

**31 October 2014**

**[22–14]**

**Administrative Assessment Report – Application A1102**

L-carnitine in Food

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| **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***

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

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| **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***

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| **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***

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| **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***

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| **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 |