

**VITAMIN AND MINERALS IN FOOD SUPPLEMENTS AND FORTIFIED FOODS:
DRAFT RESPONSE TO THE EC DISCUSSION DOCUMENT**

Executive Summary

1. The European Commission has published a discussion paper, for consultation, on the setting of minimum and maximum levels for vitamins and minerals in foodstuffs. Responses have been requested by 30 September and the Agency has held two meetings to listen to the views of stakeholders and to take these into account in drafting a response to the questions raised by the European Commission. The final UK Government response will be agreed by Health Ministers.
2. The Board is asked to:
 - **agree** the draft response to the questions raised by the European Commission.

NOVEL FOODS, ADDITIVES AND SUPPLEMENTS DIVISION

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**VITAMINS AND MINERALS IN FOOD SUPPLEMENTS AND FORTIFIED FOODS:
DRAFT RESPONSE TO THE EC DISCUSSION DOCUMENT****Issue**

1. The Board was informed at its June meeting that the European Commission had published a discussion document on setting minimum and maximum levels of vitamins and minerals in foodstuffs. There are commitments to set these in both the food supplements directive and the proposed EC Regulation on the addition of vitamins and minerals to foods (fortification). In July the Board agreed the strategy for the Agency's engagement with stakeholders for seeking views on the questions raised in the discussion document, and four key principles which would underpin the discussions.
2. The Agency has held two stakeholder meetings to inform its response to the questions raised by the Commission. The Board is asked to agree the draft response to the questions raised by the Commission. This will then be forwarded to Health Ministers who will agree the final UK Government response to the Commission.

Strategic Aims

3. Protecting consumer interests by ensuring that regulation of food supplements is evidence-based and proportionate represents one of the aims of the Agency's strategic plan.

Background

4. The Board discussed the setting of maximum levels of vitamins and minerals in food supplements in September 2005 in the absence of any proposals from the European Commission. At that meeting the Board reiterated its support for the work of the Expert Group on Vitamins and Minerals and proposed that a two tier approach should be considered in establishing maximum levels for vitamins and minerals in food supplements.
5. During its discussion in September 2005 the Board asked for further information to be provided on the UK supplements market, in particular regarding high dose products, to enable the Board to refine its thinking as the discussions on this subject move forward. This information was provided to the Board in July 2006. In addition the Board had requested that further research should be undertaken to identify intakes through the diet for consumers, including children. Information was provided to the Board in July from the NDNS survey. However, the Board requested that further consideration should be given to intakes by children, taking

into account the example of paediatric medicine and data available from the British National Formulary, and a response will be provided in due course.

6. The Commission subsequently published a discussion document on 6 June 2006 and is seeking comments by 30 September 2006. A copy of the document was provided to the Board at its meeting in July. This document takes into account the need for setting levels for both food supplements and fortified foods. Discussions by the Board prior to publication of this document have focussed only on food supplements.
7. The document is published on the Commission web site and stakeholders as well as member states are invited to submit comments. This is an information gathering exercise. The Commission has not scheduled a meeting with member states or with stakeholders to discuss the document in advance of its deadline, but has indicated that it may hold such meetings in the future. The Commission plans to publish proposals within 2 years, which will form the basis of negotiations with member states. In the interim period discussions will continue with the Commission and member states, and the Board will be updated on progress. When the Commission publishes its proposals the Board will be invited to comment on them and to review its position on the two tier approach agreed in 2005.
8. In July the Board agreed four principles which should underpin discussions in informing the Agency's response to the questions raised by the Commission¹. These principles are:
 - Consumers should have the right to make an informed choice.
 - An evidence base is necessary to ensure consumer safety is safeguarded.
 - The evidence base needs to take into account the risk assessment by scientific experts (particularly drawing on the UK 2003 report from the Expert Group on Vitamins and Minerals), and the more recent advances in global risk management modelling post 2003.
 - There is a need for ongoing monitoring in the market place to continue to inform the evidence base.
9. The Commission document specifically asks a series of technical questions where input is requested. The document does not open up wider discussion on the Food Supplements Directive. The Agency sought the views of stakeholders via two meetings held on 25 July and 4 September and written comments were also invited. Information was also placed on the Agency's web site and a letter sent to interested parties inviting them to attend the meetings and in addition

¹ FSA 06/09/01, paragraphs 34 - 45

encouraging them to respond directly to the Commission. Given the short time scale to respond to the Commission the Agency was unable to allow a 3-month consultation period for receiving input from stakeholders.

10. The Agency received a good response to its invitation to the stakeholder meetings, with over 60 people attending each meeting. A wide range of stakeholders attended and this included representatives from the supplements industry trade associations, representatives from the food industry, British Retail Consortium, British Soft Drink Association, British Dietetic Association, British Nutrition Foundation, Nutrition Society, Which? and Consumers for Health Choice. Officials from other Government departments (e.g. Cabinet Office, FCO, Defra, DH) also attended. The independent scientific advisory committees, the Scientific Advisory Committee on Nutrition and the Committee on Toxicity, were also consulted.
11. Members of the FSA advisory committees in Scotland, Wales and Northern Ireland were invited to attend the meetings, and the NIFAC Chair and members of NIFAC attended via video-link. All three committees have discussed the draft response to the questions at recent meetings.
12. The draft response (Annex 1) explains where there are divergent views from stakeholders to the questions and the opinion of the Agency having taken these views into account. In particular, different views were expressed regarding whether there is a need to set maximum levels for vitamins and minerals where even at high levels of intake the risk of adverse effects is extremely low or non-existent. There were also differences of opinion on whether and how levels should be allocated for use in food supplements and fortified foods. The extent to which the intakes of different populations groups such as children and the elderly should be taken into account when setting levels was also discussed.
13. The Agency will be responding on behalf of the UK Government given our policy lead in this area. Health Ministers will consider the draft response from the Agency and agree the final UK Government response to the Commission.

Impact

14. A Regulatory Impact Assessment is not required as formal proposals have yet to be published by the Commission.

Conclusion

15. The Agency has engaged with stakeholders to inform its response to the questions raised by the Commission in its discussion document. The final UK response to the Commission will be agreed by Health Ministers.

Board Action Required

16. The Board is asked to:

- **agree** the draft response to the questions raised by the European Commission.