

**31 October 2014**  
**[22–14]**

## **Administrative Assessment Report – Application A1102**

### **L-carnitine in Food**

<p><b>Date received: 3 September</b>  <b>Date due for completion of administrative assessment: 24 September 2014</b>  <b>Date completed: 24 September 2014</b></p>		
<p><b>Applicant:</b> Lonza Ltd</p>		<p><b>Potentially affected Standards (as identified by the Applicant):</b></p> <ul style="list-style-type: none"> <li>1.3.4 – Identity and purity</li> <li>2.1.1 – Cereal and cereal products</li> <li>2.5.1 - Milk</li> <li>2.5.3 – Fermented milk products</li> <li>2.6.1 – Fruit juice and vegetable juice</li> <li>2.6.2 – Non-alcoholic beverages and brewed soft drinks</li> <li>2.6.4 – Formulated caffeinated beverages</li> <li>2.9.3 – Formulated meal replacements</li> <li>2.9.4 – Formulated supplementary sports foods</li> </ul>
<p><b>Brief description of Application:</b>          To permit the addition of L-carnitine in a variety of food categories including dairy products (excluding butter and butter fat), confectionery, cereal and cereal products, food intended for particular nutritional uses, non-alcoholic beverages and gels.</p>		
<p><b>Procedure:</b> General</p>	<p><b>Estimated total hours:</b> More than 1000 hours</p> <p>Reasons why:</p> <ul style="list-style-type: none"> <li>• The Application is for the addition of L-carnitine to a broad range of foods.</li> <li>• There is a large volume of studies on L-carnitine that FSANZ will need to review.</li> </ul>	<p><b>Estimated start work:</b> Mid-Jan 2015</p>

### ***Decision***

**Application accepted**  
**Date: 24 September 2014**

**Has the Applicant requested confidential commercial information status?**

Yes ✓ No

What documents are affected?

Appendix B, C, D, H, I, J, M

**Has the Applicant provided justification for confidential commercial information request?**

Yes ✓ No N/A

### ***Charges***

**Does FSANZ consider that the application confers an exclusive capturable commercial benefit on the Applicant?**

Yes No ✓

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

Yes No Not known ✓

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

**Which Guidelines within the Part 3 of the *Application Handbook* apply to this Application?**

3.1.1, 3.3.3

**Is the checklist completed?**

Yes ✓ No

**Does the Application meet the requirements of the relevant Guidelines?**

Yes ✓ No

**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 ✓ No

**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?**

Yes No ✓ - Application is not similar to others.

**If no, why not?**

Application is requesting permission to add the nutritive substance to a wide range of foods.

**Did the Applicant identify the Procedure that, in their view, applies to the consideration of this Application?**

Yes ✓ No

**If yes, indicate which Procedure:**

General

**Other Comments or Relevant Matters:**

Nil

### ***Consultation & assessment timeframe***

**Proposed length of public consultation period:**

6 weeks

Some targeted stakeholder consultation may be required.

**Proposed timeframe for assessment:**

**'Early Bird Notification' due: 31 October 2014**

General Procedure:

Commence assessment (clock start)	Early March 2015
Completion of assessment & preparation of draft food reg measure	Early July 2015
Public comment	Mid-July – late Aug 2015
Board to complete approval	Early Dec 2015
Notification to Forum	Mid-Dec 2015
Anticipated gazettal if no review requested	Late Feb 2016