



Pre-Notification Consultation Form

I. Contact Information

Name and Title	Date
Corporation Name	Email
Corporate Address	Telephone Number

II. Explicit Substance Name

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III. Known Trade Name(s) or Synonym(s) of the Explicit Substance Name

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IV. Substance Identifier (if available)

Chemical, biochemical, nanomaterial, polymer or biopolymer identifier CAS Registry Number Enzyme Commission number Other (please specify)	
Organism identifier ATCC number Other (please specify)	

V. Substance Type (select all that apply)

Substance type	Chemical	Polymer	Organism
Substance sub-type	Biochemical Nanomaterial UVCB	Biopolymer Meets the RRR polymer criteria All reactants on the DSL or NDSL	Micro-organism Organism other than a micro-organism
Special categories	Research & Development Contained Export Only Contained Site Limited Intermediate	Research & Development Not for introduction outside a contained facility	

VI. Intended Use Type (select one)

1. This substance is intended to be manufactured or imported <u>solely</u> for use in products regulated by the Food and Drugs Act (F&DA Use Only)
2. This substance is intended to be manufactured or imported for an industrial, commercial, and/or consumer use <u>other than</u> for use in products regulated by the F&DA (Industrial Use)
3. This substance is intended to be manufactured or imported for use in products regulated by the F&DA <u>and</u> in industrial, commercial, and/or consumer products (Dual Use)

VII. Activity (select one)

Manufacture	Import	Manufacture and Import
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VIII. Annual Quantity to Import or Manufacture (select one)

Chemical, biochemical, nanomaterial, polymer or biopolymer quantity ≥ 100 kg ≥ 1000 kg ≥ 10 000 kg ≥ 50 000 kg	Micro-organism quantity (import only) < 50 mL or 50 g ≥ 50 mL or 50 g Micro-organism quantity (manufacture only) < 250 L ≥ 250 L and < 1000 L ≥ 1000 L
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IX. Date When Importation or Manufacturing Activities are Expected to Begin:

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X. Intended Schedule:

XI. Intended Use of the Substance

XII. Questions and/or Concerns to be Answered by the New Substances Program

XIII. Confidential Business Information (CBI) (select all that apply)

Name of manufacturer or importer

Activity with the substance

Quantity of substance

Substance identity

Substance use

XIV. Other Information (if applicable, include as separate attachments)

Any substance data and test reports in the notifier's possession

Molecular structure and/or list of reactants/monomers (for chemicals and polymers)

A brief agenda (if a conference call is requested)

XV. Previous New Substances Notification (NSN) Number, Pre-Notification Consultation Number or Other Consultative Process (check below if none)

None

Process

Number

Date (YYYY/MM/DD)



Pre-Notification Consultation (PNC)

A PNC is an option for notifiers who wish to consult with the New Substances (NS) program during the planning or preparation of their New Substances Notification (NSN) to discuss any questions or concerns regarding information requirements. A PNC request is recommended when assistance is needed in determining the acceptability of waiver requests, test protocols, consolidated notifications, alternative data, or other endpoints, or when clarification is needed regarding substance classification.

Detailed guidance for a PNC request is included in Section 8.8 of the [Guidance document for the New Substances Notification Regulations \(Chemicals and Polymers\)](#) (for chemicals/polymers) and Section 6 of the [Guidelines for the Notification and Testing of New Substances: Organisms](#) (for living organisms).

PNC requests can be addressed in writing (e-mail) or through a meeting or conference call. For meeting and conference call PNC requests, the NS program will make every effort to respond to the proposed queries during the meeting. The NS program requests a minimum of two weeks between receiving the preliminary PNC request, which contains sufficient information, and conducting the meeting.

The information required to begin a PNC includes (refer to PNC form, and/or provide NSN form):

1. Substance identity information
 - a. **for chemicals and polymers** this may include substance name, trade name, CAS registry number, molecular structure, or a list of reactants
 - b. **for organisms** this may include ATCC number, explicit biological name, trade name, biochemical assay results, or genetic sequencing data;
2. Contact information (contact name, title, company, email, and mailing address);
3. Intended notification Schedule of the [New Substances Notification Regulations \(Chemicals and Polymers\)](#) or [New Substances Notification Regulations \(Organisms\)](#);
4. Intended use(s) of the substance;
5. The specific questions and/or concerns to be answered by the NS program;
6. Provide the relevant data and test reports based on the purpose of the PNC (Note that full test reports must be provided, summaries are not acceptable to meet data requirements)
 - a. provide a well-documented scientific rationale for each requirement for which you wish alternative approaches to meet the information requirements.
 - b. If using computational methods, provide the outputs
 - c. If using surrogate data, or establishing a surrogate, provide the surrogate data and the rationale for the surrogate.
 - d. **For living organisms:** provide the supporting literature search and results
7. Confidential Business Information (CBI) claims (corporation, activity, amount, substance identity, or use), if applicable; and
8. A brief agenda (if a conference call is requested) and availabilities at least 2 weeks after the PNC was submitted.

It is recommended to submit your PNC request via email to substances@ec.gc.ca or through [Environment Canada's Single Window Information System \(SWIM\)](#). You may also submit via mail/courier to the following address:

Substance Prioritization, Assessment and Coordination Division
Environment and Climate Change Canada
351 St-Joseph Boulevard
Place Vincent Massey
Gatineau, Quebec
K1A 0H3
If you are using FedEx, please use J8Y 3Z5 as the postal code instead of K1A 0H3

Completing the Form

Block I. Contact Information

Fill out all contact information under BLOCK I including the contact name, title, company, email, and mailing address. The person's name and title, name of the corporation, the full address of the main office, an email address, and phone number must be included under BLOCK I.

Block II. Explicit Substance Name

For chemicals and polymers, the explicit substance name of the substance should be a recognized chemical name, established in accordance with chemical nomenclature rules of either the International Union of Pure and Applied Chemistry (IUPAC), Chemical Abstracts Service (CAS), or International Union of Biochemistry and Molecular Biology (IUBMB).

For living organisms, enter the explicit biological name.

Block III. Known Trade Name(S) or Synonym(s) of the Explicit Substance Name

Trade names, commercial names, internal identifiers, or synonyms that can be used to identify the substance. This could also include the name of a finished product containing the substance. Any identifiers of the substance in provided attachments, should be included here.

Block VI. Substance Identifier

Enter the unique identifier number assigned to the substance, if one exists. Indicate the type of identifier (CAS Registry Number, Enzyme Commission number, ATCC number, or other) by selecting the appropriate box.

Block V. Substance Type

Select all boxes that apply to the substance: substance type (chemical, polymer, or organism), substance sub-type (such as biochemical, biopolymer, nanomaterial, micro-organism, organism other than a microorganism), and any special categories (such as research & development, contained export only, contained site limited intermediate, or not for introduction outside a contained facility). For more information on types and special categories of chemical and polymer substances, please refer to section 3.3 of the *Guidance document for the New Substances Notification Regulations (Chemicals and Polymers)*. For organisms, please refer to section 3 of the *Guidelines for the Notification and Testing of New Substances: Organisms*. For a description of the Domestic Substances List and Non-domestic Substances List and for information on how to access these lists, see section 2 of the *Guidance document for the New Substances Notification Regulations (Chemicals and Polymers)*.

Block VI. Intended Use Type

Select the Use Type (F&DA Use Only, Industrial Use, Dual Use). If the substance is intended to be manufactured or imported solely for use in products regulated by the [Food and Drugs Act](#) (F&DA), select the first option. If the substance is intended to be manufactured or imported for an industrial, commercial, and/or consumer use other than for use in products regulated by the F&DA, select the second option. If the substance is intended to be manufactured or imported for use in products regulated by the F&DA and in industrial, commercial, and/or consumer products, select the third option.

Block VII. Activity

Select the type of commercial activity that will occur with the substance in Canada (import, manufacture or both).



Block VIII. Annual Quantity to Import or Manufacture

Select the total annual quantity of the substance that will be imported into and/or manufactured in Canada.

Block IX. Date When Importation or Manufacturing Activities are Expected to Begin

Enter the date that importation and/or manufacturing activities with the substance are expected to begin.

Block X. Intended Schedule

Select the intended notification Schedule of the NSNR from the drop-down menu. For chemicals and polymers, please refer to appendix 2 of the *Guidance document for the New Substances Notification Regulations (Chemicals and Polymers)*. For organisms, please refer to section 3.2.1 of the *Guidelines for the Notification and Testing of New Substances: Organisms*.

Block XI. Intended Use of the Substance

A brief description of the intended use of the substance. If the space provided on the form is not sufficient, please provide the information as a separate attachment.

Block XII. Questions and/or Concerns to be Answered by the New Substances Program

A description of the reason for requesting a PNC. This could include any specific questions or details you wish to be addressed. If the space provided on the form is not sufficient, please provide the information as a separate attachment.

Block XIII. Confidential Business Information (CBI)

Check the appropriate boxes to indicate whether the information is confidential or not. If the information is considered CBI, the notifier must provide the supplementary information detailed in section 7.2 of *Guidance document for the New Substances Notification Regulations (Chemicals and Polymers)*. "Name of manufacturer or importer" refers to the link of the substance identity to the corporation, persons indicated on the form, or contacts on any supplementary attachments indicated in BLOCK I. "Activity with the substance" refers to link between the corporation identified in the form and the manufacturing and/or importation activities indicated in BLOCK VII. "Quantity of substance" refers to the quantity of the substance the notifier anticipates exceeding as well as the expected start date of the manufacturing or importation activities indicated in BLOCKS VIII and IXI. "Substance identity" refers to the identity of the substance indicated in BLOCKS II, III, IV and in any additional information provided in BLOCK XIV. "Substance use" refers to the intended and anticipated use of the substance indicated in BLOCK XI.

Block XIV. Other Information

Please include any other relevant substance data and test reports in the notifier's possession. Check the box on the form and submit these as separate attachments with your PNC submission. If requesting a meeting/conference call, the NS program asks that you submit a brief agenda. Check the box on the form and include this as a separate attachment with your PNC form.

Block XV. Previous New Substances Notification (NSN) Number, Pre-Consultation Number or Other Consultative Process

Please include the reference number(s) for any previous New Substance Notifications or Pre-notification Consultations related to this substance. If there were no previous files, please select 'None'.