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

(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 the second indent of the third subparagraph of 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 criteria for infant formulae.

(2) Directive 2006/141/EC provides that only the substances listed in Annex III thereto may be used in the manufacture of infant formulae in order to satisfy the requirements on *inter alia* amino acids and other nitrogen compounds.

(3) Annex III of that Directive should be amended to permit the use of L-arginine and its hydrochloride in the infant formulae.

(4) Directive 2006/141/EC also provides that infant formulae manufactured from protein hydrolysates defined in point 2.2 of Annex I thereto with a protein content between the minimum and 0,56 g/100 kJ (2,25 g/100 kcal) are to be in accordance with the appropriate specifications set out in Annex VI. That Annex sets out specifications for the protein content and source and the processing of protein used in the manufacture of such infant formulae manufactured from hydrolysates of whey proteins derived from cows' milk protein.

(5) 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 [3] authorises the placing on the market of infant formulae based on hydrolysates of cows' milk in accordance with specifications for the protein content, source, processing and quality set out in the Annex thereto. That authorisation expires on 27 October 2008.

(6) Directive 2006/141/EC provides on a permanent basis for the authorisation laid down in Regulation (EC) No 1609/2006. Annex VI to Directive 2006/141/EC set out the specifications for the protein content, protein source and protein processing for the infant formulae in question. However, the particular compositional requirements relating to the protein quality were not included in that Annex. The absence of such requirements would prevent the placing on the market of infant formulae manufactured from protein hydrolysates following the expiry of Regulation (EC) No 1609/2006.

(7) The missing specifications concerning protein quality, which were included in the authorisation laid down in Regulation (EC) No 1609/2006, should be added to Annex VI to Directive 2006/141/EC. That Annex should therefore be amended accordingly.

(8) In order to avoid any disruption on the market for infant formulae, this Regulation should apply from 28 October 2008.

(9) 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:

Article 1

Annexes III and VI to Directive 2006/141/EC are amended in accordance with the Annex to this Regulation.

[1] OJ L 186, 30.6.1989, p. 27.
[2] OJ L 401, 30.12.2006, p. 1.
[3] OJ L 299, 28.10.2006, p. 9.

Article 2

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

It shall apply from 28 October 2008.

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

Done at Brussels, 12 December 2008.

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX

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

1. In Section 3 of Annex III, the following substance is inserted at the top of the list entitled 'Amino acids and other nitrogen compounds':

'L-arginine and its hydrochloride [1]

[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).'

2. In Annex VI, the following point 4 is added:

'4. **Protein quality**

The indispensable and conditionally indispensable amino acids in breast milk, expressed in mg per 100 kJ and 100 kcal, are the following:

	Per 100 kJ [1]	Per 100 kcal
Arginine	16	69
Cystine	6	24
Histidine	11	45
Isoleucine	17	72
Leucine	37	156
Lysine	29	122
Methionine	7	29
Phenylalanine	15	62
Threonine	19	80
Tryptophan	7	30
Tyrosine	14	59
Valine	19	80

[1] 1 kJ = 0,239 kcal.'