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APPLICATION – EXECUTIVE SUMMARY

DECEMBER 2015

TO:
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

IN RELATION TO:
APPLICATION FOR APPROVAL OF ENDOβ(1-4) XYLANASE FROM A GENETICALLY MODIFIED STRAIN OF BACILLUS SUBTILIS LMG S-24584 AS A PROCESSING AID

EXECUTIVE SUMMARY

(As per section 3.1.1B of the Application Handbook 1 September 2013)

Purpose

The purpose of this Application is to amend Schedule 18 – Processing Aids, of the Australia New Zealand Food Standards Code (hereafter the Code) to include the food enzyme endo β(1,4) xylanase (EC 3.1.2.8) from *Bacillus subtilis* containing the gene for endo β(1,4) xylanase from *Pseudoalteromonas haloplanktis* in 18-4 Permitted Enzymes.

Approval is required due to the use of a genetically modified source microorganism for the preparation of the enzyme.

Endo β(1-4) xylanase does not perform any technological function in the final foods containing ingredients prepared with this enzyme. Moreover, the food products prepared with endo β(1-4) xylanase do not have characteristics or nutritional value other than what is expected by the consumer.

Uses of the Food Enzyme in Food Production

The food enzyme endo β(1,4) xylanase is used as a processing aid in the manufacture of baked cereal products such as bread, biscuits and cakes. The use of this endo β(1-4) xylanase from *Pseudoalteromonas haloplanktis* provides improved effectiveness under typical production conditions for bakery manufacturers.

The food enzyme catalyses, i.e. accelerates, the conversion of substrate arabinoxylan into products arabinoxylan oligosaccharides. Endoβ(1-4) xylanase is present in many cereal based raw materials and ingredients, and therefore the food enzyme is typically used in the baking food processes.

The transformation of substrate arabinoxylans provides the following benefits, of interest during baking processing:

- Facilitate the handling of the dough (improved extensibility and stability; less stickiness leading to reduced loss of dough)
- Improve the dough's structure and behaviour during the baking step
- Ensure a uniform volume and an improved crumb structure of the bakery product, which might otherwise be impaired by processing of the dough
- Reduce batter viscosity, beneficial in the production process for e.g. waffles, pancakes and biscuits

The food enzyme is denatured before the end of the food manufacturing process, therefore it cannot have any technological function in final foods.

Production Method

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

Bacillus Subtilis has been used for decades for the production of food enzymes.

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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 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (Food Hygiene Regulation (852/2004)).

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

Existing Authorizations of the Food Enzyme

The food enzyme object of the present dossier has been evaluated and authorized in France, Brazil, the USA, Canada and the EU.

Toxicological Studies

The food enzyme object of the present dossier 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 several 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 dossier is safe in its intended uses.