5th July 2023

SECOND CALL FOR SUBMISSIONS – PROPOSAL P1028 INFANT FORMULA

INTRODUCTION

This submission has been prepared by Abbott Nutrition. Abbott Nutrition believes that proper nutrition is the foundation for living the best live possible. Our aim is to make every stage of life a healthy one which is why we are dedicated to developing science-based nutrition products for people of all ages. Abbott Nutrition is committed to ethically marketing our products and supports the voluntary restriction of marketing practices for infant formula products to support government policies which protect and promote breastfeeding. Abbott Nutrition believes that breastfeeding provides the best nutrition for infants and supports, educates and encourages mothers to breastfeed for as long as possible. When breastmilk is not given to an infant, infant formula is the only safe and recommended alternative. Abbott Nutrition welcomes the opportunity to consider the issues and views proposed in this second Call for Submission – Proposal P1028 Infant Formula (the **CFS2**), and to provide comment and information to Food Standards Australia New Zealand (**FSANZ**) on the Regulation of Infant Formula.

A. Flexibility for products for special medical purposes for infants (SMPPi)

Abbott Nutrition proposes a framework that allows products for special medical purposes for infants (SMPPi) to be able to enter Australia and New Zealand without compositional or labelling change to those same products that are produced in the EU or the USA.

Since some of these specialized products for infants are only produced in small quantities worldwide, and there is an even smaller demand for these in Australian and New Zealand based on population size, allowing entry of these products into these countries would eliminate trade barriers. Not to do so would present a risk to the health outcomes for infants in need of these products and there is no viable option to import most of these products other than to share a product and label with another country.

B. Food Technology for Infant Formula Products

6.1 Food additives

On food additives, Abbott Nutrition is not supportive for the FSANZ proposal to remove permission for additive Diacyltartaric and fatty acid esters of glycerol (INS 472e).

Diacyltartaric and fatty acid esters of glycerol (INS 472e): FSANZ proposes to remove the permission for this additive.

Abbott Nutrition recommends continued permission for this food additive for use as an emulsifier and listed in "Substances that may be used as food additives" Schedule 15—5, Food Category 13.1.1. Special medical purpose products for infants (SMPPi). The entry in S15—5 Table 13.1.1 would then read:

INS 472e Diacyltartaric and fatty acid esters of glycerol 2500 mg/L.
The amendments we propose reflect industry's current actual usage and are also aligned to JECFA/EFSA review.

For SMPPI, a summary table is provided below.

13.1.1 Special medical purpose products for infants

INS	Description	Proposed	Reason
472e	Diacyltartaric and fatty acid esters of glycerol	2500 mg/L	JECFA/EFSA review

General safety evaluation information and technological justification is presented as follows:

General safety evaluation information

Diacetyltartaric acid esters of mono- and diglycerides (DATEM) is a food additive (INS 472e) that is readily metabolised to products that are all normal dietary constituents: mono- and diglycerides, tartaric acid, and tartaric acid esters. DATEM was evaluated for safety by the Joint FAO/WHO Expert Committee on Food (JECFA) in 2003.[1]. At that time, JECFA concluded that the acceptable daily intake (ADI) of DATEM was up to 50 mg/kg, based on this ensuring that the intake of one of its primary metabolites (tartaric acid) would not exceed its ADI.

More recently, EFSA concluded that the ADI for DATEM was 600 mg/kg, also based on the ADI for tartaric acid (which for EFSA is 240 mg/kg)[2]. The JECFA and EFSA conclusions were based on extensive safety studies. These studies demonstrated DATEM to be non-genotoxic in the bacterial reverse mutation assay and the chromosomal aberration assay, and in a 2-year study in rats administered a diet containing 10% DATEM, no adverse effects were seen, including no evidence for carcinogenicity.

In addition, a 21-day study in neonatal piglets was conducted to evaluate the potential effects in an infant population. [3] In this study, piglets were administered a liquid control diet or a liquid diet containing the intended concentration of DATEM, (2500mg/L) or a liquid diet containing a concentration of DATEM 2-fold higher than the intended product

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concentration (5000mg/L). No adverse effects were seen in this study at either concentration of DATEM. The proposed 2500mg/L concentration for DATEM to be added in SMPPi aligns with this piglet study.

Technological justification for the use of diacyltartaric and fatty acid esters of glycerol (DATEM, 472e) in SMPPi includes

a) DATEM is a strongly hydrophilic, anion-active emulsifier derived from edible, refined vegetable fat. DATEM is currently used by industry as an emulsifier in amino acid-based infant formula. We respectfully request that the use of DATEM continue to be allowed as an emulsifier in the manufacture of infant formulas containing isolated amino acids at a maximum level of 2500 mg/L (as consumed).
b) All lipid containing nutritional formulations include an emulsification ingredient. Unlike the sources (e.g., milk, soy) used in standard infant formulas that are intact proteins, amino acids do not have any significant emulsifying functionality. These formulas require the use of a strong emulsifier, such as DATEM, to ensure that the product can be manufactured properly, and that the final formulation delivers nutrients in a homogenous matrix. Furthermore, the emulsifiers used in these highly specialized formulas must not contain any intact protein. This eliminates the use of certain naturally derived emulsifiers, such as soy lecithin, as they contain low levels of protein.
c) A stable emulsification is important for two main reasons:
    i) Manufacturability: The product must be homogenous throughout the manufacturing process. A poor emulsion will result not only in an inhomogeneous product and concerns with regards to nutrient delivery, but also difficulties in manufacturing due to product separation, which can lead to equipment fouling and poor physical quality of the final product. Non-homogeneity during the process also creates the potential that the infant formula may not have uniformly distributed nutrients from can to can or even from scoop to scoop.
    ii) Reconstituted stability: Emulsifiers, like DATEM, continue to function after reconstitution. In their absence, the reconstituted product will suffer physical stability defects, such as separation or creaming.

In conclusion, DATEM is currently used by industry as an emulsifier in infant formula based on isolated amino acids. Studies evaluating its use have confirmed it provides the emulsification necessary to ensure homogeneity during the manufacturing process as well as stability after reconstitution.

References:

1.JECFA (2003). Safety evaluation of certain food additives and contaminants. Joint FAO /WHO Expert Committee on Food Additives (JECFA) sixty-first meeting, *WHO food additives series* 52, 2003.

2. EFSA Panel on Food Additives and Flavorings' (2020). Re-evaluation of acetic acid, lactic acid, citric acid, tartaric acid, mono- and diacetyltartaric acid, mixed acetic and tartaric acid esters of mono- and diglycerides of fatty acids (E 472a-f) as food additives. *EFSA Journal, 2*020; 18(3): 6032. http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2020.6030/full and DOI: 10.2903/j.efsa.2020.6032.

3. Abbott Nutrition. Unpublished study, "DATEM (INS 472e): A 3-week dietary safety study in farm piglets". 2018.