

25 October 2018

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Dear Sir/Madam

Attached are the comments that the New Zealand Food & Grocery Council wishes to present on the ***Call for submissions – Application A1102: Addition of L-carnitine to foods.***

Yours sincerely



***Call for submissions – Application A1102:  
Addition of L-carnitine to foods***

**Submission by the New Zealand Food & Grocery  
Council**

**25 October 2018**

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## NEW ZEALAND FOOD & GROCERY COUNCIL

1. The New Zealand Food & Grocery Council (“NZFGC”) welcomes the opportunity to comment on the ***Call for submissions – Application A1102: Addition of L-carnitine to foods.***
2. NZFGC represents the major manufacturers and suppliers of food, beverage and grocery products in New Zealand. This sector generates over \$34 billion in the New Zealand domestic retail food, beverage and grocery products market, and over \$31 billion in export revenue from exports to 195 countries – some 72% of total merchandise exports. Food and beverage manufacturing is the largest manufacturing sector in New Zealand, representing 44% of total manufacturing income. Our members directly or indirectly employ more than 400,000 people – one in five of the workforce.

### The Application

3. Lonza Ltd, a Swiss company based in Basel, applied to FSANZ in July 2014 to permit the sale and use of L-carnitine and L-carnitine L-tartrate as food and beverage ingredients to deliver a dietary source of L-carnitine in 32 classes of foods and beverages at various levels (ranging from 0.05g per serving to 0.5g per serving with most around 0.25g per serving). The classes of foods include dairy products, cereal and cereal products, fruit and vegetable juices, confectionery, foods and beverages for particular nutritional uses, non-alcoholic beverages and gels. Lonza also applied to increase the permitted amount of L-carnitine in formulated supplementary sports foods.

### COMMENTS

4. NZFGC supports in part the conclusion of FSANZ that, in relation to most of the claimed effects of the addition of L-carnitine to general purpose foods, the evidence is not compelling enough to result in permissions. NZFGC concurs with FSANZ that the level of L-carnitine and L-carnitine L-tartrate be raised for formulated sport foods. However, contrary to the FSANZ view, NZFGC supports a permission for the addition of L-carnitine in foods for the elderly and for vegetarians/ vegans for the purpose of assisting with maintenance or restoration of L-carnitine levels in skeletal muscle on the basis that any supplementation is positive.
5. L-carnitine is ‘an essential co-factor for fatty acid metabolism and other metabolic pathways, with body stores primarily maintained in skeletal muscle. The majority of the body’s L-carnitine is supplied in the diet from meats’<sup>1</sup> and is described as a ‘conditionally essential nutrient’ in the scientific literature.
6. Several European, American (Canada and Brazil) and Asian (China, Japan, South Korea and Malaysia) countries already permit the addition of L-carnitine to a range of foods and it is on the US GRAS list (self-affirmed by Lonza). Lonza also has applications for permissions in Canada and India. Canada already permits addition in natural health foods and for medicinal purposes and for other foods on a case-by-case basis.
7. This is the first application that FSANZ has assessed of the addition of a nutritive substance to general purpose foods other than vitamins and minerals. L-carnitine is permitted, in the Australia New Zealand Food Standards Code (the Food Standards Code) to be included in infant formula products up to 0.8mg/100kJ, formulated supplementary sports foods (100mg per one-day quantity) and foods for special medical purposes. Its public health and

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<sup>1</sup> Application for approval of L-carnitine as a nutritive substance under the Australia New Zealand Food Standards Code. Lonza Ltd 2014.

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safety status has therefore already been assessed for the most vulnerable population group, infants.

8. Four particular population groups were identified as benefiting most from the addition of L-carnitine to food and beverages:
  - adult vegetarians (to increase levels generally but also to obtain high energy for exercising);
  - the elderly (to restore L-carnitine levels and contribute to energy metabolism);
  - weight loss persons (to improve lipid profiles and contribute to energy generation); and
  - athletes (to replenish L-carnitine stores contribute to exercise recovery).
9. FSANZ undertook technical, hazard and dietary exposure assessments. The technical assessment confirmed L-carnitine and L-carnitine tartrate as already provided for in the Food Standards Code. The hazard assessment considered data from a wide range of sources relevant to safety. No adverse effects were attributable to L-carnitine below 3g per day. Above this level, there was some nausea, gastrointestinal disturbances and fishy body/urine. FSANZ concluded that at levels below 3g per day there was no public health or safety concerns.
10. In its assessment of health effects, FSANZ found that many studies were unable to be reproduced, were inconsistent or did not explore the range of effects or elements of interest. For example, no studies investigated L-carnitine restoration in the muscles of the elderly, no studies supported the stated weight loss impacts in relation to body fat, carbohydrate metabolism, or bodyweight at the levels proposed, while for athletes, there was some evidence. There were also some favourable results for doses of 1.5g to 4g/day in the elderly over 70 years for muscle mass, loss of fat, and improved physical function but in the two studies which tested 1.5g/day, only one reported a favourable effect.
11. The advantage of a broad approval for consumers would be a greater range of food and beverage products containing L-carnitine. Currently L-carnitine containing products are available in Europe and would not be compliant for import and sale in New Zealand or Australia.
12. NZFGC appreciates that some of the effects sought have not been demonstrated (levels in the muscles of the elderly under 70 years and energy metabolism in the elderly irrespective of age, energy boost for vegetarians and lipid profiles or energy metabolism for weight loss persons) but there have been a few exceptions: L-carnitine in the muscle concentrations for the elderly over 70 and L-carnitine in the muscle concentrations for vegetarians (but within the normal range).
13. In relation to the elderly over 70 years, while the muscle concentrations at the level proposed has limited evidence, at higher levels of supplementation there was evidence of increased muscle concentrations. NZFGC would support permission for inclusion in foods for the elderly on the basis that any increase however minimal, is better than none. We liken it to the voluntary fortification of bread with folic acid in New Zealand aimed at women of child bearing age. The amount would be unlikely to meet the ideal protective effect but some increase is better than none. Similarly for vegetarians and vegans, while the muscle concentrations increased slightly but within normal the normal range with intakes of 2g/day, some increase is better than none.
14. For these two groups (elderly and vegetarians/vegans, permitting L-carnitine to be added to foods and beverages targeting them could have positive impacts without any safety concerns.

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15. NZFGC therefore supports in part the conclusion of FSANZ that in relation to most of the claimed effects of the addition of L-carnitine to general purpose foods, the evidence is not compelling enough to result in permissions. NZFGC also supports raising the level of L-carnitine and L-carnitine L-tartrate for formulated sport foods. NZFGC also supports a permission for the addition of L-carnitine in foods for the elderly and for vegetarians/ vegans for the purpose of assisting with maintenance or restoration of L-carnitine levels in skeletal muscle.