8 September 2021

Project Manager
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NEW ZEALAND

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Dear Sir/Madam

Attached are the comments that the New Zealand Food & Grocery Council wishes to present on the *Call for submissions – Application A1211: Maltogenic alpha-amylase enzyme from GM* Bacillus licheniformis.

Yours sincerely

[redacted]

[redacted]

[redacted]

Call for submissions – Application A1211: Maltogenic alpha-amylase enzyme from GM *Bacillus licheniformis*

Submission by the New Zealand Food & Grocery Council

8 September 2021

NEW ZEALAND FOOD & GROCERY COUNCIL

1. The New Zealand Food & Grocery Council ("NZFGC") welcomes the opportunity to comment on the "*Call for submissions – Application A1211: Maltogenic alpha-amylase enzyme from GM* Bacillus licheniformis"*.*

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. Danisco New Zealand made the application on behalf of DuPont Nutrition & Biosciences for approval for a "Maltogenic α-amylase (EC 3.2.1.133)" enzyme. The enzyme is proposed for use as processing aid in bakery, potable alcohol, brewing and starch processing applications. The enzyme is derived from a selected non-pathogenic, non-toxigenic strain of *Bacillus licheniformis* (*B. licheniformis*) which is genetically modified to express the α-amylase gene from *Geobacillus stearothermophilus* (*G. stearothermophilus*)*.*

4. The enzyme is intended for use in baking, potable alcohol, brewing and starch processing. In these applications, maltogenic α-amylase will be used as a processing aid where the enzyme is either not present in the final food or present in insignificant quantities having no function or technical effect in the final food.

COMMENTS

5. This Application follows an earlier one from this year, Application A1210, which was made by a different company also for a maltogenic α-amylase (EC 3.2.1.133) enzyme but derived from a genetically modified strain of *Bacillus subtilis*. In our view, any issues would be the same or so similar as to have benefitted from a joined up assessment had such a facility been available under the *Food Standards Australia New Zealand Act 1981*. Such an approach would have greatly streamlined the process.

6. From the Food Standards Australia New Zealand (FSANZ) assessment report we understand that:
   - maltogenic α-amylase from *B. licheniformis* (the enzyme) is genetically modified to express the α-amylase gene from *G. stearothermophilus*
   - the enzyme is used in the manufacture of bakery products, potable alcohol, brewing and in starch processing applications
   - the enzyme is not intended to perform a function in these products at the point of sale
     - this qualifies it for use as a processing aid
   - both *B. licheniformis* and *G. stearothermophilus* have a history of safe use for the production of food enzymes
   - the Australia New Zealand Food Standards Code (the Food Standards Code) permits maltogenic α-amylase derived from a genetically modified strain of *Bacillus subtilis* to be used as a processing aid in the manufacture of all foods.

7. The FSANZ safety assessment covered:
   - a microbiological assessment that concluded that the host strain has a recognised safe history of use, is neither pathogenic nor toxigenic

- a biotechnology assessment found the production strain was safe.
- a food technology assessment confirmed the enzyme achieves its stated purpose and meets international purity specifications
- a toxicological assessment combined with a dietary exposure assessment found the use of the enzyme was safe and it had no similarity known toxins.

8. FSANZ concluded there were no safety concerns associated with the use of maltogenic α-amylase produced by microbial fermentation as a processing aid.

9. In terms of international precedent, this enzyme has received Generally Recognised as Safe (GRAS) approval from the US Food and Drug Administration (FDA). It is also approved in Denmark, Singapore and Brazil and applications to seek approval for its use in the EU and Canada are underway.

10. There are no 'genetically modified' labelling requirements for use of this enzyme when used as a processing aid in the production of food.

11. In light of the foregoing and FSANZ's conclusion that there were no public health and safety issues associated with the use of maltogenic α-amylase from *B. licheniformis* as genetically modified to express the α-amylase gene from *G. stearothermophilus*, NZFGC supports Application A1211.