



## New Substances Program Advisory Note 2007-07

### Streamlining the notification process for naturally occurring micro-organisms with a low hazard potential

This advisory note is to inform manufacturers and importers of biotechnology products and any other stakeholders of the intention by the Minister of the Environment to set out a policy with respect to the waiver of information requirements provided for under paragraph 106(8)(a) of the Act for naturally occurring micro-organisms with a low hazard potential

#### **Background**

The New Substances Program of Environment Canada and Health Canada is responsible for administering the *New Substances Notification Regulations (Organisms)* [the Regulations], a regulation made under the *Canadian Environmental Protection Act, 1999* (the Act).

The objective of this Advisory Note is to set out a policy with respect to the waiver of information requirements provided for under paragraph 106(8)(a) of the Act for naturally occurring micro-organisms with a low hazard potential. This policy may result in lessening the sum of information required from the importer or manufacturer, while affording continued protection of the environment, biodiversity and human health.

#### **Criteria**

The Minister will consider granting a waiver under paragraph 106(8)(a) of the Act with respect to a naturally occurring micro-organism with a low hazard potential if the micro-organism meets the following six criteria. The micro-organism must:

- 1) be found naturally in the Canadian environment and its genome must not be modified;
- 2) have a history of safe use;
- 3) not be known as a cause of disease in healthy or vulnerable humans;
- 4) not be known as a plant pathogen nor an animal pathogen;
- 5) not produce toxins, or by-products known for having negative effects on environment or human health; and
- 6) not be known to be invasive (i.e. not having the ability to establish itself, persist, out-compete indigenous species, take over the new environment and threaten biological diversity).

#### **Notification Instruction**

**Importers and manufacturers of micro-organisms, including naturally-occurring micro-organisms with low hazard potential, subject to section 106 of the Act must provide the information required under the Regulations before they import or manufacture.**

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Under paragraph 106(8)(a) of the Act, the Minister of the Environment is authorized to waive, at the regulatee's request, any of the prescribed information requirements if, in the opinion of the Ministers of the Environment and of Health, the information is not needed in order to determine whether the living organism is toxic or capable of becoming toxic.

For naturally-occurring micro-organisms with a low hazard potential, some of the information required under the Regulations may not be necessary to assess the environmental and human health risk. For example, pathogenicity and toxicity test data may not be needed to assess the environmental and human health risk of a naturally-occurring micro-organism with a low hazard potential, and therefore this information requirement may be waived under paragraph 106(8)(a) of the Act.

Waiver requests must be prepared by the importer or manufacturer and provided to the Minister (care of: New Substances Program) at the same time as the new substances notification. Each waiver request must be supported by a scientific justification for each of the six criteria.

You may consult the New Substances Program when preparing notifications under the Regulations to help you determine if the present policy applies to your situation.

**Contact Information:**

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***Original signed by***

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Signed on October 2, 2007