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(1) and sections 16(1)(e), 17(1) and 48(1) of the Food Safety Act 1990(2)(3).

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(4).

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(5).

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(6) there has been open and transparent public consultation during the preparation and evaluation of these Regulations.
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(7) are amended as follows.

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


   (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”.

(7) S.I. 2007/3521, amended by S.I. 2011/3012. There are other amending instruments but none is relevant.
Signed by authority of the Secretary of State for Health.

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

19th December 2013
EXPLANATORY NOTE

(This note is not part of the Regulations)


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).