

**FOOD SUPPLEMENTS DIRECTIVE - MAXIMUM SAFE LEVELS OF VITAMINS AND MINERALS IN SUPPLEMENTS**

**Executive Summary**

1. The Board is asked to consider the approaches proposed for establishing maximum safe levels for vitamins and minerals in food supplements described in this paper and decide on the advice that the Agency should give to Health Ministers on the input that the UK should make to the EC discussions on establishing such levels in EC legislation.
2. This paper sets out how levels of vitamins and minerals in food supplements might be established by the European Commission to take into account the variation in nutrient dietary intake in member states.
3. The Board is asked to:
  - **note** the recommendations made by the EVM which were accepted by the Board in May 2003
  - **agree** that the Agency's advice to Health Ministers on the setting of maximum safe levels of vitamins and minerals in food supplements in EC legislation should be based on scientific risk assessment.
  - **agree** that the preferred option is a two-tier risk assessment approach enabling maximum safe levels to be established on an EC basis and permitting additional guidance levels to be agreed on a national basis.

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## **FOOD SUPPLEMENTS DIRECTIVE - MAXIMUM SAFE LEVELS OF VITAMINS AND MINERALS IN SUPPLEMENTS**

### **Issue**

1. To provide advice to Health Ministers on the input that the UK should make to the EC discussions on establishing maximum safe levels of vitamins and minerals in food supplements in EC legislation.

### **Strategic Aims**

2. The Food Standards Agency's policy in relation to food supplements is to ensure safety and consumer choice. This paper relates to our overall aim of seeking a proportionate, safety-based approach to setting of maximum levels of vitamins and minerals in food supplements.

### **Background**

#### **Role of Food Standards Agency**

3. The Agency's role in the setting of maximum safe levels of vitamins and minerals in food supplements is to provide advice to Health Ministers on the UK negotiating line in respect of future EC proposals to be published by the European Commission. The UK Government position is then decided collectively with input from other Health Ministers. Agency staff will be responsible for taking forward negotiations in Europe on behalf of the UK Government.
4. The Agency's position on the food supplements directive, which formed the basis for the UK negotiating position at the time, was agreed with the FSA Chair on behalf of the Board but not discussed by the full Board. The Board discussed the safety of vitamins and minerals as part of its discussion on the report of the Expert Group on Vitamins and Minerals (EVM) in May 2003 (Annex 1). The Board was also provided with an information paper on the use of advisory statements, which were agreed between the Agency and the supplements industry in May 2004 (Annex 2).

## **Food Supplements Directive – setting maximum safe levels**

5. The European Commission proposed the EC Food Supplements Directive in May 2000 in order to introduce a harmonised safety-based approach to food supplements and to promote free trade across member states. It came into force in July 2002. The subsequent National regulations were put in place on 3 July 2003 and came into force on 1 August 2005 in accordance with the timetable specified in the Directive.
6. In accordance with the provisions of the Directive, the Commission is due to bring forward as the next step proposals to set maximum safe levels for vitamins and minerals in supplements. It is likely that the Commission will initially produce documents for discussion later in 2005 or early in 2006 before publishing formal proposals in this area. The UK therefore needs to be able to make an input as soon as possible. In order to establish maximum safe levels for vitamins and minerals in food supplements consideration has to be given to the intake of vitamins and minerals obtained through dietary sources in addition to that which may be obtained through supplementation.
7. The results of risk assessments of 34 vitamins and minerals were published by the EVM, an independent expert UK advisory committee in 2003.
8. The EVM considered that the safety assessment of vitamins and minerals should take into account intakes from all sources. It therefore recommended safe upper levels or guidance levels for both total and supplementary nutrient intake, based on an assessment of the available toxicological data on each vitamin and mineral and estimates of dietary intake of UK consumers, primarily obtained from the National Diet and Nutrition Survey (NDNS) programme. The Board accepted the recommendations of the EVM in May 2003 and it is proposed that the setting of maximum safe levels for supplements at EC levels should therefore be based on this risk assessment approach.
9. The majority of food supplement products on the UK market contain amounts of vitamins and minerals that are well below the safe upper levels set by the EVM. However, a small number of products contain amounts higher than the safe upper level set by the EVM, in single dose form, which could cause adverse effects in some individuals if taken on a regular basis. These are products containing vitamin C, iron, calcium, magnesium, nickel, beta-carotene, nicotinic

acid, zinc, manganese, phosphorus, vitamin B6. In consultation with industry representatives, advisory statements for consumers were agreed in May 2004 which provide information on the labels for all such products (Annex 2).

10. Advisory committees of the European Union have also advised on overall safe upper levels of intake of vitamins and minerals. This work was initially conducted by the European Commission's Scientific Committee on Food (SCF), and was transferred to the European Food Safety Authority (EFSA) when it was established in 2003.
11. In general, the upper levels recommended by the SCF and EFSA are similar to those of the EVM, however, unlike the EVM, they focussed on total nutrient intakes, and did not distinguish between dietary and supplemental use unless there was specific concern about the safety of vitamins or minerals taken in tablet form, for example high dose tablets of vitamin C which can cause diarrhoea.

## **Discussion**

12. The Directive recognises that consistently high total intakes of some vitamins and minerals may result in adverse effects and this necessitates the setting of maximum safe levels for them in supplements, as appropriate. The Directive also states that when these levels are set account should be taken of the upper safe levels of the vitamins and minerals, as established by scientific risk assessment based on generally acceptable scientific data, and of intakes of those nutrients from the normal diet. It also says that due account should be taken of reference intake amounts which is the amount considered necessary to ensure nutritional sufficiency. However, intakes of vitamin and minerals from the diet vary across member states due to the differing food habits, which will lead to problems in agreeing maximum safe levels for supplements which will apply across the whole of the EC.
13. The UK has a liberal, safety-based approach to the use and sale of vitamins and minerals and many high dose products are available on the UK market albeit with warnings where necessary, allowing considerable consumer choice. A number of other member states have more restrictive measures in place. For example, some restrict levels to the recommended daily allowance, whilst others consider food supplements should be treated as medicines. The wording in the Directive requires maximum levels to be set by the Commission in agreement with the

member states but allows an element of discretion for how such levels should be established.

14. There may also be significant variation in dietary intakes between different communities within a member state that may create health risks for some if overall intakes are significantly increased by the taking of high doses of supplements (e.g. higher levels of vitamin A being consumed by those who regularly eat liver) and some groups may be more vulnerable in certain circumstances such as pregnant women. In the UK dietary advice regarding vitamins and minerals are provided by the Agency on its web site.
15. Given that both the EVM and EFSA have recommended overall maximum safe levels for vitamins and minerals it would be preferable to use these recommendations, which are based on scientific risk assessment and not dietary need, to establish maximum safe levels for supplements across the EC. This would ensure both safety and choice for consumers. The EVM has taken into account dietary intake of vitamins and minerals for the UK diet and its advice could therefore be used in agreeing maximum safe levels for supplement usage in the UK. The EFSA levels alone cannot be used as the EC maximum safe levels for supplements because of the variations in intakes from the diet in different countries.
16. The following options could be used to set maximum safe levels of vitamins and minerals in food supplements in EC legislation taking into account the variation in diet across member states and the different situations in member states with respect to the use of food supplements.

### **Option 1 – EU level**

17. This option would allow harmonised levels across the EC to be established for all vitamins and minerals in supplement form. The levels agreed in each case could be based on the overall levels determined by EFSA but taking into account available data on the highest intake from dietary sources for each vitamin and mineral across member states. Supplements on sale in any member state would not exceed the maximum safe total level recommended by EFSA and would be an approach permitted under the existing provisions of the Directive.

18. There are 19 nutrients for which EFSA was unable to recommend a safe total level due to a lack of evidence. For these further discussion will be needed on how to set maximum safe levels on an EC basis and the Agency would propose for those the recommendations of the EVM are taken into account.
19. Such an approach would be in line with the single market intention of the Directive whilst protecting consumer safety as the agreed level would be based on a scientific risk assessment. However for some member states this approach would be excessively precautionary and therefore unnecessarily restrict consumer choice where the dietary contribution was below the figure chosen for the EC as a whole. It would also prevent many of the existing products available in the UK from being freely traded across the EC and some higher dose products available from elsewhere being imported.

### **Option 2 – two tier approach**

20. In this approach common maximum safe levels for individual vitamins and mineral supplements would be established across the EU for the purposes of intra community trade based on EFSA's recommendations as described above in option 1. In addition, a second tier of higher maximum levels for each supplement could be set at national level in individual members states where there was evidence that dietary intake levels at a national level were lower than the figure for those used in Option 1 or a national expert opinion supported safe supplemental intakes.
21. Consumer safety would be protected throughout the Community, as the levels set at the EU level and separately at the national level (where appropriate) would be based on scientific risk assessment and dietary intake. Trade would be permitted across the EU for vitamins and minerals at an agreed level, but consumer choice would not be restricted in member states as in option 1 if the levels agreed across the EC were lower than those currently available. The UK market would be maintained and products of higher dose than the EC maximum could be imported. However, products where a single dose would exceed the overall toxicological limit would not be permitted to be sold. This would reduce some of the choice currently available to the UK consumer.
22. The drawback with this option is that the Directive, which is a single market measure, makes no mention of levels by individual member states being able to

be set on a national basis so there is considerable uncertainty whether it would be allowable without an amendment being made.

### **Option 3 – EU level + national guidance**

23. This option would follow the same approach as option 2 except that the maximum permitted national levels would be replaced by national guidance levels. This would permit single dose supplements that exceeded these levels to be sold at the discretion of national governments provided that they carried warning labels. This approach recognises that the taking of supplements is a matter of personal consumer choice.

24. This option would provide consumer safety and allow consumers to make an informed choice about the consumption of supplements. The full choice of supplements currently enjoyed by UK consumers would continue. However, it would suffer from the same disadvantages as described for option 2.

### **Impact**

25. We are waiting for the Commission to bring forward discussion documents and then later proposals, and therefore a regulatory impact assessment has not been prepared. An RIA will be drafted based on the proposals.

26. The impact of this work on the Agency will be managed within existing resources.

### **Risks**

27. This is likely to be a contentious area for discussion given the existing restriction in a number of member states regarding maximum levels of food supplements and the variation in intakes from the diet across the Community.

28. The concept of a two-tier approach is not presented in the Directive and may require the Directive to be redrafted to allow this approach to be used.

### **Conclusion**

29. Three options are presented for setting maximum levels of vitamins and minerals. All the options would ensure consumer safety but the establishment of a two-tier

approach option whilst allowing some trade across the EU for certain products would not restrict consumer choice within the UK.

30. Option 1 would establish one maximum level for each vitamin and mineral supplement throughout the EC thereby facilitating trade but could reduce the level of choice enjoyed by UK consumers.

31. Option 2 will provide the same provision as option 1 but with higher national maximum levels where the intake from dietary sources permits this. Thus increasing UK consumer choice above that provided for in Option 1.

32. Option 3 would provide the same provision as option 1 but allow maximum choice for UK consumers equivalent to the current situation. Guidance on national levels would allow single dose supplements to be sold that exceed national levels as long as advisory labels are attached.

33. Option 3 is recommended.

### **Board Action Required**

34. The Board is invited to:

- **note** the recommendations made by the EVM and which were accepted by the Board in May 2003;
- **agree** that the Agency's advice to Health Ministers on the setting of maximum safe levels of vitamins and minerals in food supplements in EC legislation should be based on scientific risk assessment; and
- **agree** that the preferred option is a two-tier risk assessment approach enabling maximum safe levels to be established on an EC basis and permitting additional guidance levels to be agreed on a national basis.