

Notification and Assessment under the *Canadian Environmental Protection Act, 1999* of *Bacillus* species strains 01 and 02 (Q&A summary)

What is it?

- *Bacillus* species 01 and 02 are naturally occurring bacteria that were isolated in 2003 from environmental samples collected in the municipality of Louiseville, Quebec. The precise species name is not disclosed at the request of the company.
- *Bacillus* species 01 and 02 belong to a species of bacteria that has a ubiquitous distribution in nature.
- Humans are continuously exposed to various levels of bacteria of the same species with no reported adverse health effects.
- *Bacillus* species 01 and 02 were selected for their capability to express useful metabolites and to exert key metabolic traits for industrial applications, to grow in an industrial fermentation process, and for their ability to remain viable for an extended period of time in the end-use products.

How is it used?

- *Bacillus* species 01 and 02 will be used as components of industrial and commercial cleaning products for use in biodegradation and odour control.
- Products may be for use in septic tanks, grease traps, refuse containers, compactors, garbage trucks, bathrooms, hydrocarbon waste traps, and wastewater of agri-food industries.

Why did the Government of Canada assess it?

- A micro-organism produced through the application of science and engineering that is not listed on the [Domestic Substances List \(DSL\)](#) and that is not subject to federal legislation listed in Schedule 4 of the [Canadian Environmental Protection Act, 1999 \(CEPA\)](#), is considered “new”. Before it is manufactured in or imported into Canada, the Government of Canada must assess its potential to harm human health and the environment under the [New Substances Notifications Regulations \(Organisms\)](#), as required by Section 106 of CEPA. *Bacillus* species 01 and 02 are not on the DSL.
- The Government of Canada conducted assessments on *Bacillus* species 01 and 02 because the company, Choisy Laboratories Ltd., submitted notifications of its intention to manufacture these new micro-organisms in Canada for use in products for biodegradation and odour control.
- These assessments were conducted under the [New Substances Notifications Regulations \(Organisms\)](#), as required by Section 106 of CEPA.

How is it released to the environment?

- *Bacillus* species 01 and 02 will only be incorporated into the manufacturer’s commercial and industrial products for biodegradation and odour-control.
- Products are for use only at specific sites and only when needed.

How are Canadians exposed to it?

- Based on the intended use in commercial and industrial applications, the general population in Canada is not expected to be significantly exposed to *Bacillus* species 01 and 02. Individuals using products containing these strains may be exposed to a limited extent.

What are the results of the assessment?

- The Government of Canada has conducted science-based risk assessments of *Bacillus* species 01 and 02.
- Risk assessments consider potential for harm to the general population in Canada (not including workplace exposures), to species present in Canada, and to the environment.
- *Bacillus* species 01 and 02 are not known to cause disease in healthy humans, animals or plants.
- Procedures are in place at the manufacturing facility to prevent unintentional release of the micro-organisms; release to the environment will occur through the normal usage of these species in products.
- *Bacillus* species 01 and 02 are therefore not considered to be harmful to human health or the environment based on the intended use, and the Government of Canada has concluded that *Bacillus* species 01 and 02 are not entering the environment in a quantity or under conditions that constitute a danger to the environment or humans.

What is the Government of Canada doing?

- Based on the conclusion of the risk assessments, the Government of Canada will take no further action on *Bacillus* species 01 and 02.