

DIRECTIVES

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)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses⁽¹⁾, and in particular Article 4(1) thereof,

Whereas:

- (1) Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC⁽²⁾ lays down, inter alia, compositional and labelling rules for infant formulae and follow-on formulae.
- (2) Directive 2006/141/EC specifically provides for infant formulae and follow-on formulae to only be manufactured from protein sources defined in that Directive. Those protein sources are cows' milk proteins and soya protein isolates, alone or in a mixture, as well as protein hydrolysates.
- (3) On request from the Commission, the European Food Safety Authority delivered, on 28 February 2012, a scientific opinion on the suitability of goat milk protein as a source of protein in infant formulae and in follow-on formulae. That opinion concluded that protein from goats' milk can be suitable as a protein source for infant formulae and follow-on formulae provided that the final product complies with the compositional criteria laid down in Directive 2006/141/EC.
- (4) On the basis of that opinion, infant formulae and follow-on formulae manufactured from goats' milk proteins should be allowed on the market provided that the final product complies with the compositional criteria laid down in Directive 2006/141/EC. Directive 2006/141/EC should therefore be amended accordingly.

- (5) On request from the Commission, the European Food Safety Authority delivered, on 5 October 2005, a scientific opinion on the safety and suitability for particular nutritional use by infants of formula based on whey protein partial hydrolysates with a protein content of at least 1,9 g/100 kcal, which was below the minimum level provided for in the Union legislation at that time. That opinion concluded that infant formula, based on hydrolysates of whey protein derived from cows' milk with a protein content of 1,9 g/100 kcal (0,47 g/100 kJ) and corresponding to the protein formulation assessed, is safe and suitable for use as the sole source of nutrition of infants. On the basis of that opinion, Directive 2006/141/EC, as amended by Commission Regulation (EC) No 1243/2008 of 12 December 2008 amending Annexes III and VI to Directive 2006/141/EC as regards compositional requirements for certain infant formulae⁽³⁾, authorises the marketing of infant formulae manufactured from protein hydrolysates with such a protein content provided that the product complies with certain specific criteria set out therein.
- (6) That opinion also concluded that, while no data on follow-on formulae based on hydrolysed whey protein with a protein content of 1,9 g/100 kcal (0,47 g/100 kJ) had been submitted, a formula with that protein formulation would be suitable for older infants in conjunction with complementary foods.
- (7) On the basis of that opinion, and in order to allow the development of innovative products, such follow-on formulae should be allowed on the market. Directive 2006/141/EC should therefore be amended accordingly.
- (8) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health, and neither the European Parliament nor the Council have opposed them,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 2006/141/EC is amended as follows:

⁽¹⁾ OJ L 124, 20.5.2009, p. 21.

⁽²⁾ OJ L 401, 30.12.2006, p. 1.

⁽³⁾ OJ L 335, 13.12.2008, p. 25.

(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.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 28 August 2013.

For the Commission

The President

José Manuel BARROSO

ANNEX

Annexes I, II, III and VI to Directive 2006/141/EC are amended as follows:

(1) Annex I is amended as follows:

(a) point 2.1 is amended as follows:

(i) the title is replaced by the following:

‘2.1. Infant formulae manufactured from cows’ milk or goats’ milk proteins’;

(ii) footnote 1 is replaced by the following:

⁽¹⁾ Infant formulae manufactured from cows’ milk or goats’ milk protein with a protein content between the minimum and 0,5 g/100 kJ (2 g/100 kcal) shall be in accordance with the second subparagraph of Article 7(1).’;

(b) in point 2.3, the title is replaced by the following:

‘2.3. Infant formulae manufactured from soya protein isolates, alone or in a mixture with cows’ milk or goats’ milk proteins’;

(c) in point 10.1, the title is replaced by the following:

‘10.1. Infant formulae manufactured from cows’ milk or goats’ milk proteins or protein hydrolysates’;

(d) in point 10.2, the title is replaced by the following:

‘10.2. Infant formulae manufactured from soya protein isolates, alone or in a mixture with cows’ milk or goats’ milk proteins’;

(2) Annex II is amended as follows:

(a) in point 2.1, the title is replaced by the following:

‘2.1. Follow-on formulae manufactured from cows’ milk or goats’ milk proteins’;

(b) in point 2.2, the table is replaced by the following:

Minimum ⁽¹⁾	Maximum
0,45 g/100 kJ (1,8 g/100 kcal)	0,8 g/100 kJ (3,5 g/100 kcal)

⁽¹⁾ Follow-on formulae manufactured from protein hydrolysates with a protein content between the minimum and 0,56 g/100 kJ (2,25 g/100 kcal) shall be in accordance with the second subparagraph of Article 7(2).’

(c) in point 2.3, the title is replaced by the following:

‘2.3. Follow-on formulae manufactured from soya protein isolates, alone or in a mixture with cows’ milk or goats’ milk proteins’;

(d) in point 8.1, the title is replaced by the following:

‘8.1. Follow-on formulae manufactured from cows’ milk or goats’ milk proteins or protein hydrolysates’;

(e) in point 8.2, the title is replaced by the following:

‘8.2. Follow-on formulae manufactured from soya protein isolates, alone or in a mixture with cows’ milk or goats’ milk proteins’;

(3) in point 3 of Annex III, footnote 1 is replaced by the following:

⁽¹⁾ L-arginine and its hydrochloride shall only be used in the manufacture of infant formulae referred to in the third subparagraph of Article 7(1) and follow-on formulae referred to in the second subparagraph of Article 7(2).’;

(4) the title of Annex VI is replaced by the following:

'Specification for the protein content and source and the processing of protein used in the manufacture of infant formulae and follow-on formulae with a protein content less than 0,56 g/100 kJ (2,25 g/100 kcal) manufactured from hydrolysates of whey proteins derived from cows' milk protein'.
