

Application to amend the Australia New Zealand Food Standard Code to permit the use of long-chain glycolipids from *Dacryopinax spathularia* (“Natural Glycolipids”) as a preservative in non-alcoholic beverages

Executive Summary

Date 13/05/2019

This application is submitted by Lanxess Deutschland GmbH in cooperation with Brooke-Taylor & Co Pty Ltd Consultants.

This application seeks an amendment Australia New Zealand Food Standard Code to permit the use of long-chain glycolipids from *Dacryopinax spathularia* (“Natural Glycolipids”) as a preservative in non-alcoholic beverages at use levels ranging from 2 to 100 ppm. Natural Glycolipids” may also be described by its product development name “AM-1”, the descriptive term “Jelly Mushroom Glycolipids” or its Trade Name “Nagardo™”.

Natural Glycolipids (CAS No: 2205009-17-0) is a natural mixture of long chain glycolipids obtained via fermentation of glucose by the edible jelly fungus *Dacryopinax spathularia*, also known as sweet osmanthus ear. The major components of Natural Glycolipids are three structurally-related glycolipid congeners. The producer organism (strain MUCL 53181) is a wild-type strain without any genetic modification (non-GMO).

Natural Glycolipids has prominent antifungal effects against common yeasts and moulds and can be used to prolong shelf life and guarantee the microbiological quality of beverages. When used as food additive in beverages, their use would be required to be declared in the ingredient list by technological function and prescribed name or number as per Standard 1.2.4, thereby ensuring that consumers are informed about their use.

The approval offers benefits to consumer and industry in the form a safe naturally derived preservative in beverages. There are no anticipated costs for consumers, industry or government from the approval of Natural Glycolipids as a preservative for beverages. Natural Glycolipids is recognised as GRAS in the USA and approval in Australia and New Zealand is anticipated to facilitate trade in beverage products with the USA.

Glycolipids are part of the normal human diet with the most abundant sources of glycolipids identified as eggs and dairy products, cereals, and soybeans¹. The fruiting bodies of *Dacryopinax spathularia* are edible and have an established history of safe food use in Asia and Africa².

The Natural Glycolipids production organism *Dacryopinax spathularia* MUCL 53181 was assessed as safe utilizing scientific procedures as outlined by Pariza and Johnson (2001)³ for safety evaluation of microbial enzyme preparations used in food processing.

Natural Glycolipids are poorly absorbed by the oral route and are primarily eliminated in the faeces without absorption. There are no identified target tissues for residence or accumulation. Systemic exposure to Natural Glycolipids or its metabolites would be very limited following oral ingestion. A suite of *in vivo* and *in vitro* toxicity studies indicates no evidence of acute toxicity or mutagenicity. In 90 day studies in rats and dogs and in reproductive and multi-generational development studies in rats, no treatment related adverse effects were observed at the highest doses tested (1000mg/kg bodyweight/day and higher). Furthermore, the highest doses were self-limiting due to the surfactant properties of strong aqueous solutions of Natural Glycolipids.

¹ Leray, C. 2015. Lipids: Nutrition and Health. CRC Press, Taylor & Francis Group. Boca Raton, FL, pp.154-155. ISBN 978-1-4822-4231-7.

² <http://www.fao.org/docrep/018/y5489e/y5489e.pdf>

³ Pariza, M.W. and Johnson, E.A. 2001. Evaluating the safety of microbial enzyme preparations used in food processing: update for a new century. Regul. Toxicol. Pharmacol. 33, 173-186.

The applicant proposes that an ADI of “not specified” is appropriate for Natural Glycolipids. Alternatively, a numerical ADI, a value of 10 mg/kg bodyweight/day, based on the application of a 100 fold safety factor to 1000 mg/kg bodyweight/day, the maximum dose tested in the 90 day oral study in dogs, would be appropriate.

Approval for the use of Natural Glycolipids as a preservative is requested for non-alcoholic beverages, including fruit and vegetable juices and fruit and vegetable juice products, non-alcoholic beverages and brewed soft drinks and non-alcoholic beers, water based flavoured drinks, formulated caffeinated beverages, formulated beverages, and ready to drink teas and similar products.. The maximum level of use requested ranges between 20-100ppm depending of the beverage matrix.

The beverage categories identified above have well established patterns of consumption and It is anticipated that most beverages in the market will continue to use existing preservatives or processing technologies.

As a food additive, its use as a preservative in beverages would be required to be declared in the ingredient list by technological function and prescribed name or number as per Standard 1.2.4. The applicant proposes the use of the Food Additive Number 246 (the same number will also be requested in the EU approval dossier currently in preparation) and the prescribed name “natural glycolipids” (the name to be used in the USA).

Assessment under the general level procedure would be appropriate for this application. The application does not contain Commercial Confidential Information and does not confer an exclusive capturable commercial benefit on the applicant.

There are currently no Codex standards relating to the use of Natural Glycolipids as a food additive preservative, although *Dacryopinax spathularia* is listed in the Food and Agriculture Organization of the United Nations (FAO) compendium on edible mushrooms⁴.

Other than GRAS status in the USA, there are currently no other national standards or regulations approving the use of Natural Glycolipids, although dossiers for approval in the EU and Canada are in preparation.

⁴ <http://www.fao.org/docrep/018/y5489e/y5489e.pdf>