New substances: risk assessment, New Substances Notifications 20941, 20942, and 20943

Schedule 1 of the *New Substances Notification Regulations (Organisms)*

Notified organisms	DGG-X™, DGG-B™, and DGG-T™	
Schedule of the NSNR(O)	Schedule 1 - Information Required in Respect of Micro-organisms	
First day of assessment period	2022/04/11	
Last day of assessment period	2022/08/08	
Organism type	Microbial consortia	
Use	Manufacture of the notified organisms for biodegradation of petroleum hydrocarbon compounds (PHCs) in groundwater (such as *o*-xylenes, benzenes, and toluenes) to non-toxic end products.	
Anticipated quantity	Annually up to 300 litres of DGG-X™, DGG-B™, and DGG-T™ each will be manufactured for use as bioaugmentation inoculums.	
Assessment level of concern	Human Health Hazard	Low
	Human Exposure	Low
	Environmental Hazard	Low
	Environmental Exposure	Low
Assessment conclusion (under section 64 of CEPA 1999)		Low risk, not suspected to be toxic
Category		Added to the Domestic Substances List on January 4, 2023.
Recommended Action	None	
Waiver	A waiver to submit the data from a test conducted to determine the pathogenicity and toxicity of the notified organisms under subparagraphs 5(a)(i) and 5(a)(ii) of Schedule 1 of the *New Substances Notification Regulations (Organisms)* [aquatic and terrestrial plants, invertebrate and vertebrate species, respectively] was granted under paragraph 106(8)(c) of the *Canadian Environmental Protection Act, 1999* due to the fact that testing is considered technically laborious or impossible to perform. In addition, *in silico* analysis of the amplicon sequences variants (ASVs) in each consortium did not indicate presence of any known plant or animal pathogens in the consortia tested.	

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Synopsis

DGG-X™, DGG-B™, and DGG-T™ (hereafter referred to as the notified consortia) are naturally occurring microbial consortia. A consortium is a complex natural combination of micro-organisms that is not a pure culture and has not been deliberately formulated. This would include, for example, a collection of diverse microorganisms isolated from sludge or soil. These microbial consortia were notified to the New Substances program for use in bioremediation of petroleum hydrocarbon compounds (PHCs) (such as *o*-xylenes, benzenes, and toluenes) in groundwater, to non-toxic end products. Bioremediation is a method in which biological systems are applied for reclamation of the contaminated soil/water by transformation of toxic pollutants into less hazardous or completely non-hazardous forms. Other potential uses include their combined use with other microbial consortia for bioremediation of groundwater and soils.

There is no evidence to suggest a potential a risk of adverse environmental and human health effects at the exposure levels predicted for the environment and general population in Canada from production of the notified consortia.

It is determined that the notified consortia are not toxic or capable of becoming toxic according to the criteria under section 64 of the Act as there is no evidence to suggest that they may 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.

No risk management is recommended.

Background information

The notified consortia are naturally occurring consortia containing strict anaerobic microorganisms that require specific hydrocarbon substrates and absence of oxygen for growth. Those consortia were developed from a mixed environmental groundwater and soil sample isolated in 1994 and 1995 from contaminated sites in Florida and Oklahoma. They were notified for use in bioremediation of *o*-xylene, benzene, and toluene, respectively. Other potential uses include their combined use with other microbial consortia for bioremediation of groundwater and soils.

The risk assessment is based on the evaluation of information submitted by the notifier and publicly available literature. The following sections give more details on the hazard and exposure.

Hazard

The environmental and human health hazard potential of the notified consortia are determined to be low because:

1) The notified consortia contain naturally occurring organisms. They have not been genetically modified, therefore no new traits have been introduced.
2) The microbial community composition and the stability of the notified consortia have been maintained and monitored for more than 20 years.
3) The notified consortia are composed of microorganisms which are closely related to those found in a variety of environments, including rice paddies, contaminated aquifers, freshwater and marine sediments, wastewater treatment facilities, soils and animal gastrointestinal tracts. Based on the environmental origin of these cultures, and literature search results, it is likely that these microorganisms may be widespread throughout Canada in certain ecozones. No cases of harmful effects to non-human species have been reported in the scientific literature.
4) According to routine genetic analyses conducted by the notifier, none of the major groups of the microorganisms present in the notified consortia are closely related to known animal or plant pathogens, meaning that they are unlikely to be pathogenic in animals or plants.
5) While DGG-X™ and DGG-T™ have no history of use outside of a laboratory setting, there are no reports of adverse human health effects from more than 20 years of use in the laboratory. There are no reports of allergic reaction or adverse immunological reactions associated to major groups of microorganisms in the notified consortia.
6) The notified consortia are susceptible to clinically relevant antimicrobial drugs. Therefore, in the highly unlikely event of a human infection, effective treatments are available.

Exposure

The environmental and indirect human exposure potential of the notified consortia are determined to be low because:

1) The notified consortia are manufactured in a containment level 2 laboratory as defined by the Canadian Biosafety Standard of the Public Health Agency of Canada (PHAC, 2022). Standard operating procedures are in place to disinfect the manufacturing waste and deal with any accidental spills. It is therefore unlikely that they will be released from the manufacturing facility.
2) The notified consortia are strict anaerobic consortia that require specific hydrocarbon substrates for growth. They are not expected to survive if exposed to aerobic conditions or upon depletion of *o*-xylene, benzene, and toluene, respectively. Furthermore, within each consortium, most microorganisms are dependent on the growth and activity of other major organisms.

3) The notified consortia will be injected directly into the soil subsurface of highly contaminated sites where no environmental receptor species are anticipated to be present.
4) Measures and standard operational procedures are described during handling and application of the notified organisms to limit their accidental release in surface waters and untreated groundwater used for irrigation. Furthermore, due to the slow flow of the groundwater, the notified consortia are not expected to reach major water sources or environmentally sensitive areas.
5) If released to the environment, minor impact would be expected as none of the major groups of the microorganisms present in the notified consortia are closely related to any known animal or plant pathogens.
6) All personnel and field technicians involved in the manufacture or field application of the notified consortia will have adequate training. It will be manufactured under controlled conditions. Further, the notified consortia will be applied in the form of subsurface injections. Taken together, exposure of the general population of people living in Canada is not expected.
7) Other potential uses of the notified consortia included their use with other microbial consortia for bioremediation of groundwater and soils. However, releases to the environment and exposure to the general population of people living in Canada is not expected to significantly increase from these potential uses.

Risk characterization

Owing to the low potential hazard and the low potential exposure, the environmental and human health risks associated with the use of the notified consortia in the bioremediation of groundwater contaminated with *o*-xylene, benzene, and toluene, respectively, and other potential uses, such as a commercial product for anaerobic digesters, composting, or to treat groundwater, wastewater, soil, alone or in combination with other consortia in Canada, are assessed to be low.

Risk assessment conclusion

There is no evidence to suggest a potential a risk of adverse environmental and human health effects at the exposure levels predicted for the environment and general population from the use of the notified consortia in the bioremediation of groundwater contaminated with *o*-xylene, benzene, and toluene, and other potential uses, such as a commercial product for anaerobic digesters, composting, or to treat groundwater, wastewater, soil, alone or in combination with other consortia in Canada. The risk to the environment and human health associated with the notified consortia are not suspected to meet the criteria in paragraphs 64(a), (b), or (c) of the *Canadian Environmental Protection Act, 1999*. No further action is recommended.

References

Arora, N. K. (2018). Bioremediation: a green approach for restoration of polluted ecosystems. Environmental Sustainability, 1(4), 305-307.

PHAC (2022). Canadian Biosafety Standard of Public Health Agency of Canada (Third Edition). https://www.canada.ca/en/public-health/services/canadian-biosafety-standards-guidelines/third-edition.html