



Christina Antoniou
European Commission
Directorate General Health and Consumers
Unit E4

B- 1049 Brussels

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Our reference
Health Claims

DSM Nutritional Products
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Per e-mail only

**Art 14 Health Claim on Vitamin D and the Risk of Falling - EFSA
Opinion ON 2382**

Dear Ms. Antoniou,

On 30th September the European Food Safety Authority (EFSA) published a positive Scientific Opinion on the substantiation of a health claim related to vitamin D and the risk of falling.

While we welcome the Opinion we note that the condition of use has been set by the EFSA NDA Panel at 800 I.U. (20 µg) per day from all sources.

As this condition will not be sufficient to set concrete amounts to be ingested via a food to achieve the claimed effect and this level of intake can most likely not be met by food, including fortified food, we would like to suggest the condition of use to be set as follows:

Supplemental intake of 20 µg per day (in addition to the baseline dietary intake) is needed to achieve the claimed effect.

The claim may be used (only) for food supplements which provide a daily dose of 20 µg of vitamin D.

This supplemental intake of 20 µg per day is justifiable as all data regarded as pertinent for the substantiation of the claim by the NDA Panel were based on supplemental intake of 800 - 1000 I.U. (20 - 25 µg), in addition to dietary intake.

We are convinced that such additional intake does not represent a safety concern as the Upper Safe Level currently set by SCF/EFSA is 50 µg per day while the dietary intake of the elderly in Europe does by far not even meet the recommended intake levels.



In Germany for instance, according to the Nutrition Survey of 2008 (NVS II)¹, the intake of vitamin D ranges from 2.6 µg (median, women 51-80) to 3.3 µg (median, men 51-80) while the recommended intake is 10 µg for the elderly. Based on the German Nutrition Report 2008² intake of institutionalized elderly is much lower still and ranges from 1.1 µg - 2 µg (median, men and women over 65 years of age). Intake surveys from other EU countries, for example Italy³, reflect a similar picture.

Furthermore we expect that recommended levels of intake and the UL in the EU will be raised in the near future in order to reflect new scientific evidence as it has been done in the United States of America in 2010⁴.

We hope that our comments are helpful to take a timely decision to allow for this claim and will be pleased to provide further information and scientific data upon request.

Thanks a lot for your attention.

With Best Regards

A handwritten signature in blue ink, appearing to read 'P. Tiersch', is written over a faint, larger version of the same signature.

Handwritten initials 'PP' in blue ink.

Petra Tiersch
Regulatory Affairs Manager
Human Nutrition & Health EMEA

¹ Nationale Verzehrstudie II Ergebnisbericht, Teil 2; Max Rubner Institut 2008, page 248

² Ernährungsbericht 2008; Deutsche Gesellschaft für Ernährung (DGE), page 186-189

³ S. Sette et al The third Italian National Food Consumption Survey, INRAN-SCAI 2005-06 - Part 1: Nutrient intakes in Italy, page 7-8

⁴ <http://www.iom.edu/Reports/2010/Dietary-Reference-Intakes-for-Calcium-and-Vitamin-D.aspx>