

**19 November 2021**

**180-21**

**Administrative Assessment Report –Application A1240**

**Polygalacturonase enzyme from GM *Aspergillus oryzae***

1. **Application details**

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| **Date received: 24 September 2021****Date due for completion of administrative assessment:** 18 October 2021 **Date completed:**  |
| **Applicant:** AB Enzymes GmbH  | **Potentially affected Schedule**18 |
| **Brief description of Application:**To permit polygalacturonase from a genetically modified strain of *Aspergillus oryzae* containing the polygalacturonase gene from *Aspergillus tubingensis*, as a processing aid in the manufacture of fruit and vegetable juices/products, coffee processing, flavouring production, and wine production. |
| **Procedure:** General Level 1 | **Estimated total variable hours:** 240 hours **Reasons why:**It will involve an assessment of relatively minor complexity, since it is assessing a new source microorganism of an already permitted enzyme | **Estimated start date:** mid-October 2022  |

1. **Decision**

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| **Application accepted** **Date**: 14 October 2021 |

1. **Additional matters**

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| **Has the Applicant requested information in the application is confidential commercial information (CCI) or confidential?** Yes CCI and confidential.**What documents are affected?** ‘Appendix CCI’ and associated appendices 1 – 13 and documents, plus country permission documents (France and Denmark) as other confidential information.**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 |
| **Has the Applicant sought special consideration e.g. novel food exclusivity, two separate applications which need to be progressed together?**No |

1. **Charges**

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

1. **Assessment against FSANZ Act 1991 requirements**

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| **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 |

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| **Does the application meet each of the following criteria required by subsection 22(2)?** |
| 1. **The application is in writing**

Yes  |
| 1. **The application is in the form specified in guideline 3.1.1 of the Application Handbook**

Yes  |
| 1. **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) |
| **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  |

1. **Consultation & assessment timeframe**

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| **Proposed length of public consultation periods:** 6 weeks  |
| **Proposed timeframe for assessment**‘Early Bird Notification’ due: 19 November 2021Commence assessment (clock start) mid-October 2022Completion of assessment & preparation of draft food reg measure early March 2023Public comment mid-March 2023 – late April 2023Board to complete approval mid-July 2023Notification to Forum late-July 2023Anticipated gazettal if no review requested late-September 2023 |