

16 June 2016
[15-16]

Administrative Assessment Report –Application A1131

Aqualysin 1 (Protease) as a Processing Aid (Enzyme)

Date received: 4 May 2016		
Date due for completion of administrative assessment: 25 May 2016		
Date completed: 13 May 2016		
Applicant: Puratos NV.		Potentially affected standard: Schedule 18
Brief description of Application: To permit the use of aqualysin 1 sourced from <i>Bacillus subtilis</i> containing the aqualysin 1 gene from <i>Thermus aquaticus</i> for use as a processing aid in the manufacture of bakery products.		
Procedure: General	Estimated total hours: Maximum 350 Reasons why: Seeking permission for a new enzyme	Provisional estimated start work: Mid-Dec 2016

Decision

Application accepted

Date: 13 May 2016

Has the Applicant requested confidential commercial information status?

Yes No

What documents are affected?

Sections 6.1.3 (chemical and physical properties), 6.1.4 (manufacturing process) and 6.4.1 (genetic stability of the recipient microorganism)

Has the Applicant provided justification for confidential commercial information request?

Yes No N/A

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

Yes No

Charges

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

Yes No

Does the Applicant want to expedite consideration of this Application?

Yes No Not known

Application Handbook requirements

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

3.1.1, 3.3.2

Is the checklist completed?

Yes No

Does the Application meet the requirements of the relevant Guidelines?

Yes No

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 No

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?

Yes No

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

Yes No

If yes, indicate which Procedure:

General

Other Comments or Relevant Matters:

Nil

Consultation & assessment timeframe

Proposed length of public consultation period:

6 weeks

Proposed timeframe for assessment:

'Early Bird Notification' due: 14 June 2016

Commence assessment (clock start)	Late January 2017
Completion of assessment & preparation of draft food reg measure	Late May 2017
Public comment	Early June–mid-July 2017
Board to complete approval	Late October 2017
Notification to Forum	Early November 2017
Anticipated gazettal if no review requested	Mid-January 2017