22 March 2023

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 A1228: Endo-1,4-beta-xylanase from GM* Trichoderma reesei *(gene donor:* Talaromyces leycettanus*) as a processing aid*.

Yours sincerely

[redacted]

[redacted]

[redacted]

Call for submissions – Application A1228: Endo-1,4-beta-xylanase from GM *Trichoderma reesei* (gene donor: *Talaromyces leycettanus*) as a processing aid.

Submission by the New Zealand Food & Grocery Council

22 March 2023

NEW ZEALAND FOOD & GROCERY COUNCIL

1. The New Zealand Food & Grocery Council ("NZFGC") welcomes the opportunity to comment on the *Call for submissions – Application A1228: Endo-1,4-beta-xylanase from GM* Trichoderma reesei *(gene donor:* Talaromyces leycettanus*) 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 has applied for an amendment to Schedule 18 of the *Australia New Zealand Food Standards Code* (**the Food Standards Code**) to allow an enzyme obtained from a GM strain of *Trichoderma reesei* (***T. reesei***) for use in the brewing, fats and oils processing, grain processing and potable alcohol production. *T. reesei* expresses a xylanase gene from *Talaromyces leycettanus (**T. leycenttanus**).* A processing aid performs a technological purpose during processing/manufacture but does not remain or appear in the final food.

COMMENTS

Assessment by FSANZ

4. ***Food Technology assessment*** – FSANZ assesses the identity and purity of all additives and processing aids intended for use in the food supply. In this case, the substance is endo-1,4-beta-xylanase from GM *T. reesei* (gene donor: *T. leycettanus)*. FSANZ verified its identity with the International Union of Biochemistry and Molecular Biology (IUBMB). IUBMB material is compiled at the University of London and makes recommendations on biochemical and organic nomenclature, symbols and terminology drawing on the expertise of global experts in the relevant field.

5. FSANZ also noted that there were relevant identity and purity specifications for the enzyme in two of the primary sources of specifications listed in Schedule 3, namely the JECFA Combined Compendium of Food Additive Specifications and the United States Pharmacopeial Convention Food chemicals codex.

6. FSANZ's conclusion was that the enzyme provided the consistency and production efficiency in manufacturing and processing of the target foods. It was therefore technologically justified in the form proposed for use in brewing, fats and oils processing, grain processing and potable alcohol production.

7. ***Safety Assessment*** – FSANZ assesses any history of use of the processing aid, its characteristics (in this case, the characterisation of the genetic modification) and the overall safety of the processing aid.

8. *T. reesei* fungus has been used in food processing since the 1980s. It is not considered pathogenic to humans. The genetic modification has a history of development and application from the early 1990s. The overall safety is focussed on any adverse health effects resulting from toxicity, anti-nutrient properties or allergenicity.

9. FSANZ addressed health and safety concerns in its risk assessment noting that:

- Endo-1,4-beta-xylanase produced using GM *T. reesei* has a history of safe use in many countries and this particular product is approved for use in Denmark, Brazil and Mexico.
- The production strain, *T. reesei*, is non-toxigenic and non-pathogenic and has been shown to be non-genotoxic
- The final enzyme product is purified so that *T. reesei* is no longer present.
- In any case as noted above, *T. reesei* is a commonly used production strain for enzymes which are already approved for use in the Food Standards Code (at least ten).

10. FSANZ concluded there were no public health and safety concerns associated with the use of endo-1,4-beta-xylanase from a GM strain of *T. reesei* which contains the xylanase gene from *T. leycenttanus.*

11. ***NZFGC Conclusion*** – On the basis of the foregoing, NZFGC supports the amendment to Schedule 18—9(3) of the Food Standards Code that would see endo-1,4-beta-xylanase from *T. reesei* containing the endo-1,4-beta-xylanase gene from *Talaromyces leycettanus* approved for use as a processing aid.