

# **Consumers Association Draft Policy Paper on Dietary Supplements 1996**

## **Comments from the Society for the Promotion of Nutritional Therapy**

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The Society for the Promotion of Nutritional Therapy (SPNT) recognises an important role for dietary supplements in health care and self-help, and we therefore have a particular interest in this area. The SPNT is an independent organisation, and has no interests in nor connections with the dietary supplements industry.

### **I Introduction**

#### **Denner Report**

This report was responsible for creating much concern over the safety and control of dietary supplements. Some members of the press gave the mistaken impression that the tryptophan/eosinophilia myalgia problem was due to inherent toxicity in tryptophan itself, and not to a new (and unsafe) cost-cutting manufacturing process introduced by one Japanese company. Accused of allowing the uncontrolled sale of dangerous substances the Government clearly felt the need to be seen to be taking action in this area. As a result its 1991 report "Dietary Supplements and Health Foods" (Denner Report) came down extremely heavily on the whole area, in a manner which is now known to be considerably exaggerated. In particular SPNT was concerned about the level of factual inaccuracy in the Denner Report. A detailed analysis of these inaccuracies may be found in our enclosed response to the 1991 European Commission Discussion Paper on Diet Integrators.

Approximately one third of the UK population are consumers of dietary supplements, and many considered the Denner Report and the subsequent proposals for European legislation by officials in other EU member states to be offensive and undemocratic. Considerable pressure was placed on the UK government to take a more consumer-friendly stance, and this resulted in assurances that the UK would lobby for the greatest possible freedom of choice in Europe, provided that safety was not compromised.

#### **Positive List System**

On the basis of the Denner Report it is perhaps not surprising that the CA advocated a Positive List System of prior approval of ingredients for dietary supplements. However with hindsight it is clear that a Positive List would not have prevented the eosinophilia myalgia syndrome problem, since this was due to product contamination, and not to an inherently unsafe product. Furthermore, a Positive List System could unduly prevent the consumer's access to products with a good safety record, simply because of protracted bureaucratic procedures.

#### **UK Position in a European Context**

The information given to CA by MAFF and DH is now out of date. After the Dutch government voted for a Positive List System and RDA-related upper dosage limits in 1992, there was a consumer outcry in Holland, and consumers successfully lobbied their government to introduce laws similar to those in the United Kingdom. As a result,

dietary supplements now fall under food law in Holland, and may be sold without restriction except for vitamins A and D, which have upper limits based on safety.

Dietary supplements are also as freely available in Sweden as they are in the UK. Danish and Irish consumers are currently lobbying their government for liberal legislation similar to that in the UK. A new international alliance known as “Consumers for Health Choice” is currently being formed to help consumers all over Europe fight for greater freedom of choice in this area.

### **Codex Alimentarius**

It is our understanding that the next Codex meeting to deal with dietary supplements will be held in October 1996, not 1997.

## **2 The Need for a Definition of Dietary Supplements**

SPNT’s definition of dietary supplements is as follows:

1. Preparations of vitamins, minerals, amino acids, essential fatty acids, enzymes, fibre and other factors which fulfil a useful or necessary physiological function and are found in food or synthesised within the body from food. These preparations may be chemically synthesised or natural extracts.
2. Concentrated plant- or animal-source preparations such as fish oils, yeast, probiotics, spirulina, kelp, royal jelly and plant or herb extracts, used to supplement the diet with the nutrients they contain, or for their health-giving properties.

## **3. Dietary supplements: Are consumers adequately protected?**

### **3.1 Safety**

CA argues that because dietary supplements come under food legislation they are not as safe as medicines. Yet the WHO figures quoted do not bear this out: 5,000 reports of possible adverse reactions to herbal medicines, as compared with 1.4 million adverse drug reactions. In the UK 42 cases over an 8-year period of probable links between dietary supplements and adverse reactions, (National Poisons Unit, 1994) as opposed to 10,000 hospital admissions a year as a result of adverse reactions to *prescribed* drugs (Social Audit, 1992). We understand that most of these UK adverse reactions to dietary supplements involved prescription iron tablets accidentally swallowed by children, illegal ethnic medicines containing mercury and lead, and novel herbs introduced from China, which should have been taken under the supervision of a qualified Chinese medical herbalist but were not.

Although consumer safety is of prime importance, it is important to view it in perspective in this particular area as in any other. Assumptions that incidents may be under-reported are not the same as actual facts and figures.

It is our understanding that food law requires any product sold under its jurisdiction to be as safe as food itself at levels of likely intake. This seems to us to be the greatest possible legal safeguard against potentially toxic products. Furthermore novel substances likely to be consumed in significant quantities are subject to safety evaluation by the Advisory Committee on Novel Foods and Processes, which would

preclude the (legal) sale of any substances which do not have a significant history of human consumption if the safety data are not considered satisfactory. Any safety problems which might occur would therefore be problems of law enforcement rather than due to a lack of suitable legislation. ACNFP evaluation is not voluntary, as the CA suggests, but compulsory, at the ACNFP's discretion.

The point also needs to be made that pre-marketing toxicological tests are hardly appropriate for products such as vitamins, minerals and popular western herbs which already have a long history of safe use by millions of consumers. As such, comparisons with medicines licensing requirements seem hardly relevant.

### **Melatonin**

The fact that melatonin has been found on sale since its withdrawal does not necessarily support the case for a notification/registration scheme, although this could be useful in other respects. Suppliers of dietary supplement products are already known to the MCA, and it would probably make little difference whether or not they "registered" a particular product. The fact is that once consumer demand arises for a product, somebody will supply it. If the legislation is not sufficiently liberal, suppliers will go underground, and this is when safety becomes truly compromised.

#### **3.1.4 Surveillance**

To our knowledge, MAFF appears to carry out regular surveillance studies on various aspects of food, including a survey into inorganic contaminants in health foods, and the National Poisons Unit investigation into adverse reactions from dietary supplements, which was Government-sponsored. This is hardly ad hoc. Would the very low incidence of public health problems arising from the use of dietary supplements justify a heavier surveillance programme?

It is a credit to the industry that the National Poisons Unit were able to identify only 42 cases of adverse reactions probably linked to dietary supplements over eight years. Regarding the cases where children accidentally ingested vitamin preparations, iron supplements prescribed by doctors are a known hazard since these are often in the form of very high doses of ferrous sulphate - a known gastrointestinal irritant frequently prescribed on the NHS for its cheapness.

### **Voluntary bans**

The voluntary withdrawal of a product may be demanded for a number of reasons, for instance:

- a) A product has been found to be contaminated
- b) A product has been found to cause previously unrecognised adverse reactions
- c) Political pressure by anti-complementary medicine campaigners as part of their PR agenda.

Where no contamination incident has occurred, and no adverse reactions have been reported, it is not unreasonable of suppliers to ignore requests for voluntary withdrawal. In particular we are referring to the case of comfrey. Our paper on this subject was sent to the CA in 1994, and we now enclose a further copy, with a request that the CA help us to follow up this affront to consumer rights.

### **3.2 Labelling**

## **Claims**

SPNT finds the area of claims to be grey and difficult. On the one hand science seems to take much too long to reach consensus on a particular issue, which seems to be the only basis for “acceptance” of a particular claim. This does a great disservice to consumers, who, for instance, should have been told in 1981 about the folic acid deficiency/neural tube defect connection, when it was first known, rather than in 1991. This is not a question of “degrees of proof”. Folic acid is not a medicine, it is a natural component of food. It was undoubtedly not a health hazard to ensure that an expectant mother would have an adequate intake of this essential vitamin, yet scientists treated it as if it was, demanding incontrovertible evidence and trial after trial. What is more important? Finding intricate trial designs to satisfy scientific dogma, or erring on the side of caution to prevent human tragedy and death?

Both consumers in the natural medicine movement, and the health food industry, feel very strongly about this state of affairs. Consumers want to know what scientists at the leading edge in this area are discovering which might help them, and manufacturers want to tell them in order to sell their products. As rightly pointed out by the CA, the “complementary” aspect of dietary supplements should be acknowledged. However this is not about a “lower” degree of proof, it is about not withholding information from consumers which would do them no harm and which they have a right to know.

### **Claims made in newspapers and magazines (editorial copy)**

The relevance of the CA’s reference to the origin of information in these articles is not entirely clear. SPNT regularly helps the press with articles on dietary supplements. We give information based on clinical trials and other research, as well as on the knowledge and experience of our members. We would suggest that journalistic codes of practice do not allow the mere regurgitation of commercial propaganda, and it would be a disservice to journalists to suggest that they do.

### **Enforcement**

The CA’s statement that test cases relating to illegal medicinal claims have not been taken to the courts by enforcement agencies as recommended by the 1991 Denner Report is not correct. The CA itself reports the details of the Tobyward case. Larkhall Natural Health was also taken to court by an enforcement agency, and the CA may be interested in the enclosed article from SPNT’s journal *Nutritional Therapy Today*, which describes the outcome of the case.

#### **3.2.2 Labelling: Clarity of information**

It is agreed that dosage instructions, units and formulations may be confusing to the consumer. The use of International Units is due to the fact that many products in the higher dosage range are American, and the IU has remained the standard for fat-soluble vitamins in both the US and UK because this is what consumers are accustomed to.

We do not understand the significance of the CA’s comment that some products have suggested daily doses of more than 100% of the RDA for a nutrient. The RDA is defined as the standard for groups of healthy people who wish to prevent nutritional deficiencies. Individuals who take higher range products usually do so because they believe that their health has been compromised by a long-term failure of normal dietary levels to meet their own personal needs. It is historically well known that a long-term

nutritional insufficiency may lead to greatly increased requirements for some nutrients. In addition, individuals with chronic irritable bowel syndrome and other conditions which may involve the malabsorption of nutrients from the diet have derived considerable health benefits from increasing their intake to several times the RDA.

### **3.2.3 Inadequate information**

A great deal of information is available on the action of dietary supplements. SPNT would be glad to produce a small reference guide and a suitable reading list for health professionals if there is enough demand for it. We would like to suggest that raising awareness about the relevance of checking patients' use of dietary supplements is likely to be counter-productive in the present-day medical climate of insisting that these products are not necessary and frowning on those patients who use them. In these circumstances patients are very unlikely to invite their doctor's disapproval by admitting that they use dietary supplements.

## **3.3 Quality assurance**

### **3.3.1 Quality concerns**

We support all the points which the CA raises in section 3.3.1.

### **3.3.2 Quality controls**

We agree that specifications for each type of product should be agreed and made compulsory, although it should be acknowledged that many companies already have very good quality control procedures and batch data recording. Any such specifications should be determined together with the industry since as the CA rightly points out, natural products are subject to natural variations in composition which make it impossible to treat them like pharmaceuticals and artificial food additives.

## **4. Consumers Association Recommendations**

There are many well-considered and helpful recommendations in this section, but our first general comment would be that this is not an area where the UK Government is likely to take action locally since it considers it to be a matter for the federal jurisdiction of the European Union. We would like to suggest that the CA accordingly lobby the European Consumers Association, BEUC, (which we understand has very different views) on behalf of British consumers, since only the input of pan-European organisations will be considered by the European Commission.

### **4.1.1 Specific requirements for dietary supplements**

#### **a) Position in regulatory framework**

With the advent of a European directive on dietary supplements, it is no longer necessary to decide whether they are "food or medicine". SPNT will press for them to have their own legal category as dietary supplements. It is agreed that dietary supplements should not be subjected to pharmaceutical regulatory considerations. We would like to correct the CA's statement that herbal remedies are controlled as medicines but with less rigorous evaluation procedures. This used to be the case until "soft licences", also known as "licences by right" were abolished by the European Union in 1990. Manufacturers may apply for product licences if they wish to make medicinal claims, but they must follow the full pharmaceutical procedures. If they are

prepared to forego claims, and provided that the products undergo minimal processing, (are not “industrially produced”) no licence is required and they remain subject to food safety legislation. (Technically this exemption from licensing is illegal under Directive 65/65/EEC, which had no intention of allowing any exemption for herbal medicines. It was contrived at the end of 1994 by the UK Government under great public pressure, to allow the survival of herbal medicines in this country).

With reference to the CA’s statement that the place of some supplements in food law can at times seem incongruous when they include things like herbal highs and natural ecstasy, we would like to remind the CA that alcoholic drinks and coffee are naturally classed as foods, yet are often consumed for their relaxing or stimulating effects. If the active ingredients were isolated and inserted into capsules, this would make them medicines (pharmaceuticals) but putting a “whole food” into a capsule does not make it a medicine.

#### **b) Mandatory notification system**

This seems reasonable and the central holding of information in ingredients and products could indeed, as suggested, be a basis for an Independent Consumer Information Service. We also agree that different approaches are needed for different types of products. The decision tree also sounds reasonable, and we suggest that the CA may wish to put this idea to BEUC, for proposal to the EU Commission.

#### **c) Specific labelling requirements**

These suggestions seem very reasonable.

#### **d) Quality controls**

These suggestions seem very reasonable.

### **4.1.2 Claims**

These suggestions seem very reasonable, although we would reiterate the point that a claim which has not received medical consensus or official backing is not necessarily based on a “lower” degree of proof.

### **4.1.3 Setting upper limits**

We would agree that upper limits should not be set for products not generally known to be toxic. Since the industry already self-regulates upper limits for products which could become toxic if consumed in excess, we do not envisage any objections to making such upper limits compulsory.

We do not quite understand the CA’s comment that there is a need for more consumer education in explaining the concept of RDAs. Can we have more details?

### **4.1.4 Independent consumer information service**

This sounds like a very reasonable idea.