

Summary of Risk Assessment Conducted Pursuant to subsection 108(1) of the *Canadian Environmental Protection Act, 1999*

New Substances Notification 20103: DGG-B™

Regulatory decisions

Under the provisions for Animate Products of Biotechnology in Part 6 of the *Canadian Environmental Protection Act, 1999* (CEPA), and pursuant to section 108 of the Act, the Minister of the Environment and the Minister of Health have assessed information in respect of the consortium DGG-B™ and have determined that it is not anticipated to enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long term harmful effect on the environment or its biological diversity, constitute or may constitute a danger to the environment on which life depends, or constitute or may constitute a danger in Canada to human life or health. Therefore, no further action is recommended as a result of this assessment.

Organism identity

DGG-B™ is a microbial consortium.

Notified and potential uses

DGG-B™ was notified according to the requirements for Schedule 3 of the *New Substances Notification Regulations (Organisms)* [NSNR(O)], which applies to its use in an experimental field study. It is proposed to be manufactured in Canada and used to remediate contaminated groundwater at a single site as part of the field study. The consortium is not eligible for addition to the *Domestic Substances List* on the basis of this assessment, and a new notification would be required before the consortium is imported or manufactured for any use outside of the experimental field study.

Environmental fate and behaviour

DGG-B™ is derived from naturally occurring microbial communities and adapted for growth under anaerobic conditions with benzene as its energy source. If released into the environment, some members of the diverse groups of micro-organisms in this consortium can survive and persist in the presence of benzene, and would likely experience growth limitations when benzene is no longer present in the environment.

Environmental assessment

Hazard Considerations

The environmental hazard potential of DGG-B™ is considered to be low for the following reasons:

- The components of the consortium occur naturally within the ecozone in which the field test is conducted. In addition, DGG-B™ includes micro-organisms that have been frequently isolated in rice paddies, contaminated aquifers, freshwater and marine sediments, and wastewater treatment facilities.
- Genomic testing of DGG-B™ did not indicate presence of any known animal, plant or other environmental pathogens. In addition, the notifier will conduct periodic genomic testing while producing cultures of DGG-B™ for this study in order to ensure that environmental pathogens are not present during production or introduced inadvertently to the site.

Exposure Considerations

The environmental exposure potential of DGG-B™ is considered to be low for the following reasons:

- Containment measures are in place at the manufacturing laboratory and during transport to the site of the field trial, limiting the potential for environmental releases.
- The consortium will be used solely in a single experimental field trial site in Canada and measures are in place to limit public access to the experimental field site where the single injection of DGG-B™ is applied.
- The potential for exposure to the consortium at the site of the field trial will be limited because it will be applied through subsurface injection deep into the ground and away from the limited potential receptor species at the surface.
- DGG-B™ is not expected to reach major drinking or surface water sources, water bodies, populated or environmentally sensitive areas because of limited growth conditions and the slow transfer of the notified consortium through the groundwater.

Human health assessment

Hazard Considerations

The human health hazard potential of DGG-B™ is considered to be low for the following reasons:

- The components of the consortium occur naturally within the ecozone in which the field trial will be conducted.
- None of the constituents identified in the consortium are genetically similar to known human pathogens.
- There is no history of use of DGG-B™ in Canada; however, the consortium has been used in a laboratory setting for more than 20 years without any reports of adverse effects in humans.
- There are no reports of allergic reactions caused by the major microbial constituents of DGG-B™.
- DGG-B™ is susceptible to a number of antimicrobial drugs, so in the unlikely event of human infection with the notified consortium, clinically relevant antibiotics are available for treatment.

Exposure Considerations

The human exposure potential of DGG-B™ is considered to be low for the following reasons:

- With the manufacturing process adhering to Large Scale requirements of the Canadian Biosafety Standards and Guidelines – Containment Level 1: Physical Design and Operational Practices, potential for human exposure and environmental releases will be limited.
- Less than ten people will be involved in the manufacturing, transportation and application of the notified consortium at the experimental field trial site.
- The consortium will be used solely in a single experimental field trial site in Canada and measures are in place to limit public access to the experimental field site.
- DGG-B™ is not expected to reach major drinking or surface water sources, water bodies, populated or environmentally sensitive areas due to limited growth conditions for the components of DGG-B™ and the slow transfer of the notified consortium through the groundwater.

Risk assessment conclusion

Risk is typically described as the probability of an adverse effect occurring based on known hazards and a particular scenario of exposure (Environment Canada and Health Canada, 2011).

In the present case, DGG-B™ will be used for remediation of contaminated groundwater at a single site. No other uses are envisaged or allowed within this notification.

Given the low environmental hazard potential and the low environmental exposure potential, the environmental risk associated with the use of DGG-B™ for remediation of contaminated groundwater at a single site is assessed to be low.

Given the low human health hazard potential and the low human exposure potential, the human health risk associated with the use of DGG-B™ for remediation of contaminated groundwater at a single site is assessed to be low.

Therefore, DGG-B™ is not anticipated to enter the environment in a quantity or under conditions that have or may have an immediate or long term harmful effect on the environment or its biological diversity, constitute or may constitute a danger to the environment on which life depends, or constitute or may constitute a danger in Canada to human life or health.

References

(excluding proprietary information or references provided by the notifier)

Environment Canada and Health Canada (2011). Framework for Science-Based Risk Assessment of Micro-Organisms Regulated under the Canadian Environmental Protection Act, 1999 (2011). http://www.ec.gc.ca/subsnouvelles-news subs/default.asp?lang=En&n=120842D5_1 (viewed June 2020).

Public Health Agency of Canada (2017) Canadian Biosafety Guideline - Containment Level 1: Physical Design and Operational Practices. <https://www.canada.ca/en/public-health/services/canadian-biosafety-standards-guidelines/guidance/containment-level-1-physical-design-operational-practices.html#a33> (viewed June 2020).