

Commission Directive 2013/46/EU of 28 August 2013 amending
Directive 2006/141/EC with regard to protein requirements for
infant formulae and follow-on formulae (Text with EEA relevance)

Article 1

Directive 2006/141/EC is amended as follows:

- (1) Article 7 is amended as follows:
 - (a) in paragraph 1, the second subparagraph is replaced by the following:

In the case of infant formulae manufactured from cows' milk or goats' milk proteins defined in point 2.1 of Annex I with a protein content between the minimum and 0,5 g/100 kJ (2 g/100 kcal), the suitability of the infant formula for the particular nutritional use by infants shall be demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.;
 - (b) in paragraph 2, the following subparagraph is added:

In the case of follow-on formulae manufactured from protein hydrolysates defined in point 2.2 of Annex II with a protein content between the minimum and 0,56 g/100 kJ (2,25 g/100 kcal), the suitability of the follow-on formula for the particular nutritional use by infants shall be demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies and shall be in accordance with the appropriate specifications set out in Annex VI.;
- (2) in Article 12, the introductory phrase is replaced by the following:

The name under which infant formulae and follow-on formulae manufactured entirely from cows' milk or goats' milk proteins are sold shall be respectively.;
- (3) Annexes I, II, III and VI are amended in accordance with the Annex to this Directive.

Article 2

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 3

1 Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 28 February 2014 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2 Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After
IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 28 August 2013.

For the Commission

The President

José Manuel BARROSO