

**2014 No. 12**

**FOOD**

**The Infant Formula and Follow-on Formula (Scotland)  
Amendment Regulations 2014**

<i>Made</i>	- - - -	<i>14th January 2014</i>
<i>Laid before the Scottish Parliament</i>		<i>16th January 2014</i>
<i>Coming into force</i>	- -	<i>28th February 2014</i>

The Scottish Ministers make the following Regulations in exercise of the powers conferred by sections 16(1)(e), 17(1) and 48(1) of the Food Safety Act 1990(a) and all other powers enabling them to do so.

In accordance with section 48(4A) of the Food Safety Act 1990, they have had regard to any relevant advice given by the Food Standards Agency(b).

There has been consultation as required by Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(c).

**Citation and commencement**

1. These Regulations may be cited as the Infant Formula and Follow-on Formula (Scotland) Amendment Regulations 2014 and come into force on 28th February 2014.

**Amendment of the Infant Formula and Follow-on Formula (Scotland) Regulations 2007**

2.—(1) The Infant Formula and Follow-on Formula (Scotland) Regulations 2007(d) are amended in accordance with paragraphs (2) to (6).

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(a) 1990 c.16. Section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990. Sections 16(1), 17(1) and 48(1) were amended by Schedule 5 to the Food Standards Act 1999 (c.28) (“the 1999 Act”). Section 17(1) was also amended by S.I. 2011/1043. By virtue of section 40(2) of the 1999 Act, amendments made by Schedule 5 to that Act are to be taken as pre-commencement enactments for the purposes of the Scotland Act 1998 (c.46). The functions of the Secretary of State, in so far as within devolved competence, were transferred to the Scottish Ministers by virtue of section 53 of the 1998 Act. In so far as not transferred, and in so far as relating to food (including drink) including the primary production of food, relevant functions were transferred to the Scottish Ministers by the Scotland Act 1998 (Transfer of Functions to the Scottish Ministers etc.) Order 2005 (S.I. 2005/849).

(b) Section 48(4A) was inserted by paragraphs 7 and 21 of Schedule 5 to the 1999 Act.

(c) OJ L 31, 1.2.2002, p.1, as last amended by Commission Regulation (EC) No 596/2009 (OJ L 188, 18.7.2009, p.14).

(d) S.S.I. 2007/549, as relevantly amended by S.S.I. 2008/322.

- (2) In regulation 2(1) (interpretation) for the definition of “the Directive” substitute—  
““the Directive” means Commission Directive 2006/141/EC on infant formulae and follow-on formulae and amending Directive 1999/21/EC(a);”.
- (3) In regulation 8(2) (compositional criteria for infant formula) after the words “cows’ milk proteins” insert “or goats’ milk proteins”.
- (4) For regulation 9 (compositional criteria for follow-on formula) substitute—  
“9.—(1) Subject to paragraph (2), follow-on formula shall comply with the compositional criteria set out in Annex II taking into account the specifications set out in Annex V.  
(2) In the case of follow-on formula manufactured from those protein hydrolysates specified in point 2.2 of Annex II with a protein content between the minimum and 0.56g/100kj (2.25g/100kcal)—  
(a) the suitability of the follow-on formula for satisfying the nutritional requirements of normal healthy infants in conjunction with complementary feeding shall be demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies; and  
(b) the follow-on formula shall be in accordance with the appropriate specifications set out in Annex VI.”.
- (5) In regulation 15 (naming of infant formula) on each occasion it occurs, after “cows’ milk proteins” insert “or goats’ milk proteins”.
- (6) In regulation 16 (naming of follow-on formula) on each occasion it occurs, after “cows’ milk proteins” insert “or goats’ milk proteins”.

*MICHAEL MATHESON*  
Authorised to sign by the Scottish Ministers

St Andrew’s House,  
Edinburgh  
14th January 2014

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(a) OJ L 401, 30.12.2006, p.1, as last amended by Commission Directive 2013/46/EU (OJ L 230, 29.08.2013, p.16).

## **EXPLANATORY NOTE**

*(This note is not part of the Regulations)*

These Regulations amend the Infant Formula and Follow-on Formula (Scotland) Regulations 2007, in order to implement Commission Directive 2013/46/EU amending Directive 2006/141/EC with regard to protein requirements for infant formulae and follow-on formulae (OJ L 230, 29.8.2013, p.16).

Regulation 2(3), (5) and (6) enables the use of goats' milk proteins in the manufacture of infant formula and follow-on formula.

Regulation 2(4) lowers the minimum protein levels permitted in follow-on formula manufactured from protein hydrolysates to bring it in line with infant formula.

A Business and Regulatory Impact Assessment of the effect these Regulations will have on the costs of business, the voluntary sector and the public sector, has been prepared and placed in the Scottish Parliament Information Centre. Copies may be obtained from the Food Standards Agency in Scotland, 6th Floor, St Magnus House, 25 Guild Street, Aberdeen, AB11 6NJ and online at [www.legislation.gov.uk](http://www.legislation.gov.uk).

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