

13 September 2018
[58–18]

Call for submissions – Application A1102

Addition of L-carnitine to foods

FSANZ has assessed an application made by Lonza Ltd, to amend the Australia New Zealand Food Standards Code to permit the sale and use of L-carnitine and L-carnitine L-tartrate within Australia and New Zealand as a nutritive substance in a wide range of general and special purpose foods. A draft food regulatory measure has been prepared. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that that we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient to receive submissions electronically through the FSANZ website via the [call for comments page](#). You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 25 October 2018

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604
AUSTRALIA
Tel +61 2 6271 2222

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6143
NEW ZEALAND
Tel +64 4 978 5630

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Supporting documents

The following documents¹ which informed the assessment of this application are available on the FSANZ website:

SD1	Technical and risk assessment
SD2	Assessment of the effect of adding a nutritive substance to food
SD3	Assessment against Ministerial policy guidelines, and social science assessment

¹ <http://www.foodstandards.gov.au/code/applications/Pages/A1102-L-carnitineInFood.aspx>

Executive summary

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 formulated supplementary sports foods. The two forms are L-carnitine and L-carnitine tartrate. The purpose of the application serves the interests of four target population groups: athletes; the elderly; vegetarians; and people actively losing weight.

This is the first time FSANZ has considered permissions for use of a nutritive substance in general purpose foods other than vitamins and minerals. It is also the first time that specific forms of nutritive substances are requested for formulated supplementary sports foods.

The Code currently permits the voluntary addition of L-carnitine to certain special purpose foods: infant formula products (with listed permitted forms), formulated supplementary sports foods (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 included 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.

The available evidence for the stated favourable effects in the population groups was also assessed by having regard to two relevant Ministerial policy guidelines. FSANZ concludes that the evidence related to reduction in muscle soreness in athletes consuming 2 g L-carnitine per day is consistent with the applicant's stated purpose as well as with the Code's defined purpose of formulated supplementary sports foods. This level of evidence is appropriate for a voluntary permission and accords with the policy guidelines that indicate the composition of a special purpose food should be consistent with its intended purpose.

Since the maximum amount of L-carnitine in table S29—19 to Standard 2.9.4 is expressed per one-day quantity rather than per serving, a sports person following label instructions on a formulated supplementary sports food containing the maximum amount of L-carnitine could consume amounts consistent with the applicant's stated purpose for athletes. Therefore, it is proposed to increase the permitted maximum amount in formulated supplementary sports foods to 2 g per one-day quantity.

The two requested forms of L-carnitine were assessed as posing no safety concerns, however no change to table S29—19 to Standard 2.9.4 is proposed to specify these forms. Doing so would specify forms for only one of several permitted nutritive substances; it would also preclude the use of other forms of L-carnitine currently added to formulated supplementary sports foods. This matter will be further considered in a future review of Standard 2.9.4.

The current evidence does not support the stated favourable effects in 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. Therefore, FSANZ proposes not to permit the addition of L-carnitine to the other 30 classes of general and special purpose food requested by the applicant.

The addition of L-carnitine to formulated supplementary sports foods is subject to generic and specific labelling requirements set by the Code. These labelling requirements help consumers make informed purchasing decisions. Formulated supplementary 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 applied to amend the Australia New Zealand Food Standards Code (the Code) to permit as nutritive substances the use or an increased amount of L-carnitine and L-carnitine L-tartrate in 32 classes of food. Lonza wishes to market refined L-carnitine and L-carnitine L-tartrate under respective trade names to broaden the potential for innovation and allow it to benefit from increased market development both domestically and overseas.

Food classes to which the use of L-carnitine, or L-carnitine L-tartrate, has been sought are available in Table 1. A maximum amount of 0.25 g L-carnitine per serving was requested for dairy products, up to 0.05 g per serving in confectionery, up to 0.25 g per serving in cereal and cereal products, between 0.1 and 0.5 g per serving in non-alcoholic beverages and gels and a maximum of 0.25 g per serving in formulated meal replacements and supplementary foods. The amount of L-carnitine in formulated supplementary sports foods, either solid or liquid, is requested to increase from the current permission of 0.1 g up to 0.5 g per serving to deliver a maximum of 2 g in a one-day quantity. The requested amounts for each food class are shown in detail in Appendix L to the application available on our website (see footnote 1).

Table 1 Food classes to which the use or increase of L-carnitine has been requested

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 applicant's stated purpose is 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. The stated purposes related to four specific population groups, excluding the general population, as follows:

- 1 Adult vegetarians will be able to increase their L-carnitine levels and obtain high energy in situations such as exercising
- 2 For the elderly, L-carnitine-fortified foods help restore L-carnitine levels in that age group, 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 is the first time FSANZ has considered permissions for the use of a nutritive substance other than a vitamin or mineral in general purpose foods. This is also the first time that specific forms of nutritive substances have been requested for formulated supplementary sports foods.

1.3 The current standards

1.3.1 Australia and New Zealand

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

- Standard 2.9.1 – Infant Formula Products – table to S29—5
 - 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 S29—19
 - Maximum amount added per one-day quantity – 100 mg
 - Permitted form: Not specified
- Standard 2.9.5 – Food for Special Medical Purposes – table to S29—20
 - 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. L-carnitine and L-carnitine L-tartrate are also permitted to be added to 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 the 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.

2 Summary of the assessment

2.1 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; and (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, 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. No adverse effects attributable to L-carnitine intake were identified for dietary intakes below 3 g per day. At doses ≥ 3 g per day, some treatment-related adverse effects have been observed such as nausea, gastrointestinal disturbances, and fishy body and/or urine odour. FSANZ also considered the relevant scientific literature and concluded that the 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.

The dietary intake assessment accounted for naturally occurring L-carnitine concentrations in foods, the maximum levels for existing L-carnitine permissions, and the additional permissions requested by the applicant. For the general populations of Australians aged 2 years and above and New Zealand aged 5 years and above, the P90 (high consumer) dietary intake of L-carnitine estimated from the applicant's request is approximately 0.9 – 1.1 g per day (Table A3.1 in SD1). As these intakes are below 3 g per day, there are no public health and safety concerns from the addition of L-carnitine to the range of general purpose and special purpose foods requested in the application.

For sports foods and beverages consumers, the scenario with the highest estimated dietary intakes includes L-carnitine intakes from 'baseline' plus L-carnitine intakes from the recommended number of serves of sports foods and beverages per day. The applicant has recommended four serves per day to achieve a total daily intake of 2 g L-carnitine from sports foods and beverages. The high consumer 90th percentile dietary intakes could increase to approximately 2.2 g/day under this scenario.

FSANZ concludes that there are no public health and safety concerns from the use of L-carnitine in the range of general purpose and special purpose foods at the amounts requested by the applicant.

2.2 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.

One uncontrolled study in vegetarians found a slight increase in muscle carnitine concentration following supplementation with 2 g/day L-carnitine for 12 weeks. However, there were no effects on the biochemical parameters investigated in this study including skeletal muscle ATP, phosphocreatinine, glycogen and lactate; exercise performance (sustained maximum cycling power) and aerobic capacity (VO₂max).

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. 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), however post-exercise muscle soreness was not investigated in this study (see SD2).

FSANZ concludes that the current evidence does not support the applicant's stated purposes for vegetarians, the elderly or people actively losing weight. However the evidence is consistent with a stated favourable effect in relation to more efficient exercise recovery in sports people consuming at least 2 g L-carnitine per day.

2.3 Risk management

FSANZ had regard to the requirements of the FSANZ Act (see section 2.5) in developing the proposed 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).

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 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).

2.3.1 Food vehicle and target population group

The applicant's total number of food classes were mostly general purpose foods with some special purpose foods. The applicant's request sought to provide favourable effects in four population groups rather than in the general population. FSANZ's assessment of the favourable effects of use of L-carnitine in foods indicated a varying quality of evidence to support the indicated usefulness for consumers.

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 based on the safety and consistency with the stated purposes of L-carnitine in each population group is as follows:

Vegetarians

L-carnitine intake by vegetarian adults slightly, but 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 observed in vegetarians consuming 2 g L-carnitine per day. Based on the applicant's request, 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 are 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 proposes 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

The current evidence did not investigate L-carnitine restoration in the muscles of elderly people as a result of the dietary intake of L-carnitine. 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.

Based on the applicant's request, 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 proposes not to permit 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.

Based on the applicant's request, the estimated L-carnitine intake of high consumers who consumed weight management or meal replacement products in Australia and New Zealand are 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 proposes not to permit the addition of L-carnitine to meal replacements that are likely to be consumed by people losing weight.

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 provided evidence in relation with the applicant's stated purpose and the Code's defined purpose of formulated supplementary sports foods. Compared with placebo, studies demonstrated that an intake of 2 g L-carnitine per day, as requested by the applicant, increased muscle carnitine concentration and improved post-exercise muscle recovery as measured by post-exercise muscle soreness.

According to a dietary modelling scenario of baseline intake plus the applicant's request for sports foods only, the estimated L-carnitine intake of high consumers of sports foods and beverages in national surveys in Australia and New Zealand is 0.8 and 0.5 g per day, respectively. Although modelled intakes are lower than the amounts observed in the evidence base, the table S29—19 to Standard 2.9.4 regulates the amount of nutritive substances in formulated supplementary sports foods in a one-day quantity (see section 2.3.2). This means that a sports person following label advice about the one day quantity could consume approximately 2 g L-carnitine per day (Table 9 in SD1). Such an intake would be safe and consistent with the applicant's stated purpose and the Code's defined purpose of formulated supplementary sports foods.

FSANZ concludes that formulated supplementary sports foods with increased amounts of L-carnitine as requested is safe and supported by evidence in exercising and sports people that is consistent with the applicant's stated purpose for that group. This level of evidence for an increased amount of L-carnitine is also consistent with the Code's defined purpose of formulated supplementary sports food and as such, accords with the policy guidelines, noting the request is for voluntary use. FSANZ therefore proposes to permit an increase in the maximum amount in a one-day quantity of formulated supplementary sports foods 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, no change to table S29—19 to Standard 2.9.4 is proposed to specify permitted forms of L-carnitine. Doing so would apply to L-carnitine alone and not to other permitted nutritive substances in the table; it would also preclude other forms of L-carnitine currently in use in formulated supplementary sports foods. This matter will be further considered in a future review of Standard 2.9.4.

2.3.2 Labelling of formulated supplementary sports foods

The addition of L-carnitine to formulated supplementary sports foods 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 formulated supplementary sports foods, 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 formulated supplementary sports foods 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.

Formulated supplementary sports foods 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 formulated supplementary sports foods 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, formulated supplementary sports foods 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.

2.3.3 Consumer awareness and behaviours in relation to L-carnitine

Since L-carnitine is permitted in formulated supplementary sports foods at present, it is not anticipated there will be any adverse changes to consumer behaviour with a permitted increase in L-carnitine in formulated supplementary sports foods (see SD3). This is because the range of foods containing L-carnitine (and carrying a nutrition content claim regarding L-carnitine) is unlikely to significantly increase as a result of the proposed change. Therefore, it is unlikely that the proposed change would result in a significant increase in awareness of L-carnitine in foods.

It is possible that some consumers already using formulated supplementary sports foods 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 formulated supplementary sports foods containing L-carnitine to do so.

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 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 formulated supplementary sports foods.

2.3.4 Conclusion

FSANZ assessed the applicant's request for use of L-carnitine in 32 classes of food by assessing the evidence for safety and consistency with the stated purposes for four identified population groups. FSANZ concludes that L-carnitine at the maximum requested amounts in all requested foods is safe. However, the applicant's request is consistent with the stated purpose for athletes only and not for other population groups; it is also consistent with the Code's defined purpose of formulated supplementary sports foods. The level of evidence in support of this conclusion accords with the policy guidelines to be consistent with the intended purpose, noting that the request is for voluntary use. FSANZ therefore proposes to increase the maximum amount of L-carnitine to 2 g per one day quantity in formulated supplementary sports foods.

Having considered the range of options available and weighed all aspects of the assessment against the statutory requirements including the Ministerial policy guidelines, FSANZ proposes the following approach and has prepared a draft variation to the Code based on that approach.

Proposed approach

To amend the table to S29—19 to increase the amount of L-carnitine in formulated supplementary sports foods to a maximum of 2 g in a one-day quantity.

No permitted forms of L-carnitine to be listed.

Use of L-carnitine not to be permitted in other general or special purpose foods requested by the applicant.

The details supporting this recommendation are outlined in the following sections. The draft variation reflecting this option is at Attachment A. The draft explanatory statement for the variation is in Attachment B.

2.4 Risk communication

2.4.1 Consultation

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

FSANZ has developed and applied a basic communication strategy to this application. Subscribers and interested parties have been notified about this call for submissions via the FSANZ Notification Circular, media release and through FSANZ's social media tools and Food Standards News.

FSANZ acknowledges the time taken by individuals and organisations to consider this application. All comments are valued and contribute to the rigour of our assessment. Comments received will be taken into account when developing any draft variation(s) for approval by the FSANZ Board.

If the draft variation to the Code is approved by the FSANZ Board, that decision will be notified to the Australia and New Zealand Ministerial Forum on Food Regulation. If the Board's decision is not subject to a request for a review, the applicant and stakeholders, including the public, will be notified of the gazettal of the variation to the Code in the national press and on the FSANZ website.

2.4.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are relevant international standards and amending the Code to permit the increased level of addition of L-carnitine to formulated supplementary sports foods is unlikely to have a significant effect on international trade as L-carnitine is already permitted in similar products overseas. The extended permission in the Code may potentially provide some trade opportunities. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.5 FSANZ Act assessment requirements

When assessing this application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

2.5.1 Section 29

2.5.1.1 *Consideration of costs and benefits*

The Office of Best Practice Regulation (OBPR) advised that, based on the information provided, the application, including increasing the maximum permitted amount of L-carnitine in formulated supplementary sports foods, is likely to have a minor regulatory impact on business, community organisations, or individuals (reference ID 18910). Therefore, a Regulation Impact Statement (RIS) was not required.

FSANZ, however, has given consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (S.29 (2)(a)).

The purpose of this consideration is to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo. This analysis considered approving the requested increase to the maximum permitted amount of L-carnitine in formulated supplementary sports foods. FSANZ is of the view that no other realistic food regulatory measures exist, however information received may result in FSANZ arriving at a different outcome.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo by approving the requested increase to the maximum permitted amount of L-carnitine in formulated supplementary sports foods.

- *Costs and benefits of approving the requested increase to the maximum permitted level of L-carnitine in formulated supplementary sports foods*

The use of L-carnitine in formulated supplementary sports foods as proposed will not pose a health or safety risk for consumers.

For athletes and others undertaking regular exercise training, studies reported that L-carnitine intake at the maximum requested amount of 2 g per day has increased muscle carnitine concentrations, aided in reducing post-exercise muscle recovery as measured by reduced post-exercise muscle soreness.

The proposed increase in the current permission is voluntary, and therefore additional L-carnitine will only be used where industry believes there will be a net benefit in doing so. With appropriate uptake of the permission by food manufacturers, labelling and advertising on the intake amount in one-day quantity, this option could make formulated supplementary sports foods with a higher L-carnitine content available should consumers wish to consume more L-carnitine.

This option may provide opportunities for product development and potential to expand markets. As the requested increased amount is consistent with similar products available in for example, the USA, it may become easier for local producers to access these markets; it could also result in a wider range of overseas products becoming available for sale in Australia and New Zealand.

There may be some minor costs to government in terms of monitoring and compliance as regulators will need to be made aware of the increase in the permitted level. No other changes to governments' costs or benefits are expected from this option.

- *Conclusions from cost benefit considerations*

FSANZ's assessment is that the direct and indirect benefits that would arise from approving the requested increase to the maximum permitted amount of L-carnitine in formulated supplementary sports foods most likely outweigh the associated costs.

2.5.1.2 Other measures more cost-effective than a regulatory measure

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.

2.5.1.3 Any relevant New Zealand standards

The proposed amendments to the Code apply to both Australia and New Zealand. In New Zealand, a food product containing added L-carnitine may be considered a supplemented food and therefore be subject to the New Zealand Supplemented Food Standard. This possibility would apply to formulated supplementary sports foods currently on the market.

2.5.1.4 Any other relevant matters

Other relevant matters considered follow.

2.5.2 Subsection 18(1)

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

2.5.2.1 Protection of public health and safety

The risk assessment concludes that the use and maximum use levels of L-carnitine in all requested foods does not pose a risk to health. L-carnitine has a history of safe use in sports foods, and in supplements, in Australia and New Zealand (See SD1). For the reasons explained above, FSANZ proposes to permit the use of an increased amount of L-carnitine as a nutritive substance in formulated supplementary sports foods only.

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

Mandatory labelling requirements are outlined in section 2.3.2 and enable an informed choice to be made by consumers.

2.5.2.3 The prevention of misleading or deceptive conduct

The provisions of the Code that are applied by food laws to govern the addition of nutritive substances to foods, including formulated supplementary sports foods, are considered adequate to address any issues relating to misleading and deceptive conduct.

2.5.3 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. These additional information contributed to FSANZ's assessments in SD1 and SD2.

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

The proposed amendment to the Code 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 proposed permissions in the Code would allow for a competitive food industry in relation to only formulated supplementary sports foods.

- **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 a formulated supplementary food. However the evidence was not found to be consistent with the applicant's stated purpose for foods targeting vegetarians, elderly or people actively losing weight.

FSANZ therefore proposes to permit the use of an increased amount of L-carnitine as a nutritive substance in formulated supplementary sports foods only. FSANZ's assessment against the two relevant Ministerial policy guidelines is provided in SD3.

3 Draft variation

The 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.

Attachments

- A. Draft variation to the Australia New Zealand Food Standards Code
- B. Draft Explanatory Statement.

Attachment A – Draft variations 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
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substitute:

L-carnitine	2 g
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Attachment B – Draft 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.

FSANZ accepted application A1102 which seeks to amend the Code to enable the sale and use of L-carnitine as L-carnitine and L-carnitine L-tartrate within Australia and New Zealand as a nutritive substance. The application seeks permission to add 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 prepared a draft variation to the Code.

2. Purpose

The Authority has prepared a 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 will include one round of public consultation following an assessment and the preparation of a draft standard and associated assessment summary.

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 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.