



Briefing Document

Update on the UK industry maximum level for vitamin D in food supplements for adults

The three industry trade associations, CRNUK, HFMA and PAGB, which represent the vast majority of companies marketing food supplements in the UK, are proposing a maximum level for vitamin D in food supplements for adults.

In 2003, a Guidance Level of 25 µg/day for long-term vitamin D supplementation was set by the UK Expert Group on Vitamins and Minerals (EVM)¹, to which industry has worked since the publication of the report.

The EVM Guidance Level has since been superseded by risk assessments undertaken by the European Food Safety Authority (EFSA) and the Institute of Medicine (IOM). A Safe Upper Level (UL) of 100 µg/day from all sources was set by the IOM in 2010² and by EFSA in 2012³.

These new ULs for vitamin D doubled the previous IOM and EFSA ULs based on more recent evidence of the safety of vitamin D.

In view of the increase in the EU UL set by EFSA, CRNUK, HFMA and PAGB have agreed a common industry position of 75 µg/day as the maximum level for vitamin D in a food supplement.

The proposed value is based on the risk management methodology developed by the European Association of Health Products Manufacturers (EHPM) and the European Responsible Nutrition Alliance (ERNA) in 2004⁴ (which refers to the 50 µg/day UL from all sources previously set by the Scientific Committee on Food (SCF)/EFSA⁵ and the IOM⁶). This model was updated by Food Supplements Europe (FSE) in 2014⁷ (referring to the revised 100 µg/day UL from all sources set by the IOM and by EFSA).

¹ Expert Vitamins and Minerals Group (EVM). Safe Upper Levels for Vitamins and Minerals. May 2003.

² Institutes of Medicine. Dietary reference Intakes for Calcium and Vitamin D. November 2010.

³ European Food Safety Authority. Scientific Opinion on the Tolerable Upper Intake Level of Vitamin D. June, 2012.

⁴ European Association of Health Products Manufacturers (EHPM) and European Responsible Nutrition Alliance (ERNA). Vitamins and mineral supplements: a risk management model. November 2004.

⁵ Scientific Committee on Food/Scientific Panel on Dietetic Products, Nutrition and Allergies. Tolerable Upper Intake Levels for Vitamins and Minerals. February 2006.

⁶ Institutes of Medicine. Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D and Fluoride. 1997.

⁷ Food Supplements Europe. Risk management approaches to the setting of maximum levels of vitamins and minerals in food supplements for adults and for children aged 4-10 years. July 2014.

The rationale for the 75 µg/day level takes into account:

- The EFSA and IOM UL of 100 µg/day for vitamin D
- Intakes from food
- Intakes from food including fortified food as well as future increases in intake resulting from increases in fortification practices, changing food habits and food choices
- An allowance for people taking a cod liver oil supplement as well as a multivitamin.

A maximum level of 75 µg/day in a food supplement is consistent with the EHPM/ERNA and FSE risk management model (see Annex for calculations).

The upper limit of 75 µg/day for vitamin D is also consistent with the amount in the Belgium Royal Decree on maximum levels in food supplements published in the Belgium Official Journal on 31st October 2017.

In December 2017, the Dutch authorities notified the European Commission and EU Member States of their intention to change the Commodities Act Order on food supplements. For vitamin D, the draft order states in Article 4.3: “*Food supplements shall contain an upper daily intake of 75 µg vitamin D, as per instructions*”.

Hence the UK industry position is consistent with the position adopted in various other EU Member States.

In the past few years there has been a renewed scientific interest in the functions of vitamin D and more certainty about the safety of supplementary use of vitamin D. Total intakes, therefore, are likely to increase.

Annex

Intake data from the latest UK National Diet and Nutrition Survey (NDNS)⁸ show that the adult mean intake from food sources only is less than 3 µg /day, while that for 65+ year old adults is slightly higher at 3.3 µg.

Intake at the 97.5%ile is highest for men, and is also higher for 65+ year old adult males. This is therefore approximated at 10 µg/day.

NDNS DATA: Years 1-4						
Vitamin D µg	Men	Men	Women	Women	All	All
<i>Age (years)</i>	<i>19-64</i>	<i>65+</i>	<i>19-64</i>	<i>65+</i>	<i>19-64</i>	<i>65+</i>
Mean	3.1	3.9	2.6	2.9	2.8	3.3
Median	2.5	3.2	2.1	2.5	2.3	2.7
SD	2.3	2.7	1.9	1.9	2.1	2.3
Upper 2.5 percentile	9.2	11.9	7.5	7.7	8.5	9.2
Lower 2.5 percentile	0.5	0.9	0.4	0.5	0.5	0.7

The calculated allowance for future food fortification and changing dietary patterns in the EHPM/ERNA and FSE models is 50% of intake at the 97.5%ile, which is therefore 5 µg/day. This is particularly relevant for vitamin D, as in view of the UK Scientific Advisory Committee on Nutrition (SACN) vitamin D report which set Dietary Reference Values for all population groups⁹, food fortification with vitamin D is likely to increase in the future.

Intake at the 97.5%ile plus the allowance for future food fortification/changing dietary patterns is therefore 15 µg/day.

As a further precautionary measure, an allowance of 10 µg/day is included for intake from a cod liver oil or multivitamin supplement giving a potential overall intake of 25 µg/day.

Subtracting from the UL of 100 µg leaves 75 µg for safe supplementation.

⁸ Public Health England. National Diet and Nutrition Survey: Results from Years 1, 2, 3 and 4 (combined) of the Rolling Programme (2008/2009 – 2011/2012).

⁹ Scientific Advisory Committee on Nutrition. Vitamin D and Health Report. 21 July 2016.