

23 October 2018
[61-18]

Administrative Assessment Report – Application A1171
Endo-inulinase from *Aspergillus oryzae* as a PA (Enzyme)

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| <p>Date received: 25 Sep 2018 Date due for completion of administrative assessment: 16 October 2018 Date completed: 16 October 2018</p> | | |
| <p>Applicant: Puratos NV (Puratos), Belgium.</p> | | <p>Potentially affected standard:</p> |
| <p>Brief description of Application: To permit the use of Endo-Inulinase produced from a GM strain of <i>Aspergillus oryzae</i> as a PA.</p> | | <p>Schedule 18</p> |
| <p>Procedure: General</p> | <p>Estimated total hours: 350 hours</p> <p>Reasons why: Seeking a new source microorganism for a permitted enzyme, as a processing aid.</p> | <p>Provisional estimated start work: May 2019</p> |

Decision

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| <p>Application accepted</p> <p>Date: 16 Oct 2018</p> |
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| <p>Has the Applicant requested confidential commercial information status? Yes ✓ What documents are affected? Appendices A1 through to A8 Has the Applicant provided justification for confidential commercial information request? Yes ✓</p> |
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Charges

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| <p>Does FSANZ consider that the application confers an exclusive capturable commercial benefit on the Applicant? No ✓</p> |
| <p>Does the Applicant want to expedite consideration of this Application? Not known ✓</p> |

Application Handbook requirements

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| <p>Which Guidelines within the Part 3 of the <i>Application Handbook</i> 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, with some additional information required (see below) ✓ If no, where did the application fail to meet requirements? The following references/Appendices will require a full or part translation to English: BAuA2010, BVL 2013, Wuthrich 1996, Appendix 5, TOS calculations in Appendix 8 Appendix 9. No data provided comparing the amino acid sequence of the enzyme to known protein toxins. A bioinformatic search against the BLAST-P program (http://blast.ncbi.nlm.nih.gov/) is required.</p> |
| <p>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>Is the Application so similar to a previous application or proposal for the development or variation of a food regulatory measure that it ought not to be accepted? No ✓</p> |
| <p>Did the Applicant identify the Procedure that, in their view, applies to the consideration of this Application? Yes ✓ If yes, indicate which Procedure: General</p> |
| <p>Other Comments or Relevant Matters: Nil</p> |

Consultation & assessment timeframe

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| <p>Proposed length of public consultation period: 6 weeks</p> |
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Proposed timeframe for assessment:

'Early Bird Notification' due:

General Procedure:

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| Commence assessment (clock start) | May 2019 |
| Completion of assessment & preparation of draft food reg measure | August 2019 |
| Public comment | October 2019 |
| Board to complete approval | December 2019 |
| Notification to Forum | January 2020 |
| Anticipated gazettal if no review requested | January 2020 |