelene -Se-  
epithio -S-  
epoxy -O-

**F:**

fluoro F-  
(fluorocarbonyl) FCO-  
fluoryle O<sub>2</sub>F-  
formamido HCONH-  
1,5-formazanidyle -N=NCH=NNH-  
1-formazano H<sub>2</sub>NN=CHN=N-  
5-formazano HN=NCH=NNH-  
formazanyle HN=NC(=NNH<sub>2</sub>)-  
formimidoyle HC(=NH)-  
formyle HCO-  
(formylamino) HCONH-

**G:**

germanetétrayle =Ge=  
germyle H<sub>3</sub>Ge-  
germylène H<sub>2</sub>Ge=  
germylidyne HGe≡  
guanyle H<sub>2</sub>NC(=NH)-

**H:**

hydrazi -NHNH-  
1,2-hydrazinediylidene =NN=  
hydrazino H<sub>2</sub>NNH-  
(hydrazinocarbonyl) H<sub>2</sub>NNHCO-  
(hydrazinoiminomethyl) H<sub>2</sub>NNHC(=NH)-  
(hydrazinosulfinyl) H<sub>2</sub>NNHSO-  
(hydrazinosulfonyl) H<sub>2</sub>NNHSO<sub>2</sub>-  
(hydrazinothioxomethyl) H<sub>2</sub>NNHCS-  
1-hydrazinyl-2-ylidene -NHN=  
hydrazo -NHNH-  
hydrazono H<sub>2</sub>NN=  
hydroperoxy HOO-  
(hydroperoxycarbonyl) HOOCO-  
(hydroperoxyiminomethyl) HOOC(=NH)-  
(hydroperoxysulfinyl) HOOS(=O)-  
(hydroperoxysulfonyl) HOOS(=O)<sub>2</sub>-  
(hydroperoxythioxomethyl) HOOCS-  
hydroxy HO-  
(hydroxyamino) HONH-

APPENDIX 7 —  
Masking of  
Substance Names

(hydroxyimino) HON=  
(hydroxyiminomethyl) HOC(=NH)-  
hydroxyl HO-  
(hydroxyphosphinyl) HOPH(O)-

**I:**

imidocarbonyl -C(=NH)-  
(imidocarbonylamino) HN=C=N-  
imino HN=  
(iminomercaptomethyl) HSC(=NH)-  
[imino (mercaptooxy)methyl] HSOC(=NH)-  
(iminomethyl) HN=CH-  
(iminonitrilo) -NHN=  
(iminophosphoranyl) H<sub>2</sub>P(=NH)-  
(iminosulfenomethyl) HOSC(=NH)-  
iodo I-  
(iodocarbonyl) ICO-  
iodosyl OI-  
iodyl O<sub>2</sub>I-  
isocyanato OCN-  
(isocyanatocarbonyl) OCNCO-  
(isocyanatosulfonyl) OCNSO<sub>2</sub>-  
isociano CN-  
(isocyanocarbonyl) CNCO-  
isonitro HON(O)=  
isonitroso HON=  
isosemicarbazido H<sub>2</sub>NC(OH)=NNH-  
isothiocyanato SCN-  
(isothiocyanatocarbonyl) SCNCO-  
(isothiocyanatosulfonyl) SCNSO<sub>2</sub>-  
isothiocyano SCN-

**K:**

Keto O=

**M:**

mercapto HS-  
(mercaptoamino) HSNH-  
(mercaptooxy) HSO-  
[(mercaptooxy)carbonyl] HSOCO-  
[(mercaptooxy)sulfinyl] HSOS(=O)-  
[(mercaptooxy)sulfonyl] HSOS(=O)<sub>2</sub>-  
[(mercaptooxy)thioxomethyl] HSOCs-  
(mercaptotelluro) HSTe-

**N :**

nitramino O<sub>2</sub>NNH-  
aci-nitramino HON(O)=N-  
nitrilio HN<sup>+</sup>=  
nitrilo N≡  
(nitrilofosforanyl) HP(=N)-

nitro O<sub>2</sub>N-  
acinitro HON(O)=  
(nitroamino) O<sub>2</sub>NNH-  
(aci-nitroamino) HON(O)=N-  
(nitrooxy) O<sub>2</sub>NO-  
nitroso ON-  
(nitrosoamino) ONNH-  
(nitrosoimino) ONN=  
(nitrosooxy) ONO-  
(nitrothio) O<sub>2</sub>NS-

**O:**

oximido HON=  
oxo O=  
(oxoboryl) OB-  
oxy -O-

**P:**

1,3-pentazadienyl H<sub>2</sub>NN=NN=N-  
perchloryl O<sub>3</sub>Cl-  
perselena Se=Se=  
perthio S=S=  
phosphinico HOP(O)=  
phosphinidene HO=  
phosphinidyne P=  
phosphinimyl H<sub>2</sub>P(=NH)-  
phosphino H<sub>2</sub>P-  
phosphinothioyl H<sub>2</sub>P(S)-  
phosphinothioylidene HP(S)=  
phosphinyl H<sub>2</sub>P(O)-  
phosphinylidene HP(O)=  
phosphinylidyne P(O)=  
phospho O<sub>2</sub>P-  
phosphono (HO)<sub>2</sub>P(O)-  
(phosphonocarbonyl) (HO)<sub>2</sub>P(CO)  
phosphononitridyl HP(=N)-  
(phosphonooxy) (HO)<sub>2</sub>P(O)O-  
phosphoranyl H<sub>4</sub>P-  
phosphoranylidene H<sub>3</sub>P=  
phosphoranylidyne H<sub>2</sub>P≡  
phosphoro -P=P-  
phosphorosio OP-  
plumbanetetrayl =Pb=  
plumbyl H<sub>3</sub>Pb-  
plumbylene H<sub>2</sub>Pb=  
plumbylidyne HPb=

**S:**

seleneno HOSe-  
 selenino HOSe(O)-  
 seleninoselenoyl Se=Se=  
 seleninyl OSe=  
 seleno -Se-  
 selenocyanato NCSe-  
 selenono (HO)SeO<sub>2</sub>-  
 selenonyl O<sub>2</sub>Se=  
 selenoxo Se=  
 selenyl HSe-  
 semicarbazido H<sub>2</sub>NCONHNH-  
 semicarbazono H<sub>2</sub>NCONHN=  
 silanetetrayl =Si=  
 silyl H<sub>3</sub>Si-  
 silylene H<sub>2</sub>Si=  
 silylidyne HSi≡  
 (silyloxy) H<sub>3</sub>SiO-  
 stannanetetrayl =Sn=  
 stannono HOSn(O)-  
 stannyl H<sub>3</sub>Sn-  
 stannylene H<sub>2</sub>Sn=  
 stannylidyne HSn≡  
 stibinico HOSb(O)=  
 stibino H<sub>2</sub>Sb-  
 stibo O<sub>2</sub>Sb-  
 stibono (HO)<sub>2</sub>Sb(O)-  
 (stibonooxy) (HO)<sub>2</sub>Sb(O)O-  
 stiboso OSb-  
 stibyl H<sub>2</sub>Sb-  
 stibylene HSb=  
 stibylidyne Sb≡  
 sulfamino HOSO<sub>2</sub>NH-  
 sulfamoyl H<sub>2</sub>NSO<sub>2</sub>-  
 sulfamyl H<sub>2</sub>NSO<sub>2</sub>-  
 sulfeno HOS-  
 (sulfenocarbonyl) HOSCO-  
 (sulfenosulfinyl) HOSS(=O)-  
 (sulfenosulfonyl) HOSS(=O)<sub>2</sub>-  
 (sulfenothioxomethyl) HOSCS-  
 sulphydryl HS-  
 sulfinimidoyl HN=S=  
 sulfino HOS(O)  
 (sulfinooxy) HOS(O)O-  
 sulfinothiyl S=S=  
 sulfinyl OS=  
 sulfo HO<sub>3</sub>S-  
 (sulfoamino) HOSO<sub>2</sub>NH-  
 sulfonimidoyl HN=S(O)=  
 sulfonodiimidoyl (HN=)<sub>2</sub>S=  
 sulfonyl -SO<sub>2</sub>-  
 (sulfooxy) HO<sub>3</sub>SO-  
 sulfuryl -SO<sub>2</sub>-

**T:**

telluro -Te-  
 telluroxo Te=  
 telluryl HTe-  
 1,4-tetraphosphinediyl -(PH)<sub>4</sub>-  
 1,7-tetrasiloxanediyl -SiH<sub>2</sub>(OSiH<sub>2</sub>)<sub>2</sub>OSiH<sub>2</sub>-  
 tetrathio -SSSS-  
 1,4-tetrazanediyl -(NH)<sub>4</sub>-  
 1,4-tetrazanediylidene =N(NH)<sub>2</sub>N=  
 1-tetrazenyl H<sub>2</sub>NNHN=N-  
 thio -S-  
 (thioarsenoso) S=As-  
 (thiocarbamoyl) H<sub>2</sub>NCS-  
 thiocarbamyl H<sub>2</sub>NCS-  
 (thiocarbonyl) -CS-  
 (thiocarboxy) HOSC-  
 thiocyanato NCS-  
 thiociano NCS-  
 (thioformyl) HCS-  
 thiohydroperoxy HOS- or HSO-  
 (thiohydroxy) HS-  
 (thionitroso) SN-  
 thionyl -SO-  
 (thioseleneno) HSSe-  
 (thiosulfeno) HSS-  
 (thiosulfo) (HO<sub>2</sub>S<sub>2</sub>)-  
 thioxo S=  
 (thioxoarsino) S=As-  
 (thioxomethyl) HCS-  
 thiuram H<sub>2</sub>NCS-  
 triazanyl H<sub>2</sub>NNHNH-  
 1-triazene-1,3-diyl -NHN=N-  
 1-triazenyl H<sub>2</sub>NN=N-  
 triseleno -SeSeSe-  
 1,3-trisilanediyyl -(SiH<sub>2</sub>)<sub>3</sub>-  
 1,3,5-trisiloxanetriyl -SiH(OSiH<sub>2</sub>)<sub>2</sub>-  
 trithio -SSS-

**U:**

uramino H<sub>2</sub>NCONH-  
 ureido H<sub>2</sub>NCONH-  
 ureylene -NHCONH-

## 1.1 Parent Masking

A parent structure that is a chain of carbon atoms or a ring system may be masked in the chemical name only by the following masked terms:

- alkyl **or** alkane
- alkenyl **or** alkene
- alkynyl **or** alkyne
- carbomonocyclic **or** carbomonocycle (*e.g.*, benzene, cyclopentane)
- carbopolycyclic **or** carbopolycycle (*e.g.*, naphthalene, spiroundecane)
- heteromonocyclic **or** heteromonocycle (*e.g.*, pyrrole, p-dioxane)
- heteropolycyclic **or** heteropolycycle (*e.g.*, indole, benzothiazole)

In the case of a coordinated metal compound, the identity of the metal atom may be masked by the term “metal” in the chemical name.

Only one such parent group or multiple occurrences of the **same** parent group should be masked.

The following examples show how several hypothetical compounds could be identified by names that mask only **one** structural detail (other than stereochemistry).

### 1.1.1 Example 1



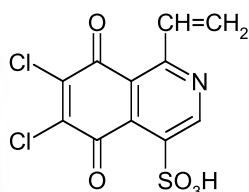
#### 1.1.1.1 Specific Substance Name

2,2,3,3,4,4,5,5,6,6,6-undecafluoro-N,N-bis(2-hydroxyethyl) hexanamide

#### 1.1.1.2 Acceptable Masked Names

- fluorine atoms masked:  
N,N-bis(2-hydroxyethyl)-2,2,3,3,4,4,5,5,6,6,6-undecahalosubstituted hexanamide
- number of fluorine atoms masked:  
polyfluoro-N,N-bis(2-hydroxyethyl)hexanamide
- hydroxyl groups masked:  
2,2,3,3,4,4,5,5,6,6,6-undecafluoro-N,N-bis(2-substituted ethyl) hexanamide
- hexane parent (plus locants) masked:  
undecafluoro-N,N-bis(2-hydroxyethyl)alkanamide
- amide group (plus nitrogen locants) masked:  
2,2,3,3,4,4,5,5,6,6,6-undecafluorobis(2-hydroxyethyl)hexane derivative

### 1.1.2 Example 2



### 1.1.2.1 Specific Substance Name

6,7-dichloro-1-ethenyl-5,8-dihydro-5,8-dioxo-4-isoquinolinesulfonic acid

### 1.1.2.2 Acceptable Masked Names

- chlorine atoms masked:  
1-ethenyl-5,8-dihydro-5,8-dioxo-6,7-dihalosubstituted-4-isoquinolinesulfonic acid
- vinyl group masked:  
1-alkenyl-6,7-dichloro-5,8-dihydro-5,8-dioxo-4-isoquinolinesulfonic acid
- oxo group masked:  
6,7-dichloro-1-ethenyl-5,8-dihydro-5,8-dihalosubstituted-4-isoquinoline sulfonic acid
- sulfo group masked:  
6,7-dichloro-1-ethenyl-5,8-dihydro-5,8-dioxo-4-substituted isoquinoline
- isoquinoline ring (plus locants) masked:  
dichloroethenyldihydrodioxo heteropolycyclic sulfonic acid or  
dichloroethenyldihydrodioxosulfo heteropolycycle

## 2.0 Substances Not Having A Definite Chemical Structure

Some substances can only be represented by partial or incomplete chemical structures; in other instances the composition can only be described in terms of a complex combination of several different known or unknown components.

The method of manufacture can also identify a substance. For a substance manufactured by a chemical reaction, identification can be stated in terms of the immediate precursor substances and other reactants that participate in the final reaction sequence used to manufacture the substance, and the nature of the reaction (*e.g.*, ethoxylation or bromination). For a substance derived from a source without chemical reaction, processing information identifies the source and method of derivation (*e.g.*, distillation, or extraction with methylene chloride).

Although the name of substances lacking a definite chemical structure may be based on variable types of information, the procedures similar to those used for substances with a definite chemical structure may be applicable.

The composition of a substance that can be represented by a partial or incomplete chemical structure diagram can generally be described by a common chemical name that encompasses the variability or incompleteness in the structure. A masked name for such a substance will usually be acceptable if the previous guidelines for substances with a definite chemical structure have been followed.

In other instances, the preferred name may identify a predominant component or components of its composition, an immediate precursor or precursors, and other reactants by specific chemical name. A proposed masked name will usually be acceptable for such a substance if it is constructed by masking the chemical name of **one** such component, precursor, or reactant.

Clearly, these guideline procedures are most useful for masking the identity of substances having a distinct chemical identity, and will only be useful for some types of substances that cannot be described with a chemical structure. In some of these latter cases, the guidelines provided may have little applicability. For consistency, notifiers must base their choice of a masked name on a CAS preferred name. The NS program will consider each such proposed masked name on a case-by-case basis.

## 2.1 Example 4

### 2.1.1 Substance Description

Linseed-oil fatty acids-fumaric acid-glycerol-maleic anhydride polymer

### 2.1.2 Specific Substance Name

Fatty acids, linseed-oil, polymers with fumaric acid, glycerol and maleic anhydride

### 2.1.3 Acceptable Masked Names

- linseed-oil masked:  
Fatty acids, polymers with fumaric acid, glycerol and maleic anhydride
- fumaric acid masked:  
Fatty acids, linseed-oil, polymers with alkenedioic acid, glycerol and maleic anhydride

## 2.2 Example 5

### 2.2.1 Substance Description

Polyethylene glycol, mono-C<sub>12-15</sub>-alkyl ethers, phosphates, potassium salts

### 2.2.2 Specific Substance Name

Poly(oxy-1,2-ethanediyl),  $\alpha$ -hydro- $\omega$ -hydroxy-, mono-C<sub>12-15</sub>-alkyl ethers, phosphates, potassium salts

### 2.2.3 Acceptable Masked Names

- potassium salts masked:  
Poly(oxy-1,2-ethanediyl),  $\alpha$ -hydro- $\omega$ -hydroxy-, mono-C<sub>12-15</sub>-alkyl ethers, phosphates, metal salts
- C<sub>12-15</sub>-alkyl group masked:  
Poly(oxy-1,2-ethanediyl),  $\alpha$ -hydro- $\omega$ -hydroxy-, monoalkyl ethers, phosphates, potassium salts
- 1,2-ethanediyl masked:  
Poly(oxyalkylenediyl),  $\alpha$ -hydro- $\omega$ -hydroxy-, mono-C<sub>12-15</sub>-alkyl ethers, phosphates, potassium salts

## 3.0 Masking of Biochemicals and Biopolymers

Biochemicals and biopolymers that do not have catalytic activity can be masked by disguising descriptive segments of the specific chemical name. Masking of more than one segment of the chemical name is considered multiple masking and would not be permitted without justification. Masking may be accomplished by substituting non-descriptive terms for distinctive parts of the chemical name. Please refer to sections 1 and 2 above.

### 3.1 Enzymatic Substances

Masked names may be created for enzymes by disguising the fourth level Enzyme Commission number description, as designated by the nomenclature committee of the IUBMB.

**Example:** substance reported:  
Cholestenone 5 $\beta$ -reductase Enzyme Commission number 1.3.1.22  
Masked name that could be proposed:  
NADP<sup>+</sup> oxidoreductase Enzyme Commission number 1.3.1



In instances where a fourth level Enzyme Commission number only consists of one entry, the NS program will accept reverting to the second level Enzyme Commission number.

**Example:** substance reported:  
6-Hydroxynicotinate reductase Enzyme Commission number 1.3.7.1  
Masked name that could be proposed:  
Acceptor oxidoreductase Enzyme Commission number 1.3

#### 4.0 Justifying the Use of Additional Masking

If strict application of these guideline procedures (*e.g.* the masking of only one single structural feature) would not adequately mask a specific substance identity, then the notifier may propose a masked name that disguises the substance identity to a greater extent. However, such additional masking must be substantiated in a written statement accompanying the notification and should be prepared in the following manner:

- a) construct each reasonably applicable masked name developed following the described procedures (*e.g.* the masking of only a single structural feature at a time);
- b) for each masked name constructed in (a), discuss the scientific rationale as to why the name is inappropriate for publication purposes. For example, the number of substances encompassed by the masked name may be very small; or, the masked name may still reveal information about the substance that in and of itself formed the basis for the confidential substance identity claim. These reasons should be clearly explained; and
- c) select a suitable masked name that disguises two aspects of the substance identity. If such double masking is still perceived as inappropriate, state the reason for rejecting each reasonably applicable doubly masked name before proceeding to propose a name that masks three or more aspects of the substance name.



# APPENDIX 8 — Examples of Waiver Conditions

The requirement to provide test data on a chemical or polymer may be waived if sufficient justification is given. Examples of conditions under which waivers may be granted by the Minister are described below. These and other conditions for accepting a waiver of information will be considered on a case-by-case basis.

## 1.0 Physical and Chemical Data

Generally applicable:

- a) if the chemical properties or physical form of the substance preclude(s) the adequate conduct of the test. The rationale should provide sound reasoning as to why it is not technically feasible or practicable to conduct the test; and
- b) if the substance cannot be isolated from the reaction medium in which it is formed and information generated on the mixture would not be meaningful for the assessment of the notified substance. Information documenting efforts to isolate the substance should be provided.

## 1.1 Examples of Justifications

### 1.1.1 Density

The substance is only stable in solution in a particular solvent and the solution density is similar to that of the solvent. In such cases, an indication of whether the solution density is higher or lower than the solvent density would be sufficient.

### 1.1.2 Vapour Pressure

The substance is unstable in the purified form.

### 1.1.3 Water Solubility

- a) The substance reacts dangerously with water (*e.g.*, liberates a poisonous gas).
- b) The substance is highly volatile; therefore, determination of water solubility is not technically feasible.
- c) The substance forms a stable emulsion in water which cannot be separated by filtration or centrifugation methods.

### 1.1.4 Partition Coefficient

- a) The substance decomposes or reacts dangerously during the performance of the test.
- b) The substance is surface active.

### 1.1.5 Adsorption-Desorption

- a) The solubility of the substance in water cannot be measured analytically; therefore, determination of adsorption is not technically feasible.
- b) The substance decomposes (*e.g.*, biodegradation or hydrolysis) or reacts dangerously during the performance of the test.

### 1.1.6 Hydrolysis as a Function of pH (Screening Portion)

- a) The substance reacts dangerously with water.

- b) The substance is a member of one or more of these groups and does not contain other functional groups that could change the hydrolysis potential of the substance:

Alcohols	Glycols
Aldehydes	Halogenated aromatics
Alkanes	Heterocyclic polycyclic aromatic hydrocarbons
Alkenes	Hydrocarbons
Alkynes	Ketones
Aromatic amines	Phenols
Aromatic nitro compounds	Polycyclic aromatic hydrocarbons
Benzenes/Biphenyls	Sulphonic acids
Carboxylic acids	
Ethers	

- c) The substance has no readily hydrolysable groups and therefore is not expected to hydrolyze.

### 1.1.7 Number-average Molecular Weight

The polymer cannot be dissolved in any solvent suitable for use in an analytical method. Information documenting the efforts to dissolve the polymer should be provided. If the polymer is soluble at >2%, a GPC should be performed and provided on the soluble portion of the polymer.

### 1.1.8 Concentration of Residual Constituents

- a) The polymer cannot be dissolved in any solvent suitable for use in an analytical method. Information documenting the efforts to dissolve the polymer should be provided.
- b) A residual constituent of the substance cannot be measured analytically; therefore, determination of its concentration is not technically feasible.

### 1.1.9 Ultraviolet-Visible Spectrum

The substance is explosive or reacts dangerously in the presence of light.

## 2.0 Ecotoxicological Data

The chemical properties or physical form of the substance preclude(s) the adequate conduct of the test. The rationale should provide sound reasoning as to why it is not technically feasible or practicable to conduct the test.

## 3.0 Health Toxicity Data

Generally applicable:

- a) if the chemical properties or physical form of the substance preclude(s) the adequate conduct of the test. The rationale should provide sound reasoning as to why it is not technically feasible or practicable to conduct the test;
- b) if the substance cannot be isolated from the reaction medium in which it is formed, and information generated on the mixture would not be meaningful for the assessment of the notified substance. Information documenting efforts to isolate the substance should be provided;

- c) if the polymer does not meet the criteria for a reduced regulatory requirement polymer solely due to the presence of the following cationic or potentially cationic groups: primary, secondary, tertiary amine groups, carbodiimides or sulphoniums. Cationic groups not specified above, including quaternary amines, hindered amines, azides, isocyanates (free and blocked) and phosphoniums will generally not be eligible for waivers of all toxicological test requirements. They may, however, be considered for waivers of certain requirements on a case-by-case basis. Polymers with an  $M_n$  of greater than 10 000 daltons will generally not be eligible for a waiver of acute and repeated dose toxicity tests if inhalation is expected to be the most significant route of exposure of the general population based on expected type of use; and
- d) if the polymer does not contain greater than 0.1% species having molecular weight less than 1000 daltons and available information (e.g. potential hydrolysis, biodegradation, toxicity) indicates that the polymer does not readily break down, and will not be biologically available.

### 3.1 Examples of Justifications

#### 3.1.1 Acute Toxicity (Oral, Dermal, or Inhalation)

- a) The substance is corrosive or highly irritating, or is expected to be corrosive or highly irritating based on consideration of factors such as pH and chemical reactivity; therefore, administration of the substance in accordance with the test protocol for the acute toxicity test would cause severe and enduring pain to the test animals.
- b) It is not technically feasible to administer known doses of the substance because of its chemical or physical properties (e.g., the substance is a gas that cannot be dissolved to a detectable level into an appropriate oral vehicle).

#### 3.1.2 Repeated Dose Toxicity (Oral, Dermal, or Inhalation)

It is not technically feasible to administer known doses of the substance because of its chemical or physical properties.

#### 3.1.3 Skin Irritation

- a) It is not technically feasible to administer the substance topically.
- b) The substance has demonstrated high acute dermal toxicity; therefore, administration of the substance in accordance with the test protocol for skin irritation would cause excessive animal deaths (e.g., >25%).

#### 3.1.4 Skin Sensitization

- a) It is not technically feasible to administer the substance topically.
- b) The substance is corrosive or highly irritating; therefore, administration of the substance in accordance with the test protocol for skin sensitization would cause severe and enduring pain to the test animals, and/or obscure any skin sensitization reaction.

#### 3.1.5 In Vitro Gene Mutation

- a) An *in vitro* mammalian chromosomal aberration assay indicates that the substance has mutagenic activity.
- b) An *in vivo* mammalian genotoxicity assay indicates that the substance has mutagenic activity.

#### 3.1.6 In Vitro Mammalian Chromosomal Abberation

- a) An *in vitro* gene mutation assay indicates that the substance has mutagenic activity.
- b) An *in vivo* mammalian genotoxicity test indicates that the substance has mutagenic activity.

#### 3.1.7 In Vivo Mammalian Mutagenicity

- a) The results of both the *in vitro* gene mutation and the *in vitro* mammalian chromosomal aberration tests indicate that the substance has no mutagenic activity in those tests.
- b) The intended use of the substance will not involve direct, repeated, or prolonged human exposure.
- c) The chemical structure of the substance, or part thereof, is not related to a known mutagen or carcinogen.



# APPENDIX 9 — International Arrangements

International arrangements are ongoing and constantly changing. The following details two currently used arrangements however it is recommended, to ensure current information, notifiers either review the NS program website at [www.ec.gc.ca/substances](http://www.ec.gc.ca/substances) or contact the NSN Information Line.

## 1.0 The Four Corners Arrangement (4CA)

The 4CA aims to achieve efficiencies of resources, for all parties, for the introduction of new substances to the North American marketplace, while continuing to protect the environment and human health. This includes, but is not limited to:

- increasing cooperation and understanding between US and Canadian governments involved in regulating new substances, notably with respect to each others' risk assessment and risk management policies and practices;
- identify and implement possible strategies for overcoming regulatory, administrative and other barriers to greater cooperation and alignment and taking appropriate actions; and
- identifying and taking appropriate actions to ensure progress toward the long term goal of greater cooperation and alignment of Canadian and US new substance regulatory schemes, for example the mutual acceptance of notifications.

A 4CA submission must be submitted to the NS program with, or after, an NSN package has been provided. At that time the information required for the 4CA submission, including the fee, is reviewed and, if accepted, a CE# is assigned to the file and an initiation letter is sent to the notifier acknowledging receipt of the 4CA submission and the fees associated to it (see Appendix 3). The notifier is advised in the initiation letter to request a Pre-manufacture Notice (PMN) filer to authorize the USEPA to send the NS program their assessment review notes. Once the information has been provided by the USEPA an acknowledgement letter is sent to the notifier indicating that the 90-day assessment period has begun. An assessment of the complete package is conducted to determine if the substance could be added to the NDSL or if specific waivers would be acceptable for some of the prescribed information requirements. A 4CA assessment outcome letter is sent to the notifier once a decision has been made. There are three possible outcomes from a 4CA submission:

- 1) approval to add to the NDSL;
- 2) acceptance of specific waivers for some data; or
- 3) not approved for either addition to the NDSL or waivers.

Additional information on the 4CA can be found in advisory notes 01-1999 and 02-2004 on our website [www.ec.gc.ca/substances/nsb/eng/ip\\_e.htm](http://www.ec.gc.ca/substances/nsb/eng/ip_e.htm).

## 2.0 The Canada-Australia Bilateral Arrangement

The cooperative arrangement between the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) of Australia and Environment Canada and Health Canada aims to achieve efficiencies of new industrial chemical notification and assessment schemes by providing greater transparency in assessments. It can also lead to possible reductions in testing and resources for new industrial chemicals and accelerate the products introduction into the marketplace for some chemicals.

This Arrangement between Canada and Australia (known as the Participants) will provide a model for the cooperation envisaged with other Organization for Economic Cooperation and Development (OECD) countries and will be consistent with the initiatives undertaken by the OECD New Chemicals Task Force. Through this work, a wealth of experience will be gained by the Participants through their collaboration on the assessment of new industrial chemical notifications that will benefit the Participants, as well as Industry notifiers, and help to advance the OECD program.

Once an NSN package has been submitted and assessed, a Canada-Australia Bilateral Arrangement form can be requested by contacting the NSN Information Line at 1-800-567-1999 (in Canada) or 819-953-7156 (outside Canada). This form allows the NS program to share the environmental and health assessments (vetted for confidential information) with NICNAS. A letter is sent by the NS program to the notifier acknowledging receipt of the Canada-Australia Information Sharing Request. NICNAS will use these assessment reports to aid in their evaluation and this may allow the notifier to be eligible for a reduction from the fees associated to a NICNAS submission.



# APPENDIX 10 — Glossary and Acronyms

## GLOSSARY

**Acceptable to the NS program** with respect to a test method, means a method that enables a sufficient quantity and quality of data to be generated for a meaningful assessment of the end-point under investigation. Important considerations of the method include the use of standards and controls; detection limits; species selected; tissues investigated; doses; adherence to GLP; validation of the method; and, statistical power of the method. (See also **Indicator of mutagenicity**).

**Act** means the *Canadian Environmental Protection Act, 1999*.

**Amphoteric polymer** means a polymer that has monomer units that are covalently bound and bear both a negative charge and a positive charge. (See also **monomer unit, polymer**.)

**Animal** includes a part of an animal, but does not include an animal or part of an animal that exists primarily as a single cell and is without the organization that characterizes tissues or organs.

**Anionic polymer** means a polymer that has one or more monomer units that are covalently bound and bear a net negative charge. (See also **monomer unit, polymer**.)

**Assessment period** means the number of calendar days before the manufacture or import of a substance exceeds a prescribed quantity, that a notifier must submit a NSN package to the NS program and also the number of calendar days that the NS program has to assess the information submitted by a notifier under the Regulations.

**Biochemical** means a chemical that is produced by a micro-organism or a protein or a nucleic acid derived from a plant or an animal. Note: dead micro-organisms are considered biochemicals.

**Biopolymer** means a polymer that is produced by a micro-organism or a protein or a nucleic acid derived from a plant or an animal. (See also **polymer**.)

**By-product** means a substance produced from a manufacturing process which is not considered the principal material.

**Canadian Agent** is used when a notifier who provides the information, under the Regulations, is not a resident in Canada, the notifier must identify, under paragraph 14(1)(b) of the Regulations, a person resident in Canada that is authorized to act on their behalf as the “Canadian Agent”. The “Canadian Agent” is required to receive any notice or correspondence that may be sent in relation to the NSN package and keep a copy of the NSN package and all correspondence and supporting data with respect to the NSN package, for the period of five years after the end of the year in which the information is provided (see section 13 of the Regulations). The “Canadian Agent” is legally responsible for complying with the Regulations.

**CAS registry number** means the identification number assigned to a substance by the Chemical Abstracts Service Division of the American Chemical Society.

**Cationic polymer** means a polymer that has one or more monomer units that are covalently bound and bear a net positive charge. (See also **monomer unit, and polymer**.)

**Chemical** means a substance that is not a polymer.

**Consumed**, in respect of a substance, means destroyed or completely converted to another substance.

**Contained**, in respect of a site-limited intermediate substance or an export-only substance, means an absolute release limit of 1 kg per day per site to the aquatic environment after wastewater treatment.

**Direct human exposure** to a substance results from direct contact with, or close proximity to, the substance during any part of its life cycle (manufacture, processing and handling, storage, transportation, use, disposal) whether knowingly or not. Direct exposure to the substance occurs by the same environmental media into which the substance was released. With respect to the Regulations, this refers to exposure of the general population in Canada. This differs from indirect human exposure, which involves exposure to the substance in a medium different from that into which the substance was released.

**Domestic Substances List (DSL)** means the list maintained by the Minister under subsection 66(1) of the Act, as amended from time to time by the Minister under subsection 66(3) or subsections 87(1) and (5) of the Act. (See also **Non-domestic Substances List**).

**Evidence that the tissue investigated was exposed to the substance or its metabolites** with respect to the *in vivo* mutagenicity test in Schedule 6 and Schedule 11 of the Regulations is necessary to determine the appropriateness of the tissue(s) investigated in assessing the *in vivo* mutagenicity of a substance, and thus the adequacy of the test. This clause indicates the need for sufficient information to support a conclusion that the tissue investigated was exposed to the test substance or its metabolites. The strength of the evidence required will be balanced with the concern of the mutagenic potential of the substance, for example: results from *in vitro* mutagenicity tests; structure; potential for exposure; tissue investigated; and test method. Examples of what may constitute evidence of tissue exposure include:

- (a) a positive result for the test endpoint in the tissue investigated;
- (b) cytotoxicity observed in the tissue investigated, *e.g.*, statistically significant reduction in the mitotic index, cell cycle delay, decrease in the ratio of polychromatic to normochromatic erythrocytes;
- (c) general organ toxicity in the tissue investigated, *e.g.*, significant change in organ weight or hyperplasia; and
- (d) data from a tissue distribution study indicating the presence of the substance or its metabolites in the tissue investigated.

**Foreign Supplier** is used when the notifier is not given access to information that is considered confidential by the supplier. The information, to support the NSN package, must be supplied directly to the NS program by the Foreign Supplier and will be identified as a “Foreign Supplier Submission”.

**Importer of Record** is considered the person importing the substance as shown on the Canadian Customs coding Form (Form B3-3) as issued by the Canada Border Services Agency.

**Impurity** means a substance whose presence with another substance is not intentional, is not necessary to the end use of the product, and does not enhance the value of the product.

**Indicator of mutagenicity** with respect to permitting an assessment of *in vitro* or *in vivo* mutagenicity means tests that are “acceptable to the NS program” for determining the *in vitro* or *in vivo* mutagenic potential of the substance. This wording is intended to permit the selection of the most appropriate test(s) for a substance, and to allow developments in the field of genotoxicity to quickly become part of a testing strategy. It is recommended that the investigator consult with NS program officials before testing to determine the acceptability of a test for that specific substance. (See also **Acceptable to the NS program**.)

**In the possession of the manufacturer or importer** means information that are in the possession of the manufacturer or importer or to which they ought to have access in the company’s offices in Canada or, if the notification was submitted by a foreign company through a “Canadian Agent”, the offices in the country where the notification originated. (See also **To which the person ought reasonably to have access**.)

**Intermediate substance** means a substance that is consumed in whole or in part in a chemical reaction used for the intentional manufacture of other substances. (See also **consumed**, **site-limited intermediate**, **transient reaction intermediate**.)

**Item** means, with respect to the new substances provisions of the Act, any manufactured item formed into a specific physical shape or design during manufacture that has, for its final use, a function or functions that depend, in whole or in part, on its shape or design.

**Masked name** means a name based on CAS, IUPAC or IUBMB nomenclature, but having one or more of the specific components identified in a manner that prevents the identification of the specific chemical structure. Masking a substance name will only be acceptable to the extent necessary to disguise the full identity of the substance, while retaining the generic molecular structure.

**Material Safety Data Sheet**, in respect of a substance, has the same meaning as in subsection 11(1) of the *Hazardous Products Act*.

**Micro-organism** means a microscopic organism that is

- (a) classified in the Bacteria, the Archaea, the Protista, which includes protozoa and algae, or the Fungi, which includes yeasts;
- (b) a virus, virus-like particle or sub viral particle;
- (c) a cultured cell of an organism not referred to in paragraph (a) or (b), other than a cell used to propagate the organisms; or
- (d) any culture other than a pure culture.

**Minister** means the Minister of the Environment; whereas, **Ministers** means the Ministers of the Environment and of Health.

**Monomer unit** means the reacted form of a monomer in a polymer. (See also **polymer**.)

**Most significant route of potential human exposure** means exposure of the general population in Canada. Consideration should be given to the expected level of the substance in the various environmental media and consumer products, and the bioavailability of the substance by ingestion, inhalation, and dermal absorption, to select the most appropriate route (oral, inhalation, dermal) for testing. The most significant route of exposure to a substance for the general population may be different from exposures for workers in an occupational setting. Consequently, data generated for occupational exposures may not meet the requirement for the most significant route of potential human exposure specified in the Regulation.

**New Substances (NS) program** consists of officials from both Environment Canada and Health Canada. Each department conducts an assessment of the information provided to the Minister in the NSN package.

**Non-domestic Substances List (NDSL)** means the list maintained by the Minister under subsection 66(2) of the Act, as amended from time to time by the Minister under subsection 66(3) or subsections 87(1) and (5) of the Act. (See also **Domestic Substances List**.)

**Non-Reduced Regulatory Requirement (non-RRR) Polymer** means one of the polymers described in section 9 of the Regulations.

**Non-Resident Importer** is a foreign company that: (a) possesses a “Canadian Importer” status; (b) has “Importer of Record” status; and (c) is importing the substance into Canada.

**NSN Package** means the information provided to the NS program that is prescribed by the Regulations.

**NSN Reference Number** means the number assigned by the NS program for all NSN packages.

**Plant** includes a part of a plant, but does not include a plant or part of a plant that exists primarily as a single cell and is without the organization that characterizes tissues or organs.

**Polymer** means a substance that consists of

- (a) molecules characterized by the sequence of one or more types of monomer units;
- (b) greater than 50% by weight of molecules having three or more monomer units that are covalently bound to one or more other monomer units or reactants;
- (c) less than 50% by weight of molecules of the same molecular weight; and
- (d) molecules distributed over a range of molecular weights whose differences in molecular weights are primarily attributable to differences in the number of monomer units.

(See also **monomer unit, reactant**.)

**Qualitative structure-activity relationship**, sometimes referred to as a “read-across estimate”, means a qualitative estimate of a property of a substance based on experimental data from other substance(s) having a closely related chemical structure. (See also **trivial structural difference**.)

**Reactant**, in respect of a polymer, means a substance that is used in the manufacture of the polymer and becomes part of its chemical composition, and includes a monomer.

**Reactive functional group** means atoms or associated group of atoms in a substance that are intended or may reasonably be expected to undergo facile chemical reaction.

**Reduced Regulatory Requirement (RRR) Polymer** means one of the polymers described in section 9 of the Regulations (see section 3.4.1.3 of these Guidelines).

**Regulations** means the *New Substances Notification Regulations (Chemicals and Polymers)* of the *Canadian Environmental Protection Act, 1999*.

**Research and Development Substance** means a substance that is undergoing systematic investigation or research, by means of experimentation or analysis other than test marketing, whose primary objective is any of the following:

- (a) to create or improve a product or process;
- (b) to determine the technical viability or performance characteristics of a product or process; or
- (c) to evaluate the substance prior to its commercialization, by pilot plant trials, production trials, including scale-up, or customer plant trials, so that technical specifications can be modified in response to the performance requirements of potential customers. (See also **test marketing**.)

**Site-limited intermediate** substance means a substance that is consumed in a chemical reaction used for the manufacture of another substance and that is

- (a) manufactured and consumed at the site of manufacture;
- (b) manufactured at one site and transported to a second site where it is consumed; or
- (c) imported and transported directly to the site where it is consumed.

**Substance**. A substance is defined in subsection 3(1) and section 80 of the Act as:

*“any distinguishable kind of organic and inorganic matter, whether animate or inanimate, and includes*

- (a) *any matter that is capable of being dispersed in the environment or of being transformed in the environment into matter that is capable of being so dispersed or that is capable of causing such transformations in the environment;*
- (b) *any element or free radical;*

- (c) *any combination of elements of a particular molecular identity that originate in nature or are the result of chemical reactions but could not practicably be formed by simply combining individual constituents; and*
- (d) *complex combinations of different molecules that originate in nature or are the result of chemical reactions but that could not practicably be formed by simply combining individual constituents.”*

But, for the purposes of the new substances provisions of the Act (section 66 and sections 80 to 89 of the Act), does not include:

- (e) *“any mixture that is a combination of substances and does not itself produce a substance that is different from the substances that were combined;*
- (f) *any manufactured item formed into a specific physical shape or design during manufacture and has, for its final use, a function or functions dependent in whole or in part on its shape or design; and,*
- (g) *any animate matter that is, or any complex mixture of different molecules that are, contained in effluents, emissions or wastes that result from any work, undertaking or activity.”*

**Test marketing**, in respect of a product, means the exploration of its market capability in a competitive situation where the creation or improvement of the product is not the primary objective. (See also **research and development substance**.)

**Toll Manufacturer** means the person who is actually producing the substance whether the activity is done on toll or otherwise for the benefit of another person.

**Transient reaction intermediate** means a substance that is formed and consumed in the course of a chemical reaction.

**To which the person ought reasonably to have access** means information in any of the company's offices worldwide, or other locations where the notifier can access the information. (See also **in the possession of the manufacturer or importer**.)

**Trigger quantity** means the quantity of substance manufactured or imported that, if exceeded, requires the notifier to provide a NSN package. For example, for a chemical on the NDSL, the trigger quantity requiring a Schedule 4 NSN package is 1 000 kg/yr.

**Trivial structural difference** means any structural variation of a substance that does not markedly alter, nor is reasonably expected to markedly alter physicochemical, biochemical, or toxicological properties.

**UVCB** is an acronym for **U**nknown or **V**ariable composition **C**omplex reaction products and **B**iological material. These materials are derived from natural sources or complex reactions and cannot be characterized in terms of constituent chemical compounds because their composition is too complex or variable. They are considered to be a single substance for notification purposes.

**LIST OF ACRONYMS**

<b>4CA</b>	Four Corners Arrangement
<b>AICS</b>	Australian Inventory of Chemical Substances
<b>ASTM</b>	American Society for Testing and Materials
<b>ATCC</b>	American Type Culture Collection
<b>CA</b>	Chemical Abstracts
<b>CAS</b>	Chemical Abstracts Service
<b>CBI</b>	Confidential Business Information
<b>CEO</b>	Contained Export-Only
<b>CEPA 1999</b>	<i>Canadian Environmental Protection Act, 1999</i>
<b>CSLI</b>	Contained Site-Limited Intermediate
<b>CTFA</b>	The Cosmetic, Toiletry and Fragrance Association
<b>DNA</b>	Deoxyribonucleic acid
<b>DSL</b>	Domestic Substances List
<b>DSN</b>	Déclaration de substances nouvelles
<b>EC</b>	Environment Canada
<b>ECOIN</b>	European Core Inventory
<b>ECL</b>	Korean – Existing Chemicals List
<b>EHO</b>	Environmental Health Organization
<b>EINECS</b>	European Inventory of Existing Commercial Chemical Substances
<b>F&amp;DA</b>	Canadian – <i>Food and Drug Act</i>
<b>FIFRA</b>	<i>Federal Insecticide Fungicide and Rodenticide Act</i>
<b>FG</b>	Functional Group
<b>FGEW</b>	Functional Group Equivalent Weight
<b>GC</b>	Gas Chromatography
<b>GLP</b>	Good Laboratory Practice
<b>GPC</b>	Gel Permeation Chromatography
<b>INN</b>	International Non-proprietary Names
<b>IR</b>	Infrared
<b>ISA</b>	Information Sharing Agreement
<b>ISO</b>	International Organization for Standardization
<b>IUPAC</b>	International Union of Pure and Applied Chemistry

<b>IUBMB</b>	International Union of Biochemistry and Molecular Biology
<b>K<sub>cat</sub></b>	Catalytic constant
<b>K<sub>m</sub></b>	Michaelis-Menten constant
<b>M<sub>n</sub></b>	Number-average Molecular Weight
<b>MSDS</b>	Material Safety Data Sheet
<b>NDSL</b>	Non-domestic Substances List
<b>NICNAS</b>	National Industrial Chemicals Notification and Assessment Scheme
<b>NMR</b>	Nuclear Magnetic Resonance
<b>Non-RRR</b>	non-Reduced Regulatory Requirement (polymer)
<b>NS</b>	New Substances
<b>NSFR</b>	<i>New Substances Fees Regulations</i>
<b>NSN</b>	New Substances Notification
<b>Regulations</b>	<i>New Substances Notification Regulations (Chemicals and Polymers)</i>
<b>OECD</b>	Organization for Economic Cooperation and Development
<b>PNC</b>	Pre-notification Consultation
<b>QSAR</b>	Quantitative Structure-Activity Relationship
<b>R&amp;D</b>	Research and Development
<b>RRR</b>	Reduced Regulatory Requirement (polymer)
<b>RTECS</b>	Registry of Toxic Effects of Chemical Substances
<b>SAR</b>	Structure-Activity Relationship
<b>SME</b>	Small and medium-size enterprise
<b>SNAc</b>	Significant New Activity (notice)
<b>SNAN</b>	Significant New Activity Notification
<b>STN</b>	Scientific and Technical Information Service
<b>TG</b>	Tests Guidelines
<b>TSCA</b>	<i>Toxic Substances Control Act</i> Inventory
<b>UN</b>	United Nations (number)
<b>USEPA</b>	United States Environmental Protection Agency
<b>UV</b>	Ultraviolet
<b>UVCB</b>	Unknown or Variable composition Complex reaction products and Biological materials





# APPENDIX 11 — Environment Canada Regional Offices

General information on the NSNR and the DSL as well as copies of both the NSN Forms are available from the Regional Offices of Environment Canada.

## For residents of Newfoundland and Labrador, Prince Edward Island, Nova Scotia, and New Brunswick:

Environmental Protection Branch – Atlantic Region  
Environment Canada  
5<sup>th</sup> Floor, Queen Square  
45 Alderney Drive  
Dartmouth NS B2Y 2N6

Telephone: 902-426-0773  
Facsimile: 902-426-3897  
E-mail: [nsn-atl@ec.gc.ca](mailto:nsn-atl@ec.gc.ca)

## For residents of Quebec:

Environmental Protection Branch – Québec Region  
Environment Canada  
105 McGill Street, 4<sup>th</sup> Floor  
Montréal QC H2Y 2E7

Telephone: 514-283-2335  
Facsimile: 514-283-5836  
E-mail: [dperrsn-nsn.quebec@ec.gc.ca](mailto:dperrsn-nsn.quebec@ec.gc.ca)

## For residents of Ontario:

Environmental Protection – Ontario  
Environment Canada  
4905 Dufferin Street  
Downsview ON M3H 5T4

Telephone: 416-739-5867  
Facsimile: 416-739-4405  
E-mail: [nsn-ontario@ec.gc.ca](mailto:nsn-ontario@ec.gc.ca)

## For residents of Manitoba, Alberta, Saskatchewan, the Northwest Territories and Nunavut:

Environmental Protection – Prairie and Northern Region  
Environment Canada  
Twin Atria #2, Room 200  
4999–98<sup>th</sup> Avenue  
Edmonton AB T6B 2X3

Telephone: 780-951-8951  
Facsimile: 780-495-2758  
E-mail: [nsn-pnr@ec.gc.ca](mailto:nsn-pnr@ec.gc.ca)

**For residents of British Columbia and the Yukon:**

Environmental Protection – Pacific and Yukon Region  
Environment Canada  
#201–401 Burrard Street  
Vancouver BC V6C 3S5

Telephone: 604-664-9100  
Facsimile: 604-666-6800  
E-mail: [nsn-pyr@ec.gc.ca](mailto:nsn-pyr@ec.gc.ca)