

**6 August 2020**

**[131-20]**

**Administrative Assessment Report – Application A1207**

Rebaudioside M as a Steviol Glycoside from Saccharomyces cerevisiae

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| **Date received: 17/07/2020**  **Date due for completion of administrative assessment:** 7 August 2020  **Date completed:** 23 July 2020 | | |
| **Applicant:** Amyris Inc. | | **Potentially affected standards:**  Schedules 3 and 18 |
| **Brief description of Application:**  To permit the use of the steviol glycoside, Rebaudioside M, that is produced by fermentation from a genetically modified *Saccharomyces cerevisiae* (*S. cerevisiae*), expressing steviol glycoside biosynthesis pathway genes, as a general purpose sweetening agent. | |
| **Procedure:**  General Level 1 | **Estimated total variable hours:**  240 hours  **Reasons why:**  Seeking a pre-market safety approval for a new production process and specification for a currently permitted intense sweetener food additive | **Provisional estimated start work:**  August 2020 |

***Decision***

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| **Application accepted**  **Date**: 23 July 2020  **Due date for ECCB fees:** 21 August 2020 |

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| **Has the Applicant requested confidential commercial information status?**  Yes ✔  **What documents are affected:** Appendices’ CCI-1, CCI-2, CCI-3, CCI-4, CCI-5, CCI-6  **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***

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| **Does FSANZ consider that the application confers an exclusive capturable commercial benefit on the Applicant?**  Yes ✔  **Reason:**  The available evidence is that the Applicant is the only party that produces Rebaudioside M according to the specific manufacturing process described in the Application.  **Due date for fees:** 21 August 2020 |
| **Does the Applicant want to expedite consideration of this Application?**  Yes ✔ (paid application ECCB) |

***Application Handbook requirements***

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| **Which Guidelines within Part 3 of the *Application Handbook* apply to this Application?**  3.1.1, 3.3.1, 3.5.1  **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 should not be accepted?**  No ✔ |
| **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 |

***Consultation & assessment timeframe***

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| **Proposed length of public consultation period:**  6 weeks |
| **Proposed timeframe for assessment:**    General Procedure:  Commence assessment (clock start) early August 2020  Completion of assessment & preparation of draft food reg measure early Nov 2020  Public comment mid Nov – late Dec 2020  Board to complete approval Late April 2021  Notification to Forum mid May 2021  Anticipated gazettal if no review requested late July 2021 |