

# New Substances Notification Regulations (Organisms)



The [New Substances Notification Regulations \(Organisms\)](#) [the Regulations] were created under the authority of the [Canadian Environmental Protection Act, 1999, \(Part 6\)](#) [CEPA] to help protect the health of Canadians and the environment. The Regulations ensure that new living organisms produced as a result of biotechnology are assessed prior to their introduction into Canada. **Biotechnology** is 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 or modified forms (see below for examples).

If you plan or are currently manufacturing or importing a living organism that is new to Canada, you may have to notify under the Regulations. You may therefore be required to provide information to Environment and Climate Change Canada (ECCC). A living organism is considered “new” if it is not found on the [Canadian Domestic Substances List \(DSL\)](#).

Failing to comply with the Regulations constitutes an offence under CEPA and may lead to inspections and enforcement action in accordance with the [Compliance and Enforcement policy](#). We all benefit when you comply with the law.

## Manufacturing or importing living organisms in Canada

Under the Regulations, **living organisms** consist of micro-organisms and organisms other than micro-organisms (also referred to as higher organisms), whether non-indigenous, genetically modified or naturally occurring. Micro-organisms can be bacteria, fungi, yeast, protozoa, algae, viruses, or eukaryotic cell culture. Higher organisms can be invertebrate and vertebrate animals, and plants.

### Examples of living organisms\*:

- Naturally occurring micro-organisms, plants and animals **that are used in biotechnology applications**, such as bioremediation, industrial enzyme production and fermentation;
- All genetically modified, bio-adapted, or other modified micro-organisms;
- All genetically modified, bio-adapted, or chimeric plants and animals; and
- Interspecies hybrids.

### Examples of sectors or products that use living organisms\*:

- Agriculture
- Aquaculture
- Biocatalysis
- Biodegradation / Bioremediation
- Biologics (such as, vaccines, gene therapy)
- Bioproduction (such as, enzymes, ethanol)
- Biosurfactants
- Cleaning products (such as, biodetergent, degreaser)
- Cosmetics
- Energy and fuel (such as, biomass fuel)
- Foods (such as, novel foods, cellular agriculture, food additives)
- Genetically modified ornamental aquarium fish
- Medical devices
- Mining (such as, bioleaching, biomining)
- Natural health products
- Pharmaceuticals (human and veterinary)
- Pulp and paper
- Textile
- Wastewater treatment

\*Please note that these lists are not exhaustive



## Living organism considered as a new substance

A **new substance** is any substance that is not on the Canadian [Domestic Substances List](#) (DSL) or that appears on the DSL and is flagged with a [Significant New Activity](#) (SNAc) notice. The DSL is an inventory of substances that are manufactured in, or imported into Canada. Substances not on the DSL (that is, non-domestic substances) are considered new to Canada.

**You must notify ECCC prior to the import or manufacturing of new substances so that they may be assessed for potential toxicity.**

**If you plan or are currently manufacturing or importing a living organism that is new to Canada, complete the following steps to fulfill your legal obligations under the Regulations.**

<b>Step 1</b>	<p>Consult the <a href="#">Guidelines for Notification and Testing of New Substances: Organisms</a> and/or <a href="#">Cell and gene therapy guidance</a> available at <a href="https://canada.ca/new-substances">canada.ca/new-substances</a> to complete the notification of the new living organism as required under the Regulations.</p> <p>Contact the Substances Management Information Line using the contact information provided below for any inquiries or to request a Pre-Notification Consultation. We can help clarify notification procedures or information requirements, and help determine appropriate Schedules in the Regulations for notification as well as the acceptability of waiver requests or test protocols.</p>
<b>Step 2</b>	<p>Identify the relevant notification Schedule (that is, category) in the guidelines document and complete the appropriate New Substances Notification (NSN) package and its supporting attachments for:</p> <ul style="list-style-type: none"><li>• <a href="#">Micro-organisms</a></li><li>• <a href="#">Higher organisms (that is, organisms other than micro-organisms)</a></li></ul>
<b>Step 3</b>	<p>Upon completion, submit the <a href="#">NSN package</a> to ECCC through the <a href="#">Single Window</a> reporting system for assessment. A written request can be made to treat the information submitted as confidential. A detailed procedure is outlined in the guidelines document referenced in Step 1 above.</p> <p>Notification assessment periods range from 30 to 120 calendar days, depending on the schedule and the new substance (organism) being manufactured or imported.</p>

## Assessment outcomes

The New Substances (NS) program will inform you on the outcome of the assessment. Possible outcomes include:

- 1. There is no suspicion of toxicity:** you can import or manufacture the substance, with no further requirements, in any quantity in Canada once the assessment period is over; **or**
- 2. There is no suspicion of toxicity for the notified activities associated with the substance provided that the activities do not change:** you can only import or manufacture the substance in Canada for the **purpose of the notified activities**.
  - If the activities change, [SNAc](#) provisions will be applied which would require further notifications before certain activities can be undertaken with the substance; **or**
- 3. There is a suspicion of toxicity:** additional information may be requested or control measures (condition or prohibition) may be imposed to manage any risks to the environment or human health in Canada.

The NS program publishes [summaries of NSNs](#) submitted for higher organisms and may invite stakeholders to share scientific information when invited, and test data related to potential risks to the environment or human health from the new living organisms.

### For additional information:

- ▶ **Visit the New Substances website:**  
[Canada.ca/new-substances](https://Canada.ca/new-substances)
- ▶ **Contact the Substances Management Information Line:**
  - **Telephone:** 1-800-567-1999 (in Canada) or 1-819-938-3232 (outside of Canada)
  - **E-mail:** [substances@ec.gc.ca](mailto:substances@ec.gc.ca)

### Disclaimer

This document provides a high level summary of the regulations and does not include all legal requirements. If there is any inconsistency or conflict between the information contained in this document and the Canada Gazette, Part II (CGII) published text and/or the Justice Canada regulatory text, the CGII and Justice Canada text prevails.

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