

Notification and Assessment under the *Canadian Environmental Protection Act, 1999* of *Pichia* species strain (Q&A summary)

What is it?

- *Pichia* species strain is a genetically modified organism that was constructed from a parental strain isolated from a corn wet milling facility in the United States. The genetic modifications consisted of removing and inserting a number of genes in order to increase the production of succinic acid. The species name is not provided as it has been claimed to be confidential by the proponent, the company BioAmber Inc., and this masked name has been accepted by the Government.
- *Pichia* species strain is considered to be an opportunistic animal and human pathogen as well as a mild plant pest.

How is it used?

- The notified *Pichia* species strain will be used under containment for the production of bio-succinic acid.

Why did the Government of Canada assess it?

- A micro-organism that is not on the *Domestic Substances List* (DSL) and is not subject to federal legislation listed in Schedule 4 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999), is considered “new” and before it is manufactured in or imported into Canada, the Government 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 1999. *Pichia* species strain is not on the DSL.
- The Government of Canada conducted an assessment of *Pichia* species strain because BioAmber Inc. submitted a notification of its intention to import and manufacture this new micro-organism into Canada for use in the production of succinic acid.

How is it released to the environment?

- Environmental releases of the notified *Pichia* species strain are expected to be low because: (i) it will be used only within a contained facility and (ii) waste containing live production strain will be adequately disinfected and sent to a landfill.

How are Canadians exposed to it?

- Based on the intended use, the general population in Canada is not expected to be exposed to *Pichia* species strain.

What are the results of the assessment?

- The Government of Canada has conducted a science-based risk assessment of *Pichia* species strain.
- Risk assessments address potential for harm to the general population in Canada (not including workplace exposures) and the environment.
- Although *Pichia* species strain is known to have the potential to cause disease in immunocompromised individuals and plants, containment measures are in place to prevent the unintentional spread of *Pichia* species strain from the contained facility into the environment.
- *Pichia* species strain is 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 *Pichia* species strain is not entering the environment in a quantity or under conditions that constitute a danger to the environment or humans.
- Failure to adequately treat the waste through inactivation of the *Pichia* species strain, can lead to large quantities of micro-organism being released in the environment that is enough to potentially cause infection in plants, animals and in immuno-compromised individuals.

What is the Government of Canada doing?

- Although exposure of the general Canadian population and of the Canadian environment to *Pichia* species strain is limited, the Government of Canada acted to ensure that remaining uncertainties are resolved and risks will be reassessed before any new use that could result in increased exposure to *Pichia* species strain.
- Therefore, the Government of Canada published a Significant New Activity (SNAC) Notice in the Canada Gazette (SNAC #17329), which requires that any use of *Pichia* species strain other than the production of bio-succinic acid in a contained facility will be notified to the Government so that the new activity can be assessed.