

**20 August 2021**

**168-21**

**Administrative Assessment Report –Application A1235**

Enzymatic production of rebaudioside I

1. **Application details**

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| **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 |

1. **Decision**

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| **Application accepted**  **Date**: 19 July 2021  **If fees for ECCB are not received, date of rejection:** 16 August 2021 |

1. **Additional matters**

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| **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 |

1. **Charges**

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| **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 |

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. 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 |

1. **Consultation & assessment timeframe**

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| **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 |