

Supporting document 3

Assessment against Ministerial policy guidelines, and social science assessment – Application A1102

L-carnitine in food

1 Ministerial policy guidelines

The two policy guidelines relevant to application A1102 are:

- The addition of substances other than vitamins and minerals (SOT), which excludes Special Purpose Foods (Part 2.9 of the Code)
- The intent of Part 2.9 of the Code – Special Purpose Foods (SPF)

The assessment against the specific policy principles of the policy guidelines are given in Table 1 and Table 2.

Table 1: Consideration of specific policy principles: the addition of substances other than vitamins and minerals (SOT Policy Guideline)

Specific Order Policy Principles: Other than to achieve a solely technological function	Assessment
a) The purpose for adding L-carnitine to food (the stated purpose) has been articulated clearly by the manufacturer	The stated purposes of the application for the four identified population groups: vegetarians, the elderly, those losing weight, and athletes/sports people is set out in section 1.2 of Approval report.
b) The proposed addition of L-carnitine to foods is safe for human consumption	The safety assessment identified the intake of L-carnitine at the maximum levels from all requested food (<3 g/day) is safe. Only possible mild side effects were evident from consumption of multiple stacked products (<7g/day), that also does not pose a health and safety concern (see Approval report and SD1).

Specific Order Policy Principles: Other than to achieve a solely technological function	Assessment
c) L-carnitine is added in a quantity and a form which is consistent with delivering the stated purpose	<p>L-carnitine, L-carnitine tartrate are appropriate forms for addition to food consistent with delivering the stated purpose (see SD2).</p> <p>A diet containing the requested maximum amounts of L-carnitine in all requested general purpose foods, meal replacements and formulated supplementary foods cannot provide L-carnitine in amounts consistent with delivering the applicant's stated purposes for vegetarians, people losing weight, athletes/sports people and the elderly consuming these foods.</p> <p>However, formulated supplementary sports foods are specifically formulated to assist sports people in achieving specific nutritional or performance goals. Consumption of one-day quantity of formulated supplementary sports food according to label directions can provide an amount consistent with the stated purpose of the food for sports people.</p>
d) The addition of the substance is not likely to create a significant negative public health impact to the general or sub populations	<p>Only the request for an increase in L-carnitine in formulated supplementary sports foods is approved. This higher amount has been observed in sports foods products currently on the market without evidence of reported adverse effects.</p>
e) The presence of the substance does not mislead the consumer as to the nutritional quality of the food	<p>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.</p>

Table 2: Consideration of specific policy principles: Special Purpose Foods (Intent of Part 2.9 Policy Guideline)

Specific Order Policy Principles	Comments
a) Special purpose foods should be targeted to specific population groups who meet the criteria outlined in the policy guideline	<p>This application does not amend the range of special purpose foods in Part 2.9 of the Code. Special purpose foods relevant to this application are meal replacements (may be marketed to those losing weight), formulated supplementary foods (may be marketed to the elderly) and formulated supplementary sports foods (may be marketed to sports people).</p>

Specific Order Policy Principles	Comments
b) The composition of special purpose food should be consistent with the intended purpose	<p>According to national surveys, a diet containing the requested maximum amounts of L-carnitine in all requested general purpose foods, meal replacements and formulated supplementary foods and formulated supplementary sports foods cannot provide L-carnitine in amounts consistent with delivering the applicant's stated purposes for vegetarians, people losing weight, sports people and the elderly consuming these foods.</p> <p>However, formulated supplementary sports foods are specifically formulated to assist sports people in achieving specific nutritional or performance goals. Consumption of a one-day quantity of formulated supplementary sports food according to label directions can provide an amount consistent with the intended purpose of the food for sports people.</p>
c) Adequate information should be provided, including through labelling and advertising of special purpose foods	<p>Labelling of formulated supplementary sports foods containing added L-carnitine is subject to generic labelling requirements under Standard 1.2.4 (declaration in the list of ingredients) and also to specific labelling requirements under Standard 2.9.4 to enable consumers to make informed purchasing decisions (See section 2.3.2 in the Call for submissions).</p>
d) Consideration, where appropriate, should be given to application of controls to restrict access to a special purpose food on the basis of risk to public health and safety	<p>Access to formulated supplementary sports foods on the market is currently not restricted. A safe increase in the amount of L-carnitine in these foods does not warrant any change to these arrangements.</p>

2 Social science assessment

The social science assessment relies on the research cited by the applicant, additional published research available through bibliographic databases, and previous related literature reviews prepared by FSANZ. The applicant states FSANZ considers that consumers are likely to become aware of the presence of L-carnitine in food products through the use of nutrition content claims. FSANZ notes that L-carnitine must also be listed in the ingredient list if added to a food and that under the current provisions in the Code, nutrition content claims are currently permissible for formulated supplementary sports foods.

Social Science research specific to L-carnitine

Market research conducted on behalf of the applicant (Lonza, 2007, 2013) reports that between 8 to 48% of consumers are aware of L-carnitine depending on the country surveyed (Australia or New Zealand were not). However, what constitutes awareness is not articulated in the provided research. The methodology used for the research provided by the Applicant is not reported aside from the mention that the surveys were ad hoc and online. As such, it is not possible to determine or infer from this research Australian and New Zealand consumer knowledge and awareness of L-carnitine.

A FSANZ search of bibliographic databases for research regarding consumers and L-carnitine has found no research conducted in Australia or New Zealand. No research was found as to whether the presence of L-carnitine in foods has or would mislead consumers about the nutritional value of a food. Low quality international evidence shows users of L-carnitine associate it with weight loss/management. One study conducted by the applicant found non-users of L-carnitine who were told about the 'benefits' (weight regulation, improved energy) of L-carnitine reported they were more likely to integrate it into their diets as a result. Another study of adolescents found the majority would not use L-carnitine (Bell et al, 2004). No research was found regarding whether consumers are seeking specific quantities of L-carnitine in the foods they buy. For example, whether foods containing higher levels of L-carnitine would be more or less appealing to consumers.

Information available to consumers

Due to the existing permission for L-carnitine in formulated supplementary sports foods in the Code, FSANZ considers that users of sport food supplements are more likely to be aware of L-carnitine than the general population. Consumer information regarding L-carnitine available via web searching reveals claims about the benefits of L-carnitine for weight loss/management, cardiovascular health, increased energy and reduced muscle damage messages.¹

Conclusion

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. 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

¹ The Applicant noted at the time of the application in 2014 that 'consumers may obtain facts about Carnipure™ crystalline and Carnipure™ tartrate from Lonza's website'. In 2017 Lonza's website presents a disclaimer indicating that the information provided is "business-to-business information intended for food and supplement producers, and is not intended for the final consume".

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.

As noted above, 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.

References

Bell A, Dorsch K, McCreary D, Hovey R. (2004). A look at nutritional supplement use in adolescents. *Journal of Adolescent Health* 34(6): 508-516.

Lonza (2007) Lonza Logo-Test in 4 Countries. IHA-GfK

Lonza (2013) Carnipure™ - GfK recognition survey. IHA-GfK