Request for Amendment of Union List Entry of 'Bovine milk basic whey protein isolate' for Foods for Special Medical Purposes and Food Supplements for Infants

SUMMARY

Armor Protéines S.A.S seeks to amend the existing Union List entry for 'Bovine milk basic whey protein isolate' (Application No NF 2018/0157) to include the below levels within the categories "foods for special medical purposes" and "food supplements" in products specifically for infants (up to 12 months of age).

Specified Food Category	Maximum Levels
Foods for special medical purposes as defined in Regulation (EU) No 609/2013[1]	Formula for special medical purposes for infants (infant formula): 30 mg/100 g (powder) 3.9 mg/100 mL (reconstituted) Formula for special medical purposes for infants (follow-on formula): 30 mg/100 g (powder) 4.2 mg/100 mL (reconstituted)
Food Supplements as defined in Directive 2002/46/EC[2]	25 mg/day for infants up to 12 months

[1]Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009. OJ L 181, 29.6.2013, p. 35–56. https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1533914468695&uri=CELEX:32013R0609.

[2]Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. OJ L 183, 12.7.2002, p. 51–57. http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32002L0046&qid=1442597959590 (Consolidated version: 26/07/2017).

To address the concerns of the Member States with respect to this age group:

- The applicant has revised the proposed entry for "formula for special medical purposes for infants" to be more clearly aligned with how the existing uses for infant and follow-on formula are presented. These products would be a replacement for standard infant formula, *i.e.*, infants would not consume both 'medical' and 'standard' formula at the same time (cumulatively). In addition, all FSMPs, particularly those for infants, are notified to Member States and consumed under medical supervision. These levels have already been assessed by EFSA and do not present a safety concern.

- The applicant has reduced the proposed use levels for food supplements for infants (up to 12 months) to 25 mg/day and has proposed advisory labelling regarding total dietary exposure. The safety margin for combined worst-case intakes (infant formula and food supplements) is between 80 and 100+ fold. This is greater than the 72-fold margin that was acceptable to EFSA for infants and toddlers.