

**6 November 2018**  
**[62-18]**

## **Administrative Assessment Report – Application A1172**

### **Enzymatic Production of Rebaudioside D**

<p><b>Date received: 10 October 2018</b>  <b>Date due for completion of administrative assessment: 1 November 2018</b>  <b>Date completed: 31 October 2018</b></p>		
<p><b>Applicant:</b> SweeGen, Inc.</p>		<p><b>Potentially affected standards:</b> Schedules 3 and 18</p>
<p><b>Brief description of Application:</b> To seek approval for a new specification for rebaudioside D produced by an enzymatic biosynthesis method.</p>		
<p><b>Procedure:</b> General</p>	<p><b>Estimated total hours:</b> Maximum 350 hours</p> <p>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 application</p>	<p><b>Provisional estimated start work:</b> November 2018</p>

#### ***Decision***

<p><b>Application accepted</b></p> <p><b>Date: 31 October 2018</b></p>
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<p><b>Has the Applicant requested confidential commercial information status?</b>          Yes✓      No</p> <p>What documents are affected?          Appendix A</p> <p><b>Has the Applicant provided justification for confidential commercial information request?</b>          Yes✓      No      N/A</p>
<p><b>Has the Applicant sought special consideration e.g. novel food exclusivity, two separate applications which need to be progressed together?</b>          Yes      No✓</p>

***Charges***

<p><b>Does FSANZ consider that the application confers an exclusive capturable commercial benefit on the Applicant?</b>          Yes✓      No</p> <p><b>If yes, indicate the reason:</b>          The application is seeking amendments to the Code permitting the specific new production method which is covered by patents. Only the applicant would receive an exclusive capturable economic benefit from a successful outcome.</p> <p><b>Due date for fees: 28 November 2018</b></p>
<p><b>Does the Applicant want to expedite consideration of this Application?</b>          Yes✓      No      Not known</p>

***Application Handbook requirements***

<p><b>Which Guidelines within the Part 3 of the <i>Application Handbook</i> apply to this Application?</b>          3.1.1, 3.3.1, 3.3.2</p> <p><b>Is the checklist completed?</b>          Yes✓      No</p> <p><b>Does the Application meet the requirements of the relevant Guidelines?</b>          Yes✓      No</p>
<p><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?</b>          Yes✓      No</p>
<p><b>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?</b>          Yes      No✓</p>
<p><b>Did the Applicant identify the Procedure that, in their view, applies to the consideration of this Application?</b>          Yes✓      No</p> <p><b>If yes, indicate which Procedure:</b>          General</p>
<p><b>Other Comments or Relevant Matters:</b>          Nil</p>

***Consultation & assessment timeframe***

<p><b>Proposed length of public consultation period:</b>          6 weeks</p>
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**Proposed timeframe for assessment:**

Commence assessment (clock start)	late Nov 2018
Completion of assessment & preparation of draft food reg measure	late March 2019
Public comment	early April–mid May 2019
Board to complete approval	early Aug 2019
Notification to Forum	mid Aug 2019
Anticipated gazettal if no review requested	late Oct 2019