Research Guideline: OR-RR-G-005.0

New Substance Notifications

Office of Administrative Responsibility: Office of Services, Research Risk

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Purpose

The purpose of this guideline is to:

- to promote compliance with federally prescribed requirements for notifications concerning research, development and registration of new products of biotechnology;
- to publicize University requirements for physical containment, containment protocols and due diligence for new substances, and resources for compliance initiatives.

Scope

This guideline applies to all University research and development involving new substances as defined by the regulations.

Guideline

Introduction

Canadian Environmental Protection Act 1999 (CEPA) is the primary legislation that ensures that all new substances, including living organisms, introduced into Canada are assessed for their potential to harm human health, the environment and biodiversity.

Notification under NSNR is not required for new substances regulated by other "CEPA-equivalent" Acts. The federal departments that have responsibilities to evaluate submissions concerning new products of biotechnology include:

- Canadian Food Inspection Agency (CFIA)
- Environment Canada
- Fisheries and Oceans Canada
- Health Canada

Under most research programs, notification under NSNR is not required because either the notification threshold is not met (see Table 1) or in the case of organisms because the organism remains in containment.

Table 1. Notification thresholds for New Substance Notifications.

Substance category	Notification threshold (kg)
Chemical	1000
Biochemical	1000
Polymer	10000
Biopolymer	10000

New Substances Notification Regulations

There are two explicit stand-alone NSNR regulations; one for inanimate new substances and one for animate new substances:

- NSNR (Chemicals and Polymers) including
    - new chemicals and polymers, biochemicals and biopolymers
- NSNR (Organisms) including:
    - microorganisms
    - organisms other than microorganisms such as plants, invertebrates and vertebrates
    - organisms developed through the application of science and engineering, i.e., genetically modified organisms (e.g., transgenics, clones, chimerics), and organisms derived from in vitro culture
    - naturally occurring organisms that are used in engineered processes such as fermentation, bioremediation, phytoremediation, industrial enzyme and drug production
    - organisms that are also regulated under the Food and Drugs Act

Guidance concerning prescribed notifications and testing for both regulations are available on the Environment and Climate Change Canada website.

Research and development organisms must not be removed from approved containment or confinement locations and may not be transferred to the possession of other parties without approval from Environment Canada.

Domestic Substances Lists (DSLs)

The DSLs are lists of federally approved, existing substances compiled under CEPA. DSL-listed substances either were in Canadian commerce between 1984 and 1986 or have been added after undergoing CEPA toxicity risk assessments (new substance notifications). DSL-listed substances may or may not have usage conditions or restrictions assigned. Substances in the lists associated with Significant New Activities (SNAcs) are identified with an “S” flag; uses beyond those approved would require additional notifications and assessments. Any ‘new’

organisms that do not appear on Canada's Domestic Substances Lists (DSL) may be subject to NSNR.

New substances in products regulated under the Food and Drugs Act (e.g., pharmaceuticals, biologics, natural health products, food additives, novel foods, medical devices, personal care products, cosmetics) must undergo safety assessments under the Food and Drugs Act and environmental assessments under NSNR. Health Canada maintains an In Commerce List (ICL) of substances for which notification requirements do not apply at present.

Inanimate Substances Exempt from NSNR (Chemicals and Polymers)

Certain inanimate new substances (e.g., those assessed under other legislation, transient reaction intermediaries, impurities and contaminants related to the preparations of new substances, substances occurring in nature) are exempt from NSNR

Living Organisms Exempt from NSNR (Organisms)

There are a number of exemptions to NSNR notification requirements including but not limited to:

- research and development (R&D) organisms that meet the following criteria:
    - microorganisms in a contained facility
        - maximum import quantity less than 50 ml or 50 g
        - maximum manufacture quantity less than 1000 L for Biosafety Level 1 or less than 250 L for Biosafety Level 2 to 4.
    - organisms other than microorganisms
        - imported or manufactured in a facility from which there is no release of the organism, the genetic material of the organism, or material from the organism involved in toxicity.
- organisms regulated by other legislation

- existing organisms listed on the Domestic Substances Lists (DSL), unless the organisms are associated with Significant New Activities
- impurities and contaminants in minimal concentrations
- living organisms in transit through Canada
- naturally occurring indigenous plants to which science and engineering has not been applied
- naturally occurring indigenous animals (domesticated, livestock, zoo, aquaria) when produced through traditional breeding, artificial insemination, surrogate hosting or embryo splitting

Notification Requirements for Chemicals and Polymers

Environmental and human health assessments are conducted on new chemicals and polymers to determine whether they are toxic or capable of become toxic. Guidelines for notification and testing of new substances (chemicals and polymers) are outlined on the Environment and Climate Change website.

Notification Requirements for Living Organisms

The information to be notified to Environment Canada is summarized in the Schedules to the NSNR (Organisms).

Microorganisms are notifiable under Schedules 1 to 4. Organisms other than microorganisms are notifiable under Schedule 5.

Assessment Outcomes

Following assessment of a notification application the following outcomes are possible:

- No suspicion of toxic, and posting to the DSL
- No suspicion of toxic for the proposed use; posting of a SNAc notice

- Suspicion of toxicity:
    - request for more information
    - control measures are imposed regarding how the organism is imported, manufactured, used and/or disposed.

Containment Standards for Research and Development

Containment standards for research and development settings can be found in the following documents:

- For microorganism, small and large animals: Canadian Biosafety Standard, 2nd edition.
- For aquatic animals: Containment Standards for Facilities Handling Aquatic Animal Pathogens
- For plant pests: Containment Standards for Facilities Handling Plant Pests

For assistance with containment design for microorganisms, contact the University's Biosafety Officer at extension 53190.

The NIH Guidelines on Recombinant DNA and Gene Transfer, Appendix Q, also describes containment and confinement practices for research involving whole animals that are transgenic, or that involve viable recombinant DNA-modified microorganisms tested on whole animals

Definitions

Living organism

in the context of NSNR, an animate product of organism biotechnology; includes microorganisms and organisms other than microorganisms (i.e., macroorganisms) developed through the application of science and engineering, or are naturally occurring but where science and engineering is being applied in their use

Manufacture

produced, developed or grown

Microorganism

a microscopic living organism; any bacteria, mycoplasma, Chlamydia, rickettesia, protozoa, fungi, 2 algae, viruses, parts of these microorganisms, and any combination (consortia) thereof, and cultured cells of an organism.

Notification

submission of a prescribed information package to Environment Canada (or other federal authority) so that a new substance may be assessed for potential environmental or human health risks.

Release

to discharge, spray, inject, inoculate, abandon, deposit, spill, leak, seep, pour, emit, empty, throw, dump, place, or exhaust.

Research and Development organism

a living organism that is undergoing systematic development investigation or research by means of organism experimentation or analysis other than test marketing, the primary objective of which is to: (a) create or improve a product or process; (b) determine the technical viability or performance characteristics of a product or process, or (c) evaluate the organism prior to its commercialization through pilot plant trials, production trials, or customer plant trials so that technical specifications can be modified in response to the performance requirements of potential customers.

Substance

any distinguishable kind of organic or inorganic matter, whether animate or inanimate, including living organisms that are microorganisms and organisms other than microorganisms (i.e., plants, animal invertebrates and animal vertebrates); a “new” substance is a substance not listed on the Domestic Substances List (DSL).

Toxic

refers to a substance that may have an immediate or long term harmful effect on the environment or its biodiversity, on the environment upon which life depends, or on human life or health.

Related External Legislation or Policy

- Canadian Environmental Protection Act (CEPA)
    - New Substance Notification Regulations (Chemicals and Polymers)
    - New Substance Notification Regulations (Organisms)

Location of Research Guideline

This guideline is published at: www.uoguelph.ca/research

Review Frequency

It is the responsibility of the Office of Administrative Responsibility to initiate review of this policy. This guideline is to be reviewed every 5 years.