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

9 February 2021
150-21

Administrative Assessment Report – Application A1222

Steviol glycosides from Yarrowia lipolytica

1. Application details

<table>
<tr><td colspan="3">Date received: 21 December 2020
Date due for completion of administrative assessment: 15 January 2021
Date completed: 15 January 2021</td></tr>
<tr><td colspan="2">Applicant: Joint submission by Cargill, Incorporated and DSM Food Specialties</td><td rowspan="2">Potentially affected standard:
Schedule 3 – 39</td></tr>
<tr><td colspan="2">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.</td></tr>
<tr><td>Procedure:
General Level 1</td><td>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.</td><td>Estimated start date:
January 2022</td></tr>
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2. Decision

Application accepted

Date: 15 January 2021

If fees for ECCB are not received, date of rejection: 19 February 2020

3. Additional matters

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

4. Charges

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

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 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

6. Consultation & assessment timeframe

Proposed length of public consultation periods:

6 weeks

Proposed timeframe for assessment

'Early Bird Notification' due: 23 February

<u>General:</u>

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