

From the Rt Hon Alan Johnson MP  
Secretary of State for Health

RECEIVED 05 FEB 2009

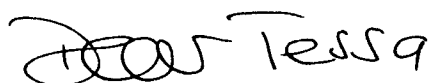
**DH** Department  
of Health

Your Ref: 01090148

MC04265 /FSAPO00383525

The Rt Hon Tessa Jowell MP  
House of Commons  
Westminster  
London SW1A 0AA

Richmond House  
79 Whitehall  
London  
SW1A 2NS  
Tel: 020 7210 3000



04 FEB 2009

Thank you for your letter of 19 January enclosing an example of correspondence you have received from a number of your constituents about food supplements and traditional herbal remedies.

If I may deal with food supplements first, the Government considers that the approach to regulation of food supplements should be safety-based and that consumers should have the right to make an informed choice unless their safety is compromised.

The Food Supplements Directive provides for the setting of maximum levels of vitamins and minerals in food supplements on the basis of science and safety. The Food Standards Agency (FSA), which reports to Parliament through Health Ministers, is responsible for issues relating to food supplements and for negotiations relating to the setting of maximum levels. FSA officials have represented the UK at the European Commission working group meetings with Member States which have taken place to date on the setting of maximum and minimum levels of vitamins and minerals in food supplements, the first of which was held in September 2007.

The UK's negotiating position on maximum levels was agreed by the FSA Board and by Ministers in 2005, this being, in the absence of proposals from the Commission, a "two tier" approach. The first tier would support common maximum safe levels for individual vitamins and minerals being established across the European Union (EU) for the purposes of intra-community trade based on recommendations from the European Food Safety Authority. The second tier would allow higher maximum levels for each vitamin and mineral to be set at a national level in individual Member States provided there was evidence that dietary intake levels at a national level were lower than the figure used across the EU, or a national expert opinion supported safe supplemental intakes. This would permit single dose supplements that exceeded the maximum levels to be sold at the discretion of national Governments provided they carried advisory labels enabling consumers to make an informed choice.

The Commission has suggested that maximum levels are established by the use of scientific modelling which takes into account individuals' intake of vitamins and minerals from all sources using dietary intake data. Member States have been invited

to participate in an ad hoc technical working group to carry out scientific simulations using their own national dietary intake data and the scientific models proposed. The UK is involved in this work and the FSA has worked in partnership with industry to carry out simulations using the UK National Diet and Nutrition Survey (NDNS) data. The output from this has been shared with the Commission and the ad hoc group. At the most recent working group meeting with all Member States on 4 December 2008 the Commission advised Member States that the next working group meeting would take place in February, at which draft proposals outlining maximum levels for vitamins and minerals will be discussed. The work to determine levels will be discussed with the ad hoc working group, of which the UK is a member, prior to discussion at the next working group meeting. The Commission will hold a stakeholder consultation on proposed draft levels after the February meeting. The UK will also undertake stakeholder consultation at this time.

FSA officials have recently held a series of bilateral meetings with their counterparts in other Member States. To date, productive meetings have been held with Sweden, Ireland, France and Italy which have enabled FSA officials to put forward the UK's position on the setting of maximum and minimum levels and learn more about the current position of the other Member States on these and other issues in relation to food supplements.

Another relatively recent development in this area is work, arranged by the Commission in the summer of 2008, to examine the economic, social and environmental impact of a number of options regarding the establishment of maximum levels. FSA officials wrote to key stakeholders to alert them to this work and provided the consultancy undertaking the work on behalf of the Commission with details of the relevant industry representative bodies in the UK. Although the options outlined by the Commission in this work cannot be considered to be formal policy proposals, they do indicate a clear understanding of the issues raised by FSA officials in representing the views of UK stakeholders. The work also provides a further opportunity for stakeholders to feed their views directly into Commission work in this area.

Turning to traditional herbal remedies, the Medicines and Healthcare products Regulatory Agency (MHRA) recognises there are significant challenges for small businesses specialising in herbal medicinal products in moving from an essentially unregulated environment into one where there are systematic standards to be met. However, it is important to note that the Traditional Herbal Medicines Directive addresses significant public health issues.

Prior to the implementation of the registration scheme in 2005, individual companies determined their own standards for herbal products. There is well documented evidence of an international trade in potentially dangerous low grade herbal medicines with numerous examples of products containing heavy metals, undeclared pharmaceuticals, or mistakenly containing the wrong, toxic, herb. Consumers have, until now, been unable to identify which herbal products are produced to acceptable standards and companies operating to high standards have often been at a commercial disadvantage.

The Directive's registration scheme introduces standards whereby consumers can identify which traditional herbal medicines adhere to assured standards of safety and quality and provides consumers with comprehensive patient information. These standards apply to all other medicines and the Directive is broadly supported by most of the main interest groups in the UK herbal sector, which accept the basic premise that the marketing of over-the-counter medicines should be subject to systematic regulation.

The standards set in the Directive deliver specific benefits, such as systematic assurance that products contain the intended ingredients, are free from harmful heavy metals, microbiological and other contaminants, and that the claimed shelf life is justified. Many companies across the UK and Europe with expertise in the safe manufacture of herbal medicines are clear that these kinds of standards are necessary.

Proportionate regulation will benefit industry, as well as consumers. A recent market research report suggested that the UK market for herbal medicines could see an increase in sales in the coming years. One important factor cited for this likely growth is the change in legislation, which should foster greater consumer trust in products.

Throughout the negotiations and implementation of the Directive, the MHRA has sought to contain and reduce regulatory impact. To further this aim the MHRA has undertaken a range of workshops, seminars and company meetings to help individual companies progress their plans and applications, and published a series of guidance documents and assessment reports on registrations granted so that potential applicants can be clear on the type of issues likely to arise with their applications.

The outcome of a Commission review in 2007 of the early operation of the Directive has now been published; its main conclusions indicate insufficient experience of the Directive to justify making substantive changes, but, it may be possible to extend the simplified registration procedure to products with a long tradition of safe use. In addition, specific areas are identified where there are issues deserving of further consideration such as the provision that at least 15 out of the 30 years' evidence of traditional use required for the registration of products should relate to usage within the European Community. The MHRA has argued that there should be greater flexibility in relation to acceptance of evidence of traditional use from outside the EU.

The MHRA has received considerable positive feedback from a wide range of companies for the helpful and pragmatic approach taken in the UK and use of the traditional herbal registration scheme in the UK continues to expand steadily. To date, the MHRA has received 53 applications to register products, from 17 companies, and registration applications have been made for 27 different herbs, helping to allay earlier fears expressed by some that the scheme would be restricted to products containing only the most popular herbs. Twenty-five applications to register products have already been granted, including six for combination products, with the remaining applications under assessment. Three of the most recent registration grants have been made to small or medium sized UK companies,

demonstrating that the regulatory standards designed to provide consumer assurance on standards of safety, quality and consumer information are achievable by a range of businesses. The MHRA expects all these numbers to grow significantly in the coming months, leading to a lively and competitive market in regulated over-the-counter herbal medicines.

I hope this information is helpful.

Yours  
Alan

**ALAN JOHNSON**