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APPLICATION – EXECUTIVE SUMMARY

SEPTEMBER 2018

TO:
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

IN RELATION TO:
APPLICATION FOR APPROVAL OF ENDO-INULINASE FROM A GENETICALLY MODIFIED STRAIN OF *ASPERGILLUS ORYZAE* AS A PROCESSING AID

EXECUTIVE SUMMARY

(As per section 3.1.1 A.2 of the Application Handbook 1 March 2016)

Purpose

Puratos is making this application to amend Schedule 18 – Processing Aids, of the Australia New Zealand Food Standards Code (hereafter the Code) to include the food enzyme endo-inulinase (EC 3.2.1.7) cloned in *Aspergillus oryzae* MUCL 44346 in S18-9(3) Permitted Enzymes.

The food enzyme shows inulinase activity as defined under IUBMB No EC 3.2.1.7 and is used as a processing aid in the production of fructo-oligosaccharides (FOS).

Approval is required of the enzyme as a processing aid as it is not currently approved for use in Australia and New Zealand.

Endo-inulinase does not perform any technological function in the final foods containing ingredients prepared with this enzyme. Moreover, the food products prepared with endo-inulinase do not have characteristics or nutritional value other than what is expected by the consumer.

Uses of the Food Enzyme in Food Production

Like any other enzyme, endo-inulinase acts as a biocatalyst - with the help of the enzyme, a certain substrate is converted into a certain reaction product.

The **function** of endo-inulinase is to catalyse the endohydrolysis of (2→1)-β-D-fructosidic linkages in inulin.

In general, the technological need for the enzymatic conversion of inulin with the help of endo-inulinase can be described as the production of FOS as a sugar alternative for sucrose.

The **substrate** for endo-inulinase is inulin. Inulin is polysaccharides composed of fructose unit chains of various length terminated by a single glucose unit, which can be found in Jerusalem artichoke and chicory (*Zittan 1981*). Consequently, the substrate for endo-inulinase occurs naturally in foods.

The **reaction product** of the hydrolysis of inulin with the help of endo-inulinase is a syrup of FOS.

Endo-inulinase performs its technological function during FOS production. The enzyme does not perform any technological function in the final food.

Production Method

The food enzyme object of this dossier is produced by fermentation of the microorganism *Aspergillus oryzae* in pure culture. No foreign microorganisms are allowed to develop during the enzyme manufacturing process.

Aspergillus oryzae has been used for decades for the production of food enzymes.

During the fermentation, run in closed vessels, the microorganism is provided with nutrients, water and aeration. It develops and produces the food enzyme.

After the fermentation is over, the microorganism is eliminated from the liquid broth containing the food enzyme. This broth is partially purified and concentrated, to maximize the enzyme contents.

The concentrate is then mixed with other ingredients, in order to stabilize it during storage, transportation and facilitate its use in food processing after standardisation of the commercial preparations.

The food enzyme preparation complies with international specifications (JECFA), ensuring absence of contamination by toxic substances or noxious microorganisms.

The enzyme is manufactured according to good manufacturing practices (GMP) and the principals of HACCP. When manufactured in the EU, it is also subject to Regulation (EC) No 852/2004 -Food Hygiene Regulation.

A HACCP plan is applied to the production of the enzyme to manage all potential risks that may come from fermentation**.**

Existing Authorizations of the Food Enzyme

The food enzyme endo-inulinase has been evaluated and/or authorized in the USA. Moreover, the food enzyme endo-inulinase has been submitted for evaluation to the JECFA and has been legally produced and used in the EU, where it has also been submitted for evaluation to the EFSA.

Toxicological Studies

The food enzyme object of the present application was subjected to several toxicological studies to confirm its safety for consumers. The mutagenicity studies supported that the food enzyme does not have the potential to damage the genetic material of living organisms, including mammals. The oral toxicity study showed that the food enzyme does not exhibit signs of toxicity, up to doses that are many times higher than those which are consumed via food.

Conclusions on the Safety of the Food Enzyme

Based on the safety of the production microorganism, on the toxicological studies, and on previous evaluations by official experts, it is concluded that the food enzyme object of this application is safe for its intended uses.