

To all interested parties

12 May 2009

Reference: **CPD/0040**

Dear Sir/Madam

Draft Commission Regulation on substances that may be added for specific nutritional purposes in foods for particular nutritional uses

Further to Vivien Lund's letter of 14 April 2009, I am now writing to inform you that at the meeting of the Standing Committee on the Food Chain and Animal Health held on 27 April 2009, the final draft Commission Regulation on substances that may be added for specific nutritional purposes in foods for particular nutritional uses was voted on and received a qualified majority vote in favour of its adoption without any further amendments.

I would like to take this opportunity to remind all interested parties that the positive list of permitted ingredients in this Regulation should be read together with the underlying EFSA opinions (http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_home.htm). This is important as the entries in the Regulation are worded in such a way that they apply only to those sources of each ingredient assessed by EFSA. In the case of alternative sources of listed ingredients, manufacturers must consider all applicable food law and in particular novel foods legislation and any legislation or advice regarding conditions of safe use such as maximum levels.

Next Steps

The Commission will now publish the finalised text in the Official Journal of the European Community in due course. This Regulation will enter into force on the 20th day following its publication. Directive 2001/15/EC and Directive 2004/6/EC will be repealed with effect from 31 December 2009 and the new Regulation will apply as from 1 January 2010.

Following publication in the Official Journal the Agency will need to provide for the enforcement of the Regulation in UK law and we will consult on a draft SI as soon as possible. However, as the SI would need to be in place by 31st December 2009, we may not be able to carry out a full 12 week consultation at that stage. In addition, as there is no change which has a cost implication associated with this Regulation in comparison to the current regulatory regime we do not anticipate carrying out an impact assessment to accompany the SI. However, **if you consider that the Regulation will impose additional costs on business or the public sector,**



please provide evidence and estimated costs to me by 11th July 2009 and we will consider preparing an impact assessment.

Commission Regulation amending Directive 2006/141/EC as regards a compositional specification of infant formulae based on hydrolysates of whey protein derived from cows' milk protein.

Further to my letter of 18 September 2008, the finalised amending Commission Regulation 1243/2008 amending Annexes III and IV to Directive 2006/141/EC as regards compositional requirements for certain infant formulae, has been published in the Official Journal of the European Union. Please see attached link:
eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:335:0025:0027:EN:PDF

Yours faithfully,

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