

17 March 2017

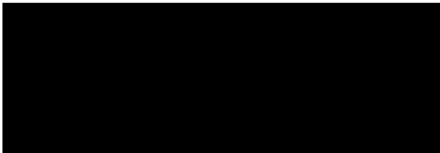
Food Standards Australia New Zealand  
PO Box 10559  
The Terrace  
WELLINGTON 6143

Email: [standards.management@foodstandards.gov.au](mailto:standards.management@foodstandards.gov.au)

Dear Sir/Madam

Attached are the comments that the New Zealand Food & Grocery Council wishes to present on the ***Call for Submissions – Application A1135: Beta-galactosidase as a Processing Aid (Enzyme)***.

Yours sincerely



Katherine Rich  
**Chief Executive**



***Call for Submissions – Application A1135:  
Beta-galactosidase as a Processing Aid  
(Enzyme)***

**Submission by the New Zealand Food & Grocery Council**

**17 March 2017**

---

## NEW ZEALAND FOOD & GROCERY COUNCIL

1. The New Zealand Food & Grocery Council ("NZFGC") welcomes the opportunity to comment on the **Call for Submissions – Application A1135: Beta-galactosidase as a Processing Aid (Enzyme)**.
2. NZFGC represents the major manufacturers and suppliers of food, beverage and grocery products in New Zealand. This sector generates over \$34 billion in the New Zealand domestic retail food, beverage and grocery products market, and over \$31 billion in export revenue from exports to 195 countries – some 72% of total merchandise exports. Food and beverage manufacturing is the largest manufacturing sector in New Zealand, representing 44% of total manufacturing income. Our members directly or indirectly employ more than 400,000 people – one in five of the workforce.

### OVERARCHING COMMENTS

3. NZFGC supports the approval of an amendment to Schedule 18 of the Australia New Zealand Food Standards Code (the Food Standards Code) to include the new source for the enzyme  $\beta$ -galactosidase (lactase) from the genetically modified strain of *Bacillus licheniformis* as a processing aid.
4. The food processing aid that is subject to the Application A1135 known as  $\beta$ -galactosidase (lactase) from the genetically modified strain of *Bacillus licheniformis* is approved for use in Denmark, the USA and Mexico and applications are pending in France and Brazil. Both  $\beta$ -galactosidase from other sources and *B. licheniformis* as a source for other enzymes have been approved for inclusion in the Food Standards Code in the past.
5. FSANZ's technological and risk assessments of the  $\beta$ -galactosidase from *B. licheniformis* application did not identify any issues of concern.
6. NZFGC considers that  $\beta$ -galactosidase from *B. licheniformis* will add choice to the manufacture of milk products such as milk, yoghurt, cream and ice cream for the benefit of New Zealand consumers.

### SPECIFIC COMMENTS

#### Current Permissions for a beta-galactosidase enzyme preparation

7. The specific lactase preparation being sought for inclusion in the Food Standards Code has been approved in Denmark, the USA and Mexico and applications from the same applicant are pending in France and Brazil. The preparation has also been submitted to the Joint FAO/WHO Expert Committee on Food Additives (JECFA) for inclusion in the Codex General Standard for Food Additives.
8. FSANZ has previously assessed and approved  $\beta$ -galactosidase from other microbial sources and has approved other enzymes using *B. licheniformis* as a source.

#### The Application

9. The application from Novozymes A/S, Denmark, seeks to amend the Food Standards Code to approve a genetically modified strain of *Bacillus licheniformis* as a new source for the enzyme  $\beta$ -galactosidase (lactase) as a processing aid. The product is used as a processing aid during the manufacture of milk and other lactose containing products e.g. milk, yogurt, cream and ice cream. Lactase converts lactose to glucose and galactose helping to produce lactose free or lactose reduced milk/dairy products.

---

## **Risk assessment**

10. The FSANZ risk and technology assessment was conducted to evaluate the safety of this new food processing aid.

### *Technology Assessment*

11. The technology assessment considered a range of food technology issues: identity, enzymatic and physical properties, product specification and production of the enzyme and technological function.
12. The conclusion was that the  $\beta$ -galactosidase (lactase) preparation was a suitable additional, alternative or replacement enzyme for lactase production. Its use is technologically justified and the manufacturing process appropriate.
13. NZFGC notes that *B. licheniformis* is generally considered to be a safe production organism with a long history of safe use for food ingredients.

### *Hazard Assessment*

The hazard assessment considered the safe use in food production processes, the hazard of the encoded protein, including potential allergenicity and toxicity, and toxicity studies (including mutagenicity) on the enzyme.

14. FSANZ concluded that *B. licheniformis* was a safe source of lactase. This conclusion was based on:
- The production organism *B. licheniformis* is not toxigenic, pathogenic or sporogenic
  - *B. licheniformis* is absent in the final enzyme preparation proposed to be used as a food processing aid.
  - *B. licheniformis* has a history of safe use as the production organism for a number of enzyme processing aids that are already permitted in the Food Standards Code.
  - Residual enzyme is expected to be present in the final food product but would be inactivated by heat-treatment or pasteurisation, or non-active because of lack of lactose, and susceptible to digestion like any other dietary protein.
  - The enzyme preparation caused no observable effects at the highest tested doses in a 90-day toxicity study in rats. The NOAEL was 0.672 g enzyme solid/kg bw/d, the highest dose tested.
  - The enzyme preparation was not mutagenic *in vitro*.

Based on the reviewed toxicological data, it was concluded that, in the absence of any identifiable hazard, an Acceptable Daily Intake 'not specified' would be appropriate. A dietary exposure assessment was therefore not required.

## **Benefits of lactase**

15. The enzyme  $\beta$ -galactosidase can be obtained from a wide variety of sources such as microorganisms, plants, and animals. There are several benefits associated with the use of  $\beta$ -galactosidase for the hydrolysis of lactose in milk and whey and it is one of the promising enzymatic applications in food and dairy processing industries. The production of lactose-reduced products including that they are easier and safer to digest for lactose-intolerant individuals and lactase results in the production of sweeter dairy products due to glucose and galactose formation so that less sugar is needed to obtain the wanted product sweetness (lower calories/kilojoules).

---

## Conclusions

16. In light of the risk and technology assessments, the approvals overseas, the existing approvals for both lactase from other sources and the *B. licheniformis* approvals, NZFGC supports the approval of this new source of the  $\beta$ -galactosidase enzyme preparation. We consider that it will add choice to manufacturers of milk products for the benefit of all consumers but particularly the lactose intolerant.