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

6 August 2020
[131-20]

Administrative Assessment Report – Application A1207

Rebaudioside M as a Steviol Glycoside from Saccharomyces cerevisiae

<table>
<tr><td colspan="3">Date received: 17/07/2020
Date due for completion of administrative assessment: 7 August 2020
Date completed: 23 July 2020</td></tr>
<tr><td colspan="2">Applicant: Amyris Inc.</td><td rowspan="2">Potentially affected standards:
Schedules 3 and 18</td></tr>
<tr><td colspan="2">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.</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 and specification for a currently permitted intense sweetener food additive</td><td>Provisional estimated start work:
August 2020</td></tr>
</table>

Decision

Application accepted

Date: 23 July 2020

Due date for ECCB fees: 21 August 2020

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

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

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

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