EXECUTIVE SUMMARY

Nestlé Australia Ltd and Nestlé New Zealand Limited (Nestlé) are proposing a change to the minimum requirement for the essential amino acid, L-histidine, in infant formula and follow-on formula. The current requirement for L-histidine in infant and follow-on formula, as stated in the Australia New Zealand Food Standards Code (ANZFSC) Standard 2.9.1, Table to Clause 22, is minimum 12 mg per 100kJ. We request consideration to reduce the minimum requirement to 10mg per 100kJ. The current L-histidine requirement is higher than the requirements in international regulations [such as Codex Alimentarius (CODEX) and the European Union] and as such, represents a trade barrier, which could potentially be cause for concern for continual supply of some products for this vulnerable population group. Further to this, there is evidence that the proposed minimum level of 10mg per 100kJ of L-histidine is safe and will promote normal growth and development in infants.

The amino acid minimum requirements in Australia New Zealand Food Standards Code (ANZFSC) are based on the breast milk composition findings from the FAO/WHO commissioned Expert Consultation on Protein Quality Evaluation (1989). Since that time, the FAO/WHO commissioned a report by the ESPGHAN International Expert Group to provide a proposal on nutrient levels in infant formula, based on scientific analysis. The recommendations from this report (Koletzko et al., 2005) with regard to amino acid minimum levels have been adapted into Annex I of the revised CODEX Standard on Infant Formula (2007). This includes the requirement for L-histidine levels to be 41mg per 100kcal (9.8 mg per 100kJ) based on the mean of human milk studies. Nestlé is proposing implementing a level of 10mg per 100kJ which would more closely align the ANZFSC with CODEX and European Union requirements. This would also align with the Council of Australian Governments Best Practice Regulation[1] principles of best practice regulatory process “to recognise the effect of regulation on individuals and the cumulative burden on business” and to “have regard to whether the existing regulatory regimes of other jurisdictions might offer a viable alternative”.

Nestlé sources infant and follow-on formula for the Australian and New Zealand markets from Europe, and the different L-histidine requirements result in additional cost and risk of supply into the market, particularly with respect to paediatric speciality products such as those required for infants with metabolic, immunological, renal, hepatic and malabsorptive conditions. Paediatric speciality

[1] Council of Australian Governments, Best Practice Regulation, A Guide for Ministerial Councils and National Standard Setting Bodies, October 2007

products represent 11.2% of the value of the total formula market in Australia[2]. These smaller volume products in the Australian/New Zealand market benefit from sharing recipes and hence manufacturing volumes, with other markets. For Nestlé, harmonised L-histidine requirements would allow the same recipe to be used for both CODEX-compliant as well as European Union markets and the Australian/New Zealand market.

There is evidence to suggest that the proposed minimum of 10mg of L-histidine per 100 kJ of infant formula is safe and will promote normal growth and development in infants. The minimum required for CODEX and EU respectively is 9.8mg and 10mg of L-histidine per 100 kJ. These values are used in European countries and all other countries that follow CODEX regulations. To the best of our knowledge, there are no known reports of inadequate normal growth and development due to insufficient L-histidine in any of these countries, where millions of non-breastfed infants have been consuming infant formula products where regulated minimum L-histidine levels are lower than that of Australia and New Zealand.

Additionally, recent international studies using lower protein levels in infant formula, and with L-histidine levels ranging between 9.6 – 10.5mg per 100kJ have all been shown to promote normal growth which is equivalent to that of the breastfed infant (Raiha 2002; Hernell 2003; Turck 2006; Sandstrom 2008; Trabulsi 2011). Some of these studies have also shown that the plasma amino acid concentrations at 2, 4, and 6 months of feeding are within normal limits and indeed slightly higher than the levels in the breastfed controls (Hernell 2003; Sandstrom 2008; Trabulsi 2011). This again emphasises that 10mg per 100 kJ of L-histidine is adequate to support infant growth and development.

It should be noted that, for the purposes of ease and speed of approval, we are requesting only a change to the L-histidine values. Similar arguments could be applied to other amino acid minimums which may be relevant when Standard 2.9.1 Infant Formula Products is next reviewed.

[2] AC Neilsen, Combined MAT Report, Period Ending 12/02/2012