

Debates of the European Parliament
SITTING OF TUESDAY, 13 FEBRUARY 2001
Food supplements

President. – The next item is the report (A5-0025/2001) by Mrs Müller, on behalf of the Committee on the Environment, Public Health and Consumer Policy, on the proposal for a European Parliament and Council directive on the approximation of the laws of the Member States relating to food supplements [COM(2000) 222 – C5-0234/2000 – 2000/0080(COD)].

Krarp (EDD). – *(DA)* Mr President, I would ask permission to speak regarding the Rules of Procedure. The proposal for a directive which is being debated ought to be rejected pursuant to Rule 143 of the Rules of Procedure which specifies that, at the beginning of the debate on a specific item on the agenda, its inadmissibility may formally be moved. I am making such a proposal, and the reason why I think the proposal for a directive ought to be considered inadmissible is that it is, in my view, contrary to the Treaty. It is contrary to Article 152 of the Treaty, relating to public health, and there is no doubt that this proposal for a directive is entirely motivated by a concern to protect public health. Article 152 specifies that incentive measures may be taken, but excluding any harmonisation of the laws and regulations of the Member States. The proposal in question provides for a particularly intensive harmonisation of the laws and regulations of the Member States and is therefore contrary to Article 152. I searched the Commission's proposal and Mrs Müller's report in vain for a discussion of this question of where authority lies. I think the debate should be considered inadmissible until it has been clarified that the problem of authority is in order, and I would request that a vote be taken.

President. – Does anyone wish to speak for the motion?

Frahm (GUE/NGL). – *(DA)* Mr President, I should like to speak in favour of the proposal, for it must stand to reason that Parliament has to keep to the basis of the Treaty. If there is the slightest suspicion that Parliament is not complying with the basis of the Treaty, then negotiations should be suspended until the matter has been clarified.

President. – Does anyone wish to speak against the motion to consider the report unacceptable?

Müller, Emilia Franziska (PPE-DE), rapporteur. – *(DE)* Mr President, Commissioner, ladies and gentlemen, when the Commission presents a proposal for a directive to us, I naturally assume that it is legally in order. That is one of the reasons why I was appointed rapporteur. I believe that there can be no question of our not voting on this directive.

President. – We have heard one speech for the motion and one against.
For the sake of clarity: if you vote for this motion, you consider this report unacceptable. If you vote against the motion, you consider it acceptable and we will therefore proceed to the debate.

Whitehead (PSE). – Mr President, with an issue of this importance it is necessary that we indicate to those still on the premises that a vote is taking place. It is very unusual for a vote to be called in this way with about 12 Members in the House. Many others outside are completely unaware – as are those of us who are here who happen to wish to speak in this debate – that this issue is being considered.

If there is a way in which you can alert those on the premises of Parliament to that fact that there is a vote and adjourn until they are present, maybe we will get a more representative result.

President. – Mrs Whitehead, I do not have the means to inform those who are elsewhere in the building. If a Member is interested he or she is in the Chamber.

Oomen-Ruijten (PPE-DE). – *(NL)* Mr President, it is highly irregular that people are behaving so undemocratically as to continue to make comments during the vote, and secondly, we have now voted. It is for you to announce the result of the vote, and then we will simply carry

on with the debate. I believe that is the only way, and the best way, to deal with a topic that we have already spoken about on so many occasions before.

[motion rejected by EV (15 votes for, 16 against, 0 abstentions)]

Müller, Emilia Franziska (PPE-DE), rapporteur. – (DE) Mr President, Commissioner, ladies and gentlemen, when we talk about food supplements, we chiefly mean vitamins, minerals, fatty acids, amino acids and certain other substances. So we are not talking about enriched food, nor about food additives. We are talking about concentrated sources of nutrients supplied either individually or combined in the form of capsules, tablets, powder or similar presentations.

Vitamins and minerals are involved in many biochemical processes in the human body. An optimal supply of these substances is vital for human health and performance. I regard it as being very positive that we can enrich our daily intake of food with vitamins and minerals.

This directive on food supplements provides for the approximation of the laws of the Member States. Some Member States currently classify food supplements as food, and others as medicines. The directive clearly classifies them as food products, which creates a level playing field for manufacturers and also removes existing barriers to trade within the single market. At the same time, we are establishing legal certainty for European consumers.

The Commission's proposal is therefore basically to be welcomed. However, discussions in Parliament have made it clear that certain parts of the proposal need to be modified. I particularly wish to highlight the area of application. The Commission's proposal for a directive adopts a rather narrow approach as regards the substances it covers. This applies firstly to permitted minerals and their compounds. Some important minerals are not covered by the Commission proposal, despite their being used in many EU countries. These minerals should be accepted as a matter of principle. Of course chemical compounds still need to be submitted to scientific tests. This needs to be done before the directive enters into force, in order to avoid important food supplements having to be withdrawn from the market. In addition to vitamins and minerals, there are also other substances covered by the term "food supplements". But we should not overreach ourselves and try to regulate everything in one go as regards food supplements on the market.

There is a consensus that other substances besides vitamins and minerals need to be subjected to scientific tests before they are covered by the directive. Nevertheless, defining these additional substances using the heading "physiological" brings with it new problems as regards classification as medicinal products or drugs, and would totally confuse the market situation, which is quite contrary to the aim of the directive. Blurring the dividing line between medicines and food supplements would lead to a lack of clarity as regards health-related claims, which have not so far been regulated. Surely none of this can be the objective of this directive on food supplements.

As regards dosage and thus consumers' health, the system of safe maximum amounts is to be welcomed. Nevertheless, we also need to ensure that consumers do not run the risk of substantially exceeding the daily requirement of food supplements when they take a daily vitamin tablet. With vitamins A, D, and B6, for example, there would be a health risk. The Commission proposal clearly covers this. I totally support this.

With regard to food supplement labelling, the proposal for a directive provides for clear consumer information. Labelling should tell consumers how to use vitamin and mineral products correctly. Products are required to meet the highest purity and quality standards. Both individual substances and the final product have to be produced in accordance with good manufacturing practice. A compulsory notification procedure is essential in order to guarantee minimum levels of official control. Above all, notification is only meaningful if a uniform procedure applies to all Member States. This directive will provide European consumers with a common legal framework which places great value on product safety and helpful labelling without limiting the range of products on the shelves. In other words, it provides a legal framework guaranteeing the free movement of goods whilst simultaneously ensuring a high level of protection.

Finally, I would like to very warmly thank the shadow rapporteur for working with me in such a cooperative way. Many thanks, Mrs Corbey.

Oomen-Ruijten (PPE-DE). – (NL) Mr President, I would like to congratulate the rapporteur, Mrs Müller, on this report, and I am full of admiration for the very open way in which she has

conducted her work and consulted with everyone. So I do not understand why Mr Bonde, Mr Blokland and friends, are now trying surreptitiously – because she also consulted with the EDD Group – to postpone this debate without reference to the rapporteur. This is unacceptable by the moral code of this House. I also have respect for the expert way in which the rapporteur has mastered the technical ins and outs of the dossier. We have Mrs Müller to thank for the fact that the text of this directive has been extended and improved.

Food supplements are used, indeed consumers often need them, but the industry varies a great deal from Member State to Member State. In addition, you can order everything from the Internet nowadays, all the products are freely available everywhere, and special firms have been set up, which makes it all the more necessary to create a single market for consumers. This means harmonisation, harmonisation for the consumer. The consumer must be given sound information and must know what is permissible and what is feasible, that is necessary. But it is also necessary for the industry because the industry is now being given the opportunity to supply the whole European market, and Mrs Müller has extended the directive in several ways which will please not only the consumer but industry too.

A discussion has now got underway on the physiological function. What occurred to me, and I have said the same to the industry today, is that when you visited the industry the first time round, you had no problem with this aspect, and at the end of the saga the members of the industry told me that they understood that they were allowed to maintain it in those countries where it is now, but that they were also very keen for us to go that extra mile. Mrs Müller has made an excellent job of presenting this proposal, which can be extended at a later date, and I would like to thank her cordially for this.

Corbey (PSE). – *(NL)* Mr President, we are discussing a very important directive today. The market for food supplements is developing apace. This has to do with people's lifestyles and eating habits. It also has to do with consumers' insecurity about their own health. People's health is a matter of the utmost concern. Food supplements can be an aid to health, so those who can afford it will gladly buy themselves good health. But we must also be aware that it is easy to talk people who are insecure into feeling that they must buy themselves good health, and that quality is not always guaranteed. We must therefore separate the wheat from the chaff. The consumer is entitled to safe products and sound information.

There are major industrial interests at stake when it comes to food supplements. There is no internal market but there are numerous rules at national level. This is inconvenient, but as the PSE Group sees it, consumer protection must take precedence at the end of the day. Divergent national provisions, uncertainty as to the safety of products and a growing market clearly demonstrate the urgent need for a European directive on food supplements. That is why the Commission's proposal is so important. The Commission has established a clear basis for determining safe upper limits of vitamins and minerals. I am pleased to compliment Mrs Müller on her consistent, professional and serious approach.

On behalf of the PSE Group, I would like to broach three subjects. Firstly, the scope of the directive. The Commission has proposed that only vitamins and minerals should be brought within the scope of application of the proposal. That is understandable but it fails to take into account how the industry has grown. Herbal extracts, amino acids, and essential fatty acids are used in food supplements too. I personally think it is important to define the scope as broadly as possible, thus including substances with a nutritional and a physiological function alike. The advantage of this broad definition is that it creates legal certainty for producers and gives consumers a wide choice of safe products.

The second point I would like to address is the need for scientific testing. Far and away the most important aspect of this proposal is the principle that only ingredients that have been scientifically tested are permissible. The maximum permitted quantities are determined according to the basic principles laid down in Article 5. That is the basis for consumer confidence. Naturally, any country may decide for itself whether or not to permit untested ingredients. The directive does not detract from this in any way. But it is unacceptable, to my mind, for them to enter into circulation in the internal market without so much as a by your leave. Scientific research and approval are required for that to happen.

Lastly, a few words about labelling. It is very important for the information to be correct and to include a warning about exceeding the dosage. A good diet is crucial and is an aid to good health. No consumer should be put to great expense as a result of misrepresentation and no consumer should feel obliged to buy good health.

All in all, I think it is a marvellous proposal. Once again, my sincere thanks to the rapporteur. We support this report wholeheartedly, subject to guarantees that ingredients are scientifically tested.

Ries (ELDR). – (FR) Mr President, in 1999, the turnover in the European Union for vitamins and minerals alone was over EUR 1 600 million, even without taking other food supplements into account. That just shows how fashionable these products have become, which is quite natural, when all is said and done. The wish to be and to stay healthy is probably the most widely shared one. Every day, then, millions of European citizens take thousands of pills, capsules and tablets. It also shows how urgent is the need for regulation of this market in Europe, a market which is expanding rapidly, lacks transparency, and, above all, varies greatly from one Member State to another, as has been noted. The differences are sometimes quite considerable and concern areas such as product composition, dosage, and criteria relating to purity, labelling or the required approval procedure.

We must, therefore, fill these gaps so that we can protect consumers, so that they are extremely well briefed and as clearly informed as is possible, while enabling the free movement of goods within the European Union, as, I am sure, everyone will agree. When voting on Mrs Müller's excellent report, on which we must congratulate her, the Committee on the Environment, Public Health and Consumer Policy included vitamins and minerals in the definition of food supplements, as well as other substances listed in the annexes. We welcome this contribution. Our aim was to ensure that, in the long term, the directive would cover all the food supplements already on the European market, so that European consumers can enjoy the same safety guarantees.

In the same spirit, our group tabled three additional amendments, Amendments Nos 33, 34 and 35. Amendments with the same effect were also tabled by the Group of the Party of European Socialists, seeking to ensure that the scope of the directive includes substances that have physiological effects, i.e. non-nutritional substances which are nonetheless vital to a person's well-being. Fibre, which is known to aid digestion, in the same way as plant extracts, is included. I would like to point out that this proposal was already included in the text of the French Presidency and is currently in that of the Swedish Presidency. The very reason that we are here today is to create a legal framework in order to harmonise the sale of these food supplements.

We should not create a legal void in Europe with regard to ingredients which have physiological functions. There are millions of consumers who would find that incomprehensible.

Ahern (Verts/ALE). – Mr President, I very much welcome the guiding principles of this directive, namely the safety of the consumer and the single market. The basic underlying food-safety legislation is that safety should be established on the basis of scientific risk assessment and that consumers should be able to purchase products of their choice provided that they are safe. It is important that safety criteria form the basis of the directive, rather than arbitrary recommended daily allowances which would be unnecessarily restrictive and not related to safety.

In the UK and Ireland we indeed have a liberal regime and consumers there do not want their rights restricted. Most vitamins and minerals have a clear nutritional function; other ingredients commonly included in supplements are not nutrients and do not therefore have a nutritional function but do have physiological function. The definition of a food supplement in the directive should reflect all supplements.

If products are now excluded from the general definition, there is a danger that such products will in the future fall outside the scope of the legislation and remain unregulated. I very much recommend that you take on board the physiological function which unfortunately the rapporteur – and I do not agree with her – asked to be excluded from the report.

Sandbæk (EDD). – (DA) Mr President, in connection with Parliament's debate on the proposal for a directive on the approximation of the laws relating to food supplements, I have received hundreds of approaches in the form of approximately 500 signatures by way of protest and a long list of detailed e-mails and letters from ordinary, concerned Danes and from professionals who are nervous that their access to food supplements might be limited. I assume that it is not only Danish consumers who are expressing this great interest in the directive. Those who have approached me have all pointed out that a number of experts have

placed many question marks over those investigations showing that vitamins C, E and A in particular may be dangerous in too high doses, and that alternative investigations seem specifically to show that high doses of these vitamins have had positive effects free from side effects. Claim and counter-claim, then. Because the need for vitamins depends upon a long list of factors which differ from one Member State to another, such as climate and which vitamins are present in the traditional food, the question arises of whether this area is at all suited to EU harmonisation. Ole Krarup also sowed the seeds of doubt about the legal basis. When these differences are taken into account and the major interest of consumers taken seriously, my conclusion is that a vote against the proposal for a directive is called for. Laws governing food supplements ought to be established at national level where both the individual consumer and the non-governmental organisations have a much greater opportunity to have their views heard and considered and where, therefore, the legislators also have a better opportunity to assess the different positions.

Bowis (PPE-DE). – Mr President, I am sorry that most of those who sought to stop this debate did not bother to stay to hear it. I compliment the rapporteur on her report and all the work she has put in.

Food supplements can be a tonic or a health aid. In rare cases the nature of the supplement or the nature of an individual mean that too great a dosage could be harmful, and so, for generations, we and other countries have set safe upper limits. With these and with proper labelling the consumer can exercise a safe, free and informed choice. In Britain, Ireland and elsewhere we have not gone down the route of some of our fellow Member States, which is to take the recommended minimum daily allowance that was set by the American Government in 1943 to ensure that GIs serving in Europe did not suffer from scurvy and beri beri, and to treat that as the basis for maximum intake before classification as a pharmaceutical. We fear that route leads to higher costs to consumers or an incentive to use unregulated foreign suppliers. Our belief is that the two systems can coexist. That is the purpose of Amendment No 50, in my name and that of Mrs Doyle and others. It allows the RDA to be taken into account when it is close to the upper safety limit.

I believe that the positive list, as it stands, is far too limited. We should at the very least expand it by the amendments to this effect. Labelling must allow for accurate health messages, such as for folic acid.

Lastly, I support the reinstatement of the word "physiological" alongside "nutritional", as otherwise a significant number of items on sale and acceptable today could risk being banned. It was a word included, I believe, at the behest of the Council's working party of experts. Folic acid is an example.

These are not just my views and those of my delegation. They are the views of the British Labour Government and, more importantly, the views of the new UK Food Standards Agency.

Whitehead (PSE). – Mr President, I am glad to be able to follow someone who has so vigorously supported the Labour Government, as Mr Bowis just did. I would also like to congratulate the rapporteur after the sometimes stormy passage of her report and the mini-ambush which she almost suffered tonight.

In the UK we are the largest manufacturer – and indeed consumer – of health supplements of one kind or another, vitamin and mineral supplements to the diet. We have been stringent in ensuring that false claims are never made for them, and that is why in the UK they have never been marketed as medicines. But they do bring benefits to millions who would accept that they are a supplement to, but not a substitute for, a balanced diet. We believe that the upper safe levels are sufficient to make the difference between foods and medicines even clearer. Obviously the situation is different in some other Member States, and any attempt to regularise the position makes sense in the general context of emergent food law.

I support the rapporteur's view that all substances which have been validly in use in the Member States, according to the laws of those countries, should continue until such time as they can be tested and perhaps found wanting. I rather doubt if many will be, and I do not think that the annexes themselves contain anything like the number of exceptions that we should see.

With every day that passes, we hear of other substances which are causing concern because they may be excluded. That is why the word physiological – and I would beg the rapporteur to think again even at this late hour – is important in terms of people who are genuine sufferers and who derive great benefit from these products. We ought to hear from the Commissioner

tonight that there will be measured progress towards effective analysis by the requisite deadline, be that 2004 or later. Effective labelling, so that the consumers can choose both the context and the regularity of what they are getting, is the best way forward. That will help many consumers and worry none.

Breyer (Verts/ALE) . – (DE) Mr President, I would like to support my colleague Nuala Ahern's comments that physiological products should of course also be included. However, I welcome the fact that vitamins and minerals are classified as food products, as I believe that we should give responsible consumers the option of using them. But I also believe that the Commission should be asking why food products are losing so much of their vitamin content, for example why broccoli has lost 80% of its vitamin content over the last 10 years. I would like to make a particular appeal for labelling not just of ingredients but also of production methods. There are vitamins which if naturally produced are more effective than when they are synthetically produced. I believe that consumers also have the right to know whether or not they have been produced using genetic engineering.

I would like to pick up one last point relating to what Mrs Sandbæk said. I particularly wish to call on the Commission to make sure that this report is not misused to support "functional" foods, because I agree with Mrs Sandbæk that traditional foods should not be artificially enriched with added vitamins. But I wish to stress that we welcome consumers being given the option of taking additional vitamins.

Titford (EDD). – Mr President, in the UK there are no specific laws controlling the sale of supplements sold as food. As a consequence, the UK consumers enjoy access to a relatively wide-range of products with minimal restrictions and competitive prices. No one is forced to buy these products and those that do buy them tend to be well informed about their purchases.

Thus, for the Commission to suggest that we approximate our laws on food supplements is in fact to propose creating laws that do not exist at present in the UK. The reason the UK Government has not created them is that there has been no need for them.

By and large the market regulates itself and where false claims are made, unsound or potentially dangerous products are marketed, the existing legal structures have proven adequate. Nor in the market where there is considerable international trade have any particular difficulties been experienced with the movement of goods and a healthy trade on the Internet has developed and is expanding.

There would seem to be scope for the admirable dictum: "if it ain't broke, don't fix it". Apart from keeping the technocrats busy with yet more interference in other people's lives, there is no need for additional law in this sphere. The Commission should not be attempting to make it. We would be better off without it.

Nisticò (PPE-DE). – (IT) Mr President, I would like to heartily congratulate Mrs Emilia Müller on the extremely well-balanced report she has produced. Indeed, as a research scientist, I cannot fail to appreciate the scientific rigour with which such a sensitive subject, where there are so many sometimes conflicting positions, has been treated.

I would like to thank the Commission for accepting the amendment I tabled on the need for good manufacturing practice to be followed in the preparation of the different vitamin and mineral supplements, for that is the greatest guarantee of quality in terms of consumer protection. Similarly, an excessively permissive position was not adopted on the doses to be used, and rightly so; indeed, the framework of the recommended daily intake was used in specifying doses, thus avoiding encouraging the idea that the greater the dose the greater the effect.

As a pharmacologist, I must point out that, both in terms of pharmacokinetics and in terms of pharmacodynamics and toxicology, for example, excessive doses can have the opposite effects to those desired or can even, if taken over long periods, harm major organs and systems of the body, which means that there is absolutely no need to increase the doses of mineral vitamins to the maximum level tolerated.

In conclusion, Mr President, in my opinion, Parliament can adopt once and for all the document adopted by the Commission.

García-Orcóyen Tormo (PPE-DE). – (ES) Mr President, I would like to join in congratulating Mrs Emilia Franziska Müller on her excellent work on this directive.

There are two principles that govern Community food legislation on which, fortunately, this directive is also based: food safety and the guarantee that the label provides adequate and correct information. It is essential that we remove any risk to the health of consumers caused by free choice, and ensure that they can make their choice based on accurate and clear information that does not lead to confusion or deception. Consumers must have access to clear instructions on the dosage and use of the product. In many cases, as had already been said, it has been found that ingesting some food supplements in excessive doses causes serious health problems. This is not acceptable, and we need to ensure, through Community legislation, that there is good, consistent information across all the Member States.

Focusing on Article 2, both the work of Mrs Emilia Franziska Müller and that of the Committee on the Environment, Public Health and Consumer Policy as a whole provide a legal concept of a balanced food supplement. The scope of application is neither too limited nor so wide that it enables products that do not comply with what a food supplement is to come under the definition.

With regard to Annex I, I think that, finally, the proposal from the Committee on the Environment, Public Health and Consumer Policy, which has been successively extended with compromise amendments, is correct and should be adopted by this House.

With regard to Article 5, which sets out the maximum quantities of vitamins and minerals in food supplements, according to letters a), b) and c) of paragraph 1, I think it is necessary to keep these sections, as the approach that we should take in Europe should be strict, maintaining control of the maximum level of vitamins and minerals based on the maximum safe intake levels. On this point, I would support the idea that a European approach should opt for greater defence of consumers as opposed to an option of greater deregulation. In this respect I welcome the fact that we are 16 against 15.

Doyle (PPE-DE). – Mr President, I should like to thank Mrs Emilia Franziska Müller for her patience with me for making her job a lot more difficult than it might otherwise have been. Quite truthfully, a lot of what Mr Titford said resonated very strongly with me. I took some persuading that a directive such as this was necessary at all. I finally accept that, for example, in relation to oil-soluble vitamins there is a case to be made in terms of safety. But having scoured medical literature and asked colleagues to point out to me the scientific and medical evidence, I cannot find examples of people who have overdosed or killed themselves with vitamin C and various others.

Commissioner, as one of the busiest commissioners it is a matter of some fascination to me that this particular directive should come out of the pile, given the workload you have. I cannot understand the priority it has been given, but I accept that there is a general need to have harmonisation at upper safe levels. Basically we must be driven by informed consumer choice and safety. We must assume that the intelligence quotient of the average European citizen is reasonable. We must desist from getting into the 'hanny state' frame of mind. Dare I suggest that the next directive – seeing as you are in this mode at the moment, Commissioner – should be a directive on bedtime. When we get up in the morning can we go to bed at night? There seems to be a need to direct our lives, to minimise risks and to tell us what to do. Please do not take me seriously but I really am frustrated with the way we are headed.

Points made in relation to the physiological effects must be reinstated. I appeal through the President to my colleague to look at this again. I am quite upset at the way the oral amendment was bounced. I do not want to be told that I cannot take fibre, garlic, cranberry juice or folic acid, if I happen to be pregnant. I do not want my life regulated to that extent. It brings the Commission and the European project into disrepute with citizens who are otherwise not Eurosceptic at all. I appeal to you to get the balance right. It is most important.

Redondo Jiménez (PPE-DE). – (ES) Mr President, Commissioner, I would also like to join in congratulating the rapporteur, who I think has done an excellent job, and the rest of the members of the Committee on the Environment, Public Health and Consumer Policy, who have also worked hard.

One of the objectives of this directive is to harmonise, and the directive has been drawn up – the Commission says so – to eliminate barriers to internal trade. But it does not fully harmonise, as there may be differences between the Member States in the way that they deal with the declarations on the products.

Ladies and gentlemen, the internal market does not work. At the end of 2000 the number of violation proceedings initiated by the Commission associated with this problem was 27.

According to the Commission, this diversity of regulations has created barriers to Community trade, and the principle of mutual recognition has not solved the problems. Harmonisation is therefore necessary.

I am going to refer specifically to Amendment No 51, which is tabled by a group of us who have a series of problems, as the situation of lack of definition that the legislation of eight Member States is currently in could result in the production and sale of these food supplements, which are not included in this directive, being banned, once it is transposed. Meanwhile, the national legislation of the other Member States that regulate these food supplements would allow them to be produced and, as a result of the rules of the internal market, to be sold across the European Union.

Commissioner, this is not harmonisation. We need to allow the production and sale of such substances in the countries where there is no national legislation, as long as their composition is identical to the substances that are already sold in one or various Member States, while Community rules, through its scientific committees, extend the scope of application of this directive.

Byrne, Commission. – Mr President, I am pleased to be here tonight for your consideration of this proposal for a directive on food supplements. This proposal aims to harmonise very divergent national rules by ensuring that consumers will be able to choose from safe products bearing adequate and appropriate labelling. I would like to thank Mrs Müller for her considerable efforts to prepare this report and for her overall support for the proposal. I know that she has had a very difficult task. This is evident from the number of amendments that were tabled in the Environment Committee and the number of additional amendments tabled for Parliament.

The most sensitive issue, judging from the amendments tabled, seems to be the range of ingredients that may be present in food supplements. Recital 6 of the Commission's proposal recognises that various nutrients, including vitamins and minerals and other substances such as fibre, plant and herbal extracts, may be ingredients of food supplements. It lays down specific provisions only on vitamins and minerals which are nutrients as a first stage, because that is how far scientific knowledge allows us to go today.

The intention is to lay down specific rules for other nutrients and other ingredients at a later stage as scientific knowledge improves. It is understood that, until the adoption of specific harmonised Community provisions and without prejudice to the provisions of the Treaty, national provisions on these other nutrients and ingredients may be applicable. I agree with the last sentence of the justification for Amendment No 1. The specific rules on vitamins and minerals laid down in the future directive should be applicable to food supplements containing vitamins, minerals and other ingredients. Otherwise it would be very easy for an unscrupulous manufacturer to avoid applying these rules by adding just a small quantity of another ingredient to a product.

I can, therefore, accept Amendment No 1 in principle with necessary drafting changes that will depend on the final wording of Article 2. Amendments Nos 29, 37 and 41 add to the text of Amendment No 1 the principle that specific rules for these other nutrients and ingredients should be prepared when the science enables us to do so. I accept this principle. However, and in terms of drafting, I can accept Amendment No 37 with some drafting changes, but I cannot accept Amendments Nos 29 and 41. Amendment No 5 purports to introduce in the definition in Article 2 what is explained in Recital 6. Food supplements are concentrated sources of nutrients and other substances, or ingredients as they are called in Recital No 6. This would clarify the definition, an essential part of the directive. I can therefore accept No 5 in principle with drafting changes to ensure coherence of the text.

Amendments Nos 33 and 44 have the same purpose as Amendment No 5 and the clarification goes further in stating that these substances have a nutritional function, as have vitamins, minerals and amino acids or a physiological function, as has fibre or some antioxidants extracted from plants. So I can accept Amendments Nos 33 and 44, provided that the status of the substances that would thus come under the scope of the directive is very clear, both in terms of the criteria that would be applicable for drawing up positive lists and their status until these positive lists are adopted.

Amendments Nos 34 and 46 refer also to Article 2 and are acceptable because they follow the same logic as Amendment No 33. However, from the drafting point of view the proposed addition should be separate from the provision of Article 2(b) so I can accept them with that drafting change.

Amendment No 45, an alternate to Amendments Nos 34 and 36, is in line with Amendment No 5 which I could accept. Here again the proposed addition should be separate from the provisions of Article 2(b). I can therefore accept Amendment No 45 with the necessary drafting change.

Amendment No 6 on the same point is an alternate that creates confusion. The justification given in the committee's report would seem to be in line with Recital 6 and with the proposed text of Amendment No 5 by acknowledging that ingredients such as amino acids, fatty acids and herbal extracts are included in food supplements. But the proposed text is in contradiction with them by limiting such ingredients to those having a nutritional function. I cannot see the reason for this limitation and therefore cannot accept Amendment No 6.

I can accept Amendment No 2 to Recital 7 and also Amendment No 4 to Recital 14, which is a technical correction to the text of the proposal.

Amendment No 7 concerns the definition of dose form. This is a highly technical matter. I understand that concern is expressed from many sources to have a workable definition that depicts current practices. This is also our aim. I can accept Amendment No 7 in principle but with drafting changes necessary to achieve the stated aim of flexibility.

Amendment No 8 would add a new paragraph to Article 3 with the same text as that proposed for addition to Recital 6. As for Amendment No 1, we have no problem with the principle but the inclusion of the same text in that article is not necessary. Therefore I would not accept Amendment No 8.

Amendment No 51 has partially similar aims to Amendment No 8 and goes further to set rules concerning the principle of free circulation of products. I hope you agree that this cannot be done in a few lines in this specific directive and I cannot accept Amendment No 51.

Amendment No 9 refers to Article 4 and the purity criteria of substances listed in Annex II. I can understand the wish to be more concrete here. In fact, since the tabling of this proposal, appropriate wording regarding purity criteria has been agreed and included in Community legislation, namely the directive on nutritional substances that may be used in the manufacture of foods for particular nutritional uses. This text refers to Community purity criteria that are already adopted for some of the substances in Annex II and to purity criteria recommended by international organisations. For the sake of coherence, the same text should be included in this proposed directive. I can accept the spirit of Amendment No 9 but with drafting that is in line with already agreed Community texts.

Amendment No 3 on Recital 9 is one of a series of amendments concerning procedures and the working rules for managing the directive. Regarding the revision of the lists of the annexes, the Commission may respond to a request by a Member State, a stakeholder including a manufacturer, or take the initiative to set in motion the procedures for adding to the annexes, or it may reject the request of the manufacturer. Amendment No 3 is not acceptable because it constitutes a restriction on the Commission's right of initiative.

Amendment No 10 reduces the procedure of modifying the annexes, which includes both scientific assessment and the subsequent adoption of a Commission directive, into a procedure of evaluation of the safety of substances. It also aims at specifying in this directive working rules for the Scientific Committee for Food. This is not a subject for legislation. Therefore, Amendment No 10 is not acceptable and for the same reason I cannot accept Amendment No 25 which also lays down working procedures for the Scientific Committee for Food. Amendment No 11 poses the same problems that I mentioned regarding Amendment No 6. It also poses problems from the procedural point of view.

The Commission must preserve its right of initiative as to when to present proposals. Therefore, I cannot accept Amendment No 11. For the same institutional reasons I cannot accept Amendments Nos 35 and 47 despite the fact that they include references to ingredients with nutritional or physiological functions.

Amendment No 13, the last on procedures, proposes that the comitology procedure referred to in Article 5(3) shall be subject to the principle of transparency. Of course, I would not deny this but I have a problem dealing with this issue in a specific vertical directive on food supplements. The principle of transparency is a general one to be applied to procedures dealing with products across the board. You are currently considering our proposal for a Food Act which includes provisions on transparency applicable to all foodstuffs. Therefore, I cannot accept Amendment No 13.

Amendment No 12 to Article 5(1) makes a valid point that requirements of children and adults be taken into account when setting maximum levels for vitamins and minerals. The principles can be extended to take into account, and I quote, "sensitivities of different consumer groups"

and not only children and adults. Further, the point may be inserted in a more appropriate place in the article than the one suggested, therefore I can accept Amendment No 12 in principle, subject to drafting changes.

I now move to a number of amendments that concern the labelling provisions of the proposal. Amendment No 14 refers to the name of the product. In terms of labelling there is very little significant difference between the name of the product and the labelling. The name of the product must be set in EU legislation otherwise Member States can do that at the national level. This would create confusion for consumers. For this reason, I cannot accept Amendment No 14, however I take note of your request that the name of the product should include the words "food supplement".

The text proposed by Amendments Nos 15 and 28 does not express a different principle than that in the text of the proposal. They are drafting amendments and I am not convinced that they achieve greater clarity on this point and therefore I would not accept Amendments Nos 15 and 28.

I consider that a statement to the effect that food supplements should not be used as a substitute for a diversified diet is important for consumers both for information and education. Therefore I cannot accept Amendment No 16 that proposes the deletion of this provision. I can accept Amendment No 17 that proposes to include on the label a statement to the effect that food supplements should be stored out of the reach of children. Such a statement would provide additional safeguards to avoid accidental ingestion of these products.

Amendment No 18, although well intended I am sure, raises a number of complicated issues. Any food supplement intended for infants under the age of one year would, be to my mind, a product for particular nutritional uses and would be excluded from the scope of this directive as mentioned in Article 1. The case of supplements for pregnant women could give rise to a similar debate. Amendment No 18 would be potentially contradictory to Article 1 and I cannot accept it.

I can accept Amendment No 19. I can also accept Amendment No 20 in principle but with drafting changes that would be in line with the justification for this amendment provided in your report. Amendment No 21 proposes the addition of two sentences to Article 9. The principle expressed in the first sentence that excess doses should be avoided is already covered in Article 6. The second sentence deals with the issue of tolerance limits for declared quantities of certain nutrients that have stability problems. This is a highly technical issue that needs to be considered by appropriate experts and, if necessary, dealt with through technical implementing measures. Therefore I cannot accept Amendment No 21.

Amendment No 22 proposes to adopt the principles of good manufacturing practices by legally binding measures. This is not the practice in the area of foodstuffs and would set a precedent. We have horizontal rules on hygiene and control that apply to all foods and will apply to food supplements also. We have purity criteria for many of the substances that are listed in Annex II and intend to adopt criteria for the rest. These binding horizontal rules seem to us to be enough. Therefore, I cannot accept Amendment No 22. Of course, nothing stops the relevant industry voluntarily adopting specific GMPs for a specific product. This happens often in the food area.

Amendment No 23 would make it obligatory for Member States to require manufacturers to notify authorities of food supplements when marketed. The Commission proposal allows Member States to waive such requirement if they can monitor these products otherwise on their territory.

Member States are opposed to such imposition because they feel this is an issue of subsidiarity and wish to have a free hand in how they monitor these products. I cannot accept Amendment No 23.

Amendment No 24 also relates to procedures and aims to impose strict time limits for Commission decisions. Such decisions may depend on advice delivered by the Scientific Committee for Food, positions of Member States and other factors beyond the control of the Commission. For this reason I cannot accept Amendment No 24.

Amendments Nos 26 and 27 add to Annexes I and II more minerals, vitamins, preparations and mineral salts. I must be clear on this issue: I cannot accept any additions there in the absence of a positive safety evaluation by the Scientific Committee for Food. I cannot accept Amendments Nos 26 and 27.

On the other hand, Amendments Nos 30, 31, 32, 36, 38, 39, 42, 48 and 49 aim to establish a list of vitamin preparations which should be given priority for safety evaluation and eventual incorporation in the list of substances that may be used in the manufacture of food

supplements. I can agree that the principle be expressed in a new recital as proposed in Amendments Nos 30, 38 and 42.

It should be noted that Annex II includes only vitamin preparations and mineral salts. It does not include other ingredients. It should also be noted that the procedure referred to in Article 13 is not applicable to the evaluation of the substances in question. That procedure concerns the addition of substances to the list and includes as a step their evaluation. Therefore the proposed new recital would have to be drafted accordingly. I can accept Amendments Nos 30, 38 and 42 with the appropriate drafting changes.

However, the corresponding article proposed by Amendments Nos 31, 36 and 48 is not acceptable either from the drafting point of view or from the institutional point of view. So I have to say "no" to Amendments Nos 31, 36 and 48. However, we should discuss this further, afterwards, to find a satisfactory solution for everybody. An article along the lines of this recital, making reference to priority for evaluation of certain substances that are listed in a separate annex could be explored by all institutions involved in the process.

Amendments Nos 32, 39 and 49 cannot be accepted because they are directly linked to Amendments Nos 31, 36 and 48. However this should not be taken as a judgment on the substances contained therein.

I should like to thank Parliament for the support it has given to the Commission in having scientific risk assessment for the basic criterion for setting maximum levels of vitamins and minerals in food supplements. Article 5 is finely balanced to ensure the required high level of protection for the consumer. Amendments Nos 40 and 50 would upset this balance and therefore cannot be accepted.

Finally, I come to Amendment No 43. I do not see what are the testing procedures set out in this directive that other ingredients should comply with. Therefore I cannot accept Amendment No 43.

In conclusion, the Commission can accept Amendments Nos 2, 4, 17, 19, 33 and 44 as such, and Amendments Nos 1, 5, 7, 9, 12, 20, 30, 34, 37, 38, 42, 45 and 46 in principle, with drafting changes. The Commission cannot accept Amendments Nos 3, 6, 8, 10, 11, 13, 14, 15, 16, 18, 21, 22, 23, 24, 25, 26, 27, 28, 29, 31, 32, 35, 36, 39, 40, 41, 43, 47, 48, 49, 50 and 51.

President. – Thank you, Commissioner.

The debate is closed.

The vote will take place tomorrow at 12 noon.