

2014 No. 123 (W. 13)

FOOD, WALES

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

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Infant Formula and Follow-on Formula (Wales) Regulations 2007 (S.I. 2007/3573 (W.316)) in order to implement Commission Directive 2013/46/EU in Wales.

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.

The Welsh Ministers' Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result it was not considered necessary to carry out a regulatory impact assessment as to the likely costs and benefits of complying with these Regulations.

2014 No. 123 (W. 13)

FOOD, WALES

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

Made 22 January 2014

Laid before the National Assembly for Wales
24 January 2014

Coming into force 28 February 2014

The Welsh Ministers make the following Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972⁽¹⁾ and sections 16(1)(e), 17(1) and 48(1) of the Food Safety Act 1990⁽²⁾ ⁽³⁾.

The Welsh Ministers have 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⁽⁴⁾.

In accordance with section 48(4A) of the Food Safety Act 1990, the Welsh Ministers have had regard to any

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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 of “the Ministers”, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by National Assembly for Wales (Transfer of Functions) Order 1999 (S.I. 1999/672) as read with section 40(3) of the 1999 Act, and subsequently transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c.32).
- (4) S.I. 2005/1971. Functions conferred on the National Assembly for Wales were subsequently transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c.32).

relevant advice given by the Food Standards Agency⁽¹⁾

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⁽²⁾ there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

Title, commencement and application

1.—(1) The title of these Regulations is the Infant Formula and Follow-on Formula (Wales) (Amendment) Regulations 2014.

(2) These Regulations come into force on 28 February 2014 and apply in relation to Wales.

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

2.—(1) The Infant Formula and Follow-on Formula (Wales) Regulations 2007⁽³⁾ are amended as follows.

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

□ “the Directive” (“*y Gyfarwydddeb*”) means Commission Directive 2006/141/EC on infant formulae and follow-on formulae and amending Directive 1999/21/EC⁽⁴⁾ as amended by Directive 2013/46/EU; □.

(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 must comply with the compositional criteria set out in Annex II taking into account the specifications in Annex V.

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- (1) The Food Standards Agency was established by section 1(1) of the 1999 Act.
- (2) 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).
- (3) S.I. 2007/3573 (W.316), amended by S.I. 2008/2602 (W.228). There are other amending instruments but none is relevant.
- (4) 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).

(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 must 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 must 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”.

Mark Drakeford

Minister for Health and Social Services, one of the Welsh Ministers.

22 January 2014