

**16 May 2019**  
**[80-19]**

## **Administrative Assessment Report –Application A1176**

### Enzymatic production of Steviol Glycosides

<p><b>Date received:</b> 19 March 2019  <b>Date due for completion of administrative assessment:</b> 9 April 2019  <b>Date completed:</b> 9 April 2019</p>		
<p><b>Applicant:</b> PureCircle Limited</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 steviol glycosides produced by an enzymatic bioconversion method using enzymes derived from genetically modified strains of <i>Escherichia coli</i> (<i>E. coli</i>).</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 food additive, including new processing aids, requiring a safety assessment of average complexity since similar to earlier applications.</p>	<p><b>Provisional estimated start work:</b> Early May 2019</p>

#### **Decision**

<p><b>Application accepted</b></p> <p><b>Date:</b> 9 April 2019</p>
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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***

**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 steviol glycosides according to the specific manufacturing process described in the Application. The Application itself also states that an ECCB is likely to be conferred on the Applicant if the measures sought by the Application are approved.

**Due date for fees:** 10 May 2019

**Does the Applicant want to expedite consideration of this Application?**

Yes

### ***Application Handbook requirements***

**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**

**Proposed length of public consultation period:**

6 weeks

**Proposed timeframe for assessment:**

**'Early Bird Notification' due: 10 May 2019**

Commence assessment (clock start)	Early May 2019
Completion of assessment & preparation of draft food reg measure	Early Sep 2019
Public comment	Mid Sep-end Oct 2019
Board to complete approval	Early Feb 2020
Notification to Forum	Mid Feb 2020
Anticipated gazettal if no review requested	End Apr 2020