EUROPEAN PARLIAMENT

2004 *2009*

Committee on Petitions

07.07.2009

NOTICE TO MEMBERS

Subject: **Petition 1037/2007 by Jill Bell (Irish), on behalf of the Irish Association of Health Stores, concerning Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements**

Petition 1184/2007 by Grace Kinirons (Irish), on behalf of Nutritional Therapists of Ireland, concerning Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements

Petition 1419/2008 by Robert Verkerk (British), on behalf of the Alliance for Natural Health, on the urgent need for a review of the risk evaluation and control options in connection with plans to restrict access by consumers to vitamins and minerals

Petition 1849/2008 by Mr Alan G. Ruth (Irish), on behalf of the Irish Health Trade Association, on Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements

Petition 0415/2009 by PA (Swedish) concerning Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements

1. Summaries of petitions

Petition 1037/2007

The Irish Association of Health Stores is a trade association representing 80% of health food stores in Ireland. While it supports rules governing food supplements, it takes the view that Directive 2002/46/EC, on the approximation of the laws of the Member States, relating to food supplements is inappropriate and particularly disproportionate to the levels of risk involved. While the ceiling limits have not yet been published, it is clear that they will unjustifiably restrict access to food supplements which have proved safe and effective in

Ireland and the United Kingdom for over 40 years. The Irish Association of Health Stores maintains that Member Stares should be able to choose whether the decision is made by the authorities, the consumers and/or the organisations concerned, thereby ensuring continued access to the above food products, which have traditionally been sold in the Member States and, in particular, Ireland and the United Kingdom.

Petition 1184/2007

The petitioners are critical of a number of provisions of the directive and are seeking to ensure in the Member States, especially Ireland and the United Kingdom, where the continued access to high quality food supplements have traditionally been freely available. They call on the Irish Government and the Commission to respect and uphold the right of consumers and those working in the health sector to freedom of choice regarding health care and in particular their right to access to non-organic and vitamin supplements which have been available in Ireland and elsewhere for the last 40 years, which should not be undermined as proposed by the directive and recommended by the Irish Food Safety Authority.

Petition 1419/2008

The petitioner calls for an urgent need for a review of the risk evaluation and control options being considered by the Commission and by the European Food Safety Authority (EFSA) with a view to restricting access for consumers to vitamins and minerals. The petitioner fears that the review and harmonisation of European legislation in this area (Directive 2002/46/EC) will lead to a restriction of consumer choice and a disproportionate impact on small and medium-sized enterprises in this sector, while there is little or no evidence that the current doses for food supplements, which are deemed too high, have a detrimental effect on public health. The petitioner also considers that the research methodologies currently in use are faulty and need revision. He calls for an independent study based on the most recent scientific evidence.

Petition 1849/2008

The petitioner wishes to draw Parliament's attention to the negative impact of Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements, claiming that setting maximum permitted levels of vitamins and minerals in food products will have a negative effect on consumer health, and lead to the closure of many SMEs which produce such food supplements in Ireland and the UK.

Petition 0415/2009

The petitioner objects to the maximum limits imposed under the above directive in respect of food supplements arguing that it would cause great difficulties for food supplement businesses in Scandinavia which use much higher levels in their products. It would also be greatly to the detriment of consumers who require high levels of food supplement and are unable to obtain it from normal food because of lack of vitamins and minerals in the soil. The petitioner argues that the setting of maximum levels is detrimental to public health.

2. Admissibility

Petition 1037/2007 : Declared admissible on 7 March 2008.
Petition 1184/2007 : Declared admissible on 8 March 2008.
Petition 1419/2008 : Declared admissible on 5 March 2009.
Petition 1849/2008 : Declared admissible on 9 April 2009.
Petition 0415/2009 : Declared admissible on 24 June 2009.

Information requested from Commission under Rule 192(4).

3. Commission reply for 1037/2007 & 1184/2007, received on 26 September 2008.

The petitioners criticise Directive 2002/46/EC on food supplements and in particular the establishment of maximum amounts of vitamins and minerals in these products. Furthermore they question the scientific safety assessment of the intake of high doses of vitamins and minerals.

Directive 2002/46/EC[1] on food supplements was adopted by the European Parliament and the Council on 10 June 2002 and fully applies as of 1 August 2005.

The Directive establishes harmonised rules for the labelling of food supplements, and introduces specific rules on vitamins and minerals in food supplements. Its aim is to facilitate the free circulation of those products, to ensure a high level of protection of public health, and to provide a clear legal framework for manufacturers.

In joined cases C-154/04 and C-155/04 *Alliance for Natural Health* (2005) ECR-I-6451,the European Court of Justice (ECJ) has examined several questions concerning Directive 2002/46/EC, and between others possible infringements of the principles of subsidiarity, proportionality and to the fundamental right to pursue an economic activity. The ECJ has concluded in its judgement on these cases that no factors of such kind affect the validity of the Directive.

The establishment of maximum amounts of vitamins and minerals is foreseen by Article 5 of Directive 2002/46/EC. The aim of this provision is to ensure that the widest possible range of safe products is available for consumers, avoiding at the same time that excessive intake of vitamins and minerals may result in adverse effects. In this context, although the Commission, in its role of risk manager, is responsible for proposing maximum levels for nutrients, its margin of manoeuvre is framed by a set of criteria which have to be taken into account when establishing those levels. The Commission has initiated the work but not yet finalised the measure.

To address the safety concerns that may arise from an excessive intake of vitamins and minerals, one of the criteria set out in the Directive for the establishment of maximum levels is to take into account the upper safe levels (i.e. the maximum level of total chronic intake of a nutrient that is unlikely to pose risk of adverse effects) for the nutrients in question as determined by scientific risk assessment.

In this context, the Commission requested the Scientific Committee of Food (SCF), and later

[1] OJ L 183, 12.7.2002, p. 51–57

the European Food Safety Agency (EFSA), to provide scientific opinions on tolerable upper intake levels of the nutrients listed in Annex I of the Directive. Where appropriate, the work of other international scientific risk assessment bodies will also be taken into account.
The role of EFSA in providing independent scientific advice for Community legislation in fields which have an impact on food safety is stipulated in Regulation (EC) 178/2002[1] laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
The criteria listed in Article 5 of Directive 2002/46/EC foresee also that the varying degree of sensitivity of different population groups and the intake of nutrients from the diet have to be taken into account when establishing maximum amounts for vitamins and minerals.

The claim by the petitioners that there are no recorded incidents of serious adverse effects caused by food supplements (classified as foods by the European legislation) in over forty years of usage, has to be considered in the light of the fact that there is no system in place to systematically report possible adverse reactions that may be caused by foodstuffs.

Products designed for specific groups of the population (ex. coeliac) and falling under the provisions of Council Directive 89/398/EEC[2] relating to foodstuffs intended for particular nutritional uses will not be affected by the maximum amounts for vitamins and minerals that will be defined under Directive 2002/46/EC on food supplements.

Conclusion

The Commission considers Directive 2002/46/EC on food supplements and its future implementing measures, such as the establishment of maximum amounts for vitamins and minerals as a valid instrument to assure that safe products are commercialised on the internal market.

On the more specific issues raised by the petitioners the Commission would also like to inform that:

- the establishment of maximum amounts for vitamins and minerals in food supplements as well as the criteria to be used is foreseen by the Directive itself
- the safety assessment on the possible consequences of excessive intakes of vitamins and minerals has been conducted in accordance with the provision of Regulation 178/2002/EC not by the Commission but by the Scientific Committee of Food (SCF) and by the European Food Safety Agency (EFSA).

4. Commission reply for 1037/2007, 1184/2007, 1419/2008, 1849/2008 and 415/2009

received on 7 July 2009

In total four petitions that concern similar issues related to food supplements have been submitted to the European Parliament. Three of them were presented by the petitioners during

[1] OJ L 31, 1.2.2002, p. 1–24

[2] OJ L 186, 30.6.1989, p. 27–32

the meeting of the Committee of Petitions on 19 January 2009 (1037/2007 on behalf of the Irish Association of Health Stores (IAHS), 1184/2007 on behalf of the Nutritional Therapists of Ireland and 1419/2008 on behalf of the Alliance for Natural Health (ANH)). Petition 1894/2008 submitted by the Irish Health Trade Association (IHTA) repeats the comments and allegations presented by the ANH and the IAHS in their respective petitions. The most recently received petition (415/2009) expresses similar concerns in relation to the Scandinavian food supplement market.

As explained in its previous communication on the petitions dating from 2007, the ECJ in its judgement of 12th July 2005 (joined cases C-154/04 and C-155/04) had already rejected the complaints about Directive 2002/46/EC, with reference to the use of vitamins and minerals in food supplements. More recently, petitioners are now seeking to cast doubt specifically on the risk assessments made in this context by the European Food Safety Authority, and the Commission's use of the results. They argue that risk assessment models which are appropriate for toxins will produce excessively restrictive limits if applied to the assessment of food supplements such as vitamins. They continue to allege unjustified consequential damage to the foods supplements business, and would prefer a labelling-based non-regulatory approach.

With regard to the criticism of the risk assessment carried out by EFSA's Panel on Food Additives and Nutrient Sources added to Food (ANS), composed of independent scientific experts, it was carried out in accordance with the rules of Regulation 178/2002/EC that provides specific guarantees for the independence and the transparency of EFSA's scientific advice. Therefore, the Commission cannot accept this criticism.

Further, the petitioners seem to anticipate that the risk management process will result in maximum permitted levels (MPLs) that will make up to 85% of food supplements currently present to disappear from the market. The Commission finds such an allegation totally unfounded and unsubstantiated.

These concerns have already been addressed to the Commission. The Commission in its reply asked the IHTA for some clarification on the terminology used of "higher potency supplements" and requested the industry group to provide data to substantiate the claims on the potential impact of setting maximum amounts on these products. Until now the Commission has not been provided with any concrete data. Neither the IAHS nor the ANH could substantiate their claims with relevant data. The few data that IAHS provided were not reliable, and data provided by the ANH on the distribution of higher dose products were considered not to be comprehensive as they did not cover the whole sector.

Unless it is provided with the relevant and reliable data to support the allegations made by the petitioners, the Commission continues to consider them to be pure speculation.

In the process of setting the maximum amounts, the Commission carried out a public consultation on the setting of maximum amounts and published, in June 2006, a Discussion Paper which identified the main issues to be considered in the exercise and obtained the views of stakeholders on how these might be addressed. The responses to this consultation are available on the SANCO website http://ec.europa.eu/food/food/labellingnutrition/supplements/index_en.htm.

The Commission is working in close cooperation with stakeholders using formulas developed by stakeholders and with support of the stakeholders.

The Commission considers Directive 2002/46/EC on food supplements and its future implementing measures, such as the establishment of maximum amounts for vitamins and minerals, as a valid instrument to ensure that products which are commercialised on the internal market are safe.