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Tēnā koe

Attached are the comments that the New Zealand Food and Grocery Council wishes to present on the *Call for submissions – Application A1275: Transglutaminase from GM* Bacillus licheniformis *as a processing aid.*

Ngā mihi nui

[redacted]

[redacted]

Call for submissions: Application A1275 – Transglutaminase from GM *Bacillus licheniformis* as a processing aid

Submission by the New Zealand Food and Grocery Council

20 November 2023

NEW ZEALAND FOOD AND GROCERY COUNCIL

1. The New Zealand Food and Grocery Council (**NZFGC**) welcomes the opportunity to comment on the *Call for submissions – Application A1275: Transglutaminase from GM* Bacillus licheniformis *as a processing aid.*

2. NZFGC represents the major manufacturers and suppliers of food, beverage and grocery products in New Zealand. This sector generates over $40 billion in the New Zealand domestic retail food, beverage and grocery products market, and over $34 billion in export revenue from exports to 195 countries – representing 65% of total good and services exports. Food and beverage manufacturing is the largest manufacturing sector in New Zealand, representing 45% of total manufacturing income. Our members directly or indirectly employ more than 493,000 people – one in five of the workforce.

THE APPLICATION

3. Novozymes Australia has applied to Food Standards Australia New Zealand (**FSANZ**) to amend the Australia New Zealand Food Standards Code (the **Food Standards Code**) to permit the use of the enzyme transglutaminase (EC 2.3.2.13) as a processing aid. The enzyme is intended for use in brewing and in the manufacture and/or processing of: bakery and other cereal-based products such as pasta and noodles, cheese, fermented dairy products, egg substitutes, and a range of protein analogues. The enzyme is produced from genetically modified (GM) *Bacillus licheniformis (**B. licheniformis**)* as the host species containing the transglutaminase gene from *Streptomyces mobaraensis,* the donor for the gene.

COMMENTS

Assessment by FSANZ

4. FSANZ addressed health and safety concerns in its risk assessment covering:
   - technological purpose
   - a characterisation of the genetic modification
   - safety of the transglutaminase enzyme including toxicological status and allergenicity
   - international assessments
   - dietary exposure assessment.

5. In relation to technological purpose, FSANZ concluded that the evidence presented by Novozymes to support its proposed use provided adequate assurance that the use of the enzyme, in the quantity and form proposed (which must be consistent with good manufacturing practice), was technologically justified and had been demonstrated to be effective in achieving its stated purpose.

6. NZFGC is aware that *B*. *licheniformis* is widely used in food-grade enzyme production and a number of food processing aids (both GM and non-GM). It has been previously assessed for safety by FSANZ in food processing aids, serine proteinase (A1098), subtilisin (A1206), Alpha-amylase (A1219), and Beta-amylase (A1220). FSANZ's assessment confirmed the inserted gene was integrated into the genome of the production strain and did not have the ability to replicate autonomously meaning the inserted gene was considered to be genetically stable. Additional data provided by Novozymes also confirmed the transglutaminase gene was expressed over multiple generations and was stable in this process.

7. Transglutaminases have been used in food processing since the 1990s and have a long history of safe use in a range of countries. FSANZ did not identify any reports of adverse

effects arising from the consumption of transglutaminase from *S. mobaraensis*, when used as a processing aid.

8. Toxicity studies conducted with the transglutaminase that is the subject of A1275 included a 13-week repeated-dose dietary study in rats, and two genotoxicity studies; a bacterial reverse mutation assay (Ames test) and an *in vitro* micronucleus assay. transglutaminase was well tolerated with no evidence of any adverse findings at any of the administered concentrations, transglutaminase showed no evidence of mutagenic activity under the conditions of the assay conducted and oral intake of transglutaminase is not anticipated to pose any food allergy concern.

9. While there were no known safety assessments by other regulatory agencies, the Danish Veterinary and Food Administration had issued a certificate that the enzyme was fit for human consumption and could be placed on the EU market without restriction.

10. Both the FSANZ and Novozyme's estimates of the theoretical maximum daily intake (**TMDI**) were overestimates of the dietary exposure. In these, the enzyme was either denatured by the processing it was exposed to by the manufacturer or, where the enzyme was not denatured by heat or removed, the substrate was depleted or the conditions, such as pH, had changed which meant that the enzyme would be inert. In both cases there was no issue with TMDI.

11. Novosyme provided details of searches it had undertaken up to 2021 for amino acid sequence homology of the transglutaminase enzyme to known allergens, using the AllergenOnline database, and four sequence alignments. No homology to sequences of known allergens was identified using these search parameters and it was concluded that oral intake of transglutaminase was not anticipated to pose any food allergy concern.

12. On the basis of the foregoing assessments by FSANZ, NZFGC supports the variation to the Food Standards Code as drafted. This will permit transglutaminase from GM *B. licheniformis* as a processing aid to be used in the Australia-New Zealand food supply but not require any labelling on the final product that it might be used in.

13. Having more processing aid options available for manufacturers is beneficial to both production and innovation in product development.