

Commission Regulation (EC) No 1609/2006 of 27 October 2006 authorising the placing on the market of infant formulae based on hydrolysates of whey protein derived from cows' milk protein for a two-year period (Text with EEA relevance)

COMMISSION REGULATION (EC) No 1609/2006

of 27 October 2006

authorising the placing on the market of infant formulae based on hydrolysates of whey protein derived from cows' milk protein for a two-year period

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses<sup>(1)</sup>, and in particular Article 4(1a) thereof,

Having consulted the European Food Safety Authority,

Whereas:

- (1) Directive 89/398/EEC concerns foodstuffs for particular nutritional uses. The specific provisions applicable to certain groups of foods for particular nutritional uses are laid down by specific Directives.
- (2) Commission Directive 91/321/EEC of 14 May 1991 on infant formulae and follow-on formulae<sup>(2)</sup> is a specific Directive adopted pursuant to Directive 89/398/EEC. Directive 91/321/EEC lays down compositional requirements for infant formulae.
- (3) The Commission received a application for the placing on the market of an innovative infant formula based on hydrolysates of whey protein derived from cows' milk with a protein content below the minimum of 0,56 g protein/100 kJ (2,25 g protein/100 kcal), as referred to in point 2.2 of Annex I to Directive 91/321/EEC.
- (4) On 5 October 2005, the European Food Safety Authority delivered its opinion<sup>(3)</sup>. That opinion stated that infant formula, based on hydrolysates of whey protein derived from cows' milk with a protein content of 0,47 g/100 kJ (1,9 g/100 kcal), is safe and suitable for use as the sole source of nutrition of infants.
- (5) Accordingly, pending the amendment of Directive 91/321/EEC, the marketing of that infant formula should be authorised for a two-year period.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

---

**Status:** Point in time view as at 31/01/2020.

**Changes to legislation:** Commission Regulation (EC) No 1609/2006 is up to date with all changes known to be in force on or before 03 November 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

---

### *Article 1*

By the way of derogation from Article 2 and Article 4(1) of Directive 91/321/EEC, the placing on the market of infant formulae based on hydrolysates of cows' milk, as set out in the Annex to this Regulation, is authorised for a two-year period from the date of adoption of this Regulation.

### *Article 2*

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 27 October 2006.

*For the Commission*

Markos KYPRIANOU

*Member of the Commisison*

---

**Status:** Point in time view as at 31/01/2020.

**Changes to legislation:** Commission Regulation (EC) No 1609/2006 is up to date with all changes known to be in force on or before 03 November 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

---

## ANNEX

Specifications for the protein source, protein processing and protein quality used in the manufacture of infant formula based on hydrolysates of whey protein derived from cows' milk protein

### (1) Protein content

Protein content = nitrogen content × 6,25

Minimum	Maximum
0,44 g/100 kJ	0,7 g/100 kJ
(1,86 g/100 kcal)	(3 g/100 kcal)

### (2) Protein source

Demineralised sweet whey protein derived from cows' milk after enzymatic precipitation of caseins using chymosin, consisting of:

- (a) 63 % caseino-glycomacropeptide free whey protein isolate with a minimum protein content of 95 % of dry matter and protein denaturation of less than 70 % and a maximum ash content of 3 %; and
- (b) 37 % sweet whey protein concentrate with a minimum protein content of 87 % of dry matter and protein denaturation of less than 70 % and a maximum ash content of 3,5 %.

### (3) Protein processing

Two-stage hydrolysis process using a trypsin preparation with a heat treatment step (from 3 to 10 minutes at 80 to 100 °C) between the two hydrolysis steps.

### (4) Protein quality

Essential and semi-essential amino acids in breast milk as set out in Annex V to Directive 91/321/EEC.

---

**Status:** Point in time view as at 31/01/2020.

**Changes to legislation:** Commission Regulation (EC) No 1609/2006 is up to date with all changes known to be in force on or before 03 November 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

---

- (1) [OJ L 186, 30.6.1989, p. 27](#). Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council ([OJ L 284, 31.10.2003, p. 1](#)).
- (2) [OJ L 175, 4.7.1991, p. 35](#). Directive as last amended by Directive 2003/14/EC ([OJ L 41, 14.2.2003, p. 37](#)).
- (3) The EFSA Journal (2005) 280, p. 1-16.

**Status:**

Point in time view as at 31/01/2020.

**Changes to legislation:**

Commission Regulation (EC) No 1609/2006 is up to date with all changes known to be in force on or before 03 November 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.