

EXPERT GROUP ON VITAMINS AND MINERALS

PAPER FOR INFORMATION

21 January 1999

Agenda Item 4

BACKGROUND PAPER ON VITAMIN AND MINERAL SUPPLEMENTS

Purpose

1. The purpose of this paper is to provide background information on the current regulatory framework within which vitamins and mineral supplements and fortified foods are controlled in the UK. It also gives a brief overview of the way in which such products are regulated in other Member States of the European Union (EU), and gives details of initiatives within the EU and in Codex.

Legislative Framework on Vitamin and Mineral Supplements in the UK

2. In the UK, products containing added vitamins and minerals which are intended to be consumed may be regarded in law as either foods or medicines.

3. Those products for which claims are made for the treatment or prevention of disease, or which are administered to restore, correct or modify physiological functions, fall within the definition of a medicine and are subject to the requirements of the Medicines Act 1968 and Directive 65/65/EEC. Such products require a marketing authorisation (licence) before they can be sold or supplied. Grant of a such a licence requires evidence of quality, safety and efficacy for the indications proposed. The legal classification of a medicine (prescription only, pharmacy or general sale list) determines the route of sale or supply. Products that are licensed as medicines are excluded from the definition of food in the Food Safety Act 1990. The control of medicines is the responsibility of the Medicines Control Agency (MCA), which is an executive agency of the Department of Health.

4. Products that do not fall within the scope of the Medicines Act are automatically regarded as foods and are subject to the requirements of the Food Safety Act 1990 and subsidiary legislation. There are basically two types

of foods which contain added vitamins and minerals: fortified foods, e.g. margarine, bread and some breakfast cereals; and dietary supplements.

5. There is no legal definition for the term “dietary supplements” nor any legislation which applies specifically to dietary supplements as a separate class of foods. Neither are there any statutory limits on the levels of vitamins and minerals that they may contain. The situation with regard to fortified foods is similar, except that there is a statutory requirement to fortify most flour and margarine. Dietary supplements and fortified foods are subject to the general provisions of the Food Safety Act 1990, which effectively require that products should not be injurious to health, and to the Food Labelling Regulations 1996, which control the labelling and advertising of food. Among other things, the Food Labelling Regulations prohibit claims in labelling or advertising that a food has the property of preventing, treating or curing a human disease, and lay down conditions for the use of nutritional claims and certain descriptions which may mislead. Dietary supplements and fortified foods are thus treated in the same way as most other products subject to food law.

Controls Applying Elsewhere in the European Union (EU)

6. Controls on dietary supplements and fortified foods are not harmonised in the EU and each Member State applies its own rules. Most limit the levels of vitamins and minerals that may be added to an amount equivalent to a population reference intake or a small multiple thereof. In these Member States products containing higher levels would normally have to be licensed as medicines, although permission for higher dose products to be sold as foods may sometimes be granted on a case by case basis. Member States with liberal regimes similar to those applying in the UK are in the minority. While some apply limits on the level of certain vitamins or minerals these are generally based on an assessment of risk rather than an arbitrary multiple of a population reference intake.

7. In June 1997, the EU Commission issued a discussion paper (Annex 1) on the need for harmonised controls on both dietary supplements and fortified foods. This reviewed the current situation and presented for consideration various issues related to the controls of such products, including the question of the need to establish maximum limits on their vitamin and mineral content. However, it did not make any firm proposals or commit the Commission to taking action. The UK’s response supported in principle the harmonisation of controls on dietary supplements if this could be justified on safety grounds, but made it clear that any maximum limits should be based on safety considerations and not on arbitrary multiples of population reference intakes.

8. We understand that the Commission is considering issuing a further paper as a basis for discussion with Member States, but it is not yet clear whether this will include formal proposals for legislation. It has asked the Scientific Committee on Food (SCF) to advise on the setting of maximum safe levels for vitamins and minerals in fortified foods and supplements. The SCF has established a Task Force to carry out this work. It comprises members of the SCF together with invited experts in nutrition and toxicology.

Codex

9. The Codex Alimentarius Commission, which develop international standards and guidelines on food to protect the consumer and to guide the world's growing food industry, is also elaborating guidelines on vitamin and mineral supplements. This issue has been under discussion for a number of years and because meetings are infrequent (the next is not scheduled to take place until 2000) it may be some time before an agreement is reached. The main sticking point of these discussions is how maximum limits should be set. Some countries believe that maximum limits should reflect nutritional need and should therefore be based on a multiple of an agreed population reference intake. Others take the view that maximum limits of vitamins and minerals should be up to a level considered safe on the basis of risk assessment considerations.

10. Codex guidelines are advisory and it is for individual governments to decide what use, if any, they wish to make of them. However, they are increasingly used as a basis for settling trade disputes.

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