

**Comments from the Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport & Resources**

**Due date of submission – 17 March 2017**

The Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources (the departments) welcome the opportunity to provide comments on Application A1135 – beta-galactosidase as a processing aid (enzyme).

From the FSANZ assessment report it is understood that:

- The purpose of the application is to permit the use of the enzyme beta-galactosidase (lactase) as a processing aid for use in the preparation of reduced-lactose or lactose-free milk and dairy products.
- Beta-galactosidase converts the milk sugar lactose into primarily glucose and galactose, which may improve the taste and flavour of products, reduce the use of added sugars and improve digestibility.
- Beta-galactosidase is produced by a genetically modified (GM) strain of *Bacillus licheniformis*. GM *Bacillus licheniformis* is used for the production of other enzymes permitted in the Code.
- The use of the enzyme is technologically justified.
- FSANZ's risk assessment conclusions provide evidence that there are no safety risks from the use of the enzyme as a processing aid.
- The purification process removes all novel DNA from the enzyme preparation. In addition, following the cleavage of the signal peptide from the secreted lactase protein, the enzyme has an amino acid sequence that is found in nature. For these reasons, this processing aid is not required to be labelled genetically modified in accordance with Standard 1.5.2 of the Code.
- The use of beta-galactosidase from *Bacillus licheniformis* is currently undergoing registration in various international jurisdictions. The enzyme preparation has been approved in Denmark and Mexico and the applicant's determination that the enzyme preparation is GRAS has been acknowledged by the USFDA.

On the basis of this understanding, the departments support the progression of the Application.