

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

**Due date of submission – 31 August 2017**

The Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources (the departments) welcome the opportunity to respond to this application to amend the Australia New Zealand Food Standards Code (the Code).

The Application A1131 – Aqualysin 1 (Protease) as a Processing Aid (Enzyme) has been submitted by Puratos NV, and seeks permission to use an enzyme (Aqualysin 1) produced and purified from a genetically modified (GM) strain of *Bacillus subtilis*.

From the Food Standards Australia New Zealand Assessment report and the documentation provided by Puratos NV it is understood that:

- The purpose of the enzyme is to hydrolyse proteins in flour to improve the characteristics of dough used for baked goods and other unbaked cereal goods including pasta, noodles and snack foods.
- The enzyme, Aqualysin 1 occurs naturally in the thermophilic bacteria *Thermus aquaticus*. As it is less active at process conditions it is more readily controlled in baking processes.
- The enzyme is inactivated during baking, and thus meets the requirements of a processing aid under the Code<sup>1</sup>.
- The genetic modification of *B. subtilis* involves the chromosomal integration of the protease gene from *T. aquaticus* in an expression cassette containing only:
  - a promotor from the host organism
  - a peptide signal which is removed from the enzyme when released from the producing cell
  - the *T. aquaticus* enzyme gene sequence; and
  - a *T. aquaticus* termination signal.
- The GM *B. subtilis* has been shown to stably maintain the modification, and the enzyme-producing strain contains several copies of the gene.
- The enzyme preparation has been approved for use in France, Canada and the United States of America.
- *B. subtilis*, in both GM and non-GM forms, has a long history of safe use as a production strain for food grade enzymes.
- There would be no GM labelling requirements for foods associated with the use of this enzyme as no novel DNA or protein would be present in those foods.

The departments acknowledge that no toxicity or allergenicity concerns were raised by FSANZ in its safety assessment of this Application.

On this basis, the departments support the progression of Application A1131.

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<sup>1</sup> 'a substance that is used as a processing aid in relation to a food is a reference to a substance that is used during the course of processing:

- (a) to perform a technological purpose in the course of processing; and
- (b) does not perform a technological purpose in the food for sale '