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

New Substances Notification 19719: *Pseudomonas migulae* ATCC 39005

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 living organism *Pseudomonas migulae* ATCC 39005 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.

Organism identity

Pseudomonas migulae ATCC 39005 is a naturally-occurring bacterium.

Notified and potential uses

Pseudomonas migulae ATCC 39005 was notified according to the requirements for Schedule 2 of the *New Substances Notification Regulations (Organisms)* [NSNR(O)], which applies to micro-organisms that are not intended for introduction outside a contained facility or are for export only. It is proposed to be imported and manufactured in Canada solely for the production of an enzyme to be used as a reagent in conjunction with a medical diagnostic device. The micro-organism 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 micro-organism is imported or manufactured for any use outside of a contained facility.

Environmental fate and behaviour

If the micro-organism were to be released to the environment, it would be expected to survive in a variety of conditions and temperatures (including 4°C). In the environment, it is more likely to be found in soil than in water.

Environmental assessment

Hazard Considerations

The environmental hazard potential of *Pseudomonas migulae* ATCC 39005 is assessed to be medium for the following reasons:

- *Pseudomonas migulae* ATCC 39005 belongs to the *P. fluorescens* group and data provided by the notifier could not discriminate between *P. migulae* and *P. fluorescens* species.

- No pathogenicity or toxicity testing has been conducted on *P. migulae* ATCC 39005. In addition, no information was found on its effects on plants and animals.

- Some strains of *P. fluorescens*, a close relative of *P. migulae,* are associated with negative effects on a few terrestrial plants, with opportunistic infections in fish species and with toxic effects to some aquatic invertebrates. There are also strains of *P. fluorescens* that are used as biocontrol agents against a variety of terrestrial invertebrates.

Exposure Considerations

The environmental exposure potential of *Pseudomonas migulae* ATCC 39005 is assessed to be low for the following reasons:

- *P. migulae* ATCC 39005 will be imported and manufactured in Canada for the notified use only (i.e., production of an enzyme in a contained facility). No living culture of the notified strain will be sold or distributed in Canada by the notifier.

- With the manufacturing process adhering to the Large Scales requirements of the Canadian Biosafety Standards and Guidelines – Containment Level 1: Physical Design and Operational Practices, environmental releases of live cells of the micro-organism from the notified use are not anticipated.

- The procedures for handling and decontamination of live cells, as well as disposing of wastes containing cells, are expected to prevent the release of live cells into the environment. There are also emergency procedures in place to deal with any accidental spills to prevent environmental contamination with the notified micro-organism.

Human health assessment

Hazard Considerations

The human health hazard potential of *Pseudomonas migulae* ATCC 39005 is considered to be low for the general population and low to medium for immunocompromised individuals for the following reasons:

- There are no cases of human infection reported for *P. migulae* ATCC 39005.

- No pathogenicity and toxicity testing has been conducted on *P. migulae* ATCC 39005; however, whole genome sequencing of the micro-organism did not indicate presence of any genes known to contribute to adverse effects in humans.

- Data provided by the notifier could not discriminate between *P. migulae* ATCC 39005 and its close relative, *P. fluorescens*.

- The optimal growth temperature for both *P. migulae* ATCC 39005 and *P. fluorescens* is below human body temperature. Nonetheless, *P. fluorescens* has been isolated from infections resulting from the use of contaminated blood products or contaminated medical devices in people with compromised immunity.

- *P. migulae* ATCC 39005 is susceptible to a number of antimicrobial drugs, so in the unlikely event of human infection with the notified strain, clinically relevant antibiotics are available for treatment.

Exposure Considerations

The human exposure potential of *Pseudomonas migulae* ATCC 39005 is considered to be low for the following reasons:

- *P. migulae* ATCC 39005 will be manufactured in Canada for the notified use with no anticipated external sale or distribution of living culture from the notified micro-organism.

- With the manufacturing process adhering to the Large Scale requirements of the Canadian Biosafety Standards and Guidelines – Containment Level 1: Physical Design and Operational Practices, human exposure and environmental releases of live cells of the micro-organism from the notified use are not anticipated.

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, *Pseudomonas migulae* ATCC 39005 will be imported and manufactured in a contained facility for the production of an enzyme to be used as a reagent in conjunction with a medical diagnostic device. No other uses are envisaged or allowed within this notification.

Despite the medium environmental hazard potential, no live cells are expected to be released from the contained manufacturing facility. Therefore, the environmental risk associated with the use of *Pseudomonas migulae* ATCC 39005 for the production of an enzyme to be used as a reagent in conjunction with a medical diagnostic device is assessed to be low.

Despite the low to medium human health hazard potential for immunocompromised individuals, no live cells are expected to be released from the contained manufacturing facility and measures are in place to prevent human exposure. Therefore, the human health risk associated with the use of *Pseudomonas migulae* ATCC 39005 for the production of an enzyme to be used as a reagent in conjunction with a medical diagnostic device is assessed to be low.

Therefore, *Pseudomonas migulae* ATCC 39005 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-newsubs/default.asp?lang=En&n=120842D5_1 (viewed June 2020).

Public Health Agency of Canada (2015) Canadian Biosafety Standard (CBS) Second Edition. (viewed June 2020).