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

20 August 2021
168-21

Administrative Assessment Report –Application A1235

Enzymatic production of rebaudioside I

1. Application details

Date received: 29 June 2021 **Date due for completion of administrative assessment:** 20 July 2021 **Date completed:** 19 July 2021		
Applicant: Sweegen, Inc		**Potentially affected standard/s:** Schedule 3 and 18
Brief description of Application: To seek approval for a new specification for the steviol glycoside, rebaudioside I, produced by enzymatic bioconversion of stevia leaf extract. The bioconversion enzymes are derived from a genetically modified yeast strain, *Pichia pastoris*.		
Procedure: General level 1	**Estimated total variable hours:** Maximum 240 hours **Reasons why:** Seeking a pre-market safety approval for a new production process and specification for a currently permitted sweetener food additive requiring a safety assessment of less than average complexity due to the similarity with previous applications.	**Estimated start date:** Mid-August 2021

2. Decision

Application accepted

Date: 19 July 2021

If fees for ECCB are not received, date of rejection: 16 August 2021

3. Additional matters

Has the Applicant requested information in the application is confidential commercial information (CCI) or confidential?

Yes

What documents are affected?

Appendix B

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

4. Charges

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

Yes

Reason:

The available evidence is that the applicant is the only manufacturer of Rebaudioside I according to the specific manufacturing process described in the application.

Due date for fees: 16 August 2021

Does the Applicant want to expedite assessment (i.e. pay) for this Application?

No

5. Assessment against FSANZ Act 1991 requirements

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

Does the application meet each of the following criteria required by subsection 22(2)?
(a) The application is in writing Yes
(b) The application is in the form specified in guideline 3.1.1 of the Application Handbook Yes
(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. Sections 3.1.1 , 3.3.1 and 3.3.2 of the Application Handbook

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

6. Consultation & assessment timeframe

Proposed length of public consultation periods:

6 weeks

Proposed timeframe for assessment

'Early Bird Notification' due: 23 August 2021

Commence assessment (clock start)	Mid-August 2021
Completion of assessment & preparation of draft food reg measure	Early December 2021
Public comment	Mid-December 2021- early February 2022
Board to complete approval	Late April 2022
Notification to Forum	Mid May 2022
Anticipated gazettal if no review requested	Late July 2022