



NEW SUBSTANCES NOTIFICATION REPORTING FORM FOR ORGANISMS OTHER THAN A MICRO-ORGANISM

This form is to be used for fulfilling the information requirements prescribed in the *New Substances Notification Regulations (Organisms)* of the *Canadian Environmental Protection Act, 1999*. If you are notifying a micro-organism, please use the NSN Reporting Form for micro-organisms.

<p>The New Substances Notification (NSN) package must be submitted to:</p> <p>Mailing Address:</p> <p>Director, New Substances Division Department of the Environment Ottawa ON K1A 0H3</p> <p>Courier Deliveries:</p> <p>Director, New Substances Division Department of the Environment 14th Floor, Place Vincent Massey 351 St. Joseph Blvd. Gatineau QC J8Y 3Y5</p>	Department Use Only
	NSN Reference No.
	Date Received:
	Total number of pages:

INSTRUCTIONS FOR COMPLETING THE NOTIFICATION FORM

The New Substances Notification (NSN) Form serves as an aid for complying with the *New Substances Notification Regulations (Organisms)* (NSNR) of the *Canadian Environmental Protection Act, 1999*. Notifiers may reproduce this form, or portions thereof, for notification purposes. The form is also available electronically from the New Substances Website (<http://www.ec.gc.ca/substances>).

Additional explanations necessary for fulfilling prescribed information requirements and completing this notification form are included in the *Guidelines for the Notification and Testing of New Substances: Organisms* (Guidelines). Hard copies of the Guidelines may be obtained, for a fee, from Environment Canada by contacting the Environmental Protection Publications at (800) 734-3232 or for callers outside Canada, (819) 953-5750 or by e-mail at epspubs@ec.gc.ca. The Guidelines are also available electronically on the New Substances (NS) program website (<http://www.ec.gc.ca/substances>).

Before completing Parts B and C of the form, you should ensure that you are providing information that is appropriate for the notification group under which the organism you intend to import or manufacture is being notified (see section 3 of the *Guidelines for the Notification and Testing of New Substances: Organisms*). Part B contains six (6) sections listing the information items required for each notification group. This list functions only as a checklist; it is expected that the information will be provided as attachments. These six (6) sections are: (1) General Information Requirements; (2) Importation or Manufacture Information Requirements; (3) Introduction Information Requirements; (4) Environmental Fate Information Requirements; (5) Ecological Effects Information Requirements; and (6) Human Health Effects Information Requirements. Part C contains one section: Additional Information and attachments. Parts B and C contain three columns which consist of: Data Codes; Attachment Number; and Confidential Information. Explanations of the use of these columns are provided on page 2 of this form.

This form is divided into three (3) sections: Parts A, B and C. Part A is used for administrative and organism identity information, Part B is for technical information, while Part C is for additional information.

Ce formulaire est disponible en français, sur demande, en communiquant avec La ligne d'information des déclarations de substances nouvelles au 1-800-567-1999 (sans frais au Canada) ou au (819) 953-7156 (de l'étranger). Le formulaire est aussi disponible électroniquement au <http://www.ec.gc.ca/substances>

Data Codes, Attachments and Confidential Information

In addition to the list of information requirements, Parts B and C contain three columns which consist of: Data Codes; Attachment Number; and Confidential Information. The following explains the use for each of these columns.

Data Codes: Each information item in this form should be marked with one of the following codes. These codes will allow government officials to quickly identify the type of information provided and whether a request for a waiver of information is being submitted. Explanatory notes for the codes are provided below:

D = Test data

S = Surrogate organism

Data or other information in respect of an organism closely related to the organism being notified (scientific rationale should be provided). The taxon of the surrogate organism should be specified. Consultation with Environment Canada and Health Canada is recommended before deciding to provide data or information on a surrogate organism;

O = Other information

Including peer-reviewed literature, unpublished reports and descriptive information;

W = Waiver requested

A request for a waiver of information should be accompanied by a justification that satisfies one of the criteria in subsection 106(8) of CEPA 1999;

NONE = No Information in itself

An example of the correct use of this code would be to indicate NONE where no patent or patent application exists;

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 notice under section 70 of CEPA 1999. Enter the applicable NSN or CEPA 1999 section 70 reference number in the attachment column.

Attachment Number: Notifiers must clearly indicate a reference for accompanying documents (e.g., Attachment 6) so they may be readily located within the NSN package. Attachments include: justifications for waivers of information; reports of experimental procedures; reports of test results; rationale for alternative data; results and validation of modeling studies; and information supplemental to a request for confidentiality.

Confidential Information: Notifiers must check the appropriate box to indicate that the information provided is considered confidential (i.e., check "Y" to indicate that the information is considered confidential or check "N" to indicate that the information is not confidential). If the information is considered confidential, the notifier should attach supplementary information specified in Section 8 of the *Guidelines for the Notification and Testing of New Substances: Organisms*. Use square brackets [] to indicate the specific text or figure that is considered confidential.

Part A - Administrative and Substance Identity Information

A.1. Certification		Statement:	
I hereby certify to the best of my information, knowledge and belief that all information provided in this form, as well as any attachments to the form, is accurate and complete; and the information for which confidentiality is claimed, meets the criteria for determining confidentiality as outlined in section 8 of the <i>Guidelines for the Notification and Testing of New Substances: Organisms</i> .			
Name and Title of the Person authorized to act on behalf of the corporation of block A.2 or A.3	Signature Date		YYYY MM DD
Name and Title of the Person in Canada authorized to act on behalf of the corporation of block A.4 (if applicable)	Signature Date		YYYY MM DD
Preferred Language of Correspondence:		English <input type="radio"/>	French <input type="radio"/>
Preferred Mode of Communication for Correspondence:		Mail <input type="radio"/>	Facsimile <input type="radio"/> (non secure)
A.2. Corporate Headquarters of the Canadian Manufacturer or Importer (Principal Place of Business in Canada): (if the importer is not located in Canada, skip to block A.3)			
Company Name:		E-Mail:	
Street:		City:	Province:
Postal Code:	Telephone No: ()	Facsimile No: ()	
A.3. Corporate Headquarters of the Non-resident Importer (if A.3 is applicable, also complete block A.4):			
Company Name:		E-Mail:	
Street:		City:	State / Country:
Zip / Postal Code:	Telephone No: ()	Facsimile No: ()	
A.4. Canadian Agent (only needed if block A.3 is applicable):			
Company Name:		E-Mail:	
Street:		City:	Province:
Postal Code:	Telephone No: ()	Facsimile No: ()	
A.5. Foreign Supplier (only needed if the technical information in Part B is provided by a third party):			
Company Name:		E-Mail:	
Street:		City:	State / Country:
Zip / Postal Code:	Telephone No: ()	Facsimile No: ()	
A.6. Proposed Site of Manufacture in Canada / Proposed Port of Entry into Canada:			
Company Name/Port of Entry:		Contact Name:	
Street:		City:	Province:
A.7. Technical Contact (Name of a person who can assist in the resolution of issues pertaining to the information provided):			
Person's Name/Title:		E-Mail:	
Street:		City:	Province / State Country:
Zip / Postal Code:	Telephone No: ()	Facsimile No: ()	

A.8 Previous NSN Reference Number (if this organism has been previously notified by you): _____
Pre-Notification Consultation (PNC) Reference Number (if applicable): _____

A.9 Activity: Manufacture Import Manufacture and Import

A.10 Date that the organism is expected to be imported or manufactured: YYYY | MM | DD

A.11 Organism Information:

- Is the organism solely for Food and Drugs Act use?: Y N
- Is the organism an aquatic animate product of biotechnology?: Y N
- Is the organism regulated under any other federal act? Y N
 If yes, provide the name of the act: _____
- Is the organism a Research & Development Organism?: Y N
 If no then provide the information in schedule 5. If yes, then:
- Will the organism be imported or manufactured in a facility such that there is no release into the environment of the organism, its genetic material or material, involved in toxicity? Y N
 If no then provide the information in schedule 5.
- Type of organism: _____

A.12 Proposed explicit biological name

(if the space provided below is not sufficient, please provide the information as a separate attachment)

Supplementary information Enclosed Attachment Number: _____

A.13 Proposed masked name if the explicit biological name has been claimed as confidential

(if the space provided below is not sufficient, please provide the information as a separate attachment)

Supplementary information Enclosed Attachment Number: _____

A.14 Confidentiality Requests:

Corporation Y Manufacture Y Import Y Amount Y Substance Identity Y
 N N N N N

A.15 Information Sharing Agreement Authorization:

I hereby grant the Minister of the Environment permission to release the name, address and phone number of the technical contact indicated in block A.7 of this form to any person who has provided the Minister of the Environment with: (1) documentation of intent to manufacture or import the substance described in block A.12 of this form; and, (2) a statement granting the Minister of the Environment permission to release the name, address and phone number of their technical contact.

Name and Title:	Signature:	Date YYYY MM DD _____
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Part B - Technical Information for Schedule 5

B.1 - General Information Requirements in respect of the organism other than a micro-organism	DATA CODE	ATTACHMENTS	Confidential Information
The identification, or current taxonomic name to species or subspecies level, strain, common names, trade name and any synonyms			Y <input type="radio"/> N <input type="radio"/>
The strain history			Y <input type="radio"/> N <input type="radio"/>
A description of any modifications to the organism including (i) the purpose of the modifications			Y <input type="radio"/> N <input type="radio"/>
(ii) the methods and steps taken to make the modifications			Y <input type="radio"/> N <input type="radio"/>
(iii) the phenotypic and genotypic changes that resulted from the steps referred to in (ii)			Y <input type="radio"/> N <input type="radio"/>
(iv) the genetic stability of the changes referred to in (iii)			Y <input type="radio"/> N <input type="radio"/>
(v) the nature, source and function of any introduced genetic material			Y <input type="radio"/> N <input type="radio"/>
A description of the methods that can be used to distinguish and detect the organism			Y <input type="radio"/> N <input type="radio"/>
A description of the biological and ecological characteristics of the organism including (i) its life cycle			Y <input type="radio"/> N <input type="radio"/>
(ii) its reproductive biology, including species with which the organism could interbreed in Canada			Y <input type="radio"/> N <input type="radio"/>
(iii) its involvement in adverse ecological effects, including pathogenicity, toxicity and invasiveness			Y <input type="radio"/> N <input type="radio"/>
(iv) a description of the geographic distribution and habitat of the organism			Y <input type="radio"/> N <input type="radio"/>
(v) the potential for dispersal of traits by gene transfer			Y <input type="radio"/> N <input type="radio"/>
(vi) the locations and situations where the organism has caused adverse ecological effects			Y <input type="radio"/> N <input type="radio"/>
(vii) its involvement in biogeochemical cycling			Y <input type="radio"/> N <input type="radio"/>
(viii) its interactions with other organisms in the environment			Y <input type="radio"/> N <input type="radio"/>
(ix) the conditions required for survival, growth, reproduction and overwintering			Y <input type="radio"/> N <input type="radio"/>
(x) its capability to act as a vector for agents involved in adverse effects			Y <input type="radio"/> N <input type="radio"/>
(xi) the mechanisms of its dispersal and the modes of interaction with any dispersal agents			Y <input type="radio"/> N <input type="radio"/>
The identification of any patent or other rights, or any application for a patent or other rights, as the case may be			Y <input type="radio"/> N <input type="radio"/>

B.2 - Importation or Manufacture Information Requirements	DATA CODE	ATTACHMENTS	Confidential Information
The identification of manufacturers, importers and vendors			Y <input type="radio"/> N <input type="radio"/>
A description of the locations of manufacture in Canada			Y <input type="radio"/> N <input type="radio"/>
A description of the product containing the organism			Y <input type="radio"/> N <input type="radio"/>
A description of any recommended procedures for the storage and disposal of the organism			Y <input type="radio"/> N <input type="radio"/>
An estimation of the quantity of the organism that will be imported into or manufactured in Canada			Y <input type="radio"/> N <input type="radio"/>
A description of the methods of manufacture and of quality control and quality assurance procedures			Y <input type="radio"/> N <input type="radio"/>

Part B - Technical Information for Schedule 5

B.3 - Introduction Information Requirements	DATA CODE	ATTACHMENTS	Confidential Information
The history of use			Y <input type="radio"/> N <input type="radio"/>
The intended and potential uses of the organism, and the potential locations of introduction			Y <input type="radio"/> N <input type="radio"/>
A description of the mode of action in relation to the intended use			Y <input type="radio"/> N <input type="radio"/>
A description of the procedures for the introduction of the organism, including (i) the method and rate of its introduction			Y <input type="radio"/> N <input type="radio"/>
(ii) any activities associated with its introduction			Y <input type="radio"/> N <input type="radio"/>
(iii) any recommended procedures for storage and handling of any surplus organism			Y <input type="radio"/> N <input type="radio"/>
(iv) any contingency plans in the event of an accidental release and any reproductive isolation measures			Y <input type="radio"/> N <input type="radio"/>
(v) its resistance to control agents			Y <input type="radio"/> N <input type="radio"/>
A description of any recommended procedures for terminating the introduction of the organism			Y <input type="radio"/> N <input type="radio"/>
A description of procedures for disposal of remaining biomass and residues of the organism			Y <input type="radio"/> N <input type="radio"/>

B.4 - Environmental Fate Information Requirements	DATA CODE	ATTACHMENTS	Confidential Information
The estimated quantities of the organism in the environment and the estimated population trends			Y <input type="radio"/> N <input type="radio"/>
A description of habitats where the organism may persist or proliferate			Y <input type="radio"/> N <input type="radio"/>
The identification of species that are likely to be exposed to the organism and other species that are likely to be affected by it			Y <input type="radio"/> N <input type="radio"/>

B.5 - Ecological Effects Information Requirements	DATA CODE	ATTACHMENTS	Confidential Information
The data from a test conducted to determine the pathogenicity, toxicity or invasiveness			Y <input type="radio"/> N <input type="radio"/>
The ecological effects of organism residues			Y <input type="radio"/> N <input type="radio"/>
The potential of the organism to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity			Y <input type="radio"/> N <input type="radio"/>

B.6 - Human Health Effects Information Requirements	DATA CODE	ATTACHMENTS	Confidential Information
The potential for the organism to be involved in adverse human health effects, and the most likely route of human exposure to the organism			Y <input type="radio"/> N <input type="radio"/>

Part C - Additional Information Requirements for Schedule 5

C - Additional Information Requirements	DATA CODE	ATTACHMENTS	Confidential Information
All other information and test data in respect of the organism that are relevant to identifying hazards to the environment and human health and that are in the person's possession or to which the person ought reasonably to have access			Y <input type="radio"/> N <input type="radio"/>
The identification of other government agencies, either outside or within Canada, that the person has notified of the manufacture or importation of the organism, and the purpose of that notification.			Y <input type="radio"/> N <input type="radio"/>
A description or specification of the test procedures followed in developing the test data, including the test methods, reference substances and quality control and quality assurance procedures			Y <input type="radio"/> N <input type="radio"/>