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

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(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[(1)], 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[(2)] 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[(3)]. 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:

Changes to legislation: Commission Regulation (EC) No 1609/2006 is up to date with all changes known to be in force on or before 08 October 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) View outstanding changes

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

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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.

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(**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.

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Changes and effects yet to be applied to :

– Regulation repeal by EUDR 2006/141 Directive