

July 2000

Consumers' Association's response to the European Commission's proposed Directive on Food Supplements

Introduction

Consumers' Association (CA), publisher of *Which?*, *Health Which?* and other consumer magazines and information, is the largest independent consumer organisation in Europe with over 700,000 members. Food issues are one of our main campaigning areas and we regularly produce information on food issues within our publications. At European level, we are members of Bureau Europeen des Unions de Consommateurs (BEUC), the European Consumer Organisation. We are also a member of the Trans-atlantic Consumer Dialogue (TACD), a forum for EU and US consumer groups and take a very active role on the Food Working Group as EU Chair.

We very much welcome the publication of the Commission's Proposal for a Directive on Food Supplements. We responded in detail to the Commission's Discussion Paper on the Addition of Vitamins and Minerals to Foods and Food Supplements in 1997 and emphasised the need for regulation in this area. Many consumers now take food supplements on a regular basis, but this has remained an area where there are limited controls, and inconsistent controls across the European Union (EU). We therefore support the Commission's efforts to harmonise legislation in this area and ensure a higher level of consumer protection.

Specific comments

Scope

Many of the supplements that are consumed are vitamin and mineral supplements and therefore we welcome the Commission's intention to tighten controls in this area. The intention is that other types of supplements will be added at a later date. Ideally, we would like the Directive to cover all food supplements as many other supplements are now available, and are taken by consumers. As stated in the explanatory memorandum, these may include a wide range of ingredients including herbal remedies, such as garlic; amino acids; essential fatty acids; algae and other natural substances. In some cases these ingredients may be included with vitamins and minerals in supplements. Many of the issues are similar to those for vitamin and mineral supplements, but

they may also raise other more specific concerns regarding safety, quality, efficacy and consumer information.

Role in the diet

We agree that ideally under normal circumstances, a varied diet should provide all of the necessary nutrients for normal development and maintenance of a healthy life. However, in some cases, consumers may need, or choose, to supplement their diets by taking vitamin and mineral supplements. It is important therefore that these consumers can use these products safely and can make an informed choice when buying and using these products.

A positive list of vitamins and minerals (Article 4)

We agree that it could be misleading if supplements were sold which contained vitamins and minerals that were non-essential. We therefore agree that a positive list of essential vitamins and minerals that can be added to supplements should be established.

Chemical form (Article 4)

We also agree that in order to ensure the safety and quality of products on the market, a list should be established setting out the chemical form of nutrients that can be added to supplements.

Maximum levels (Article 5)

It is clear that many consumers want to take supplements and in some cases to take doses higher than the Recommended Daily Amount (RDA). We do not consider that consumers should be denied this choice, however we do consider it essential that supplements do not contain nutrients at levels that could be harmful to health. We therefore agree that European-wide maximum levels (also referred to as upper safe intake levels or safe upper limits) for the addition of vitamins and minerals to food supplements should be established. We hope that this approach can also be adopted for other nutrients or ingredients that may be used in supplements, when the Commission expands the scope of the Directive. When establishing these limits it is important to take into account the total dietary intake, including levels in fortified foods. We therefore hope that the Commission will adopt a similar approach when it publishes a proposal for a directive on fortified foods in September. We welcome the work being done by the Scientific Committee on Food and the UK's Expert Group on Vitamins and Minerals in this area. It is also important that the practice of using 'overages' is taken into account when establishing maximum levels, together with any implications for the shelf-life of products.

Minimum levels (Article 5)

It is important that supplements contain a significant enough amount of the nutrient consumers are paying for, so that they get the benefit they expect. We therefore agree that minimum levels that should be present when a particular nutrient is added to a supplement should also be established.

Labelling

Safe usage (Article 6):

It is essential that consumers can take these products safely and therefore we agree that food supplements should be labelled with clear instructions about how the product should be used safely, including the amount that should be consumed. This will be particularly important where it is possible to overdose on a particular nutrient.

Warnings (Article 6):

Where a nutrient may present a particular risk to certain sections of the population, a warning should also be clearly labelled on the product.

We agree that where it would be possible to confuse the product with a licensed medicine, it should clearly state 'This is not a medicinal product'.

Statement (Articles 6 and 7):

We also agree that food supplements should be required to state that they should not be used as a substitute for a diversified or balanced diet.

Conversely, the label or other promotional material should not state or imply that an adequate and balanced diet cannot provide appropriate quantities of nutrients. However, it is important that the Directive acknowledges that there may be some specific exceptions, for example, in the case of folic acid.

Nutrition labelling (Articles 8 and 9) :

We agree that it should be a mandatory requirement to label the levels of vitamins and minerals present in food supplements. This should be provided in a standardised, user-friendly format. We also agree that this would be most meaningful if declared according to the manufacturers recommended daily consumption, as well as per unit dose. It is important that terminology is standardised.

We agree that it is appropriate, given the variability of the manufacturing process involved, that this information should be based on analysis by the manufacturer rather than based on food composition tables to ensure its accuracy.

Our own research analysing the levels of vitamins present in multi-vitamin supplements has however raised concerns about the difficulties of independently testing vitamin supplements. In particular, our analysis highlighted the difficulty of extracting some vitamins from some forms of supplements for analysis due to the different ways that products are formulated. It is therefore important that standardised test methods are established for the analysis of food supplements.

Dietary reference values (Article 8):

It is important that consumers can put the amount of nutrients present, and suggested daily dose, into context. We agree that it should be a mandatory requirement to give the dietary reference values and it seems sensible to base this on the reference values set out in the Annex to Directive 90/496/EEC until these have been reviewed.

Claims (Article 6):

It is essential that consumers are not misled by the claims made on food supplements. While claims relating to prevention, treatment or cure of disease are prohibited, many food supplements make 'health claims'. We are concerned that these claims do not have to be approved before they can be used to ensure that they can be substantiated. Our research has suggested that UK consumers have little confidence in these claims, with only three in ten people agreeing that they 'believe all of the health claims that appear on products nowadays' in a survey of 2000 people conducted in May 2000. It is essential that legislation is introduced in this area that ensures that consumers are not misled as to the potential health benefits of food products, including food supplements. We hope that this will be adequately addressed when the Commission publishes its proposal for amending Directive 79/112/Eec on the labelling, presentation and advertising of foodstuffs to specify the conditions under which 'functional claims' (referred to as 'health claims' in the UK) and 'nutritional claims' may be made in July 2001. In the meantime, we have supported a UK voluntary system of prior assessment of claims, the Joint Health Claims Initiative, although we consider that legislation rather than voluntary codes are ultimately needed to tackle this area.

Notification (Article 10)

It is important that national authorities are aware of the types of products that are on the market. In order to effectively monitor the impact of food supplements on the diet, we agree that there should be a notification procedure which would require manufacturers or importers of food supplements to inform the competent authorities of Member States when food supplements are placed on the market. We do not however, believe that Member states should have the possibility of an exemption from this requirement. It is essential that such a system is mandatory.

This centrally held information would ensure that dietary surveys could more accurately take account of the implications of consumption of food supplements. It would also mean that information on these products and the ingredients they contain could be held centrally, enabling an effective system of product recall if any safety problems were to be identified. Another benefit would be the ability to quickly notify manufacturers should potential concerns about ingredients or products which need to be monitored arise. We agree that forwarding a copy of the label would be an appropriate way to do this, but more detailed requirements may also need to be stipulated in the Directive to ensure consistent and comprehensive collection of information across the EU. This may, for example, include information such as details of the origin of the ingredients. All products that are already on the market would also need to be included within this procedure within a reasonable time-frame.

Other issues

We are also concerned that there is currently no clear way of identifying adverse reactions that may arise as a result of consumption of ingredients used in supplements. Member States should therefore introduce a reporting scheme for adverse reactions to food supplements.

Consumers' Association
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