EXECUTIVE SUMMARY

(As per section 3.1.1B of the Application Handbook 1 September 2013)

Lonza seeks to amend the *Australia New Zealand Food Standards Code* in order to extend the permission for use of L-carnitine as a nutritive substance. The purpose of using L-carnitine as an ingredient in foods 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.

L-carnitine is an essential co-factor for fatty acid metabolism and other metabolic pathways. The majority of the body's L-carnitine is supplied in the diet from meats and meat-based foods; however, L-carnitine is also synthesized endogenously from lysine and methionine supported by certain vitamins and minerals. Thus, L-carnitine cannot be considered an essential nutrient, *per se*, although the term "conditionally essential nutrient" is often encountered in the scientific literature.

L-carnitine crystalline and L-carnitine L-tartrate are proposed for use as a dietary source of L-carnitine for food in the categories dairy products (excluding butter and butter fat), confectionary, cereal and cereal products, foods intended for particular dietary uses, non alcoholic beverages and gels. Depending on the food category levels between 50 and 250 mg L-carnitine/ serving and 73.6 to 368 mg L-carnitine L-tartrate/serving are proposed. Concerning sports and energy drinks a level of 500 mg L-carnitine/ serving respectively 736 mg L-carnitine L-tartrate is proposed. L-carnitine and L-carnitinie L-tartrate are already approved for its use in food in many countries. Therefore the extension of the use of L-carnitine in this range of food products will also widen the possibilities for innovation by national manufacturers and allow them to benefit from increased market development both domestically and overseas.

The safety of L-carnitine is based on knowledge regarding the historical consumption of L-carnitine as a common component of the typical human diet, the endogenous biosynthesis of L-carnitine as a normal body metabolite, the absorption, distribution, metabolism and excretion of L-carnitine, published toxicological safety data in rats, rabbits and dogs, as well as human studies without indication of adverse effects on human health and support the safety of the intended use and dosage level of L-carnitine and L-carnitine L-tartrate in food.

Lonza intends to market L-carnitine crystalline and its salt L-carnitine L-tartrate under the trade names Carnipure™ crystalline and Carnipure™ tartrate. Carnipure™ crystalline is a purified, crystallized powder produced through a 2-step chemical process. Carnipure™ tartrate is the crystallized stable salt of Carnipure™ crystalline free base and food-grade L-tartaric acid, in a molar ratio of 2:1. Both Carnipure™ crystalline and Carnipure™ tartrate comply with Good Manufacturing Practice for dietary supplements and the Food Safety System Certification 22000:2011. The specifications for Lonza's L-carnitine meet appropriate specifications listed in the United States Pharmacopoeia/National Formulary and the Food Chemical Codex.

To: Food Standards Australia New Zealand
In relation to: Application for approval of L-carnitine as a Nutritive Substance under the Australian New Zealand Food Standards Code