



## **Application A1102**

### **Addition of L-carnitine to foods**

#### **Call for submissions paper**

#### **Submission**

The NSW Food Authority (NSWFA) welcomes the opportunity to comment on Application A1102 – Addition of L-carnitine to foods, which seeks to amend Schedule 29 of the Australia New Zealand Food Standards Code (the Code) to increase the permitted amount of L-carnitine in formulated supplementary sports foods from 100mg per one day quantity to 2g per one day quantity.

#### **Summary position**

NSW is concerned that the scope of the FSANZ risk assessment is too narrow and may not have considered consumption of L-carnitine in conjunction with the common marketing strategy of 'stacking', where multiple products containing L-carnitine are sold as a bundle. Stacking greatly increases the likelihood of consuming more than the 3 gram per day adverse effect threshold cited by FSANZ in its risk assessment. The maximum daily consumption of 7 g per day modelled in the FSANZ risk assessment therefore needs to be increased to account for quantities available through 'stacking'.

NSW notes that Australia New Zealand Ministerial Forum for Food Regulation (11 October 2018) asked FSANZ, as a priority, to review Standard 2.9.4 (Formulated supplementary sports foods) and involve the Therapeutic Goods Administration in this review. NSW is concerned that A1102 is being progressed ahead of this review given the overlapping concerns that exist between Standard 2.9.4 and A1102.

Products that already contain L-carnitine are typically marketed as 'thermogenic', 'fat burning' and 'fat metabolising'. It is anticipated that these marketing strategies and 'stacking' would be extended to products that may come to market under A1102. Some of the existing L-carnitine products are ARTG listed therapeutic goods, supplemented foods (possibly NZ standard), dietary supplements (possibly NZ regulation), supplementary sports foods (Standard 2.9.4) and caffeinated energy beverages (Standard 2.6.4). L-carnitine levels in these products vary depending on which regulatory system controls supply. Most consumers will not recognise that their total daily intake of L-carnitine needs to consider all sources, irrespective of which regulatory system controls supply.

NSW preferred position is that FSANZ defer work on A1102 until the review of Standard 2.9.4 is complete. If this is not possible, NSW suggests that additional risk management measures are required for A1102 to ensure consumers are aware of the risks associated with consuming more than 3 grams of L-carnitine per day. NSW

suggests that all supplementary sports food and caffeinated energy beverages containing L-carnitine declare the quantity in the Nutrition Information Panel, irrespective of whether a claim is made. NSW further suggests that supplementary sports foods containing L-carnitine be labelled with a warning statement along the lines of 'consuming more than 3 grams of L-carnitine per day is known to cause adverse effects'.

NSW proposes these additional risk management measures as total dietary sources of L-carnitine marketed by supplement suppliers/retailers go beyond the remit of Standard 2.9.4 and Standard 2.6.4. NSW acknowledges that FSANZ cannot amend TGA lists or NZ legislation, however warning messages on foods regulated by Standard 2.9.4 and 2.6.4 should help consumers make informed choices on supplement purchases.

Specific comments in support of the above points is offered below.

**'Thermogenic', 'fat burning' effects, 'fat metabolism' or weight loss statements:**

An internet search of the following supplement retailers for L-carnitine has revealed that this product is commonly marketed as a 'thermogenic fat burner' or under weight loss products, in addition to muscle recovery.

<https://www.bulknutrients.com.au/categories/weightloss.html>

<https://shop.bodyscience.com.au/weight-management/thermogenics.html>

<https://www.elitesupps.com.au/collections/weight-loss-supplements>

<https://suppkings.com.au/goal/fat-loss/>

<https://www.mrsupplement.com.au/lose-weight>

Further review of these websites under the above-mentioned headings shows that L-carnitine containing products appear to be supplied through several legislative remits including ARTG listed products (Therapeutic goods), Supplemented Foods (possibly NZ supplements food standard), dietary supplements (possibly NZ dietary supplements regulation), formulated supplementary sports foods (Standard 2.9.4) and caffeinated energy beverages (Standard 2.6.4).

NSW queries whether the variant supply channels for L-carnitine in existing products have been considered in the dietary exposure assessment conducted for this application. Some L-carnitine containing products are cited on these websites as 'best sellers' – e.g. 'Oxyshred' by EHP labs. NSW would appreciate clarity from FSANZ whether the dietary exposure assessment for L-carnitine all known sources of L-carnitine.

NSW does not consider that the marketing practices currently employed for L-carnitine in the supplements industry will change following Application 1102, it will simply add more dietary sources. NSW suggests that the current prohibition on slimming claims in Standard 1.2.7-15 and prohibited representations in Standard 2.9.4-7 are clarified to ensure that 'thermogenic', 'fat burning', 'fat metabolising'

claims may not be made on foods regulated by Standard 2.9.4 or Standard 2.9.4. NSW would further appreciate advice on whether the marketing of these foods under 'weight loss', 'weight management' or similar on supplier/retailer websites constitutes a breach under current arrangements.

### **'Stacking'**

'Stacking' refers to the common practice in the supplements industry of selling multiple products together in a bundle marketed towards a particular goal or population sector.

Review of 'stacks' marketed on supplement retailer websites shows that stacks targeted at women contain multiple products with L-carnitine.

#### **1. Elite Supplements**

<https://www.elitesupps.com.au/collections/weight-loss-supplements/products/elite-supps-female-tone-stack-2>

This 'stack' provides that 'Oxyshred' may be stacked with ATP science Acetyl L-carnitine. 'Oxyshred' is labelled as a 'supplemented food' and ATP Acetyl L-carnitine as either a 'dietary supplement' or 'supplementary sports food'. Review of ingredient list for 'Oxyshred' on the US supplier website (EHP labs) suggests that 'Oxyshred' contains 3.6 g of Acetyl L-carnitine per 2 scoops (listings on Australian website do not provide specific quantity of Acetyl L-carnitine). If 'Oxyshred' is stacked with ATP science Acetyl L-carnitine with usage instructions of one 2 g scoop before, during and after training, it seems that a person taking this stack would consume 9.6g of Acetyl L-carnitine. This quantity is above that modelled by FSANZ in its risk assessment. NSW would appreciate advice from FSANZ whether the dietary exposure assessment included 'stacking'.

#### **2. Mr Supplements**

<https://www.mrsupplement.com.au/lose-weight>

The EHP labs Acetyl L-carnitine sold on this website, marketed as a 'dietary supplement' carries the claim 'stack safe' with 'Oxyshred' listed as a stacking product. Directions for use on EHP labs Acetyl L-carnitine suggest that 1-2g should be taken as a dose, but do not exceed 5 g in a day. When stacked with 'Oxyshred' this could provide a dose of Acetyl L-carnitine of somewhere between 4.6g – 7.6g per day.

### **Labelling requirements for nutritive substances**

NSW understands that numerical composition declarations through the Nutrition Information Panels are only mandatory for Standard 2.9.4-5 if a claim is made about presence in the food.

Given that many products already on the market containing L-carnitine do not make front of pack label claim about L-carnitine (N.B. NSW does not consider 'Acetyl L-carnitine' as the name of the product to be a claim), and these products are stacked,

NSW suggests that all formulated supplementary sports foods and caffeinated energy beverages containing L-carnitine must declare the quantity present in the Nutrition Information Panel. This would assist consumers in reviewing L-carnitine concentration in these products to avoid over consumption of this substance at levels indicated by FSANZ in its risk assessment to give rise to adverse effects (above 3 g per day where nausea, gastrointestinal disturbances, and fishy body and/or urine colour were observed).

Given that dietary sources of L-carnitine are broader than just supplementary sports foods, NSW suggests that a warning statement be included on all foods regulated by the Food Standards Code that contain L-carnitine to advise consumers not to consume over 3g of L-carnitine per day from all dietary sources. This is to promote awareness in consumers to review all dietary sources of L-carnitine in making purchase decisions.

### **Listing of L-carnitine in Schedule 29**

NSW queries why L-carnitine is not listed in Schedule 29-18 as an amino acid. A literature review of this substance appears to confirm that it is. Schedule 29-19 provides that it is a nutritive substance. NSW considers this may be resulting in confusion in Nutrition Information Panels of some supplements not listing any protein but having L-carnitine as the first ingredient on the ingredient list. 'Oxyshred' is an example of such a product.

### **Further consideration of Application 1102**

NSW preferred position on the Application is that it is deferred until the review of Standard 2.9.4 as requested by Food Ministers is completed. Should this option not be possible under the FSANZ Act 1991 NSW requests that FSANZ consider and respond to concerns raised in this submission.

Some examples of product labels are provided at Attachment 1.

### **ENDS**

**The views expressed in this submission may or may not accord with those of other NSW Government agencies. The NSW Food Authority has a policy which encourages the full range of NSW agency views to be submitted during the standards development stages before final assessment. Other relevant NSW Government agencies are aware of and agree with this policy.**