



6 August 2020
[131-20]

Administrative Assessment Report – Application A1206

Subtilisin from GM *Bacillus licheniformis* as a processing aid (enzyme)

Date received: 11 June 2020 Date due for completion of administrative assessment: 02 July 2020 Date completed: 2 July 2020		
Applicant: Novozymes Australia Pty Ltd		Potentially affected standards: Standard 1.3.1 Schedule 18
Brief description of Application: To permit the use of subtilisin from a genetically modified strain of <i>Bacillus licheniformis</i> containing the subtilisin gene from <i>Pyrococcus furiosus</i> , as a processing aid in the production of potable alcohol.		
Procedure: General Level 1	Estimated total variable hours: Maximum 240 Reasons why: Seeking permission for a new GM microbial gene source for a permitted enzyme as a processing aid.	Provisional estimated start work: July 2021

Decision

Application accepted Date: 2 July 2020

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Has the Applicant requested confidential commercial information status?

Yes

What documents are affected?

Appendix 6

Has the Applicant provided justification for confidential commercial information request?

Yes

Has the Applicant sought special consideration e.g. novel food exclusivity, two separate applications which need to be progressed together?

No

Charges

Does FSANZ consider that the application confers an exclusive capturable commercial benefit on the Applicant?

No

Does the Applicant want to expedite consideration of this Application?

Not known

Application Handbook requirements

Which Guidelines within Part 3 of the *Application Handbook* apply to this Application?

3.1.1, 3.3.2

Is the checklist completed?

Yes

Does the Application meet the requirements of the relevant Guidelines?

Yes

Does the Application relate to a matter that may be developed as a food regulatory measure, or that warrants a variation of a food regulatory measure?

Yes

Is the Application so similar to a previous application or proposal for the development or variation of a food regulatory measure that it should not be accepted?

No

Did the Applicant identify the Procedure that, in their view, applies to the consideration of this Application?

Yes

Indicate which Procedure:

General

Other Comments or Relevant Matters:

Nil

Consultation & assessment timeframe

Proposed length of public consultation period:

6 weeks

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Proposed timeframe for assessment:

9 months

'Early Bird Notification' due: 6 August 2020

General Procedure:

Commence assessment (clock start)	early July 2021
Completion of assessment & preparation of draft food reg measure	early November 2021
Public comment	mid November – end December 2021
Board to complete approval	early April 2022
Notification to Forum	mid April 2022
Anticipated gazettal if no review requested	mid June 2022