Government of Canada / Gouvernement du Canada

NEW SUBSTANCES NOTIFICATION (NSN) 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)* [NSNR (Organisms)] of the *Canadian Environmental Protection Act, 1999* (CEPA 1999) for organisms other than micro-organisms. If you are notifying a micro-organism, please use the NSN Reporting Form for micro-organisms.

The NSN package must be submitted to:

Mailing Address:

Executive Director, Substance Prioritization, Assessment and Coordination Division
Department of Environment and Climate Change Canada
351 St-Joseph Blvd. Ottawa ON K1A 0H3

Courier Deliveries:

Executive Director, Substance Prioritization, Assessment and Coordination Division
Department of Environment and Climate Change Canada
351 St-Joseph Blvd. Ottawa ON **J8Y 3Z5**

Departmental Use Only
NSN Reference No.:
Date Received:
Mail Log:

Total number of pages:

INSTRUCTIONS FOR COMPLETING THE NOTIFICATION FORM

The NSN Reporting Form serves as an aid for complying with the NSNR (Organisms) of CEPA 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/subsnouvelles-newsubs).

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*. Hard copies of the Guidelines may be obtained from Environment Canada, for a fee, by contacting the Substances Management Information Line at 1-800-567-1999 (toll free in Canada), or (819) 953-7156 for callers outside of Canada; or via substances@ec.gc.ca. The Guidelines are also available on the aforementioned New Substances website.

This form is divided into parts A, B and C. Part A is for administrative and organism identity information, Part B is for technical information, and Part C is for additional information.

Before completing parts B and C, 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 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 sections are: (1) General Information Requirements in regards to micro-organisms; (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 Requirements. Parts B and C contain four columns: Submit with Schedule; Data Codes; Attachment Number; and Confidential Information. Explanations of the use of these columns are provided on page 2 of this form.

Ce formulaire est disponible en français, sur demande, en communiquant avec la Ligne d'information de la gestion des substances au 1-800-567-1999 (sans frais au Canada) ou au 819-953-7156 (de l'étranger). Le formulaire est aussi disponible en format électronique au http://www.ec.gc.ca/subsnouvelles-newsubs

Data Codes, Attachments and Confidential Information

In addition to the list of information requirements, Parts B and C contain three columns: 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 codes indicated below. 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.

D = Test data

S = Surrogate organism

Data or other information in respect of an organism closely related to the organism being notified (the 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

This includes 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 NSN 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 that 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 modelling 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, i.e., [ ], 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 knowledge that all information provided in this form, as well as any attachments to the form, are accurate and complete; and that the information for which confidentiality is claimed meets the criteria for determining confidentiality as outlined in section 8 of the *Guidelines for the Notification and Testing of New Substances: Organisms*.

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 ☐ French ☐

Preferred Mode of Communication for Correspondence: Mail ☐ Facsimile ☐ (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:		Email:	
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:		Email:	
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:		Email:	
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:		Email:	
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:		Email:	
Street:		City:	Province/State / Country:
Zip/Postal Code:	Telephone No: ( )	Facsimile No: ( )	

Part A — Administrative and Substance Identity Information

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 organism with novel traits? **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, 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, 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:

☐ Supplementary Information Enclosed Attachment Number:_____

A.14 Confidentiality Requests:

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

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 ☐ N ☐
The strain history			Y ☐ N ☐
A description of any modifications to the organism, including: (i) the purpose of the modifications			Y ☐ N ☐
(ii) the methods and steps taken to make the modifications			Y ☐ N ☐
(iii) the phenotypic and genotypic changes that resulted from the steps referred to in (ii)			Y ☐ N ☐
(iv) the genetic stability of the changes referred to in (iii)			Y ☐ N ☐
(v) the nature, source and function of any introduced genetic material			Y ☐ N ☐
A description of the methods that can be used to distinguish and detect the organism			Y ☐ N ☐
A description of the biological and ecological characteristics of the organism, including: (i) its life cycle			Y ☐ N ☐
(ii) its reproductive biology, including species with which the organism could interbreed in Canada			Y ☐ N ☐
(iii) its involvement in adverse ecological effects, including pathogenicity, toxicity and invasiveness			Y ☐ N ☐
(iv) a description of the geographic distribution and habitat of the organism			Y ☐ N ☐
(v) the potential for dispersal of traits by gene transfer			Y ☐ N ☐
(vi) the locations and situations where the organism has caused adverse ecological effects			Y ☐ N ☐
(vii) its involvement in biogeochemical cycling			Y ☐ N ☐
(viii) its interactions with other organisms in the environment			Y ☐ N ☐
(ix) the conditions required for survival, growth, reproduction and overwintering			Y ☐ N ☐
(x) its capability to act as a vector for agents involved in adverse effects			Y ☐ N ☐
(xi) the mechanisms of its dispersal and the modes of interaction with any dispersal agents			Y ☐ N ☐
The identification of any patent or other rights, or any application for a patent or other rights, as the case may be			Y ☐ N ☐

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

Part B — Technical Information for Schedule 5

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

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 ☐ N ☐
A description of habitats where the organism may persist or proliferate			Y ☐ N ☐
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 ☐ N ☐

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 ☐ N ☐
The ecological effects of organism residues			Y ☐ N ☐
The potential of the organism to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity			Y ☐ N ☐

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 ☐ N ☐

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 ☐ N ☐
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 ☐ N ☐
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 ☐ N ☐