New Substances Notification Advisory Note 2002-01

Guidance concerning the application of s. 29.16 of the New Substances Notification Regulations (Exemption of Research and Development Organisms other than Micro-organisms)

Preamble

This note has been prepared to assist persons who intend to import or manufacture an animate product of biotechnology that is (i) a new substance; (ii) an organism other than a micro-organism; and (iii) a research and development substance, to meet their obligations under s. 29.16 of the New Substances Notification (NSN) Regulations of the *Canadian Environmental Protection Act*, *1999* (CEPA 1999).

If the requirements of s. 29.16 cannot be satisfied, importers or manufacturers of R&D organisms other than micro-organisms, are required to notify Environment Canada and provide the information set out in Schedule XIX of the NSN Regulations at least 120 days before importing into or manufacturing in Canada.

Scope of Part II.1 of the NSN Regulations

Part II.1 of the NSN Regulations implements certain provisions of Part 6 of CEPA 1999 by prescribing the information as well as the timelines for the notification to Environment Canada of the intent to manufacture or import animate products of biotechnology. Animate products of biotechnology include micro-organisms, and organisms other than micro-organisms (e.g. animals, fish and plants). Part II.1 of the NSN Regulations came into force on September 1, 1997 under the former *Canadian Environmental Protection Act*, and was amended on March 31, 2000 to reflect legislative changes as a consequence of its replacement by CEPA 1999.

Information provided under the NSN Regulations is used by Environment Canada and Health Canada to assess animate products of biotechnology before they are imported into or manufactured in Canada. The assessment is to ensure that the environment, including biological diversity, and human life and health, are protected.

Animate products of biotechnology are not notifiable under the NSN Regulations if they are regulated under other federal Acts and regulations that are listed in Schedule 4 of CEPA 1999. More information can be found by consulting the Environment Canada website at:
http://www.ec.gc.ca/ceparegistry/regulations/FINAL-RoadMap_e.pdf

Section 29.16 of the NSN Regulations

"A person who manufactures or imports an organism other than a micro-organism shall provide the information specified in Schedule XIX, unless the organism is a research and development substance and is imported to or manufactured in a facility from which there is no release, into the environment, of
(a) *the organism*
(b) *the genetic material of the organism; or*
(c) *material from the organism involved in toxicity."*

Guidance concerning Section 29.16

Interpretation of terms:

"organism" refers to a living organism as defined in s. 104 of CEPA 1999, namely a "substance that is an animate product of biotechnology";

(Examples: a livestock animal, a fish, a fertilized egg, frozen embryos, produced through biotechnology, that are alive.)

"the genetic material of the organism" means the deoxyribonucleic acid (DNA) or the haploid set of chromosomes as found in eggs, sperm, or any other reproductive body;

(Example: an un-fertilized fish egg.)

"material from the organism involved in toxicity" means material, including DNA and RNA, that has the potential to elicit a harmful effect such as a pathogenic or infective effect or an adverse effect due to a toxin;

(Examples: a plasmid which encodes a toxin; pathogenic micro-organisms that may be found in untreated manure; hazardous chemicals extracted from the organism; potentially hazardous substances found in the carcass of a modified animal that would not be found in the carcass of the unmodified animal.)

"research and development substance" is defined in s. 2(1) of the NSN Regulations as "a substance that is undergoing systematic investigation or research, by means of experimentation or analysis other than test marketing[1], the primary objective of which is

(a) to create or improve a product or process, or

(b) to determine the technical viability or performance characteristics of a product or process"; and

"facility" means the enclosed building to which the research and development substance is confined and may include transportation from one facility to another for the purpose of disposal or for additional experimentation, provided the criteria in paragraphs a), b) and c) of s. 29.16 continue to be met.

Requirements

In order to meet the criteria set out in s. 29.16, proponents are expected to ensure that the organism meets the definition of a research and development substance, and that material specified in paragraphs (a), (b), and (c) of s. 29.16 is not released from the facility.

To meet these requirements, the proponent is expected to ensure that operating procedures and practices are in place such that the organism, tissues derived from it, carcasses and wastes including manure, undergo appropriate treatment before being released from the facility.

Such treatment could be physical, chemical, biological or any combination of treatments, and proponents should keep records of the procedures, how they are applied and what efficacy results are attained.

The handling and care of experimental animals should be in accordance with the recommendations outlined in the *Guide to the Care of Experimental Animals*, published by the Canadian Council on Animal Care (http://www.ccac.ca) and as amended from time to time.

[1] defined in s. 2(1) of the NSN Regulations, "the exploration of the market capability of a product in a competitive situation where the creation or improvement of the product is not the primary objective".

CONTACT INFORMATION

New Substances Notification Information Hot Line

Telephone
1-800-567-1999 (toll-free in Canada)
(819)953-7156 (outside Canada)

For further information or documentation regarding the NSN Regulations, please visit the Environment Canada Web site at http://www.ec.gc.ca/substances/

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