

Advisory Note
DFO 2006-01

**Importing or Manufacturing Aquatic Organisms that are
Animate Products of Biotechnology
New Substances Notification Regulations (Organisms)**

**Office of Aquatic Biotechnology
Fisheries and Oceans Canada**

This Advisory Note is to inform manufacturers and importers of aquatic organisms¹ that are animate products of biotechnology² of their regulatory obligations under the *New Substances Notification Regulations (Organisms)*, a regulation made under the *Canadian Environmental Protection Act, 1999*.

Background

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) and its *New Substances Notification Regulations (Organisms)* [NSNR (Organisms)] apply to new living organisms, including aquatic organisms, which are manufactured (e.g. developed, produced or bred) in or imported into Canada. For the purposes of CEPA 1999, a “living organism” is an animate product of biotechnology and is “new” if it is not listed on the Domestic Substances List (DSL). Manufacturers and importers of new living organisms other than micro-organisms are required to provide the information prescribed in Schedule 5 of the NSNR (Organisms) a minimum of 120 days before the intended date of manufacture or import. This information is used in the conduct of a risk assessment to determine if the living organism may pose a risk (i.e. is “toxic” as per the criteria set out in CEPA 1999

¹ “*Aquatic organisms*” are fresh water and marine organisms, including fish* as defined in the *Fisheries Act*.

* “*Fish*” as defined in the *Fisheries Act*, includes (a) parts of fish, (b) shellfish, crustaceans, marine animals and any parts of shellfish, crustaceans or marine animals, and (c) the eggs, sperm, spawn, larvae, spat and juvenile stages of fish, shellfish, crustaceans and marine animals.

² “*biotechnology*” means 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.

³) to the environment or to the health of Canadians. Living organisms determined or suspected to pose a risk may be controlled as necessary, including by prohibiting or imposing conditions on their manufacture or import.

Examples of aquatic living organisms that could be subject to the NSNR (Organisms) include:

- Genetically modified plants and animals (including vertebrates and invertebrates)
- Interspecies hybrids
- Naturally occurring, exotic plants and animals used in biotechnology applications such as bio-remediation and industrial enzyme production.

Aquatic animal strains that are indigenous to Canada including Canadian wildlife species and their progeny produced through traditional breeding, artificial insemination or surrogate hosting are not subject to the NSNR (Organisms). Aquatic living organisms that are research and development organisms⁴ and that meet the containment criteria specified in subsection 2(4) of the NSNR (Organisms) are not subject to the NSNR (Organisms).

The Departments of Fisheries and Oceans Canada (DFO), Environment Canada and Health Canada have signed a Memorandum of Understanding respecting the implementation of the NSNR (Organisms) for certain new aquatic living organisms. As such, DFO will assist in administering the NSNR (Organisms), which will include conducting risk assessments and compliance promotion for these organisms. All decision-making, including the application of any necessary risk management measures and the enforcement of the NSNR (Organisms), remains the statutory responsibility of the Ministers of the Environment and of Health.

Legal Obligations and Responsibilities

Under section 106 of CEPA 1999, any person intending to manufacture or import a new living organism, including an aquatic living organism, must provide the information prescribed in section 8 and Schedule 5 of the NSNR (Organisms) at

³ Under section 64 of CEPA 1999, a substance is *toxic* if it is entering or may enter the environment in a quantity or concentration or under conditions that (a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity; (b) constitute or may constitute a danger to the environment on which life depends; or (c) constitute or may constitute a danger in Canada to human life or health.

⁴ "research and development organism" means an organism that is undergoing systematic investigation or research, by means of experimentation or analysis other than test marketing, whose primary objective is any of the following:

- (a) to create or improve a product or process;
- (b) to determine the technical viability or performance characteristics of a product or process; or
- (c) to evaluate the organism prior to its commercialization, by pilot plant trials, production trials, including scale-up, or customer plant trials so that technical specifications can be modified in response to the performance requirements of potential customers.

least 120 days prior to the intended date of manufacture or import. The text of the regulations is available at:

<http://canadagazette.gc.ca/partII/2005/20050921/html/sor248-e.html>

The information must be provided in duplicate to the:

Minister of the Environment,
c/o Director
New Substances Division,
Department of the Environment,
Ottawa, Ontario,
K1A 0H3

For a new aquatic living organism, notifiers are also encouraged to advise the Office of Aquatic Biotechnology, DFO, that a regulatory submission in respect of an aquatic organism has been made to the Minister of the Environment. This can be done by providing a copy of the New Substances Notification form to:

Office of Aquatic Biotechnology
Fisheries and Oceans Canada
200 Kent St., 12S029
Ottawa, ON
K1A 0E6
Canada

Facsimile: (613) 990-6199 (non secure)

Telephone:
(866) 633-6676 (toll free within Canada)
(613) 990-0258 (outside Canada)

Email: aquabiotech@dfo-mpo.gc.ca

Website: www.dfo-mpo.gc.ca/biotech

Contacts for More Information

Further information regarding the applicability of CEPA 1999 and of the NSNR (Organisms) to aquatic living organisms, and the process for making a notification, can be obtained by contacting the New Substances Notification Information Line of Environment Canada at the address listed below, and by obtaining the document entitled *Guidelines for the Notification and Testing of New Substances: Organisms* that explains the technical information requirements prescribed in Schedule 5 of the NSNR (Organisms), available at the website listed below:

New Substances Notification Information Line
New Substances Division
Environment Canada
Ottawa, ON
K1A 0H3.

Telephone:
(800) 567-1999 (toll free within Canada)
(819) 953-7156 (outside Canada)

Facsimile: (819) 953-7155

E-mail: nsn-infoline@ec.gc.ca

Website: http://www.ec.gc.ca/substances/nsb/eng/biotech_e.shtml