

27 April 2022

197-22

Administrative Assessment Report – Application A1250

Pullulanase from *Bacillus subtilis*

1. Application details

<p>Date received: 13 January 2022 Date due for completion of administrative assessment: Thursday 3 Feb 2022 Date completed: 26 January 2022</p>		
<p>Applicant: Novozymes.</p>		<p>Potentially affected standard: Schedule 18</p>
<p>Brief description of Application: To permit pullulanase sourced from a genetically modified strain of <i>Bacillus subtilis</i> containing the pullulanase gene from <i>Bacillus deramificans</i>, as a processing aid in starch processing for the production of glucose syrups and other starch hydrolysates.</p>		
<p>Procedure: General</p>	<p>Estimated total variable hours: 240 hours</p> <p>Reasons why: It will involve an assessment of relatively minor complexity, since it is assessing a new GM source microorganism for an already permitted enzyme.</p>	<p>Estimated start date: February 2023</p>

2. Decision

<p>Application accepted / Application rejected</p> <p>Date: 2 February 2022</p>

3. Additional matters

Has the Applicant requested information in the application is confidential commercial information (CCI) or confidential?

Yes, CCI

What documents are affected?

Various documents detailing information on the raw materials used in production of the enzyme preparation and construction and characteristics of the genetically modified production strain.

Has the Applicant provided redacted copies of documents containing CCI (i.e. CCI version and non CCI version and non CCI executive summary)?

Yes

Has the Applicant provided justification for why information is CCI or confidential?

Yes

4. Charges

The FSANZ Act provides that a charge must be imposed if the application confers an exclusive capturable commercial benefit (ECCB) on the Applicant.

Does FSANZ consider that the application confers an ECCB on the Applicant?

No

If the application does not confer an ECCB on the applicant, the FSANZ Act provides that an applicant can choose to pay a charge to expedite assessment of their application.

Does the Applicant want to expedite assessment (i.e. pay) for this Application?

Not known

5. Assessment against FSANZ Act 1991 requirements

Subsection 26(2)

(b) 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

(c) 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

(d) Are there any other matters relevant to the decision whether to accept or reject the application?

No

Does the application meet each of the following criteria required by subsection 22(2)?

(a) The application is in writing

Yes

(b) The application is in the form specified in guideline 3.1.1 of the Application Handbook

Yes

(c) The application includes all information and each thing that the section 23 guidelines of the Act state must be included in such an application.

Yes

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

Yes

Indicate which Procedure:

General, Level 1

Other Comments or Relevant Matters:

Nil

6. Consultation & assessment timeframe

Proposed length of public consultation periods:

6 weeks

Proposed timeframe for assessment

Minor Procedure:

Commence assessment (clock start)	Early Feb 2023
Comment from Applicant, Govt Agencies and Interested Parties	Early July – Mid Aug 2023
Board to complete approval	Late-Oct 2023
Notification to Food Ministers' Meeting	Early Nov 2023
Anticipated gazettal if no review requested	Early Jan 2024

