Foods for Special Medical Purposes

IBFAN and Baby Feeding Law Group
Recommendations for ending bogus medical claims and for closing regulatory loopholes

babymilkaction.org
In 2013 the European Parliament, the European Council and the European Commission adopted a Regulation on Foods for Specific Groups (FSG) 609/2013 in order to rationalise and simplify legislation covering various foods, including formulas for infants and young children. The European Commission is currently hosting expert working group meetings with Member States in preparation for the Commission’s new ‘Delegated Acts’ that will come into force in 2015 and 2016.

In this process, the European Parliament’s recommendations, adopted in June 2013, must be taken into account. These include:

- tighter controls on follow-on milks
- no baby pictures and idealising text
- stricter controls on foods claiming to be ‘for special medical purposes’ (FSMPs)
- increased transparency,
- the use of the Precautionary Principle
- more democratic oversight
- MEP reviews of new ingredients.

Several other developments in 2014 indicate that the rules governing baby feeding products should be strengthened:

- **In April**, EFSA’s evaluation on the essential composition of formulas will be the subject of a 6-week public consultation. The preliminary report found no evidence (or insufficient evidence) to support the inclusion of many commonly used ‘optional’ ingredients, prompting renewed calls for a ban on promotional claims.


- **In May** the World Health Assembly will discuss infant and young child feeding and the 5 principles that should be used to determine appropriate marketing of foods and drinks for infants and young children. 

**Foods for Special Medical Purposes**

Foods for Special Medical Purposes (FSMPs) are necessary products for infants who have metabolic disorders where breastfeeding is contraindicated or where full or partial feeding with specialised formulas is needed. The number of babies needing such feeding is extremely small [globally possibly less than 25,000 babies]. Maple Syrup Disease (0.0005% of 129 million) and babies with PKU are often cited. However, even though PKU babies need a formula without phenylalanine, they benefit from the addition of partial, carefully managed breastfeeding as do babies with other inborn errors of metabolism.

- The majority of sick babies need breastfeeding or donor human milk. However they are fed, all babies and especially sick babies, need the protection of the International Code of Marketing of Breast-milk Substitutes and WHA Resolutions.

- FSMPs are often the sole food for children at a vulnerable stage of growth and development when the energy and nutrient intake per kilo bodyweight is greater. Their manufacturing and marketing requires more - not less - care.

- The EU Commission now acknowledges that the exploitation of its lax rules has led to a growth in the market for products claiming to be FSMPs. Many of these products are simply avoiding composition and other safeguards, such as the legal requirement for a ‘breastfeeding is best’ statement. Many contain thickeners and other ingredients that would not otherwise be permitted. (See Box on Page 3).

- The EU has agreed that FSMPs should be subject to additional specific rules, in addition to compositional requirements. 20 Member States have gathered data about FSMP marketing.

- There is limited evidence of efficacy for many of the products claiming to be FSMPs. Many are more expensive than standard formulas. Many carry highly promotional, misleading and unsubstantiated claims and brand names, such as Staydown, Anti-Reflux, Comfort, Easy Digest, that medicalise common feeding occurrences.
What needs to be done

BFLG/IBFAN Recommendations

1. Widen the scope of the EU Directive on infant formulas and follow-on formulas (2006/141)\(^8\) to include FSMPs for infants and young children. Grouping FSMPs with standard formulas, possibly as a Section B, as is the case with the Codex standard, \(^9\) would facilitate the inclusion of much-needed safeguards and aid harmonisation of export rules.

2. Whatever decision is taken, and even if the misclassification of FSMPs is addressed, all the safeguards of the International Code of Marketing of Breastmilk Substitutes and subsequent, relevant WHA Resolutions should apply to FSMPs for infants and young children.

3. FSMPs should only be available on prescription in order to avoid needless use and misuse.

4. The definition of FSMPs should stress the need for continuing medical supervision: ‘Foods specially processed or formulated and with independently verified evidence of effectiveness for the dietary management of infants and young children, to be used solely under continuing medical supervision.’ (eg. extreme prematurity, high dependency care, congenital metabolic syndromes, organ failure and severe malnutrition.)

5. FSMPs for infants and young children that are fed orally must carry all the warnings and notices required by the International Code regarding the superiority of breastfeeding and risks of artificial feeding, alongside the necessary precautions, known side-effects, contraindications, product-drug interactions, and alongside appropriate information about the correct use of the product. The argument that including the breastfeeding statement poses risks to health is not valid in the vast majority of cases.

6. FSMP labelling and information should state that products should only be used on advice of health care professionals, free commercial product influence, as to the need for its use and the proper method of use.

7. FSMP labelling and information should not carry nutrition, health or disease risk reduction claims, but should carry clear information regarding their appropriate use.

8. FSMP labelling and information should have no pictures of infants and women or pictures or text which idealize the use of the product.

9. FSMP labelling and information should avoid any risk of confusion between infant formula, follow-up formula, and formulas for special medical purposes.

10. FSMP labelling and information for powdered formulas should carry the preparation instructions recommended by the WHO/FAO.\(^8\) (Many FSMPs do not recommend reconstitution with water at 70\(^\circ\).)

11. All the above requirements must apply to exports of FSMPs for infants and young children and the marketing practices carried out by EU-based companies in Third Countries.

“One thing is clear, if infant and young child health is to be protected a radical rethink and strengthening of the rules governing this sector is needed”

“...Differing interpretation and enforcement of the definition of FSMPs by national authorities has contributed to a proliferation of these products in the market (the examples of products based on rice protein, not allowed for infant and follow-on formula, and of some anti-regurgitation products were mentioned). This in turn led to the use of wider and often similar distribution channels as those for infant formula and inevitably to labelling, advertising and marketing practices that were taking advantage of the absence of relevant rules for these products.”

Summary Record of the Standing Committee on the Food Chain and Animal Health, 22 June 2012
These recommendations are endorsed by IBFAN and the BFLG

The International Baby Food Action Network (IBFAN) is a global network of 273 groups in 168 countries. IBFAN is an independent watchdog that protects babies and their families. IBFAN monitors company practices and highlights conflict of interests in policies and programmes. IBFAN takes no funding from companies.

The Baby Feeding Law Group (BFLG) is a coalition of 23 leading health professional and lay organisations. BFLG was founded in 1997 to bring UK and EU legislation into line with World Health Assembly Resolutions.

BFLG members

Association of Breastfeeding Mothers
Association for Improvements in the Maternity Services
Association of Radical Midwives
Baby Milk Action (secretariat)
Best Beginnings
Breastfeeding Community
Breastfeeding Network
Community Practitioners and Health Visitors Association
First Steps Nutrition Trust
Heart of Mersey
Lactation Consultants of Great Britain
La Leche League (GB)
Little Angels - site
Midwives Information and Resource Service
NCT
Royal College of Midwives
Royal College of Nursing
Royal College of Paediatrics and Child Health
The Baby Café
UK Association for Milk Banking
Unicef UK Baby Friendly Initiative
UNISON
Women’s Environmental Network

Contacts

Patti Rundall, Baby Milk Action/IBFAN/BFLG: prundall@babymilkaction.org

Maryse Arendt, Initiativ Lewensufank/IBFAN: maryse.arendt@liewensufank.lu

Colin Michie: Royal College of Paediatrics/ BFLG: colin.michie@nhs.net

Rosie Dodds: NCT/BFLG
Rosemary.Dodds@nct.org.uk

Helen Crawley: First Steps Nutrition Trust/ BFLG: helen@firststepsnutrition.org