FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

15 August 2019
[90-19]

Administrative Assessment Report – Application A1183

Enzymatic Production of Rebaudioside E from Stevia Leaf Extract

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Date received: 20 June 2019 **Date due for completion of administrative assessment: 11 July 2019** **Date completed: 11 July 2019**		
Applicant: Blue California		**Potentially affected standards:** Schedules 3 and 18
Brief description of Application: To seek approval for a new specification for the steviol glycoside Rebaudioside E produced by an enzymatic conversion method, using enzymes derived from a genetically modified strain of the yeast, *Pichia pastoris.*		
Procedure: General	**Estimated total hours:** Maximum 350 hours Reasons why**:** Seeking a pre-market safety approval for a new production process and specification for a currently permitted intense sweetener food additive requiring a safety assessment of average complexity since similar to earlier applications	**Provisional estimated start work:** Early August 2019

Decision

Application accepted **Date: 11 July 2019**

Has the Applicant requested confidential commercial information status?

Yes

What documents are affected?

Appendix A

Has the Applicant provided justification for confidential commercial information request?

Yes

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

No

Charges

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

Yes

If yes, indicate the reason:

The available evidence is that the Applicant is the only party that produces Rebaudioside E according to the specific manufacturing process described in the Application.

Due date for fees: 8 August 2019

Does the Applicant want to expedite consideration of this Application?

Yes

Application Handbook requirements

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

3.1.1, 3.3.1, 3.3.2

Is the checklist completed?

Yes

Does the Application meet the requirements of the relevant Guidelines?

Yes

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

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

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

Yes

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:

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