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Health Canada Santé Canada

Guide to New Substances Notification for Products Regulated Under the *Food and Drugs Act*

Guidance to industry on current New Substances Notification requirements for substances in products regulated under the *Food and Drugs Act*, with regard to both human health and the environment.

Canada

Publication Notes:

Guide to New Substances Notification for Products Regulated Under the Food and Drugs Act

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Purpose and Scope

This guide is intended to assist importers and manufacturers, of products subject to regulation under the *Food and Drugs Act* (F&DA), to comply with the *New Substances Notification Regulations* (NSNRs) under the *Canadian Environmental Protection Act, 1999* (CEPA 1999). These products include pharmaceuticals, human biologics and genetic therapies, cosmetics, natural health products, medical devices, veterinary drugs, novel foods and food additives. This guide provides information on the types of substances that must be notified and how the process of submitting the required information should be done.

This guide should be used as your first source of information when considering the process of submitting information on substances that require notification under the NSNRs. It is designed to answer common questions, and provides the basics you need to determine whether notification is required and how to begin the process of developing a submission.

This guide provides information on the following:

- Types of substances that must be notified
- Health Canada policy with respect to new substances regulations
- Information requirements
- How notifications should be organized
- How notifications are processed

Using This Guide

This guide is not a stand-alone publication. It should be used in conjunction with the CEPA 1999 NSNRs and the two guidelines developed by Environment Canada and Health Canada with respect to new substances notification (*Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers* and *Guidelines for the Notification and Testing of New Substances: Organisms*). These documents are available at **www.ec.gc.ca/substances/nsb/eng/reporting_e.htm.**

If after referring to both this guide and the above-noted references you still have questions, please feel free to contact Health Canada as described in Section 6, "Whom to Contact."

1. Introduction

The *Canadian Environmental Protection Act*, *1999* (CEPA 1999) requires that all new substances be assessed for environmental and human health effects and risks prior to import or manufacture in Canada. This assessment may be done under the CEPA 1999 *New Substances Notification Regulations* (NSNRs) or under another Act and Regulations listed in CEPA 1999 Schedules 2 or 4.

The Minister of Health is responsible for the safety, efficacy, and quality of products under the *Food and Drugs Act* (F&DA). The new substances notification process is being undertaken as part of Health Canada's mandate to improve and protect the health and safety of Canadians and its shared responsibility for the protection of the environment. Health Canada is committed to ensuring that Canadians have access to safe and effective products while protecting the environment.

The *Food and Drugs Act* and *Regulations* are not listed in a CEPA 1999 schedule. Health Canada is developing appropriate regulations for new substances in products regulated under the F&DA (i.e., novel food, food additives, pharmaceuticals, human biologics and genetic therapies, medical devices, natural health products, veterinary drugs, and cosmetics). However, until such time as the Health Canada regulations are listed in CEPA 1999, the NSNRs will apply to new substances in these products.

Health Canada assessments are the same as those currently being undertaken by Environment Canada. Health Canada has established its own Environmental Assessment Unit (EAU) in order to take on responsibility for assessing substances in products regulated under the F&DA.

1.1 Background

CEPA 1999 requires notification and assessment of all new substances for potential toxicity prior to import or manufacture in Canada. This requirement is aimed at preventing potentially harmful substances from entering into the Canadian environment.

Other acts and regulations can provide a new substances notification assessment process for specific applications. This is recognized by listing under Schedule 2 (chemicals and polymers) or Schedule 4 (living organisms) of CEPA 1999.

Listing on these CEPA 1999 schedules enables the continuation of a multi-departmental assessment system, where departments continue to receive notification and conduct assessments for the sectors for which they have expertise.

To meet the requirements for listing, regulations for new substances in products regulated under the F&DA must be developed to address the requirement for notification and assessment of new substances prior to importation, manufacture or sale. Until this occurs, new substances in products regulated under the F&DA will also be subject to the notification and assessment processes for new substances under CEPA 1999.

The information required for notification and assessment of chemical and polymer substances is based on recommendations contained in an *Organization for Economic Cooperation and Development* (OECD) *Council Act* (1982). This Act called upon member countries to institute notification of new industrial chemicals and polymers to permit an initial assessment of these substances prior to their introduction to the marketplace. Other OECD member countries (United States, Japan, Australia, members of the Commission of the European Communities) have already implemented similar programs, some as early as 1976.

Similarly, the information requirements for the living organisms part of the NSNRs are consistent with those of other OECD countries.

1.2 Canadian Environmental Protection Act (CEPA)

CEPA 1999 provides a framework for protecting Canadians and the Canadian environment from pollution caused by toxic substances. The new substances provisions in CEPA 1999 ensure that the potential risks posed by new chemical and biotechnology substances (animate or inanimate) will be properly assessed. They also provide for appropriate controls of substances suspected of being toxic and specify time frames for developing and implementing plans for such controls. While substances may already be regulated under other acts and regulations such as the F&DA, CEPA 1999 can act as a safety net that complements other laws. This will ensure that all new substances undergo an appropriate assessment from an environmental perspective for their potential to harm human health or the environment before introduction in Canada.

Under CEPA 1999, a substance is classified as "**toxic**" if it is entering or may enter the environment in a quantity or concentration or under conditions that

a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;

b) constitute or may constitute a danger to the environment on which life depends; or

c) constitute or may constitute a danger in Canada to human life or health.

For complete information on CEPA 1999, see the CEPA registry web site: **www.ec.gc.ca/CEPARegistry/default.cfm**.

1.3 The New Substances Notification Regulations (NSNRs)

The *New Substances Notification Regulations* (NSNRs) are an important component of CEPA 1999. The NSNRs were created to ensure that no new substances are introduced into the Canadian marketplace before an assessment is done of whether they are potentially toxic, and appropriate control measures have been taken.

For more information, see **www.ec.gc.ca/substances/nsb/eng/reporting_e.htm**

1.4 CEPA New Substances Notification Guidelines

The CEPA *Guidelines for the Notification and Testing of New Substances* (also referred to as the *NSN Guidelines*) were written to assist importers and manufacturers in complying with the NSNRs. The *NSN Guidelines* exist in two forms, those that address substances other than living organisms (*NSN Guidelines: Chemicals and Polymers*) and those that address living organisms (*NSN Guidelines: Organisms*). The guidelines provide the following:

- Detailed explanation on how those responsible for notification determine whether a substance is subject to notification under the NSNRs, and how to identify the applicable information requirements.
- Step-by-step instructions on the completion of a New Substance Notification form, consideration of technical information requirements, identification of appropriate test procedures and practices, and treatment of confidential information.
- An explanation of how Environment Canada and Health Canada assess the information submitted in the New Substance Notification, and what the consequences of assessment decisions are on those responsible for notification.

The *NSN Guidelines* and other information relative to the NSNRs and the New Substances Program can be found at **www.ec.gc.ca/substances/nsb/eng/gui_e.htm**

2. Application

2.1 What Is a Substance?

For the purposes of the new substances provisions of the *Canadian Environmental Protection Act*, *1999* (CEPA 1999), "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 their 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 What Is a New Substance?

A new substance is any chemical, polymer, or living organism that is not on the Domestic Substances List (DSL). Once a new substance is evaluated and determined not to be toxic (as defined under CEPA 1999), a separate process is initiated to place it on the DSL.

2.3 Products Versus Substances

Products are considered any food, drug, cosmetic or medical device that are subject to notification under the *Food and Drugs Act* (F&DA).

A product may consist of one or more substances. For example, a food additive may be a single substance whereas a drug may contain one substance that is the active ingredient and a number of substances that are "excipients." Only individual substances are notifiable under the *New Substances Notification Regulations* (NSNRs). See subsection 2.3.1.1 of the *NSN Guidelines: Chemicals and Polymers* for consideration of "mixtures" in the context of substances.

2.4 Domestic Substances List (DSL)

The Domestic Substances List (DSL) is a comprehensive inventory of known substances in Canadian commerce (past and current). At present the DSL contains close to 24,000 substances. The DSL is the sole basis for determining whether a substance is new for the purposes of CEPA 1999 and the NSNRs. Substances on the DSL are considered to exist in Canadian commerce and do not require 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 66(1) of CEPA 1999); or

b) the government has received all the prescribed information under Sections 81 or 106 of CEPA 1999 and any additional information or test results specified, and is satisfied that manufacture or importation has taken place (in a required quantity, for chemical and polymer substances), that the assessment period has expired, and that no conditions remain in effect (Section 87 and Section 112 of CEPA 1999).

The complete DSL and its amendments are published in the *Canada Gazette*. You can also determine if a substance is listed on the DSL by using the search engine at **www.ec.gc.ca/substances/nsb/eng/cas_e.htm**

2.5 Non-domestic Substances List (NDSL)

The Non-domestic Substances List (NDSL), is a compilation of substances (other than living organisms) 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* inventory. Substances that are not on the DSL, but are listed on the NDSL, are still subject to notification, but the information requirements are reduced because of the previous experience in the United States.

The complete NDSL and its amendments are published in the *Canada Gazette*. You can also determine if a substance is listed on the NDSL by using the search engine at **www.ec.gc.ca/substances/nsb/eng/cas_e.htm**

3. Health Canada Policy

3.1 Substances on the Market Between January 1, 1984 and December 31, 1986

Substances in F&DA products that were in commerce between 1984 and 1986 are eligible for addition to the Domestic Substances List (DSL). For these substances that are not currently on the DSL, Health Canada will:

a) Identify any of these substances that are present in Health Canada's databases, and have them added to the DSL through a regulatory amendment. These substances will be assessed through the process established to review and assess the DSL.

b)Post a list of these substances on the Environmental Assessment Regulations web site: www.hc-sc.gc.ca/ear-ree/index_e.html

As Health Canada's databases (for pharmaceuticals and veterinary drugs) contain only "active" substances, industry is encouraged to contact Environment Canada's New Substances Notification hotline (1–800–567–1999 or (819) 953–7156) to add any substances known to have been on the market between January 1, 1984 and December 31, 1986 that currently are on neither the DSL or the Health Canada list.

3.2 Substances on the Market Prior to September 14, 2001

For substances in products approved under the *F&DA* between January 1, 1987 and September 13, 2001, Health Canada will identify any of these substances that are present in Health Canada's databases and post a list of these substances on the Environmental Assessment Regulations web site. Health Canada will also take the following risk assessment and risk management actions:

a) Screen all these substances to select those that may require priority assessment under CEPA and the NSNRs due to their potential toxicity, bio-accumulation, or persistence and recommend appropriate control measures to Environment Canada based on the assessment.

b) For those substances that do not require priority assessment under CEPA and the NSNRs, prioritize them for future assessment under the new environmental assessment regulations and take appropriate control measures based on the assessment.

3.3 Substances Submitted to Health Canada for Approval Prior to September 14, 2001

For substances in products submitted for approval to Health Canada prior to September 13, 2001 but not yet approved Health Canada will take the following risk assessment and risk management actions:

a) **Obtain available information from proponents relevant to an assessment of "toxic";**

b) **Evaluate this information in order to determine appropriate action and;**

c) **Either assign the substances for future evaluation as set out in subsection 3.2 (b) or obtain additional information from the proponent drawn from the NSNR schedules on these substances and, where appropriate, recommend control measures to Environment Canada.**

3.4 Substances on the Market After September 13, 2001

For substances in products submitted for approval to Health Canada after September 13, 2001 Health Canada will take the following risk assessment and risk management actions:

a) **Where these substances are also found in products on the market between January 1, 1987 and September 13, 2001, treat them in the same manner as described in subsection 3.2.**

b) **For all other substances, apply the NSNRs and, for substances of concern, recommend appropriate measures to Environment Canada within the prescribed assessment periods.**

3.5 Applicability

CEPA 1999 and the NSNRs establish firm criteria for new substances that do not require notification. These include the following criteria:

a) **Mixtures, manufactured items, wastes, transient reaction intermediates, substances produced by incidental reactions, substances carried through Canada, and substances that are not manufactured or imported in amounts greater than the regulatory trigger quantities.**

b) **Research and development that is not intended for introduction outside a contained facility and is not in excess of the maximum prescribed quantities (this may include clinical trials and other related research activities).**

c) Animate products of biotechnology used solely for:

i) *in situ* stimulation of organisms growth through the addition of nutrients or by physical means such as tilling;

ii) municipal and industrial waste water treatments that do not isolate the organism from its natural environment and process the organism; and

iii) composting and septic tank operations that do not isolate the organism from its natural environment and process the organism from treated waste.

NOTE: Precursor materials that are not listed on the DSL, and are excluded from the scope of the *Food and Drugs Act* and *Regulations* are subject to notification under the NSNRs. These include isolated reaction intermediates, production organisms, feedstocks, and other starting materials used in the manufacture of any new substance in products covered under the *Food and Drugs Act* and Regulations.

4. Notification

Under the NSNRs, before any new substance may be imported into, or manufactured in Canada, a notification must be submitted and the prescribed assessment period must expire. The NSNRs prescribe the information that must be submitted in the notification. This information is used by government evaluators when conducting their environmental and human health risk assessments on new substances. This section describes who is affected by the notification requirement, who is responsible for submitting the notification, and when notification should be made.

4.1 Who Is Responsible for Notification?

Importers and manufacturers of new substances in products regulated under the F&DA and Regulations are responsible for providing notification.

4.2 When Is Notification Required?

Notification is required when a substance is not on the DSL. A notifier should determine whether a substance is "new" (see subsection 2.2) before considering schedules or notification periods.

Various schedules to the NSNRs provide details on the information that is to be submitted for different types of substances. The timing of a notification depends on the schedule of information required. For chemicals and polymers, the timing of a notification also depends on when the trigger quantity for a substance is exceeded.

Once a notifier determines that a substance is "new", the class of the substance (i.e., chemical, polymer, biological) must then be determined. Each class has a different set of trigger quantities that require notification at different volumes.

Health Canada must be notified before the trigger quantities are exceeded; importation or manufacture of a substance cannot exceed such levels until an assessment is complete. Notifiers should use the schedules to determine the appropriate notification period for their substance (e.g., 5, 45, 90 days) and submit notification at least that many days prior to the date the company expects to exceed the trigger quantity (to avoid costly delays in the process).

NOTE: Notifiers typically submit notifications well in advance of the date of their trigger quantity to account for delays or possible extensions of the notification period.

The *NSN Guidelines* provide detailed information on trigger quantities and notification periods for substances covered under various schedules. For example,

chemicals are covered under schedules I through V and polymers are covered under schedules VI through VIII and XI through XIII. Notification periods are outlined in Table 4-1.

NOTE: Please consult the flow chart diagrams provided in the *NSN Guidelines* for detailed information on situations that may involve an effect on trigger quantity.

Table 4-1: Notification Periods

Schedule (chemicals)	Trigger Quantity	Notification Period	Schedule (polymers)	Trigger Quantity	Notification Period
I	> 20 kg/yr and ≤ 1,000 kg/yr and ≤ 5,000 kg acc*	5	VI	> 1,000 kg/yr and ≤ 10,000 kg/yr or >5,000 kg acc and ≤ 50,000 kg acc	45
II	> 1,000 kg and < 10,000 kg/yr or > 5,000 kg acc and ≤ 50,000 kg acc	45	VII	> 10,000 kg/yr** or >50,000 kg acc**	45
III	> 1,000 kg/yr or > 50,000 kg acc	90	VIII	> 10,000 kg/yr*** and >50,000 kg acc***	90
IV	> 1,000 kg/yr and > 5,000 acc and < 50,000 kg acc	21	XI	> 1,000 kg/yr and ≤ 10,000 kg/yr and > 5,000 kg and ≤ 50,000 kg acc	5
V	> 1,000 kg/yr or > 5,000 kg acc and ≤ 10,000 kg at one time	21	XII	> 10,000 kg/yr or ≤ 50,000 kg acc	21
			XIII	Site Limited > 10,000 kg and ≤ 20,000 kg and ≤ 50,000 kg acc or Export Only > 10,000 kg and ≤ 20,000 kg	21

Notification Period = Days before manufacture/import, by which time the complete notification is required.

*** See Schedules for chemicals and polymers**

*** accumulated total**

**** if all reactants on DSL**

***** if not all reactants are on DSL**

4.2.1 Trigger Quantities

A trigger quantity is the amount of a substance intended for importation into or manufacture in Canada that, if exceeded, requires the proponent to provide a New Substance Notification (NSN). The notifier must provide the notification prior to exceeding the appropriate trigger quantity. Trigger quantity also exist for approved substances, beyond which a new notification is required.

See the *NSN Guidelines* for specifics on trigger quantities.

4.3 Is Notification Mandatory?

Notification is mandatory. Subsections 81(1), 81(2), 106(1), and 106(2) of CEPA 1999 prohibit the importation or manufacture of any substance that is not listed on the Domestic Substances List (DSL), unless the prescribed information and fee have been provided on or before the prescribed assessment date, and the assessment period has expired.

5. Submission Process

This section provides an introduction to the submission process, from classifying a substance and determining what information should be included in a submission to preparing and submitting the notification form.

5.1 Classification

The first step in determining the information that must be provided in a New Substance Notification (NSN) is classifying the substance in question. Detailed information on how to classify a substance can be found in subsection 3.1 (Classification of Substances) of the *NSN Guidelines*.

5.1.1 Classifying the Substance

New substances are grouped into three major classes. Each of these classes has its own specific information requirements with respect to notification. These classes are

- **polymers and biopolymers**
- **living organisms**
- **chemicals and biochemicals**

Polymers and Biopolymers

A polymer is a substance that consists 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 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.

A biopolymer is a substance that meets the definition of a polymer and is the product of microorganisms.

Living Organisms

Organisms can be naturally occurring or genetically modified through the application of methods such as recombinant DNA techniques. This includes all living organisms (whether they are microorganisms or not).

A microorganism is an alive microscopic organism that is

a) classified in the Bacteria, the Archaea, or the Protista (which includes protozoa and algae), or the Fungi (which includes yeasts);

b) a virus, virus-like particle, or sub-viral particle;

c) a cultured cell of an organism not referred to in paragraphs a) and b), other than a cell used to propagate such organism; or

d) any culture other than a pure culture.

Chemicals and Biochemicals

Chemicals include all substances that are not polymers, biopolymers, organisms, or biochemicals.

A biochemical is a chemical produced by a microorganism.

5.2 What Information Is Required as Part of the Notification?

Two categories of information are required as part of the notification–administrative and technical. The administrative category concerns information that is required to fill out certain aspects of the New Substance Notification form. These elements are described in subsection 5.3.4, "Completing the Notification Form."

NSN forms can be obtained at www.ec.gc.ca/substances/nsb/eng/reporting_e.htm

5.2.1 Technical Information Requirements

Technical information requirements regarding the nature of the substance are listed in the tables contained in Appendix A. In addition, technical information required as part of the submission includes some or all of the following elements, according to the appropriate schedule:

- **Substance Identity Information. Such information includes, but is not limited to, substance name, structural formula, molecular formula, additives and their concentration, monomers and reactants.**
- **Experimental Data. Data includes physical–chemical data, toxicological data, and ecotoxicological data.**

- **Exposure Information. Such information includes, but is not limited to, information on manufacture, import, and specific uses, information on distribution, storage, and handling, disposal, environmental release, and human exposure.**

Information must also be provided of any known circumstances where the import or manufacture of a new substance was reported to another agency or government and why. Other additional data relevant to environmental and health hazard identification must also be provided. Detailed information can be found in the *NSN Guidelines*.

5.2.2 Identifying Information Needed in the Submission

Subsection 3.2, "How to identify the Required Notification Information" of the *NSN Guidelines* provides details on how to identify the information required as part of the submission. The requirements themselves are found in Appendix 1 of the *NSN Guidelines* (which contains the NSNRs including all of its schedules). The requirements that are listed in the NSNRs for each type of substance (chemical, polymer, living organisms) are tailored to the type, use, and, for chemicals and polymers, to the quantity of the substance.

In addition, the *NSN Guidelines* (see Section 3, figures 1 through 6) provide decision flow charts that will assist you in selecting the appropriate schedule of the NSN Regulations to review in order to determine specific information requirements.

5.2.3 Waiver of Information Requirements

Under subsections 81(8) or 106(8) of CEPA 1999, a request to obtain a waiver for certain information requirements can be made. The decision to grant a waiver is made on a case-by-case basis by Environment Canada and Health Canada. In order to be granted a waiver, at least one of the following three criteria must be met:

a) in the opinion of the Ministers, the information is not needed in order to determine whether the substance is toxic or capable of becoming toxic;

b) a substance is to be used for a prescribed purpose or manufactured at a location where, in the opinion of the Ministers, the 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 the notification package. A well-documented rationale to support the request should be provided. Keep in mind, however, that a rejected waiver request may result in a delay in the assessment of your submission. To avoid such delays, you are encouraged to discuss your proposal

with an appropriate Health Canada official before the notification is submitted (see subsection 6.1, "Pre-notification Consultation").

5.3 How to Prepare Your Submission

5.3.1 Acceptability of Information Generated for Other Countries

The submission must be a stand-alone document that provides all of the information required. Submissions developed in the format required for other countries are not acceptable. However, the data generated for such submissions may be acceptable in fulfilling information requirements under the NSNRs

The information/data for a requirement under CEPA 1999 will be accepted if it is scientifically valid and the conditions of the study are applicable to Canada (e.g., species tested, soil or sediment used).

5.3.2 Appropriate Notification Schedules

NSN notification schedules include

- **Chemicals** **Schedules I through V**
- **Polymers** **Schedules VI through VIII and XI through XIII**
- **Biochemicals/Biopolymers** **Schedule XIV**
- **Living Organisms** **Schedules XV through XIX**

5.3.3 How to Organize Your Submission

Attention to detail in the organization of the information will assist the screening and the review of the Notification. Ensure that all information requested under the NSNRs has been included in the Notification package, including a signed and completed Notification form. An index of all submitted information, and where that information is located in the package, should be included. Each required item should be clearly labelled to indicate which information requirement is being addressed.

When referring to the *NSN Guidelines*, specify the *Guidelines for Notification and Testing of New Substances: Chemicals and Polymers* or the *Guidelines for Notification and Testing of New Substances: Organisms*, as appropriate.

5.3.4 Completing the Notification Form

The Notification form serves as an aid for complying with the NSN Regulations. The form is divided into two sections:

- **Part A—Administrative and Substance Identity Information**
- **Part B—Technical Information**

A complete notification submission contains all of the information required for parts A and B of the form, as well as all laboratory reports, waiver justifications, and other attachments necessary to fulfill the notification requirements.

The form should be completed by the following means:

- **A typewriter,**
- **Legible printing in black ink, or**
- **Using computer software and submitted on printed hard copy.**

The information must be provided in one of the two official languages (English or French).

Part A—Administrative and Substance Identify Information

The administrative part of the form contains the following components, all of which are described in the *NSN Guidelines*:

- **Certification Statement**
- **Corporate Headquarters**
- **Proposed Site of Manufacture or Port of Entry**
- **Canadian Agent**
- **Technical Contact**
- **Amount**
- **Date of Exceedence**
- **Activity**
- **Schedule of Information**
- **Correspondence**
- **Substance Information**
- **Confidentiality Requests**
- **Information Sharing Agreement**

Part B—Technical Information

The technical part of the form must provide some or all of the following components, whose content is described in subsection 5.2.1, "Technical Information Requirements":

- **Physical–Chemical Properties**
- **Mammalian Toxicity**
- **Ecotoxicity**
- **Exposure Information**
- **Other Agencies Notified**
- **Additional Information**

5.3.5 Confidential Information

Under Section 313 of CEPA 1999, 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 such information be treated as confidential. 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 314 to 321 of CEPA 1999. This feature ensures that genuine confidential business information is protected from public disclosure.

In general, confidentiality claims must meet 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;

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.

Details on making a confidentiality claim can be found in the *NSN Guidelines*.

5.3.6 Information Sharing

There may be instances where notification of a substance has been made, but the substance has not been published on the Domestic Substances List (DSL). This may happen if the substance does meet all of the relevant criteria or because the assessment or processing of the notification is still underway. While a complete Notification package for the substance must still be submitted, a notifier can obtain the required information directly from a previous notifier through use of an

Information Sharing Agreement (ISA).

An ISA starts when a notifier provides

- **documentation indicating intent to import or manufacture a particular substance, and**
- **authorization to release the name of the technical contact within the company to any other company.**

A search will be conducted for ISA candidates. If any exist, the name, telephone number, and technical contact of the other company or companies will be provided to all candidates.

Information Sharing Agreements are covered in subsection 4.4 (Living Organisms) and subsection 4.6 (Chemicals and Polymers) of the *NSN Guidelines*.

5.4 Where Are Notification Packages Submitted?

Depending on the category of product, the substance notification package should be sent to one of the addresses below. Please note that these addresses are different from the one given in the *NSN Guidelines*.

Novel Foods

Novel Food Notification
Food Directorate
Sir Frederick G. Banting Research Centre
Tunney's Pasture, AL 2204A1
Ottawa, Ontario
K1A 0L2

Food Additives

Division Chief
Chemical Health Hazard Assessment Division
Bureau of Chemical Safety
Food Directorate
Health Products Food Branch
Sir Frederick G. Banting Research Centre
Tunney's Pasture, PL 2201B1
Ottawa, Ontario
K1A 0L2

Cosmetics

Cosmetics Programs
MacDonald Building
123 Slater Street, 4th Floor
Address locator: 3504D
Ottawa, Ontario
K1A 0K9

Veterinary Drugs

Veterinary Drugs Directorate
Submission and Knowledge Management Division
Holland Cross Complex
Tower A, Ground Floor
14–11 Holland Avenue, AL 3000A
Ottawa, Ontario
K1A 0K9

Medical Devices

Medical Devices Bureau
Room 1605, Statistics Canada Main Building
Tunney's Pasture, AL 0301H1
Ottawa, Ontario
K1A 0L2

Drugs, Biologics, and Natural Health Products

Submission Information Policy Division
Therapeutic Products Division
Finance Building
AL 0201A1
Ottawa, Ontario
K1A 1B9

5.5 How Are Submissions Processed?

Submissions are processed according to a four stage process as shown in Figure 5.1. All correspondence will be sent from Environment Canada (on Environment Canada letterhead), even though Health Canada handles the notification.

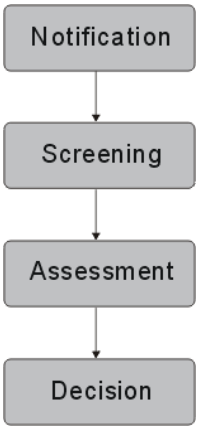

Figure 5.1: Submission Process

5.5.1 Notification

Upon receipt of the Notification, a tracking number will be assigned to the submission by Health Canada.

5.5.2 Screening

The information will be screened for completeness. This process will determine if all the information prescribed in the NSNRs has been addressed (e.g., the presence of information, data or waiver requests). The applicant will be informed by letter if the information is complete or if additional information is required. If the information is complete, the letter will indicate the beginning and end of the assessment period.

5.5.3 Assessment

After verification that the package is complete, Health Canada will assess the information provided by the notifier, and any information it may already have. This assessment will determine whether there is a suspicion of toxicity.

5.5.4 Decision

A decision will be made whether the substance is suspected of being "CEPA toxic." Substances suspected of being toxic may be controlled by one of the means laid out in CEPA 1999, including:

a) controls on import or manufacture,

b) the prohibition of import or manufacture, or

c) prohibition pending submission and assessment of additional information determined to be required by the departments.

5.6 How Long Does the Process Take?

Submissions are processed according to legislated time frames that prescribe the allotted time (calendar days) that the government has to assess an NSN. (Assessment periods are described in the *NSN Guidelines*.)

Day one of an assessment period is the day that the NSN is accepted for review. The assessment time clock may be affected by missing or incomplete information, as described in the *NSN Guidelines*. The clock can be paused at the notifier's request, and will be restarted at the point at which it was stopped.

5.7 Post-notification Responsibilities

Once a notification is submitted, a notifier is responsible for

- correcting any information determined to be erroneous after notification was submitted.
- notifying Health Canada when trigger quantities are exceeded.
- providing any new information (under Section 70 of CEPA 1999) that comes to light after the notification has been submitted.

Each of these circumstances is described in Section 11 of the *NSN Guidelines*.

5.8 Correspondence

The types of official correspondence a notifier may receive throughout the assessment process include:

- Acknowledgement. After receipt and preliminary screening of the notification, an acknowledgement specifying the start date of the assessment period and the reference number will be issued.
- Notice of interruption or rejection. This type of notice is issued for either a rejection or a pause.
  - A rejection occurs when there are errors or omissions that invalidate the notification. The package is returned to the notifier, and the assessment is over. If the notificer wants to re-notify, the assessment starts again at day one.

  - **A pause may be requested by a notifier when missing information does not invalidate the notification. In this case, the clock is stopped until the required information is received by Health Canada. The assessment will then continue from the day it was paused. The notice acknowledges the pause request, notes the date the assessment was paused, and describes all of the deficiencies in the notification.**

- **Notice of extension of assessment period. When the Minister is satisfied that 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.**
- **Statement of assessment conclusions. Before the end of the assessment period, the notifier will be advised, in writing, whether the substance is suspected to be toxic or capable of being toxic, and what action, if any, will be taken by the government.**

All correspondence will be sent from Environment Canada (on Environment Canada letterhead), even though Health Canada handles the notification.

6. Whom to Contact

If you have any questions on the information contained in this guide, or would like guidance on where to go for additional information, contact:

The Environment Assessment Regulations Project
1–888–492–1104
e-mail: ear-ree@hc-sc.gc.ca

Web site: www.hc-sc.gc.ca/ear-ree/

If you have any questions regarding your environmental assessment submission, please contact the Environmental Assessment Unit (EAU) at (613) 941–0144.

6.1 Pre-notification Consultation

Notifiers may request pre-notification consultation with Health Canada. Such consultations may be particularly useful meeting responsibilities under CEPA 1999.

The pre-notification consultation provides an opportunity for notifiers to discuss concerns regarding regulatory process and data requirements, and resolve issues regarding the development of the submission. It also provides Health Canada with an opportunity to provide guidance on the criteria for acceptability of the information to be submitted.

Requests for a pre-notification consultation meeting should be submitted in writing by the sponsor. Requests should include a covering letter proposing four dates and times suitable for a pre-submission meeting, and should be accompanied by five (5) copies of the information package. Health Canada will acknowledge receipt of the package and confirm the meeting date.

7. Glossary of Terms

Assessment period:	**The number of calendar days that the government has to assess the information submitted by a notifier under the NSNRs.**
Biochemical:	**A chemical produced by a microorganism.**
Biopolymer:	**A polymer produced by microorganisms.**
Biotechnology:	**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 and modified forms.**
Chemical:	**All substances that are not polymers, biopolymers, organisms, or biochemicals.**
Domestic Substances List (DSL):	**The list compiled by the Minister of the Environment under subsection 66(1) of CEPA 1999, as amended from time to time by the Minister under subsection 66(3) of the Act.**
Microorganism:	**An alive microscopic organism that is** **(a) classified in the Bacteria, the Archaea, or the Protista (which includes protozoa and algae), or the Fungi (which includes yeasts);** **(b) a virus, virus-like particle, or sub-viral particle;** **(c) a cultured cell of an organism not referred to in paragraphs (a) and (b), other than a cell used to propagate such an organism; or** **(d) any culture other than a pure culture.**
Non-domestic Substances List (NDSL):	**The list compiled by the Minister of the Environment under subsection 66(1) of CEPA 1999, as amended from time to time by the Minister under subsection 73(3) of the Act.**
Polymer:	**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 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.**
Toxic:	**A substances is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that** **(a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;** **(b) constitute or may constitute a danger to the environment on which human life depends; or** **(c) constitute or may constitute a danger in Canada to human life or health.**
Toxicity:	**The capacity of any substance to cause injury to humans, animals, plants or microorganisms.**
Trigger Quantity:	**The quantity of substance imported or manufactured that, if exceeded, requires the notifier to provide a New Substance Notification.**

8. References

If the information in this guide as well as the indicated references do not provide the information you need, please feel free to contact Health Canada as described in Section 6, "Whom to Contact."

Please refer to the following documents:

- **The *Canadian Environmental Protection Act, 1999* (CEPA 1999)**
  www.ec.gc.ca/ceparegistry/default.cfm
- ***Domestic Substances List* (DSL)**
  www.ec.gc.ca/CEPARegistry/subs_list/Domestic.cfm
- **The *Food and Drugs Act* and *Regulations* (F&DA)**
  www.hc-sc.gc.ca/food-aliment/friia-raaii/food_drugs-aliments_drogues/act-loi/e_index.html
- ***New Substances Notification Regulations* (NSNRs)**
  www.ec.gc.ca/CEPAregistry/regulations/detailreg.cfm?intReg=13&y=10
- ***Non-domestic Substances List* (NDSL)**
  www.ec.gc.ca/substances/nsb/download/NDSL.pdf
- ***Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers***
  www.ec.gc.ca/substances/nsb/eng/reporting_e.htm
- ***Guidelines for the Notification and Testing of New Substances: Organisms***
  www.ec.gc.ca/substances/nsb/eng/reporting_e.htm