

NEW SUBSTANCES NOTIFICATION REGULATIONS (ORGANISMS)



To help protect the health of Canadians and the environment, the *New Substances Notifications Regulations (Organisms)* were created to ensure the proper assessment of new living organisms introduced into the Canadian marketplace.

If you plan to manufacture or import a new living organism subject to notification under the Regulations, you are required to provide information to Environment and Climate Change Canada (ECCC).



DO YOU MANUFACTURE OR IMPORT LIVING ORGANISMS OR ANIMATE PRODUCTS OF BIOTECHNOLOGY?

A **living organism** is a substance that is an animate product of **biotechnology**. It can consist of micro-organisms like bacteria, fungi, yeasts, protozoa, algae, viruses, or eukaryotic cell culture. It can also consist of other organisms including animals and some plants, such as those that are not indigenous to Canada or are genetically modified.

Examples include:

- Naturally occurring micro-organisms, plants and animals used in biotechnology applications, such as bioremediation, industrial enzyme production and fermentation;
- All genetically modified or bio-adapted micro-organisms;
- All genetically modified, bio-adapted, and chimeric plants and animals, including vertebrates and invertebrates;
- Interspecies hybrids; and
- Animals derived from in-vitro culture.

Biotechnology is the application of science and engineering in the direct or indirect use of living organisms or parts of products of living organisms in their natural or modified forms.

Products derived from biotechnology can be used in a variety of sectors* including:

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|-----------------------------------|--|------------------------|
| ▪ Aquaculture | ▪ Biodetergent / Degreaser | ▪ Medical (diagnostic) |
| ▪ Biocatalysis / Biosurfactant | ▪ Cosmetic | ▪ Pharmaceutical |
| ▪ Biodegradation / Bioremediation | ▪ Energy and Fuel | ▪ Pulp and Paper |
| ▪ Bioleaching / Biomining | ▪ Food | ▪ Textile |
| ▪ Biomass fuel | ▪ Human health (vaccines, gene therapy etc.) | ▪ Wastewater treatment |

**Please note that this list is not exhaustive*





IS THE LIVING ORGANISM OR ANIMATE PRODUCT OF BIOTECHNOLOGY A “NEW SUBSTANCE”?

A **new substance** is any substance that is not included in the *Canadian Environmental Protection Act, 1999* (CEPA) domestic substances list (DSL). The DSL is a searchable database available online as part of the CEPA registry.

Substances not appearing on the DSL are considered to be new to Canada and are subject to notification prior to their manufacture or importation.

If you have answered ‘yes’ to the questions above, complete the following steps to fulfill your legal obligations under the Regulations.

STEP 1 Identify the relevant notification category and schedule in the Regulations based on organism type and proposed use.

Collect the required information for the notification form. A guidance document is available online as a helpful resource in completing this step.

STEP 2 canada.ca/new-substances Search “Guidelines for organisms”.

Contact us at the Substances Management Information Line provided below to request a pre-notification consultation to clarify notification procedures or information requirements, and help determine appropriate schedules for notification and the acceptability of test protocols.

Complete and submit the notification form available on the New Substances website.

canada.ca/new-substances Search “New substances: biotechnology notification forms”.

STEP 3 Upon completion, submit the form to ECCC for assessment. Assessment periods range from 30 to 120 calendar days, depending on the schedule and the new substance (organism) being manufactured or imported.

A written request can be made to treat the information submitted as confidential. A detailed procedure is outlined in the Guidance document referenced in Step 2 above.

Await the processing of the new substance notification by ECCC and Health Canada.
Possible outcomes:

- STEP 4**
1. There is **no** suspicion of toxicity. You can import or manufacture the substance in Canada.
 2. There is **no** suspicion of toxicity for the notified activities associated with the substance. However, if the government has a suspicion of toxicity for a new activity, then significant new activity (SNAc) provisions may be adopted forcing further declarations before certain activities are undertaken with the substance.
 3. There is a suspicion of toxicity. Additional information may be requested or control measures may be imposed to manage any risks to the environment or human health in Canada.

FOR ADDITIONAL INFORMATION:

Visit the New Substances website at the following address:

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: eccc.substances.eccc@canada.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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