



16 May 2019
[80-19]

Approval report – Application A1102

L-carnitine in food

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Lonza Ltd. to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of two forms of L-carnitine as a nutritive substance in 30 classes of foods; and to increase the permitted amount of L-carnitine in formulated supplementary sports foods.

On 13 September 2018, FSANZ sought [submissions](#) on a draft variation and published an associated report. FSANZ received eight submissions.

FSANZ approved the draft variation on 1 May 2019. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 15 May 2019.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

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Supporting documents

The following documents which informed the assessment of this Application are available on the FSANZ website here: <http://www.foodstandards.gov.au/code/applications/Pages/A1102-L-carnitineInFood.aspx>

SD1	Risk and technical assessment
SD2	Assessment of health effects
SD3	Assessment against Ministerial Policy Guidelines and social science assessment

Executive summary

Lonza Ltd. applied to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of L-carnitine in two forms as a nutritive substance in 30 classes of foods and to increase the permitted amount of L-carnitine in these forms in 2 classes of formulated supplementary sports foods (FSSF). The purpose of the application was to serve the interests of four target population groups: athletes; the elderly; vegetarians; and people actively losing weight.

The Code currently permits the voluntary addition of L-carnitine to certain special purpose foods: infant formula products (with listed permitted forms), FSSF (no listed permitted forms), and food for special medical purposes (with listed permitted forms). Several countries in Europe, Asia and the Americas permit the addition of L-carnitine to a range of foods.

FSANZ conducted technical and risk assessments of the applicant's request, noting that various forms of L-carnitine were used in the evidence base. No public health and safety concerns were associated with the estimated dietary intake of L-carnitine at maximum use levels in the requested foods. Following submissions, intake of higher amounts from a theoretical consumption of stacked products containing L-carnitine was also found to pose no safety concerns.

Ministerial policy guidelines state that the addition to food of substances such as L-carnitine in the quantity and a form proposed by the applicant should be consistent with delivering the applicant's stated purpose for that addition. The applicant identified 4 target population groups to benefit from additional dietary L-carnitine. Evidence for the stated favourable effects in the four target population groups was therefore assessed.

FSANZ's assessment concluded that current evidence does not support the stated favourable effects in three groups: the elderly, vegetarians or in people actively losing weight. The estimated dietary intake showed that the requested permissions would not allow even high consumers to reach the intakes examined in the evidence base.

However, FSANZ's assessment concluded that the evidence related to reduction in muscle soreness in athletes consuming 2 g L-carnitine per day was sufficient and achievable when consumed in a one day quantity of FSSF. As such, it was consistent with the applicant's stated purpose as well as with the Code's defined purpose for FSSF; it also accorded with policy guidelines and was therefore considered appropriate for a voluntary permission.

Since the maximum amount of L-carnitine in the table to section S29—19 is expressed per one-day quantity rather than per serving, a sports person following label instructions on a FSSF containing the maximum amount of L-carnitine could consume amounts consistent with the applicant's stated purpose for athletes.

FSANZ therefore decided to partially approve the applicant's request to increase the maximum permitted amount of L-carnitine in FSSF (i.e. to 2 g per one-day quantity) but not to approve addition of L-carnitine to the many other food classes sought by the applicant.

The two requested forms of L-carnitine, L-carnitine and L-carnitine tartrate, were assessed as posing no safety concerns. However, FSANZ decided not to amend the table to section S29—19 to specify these forms in FSSF. Doing so would have specified forms for only one of several permitted nutritive substances; it would also have precluded the use of other forms of L-carnitine currently added to these FSSF. The matter of permitted forms will be further considered in a future review of Standard 2.9.4.

The addition of L-carnitine to FSSF is subject to generic and specific labelling requirements set by the Code. These labelling requirements help consumers make informed purchasing decisions. Sports foods cannot make health claims about enhanced athletic performance or beneficial physiological effects except where express permission is provided in the Code.

1 Introduction

1.1 The applicant

The applicant is Lonza Ltd, a manufacturer and supplier of several food ingredients and nutritive substances including L-carnitine compounds, based in Basel, Switzerland.

1.2 The application

Lonza Ltd. applied to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of two forms of L-carnitine as a nutritive substance in 30 classes of foods and to increase the permitted amount of L-carnitine in these forms in 2 classes of formulated supplementary sports foods (FSSF). The applicant sought to market L-carnitine and L-carnitine-L-tartrate under respective trade names to broaden the potential for innovation and to further develop domestic and overseas markets.

The food categories sought for addition of L-carnitine are given in Table 1. Requested amounts of L-carnitine ranged from 0.05 g to 0.25 g per serving depending on food category. The amount sought in formulated supplementary sports foods was raised from 0.1 g to 2 g per one day quantity (0.5 g per serving x 4 servings/day). The requested amounts for each food category are shown in detail in Appendix L to the application available on our website (see above link).

Table 1 Food categories

Food classes			
<i>General purpose foods</i>		<i>Special purpose food</i>	
1.	Flavoured milk	23.	Formulated meal replacement drinks prepared
2.	Cultured dairy products	24.	Formulated meal replacement mixes
3.	Yogurt	25.	Formulated meal replacement biscuits and bars
4.	Cup yoghurts sweetened	26.	Formulated supplemented drinks prepared
5.	Yoghurt beverages	27.	Formulated supplementary food mixes
6.	Chocolate	28.	Formulated supplementary food
7.	Soft candy	29.	Meal replacement drinks
8.	Hard candy	30.	Meal replacement bars
9.	Bubble gum and chewing gum	31.	Sports bars
10.	Low joule chewing gum	32.	Sport drinks (e.g. protein)
11.	Hot cereal		
12.	Ready-to-eat (RTE), flaked, extruded		
13.	Breakfast cereal bars		
14.	Cereal bars		
15.	Fruit and vegetable juices		
16.	Soy beverages		
17.	Flavoured soy milk		
18.	Regular soft drinks		
19.	Sports and isotonic drinks		
20.	Flavoured drinks		
21.	Tea and coffee dry mixes		
22.	Caffeinated energy drinks		

The application's stated purpose or rationale for the request was to maintain the normal carnitine status of the body, particularly in those individuals consuming foods with minimal L-carnitine content and/or inadequate supply of micronutrients caused by certain forms of

nutrition or changed eating habits. Stated purposes related to four specific population target groups, excluding the general population, are as follows:

- 1 Adult vegetarians could increase their L-carnitine levels and obtain high energy in situations such as exercising.
- 2 For the elderly, L-carnitine-fortified foods help restore their L-carnitine levels, which leads to multiple effects related to energy metabolism.
- 3 In people actively undertaking weight loss, L-carnitine fortified foods of low energy density help to maintain L-carnitine levels during dieting and with energy generation via its buffering function of coenzyme A, while also helping to improve lipid profiles and body weight and body mass index.
- 4 L-carnitine-fortified foods help athletes replenish their L-carnitine stores, and contribute to more efficient exercise recovery.

This was the first time FSANZ has considered permissions for the use of a nutritive substance other than a vitamin or mineral in general purpose foods. It was also the first time specific forms of any nutritive substance were requested for formulated supplementary sports foods.

1.3 The current Standards

1.3.1 Australia and New Zealand

L-carnitine is currently permitted to be added to the following special purpose foods:

- Standard 2.9.1 – Infant Formula Products – table to section S29—5 in Schedule 29
 - Minimum amount per 100 kJ for labelling purposes – 0.21 mg
 - Maximum amount per 100 kJ – 0.8 mg
 - Permitted form: L-carnitine
- Standard 2.9.4 – Formulated Supplementary Sports Foods – table to section S29—19 in Schedule 29
 - Maximum amount added per one-day quantity – 100 mg
 - Permitted form: Not specified
- Standard 2.9.5 – Food for Special Medical Purposes – table to section S29—20 in Schedule 29
 - Permitted forms: L-carnitine, L-carnitine hydrochloride and L-carnitine L-tartrate.

1.3.2 Overseas and international standards

1.3.2.1 *Codex Alimentarius*

L-carnitine is regarded as an essential nutrient in infant formula and formulas for special medical purposes intended for infants (Codex STAN 72-1981). L-carnitine and L-carnitine L-tartrate are listed in the advisory list of nutrient compounds for use in foods for special dietary uses intended for infants and young children (CAC/GL 10-1979).

1.3.2.2 *United States of America (USA)*

Lonza has self-affirmed L-carnitine and L-carnitine L-tartrate as Generally Recognized as Safe (GRAS) for use in a similar range of foods and at similar maximum levels requested in the application to FSANZ. These foods include beverages and beverage bases, coffee and tea, dairy product analogues, grain products and pastas, hard and soft candies, milk products, processed fruits and fruit juices and special purpose foods including sports drinks and meals replacement products.

1.3.2.3 Canada

L-carnitine and acetyl-L-carnitine are permitted novel food ingredients that can be used in a specific classes of supplemented foods after obtaining a Temporary Marketing Authorization Letter from Health Canada on a case-by-case basis.

L-carnitine and its salts and derivatives are permitted to be used as a natural health product or medicinal ingredient in workout supplements and other health products. To achieve physiological and biochemical effects similar to those stated in the current application, Health Canada recommends single doses and daily intake similar to those requested in the current application.

1.3.2.4 European Union (EU)

L-carnitine crystalline and L-carnitine L-tartrate are grandfathered and marketed in the EU and are thus not regarded as novel food. L-carnitine and L-carnitine L-tartrate are permitted for use in infant formula, follow-on formula, processed cereal-based foods and foods for infants and young children. These forms are also permitted in foods for special nutritional uses intended for infants and young children, food for special medical purposes, and total diet replacements for weight control.

1.3.2.5 Brazil

L-carnitine is approved as L-carnitine, L-carnitine L-tartrate and L-carnitine chloride, for use in infant formula, follow-on formula, special purpose foods, and other foods as a nutritive substance.

1.3.2.6 Asia

China

L-carnitine and L-carnitine L-tartrate are permitted for use in infant formula, follow-on formula, and as a nutritional fortification substance in some general and special purpose foods. Amounts permitted in dairy products for adults and sports drinks range between 0.3 and 3 g per kg.

Japan

L-carnitine and L-carnitine L-tartrate can be used in foods and dietary supplements with a maximum daily intake up to 1 g per day or 20 mg per kg body weight per day.

South Korea

L-carnitine is permitted as a food additive and health food functional ingredient for reducing body fat. The daily dosage is approved up to 2 g of L-carnitine.

Malaysia

L-carnitine, L-carnitine L-tartrate and L-carnitine hydrochloride are permitted as amino acids and can be added, without clear limits, to all food products.

1.4 Reasons for accepting application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the FSANZ Act

- it related to a matter that warranted the variation of a food regulatory measure
- it was not so similar to a previous application for the variation of a food regulatory measure that it ought to be rejected.

1.5 Procedure for assessment

The application was assessed under the General Procedure.

1.6 Decision

The draft variation proposed following assessment (as at the call for submissions), was approved without change. The variations take effect on gazettal. The approved draft variation, is at Attachment A.

The related explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

2 Summary of the findings

2.1 Summary of issues raised in submissions

Eight submissions were received: four from jurisdictions—Queensland, NSW, Victoria and NZMPI; one from public health—DAA, and three from industry groups – NZBC, ABC, NZFGC. Submissions can be accessed on the FSANZ website here:

<http://www.foodstandards.gov.au/code/applications/Pages/A1102-L-carnitineInFood.aspx>

Five submissions supported the proposed changes but Australian jurisdictions raised several issues as noted in Table 2. Two of these jurisdictions suggested either not progressing work or deferring further work until the conclusion of the forthcoming sports foods review. Since the release of the Call for Submissions report, the Forum on Food Legislation requested FSANZ to review Standard 2.9.4 – Formulated Supplementary Sports Foods as a matter of priority. FSANZ is currently considering this request.

Table 2: Summary of issues

Issue	Raised by	FSANZ response
Deferring or stopping work (after CFS) on A1102.	NSW/Victoria	Not supported. Deferral of a decision indefinitely or for a period of some years is considered unwarranted in the circumstances. FSANZ approved the draft variation for the reasons summarised in this report. FSANZ also notes the ability of applicants to seek judicial review of any decision to defer.

Issue	Raised by	FSANZ response
<p>Stacking: The marketing practice of stacking (i.e. selling multiple sports products with complementary attributes as one purchase) may result in some individuals exceeding 3 g L-carnitine/day above which some side effects may occur.</p>	<p>Victoria/NSW/Queensland</p>	<p>Noted.</p> <p>This issue is addressed in section 2.2.1 below. FSANZ assessed the evidence for safety at intakes higher than 3 g/day.</p> <p>FSANZ risk assessment based on the best available evidence concluded that intake of L-carnitine up to 3 g /day is not associated with adverse effects. Oral L-carnitine doses as high as 7 g/day for durations of up to 12 months have been investigated, including in studies in elderly subjects, and in pregnant women. L-carnitine bioavailability declines markedly with dose and no systemic toxicity has been observed. At doses ≥ 3 g per day, mild side effects of nausea, gastrointestinal disturbances, and fishy body and/or urine odour have been observed. The favourable safety profile of L-carnitine is supported by clinical trials using intravenous administration which can achieve substantially greater systemic exposure than the oral route.</p> <p>A theoretical consumption of L-carnitine from diet and stacked sports products and supplements was estimated. L-carnitine intake from this scenario could theoretically reach the maximum tested oral dose of 7 g/day. On this basis that this scenario is unlikely to occur in practice, FSANZ concluded that use of stacked products containing L-carnitine is unlikely to pose safety concerns.</p> <p>To correct a submitter, L-carnitine is not permitted to be added to formulated caffeinated beverages (Standard 2.6.4).</p>

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Issue	Raised by	FSANZ response
<p>Risk management: If deferral is not possible and if 2 g/one day quantity is permitted, further advisory/warning statements are needed: in FSSF, e.g. an advisory/warning statement on potential adverse effects at >3 g/day from all supplementary sources of L-carnitine.</p>	<p>Victoria/Queensland/NSW</p>	<p>Not supported.</p> <p>Subparagraph 2.9.4—4(1)(a)(iii) requires the following warning statement on FSSF: <i>Not suitable for children under 15 years of age or pregnant women: Should only be used under medical or dietetic supervision.</i> No evidence was submitted to support the need for, or to demonstrate the effectiveness of, additional warning statements.</p> <p>Noting the safety of L-carnitine, applying the suggested additional warning to only one substance (L-carnitine), while remaining silent on all other substances added to FSSF, may give a distorted/inconsistent message to consumers. For example, consumers may infer that L-carnitine is less safe than other substances added to FSSF, which may not be the case.</p> <p>Risk management approaches for substances added to FSSFs can be considered more broadly in the review of Standard 2.9.4. Whether further warning statements for such substances are warranted having regard to the evidence, cost benefit analysis etc would best be considered more broadly in that review.</p>
<p>NIP: Standard 2.9.4 does not require nutritive substances such as L-carnitine to be quantified on the label (unless a claim is made). If permission is approved for the increased L-carnitine in FSSF, mandatory declaration of the amount of L-carnitine in the food on the NIP is recommended.</p>	<p>Victoria/NSW</p>	<p>Not supported.</p> <p>No evidence was submitted to support the need for this measure, or to demonstrate its potential effectiveness. The mandatory list of energy and six nutrients in the current NIP is based on their public health significance. All other nutrients or substances in the NIP are either voluntarily declared or in response to a label claim. Requiring the amount of one substance added to FSSF in the NIP but not the amounts of other added substances would be an inconsistent approach. FSANZ therefore considered that the possible declaration in the NIP of the amounts of substances added to FSSF would best be considered more broadly in the review of Standard 2.9.4.</p>

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Issue	Raised by	FSANZ response
<p>Scope of prohibition on slimming claims: it was suggested that the current prohibition on slimming claims in section 1.2.7—15 and prohibited representations in section 2.9.4—7 be clarified to ensure that thermogenic, fat burning and fat metabolising claims are not made on foods regulated by the Code. Also, clarification on whether references to weight loss, weight management or similar claims on websites constitute a breach under current provisions.</p>	<p>NSW</p>	<p>Not supported.</p> <p>Section 2.9.4—7 prohibits certain representations on FSSFs unless permitted elsewhere in the Standard (...<i>enhanced athletic performance or beneficial physiological effects</i>). Section 1.2.7—15 prohibits the use of synonyms for the descriptor <i>diet</i> in the context of nutrition content claims about the property of food, energy. The intent of this section is to clarify that words which imply slimming, weight loss or weight maintenance properties cannot be used as synonyms for <i>diet</i> in a nutrition content claim about energy.</p> <p>The question of whether label/internet claims that foods or properties of food are <i>thermogenic, fat burning or fat metabolising</i> are in breach of the Code and the food laws that apply the Code is a matter for regulators. Jurisdictions have not provided FSANZ with evidence of a problem with the interpretation and application of sections 1.2.7—15 and 2.9.4—7.</p>
<p>Dietary Intake Assessment (DIA): it was queried whether the DIA accounts for all sources of L-carnitine including from stacking. It was suggested that the DIA may need to be revised to assess potential consumption of multiple products, including therapeutic goods and complementary medicines that can also contain L-carnitine.</p>	<p>Queensland/NSW</p>	<p>Noted.</p> <p>Currently available national survey information representing Australian and New Zealand populations are the best available data for this cohort at present. FSANZ acknowledges that these surveys have not oversampled sports people/athletes as a subpopulation. No information is available on the incidence, frequency and consistency of product stacking in the marketplace. Also no information exists on whether stacking affects actual upper levels of intake over time, or if intakes from non-food sources would be acute or chronic in duration. A theoretical scenario of natural dietary L-carnitine intake with stacked products and supplements is given in section 2.2.</p>
<p>Dietary Intake Assessment (DIA): Suggests that the DIA acknowledges statistical limitations of small sample sizes in NZ results –sports food/beverages (n = 61) and weight management/meal replacement products (n= 56).</p>	<p>MPI</p>	<p>Noted.</p> <p>Although a smaller number of consumers of sports food/beverage and weight management/meal replacement products are in New Zealand compared to Australia, the total consumer numbers are sufficient to derive meaningful mean and P90 dietary intakes of L-carnitine. This is consistent with the FSANZ approach for deriving percentiles that apply to all dietary intake estimates.</p>

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Issue	Raised by	FSANZ response
<p>Other food categories: supports proposed permission for L carnitine in FSSF but suggests permitted amounts in foods for elderly and vegetarians also – for assisting maintenance or restoration of LC in skeletal muscle in these groups while acknowledging that permissions would not deliver the amount to achieve the effect. Likened it to NZ voluntary folic acid fortification where intakes were expected to be increased but not necessarily achieve the intended endpoint.</p>	<p>NZFGC</p>	<p>Noted.</p> <p>FSANZ concluded (section 2.4.1) that the current evidence does not support the applicant’s stated purposes for L-carnitine for vegetarians or the elderly.</p>
<p>Suggest listing L-carnitine in S29—18 as an amino acid. Suggests there could be confusion with nutrition information panels not listing any protein.</p>	<p>NSW</p>	<p>Not supported.</p> <p>L-carnitine is an unclassified nutritive substance or substance for the purposes of infant formula products (S29—5), formulated supplementary sports foods (29—19) and foods for special medical purposes (S29—20). The biochemistry and physiology of L-carnitine set out in section 3.1.1 of SD1 indicates that L-carnitine is not an amino acid incorporated into protein. It is therefore inappropriate for L-carnitine to contribute to declared protein in a nutrition information panel.</p>

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2.2 Risk and technical assessment

The risk and technical assessment (see SD1) included:

- (i) a food technology assessment of L-carnitine and L-carnitine-L-tartrate
- (ii) a hazard assessment to identify potential adverse effects associated with L-carnitine intake, the intake levels associated with any such effects, and an estimate of a safe upper level of intake
- (iii) a dietary intake assessment to estimate the total dietary intake of L-carnitine due to baseline intake and intake resulting from the addition of L-carnitine to the proposed foods
- (iv) a risk characterisation comparing dietary intake levels (at baseline and under a possible addition scenario) with the highest intake associated with no adverse effects in human studies.

The food technology assessment concluded that the L-carnitine and L-carnitine-L-tartrate are well characterised, with appropriate specifications and methods of analysis. The two substances are highly soluble in water with acceptable stability and would be expected to be readily incorporated into various food matrices.

The hazard assessment considered information on the physiology, biochemistry and pharmacokinetics of L-carnitine, L-carnitine-L-tartrate, L-carnitine chloride, acetyl L-carnitine and data from animal and human studies investigating a wide range of parameters relevant to safety. The available evidence supports a conclusion that L-carnitine and its compounds are not likely to be carcinogenic, or reproductive or developmental toxicants.

In human studies, oral L-carnitine doses as high as 7 g/day for durations of up to 12 months have been investigated, including in studies in elderly subjects, and in pregnant women. L-carnitine bioavailability declines markedly with dose and no systemic toxicity has been observed. No adverse effects attributable to L-carnitine intake were identified for dietary intakes below 3 g per day. At doses ≥ 3 g per day, mild side effects of nausea, gastrointestinal disturbances, and fishy body and/or urine odour have been observed. The favourable safety profile of L-carnitine is supported by clinical trials using intravenous administration which can achieve substantially greater systemic exposure than the oral route.

FSANZ also considered the relevant scientific literature and concluded that the current evidence does not support that trimethylamine *N*-oxide (TMAO), a metabolite of L-carnitine, plays a causal role in initiating or promoting adverse cardiovascular effects.

It is concluded that intake of L-carnitine up to 3 g/day is not associated with adverse effects. At higher doses, up to the maximum tested oral dose of 7 g/day, only minor adverse effects have been observed with no evidence of systemic toxicity.

2.2.1 Dietary intake assessment and conclusions

The dietary intake assessment accounted for naturally occurring L-carnitine concentrations in foods, the maximum levels for existing L-carnitine permissions in the Code, and the additional permissions requested by the applicant.

From national surveys of Australians aged 2 years and above and New Zealanders aged 15 years and above, the mean and P90 (high consumer) dietary intake of L-carnitine estimated from the applicant's request is given in Table A3.1 in SD1. General population high consumer dietary intake is approximately 0.9–1.1 g per day respectively.

The dietary intakes of each of the four identified populations groups in both countries are also given in that Table and rely on reported dietary patterns as proxies for the dietary intakes of these population groups. The high consumer dietary intakes of these groups are ranked in the same order in both countries and range from the elderly to vegetarians, those losing weight, and sports people. For Australian high consumers in those groups, dietary intake (2 days data) range from 0.6 g/day (elderly) to 1.6 g (people consuming sports foods). The New Zealand intakes (1 day data) for these two groups range from 0.7–1.4 g/day.

Another scenario was considered for sports food and beverage consumers that took account of regulation of added nutritive substances to FSSF in a one day quantity as advised on the food label. This scenario estimated 'baseline' L-carnitine dietary intake plus a one day quantity of sports foods and beverages (Table 9 in SD1). The high consumer dietary intakes under this scenario could increase to approximately 2.2 g/day.

As all mean and high percentile intakes in all scenarios are below 3 g per day, FSANZ concluded there are no safety concerns from the addition of L-carnitine to the range of general purpose and special purpose foods requested in the application.

Practice of stacking

Submissions referred to concern about the practice of stacking, i.e. selling multiple sports products with complementary attributes as one purchase. This suggests that daily intakes of L-carnitine from more than one product were possible. FSANZ reviewed website promotion of stacked sports products and observed that no more than 2 products in a stack contained L-carnitine. FSANZ also observed that sports foods and like products containing 2 g per one-day quantity are currently available on the market.

Consumption of up to 1 g L-carnitine from supplements (e.g. capsules, tablets) was recorded in the 2011–12 Australian national survey by less than 1% of the Australian population. No L-carnitine supplements were consumed on the day of the survey by people over 70 years or by those who consumed sports foods, weight reduction products, or who didn't eat meat. There was an insufficient number of consumers to derive a reliable estimate of L-carnitine intake from dietary supplements for New Zealand. However dosage instructions on supplements containing L-carnitine range from 0.3 – 2 g/day, averaging around 1.5 g/day.

A theoretical daily intake of one stack of sports foods in which 2 products contained the maximum amount of L-carnitine plus a supplement could be as high as 6 g; and less than a total of 7 g after accounting for naturally occurring sources from the diet. The risk of these theoretical intakes was assessed (section 2.1) and it was noted that only minor adverse effects were observed with no evidence of systemic toxicity for doses up to the maximum tested oral dose of 7 g/day. On the basis of the additional safety assessment of theoretically higher intakes from stacking, FSANZ concluded that FSSF with increased amounts of L-carnitine as proposed are unlikely to pose safety concerns.

2.3 Assessment of the health effects

Assessment of the health effects (SD2) concluded that plasma carnitine concentration is not a reliable marker of the body carnitine status but found that muscle carnitine concentration is the most suitable indicator of the body carnitine status. No evidence has been identified that muscle carnitine concentration ranges differ between the general healthy population and population sub-groups of relevance to the application i.e. vegetarians, elderly people, people actively losing weight and in athletes (see SD2).

Human supplementation studies with L-carnitine and L-carnitine-L-tartrate have investigated a large number of parameters of relevance to this application. This assessment has considered 43 studies investigating the potential favourable effects of oral L-carnitine supplementation in healthy subjects, including population sub-groups relevant to the application. Most of the studies use daily dosing at levels of around 2–3 g per day and most were conducted with male participants and used small subject numbers. In most studies L-carnitine or L-carnitine-L-tartrate were provided as tablets or capsules, however no information has been identified that indicates a difference in the absorption of L-carnitine from food compared to oral supplements. All repeat-dose studies gave L-carnitine at least once per day. No studies were found which examined the effect of less frequent intakes such as several times per week.

There is inconsistent evidence that muscle carnitine concentration can be increased slightly in vegetarians. For example, supplementation with a high intake of L-carnitine (4000 mg/day as tablets) for 3 months to adult males resulted in a 2-fold increase in plasma total carnitine, however muscle carnitine concentration was unaffected (Wächter et al. 2002). On the other hand, in a study in 16 adult male vegetarians and 8 adult male omnivores, supplementation with L-carnitine (2000 mg/day as capsules) for 12 weeks resulted in increased plasma carnitine concentration in both groups (by 24% in omnivores and 31% in vegetarians) while muscle total carnitine was increased only in vegetarians (by 13%, and remained within the normal range) (Novakova et al. 2016). However, neither of these studies included a placebo control group and there were no effects on the other parameters investigated by Novakova et al. (2016) [biochemical parameters including skeletal muscle ATP, phosphocreatinine, glycogen and lactate; exercise performance (sustained maximum cycling power) and aerobic capacity (VO₂max)].

Inconsistent favourable effects of supplementary L-carnitine intake have been reported in studies in elderly subjects (70 years and over). These studies, which used L-carnitine doses of 1.5 to 4 g/day for 4 weeks to 6 months, reported increases in muscle mass, loss of fat, and improved physical function following L-carnitine supplementation. However, of the two studies which tested 1.5 g/day, only one reported a favourable effect.

L-carnitine has not been shown to improve body composition or body weight in adults under 70 years who are actively losing weight. Findings for most parameters show a lack of both consistency and reproducible effects between studies investigating body weight and composition or changing protein, fat, and carbohydrate metabolism. Similarly, L-carnitine did not improve maximal oxygen uptake; blood and muscle lactate; muscle glycogen; blood glucose; muscle fibre composition; and mitochondrial enzyme activity.

For sports people, L-carnitine intake between 2 and 4 g/day did not improve the exercise performance (e.g. swimming, cycling, and running). However, in athletes and others undertaking regular exercise, three randomised, placebo-controlled trials (RCTs) have reported that L-carnitine reduces post-exercise muscle soreness. All three studies found an effect for an intake of 2 g L-carnitine per day on the first day but there was variation in the duration of the effect after that. It has been suggested that L-carnitine supplementation can result in increased muscle carnitine concentrations, and that this may aid post-exercise muscle recovery. However, increased muscle carnitine concentrations in omnivorous humans have only been reliably demonstrated in a study where L-carnitine (2.7 g/day for 24 weeks) was co-ingested with large amounts of carbohydrate (2 x 80 g per day of a glucose polymer mixture); post-exercise muscle soreness was not investigated in this study (see SD2).

FSANZ concluded that the current evidence does not support the applicant's stated purposes for vegetarians, the elderly or people actively losing weight.

2.4 Risk management

FSANZ had regard to the requirements of the FSANZ Act (see section 2.6) in developing and approving the draft regulatory measure. Since the technical and risk assessment concluded that the different L-carnitine forms are safe at the maximum proposed amounts (see SD1), FSANZ also considered the usefulness for consumers and matters covered in the following two Ministerial policy guidelines (see SD2 and SD3).

- Substances other than vitamins and minerals (for general foods)
- The intent of Part 2.9 of the Code (for special purpose foods).

These Ministerial policy guidelines state that the addition to food of substances such as L-carnitine in the quantity and a form proposed by the applicant should be consistent with delivering the applicant's stated purpose for that addition or with the intended purpose of the food. The response of potential consumers to food containing added L-carnitine was also considered to assess whether any significant negative impacts on public health would arise from approving this application (see SD3).

2.4.1 Food vehicle and target population group

The applicant's food categories were mostly general purpose foods with some special purpose foods relevant to the four identified population groups rather than the general population.

The dietary intake of L-carnitine was estimated by considering the concentrations of naturally occurring L-carnitine and the existing maximum permissions for L-carnitine at baseline and the amounts requested by the applicant. The dietary intake of high consumers of each population group using the most recent 2-day Australian and 1-day New Zealand nutrition surveys (Table A3.1 in SD1) were compared with the amounts consumed in studies comprising the evidence base of favourable effects.

Risk management considerations of the consistency with the applicant's stated purposes for the identified population groups is summarised in Table 3 and described thereafter.

Table 3: Decision-making related to evidence of favourable effects

Population group who...	Favourable health effect		High consumer intake meets minimum dose?		Permit L-carnitine?; relevant foods
	Sufficient evidence?	Min dose?	No (Table A3.1, SD1*)	Yes (Table 9, SD1**)	
Do not eat meat (vegetarians)	No	2 g	0.8 g Aus; 1.2 g NZ		No; general foods
Are aged over 70 years (elderly)	No	1.5 g	0.6 g Aus; 0.7 g NZ		No; general foods and supplementary foods
Consume meal replacements, weight loss products (weight losers)	No	2 g	1.2 g Aus; 1.4 g NZ		No; general foods and meal replacements

Consume sports foods (athletes/sports people)	Yes	2 g	1.6 g Aus; 1.4 g NZ	2.2 g Aus; 2.2 g NZ	Yes; formulated supplementary sports foods
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* consumer behaviour model ** one day quantity model

Vegetarians

L-carnitine intake by vegetarian adults inconsistently increased the muscle content of L-carnitine without improving energy metabolism or physical performance of this target group. Therefore, the current evidence does not support that muscle carnitine concentration can be generally increased in vegetarians supplemented with L-carnitine. Favourable health effects associated with L-carnitine intake by vegetarians as stated by the applicant are also not supported by the available evidence.

The evidence in relation to muscle carnitine content is examined in vegetarians consuming at least 2 g L-carnitine per day. Modelling found that if all permissions sought by the applicant were granted, the intake of high consumers of L-carnitine in people who did not eat meat (as a proxy for vegetarians) in Australia and New Zealand would be 0.8 and 1.2 g per day, respectively. Intake estimates therefore are considerably lower than that shown in the evidence base. Accordingly, the applicant's stated purpose for delivering favourable effects to vegetarians is neither supported by evidence nor achievable if L-carnitine were maximally added to all requested foods consumed by vegetarians. Therefore, FSANZ decided not to permit the addition of L-carnitine to general purpose foods or supplementary foods that are likely to be consumed by vegetarians.

Elderly people

Studies using supplementary L-carnitine doses between 1.5 and 4 g per day do not support the evidence for enhancing energy metabolism in elderly people or providing them with the stated favourable effects. Unlike for other groups, the submitted evidence did not investigate L-carnitine restoration in the muscles of elderly people as a result of the dietary intake of L-carnitine.

Modelling found that if all permissions sought by the applicant were granted, the dietary intake of high consumers of L-carnitine by elderly people (71 years and above) is estimated at approximately 0.6 g per day in both Australia and New Zealand. The intake estimates are therefore considerably lower than the evidence base. Therefore, FSANZ decided not to approve the addition of L-carnitine to general purpose foods or supplementary foods that are likely to be consumed by elderly people.

Weight loss

The current evidence does not support the stated effects of L-carnitine on carbohydrate metabolism, body fat, bodyweight or the body composition at intakes of 2–4 g per day in people actively losing weight. Therefore, adding L-carnitine to formulated meal replacements that are sometimes labelled as intended for inclusion in a weight loss diet, and regulated by the Code as a special purpose food, is not supported by the evidence.

Modelling found that if all permissions sought by the applicant were granted, the estimated L-carnitine intake of high consumers who consumed weight management or meal replacement products in Australia and New Zealand would be 1.2 and 1.4 g per day, respectively. Therefore, L-carnitine supplementation at 2 g per day or more would remain higher than the estimated intake by people losing weight in Australia and New Zealand. Therefore, FSANZ

decided not to approve the addition of L-carnitine to general purpose foods or meal replacements that are likely to be consumed by people losing weight.

Sports people/Athletes

Randomised, placebo-controlled trials showed that L-carnitine supplementation of exercising and sports people at doses ranging between 1 and 5 g per day were provided in relation to the applicant's stated purpose and the Code's defined purpose of FSSF. Compared with placebo, studies consistently demonstrated that an intake of 2 g L-carnitine per day improved post-exercise muscle recovery as measured by post-exercise muscle soreness.

Modelling found that, if all permissions sought by the applicant (i.e. all 30 classes of foods listed in Table 1) were granted, the estimated L-carnitine intake of high consumers of sports foods and beverages as recorded in national surveys in Australia and New Zealand is 1.6 and 1.4 g per day, respectively.

However, the table to section S29—19 regulates the amount of nutritive substances in FSSF in a labelled one-day quantity rather than per serving. This means that a sports person following the one-day-quantity label advice for FSSF could consume slightly more than 2 g total dietary L-carnitine per day (Table 9 in SD1) mostly from one sports food. Such an intake would be safe and consistent with the applicant's stated purpose and the Code's defined purpose of FSSF. This was also the case after further considering L-carnitine consumption from a stack of FSSF.

The evidence for favourable effects in sports people has been assessed as consistent with the applicant's stated purpose for that group. The evidence for an increased amount of L-carnitine is also consistent with the Code's defined purpose of FSSF and as such, accords with the policy guidelines, noting the permission is for voluntary use. FSANZ therefore decided to approve an increase in the maximum amount in a one-day quantity of FSSF from 100 mg to 2 g as requested.

Although the two forms of L-carnitine requested by the applicant were assessed as posing no safety concerns, FSANZ decided not to change to the table to section S29—19 to specify permitted forms of L-carnitine. Doing so would apply to the two forms of L-carnitine but not to other permitted nutritive substances in the table or to other forms of L-carnitine currently in use in FSSF on the market. The matter of permitted forms will be further considered in a future review of Standard 2.9.4.

2.4.2 Labelling of formulated supplementary sports foods

The addition of L-carnitine to FSSF is subject to generic labelling requirements and also to specific labelling requirements in Standard 2.9.4.

Should manufacturers choose to add L-carnitine to FSSF, L-carnitine must be included in the statement of ingredients (Standard 1.2.4 – Information requirements – statement of ingredients).

Section 2.9.4—4(1)(b) specifies that FSSF must include directions for use stating the recommended amount and frequency of intake of the food, a statement of the recommended consumption in one day and a nutrition information panel.

Section 2.9.4—5 sets out labelling requirements should a manufacturer include a statement referring to the presence of a substance that is used as a nutritive substance (such as L-carnitine), on a label. If the statement is used, then the label must state the amount of L-carnitine immediately after the statement referring to the presence of the substance, or

immediately following the name of the substance in the statement of ingredients, or in the nutrition information panel.

FSSF must carry statements to the effect that the food is not a sole source of nutrition and that the food should be used in conjunction with an appropriate physical training or exercise program. The following statement is also required: *Not suitable for children under 15 years of age or pregnant women: Should only be used under medical or dietetic supervision.* These labelling requirements enable consumers to make informed purchasing decisions.

In relation to certain health claims, Division 3 of Standard 2.9.4 sets out permissions for particular FSSF that meet one of three types of compositional specifications (high carbohydrate; protein energy, or energy) to carry certain claims on their labels e.g. *the product is useful before, during and after sustained strenuous exercise.* Apart from these claims permitted under Division 3, Section 2.9.4—7 prohibits representations about enhanced athletic performance and beneficial physiological effects, by the following:

Unless specific permission is given in this Part, the label on a package of formulated supplementary sports food must not include an express or implied representation that relates to any property or proposed use of the food to enhanced athletic performance or beneficial physiological effects.

Standard 1.2.7 – Nutrition, health and related claims provides for health claims to be made about foods, including health claims about physical performance, providing such foods meet certain claim criteria. However, as noted above, FSSF are currently prevented from making health claims about *enhanced athletic performance or beneficial physiological effects* except where express permission is provided in Standard 2.9.4 for making certain claims. Section 1.2.7—6 states that Standard 1.2.7 does not apply when a claim is expressly permitted by the Code.

2.4.3 Consumer awareness and behaviours in relation to L-carnitine

The response of potential consumers to food containing added L-carnitine was considered in the Call for Submissions¹.

Since L-carnitine is permitted in FSSF at present, it is not anticipated there will be any adverse changes to consumer behaviour with a permitted increase in L-carnitine in FSSF. This is because the range of foods containing L-carnitine (and carrying a statement about the presence of L-carnitine) is unlikely to significantly increase as a result of the change sought by the applicant. Therefore, it is unlikely that this change would result in a significant increase in awareness of L-carnitine in foods.

It is possible that some consumers already using FSSF containing L-carnitine will notice a change in the quantity of L-carnitine in some products (through voluntary declarations in the NIP, for example). This may lead them to switch from one brand to another. However, the increased quantity is unlikely to lead consumers who were not previously consuming FSSF containing L-carnitine to do so.

The social science assessment concluded that the evidence base concerning consumers and L-carnitine is limited with no research identified at present concerning Australian and New Zealand populations. International studies have generally been limited to individuals

¹ See Supporting document 3 – Assessment against Ministerial policy guidelines, and social science assessment <http://www.foodstandards.gov.au/code/applications/Pages/A1102-L-carnitineInFood.aspx>

who engage in regular exercise and health related activities. In addition, there is no evidence relating to how consumers would respond to higher levels of L-carnitine in FSSF.

2.4.4 Conclusion

FSANZ assessed the applicant's request for use of L-carnitine as a nutritive substance in 32 classes of food by assessing the evidence for safety and consistency with the stated purposes for four identified population groups. FSANZ concluded that L-carnitine at the maximum requested amounts in all requested foods is safe. However, the applicant's request is consistent only with the stated purpose for athletes and not for other population groups; it is also consistent with the Code's defined purpose of FSSF. The evidence in support of this conclusion accords with the ministerial policy guidelines for consistency with the intended purpose, noting that the permission is for voluntary use. FSANZ therefore decided to grant a partial approval to raise the maximum amount of L-carnitine per one day quantity in FSSF to 2 g, but not to permit addition of L-carnitine to other requested classes of food.

Having considered the submissions and weighed all aspects of the assessment against the statutory requirements including the ministerial policy guidelines, FSANZ approved a draft variation to the Code.

2.5 Risk communication

2.5.1 Consultation

Consultation is a key part of FSANZ's standards development process.

A public consultation paper calling for submissions was released from 13 September for a six week period.

Eight submissions were received: four from jurisdictions—Queensland, NSW, Victoria and NZMPI; one from public health—DAA, and three from industry groups—NZBC, ABC, NZFGC. Issues raised in the submissions are noted in Section 2.1 of this report along with FSANZ's response.

In response to submissions, further targeted consultation was undertaken with jurisdictions to help inform the final decision.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application. All comments are valued, and considered by the FSANZ Board, and contribute to the rigour of our assessment.

2.6 FSANZ Act assessment requirements

2.6.1 Section 29

2.6.1.1 Consideration of costs and benefits

For the reasons stated in the call for submissions report, FSANZ's assessment was that the direct and indirect benefits that would arise from a food regulatory measure varied as a result of Application A1102 outweigh the costs to the community, government or industry. No evidence was provided in response to the call for submissions report to warrant a change in that assessment.

2.6.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the application.

2.6.1.3 Any relevant New Zealand standards

The amendments to be made by approved draft variation are to standards that apply in both Australia and New Zealand. In New Zealand, a food product containing added L-carnitine may be a supplemented food and therefore be subject to the New Zealand Supplemented Food Standard.

2.6.1.4 Any other relevant matters

Other relevant matters are considered below.

2.6.2 Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.6.2.1 Protection of public health and safety

The risk assessment concluded that the maximum use levels of L-carnitine (in all requested foods) posed no safety concerns. L-carnitine intake up to 3 g/day is not associated with adverse effects. At higher doses, up to 7 g/day, from consumption of multiple sources of L-carnitine, only minor adverse side effects have been observed with no evidence of systemic toxicity (see section 2.2 and SD1).

For the reasons explained above, FSANZ decided to partially approve the use of an increased amount of L-carnitine as a nutritive substance in FSSF only.

2.6.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

Mandatory labelling requirements are outlined in section 2.4.2 and enable an informed choice to be made by consumers.

2.6.2.3 The prevention of misleading or deceptive conduct

Food laws and the provisions of the Code applied by these laws govern the addition of nutritive substances to foods, including FSSF. These are considered adequate to address any issues relating to misleading and deceptive conduct.

2.6.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ has used the best available scientific evidence to assess this application. In light of evidence emerging during the assessment, the applicant was asked to provide further evidence and to clarify the purpose for the use of L-carnitine in the requested foods. This

was to ensure that the assessment was based on the best available evidence. This additional information contributed to FSANZ's assessments provided in SD1 and SD2.

- **the promotion of consistency between domestic and international food standards**

The permission provided by the approved draft variation is consistent with similar permissions for L-carnitine in many countries in the Americas, Europe and Asia. Codex does not address addition of L-carnitine to food other than to a small number of special purpose foods.

- **the desirability of an efficient and internationally competitive food industry**

The permission provided by the approved draft variation would allow for a competitive food industry in relation to FSSF.

- **the promotion of fair trading in food**

No negative impact is anticipated on fair trading.

- **any written policy guidelines formulated by the Forum on Food Regulation**

The usefulness for consumers and matters covered in the following two ministerial policy guidelines (see SD2 and SD3) were considered:

- Substances other than vitamins and minerals (for general foods)
- The intent of Part 2.9 of the Code (for special purpose foods).

Both policy guidelines refer to a similar need for the proposed change to be consistent with the applicant's stated purpose or with the intended purpose of the food.

The evidence in support of the applicant's request was considered to be consistent with the applicant's stated purpose for athletes as well as with the defined purpose of FSSF. However the evidence was not found to be consistent with the applicant's stated purpose of additional L-carnitine in foods targeting vegetarians, the elderly or people actively losing weight.

FSANZ therefore partially approved the use of the increased amount of L-carnitine as a nutritive substance in FSSF only. FSANZ's assessment against the two relevant policy guidelines is provided in SD3.

3 Implementation and review

The approved draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

FSANZ has been requested by Ministers to review Standard 2.9.4.

Attachments

- A. Approved draft variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement

Attachment A – Approved draft variation to the *Australia New Zealand Food Standards Code*



Food Standards (Application A1102 – L-carnitine in Food) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[Insert name and position of Delegate]

Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1102 – L-carnitine in Food) Variation*.

2 Variation to a standard in the *Australia New Zealand Food Standards Code*

The Schedule varies a Standard in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

[1] Schedule S29

[1.1] The table to section S29—19

Omit

L-carnitine	100 mg
-------------	--------

substitute:

L-carnitine	2 g
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Attachment B – Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

The Authority accepted Application A1102 which seeks to amend the Code to permit the addition of L-carnitine to a range of general purpose foods and some special purpose food classes, including formulated supplementary sports food, regulated under Standard 2.9.4. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation to the Code.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislation Act 200*

2. Purpose

The Authority has approved a draft variation to the table to section S29—19 of Schedule 29 of the Code. The variation will increase the maximum amount of L-carnitine that may be added to formulated supplementary sports food.

3. Documents incorporated by reference

The variation does not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of application A1102 included one round of public consultation following an assessment and the preparation of a draft standard and associated assessment summary.

Submissions were called for on 13 September 2018 for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variation to the table to Section S29—19 is likely to have a minor impact on business and individuals.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

Item [1] of the approved draft variation amends the table to S29—19 in Schedule 29 of the Code. The item omits the existing entry in the table for L-carnitine and substitutes a new entry for L-carnitine with an increased maximum amount.

The effect of the variation is to permit the use of L-carnitine as a nutritive substance in formulated supplementary sports foods subject to the condition that the maximum amount of L-carnitine that may be added to a one-day quantity of a formulated supplementary sports foods is 2 grams.