

*Canadian  
Environmental  
Protection Act*

**Guidelines for  
the Notification  
and Testing of  
New Substances:**

**Chemicals and  
Polymers**

**Pursuant to  
The New Substances  
Notification Regulations  
of the  
*Canadian  
Environmental  
Protection Act***

 Government of  
Canada


Gouvernement  
du Canada

TD  
196.C45 Environment  
685 Canada

Environnement  
Canada

C. 2 Health and Welfare  
Canada

Santé et Bien-être social  
Canada

**Canada**

**Please note**

When this document was first published in March 1993, the full text of the draft *New Substances Notification Regulations* was provided in Appendix A (pages 85 to 134). Since then, the Regulations have been modified and the final version has been published in the *Canada Gazette* on April 6, 1994. Consequently, Appendix A has been removed from this reprint. For more information, please call the New Substances Notification Information Line at 1-800-567-1999 or, if calling from outside Canada, at 1-819-953-7156 (fax: 1-819-953-7155).

January 1996

# **Guidelines for the Notification and Testing of New Substances:**

## **Chemicals and Polymers**

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The New Substances Notification Regulations  
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*Canadian Environmental Protection Act*

Government of Canada  
Environment Canada  
Health and Welfare Canada

March 1993

## CANADIAN CATALOGUING IN PUBLICATION DATA

Main entry under title:

Guidelines for the notification and testing of new substances: chemicals and polymers: pursuant to the new substances notification regulations of the *Canadian Environmental Protection Act*.

Issued also in French under title: Directives pour la déclaration et les essais de substances nouvelles : substances chimiques et polymères : en vertu du Règlement sur les renseignements concernant les substances nouvelles de la *Loi canadienne sur la protection de l'environnement*.

ISBN 0-662-20542-1

DSS cat. no. En49-29/2-1993E

1. Polymers -- Environmental aspects.
2. Pollution -- Environmental aspects.
3. Environmental monitoring -- Canada.
  - I. Canada. Environment Canada.
  - II. Canada. Health and Welfare Canada.
  - III. Title: Chemicals and polymers.

TD196.C45G84 1993

363.73'84

C93-099551-1

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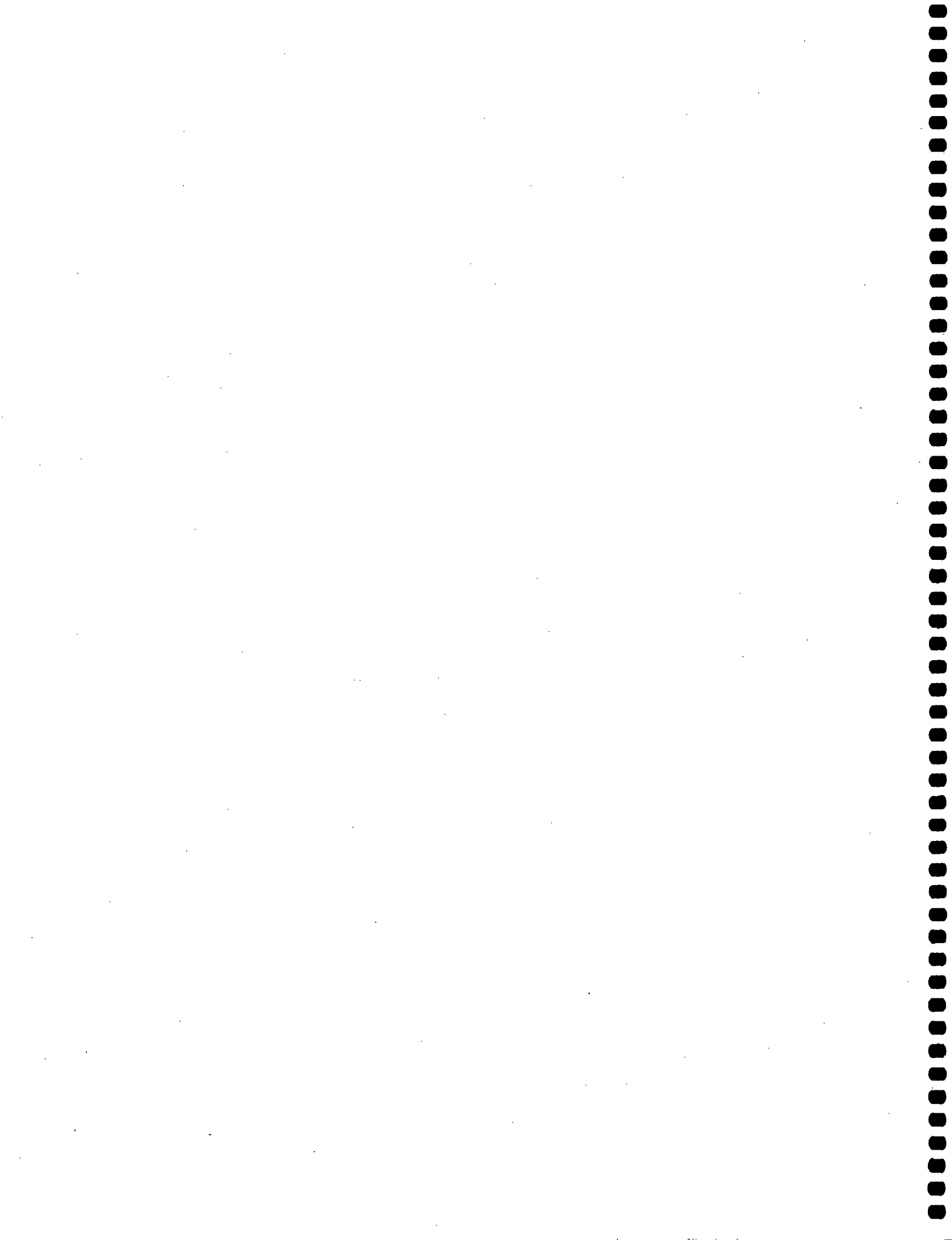
Telephone: (800) 567-1999 (toll-free in Canada)  
(819) 953-7156 (outside Canada)

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

Publications de la Protection de l'environnement  
Conservation et Protection  
Environnement Canada  
Ottawa (Ontario)  
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*Although care has been taken to ensure that these Guidelines accurately reflect requirements prescribed in the Canadian Environmental Protection Act and the New Substances Notification Regulations, notifiers are advised that, should any inconsistencies be found, the Act and the Regulations will prevail.*





## Abstract

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

These guidelines explain, in detail, how notifiers determine whether a substance is subject to notification under the New Substances Notification Regulations and identify the applicable information requirements. In addition, these guidelines provide step-by-step instructions on the completion of a New Substances Notification (NSN) Form, elaborate the technical considerations of the information requirements, identify appropriate test procedures and practices, and outline how confidential information should be treated. These guidelines conclude with an explanation of how Environment Canada and Health and Welfare Canada assess the information submitted in an NSN, and what the consequences of assessment decisions are on notifiers.

## Résumé

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Le présent document a été préparé pour aider les personnes (déclarants) responsables d'observer le *Règlement sur les renseignements concernant les substances nouvelles* de la *Loi canadienne sur la protection de l'environnement*.

Les directives expliquent en détail aux déclarants comment établir si une substance doit être déclarée aux termes du Règlement et comment déterminer les renseignements à fournir. Elles renferment aussi des instructions détaillées pour remplir la Déclaration de substance nouvelle, des précisions sur les renseignements techniques exigés, des informations sur les procédés et méthodes d'essai appropriés, ainsi qu'un aperçu du mode de traitement des renseignements confidentiels. En conclusion, on explique comment Environnement Canada et Santé et Bien-être social Canada évaluent les renseignements fournis dans la Déclaration et quelles sont les conséquences des décisions d'évaluation pour les déclarants.



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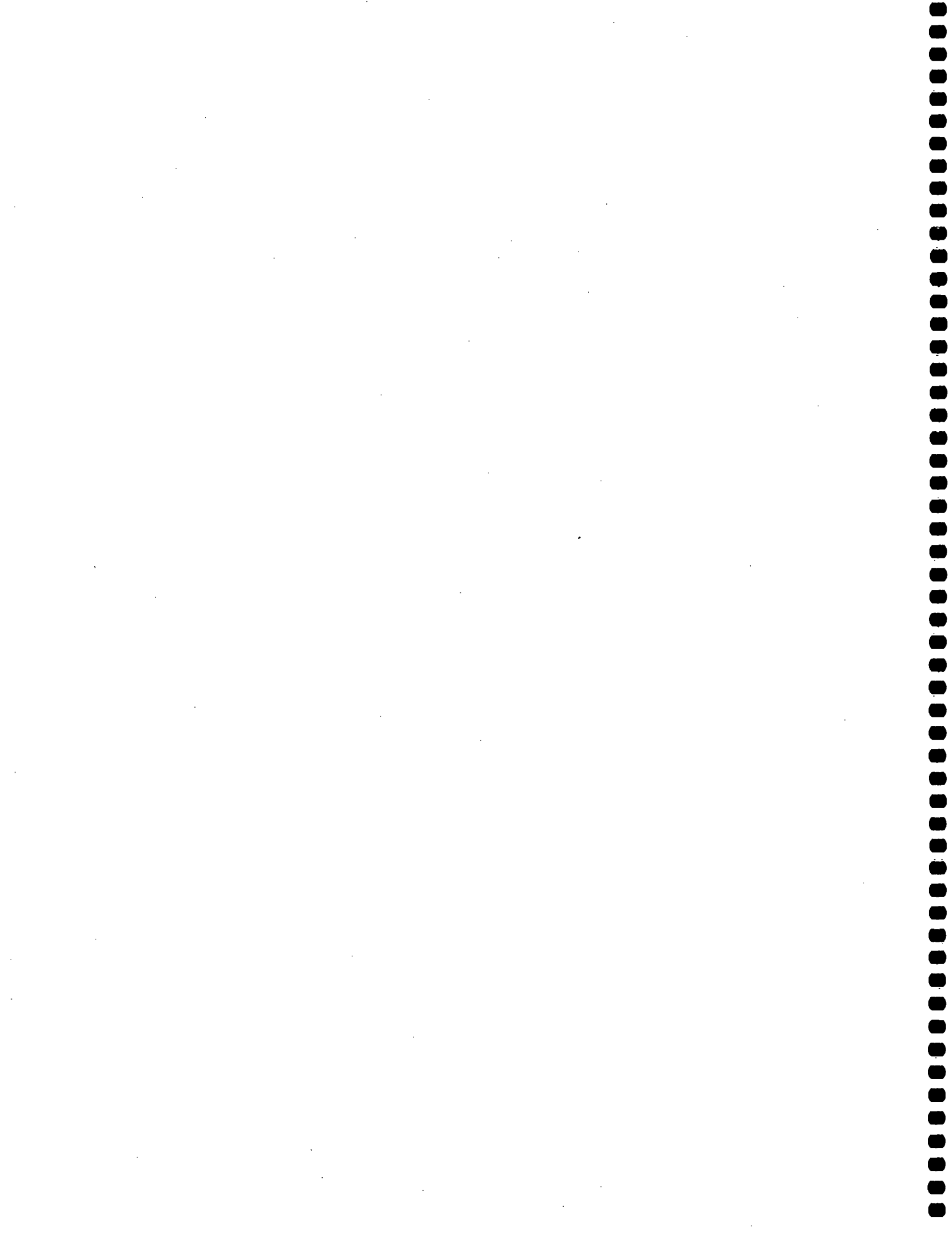
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## List of Acronyms

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ASTM . . . .	American Society for Testing and Materials
CA . . . . .	Chemical Abstracts
CAS . . . . .	Chemical Abstracts Service
CBI . . . . .	Confidential Business Information
CEC . . . . .	Commission of European Communities
CEPA . . . .	<i>Canadian Environmental Protection Act</i>
CID . . . . .	Confidential Information Disclosure
CTFA . . . .	The Cosmetic, Toiletry and Fragrance Association
DOE . . . . .	Department of the Environment
DSL . . . . .	Domestic Substances List
ECAACC . . .	Environmental Contaminants Act Amendments Consultative Committee
ECOIN . . . .	European Core Inventory
EINECS . . .	European Inventory of Existing Commercial Chemical Substances
FIFRA . . . .	<i>Federal Insecticide Fungicide and Rodenticide Act</i>
GC . . . . .	Gas Chromatography
GLP . . . . .	Good Laboratory Practice
GPC . . . . .	Gel Permeation Chromatography
HPB . . . . .	Health Protection Branch
HPLC . . . .	High Performance Liquid Chromatography
INN . . . . .	International Non-proprietary Names
IR . . . . .	Infrared
ISO . . . . .	International Standards Organization
ISA . . . . .	Information Sharing Agreement
IUPAC . . . .	International Union of Pure and Applied Chemistry
$M_n$ . . . . .	Number-average Molecular Weight
MS . . . . .	Mass Spectrometry
MSDS . . . .	Material Safety Data Sheet
$M_w$ . . . . .	Weight-average Molecular Weight
NDSL . . . . .	Non-domestic Substances List
NHW . . . . .	National Health and Welfare
NMR . . . . .	Nuclear Magnetic Resonance
NSN . . . . .	New Substances Notification
OECD . . . .	Organization for Economic Cooperation and Development
PIN . . . . .	Product Identification Number
QSAR . . . .	Quantitative Structure-Activity Relationship
RI . . . . .	Refractive Index
RTECS . . . .	Registry of Toxic Effects of Chemical Substances
SAR . . . . .	Structure-Activity Relationship
SFC . . . . .	Supercritical Fluid Chromatography
STN . . . . .	Scientific and Technical Information Service

TLC . . . . .	Thin Layer Chromatography
TSCA . . . . .	<i>Toxic Substances Control Act</i>
USAN . . . . .	United States Adopted Names
U.S. EPA . . . . .	United States Environmental Protection Agency
USP . . . . .	United States Pharmacopeial Convention
UV . . . . .	Ultraviolet
UVCB . . . . .	Unknown or Variable composition Complex reaction products and Biological materials
WHO . . . . .	World Health Organization

## How to Use these Guidelines

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These Guidelines have been prepared for the benefit of individuals responsible for complying with the information provisions of the New Substances Notification Regulations of the *Canadian Environmental Protection Act (CEPA)*. It is recommended that the entire text be read before a notification dossier is prepared. Although the complexity of the legislative provisions and accompanying regulations may appear arduous, a sequential review of the Sections will allow the reader to focus on requirements specific to their circumstance. The key to avoiding unnecessary delays or expenses when preparing a notification is to understand thoroughly the new substances notification program. These Guidelines are organized into eleven Sections:

1. **Introduction** — explains the purpose, powers, and features of the new substances program.
2. **Substances Subject to Notification** — helps to determine whether the substance to be imported or manufactured must be "notified".
3. **Information Requirements** — if the substance must be notified, this section helps identify the information that must be included in the notification dossier, and the time available to provide the information to Environment Canada.
4. **Technical Information Requirements** — describes the meaning and intent of each information requirement, and elaborates exemptions for specific data requirements.
5. **Test Procedures and Practices** — provides guidance on acceptable test methods and "alternate" information.
6. **Waiver of Information Requirements** — describes features of Subsection 26(4) of CEPA, which provides for the waiver of information requirements when one of several criteria is met.
7. **Pre-notification Consultation** — encourages consultation with government officials to resolve notification issues while the notification dossier is being prepared.
8. **Preparing a New Substances Notification** — provides instructions for completing a notification form.
9. **Confidential Information** — describes issues pertaining to confidential business information, such as confidentiality claims, masking of substance identities, and determining the presence of confidential substances on the Domestic and Non-domestic Substances List.

10. **Processing a Notification** — explains what happens after a notification is received, including how a notification is processed and reviewed, and the types of correspondence that will be sent by the government.
11. **Post-notification Responsibilities** — reviews obligations after a notification has been submitted.

Further clarification on any topic covered by these guidelines can be obtained from the New Substances Notification Information Line at (800) 567-1999 or (819) 953-7156 (outside Canada), or by facsimile at (819) 953-7155.

## Section 1

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### Introduction

These Guidelines provide detailed information on the chemical<sup>1</sup> and polymer portions of the New Substances Notification Regulations to clarify the obligations of notifiers and to assist with the preparation of notifications. Information on biotechnology products is found in the Guidelines that deal with those substances.

#### **1.1        *The Canadian Environmental Protection Act***

Because of advances in chemical technology, a substantial number of new substances enter the Canadian marketplace each year. This growth in commercial chemicals has given the government a responsibility to identify, prior to market introduction, the potential adverse effects of these new substances on human health and the environment. In 1985, the federal government established a multipartite stakeholder committee to formulate recommendations on the control of commercial chemicals in Canada. This group, known as the Environmental Contaminants Act Amendments Consultative Committee (ECAACC), included representatives from Environment Canada, Health and Welfare Canada, provincial governments, industry, non-governmental environmental interest groups, and labour. The Committee's deliberations culminated in a series of consensus recommendations published in October 1986. These recommendations were accepted by the federal government and served as the framework for the *Canadian Environmental Protection Act*, which includes provisions for the control of substances new to Canada.

#### **1.2        *Overview of New Substances Provisions Under the Canadian Environmental Protection Act***

The *Canadian Environmental Protection Act* (CEPA), promulgated on June 30, 1988, provides the federal government with authority to address pollution problems on land, in water, and through all layers of the atmosphere. As part of a "cradle to grave" management approach to toxic substances, the provisions for Substances New to Canada in CEPA are intended to ensure that no new substance is introduced into the Canadian marketplace before an assessment of its "toxicity" has been completed. Toxicity, as defined in CEPA, refers to risk to human health or the environment. Features of the new substances program include criteria for identifying "new substances", a mechanism for assessing new substances, and, when necessary, the enabling powers to implement specific controls.

The CEPA approach for the control of new substances is preventative and employs a pre-import or pre-manufacture assessment process. Substances suspected of being "toxic" may

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<sup>1</sup> "Chemicals" refers to substances other than polymers or biotechnology products.

be controlled as necessary, including prohibiting their import or manufacture. The assessment process is initiated when Environment Canada receives a new substance notification prepared by the company or individual that proposes to import or manufacture a substance. New substance notifications must contain all required administrative and technical data and must be provided to Environment Canada by a prescribed date that precedes manufacture or import. Notification information is jointly assessed by the Departments of Environment and National Health and Welfare to determine the potential adverse effects of the substance on the environment and human health. This assessment, which must be completed within a time specified by regulation, will result in:

- (a) a determination that the substance is not suspected of being toxic;
- (b) a suspicion that the substance is toxic, which may require: (i) controls on, or prohibition of, import and manufacture, or (ii) prohibition pending submission and assessment of additional information determined to be required by the Departments; or
- (c) limiting the purpose for which a substance may be used to permit the waiver of information requirements defined under Paragraph 26(4)(b) of CEPA.

The provisions for Substances New to Canada were not promulgated on June 30, 1988 with the remainder of CEPA. Their implementation was delayed until: (1) a list of substances known to have been used in Canada during a specified period could be compiled (Domestic Substances List); and (2) the notification regulations could be completed.

### ***1.3 New Substances Notification Regulations***

The statutory powers for the development of notification regulations within CEPA allowed the Departments of the Environment and of National Health and Welfare to establish a new substances assessment program that had the flexibility recommended by the ECAACC consultation process. The main regulatory features of the program are: establishment of classes of substances; identification of administrative and information requirements; timing of notification prior to import or manufacture; requirements for the Departments to assess information within a set time; and specification of conditions, test procedures, and laboratory practices to be followed when developing test data.

To meet the need for flexibility when dealing with certain classes of substances, information requirements are tiered. Consequently, substances are categorized on the basis of such factors as generic class (e.g., polymers, products of biotechnology), volume of import/manufacture, or proposed use (e.g., research and development). This system of tiered information requirements allows the Departments to match information requirements with anticipated concerns about quantities and characteristics of specific classes of substances, and to ensure suitable assessment of potential health and environmental hazards.



## Section 2

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### Substances Subject to Notification

Notification is required if the material proposed for import or manufacture is subject to the provisions of the Substances New to Canada portion of CEPA (Sections 25 to 32). Materials that require notification are: (1) "substances" as defined in the Act; (2) "new" in the context of CEPA; and (3) neither excluded nor exempted from notification as specified in Section 3 or Subsection 26(3) of CEPA.

#### 2.1 *Definition of "Substance"*

For the purposes of CEPA, "substance" has been defined in Section 3 of the Act 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 (UVCBs) and are considered a single substance for notification purposes.

#### 2.2 *Definition of "New" Substance*

The Domestic Substances List (DSL) is the sole basis for determining whether a substance is new for the purposes of CEPA. Substances on the DSL are considered to exist in Canadian commerce and do not require notification. Substances not appearing on the DSL are considered to be new to Canada and are subject to notification. The DSL includes the original list, published on January 26, 1991 as a supplement to the *Canada Gazette*, and all

additions or deletions subsequently published in the *Canada Gazette*. Substances may be included on the DSL based on either:

- (a) commercial use in Canada between January 1, 1984 and December 31, 1986 (Subsection 25(1) of CEPA); or
- (b) the government has received all the prescribed information under Section 26 of CEPA, and an assessment by the Departments has determined that no controls should be imposed and that the import or manufacture has exceeded the prescribed volumes (Section 30 of CEPA).

Information on obtaining and searching the DSL for specific substances is described in Section 3.6 of these Guidelines.

### **2.2.1 Substances Considered to be on the Domestic Substances List**

**2.2.1.1 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 present on the DSL, all hydrated forms are also considered to be present on the DSL, and thus are not notifiable substances.

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 present on the DSL. An example of a metal hydroxide is copper hydroxide,  $\text{Cu}(\text{OH})_2$ .

**2.2.1.2 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 nonmetallic elements (e.g., certain carbon steels), are considered mixtures and are not notifiable. Intermetallic compounds of well-defined stoichiometry are not considered alloys and should be notified.

**2.2.1.3 Special Categories.** Substances that can be categorized within one of the following special categories are considered to be present on the DSL and are not notifiable:

- |     |  |               |
|-----|--|---------------|
| (a) | Glass, oxide, chemicals                | [65997-17-3*] |
| (b) | Frits, chemicals                       | [65997-18-4*] |
| (c) | Ceramic materials and wares, chemicals | [66402-68-4*] |
| (d) | Steel manufacture, chemicals           | [65997-19-5*] |
| (e) | Cement, alumina, chemicals             | [65997-16-2*] |
| (f) | Cement, portland, chemicals            | [65997-15-1*] |

Definitions of these categories are found in their respective DSL listing or can be obtained by contacting the NSN Information Line at:

(800) 567-1999 (within Canada) or  
(819) 953-7156 (outside Canada).

**2.2.1.4 Substances Occurring in Nature.** Substances occurring in nature are considered to be on the DSL, although they may not be listed individually. These substances are defined as naturally occurring, and are: 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.

## **2.3 Substances not Subject to the New Substances Provisions of the Canadian Environmental Protection Act**

### **2.3.1 Exclusions from the Definition of a Substance**

For the purposes of the Substances New to Canada portion of CEPA, limitations on the statutory definition of "substance" are imposed under Section 3 of CEPA. Substances described by the following definitions are not subject to the New Substances provisions of CEPA and are therefore excluded from notification.

**2.3.1.1 "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 deliberately prepared formulations, or reaction mixtures that are fully characterized in terms of constituent substances (except for minor impurities) are not considered substances and, consequently, not candidates for notification. Examples include paints and coatings, blended fuels, and solvent mixtures. However, if any constituent of a mixture is a new substance, that constituent is considered to be a notifiable substance.

Mixtures derived from natural sources or complex reactions that cannot be characterized because their composition is too complex or variable (i.e., UVCBs) are considered single substances and are subject to notification.

**2.3.1.2 "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".** Materials that meet the above criteria for a manufactured item will possess a definite shape or design necessary to its final function.

Shape describes the macrostructure, i.e., the physical three-dimensional structure of the final item. Items whose end use depends on final manufactured shape include clothing, storage containers, furniture, tiles, and electrical wire. 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:

- (a) 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 and yarns; and dyed fabrics); or
- (b) 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 and ink in pens, stamp pads, and typewriter ribbons).

**2.3.1.3** *"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 subsequently used as a commercial product, it will be considered a notifiable substance and, if not listed on the DSL, will be subject to the notification regulations.

### **2.3.2** *New Substances Not Requiring Notification*

Subsection 26(3) of CEPA establishes criteria for new substances that do not require notification. Substances described in this section are not subject to the New Substances Notification Regulations.

**2.3.2.1** *"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 prior to the manufacture, import or sale of the substance and for an assessment of whether it is toxic"*. Chemical and polymer substances excluded from notification under the New Substances

Notification Regulations include compounds under the jurisdiction of the following Federal Acts:

- (a) the *Pest Control Products Act*;
- (b) the *Food and Drugs Act*;
- (c) the *Atomic Energy Control Act*;
- (d) the *Fertilizer Act*; or
- (e) the *Feeds Act*.

Specific categories of substances that are encompassed by these Acts are described below. This list of legislation and the specific categories that are described are not intended to be all inclusive. To determine whether this provision applies to circumstances not described in this section, the notifier should contact the NSN Information Line.

***Pest Control Products Act.*** This Act defines a pesticide or "control product" as:

*"any product, device, organism, substance or thing that is manufactured, represented, sold or used as a means for preventing, destroying, mitigating, attracting or repelling any pest, and includes:*

- (a) *any compound or substance that enhances or modifies or is intended to modify the physical or chemical characteristics of a control product to which it is added, and*
- (b) *any active ingredient used for the manufacture of a control product."*

Therefore, all components of a pesticide formulation (e.g., active ingredients, emulsifiers, carriers, and solvents) are subject to the *Pest Control Products Act* and its Regulations. These substances are exempt from the New Substances Notification Regulations regardless of whether the component is imported in a pesticide formulation or imported or manufactured as a single substance, provided that its use in a pesticide formulation is the only use for that substance in Canada.

A constituent used solely to control the growth of unwanted organisms in an imported non-pesticidal formulation does not meet the definition of a "pest control product" and is subject to the New Substances provisions of CEPA.

***Food and Drugs Act.*** Substances imported into, manufactured, sold, used, or represented as foods, cosmetics, and drugs in Canada are subject to the provisions of the *Food and Drugs Act* and its Regulations.

- (a) *Foods: "includes any article manufactured, sold or represented for use as a food or drink for man, chewing gum, and any ingredient that may be mixed with food for any purpose whatever".*

Substances noted in the 15 tables of Division B.16 and the single table of Division D.03 of "Departmental Consolidation of the Food and Drugs Act and of the Food and Drugs Regulations" (Department of Supply and Services, Ottawa, Report H41-1-1988E) are considered to be reported pursuant to the *Food and Drugs Act*. These substances should not be notified under the New Substances Notification Regulations if they have no commercial use other than as a food or food additive.

- (b) Cosmetics: *"includes any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth, and includes deodorants and perfumes"*.

Substances that are constituents of cosmetic products and have been or will be reported pursuant to the *Food and Drugs Act* should not be notified under the New Substances Notification Regulations if they have no other commercial use.

- (c) Drugs: *"includes any substance or mixture of substances, manufactured, sold, or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or the symptoms thereof, in man or animal, restoring, correcting or modifying organic functions in man or animal, or disinfection in premises in which food is manufactured, prepared or kept"*.

The medicinal ingredients (active substances) described in Appendix E of the "Canadian Drug Identification Code" (Department of Supply and Services, Ottawa, Report H42-1/1-1987) are considered to be reported pursuant to the *Food and Drugs Act*. These medicinal ingredients should not be notified under the New Substances Notification Regulations if they have no other commercial use.

Substances manufactured in Canada solely for use as a pharmaceutical in a foreign country, do not meet the definition of "drug" under the *Food and Drug Act* and are subject to the New Substances provisions of CEPA.

**Atomic Energy Control Act.** Substances imported into, exported from, prospected for, mined, refined, produced, used, sold, or possessed for any purpose whatever in Canada, and designated as being capable of releasing atomic energy, or as being requisite for the production, use, or application of atomic energy in Canada, are subject to the licensing provisions of the *Atomic Energy Control Act* and its Regulations. These substances include uranium, thorium, plutonium, neptunium, deuterium, and their respective derivatives and compounds and any other substances designated by regulation.

**Fertilizer Act.** Substances imported into, sold, offered, exposed or possessed for sale, or distributed in Canada and represented as fertilizers or supplements to promote plant growth are subject to the registration provisions of the *Fertilizers Act* and its Regulations. Fertilizers are defined as substances or mixtures of substances containing nitrogen, phosphorus, potassium, or other plant food, manufactured, sold, or represented for use as a plant nutrient.

Supplements include substances or mixtures of substances, other than a fertilizer, that are manufactured, sold, or represented for use to improve the physical condition of soils or to aid plant growth or crop yields.

**Feeds Act.** Substances imported into, manufactured, sold, offered, exposed or possessed for sale, or distributed in Canada and represented as feeds for consumption by livestock, for providing the nutritional requirements of livestock, and for preventing or correcting nutritional disorders in livestock are subject to the registration provisions of the *Feeds Act* and its Regulations.

**Precursor Materials and New Uses for Substances Subject to Other Acts of Parliament.** Substances manufactured or imported for use as a chemical precursor in the manufacture of substances regulated by these Acts are subject to the New Substances Notification Regulations. Precursors include starting materials and isolated reaction intermediates, but do not include constituents (e.g., solvents, binding agents, and emulsifiers) of formulations assessed under another Act of Parliament.

Substances addressed by these Acts are subject to notification if used in applications other than those regulated by these Acts. In these instances, CEPA notification is required before manufacture or import commences for the new use.

**2.3.2.2 "Transient reaction intermediates that are not isolated and are not likely to be released into the environment".** 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 (i.e., 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.

Companies 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". This information only needs to be retained while the company is actively manufacturing the transient reaction intermediate substance.



**2.3.2.3** *"Impurities, contaminants and partially unreacted materials the formation of which is related to the preparation of a substance"*. 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 commercial value of the substance.

**2.3.2.4** *"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"*. Examples of incidental reaction products include substances formed from chemical reactions during:

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

**2.3.2.5** *"A substance that is manufactured or imported in a quantity that does not exceed the maximum quantity prescribed as exempt from this section (Section 26 of CEPA)"*. Substances manufactured or imported in quantities that do not exceed the minimum notification quantities do not require notification. The specific minimum notification quantities for each information schedule can be found in Section 3 of these Guidelines.

### **2.3.3** *Substances Carried through Canada*

The New Substances Notifications Regulations do not apply to a substance that is loaded on a carrier outside Canada and moved through Canada to a point outside Canada. This exclusion applies even if 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 notification requirements.

#### 2.3.4 *Polymers Subject to the "Two Percent Rule"*

A polymer, manufactured by modifying the formulation of a polymer specified on the DSL by adding reactants, none of which constitutes more than two percent by weight of the polymer, is exempt from notification. 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.

#### 2.4 *Notifiable Transitional Substances*

Substances not listed on the DSL, and manufactured or imported in a quantity greater than 20 kg in any calendar year during the transitional period (between January 1, 1987 and the implementation date of Subsection 26(1) of CEPA), are subject to the transitional provisions of Subsection 26(2). Subsection 26(2) allows the manufacture or import of these "transitional substances" to continue after Subsection 26(1) is in force, if the prescribed information is provided to Environment Canada before a prescribed date.

### *Section 3*

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## **Information Requirements**

Subsections 26(1) and 26(2) of CEPA prohibit the import or manufacture of any substance not listed on the DSL unless the prescribed information is provided within the prescribed time, and the period for assessing the information has expired. The prescribed information specified in the New Substances Notification Regulations (Appendix 1) consists of both technical and administrative information (described in Sections 4 and 8, respectively).

The New Substances Notification Regulations provide a tiered approach to notification that links information requirements to factors such as quantity, use, intrinsic properties, and chemical class. This section will help identify both the technical information necessary to comply with the Regulations and the date before which notifications must be submitted to Environment Canada.

### **3.1            *Classification of Substances***

For the purposes of the New Substances Notification Regulations, new substances are grouped into three major classes, each subject to their own specific information requirements. These classes are non-polymeric chemicals (referred to in these Guidelines as chemicals), polymers, and biotechnology products.

#### **3.1.1            *Chemicals***

The information requirements for chemicals are prescribed in Part I of the Regulations and apply to all substances that are neither polymers nor products of biotechnology except for biotechnology products derived from a whole plant or animal or from parts of a whole plant or animal. Cell cultures are not considered to be part of a whole plant or animal; therefore, products derived from cell cultures are subject to the Biotechnology portion of the Regulations.

#### **3.1.2            *Polymers***

The information requirements for polymers are prescribed in Part II of the Regulations and apply to substances consisting of:

- (a) molecules characterized by the sequence of one or more types of monomer units;
- (b) a simple weight majority (> 50% by weight) of molecules containing at least three monomer units covalently bound to at least one other monomer unit or reactant;
- (c) less than a simple weight majority of molecules of the same molecular weight; and

- (d) molecules distributed over a range of molecular weights, and differences in the molecular weights are primarily attributable to differences in the number of monomer units.

Part II of the Regulations does not apply to polymers produced through the application of biotechnology, except for polymers derived from a whole plant or animal or from parts of a whole plant or animal. Cell cultures are not considered to be part of a whole plant or animal; therefore, products derived from cell cultures are subject to the Biotechnology portion of the Regulations.

A polymer manufactured by modifying the formulation of a polymer specified on the DSL by adding reactants, none of which constitutes more than two percent by weight of the polymer, is exempt from notification. 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.

### **3.1.3 *Biotechnology Products***

The biotechnology products portion of the Regulations addresses microorganisms, parts of microorganisms, and substances produced by microorganisms or cell cultures. Notification Regulations for biotechnology products are being developed and published separately.

Products of microorganisms or cell cultures (i.e., biochemicals and biopolymers) are subject to information requirements similar to those for chemicals and polymers. These requirements will be prescribed in the Biotechnology Regulations and guidelines accompanying those Regulations.

## **3.2 *How to Identify the Required Notification Information***

These guidelines deal only with information requirements of the chemical and polymer portions of the Regulations.

### **3.2.1 *Chemicals***

The New Substances Notification Regulations prescribe information requirements tailored to the use and quantity of the chemical. These requirements are specified in the schedules in Appendix 1. Decision flowcharts are provided in Subsection 3.2.1.5 to help select the appropriate schedule.

Before using the flowcharts, Subsections 3.2.1.1 to 3.2.1.4 should be reviewed to determine:

- (a) whether the chemical exists on the Non-domestic Substances List (NDSL);
- (b) whether the substance meets the criteria for a transitional substance;

- (c) whether the chemical falls within any of the prescribed special categories; and
- (d) an estimate of the yearly and cumulative manufacture or import quantities.

**3.2.1.1 Chemicals on the Non-domestic Substances List.** The Non-domestic Substances List (NDSL) specifies substances that are not on the DSL but are believed to be in international commerce. As a basis for this list, Environment Canada chose the United States *Toxic Substances Control Act* (TSCA) Inventory of 1985, which lists more than 58 000 substances as representative of substances in international commerce. The NDSL, published on January 26, 1991, consisted of the 1985 version of the TSCA list minus the substances on the DSL. Substances listed on the NDSL require less detailed notification packages for assessment than substances that are new to both the Canadian marketplace and world commerce.

The NDSL also contains a listing of confidential substances that originated from the confidential part of the TSCA inventory. These substances were listed on the confidential NDSL only if the nominating company could demonstrate that the substance existed on the confidential TSCA inventory. Procedures for determining the presence of confidential substances on the NDSL and the DSL are described in Section 9.3 of these Guidelines.

**Updates to the NDSL.** Beginning in 1995, the NDSL will undergo an annual revision that will add or delete all substances incorporated into, or removed from, the TSCA inventory five or more years before the date of the NDSL revision. The first NDSL update will therefore include substances in the 1990 supplement of the TSCA inventory.

All additions to the NDSL will remain as inactive entries (i.e., will not be deemed NDSL entries) unless information has been provided to satisfy the following criteria:

- (a) the substance is in commerce in the United States;
- (b) the proposed uses in Canada are consistent with use patterns in the United States;
- (c) there are no known adverse health or environmental effects related to the use of the substance in the United States; and
- (d) there are no controls under TSCA governing the manufacture, import, or use of the substance in the United States.

All additions to the original NDSL will be "flagged" to indicate their inactive status. After receipt and acceptance of information that satisfies these criteria, the "flag" will be removed in the next supplement of the NDSL published in the *Canada Gazette*. Publication of NDSL supplements will occur as frequently as every week. However, if the required information is supplied well in advance of an annual update, the substance will automatically appear as an active entry in the NDSL update.

Substances can be listed on the confidential NDSL only if the nominating company can demonstrate that the substance exists on the confidential TSCA inventory. Instructions for nominating substances to the confidential NDSL are on the back of the Domestic Substances List Report Form C, which can be obtained through the New Substances Notification (NSN) Information Line (see Section 3.5 of these Guidelines).

**3.2.1.2 Transitional Chemicals.** Chemicals, not listed on the DSL, that were manufactured or imported in a quantity greater than 20 kg in any calendar year during the transitional period (between January 1, 1987 and the implementation date of Subsection 26(1) of CEPA) are defined as transitional chemicals. The information requirements and notification time periods for transitional chemicals vary depending on when "trigger quantities" (see Appendix 8) were exceeded. The prescribed dates for notifying transitional substances are described in Section 3.3 of these Guidelines.

If a trigger quantity was exceeded during the transitional period, then the notifier is subject to the transitional provisions of Subsection 26(2) of CEPA. Subsection 26(2) allows the manufacture or import of transitional chemicals to continue after Subsection 26(1) comes into force, if the prescribed information is provided to Environment Canada before a prescribed date. However, notification is not necessary if the manufacture or import of the transitional substance was discontinued before the end of the transitional period.

If a transitional chemical exceeds a trigger quantity after the implementation date of Subsection 26(1) of CEPA, the substance will be subject to the provisions of Subsection 26(1). For these substances, notifications must be submitted before the trigger quantity is exceeded (refer to Section 3.3 of these Guidelines). Notifiers of transitional chemicals, which exceed a trigger quantity within five years of the implementation date of Subsection 26(1) of CEPA, need only provide information requirements identical to the information requirements of Subsection 26(2). However, when a trigger quantity for a transitional chemical is exceeded after this five-year period, the substance will be subject to requirements similar to those for non-transitional chemicals, unless the notifier has provided the most comprehensive information package for transitional chemicals (i.e., Schedule II) before the end of the five-year period.

**3.2.1.3 Special Categories of Chemicals**

**Research and Development.** Research and development chemicals are chemicals that are the subject of systematic investigation or search (by means of experimentation or analysis, or both) that has as its primary objective the creation or improvement of a product. This category includes chemicals being manufactured on toll for domestic or foreign customers that are conducting research.

**Product Development.** Product development chemicals are research and development chemicals evaluated before full commercialization using pilot plants, production trials, or customer trials in one program that is two years or less in length. The intent of this activity is to modify technical specifications in response to performance requirements of potential

customers; however, test marketing is not included. This category includes chemicals being manufactured on toll for domestic or foreign customers that are conducting research.

**Export Only.** This category is limited to chemicals imported into, or manufactured in, Canada and destined solely for foreign markets.

**Site-limited Intermediates.** An intermediate chemical is a chemical that is consumed, in whole or in part, in a chemical reaction used for the intentional manufacture of another substance. A site-limited intermediate is defined in the Regulations as an intermediate:

- (a) not exceeding an accumulated quantity of 50 000 kg; and
- (b) at any one time, the combined inventory of the chemical:
  - (1) manufactured for the purpose of being consumed on the site of manufacture;
  - (2) manufactured at one site in Canada and then transported to a second site in Canada where it is consumed; or
  - (3) imported and transported directly to one site where it is consumed, does not exceed 10 000 kg.

"Consumed" in this case implies that the reaction has proceeded to the point where no further conversion of the substance is likely under the reaction conditions, i.e., some of the site-limited substance may remain as a minor impurity in the final product.

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

Chemicals that are a direct precursor in the manufacture of an item defined in Subsection 2.3.1.2 of these Guidelines are not considered site-limited intermediates, 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" (Subsection 2.3.2.2), it would not be subject to notification.

**3.2.1.4 Annual and Accumulated Quantities.** The notifier must develop an accurate estimate of the annual (calendar year) quantities and the accumulated total amount of the new chemical imported and/or manufactured. This information is needed to ensure that additional information requirements are submitted before higher "trigger" quantities are reached. The prescribed trigger quantities relate to the actual amount of chemical manufactured and imported, not to the quantity of formulation containing the chemical. For example, if 10 000 kg of Formulation A, which contains 13% of new chemical X is to be imported during a calendar year, then the annual import quantity of chemical X would be 1 300 kg. Repetition of this yearly 1 300 kg transaction over eight years would result in an accumulated total of 10 400 kg.



For transitional chemicals, the quantities are calculated from the date the notifier first manufactured the chemical in Canada, or first imported the chemical into Canada, after December 31, 1986.

**3.2.1.5 Decision Schemes.** The decision schemes shown in Figures 1 to 6 can be used to determine the required schedule of information for chemicals. The dates before which the information requirements must be provided are given in Section 3.3 of these Guidelines.

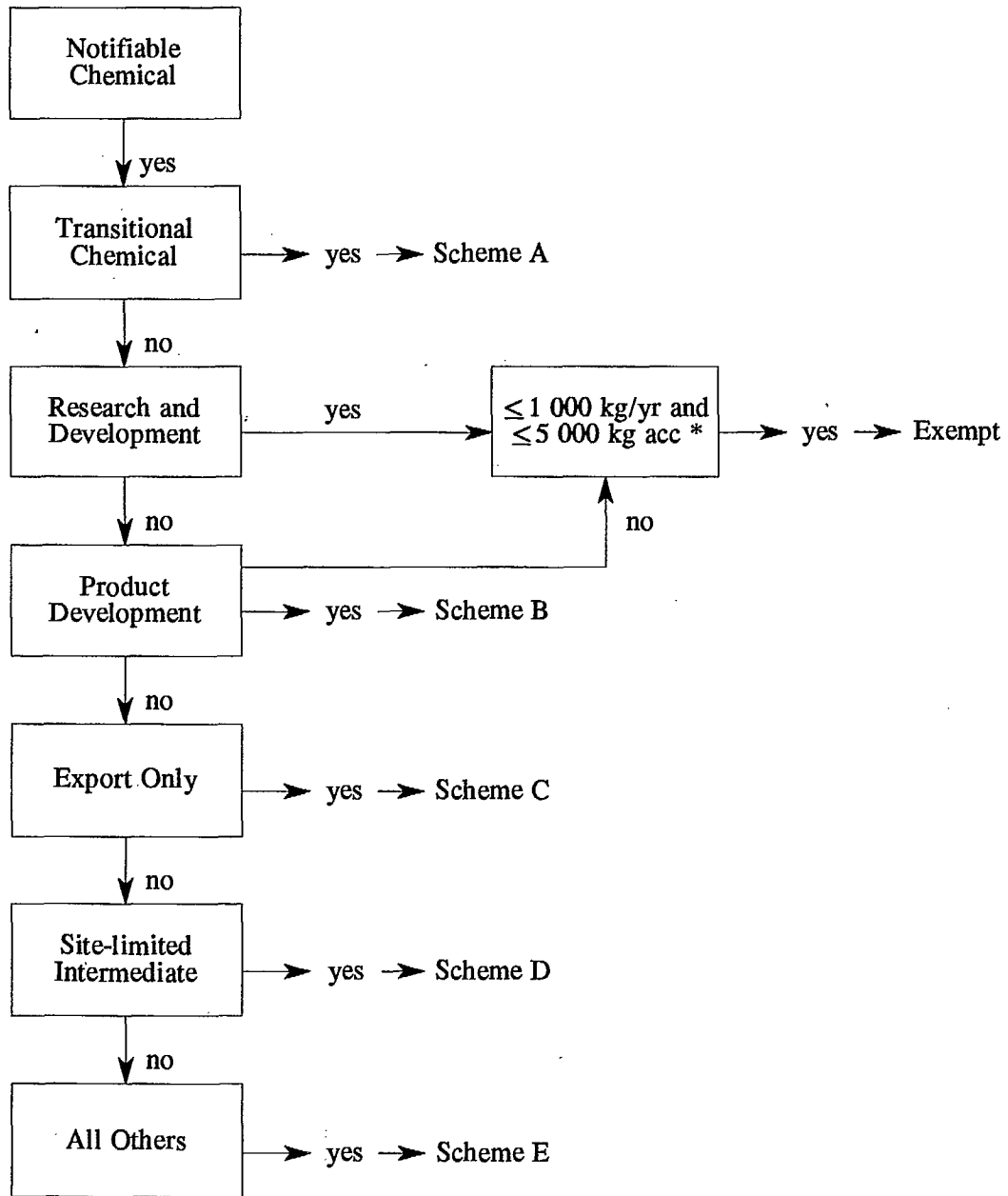
### 3.2.2 Polymers

The New Substances Notification Regulations prescribe information requirements tailored to the type, use, and quantity of the polymer. These requirements are specified in schedules found in Appendix 1. A decision flowchart is provided in Subsection 3.2.2.7 to help select the appropriate schedule. Before using the flowchart, Subsections 3.2.2.1 to 3.2.2.6 should be reviewed to determine:

- (a) whether the substance meets the definition of a polymer given in the Regulations (refer to Section 3.1 of these Guidelines);
- (b) whether the substance meets the criteria for a transitional substance;
- (c) whether the polymer is listed on the NDSL;
- (d) whether or not each monomer and reactant appears on the NDSL or the DSL;
- (e) whether the polymer meets the criteria for a low-concern polymer;
- (f) whether the polymer falls within any of the prescribed special categories; and
- (g) an estimate of the yearly and cumulative manufacture or import quantities.

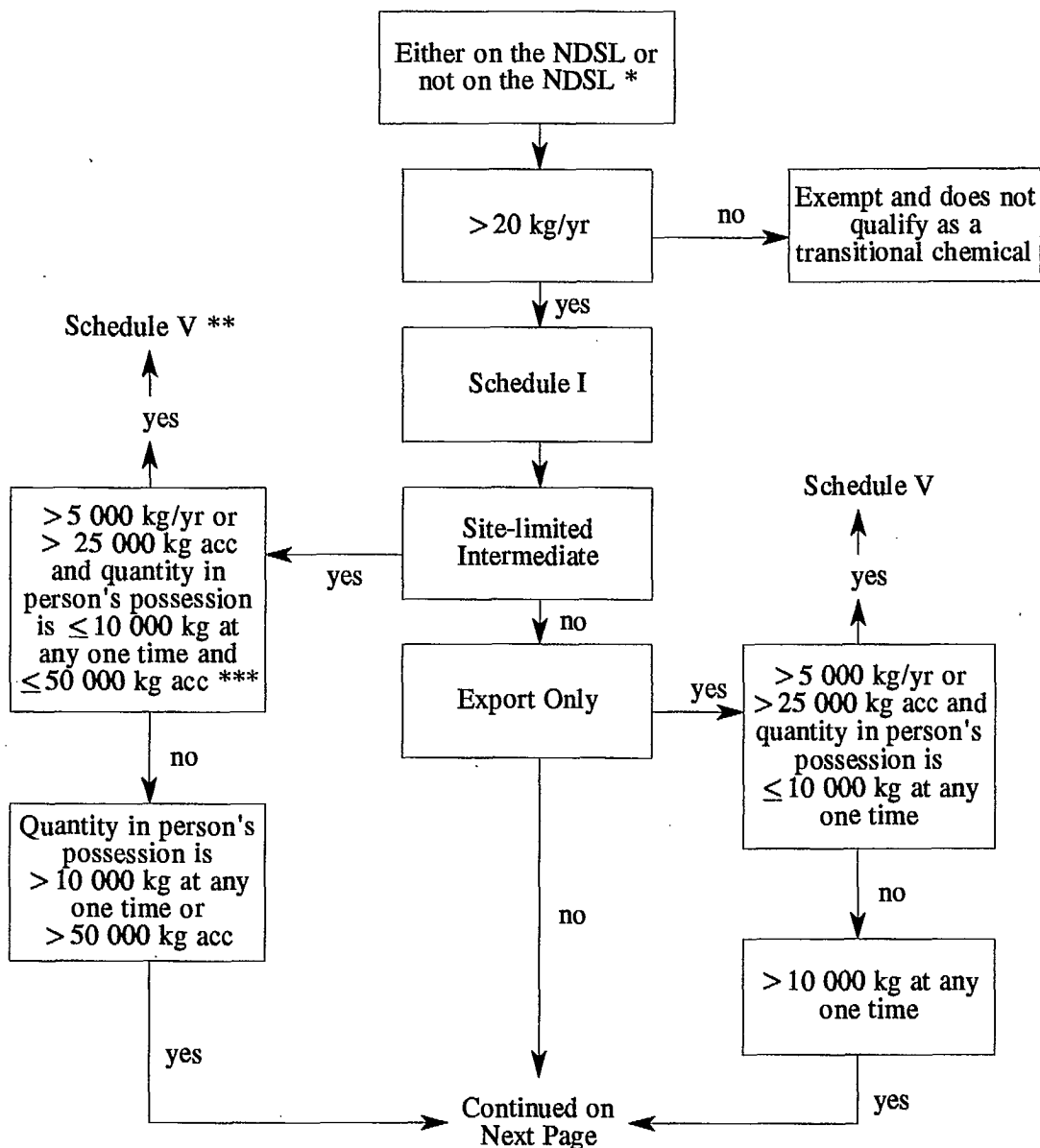
**3.2.2.1 Polymers on the Non-domestic Substances List.** The Non-domestic Substances List (NDSL) specifies substances that are not on the DSL but are believed to be in international commerce. As a basis for this list, Environment Canada chose the United States *Toxic Substances Control Act* (TSCA) Inventory of 1985, which lists more than 58 000 substances as representative of substances in international commerce. The NDSL, published on January 26, 1991, consisted of the 1985 version of the TSCA list minus the substances on the DSL. Substances listed on the NDSL require less detailed notification packages for assessment than substances that are new to both the Canadian marketplace and world commerce.

The NDSL also contains a listing of confidential substances that originated from the confidential part of the TSCA inventory. These substances were listed on the confidential NDSL only if the nominating company could demonstrate that the substance existed on the



\*acc = accumulated total

Figure 1 Notification Requirements for New Chemicals



\*When notification of the most comprehensive transitional information package (i.e., Schedule II for chemicals) is received during the five-year post-transitional period, no additional notification obligations will be imposed even if a non-NDSL substance exceeds a Schedule III trigger quantity after the five-year period expires.

\*\*Site-limited intermediates that are not transported off-site are exempt from hydrolysis, ready biodegradability, and acute mammalian toxicity requirements (items 3 and 4 of Schedule V).

\*\*\*acc = accumulated total.

Figure 2 Scheme A: Transitional Chemicals

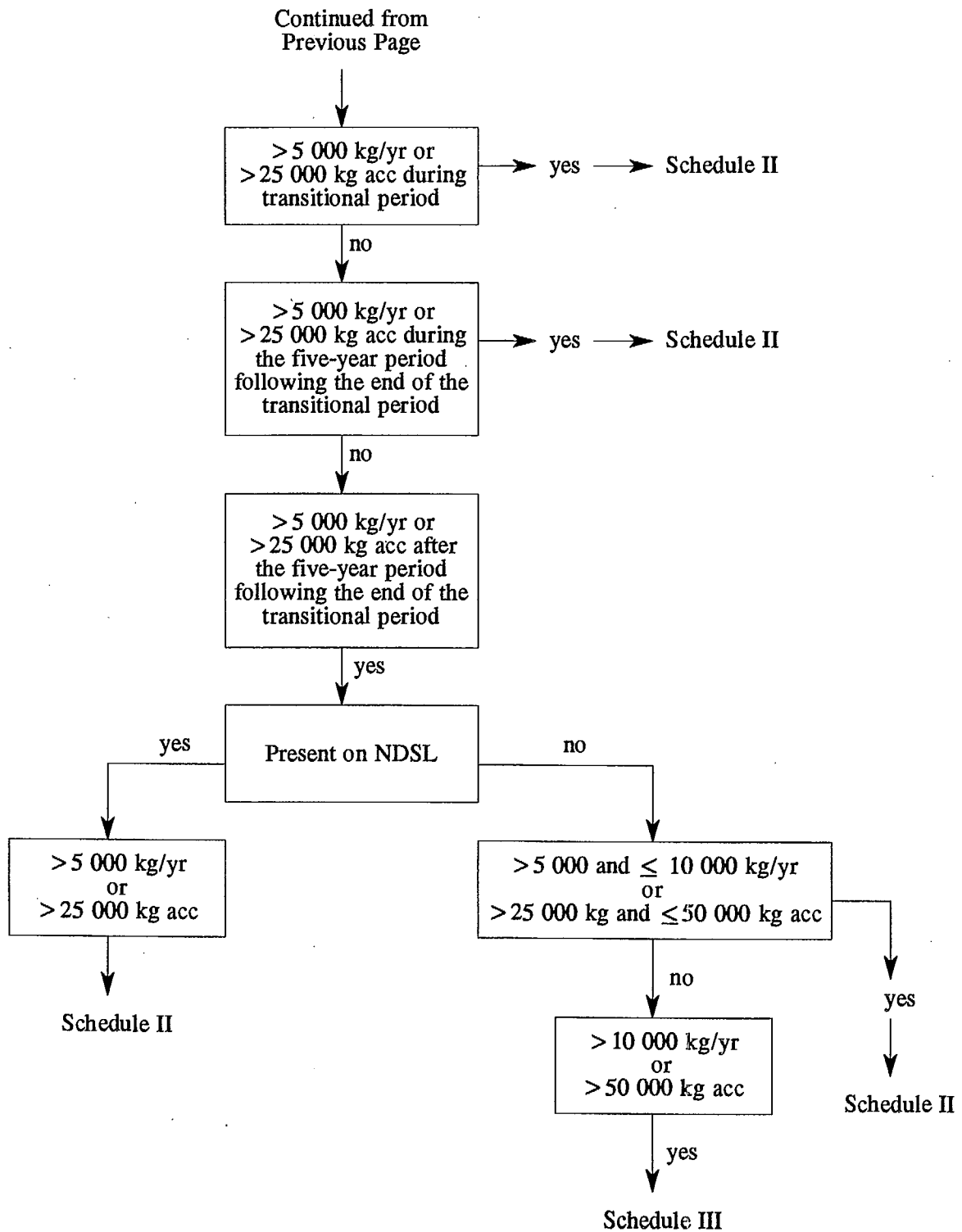
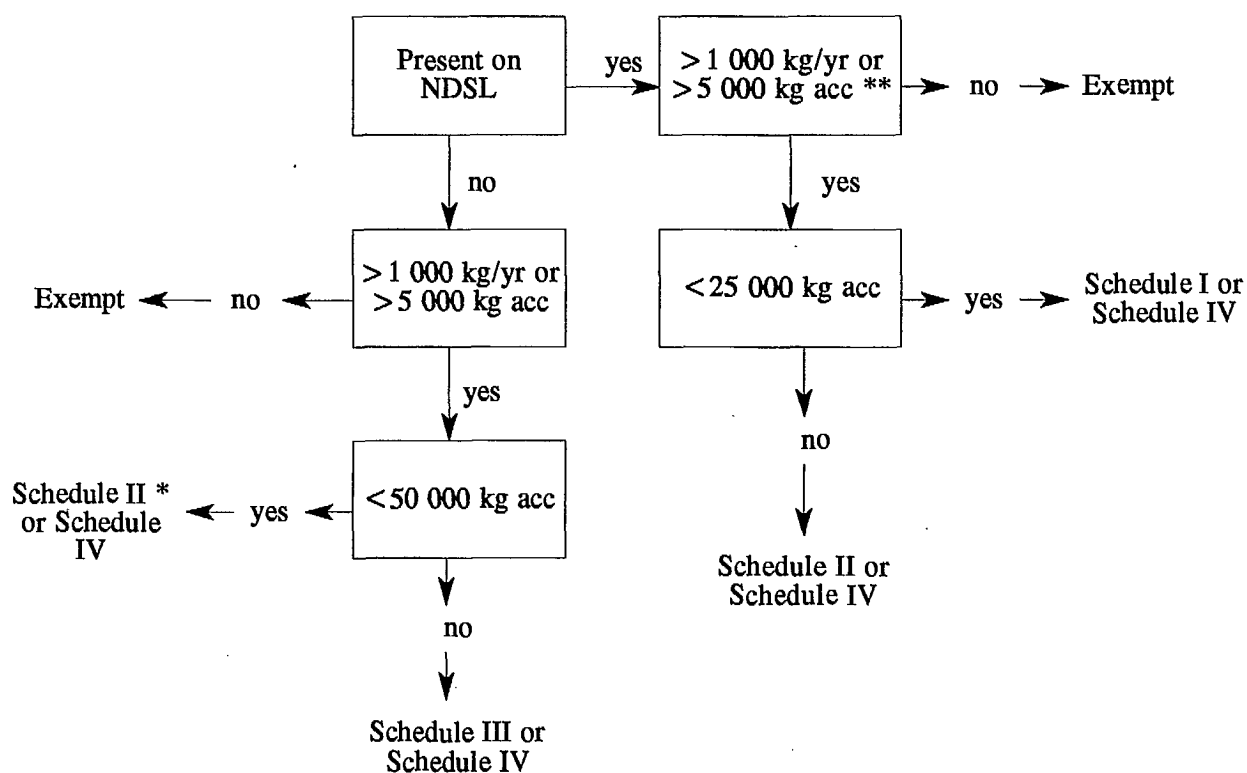


Figure 2 Scheme A: Transitional Chemicals (continued)



\*Except for adsorption-desorption screening test data and hydrolysis as a function of pH test data (items 2(1)(i) and 2(1)(j) of Schedule II).

\*\*acc = accumulated total

**Figure 3**      **Scheme B: Product Development Chemicals**

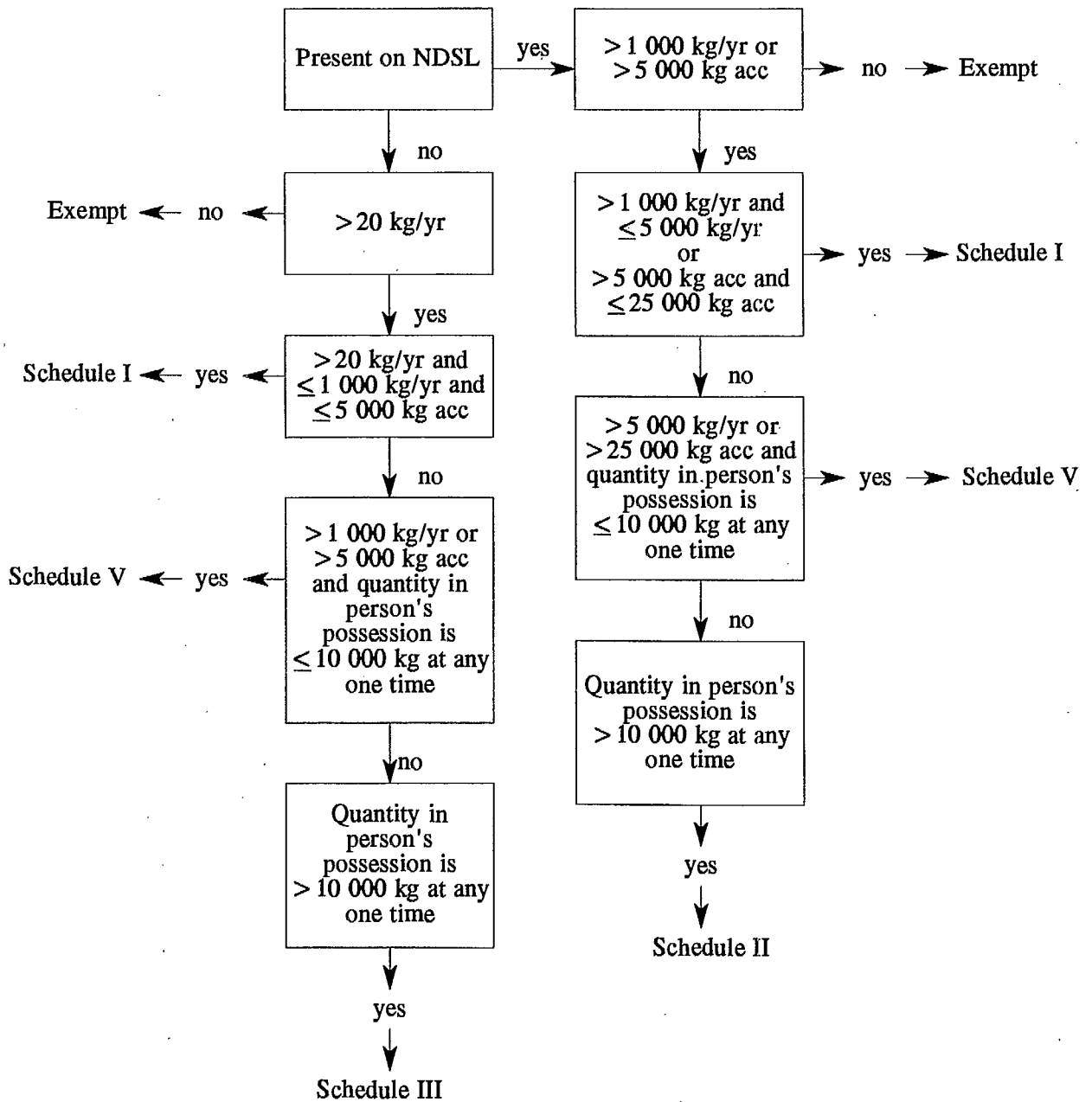
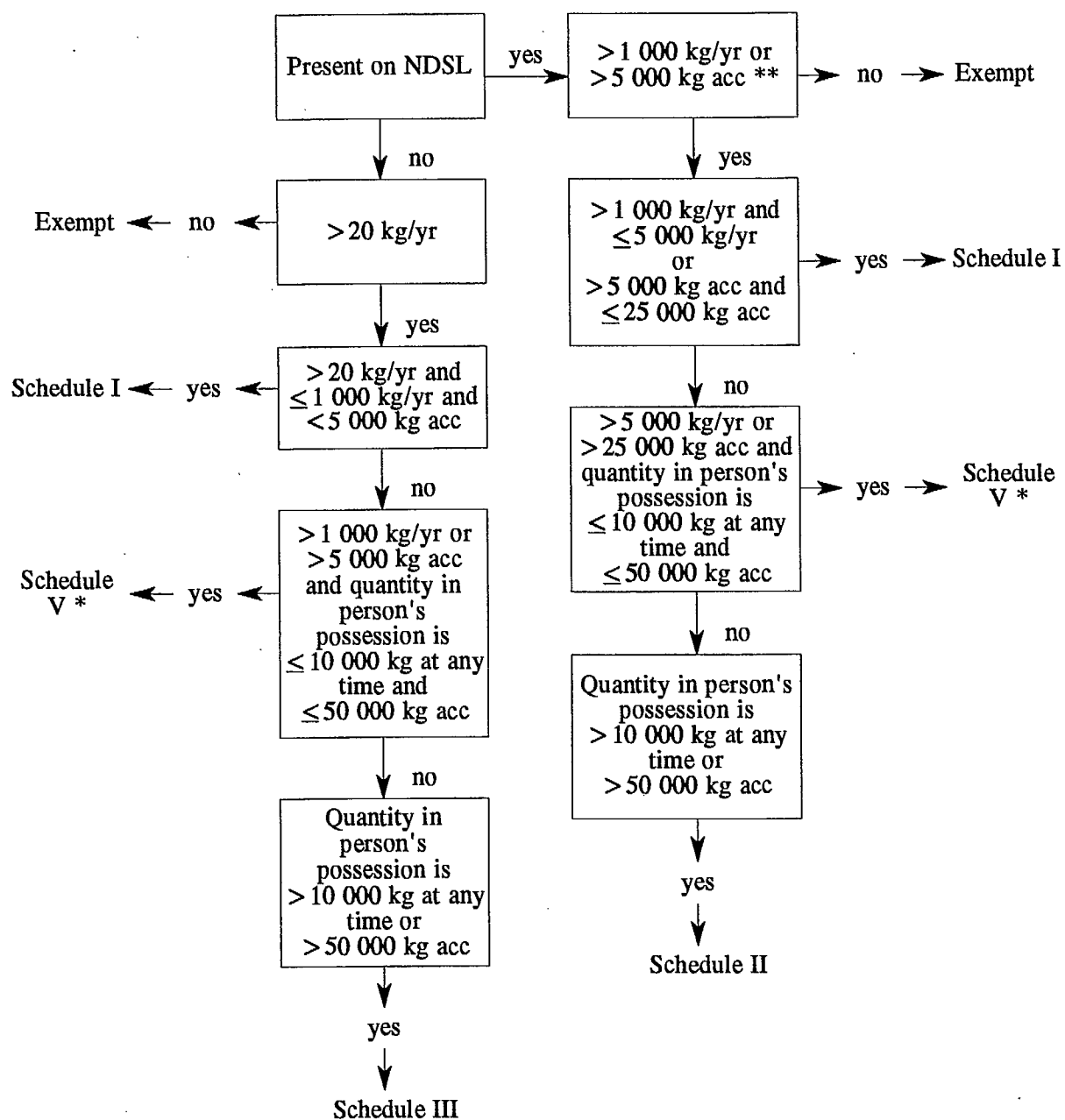


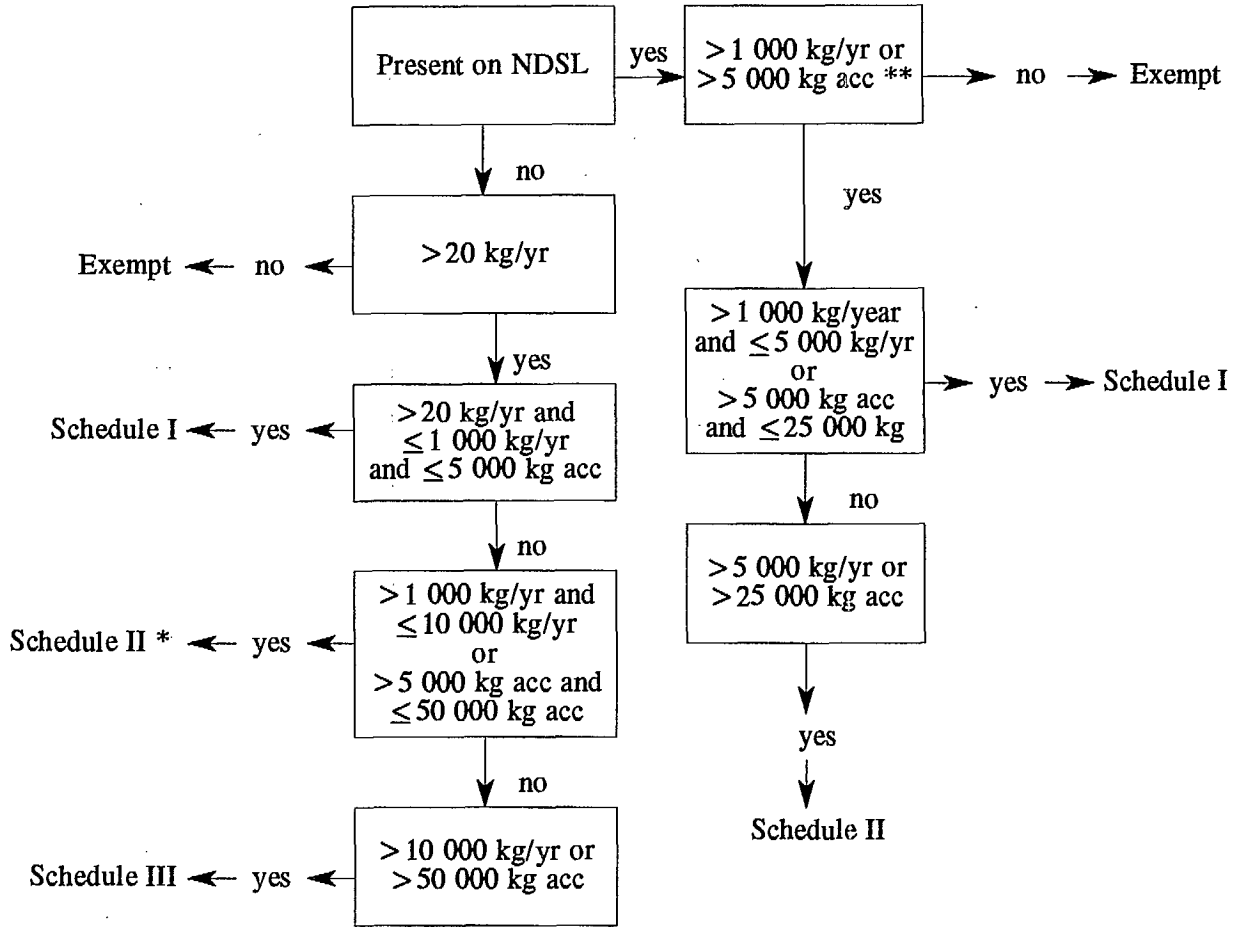
Figure 4 Scheme C: Export-only Chemicals



\*Site-limited intermediates that are not transported off-site are exempt from hydrolysis, ready biodegradability, and acute mammalian toxicity requirements (items 3 and 4 of Schedule V).

\*\*acc = accumulated total

Figure 5 Scheme D: Site-limited Intermediate Chemicals



\*Except for adsorption-desorption screening test data and hydrolysis as a function of pH test data (subitems 2(1)(i) and 2(1)(j) of Schedule II).

\*\*acc = accumulated total

**Figure 6**      **Scheme E: All Other Chemicals**



confidential TSCA inventory. Procedures for determining the presence of confidential substances on the NDSL and the DSL are described in Section 9.3 of these Guidelines.

*Updates to the Non-domestic Substances List.* Beginning in 1995, the NDSL will undergo an annual revision that will add or delete all substances incorporated into, or removed from, the TSCA inventory five or more years before to the date of the NDSL revision. The first NDSL update will therefore include substances in the 1990 supplement of the TSCA inventory.

All additions to the NDSL will remain as inactive entries (i.e., will not be deemed NDSL entries) until information has been provided to satisfy the following criteria:

- (a) the substance is in commercial use in the United States;
- (b) the proposed uses in Canada are consistent with use patterns in the United States;
- (c) there are no known adverse health or environmental effects related to the use of the substance in the United States; and
- (d) there are no controls placed on the manufacture, import, or use of the substance in the United States.

All additions to the original NDSL will be "flagged" to indicate their inactive status. After receipt and acceptance of information that satisfies these criteria, the "flag" will be removed in the next supplement of the NDSL published in the *Canada Gazette*. Publications of NDSL supplements will occur as frequently as every week. However, if this information is supplied well in advance of an annual update, the substance will automatically appear as an active entry in the annual NDSL update.

Substances can be listed on the confidential NDSL only if the nominating company can demonstrate that the substance exists on the confidential TSCA inventory. Instructions for nominating substances to the confidential NDSL are on the back of the Domestic Substances List Report Form C, which can be obtained through the NSN Information Line (see Section 3.5 of these Guidelines).

**3.2.2.2** *Transitional Polymers.* Polymers, not listed on the DSL, that were manufactured or imported in a quantity greater than 20 kg in any calendar year during the transitional period (between January 1, 1987 and the implementation date of Subsection 26(1) of CEPA) are defined as transitional polymers. The information requirements and notification periods for transitional polymers depend on when trigger quantities are exceeded. The prescribed dates for notifying transitional substances are described in Section 3.3 of these Guidelines.

If a trigger quantity was exceeded during the transitional period, then the notifier is subject to the transitional provisions of Subsection 26(2) of CEPA. Subsection 26(2) allows the manufacture or import of transitional polymers to continue after Subsection 26(1) comes into force, if the prescribed information is provided to Environment Canada before a prescribed date. However, notification is not necessary if the manufacture or import of the transitional substance was discontinued before the end of the transitional period.

If a transitional polymer exceeds a trigger quantity after the implementation date of Subsection 26(1) of CEPA, the substance will be subject to the provisions of Subsection 26(1). For these substances, notifications must be submitted in advance of exceeding the trigger quantity (refer to Section 3.3 of these Guidelines). Notifiers of transitional polymers that exceed a trigger quantity within five years of the implementation date of Subsection 26(1) of CEPA, need only provide information requirements identical to the information requirements of Subsection 26(2). However, when a trigger quantity for a transitional polymer is exceeded after the five-year period, the substance will be subject to requirements similar to those for non-transitional polymers, unless the notifier has provided the most comprehensive information package for transitional polymers before the end of the five-year period.

**3.2.2.3 Monomers and Reactants on the Non-domestic Substances List and the Domestic Substances List.** 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 appear on the DSL or NDSL.

**3.2.2.4 Low-concern Polymers.** Low-concern polymers include polymers of high number-average molecular weight that have a limited percentage of low molecular weight components and that are chemically stable and do not contain certain reactive or cationic moieties.

Low-concern polymers include those polymers that:

- (a) are not described in items 1, 2, 3, or 4 of Schedule IX and have a number-average molecular weight greater than 10 000 daltons, and less than 2% of components have a molecular weight less than 500 daltons, and less than 5% of components have a molecular weight less than 1 000 daltons;
- (b) are not described in Schedule IX and have a number-average molecular weight greater than 1 000 daltons, and less than 10% of components have a molecular weight less than 500 daltons, and less than 25% of components have a molecular weight less than 1 000 daltons; or
- (c) are polyesters manufactured solely from reactants on the DSL and listed in Schedule X, unless the polyester is manufactured from a combination of reactants that includes both 1-butanol and (*E*) 2-butenedioic acid.

**Polymers Described in Schedule IX.** Items 1 to 5 of Schedule IX describe types of polymers that have the potential to pose a relatively higher risk to the environment or human health. The following points provide clarification of items 1, 4, and 5:

**Item 1.** Cationic polymers are considered of "higher concern" if the equivalent weight of all the cationic groups is less than 5 000 daltons. The combined equivalent weight for the cationic group(s) is the molecular weight of the whole polymer ( $MW_{\text{polymer}}$ ) divided by the sum of the fragment weights of all of the cationic groups in the polymer ( $FW_{\text{cationic group}}$ ). The fragment weight of a cationic group is the sum of the atomic weights of all of the atoms in the group divided by its charge (this is normally 1). Therefore, equivalent weight is calculated as:

$$\frac{MW_{\text{polymer}}}{(FW_{\text{cationic group1}} + FW_{\text{cationic group2}} + \dots \text{etc.})}$$

For example, a polymer with a molecular weight of 10 000 daltons containing two quaternary ammonium groups ( $FW/\text{charge}$ , 18 daltons) would have a ratio of  $10\,000/(2 \times 18) = 278$  and be included in Item 1; whereas, a polymer with a molecular weight of 100 000 daltons containing one quaternary ammonium group would have a ratio of  $100\,000/18 = 5\,556$  and would not be included in Item 1.

**Item 4.** Higher concern polymers are those that contain any elements or ions not included in the following list:

carbon	fluorine	Na <sup>+</sup> ion	Cl <sup>-</sup> ion
hydrogen	chlorine	Mg <sup>2+</sup> ion	Br <sup>-</sup> ion
nitrogen	bromine	Al <sup>3+</sup> ion	I <sup>-</sup> ion
oxygen	iodine	K <sup>+</sup> ion	
silicon		Ca <sup>2+</sup> ion	
sulphur			

Elements not listed can be present as impurities. A combined weight of lithium, boron, phosphorus, titanium, manganese, iron, nickel, copper, zinc, tin, or zirconium not exceeding 0.2% by weight is not considered of "higher concern" for the purposes of Item 4.

**Item 5a.** "Higher concern" polymers include polymers that contain reactive functional groups other than: carboxylic acid groups, aliphatic hydroxyl groups, unconjugated olefinic groups, butenedioic groups, cyano groups, blocked isocyanates including ketoxime-blocked isocyanates, unconjugated nitrile groups, halogens excluding halides, and conjugated olefinic groups in naturally occurring fats, oils, and carbohydrates, in combined amounts

greater than 1 in 5 000. One part in 5 000 refers to the ratio of the sum of fragment weights of all functional groups present in the polymer to the molecular weight of the polymer.

*Item 5b.* If the polymer described in Item 5a contains only the following reactive functional groups: acid halides, acid anhydrides, aldehydes, hemiacetals, methylol-amides, methylol-amines, methylol-ureas, alkoxysilanes containing more than two carbon atoms, allyl ethers, conjugated olefins, cyanates, epoxides, imines or unsubstituted positions *ortho* or *para* to phenolic hydroxyl, it will be considered "higher concern" if the reactive groups are present in combined amounts greater than 1 in 1 000. One part in 1 000 refers to the ratio of the sum of fragment weights of all functional groups in the polymer to the molecular weight of the polymer.

### 3.2.2.5 *Special Categories of Polymers*

**Research and Development.** Research and development polymers are polymers that are the subject of systematic investigation or search (by means of experimentation or analysis, or both) that has as its primary objective the creation or improvement of a product. This category includes polymers being manufactured on toll for domestic or foreign customers that are conducting research.

**Product Development Polymers.** Product development polymers are research and development polymers evaluated before full commercialization using pilot plants, production trials, or customer trials in one program that is two years or less in length. The intent of this activity is to modify technical specifications in response to performance requirements of potential customers; however, test marketing is not included. This category includes polymers being manufactured on toll for domestic or foreign customers that are conducting research.

**Export Only.** This category includes polymers imported into, or manufactured in, Canada and destined solely for foreign markets.

**Site-limited Intermediates.** An intermediate substance is a substance that is consumed, in whole or in part, in a chemical reaction used for the intentional manufacture of another substance. A site-limited intermediate polymer is defined in the Regulations as an intermediate:

- (a) not exceeding an accumulated quantity of 50 000 kg; and
- (b) at any one time, the combined inventory of the polymer:
  - (1) manufactured for the purpose of being consumed on the site of manufacture;
  - (2) manufactured at one site in Canada and then transported to a second site in Canada where it is consumed; or
  - (3) imported and transported directly to one site at which it is consumed does not exceed 20 000 kg.

"Consumed" in this case implies that the reaction has proceeded to the point where no further conversion of the substance is likely under the reaction conditions, i.e., some of the site-limited substance may remain as a minor impurity in the final product.

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

Polymers that are a direct precursor in the manufacture of an item defined in Subsection 2.3.1.2 of these Guidelines are not considered site-limited intermediates, 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" (Subsection 2.3.2.2), it would not be subject to notification.

**3.2.2.6 Annual Quantities and Accumulated Totals.** The notifier must develop an accurate estimate of the annual (calendar year) quantities and the accumulated total amount of the new substance destined for import and/or manufacture. This information is needed to ensure that additional notification requirements are submitted before higher "trigger" quantities are reached. The prescribed trigger quantities relate to the actual amount of substance manufactured and imported, not to the quantity of formulation containing the substance. For example, if 10 000 kg of Formulation A, which contains 13% of new substance X is to be imported during a calendar year, then the annual import quantity of substance X would be 1 300 kg. Repetition of this yearly 1 300 kg transaction over eight years would result in a cumulative total of 10 400 kg.

For transitional substances, the quantities are calculated from the date that the chemical was first manufactured in Canada, or imported into Canada, after December 31, 1986.

**3.2.2.7 Decision Scheme.** The decision schemes shown in Figures 7 and 8 can be used to determine the required schedule of information for polymers.

### **3.3 When to Notify the Government**

The timing of a notification depends on the schedule of information required, and whether the trigger quantity is exceeded during or after the transitional period.

#### **3.3.1 Notification of Substances Exceeding Trigger Quantities During the Transitional Period**

All transitional substances will require a preliminary notification shortly after the Regulations come into force. For chemicals, the information specified in Schedule I must be submitted within 90 days of the Regulations coming into force. For all transitional polymers, the information specified in Schedule VI or XI must be submitted within 120 days of the

Regulations coming into force. However, if the transitional substance is not manufactured or imported after the transitional period, no notification is needed.

If additional trigger quantities were exceeded during the transitional period, additional notifications are required within a prescribed time after the transitional period. The timing for these subsequent notifications depends on the year that the trigger quantity was exceeded (see Table 1). For example, if 10 000 kg of a new chemical was imported for the first time in 1989, the information prescribed in Schedule I must be provided within 90 days of the date the Regulations came into force, and be followed by a Schedule II notifications no later than 18 months after the date the Regulations came into force.

### **3.3.2            *Notification of Substances that Exceed Trigger Quantities After the Transitional Period***

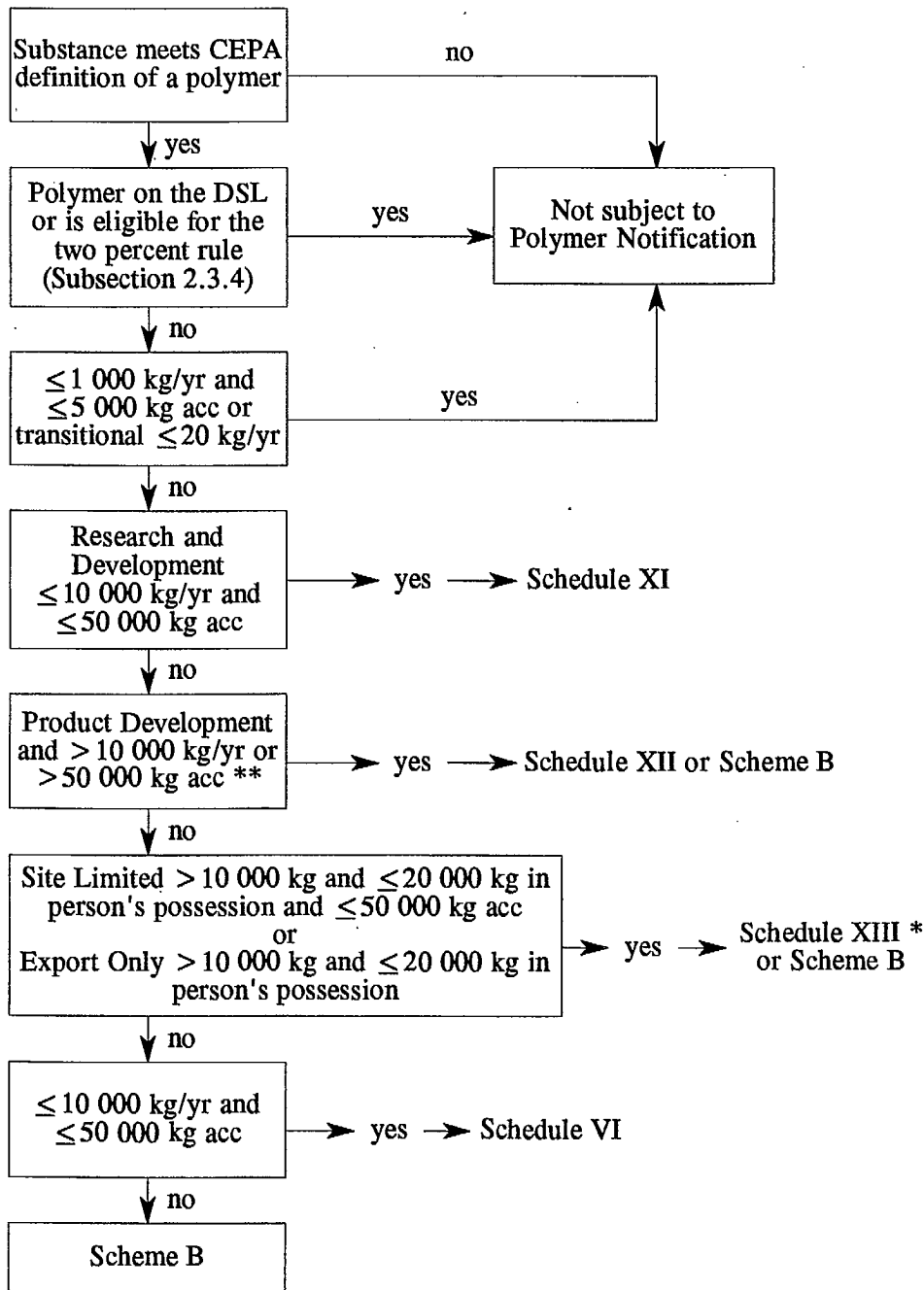
Notifications of substances (including transitional substances) that exceed the trigger quantity after the transitional period, must be provided within a prescribed time period in advance of the trigger quantity being exceeded (see Table 2).

### **3.4                *Notification of Product Development Substances***

The Regulations offer the person who is importing or manufacturing product development substances the choice of submitting either the regularly prescribed information or the information listed in the Product Development Plan Schedule IV (chemicals) or XII (polymers). If a Schedule IV or XII is used, the information must be submitted 21 days in advance of exceeding the prescribed trigger quantity.

Product development programs cannot exceed a period of two years. During this period, product development update reports must be submitted every six months, or less, until the program is completed. Update reports must contain all the information and test data relevant to environmental and health hazard identification that has been obtained since the previous report. After the development program has terminated, a request for another product development program can be submitted if the substance is being developed for an alternate purpose.

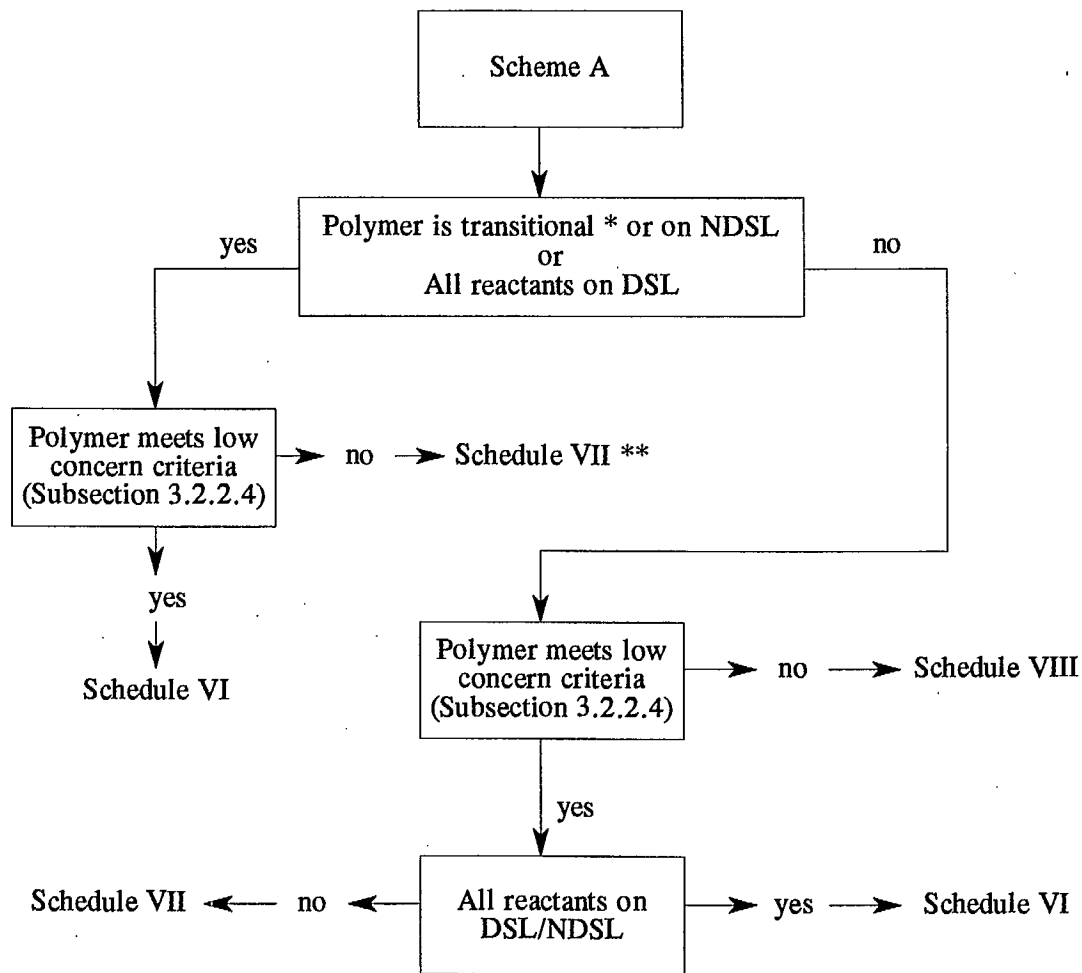
The Departments of Environment and National Health and Welfare will assess the submitted product development plan and indicate if the plan is inadequate. This development plan may not contain test marketing activity, i.e., the exploration of market capability in a competitive situation where the creation or improvement of the substance, or a product containing the substance, is no longer the primary objective.



\*Site-limited intermediates that are not transported off-site are exempt from molecular and structural formulae, number average molecular weight, percentage residual constituents, water solubility, octanol solubility, and acute mammalian toxicity information requirements (items 1(4), 1(5), 2, and 3 of Schedule XIII).

\*\*acc = accumulated total.

Figure 7 Notification Requirements for New Polymers: Scheme A



\*The provisions for transitional substances expire five years after the New Substances Notification Regulations come into force. When the most comprehensive information package is received during the five-year post-transitional period, no additional notification obligations will be imposed after the five-year period expires.

\*\*Acute fish or *Daphnia* toxicity [subitem 2(2)] not required for NDSL polymers.

**Figure 8** Notification Requirements for New Polymers: Scheme B



**Table 1 Notification Periods for Substances that Exceed Trigger Quantities during the Transitional Period**

Schedule	Year Trigger Quantity Exceeded	Notification Period (after Regulations are in force)
I	1987 to 1993	90 days
VI or XI	1987 to 1993	120 days
II, V, VI, VII, XIII	1987	6 months
II, V, VI, VII, XIII	1988	1 year
II, V, VI, VII, XIII	1989	1.5 years
II, V, VI, VII, XIII	1990	2 years
II, V, VI, VII, XIII	1991	2.5 years
II, V, VI, VII, XIII	1992	3 years
II, V, VI, VII, XIII	1993	3.5 years

**Table 2 Notification Periods for Substances that Exceed Trigger Quantities after the Transitional Period**

Schedule (chemicals)	Notification Period (days before manufacture/import)	Schedule (polymers)	Notification Period (days before manufacture/import)
I	5	VI	45
II	45	VII	45
III	90	VIII	90
IV	21	XI	5
V	21	XII	21
		XIII	21

### **3.5        *New Substances Notification Information Line***

Individuals who have technical questions or who require additional information on procedures for new substances notifications or on the status of submitted notifications, may contact Environment Canada Headquarters. Inquiries should be directed to:

New Substances Division  
Commercial Chemicals Branch  
Conservation and Protection  
Environment Canada  
14th Floor, Place Vincent Massey  
Ottawa, Canada  
K1A 0H3

Telephone:    (800) 567-1999 (toll-free in Canada)  
                  (819) 953-7156 (outside Canada)  
Facsimile:    (819) 953-7155

### **3.6        *Supporting Documentation***

#### **3.6.1      *Notification Forms and Guidelines***

Additional copies of the guidelines and notification forms may be obtained from Environment Canada by contacting one of the regional offices (Appendix 2) or Environment Canada Headquarters in Ottawa. Notification forms may be reproduced without permission.

#### **3.6.2      *Inventories***

The Domestic Substances List (DSL) and the Non-domestic Substances List (NDSL) are available in hard copy, standard 5.25-inch diskette (MS-DOS, ASCII file), and CD-ROM. Chemicals appearing on the DSL and the NDSL are named using Chemical Abstracts Service (CAS) preferred nomenclature (English) and International Union of Pure and Applied Chemistry (IUPAC) nomenclature (French). Polymers appearing on the DSL are named in terms of their starting reactants. Confidential substances are published using masked identities that are named in a manner prescribed by the Confidential Information Disclosure Regulations (see Section 9 of these Guidelines):

The original lists were published on January 26, 1991 as a supplement to the *Canada Gazette*, Part I. Updates will be published weekly when warranted. The *Canada Gazette* is available in subscribing libraries and institutions as well as in the regional and district offices of Environment Canada (Appendix 2). Published formats of the Lists may be purchased through the following suppliers:

**in Canada:**

Canada Communication Group (Publishing)  
Ottawa, Ontario, Canada K1A 0S9

Telephone: (819) 956-4802

Facsimile: (819) 994-1498

**in the United States:**

International Specialized Book Services Inc.  
5602 NE Hassalo Street  
Portland, OR  
U.S.A. 97213

Telephone: (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

The following information must be included with the order:

Domestic Substances List — CAT No: EN40-397-1991  
Liste intérieure des substances — ISBN: 0-660-56393-2

Non-domestic Substances List — CAT No: EN40-398-1991  
Liste extérieure des substances — ISBN: 0-660-56394-0

Standard 5.25-inch diskette (MS-DOS, ASCII file) versions of the DSL and NDSL containing CAS Registry Numbers only can be obtained by telephoning or faxing the NSN Information Line. Note that the diskette contains no chemical names, only CAS Registry Numbers.

The DSL and NDSL are also available on CD-ROM as part of the CCINFO disc packages prepared and distributed by CCINFO Service, Canadian Centre for Occupational Health and Safety, 250 Main Street East, Hamilton, Ontario L8N 1H6 (Telephone: 1-800-263-8340). This version permits both CAS Registry Number and chemical name searches.

## Section 4

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# Technical Information Requirements

The New Substances Notification Regulations contain two categories of prescribed information — "administrative" and "technical" data. Explanations of many of the information requirements prescribed in the various Schedules are provided to assist with the compilation and generation of the technical data prescribed in the Regulations. These explanatory notes elaborate details such as: the naming of substances; the conditions under which various tests are required; and what constitutes complete and adequate information in the opinion of the Departments. Discussions of the prescribed administrative information are provided in Section 8.

### 4.1 Substance Identity Information

#### 4.1.1 Substance Name

Chemicals must be identified using the exact name of the substance established in accordance with the nomenclature rules of IUPAC or CAS. The name should enable an unambiguous chemical structural diagram to be drawn, unless the 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 3 of these Guidelines.

Polymer nomenclature, including pre-polymers, incorporates the identity of monomers and reactants used in the manufacture of the polymer. 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 two percent or less by weight. However, these substances must be included in the description of the polymer composition (see Subsection 4.1.9 "Monomers and Reactants"). Examples of polymer nomenclature are:

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

#### 4.1.2 *Masked Name*

If the substance identity is claimed as confidential, a masked name must be provided. Procedures for generating masked names are described in the Confidential Information Disclosure (CID) Regulations<sup>2</sup> of CEPA and Subsection 9.2.2 of these Guidelines.

#### 4.1.3 *Chemical Abstracts Service Registry Number*

The most precise CAS Registry Number available for the 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 requirement for providing the CAS Registry Number depends on the Schedule of information:

- (a) for Schedules IV and XII, the CAS Registry Number should be provided only if the notifier possesses the number;
- (b) for Schedules I, V, XI, and XIII the CAS Registry Number should be provided if it already has been assigned to the substance; and
- (c) for Schedules II, III, VI, VII, VIII, the CAS Registry Number must be provided if the CAS is able to assign a number. This provision does not apply to substances if the CAS will not assign a Registry Number to a substance because of its confidential status.

Sources of existing CAS Registry Numbers are described in Appendix 4. To obtain information on CAS Registry Numbers, contact:

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

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<sup>2</sup> Although the CID Regulations will not be promulgated when this document is published, the masking portion of the CID Regulations will be based on the procedures described in Appendix 7 of these Guidelines.

Telephone: (614) 447-3600  
 (800) 848-6538 Ext 3731 (Canada and United States)  
 Facsimile: (614) 447-3713

#### 4.1.4 *Structural Formula*

The structural formula diagram must clearly indicate the identity of all atoms, type of bonds, ionic charges, and the stereochemistry. 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.

For UVCB substances, the name and, if known, CAS Registry Number of immediate precursors is required. 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>].

For polymers, the structural formula should consist of a simple representative diagram that illustrates the key structural features of the polymer molecule (e.g., types of linkages, functional groups, range, and typical values for the number of repeating units). In addition, the type of polymerization (e.g., graft, block, random) must be indicated.

Additional information and examples of structural formulae are provided in Appendix 3 of these Guidelines.

#### 4.1.5 *Molecular Formula*

The molecular formula is only required for polymers. The empirical formula must be provided and should identify each of the monomer units. Examples are:

- (a) methyl methacrylate, polymer with ethyl acrylate  
 $(C_5H_8O_2 \cdot C_5H_8O_2)_x$ ; and
- (b) polyoxyethylene sorbitol tetraoleate  
 $(C_2H_4O)_n(C_2H_4O)_n(C_2H_4O)_n(C_2H_4O)_n(C_2H_4O)_n(C_2H_4O)_n C_{78}H_{142}O_{10}$

#### 4.1.6 *Molecular Weight*

The gram molecular weight is only required 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 Subsection 4.2.2.

#### **4.1.7        *Impurities and their Concentration***

Impurities are substances 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 (including microorganisms if a reaction precursor was a biotechnology product) and reaction by-products. The name, CAS Registry Number, and percentage by weight of each impurity must be given, if known.

#### **4.1.8        *Additives and their Concentration***

Additives are deliberately introduced into a product, and include stabilizers, emulsifiers, and anti-oxidants. The name, CAS Registry Number, and percentage by weight of additives that are essential for marketing must be given.

#### **4.1.9        *Monomers and Reactants***

Monomers and reactants include compounds such as initiators, cross-linking agents, chain-terminating agents, and chain-transfer agents that are intended to become part of the polymer. The name, CAS Registry Number, and percentage by weight of each monomer and reactant must be given. Monomers or reactants, either incorporated into the polymer or charged to the reaction vessel at two percent 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.

#### **4.1.10       *Material Safety Data Sheet***

The Material Safety Data Sheet (MSDS), as defined in Paragraph 13(a) of the *Hazardous Products Act* and detailed in the Controlled Products Regulations, must be provided if one has been prepared.

### **4.2           *Experimental Data***

Prescribed and alternative test protocols, as well as laboratory practices, that are acceptable for the generation of experimental data are described in Section 5. Explanations of the conditions under which waivers of prescribed information may be granted are described in Section 6, and examples are given in Appendix 5.

#### **4.2.1        *Physical-Chemical Data — Chemicals***

**4.2.1.1       *Melting and Boiling Point.*** A melting or 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 substance undergoes a chemical reaction (e.g., degradation, rearrangement) at a temperature below the melting or boiling point, that temperature must be

reported. In addition, a pour point, softening point, or sublimation point may be provided instead of a melting point, when this is appropriate.

**4.2.1.2 Fat Solubility.** Fat solubility is required for all chemicals subject to Schedule III notification; whereas, Schedule II specifies that this information is only required for substances with water solubility less than  $10^{-6}$  g/L.

**4.2.1.3 Vapour Pressure.** The vapour pressure is not required if the chemical has a boiling point of less than  $0^{\circ}\text{C}$ .

**4.2.1.4 Octanol-Water Partition Coefficient.** The octanol-water partition coefficient is not required if the water solubility of the chemical is less than  $10^{-6}$  g/L.

**4.2.1.5 Particle Size or Fibre Length Distribution.** The particle size or fibre length distribution of the chemical only needs to be provided if the chemical is a solid with a water solubility of less than  $10^{-6}$  g/L.

**4.2.1.6 Hydrolysis as a Function of pH.** This test is required for: chemicals that are subject to Schedule V (site-limited intermediates, and export only) and will be transported; chemicals subject to Schedule III; and NDSL chemicals subject to Schedule II. The identity of any known hydrolysis products must also be provided.

**4.2.1.7 Adsorption-Desorption.** This test is required for chemicals subject to Schedule III, and NDSL substances subject to Schedule II. The desorption part of this test is not necessary if less than 25% of the chemical is adsorbed during the initial portion of the test. Under these circumstances, a request for a waiver of desorption information is not required.

**4.2.1.8 Spectroscopy.** At least one spectrum suitable for characterization of the chemical is required. Details of the methodology used (e.g., solvent, ionization technique, field strength, band width, instrumentation) must also be provided.

#### **4.2.2 Physical-Chemical Data — Polymers**

Generally, if the polymer is available in a series of different molecular weight compositions, information must be developed using the lowest number-average molecular weight composition. However, pre-existing information developed on higher molecular weight compositions will also be considered.

**4.2.2.1 Number-average Molecular Weight.** The number-average molecular weight must be determined on the composition having the lowest average molecular weight of any composition intended for import or manufacture. This information is not required for polymers that are subject to Schedule XIII (site-limited and export only) and will not be transported. Procedures are given in Section 1 of Appendix 6 "Polymer Test Methods".



**4.2.2.2 Residual Constituents with Molecular Weights of Less than 500 daltons and Less than 1000 daltons.** The percentage of residual constituents must be determined on the composition that has the lowest average molecular weight of any composition intended for import or manufacture. This information is not required for polymers that are subject to Schedule XIII (site-limited and export only) and will not be transported. Procedures are given in Section 2 of Appendix 6 "Polymer Test Methods".

**4.2.2.3 Water Solubility.** Water solubility at pH 7 is required for polymers that are subject to Schedule VII or VIII, and for polymers that are subject to Schedule XIII (site-limited and export only) and will be transported. This requirement is not applicable if the solubility in water can be shown to be less than 10 mg/L. For polymers subject to Schedules VII or VIII, solubility at pH 1 and 10 is also required, unless the solubility at these pH values is less than 50 mg/L.

Additional information on water solubility testing for polymers is given in Section 3 of Appendix 6 "Polymer Test Methods".

**4.2.2.4 Dispersibility in Water.** The degree of dispersibility need not be determined; however, if the polymer is intended to be formulated for dispersal in water, this must be stated.

**4.2.2.5 Hydrolysis as a Function of pH.** Hydrolysis as a function of pH is only required for polymers that are subject to Schedule VIII and have a solubility in water of more than 50 mg/L. The identity of any known hydrolysis products must also be provided. Additional information on hydrolysis of polymers is given in Section 4 of Appendix 6 "Polymer Test Methods".

**4.2.2.6 Ultraviolet-visible Spectrum.** An ultraviolet-visible spectrum that can be used to determine the potential for photodegradation of the polymer is required. Therefore, the wavelength range from 290 to 700 nm must be covered. The methodology used (e.g., solvent, instrumentation, band width) must also be provided.

**4.2.2.7 Solubility in n-Octanol.** Solubility in n-octanol is not required if the octanol solubility is less than 50 mg/L. If the polymer is subject to Schedule VII or VIII, either the octanol-water partition coefficient or the octanol solubility can be provided.

Additional information on n-octanol solubility testing for polymers is given in Section 5 of Appendix 6 "Polymer Test Methods". This information is not required for polymers that are subject to Schedule XIII (site-limited and export only) and will not be transported.

#### **4.2.3 Toxicological Data**

**4.2.3.1 Acute Mammalian Toxicity.** Test animals must be dosed using the same route(s) of exposure that is (are) anticipated to be the most significant route(s) for potential

human exposure. The most significant route of potential human exposure for these Regulations refers to exposure of the general population in Canada. To select the most appropriate route for testing, the expected level of the 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(s) would be the most appropriate for testing under CEPA, officials at National Health and Welfare (Section 7) should be consulted.

Acute mammalian toxicity testing is not required for chemicals that are subject to Schedule V, or for polymers that are subject to Schedule XIII and will not be transported.

**4.2.3.2 Skin Irritation and Skin Sensitization.** In most cases, properly conducted human patch tests (positive or negative response) are an acceptable alternative to animal testing for skin irritation or skin sensitization. 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 as accurately as possible. Anecdotal information from persons handling or exposed to the substance is not an acceptable surrogate for performing a prescribed test.

**4.2.3.3 Repeated Dose Mammalian Toxicity.** 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 Regulations in *Canada Gazette*, Part II. In that case, data from the 14-day test are acceptable. As described in Subsection 4.2.3.1 "Acute Mammalian Toxicity", test animals must be dosed using the most significant route of potential exposure for the general population in Canada.

**4.2.3.4 Mutagenicity.** Schedule II requires an *in vitro* test for gene mutation, chromosomal aberrations in mammalian cells, or another acceptable indicator of mutagenicity that permits an assessment of *in vitro* mutagenicity. The most appropriate test should be selected based on the structure of the substance.

The mutagenicity test requirements in Schedules III and VIII consist of: an *in vitro* test for gene mutation; an *in vitro* test for chromosomal aberrations in mammalian cells; and an *in vivo* mammalian test for gene mutation, chromosomal aberrations, or another indicator of mutagenicity that permits an assessment of mutagenicity acceptable to the Departments. 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* mutagenicity tests, the structure and mechanism of action of the substance, and developments in the field of genotoxicity.

An adequate *in vivo* mutagenicity test must include evidence that the tissue investigated was exposed to the substance or its metabolites. 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 Departments" are described in Appendix 8.

The actual number and type of mutagenicity tests that must be performed on a substance depends 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 exposure of the substance to humans. If it can be demonstrated that the information from a mutagenicity 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 6). Examples of conditions under which waivers may be granted for mutagenicity tests are given in Appendix 5.

#### 4.2.4 *Ecotoxicological Data*

**4.2.4.1 *Fish and Daphnia Acute Toxicity.*** For chemicals subject to Schedule III, both fish and *Daphnia* acute toxicity tests (limit or LC<sub>50</sub>) are required. For polymers subject to Schedule VII or VIII, data from either a fish or a *Daphnia* test is required on the water soluble portion of the polymer if the water solubility of the polymer is greater than 10 mg/L. However, if the polymer is expected to be cationic in an aquatic environment, data are required from both fish and *Daphnia* acute toxicity tests performed on the entire polymeric substance.

**4.2.4.2 *Algal Acute Toxicity.*** An algal acute toxicity test, performed on regular growth medium, is required for all anionic polymers subject to Schedules VII or VIII. Because the toxicity of polycarboxylic acids may be mitigated by the presence of Ca<sup>2+</sup> or Mg<sup>2+</sup> ions, algal toxicity of polycarboxylic acids must 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<sub>3</sub>). For polycarboxylic acids used as scale inhibitors, an algal toxicity test must, in addition, be conducted under a third condition (the addition of an equivalent of Ca<sup>2+</sup> ion to the test compound stock solution).

**4.2.4.3 *Biodegradation.*** Biodegradation data are required for chemicals that are subject to Schedule III, and for chemicals that are subject to Schedule V (site-limited intermediates or export only) and will be transported. For polymers subject to Schedule VIII, biodegradation information is required for the water soluble portion of the polymer if the water solubility of the polymer is greater than 50 mg/L. The biodegradability requirement in Schedule VII is limited to cationic polymers. The identity of any known products of biodegradation must be provided.

### **4.3            *Exposure Information***

Information submitted for the following sections should provide sufficient detail to help predict releases into the environment and potential human exposures.

#### **4.3.1            *Manufacture Information***

For substances manufactured in Canada, manufacture information must include the following:

- (a) 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;
- (b) a flow diagram of the manufacturing process that includes such features as process tanks, holding tanks, and distillation towers;
- (c) the major steps in operations, the chemical conversions, the points of entry of all feedstocks, and the points of release of substances; and
- (d) the sites of manufacture and estimates of annual production at each of the sites for the first 12 months, and of production during the maximum 12-month period in the first three years.

For substances imported into Canada, manufacture information must include (if known) the identity of any precursors and a brief description of reaction conditions (e.g., temperature, pressure, catalysts, and reaction stoichiometry).

#### **4.3.2            *Import Information***

Import information must include:

- (a) the name of the importer;
- (b) the planned destinations (e.g., manufacturing plants, processing plants, or distribution centres); and
- (c) estimates of the annual imports for the first 12 months, and of imports in the maximum 12-month period in the first three years.

#### **4.3.3            *Specific Use Information***

Use information must include the following (if known):

- (a) the intended function, specific application, and any other known uses of the notified substance;
- (b) the quantity intended for each application or use;
- (c) the sites of formulation, processing, and end use, and an indication of whether the use includes resale or storage;
- (d) an indication of whether the use is highly dispersive (paint solvents, aerosol), dispersive (soaps, fabric softeners), non-dispersive (inks, dyes), contained (capacitor fluids, catalysts), consumed (fuels, reaction intermediates), or is in the "other" category; and
- (e) the type of use, e.g., industrial (reaction intermediate), commercial (dry cleaning solvent), or consumer (household cleaners, polish). A substance may have uses in more than one category.

Use information should provide sufficient detail to help predict potential human exposure and the likelihood of release into the environment. Use codes used in "Reporting for the Domestic Substances List" (DSS No. EN 40-364/1988E) are not considered a sufficient description of use.

#### **4.3.4            *Distribution, Storage, and Handling Information***

Distribution, storage, and handling information must include:

- (a) the expected modes of transport and (if known) the Product Identification Number (PIN)<sup>3</sup>, the packaging type (container or bulk), and the concentration of the substance in the marketed preparation;
- (b) handling precautions, personal protection equipment, and storage requirements; and
- (c) emergency measures, which include first aid measures, procedures for cleanup in case of an accidental spill or release during manufacturing, processing, distribution or storage, and (if known) fire fighting information and possible dangerous reactions.

#### **4.3.5            *Disposal Information***

Disposal information must include (if known):

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<sup>3</sup> The Product Identification Number (PIN) 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 (see Section 3.6 of these Guidelines).

- (a) a description of the proposed disposal method for consumer, commercial, and industrial applications (e.g., lined landfill site, high temperature incineration, or recycling);
- (b) the expected amount of the substance that will be disposed by each method;
- (c) provincial waste classification(s); and
- (d) the site(s) of disposal.

#### **4.3.6 Environmental Release Information**

##### **4.3.6.1 Manufacturing Process.** The following information must be provided:

- (a) a flow diagram, corresponding to the manufacturing process, that indicates locations where releases from the manufacturing process are likely to occur;
- (b) 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;
- (c) an estimate of fugitive emissions (if known);
- (d) 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;
- (e) 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);
- (f) an indication, for effluents and emissions, of the amount of substance expected to be released (as kg/day for continuous operations and kg/batch for batch operations), as well as the average and peak concentrations; and
- (g) 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.

**4.3.6.2 Import.** Provide information that indicates the stages in the import process where emissions or discharges to the environment may occur, and the likely quantities and concentrations of these releases.

**4.3.6.3**      *End-use Activities.* If any information on processing by domestic customers is known, potential releases should be described as in Subsection 4.3.6.1 "Manufacturing Processes". Potential releases from commercial or consumer products should also be provided (if known).

**4.3.7**      *Human Exposure Information*

Estimates of the number of persons (in the general population and in occupational settings) that may be exposed to the substance must be provided (if known). This estimate would include information obtained from studies of the level of exposure to employees, customers, and the public from the use of the substance at each of the stages in the life-cycle of the substance:

- (a) manufacturing (including research and development, pilot plant, and commercial production);
- (b) transportation and handling;
- (c) processing;
- (d) storage;
- (e) intended use; and
- (f) disposal, destruction, and recycling.

Not all individuals in a population may be equally exposed; therefore, when the information is available, the possible routes of exposure at each stage should be included and the exposure should be described as quantitatively as possible.

**4.3.8**      *Analytical Test Methods*

**4.3.8.1**      *Below the Reported Median Lethal Concentration ( $LC_{50}$ ).* For substances subject to Schedule III, a full description of, or specific reference to, an analytical method that can detect the substance in water at or below the lowest reported  $LC_{50}$  or limit test for fish or *Daphnia*, must be provided. An analytical test method is not needed if the acute aquatic toxicity tests have been waived. In this case, it is not necessary to request a waiver.

**4.3.8.2**      *In the Environment.* This information is required for product development substances only (Schedules IV and XII). Analytical test methods must be provided that detect the substance in the environment if the methods are in the person's possession or within reasonable access (see Section 4.5 "Additional Information"). The analytical method(s) capable of detecting the substance in the environment must be described in full, or specifically referenced.

#### 4.4 *Other Agencies Notified*

Information must be provided of any known circumstances where the import or manufacture of the new substance has been notified to another agency or government, and the purpose of such notification must be given. 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 United States Environmental Protection Agency under the premanufacture notification provisions of the *Toxic Substances Control Act* (TSCA).

#### 4.5 *Additional Information*

All information and data relevant to environmental and health hazard identification must be provided, such as:

- (a) experimental data (including negative results);
- (b) summaries of literature reviews;
- (c) results of searches from databases to which the notifier has access;
- (d) structure-activity relationship analyses performed on the substance or structurally related substances; and
- (e) 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.

Additional information encompasses information in the person's possession or to which the person should reasonably have access. "In the person's possession" means information 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. The phrase "to which the person ought reasonably to have access" means information in any of the company's offices worldwide, or other locations where the person can access the information.

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

- (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.

#### ***4.6 Information Sharing Agreements***

Instances will occur where a substance has been notified, but it has not been published on the DSL, either because the substance did not meet all of the criteria in Section 30 of CEPA or because the assessment or processing of the notification is still in progress. In such cases, a second party intending to manufacture or import that substance will be required to provide a complete notification package. To reduce both duplicate testing and the expense of developing information for a notification, Environment Canada will provide an opportunity to obtain information directly from a previous notifier through the use of an Information Sharing Agreement (ISA).

An Information Sharing Agreement starts when a notifier provides Environment Canada with: (1) documentation of intent to import or manufacture a particular substance; and (2) authorization to release the name of the technical contact within the company to any other company that has met these two criteria. Documentation of intent to import or manufacture a substance may be either a New Substances Notification or the information described in Section 9.3 of these Guidelines. After receipt and acceptance of this documentation, Environment Canada will conduct a search for ISA candidates and, if any exist, will simultaneously provide each company with the name, address, and phone number of the technical contact of the other company or companies. Environment Canada's contribution to the process will end at this point, and the companies may then proceed to negotiate an Information Sharing Agreement. Procedures to indicate willingness to enter into an ISA are described in Section 8.

## Section 5

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### Test Procedures and Practices<sup>4</sup>

#### 5.1 *Organization for Economic Cooperation and Development Test Guidelines*

The conditions and test procedures used for the development and reporting of test data must be consistent with the conditions and test procedures of the Organization for Economic Cooperation and Development (OECD) "Guidelines for Testing of Chemicals" that are current at the time of testing.

The appropriateness of the OECD method for the substance must be determined, and any necessary modification should be made (including the use of an alternative method) to ensure the acceptability of test data. Any deviations from the OECD guidelines should be clearly noted and explained. The OECD Test Guidelines are not designed to serve as rigid test procedures appropriate for all substances, rather, they allow flexibility for expert judgement and adjustments to new developments. Therefore, credible alternative procedures (see Section 5.4) are considered consistent with the spirit of the OECD guidelines.

#### 5.2 *Good Laboratory Practice*

The laboratory practices used to develop test data for a new substance notification must be consistent with the "Principles of Good Laboratory Practice" (GLP) set out by the OECD.

All factors (test procedures and results as well as adherence to OECD GLP) relative to the development of a specific data requirement in a notification will be assessed by the Departments on a case-by-case basis. Such data must include the name and address of the head of the quality assurance unit of the testing laboratory. In addition, for data developed after the Regulations came into force and that employ a non-OECD<sup>5</sup> GLP, provide a description of the GLP including quality control and quality assurance procedures and an indication of reference substances. Notifiers who are uncertain about the suitability of planned GLP may contact the NSN information Line.

In keeping with commitments to OECD, the Departments of Environment and National Health and Welfare are currently developing a Canadian GLP program based on OECD GLP requirements.

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<sup>4</sup> Sources of information on test procedures and practices are given in Section 5.6.

<sup>5</sup> Laboratory practices that do not meet the requirements of another agency's GLP (e.g., United States Food and Drug Administration) may meet the requirements of OECD GLP.

### 5.3 *Health Protection Branch Mutagenicity Test Guidelines*

The Health Protection Branch (HPB) mutagenicity test guidelines should be regarded as the standard methods for developing mutagenicity test data for new substance notifications. The HPB Guidelines are functionally very similar to the equivalent OECD mutagenicity test guidelines; however, they provide additional advice, or different guidance, on the conduct of some tests. The OECD or other mutagenicity test guidelines will be acceptable when, in the opinion of the Departments, they are equally or better suited to measure the mutagenic potential of the substance under investigation.

### 5.4 *Alternative Procedures*

Information in support of a notification may also be obtained from alternative test protocols or from calculation or estimation methods. These alternative procedures will be acceptable when, in the opinion of the Departments, they are equally or better suited to measure the endpoint under investigation. Contact the NSN Information Line or refer to the tables in Subsection 5.4.1 to determine if a procedure is acceptable. Requests for waivers of information are not required for the submission of information from an approved alternative procedure.

#### 5.4.1 *Alternative Test Protocols*

Alternative protocols include other domestic or internationally recognized protocols (e.g., test methods developed by the Departments of Environment or National Health and Welfare, International Standards Organization (ISO), American Society for Testing and Materials (ASTM), the United States *Federal Insecticide, Fungicide, and Rodenticide Act* (FIFRA), and the United States *Toxic Substances Control Act* (TSCA)). In addition, protocols developed by individual companies or associations may also be acceptable. The method used 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 Departments and must be described 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, U.S. EPA, ISO) may not need to be provided, but must be referenced. If the data were generated prior to establishment of current standards of laboratory practice and method sensitivity, appropriate government evaluators should be consulted to determine the acceptability of these data.

The alternative protocol will be assessed by government evaluators to determine whether it is acceptable. If the alternative protocol is not acceptable, the submission will be considered incomplete and the assessment period will not commence until data from an acceptable protocol are provided. It is recommended that any alternative protocols, or modifications to OECD protocols, be discussed with appropriate individuals at National Health and Welfare or Environment Canada before carrying out the test. Modifications or additions to the test protocol, or the use of another protocol, may be recommended.

The government supports the use of testing methods that reduce the number of animals used and that minimize animal suffering, when the quality of data generated is not affected. Consequently, the use of limit tests and validated *in vitro* test methods, where appropriate, is encouraged.

In most cases, properly conducted human patch tests (positive or negative response) are an acceptable alternative to animal testing for skin irritation or skin sensitization. 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 as accurately as possible. Anecdotal information from persons handling or exposed to the substance is not an acceptable surrogate for performing a prescribed test.

Examples of test methods recommended by the Departments of Environment and National Health and Welfare for the generation of physical-chemical, toxicity, and ecotoxicity data are provided in Tables 3 to 6. The acceptability of these test methods depends on the applicability of the method to the substance under investigation. Sources of test methods listed in Tables 3 to 6 are given in Section 5.6 of these Guidelines.

#### **5.4.2        *Structure-Activity Relationships***

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 structure-activity relationships (SARs) fall into two main categories: (a) estimates based on qualitative structure-activity relationships ("read-across"); 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.

**5.4.2.1        *Qualitative Structure-Activity Relationships.*** Qualitative structure-activity relationships, referred to as "read-across", provide a qualitative estimate of a particular property and are derived from experimental data on a reference substance or substances (substances with a chemical structure closely related to that of the new substance). Read-

**Table 3 Physical-Chemical Test Methods (Chemicals)**

Data Requirement	Schedules	Test Method
Melting Point	II, III	OECD Guideline 102
Boiling Point	II, III	OECD Guideline 103
Density	II, III	OECD Guideline 109
Vapour Pressure	II, III	OECD Guideline 104
Water Solubility	II, III	OECD Guideline 105
Octanol-Water Partition Coefficient	II, III	OECD Guideline 107
IR, UV, Mass, or NMR spectrum	II, III	As appropriate
Dissociation Constant(s)	II, III	OECD Guideline 112
Adsorption-Desorption (screening test)	II <sup>a</sup> , III	OECD Guideline 106
Hydrolysis as a Function of pH (preliminary test)	II <sup>a</sup> , III, V <sup>b</sup>	OECD Guideline 111
Particle Size Distribution	II, III	OECD Guideline 110
Fat Solubility	III	OECD Guideline 116

<sup>a</sup> Non-NDSL Schedule II chemicals are exempt from this requirement.

<sup>b</sup> Site-limited intermediates not transported off-site are exempt from this requirement.

**Table 4 Physical-Chemical Test Methods (Polymers)**

Data Requirement	Schedules	Test Method
Number-average Molecular Weight	VI, VII, VIII, XII, XIII <sup>a</sup>	See Appendix 6
Residual Constituents with MW <500 daltons and <1000 daltons	VI, VII, VIII, XII, XIII <sup>a</sup>	See Appendix 6
Water Solubility	VII, VIII, XIII <sup>a</sup>	See Appendix 6
Hydrolysis as a Function of pH	VIII	See Appendix 6
Ultraviolet Spectrum	VIII	See Appendix 6
n-Octanol Solubility	VII, VIII, XIII <sup>a</sup>	See Appendix 6

<sup>a</sup> Site-limited intermediates not transported off-site are exempt from this requirement.

**Table 5 Toxicological Test Methods (Chemicals and Polymers)**

Data Requirement	Schedules	Test Method
Acute Mammalian Toxicity	II, III, V <sup>a</sup> , VII, VIII, XIII <sup>a</sup>	OECD Guideline 401, 402, 403
Skin Irritation	III, VIII	OECD Guideline 404
Skin Sensitization	III, VIII	OECD Guideline 406
Repeated Dose Toxicity	III, VIII	OECD Guideline 407, 410, 412
Mutagenicity	II, III, VIII	NHW-HPB Guidelines, OECD Guideline 471, 473, 474, 475 <sup>b</sup>

<sup>a</sup> Site-limited intermediates not transported off-site are exempt from this requirement.

<sup>b</sup> Data generated in accordance with OECD test guideline 475 (*in vivo* mammalian cytogenetics) are acceptable only if first division cells are analyzed (described in the HPB Guidelines).

**Table 6 Ecotoxicological Test Methods (Chemicals and Polymers)**

Data Requirement	Schedules	Test Method
Fish Acute Toxicity	III, VII <sup>a</sup> , VIII	OECD Guideline 203, EC/BTM
<i>Daphnia</i> Acute Toxicity	III, VII <sup>a</sup> , VIII	OECD Guideline 202, EC/BTM
Algal Toxicity	VII, VIII	EPA Protocol, EC/BTM
Ready Biodegradability	III, V <sup>b</sup> , VII, VIII	OECD Guideline 301

<sup>a</sup> NDSL polymers are exempt from subitem 2(2).

<sup>b</sup> Site-limited intermediates not transported off-site are exempt from this requirement.

across data estimates submitted in place of experimental data must be supported by information such as:

- (a) physical and chemical properties of the new and reference substance(s) that will help validate the estimate for the test under consideration;
- (b) test report(s) for the reference substance(s) for the test under consideration, which must contain sufficient information to assess the test results;
- (c) sufficient description of the method used to generate the test data for the reference substance(s) to assess the appropriateness of the method for the particular test, if the method is an alternative protocol;
- (d) test data on the notified substance from a range-finding test, if applicable (e.g., a limit test); and,
- (e) a structure-activity analysis for the two or more substances under consideration.

The validity of read-across estimates will largely depend on the structural similarity between the notified and reference substance(s). Read-across estimates are thus applicable where: (a) the notified substance possesses a "trivial" structural difference from the reference substance(s); or (b) the structural difference between the notified substance and the reference 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.

Examples of what may constitute a trivial structural change are: (a) a change in a counter ion of a large charged organic chemical (e.g., sodium dodecyl sulphonate to potassium dodecyl sulphonate); or (b) the addition or subtraction of a single methylene group in a long alkyl chain (e.g.,  $C_{10}H_{22}$  to  $C_{11}H_{24}$ ).

However, trivial structural changes would generally not include such differences as: (a) a change, modification, introduction, or removal of functional groups or multiple bonds; or (b) positional or geometric isomers.

Examples of possible read-across applications include:

- (a) if an ester was shown to hydrolyze rapidly, toxicity data (excepting dermal toxicity, irritation, and sensitization) for the alcohol and the acid might be acceptable;
- (b) if a high molecular weight substance had repeating units, an estimate of the

physical-chemical properties or toxicity of reference substances that possess fewer or more units might be acceptable;

- (c) the water solubility of an ionizable substance might be estimated to be greater than an appropriate similar substance that possessed fewer ionizable functional groups and exhibited very high water solubility; and
- (d) 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 reference substances might be acceptable.

Confidence in a read-across estimate 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.

**5.4.2.2** *Quantitative Structure-Activity Relationship Estimates.* Quantitative structural-activity relationships provide quantitative estimates of particular properties and are usually generated by computer programs that use either 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.

All QSAR estimates must be validated by determining: whether all of the structural features of the new substance are represented in the equation or by the substances used to generate the estimate; whether the estimate is reasonable in comparison with measured data on structurally similar substances; and whether these substances contain any structures that may invalidate the estimate.

Information to support the acceptance of data based on QSARs should include: (a) a validation of the estimate using the recommended standard procedures for the model (this may include printouts of chemicals and/or structures used to generate the estimate and the experimental data for these chemicals); and (b) the level of confidence associated with the estimate.

### **5.4.3** *Other Calculation Methods*

Other methods used to calculate data for a notification (e.g., extrapolation of data generated at different temperatures to provide a value at ambient temperature) will be accepted on a case-by-case basis.



## 5.5 *Test Data on UVCBs and Impure Substances*

Materials derived from natural sources or complex reactions that cannot be characterized in terms of their constituent chemical compounds, because their composition is too complex or variable, are termed UVCB substances. These substances are considered a single substance under the New Substances provisions of CEPA; 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. Furthermore, 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.

## 5.6 *Sources of Test Methods*

1. (a) *Organization for Economic Cooperation and Development (OECD) "Guidelines for Testing of Chemicals"*
- (b) *Organization for Economic Cooperation and Development (OECD) "Principles of Good Laboratory Practice"*

### **Available in Canada from:**

Renouf Publishing Company  
1294 Algoma Road  
Ottawa, Ontario  
K1B 3W8

Les Editions La Liberte  
3020, chemin Sainte-Foy  
Sainte-Foy (Quebec)  
G1X 3V6

Federal Publications Ltd.  
165 University Avenue  
Toronto, Ontario  
M5H 3B8

**Available internationally from:**

OECD  
Publications Service  
2, rue André-Pascal  
75775 Paris Cedex 16  
France

2. (a) *"The Assessment of Mutagenicity - Health Protection Branch Mutagenicity Guidelines" (1992)*
- (b) *"Conducting and Reporting of Mutagenicity Tests: Assays Recommended by the Health Protection Branch" (1993)*

**Available from:**

Office of the Director General  
Environmental Health Directorate  
Health Protection Branch  
Health and Welfare Canada  
Tunney's Pasture  
Ottawa, Ontario  
K1A 0L2

3. (a) *"Environment Canada. Biological Test Methods: Acute Lethality Test - Rainbow Trout" (July 1990). Report EPS1/RM/9.*
- (b) *"Environment Canada. Biological Test Methods: Acute Lethality Testing - Daphnia magna" (July 1990). Report EPS1/RM/11.*
- (c) *"Environment Canada. Biological Test Methods: Growth Inhibition Test Using the Freshwater Alga - Selenastrum capricornutum" (September, 1992). Report EPS1/RM/25.*

**Available from:**

Environmental Protection Publications  
Conservation and Protection  
Environment Canada  
Ottawa, Ontario  
K1A 0H3

Order by facsimile: (819) 953-9029

4. (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  
U.S.A. 87007

## Section 6

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# Waiver of Information Requirements

## 6.1 Introduction

Under Subsection 26(4) of the *Canadian Environmental Protection Act*, a request to waive the requirement for any of the prescribed information may be made to the Department of the Environment. The decision to grant a waiver will be made, on a case-by-case basis, by officials within Environment Canada and National Health and Welfare based on whether at least one of three criteria have been met. The statutory criteria for a waiver of information that are identified in Subsection 26(4) of CEPA are:

- " (a) *in the opinion of the Ministers, the information is not needed in order to determine whether the substance is 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 person requesting the waiver is able to contain the substance so as to satisfactorily protect the environment and human life;*
- (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 a notification 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 (Section 10.1 of these Guidelines). To avoid delays, it is recommended that the proposed waiver request be discussed with appropriate officials at Environment Canada and National Health and Welfare before the notification is submitted (Section 7).

Appendix 5 provides examples of conditions under which waivers may be granted. This list is not intended to be comprehensive, but to describe 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.

If the government has granted a waiver of information, then the particulars of the waiver will be published in the *Canada Gazette* in accordance with Subsection 26(5) of CEPA. The waiver notice will only contain: (a) the name of the person (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.

Substances for which waivers have been granted under Paragraphs 26(4)(a) or 26(4)(c) will be eligible for entry onto the DSL if the criteria under Subsection 30(1) of CEPA have been satisfied. Because inclusion of the substance on the DSL may permit unrestricted use, any substance for which waivers have been granted on the basis of limited exposure under Paragraph 26(4)(b) of CEPA, may not be entered onto the DSL because the criterion under Paragraph 30(1)(a) of CEPA will not be satisfied (Subsection 10.4.2 of these Guidelines).

## **6.2            *Waivers Requested Under Paragraph 26(4)(a) of the Canadian Environmental Protection Act***

Waiver requests may be accepted if it can be established that the test is unnecessary to determine the toxicity of the substance. 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 appropriate officials at National Health and Welfare or Environment Canada. After receipt of the notification, government evaluators will assess the submitted information to determine whether all the appropriate tests were performed.

Examples of situations in which information may be waived on this basis are:

- (a) the hydrolysis test may be waived if the substance contains only functional groups that are not known to 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; and
- (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.

## **6.3            *Waivers Requested Under Paragraph 26(4)(b) of the Canadian Environmental Protection Act***

Waiver requests may be accepted if it can be established that the substance will be contained throughout its life-cycle (manufacture, transportation and handling, processing storage, intended use, and disposal) in a manner sufficient to protect the environment and human health. This condition can be satisfied if the substance will be used for a limited purpose (e.g., a chemical reaction catalyst within a closed system), or if it is manufactured and contained at a location where releases are controlled. Assessment of each request for a waiver will be based on the information supplied and will place particular emphasis on the containment of the substance.

If a request for a waiver is based on the substance being used for a defined purpose, regulations may be made under Paragraph 32(1)(e) of CEPA. This "prescribed purpose"

regulation will specify the information requirement(s) being waived and prescribe the uses that permit the waiver(s) to be granted. If the substance is to be used in a manner not specified in the "prescribed purpose" regulation, the company must either request an amendment to that regulation or supply the waived information.

Substances with a purpose prescribed by a regulation under Paragraph 32(1)(e) will be excluded from the DSL and, therefore, will continue to be a "new" substance under CEPA. Consequently, a second party planning to manufacture or import that substance will be required to provide all the information prescribed in the New Substance Notification Regulations<sup>6</sup>. However, if the second party intends to use the substance in a manner identical to the prescribed purpose, they may also benefit from the waivers granted in the "prescribed purpose" regulation.

Examples of situations in which information may be waived under Paragraph 26(4)(b) of CEPA are:

- (a) the substance is incorporated into a matrix and will not be released from this matrix during its intended use; and
- (b) the substance is an isolated reaction intermediate that is not released during manufacture.

Isolated reaction intermediates that exceed quantities defined for site-limited intermediates (described in Subsections 3.2.1.3 and 3.2.2.5 of these Guidelines) are still eligible for waivers under Paragraph 26(4)(b) of CEPA.

#### **6.4            *Waivers Requested Under Paragraph 26(4)(c) of the Canadian Environmental Protection Act***

Many of the potential waivers that can be requested under Paragraph 26(4)(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) fat solubility determinations for substances that are highly volatile.

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<sup>6</sup> Companies are encouraged to contact Environment Canada to determine whether the original notifier is willing to undertake an Information Sharing Agreement (see Section 4.6 of these Guidelines).

The use of alternative protocols or data to fulfil the information requirement should be considered before it is judged to be infeasible or impractical to provide certain information. The cost of obtaining data cannot alone be used as a reason for the infeasibility or impracticability of providing the prescribed information.

*Section 7*

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**Pre-notification Consultation**

Individuals who wish to consult with Environment Canada and/or National Health and Welfare Canada during the planning or preparation of their notification may indicate this desire through the NSN Information Line. These discussions can clarify notification procedures or information requirements, and assist in determining the acceptability of:

- (a) waiver requests;
- (b) test protocols; or
- (c) data based on calculation or estimation methods (e.g., structure-activity relationships)

Discussions will take place after a preliminary package has been submitted that contains sufficient information to permit government officials to make an informed response to the question at hand. The government will make every effort to respond to a query within a period equivalent to the assessment period for that substance. For example, for substances that will be subject to Schedule II requirements, a response should be issued within 45 days.

Officers from the Departments of Environment and National Health and Welfare will give opinions based on the information package tabled at the time of the pre-notification dialogue. The professional opinions of assessment officers expressed during the pre-notification dialogue are not an official commitment because technical conclusions may differ after a more in-depth study of the final notification package.

In addition to pre-notification consultations, the government encourages discussions to clarify any other issues related to the New Substances Notification program.



*Section 8*

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**Preparing a New Substances Notification****8.1            *The Notification Form***

The New Substances Notification (NSN) form is intended to serve as an aid for complying with the New Substances Notification Regulations of the CEPA. The notification form is divided into two sections: Part A — Administrative and Substance Identity Information; and Part B — Technical Information. Please note that a complete notification must contain the information requirements of Part A and Part B, and all laboratory reports, waiver justifications, and other attachments necessary to fulfil the requirements set by regulation.

The notification form should be completed using a typewriter or by printing legibly in black ink. The form may also be reproduced using computer software and submitted on hard copy. The form or sections of the form may be reproduced as often as required. All information (except for "Additional Information" as described in Section 4.5 of these Guidelines) must be provided in one of the two official languages (English or French). Two copies of the complete notification should be sent by mail or courier to:

**Mailing Address:**

Chief, New Substances Division  
Commercial Chemicals Branch  
Conservation and Protection  
Environment Canada  
14th Floor, Place Vincent Massey  
Ottawa, Ontario  
K1A 0H3

**Courier Deliveries:**

351 St. Joseph Blvd.  
Hull, Quebec  
J8Y 3Z5

Environment Canada will confirm receipt of the notification and provide a NSN Reference Number (Section 9.1 of these Guidelines) that is to be used in all further correspondence concerning that notification.

**8.2            *Proprietary Information***

Any information submitted to Environment Canada may be claimed as confidential (see Section 9 for details).

### **8.2.1**      *Substance Identity*

When a person intends to import a substance, or mixture of substances, the identity of which the foreign supplier considers to be proprietary, the importer is responsible for determining whether any components are notifiable. If the foreign supplier indicates that a product contains notifiable substances, the importer must submit a notification minus the proprietary information and indicate that this information will be provided by the supplier. The identity of the substance will be kept confidential from the importer.

The importer should give the supplier the NSN Reference Number for use in submitting proprietary information directly to Environment Canada.

### **8.2.2**      *Data*

Foreign suppliers may also consider certain data to be proprietary. In such cases, the importer must submit the incomplete notification and ask the supplier to provide the outstanding proprietary information directly to Environment Canada. The notification assessment period will not begin until all the required information has been received (refer to Subsection 10.1.1 of these Guidelines). Any third party proprietary information will be kept confidential from the importer.

## **8.3**            *Completing the Notification Form*

To assist you in completing the NSN form, explanations of the various administrative information requirements are provided. The alpha-numeric character associated with these explanations corresponds with the appropriate block on the NSN form. Explanatory notes on many of the technical information requirements are given in Section 4.

### **8.3.1**      *Part A – Administrative Information and Substance Identity*

#### **A.1**            *Certification Statement*

The person named in this block as providing information is considered to be the notifier and must sign the certification statement. The signature is an affirmation by the notifier that the information and the statements provided in this notification are accurate and true to the best of his/her knowledge. If the notifier is not a Canadian resident, the Canadian agent must also sign this statement. All signatures must be original.

#### **A.2**            *Corporate Headquarters*

Provide the name of the Corporation and the address of the Corporate Headquarters regardless of its location. If the Corporate Headquarters is not located in Canada, the notifier must also provide the name and address of a Canadian agent (Block A.4).

**A.3**            *Proposed Site of Manufacture or Port of Entry*

If the notified substance is manufactured in Canada, provide the name of the manufacturer and the location of the manufacturing site(s). For substances that are imported, provide the name of the corporation importing the substance and the planned port(s) of entry into Canada. If there are more than one sites of manufacture or import, please provide an attachment.

**A.4**            *Canadian Agent*

The name and address of a Canadian agent must be provided only if the corporate headquarters is located outside Canada (an agent is not required if the corporate headquarters is within Canada). In these circumstances, the Canadian agent<sup>7</sup> is legally responsible for the import of the substance and for providing the notification to Environment Canada. Consequently, any notice or correspondence regarding the notification will be sent to the agent at the address specified in this block. However, as described in Section 8.2, if the foreign notifier considers any information to be proprietary, the agent must submit a notification minus the proprietary information, and the foreign notifier must submit the remaining information directly to Environment Canada. The proprietary information will be kept confidential from the agent.

If the corporate headquarters is not in Canada and the name and address of an agent has not been provided, the notification will be considered incomplete and will be returned.

**A.5**            *Technical Contact*

The name of an individual who is familiar with the content of the notification and can assist in the resolution of issues pertaining to ambiguous, incomplete, or missing information must be provided. Identify this person by name, position, company, address, and telephone and facsimile numbers. The technical contact need not be a resident of Canada.

**A.6**            *Amount*

Indicate the trigger quantity that the notifier expects to exceed on the date given in Block A.7.

**A.7**            *Date of Exceedence*

Provide the date(s) on which manufacture or import is anticipated to exceed the trigger(s) quantity selected in Block A.6.

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<sup>7</sup> If a foreign company has contracted more than one agent, please provide their names and addresses and a description of the responsibilities of each agent.

**A.8            *Activity***

Check the appropriate block to indicate whether the substance will be manufactured and/or imported.

**A.9            *Schedule Information***

Circle the appropriate Roman numeral to indicate the schedule provided and mark the box with an "X" to indicate substance type (polymer, Research and Development, on NDSL, etc.).

**A.10           *Correspondence***

Indicate the preferred official language of correspondence.

**A.11           *Substance Information***

Environment Canada must receive complete and unambiguous identification of the new substance (Section 4.1 of these Guidelines). If the 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.

**A.11.1        *Substance Name***

Mark the appropriate block to specify the use of CAS or IUPAC nomenclature and provide the appropriate name.

**A.13           *Confidentiality Requests***

Notifiers must enter either a "C" to indicate that the information is considered confidential or an "N" to indicate that the information is considered non-confidential. If the information is considered confidential, the notifier should attach supplementary information specified in the Confidential Information Disclosure Regulations of CEPA (see Section 9.2 of these Guidelines).

Entering a "C" in the respective claim box infers the following:

**Corporation:** The link of the substance identity to the corporation or persons in any or all of Blocks A.2 to A.5 is confidential.

**Manufacture:** The fact that the corporation identified in Block A.2 manufactures the substance for commercial purposes at the site identified in A.3, or at any site indicated on any attachment provided with this form, is confidential.

**Import:** The fact that the corporation identified in Block A.2 imports the substance for commercial purposes at the port of entry identified in A.3, or at any port of entry indicated on any attachment provided with this form, is confidential.

**Amount:** The amount of substance the notifier anticipates exceeding as well as the expected date of the exceedence is confidential.

**Substance Identity:** The identity of this substance is confidential. The supplemental information described in Subsection 9.2.2 of these Guidelines (Masked Names) must also accompany these claims.

#### **A.14**            *Information Sharing Agreement*

Where a notifier is willing to enter into an Information Sharing Agreement (see Section 4.6 of these Guidelines), the Information Sharing Agreement Authorization must be signed. If authorization is denied, strike a line through Box A.14 and do not sign the statement.

#### **8.3.2** *Part B – Technical Data*

Part B of the notification form contains six portions:

- B.1    Physical-Chemical Properties;
- B.2    Mammalian Toxicity;
- B.3    Ecotoxicity;
- B.4    Exposure Information;
- B.5    Other Agencies Notified; and
- B.6    Additional Information.

Explanatory notes for many of the technical information requirements are given in Section 4.

**8.3.2.1**        *Experimental Data.* Test reports included with the notification must be consistent with the format described in the "Test Report" section of the appropriate test guideline or protocol (Section 5 of these Guidelines). Summaries of test reports are not sufficient. Reports must include the name and address of the head of the quality assurance unit of the testing laboratory. In addition, for data developed after the Regulations came into force and that employ a non-OECD GLP, provide a description of the GLP including quality control and quality assurance procedures and an indication of reference substances. Test reports submitted in a previous New Substances Notification or Section 17 notice need not be resubmitted; however, the appropriate Reference Number must be supplied [see "P" code in Subsection 8.3.2.3(a)].

Although physical-chemical data will be included in test reports, values and conditions should also be provided in Section B.1 of the form. This section of the form will act as a

worksheet to help the submitter prepare a rationale to support a waiver request, describe non-applicable information, and discuss notifications with review officers.

For polymers, two information requirements, "dispersibility 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 notification form.

**8.3.2.2 *Research and Development Activity.*** This provision is required only for research and development polymers subject to the information requirements of Schedule XI. This provision requires a brief statement of the research activity that is being conducted and should not normally exceed a few sentences in length.

**8.3.2.3 *Information Available on Material Safety Data Sheets.*** If any of the information specified in Subsections 4.3.4 or 4.3.5 of these Guidelines is described in sufficient detail on the MSDS, the appropriate section of the MSDS can be referred to in the Attachment column of the Notification Form.

**8.3.2.4 *Data Codes, Attachments, and Confidential Information.*** In addition to the list of information requirements, each section contains a column to indicate Data Code, Attachment Reference, and Confidential Information. The section for Physical-Chemical Properties also contains a column for Values and Conditions. Explanations for the use of these columns also appear on the form.

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

D = test data on notified substance, recommended test protocol

The data provided have been generated on the notified substance using protocols listed in Tables 3 to 6 of these Guidelines. This code is to be used even if the information is provided under the Additional Information requirements of the schedules (refer to Section 4.5 "Additional Information" of these Guidelines).

A = alternative procedures

The data provided have been generated using: (1) an alternative test protocol; (2) structure-activity relationships including "read-across" and QSAR; or (3) other calculation methods (refer to Section 5.2 of these Guidelines). This code is to be used even if the information is provided under the Additional Information requirements of the schedules (refer to Section 4.5 "Additional Information" of these Guidelines).

W = waiver requested

Requests for waiver of information must be accompanied by justifications that satisfy any of the waiver criteria listed in Subsection 26(4) of CEPA (refer to Section 6 of these Guidelines).

N/A = not applicable

This code is used if the regulations specify that the provision of information is not required under certain conditions. For example, the octanol-water partition coefficient is not required when the water solubility is less than  $10^{-6}$  g/L. This code cannot be used as an abbreviation for "not available".

NR = not required

This code should appear when the information has not been provided and is not required by regulation.

P = previous notification

This code is to be used if the notifier has already provided the information to Environment Canada in a previous New Substances Notification or a Section 17 notice. The applicable NSN or Section 17 Reference Number must be entered in the Attachment column.

**Attachments.** Indicate a reference for accompanying documents (e.g., Appendix 6) so they may be readily located within the notification package. Attachments include: justifications for waivers of information; reports of experimental procedures; reports of test results; rationale for alternative data; results and validation of modelling studies; rationale for why information is considered "not applicable"; or information supplemental to a request for confidentiality.

**Confidential Information.** Notifiers must enter either a "C" to indicate that the information is considered confidential or an "N" to indicate that the information is considered non-confidential. If the information is considered confidential, the notifier should attach supplementary information specified in the Confidential Information Disclosure Regulations of CEPA (see Section 9.2 of these Guidelines).

## Section 9

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### **Confidential Information**

Under Section 19 of CEPA, any person who provides information to the government in support of a new substance notification may, at the same time, submit a written request that information be treated as confidential. This feature ensures that genuine confidential business information is protected from public disclosure. The degree of protection given to information claimed to be confidential will be consistent with the provisions of the *Access to Information Act* and with Sections 20 to 24 of CEPA.

#### **9.1 Claiming Confidentiality**

The confidentiality privileges described in Section 19 of CEPA can be satisfied by: (1) indicating which particular information is confidential using the New Substances Notification form; and (2) providing the information prescribed in the Confidential Information Disclosure Regulations (refer to Section 9.2 of these Guidelines).

#### **9.2 Information Supplemental to a Confidentiality Claim**

Each claim for confidentiality in a New Substances Notification must be accompanied by the supplementary information prescribed in the Confidential Information Disclosure Regulations (detailed in Subsections 9.2.1 and 9.2.2). Environment Canada 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 not be respected, or alternatively, the company may choose to withdraw the notification.

##### **9.2.1 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 company (or person);
- (b) the company 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 company; 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 must be indicated on the notification form, and the Certification Statement appearing on the front of the Notification Form must be signed. The Certification Statement includes the following phrase:

*"I hereby certify to the best of my information, knowledge, and belief ... the information for which confidentiality is claimed, meets the criteria for determining confidentiality as outlined in Subsection 9.2.1 of the Guidelines for the Notification and Testing of New Substances. "*

#### **9.2.2 Confidential Substance Identity Claims**

Publication of a masked name is required under Section 31 of CEPA if publication of the actual identity of a substance would result in the release of confidential business information. Therefore, when claiming confidentiality for substance identity, the notifier must, in addition to the certification described in Subsection 9.2.1, provide the following information as prescribed in the Confidential Information Disclosure Regulations:

- (a) a proposed masked name developed in accordance with the prescribed masking procedure (see Appendix 7);
- (b) justification for masking more than one descriptive segment (see Appendix 7); and
- (c) the following information:
  - (1) the detrimental effects to the competitive position of the company that would result from the identity of the substance appearing on the DSL or in any other publication;
  - (2) the manner in which a competitor could use the identity of the substance;
  - (3) 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;
  - (4) an indication of whether the substance has been patented and, consequently, disclosed through the patent;
  - (5) 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 for commercial purposes;

- (6) the measures that have been taken to prevent undesired disclosure of substance identity and the extent of any disclosures to date;
- (7) an indication of whether the substance is, or will be, in an effluent, emission, or waste entering the environment;
- (8) 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;
- (9) the purpose for which the substance is being, or will be, manufactured, imported, or used;
- (10) an indication, to the best of your knowledge, of whether Environment Canada, National Health and Welfare, another federal agency, a provincial agency, or the agency of a foreign government has ever made a determination that this substance: (i) has an immediate or long-term effect on the environment; (ii) constitutes, or may constitute, a danger to the environment; or (iii) constitutes, or may constitute, a danger to human life or health (if such a determination has been made, provide details).

**9.2.2.1** *Masking Substance Identity.* The procedures for generating a masked name are also prescribed in the Confidential Information Disclosure 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 only be acceptable to the extent necessary to disguise the full 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 Subsection 9.2.2, item b).

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 Confidential Information Disclosure Regulations. If judged consistent with these 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. Environment Canada will try to reach a consensus with the company on a masked name. If a consensus is not reached, the government will publish a masked name that, in its opinion, will respect the confidentiality claim of the company while retaining the generic molecular structure of the substance. Alternatively, the company may choose to withdraw the notification.

### 9.3 *Determining the Presence of Confidential Substances on Lists*

Substances listed on the confidential portion of the DSL or NDSL are published under masked names (see Appendix A "Masked Names for Confidential Substance Identities" of these Lists). Any person who intends to manufacture or import a substance that they believe to be listed on the confidential portion of one of these lists may seek confirmation from Environment Canada. Environment Canada will only respond to such an inquiry if the person provides Environment Canada with documentation attesting to a *bona fide* intent to manufacture or import the substance for commercial purposes.

To document a *bona fide* intent to manufacture or import, the proponent must supply the following information to Environment Canada at the address provided in Section 3.5 of these Guidelines:

- (a) the specific chemical identity of the substance established in accordance with the nomenclature rules of the IUPAC or CAS;
- (b) the CAS Registry Number (if available);
- (c) a statement, signed by a person resident in Canada, declaring that the person intends to manufacture or import the substance for commercial purposes and that the substance would be subject to the New Substances Notification Regulations if it is not listed on the DSL;
- (d) if manufactured in Canada, a description of the research and development activities conducted to date (i.e., 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 imported, a description of the manufacturing history of the substance in international commerce (if known);
- (f) an elemental analysis; and
- (g) valid spectral analysis or analyses that confirm(s) the identity of the substance.

If an importer is unable to supply all of the required information because the foreign supplier considers this information confidential, the foreign supplier may submit the information directly to Environment Canada. After the proponent has provided documentation of a *bona fide* intent to manufacture or import the substance, Environment Canada will search the confidential portion of the DSL and NDSL. Environment Canada will respond to a written inquiry into confidential listings within 30 days of receipt of complete documentation and will indicate whether or not the substance is on either of the Lists.

## Section 10

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### Processing a Notification

This section describes the administrative procedures and responsibilities of the government when a New Substance Notification (NSN) is received.

#### **10.1**      *Receipt of a New Substance Notification*

##### **10.1.1**      *Assessment "Time Clock"*

The assessment "time clock" refers to the allotted time (calendar days) the government has to assess an NSN (see Section 3 of these Guidelines). The assessment periods for substances exceeding trigger quantities after the transitional period correspond with the notification periods listed in Table 2. Substances exceeding trigger quantities during the transitional period have notification periods (Table 1) but do not have a prescribed assessment period.

Day 1 of an assessment period is the day that the NSN is received by the Commercial Chemicals Branch, Environment Canada. The assessment time clock may be affected by missing or incomplete information. For example:

- (a) if a notification package is grossly inadequate or incomplete, the entire package will be returned and the assessment will begin when a corrected package is received;
- (b) if information within the NSN is found to be erroneous and, therefore, the assessment in progress is invalidated, the assessment will be terminated and reset at Day 1 when the correct information is received;
- (c) if information within the NSN is found to be erroneous, but does not invalidate the assessment in progress, the assessment time clock will be stopped at Day *X* and will continue at Day *X* + 1 when the correct information is received;
- (d) if 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 an assessment officer; or
- (e) if proprietary information is being sent directly to Environment Canada by a foreign supplier, the time clock will not start until all the required information has been received.

##### **10.1.2**      *New Substance Notification Reference Number*

When a New Substance Notification is received by Environment Canada, an NSN Reference Number will be assigned. This number will appear on all correspondence issued by the

government concerning that notification and should be used in any subsequent communications regarding that notification.

## **10.2**            *Correspondence*

Official correspondence between the Environment Canada and the notifier or 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. However, Environment Canada will not send confidential business information (CBI) by facsimile transmission. Environment Canada also advises notifiers not to send CBI by facsimile transmission. The types of correspondence a notifier may receive are:

### **10.2.1**            *Acknowledgement*

After receipt and preliminary screen of the NSN, an acknowledgement will be issued specifying the starting date of the assessment period and the NSN Reference Number. Acknowledgement indicates that the administrative information is satisfactory and that all required information has been received but not yet reviewed.

### **10.2.2**            *Notice of Interruption or Rejection*

A rejection or interruption notice will be issued if the NSN contains significant omissions or errors in the mandatory information requirements. These notices will describe all deficiencies in the NSN. Original documentation may be returned.

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

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

Evaluators will attempt to contact the notifier by telephone to resolve difficulties before a rejection or interruption notice is issued.

### **10.2.3**            *Notice of Extension of Assessment Period*

When additional time is required to complete an assessment, the notifier will be advised of an extension of the assessment period before the end of the initial assessment period. The government may extend the assessment period only once, for a length of time not exceeding the initial assessment period.

#### **10.2.4**        *Statement of Assessment Conclusions*

The notifier will be advised in writing, before the end of the assessment period, whether or not the government suspects that the substance is toxic, and what action, if any, will be taken by the government (see Section 11.4 of these Guidelines).

#### **10.3**        *Assessment of the Notification*

The purpose of the assessment and control process is to ensure that, either because of the inherent properties of the substance or measures taken to control exposure to the substance, the commercial use of the substance will pose only minimal risk to human health or the environment.

##### **10.3.1**        *Information Review*

Evaluators within Environment Canada and National Health and Welfare will assess the notification package to determine the acceptability of: substance identity and masked names; claims for confidential business information; test protocols and procedures; test data; rationales for requests for waivers of information; and exposure information.

Deficiencies in the submitted information that cannot be easily resolved may result in the rejection of the notification or interruption of the assessment (see Section 10.2 of these Guidelines).

##### **10.3.2**        *Assessment for Toxicity*

The purpose of the New Substance Notification assessment process is to determine whether or not the substance is, or is suspected of being, "toxic" as interpreted in Section 11 of CEPA and stated below:

*"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;*
- (b) constituting or that may constitute a danger to the environment on which human life depends; or*
- (c) constituting or that may constitute a danger to human life or health."*

Consequently, the determination of whether a substance is, or is suspected of being, toxic involves assessment of the potential for exposure to 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 that the substance might be used if it were placed 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 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", CEPA has a unique provision, under Subsection 29(1), that permits the government to undertake one of several control options (see Subsection 10.4.1 of these Guidelines).

#### ***10.4 Action Taken After an Assessment***

After the assessment, the notifier will be advised of whether or not there is a suspicion of toxicity. If there is no suspicion that the substance is toxic, the notifier may proceed with import or manufacture after the assessment period has expired. When the government suspects that the substance may be toxic, control measures may be applied to minimize any risk to human health or the environment.

##### ***10.4.1 Control Measures***

When the government suspects that a substance may be toxic, the following measures under Section 29 of CEPA 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 34 of CEPA is published in the *Canada Gazette*); or

- (c) prohibit the manufacture or import of the substance until supplementary information or test results have been submitted to the government 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).

Measures under Section 29 of CEPA must be taken by the government before the expiration of the assessment period. The notifier must comply with these measures or withdraw the notification.

When a condition or prohibition is issued or altered, a notice must be published in the *Canada Gazette* describing the action and the substance to which it applies. The name of the notifier is not included in this notice. Furthermore, if the publication of the substance name would result in the release of confidential business information, a masked name will be published.

#### **10.4.2        *Additions to the Domestic Substances List***

When the period for assessment has expired, Environment Canada is obliged under Section 30 of CEPA to place the substance on the DSL if all of these criteria have been met:

- (a) Environment Canada has been provided with the information prescribed in Section 26 or 27 of CEPA — because inclusion of a substance on the DSL may permit unrestricted use, any substance for which the full complement of information requirements (i.e., Schedules II, III, VI, VII, or VIII) were reduced as a result of limited use or exposure, or for which waivers were granted under Paragraph 26(4)(b), may not have satisfied this criterion;
- (b) Environment Canada is satisfied that the substance has been imported or manufactured in excess of:
  - (1) 5 000 kg in any calendar year or an accumulated total of 25 000 kg for chemicals listed on the NDSL;
  - (2) 10 000 kg in any calendar year or an accumulated total of 50 000 kg for chemicals not listed on the NDSL;
  - (3) 5 000 kg in any calendar year or an accumulated total of 25 000 kg for transitional chemicals, provided that the notifier has submitted a Schedule II notification within five years after the New Substances Notification Regulations are in force; or
  - (4) 10 000 kg in any calendar year or an accumulated total of 50 000 kg for all polymers; and
- (c) no conditions have been imposed on the substance under Section 29(1)(a) of CEPA.



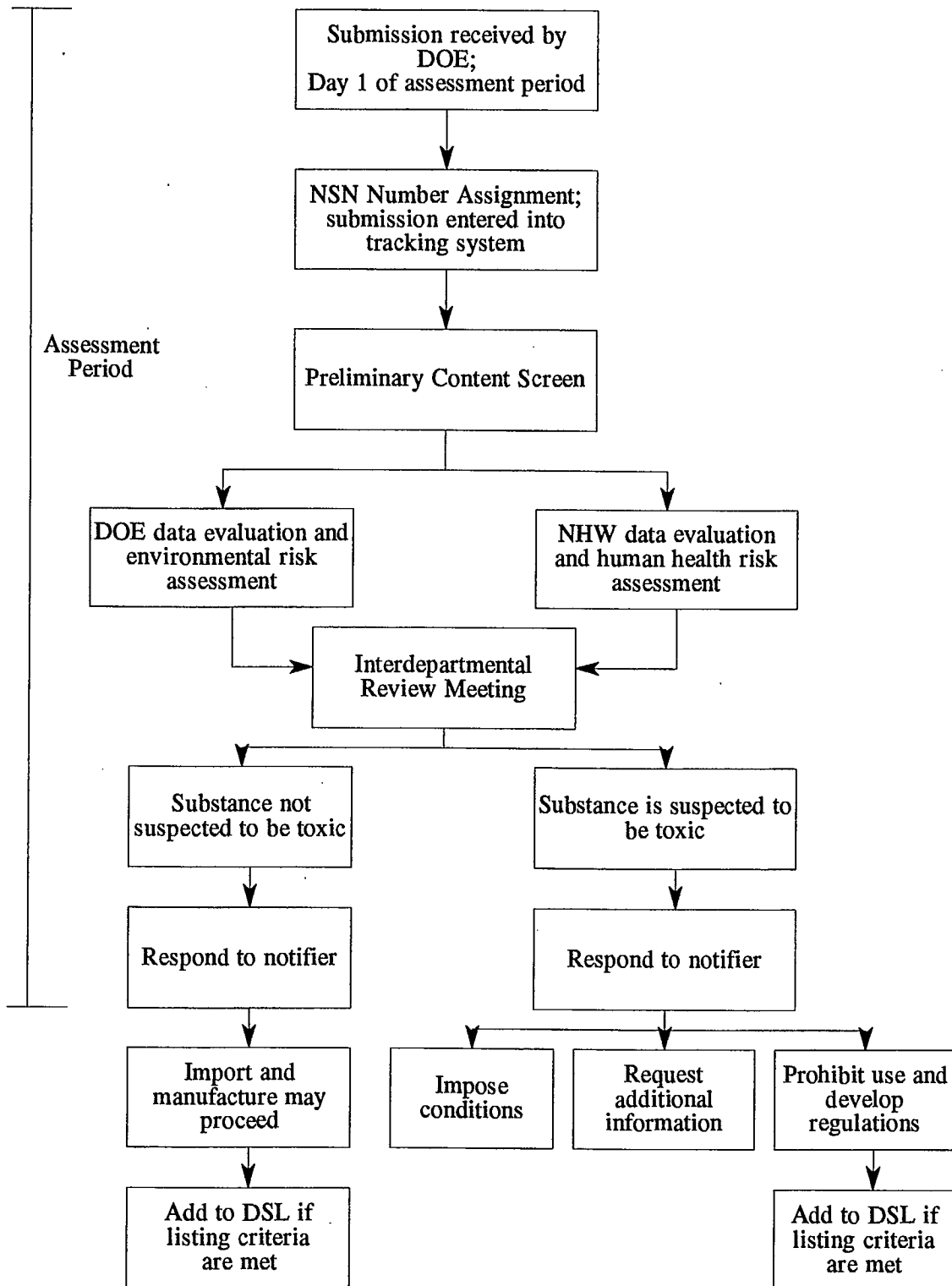


Figure 9 Overview of New Substances Notification Assessment Process

Substances that are not anticipated to pose a risk to Canadians, regardless of their use or quantity, will be placed on the DSL without restrictions. Substances that were suspected of being toxic in the assessment can only be placed on the DSL if they are controlled under Section 34 of CEPA.

Substances notified under the New Substances Notification Regulations will remain "new" substances (and thus notifiable for a second party) until they are published as a supplement to the DSL in the *Canada Gazette*. Supplements to the DSL will be published on a weekly basis when practical. Quarterly updates to the DSL will also be available on CD-ROM through the Canadian Centre for Occupational Health and Safety.

### **10.5            *Program Overview***

A schematic overview of the New Substances Notification assessment process is shown in Figure 9.

*Section 11*

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**Post-notification Responsibilities****11.1      *Correction of Information***

Any person who has submitted information in support of a notification and later determines that the information is erroneous must immediately notify Environment Canada of that fact and submit the necessary correction.

This requirement relates only to information that existed at the time of the notification. Information generated after a notification that reasonably supports the conclusion that the substance is toxic<sup>8</sup>, or is capable of becoming toxic, must be provided to Environment Canada under the provisions of Section 17 of CEPA (see Section 11.3).

**11.2      *Notice of Excess Quantity***

After proceeding with the import or manufacture of the substance, Subsection 26(7) of CEPA requires notifiers to advise Environment Canada when the manufactured or imported quantity exceeds:

- (a) 5 000 kg in any calendar year or an accumulated total of 25 000 kg for chemicals listed on the NDSL; or
- (b) 10 000 kg in any calendar year or an accumulated total of 50 000 kg for chemicals not listed on the NDSL; or
- (c) 10 000 kg in any calendar year or an accumulated total of 50 000 kg for polymers; or
- (d) 5 000 kg in any calendar year or an accumulated total of 25 000 kg for transitional chemicals provided these quantities are exceeded after the New Substances Notification Regulations come into force (a notice of exceedance under Subsection 26(7) is not required for transitional substances that exceeded the above quantities prior to the New Substances Notification Regulations coming into force).

Notification that any of the above prescribed quantities has been exceeded must be provided, within 30 days of exceeding the quantity, to:

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<sup>8</sup> The term "toxic" refers to the interpretation in Section 11 of CEPA and is described in Subsection 10.3.2 of these Guidelines.

New Substances Division  
Commercial Chemicals Branch  
Conservation and Protection  
Environment Canada  
14th Floor, Place Vincent Massey  
Ottawa, Ontario  
K1A 0H3  
Canada

This notice will oblige Environment Canada to add the substance to the DSL if all of the criteria described in Section 30 of CEPA have been met (refer to Subsection 10.4.2 of these Guidelines).

### ***11.3 Section 17 of the Canadian Environmental Protection Act***

If, subsequent to the notification of a new substance, a notifier obtains new information that reasonably supports the conclusion that the substance is toxic, or is capable of becoming toxic, the notifier is obliged under Section 17 of CEPA to provide that information to Environment Canada without delay. This information must be provided unless the notifier has actual knowledge that Environment Canada already has the information.

There may be instances when a Section 17 notice has been provided on a substance that is subsequently the subject of a New Substance Notification. In these cases, the notifier has the option of either resubmitting this information or referencing the Section 17 correspondence containing the submission.

Procedures and criteria for submitting a Section 17 notice are described in the guidelines for Section 17 of CEPA.

### ***11.4 Enforcement Information***

The CEPA enforcement policy for offences under the Substances New to Canada portion of the Act is described in the Environment Canada publication "Enforcement and Compliance Policy of CEPA" (DSS No. EN 40-356/1988E). The various offenses, fines, and punishments relating to contraventions of the Act are stated in Sections 111 to 126 of CEPA.

*Appendix 1*

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**REGULATIONS RESPECTING NOTIFICATION OF  
SUBSTANCES NEW TO CANADA<sup>1</sup>***Short Title*

1. These Regulations may be cited as the *New Substances Notification Regulations*.

*Interpretation*

2. (1) In these Regulations,

"Act" means the *Canadian Environmental Protection Act*; (*Loi*)

"anionic polymer" means a polymer that contains one or more monomer units that are covalently bound and bear a net negative charge; (*polymère anionique*)

"biotechnology product" means a substance that is produced by means of biotechnology; (*produit biotechnologique*)

"cationic polymer" means a polymer that contains one or more monomer units that are covalently bound and bear a net positive charge; (*polymère cationique*)

"consumed", in respect of a substance, means destroyed or completely converted to another substance; (*consommé*)

"DSL" means the Domestic Substances List compiled by the Minister under subsection 25(1) of the Act, as amended from time to time; (*LIS*)

"intermediate substance" means a substance that is consumed in a chemical reaction used for the intentional manufacture of another substance; (*substance intermédiaire*)

"monomer unit" means the reacted form of a monomer in a polymer; (*unité monomère*)

"NDSL" means the Non-domestic Substances List compiled by the Minister under subsection 25(2) of the Act, as amended from time to time; (*LES*)

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<sup>1</sup> These Regulations are the version proposed in *Canada Gazette*, Part I. The final version, which will be published in *Canada Gazette*, Part II, may or may not include modifications.

"polyester" means a polymer whose molecules contain two or more carboxylic acid ester linkages at least one of which links monomer units; (*polyester*)

"polymer" means a substance that consists of

- (a) molecules characterized by the sequence of one or more types of monomer units,
- (b) a simple weight majority of molecules containing three or more monomer units that are covalently bound to one or more other monomer units or reactants,
- (c) less than a simple weight majority of molecules of the same molecular weight, and
- (d) molecules distributed over a range of molecular weights where the differences in the molecular weights are primarily attributable to differences in the number of monomer units; (*polymère*)

"product development substance" means a research and development substance that is in the process of being evaluated in a single program of two years or less in duration prior to its full commercialization, which program includes pilot plant trials, production trials or customer trials other than test marketing, in order to modify the technical specifications of the research and development substance in response to the performance requirements of potential customers; (*substance destinée au développement de produits*)

"reactant", in respect of a polymer, means a substance that is used intentionally in the manufacture of the polymer and becomes part of the chemical composition of the polymer; (*réactif*)

"reactive functional group" means an atom or associated groups of atoms in a substance that are intended or may reasonably be expected to undergo facile chemical reaction; (*groupe fonctionnel réactif*)

"research and development substance" means a substance that is undergoing systematic investigation or research, by means of experimentation or analysis other than test marketing, the primary objective of which is

- (a) to create or improve a product or process, or
- (b) to determine the technical viability or performance characteristics of a product or process; (*substance utilisée pour la recherche et le développement*)

"site-limited intermediate substance" means a substance, other than a biotechnology product, that is manufactured or imported by a person in a quantity that does not exceed an accumulated total of 50 000 kg and 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 of consumption where it is consumed,

where the combined quantity of the substance in the possession of the person at the sites referred to in paragraphs (a) to (c) and in transport does not, at any one time, exceed 10 000 kg in respect of a substance other than a polymer and 20 000 kg in respect of a polymer; (*substance intermédiaire limitée au site*)

"test marketing" means the exploration of the market capability of a product in a competitive situation where the creation or improvement of the product is not the primary objective; (*test de marché*)

"transitional period" means the period beginning on January 1, 1987 and ending on September 10, 1993<sup>2</sup>; (*période transitoire*)

"whole animal" means an animal or 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; (*animal entier*)

"whole plant" means any plant or 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. (*plante entière*)

(2) In these Regulations,

(a) a reference to a calendar year within the transitional period means, in respect of 1993, the period beginning on January 1, 1993 and ending on September 10, 1993; and

(b) a reference to a calendar year within the 5-year period beginning on September 11, 1993 and ending on September 10, 1998 means

(i) in respect of 1993, the period beginning on September 11, 1993 and ending on December 31, 1993, and

(ii) in respect of 1998, the period beginning on January 1, 1998 and ending on September 10, 1998.

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<sup>2</sup> The *Canada Gazette*, Part II publication may contain a different date.

*Application*

3. These Regulations do not apply in respect of a substance that is loaded on a carrier outside Canada and moved through Canada to a location outside Canada, whether or not there has been a change of carrier during transit.

*Maximum Exempt Quantities*

4. For the purposes of paragraph 26(3)(e) of the Act, a substance is exempt from the application of subsections 26(1) and (2) of the Act where it is manufactured or imported in a quantity that does not exceed the quantity that first triggers a requirement to provide information under these Regulations.

## PART I

## NEW SUBSTANCES OTHER THAN POLYMERS AND CERTAIN BIOTECHNOLOGY PRODUCTS

*Application*

5. This Part does not apply in respect of

(a) polymers;

(b) biotechnology products that are polymers; or

(c) biotechnology products that are substances other than polymers, unless those substances are derived from whole animals or whole plants.

*Substances Other Than Product Development Substances, Site-limited Intermediate Substances and Substances Manufactured or Imported for Export Only*

6. (1) Subject to section 7, where a person manufactures or imports a substance that is not specified on the NDSL and subsections (3) and (4) do not apply, the person shall provide the following information:

(a) the information specified in Schedule I, where the substance is not a research and development substance and the quantity of the substance that the person manufactures or imports exceeds 20 kg but does not exceed 1 000 kg in any calendar year;



(b) the information specified in Schedule II, except the information specified in paragraphs 2(1)(i) and (j) of that Schedule, where the quantity of the substance that the person manufactures or imports

(i) exceeds 1 000 kg but does not exceed 10 000 kg in any calendar year, or

(ii) exceeds an accumulated total of 5 000 kg but does not exceed an accumulated total of 50 000 kg; and

(c) the information specified in Schedule III, where the quantity of the substance that the person manufactures or imports

(i) exceeds 10 000 kg in any calendar year, or

(ii) exceeds an accumulated total of 50 000 kg.

(2) Subject to section 7, where a person manufactures or imports a substance that is specified on the NDSL and subsections (3) and (4) do not apply, the person shall provide the following information:

(a) the information specified in Schedule I, where the quantity of the substance that the person manufactures or imports

(i) exceeds 1 000 kg but does not exceed 5 000 kg in any calendar year, or

(ii) exceeds an accumulated total of 5 000 kg but does not exceed an accumulated total of 25 000 kg; and

(b) the information specified in Schedule II, where the quantity of the substance that the person manufactures or imports

(i) exceeds 5 000 kg in any calendar year, or

(ii) exceeds an accumulated total of 25 000 kg.

(3) Subject to section 7, a person who manufactures or imports a substance that is specified on the NDSL shall, where the person manufactured or imported more than 20 kg of the substance in any calendar year during the transitional period, provide the information specified in Schedule II, where the quantity of the substance that the person manufactures or imports

(a) exceeds 5 000 kg in any calendar year; or

(b) exceeds an accumulated total of 25 000 kg.

(4) Subject to section 7, a person who manufactures or imports a substance that is not specified on the NDSL shall, where the person manufactured or imported more than 20 kg of the substance in any calendar year during the transitional period, provide the following information:

(a) the information specified in Schedule II, where the quantity of the substance that the person manufactures or imports

(i) exceeds 5 000 kg in any calendar year within the 5-year period beginning on September 11, 1993 and ending on September 10, 1998,

(ii) exceeds, at any time during the 5-year period referred to in subparagraph (i), an accumulated total of 25 000 kg,

(iii) exceeds 5 000 kg but does not exceed 10 000 kg in the period beginning on September 11, 1998 and ending on December 31, 1998 or in any calendar year after 1998, or

(iv) exceeds, at any time after September 10, 1998, an accumulated total of 25 000 kg but does not exceed an accumulated total of 50 000 kg; and

(b) subject to subsection (5), the information specified in Schedule III, where the quantity of the substance that the person manufactures or imports

(i) exceeds 10 000 kg in any calendar year within the 5-year period beginning on September 11, 1998 and ending on December 31, 1998 or in any calendar year after 1998, or

(ii) exceeds, at any time after September 10, 1998, an accumulated total of 50 000 kg.

(5) The information specified in Schedule III is not required to be provided by a person to whom subsection (4) applies where that person has, during the 5-year period beginning on September 11, 1993 and ending on September 10, 1998, provided the information specified in Schedule II.

7. Section 6 does not apply in respect of a substance while it is

(a) a product development substance;

(b) a site-limited intermediate substance; or

(c) a substance that is being manufactured or imported by a person for export only, if the quantity of the substance in the person's possession at any one time does not exceed 10 000 kg.

*Product Development Substances*

8. (1) Where a person manufactures or imports a product development substance that is not specified on the NDSL, the person shall provide the following information:

(a) the information specified in Schedule II, except the information specified in paragraphs 2(1)(i) and (j) of that Schedule, or the information specified in Schedule IV, where the quantity of the product development substance that the person manufactures or imports

(i) exceeds 1 000 kg in any calendar year, or

(ii) exceeds an accumulated total of 5 000 kg but does not exceed an accumulated total of 50 000 kg; and

(b) the information specified in Schedule III or IV, where the quantity of the product development substance that the person manufactures or imports exceeds an accumulated total of 50 000 kg.

(2) Where a person manufactures or imports a product development substance that is specified on the NDSL, the person shall provide the following information:

(a) the information specified in Schedule I or IV, where the quantity of the product development substance that the person manufactures or imports

(i) exceeds 1 000 kg in any calendar year, or

(ii) exceeds an accumulated total of 5 000 kg but does not exceed an accumulated total of 25 000 kg; and

(b) the information specified in Schedule II or IV, where the quantity of the product development substance that the person manufactures or imports exceeds an accumulated total of 25 000 kg.

*Site-limited Intermediate Substances or Substances for Export Only*

9. Section 10 applies in respect of a person who manufactures or imports a substance for export only, only if the quantity of the substance in the person's possession at any one time does not exceed 10 000 kg.

10. (1) Where a person manufactures or imports a site-limited intermediate substance that is not specified on the NDSL or a substance for export only that is not specified on the NDSL and subsection (3) does not apply, the person shall provide the following information:

(a) the information specified in Schedule I, where the quantity of the substance that the person manufactures or imports exceeds 20 kg but does not exceed 1 000 kg in any calendar year; and

(b) subject to subsection (4), the information specified in Schedule V, where the quantity of the substance that the person manufactures or imports

(i) exceeds 1 000 kg in any calendar year, or

(ii) exceeds an accumulated total of 5 000 kg.

(2) Where a person manufactures or imports a site-limited intermediate substance that is specified on the NDSL or a substance for export only that is specified on the NDSL and subsection (3) does not apply, the person is required to provide the following information:

(a) the information specified in Schedule I, where the quantity of the substance that the person manufactures or imports

(i) exceeds 1 000 kg but does not exceed 5 000 kg in any calendar year, or

(ii) exceeds an accumulated total of 5 000 kg but does not exceed an accumulated total of 25 000 kg; and

(b) subject to subsection (4), the information specified in Schedule V, where the quantity of the substance that the person manufactures or imports

(i) exceeds 5 000 kg in any calendar year, or

(ii) exceeds an accumulated total of 25 000 kg.

(3) Subject to subsection (4), a person who manufactures or imports a site-limited intermediate substance or a substance for export only shall, where the person manufactured or imported more than 20 kg of the substance in any calendar year during the transitional period, provide the information specified in Schedule V, where the quantity of the substance that the person manufactures or imports

(a) exceeds 5 000 kg in any calendar year; or

(b) exceeds an accumulated total of 25 000.

(4) The information specified in items 3 and 4 of Schedule V is not required to be provided in respect of a site-limited intermediate substance that is manufactured and consumed at the site of manufacture.

*Information Provision Dates*

11. Information specified in a schedule referred to in sections 6 to 10 shall be provided as follows:

- (a) for Schedule I, at least 5 days before the day on which a person manufactures or imports a substance in a quantity that triggers the requirement to provide the information specified in Schedule I;
- (b) for Schedule II, at least 45 days before the day on which a person manufactures or imports a substance in a quantity that triggers the requirement to provide the information specified in Schedule II;
- (c) for Schedule III, at least 90 days before the day on which a person manufactures or imports a substance in a quantity that triggers the requirement to provide the information specified in Schedule III; and
- (d) for Schedule IV or V, at least 21 days before the day on which a person manufactures or imports a substance in a quantity that triggers the requirement to provide the information specified in Schedule IV or V, as the case may be.

*Assessment Periods*

12. The periods within which the Ministers shall assess the information specified in a schedule referred to in sections 6 to 10 are as follows:

- (a) for Schedule I, a period of 5 days following receipt of the information;
- (b) for Schedule II, a period of 45 days following receipt of the information;
- (c) for Schedule III, a period of 90 days following receipt of the information; and
- (d) for Schedules IV and V, a period of 21 days following receipt of the information.

*Transitional Period*

13. (1) Subject to subsection (2), a person who manufactured or imported a substance during the transitional period shall provide the following information:

- (a) the information specified in Schedule I, where the quantity of the substance that the person manufactured or imported exceeded 20 kg but did not exceed 5 000 kg in any calendar year within the transitional period; and

(b) the information specified in Schedule II, where the quantity of the substance that the person manufactured or imported

(i) exceeded 5 000 kg in any calendar year within the transitional period, or

(ii) exceeded, at any time within the transitional period, an accumulated total of 25 000 kg.

(2) Subsection (1) does not apply in respect of a substance while it is

(a) a site-limited intermediate substance; or

(b) a substance that is being manufactured or imported by a person for export only, if the quantity of the substance in the person's possession at any one time does not exceed 10 000 kg.

14. (1) Subject to subsection (2), a person who manufactured or imported a site-limited intermediate substance, or a substance for export only, during the transitional period shall provide the following information:

(a) the information specified in Schedule I, where the quantity of the substance that the person manufactured or imported exceeded 20 kg but did not exceed 5 000 kg in any calendar year within the transitional period; and

(b) subject to subsection (3), the information specified in Schedule V, where the quantity of the substance that the person manufactured or imported

(i) exceeded 5 000 kg in any calendar year within the transitional period, or

(ii) exceeded, at any time within the transitional period, an accumulated total of 25 000 kg.

(2) Subsection (1) applies in respect of a person who manufactured or imported a substance for export only, only if the quantity of the substance in the person's possession at any one time during the transitional period did not exceed 10 000 kg.

(3) The information specified in items 3 and 4 of Schedule V is not required to be provided in respect of a site-limited intermediate substance that is manufactured and consumed at the site of manufacture.

15. (1) The information that is specified in Schedule I and referred to in sections 13 and 14 shall be provided on or before December 10, 1993.

(2) Subject to subsection (3), the information that is specified in Schedule II or V, as the case may be, and referred to in sections 13 and 14 shall, where the quantity that triggers the requirement to provide that information

(a) was exceeded in 1987, be provided on or before March 10, 1994;

(b) was exceeded in 1988, be provided on or before September 10, 1994;

(c) was exceeded in 1989, be provided on or before March 10, 1995;

(d) was exceeded in 1990, be provided on or before September 10, 1995;

(e) was exceeded in 1991, be provided on or before March 10, 1996;

(f) was exceeded in 1992, be provided on or before September 10, 1996; and

(g) was exceeded during the period beginning on January 1, 1993 and ending on September 10, 1993, be provided on or before March 10, 1997.

(3) Where the information specified in Schedule I is not provided, the information specified in the following items and subitems of Schedules II or V, as the case may be, shall be provided on or before December 10, 1993:

(a) subitems 1(1), (2), (3) and (5), that portion of subitem 2(5) that specifies the information, other than test data, in respect of the substance that is relevant to identifying hazards to human health and the environment and that is in the person's possession, and item 4 of Schedule II; and

(b) subitems 1(1), (2), (3) and (4), that portion of subitem 2(1) that specifies the information, other than test data, in respect of the substance that is relevant to identifying hazards to human health and the environment and that is in the person's possession, and item 6 of Schedule V.

*DSL*

16. The quantity of a substance prescribed for the purposes of subparagraph 30(1)(b)(iii) of the Act is

(a) in respect of a substance that is not specified on the NDSL, where the person did not manufacture or import the substance during the transitional period, a quantity that exceeds 10 000 kg in any calendar year or an accumulated total of 50 000 kg;

(b) in respect of a substance that is not specified on the NDSL, where the person manufactured or imported the substance during the transitional period,

- (i) a quantity that exceeds 5 000 kg in any calendar year within the 5-year period beginning on September 11, 1993 and ending on September 10, 1998, or exceeds at any time during the 5-year period an accumulated total of 25 000 kg, and
  - (ii) a quantity that exceeds 10 000 kg in the period beginning on September 11, 1998 and ending on December 31, 1998 or in any calendar year after 1998, or exceeds at any time after September 10, 1998 an accumulated total of 50 000 kg; and
- (c) in respect of a substance that is specified on the NDSL, 5 000 kg in any calendar year or an accumulated total of 25 000 kg.

## PART II

### NEW SUBSTANCES THAT ARE POLYMERS INCLUDING CERTAIN BIOTECHNOLOGY PRODUCTS

#### *Application*

17. (1) This Part does not apply in respect of a polymer that is manufactured by modifying the formulation of a polymer specified on the DSL through the addition of reactants no single one of which constitutes more than 2 per cent by weight of the polymer.

(2) This Part does not apply in respect of biotechnology products that are polymers unless those polymers are derived from whole animals or whole plants.

#### *Polymers Other Than Product Development Substances, Site-limited Intermediate Substances and Substances Manufactured or Imported for Export Only*

18. (1) Subject to section 20, where a person manufactures or imports a polymer other than a polymer to which section 19 applies, and subsection (2) does not apply, the person shall provide the following information:

(a) where the person manufactures or imports the polymer in a quantity that exceeds 1 000 kg but does not exceed 10 000 kg in any calendar year, or exceeds an accumulated total of 5 000 kg but does not exceed an accumulated total of 50 000 kg,

(i) if the polymer is not a research and development substance, the information specified in Schedule VI, and

(ii) if the polymer is a research and development substance, the information specified in Schedule XI; and



(b) where the person manufactures or imports the polymer in a quantity that exceeds 10 000 kg in any calendar year or an accumulated total of 50 000 kg,

(i) if the polymer is specified on the NDSL, the information specified in Schedule VII, except the information specified in subitem 2(2) of that Schedule, and

(ii) if the polymer is not specified on the NDSL,

(A) in the case of a polymer that is manufactured solely from reactants that are substances specified on the DSL, the information specified in Schedule VII, and

(B) in any other case, the information specified in Schedule VIII.

(2)<sup>3</sup> Subject to section 20, a person who manufactures or imports a polymer other than a polymer to which section 19 applies shall, where the person manufactures or imports the polymer in a quantity that exceeds 10 000 kg in any calendar year or an accumulated total of 50 000 kg and the person manufactured or imported more than 20 kg of the polymer in any calendar year during the transitional period, provide the following information:

(a) if the polymer is specified on the NDSL, the information specified in Schedule VII, except the information specified in subitem 2(2) of that Schedule; and

(b) if the polymer is not specified on the NDSL, the information specified in Schedule VII.

19. (1) This section applies in respect of a polymer that

(a) is not one of the types of polymers listed in items 1 to 4 of Schedule IX and has a number average molecular weight greater than 10 000 daltons, less than 2 per cent of its components with molecular weights of less than 500 daltons and less than 5 per cent of its components with molecular weights of less than 1 000 daltons;

(b) is not one of the types of polymers listed in Schedule IX and has a number average molecular weight greater than 1 000 daltons, less than 10 per cent of its components with molecular weights of less than 500 daltons and less than 25 per cent of its components with molecular weights of less than 1 000 daltons; or

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<sup>3</sup> The provisions of subsection 18(2) only apply to substances exceeding trigger quantities during the five-year period following the date that subsection 26(1) of CEPA came into force, unless the most comprehensive notification is received before the end of the five-year period. Substances exceeding trigger quantities after the five-year period will be subject to information requirements similar to the provisions of 18(1).

(c) is a polyester manufactured solely from reactants listed in Schedule X, or an anhydrous form of those reactants, other than the reactants or the anhydrous forms of those reactants that include both 1-butanol and 2-butenedioic acid (E).

(2) Subject to section 20, where a person manufactures or imports a polymer to which this section applies, and subsection (3) does not apply, the person shall provide the following information:

(a) where the person manufactures or imports the polymer in a quantity that exceeds 1 000 kg but does not exceed 10 000 kg in any calendar year, or exceeds an accumulated total of 5 000 kg but does not exceed an accumulated total of 50 000 kg,

(i) if the polymer is not a research and development substance, the information specified in Schedule VI, and

(ii) if the polymer is a research and development substance, the information specified in Schedule XI; and

(b) where the person manufactures or imports the polymer in a quantity that exceeds 10 000 kg in any calendar year or an accumulated total of 50 000 kg,

(i) if the polymer is specified on the NDSL, the information specified in Schedule VI, and

(ii) if the polymer is not specified on the NDSL,

(A) in the case of a polymer that is manufactured solely from reactants that are substances specified on the DSL or NDSL, the information specified in Schedule VI, and

(B) in any other case, the information specified in Schedule VII.

(3) Subject to section 20, a person who manufactures or imports a polymer to which this section applies shall, where the polymer is a research and development substance and the person manufactured or imported more than 20 kg of the polymer in any calendar year during the transitional period, provide the information specified in Schedule VI, if the person manufactures or imports the polymer in a quantity that

(a) exceeds 10 000 kg in any calendar year; or

(b) exceeds an accumulated total of 50 000 kg.

20. Sections 18 and 19 do not apply in respect of a polymer while it is

- (a) a product development substance;
- (b) a site-limited intermediate substance; or
- (c) a polymer that is being manufactured or imported by a person for export only, if the quantity of the polymer in the person's possession at any one time does not exceed 20 000 kg.

*Product Development Substances*

21. Where a person manufactures or imports a polymer that is a product development substance in a quantity that exceeds 10 000 kg in any calendar year or exceeds an accumulated total of 50 000 kg, the person shall provide the following information:

- (a) the information specified in a schedule referred to in paragraph 18(1)(b) or 19(2)(b), as appropriate; or
- (b) the information specified in Schedule XII.

*Site-limited Intermediate Substances or Substances Manufactured or Imported for Export Only*

22. Section 23 applies in respect of a person who manufactures or imports a polymer for export only, only if the quantity of the polymer in the person's possession at any one time does not exceed 20 000 kg.

23. (1) Where a person manufactures or imports, in a quantity that exceeds 10 000 kg in any calendar year, a polymer that is a site-limited intermediate substance or a polymer for export only and subsection (2) does not apply, the person shall provide the following information:

- (a) the information specified in a schedule referred to in paragraph 18(1)(b) or 19(2)(b), as appropriate; or
- (b) subject to subsection (3), the information specified in Schedule XIII.

(2) Subject to subsection (3), a person who manufactures or imports, in a quantity that exceeds 10 000 kg in any calendar year, a polymer that is a site-limited intermediate substance or a polymer for export only shall, where the person manufactured or imported more than 20 kg of the polymer in any calendar year during the transitional period, provide the following information:

- (a) in the case of a polymer other than a polymer to which section 19 applies,

(i) if the polymer is specified on the NDSL, the information specified in Schedule VII, except the information specified in subitem 2(2) of that Schedule, or the information specified in Schedule XIII, and

(ii) if the polymer is not specified on the NDSL, the information specified in Schedule VII or XIII; and

(b) in the case of a polymer to which section 19 applies, the information specified in Schedule VI or XIII.

(3) The information specified in subitems 1(4) and (5) and items 2 and 3 of Schedule XIII is not required to be provided in respect of a site-limited intermediate substance that is manufactured and consumed at the site of manufacture.

#### *Information Provision Dates*

24. Information specified in a schedule referred to in sections 18 to 23 shall be provided as follows:

(a) for Schedule VI or VII, at least 45 days before the day on which a person manufactures or imports a polymer in a quantity that triggers the requirement to provide the information specified in Schedule VI or VII, as the case may be;

(b) for Schedule VIII, at least 90 days before the day on which a person manufactures or imports a polymer in a quantity that triggers the requirement to provide the information specified in Schedule VIII;

(c) for Schedule XI, at least 5 days before the day on which a person manufactures or imports a polymer in a quantity that triggers the requirement to provide the information specified in Schedule XI; and

(d) for Schedule XII or XIII, at least 21 days before the day on which a person manufactures or imports a polymer in a quantity that triggers the requirement to provide the information specified in Schedule XII or XIII, as the case may be.

#### *Assessment Periods*

25. The periods within which the Ministers shall assess the information specified in a schedule referred to in sections 18 to 23 are as follows:

(a) for Schedules VI and VII, a period of 45 days following receipt of the information;

- (b) for Schedule VIII, a period of 90 days following receipt of the information;
- (c) for Schedule XI, a period of 5 days following receipt of the information; and
- (d) for Schedules XII and XIII, a period of 21 days following receipt of the information.

*Transitional Period*

26. (1) Subject to subsection (3), a person who manufactured or imported during the transitional period a polymer other than a polymer to which section 19 applies shall provide the following information:

(a) where the person manufactured or imported the polymer in a quantity that exceeded 20 kg but did not exceed 10 000 kg in any calendar year within the transitional period,

(i) if the polymer is not a research and development substance, the information specified in Schedule VI, and

(ii) if the polymer is a research and development substance, the information specified in Schedule XI; and

(b) where the person manufactured or imported the polymer in a quantity that exceeded 10 000 kg in any calendar year within the transitional period, or exceeded, at any time within the transitional period, an accumulated total of 50 000 kg,

(i) if the polymer is specified on the NDSL, the information specified in Schedule VII, except the information specified in subitem 2(2) of that Schedule, and

(ii) if the polymer is not specified on the NDSL, the information specified in Schedule VII.

(2) Subject to subsection (3), a person who manufactured or imported during the transitional period a polymer to which section 19 applies shall provide the following information:

(a) if the polymer is not a research and development substance and the person manufactured or imported the polymer in a quantity that exceeded 20 kg in any calendar year within the transitional period, the information specified in Schedule VI; and

(b) if the polymer is a research and development substance,

(i) the information specified in Schedule XI, if the person manufactured or imported the polymer in a quantity that exceeded 20 kg but did not exceed 10 000 kg in any calendar year within the transitional period, and

(ii) the information specified in Schedule VI, if the person manufactured or imported the polymer in a quantity that

(A) exceeded 10 000 kg in any calendar year within the transitional period, or

(B) exceeded, at any time within the transitional period an accumulated total of 50 000 kg.

(3) Subsections (1) and (2) do not apply in respect of a polymer while it is

(a) a site-limited intermediate substance; or

(b) a polymer that is being manufactured or imported by a person for export only, if the quantity of the polymer in the person's possession at any one time does not exceed 20 000 kg.

27. (1) Subject to subsections (2) and (3), a person who manufactured or imported, in a quantity that exceeded 10 000 kg in any calendar year within the transitional period, a polymer that is a site-limited intermediate substance or a polymer for export only shall provide the following information:

(a) in the case of a polymer other than a polymer to which section 19 applies,

(i) if the polymer is specified on the NDSL, the information specified in Schedule VII, except the information specified in subitem 2(2) of that Schedule, or the information specified in Schedule XIII, and

(ii) if the polymer is not specified on the NDSL, the information specified in Schedule VII or XIII; and

(b) in the case of a polymer to which section 19 applies, the information specified in Schedule VI or XIII.

(2) Subsection (1) applies in respect of a person who manufactured or imported a polymer for export only, only if the quantity of the polymer in the person's possession at any one time during the transitional period did not exceed 20 000 kg.

(3) The information specified in subitems 1(4) and (5) and items 2 and 3 of Schedule XIII is not required to be provided in respect of a site-limited intermediate substance that is manufactured and consumed at the site of manufacture.

28. (1) Subject to subsection (2), the information specified in Schedule VI or XI, as the case may be, and referred to in sections 26 and 27 shall be provided on or before December 30, 1993.

(2) Where the information specified in Schedule XI has been provided in accordance with subparagraph 26(2)(b)(i) in respect of a polymer, Schedule VI is not required to be provided in respect of that polymer until the appropriate date set out in subsection (3).

(3) Subject to subsection (4), the information specified in Schedule VI, if appropriate, and Schedule VII or XIII, as the case may be, and referred to in sections 26 and 27 shall, where the quantity that triggers the requirement to provide that information

(a) was exceeded in 1987, be provided on or before March 10, 1994;

(b) was exceeded in 1988, be provided on or before September 10, 1994;

(c) was exceeded in 1989, be provided on or before March 10, 1995;

(d) was exceeded in 1990, be provided on or before September 10, 1995;

(e) was exceeded in 1991, be provided on or before March 10, 1996;

(f) was exceeded in 1992, be provided on or before September 10, 1996; and

(g) was exceeded during the period beginning on January 1, 1993 and ending on September 10, 1993, be provided on or before March 10, 1997.

(4) The information specified in the following items, subitems and paragraphs of Schedules VII or XIII, as the case may be, shall be provided on or before January 9, 1994:

(a) subitems 1(1) to (7), paragraphs 2(1)(a) to (c), subitems 2(7) and 3(1) and item 4 of Schedule VII; and

(b) subitems 1(1) to (7), paragraphs 2(1)(a) to (c) and items 4 to 6 of Schedule XIII.

*DSL*

29. The quantity of a substance prescribed for the purposes of subparagraph 30(1)(b)(iii) of the Act is, in respect of a polymer, a quantity that exceeds 10 000 kg in any calendar year or an accumulated total of 50 000 kg.

## PART III

## ADMINISTRATIVE AND TESTING REQUIREMENTS

*Administrative Requirements*

30. (1) The information that is specified in a schedule to these Regulations and provided to the Minister shall include

(a) the name, address and signature of the person manufacturing or importing the substance;

(b) the name and address of the head of the quality assurance unit of every laboratory that developed test data included in the information; and

(c) an indication of whether the substance will be manufactured in or imported into Canada and the site of manufacture or the port of entry of the substance, if known.

(2) The information that is specified in a schedule to these Regulations and provided to the Minister shall be sent to the Chief, New Substances Division, Commercial Chemicals Branch, Environment Canada, Ottawa, Ontario, K1A 0H3.

(3) Where a person who provides the information specified in a schedule to these Regulations is not resident in Canada, the person shall provide the name and address of an agent resident in Canada to whom any notice or correspondence intended for the person under the Act and these Regulations may be sent.

(4) Where information specified in a schedule to these Regulations is provided by an agent referred to in subsection (3), the information shall include the name and address of the agent and be signed by the agent.

*Testing Requirements*

31. (1) The conditions and test procedures to be followed in developing test data in respect of a substance in order to comply with the information requirements of section 26 of the Act or requests for information under paragraph 29(1)(c) of the Act shall be consistent with the conditions and procedures set out in the "OECD Test Guidelines", being Annex 1 of the *OECD Guidelines for Testing of Chemicals*, adopted by the Organization for Economic Cooperation and Development Council on May 12, 1981, that are current at the time the test data are developed.



(2) The laboratory practices to be followed in developing test data referred to in subsection (1) shall be consistent with the practices set out in the "Principles of Good Laboratory Practice", being Annex 2 of the *OECD Guidelines for Testing of Chemicals*, adopted by the Organization for Economic Cooperation and Development Council on May 12, 1981.

SCHEDULE I

(Paragraphs 6(1)(a) and (2)(a), 8(2)(a), 10(1)(a) and (2)(a), 11(a), 12(a), 13(1)(a) and 14(1)(a))

INFORMATION REQUIRED IN RESPECT OF SUBSTANCES OTHER THAN PRODUCT DEVELOPMENT SUBSTANCES, SITE-LIMITED INTERMEDIATE SUBSTANCES AND SUBSTANCES MANUFACTURED OR IMPORTED FOR EXPORT ONLY

1. (1) The chemical name of the substance, established in accordance with the chemical nomenclature rules of the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service.  
  
(2) The trade names of the substance and the synonyms of its chemical name, if known.  
  
(3) The Chemical Abstracts Service registry number of the substance, if such a number has been assigned.  
  
(4) A material safety data sheet, as defined in subsection 11(1) of the *Hazardous Products Act*, in respect of the substance, if available.
2. All information in respect of the substance that is relevant to identifying hazards to human health and the environment and that is in the person's possession.
3. The intended uses of the substance.
4. The identification of other government agencies, either foreign or within Canada, that the person has notified of the manufacture or importation of the substance, and the purpose of such notification.

## SCHEDULE II

(Paragraphs 6(1)(b) and (2)(b), subsection 6(3), paragraph 6(4)(a), subsection 6(5), paragraphs 8(1)(a) and (2)(b), 11(b), 12(b) and 13(1)(b) and subsection 15(3))

INFORMATION REQUIRED IN RESPECT OF SUBSTANCES OTHER THAN PRODUCT DEVELOPMENT SUBSTANCES, SITE-LIMITED INTERMEDIATE SUBSTANCES AND SUBSTANCES MANUFACTURED OR IMPORTED FOR EXPORT ONLY

1. (1) The chemical name of the substance, established in accordance with the chemical nomenclature rules of the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service.

(2) The trade names of the substance and the synonyms of its chemical name, if known.

(3) The Chemical Abstracts Service registry number of the substance, if such a number can be assigned.

(4) The following identification information in respect of the substance:

(a) its structural formula;

(b) its gram molecular weight;

(c) the degree of purity in its technical grade composition, if applicable;

(d) any known impurities present and their concentration by weight; and

(e) any additives and stabilizers that are essential for the purposes of marketing the substance, and their concentrations by weight.

(5) A material safety data sheet, as defined in subsection 11(1) of the *Hazardous Products Act*, in respect of the substance, if available.

2. (1) The following physical and chemical data in respect of the substance:

(a) its melting point or the temperature at which it decomposes

(i) expressed in degrees Celsius, where its melting point or the temperature at which it decomposes is  $-50^{\circ}\text{C}$  or greater but not greater than  $300^{\circ}\text{C}$ , and

(ii) in any other case, expressed as "less than  $-50^{\circ}\text{C}$ " or "greater than  $300^{\circ}\text{C}$ ", as appropriate;

SCHEDULE II - *Continued*

- (b) its boiling point or the temperature at which it decomposes
- (i) expressed in degrees Celsius, where its boiling point or the temperature at which it decomposes is  $-50^{\circ}\text{C}$  or greater but not greater than  $300^{\circ}\text{C}$ , and
  - (ii) in any other case, expressed as "less than  $-50^{\circ}\text{C}$ " or "greater than  $300^{\circ}\text{C}$ ", as appropriate;
- (c) its density;
- (d) its vapour pressure, if it has a standard boiling point of  $0^{\circ}\text{C}$  or greater;
- (e) its water solubility;
- (f) its octanol-water partition coefficient, if its solubility in water is  $10^{-6}$  g/L or greater;
- (g) one of an infra-red, ultra-violet, mass or nuclear magnetic resonance spectrum suitable for characterization of the substance;
- (h) its dissociation constants;
- (i) adsorption-desorption screening test data;
- (j) its hydrolysis rate as a function of pH and, if known, an identification of the products of the hydrolysis;
- (k) if the substance is a solid at room temperature and its water solubility is less than  $10^{-6}$  g/L, particle size or fibre length distribution data, if applicable; and
- (l) its fat solubility, if its solubility in water is less than  $10^{-6}$  g/L.
- (2) Data from the most appropriate type of acute mammalian toxicity test of the substance, namely oral, dermal or inhalation, selected on the basis of the most significant route of potential human exposure to the substance.
- (3) For a test referred to in subitem (2), the following information:
- (a) the age, sex, number, species, strain and source of the animals tested;

SCHEDULE II - *Concluded*

- (b) the route by which the substance is administered and the conditions under which the test is conducted; and
- (c) the dose of the substance, the vehicle by means of which the substance is administered and the concentration of the substance in the vehicle.
- (4) Mutagenicity data obtained from one *in vitro* test of the substance, with and without metabolic activation, for chromosomal aberrations or gene mutations or another indicator of mutagenicity that permits an assessment of *in vitro* mutagenicity.
- (5) All other information and test data in respect of the substance that are relevant to identifying hazards to human health and the environment and that are in the person's possession or to which the person ought reasonably to have access.
- (6) A description or specification of the test procedures followed in developing the test data, including, for data developed after September 10, 1993 or for test procedures that are not prescribed, test methods, reference substances and quality control and quality assurance procedures.
3. (1) Manufacture, importation, use and disposal information, including an estimate of the quantity of the substance to be manufactured and imported annually, its intended uses, the methods recommended for its destruction or disposal and the expected transportation modes for its distribution.
- (2) Recommended precautions and emergency measures, including personal protective equipment to be used, engineering controls, leak and spill clean-up procedures, handling procedures, storage requirements and first-aid measures.
- (3) The anticipated nature and extent of the substance's release into the environment.
- (4) The estimated number of persons who may become exposed to the substance.
4. The identification of other government agencies, either foreign or within Canada, that the person has notified of the manufacture or importation of the substance, and the purpose of such notification.

## SCHEDULE III

(Paragraphs 6(1)(c) and (4)(b), subsection 6(5) and paragraphs 8(1)(b), 11(c) and 12(c))

INFORMATION REQUIRED IN RESPECT OF SUBSTANCES OTHER THAN PRODUCT DEVELOPMENT SUBSTANCES, SITE-LIMITED INTERMEDIATE SUBSTANCES AND SUBSTANCES MANUFACTURED OR IMPORTED FOR EXPORT ONLY

1. (1) The chemical name of the substance, established in accordance with the chemical nomenclature rules of the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service.

(2) The trade names of the substance and the synonyms of its chemical name, if known.

(3) The Chemical Abstracts Service registry number of the substance, if such a number can be assigned.

(4) The following identification information in respect of the substance:

(a) its structural formula;

(b) its gram molecular weight;

(c) the degree of purity in its technical grade composition, if applicable;

(d) known impurities present and their concentration by weight; and

(e) any additives and stabilizers that are essential for the purposes of marketing the substance, and their concentrations by weight.

(5) A material safety data sheet, as defined in subsection 11(1) of the *Hazardous Products Act*, in respect of the substance, if available.

2. (1) The following physical and chemical data in respect of the substance:

(a) its melting point or the temperature at which it decomposes

(i) expressed in degrees Celsius, where its melting point or the temperature at which it decomposes is  $-50^{\circ}\text{C}$  or greater but not greater than  $300^{\circ}\text{C}$ , and

(ii) in any other case, expressed as "less than  $-50^{\circ}\text{C}$ " or "greater than  $300^{\circ}\text{C}$ ", as appropriate;

SCHEDULE III - *Continued*

- (b) its boiling point or the temperature at which it decomposes
    - (i) expressed in degrees Celsius, where its boiling point or the temperature at which it decomposes is  $-50^{\circ}\text{C}$  or greater but not greater than  $300^{\circ}\text{C}$ , and
    - (ii) in any other case, expressed as "less than  $-50^{\circ}\text{C}$ " or "greater than  $300^{\circ}\text{C}$ ", as appropriate;
  - (c) its density;
  - (d) its vapour pressure, if it has a standard boiling point of  $0^{\circ}\text{C}$  or greater;
  - (e) its water solubility;
  - (f) its octanol-water partition coefficient, if its solubility in water is  $10^{-6}$  g/L or greater;
  - (g) one of an infra-red, ultra-violet, mass or nuclear magnetic resonance spectrum suitable for characterization of the substance;
  - (h) its dissociation constants;
  - (i) adsorption-desorption screening test data;
  - (j) its hydrolysis rate as a function of pH and, if known, an identification of the products of the hydrolysis;
  - (k) if the substance is a solid at room temperature and its water solubility is less than  $10^{-6}$  g/L, particle size or fibre length distribution data, if applicable; and
  - (l) its fat solubility.
- (2) Data from the two most appropriate types of acute mammalian toxicity tests of the substance, namely, oral, dermal or inhalation, selected on the basis of the two most significant routes of potential human exposure to the substance.
- (3) Data from one skin irritation test and one skin sensitization test of the substance.
- (4) Data from one repeated dose mammalian toxicity test of the substance of at least 28 days duration, or of at least 14 days duration where it can be demonstrated that the data were obtained on or before September 11, 1993, selected on the basis of the most significant route of potential human exposure to the substance.

SCHEDULE III - *Continued*

- (5) For the tests referred to in subitems (2) to (4), the following information:
- (a) the age, sex, number, species, strain and source of the animals tested;
  - (b) the route by which the substance is administered and the conditions under which the test is conducted; and
  - (c) the dose of the substance, the vehicle by means of which the substance is administered and the concentration of the substance in the vehicle.
- (6) Mutagenicity data obtained from the following tests of the substance:
- (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 evidence that the tissue investigated was exposed to the substance or its metabolites, permits an assessment of *in vivo* mutagenicity.
- (7) Fish and daphnia acute toxicity test data in respect of the substance, including, as appropriate, limit test results or LC<sub>50</sub> results.
- (8) Ready biodegradability test data in respect of the substance and, if known, identification of the products of biodegradation.
- (9) All other information and test data in respect of the substance that are relevant to identifying hazards to human health and the environment and that are in the person's possession or to which the person ought reasonably to have access.
- (10) A description or specification of test procedures followed in developing the test data, including, for data developed after September 10, 1993 or for test procedures that are not prescribed, test methods, reference substances and quality control and quality assurance procedures.
3. (1) Manufacture, importation, use and disposal information, including an estimate of the quantity of the substance to be manufactured and imported annually, its intended uses, the methods recommended for its destruction or disposal and the expected transportation modes for its distribution.



SCHEDULE III - *Concluded*

(2) Recommended precautions and emergency measures, including personal protective equipment to be used, engineering controls, leak and spill clean-up procedures, handling procedures, storage requirements and first-aid measures.

(3) The anticipated nature and extent of the substance's release into the environment.

(4) The estimated number of persons who may become exposed to the substance.

4. Full descriptions of or specific reference to analytical test methods that can be used for the detection and determination of concentrations of the substance at or below the limit test results or the LC<sub>50</sub> results provided under subitem 2(7).

5. The identification of other government agencies, either foreign or within Canada, that the person has notified of the manufacture or importation of the substance, and the purpose of such notification.

## SCHEDULE IV

(Section 8 and paragraphs 11(d) and 12(d))

INFORMATION REQUIRED IN RESPECT OF PRODUCT DEVELOPMENT  
SUBSTANCES

1. (1) The chemical name of the product development substance established in accordance with the chemical nomenclature rules of the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service.

(2) The Chemical Abstracts Service registry number of the product development substance, if known.

2. The following identification information in respect of the product development substance:

(a) its structural formula;

(b) its gram molecular weight;

(c) its degree of purity; and

(d) any known impurities present and their concentration by weight.

3. All information and test data in respect of the product development substance that are relevant to identifying hazards to human health and the environment and that are in the person's possession or to which the person ought reasonably to have access.

4. (1) A description of the plan for product development including the following information in respect of the product development substance:

(a) the manufacturing and import activities;

(b) its storage;

(c) its transport;

(d) its intended uses;

(e) an assessment of the potential for its release into the environment or for persons to be exposed to it, and any measures that will be taken to protect against such release or exposure;

SCHEDULE IV - *Concluded*

(f) the environmental fate; and

(g) analytical test methods that detect the product development substance in the environment that are in the person's possession or to which the person ought reasonably to have access.

(2) A complete description of the plan for disposing of the product development substance outlining

(a) all products in which the product development substance will be used;

(b) the plan for recalling, recapturing and disposing of the product development substance; and

(c) the ultimate mass balance of the product development substance based on the quantity produced and its disposition.

## SCHEDULE V

(Paragraphs 10(1)(b) and (2)(b), subsections 10(3) and (4), paragraphs 11(d), 12(d) and 14(1)(b) and subsections 14(3) and 15(3))

INFORMATION REQUIRED IN RESPECT OF SITE-LIMITED INTERMEDIATE  
SUBSTANCES AND SUBSTANCES MANUFACTURED OR IMPORTED  
FOR EXPORT ONLY

1. (1) The chemical name of the site-limited intermediate substance or substance for export only, established in accordance with the chemical nomenclature rules of the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service.

(2) The trade names of the site-limited intermediate substance or substance for export only and the synonyms of its chemical name, if known.

(3) The Chemical Abstracts Service registry number of the site-limited intermediate substance or substance for export only, if such a number has been assigned.

(4) A material safety data sheet, as defined in subsection 11(1) of the *Hazardous Products Act*, in respect of the site-limited intermediate substance or substance for export only, if available.

2. (1) All information and test data in respect of the site-limited intermediate substance or substance for export only that are relevant to identifying hazards to human health and the environment and that are in the person's possession or to which the person ought reasonably to have access.

(2) A description or specification of the test procedures followed in developing the test data, including, for data developed after September 10, 1993 or for test procedures that are not prescribed, test methods, reference substances and quality control and quality assurance procedures.

3. Data from environmental degradation tests including hydrolysis rate as a function of pH and ready biodegradability and, if known, an identification of the products of the hydrolysis and biodegradation.

4. Data from the most appropriate type of acute mammalian toxicity test, namely, oral, dermal or inhalation, selected on the basis of the most significant route of potential human exposure to the substance.

SCHEDULE V - *Concluded*

5. A description of the manufacturing and import activities in respect of the substance, information in respect of its storage, transport and uses, the potential for its release into the environment or for persons to be exposed to it, any protection measures that will be taken to protect against such release or exposure and the environmental fate.

6. The identification of other government agencies, either foreign or within Canada, that the person has notified of the manufacture or importation of the substance and the purpose of such notification.

## SCHEDULE VI

*(Subparagraphs 18(1)(a)(i) and 19(2)(a)(i), paragraph 19(2)(b), subsection 19(3), paragraphs 23(1)(a) and (3)(b), 24(a) and 25(a), subparagraph 26(1)(a)(i), paragraph 26(2)(a), subparagraph 26(2)(b)(ii) and paragraph 27(1)(b))*

**INFORMATION REQUIRED IN RESPECT OF POLYMERS OTHER THAN PRODUCT DEVELOPMENT SUBSTANCES, SITE-LIMITED INTERMEDIATE SUBSTANCES AND SUBSTANCES MANUFACTURED OR IMPORTED FOR EXPORT ONLY**

1. (1) 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.

(2) The trade names of the polymer and the synonyms of its chemical name, if known.

(3) The Chemical Abstracts Service registry number of the polymer, if such a number can be assigned.

(4) The molecular formula of the polymer, if possible.

(5) The structural formula of the polymer, if possible, or else a partial structural formula.

(6) The composition of the polymer, including constituents such as monomers, other reactants, known impurities expressed in per cent by weight and additives that are essential for the purpose of marketing.

(7) A material safety data sheet, as defined in subsection 11(1) of the *Hazardous Products Act*, in respect of the polymer, if available.

2. (1) The following physical and chemical data in respect of the polymer:

(a) its number average molecular weight;

(b) the maximum concentration, in per cent, of all constituents with molecular weights of less than 500 daltons and all constituents with molecular weights of less than 1 000 daltons; and

(c) its physical state.

(2) All other information and test data in respect of the polymer that are relevant to identifying hazards to human health and the environment and that are in the person's possession or to which the person ought reasonably to have access.

SCHEDULE VI - *Concluded*

(3) A description or specification of the test procedures followed in developing the test data, including, for data developed after September 10, 1993 or for test procedures that are not prescribed, test methods, reference substances and quality control and quality assurance procedures.

3. (1) Manufacture, importation, use and disposal information, including an estimate of the quantity of the polymer to be manufactured and imported annually, its intended uses, the methods recommended for its destruction or disposal and the expected transportation modes for its distribution.

(2) Recommended precautions and emergency measures, including personal protective equipment to be used, engineering controls, leak and spill clean-up procedures, handling procedures, storage requirements and first-aid measures.

4. The identification of other government agencies, either foreign or within Canada, that the person has notified of the manufacture or importation of the polymer, and the purpose of such notification.

## SCHEDULE VII

*(Subparagraph 18(1)(b)(i), clause 18(1)(b)(ii)(A), subsection 18(2), clause 19(2)(b)(ii)(B), paragraphs 23(1)(a) and (2)(a), 24(a), 25(a), 26(1)(b) and 27(1)(a) and subsection 28(4))*

INFORMATION REQUIRED IN RESPECT OF POLYMERS OTHER THAN PRODUCT DEVELOPMENT SUBSTANCES, SITE-LIMITED INTERMEDIATE SUBSTANCES AND SUBSTANCES MANUFACTURED OR IMPORTED FOR EXPORT ONLY

1. (1) 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.

(2) The trade names of the polymer and the synonyms of its chemical name, if known.

(3) The Chemical Abstracts Service registry number of the polymer, if such a number can be assigned.

(4) The molecular formula of the polymer, if possible.

(5) The structural formula of the polymer, if possible, or else a partial structural formula.

(6) The composition of the polymer, including constituents such as monomers, other reactants, known impurities expressed in per cent by weight and essential additives for the purpose of marketing.

(7) A material safety data sheet, as defined in subsection 11(1) of the *Hazardous Products Act*, in respect of the polymer, if available.

2. (1) The following physical and chemical data in respect of the polymer:

(a) its number average molecular weight;

(b) the maximum concentration, in per cent, of all residual constituents with molecular weights of less than 500 daltons and all residual constituents with molecular weights of less than 1 000 daltons;

(c) its physical state;

(d) whether it is formulated for dispersal in water;

(e) its solubility in water at pH 7



SCHEDULE VII - *Continued*

- (i) expressed in milligrams per litre, where its solubility is 10 mg/L or greater, and
- (ii) expressed as "less than 10 mg/L", where its solubility is less than 10 mg/L;
- (f) its solubility in n-octanol or its octanol-water partition coefficient expressed, for solubility in n-octanol,

- (i) in milligrams per litre, where its solubility is 50 mg/L or greater, and

- (ii) as "less than 50 mg/L", where its solubility is less than 50 mg/L; and

- (g) its solubility in water at pH 1 and pH 10, where its solubility is 50 mg/L or greater.

(2) Data from one acute lethal toxicity test with one representative species of fish or daphnia for the water-soluble portion of the polymer, where its solubility in water is 10 mg/L or greater.

(3) In respect of a cationic polymer or a polymer expected to become cationic in the aquatic environment, data from

- (a) one aquatic acute lethal toxicity test, other than a test referred to in subitem (2), with one representative species of fish or daphnia; and

- (b) one ready biodegradability test for the water-soluble portion of the polymer, where its solubility in water is 50 mg/L or greater.

(4) In respect of an anionic polymer, data from tests on freshwater green algae.

(5) Data from one acute mammalian oral toxicity test of the polymer.

(6) For the test referred to in subitem (5), the following information:

- (a) the age, sex, number, species, strain and source of the animals tested;

- (b) 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.

(7) All other information and test data in respect of the polymer that are relevant to identifying hazards to human health and the environment and that are in the person's possession or to which the person ought reasonably to have access.

SCHEDULE VII - *Concluded*

(8) A description or specification of the test procedures followed in developing the test data, including, for data developed after September 10, 1993 or for test procedures that are not prescribed, test methods, reference substances and quality control and quality assurance procedures.

3. (1) Manufacture, importation, use and disposal information, including an estimate of the quantity of the polymer to be manufactured and imported annually, its intended uses, the methods recommended for its destruction or disposal and the expected transportation modes for its distribution.

(2) Recommended precautions and emergency measures, including personal protective equipment to be used, engineering controls, leak and spill clean-up procedures, handling procedures, storage requirements and first-aid measures.

(3) The anticipated nature and extent of the polymer's release into the environment.

(4) The estimated number of persons who may become exposed to the polymer.

4. The identification of other government agencies, either foreign or within Canada, that the person has notified of the manufacture or importation of the polymer, and the purpose of such notification.

## SCHEDULE VIII

(Clause 18(1)(b)(ii)(B) and paragraphs 24(b) and 25(b))

INFORMATION REQUIRED IN RESPECT OF POLYMERS OTHER THAN PRODUCT DEVELOPMENT SUBSTANCES, SITE-LIMITED INTERMEDIATE SUBSTANCES AND SUBSTANCES MANUFACTURED OR IMPORTED FOR EXPORT ONLY

1. (1) 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.
- (2) The trade names of the polymer and the synonyms of its chemical name, if known.
- (3) The Chemical Abstracts Service registry number of the polymer, if such a number can be assigned.
- (4) The molecular formula of the polymer, if possible.
- (5) The structural formula of the polymer, if possible, or else a partial structural formula.
- (6) The composition of the polymer, including constituents such as monomers, other reactants, known impurities expressed in per cent by weight and essential additives for the purpose of marketing.
- (7) A material safety data sheet, as defined in subsection 11(1) of the *Hazardous Products Act*, in respect of the polymer, if available.
2. (1) The following physical and chemical data in respect of the polymer:
  - (a) its number average molecular weight;
  - (b) the maximum concentrations, in per cent, of all residual constituents with molecular weights of less than 500 daltons and of all residual constituents with molecular weights of less than 1 000 daltons;
  - (c) its physical state;
  - (d) whether it is formulated for dispersal in water;
  - (e) its solubility in water at pH 7
    - (i) expressed in milligrams per litre, where its solubility is 10 mg/L or greater, and

SCHEDULE VIII - *Continued*

- (ii) expressed as "less than 10 mg/L", where its solubility is less than 10 mg/L;
  - (f) its solubility in n-octanol or the octanol-water partition coefficient expressed, for solubility in n-octanol,
    - (i) in milligrams per litre, where its solubility is 50 mg/L or greater, and
    - (ii) as "less than 50 mg/L", where its solubility is less than 50 mg/L;
  - (g) its solubility in water at pH 1 and pH 10, where its solubility is 50 mg/L or greater;
  - (h) one ultra-violet spectrum; and
  - (i) its hydrolysis rate as a function of pH where its solubility in water is 50 mg/L or greater and, if known, an identification of the products of the hydrolysis.
- (2) Data from one acute lethal toxicity test with one representative species of fish or daphnia for the water-soluble portion of the polymer, where its solubility in water is 10 mg/L or greater.
- (3) Data from one ready biodegradability test on the water-soluble portion of the polymer, where its solubility in water is 50 mg/L or greater.
- (4) In respect of a cationic polymer or a polymer expected to become cationic in the aquatic environment, data from one aquatic acute lethal toxicity test, other than a test referred to in subitem (2), with one representative species of fish or daphnia.
- (5) In respect of an anionic polymer, data from tests on freshwater green algae.
- (6) Data from one acute mammalian oral toxicity test of the polymer.
- (7) Data from one skin irritation test and one skin sensitization test of the polymer.
- (8) Data from one repeated dose mammalian toxicity test of the polymer of at least 28 days duration, or of at least 14 days duration where it can be demonstrated that the data were obtained on or before September 11, 1993, selected on the basis of the most significant route of potential human exposure.
- (9) For the tests referred to in subitems (6) to (8), the following information:
- (a) the age, sex, number, species, strain and source of the animals tested;

SCHEDULE VIII - *Continued*

(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.

(10) Mutagenicity data obtained from 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 evidence that the tissue investigated was exposed to the polymer or its metabolites, permits an assessment of *in vivo* mutagenicity.

(11) All other information and test data in respect of the polymer that are relevant to identifying hazards to human health and the environment and that are in the person's possession or to which the person ought reasonably to have access.

(12) A description or specification of the test procedures followed in developing the test data, including, for data developed after September 10, 1993 or for test procedures that are not prescribed, test methods, reference substances and quality control and quality assurance procedures.

3. (1) Manufacture, importation, use and disposal information, including an estimate of the quantity of the polymer to be manufactured and imported annually, its intended uses, the methods recommended for its destruction or disposal and the expected transportation modes for its distribution.

(2) Recommended precautions and emergency measures, including personal protective equipment to be used, engineering controls, leak and spill clean-up procedures, handling procedures, storage requirements and first-aid measures.

(3) The anticipated nature and extent of the polymer's release into the environment.

(4) The estimated number of persons who may become exposed to the polymer.

4. The identification of other government agencies, either foreign or within Canada, that the person has notified of the manufacture or importation of the polymer, and the purpose of such notification.

## SCHEDULE IX

*(Paragraphs 19(1)(a) and (b))*

## TYPES OF POLYMERS

1. A cationic polymer or a polymer that is expected to become cationic in the aquatic environment, except for a polymer that has a combined equivalent weight for the cationic group greater than 5 000.
2. A polymer that is designed, or can be expected, to degrade, decompose or depolymerize.
3. A polymer that includes no more than one of the following elements, namely, carbon, hydrogen, nitrogen, oxygen, silicon and sulphur.
4. A polymer containing
  - (a) any elements other than carbon, hydrogen, nitrogen, oxygen, silicon, sulphur, fluorine, chlorine, bromine or iodine;
  - (b) any monatomic counterions other than chlorine ion, bromine ion, iodine ion, sodium ion, divalent magnesium, trivalent aluminum, potassium ion or divalent calcium; and
  - (c) any elements other than lithium, boron, phosphorus, titanium, manganese, iron, nickel, copper, zinc, tin or zirconium, unless any combination of these elements is present at 0.2 per cent or more by weight.
5. A polymer that contains any reactive functional groups, other than carboxylic acid groups, aliphatic hydroxyl groups, unconjugated olefinic groups, butenedioic groups, cyano groups, blocked isocyanates including ketoxime-blocked isocyanates, unconjugated nitrile groups, halogens excluding halides, and conjugated olefinic groups in naturally occurring fats, oils and carboxylic acids, in combined amounts greater than
  - (a) 1 part in 5 000; or
  - (b) where the only reactive functional groups present are part of acid halides, acid anhydrides, aldehydes, hemiacetals, methylol-amides, methylol-amines, methylol-ureas, alkoxysilanes containing more than 2 carbon atoms, allyl ethers, conjugated olefins, cyanates, epoxides, imines, unsubstituted positions ortho or para to phenolic hydroxyl, 1 part in 1 000.

## SCHEDULE X

*(Paragraph 19(1)(c))*LIST OF REACTANTS AND THEIR CHEMICAL ABSTRACTS SERVICE  
REGISTRY NUMBER*Monobasic Acids and Natural Oils*

Benzoic acid (65-85-0)  
Coconut oil (8001-31-8\*)  
Corn oil (8001-30-7\*)  
Cottonseed oil (8001-29-4\*)  
Dodecanoic acid (143-07-7)  
Fatty acids, coco (61788-47-4\*)  
Fatty acids, linseed oil (68424-45-3\*)  
Fatty acids, safflower oil (84625-38-7\*)  
Fatty acids, soyabean oil (68308-53-2\*)  
Fatty acids, sunflower oil (8001-21-6\*)  
Fatty acids, tall-oil conjugated  
Fatty acids, tall-oil (61790-12-3\*)  
Fatty acids, vegetable oil (61788-66-7\*)  
Heptanoic acid (111-14-8)  
Hexanoic acid, 3,3,5-trimethyl (3302-10-1)  
Hexanoic acid (142-62-1)  
Linseed oil (8001-26-1\*)  
Nonanoic acid (112-03-0)  
Oils, anchovy  
Oils, babassu palm (91078-92-1\*)  
Oils, cannabis  
Oils, herring (68153-06-0\*)  
Oils, menhaden (8002-50-4\*)  
Oils, oiticica (8016-35-1\*)  
Oils, palm kernel (8023-79-8\*)  
Oils, perilla (68132-21-8\*)  
Oils, sardine (93334-41-9\*)  
Oils, walnut (8024-09-7\*)  
Safflower oil (8001-23-8\*)  
Soyabean oil (8001-22-7\*)  
Sunflower oil (8001-21-6\*)  
Tung oil (8001-20-5\*)

SCHEDULE X - *Continued**Dibasic and Tribasic Acids*

1,2-Benzenedicarboxylic acid (88-99-3)  
1,3-Benzenedicarboxylic acid (121-91-5)  
1,4-Benzenedicarboxylic acid (100-21-0)  
1,2,4-Benzenetricarboxylic acid (528-44-9)  
Butanedioic acid (110-15-6)  
2-Butenedioic acid (E) (110-17-8)  
Decanedioic acid (111-20-6)  
Hexanedioic acid (124-04-9)  
Nonanedioic acid (123-99-9)

*Polyols*

1,3-Butanediol (107-88-0)  
1,4-Butanediol (110-63-4)  
1,4-Cyclohexanedimethanol (105-08-8)  
1,2-Ethandiol (107-21-1)  
1,6-Hexanediol (629-11-8)  
1,3-Pentanediol, 2,2,4-trimethyl (144-19-4)  
1,2-Propanediol, (57-55-6)  
1,3-Propanediol, 2,2-bis (hydroxymethyl) (115-77-5)  
1,3-Propanediol, 2,2-dimethyl (126-30-7)  
1,3-Propanediol, 2-ethyl-2-(hydroxymethyl) (77-99-6)  
1,3-Propanediol, 2-(hydroxymethyl)- 2-methyl (77-85-0)  
1,2,3-Propanetriol (56-81-5)  
1,2,3-Propanetriol, homopolymer (25618-55-7)  
2-Propen-1-ol, polymer with ethenylbenzene (25119-62-4)

*Modifiers*

Acetic acid, 2,2'-oxybis (110-99-6)  
1-Butanol (71-36-3)  
Cyclohexanol (108-93-0)  
Cyclohexanol, 4,4'-(1-methylethylidene) bis (80-04-6)  
Ethanol, 2-(2-butoxyethoxy) (112-34-5)  
1-Hexanol (111-27-3)



SCHEDULE X - *Concluded*

- Methanol, hydrolysis products with trichlorohexylsilane and trichlorophenylsilane  
(72318-84-4\*)<sup>4</sup>
- 1-Phenanthrenemethanol, tetradecahydro-1, 4a-dimethyl-7-(1-methylethyl) (13393-93-6)
- Phenol, 4,4'-(1-methylethylidene)bis-polymer with 2,2'-((1-methylethylidene)bis(4,1-phenyleneoxymethylene)) bis (oxirane) (25036-25-3)
- Siloxanes and Silicones, dimethyl, diphenyl; polymers with phenyl silsesquioxanes, methoxy-terminated (68440-65-3\*)
- Siloxanes and Silicones, dimethyl, methoxy phenyl; polymers with phenyl silsesquioxanes, methoxy-terminated (68957-04-0\*)
- Siloxanes and Silicones, methyl phenyl, methoxy phenyl; polymers with phenyl silsesquioxanes, methoxy- and phenyl-terminated (68957-06-2\*)
- Silsesquioxanes, phenyl propyl (68037-90-1\*)

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<sup>4</sup> The asterisk indicates chemical substances of Unknown or Variable composition Complex reaction products and Biological materials.

## SCHEDULE XI

(Subparagraphs 18(1)(a)(ii) and 19(2)(a)(ii), paragraphs 24(c) and 25(c) and subparagraphs 26(1)(a)(ii) and (2)(b)(i))

INFORMATION REQUIRED IN RESPECT OF POLYMERS THAT ARE RESEARCH  
AND DEVELOPMENT SUBSTANCES

1. (1) 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.  
  
(2) The trade names of the polymer and the synonyms of its chemical name, if known.  
  
(3) The Chemical Abstracts Service registry number of the polymer, if such a number has been assigned.  
  
(4) The identification of the reactants and monomers from which the polymer is manufactured.  
  
(5) A material safety data sheet, as defined in subsection 11(1) of the *Hazardous Products Act*, in respect of the polymer, if available.
2. (1) All information in respect of the polymer that is relevant to identifying hazards to human health and the environment and that is in the person's possession.  
  
(2) The physical state of the polymer.
3. A description of the intended research and development activity for which the polymer is to be used and the location of the activity.

## SCHEDULE XII

(Paragraphs 21(b), 24(d) and 25(d))

## INFORMATION REQUIRED IN RESPECT OF POLYMERS THAT ARE PRODUCT DEVELOPMENT SUBSTANCES

1. (1) 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.
  - (2) The Chemical Abstracts Service registry number of the polymer, if known.
  - (3) The molecular formula of the polymer, if possible.
  - (4) The structural formula of the polymer, if possible, or else a partial structural formula.
  - (5) The composition of the polymer, including monomers, other reactants, additives and impurities of the polymer.
  - (6) A material safety data sheet, as defined in subsection 11(1) of the *Hazardous Products Act*, in respect of the polymer, if available.
2. The following physical and chemical data in respect of the polymer:
  - (a) its number average molecular weight;
  - (b) the maximum concentration, in per cent, of all residual constituents with molecular weights of less than 500 daltons and all residual constituents with molecular weights of less than 1 000 daltons; and
  - (c) its physical state.
3. (1) All information and test data in respect of the polymer that are relevant to identifying hazards to human health and the environment and that is in the person's possession or to which the person ought reasonably to have access.
  - (2) A description or specification of the test procedures followed in developing the test data, including, for data developed after September 10, 1993 or for test procedures that are not prescribed, test methods, reference substances and quality control and quality assurance procedures.

SCHEDULE XII - *Concluded*

4. (1) A description of the plan for product development including the following information in respect of the polymer:

- (a) the manufacturing and import activities;
  - (b) its storage;
  - (c) its transport;
  - (d) its the intended uses;
  - (e) an assessment of the potential for its release into the environment or for persons to be exposed to it, and any measures that will be taken to protect against such release or exposure;
  - (f) the environmental fate; and
  - (g) analytical test methods that detect the polymer in the workplace and in the environment that are in the person's possession or to which the person ought reasonably to have access.
- (2) A complete description of the plan for disposing of the polymer outlining
- (a) all products in which the polymer will be used;
  - (b) the plan for recalling, recapturing and disposing of the polymer; and
  - (c) the ultimate mass balance of the polymer based on the quantity produced and its disposition.

## SCHEDULE XIII

(Paragraphs 23(1)(b), subsections 23(2) and (3), paragraphs 24(d) and 25(d) and subsections 27(1) and (3) and 28(4))

INFORMATION REQUIRED IN RESPECT OF POLYMERS THAT ARE  
SITE-LIMITED INTERMEDIATE SUBSTANCES OR MANUFACTURED  
OR IMPORTED FOR EXPORT ONLY

1. (1) 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.

(2) The trade names of the polymer and the synonyms of its chemical name, if known.

(3) The Chemical Abstracts Service registry number of the polymer, if such a number can be assigned.

(4) The molecular formula of the polymer, if possible.

(5) The structural formula of the polymer, if possible, or else a partial structural formula of the polymer.

(6) The composition of the polymer, including such constituents as monomers, other reactants, known impurities expressed in per cent by weight and additives that are essential for the purpose of marketing.

(7) A material safety data sheet, as defined in subsection 11(1) of the *Hazardous Products Act*, in respect of the polymer, if available.

2. The following physical and chemical data in respect of the polymer:

(a) its number average molecular weight;

(b) the maximum concentrations, in per cent, of all residual constituents with molecular weights of less than 500 daltons and all residual constituents with molecular weights of less than 1 000 daltons;

(c) its physical state;

(d) its solubility in water at pH 7

SCHEDULE XIII - *Concluded*

- (i) expressed in milligrams per litre, where its solubility is 10 mg/L or greater, and
  - (ii) expressed as "less than 10 mg/L", where its solubility is less than 10 mg/L;
- (e) its solubility in n-octanol or its octanol-water partition coefficient expressed, for solubility in n-octanol,
- (i) in milligrams per litre, where its solubility is 50 mg/L or greater, and
  - (ii) as "less than 50 mg/L", where its solubility is less than 50 mg/L; and
- (f) its solubility in water at pH 1 and pH 10, where its solubility is 50 mg/L or greater.
3. (1) Data from at least one acute mammalian oral toxicity test of the polymer.
- (2) For the test referred to in subitem (1), 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.
4. (1) All other information and test data in respect of the polymer that are relevant to identifying hazards to human health and the environment and that are in the person's possession or to which the person ought reasonably to have access.
- (2) A description or specification of the test procedures followed in developing the test data, including, for data developed after September 10, 1993 or for test procedures that are not prescribed, test methods, reference substances and quality control and quality assurance procedures.
5. A description of the manufacturing and import activities in respect of the polymer, information in respect of its storage, transport and use, the potential for it to be released into the environment or for persons to be exposed to it, any protection measures that will be taken to protect against such release or exposure and the environmental fate.
6. The identification of other government agencies, either foreign or within Canada, that the person has notified of the manufacture or importation of the polymer, and the purpose of such notification.

*Appendix 2*

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## **Environment Canada Regional Offices**

General information on the New Substances Notification Regulations and the Domestic Substances List as well as copies of both the notification forms and this document 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 - Atlantic  
Conservation and Protection  
Environment Canada  
45 Alderney Drive  
Dartmouth, Nova Scotia  
B2Y 2N6

Telephone: (902) 426-5048

### **For residents of Quebec:**

Environmental Protection - Quebec  
Conservation and Protection  
1141 Route de l'Eglise  
P.O. Box 10100  
Sainte Foy, Quebec  
G1V 4H5

Telephone: (514) 496-6851

### **For residents of Ontario:**

Environmental Protection - Ontario  
Conservation and Protection  
25 St. Clair Avenue East, 7th floor  
Toronto, Ontario  
M4T 1M2

Telephone: (416) 973-1060

**For residents of Manitoba, Alberta, Saskatchewan, and the Northwest Territories:**

Environmental Protection - Western and Northern  
Conservation and Protection  
Environment Canada  
4999-98th Avenue  
Edmonton, Alberta  
T6B 2X3

Telephone: (403) 468-8075

**For residents of British Columbia and the Yukon:**

Environmental Protection - Pacific Yukon  
Conservation and Protection  
Environment Canada  
224 West Esplanade  
North Vancouver, British Columbia  
V7M 3H7

Telephone: (604) 666-6711



## Appendix 3

## Naming Substances

### 1.0 Representing Substances with Well-defined Structures

#### 1.1 Specific Substance Name

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 any subsequent publication on the DSL. Abbreviations, acronyms, laboratory designations, trade names, trademarks, or any trivial names that are not chemically descriptive should not be submitted. Further clarification of the level of specificity required is provided in Table 7.

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-referred to Colour Index Names 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.

Inorganic substance names should 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

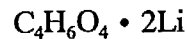
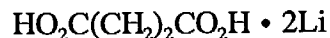
The molecular formula is a summation of the actual numbers and kinds of atoms present in a molecule of a substance. In the case of salts or addition compounds, the molecular formula may be presented as a single summation formula or in the "dot-disconnect" format used by CAS.

Example: Succinic acid, dilithium salt



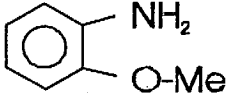
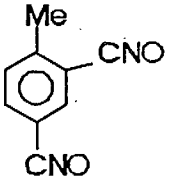
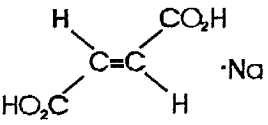
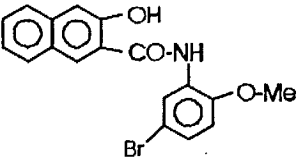
(summation)

or



(dot-disconnect)

Table 7 Specific Substance Names for Well-defined Substances

Substance	Unacceptable Name	Acceptable Name
	Ansidine	<u>o</u> -Anisidine or 2-Methoxyaniline
	Toluene diisocyanate or TDI	Toluene 2,4-diisocyanate
	Sodium fumarate or Monosodium butenedioate	Monosodium fumarate or Monosodium <u>trans</u> -butenedioate or Monosodium- <u>E</u> -butenedioate
$\begin{array}{c} \text{H}_3\text{C}(\text{CH}_2)_5\text{CHCH}_2\text{O}-\text{CO}(\text{CH}_2)_2\text{CO}_2\text{H} \\   \\ \text{Et} \end{array}$	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
$\begin{array}{c} \text{HO}(\text{CH}_2)_2\text{NH} \\   \\ (\text{CH}_2)_2\text{OH} \end{array} \cdot \text{H}_3\text{C-CO}_2\text{H}$	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- <u>o</u> - anisidide or N-(5-bromo-2-methoxyphenyl)-3- hydroxy-2-naphtha-lenecarboxamide
$\text{O}=\text{Ti-O-Ti}=\text{O}$	Titanium oxide	Titanium oxide ( $\text{Ti}_2\text{O}_3$ )

### 1.3 Structural Information

The structural diagram should clearly indicate the identity of the atoms and the nature of the bonds joining them. Guidelines for preparing these diagrams are included in this appendix .

Common abbreviations are acceptable as long as they are unambiguous. Table 8 presents examples of abbreviations that may be used.

**Table 8 Common Abbreviations that can be used to Indicate Structural Information**

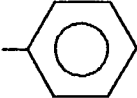
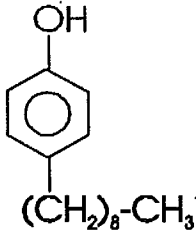
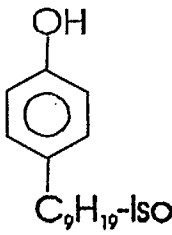
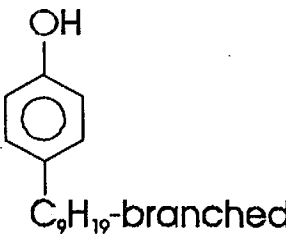
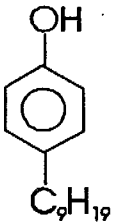
Structure	Abbreviation	Structure	Abbreviation
-CH <sub>3</sub>	Me-	$\begin{array}{c} \text{-C=O} \\   \\ \text{OH} \end{array}$	-CO <sub>2</sub> H
-CH <sub>2</sub> CH <sub>3</sub>	Et-	$\begin{array}{c} \text{-C-} \\    \\ \text{O} \end{array}$	-CO-
-(CH <sub>2</sub> ) <sub>2</sub> CH <sub>3</sub>	Pr-	-CH=O	-CHO
$\begin{array}{c} \text{-CHCH}_3 \\   \\ \text{CH}_3 \end{array}$	-Pr- <i>i</i> or -Pr- <i>iso</i>	$\begin{array}{c} \text{-C=O} \\   \\ \text{CH}_3 \end{array}$	-Ac
-(CH <sub>2</sub> ) <sub>3</sub> CH <sub>3</sub>	-Bu	$\begin{array}{c} \text{O} \\    \\ \text{-S-OH} \\    \\ \text{O} \end{array}$	-SO <sub>3</sub> H
$\begin{array}{c} \text{-CH}_2\text{CHCH}_3 \\   \\ \text{CH}_3 \end{array}$	-Bu- <i>i</i> or -Bu- <i>iso</i>	$\begin{array}{c} \text{O} \\    \\ \text{-S-} \\    \\ \text{O} \end{array}$	-SO <sub>2</sub> -
$\begin{array}{c} \text{-CHCH}_2\text{CH}_3 \\   \\ \text{CH}_3 \end{array}$	-Bu- <i>s</i> or -Bu- <i>sec</i>	-N=O	-NO
$\begin{array}{c} \text{CH}_3 \\   \\ \text{-C-CH}_3 \\   \\ \text{CH}_3 \end{array}$	-Bu- <i>t</i> or -Bu- <i>tert</i>		-Ph

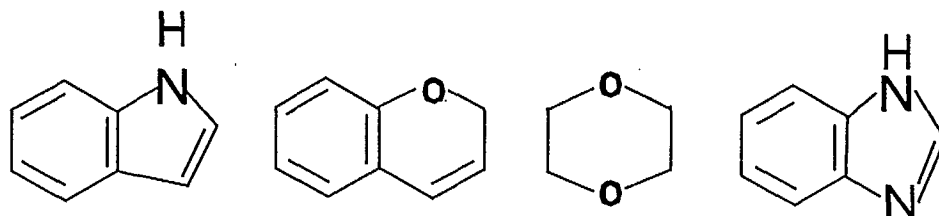
Table 9 Representations for Nonylphenol

Submitted Name	Structural Representation	CAS Registry Number	CA Index Name
p-Nonylphenol		104-40-5	Phenol, 4-nonyl-
p-Isononylphenol		26543-97-5	Phenol, 4-isononyl-
Branched, 4-nonylphenol		84852-15-3*	Phenol, 4-nonyl-branched
p-Tripropylene phenol		87247-00-5	Phenol, 4-tripropylene-

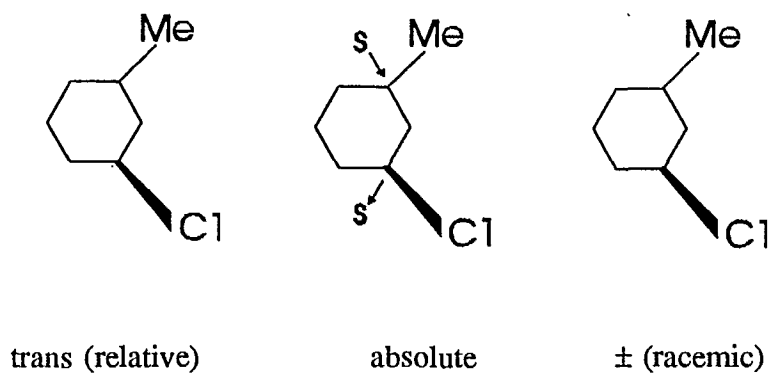
Alkyl groups will be assumed to be normal (linear) unless otherwise designated. If a substance has alkyl groups that are not linear, then the nature of the branching should be described as specifically as possible. Table 9 illustrates several different representations for nonylphenol.

Carbon atoms in ring systems and their attached hydrogen atoms need not be explicitly shown.

For example:

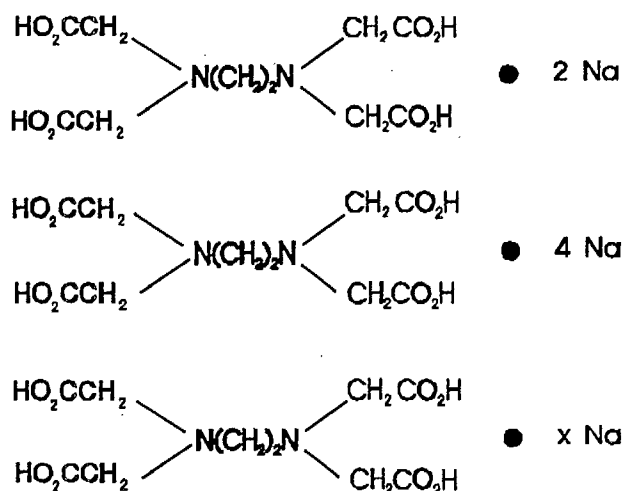


All known stereochemical details should be provided. Indicate whether the stereochemistry is absolute or relative. For example:



The ratio of the components of an addition compound or salt should be clearly indicated if more than one form is theoretically possible. It should also be noted if the ratio is unknown.

For example:



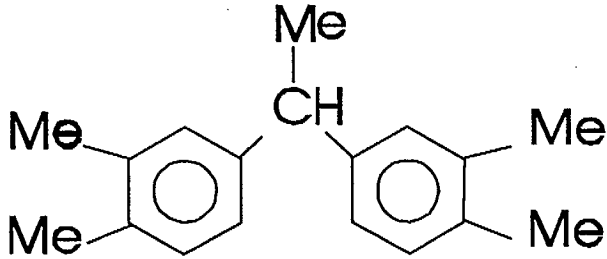
### 1.3.1 Examples of Well-defined Substances

The examples that follow illustrate the information necessary to uniquely identify and represent substances with a well-defined structure.

#### EXAMPLE 1

Specific Substance Name: N-(s-Butoxymethyl) acrylamide
Molecular Formula: $\text{C}_8\text{H}_{15}\text{NO}_2$
Structural Information:  $\text{H}_2\text{C}=\text{CH}-\text{CO}-\text{NH}-\text{CH}_2-\text{O}-\text{Bu-sec}$
<b>COMMENT:</b> <i>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></i>
$\text{H}_2\text{C}=\text{CH}-\text{CO}-\text{NH}-\text{CH}_2-\text{O}-\text{Bu}$

## EXAMPLE 2

Specific Substance Name:	1, 1-Di-3,4-xylylethane; 1, 1-Bis(3,4-dimethylphenyl)ethane
Molecular Formula:	$C_{18}H_{22}$
Structural Information:	 <p><b>COMMENT:</b> The semicolon is used to separate the two names. Both names cite locants. Dixylylethane would not be an appropriate name for this substance.</p>

## EXAMPLE 3

Specific Substance Name:	Sodium sebacate; Sodium decanedioate.
Molecular Formula:	$C_{10}H_{18}O_4 \cdot x Na$
Structural Information:	$HO_2C-(CH_2)_8-CO_2H \cdot x Na$ <p><b>COMMENT:</b> Use of "x" in the molecular formula and structure diagram clearly indicates the ratio of the salt is unknown.</p>

## EXAMPLE 4

Specific Substance Name: Disodium sebacate; Disodium decanedioate
Molecular Formula: $C_{10}H_{18}O_4 \cdot 2 Na$
Structural Information:  $HO_2C-(CH_2)_8-CO_2H \cdot 2 Na$  <i>COMMENT: When known, ratios should be cited in the name, formula, and structure. The formula could also be given as <math>C_{10}H_{16}Na_2O_4</math>. The structure could also be shown as</i>  $NaO_2C-(CH_2)_8-CO_2Na$

## EXAMPLE 5

Specific Substance Name: 1,3-Pentadiene; Piperylene
Molecular Formula: $C_5H_8$
Structural Information:  $H_2C=CH-CH=CH-CH_3$  <i>COMMENT: Stereochemistry is not cited in the name or structure. See EXAMPLE 6 for a specific stereoisomer.</i>



## EXAMPLE 6

Specific Substance Name:	cis-1,3-Pentadiene; Z-1,3-Pentadiene; cis-Piperylene
Molecular Formula:	C <sub>5</sub> H <sub>8</sub>
Structural Information:	$  \begin{array}{c}  \text{H} \quad \quad \text{H} \\  \diagdown \quad \diagup \\  \text{C} = \text{C} \\  \diagup \quad \diagdown \\  \text{H}_2\text{C}=\text{CH} \quad \quad \text{CH}_3  \end{array}  $ <p><b>COMMENT:</b> Stereochemistry is cited in both the name and structure. See EXAMPLE 5 for an example of a non-stereospecific substance.</p>

## EXAMPLE 7

Specific Substance Name:	Manganese (II) chromate (IV); Manganese chromate (MnCrO <sub>4</sub> ); Chromium manganese oxide (MnCrO <sub>4</sub> )
Molecular Formula:	H <sub>2</sub> CrO <sub>4</sub> Mn
Structural Information:	$  \begin{array}{c}  \text{O} \\     \\  \text{HO}-\text{Cr}-\text{OH} \quad \cdot \text{Mn} \\     \\  \text{O}  \end{array}  $ <p><b>COMMENT:</b> Stock numbers or empirical formulae should be included in the name when known. The following diagram is also acceptable:</p> $  \begin{array}{c}  \text{O} \\     \\  \ominus \text{O}-\text{Cr}-\text{O} \ominus \quad \cdot \text{Mn}^{(2+)} \\     \\  \text{O}  \end{array}  $

## EXAMPLE 8

Specific Substance Name: PVC; Polyvinyl chloride
Molecular Formula: $(C_2H_3Cl)_x$
Structural Information: <p style="text-align: center;"><math>ClCH=CH_2 + ABIN \rightarrow \text{Polyvinyl chloride}</math></p> <p><b>COMMENT:</b> <i>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.</i></p>

**EXAMPLE 9**

Specific Substance Name: Maleic acid-dimethyl phthalate-ethylene glycol copolymer; cis-2-Butenedioic acid-dimethyl phthalate-ethylene glycol polymer
Molecular Formula: $(C_2H_6O_2 - C_4H_4O_4 - C_{10}H_{10}O_4)_x$
Structural Information: <div style="text-align: center;"> </div>

## EXAMPLE 10

Specific Substance Name: Styrene-polyethyleneglycol monoallylether				
Molecular Formula: $((C_2H_4O)_n C_3H_6O \cdot C_8H_8)_x$				
Structural Information: <div style="text-align: center; padding: 20px;"> <table style="border: 1px solid black; width: 80%; margin: auto;"> <tr> <td style="padding: 5px;"><math>H_2C=CH-CH_2-(O-CH_2-CH_2)_n-OH</math></td> <td style="padding: 5px;"><math>Ph-CH=CH_2</math></td> </tr> <tr> <td style="padding: 5px;">CAS Registry Number 27274-31-3</td> <td style="padding: 5px;">CAS Registry Number 100-42-5</td> </tr> </table> <p style="text-align: right; margin-top: 10px;">x</p> </div>	$H_2C=CH-CH_2-(O-CH_2-CH_2)_n-OH$	$Ph-CH=CH_2$	CAS Registry Number 27274-31-3	CAS Registry Number 100-42-5
$H_2C=CH-CH_2-(O-CH_2-CH_2)_n-OH$	$Ph-CH=CH_2$			
CAS Registry Number 27274-31-3	CAS Registry Number 100-42-5			
<b>COMMENT:</b> Names and CAS Registry Numbers rather than structure diagrams may be used to describe reactants. Polyglycol derivatives should be represented on the basis of their polymeric structure.				

## EXAMPLE 11

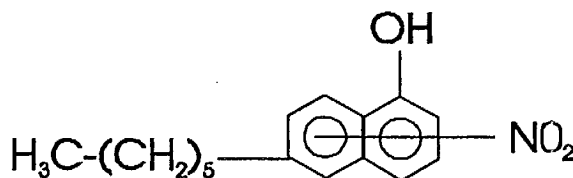
Specific Substance Name: 2,4,4-Trimethyl-2-pentene
Molecular Formula: $C_8H_{16}$
Structural Information: <div style="text-align: center; padding: 20px;"> <math display="block">  \begin{array}{c}  CH_3 \quad CH_3 \\    \quad   \\  H_3C-C=CH-C-CH_3 \\    \\  CH_3  \end{array}  </math> </div>
<b>COMMENT:</b> Isobutylene dimer would not be an appropriate specific substance 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**

Specific Substance Name: ar-Nitro-6-hexyl-1-naphthol; ar-Nitro-6-hexyl-1-hydroxynaphthalene

Molecular Formula:  $C_{16}H_{19}NO_3$

Structural Information:



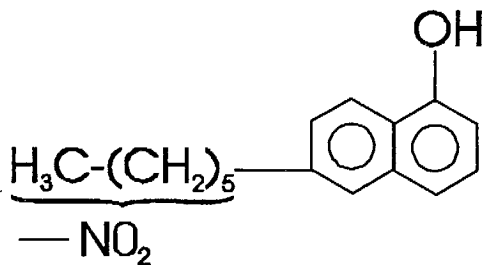
**COMMENT:** Compare to EXAMPLES 13 and 14. The structural representation should represent all known specificity.

**EXAMPLE 13**

Specific Substance Name: 6-(Nitrohexyl)-1-naphthol;  
6-(Nitrohexyl)-1-hydroxynaphthalene

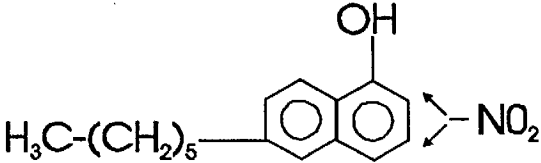
Molecular Formula:  $C_{16}H_{19}NO_3$

Structural Information:



**COMMENT:** Compare to EXAMPLES 12 and 14. The structural representation should represent all known specificity.

## EXAMPLE 14

Specific Substance Name: 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:  <div style="text-align: center;">  </div> <p><i>COMMENT: Compare to EXAMPLES 12 and 13. The structural representation should represent all known specificity.</i></p>

## EXAMPLE 15

Specific Substance Name: Aluminum nickel
Molecular Formula: $Ni_3Al$
Structural Information:  <div style="text-align: center;"> <math>Ni_3Al</math> </div> <p><i>COMMENT: Known stoichiometry should be indicated. Ni-Al would be unacceptable.</i></p>

## EXAMPLE 16

Specific Substance Name: Synthetic geikielite
Molecular Formula: $Mg \cdot O_3Ti$
Structural Information:
<b>COMMENT:</b> <i>Synthetic minerals should indicate in the Specific Substance Name that they are synthetic.</i>

## EXAMPLE 17

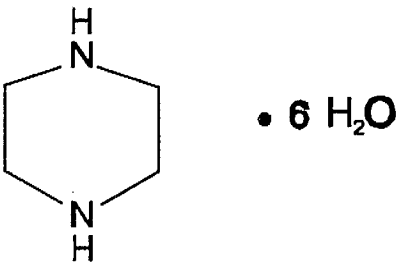
Specific Substance Name: Piperazine, hexahydrate; Arpezine
Molecular Formula: $C_4H_{10}N_2 \cdot 6H_2O$
Structural Information:

<b>Figure 22:</b>
<b>COMMENT:</b> <i>Substances that are described as hydrates should be represented as the anhydrous form.</i>

Table 10 Specific Substance Names for Complex and Variable Substances

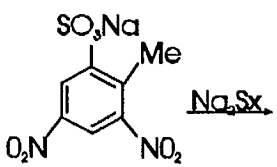
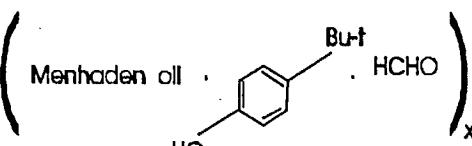
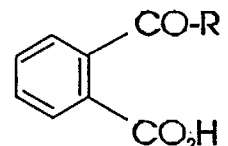
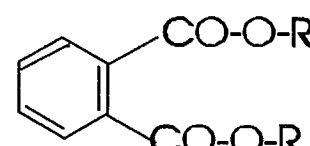
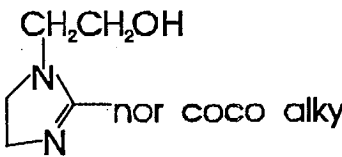
Substance	Unacceptable Name	Acceptable Name
	RGP Brown or Sodium dinitrotoluenesulfonic acid polysulfide	C.I. Sulphur Brown 42 or C.I. 53030 or Thionone Brown R0 or Sodium 3,5-dinitro- <i>p</i> -toluenesulfonic acid reaction product with sodium polysulfide
$\text{H}_2\text{C}=\text{CH}-\text{R}$ <p style="text-align: center;"> <math>\xrightarrow[\text{chlorination}]{\text{bromination}}</math> </p> $\text{R} = \text{C}_{10-28} \text{ Alkyl}$	Halogenated $\text{C}_{12-30}$ $\alpha$ -alkenes or Bromo and chloroalkenes	$\text{C}_{12-30}$ $\alpha$ -alkenes bromo and chloro derivs. or $\text{C}_{12-30}$ $\alpha$ -(alkenes, brominated and chlorinated) or Alkenes, $\text{C}_{12-30}$ $\alpha$ -brominated and chlorinated
	Fish oil-butyl phenol-formaldehyde resin or Marine oil, <i>p</i> - <i>tert</i> -butylphenol, formaldehyde resin or Menhaden oil, 4-butylphenol, formaldehyde resin	Menhaden oil, <i>p</i> - <i>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
 $\text{R} = \text{C}_{8-10} \text{ branched alkyl}$	Nonyl phthalate or Isononyl phthalate or Mono- $\text{C}_{8-10}$ -alkyl phthalate	Mono- $\text{C}_{8-10}$ -branched alkyl phthalate or 1,2-Benzenedicarboxylic acid, mono- $\text{C}_{8-10}$ -branched alkyl esters
 $\text{R} = \text{C}_{8-10} \text{ branched alkyl}$	Dinonyl phthalate or Diisononyl phthalate or Di- $\text{C}_{8-10}$ -alkyl phthalate	Di- $\text{C}_{8-10}$ -branched alkyl phthalate or 1,2-Benzenedicarboxylic acid, di- $\text{C}_{8-10}$ -branched alkyl esters

Table 10 (continued) Specific Substance Names for Complex and Variable Substances

Substance	Unacceptable Name	Acceptable Name
Coconut all fatty acids + $\xrightarrow{\text{salt formation}}$ $\text{HOCH}_2\text{CH}_2\text{NHCH}_2\text{CH}_2\text{OH}$	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
$\text{HOCH}_2\text{CH}_2\text{NHCH}_2\text{CH}_2\text{O-CO-R}$ -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 alkylimidazolineethanol	Coconut oil and N-(2-aminoethyl)ethanolamine cyclization product or 1H-Imidazole-ethanol, 4,5-dihydro-2-norcoco alkyl derivs.

## 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 substances of Unknown or Variable Composition, Complex reaction products, or Biological materials (UVCBs).

### 2.1 Specific Substance Name

The guidelines for names for UVCB substances are similar to the instructions given in Subsection 1.3.1 of Appendix 3 for Well-Defined Substances and should be reviewed for additional information. See Table 10 for further clarification of the level of specificity required.

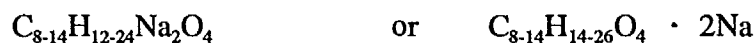
### 2.2 Molecular Formula

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



### 2.3 General Guidelines

Because, in most cases, a unique structure diagram cannot be provided, descriptive information for the substance, components, or precursors should be given.

If a partial structural diagram can be provided, this diagram should 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 should describe all known specificity, such as salt ratios and stereochemical details.

The examples are intended to illustrate the level of specificity that should be provided. It is strongly recommended that the notifier follow the style of the examples.

#### EXAMPLE 18

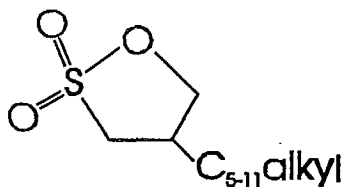
Specific Substance Name: <i>N,N</i> -Diisopropyl tall oil fatty amides
Molecular Formula:
Structural Information: <div style="text-align: center;"> <p style="text-align: center;">-CO-R = tall oil fatty acyl</p> </div>
<b>COMMENT:</b> A substance can be described in terms of a partial structure diagram.

## EXAMPLE 19

Specific Substance Name: 4-(C<sub>5-11</sub> -alkyl)-1,2-oxathiolane, S,S-dioxide

Molecular Formula:

Structural Information:



**COMMENT:** Carbon ranges of alkyl groups must be defined.

## EXAMPLE 20

Specific Substance Name: C<sub>8</sub> branched alkylphenol ethoxylate

Molecular Formula:

Structural Information:



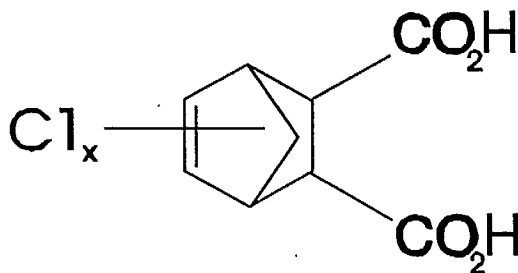
**COMMENT:** Representations should describe all known specificity, including structural information for alkyl groups.

## EXAMPLE 21

Specific Substance Name: Chlorinated 5-norbornene-2,3-dicarboxylic acid;  
Bicyclo[2.2.1]hept-5-ene-2,3-dicarboxylic acid, chloro derivs.

Molecular Formula:

Structural Information:

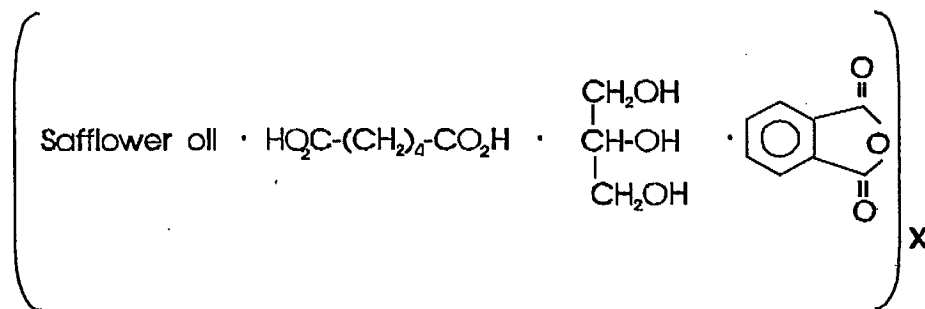


## EXAMPLE 22

Specific Substance Name: Safflower oil, polymer with adipic acid, glycerol and phthalic anhydride

Molecular Formula:

Structural Information:

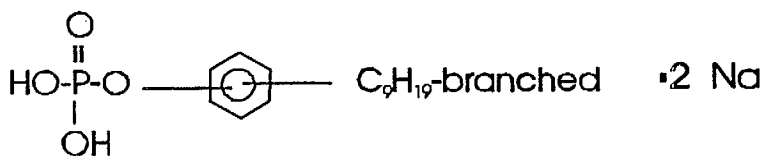


**EXAMPLE 23**

Specific Substance Name: 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 examples are intended to illustrate the level of specificity that should 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

Specific Substance Name: Soybean fatty acids, diethylenetriamine salt
Molecular Formula:
Structural Information:  Soya fatty acids • x $\text{H}_2\text{NCH}_2\text{CH}_2\text{NHCH}_2\text{CH}_2\text{NH}_2$

## EXAMPLE 25

Specific Substance Name: Mixed vegetable oils fatty acids methyl esters
Molecular Formula:
Structural Information:  Methyl esters of mixed vegetable oils fatty acids
<b>COMMENT:</b> <i>If a substance is obtained from a manufacturing process that used different types of plants to produce an oil, then the term, "mixed vegetable" should be used in the name.</i>

## EXAMPLE 26

Specific Substance Name: 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

Specific Substance Name: <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 specific chemical name because bergamot oil is also extracted from Citrus bergamia.</i>

## EXAMPLE 28

Specific Substance Name: Acetylated lemongrass oils
Molecular Formula:
Structural Information:  Lemongrass oil $\xrightarrow{\text{acetylation}}$ 8007-02-1*
<b>COMMENT:</b> <i>The genus and species, Cymbopogon citratus, is associated with CAS Registry Number 8007-02-1* in the Chemical Definition Section of TSCA.</i>

## EXAMPLE 29

Specific Substance Name: Terpene-free bergamot oil fraction
Molecular Formula:
Structural Information:  Terpene-free fraction distilled from oil extracted from <i>Citrus bergamia</i> .

**EXAMPLE 30**

Specific Substance Name:    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 should 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 should 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 should meet the specifications discussed previously.

The examples are intended to illustrate the level of specificity that should be provided.

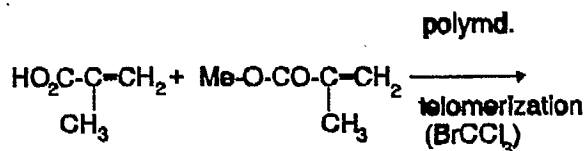


## EXAMPLE 31

Specific Substance Name: Polymer of methyl methacrylate, methacrylic acid, and bromotrichloromethane

Molecular Formula:  $(C_4H_6O_2 \cdot C_5H_8O_2)_x \cdot x CBrCl_3$

Structural Information:

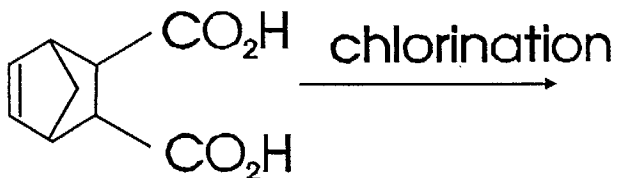


## EXAMPLE 32

Specific Substance Name: Chlorinated 5-norbornene-2,3-dicarboxylic acid;  
Bicyclo[2.2.1]hept-5-ene-2,3-dicarboxylic acid, chloro derivs.

Molecular Formula:

Structural Information:



**COMMENT:** Compare to EXAMPLE 21. Either method is acceptable. Both depict the same degree of specificity.

## EXAMPLE 33

Specific Substance Name:	Phosphoric acid, mono(branched nonyl) phenyl ester, disodium salt
Molecular Formula:	
Structural Information:	<p><i>COMMENT:</i> Compare to EXAMPLE 23. Either method is acceptable. Both depict the same degree of specificity.</p>

## EXAMPLE 34

Specific Substance Name:	Phthalic anhydride-trimethylolpropane copolymer, pelargonate
Molecular Formula:	
Structural Information:	

## EXAMPLE 35

Specific Substance Name: C.I. Acid Black 47; C.I. 56055; Sulfonine Grey G
Molecular Formula:
Structural Information: <div style="text-align: center; margin: 10px 0;"> </div>

## EXAMPLE 36

Specific Substance Name: Tallow fatty acid ethanolamine amides salt
Molecular Formula:
Structural Information: <div style="text-align: center; margin: 10px 0;"> <math display="block">\text{Tallow fatty acids} + \text{H}_2\text{NCH}_2\text{CH}_2\text{OH} \longrightarrow \text{amides}</math> </div> <p><b>COMMENT:</b> <i>Because tallow fatty acids and ethanolamine may react to form a variety of different products (e.g., salts, esters, cyclization products), the product description should be as specific as possible and include typical composition.</i></p>

## 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 should include precursors, method of preparation, process terms (low-boiling, catalytic reformed), physical properties (if known), and typical chemical composition. Specifically, the substance information should describe the substance as uniquely as possible and include (if known):

- (a) process description (catalytic cracking, dewaxed, destructive distillation);
- (b) carbon (alkyl) range ( $C_4$  through  $C_{12}$ );
- (c) physical properties (boiling range, viscosity, solid, slag, and softening point);
- (d) principal chemical composition (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 examples are intended to illustrate the level of specificity that should be provided. Additional examples of the type of descriptive information required can be found in the Chemical Substance Definitions sections of TSCA.

### EXAMPLE 37

Specific Substance Name: $C_{9-13}$ Alkylbenzene distillation residues
Molecular Formula:
Structural Information:  Complex residue from the distillation of $C_{9-13}$ alkylbenzenes having a boiling point > 600°F. Composed primarily of diphenylalkanes, dialkylbenzenes, and diphenyldialkanes. The alkyl groups are linear $C_{9-13}$ .

**EXAMPLE 38**

Specific Substance Name: 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**

Specific Substance Name: 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 42**

Specific Substance Name: 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**

Specific Substance Name: 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 boiling in the range of approximately 30 to 250°C.

**EXAMPLE 44**

Specific Substance Name:    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**

Specific Substance Name:    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.

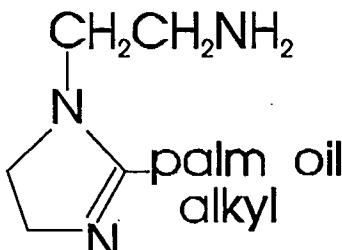


## 2.7 Combinations of UVCB Substances

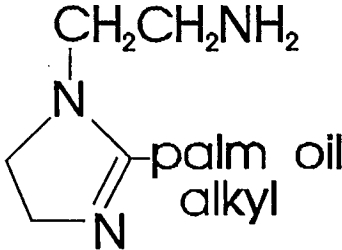
Because of their complexity, it is necessary to describe the precursors, reactants, reaction scheme, and nominated substance as specifically as possible when notifying substances produced by the combination of UVCB substances. It is strongly recommended that before reporting these types of substances all sections of this appendix be carefully reviewed.

The examples are intended to illustrate the level of specificity that should be provided.

### EXAMPLE 46

Specific Substance Name:	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

Specific Substance Name:	Palm oil and diethylenetriamine cyclization product, compound with oxidized light petroleum distillates
Molecular Formula:	
Structural Information:	 <p>Oxidized light + petroleum distillates → salts 64742-98-9*</p> <p><b>COMMENT:</b> The use of CAS Registry Number 64742-98-9* eliminates the need for the inclusion of a lengthy description of the starting material.</p>



*Appendix 4***Locating Chemical Abstracts Service 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.

**I. *Toxic Substances Control Act (TSCA) Chemical Substance Inventory***

The TSCA Inventory of 1985 published by the U.S. EPA is an inventory of over 58 000 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.

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 submitter wishes to verify that it represents the substance that is being reported. This verification is done by reviewing the CA Index or Preferred Name associated with the CAS Registry Number. It should 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 should be reviewed to ensure accurate verification.

Volumes II and III are the Substance Name section of TSCA and should 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. 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 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, 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 if the molecular formula of a substance is known. This section lists TSCA substances of known chemical constitution according to the Hill System. 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 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 substances of Unknown or Variable Composition, Complex Reaction Products, and Biological Materials (UVCBs). Subset Headings identify categories of closely related UVCB substances and provide a method of organizing UVCBs into subsets containing a relatively small number of entries.

## 2. *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. The Name Index, the Molecular Formula Index, and the UVCB Index are similar to the corresponding indexes that were described for the TSCA Inventory.

## 3. *Chemical Abstracts*

Chemical Abstracts 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, CAS 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 CA Abstract Numbers.

#### 4. *Chemical Abstracts Index Guide*

To help users of CA Indexes 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.

#### 5. *Registry Handbook – Common Names*

A microform publication, this handbook is an alphabetic 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.

#### 6. *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.

#### 7. *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 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.

#### 8. *Chemical Abstracts Service Registry Services*

Using CAS Registry Services, submitters 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.

**9.           *The Cosmetic, Toiletry and Fragrance Association Cosmetic Ingredient Dictionary***

This book, published by The Cosmetic, Toiletry and Fragrance Association, Inc., provides nomenclature recommendations for ingredients of formulations used by the cosmetic industry. It is an alphabetic 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.

**10.           *International Nonproprietary Names for Pharmaceutical Substances***

This publication is a computer printout of several lists of international nonproprietary 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.

**11.           *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.

**12.           *The Merck Index***

The Merck Index published by Merck and Company Inc., is an alphabetic 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.

**13.           *USAN and the USP Dictionary of Drug Names***

This publication by the United States Pharmacopoeial Convention, Inc. is a dictionary of nonproprietary names, brand names, code designations, and CAS Registry Numbers for drugs. The names are listed in alphabetic order by INN.

*Appendix 5*

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**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 will be described. These and other conditions for granting a waiver of information will be considered on a case-by-case basis.

**1.            *Physical and Chemical Data*****1.1           *Density***

- (a) 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.

**1.2           *Vapour Pressure***

- (a) The substance has a vapour pressure less than  $10^{-5}$  Torr ( $1.3 \times 10^{-3}$  Pa), in which case an approximate value should be given.

**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 has a water solubility less than  $10^{-6}$  g/L, in which case an approximate value should be given.

**1.4           *Partition Coefficient***

- (a) The substance decomposes or reacts dangerously during the performance of the test.
- (b) The substance is surface active.

**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 has a very high water solubility (e.g., greater than 100 g/L) and its solubility in octanol or fat is less than one thousandth of its water solubility (e.g.,  $\log K_{ow}$  less than -3).
- (c) The substance decomposes (e.g., biodegradation or hydrolysis) or reacts dangerously during the performance of the test.

### 1.6 *Dissociation Constant(s)*

- (a) The solubility of the substance in water cannot be measured analytically; therefore, determination of dissociation constant(s) is not technically feasible.
- (b) The substance reacts dangerously with water.
- (c) The  $pK_a$  of the substance is less than 3 or greater than 10.

### 1.7 *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
Alkenes	aromatic hydrocarbons
Alkynes	Ketones
Aromatic amines	Phenols
Aromatic nitro	Polycyclic aromatic
compounds	hydrocarbons
Benzenes/Biphenyls	Sulphonic acids
Carboxylic acids	
Ethers	

### 1.8 *Particle Size or Fibre Length*

- (a) The substance is unlikely to be in a powder form (e.g., an amorphous waxy solid).
- (b) The substance does not contain particles having an aerodynamic diameter less than 10  $\mu\text{m}$ .



### **1.9**            *Fat Solubility*

- (a) The substance decomposes or reacts during the performance of the test.
- (b) The substance is highly volatile; therefore, determination of fat solubility is not technically feasible.
- (c) The substance has a very high water solubility (e.g., greater than 100 g/L) and its octanol solubility is less than one thousandth of its water solubility (e.g.,  $\log K_{ow}$  less than -3)

### **1.10**           *Number-average Molecular Weight*

- (a) The polymer cannot be dissolved in any solvent suitable for use in an analytical method.

### **1.11**           *Concentration of Residual Constituents*

- (a) The polymer cannot be dissolved in any solvent suitable for use in an analytical method.
- (b) A residual constituent of the substance cannot be measured analytically; therefore, determination of its concentration is not technically feasible.

### **1.12**           *Ultraviolet - Visible Spectrum*

- (a) The substance is explosive or reacts dangerously in the presence of light.

## **2.**            *Toxicological Data*

### **2.1**            *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).

## **2.2            *Repeated Dose Toxicity (Oral, Dermal, or Inhalation)***

- (a) The substance is incorporated into a matrix and will not be released during its intended use, or any reasonable misuse. The matrix must be able to resist physical, chemical, and biological degradation.
- (b) It is not technically feasible to administer known doses of the substance because of its chemical or physical properties.
- (c) The substance will be adequately contained at all times during its existence (manufacture, storage, transport, use, and disposal) to prevent environmental release and human exposure.

## **2.3            *Skin Irritation***

- (a) It is not technically feasible to administer the substance topically.
- (b) The substance has a demonstrated pH of 2 or less or 11.5 or more, or demonstrated chemical reactivity likely to cause skin irritation.
- (c) 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%).
- (d) The substance was found to be an irritant in an acute dermal toxicity study.

## **2.4            *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.

## **2.5            *Mutagenicity Tests***

### **2.5.1        *In Vitro Gene Mutation***

- (a) The chemical properties or physical form of the substance preclude(s) the adequate conduct of the test.

- (b) An *in vitro* mammalian chromosomal aberration assay indicates that the substance has mutagenic activity.
- (c) An *in vivo* mammalian genotoxicity assay indicates that the substance has mutagenic activity.

#### 2.5.2 *In Vitro Mammalian Chromosomal Aberration*

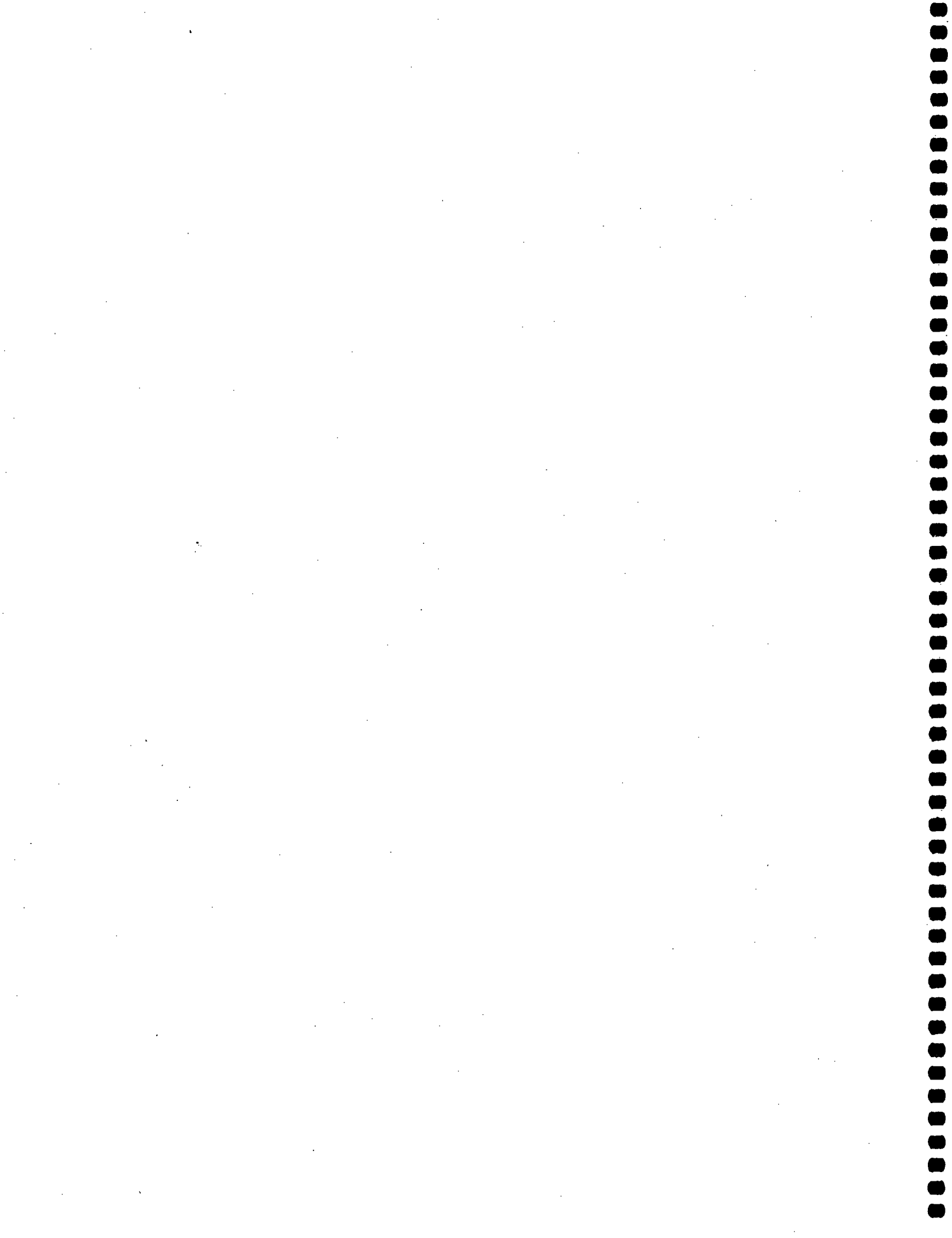
- (a) The chemical properties or physical form of the substance preclude(s) the adequate conduct of the test.
- (b) An *in vitro* gene mutation assay indicates that the substance has mutagenic activity.
- (c) An *in vivo* mammalian genotoxicity test indicates that the substance has mutagenic activity.

#### 2.5.3 *In Vivo Mammalian Mutagenicity Test*

- (a) The chemical properties or physical form of the substance preclude(s) the adequate conduct of the test.
- (b) The substance will be adequately contained at all times during its existence (manufacture, storage, transportation, use, and disposal) to prevent environmental release and human exposure.
- (c)
  - (1) 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;
  - (2) the intended use of the substance will not involve direct, repeated, or prolonged human exposure; and
  - (3) the chemical structure of the substance, or part thereof, is not related to a known mutagen or carcinogen.

### 3. *Ecotoxicological Data*

- (a) The chemical properties or physical form of the substance preclude(s) the adequate conduct of the test.



## Polymer Test Methods

### 1. *Number-average Molecular Weight ( $M_n$ )*

#### 1.1 *Introduction*

Molecular weight is the physical parameter that is typically used to describe the size of a polymer. Polymers consist of chains having varying lengths and varying molecular weights. Thus, a typical polymer has a distribution of molecular weights that can be depicted as a frequency distribution curve. Several mathematical moments can be described for such a curve and the first moment is called the number-average molecular weight ( $M_n$ ). This parameter is very sensitive to the presence of small molecules in the polymer mixture. The second moment of the frequency distribution curve is called the weight-average molecular weight ( $M_w$ ) and depends more on the number of heavier molecules present. The  $M_w$  values are related to bulk properties of the polymer associated with large deformations, such as viscosity and toughness. The ratio of  $M_n/M_w$  is called the polydispersity index and can be used to describe the molecular weight heterogeneity of polymers. A third moment, called the z-average molecular weight, can be related to the melt elasticity of the polymer. Therefore, several measures of polymer molecular weight can be made depending on which of the properties of the polymer are of interest. For environmental and toxicological assessment purposes,  $M_n$  is important because it is most closely related to the thermodynamic properties of the polymer, which control the degree to which the substance can be dissolved or transported in the environment.

The  $M_n$  is related to the colligative properties of the polymer molecule and can be determined by several different methods that measure such properties. These include: ebulliometry (elevation of boiling point); osmometry (both membrane and vapour pressure); and cryoscopy (depression of freezing point). Other methods for measuring  $M_n$  include: end-group analysis; and gel permeation chromatography (also known as size-exclusion chromatography). The latter technique is currently the method of choice for a wide range of polymers.

No single procedure is applicable over the entire range of polymer molecular weights. The choice of procedure is determined by the type of polymer being investigated and its molecular weight range.

#### 1.2 *Ebulliometry*

- (a) This is a classical method that measures the change in boiling temperature of a solvent caused by introduction of a soluble and non-volatile material.
- (b) The method can measure  $M_n$  over the range of 500 to 20 000 daltons routinely, and

up to 100 000 daltons with very sensitive apparatus and careful technique. Precision ranges from 1 to 5% at low molecular weights to 10 to 15% at high molecular weights.

- (c) Determination of boiling point elevation at several concentrations and extrapolation to zero concentration (infinite dilution) is required to satisfy requirements for an ideal solution where polymer-polymer interactions are at a minimum.
- (d) For discussion of the technique, apparatus, and precautions see Bonnar *et al.* (1958) and Glover (1966).

### 1.3 Cryoscopy

- (a) This is a classical method, similar to ebulliometry, that measures the change in freezing temperature of a solvent caused by introduction of a soluble and non-volatile material.
- (b) The method can measure  $M_n$  over the range of 500 to 20 000 daltons with a precision of 5 to 10%.
- (c) Determination at several concentrations and extrapolation to zero concentration (infinite dilution) is required to satisfy the requirements for an ideal solution.
- (d) For techniques, apparatus, and precautions, see Bonnar *et al.* (1958).

### 1.4 Osmometry

- (a) Two osmometry techniques which are currently used to determine polymer molecular weights. These are membrane osmometry and vapour pressure osmometry.

#### 1.4.1 Membrane Osmometry

- (a) In this method, the hydrostatic pressure necessary to maintain isothermal equilibrium between a solution of the sample on one side of a semi-permeable membrane, and the pure solvent on the other side of the membrane, is measured.
- (b) The method can routinely measure  $M_n$  over the range of 15 000 to 500 000 daltons with a precision of 1 to 10%. With special apparatus and a suitable choice of membrane materials, a range up to 4 000 000 daltons can be achieved.
- (c) Polymer samples with a broad range of molecular weights can cause problems with this technique because of solute permeation of the osmometer membrane by the low molecular weight fractions of the polymer. Suitable calibration and blank determinations can be used to alleviate this problem.

- (d) Determination at several concentrations and extrapolation to infinite dilution conditions is required.

#### 1.4.2 *Vapour Phase Osmometry*

- (a) This is currently a popular method of determining absolute values of  $M_n$  for molecular weights up to 20 000 daltons.
- (b) This technique does not use a membrane. A drop of polymer solution and a drop of solvent are placed on adjacent thermistors. The difference in solvent activity brings about a distillation of solvent from the solvent bead to the solution. The temperature change that results from the differential evaporation and condensation can be calibrated in terms of the number-average molecular weight of the polymer solute.
- (c) The method is rapid, however, determination at multiple concentrations and extrapolation to infinite dilution are still required.
- (d) Recommended methodology: ASTM D3750, Membrane Osmometry; ASTM D3592 (pre-1989), Vapour Pressure Osmometry.

#### 1.5 *End-group Analysis*

- (a) In this method, the concentration of characteristic end-groups in a polymer is determined using a suitable chemical or physicochemical method and, from this, a value for  $M_n$  can be estimated.
- (b) The method is normally used to estimate  $M_n$  up to 25 000 daltons in polymers, with a precision of about 5%.
- (c) The method applicability and precision normally depend on the type of sample, and often it is necessary to tailor the analysis method to the individual sample.
- (d) Examples of typical methods include the determination of molecular weights for polyethylene terephthalate by titration of carboxylic and hydroxyl (converted to carboxylic) end-groups; polythioamides by ultraviolet (UV) spectroscopy of amine and thioester end-groups; polyvinyl acetate by titration of carboxyl end-groups; polyesters by infrared (IR) spectrophotometry of hydroxyl groups; and polyether polyols and hydroxyl end-capped polystyrene by nuclear magnetic resonance (NMR) spectroscopy of the hydroxyl group hydrogen (ASTM D4273).

#### 1.6 *Gel Permeation Chromatography (GPC)*

- (a) This method is currently the most widely used to determine polymer molecular weights.

- (b) A solution of the sample in a suitable solvent is injected onto a column packed with a porous gel material of various pore sizes that separates sample molecules according to their effective sizes in solution (their hydrodynamic volumes). Molecules too large to penetrate any of the pores are not retained by the column packing and elute first. Molecules small enough to penetrate any or all of the pores are retained on the column and elute later. After injection of the sample solution onto the column, the hydrodynamic volume of the retained species eluted decreases logarithmically with increasing time. By injecting samples of known molecular weights (standards), the retention times or retention volumes of the observed peaks for each sample molecule can be correlated to specific molecular weights. This correlation becomes the basis of molecular weight calibration and allows the molecular weight of an unknown sample to be calculated in relation to a known standard. The detector response gives a measure of the amount of a particular molecular weight species in the sample. From a knowledge of the detector response and the calibration,  $M_n$  can be calculated.
- (c) The technique requires the use of standards, usually commercially available. There may not be standards available for the analysis of certain polymer types. A standardization technique called "universal calibration" can often be used for these polymers. The universal calibration technique, however, should be used with caution because it depends on a relationship between the hydrodynamic volume of the polymer molecule of interest and the product of its molecular weight and intrinsic viscosity. The constants in this relationship, known as Mark-Houwink constants, are determined by independent methods, and can be very sensitive to small variations in the GPC experimental parameters such as baseline uncertainties and interactions other than steric exclusion between the sample polymer and the separating gel. These variations can, in turn, create large errors in the calculated molecular weights for the polymer samples. Significant variations are also found in the literature for Mark-Houwink constants for particular polymers, depending on the method by which they were determined.
- (d) The type of solvent used in the analysis is very important. Some samples may not be soluble in a solvent suitable for use in GPC.
- (e) The technique has limitations due to adsorption, ion inclusion and related affinity effects, and ion exclusion. These effects can give false indications of molecular weights unless calibration is done with polymers of the same type as the one in which the affinity effect is being observed.
- (f) Copolymers are difficult to analyze because the molecular size of random and block copolymers of the same molecular weight and comonomer composition in solution may not be the same. In addition, the detector response within the same molecular weight range may not vary linearly with the change in comonomer composition.
- (g) Molecular weights obtained are not absolute values.



- (h) The method can be applied over the whole range of polymer molecular weights as long as suitable solvents and standards are available.
- (i) An example of a recommended methodology is ASTM D3593-08.03.

## 2. *Concentrations of Residual Constituents with Molecular Weights Less than 500 daltons and Less than 1000 daltons*

### 2.1 *Introduction*

Residual constituents include both polymer additives and low molecular weight oligomers. Several techniques can be used to identify and quantify these constituents and, in some cases, a combination of techniques may be required to identify all residuals. These techniques include: gel permeation chromatography (GPC); high performance liquid chromatography (HPLC); gas chromatography (GC), which may include the use of headspace sampling techniques, derivitization, and special detectors such as mass spectrometric detectors and infra-red detectors; supercritical fluid chromatography (SFC); spectroscopy; and chemical analysis. The most commonly used of these techniques for the analysis of residual constituents will be discussed.

The two most common detectors used in GPC and HPLC are refractive index (RI) and ultraviolet (UV) detectors. Each of these can be used to determine the concentration of residual components or oligomers that are absolutely homogeneous. However, many polymer products have heterogeneous molecular structures, i.e., they may be random block or graft copolymers or blends of polymers. As neither the RI nor the UV detector is mass sensitive, quantitation of heterogeneous components can be in error by several orders of magnitude. Flame ionization detectors, which are commonly used in both GC and SFC, are mass sensitive and are thus more widely applicable.

### 2.2 *Gel Permeation Chromatography*

- (a) The method can be used either to analyze constituents directly or as a fractionation technique for further analysis by other techniques.
- (b) GPC is particularly applicable to the analysis of low molecular weight oligomers. These will be eluted after the normal polymer fractions and, depending on the conditions used and the type of polymer, some separation may be observed.
- (c) The normal limitations of the GPC technique apply, including ion exclusion, ion inclusion, and ion affinity effects.
- (d) When GPC is used to analyze for residual constituents rather than for monomer or low molecular weight oligomers, care should be taken to ensure that the components

of interest do not co-elute with the polymer fractions. Because a residual constituent may be an entirely different chemical from the bulk polymer, any external calibration based on the polymer material itself will not be valid for quantitation of the residual chemical.

- (e) GPC has been successfully applied to the analysis of residual isocyanates in urethane adhesives, styrene in copolymers, plasticizer in polystyrene, and phosphite and epoxide stabilizers in polystyrene and polyvinyl chloride.
- (f) The method has been used as a pre-fractionation technique for subsequent fraction analysis by capillary GC or by HPLC.

### 2.3 *High Performance Liquid Chromatography*

- (a) This technique is probably the most generally applicable to the analysis of residual components, both additives and low molecular weight oligomers.
- (b) Both UV and RI detectors are commonly used, neither of which is mass sensitive; therefore, the technique is subject to the limitations described earlier. Although flame ionization detectors have been developed for HPLC, they are not generally used and have some severe limitations in this application.
- (c) The technique is most applicable to the analysis of residual additives. Some described methods fractionate the sample by GPC prior to analysis of the fractions by HPLC.
- (d) HPLC can be coupled to MS and IR for identification of the residual compounds.

### 2.4 *Gas Chromatography*

- (a) The technique is generally only applicable to the analysis of residual additives, although some low molecular weight oligomers have been analyzed with suitable derivatization.
- (b) GC can be used with dynamic headspace sampling techniques to avoid solvent extraction procedures.
- (c) Derivatization is often required to make samples volatile enough for analysis by GC.
- (d) Both packed and capillary column analyses have been described for this application. However, capillary column GC is the most efficient for a wide range of compounds.
- (e) GC can be coupled to MS or IR for identification of the sample compounds.
- (f) The most commonly used GC detector is the flame ionization detector, which is mass

sensitive. Therefore, some compounds that are difficult to analyze can be determined using this method.

## 2.5 *Supercritical Fluid Chromatography*

- (a) This is a relatively new analytical technique; therefore, few methodologies are reported in the literature. However, the technique has the potential to be applied to the analysis of a wide range of compounds with low volatility.
- (b) Supercritical Fluid Chromatography (SFC) uses flame ionization detection and can be coupled to MS or IR instruments.
- (c) Supercritical fluid extraction can be used to introduce the sample to the chromatograph. This technique uses relatively mild conditions and, therefore, sample loss and degradation are minimized.

## 2.6 *Spectroscopy*

- (a) A suitable sample extraction step is required.
- (b) Any of the techniques of ultraviolet (UV) spectrophotometry, infrared (IR) spectrophotometry, nuclear magnetic resonance (NMR) spectroscopy, and mass spectrometry (MS) can be used to obtain qualitative and/or quantitative information on residual chemicals.
- (c) Most of these techniques require a pre-separation step, usually by a form of chromatography (e.g., column, TLC, GC, HPLC).

## 3. *Water Solubility*

### 3.1 *Introduction*

Water solubility should be determined on the notified polymer, however, it is recognized that a representative sample of the notified substance may not be available at the time of testing. Before the water solubility is determined, the sample on which testing is to be carried out should be made prepared to make it as similar as possible to the notified polymer. For example, residual solvent should be removed. This may be accomplished by subjecting the sample to an initial water extraction, by heating the sample, or by using a vacuum apparatus.

### 3.2 *Methods*

- (a) Determination of solubility at pH 7. One suitable method is OECD Guideline 105.

- (b) Determination of solubility at pH 1 and 10. One suitable method is to modify OECD Guideline 105 by using hydrochloric acid to adjust to pH 1 or, for solubility at pH 10, by using sodium or potassium hydroxide to adjust to the desired pH (CEC Annex V methodology).
- (c) For consistency in analytical procedures, and in the accuracy and precision of the results obtained, the flask method of water solubility determination is the preferred choice.
- (d) The water soluble portion can be analyzed directly, or after solvent extraction and concentration, by chromatographic or spectroscopic techniques. Any components in this residue that can be identified as additives should be discounted for the purpose of determining the solubility of the polymer itself.

#### **4. *Solubility in n-Octanol and Octanol-Water Partition Coefficient***

##### **4.1 *Introduction***

Tests for solubility in n-octanol and the octanol-water partition coefficient should be carried out on the notified substance or on a sample that has been prepared to be representative of the notified substance. See water solubility for details.

- (a) A recommended procedure is to modify the flask method (described in OECD Guideline 105) by using analytical grade n-octanol as the solvent and by running the determination at 20°C.
- (b) The n-octanol extract should be analyzed directly for the dissolved polymer by a suitable method; or the n-octanol should be evaporated under reduced pressure and the residue analyzed for the polymer, again by a suitable method. For the aqueous solubility tests, any components identified as additives should be discounted to determine the true solubility of the polymer itself.
- (c) Recommended methods for the determination of the octanol-water partition coefficient are OECD methods 107 and 117.

#### **5. *Hydrolysis as a Function of pH***

- (a) A recommended method is OECD Guideline 111.
- (b) It is also required that, if the products of hydrolysis are known, they should be identified by a suitable technique. Suggested methods include solvent extraction of the product followed by concentration and analysis by GC, HPLC, spectroscopy, or appropriate chemical analysis.

## 6. *Ultraviolet - Visible Spectrum*

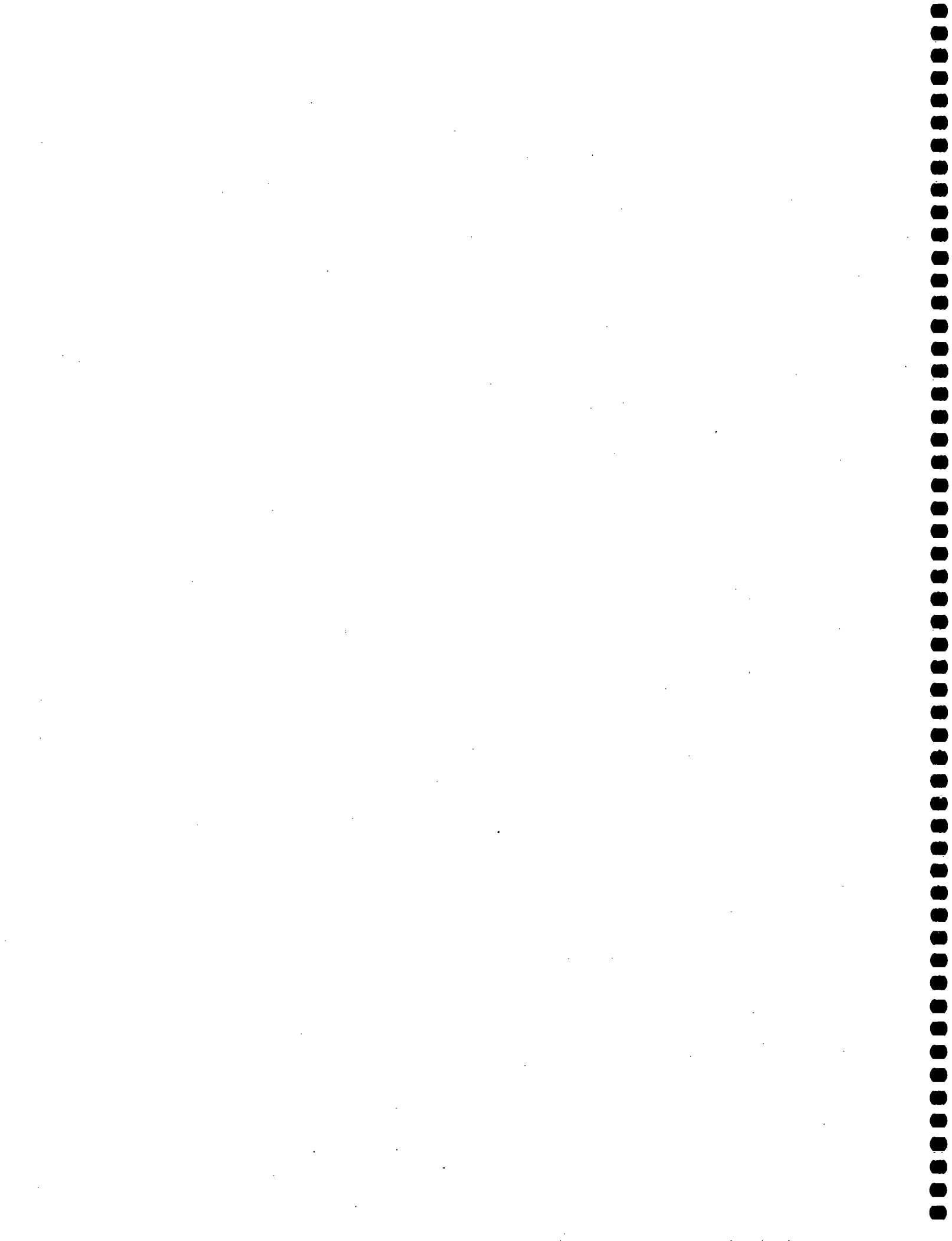
- (a) The purpose of this test is to provide an indication of the photochemical stability of the polymer by measuring its absorbance in the region of solar incident radiation from a wavelength of 290 to 700 nm.
- (b) A recommended procedure (devised by the U.S. EPA Office of Toxic Substances) measures the spectrum of a solution of the polymer in a suitable non-associative solvent (e.g., hexane, cyclohexane, carbon tetrachloride, or methylene chloride) over the wavelength range of 290 to 700 nm. Because solvent effects cannot be predicted, determinations with solutions in at least two solvents that result in the same absorption spectrum should be made.

## 7. *Ready Biodegradability*

- (a) The recommended method is OECD Guideline 301. Only Guidelines 301B, 301C, and 301D are suitable for the analysis of insoluble substances.

## 8. *References*

- (a) Bonnar, R.U., M. Dimbat, and F. H. Stross, *Number-Average Molecular Weights - Fundamentals and Determination*, Interscience, New York, NY (1958).
- (b) Glover, C.A. "Determination of Molecular Weights by Ebulliometry," In *Advances in Analytical Chemistry and Instrumentation*. Volume 5. Reilley, C.N. and F. W. McLafferty, (eds.) Interscience, New York, NY (1966).



*Appendix 7*

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## Masking of Substance Names

The procedures presented below are based on guidelines developed by the U.S. EPA for purposes of the TSCA Inventory. They have been modified for Canadian use and are included to provide guidance to persons submitting New Substance Notifications and wishing to claim specific identities as confidential. Consequently, a masked name must be submitted for publication purposes. The intent of masking is to disguise, only to the extent necessary, the full 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.

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.

### *1. Substances Having a Definite Chemical Structure*

Substances having a definite chemical structure can be represented by an unique structure diagram. The names of substances with a distinct chemical identity normally disclose the following structural information:

- (a) the identity of parent structure (i.e., a chain of carbon atoms, a ring system, or a coordinated metal);
- (b) the identity, number, and position of chemical group(s) that are attached to the parent structure(s) or to other chemical groups;
- (c) the identity and number of counter ions (for salts); and
- (d) the 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) a locant that specifies the placement of a single chemical group;
- (b) the locant and multiplicative prefixes (e.g., di-, tri-, and tetra-) that together specify the number and placement of a given chemical group;
- (c) the identity (but not placement and number) of a given chemical group;
- (d) the identity of a given parent structure, and locants of a substituent chemical group; and
- (e) the identity and multiplicative prefixes (specifying the number) of a given simple cation or anion of a salt.

Table 11 lists by name and molecular formula the type of chemical groups that can be masked. The groups of atoms found in Table 11 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 11 include hydrogen atoms that are often additionally substituted, e.g., an ethyl group may be substituted for a hydrogen of the sulfamyl group ( $\text{H}_2\text{NSO}_2^-$ ) to give  $\text{C}_2\text{H}_5\text{NHSO}_2^-$ . If additionally substituted, **only** the chemical group listed in Table 11 should be masked, **not** the substituent.

Table 11 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 11 and, accordingly, may be used in masking.

#### Table 11 List of Common Chemical Structural Units

aldo O=

amidino  $\text{H}_2\text{NC}(=\text{NH})-$

amino  $\text{H}_2\text{N}-$

(aminoamidino)  $\text{H}_2\text{NC}(=\text{NNH}_2)-$  or  $\text{H}_2\text{NNHC}(=\text{NH})-$

(aminocarbonyl)  $\text{H}_2\text{NCO}-$

[(aminocarbonyl)amino]  $\text{H}_2\text{NCONH}-$

(continued)



Table 11(continued)

## List of Common Chemical Structural Units

[2-(aminocarbonyl) hydrazino]  $H_2NCONHNH-$   
 [(aminocarbonyl) hydrazono]  $H_2NCONHN=$   
 (aminohydrazonomethyl)  $H_2NC(=NNH_2)-$   
 [(aminohydroxymethylene) hydrazino]  $H_2NC(OH)=NNH-$   
 (aminoiminomethyl)  $H_2NC(=NH)-$   
 (aminoiminophosphoranyl)  $H_2NPH(=NH)-$   
 (P-aminophosphinimyl)  $H_2NPH(=NH)-$   
 (aminosulfinyl)  $H_2NSO-$   
 (aminosulfonyl)  $H_2NSO_2-$   
 (aminothio)  $H_2NS-$   
 (aminothioxomethyl)  $H_2NCS-$   
 ammonio  $H_3N-$   
 antimonio  $-Sb=Sb-$   
 arseno  $-As=As-$   
 arsenoso  $OAs-$   
 arsinico  $HOAs(O)\equiv$   
 arsinidene  $AsH=$   
 arsinidyne  $As\equiv$   
 arsinimyl  $AsH_2(=NH)-$   
 arsino  $AsH_2-$   
 arsinothioyl  $AsH_2(S)-$   
 arsinyll  $AsH_2(O)-$   
 arsinylidene  $AsH(O)\equiv$   
 arso  $O_2As-$   
 arsono  $(HO)_2As(O)-$   
 (arsonooxy)  $(HO)_2As(O)O-$   
 arsononitridyl  $AsH(=N)-$   
 arsoranyl  $AsH_4-$   
 arsoranylidyne  $AsH_2\equiv$   
 arsylene  $AsH=$   
 arsylidyne  $As\equiv$   
 astato  $At-$   
 astatoxy  $O_2At-$   
 astatyl  $O_2At-$   
 azi  $-N=N-$   
 azido  $N_3-$   
 (azidocarbonyl)  $N_3CO-$   
 (azidofurmyl)  $N_3CO-$   
 (azidosulfonyl)  $N_3SO_2-$   
 azino  $=NN=$   
 azo  $-N=N-$

(continued)

Table 11(continued)

## List of Common Chemical Structural Units

---

 azoxy  $-N(O)=N-$ 
bismuthino  $BiH_2-$ bismuthylene  $BiH=$ bismuthylidyne  $Bi\equiv$ borono  $(HO)_2B-$ (boronooxy)  $(HO)_2BO-$ boryl  $BH_2-$ borylene  $BH=$ borylidyne  $B\equiv$ bromo  $Br-$ (bromocarbonyl)  $BrCO-$ (bromoiminomethyl)  $BrC(=NH)-$ (bromosulfonyl)  $BrSO_2-$ carbamido  $H_2NCONH-$ carbamoyl  $H_2NCO-$ carbanyl  $H_2NCO-$ carbonimidoyl  $-C(=NH)=$ (carbonimidoylamino)  $H_2N=C=N-$ carbonothioyl  $-CS-$ carbonyl  $-CO-$ (carbonylidiimino)  $-NHCONH-$ (carbonyldioxy)  $-OC(O)O-$ carboxy  $HO_2C-$ chloro  $Cl-$ (chlorocarbonyl)  $ClCO-$ (chloroformyl)  $ClCO-$ (chloroiminomethyl)  $ClC(=NH)-$ (chlorosulfinyl)  $ClSO-$ (chlorosulfonyl)  $ClSO_2-$ chlorosyl  $OCl-$ (chlorothio)  $ClS-$ chloryl  $O_2Cl-$ cyanato  $NCO-$ cyano  $NC-$ 1,2-diarsenediyl  $-As=As-$ diarsenyl  $HAs=As-$ diarsinetetrayl  $=AsAs=$ diarsinyl  $H_2AsAsH-$ 1,2-diazenediyl  $-N=N-$ 

(continued)

Table 11(continued)

## List of Common Chemical Structural Units

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diazeno  $\text{HN}=\text{N}-$   
 diazo  $\text{N}_2=$   
 diazoamino  $-\text{NHN}=\text{N}-$   
 diazonio  $\text{N}_2^+-$   
 1,2-diborane(4)diylidene  $=\text{BB}=\text{}$   
 diborane(4)tetrayl  $=\text{BB}=\text{}$   
 digermanylene  $-\text{GeH}_2\text{GeH}_2-$   
 digermathianyl  $\text{H}_3\text{GeSGeH}_2-$   
 dioxy  $-\text{OO}-$   
 1,2-diphosphenediyl  $-\text{P}=\text{P}-$   
 1,2-diphosphinediyl  $-\text{PPH}-$   
 1,2-diphosphinediylidene  $=\text{PP}=\text{}$   
 diphosphinetetrayl  $=\text{PP}=\text{}$   
 diphosphinyl  $\text{H}_2\text{PPH}-$   
 diseleno  $-\text{SeSe}-$   
 1,2-disilanediyyl  $-\text{SiH}_2\text{SiH}_2-$   
 disilanoxy  $\text{H}_3\text{SiSiH}_2\text{O}-$   
 disilanyl  $\text{H}_3\text{SiSiH}_2-$   
 disilanylene  $-\text{SiH}_2\text{SiH}_2-$   
 (disilanyloxy)  $\text{H}_3\text{SiSiH}_2\text{O}-$   
 (disilathianyloxy)  $\text{H}_3\text{SiSSiH}_2\text{O}-$   
 disilazanoxy  $\text{H}_3\text{SiNHSiH}_2\text{O}-$   
 disilazanyl  $\text{H}_3\text{SiNHSiH}_2-$   
 2-disilazanyl  $(\text{H}_3\text{Si})_2\text{N}-$   
 (disilazanyloxy)  $\text{H}_3\text{SiNHSiH}_2\text{O}-$   
 1,3-disiloxanediyl  $-\text{SiH}_2\text{OSiH}_2-$   
 1,3-disiloxanediylidene  $=\text{SiHOSiH}=\text{}$   
 disiloxanoxy  $\text{H}_3\text{SiOSiH}_2\text{O}-$   
 disiloxanylene  $-\text{SiH}_2\text{OSiH}_2-$   
 (disiloxanyloxy)  $\text{H}_3\text{SiOSiH}_2\text{O}-$   
 disilthianoxy  $\text{H}_3\text{SiSSiH}_2\text{O}-$   
 1,2-distannanediyl  $-\text{SnH}_2\text{SnH}_2-$   
 distannanylene  $-\text{SnH}_2\text{SnH}_2-$   
 1,3-distannathianediylidene  $=\text{SnHSSnH}=\text{}$   
 1,2-distibenediyyl  $-\text{Sb}=\text{Sb}-$   
 disulfinyl  $-\text{S}(\text{O})\text{S}(\text{O})-$   
 dihydro  $-\text{SS}-$   
 (dithiocarboxy)  $\text{HSCS}-$   
 (dithiohydroperoxy)  $\text{HSS}-$   
  
 epidioxy  $-\text{OO}-$

(continued)

Table 11(continued)

## List of Common Chemical Structural Units

epidiseleno -SeSe-

epidithio -SS-

epioxy -O-

episeleno -Se-

epithio -S-

epoxy -O-

fluoro F-

(fluorocarbonyl) FCO-

fluoryl O<sub>2</sub>F-

formamido HCONH-

1,5-formazanidyl -N=NCH=NNH-

1-formazano H<sub>2</sub>NN=CHN=N-

5-formazano HN=NCH=NNH-

formazanyl HN=NC (=NNH<sub>2</sub>)-

formimidoyl HC(=NH)-

formyl HCO-

(formylamino) HCONH-

germanetetrayl =Ge=

germyl H<sub>3</sub>Ge-germylene H<sub>2</sub>Ge=

germylidyne HGe≡

guanyl H<sub>2</sub>NC(=NH)-

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>-

(continued)

Table 11(continued)

## List of Common Chemical Structural Units

(hydroperoxythioxomethyl) HOCS-  
 hydroxy HO-  
 (hydroxyamino) HONH-  
 (hydroxyimino) HON=  
 (hydroxyiminomethyl) HOC(=NH)-  
 hydroxyl HO-  
 (hydroxyphosphinyl) HOPH(O)-  
  
 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-  
 iodanyl OI-  
 iodyl O<sub>2</sub>I-  
 isocyanato OCN-  
 (isocyanatocarbonyl) OCNCO-  
 (isocyanatosulfonyl) OCNSO<sub>2</sub>-  
 isocyano 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-  
 (isothiocyantocarbonyl) SCNCO-  
 (isothiocyantosulfonyl) SCNCO<sub>2</sub>-  
 isothiocyano SCN-  
  
 keto O=  
  
 mercapto HS-  
 (mercaptoamino) HSNH-

(continued)

Table 11(continued)

## List of Common Chemical Structural Units

(mercaptooxy) HSO-  
 [(mercaptooxy) carbonyl] HSOCO-  
 [(mercaptooxy) sulfinyl] HSOS(=O)-  
 [(mercaptooxy) sulfonyl] HSOS(=O)<sub>2</sub>-  
 [(mercaptooxy) thioxomethyl] HSOCS-  
 (mercaptotelluro) HSTe-

nitramino O<sub>2</sub>NNH-  
aci-nitramino HON(O)=N-  
 nitrilio HN+≡  
 nitrilo N=  
 (nitrilophosphoranyl) 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-

oximido HON=  
 oxo O=  
 (oxoboryl) OB-  
 oxy -O-

1,3-pentazadienyl H<sub>2</sub>NN=NN=N-  
 perchloryl O<sub>3</sub>Cl-  
 perselene 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)=

(continued)

Table 11(continued)

## List of Common Chemical Structural Units

---

phosphinylidyne  $\text{P(O)=}$   
 phospho  $\text{O}_2\text{P-}$   
 phosphono  $(\text{HO})_2\text{P(O)-}$   
 (phosphonocarbonyl)  $(\text{HO})_2\text{P(CO)}$   
 phosphononitridyl  $\text{HP(=N)-}$   
 (phosphonooxy)  $(\text{HO})_2\text{P(O)O-}$   
 phosphoranyl  $\text{H}_4\text{P-}$   
 phosphoranylidene  $\text{H}_3\text{P=}$   
 phosphoranylidyne  $\text{H}_2\text{P}\equiv$   
 phosphoro  $-\text{P}=\text{P-}$   
 phosphoroso  $\text{OP-}$   
 plumbanetetrayl  $=\text{Pb}=\text{}$   
 plumbyl  $\text{H}_3\text{Pb-}$   
 plumbylene  $\text{H}_2\text{Pb}=\text{}$   
 plumbylidyne  $\text{HPb}=\text{}$

seleneno  $\text{HOSe-}$   
 selenino  $\text{HOSe(O)-}$   
 seleninoselenoyl  $\text{Se=Se=}$   
 seleninyl  $\text{OSe=}$   
 seleno  $-\text{Se-}$   
 selenocyanato  $\text{NCSe-}$   
 selenono  $(\text{HO})\text{SeO}_2\text{-}$   
 selenonyl  $\text{O}_2\text{Se=}$   
 selenoxo  $\text{Se=}$   
 selenyl  $\text{HSe-}$   
 semicarbazido  $\text{H}_2\text{NCONHNH-}$   
 semicarbazono  $\text{H}_2\text{NCONHN=}$   
 silanetetrayl  $=\text{Si}=\text{}$   
 silyl  $\text{H}_3\text{Si-}$   
 silylene  $\text{H}_2\text{Si}=\text{}$   
 silylidyne  $\text{HSi}\equiv$   
 (silyloxy)  $\text{H}_3\text{SiO-}$   
 stannanetetrayl  $=\text{Sn}=\text{}$   
 stannono  $\text{HOSn(O)-}$   
 stannyl  $\text{H}_3\text{Sn-}$   
 stannylene  $\text{H}_2\text{Sn}=\text{}$   
 stannylidyne  $\text{HSn}\equiv$   
 stibinico  $\text{HOSb(O)=}$   
 stibino  $\text{H}_2\text{Sb-}$   
 stibo  $\text{O}_2\text{Sb-}$

(continued)

Table 11(continued)

## List of Common Chemical Structural Units

stibono  $(\text{HO})_2\text{Sb}(\text{O})-$   
 (stibonooxy)  $(\text{HO})_2\text{Sb}(\text{O})\text{O}-$   
 stiboso  $\text{OSb}-$   
 stibyl  $\text{H}_2\text{Sb}-$   
 stibylene  $\text{HSb}=\text{}$   
 stibylidyne  $\text{Sb}\equiv\text{}$   
 sulfamino  $\text{HOSO}_2\text{NH}-$   
 sulfamoyl  $\text{H}_2\text{NSO}_2-$   
 sulfamyl  $\text{H}_2\text{NSO}_2-$   
 sulfeno  $\text{HOS}-$   
 (sulfenocarbonyl)  $\text{HOSCO}-$   
 (sulfenosulfinyl)  $\text{HOSS}(=\text{O})-$   
 (sulfenosulfonyl)  $\text{HOSS}(=\text{O})_2-$   
 (sulfenothioxomethyl)  $\text{HOSCS}-$   
 sulfhydryl  $\text{HS}-$   
 sulfinimidoyl  $\text{HN}=\text{S}=\text{}$   
 sulfino  $\text{HOS}(\text{O})$   
 (sulfinooxy)  $\text{HOS}(\text{O})\text{O}-$   
 sulfinothieryl  $\text{S}=\text{S}=\text{}$   
 sulfinyl  $\text{OS}=\text{}$   
 sulfo  $\text{HO}_3\text{S}-$   
 (sulfoamino)  $\text{HOSO}_2\text{NH}-$   
 sulfonimidoyl  $\text{HN}=\text{S}(\text{O})=\text{}$   
 sulfonodiimidoyl  $(\text{HN}=\text{S})_2\text{S}=\text{}$   
 sulfonyl  $-\text{SO}_2-$   
 (sulfooxy)  $\text{HO}_3\text{SO}-$   
 sulfuryl  $-\text{SO}_2-$

telluro  $-\text{Te}-$   
 telluroxo  $\text{Te}=\text{}$   
 telluryl  $\text{HTe}-$   
 1,4-tetraphosphinediyl  $-(\text{PH})_4-$   
 1,7-tetrasiloxanediyl  $-\text{SiH}_2(\text{OSiH}_2)_2\text{OSiH}_2-$   
 tetrathio  $-\text{SSSS}-$   
 1,4-tetrazanediyl  $-(\text{NH})_4-$   
 1,4-tetrazanediylidene  $=\text{N}(\text{NH})_2\text{N}=\text{}$   
 1-tetrazenyl  $\text{H}_2\text{NNHN}=\text{N}-$   
 thio  $-\text{S}-$   
 (thioarsenoso)  $\text{S}=\text{As}-$   
 (thiocarbamoyl)  $\text{H}_2\text{NCS}-$   
 thiocarbamyl  $\text{H}_2\text{NCS}-$

(continued)



Table 11(*continued*)

## List of Common Chemical Structural Units

---

(thiocarbonyl) -CS-  
 (thiocarboxy) HOSC-  
 thiocyanato NCS-  
 thiocyano NCS-  
 (thioformyl) HCS-  
 thiohydroperoxy HOS- ou 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>NNH-  
 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-  
  
 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)

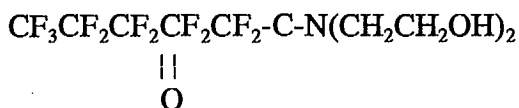
carbopolycyclic or carbopolycycle (e.g., naphthalene,  
spiroundecane)  
heteromonocyclic or heteromonocycle (e.g., pyrrole,  
p-dioxane)  
heteropolycyclic or heteropolycycle (e.g., indole,  
benzothiazole)

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 Fully Defined Name**

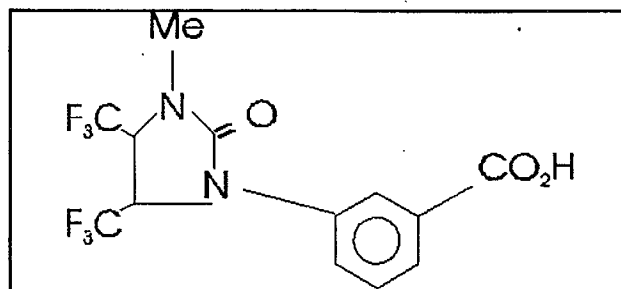
2,2,3,3,4,4,5,5,6,6,6-undecafluoro-N,N-bis(2-hydroxy-ethyl) hexanamide

**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



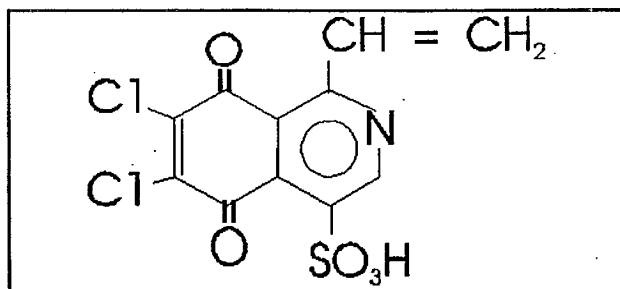
#### 1.1.2.1 Fully Defined Name

4-(3-methyl-2-oxo-4,5-bis(trifluoromethyl)-1-imidazolidinyl)benzoic acid

#### 1.1.2.2 Acceptable Masked Names

- oxo group masked:  
4-(3-methyl-2-substituted-4,5-bis(trifluoromethyl)-1-imidazolidinyl) benzoic acid  
(NOTE: Only the oxo and not the carbonyl group has been masked.)
- fluorine atoms masked:  
4-(3-methyl-2-oxo-4,5-bis(trihalosubstituted methyl)-1-imidazolidinyl) benzoic acid
- imidazolidine ring (plus locants) masked:  
4-[methyloxobis(trifluoromethyl)heteromonocycle]benzoic acid

1.1.3 *Example 3*



1.1.3.1 *Fully Defined Name*

6,7-dichloro-1-ethenyl-5,8-dihydro-5,8-dioxo-4-isoquinolinesulfonic acid

1.1.3.2 *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. *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, submitters must base their choice of a masked name on a CAS Preferred Name. Environment Canada 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 Chemical 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*

Reaction product of 1,8-dihydroxy-4,5-dinitro-9,10-anthracenedione with aniline and 2-chloroethanol

### 2.2.2 *Specific Chemical Name*

1,8-dihydroxy-4,5-dinitro-9,10-anthracenedione reaction products with aniline and 2-chloroethanol

### 2.2.3 *Acceptable Masked Names*

- hydroxyl groups masked:

1,8-disubstituted-4,5-dinitro-9,10-anthracenedione reaction products with aniline and 2-chloroethanol

- anthracene parent (plus locants) masked:

dihydroxydinitrodioxopolycycle reaction products with aniline and 2-chloroethanol

- chlorine atom masked:

1,8-dihydroxy-4,5-dinitro-9,10-anthracenedione reaction products with aniline and 2-halosubstituted ethanol

## 2.3 *Example 6*

### 2.3.1 *Substance Description*

Polyethylene glycol, mono-C<sub>12-15</sub>-alkyl ethers, phosphates, potassium salts

### 2.3.2 *Specific Chemical Name*

Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-, mono-C<sub>12-15</sub>-alkyl ethers, phosphates, potassium salts

### 2.3.3 *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. *Justifying the Use of Additional Masking*

Submitters who determine that strict application of these guideline procedures would not adequately mask the confidential substance identity may propose a masked name that disguises the substance identity to a greater extent than provided for by these procedures. Such additional masking should be substantiated in a written statement accompanying the notification. The statement should be prepared in the following manner:

- (a) Construct each reasonably applicable masked name developed following the described procedures.
- (b) For each masked name constructed, discuss the reason 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.

- (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*

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**Glossary**

**Acceptable to the Departments** 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**)

**Adequately contained** means all precautions and measures necessary to prevent the release of the substance to the environment. With respect to the transportation of a substance, adequate containment requires full compliance with the *Transportation of Dangerous Goods Act*.

**Anionic polymer** means a polymer that contains one or more covalently linked monomer units that bear a net negative charge (see also **monomer unit, polymer**).

**Assessment period** means the number of calendar days that the government has to assess the information submitted by a notifier under the New Substances Notification Regulations (see also **notification period**).

**Biotechnology** means the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms.

**Biotechnology product** means a substance manufactured using biotechnology. For the New Substances Notification Regulations, biotechnology products are microorganisms, parts of microorganisms, or substances produced by microorganisms, other organisms, or cell cultures.

**By-product** means a substance produced without separate commercial intent during the manufacture of another substance.

**Cationic polymer** means a polymer that contains one or more covalently linked monomer units that bear a net positive charge (see also **monomer unit, polymer**).

**Chemical**, with respect to the New Substances Notification Regulations, means a substance that is neither a polymer nor a product of biotechnology (see also **biotechnology product, polymer**).

**Consumed** means the destruction of a substance or its complete conversion to another substance. "Complete conversion" implies that the reaction has proceeded to the point where no further conversion of the substance is likely under the reaction conditions.

**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. This differs from indirect human exposure, which involves exposure to the substance in a media different from that into which the substance was released.

**Domestic Substances List (DSL)** means the list compiled by the Minister of the Environment under Subsection 25(1) of the CEPA, as amended from time to time by the Minister under Subsection 25(3) or Section 30 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 III and Schedule VIII 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.

**Flagged**, with respect to additions to the NDSL, means that the listing of the substance is inactive, and as such is not eligible for notification as an NDSL substance until certain criteria are met (described in Subsections 3.2.1.1 and 3.2.2.1 of these Guidelines).

**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 commercial 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 Departments" 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 Health and Welfare Canada officials before testing to determine the acceptability of a test for that specific substance. (see also **Acceptable to the Departments**)

**In the person's possession** means information 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.

**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 CEPA, 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 or IUPAC 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.

**Minister** means the Minister of the Environment; whereas, **Ministers** means the Ministers of the Environment and of National Health and Welfare.

**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.

**Non-domestic Substances List (NDSL)** means the list compiled by the Minister under Subsection 25(2) of the CEPA, as amended from time to time by the Minister under Subsection 25(3) or Section 30 of the Act (see also **Domestic Substances List**).

**Notification 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 New Substances Notification to Environment Canada (see also **assessment period**).

**Polymer** means a substance consisting of:

- (a) molecules characterized by the sequence of one or more types of monomer units;
- (b) a simple weight majority of molecules containing at least three monomer units that are covalently bound to at least one other monomer unit or reactant;
- (c) less than a simple weight majority of molecules of the same molecular weight; and
- (d) molecules distributed over a range of molecular weights wherein differences in the molecular weights are primarily attributable to differences in the number of monomer units. (see also **monomer unit, reactant**)

**Product development substance** means a research and development substance that is evaluated in one program of two years or less in length before full commercialization by means of pilot plant trials, production trials, or customer trials to modify technical specifications in response to performance requirements of potential customers but does not include test marketing (see also **research and development substance, test marketing**).

**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 **read-across estimate, trivial structural difference**).

**Reactant** means, with respect to a polymer, a substance that is used intentionally in the manufacture of the polymer to become chemically part of the polymer composition (see also **polymer**).

**Reactive functional group** means an atom or associated groups of atoms in a substance that is intended to, or can be reasonably anticipated to, undergo facile chemical reaction.

**Read-across estimate** means a qualitative estimate of a property of a substance based upon experimental data from another compound(s) having a closely related chemical structure (see also **qualitative structure-activity relationship**, **trivial structural difference**).

**Regulations** means the New Substances Notification Regulations of the *Canadian Environmental Protection Act*.

**Research and development substance** means a substance that is the subject of the systematic investigation or search, by means of experimentation or analysis, or both, that has as its primary objective the creation or improvement of a product or process including the determination of technical viability or performance characteristics, or both, but does not include test marketing (see also **product development substance**, **test marketing**).

**Site-limited intermediate substance** means a substance that is not a biotechnology product and that is manufactured or imported in a quantity that does not exceed an accumulated total of 50 000 kg and is:

- (a) manufactured and consumed on the site of manufacture;
- (b) involved in two sites by being manufactured at one site, transported to the second site, and consumed; or
- (c) imported, transported directly to the site of consumption, and consumed such that the sum of the quantities of the substance referred to in paragraphs (a), (b), and (c) does not exceed 10 000 kg or for polymers does not exceed 20 000 kg at any one time (see also **consumed**, **intermediate substance**).

**Substance.** A substance is defined in Section 3 of CEPA 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 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."*

But, for the purposes of the new substances provisions of CEPA (Sections 25 to 32), 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 mixtures of different molecules that are, contained in effluents, emissions or wastes that results from any work, undertaking or activity."*

**Substance occurring in nature** means a substance that is naturally occurring, and is: 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. These substances are considered to be on the DSL although they may not have been listed.

**Test marketing** means the exploration of market capability in a competitive situation where the creation or improvement of a product is not the primary objective (see also **product development substance, research and development substance**).

**Transient reaction intermediate** means a substance that is formed and consumed in the course of a chemical reaction.

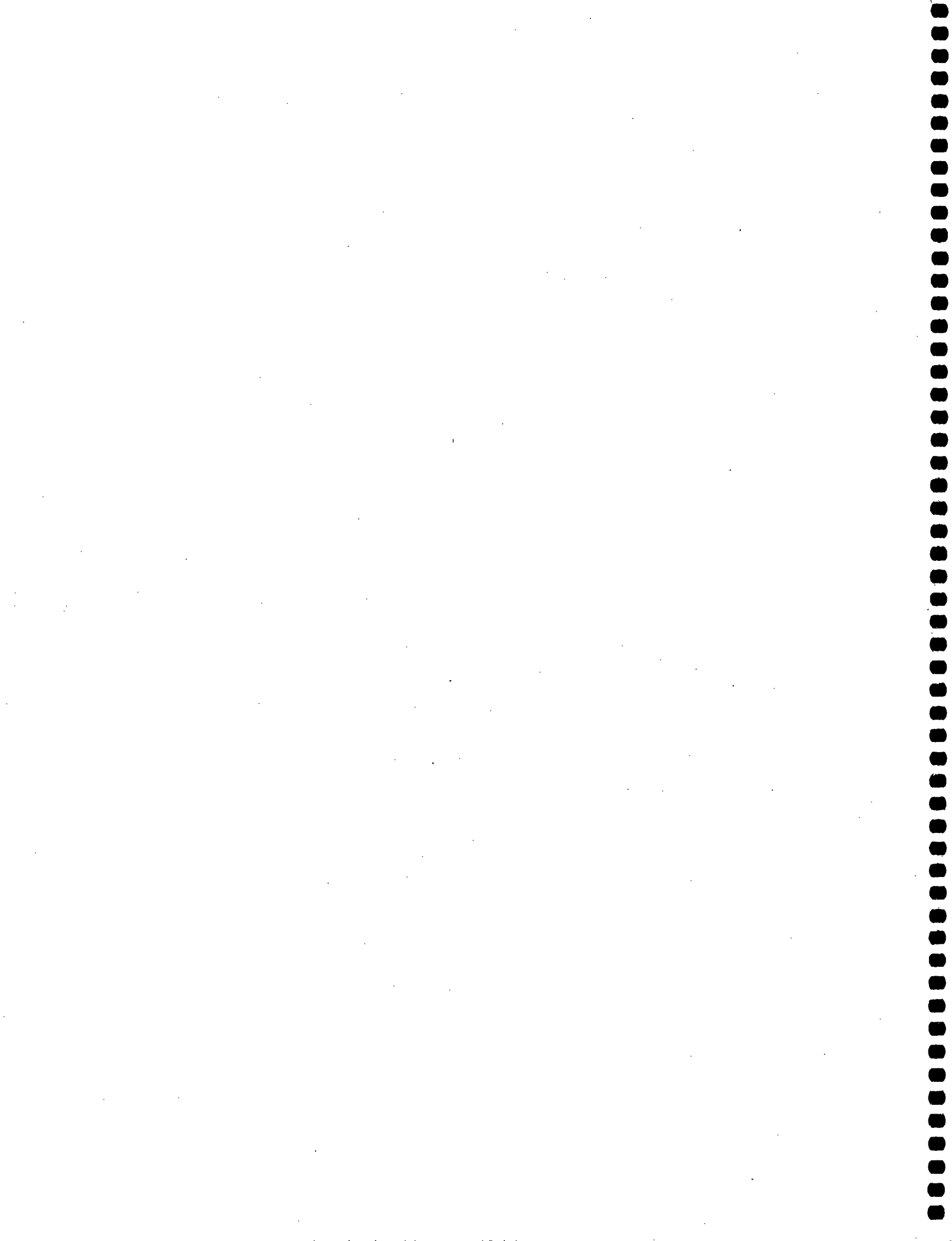
**Transitional period** means the period between January 1, 1987 and the day on which these Regulations came into force.

**To which the person ought reasonably to have access** means information in any of the offices of the company worldwide or other locations where the person can access the information (see also **in the person's possession**).

**Trigger quantity** means the quantity of substance imported or manufactured that, if exceeded, requires the notifier to provide a New Substance Notification. For example, for a non-transitional NDSL chemical, the trigger quantity requiring a Schedule I notification is 1 000 kg/yr or 5 000 kg accumulated, whichever is exceeded first.

**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 **Unknown or Variable composition Complex reaction products and Biological 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.





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