



NEW SUBSTANCES PROGRAM BIOTECHNOLOGY NEWSLETTER

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TABLE OF CONTENTS

Purpose of the Newsletter	2
Introduction	2
The New Substances program.....	2
<i>Canadian Environmental Protection Act, 1999</i>	2
<i>New Substances Notification Regulations (Organisms)</i>	3
Intended Uses	3
Exemptions Under CEPA and the Regulations	3
Exemptions under CEPA Part 6	3
Exemptions under Regulations as specified in Section 2 of the Regulations	3
Overview of Risk Assessment and Risk Management	4
Notification Process	4
Risk Assessment Summaries	4
Activities and Stakeholder Engagement.....	4
Consultations on Certain New Living Organisms.....	5
Overview of Consultation Process	5
Examples of Past Consultations	5
The New Substances program participation in International events	5
Convention on Biological Diversity	5
Organisation for Economic Co-operation and Development	6
Contact Information and Useful Links	6
Contact Information	6
E-mail	6
Telephone	6
Mail or courier	6
Useful links	6

PURPOSE OF THE NEWSLETTER

This newsletter aims to increase awareness of the [New Substances \(NS\) program](#), enhance engagement with the public, stakeholders, Indigenous partners, and reach potentially regulated parties including, but not limited to:

- Corporations;
- Individuals;
- Academic & research institutions;
- Government organizations;
- Hospitals;
- Other legal entities (e.g., non-profit organizations),

who may not be aware of their legal obligations to notify to the NS program before introducing animate products of biotechnology (hereafter referred to as “living organisms”) into the Canadian market. This newsletter also highlights recent accomplishments and partnerships that support and advance this work.

This newsletter is for informational purposes only. It does not cover all aspects of the [Canadian Environmental Protection Act, 1999](#) (CEPA) or the [New Substances Notification Regulations \(Organisms\)](#) [hereafter referred to as “the Regulations”]. In the case of any discrepancy between the information in this newsletter and CEPA or the Regulations, the official version of CEPA and the Regulations prevail.

INTRODUCTION

The NS program is jointly administered by Environment and Climate Change Canada (ECCC) and Health Canada (HC).

THE NEW SUBSTANCES PROGRAM

- Assesses risks associated with any new living organism under Part 6 of CEPA and the Regulations before they are imported into or manufactured in Canada;
- Ensures that no new living organism is introduced before the expiry of the assessment period and if necessary, appropriate control measures have been implemented; and
- Supports proactive (pre-market) risk management.

CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999

CEPA provides a legislative basis for a range of federal environmental and health protection programs. Part 6 of CEPA ensures that new living organisms are assessed to determine whether they are toxic or capable of becoming toxic to people or the environment before being imported into or manufactured in Canada.

For clarity:

- Any living organism not listed on the Canadian [Domestic Substances List](#) (DSL) is considered new to Canada and must be notified to the NS program, unless subject to exemptions under CEPA or the Regulations.
- New living organisms cannot be manufactured or imported unless they have been notified and the prescribed assessment period has expired, or unless such manufacture or import is authorized pursuant to any specified conditions prior to the expiry of that assessment period.

[Bill S-5 \(Strengthening Environmental Protection for a Healthier Canada Act\)](#), which received Royal Assent in 2023, amended CEPA to recognize that every individual in Canada has a right to a healthy environment as provided under the Act. For more information refer to the [Right to a healthy environment portal under CEPA](#).

NEW SUBSTANCES NOTIFICATION REGULATIONS (ORGANISMS)

The Regulations:

- Establish administrative information requirements for submitting notification;
- Prescribe the technical information that notifiers must provide to support the conduct of environmental and human health risk assessments;
- Define timelines for the risk assessment period.

INTENDED USES

In addition to industrial and household applications (e.g., biochemical production, cleaning products, energy and fuel, bioremediation), the Regulations apply to new living organisms intended for use in products regulated under the *Food and Drugs Act* (F&DA) such as novel foods, food additives, biologic drugs (e.g. vaccines, cell and gene therapies), natural health products (e.g. probiotics), veterinary drugs and cosmetics.

New living organisms intended for use in products regulated under the F&DA are subject to the Regulations prior to import into or manufacture in Canada, while the products themselves are subject to the F&DA. Regulated parties are responsible for meeting the requirements of both Acts. A guidance document was developed for new living organisms used in cell and gene therapies that are also subject to assessment under the F&DA: [Guidance for notification related to organisms used in cell and gene therapy and administered to humans](#).

EXEMPTIONS UNDER CEPA AND THE REGULATIONS

Some living organisms that are not on the DSL may be subject to exemptions under CEPA or the Regulations.

EXEMPTIONS UNDER CEPA PART 6

The manufacture or import of a new living organism for an intended use that is regulated under another federal Act listed in [Schedule 4](#) of CEPA is exempt from notification and assessment under CEPA.

EXEMPTIONS UNDER REGULATIONS AS SPECIFIED IN SECTION 2 OF THE REGULATIONS

1. Exemption for research and development (R&D) micro-organisms – Exemptions apply when used in a contained facility that comply with [Canadian Biosafety Standard, Third Edition, Canadian Biosafety Guideline - Containment Level 1: Physical Design and Operational Practices](#) or [Appendix K of the NIH guidelines](#), with volume limits based on risk group.
 - Facilities using Risk Group (RG)1 micro-organisms must keep volumes under 1000L
 - Those handling RG2, RG3, and RG4 micro-organisms must not exceed 250L and the facility must be licensed by Public Health Agency of Canada
 - The quantity of the organism must not exceed 50mL or 50g for import
2. Exemption for R&D higher organisms – R&D higher organisms must be imported or manufactured in a contained facility designed to prevent the release of organisms themselves, any of its genetic material, or any biological material from the organism that could be involved in toxicity.
3. Exemption for R&D organism for introduction in an agricultural research study conducted on plants.
4. Exemption for organisms in Transit – A situation where a living organism is loaded onto a carrier outside Canada and moved through Canada to a location outside Canada, whether or not there is a change of carrier during transit.

OVERVIEW OF RISK ASSESSMENT AND RISK MANAGEMENT

Any new living organism notified to the NS program is evaluated under the Regulations as outlined in the resources found in the [overview and guidance documents webpage](#). Following the risk assessment, notifiers are informed whether the notified organism is suspected to be toxic or capable of becoming toxic. If no suspicion is identified, notifiers may proceed with import or manufacture after the assessment period has expired.

When the NS program suspects that a new living organism is toxic or capable of becoming toxic, the following risk management measures may be applied before the expiry of the assessment period:

- Request for additional information to require further data or test results necessary to assess the organism;
- Impose conditions on the import or manufacture of the new living organism to mitigate risks (i.e. ministerial conditions); and
- Prohibit any person from importing or manufacturing the new living organism (i.e. ministerial prohibition).

The [significant new activity \(SNAc\)](#) provisions are applied when a new living organism has been assessed and there is a suspicion that new activities may pose a risk to human health and/or the environment. The SNAc provisions trigger an obligation for a person to provide specific information when proposing to use the new living organism for a SNAc. The government will assess the prescribed information to determine whether the new living organism, if used for a significant new activity, could pose a risk to the environment or to human health and, if so, whether risk management is required.

NOTIFICATION PROCESS

For information on when and how to submit a New Substances Notification (NSN) or a Significant New Activity Notification (SNAN), refer to [NS: guidelines for organisms](#) or contact the NS program using the [Contact Information](#) outlined at the end of this newsletter.

Stakeholders who wish to consult with the NS program during the planning or preparation of their new living organism NSN have the option to submit a pre-notification consultation (PNC) request, to discuss any questions or concerns regarding information requirements.

RISK ASSESSMENT SUMMARIES

To promote transparency of the NS program, ECCC and HC jointly publish summaries of environmental and human health risk assessment reports for new living organisms assessed under the Regulations. While the NS program reviews a large number of NSNs annually, the publication of summaries is selective and does not reflect the full scope or volume of assessments conducted.

In order to increase accessibility of these and other summaries for new living organisms, the [Risk assessment summaries for living organisms](#) page includes links to all published summaries and [Substances Search](#) includes the list of “*New Substances (Organisms) Risk Assessment Summaries*”.

The most recent publication of the [Canadian Environmental Protection Act, 1999, annual report to Parliament for April 2023 to March 2024](#) under section 3.2 outlines the summary of risk assessment and management decisions for new living organisms from April 2023 to March 2024.

ACTIVITIES AND STAKEHOLDER ENGAGEMENT

For more information on the changes that the NS program is proposing / considering, and feedback we have received during past engagement opportunities, please see our [Consultation and engagement on amendments to the New Substances Notification Regulations \(Organisms\)](#) page.

CONSULTATIONS ON CERTAIN NEW LIVING ORGANISMS

OVERVIEW OF CONSULTATION PROCESS

For the risk assessment of higher organisms (i.e. any organisms other than micro-organisms), ECCC and HC are promoting transparency and public engagement during the NSN risk assessment period. Under CEPA, all new vertebrate assessments require public consultation. More detailed information on the past consultations, including summaries of the organisms, results of the risk assessments, and responses to the comments submitted to the NS program are available on the [Consultations on certain living organisms new to Canada](#) webpage.

EXAMPLES OF PAST CONSULTATIONS

Gene-edited pigs

- Gene-edited (GE) pigs, notified by Genus PLC, have been genetically edited to remove the binding site for the virus that causes Porcine Reproductive and Respiratory Syndrome (PRRS). No foreign genetic material has been introduced into the notified substances.
- Based on the assessment of the notified information, the Ministers do not suspect that the GE pigs are toxic or capable of becoming toxic.¹

Genetically modified fish

- Domesticated *Corydoras aeneus* fish, commonly referred to as “Cory catfish”, notified by GloFish LLC, have been genetically engineered to produce unique colors and fluorescence for use in home aquaria.
- Based on the assessment of the notified information, the Ministers do not suspect that the three lines of fish are toxic or capable of becoming toxic.

Genetically modified fruit flies

- *Drosophila melanogaster* fruit flies, notified by Future Fields, were genetically engineered to act as tiny “living factories” with each line producing a specific growth factor, either bovine or human FGF2, that is used as a supplement to support cell growth in R&D.
- Based on the assessment of the notified information, the Ministers do not suspect that the fruit flies are toxic or capable of becoming toxic.

THE NEW SUBSTANCES PROGRAM PARTICIPATION IN INTERNATIONAL EVENTS

CONVENTION ON BIOLOGICAL DIVERSITY

- Canada submitted its 7th National Biodiversity Report (2020–2025), outlining progress under the Kunming–Montreal Global Biodiversity Framework, including work on biosafety and benefit-sharing from biotechnology. As a part of the Convention on Biological Diversity’s Scientific, Technical and Technological advisory group, ECCC leads Canada’s work on synthetic biology, and consults with other interested departments. This includes shaping international policy, providing substantive input to the synthetic biology action plan, and actively advancing Canada’s positions in global discussions.
- ECCC and Parks Canada jointly led the development of Canada’s position for the October 2025 International Union for Conservation of Nature Congress. This included advancing Canada’s approach on synthetic biology, as well as engagement on discussions concerning genetically engineered wild species (where a proposed moratorium was not adopted).

¹ Section 64 of CEPA sets out the criteria for determining if a substance, including a living organism, is toxic or capable of becoming toxic.

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

- The NS program is an active member of the Organization for Economic Co-operation and Development (OECD) Working Party on the Harmonization of Regulatory Oversight in Biotechnology (WP-HROB) and contributes to advancing Canada's international regulatory engagement on biotechnology. Canada participated in the joint session of the 40th WP-HROB and the 33rd Working Party on the Safety of Novel Foods and Feeds (WP-SNFF), held in The Hague, Netherlands, from April 22–24, 2026.
- Discussions focused on regulatory developments for New Breeding Techniques, emerging technologies such as synthetic biology, and safer innovation approaches for biotechnology products. The NS program plays a leadership role internationally, including leading the extension of the OECD Unique Identifier System to transgenic animals, co-leading the development of the Consensus Document on Information Used in the Assessment of Environmental Applications Involving Photoautotrophic Microalgae for Biomass Production, and contributing to the development of a framework on Moving towards Safe(r) Innovation Approach in the context of modern biotechnology.
- NS program also presented its report, *"Overview of Regulatory Frameworks for Products of Biotechnology Across Selected International Jurisdictions,"* which was well received. The report will be published on the OECD website and maintained as an evergreen resource.

CONTACT INFORMATION AND USEFUL LINKS

CONTACT INFORMATION

E-MAIL

If you have any questions, please contact the Substances Management Information Line by email at substances@ec.gc.ca.

Please note that the file size limit for this email address is 25 megabytes.

TELEPHONE

1-800-567-1999 (Toll free in Canada)

1-819-938-3232 (Outside of Canada)

MAIL OR COURIER

Regulatory Operations & Emerging Science Division
351 St. Joseph Blvd, Place Vincent Massey
Gatineau QC K1A 0H3

USEFUL LINKS

- [Canadian Environmental Protection Act, 1999](#)
- [New Substances Notification Regulations \(Organisms\)](#)
- [Significant new activity provisions: Canadian Environmental Protection Act](#)
- [New substances: Ministerial conditions](#)
- [New substances: Ministerial prohibitions](#)
- [Overview, guidelines, fact sheets, and technical frameworks](#)
- [New substances: guidelines for substances](#)
- [Canadian Biosafety Standard](#)
- [Canadian Biosafety Guideline - Containment Level 1: Physical Design and Operational Practices](#)
- [Appendix K of the NIH guidelines](#)
- [Guidance for notification related to substances used in cell and gene therapy and administered to humans](#)
- [Notification forms](#)
- [Risk assessment summaries](#)

- [Microbial risk assessment framework \(MRAF\) under the New Substances Notification Regulations \(Substances\) of the Canadian Environmental Protection Act, 1999](#)
- [Microbial Identification Framework for Risk Assessment](#)
- [Consultations on certain living organisms new to Canada](#)
- [Consultation and engagement on amendments to the New Substances Notification Regulations \(Organisms\)](#)
- [DSL substance search](#)
- [General services and information](#)