

27 October 2009

Reference: CPD/0019

To all interested parties,

REGULATION (EC) NO 1925/2006 ON THE ADDITION OF VITAMINS AND MINERALS AND OF CERTAIN OTHER SUBSTANCES TO FOODS: END OF THE TRANSITION PERIOD FOR USE OF SUBSTANCES NOT LISTED IN THE ANNEXES AND DEADLINE FOR SUBMITTING DOSSIERS TO THE EUROPEAN COMMISSION

It is not long to the deadline for submitting dossiers in support of including additional vitamins or minerals, or additional forms of vitamins and minerals, in the lists of permitted substances in Annexes I and II of Regulation (EC) No 1925/2006. I am therefore writing to ask that if you wish to submit a dossier via the Food Standards Agency you do so by **30 November 2009** and that you inform us of your intention to do so by **11 November 2009**.

Background

Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods lists the vitamins and minerals (Annex I) and the vitamin formulations and mineral substances (Annex II) that may voluntarily be added to food; the requirements of the Regulation applied from 1 July 2007 and the text can be accessed at

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:404:0026:0038:EN:PDF> .

In addition, it is likely that one mineral (boron) will be added to Annex I and two

vitamin formulations¹ and eight mineral substances² will be added to Annex II in the near future (see <http://www.food.gov.uk/consultations/consulteng/2009/supvitmin>).

However, vitamins and minerals not listed in Annex I, or in forms not listed in Annex II, can continue to be used until 19 January 2014, as long as they were used in food that was marketed on 19 January 2007 and dossiers in support of their use are submitted, via EU Member States, before 19 January 2010. These transitional measures are set out in Article 17 of Regulation (EC) No 1925/2006 and apply to substances for use in foods other than food supplements. Article 17 also says that if, before 19 January 2014, the Commission reaches a negative decision on use of a substance it will no longer be permitted to be added to food. Our guidance notes, dated April 2008, also make this clear (<http://www.food.gov.uk/foodindustry/guidancenotes/foodguid/avmcomplianceguide>).

Requirements for dossiers

Guidance on the submission of dossiers may be found at

http://ec.europa.eu/food/food/labellingnutrition/nutritional/adm_guidance_safety_substances_en.pdf . You should note that:

- Dossiers should concern vitamins and minerals or their forms not already present in Annexes I or II of the Regulation.
- The substance in question should have been used for the addition to foods on 19 January 2007.
- The substance must not require authorisation under Regulation EC 258/97 of 27 January 1997 of the European Parliament and the Council concerning novel foods and novel food ingredients. Therefore, the concerned substance should have been used for addition to foods before 15 May 1997. Its use in

¹ menaquinone, calcium-L-methylfolate

² calcium citrate malate, calcium malate, magnesium potassium citrate, ferrous bisglycinate, zinc bisglycinate, selenium enriched yeast, boric acid, sodium borate

food supplements on this date cannot be taken into consideration for that purpose.

Who is preparing dossiers?

At the Food Standards Agency (FSA) we ourselves are not preparing any dossiers however, as required by the Regulation, we will submit dossiers prepared by stakeholders if requested to do so. If you intend to send a dossier to us, for submission to the European Commission, please respect the timings below.

Timings

According to Article 17 (1)(b) of Regulation (EC) No 1925/2006 dossiers supporting the inclusion of new substances in Annex I or Annex II should be submitted to the Commission, via EU Member States, no later than 19 January 2010. It would help us if we knew how many dossiers to expect therefore if you intend to submit a dossier via the FSA, please **let me know by Wednesday 11 November**.

Upon receipt of a dossier we will not look at the content in detail however we will do a superficial check to see if it appears to be in accordance with the guidance. In order to give us time to do this please send **dossiers to me by Monday 30 November**.

If you have any questions please do not hesitate to contact me.

Yours faithfully,

Vivien Lund.

Nutrition Division