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NEW SUBSTANCES NOTIFICATION REPORTING FORM FOR MICRO-ORGANISMS

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 an organism other than micro-organism, please use the NSN Reporting Form for organisms other than a micro-organism.

The New Substances Notification (NSN) package must be submitted to:

Mailing Address:

Director, New Substances Division
Department of the Environment
Ottawa ON K1A 0H3

Courier Deliveries:

Director, New Substances Division
Department of the Environment
14th Floor, Place Vincent Massey
351 St. Joseph Blvd.
Gatineau QC J8Y 3Y5

Department Use Only
NSN Reference No.
Date Received:

Total number of pages:

INSTRUCTIONS FOR COMPLETING THE NOTIFICATION FORM

The New Substances Notification (NSN) 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). 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.

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 four columns which consist of: 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 aved 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 four columns which consist of: Submit with schedule; Data Codes; Attachment Number; and Confidential Information. The following explains the use for each of these columns.

Submit with Schedule: This is a quick reference column that allows you to determine, at a glance, which Schedule requires the information to be provided. Take note of the footnotes for certain exceptions and conditions associated with certain data elements.

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 *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:		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: ( )	

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 Micro-organism Information:

- Is the micro-organism solely for Foods and Drugs Act use?: **Y** ◯ **N** ◯
- Is the micro-organism a Research & Development Organism?: **Y** ◯ **N** ◯
- Is the micro-organism/use regulated under any other federal act? **Y** ◯ **N** ◯

  If yes, provide the name of the act: _____
- Is the micro-organism a known plant, human or animal pathogen? **Y** ◯ **N** ◯
- What is the biosafety level of the micro-organism? **I** ◯ **II** ◯ **III** ◯ **IV** ◯

  If biosafety level III or IV, was an import permit or an approval in writing to transfer been granted in respect of the micro-organism under the *Human Pathogens Importation Regulations*? **Y** ◯ **N** ◯
- Quantity for import:
  - < 50 mL or 50 g ◯
  - > 50 mL or 50 g ◯
  - Not for Import ◯
- Quantity for manufacture:
  - < 250 L ◯
  - > 250 L and < 1 000 L ◯
  - > 1 000 L ◯
  - Not for manufacture ◯

Type of organism:
- ◯ Bacterium
- ◯ Fungus
- ◯ Protist
- ◯ Archea
- ◯ Consortium
- ◯ Virus, virus like particle or sub-viral particle
- ◯ Cultured plant or animal cell

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:_____

Part A - Administrative and Substance Identity Information

A.14 Notification Group:

☐ **Introduction anywhere in Canada** (Provide all information in Schedule 1)

☐ **Introduction into an ecozone where it is not indigenous** (Provide all information in Schedule 1[1] and additional information in paragraph 3(2)(a) of the NSNR (Organisms)) Attachment Number:_____

Intended ecozone of introduction: _____

Introduction outside of the above listed ecozone but within 10 Km of the ecozone boundary **Y** ◯ **N** ◯

If yes, provide the information in paragraph 3(3) of the NSNR (Organisms) Attachment Number :_____

☐ **Introduction in accordance with confinement procedures** (Provide all information in Schedule 1[2] and additional information in paragraph 3(2)(b) of the NSNR (Organisms)) Attachment Number:_____

☐ **Introduction into an ecozone to which it is indigenous** (Provide all information in Schedule 1[3] and additional information in paragraph 3(2)(c) of the NSNR (Organisms)) Attachment Number:_____

Intended ecozone of introduction: _____

Introduction outside of the above listed ecozone but within 10 Km of the ecozone boundary **Y** ◯ **N** ◯

If yes, provide the information in section 3(3) of the NSNR Attachment Number: _____

☐ **Introduction in a contained facility or for export only** (Provide all information in Schedule 2)

Containment level of the facility: _____

☐ **Introduction in an experimental field study** (Provide all information in Schedule 3)

☐ **Introduction at the same site were isolated** (Provide all information in Schedule 4)

A.15 Confidentiality Requests:

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

A.16 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

[1] except paragraph 5(a) of the NSNR (Organisms)

[2] except paragraph 5(a), 6(c)(d) of the NSNR (Organisms)

[3] except subparagraph 1(f)(i)(iii)(iv) and paragraphs 1(i) and 5(a) of the NSNR (Organisms)

Part B - Technical Information

B.1 - General Information Requirements in respect of the micro-organism	Submit with schedule	DATA CODE	ATTACHMENTS	Confidential Information
The identification and the information substantiating the identification	1,2,3,4			Y ◯ N ◯
Common and superseded names and any synonyms	1,2,3			Y ◯ N ◯
The strain history	1,2,3			Y ◯ N ◯
A description of any modifications made to the organism including (i) the purpose of the modifications	1,2,3			Y ◯ N ◯
(ii) the methods and steps taken to make the modifications	1,2,3			Y ◯ N ◯
(iii) the phenotypic and genotypic changes that resulted from the steps referred to in (ii)	1,2,3			Y ◯ N ◯
(iv) the stability of the changes referred to in (iii)	1,2,3			Y ◯ N ◯
(v) the nature, source and function of any inserted genetic material	1,2,3			Y ◯ N ◯
A description of the methods that can be used to distinguish and detect the micro-organism	1,2,3			Y ◯ N ◯
A description of the biological and ecological characteristics of the micro-organism, including (i) its life cycle	1[4],3[5]			Y ◯ N ◯
(ii) its infectivity, pathogenicity to non-human species, toxicity and toxigenicity	1,2,3,4			Y ◯ N ◯
(iii) its resistance to antibiotics and tolerance to metals and pesticides	1[4],3[5]			Y ◯ N ◯
(iv) its involvement in biogeochemical cycling	1[4],3[5]			Y ◯ N ◯
(v) the conditions required for, and conditions that limit, survival, growth and replication	1,2,3			Y ◯ N ◯
(vi) the mechanisms of its dispersal and the modes of interaction with any dispersal agents	1,3			Y ◯ N ◯
A description of the mode of action in relation to the intended use (or in relation to the objective of the experimental field study)	1,2,3			Y ◯ N ◯
The identification of any patent or any application for a patent	1,2,3			Y ◯ N ◯
The dispersal by gene transfer of traits of pathogenicity to non-human species, toxigenicity and resistance to antibiotics including a description of: (i) the genetic basis for pathogenicity to non-human species, toxigenicity and resistance to antibiotics	1[4],3[5]			Y ◯ N ◯
(ii) the capability to transfer genes	1[4],3[5]			Y ◯ N ◯
(iii) the conditions that might select for dispersal of traits of pathogenicity to non-human species, toxigenicity and resistance to antibiotics, and whether the conditions are likely to exist at the locations of introduction (or at the site of the experimental field study) or within the range of dispersal of the micro-organism	1[4],3[5]			Y ◯ N ◯
A description of the geographic distribution of the micro-organism	1,3			Y ◯ N ◯
A description of the reasonably expected by-products following introduction	4			Y ◯ N ◯

4 Not required for notification under paragraph 3(2)(c) of the NSNR (Organisms)
5 Required only if the micro-organism is not indigenous to the ecozone where the field trial is located

Part B - Technical Information

B.2 - Importation or Manufacture Information Requirements	Submit with schedule	DATA CODE	ATTACHMENTS	Confidential Information
The identification of trade names and manufacturers, importers and vendors	1,2,3			Y ◯ N ◯
The identification of locations of manufacture in Canada	1,2			Y ◯ N ◯
The containment level for each manufacturing facility in Canada or for each facility to which the micro-organism will be imported, determined in accordance with the physical and operational requirements set out in either the Laboratory Biosafety Guidelines or Appendix K of the NIH Guidelines	2			Y ◯ N ◯
The physical state of the formulation	1,3			Y ◯ N ◯
The concentration of the micro-organism in the formulation	1,3			Y ◯ N ◯
The identification and concentration of other ingredients and of any contaminants in the formulation	1,3			Y ◯ N ◯
The viability of the micro-organism in the formulation	1,3,4			Y ◯ N ◯
A description of any recommended storage and disposal procedures	1, 2[6], 3			Y ◯ N ◯
An estimation of the quantity of the micro-organism that will be imported or manufactured in Canada	1,2,3,4			Y ◯ N ◯
A description of the equipment and methods of manufacture and of quality control and quality assurance procedures	1,2,3,4			Y ◯ N ◯
A description of the location of manufacturing facilities in Canada	1,3			Y ◯ N ◯
A description of the nature of potential releases of the micro-organism from the manufacturing facilities in Canada or from faciltiies to which the micro-organism will be imported, and the procedures to control releases	1,3			Y ◯ N ◯
A description of the procedures for the treatment and disposal of wastes containing the micro-organism from the manufacturing facilities in Canada	1,3,4			Y ◯ N ◯
Data to substantiate that the micro-organism was isolated from the site of introduction	4			Y ◯ N ◯

B.3 - Introduction Information Requirements	Submit with schedule	DATA CODE	ATTACHMENTS	Confidential Information
The intended and potential uses	1, 2, 4[7]			Y ◯ N ◯
The following information in respect of the experimental field study (or introduction): (i) the objectives	3			Y ◯ N ◯
(ii) its start and duration	3, 4			Y ◯ N ◯
(iii) a description of the procedures for transporting the micro-organism to and from the site of the experimental field study	3			Y ◯ N ◯
The history of use of the micro-organism	1,2,3			Y ◯ N ◯
A description of the procedures for the introduction of the micro-organism, (or a description of the procedures and design for the experimental field study), including (i) the method of application of the micro-organism	1,3,4			Y ◯ N ◯
(ii) the quantity, frequency and duration of application of the micro-organism	1,3,4			Y ◯ N ◯
(iii) any activities associated with the introduction (or with the experimental field trial)	1,3,4			Y ◯ N ◯
A comparison of the natural habitat of the micro-organism to the habitat at the potential locations of its introduction (or at the site of the experimental field study), and the nature of the selection that may operate on the micro-organism at the potential locations of introduction (or at the site of the experimental field study)	1,3			Y ◯ N ◯

6 only a description of recommended storage procedures is required for Schedule 2

7 only intended use is required for Schedule 4

Part B - Technical Information

B.3 - Introduction Information Requirements (CONT'D)	Submit with schedule	DATA CODE	ATTACHMENTS	Confidential Information
The following information in respect of the site of the experimental field study (or site of introduction): (i) its location and a map	3,4			Y ◯ N ◯
(ii) its size	3			Y ◯ N ◯
(iii) the distance to populated areas	3			Y ◯ N ◯
(iv) the distance to any protected areas	3			Y ◯ N ◯
(v) a description of the geological landscape at the site and surrounding the site	3			Y ◯ N ◯
(vi) a description of the biological diversity found at the site and surrounding the site including: (i) the identification of the endangered or threatened species	3			Y ◯ N ◯
(ii) if infectivity, pathogenicity to non-human species, toxicity and toxigenicity have been identified, the identification of the receptor species	3			Y ◯ N ◯
A description of any contingency plans in the event of an accidental release	1,3			Y ◯ N ◯
A description of any recommended procedures for terminating the introduction of the micro-organism (or the experimental field study)	1,3			Y ◯ N ◯
A description of any confinement procedures and biosafety conditions for the micro-organism at the site of the experimental field study (or site of introduction), and a description of their effectiveness	3, 4			Y ◯ N ◯
A description of any procedures for monitoring the micro-organism and its ecological effects at the site of the experimental field study, during and after the experimental field study	3			Y ◯ N ◯
A description of the security measures at the site of the experimental field study	3			Y ◯ N ◯
The identification of the ecozone of intended introduction	1[8]			Y ◯ N ◯
If the micro-organism is indigenous to the ecozone of introduction (or at the site of the experimental field trial), data to demonstrate that it is indigenous	1[9],3			Y ◯ N ◯
A description of those confinement procedures and their effectiveness in restricting the exit or dispersal of the micro-organism from the locations of introduciton	1[10]			Y ◯ N ◯

B.4 - Environmental Fate Information Requirements	Submit with schedule	DATA CODE	ATTACHMENTS	Confidential Information
The identification of the plant and animal species likely to be exposed and, if infectivity, pathogenicity to non-human species, toxicity and toxigenicity have been identified, the identification of the receptor species likely to be exposed.	1			Y ◯ N ◯
A description of habitats where the micro-organism may persist or proliferate	1,3			Y ◯ N ◯
The estimated quantities of the micro-organism in the air, water and soil at the points of introduction, and the estimated population trends.	1,3			Y ◯ N ◯
Any other information on the environmental fate of the micro-organism	1,3			Y ◯ N ◯

8 Required for notifications under paragraph 3(2)(a) and (c) of the NSNR (Organisms)
9 Required for notifications under paragraph 3(2)(c) of the NSNR (Organisms)
10 Required for notifications under paragraph 3(2)(b) of the NSNR (Organisms)

Part B - Technical Information

B.5 - Ecological Effects Information Requirements	Submit with schedule	DATA CODE	ATTACHMENTS	Confidential Information
The data from tests conducted to determine the effects of the micro-organism on (i) aquatic plant, invertebrate and vertebrate species likely to be exposed to it, and	1[11]			Y ◯ N ◯
(ii) terrestrial plant, invertebrate and vertebrate species likely to be exposed to it	1[11]			Y ◯ N ◯
The data from tests conducted to determine the effects of the micro-organism on plant, invertebrate and vertebrate species likely to be exposed	1[12]			Y ◯ N ◯
The involvement of the micro-organism in adverse ecological effects	1,3			Y ◯ N ◯
The potential of the micro-organism to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity	1,3			Y ◯ N ◯

B.6 - Human Health Effects Information Requirements	Submit with schedule	DATA CODE	ATTACHMENTS	Confidential Information
Any documented involvement of the micro-organism in adverse human health effects and a description of the characteristics of the micro-organism that distinguish it from known pathogens.	1,2,3,4			Y ◯ N ◯
The data from tests of antibiotic susceptibility	1,2,3			Y ◯ N ◯
The data from tests of pathogenicity that are valid for related micro-organisms that are pathogenic to humans.	1[13]			Y ◯ N ◯
The potential for adverse immunologic reactions in persons exposed to the micro-oragnism.	1[13]			Y ◯ N ◯
The estimated number of persons that may become exposed and the degree of their exposure to the micro-organism.	1,3,4			Y ◯ N ◯

Part C - Additional Information Requirements

C - Additional Information Requirements	Submit with schedule	DATA CODE	ATTACHMENTS	Confidential Information
All other information and test data in respect of the micro-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.	1,2,3,4			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 micro-organism, and the purpose of that notification.	1,2,3,4			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.	1,2,3,4			Y ◯ N ◯

11 Not required for notifications under paragraph 3(2)(a)(b) or (c) of the NSNR (Organisms)
12 Required only for notifications under paragraph 3(2)(a) of the NSNR (Organisms)
13 Not required for notifications under paragraph 3(2)(b) of the NSNR (Organisms)