

19 November 2021

180-21

Administrative Assessment Report –Application A1240

Polygalacturonase enzyme from GM *Aspergillus oryzae*

1. Application details

<p>Date received: 24 September 2021 Date due for completion of administrative assessment: 18 October 2021 Date completed:</p>		
<p>Applicant: AB Enzymes GmbH</p>		<p>Potentially affected Schedule 18</p>
<p>Brief description of Application: To permit polygalacturonase from a genetically modified strain of <i>Aspergillus oryzae</i> containing the polygalacturonase gene from <i>Aspergillus tubingensis</i>, as a processing aid in the manufacture of fruit and vegetable juices/products, coffee processing, flavouring production, and wine production.</p>		
<p>Procedure: General Level 1</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 source microorganism of an already permitted enzyme</p>	<p>Estimated start date: mid-October 2022</p>

2. Decision

<p>Application accepted</p> <p>Date: 14 October 2021</p>

3. Additional matters

<p>Has the Applicant requested information in the application is confidential commercial information (CCI) or confidential? Yes CCI and confidential.</p> <p>What documents are affected? 'Appendix CCI' and associated appendices 1 – 13 and documents, plus country permission documents (France and Denmark) as other confidential information.</p> <p>Has the Applicant provided redacted copies of documents containing CCI (i.e. CCI version and non CCI version and non CCI executive summary)? Yes</p> <p>Has the Applicant provided justification for why information is CCI or confidential? Yes</p>
<p>Has the Applicant sought special consideration e.g. novel food exclusivity, two separate applications which need to be progressed together? No</p>

4. Charges

<p>Does FSANZ consider that the application confers an exclusive capturable commercial benefit (ECCB) on the Applicant? No</p>
<p>Does the Applicant want to expedite assessment (i.e. pay) for this Application? Yes</p>

5. Assessment against FSANZ Act 1991 requirements

<p>Subsection 26(2)</p>
<p>(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</p>
<p>(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</p>
<p>(d) Are there any other matters relevant to the decision whether to accept or reject the application? No</p>

<p>Does the application meet each of the following criteria required by subsection 22(2)?</p>
<p>(a) The application is in writing Yes</p>
<p>(b) The application is in the form specified in guideline 3.1.1 of the Application Handbook Yes</p>
<p>(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 3.1.1, 3.3.2 and 3.5.1 (section A)</p>
<p>Did the Applicant identify the Procedure that, in their view, applies to the consideration of this Application? Yes Indicate which Procedure: General</p>

Other Comments or Relevant Matters:

Nil

6. Consultation & assessment timeframe

Proposed length of public consultation periods:

6 weeks

Proposed timeframe for assessment

'Early Bird Notification' due: 19 November 2021

Commence assessment (clock start)	mid-October 2022
Completion of assessment & preparation of draft food reg measure	early March 2023
Public comment	mid-March 2023 – late April 2023
Board to complete approval	mid-July 2023
Notification to Forum	late-July 2023
Anticipated gazettal if no review requested	late-September 2023

