

# BRIEFING

BABY MILK  
ACTION



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**The case for the generic labelling of  
infant formula in health care settings**

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## 1 Introduction

2 This report looks at the case for providing infant formula in packaging with generic labels, the  
3 implications of doing so and possible mechanisms for providing generically packaged formula in  
4 health care settings.

5 Infant formula has been described as a semi-medicinal food or 'nutritional medicine' which  
6 should only be used on the advice (and ideally under the supervision) of health workers."<sup>1</sup>

7 It is a processed food, based on cow's milk or soya, intended for use when babies are not  
8 breastfed by their mothers and do not otherwise have access to breastmilk (from a donor milk  
9 bank, for example).

10 Breastmilk substitutes are unlike other foods in that they are the sole source of nutrition during  
11 a critical period of rapid growth and development.

12 Processed formulas can only ever be an imperfect approximation of human breastmilk which is  
13 a living substance that changes as the baby grows. A mother's breastmilk contains antibodies  
14 and other protective factors that are tailored to her baby's needs. It is impossible to mimic a  
15 mother's breastmilk, which is delivered to her baby in a uniquely safe way. In every stage of the  
16 manufacture, storage and delivery of formulas, there are countless opportunities for  
17 contamination, human error and corruption.

18 In addition to these problems, minor modifications and omissions in the ingredients used in  
19 these products can have major effects on infant health. *The Report of the Scientific Committee on  
20 Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae*<sup>2</sup>  
21 identified some of the problems that have occurred with the introduction of modified infant  
22 formulae. Examples included reduced protein availability with impairment of growth; trace  
23 element deficiency with severe clinical disease; chloride deficiency with long-term neurological  
24 damage and thiamine deficiency with severe clinical disease, including neurological damage and  
25 several cases of infant death

26 Breastmilk substitutes may be required when a child is orphaned, the mother is incapacitated or  
27 drugs are contraindicated (though expert pharmacists should be consulted as breastfeeding is  
28 possible with many drugs, even when the standard information indicates otherwise as a routine  
29 recommendation - contact the Drugs in Breastmilk Helpline).

30 In the UK, a large proportion of mothers use formula with no medical need. Indeed, the  
31 preliminary results from the Infant Feeding Survey 2010 show that nearly a fifth (19%) of  
32 babies in the UK are never breastfed. The last full published survey (2005) found that the  
33 number of babies breastfed exclusively until 6 months, as recommended by the Departments of  
34 Health and the World Health Organisation, is insignificant; only 21% of babies are still being  
35 exclusively breastfed at 6 WEEKS of age in the UK.

36 Mothers (and carers when the mothers are absent) who are unable or unwilling to breastfeed  
37 and do not have access to breastmilk by other means will require access to breastmilk  
38 substitutes (infant formula) when in hospital with their babies.

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<sup>1</sup> *Infant formula and related trade issues in the context of the international code of marketing of breast-milk substitutes, health implications of direct advertising of infant formula.*  
[www.who.int/nutrition/.../infant\\_formula\\_trade\\_issues\\_eng.pdf](http://www.who.int/nutrition/.../infant_formula_trade_issues_eng.pdf)

<sup>2</sup> Report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae SCF/CS/NUT/IF/65 Final 18 May 2003

40 **Section One: The case for generic labelling**

41 **Composition of infant formulas - key facts:**

- 42 • Any product sold as an infant formula must comply with the compositional criteria set  
43 out in legislation and the basic nutritional profile of the majority of formulas is very  
44 similar.
- 45 • There is no proven benefit from optional ingredients.
- 46 • Six nutrition claims and one disease risk reduction claim are specifically permitted for  
47 infant formulas and follow-on formulas.<sup>3</sup>
- 48 • A brand name cannot be an implied health or nutrition claim unless that claim is legally  
49 permitted.<sup>4</sup>
- 50 • Additional claims may be allowed for follow-on formulas and formulas and foods for  
51 older babies which may all share the same brand name as infant formula. These claims  
52 must be permitted by specific EU claims legislation.<sup>5</sup>
- 53 • Formulas for special medical purposes (including for low birth weight babies) are  
54 covered by separate legislation so may carry implied health and nutrition claims and  
55 promotional text.<sup>6</sup>
- 56 • Some babies may have an adverse reaction to certain ingredients.
- 57 • Parents may have ethical issues about certain ingredients.
- 58 • Manufacturer and composition information should be communicated to users in a  
59 factual, non-promotional manner.
- 60 • Manufacturers have the legal right to market products in the UK provided they meet EU  
61 Requirements. Regulations in other EU member states vary considerably so products  
62 that do not meet UK standards can be legally marketed in the UK.<sup>7</sup> (add the chart)
- 63 • The detailed rules laid down in the Infant Formula and follow-on formula Regulations  
64 2007, have precedence over the general food labelling rules.
- 65 • Health or nutrition claims and idealising images and text, distort parents perceptions of  
66 the nutritional value and safety of products.

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<sup>3</sup> The Infant Formula and Follow-on Formula (England) Regulations 2007, Section 4 Prohibition on the marketing of products other than infant formula for normal healthy infants

<sup>4</sup> Summary Report of The Standing Committee on the Food Chain and Animal Health (SCoFCaH), 22 June 2012

<sup>5</sup> EU Register On Nutrition & Health Claims providing an updated list of all the permitted health and nutrition claims: <http://ec.europa.eu/nuhclaims/>

<sup>6</sup> Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes <sup>6</sup>