

**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***

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| **Application accepted**  **Date: 11 July 2019** |

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| **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***

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| **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***

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| **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***

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| **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 |