

# BRIEFING



## Foods for Special Medical Purposes

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



In 2013 the European Parliament, the European Council and the European Commission adopted a **Regulation on Foods for Specific Groups (FSG) 609/2013**<sup>1</sup> 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.<sup>2</sup>

In this process, the European Parliament's recommendations, adopted in June 2013,<sup>3</sup> 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 February**, Member States adopted an **EU Action Plan on Childhood Obesity 2014-2020**<sup>5</sup> that among other things calls for more support for breastfeeding and monitoring of the **Directive 2006/141** and the **International Code of Marketing of Breastmilk Substitutes**.
- **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.<sup>6</sup>

## 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.<sup>7</sup>
- 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.

## BFLG/IBFAN Recommendations.....

**1** Widen the scope of the EU Directive on infant formulas and follow-on formulas (2006/141)<sup>8</sup> 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,<sup>9</sup> 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 mis-use.

**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.<sup>9</sup> (Many FSMPs do not recommend reconstitution with water at 70°).

**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.



[www.babyfeedinglawgroup.org.uk](http://www.babyfeedinglawgroup.org.uk)

### 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

## Notes

- 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 [http://www.fsai.ie/uploadedFiles/Reg609\\_2013.pdf](http://www.fsai.ie/uploadedFiles/Reg609_2013.pdf)
- 2 *Law-makers can give the EU Commission the option to supplement or amend certain non-essential elements of the EU law or framework law by delegating authority. The Lisbon Treaty introduces delegated acts as a special category of law in addition to EU directives and regulations. Delegated acts have supremacy over national laws and national constitutions although they are to be approved in an organ where all member states are not represented.* <http://en.euabc.com/word/271>
- 3 *New strengthened rules for food for infants, young children and food for specific medical purpose, 11.6.13* [http://europa.eu/rapid/press-release\\_IP-13-522\\_en.htm](http://europa.eu/rapid/press-release_IP-13-522_en.htm)
- 4 *Preparatory work for the evaluation of the essential composition of infant and follow-on formulae and growing-up milk* <http://www.efsa.europa.eu/en/supporting/pub/551e.htm>
- 5 [http://ec.europa.eu/health/nutrition\\_physical\\_activity/docs/childhoodobesity\\_actionplan\\_2014\\_2020\\_en.pdf](http://ec.europa.eu/health/nutrition_physical_activity/docs/childhoodobesity_actionplan_2014_2020_en.pdf)
- 6 *Maternal, infant and young child nutrition Report by the Secretariat* EB 134/15, 20.12.13. [http://apps.who.int/gb/ebwha/pdf\\_files/EB134/B134\\_15-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/EB134/B134_15-en.pdf)
- 7 *Scientific and technical advisory group on Inappropriate promotion of foods for infants and young children* [www.who.int/nutrition/events/2013\\_STAG\\_meeting\\_24to25June/en/](http://www.who.int/nutrition/events/2013_STAG_meeting_24to25June/en/)
- 8 Commission Staff Working Document on certain requirements for FSMPs (supporting Document for the Expert Group meeting of 7 February 2014.)
- 9 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006L0141:EN:NOT>
- 10 *Standard For Infant Formula And Formulas For Special Medical Purposes Intended For Infants* Codex Stan 72 – 1981
- 11 *FAO/WHO. 2007. Safe preparation, storage and handling of powdered infant formula: guidelines.*

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