

**9 February 2021**

**150-21**

**Administrative Assessment Report – Application A1222**

Steviol glycosides from Yarrowia lipolytica

1. **Application details**

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| **Date received:** 21 December 2020  **Date due for completion of administrative assessment:** 15 January 2021  **Date completed:** 15 January 2021 | | |
| **Applicant:** Joint submission by Cargill, Incorporated and DSM Food Specialties | | **Potentially affected standard:**  Schedule 3 – 39 |
| **Brief description of Application:**  To permit the use of a steviol glycoside mixture, Rebaudioside MD, that is produced by fermentation from a genetically modified *Yarrowia lipolytica (Y. lipolytica*), expressing steviol glycoside biosynthesis pathway genes, as an intense sweetener. | |
| **Procedure:**  General Level 1 | **Estimated total variable hours:**  240 hours  **Reasons why:**  Seeking a pre-market safety approval for a new production process for a currently permitted intense sweetener food additive, requiring a safety assessment of average complexity. | **Estimated start date:** January 2022 |

1. **Decision**

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| **Application accepted**  **Date**: 15 January 2021  **If fees for ECCB are not received, date of rejection: 19 February 2020** |

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?**  Appendices C-1, C-2, C-3, C-4, and C-5  Lineage map for the production organism and related documents  **Has the Applicant provided redacted copies of documents containing CCI (i.e. CCI version and non CCI version and non CCI executive summary)?**  Yes, non CCI summaries provided  **Has the Applicant provided justification for why information is CCI or confidential?**  Yes |
| **Has the Applicant sought special consideration e.g. novel food exclusivity, two separate applications which need to be progressed together?**  No |

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 applicant is not the only manufacturer of steviol glycosides; however, due to the nature of the yeast strain technology, it is FSANZ’s understanding that only the applicant will be able to commercially benefit from of the production of Reb MD from this specific *Y. lipolytica* strain for use in Australia and New Zealand upon approval of this application.  **Due date for fees:** 18 February 2021 |
| **Does the Applicant want to expedite assessment (i.e. pay) for this Application?**  Yes |

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  Guideline 3.1 – General requirements  3.3.1 – Food additives  3.3.2 – Processing aids (to cover the GM component) |
| **Did the Applicant identify the Procedure that, in their view, applies to the consideration of this Application?**  Yes  **Indicate which Procedure:**  General Level 1 |
| **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 February  General:  Commence assessment (clock start) mid-February 2021  Completion of assessment & preparation of draft food reg measure late May  Public comment early June – mid July  Board to complete approval (Board T/C 27 October 2021) late October 2021  Notification to Forum early November 2021  Anticipated gazettal if no review requested mid-January 2022 |