

Parliamentary Questions on Vitamin D

Question E-9154/2010 for written answer to the Commission

János Áder (PPE)

Subject: EFSA's work on micronutrients

According to the reply to Written Question E-7015/2010, the EFSA Panel on Dietetic products, Nutrition and Allergies (NDA) is currently finalising the work related to dietary reference values for micronutrients and energy, and the work on micronutrients including vitamin D will only start at the end of 2010.

In the light of the above, could the Commission provide us with the exact date of the completion of its work on dietary reference values for Vitamin D? When can the results be expected?

Question for written answer E-7014/2010 to the Commission

Jim Higgins (PPE)

Subject: Vitamin D

How does the Commission ensure that the latest scientific research on Vitamin D is incorporated into its evaluation of the economic impact of Vitamin D deficiency? Would the Commission consider involving the European Parliament in the process? Up-to-date and correct data is essential and this was highlighted in Point 3 of Question E-3202/10 when €187 billion as mentioned in the Grant Report was misread as €187 million.

E-7014/10EN

Answer given by Mr Dalli on behalf of the Commission

21 October 2010

The Commission does not currently perform economic impact analyses related to vitamin D status.

According to the cost-benefit estimation of increased vitamin D intake in Europe, referred to in written question E-3202/10 by Mr Skylakakis, Mr Tsoukalas and Mrs Weisgerber¹, the economic burden attributed to insufficient vitamin D consumption is estimated at EUR 187,000 million per year².

¹ <http://www.europarl.europa.eu/QP-WEB>

² Progress in Biophysics and Molecular Biology Volume 99, Issues 2-3, February-May 2009, pages 104-113.

Question for written answer E-7015/2010 to the Commission

Jim Higgins (PPE)

Subject: Vitamin D

Could the Commission provide an update on EFSA's review process with regard to the work and research by EURRECA? Could it also explain to what extent EFSA will draw on the recommendations on Vitamin D currently prepared by the Institute of Medicine in the US?

EFSA's reply to Written Question E- E-7015/2010

In 2005, EFSA has received from the European Commission a request to review the existing Dietary Reference Values which had been established by the Scientific Committee on Food in 1993 as since then new scientific evidence and new reports on Dietary Reference Values from several national and international scientific bodies have become available. The EFSA's Panel on Dietetic products, nutrition and allergies (NDA) is currently finalising the work related to Dietary Reference Values for macronutrients (carbohydrates, protein, fat) and energy, and the work on micronutrients including vitamin D will only start at the end of 2010.

As a rule EFSA carefully reviews and weighs in its opinions all available pertinent scientific evidence including the evidence provided by opinions from other authoritative bodies, such as the US Institute of Medicine (IoM).

EFSA is aware that, in 2008, the Food and Nutrition Board of IoM set out to assess current relevant scientific data and update as appropriate the Dietary Reference Intakes for vitamin D and calcium. The IoM Committee's report is expected to be publicly available by November 2010. EFSA will carefully analyse their work and the date considered. Thus, the report of the IoM Committee will certainly be of high value for the work of EFSA for deriving Dietary Reference Values for Vitamin D for the European population.

With regard to EFSA's involvement in the work of EURRECA, EFSA follows closely EURRECA's work, e.g. participation in various meetings, scientific exchange with partners of the EURRECA network on issues covered by EURRECA. The aim of this cooperation is to avoid duplication of work to be conducted by EFSA and EURRECA and to ensure that supportive and complementary work is provided to the task to be conducted by EFSA.

Question for written answer E-7016/2010 to the Commission

Jim Higgins (PPE)

Subject: Vitamin D

The Commission has indicated in its answers to questions that further scientific research is needed to assess Vitamin D deficiency. To what extent and within which framework could the Commission support further research (e.g. in the form of clinical trials) on the link between Vitamin D and diseases related to heart health, the immune system, cancer etc.?

Answer given by Ms Geoghegan-Quinn on behalf of the Commission

29 September 2010

The Commission is aware of the importance of Vitamin D in disease prevention and the potential impact of its deficiency and has been undertaking actions to further the scientific knowledge on this subject throughout its Framework Programmes for Research and Technological Development.

Previous efforts undertaken within the "Life Sciences, Genomics and Biotechnology for Health Programme" of the 6th Framework Programme for Research and Technological Development (FP6, 2002–2006) led to the support of the Network of Excellence EURRECA³ (EUR 13,2 million). Started in 2007, and bringing together 39 partners from 17 European countries, this project aimed at developing a framework for harmonised advice on micronutrients including vitamin D. Key objectives include the delivery and setting up of evidence-based basis for establishing micronutrient requirements and devising micronutrient recommendations as well as identifying the particular needs of specific vulnerable groups (e.g. infants, children, pregnant women, elderly, etc).

Efforts in this area are being pursued within the 7th Framework Programme for Research and Technological Development⁴ (FP7, 2007–2013) under the themes "Health" which has set a priority for translational research in major diseases (e.g. cancer, cardiovascular diseases) and "Food, Agriculture and Fisheries, and Biotechnology" which, within its nutrition area, aims at fostering the understanding of the importance of dietary factors as well as the specific needs and habits of population groups as a major controllable factor in the development and reduction of occurrence of diet-related diseases and disorders.

In this context, three projects specifically addressing the link between vitamin D and diseases are being supported with an EU contribution of EUR 18 million as a result of the FP 7 calls for proposals launched during the 2007-2010 period. Two of these initiatives intend to establish, through clinical trials, the role of Vitamin D as a preventive measure against gestational diabetes development (DALI⁵), as well as assessing the immuno-modulation properties of Vitamin D with a view to developing novel immunotherapy strategies preventing the destruction of pancreatic cells (NAIMIT⁶). The EFRAIM⁷ project intends to evaluate the role of vitamin D status in relation to the development of allergic diseases in five birth cohorts from European countries (Germany, Switzerland, Austria, Finland and France).

Further prospects for research on vitamin D are expected to become available in future calls for proposals.

³ EURRECA (Aligning nutrient recommendations across Europe with special focus on vulnerable groups and consumer understanding); <http://www.eurreca.org/everyone>.

⁴ COM (2005)119 final.

⁵ DALI (Vitamin D And Lifestyle Intervention for Gestational Diabetes Mellitus (GDM) Prevention); <http://www.dali-project.eu/partner.html>.

⁶ NAIMIT (Natural immunomodulators as novel immunotherapies for type 1 diabetes); http://naimit.eu/?page_id=28.

⁷ EFRAIM (Mechanisms of early protective exposures on allergy development); <http://www.efraim-online.com>

Elena Oana Antonescu

11 May 2010

WRITTEN QUESTION by Elena Oana Antonescu (PPE) to the Commission

Subject: Action to combat vitamin D deficiency

Vitamin D deficiency is a major health problem associated with increased risks of osteoporosis, heart disease, tuberculosis, certain forms of cancer, diabetes, periodontitis, multiple sclerosis, chronic fatigue, depression, loss of muscular strength and the formation of adipose tissue. It is estimated that over 50 % of adults suffer from vitamin D deficiency, with numbers significantly exceeding the European average in certain countries (the problem being more acute in Spain and the eastern European countries than in the northern European countries(1)).

The problem has many causes, depending on geographic location, age, exposure to the sun and diet. A comprehensive approach to it must take account of such diverse factors if an effective solution is to be found. In general, efforts to resolve the problem have been concentrated on vitamin D supplements (2) contained in pharmaceuticals or vitaminised foods.

Does the Commission intend to propose a set of harmonised EU policies to reduce vitamin D deficiency levels, aside from setting minimum and maximum dose levels regarding food supplements, which get to grips with other contributory factors?

(1) Lips P., Vitamin D status and nutrition in Europe and Asia, The Journal of Steroid Biochemistry and Molecular Biology, Volume 103, Issues 3-5, March 2007, Pages 620-625, 10.1016/j.jsbmb.2006.12.076.

(2) Answer by Mr. Dalli on behalf of the Commission to Written Question E-1346/10.

Answer given by Mr. Dalli on behalf of the Commission

22 June 2010

Referring to the previous Written Questions [E-2231/10](#) and [E-3202/10](#)⁽¹⁾, the Commission would like to underline that it is fully aware of the importance of vitamin D for different aspects of human health and for disease prevention.

The maximum and minimum amounts of vitamins and minerals present in foods, including food supplements, foreseen by Directive 2002/46/EC⁽²⁾ and Regulation (EC) No 1925/2006⁽³⁾ will be established on a safety basis taking into account scientific assessment carried out by the European Food Safety Authority⁽⁴⁾ and by other recognised scientific assessment bodies.

The work on setting maximum amounts is ongoing and, the Commission has consulted extensively with Member States and interested stakeholders on the issue. Every effort will be made to ensure that the widest possible range of safe products is available for consumers, avoiding at the same time the risks of both deficiency and excessive intakes.

The only EU instrument to provide financial support to awareness-raising on public health is the EU Health Programme. However, given that further scientific research on vitamin D deficiency is needed, the Commission does not envisage at this moment action on awareness-raising on vitamin D deficiency under the EU Health Programme.

⁽¹⁾ <http://www.europarl.europa.eu/QP-WEB>

[\(2\)](#) OJ L 183, 12.7.2002.

[\(3\)](#) OJ L 404, 30.12.2006.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178633962601.htm

Ioannis A. Tsoukalas, Theodoros Skylakakis and Anja Weisgerber

7 May 2010

WRITTEN QUESTION by Ioannis A. Tsoukalas (PPE), Theodoros Skylakakis (PPE) and Anja Weisgerber (PPE) to the Commission

Subject: Vitamin D deficiency

The European population's exposure to sunlight, which is the main source for Vitamin D intake, has been decreasing due to the evolution of modern lifestyles and change of habits. Vitamin D is essential for bone and muscle health as well as for the general health of the human body. The deficiency of this vitamin is related to serious diseases, including osteoporosis, cardiovascular disease, some types of cancer, diabetes mellitus, increased susceptibility to infections and, consequently, increased mortality (1). It is reported that at least 50 % of the European population is presenting a Vitamin D deficiency (2). It is also reported that the treatment of Vitamin D deficiency in the European population by receiving 1 000 IU of Vitamin D daily could lead to a reduction in mortality caused by cancer(3).

Increasing the intake of foods enriched with sufficient vitamin amounts can contribute to tackling the problem. However, the production of such foods is not possible, due to the fact that the existing limit for Vitamin D is 5 µg (200 IU — International Units, Directive 2008/100/EC(4)), a percentage that is also reported not to correspond to current scientific data that suggest a minimum of 20 µg (800 IU).

Vitamin D is not covered by any patent and its production is comparatively low-cost, therefore there is a lack of significant economic interest encouraging its widespread consumption.

In light of the above, the Commission is asked to answer the following questions:

1. How does it intend to use the data available on the benefits of Vitamin D, and what measures are planned by the Commission and the Member States in order to deal with Vitamin D deficiency and insufficiency in the European population?
2. Does the Commission intend to proceed to a review of the current limits so that the production of foods enriched with sufficient quantities of Vitamin D is enabled?
3. Does the Commission possess data on the estimated decrease of the costs to European health systems which would arise from the intake of adequate amounts of Vitamin D by the population?
4. Does the Commission intend to take steps to inform health professionals and consumers on the effects of Vitamin D deficiency, and encourage Member States to do the same?
5. How does the Commission intend to reinforce research on the status of the European population concerning Vitamin D, its effects on its health and the possible negative side-effects resulting from an increased intake of this vitamin? Which relevant research actions are funded by the EC?

(1) Heaney Robert P., The case for improving vitamin D status, *The Journal of Steroid Biochemistry and Molecular Biology*, Volume 103, Issues 3-5, 13th Workshop on Vitamin D (Victoria, British Columbia, Canada, April 2006), March 2007, pp. 635-641, ISSN 0960-0760.

(2) Lips P., Vitamin D status and nutrition in Europe and Asia, *The Journal of Steroid Biochemistry and Molecular Biology*, Volume 103, Issues 3-5, 13th Workshop on Vitamin D (Victoria, British Columbia, Canada, April 2006), March 2007, pp. 620-625, ISSN 0960-0760.

(3) Grant, W. B., Garland, C. F. and Gorham, E. D., An estimate of cancer mortality rate reductions in Europe and the US with 1 000 I.U. of oral vitamin D per day, *Recent Results in Cancer Research*, Volume 174, February 2007, pp 225-234, ISSN: 0080-0015.

(4) OJ L 285, 29.10.2008, p. 9.

E-3202/10DE

Answer given by Mr Dalli on behalf of the Commission

(21.6.2010)

The Commission is fully aware of findings showing that the deficiency of vitamin D may have an impact on human health.

1. Preclinical and epidemiologic data suggest the causality between vitamin D status and major diseases. However, clinical trials for cardio vascular diseases and others not related to bone or muscle affections are still not available(1). More analysis is still needed.

2. The addition of vitamins and minerals to foodstuffs is regulated at European level by Regulation (EC) 1925/2006 on the addition of vitamins and minerals and other substances to foods(2). The aim of this legislation is to ensure the functioning of the internal market for foods to which vitamins and minerals have been added, whilst providing a high level of consumer protection. This legislation provides for the setting of maximum amounts of vitamins and minerals in foodstuffs, including vitamin D. However no proposal has yet been presented on vitamin D. The Recommended Daily Allowance for vitamin D is 5 micrograms as laid down in Annex to Directive 90/496/EEC on nutrition labelling for foodstuffs(3). In accordance with Regulation 1925/2006, the addition of a vitamin to a food shall result in its presence in a significant amount. The minimum amount of vitamin D in fortified foods would equal 0.75 micrograms.

As regard setting maximum amounts, scientific data, such as the report of the Scientific Committee on Food(4) which considered the adverse effects of high intakes of vitamin D, will be taken into account in any possible consideration to setting these levels. The Commission has already consulted Member States and stakeholders in this regard.

3. According to a scientific cost-benefits estimation of increased vitamin D intake in Europe, the ill health related economic burden attributed to vitamin D insufficient consumption is estimated at EUR 187 million per year.

4. Taking into account that further scientific research on vitamin D deficiency is needed, the Commission does not envisage at this moment action on awareness raising on vitamin D deficiency under the EU Health Programme.

5. The Commission is funding a research programme, EUROpean micronutrients RECommendations Aligned, that has developed best practice guidelines describing biomarkers of vitamin D status. A systematic-review of vitamin D intake is under consideration within this project.

(1) CPME/AD/Brd/241009/179_Final/EN

(2) OJ L 404, 30.12.2006.

(3) OJ L 276, 6.10.1990.

(4) http://www.efsa.europa.eu/en/scdocs/oldsc/upper_level_opinions_full-part33.pdf

Jim Higgins

9 April 2010

WRITTEN QUESTION by Jim Higgins (PPE) to the Commission

Subject: Vitamin D

In view of the fact that 50% of the EU's population is deficient in Vitamin D, and that Vitamin D is not only essential for optimal bone and muscle health, but is also a key preventative factor in warding off diseases such as osteoporosis, heart diseases, many forms of cancer, diabetes, asthma and multiple sclerosis, is the Commission planning to propose any public education programmes in order to highlight the nutritional importance of Vitamin D?

28 May 2010

Answer given by Mr Dalli on behalf of the Commission

The Commission is aware of the importance that a deficiency of vitamin D may have for different aspects of human health and possible applications in disease prevention.

The Commission's only instrument to give financial support to work on awareness-raising on public health is the EU Health Programme. However, given that nutritional advice is best given at Member State level and considering the fact that further scientific research on vitamin D deficiency is needed, the Commission does not envisage at this moment action on awareness-raising on vitamin D deficiency under the EU Health Programme.

Syed Kamall

8 March 2010

WRITTEN QUESTION by Syed Kamall (ECR) to the Commission

Subject: Vitamin D supplements

I have been contacted by constituents regarding vitamin D supplements. My constituent has told me that British people need higher levels of vitamin D supplements than those in sunny EU countries and that new studies has shown that rickets bone disease has increased to several hundred cases a year in the UK because of a shortage of vitamin D in children. The studies have also shown that over half the UK adult population were shown to be deficient in vitamin D during spring and winter.

My constituents are concerned that the EU Food Supplements Directive (2002/46/EC(1)) threatens to remove considerable numbers of safe and popular higher potency food supplements, particularly vitamins and minerals, from the UK market. They claim that this would lead to the closure of large numbers of health food stores and the potential loss of thousands of jobs across the UK.

Could the Commission confirm whether:

1. The maximum permitted dose levels for vitamins and minerals in food supplements will not be set at unnecessarily low levels;
2. The new EU Health Commissioner will make sure that his officials do not bring forward proposals which will deny millions of consumers across Europe continued access to safe and popular higher potency vitamin and mineral supplements of their choice?

(1) OJ L 183, 12.7.2002, p. 51.

22 March 2010

Answer given by Mr Dalli on behalf of the Commission

Vitamins and minerals are essential nutrients but in some cases excessive intake can lead to adverse health effects. The maximum amounts of vitamins and minerals present in food supplements foreseen by Article 5 of Directive 2002/46/EC(1) will be established on a safety basis taking into account scientific assessment carried out by the European Food Safety Authority(2) and by other recognised scientific assessment bodies. Those criteria listed in Article 5 include:

- upper safe levels of the vitamins and minerals established by scientific risk assessment (UL, the maximum level of total chronic intake of a nutrient judged to be unlikely to pose risk of adverse health effects to humans);
- intake of vitamins and minerals from other dietary sources.

The reference intakes of vitamins and minerals for the population will also be considered when establishing these maximum amounts.

The work on setting maximum amounts is ongoing, but no proposal has yet been presented. The Commission has consulted extensively with Member States and interested stakeholders on the issue. All the available data on the potential effects on economic operators and consumers of the setting of maximum amounts of vitamins and minerals in foods, including food supplements will be taken into account. However, whilst the economic impact of the levels will be taken into account, the levels will

be set based on risk assessment. Every effort will be made to ensure that the maximum amounts set will take into account the concerns expressed by all interested parties.

The Commission will take proportionate risk management measures to ensure that the widest possible range of safe food supplement is available for consumers, avoiding at the same time the risks of both deficiency and excessive intakes.

In conclusion, Directive 2002/46/EC on food supplements will not result in reduction of consumers' choice but will rather ensure that food supplements placed on the market contain nutrients at safe levels and thus will allow consumers to choose from a wide range of safe products. In that context, the Commission is convinced that an adequate range of vitamin D supplements will be available.

(1) OJ L 183, 12.7.2002.

(2) http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178633962601.htm