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STATUTORY INSTRUMENTS

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**2013 No. 3243**

**FOOD, ENGLAND**

**The Infant Formula and Follow-on Formula  
(England) (Amendment) Regulations 2013**

*Made* - - - - *19th December 2013*  
*Laid before Parliament* *30th December 2013*  
*Coming into force* - - *28th February 2014*

The Secretary of State makes the following Regulations. He does so in exercise of the powers conferred by section 2(2) of the European Communities Act 1972<sup>(1)</sup> and sections 16(1)(e), 17(1) and 48(1) of the Food Safety Act 1990<sup>(2)(3)</sup>.

The Secretary of State has been designated for the purposes of section 2(2) of the European Communities Act 1972 in relation to measures relating to food (including drink) including the primary production of food<sup>(4)</sup>.

In accordance with section 48(4A) of the Food Safety Act 1990, the Secretary of State has had regard to any relevant advice given by the Food Standards Agency<sup>(5)</sup>.

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<sup>(6)</sup> there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

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- (1) 1972 c.68. Section 2(2) was amended by section 27(1)(a) of the Legislative and Regulatory Reform Act 2006 (c.51) and section 3(3) of and Part 1 of the Schedule to the European Union (Amendment) Act 2008 (c.7).
- (2) 1990 c.16. Section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990. Sections 17(1) and 48(1) were amended by paragraphs 7 and 8 of Schedule 5 to the Food Standards Act 1999 (c.28) (“the 1999 Act”). Section 17(1) was also amended by paragraph 12 of Schedule 5 to the 1999 Act.
- (3) Functions under the Food Safety Act 1990 (c.16) formerly exercisable by “the Ministers” (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the 1999 Act. Those functions, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by S.I. 1999/672 as read with section 40(3) of the 1999 Act and thereafter transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c.32). Those functions, so far as exercisable in relation to Scotland, were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c.46) as read with section 40(2) of the 1999 Act.
- (4) S.I. 2003/2901.
- (5) The Food Standards Agency was established by section 1(1) of the 1999 Act.
- (6) OJ No L 31, 1.2.2002, p.1, as last amended by Regulation (EC) No 596/2009 (OJ No L 188, 18.7.2009, p.14).

## **Title, commencement and application**

### **1. These Regulations—**

- (a) may be cited as the Infant Formula and Follow-on Formula (England) (Amendment) Regulations 2013;
- (b) come into force on 28th February 2014; and
- (c) apply in relation to England only.

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

**2.—(1)** The Infant Formula and Follow-on Formula (England) Regulations 2007<sup>(7)</sup> are amended as follows.

(2) In regulation 2(1) (interpretation) for the definition of “the Directive” substitute the following definition—

““the Directive” means Commission [Directive 2006/141/EC](#) on infant formulae and follow-on formulae and amending [Directive 1999/21/EC](#)<sup>(8)</sup>.”

(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 the following regulation—

### **“Compositional criteria for follow-on formula**

**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 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) in both paragraphs, after “cows’ milk proteins” insert “or goats’ milk proteins”.

(6) In regulation 16 (naming of follow-on formula) in both paragraphs, after “cows’ milk proteins” insert “or goats’ milk proteins”.

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<sup>(7)</sup> [S.I. 2007/3521](#), amended by [S.I. 2011/3012](#). There are other amending instruments but none is relevant.

<sup>(8)</sup> OJ No L 401, 30.12.2006, p.1. The Directive was last amended by Commission Directive 2013/46/EU (OJ No L 230, 29.08.2013, p.16).

Signed by authority of the Secretary of State for Health.

19th December 2013

*Jane Ellison*  
Parliamentary Under-Secretary of State,  
Department of Health

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**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

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## EXPLANATORY NOTE

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

These Regulations amend the Infant Formula and Follow-on Formula (England) Regulations 2007 in order to implement Commission Directive 2013/46/EU in England.

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 full impact assessment has not been produced for this instrument as no cost impact in the private or voluntary sector is foreseen. An Explanatory Memorandum is available alongside this instrument on the legislation website ([www.legislation.gov.uk](http://www.legislation.gov.uk)).