EXECUTIVE NOTE

THE INFANT FORMULA AND FOLLOW-ON FORMULA (SCOTLAND) AMENDMENT REGULATIONS 2008
SSI/2008/322

The above instrument was made by Scottish Ministers in exercise of the powers conferred by section 16(1)(e), 17(1), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990. This instrument is subject to negative resolution procedure.

Policy Objective

This instrument, which extends to Scotland only, is necessary to give effect to the decision of the Court of Session in the Petition of the Infant and Dietetic Foods Association Limited and others for Judicial Review of a decision by the Scottish Ministers to make and lay the Infant Formula and Follow-on Formula (Scotland) Regulations 2007 ("the 2007 Regulations").

The Court's judgement was issued on 10 June 2008 and held that the 2007 Regulations, in relation to the enforcement of the labelling requirements, were invalid[1]. The 2007 Regulations 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 2007 Regulations. This instrument corrects that position by amending the 2007 Regulations to create transitional arrangements that apply in relation to:

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

and makes related consequential amendments.

These Regulations also amend the Foods for Special Medical Purposes (Scotland) Regulations 2000 (S.S.I 2000/130) to provide transitional arrangements.

In addition, Regulation 2(7) makes a minor amendment to the schedule to the 2007 Regulations to correct an error which was reported by the Subordinate Legislation Committee, and which the FSA undertook to correct.

Policy Background

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

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[1] The full Opinion of the Judge can be accessed at http://www.scotcourts.gov.uk/opinions/2008csoh87.html (paragraphs 24 - 27 contain the decision)

The Directive consolidates existing Community legislation on the composition, labelling and marketing of infant formulae and follow-on formulae. 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.

The effect of the Court of Session 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 the Directive. It is considered that the rationale of the judgement should also be applied to the presentation of infant formula and follow-on formula (in so far as it relates to shape, appearance and packaging).

Therefore the Infant Formula and Follow-on Formula (Scotland) Amendment Regulations 2008 amend the 2007 Regulations to:

- provide a transitional period until 1 January 2010 as regards labelling of infant formula and follow-on formula
- provide a transitional period until 1 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.

The 2008 Regulations also provide transitional arrangements with regard to the Foods for Special Medical Purposes (Scotland) Regulations 2000 (S.S.I 2000/130).

The advertising provisions within the 2007 Regulations applied from 11 January this year and are unaffected by the amendments made by the 2008 Regulations. The existing transitional period (until 1 January 2010) for compositional requirements is retained.

Consultation

The Court continued the case to allow the Scottish Ministers to bring forward this amending instrument. Although the timescale did not allow for a full formal consultation, a letter was sent to all Scottish stakeholders inviting comment on the proposed amendment, providing a four week period for responding.

FSA Scotland did not receive any responses; however, a response was received in the Agency's London office that requested comments were extended to the equivalent draft Regulations in Scotland, Wales and Northern Ireland. As a result the draft amending regulations were revised so that the rationale of the judgement was also applied to the presentation of infant formula and follow-on formula (in so far as it relates to the shape, appearance and packaging). A specific transitional provision was also included for medical foods as regards compositional requirements.

Financial Implications

The FSA has not produced a Regulatory Impact Assessment (RIA) for this instrument because no impact is foreseen on the private or voluntary sectors. A full RIA accompanied the 2007 Regulations.

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