

To all interested parties

11 January 2008

Reference: CPD/0038  
CPD/0043

Dear Sir/Madam

**Article 14 of EU Regulation 1924/2006: health claims referring to children's development and health**

I am writing to advise you of the implications of two recent developments in Europe and how these may affect you.

**1. Definition of health claims referring to children's development and health**

The first is that the European Commission's guidance on the implementation of EU Regulation 1924/2006 on nutrition and health claims made on foods has now been agreed with Member States. This defines the borderline between Article 13 and Article 14 health claims, including claims referring to children's development and health. This guidance is now being finalised for publication<sup>1</sup>, and it notes that "Health claims used on products for follow on formulae and cereal based baby foods, as defined by Directive 2006/141/EC and Directive 2006/125/EC, shall be subject to the procedure and requirements laid down in Article 14".

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<sup>1</sup> This will be published on the Commission website.

## **2. Transition period for health claims referring to children's development and health**

The second is the agreement by the European Council today of an amendment to EU Regulation 1924/2006 to **introduce a transition period for health claims referring to children's development and health**. This will be published in the Official Journal of the European Union in the near future. **Any claim of this kind on the market, which has not been the subject to an evaluation by a member state, must apply for an authorisation before 19 January 2008.**

The Agency will still require notification of all applications before 19 January so these claims can remain on the market during the transition period. If you are not a member of a trade association and have a claim that is not being dealt with by IDACE or the CIAA, your applications should be made directly to us using the contact details below (we will accept applications until close of play 21 January).

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Applications should be accompanied by a dossier containing as much of the required information as possible, including references to scientific substantiation. All applications should include some level of scientific evidence. Applications must be completed in line with EFSA guidance (see link to EFSA guidance below) and provide the required information as outlined in (a) – (g) of Article 15 (3) of 1924/2006.

The EFSA process does allow applicants to be asked for more information, if that originally provided is deemed inadequate.

Link to EFSA guidance:

[http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1178623592448.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178623592448.htm)

The Agency, as the competent authority will acknowledge applications within 14 days and inform the European Food Safety Authority (EFSA) of applications received. Once this has happened the application and accompanying dossier will be forwarded to EFSA, who may seek more information direct from the applicant. Our intention would therefore be to ensure all applications received are forwarded before the end of February 2008.

I hope this helps clarify the position regarding health claims on the products defined by Directive 2006/141/EC and Directive 2996/125/EC.

If you have any queries on this process please do not hesitate to contact Clare Lowrie (contact details given above).

Yours faithfully

Bindiya Shah