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APPLICATION – EXECUTIVE SUMMARY

APRIL 2016

TO:
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

IN RELATION TO:
APPLICATION FOR APPROVAL OF PROTEASE AQUALYSIN 1 FROM A GENETICALLY MODIFIED STRAIN OF BACILLUS SUBTILIS 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 Aqualysin 1 protease (EC 3.4.21.111) (hereafter Aqualysin 1) from *Bacillus subtilis* containing a protease gene from *Thermus aquaticus* in S18-4 Permitted Enzymes.

The food enzyme Aqualysin 1 is used as a processing aid in the manufacture of bakery products such as, but not limited to, bread, biscuits, steamed bread, cakes, pancakes, tortillas, wafers and waffles. Proteins provide functional properties during manufacture due to their ability to influence the dough's elasticity, plasticity and extensibility. Limited hydrolysis of the peptide bonds in gluten proteins with the help of proteases results in improved process ability which enhances the functional baking properties of these compounds.

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

Aqualysin 1 does not perform any technological function in the final foods containing ingredients prepared with this enzyme. Moreover, the food products prepared with Aqualysin 1 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 is used as a processing aid in the manufacture of baked cereal products such as bread, biscuits and cakes. The use of Aqualysin 1 from *Thermus aquaticus* cloned in *Bacillus subtillis* is the prevention or retardation of staling during the baking process. Bread staling is a complex phenomenon. It is perceived as a softening of the crust, a hardening of the crumb and the disappearance of fresh bread flavour.

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.

Proteases have a long history of use in the bakery sector. The benefits of the use of Aqualysin 1 in baking processes may include:

- Faster dough development upon mixing;
- Better dough machinability;
- Reduced dough rigidness which results in processing tolerance;
- Improved dough's structure and extensibility during the shaping or moulding step;
- Uniform shape of the bakery product, which might otherwise be impaired by processing of the dough;
- Regular batter viscosity, beneficial in the production process for e.g. waffles, pancakes and biscuits; and

- Improved short-bite of certain products like hamburger breads.

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.

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 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 Canada, France, and the USA.

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 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 dossier is safe in its intended uses.