

EXPLANATORY MEMORANDUM TO
THE INFANT FORMULA AND FOLLOW-ON FORMULA (ENGLAND)
(AMENDMENT) REGULATIONS 2008

2008 No. 2445

1. This explanatory memorandum has been prepared by the Food Standards Agency and is laid before Parliament by Command of Her Majesty.

2. Description

2.1 These Regulations amend the Infant Formula and Follow-on Formula (England) Regulations 2007 to create transitional arrangements that apply in relation to

- the enforcement of the labelling requirements for infant formula and follow-on formula and
- the enforcement of the requirements that apply in relation to the shape, appearance and packaging of infant formula and follow-on formula

and make related consequential amendments.

2.2 These Regulations also amend the Medical Food (England) Regulations 2000 to provide transitional arrangements.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

4. Legislative Background

4.1 This instrument makes the legislative provisions considered necessary to give effect in England to the judgement of the High Court of Justice in the case called *R v. The Secretary of State for Health and the Welsh Ministers on the application of the Infant and Dietetic Foods Association Limited* (action number CO/230/2008). Following the judgement delivered on 29 February 2008, the High Court granted a declaration that the Infant Formula and Follow-on Formula (England) Regulations 2007 (S.I. 2007/3521) fail to comply with Commission Directive 2006/141/EC on infant formulae and follow-on formulae and amending Directive 1999/21/EC to the extent that they prohibit as from 11 January 2008 (instead of as from 31 December 2009) trade in infant formula and follow-on formula whose labelling satisfies the labelling requirements of

the Infant Formula and Follow-on Formula Regulations 1995 (S.I. 1995/77) but does not satisfy the labelling requirements of the Infant Formula and Follow-on Formula (England) Regulations 2007.

5. Territorial Extent and Application

5.1 This instrument applies to England. Separate but parallel legislation is being enacted for Scotland, Wales and Northern Ireland.

6. European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 The Infant Formula and Follow-on Formula (England) Regulations 2007 (the 2007 Regulations) implement, in England, Directive 2006/141/EC on Infant Formulae and Follow-on Formulae and amending Directive 1999/21/EC and Council Directive 92/52/EEC on Infant Formulae and Follow-on Formulae intended for export to third countries.

7.2 In summary, the EC legislation seeks to ensure that:

- the essential composition of infant formulae and follow-on formulae satisfy the nutritional requirements of infants in good health as established by generally accepted scientific data
- the labelling of infant formulae and follow-on formulae allows the proper use of such products whilst promoting and protecting breastfeeding
- the rules on composition, labelling and advertising are in line with the principles and aims of the International Code of Marketing of Breast-Milk Substitutes ("the Code")
- information provided to carers about infant feeding does not counter the promotion of breastfeeding.

7.3 The effect of the High Court judgement is that manufacturers of infant formula and follow-on formula have until 1 January 2010 to introduce the new labelling requirements provided for in Directive 2006/141/EC. It is considered that the rationale of the judgement should be applied to the presentation of infant formula and follow-on formula (in so far as it relates to shape, appearance and packaging).

7.4 Therefore, the Infant Formula and Follow-on Formula (England) (Amendment) Regulations 2008 (the 2008 Regulations) amend the 2007 Regulations to

- provide a transitional period until 1st January 2010 as regards labelling of infant formula and follow-on formula
 - provide a transitional period until 1st January 2010 as regards presentation in so far as it relates to the shape, appearance and packaging of infant formula and follow-on formula
- make related consequential amendments.

7.5 The 2008 Regulations also provide transitional arrangements with regard to the Medical Food (England) Regulations 2000 (S.I. 2000/845).

7.6 The advertising provisions within the 2007 Regulations applied from 29 February this year and are unaffected by the amendments made by the 2008 Regulations. The existing transitional period (until 1st January 2010) for compositional requirements is retained.

8. Impact

8.1 An Impact Assessment is not attached to this memorandum because no impact is foreseen on the private or voluntary sectors. A full Regulatory Impact Assessment accompanied the Infant Formula and Follow-on Formula (England) Regulations 2007.

9. Contact

Bindiya Shah at the Food Standards Agency (Tel: 02072768173 or e-mail: bindiya.shah@foodstandards.gsi.gov.uk) can answer any queries regarding the instrument.