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Vitamin B6

As has been widely reported in the UK media, the Government are trying to introduce restrictions on the free sale of vitamin B6, an important nutrient that many people - especially women during their menstrual cycle - find invaluable, but only at doses up to ten times higher than that which Jeff Rooker MP, the Minister responsible, wishes to introduce.

After a great deal of adverse public reaction Mr Rooker asked the Agriculture Committee to produce a report on this issue. They have now reported and have recommended that Mr Rooker drop his "scientifically unjustifiable" proposal. The whole of the nutritional supplements industry see this as a major victory - a Government body has confirmed what the industry has been trying to make Mr Rooker see.

However, we have only won a battle, not the war. Mr Rooker has yet to make a decision and it is not certain that he will abandon his plans. Also, the EC is once again looking to restrict the free sale of nutritional supplements in the UK to bring us into line with our European partners. None of this can be good news for the consumer who's freedom of choice is again under threat.

Make sure that your MP and your MEP are aware of your opposition to any restrictions on the free sale of nutritional supplements.

Select Committee on Agriculture Fifth Report

VITAMIN B6

INTRODUCTION

In 1995 the Department of Health's Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) was asked by Ministers to advise on the toxicity of vitamin B6, following concerns expressed by the Consumers' Association about high levels of vitamins and minerals, especially vitamin B6, in dietary supplements. COT came to the conclusion that the level of vitamin B6 in dietary supplements sold under food law should be limited to 10 milligrammes (mg) per daily dose[1]. COT's advice was considered by MAFF's Food Advisory Committee (FAC), which explored with the health food industry the possibility of introducing such a limit on a voluntary basis. The industry, seeing no scientific justification for the proposed limit, was unwilling to do this. Consultations undertaken by the FAC with the industry and consumers showed a number of concerns about COT's advice, and COT therefore reviewed the evidence a second time, standing by its original advice in a statement issued in June 1997[2]. COT's advice followed two separate paths: in respect of medicines containing vitamin B6 it was considered by the Committee on Safety of Medicines (CSM) and the Medicines Commission, and in respect of food supplements containing vitamin B6 by the FAC.

The FAC issued a statement in June 1997 endorsing COT's advice and recommending that:

dietary supplements should not provide a daily dose of vitamin B6 above 10mg;

all dietary supplements containing vitamin B6 should carry a warning label about the risk of harmful effects from intakes of above 10 mg a day.

The FAC said that these requirements should be made the subject of legislation if necessary[3]. The Government accepted these recommendations[4], and has drafted legislation under the Food Safety Act 1990 to implement the necessary controls. The draft Vitamin B6 in Food Regulations were issued for consultation on 2 April 1998, with a deadline of 26 June 1998 for comments. Separate and analogous legislation relating to the sale and supply of medicinal products containing vitamin B6 is intended to come into effect at the same time as the legislation on vitamin B6 food supplements. Should these legislative changes come into effect, the position will be as follows:

food supplements and medicines containing 10 mg or less of vitamin B6 per daily dose will remain on general sale;

medicines containing between 11 and 49 mg of vitamin B6 per daily dose will be obtainable over the counter from pharmacies;

medicines containing 50 mg and over of vitamin B6 per daily dose will be obtainable on a doctor's prescription[5].

In other words, all dietary supplements containing more than 10 mg of vitamin B6 per daily dose will be banned, with higher-dose products requiring marketing authorisations as medicines, under the Medicines Act 1968, before they can be sold or supplied. We heard evidence that the effect of the proposed controls would be to limit consumers to purchases of products containing 10 mg or less of vitamin B6. This is because the cost of establishing the efficacy of vitamin B6 as a medicinal product for sale at dosages of 11 mg per day and above would be so

great as to make the proposition uneconomic[6]. It should be noted, however, that it would still be impossible to prevent people achieving an intake of vitamin B6 of up to 200 mg/day, or even higher, simply by taking many times the 10 mg daily dosage remaining on free sale.

The Government's proposals to restrict the levels of vitamin B6 in food supplements on general sale have provoked sustained and strong opposition from health food manufacturers and retailers and individual consumers of food supplements. Some scientific experts and medical practitioners have also publicly opposed the restrictions. Many thousands of protest letters have been received by Ministers and Members of Parliament.

Against this background, we decided to inquire into the issue, and published terms of reference by press release on 10 March 1998, calling for evidence on:

the levels of public use of dietary supplements in the UK containing vitamin B6, the degree of risk posed to human health by high levels of intake of vitamin B6, and the state of current scientific understanding of the toxic effects of vitamin B6;

the existing and future role of the Government, its expert advisory committees and Executive Agencies (including the proposed Food Standards Agency), and the Expert Group on Vitamins and Minerals in determining the degree of health risk to individuals from high levels of intake of vitamin B6 and taking any necessary action;

developments in EU policy on the addition of vitamins and minerals to food and food supplements, in relation to vitamin B6[7].

We received several hundred memoranda and letters, and held two oral evidence sessions on 19 May. In the morning we heard from Consumers for Health Choice and the Health Food Manufacturers' Association, two organisations which have been instrumental in mobilizing opposition to the Government's proposals, together with individual experts who felt, for a variety of reasons, that COT's advice was scientifically unsound. In the afternoon we took evidence from the Chairman of COT, Professor H F Woods, and then from the MAFF Minister of State, Mr Jeff Rooker MP. This oral evidence, and the more substantive items of written evidence, are published together with this Report. The rest of the written evidence which we received has been placed in the House of Lords Record Office where it may be consulted by the public.

The controversy surrounding COT's advice, and the Government's decision to act on the basis of that advice, has generated a host of insinuations and allegations from people on both sides of the debate designed to discredit the case of their opponents. We have heard allegations, for example, that:

COT lacks the scientific expertise to deal with a nutrient such as vitamin B6[8];

it is wrong that the safety assessment of a nutrient should be undertaken by a committee most of whose members have connections with the pharmaceutical industry[9];

the health food industry has been obstructive and unco-operative in discussions about vitamin B6[10];

supporters of the health food industry have made unsubstantiated claims for the efficacy of high-dose vitamin B6 supplements in treating various conditions[11].

Though we have taken note of these allegations, for the purposes of reaching conclusions in this Report we have disregarded them because they are peripheral to the central argument about the validity of COT's advice and the scientific evidence on which it is founded. We have adopted a similar approach to evidence which we received about the potential economic effects on the health food industry of the Government's proposed restrictions. This is not because these are not issues of legitimate public concern and debate. It is because the central issue is whether or not the potential dangers of vitamin B6 are so great as to legitimise severe restrictions on the consumer's right to consume vitamin B6.

According to MAFF, the European Commission is concerned at the trade difficulties caused by differing national controls on dietary supplements throughout the European Union, and has recently consulted for the second time on the possible harmonisation of controls. No legislative proposals are imminent, however, and there is no guarantee that proposals will be forthcoming[12]. Apart from the Netherlands, which has no maximum limit on vitamin B6 dosage in dietary supplements, all other EU member states for which information is available restrict daily dosages to between 2 and 6 mg, some simply basing their limit on a low multiple of the Recommended Daily Amount (RDA)[13]. Mr Rooker emphatically stated that the UK would not adopt such a policy: "We will only take action based on the risk and the evidence of the particular product"[14].

VITAMIN B6

Vitamin B6 is the generic term for a group of six closely-related chemicals: pyridoxine, pyridoxal, pyridoxamine and their associated phosphates. Like other vitamins, vitamin B6 performs essential biochemical functions in the human body. It is involved in the metabolism of proteins and amino acids (the constituents of proteins), and is found in a wide range of foods contained in a normal diet, including meat, fish, potatoes, cereals, milk, bananas and beers. The Committee on Medical Aspects of Food and Nutrition Policy (COMA) has set a Reference Nutrient Intake (RNI) for vitamin B6 of 1.4 mg/day for adult men and 1.2 mg/day for adult women. The Reference Nutrient Intake, which is analogous to the RDA, represents the amount of a nutrient which is enough to meet the needs of nearly all of a given group. In the case of vitamin B6, because of its role in amino acid metabolism, the RNI is related to protein intake: it represents 15 microgrammes of vitamin B6 per gramme of protein per day. The symptoms of vitamin B6 deficiency include anaemia, muscle cramps and convulsions, though this is rare in the UK where average intakes of vitamin B6 from food are well above the RNI[15]. These basic facts about vitamin B6 are not in dispute, although some people believe that certain individuals have a somewhat higher daily requirement for vitamin B6[16].

There is also little dispute that, in very high doses taken over a prolonged period, vitamin B6 has toxic effects which produce a condition known as peripheral sensory neuropathy, affecting the nerves which transmit messages from receptors to the central nervous system. Typical symptoms are tingling (pins and needles), clumsiness and numbness. In a seminal study in 1983, cases of severe sensory neuropathy were identified in seven individuals who had taken between 2,000 and 6,000 mg (i.e. 2 to 6 g) of vitamin B6 daily over periods ranging from 2 to 40 months[17]. In general, it is agreed that, in COT's words, studies involving high doses demonstrated that: "the clinical signs of toxicity were reversible once ingestion of high doses of vitamin B6 had ceased. However, in

some instances where the dose of this vitamin was especially high, signs of damage remained"[18].

At daily dosages of vitamin B6 below 500 mg, the evidence of adverse effects is more equivocal. In one study, 70 patients with diabetic neuropathy or carpal tunnel syndrome were treated with 100 to 150 mg of pyridoxine per day for periods of up to 5 years, with no neurological problems emerging[19]. Taking this and other corroborative research into account, the US's Institute of Medicine has concluded that 500 mg/day represents the lowest-observed-adverse-effect-level (LOAEL) for vitamin B6 intake[20]. This report also arrives at a no-observed-adverse-effect-level (NOAEL) of 200 mg/day. It dismisses the 1987 study by Dalton and Dalton, which reported peripheral sensory neuropathy in patients consuming between 50 and 500 mg of pyroxidine per day, in the following terms: "the weaknesses of this study and the inconsistency of the results with the weight of evidence pertaining to the safety of higher doses of pyridoxine rule out the use of these data to base a [Tolerable Upper Intake Level]"[21].

COT effectively bases its case on the Dalton and Dalton study. In written evidence, Professor Woods stated:

"although all relevant data were assessed, it is the nature of risk assessment that the review of the totality of data leads to the use of one or two critical studies for the determination of safe doses. In humans, the lowest reported adverse effect level was 50 mg/day. This was reported by Dalton and Dalton (1987) who investigated women attending a clinic for premenstrual tension"[22].

In its 1995 consideration of the toxicity of vitamin B6, COT divided the 50 mg/day LOAEL by safety factor of 5 to set an upper limit of 10 mg/day of vitamin B6[23]. This advice was reiterated in 1997. In its first consideration, COT agreed that "it was not necessary to consider the animal toxicity data on vitamin B6" because "adequate human data were available"[24]. In its 1997 statement, COT explicitly calls in aid animal toxicity data from a 1978 study of beagle dogs[25] to support its recommendation of a 10 mg/day upper safe level in humans[26]. Notwithstanding the greater significance attached by COT to the Phillips study of dogs in its second consideration of the toxicity of vitamin B6, it is clearly the 1987 Dalton and Dalton study which is of primary importance in assessing the validity of COT's advice.

The Dalton and Dalton study involved 172 women attending a private practice specialising in the treatment of premenstrual tension who had been taking vitamin B6 and who, on examination, were found to have raised blood serum B6 levels. Of the 172 women, 103 complained of neurological symptoms, including paraesthesia (ie abnormal sensations in parts of the body), muscle weakness and numbness. The remaining 69 women, who did not report neurological symptoms, comprised a control group. The main difference between the two groups, according to Dalton and Dalton, was that the "neurotoxic" group had been taking vitamin B6 over a longer period (an average of 2.9 years as opposed to 1.6 years for the control group). Three months after stopping B6, 55 per cent of the neurotoxic group reported "partial or complete recovery" of neurological symptoms; after 6 months all reported complete recovery. Women who inadvertently continued to take B6, or restarted taking it, reported continuing or re-emerging symptoms. Dalton and Dalton state that:

"The duration of drug exposure was greater in this series than in previous reports and appears to have been a significant factor in the development of neurological

symptoms,If duration is an important factor in the development of neurological symptoms it would explain the absence of side effects in reports of double blind controlled trials lasting only a few months"[27].

COT use a similar argument to explain the apparent lack of corroboration of Dalton and Dalton's findings in other research: "We consider that the small number of individuals involved and/or the short duration of administration may explain the absence of signs of sensory peripheral neuropathy in some studies"[28].

COT concedes that the Dalton and Dalton study has "some methodological deficiencies"[29] but argues that the symptoms described are consistent with peripheral sensory neuropathy and with the reported symptoms of patients in other studies involving higher doses of vitamin B6. Others claim that the methodological deficiencies of the Dalton and Dalton study wholly invalidate its findings. Professor André McLean, Professor of Toxicology at the University College London Medical School, said that although Dr Katharina Dalton was "a most eminent gynaecologist and an inspiring woman", the underlying reasoning and the method employed in her study were "quite wrong"[30].

A long list of criticisms of the Dalton and Dalton study was provided by the Vitamin B6 Scientific Task Group. These included:

the lack of an untreated control group;

a methodology including the asking of leading questions;

a retrospective methodology, which therefore failed to take account of possible confounding factors and relied on the recall of participants about their past vitamin B6 intake;

rechallenges with vitamin B6 were not conducted in a blinded fashion;

the symptoms described could have been due to other factors than vitamin B6 - induced neuropathy, including premenstrual tension itself[31].

Professor Woods has made some response to a number of the criticisms levelled at the Dalton and Dalton study, and therefore, by implication, at COT's advice. In written evidence to us he stated that "The safety of long-term intake of low doses of vitamin B6 has not been adequately studied", and that "The data of the Dalton and Dalton study are weak but consistent with an inverse relationship between dose, duration and time to adverse effects"[32]. He claimed that it would have been "remiss" of COT to ignore the Dalton and Dalton study[33]. In relation to other criticisms, he denied that the lack of an untreated control group negated Dalton and Dalton's findings[34]; stated that toxicological studies were commonly retrospective[35]; denied that Dalton and Dalton had used leading questions[36]; and said that he did not think that the symptoms described by Dalton and Dalton could be attributed to factors other than vitamin B6 neuropathy[37].

Opponents of the Government's proposed 10 mg daily limit have claimed that Dalton and Dalton's findings have in important respects been contradicted by subsequent research and by a lack of evidence of cases of vitamin B6-related peripheral sensory neuropathy in the general population in the years following the publication of their study. We have heard evidence that up to 3 million people in the UK alone regularly take vitamin B6 in dietary supplements, many at

continuous dosages exceeding 50 mg/day[38]. It is argued that, had Dalton and Dalton been correct, at the very least many thousands of individual cases of peripheral sensory neuropathy would have occurred in the eleven years since the study was published[39]. Professor Woods has stated that nothing seen by COT would support a statement that no significant hazards had emerged from vitamin B6 consumption at levels up to 200 mg/day[40]. He argued that there was no surveillance system for the effects of vitamin B6 in dietary supplements which would allow such data to emerge[41].

Just as opponents of COT's advice have sought to discredit the Dalton and Dalton study, so COT and MAFF have sought to discredit research which has contradicted the Dalton and Dalton findings. A survey in 1997 carried out in the USA by Alan Gaby showed that "the symptoms Dalton attributed to vitamin B6 toxicity are extremely common among women with PMS or depression, regardless of whether or not they have been taking vitamin B6"[42]. Professor Woods did not consider that the Gaby study altered COT's view that there was no "satisfactory long-term epidemiological study" of vitamin B6 toxicity. At a symposium held at the Royal College of Physicians in September 1997 Linda Ferguson of Taylor Nelson AGB Healthcare presented the findings of a controlled retrospective study of long-term vitamin B6 users which showed that the proportion of people reporting tingling fingers was about the same for vitamin B6 consumers (7%) as for non-consumers (8%), and there was also no appreciable difference between consumers of differing dosages of vitamin B6 up to 200 mg/day[43]. Professor Woods stated that this study "can be criticised as an epidemiological study" and had appeared in a "non-peer reviewed publication"[44]. Finally, COT remained unmoved by the US National Academy of Sciences' Institute of Medicine's recommendation of a Tolerable Upper Intake Level of 100 mg/day, arguing that:

the safety factor of 2 used by the NAS in deriving a Tolerable Upper Intake Level of 100 mg/day from a NOAEL of 200 mg/day was inappropriately low; and

although Dalton and Dalton had weaknesses, there were also weaknesses in reports used by the NAS in determining the NOAEL[45].

The 1978 study of beagle dogs by Phillips et al is cited by COT as establishing the lowest observed adverse effect level of vitamin B6 in animals of 50 mg per kg of bodyweight per day. COT state that: "With a safety factor of 300 (10 for the use of animal data, 10 for inter-individual human variation, 3 for the use of a lowest observed adverse effect level) and assuming that an individual weighs 60 kg, extrapolation from the lowest observed adverse effect level in dogs... would give a maximum daily safe dose for humans of 10 mg"[46]. Critics of COT's conclusions do not dispute the rigour of the Phillips study, but question the size of the safety factor used by COT to translate the animal data to humans. Professor McLean described COT's methodology as "most unusual and not accepted procedure"[47], and the Vitamin B6 Scientific Task Group claimed that "the 300-fold safety factor was designed to be used in conjunction with chemicals that are foreign to the body such as pesticides, drugs, and food additives. It is quite absurd to apply this factor to an essential nutrient"[48]. Professor Woods, on the other hand, maintained that the use of safety factors for xenobiotics (i.e. substances foreign to the body) but not for nutrients was an unscientific distinction which was difficult to justify provided that the resulting recommended intake was nutritionally adequate[49].

CONCLUSIONS

The investigation of the toxicity of vitamin B6 began in the context of wider concerns about the dietary supplement industry. The policy eventually adopted on controlling vitamin B6 dosages will inevitably form a precedent for a much wider range of products. It is vital that the Government's decisions are based on a clear philosophy of how and why it should intervene in this area together with a proper understanding of the toxicity of vitamin B6 and any risks involved, balanced with a recognition of the consumer's absolute freedom to consume such products when the risks are negligible or non-existent. There is often a tension between safety and liberty.

There is a case for the proposition that the Government should not intervene at all in this matter, apart from publishing its view of the potential risks, leaving the issue to the informed decisions of individual consumers. The fact of the toxicity of vitamin B6 in excess is probably not appreciated by many consumers but then nor are the effects of the consumption to excess of other foodstuffs. But the Government, after all, does not seek to regulate or limit consumption of toxic substances occurring in food and drink, such as caffeine, alcohol or salt. Without a clear policy framework it is hard to judge how to treat dietary supplements, which are, by definition, not constituents of a normal diet composed of natural foodstuffs. There is no evidence of any urgent health risk from B6 consumption. **We would therefore urge that the Expert Group on Vitamins and Minerals be asked to produce recommendations for a framework for deciding whether regulation of dietary supplements is necessary at all, or whether consumer advice is sufficient.**

We consider that the arguments over the 300-fold safety factor applied by COT to the Phillips study are inconclusive, and that COT's case therefore stands or falls on the validity of the findings of Dalton and Dalton. **It is our view that the doubts concerning the 1987 Dalton and Dalton study are so serious that it is scientifically unjustifiable to use them as the basis for establishing a lowest observed adverse effect level in relation to vitamin B6 intake.** We base this conclusion principally on the following points:

the methodological flaws in the Dalton and Dalton study are such as to render it unreliable in drawing firm conclusions which could form the basis of regulatory action. We note that Dr Katharina Dalton herself has stated that "the only reason our 1987 paper was written was to alert our medical colleagues of the possibility of vitamin B6 overdose neuropathy"[50]. We also note that COT did not approach Dr Dalton for clarification of the methodology used in the study because it was not the policy of the committee to do so[51];

no other piece of scientific evidence has been adduced to illustrate that vitamin B6 has toxic effects in adult humans at levels of intake below 500 mg/day[52], and, indeed, a number of studies have indicated that intakes of up to 200 mg/day, for periods longer than those reported by the patients in the Dalton and Dalton study, have produced no evidence of neurotoxicity whether by subjective or objective neurological assessment[53];

we do not agree with Professor Woods' view that there is no evidence available to support the statement that no significant hazards have emerged from the use of vitamin B6 by millions of people at levels above 50 mg/day. We find it worthy of note that, in the eleven years since the Dalton and Dalton study was published, and particularly in the last twelve months when there has been so much publicity about the possible toxicity of vitamin B6, not a single case of peripheral sensory

neuropathy shown to be related to vitamin B6 has come to light. The probability that this could have occurred, had Dalton and Dalton been correct, is, in our view, infinitesimal.

The scientific evidence pointing towards a NOAEL of 200 mg/day and a LOAEL of 500 mg/day is not perfect, but it is a good deal stronger and more consistent than the evidence on which COT has based its advice. We have been dismayed by the stubbornness and defensiveness which COT has displayed following the serious scientific challenges which have been made to its findings. Although Professor Woods responded fully to our questions when he gave evidence to us, COT has been curt almost to the point of rudeness in responding to articulate and well-argued criticisms from organisations such as the Vitamin B6 Scientific Task Group[54]. When it has been coaxed out of its defensiveness to respond to specific questions, COT has tied itself up in casuistical knots in its efforts to strengthen its own case and discredit its opponents, particularly in claiming that the absence of evidence of vitamin B6 toxicity from general clinical experience does not affect the question at issue.

In oral evidence, Mr Rooker referred to a paper prepared by the COT secretariat for that Committee in its consideration of vitamin B6 toxicity[55]. That paper, which provides a comprehensive summary of the research base and other documentation relating to vitamin B6, was subsequently supplied to us on a commercial-in-confidence basis, and we have taken it into account in reaching our conclusions. We make no criticism of the thoroughness with which the COT secretariat went about the task of collating and summarizing published research on vitamin B6 toxicity for the Committee, but consider that the conclusions drawn by COT from this evidence are palpably wrong. The crucial error made by COT was not to establish clear criteria for evaluating the significance of different research data. In other words, it failed to establish criteria for distinguishing between "good" and "bad" science. These criteria would include factors such as study size (i.e. number of subjects) and study design (i.e. whether the study is randomised, controlled and blinded), which are precisely those at issue in judging whether the Dalton and Dalton study or conflicting research is more reliable. The error made by the FAC was not to place any B6 risk in a context of other unregulated food risks or to advise that a clearer rationale for intervention in this food sector was required before tackling one product in isolation.

It follows from our assessment of COT's advice on the toxicity of vitamin B6 that we do not feel that the Government would be correct to follow that advice. **In relation to dietary supplements, the Government should withdraw its proposed draft regulations to limit the level of vitamin B6 per daily dose to 10 mg.**

We consider that the scientific evidence we have heard tended to support the US's National Academy of Sciences report that the weight of evidence on vitamin B6 points towards an LOAEL of 500 mg/day, and an NOAEL of 200 mg/day. Inevitably there is a degree of arbitrariness in determining any safety factor which should be applied to these levels, but we concur with the NAS, given the extent of evidence available from scientific research and wider experience of the use of vitamin B6 dietary supplements in society, that a factor of 2 applied to the NOAEL is appropriate in the light of current knowledge. We note that the resultant upper safe limit of 100 mg/day represents the same safety factor of 5 in relation to the NAS's 500 mg/day LOAEL as was applied by COT to their LOAEL of 50 mg/day. Although the establishment of food safety controls can never be a bargaining process, we also note that supplement consumers and the health food

industry would consider a 100 mg/day limit to be acceptable[56]. **We recommend that the Government should seek to introduce a voluntary limit, pending the report of the Expert Group on Vitamins and Minerals, with the industry, of 100 mg per daily dose. All dietary supplements containing vitamin B6 should display a clear warning that intakes above this level may carry health risks, particularly when taken over an extended period. No legislation should be considered until the Expert Group has reported.**

Our conclusions should not be taken as endorsement of all the practices of that industry, nor as an absence of concern on our part about the position of dietary supplements under food law. We are concerned, for example, that certain dietary supplements may be promoted as beneficial to general health when no proof of efficacy exists. **The evidence on the efficacy of vitamin B6 is inconclusive, and many consumers may experience a placebo effect rather than any actual health benefit. Nevertheless, such people are perfectly entitled to make such choices for themselves, so long as they are provided with sufficient information to avoid the potential health risks of high levels of intake, and so long as dietary supplements do not make medicinal claims. These issues should have no bearing on the toxicological assessments of the safety of vitamins and minerals, whether in the case of vitamin B6 or in the case of the wider review of dietary supplements to be undertaken over the next 18 months or so by the new Expert Group on Vitamins and Minerals. We trust that the unfortunate row which has taken place over vitamin B6 will act as a constant reminder to that group of the need to base its recommendations and advice on sound and substantiated scientific knowledge, and adherence to a clear definition of the role and limits of Government intervention in this area as it recommends and Parliament agrees.**

The membership of the Expert Group is being drawn from the existing membership of COT, the FAC, COMA and the CSM, with provision for the industry, complementary medicine and consumer interests to nominate observers[57]. **We recommend that, to assist in avoiding any repeat of the vitamin B6 controversy, consumer and industry interests should be able to nominate one or two independent scientific experts in nutrition and toxicology for appointment as full members of the Group.**