31 October 2014
[22–14]

Administrative Assessment Report – Application A1102
L-carnitine in Food

Date received: 3 September
Date due for completion of administrative assessment: 24 September 2014
Date completed: 24 September 2014

Applicant: Lonza Ltd

Potentially affected Standards (as identified by the Applicant):
1.3.4 – Identity and purity
2.1.1 – Cereal and cereal products
2.5.1 – Milk
2.5.3 – Fermented milk products
2.6.1 – Fruit juice and vegetable juice
2.6.2 – Non-alcoholic beverages and brewed soft drinks
2.6.4 – Formulated caffeinated beverages
2.9.3 – Formulated meal replacements
2.9.4 – Formulated supplementary sports foods

Brief description of Application:
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.

Procedure:
General

Estimated total hours:
More than 1000 hours

Reasons why:
• The Application is for the addition of L-carnitine to a broad range of foods.
• There is a large volume of studies on L-carnitine that FSANZ will need to review.

Estimated start work:
Mid-Jan 2015

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*

<table>
<thead>
<tr>
<th>General Procedure</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commence assessment (clock start)</td>
<td>Early March 2015</td>
</tr>
<tr>
<td>Completion of assessment &amp; preparation of draft food reg measure</td>
<td>Early July 2015</td>
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<tr>
<td>Public comment</td>
<td>Mid-July – late Aug 2015</td>
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<tr>
<td>Board to complete approval</td>
<td>Early Dec 2015</td>
</tr>
<tr>
<td>Notification to Forum</td>
<td>Mid-Dec 2015</td>
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<tr>
<td>Anticipated gazetral if no review requested</td>
<td>Late Feb 2016</td>
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