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POSITION PAPER

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Working with companies that manufacture breastmilk substitutes: An EAACI position paper

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Abstract

Breastmilk is the optimal source of nutrition for infants and should ideally be provided exclusively for the first 6 months of life, and alongside complementary food until 2 years of life. However, there are circumstances where a breastmilk substitute (BMS) may be required. This includes maternal and/or child conditions or personal preference. Whilst these circumstances should never be used as an opportunity to promote BMS, healthcare professionals (HCPs) need to have the knowledge of suitable alternatives and should always be guided by scientific and health motives when recommending a BMS. The Task Force 'Milk Formula Industry Sponsorship' from the European Academy of Allergy and Clinical Immunology (EAACI), provides with this publication recommendations for EAACI interactions with the BMS manufacturers and how this will be supervised.

KEYWORDS
breastmilk, breastmilk substitutes, feed for special medical purpose, food allergy, industry

1 | BACKGROUND

Breastmilk is the optimal source of nutrition for infants and should be ideally provided exclusively for the first 6 months of life, and alongside complementary food until 2 years of age or beyond, according to the World Health Organization (WHO).[1] The European Society for Paediatric Gastroenterology, Hepatology and Nutrition suggests that 'exclusive or full breastfeeding should be promoted for at least 4 months and exclusive or predominant breastfeeding for approximately 6 months is a desirable goal'.[2] Breastmilk provides all the nutrients necessary to ensure optimal growth and development and also contains non-nutritive ingredients that reduce infections, support the development of a normal immune response and have a long-term benefit in reducing diabetes, asthma, heart disease and obesity, as well as cot death.[3–5] Mothers also benefit from the act of breastfeeding in that it protects them from breast and ovarian cancers.[1,4] However, there are circumstances where a breastmilk substitute (BMS) (see Table 1 for the definition of these products) may be required. This includes maternal and/or child conditions or personal preference. Whilst these circumstances should never be used as an opportunity to promote BMS, healthcare professionals (HCPs) need to have the knowledge of suitable alternatives and should always be guided by scientific and health motives when recommending a BMS. Additionally, the interaction required between HCPs and manufacturing companies should be regulated.

There has been growing concern regarding the inappropriate promotion of BMS in particular in children with cow's milk allergy (CMA) since it can diminish the rate of infants benefiting from breastfeeding and devalue the importance of breastmilk's health properties.[6,7] Because of this, many professional bodies have re-evaluated their relationship with the industry, including sponsorship of events. The Task Force (TF) 'Milk Formula Industry Sponsorship' from the European Academy of Allergy and Clinical Immunology (EAACI), provides recommendations for EAACI interaction with the BMS manufacturers and how this will be supervised. For this statement, the EAACI TF considered the World Health Organisation (WHO) 1981 International Code of Marketing of BMS, World Health Assembly (WHA) 2016 guidance and the Specialist Nutrition Europe code of conduct as primary background documents.[8,9]

1.1 | BMS and prevention of allergic diseases

Multiple trials and studies have been performed to evaluate the consequences of feeding with BMS in infants and children. Of note, several studies compared the effect of BMS and breastmilk over the prevention of allergic diseases. A recent narrative review of 13 studies performed between 1988 and 2022 indicated that early exposure (within the first week) to BMS, followed by a period of avoidance once breastfeeding is initiated, might increase

TABLE 1 Definitions of Terminology Used in this Statement.

Terminology	Definition	Example
Breastmilk Substitute (BMS)	Any feed/food being marketed or otherwise represented as a partial or total replacement for breastmilk	Standard whole protein infant formula, Partially hydrolysed formula (PHF), extensively hydrolysed formula (EHF), hydrolysed rice formula (HRF), amino acid formula (AAF) and soya formula (SF)
Food for Special Medical Purpose (FSMP)	Feeds for patients who, because of a particular disease, disorder or medical condition, have nutritional needs that cannot be met by consuming standard foodstuffs. Specifically, according to EU legislation they are intended for patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolize or excrete ordinary foods, or certain nutrients or metabolites; or with other medically *nutrient* requirements whose dietary management cannot be achieved by modification of the normal diet alone. FSMPs should be used only under medical supervision and must carry labelling information about their intended use	Extensively hydrolysed formula (EHF), hydrolysed rice formula (HRF), amino acid formula (AAF), hypoallergenic complementary foods

the risk of CMA.[10] Therefore, authors concluded that exclusively breastfed infants should avoid supplementation with BMS within the first week of life. Another meta-analysis of 37 intervention trials (19,000 subjects) analysed the frequency of allergic and autoimmune diseases until the age of 4 years in infants who received either partially or extensively hydrolysed formula (PHF and EHF, respectively), conventional BMS or breastfeeding.[11] This work concluded that there is a lack of evidence to support the use of PHF/EHF to prevent allergic diseases, including CMA, atopic dermatitis, allergic rhinitis or recurrent wheezing, even in those children with a high risk of developing these pathologies. The current EAACI guidelines on Allergy prevention do not make a recommendation for or against using PHF or EHF to prevent food allergy in infants and young children when exclusive breastfeeding is not possible. Additionally, they recommend the avoidance of supplementing with conventional BMS in breastfed infants during the first week of life to prevent CMA later in life.[5]

1.2 | Management of CMA using foods for special medical purposes (FSMP)

CMA is one of the most common food allergies, with an estimated prevalence of 2%–3% in infants.[8] Different types of CMA are typically distinguished based on the clinical manifestations and the underlying mechanism, which is IgE-mediated, non-IgE-mediated and mixed. The avoidance of cow's milk and its derivates remains the cornerstone in the management of patients with CMA. All current guidelines, including the EAACI guidelines, support breastfeeding as the ideal source of nutrition in children with CMA.[5,12] When breastmilk is insufficient, not tolerated or unavailable, different types of FSMP [extensively hydrolysed formulas (EHF), rice hydrolysed formulas, or amino acid formulas (AAF)] can be considered. Overall, EHF or hydrolysed rice formula (HRF) is recommended as the first-line formula in CMA. Moreover, in severe CMA (i.e. anaphylaxis) or eosinophilic oesophagitis, an AAF might be indicated.[13,14] In addition to proven efficacy, these formulas need to be nutritionally complete and support normal growth and development.[15] Whilst soya formula (SF) is not an FSMP, this formula can be used in infants >6 months as long as they are not soya allergic. Indeed, SF is commonly used as an alternative in low-income countries, however, caution of sensitization to soy should be highlighted.[13]

2 | EAACI POSITION

2.1 | Academic perspective

EAACI supports the principles and aims of the 1981 WHO International Code of Marketing of BMS,[8] the subsequent further guidance in 2016[9] and the EU Regulation on FSMP (EU2016/128 and 609/2012)[16] to ensure that breastfeeding is not discouraged. As such, EAACI Food Allergy and Prevention Guidelines support breastfeeding, taking the current evidence into account.[12,17]

EAACI further acknowledges that there are circumstances in which a BMS, which may also be an FSMP, is necessary to meet the nutritional needs of infants/young children with food allergies. This may be because breastfeeding has ceased or due to a medical condition where breastfeeding requires supplementation or is contraindicated, as described by the WHO and UNICEF.[15] These include infant conditions (i.e. infants with certain inborn errors of metabolism, infants born <1500 g and/or <32 weeks) or maternal conditions (i.e. severe maternal illness, Herpes simplex virus type 1 with direct lesion contact, cytotoxic chemotherapy, sedating psychotherapeutic drugs, anti-epileptic drugs).[18] EAACI understands that any collaboration with manufacturers of BMS requires adequate supervision to avoid the inappropriate marketing of BMS and that this cooperation has to be conducted in an open and transparent way. Of note, it is crucial to ensure that all BMS, and in particular FMSP, are appropriate, safe and efficacious for the food-allergic population. Additionally, EAACI also understands the importance for its members to have access to accurate information on BMS to ensure that healthcare professionals stay abreast with the most recent scientific data and ensure that BMS, where indicated, are used appropriately for the intended patient, while favouring breastfeeding over BMS whenever possible.

2.2 | Patient Organisation Committee perspective

EAACI Patient Organisation Committee (POC) represents allergy and asthma patients as well as caregivers of infants who require BMS, including FSMP, which is to be used only under medical supervision for dietary management. Local jurisdictions and existing regulations and/or local policies about marketing, distribution and sale of BMS products vary from country to country. POC members continue to promote breastfeeding as the best option for infants and recognize BMS products only as an alternative when breastfeeding is not possible as advised by a medical professional or where this is the parents' choice discussed with an HCP. POC members are committed to avoiding any action that may undermine breastfeeding and to disseminating up-to-date scientific data on FSMP formulas and adequate substantiation for any kind of product claims. HCPs have a crucial role in raising awareness and explaining the importance of breastfeeding, especially for parents with poor health literacy and understanding cultural stigma and how this may lead parents to consider BMS as an easier and more convenient option. EAACI POC ensures that its members understand that EAACI's compliance directives apply equally to all EAACI members and are aware of the importance of abiding by EAACI's guidelines during all collaborations with or on behalf of POC.

2.3 | EAACI position on collaboration with BMS industry

In order to uphold the strong support of EAACI and its stakeholders for promoting breastfeeding and also to provide its members with updated scientific evidence, the following points are emphasized, and actions will be undertaken:

1. EAACI fully supports breastmilk as the best source of nutrition for infants and young children with food allergies.
2. EAACI is fully committed to improving the education of its members to support breastfeeding but also to gain access to scientific information on the choice of BMS when breastmilk is insufficient or not available.
3. EAACI will ensure that their Knowledge Hub platform will include educational material to support the use of breastmilk as the best source of nutrition.
4. EAACI will continue to allow manufacturers to sponsor EAACI events under the following circumstances.
   a. They are signed up to the Specialist Nutrition Europe (SNE) (*This Code of Practice lays down best practices for SNE member associations and their members. It covers any interaction listed in this Code of Practice, organized or sponsored in the countries of SNE's member associations, by national association members (e.g. Manufacturers), and addressed to Healthcare Professionals, Health Organizations or health care facilities regarding: (1) infant formula, (2) follow-on formula and (3) FSMP intended for infants.) Code of Practice (https://www.specialisednutritioneurope.eu/interactions-with-healthcare-professionals/).
   b. Manufacturers and distributors of BMS must indicate in all the EAACI activities they will participate in that breastfeeding is superior to BMS and that infants and young children should ideally be breastfed.
   c. Any manufacturer of BMS that sponsors any EAACI event and/or has an exhibition booth at an EAACI event is not allowed to distribute samples or exhibit tins of BMS.
   d. Only scientific information is allowed to be distributed at EAACI events. The information has to comply with the SNE code of practice and must be accurate, science-based, balanced, fair, objective and sufficiently complete to enable the HCP to form his/her own opinion of the value of the BMS concerned. It must not be misled by distortion, exaggeration, undue emphasis, omission or in any other way.
   e. Companies manufacturing BMS are not allowed to provide gifts of any form (i.e. including pens with their logo, food/drink at the stand) to attendees at any EAACI event, in addition to monetary advantages to HCPs or their families as an inducement for the supply, recommendation, use or sale of the products or for the purpose of promoting the BMS. Further details for BMS companies are provided in SNE.
   f. The programme of BMS-sponsored symposium has to be approved by the EAACI Scientific Programme Committee Chair and the Board of Officers prior to the EAACI event to ensure that this symposium complies with the guidance and that the information presented is evidence-based and not pure marketing of BMS products. Additionally, speaker reimbursement should comply with the SNE code of practice.
   g. Manufacturers and distributors of BMS must sign a declaration of assent to follow EAACI guidance and have to be aware that proper steps will be taken by EAACI if non-adherence to this guidance appears.
   h. If any EAACI stakeholder becomes aware of the industry violating the EAACI guidance, the latter will be referred to the Executive Committee for a decision on appropriate actions.
   i. Any other collaborative learning activities shall comply with all relevant aspects of applicable codes of conduct, ethical rules or statutes of HCPs and their institutions.
5. EAACI members have to declare their conflict of interest (COI) when collaborating on any research or performing any lectures for any manufacturers of BMS at any EAACI events. The existing procedure from EAACI for COI will be used. https://eaaci.org/images/COI_Guidelines.pdf.

AUTHOR CONTRIBUTIONS

Stefania Arasi: Conceptualization; writing – original draft; methodology; writing – review and editing; supervision. **Jean-Christoph Caubet:** Writing – original draft; writing – review and editing. **Ozlem Ceylan:** Writing – original draft; writing – review and editing. **Ibon Eguíluz-Gracia:** Conceptualization; writing – original draft; writing – review and editing; supervision; project administration. **Stefano Del Giacco:** Writing – original draft; writing – review and editing. **Aslı Gelincik:** Writing – original draft; writing – review and editing. **Marek Jutel:** Writing – original draft; writing – review and editing. **Rosan Meyer:** Conceptualization; writing – original draft; writing – review and editing; methodology; supervision. **Markus Ollert:** Writing – original draft; writing – review and editing. **Maria J. Torres:** Conceptualization; funding acquisition; writing – original draft; writing – review and editing; project administration; resources.

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CONFLICT OF INTEREST STATEMENT

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REFERENCES

1. Organization WH. Breastfeeding. 2024. https://www.who.int/health-topics/breastfeeding#tab=tab_2
2. Fewtrell M, Bronsky J, Campoy C, et al. Complementary feeding: a position paper by the European Society for Paediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN) committee on nutrition. *J Pediatr Gastroenterol Nutr*. 2017;64(1):119-132.
3. Xue M, Dehaas E, Chaudhary N, O'Byrne P, Satia I, Kurmi OP. Breastfeeding and risk of childhood asthma: a systematic review and meta-analysis. *ERJ Open Res*. 2021;7(4):00504-02021.
4. UNCFBF. Benefits of breastfeeding. 2023. https://www.unicef.org.uk/babyfriendly/about/benefits-of-breastfeeding/
5. Halken S, Muraro A, de Silva D, et al. EAACI guideline: preventing the development of food allergy in infants and young children (2020 update). *Pediatr Allergy Immunol*. 2021;32(5):843-858.
6. Boyle RJ, Shamji MH. Allergy societies and the formula industry. *Clin Exp Allergy*. 2021;51(10):1260-1261.
7. Mehta S, Allen HI, Campbell DE, Arntsen KF, Simpson MR, Boyle RJ. Trends in use of specialized formula for managing cow's milk allergy in young children. *Clin Exp Allergy*. 2022;52(7):839-847.
8. Organization WH. *International Code of Marketing Breastmilk-Substitutes*. World Health Organization; 1981. https://www.who.int/publications/i/item/924154160113
9. Organization WH. *Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children*. World Health Assembly; 2016. Contract No.: A69/7 Add.1.
10. Ulfman L, Tsuang A, Sprikkelman AB, Goh A, van Neerven RJJ. Relevance of early introduction of cow's milk proteins for prevention of cow's milk allergy. *Nutrients*. 2022;14(13):2659.
11. Boyle RJ, Ierodiakonou D, Khan T, et al. Hydrolysed formula and risk of allergic or autoimmune disease: systematic review and meta-analysis. *BMJ*. 2016;352:i974.
12. Muraro A, Werfel T, Hoffmann-Sommergruber K, et al. EAACI food allergy and anaphylaxis guidelines: diagnosis and management of food allergy. *Allergy*. 2014;69(8):1008-1025.
13. Antonio Bognanni AF, Arasi S, Chu DK, et al. World Allergy Organization (WAO) Diagnosis and Rationale for Action Against Cow's Milk Allergy (DRACMA) guideline update – XII – recommendations on milk formula supplements with and without probiotics for infants and toddlers with CMA. *World Allergy Organ J*. 2024;17:17.
14. Lucendo AJ, Molina-Infante J, Arias A, et al. Guidelines on eosinophilic esophagitis: evidence-based statements and recommendations for diagnosis and management in children and adults. *United European Gastroenterol J*. 2017;5(3):335-358.
15. Pediatrics AAP. Hypoallergenic infant formulas. *Pediatrics*. 2000;106:346-349.
16. Union E. *Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 Supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as Regards the Specific Compositional and Information Requirements for Food for Special Medical Purposes*. European Union; 2021.
17. Muraro A, de Silva D, Halken S, et al. Managing food allergy: GA(2)LEN guideline 2022. *World Allergy Organ J*. 2022;15(9):100687.
18. UNICEF WHOa. *Acceptable Medical Reasons for Use of Breast-Milk Substitutes*. World Health Organization; 2009. Report No.: WHO/FCH/CAH/09.01.

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