WRITTEN QUESTION E-2841/09
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to the Commission

Subject: Directive 2002/46/EC and the European Commission proposal to harmonise maximum levels of vitamin and mineral food supplements

On the basis of Article 5 of Directive 2002/46/EC[1], the European Commission is preparing to propose maximum permitted levels for vitamins and mineral food supplements (and fortified foods) for harmonisation across the EU. The levels are expected to be derived from a risk management model, applied to 'tolerable upper levels', as developed or approved by the European Food Safety Authority.

We would like to raise the following questions:

1. Will population requirements in different geographic areas of the EU be adequately taken into account? For example, Scandinavians require considerably greater amounts of supplemental vitamin D3 than southern Europeans; will harmonised MPLs prevent Scandinavians from consuming sufficient vitamin D3?

2. On the basis of the above, would the intended purposes of the Directive, namely the functioning of the single market and a high level of consumer protection, not be better served by creating a partial harmonisation measure for MPLs, whereby the relevant competent authorities of Member States are given legal authority to adjust MPLs for their own populations in order to meet their specific nutritional requirements?

3. Will the proposed MPLs, and the tolerable upper levels on which they are based, be determined using models on 'the basis of the most reliable scientific data available and the most recent results of international research' (paragraph 73 of *Alliance for Natural Health and others* v *UK* [2005]; ECJ Cases C-154/04 and C-155/04) which should include validation against levels in the diet or from supplements that are known to be safe and beneficial?

4. Will the proposals for MPLs take into account differences in the safety profile of different forms of the same nutrient? While most authorities for example currently recognise differences between two forms of vitamin B3, namely nicotinic acid and nicotinamide, differences with respect to other nutrients have thus far been ignored by the Commission.

[1] OJ L 183, 12.7.2002, p. 51.