

Debates of the European Parliament
SITTING OF TUESDAY, 12 MARCH 2002
Food supplements

President. – The next item is the recommendation for second reading (A5-0044/2002), by Mrs Emilia Franziska Müller, on behalf of the Committee on the Environment, Public Health and Consumer Policy, on the Council common position for adopting a European Parliament and Council directive on the approximation of the laws of the Member States relating to food supplements [12394/2/2001 – C5-0640/2001 – 2000/0080(COD)].

Jackson (PPE-DE). – Mr President, on a point of order, I wanted to announce, before Mrs Emilia Franziska Müller gets started, that the fact that the screen showing the list of names of the speakers has gone wrong may perhaps explain why people might not come to the debate. Also, we are only getting the German interpretation in our offices. This is a great help to me because I am doing a course at the Goethe Institute, but other people may find it a little difficult.

President. – There you are, Mrs Jackson, it is an ill wind that blows nobody any good! I announced this problem just now and the technicians are trying to resolve it. I hope that they manage to sort it out as soon as possible. However, you are extremely optimistic when you say that the only reason there are so few Members in the Chamber is because we have got a few technical display problems. If only that were so!

Müller, Emilia Franziska (PPE-DE), rapporteur. – (DE) Mr President, Commissioner, ladies and gentlemen, about 20% of all Europeans regularly supplement their daily diets. In 1999, European consumers spent EUR 1 615 million on vitamins and minerals alone. Demand is rising constantly, because people's living and eating habits have changed radically. Vitamins and minerals are involved in numerous biochemical processes in the human organism. It is crucial to people's health and to their physical and mental capacity that they optimise their intake of these substances.

I believe that the opportunity to enrich our daily food intake with additional vitamins and minerals is very valuable. When we speak here today of food supplements, we primarily mean vitamins and minerals that are marketed in the form of tablets, capsules and powders. The directive on food supplements is designed to harmonise the laws of the Member States. This will give manufacturers easier access to all markets, subjecting their production and marketing practices to a uniform set of conditions.

The directive unequivocally assigns food supplements to the domain of foodstuffs. Food supplements are not medicinal products, nor can they serve as substitutes for medicinal products. Through their categorisation as foodstuffs, food supplements are subjected to all the provisions that apply to foodstuffs in the European Union, including the provisions of quality, hygiene and safety legislation. The consumer must be able to rely on the complete safety of all foodstuffs, particularly of substances such as vitamins and minerals, where stability levels sometimes differ between products.

The new directive targets two specific areas: consumer safety and the completion of the single market in food supplements. The Council of Ministers has adopted Parliament's key demands from the first reading.

Parliament welcomes the fact that the Council took account of our position regarding the need to include more substances in the directive. The substances in question are already on the market but have not yet been evaluated by the competent scientific committee. These are to be included in the annex to the directive. In the common position, a period of 18 months has been set for the preparation and submission of a dossier. The Committee on the Environment has extended this 18-month period to 36 months in order to give small and medium-sized businesses in particular sufficient time to compile the relevant data on their products.

The House now has two further amendments on the table – one for 24 and one for 30 months. I would personally argue for 30 months, because I believe that two and a half years should be enough time to prove the safety of a product that has been sold to consumers for years. I attach great importance to the principle that substances should be scientifically tested before they become the object of Community legislation.

As far as doses, and hence optimum consumer care, are concerned, Parliament welcomes the system of maximum safe doses combined with the reference quantities per head of

population. In other words, manufacturers' dosage instructions must not be based on the limits of human tolerance. On the other hand, they need not be bound by the recommended daily allowances, which are normally set at very low levels. On this particular point, the directive manages to take account of both the wishes of consumers and the need to protect them.

The common position has come up with a compromise here that I entirely support. For this reason we reject Amendment No 6 to Article 5 of the directive. With regard to product labelling, the directive provides for clear dosage recommendations. The substance of Amendment No 8 on greater transparency is already clearly covered by Articles 38 and 42 of Regulation (EC) No 178/2002 of 28 February 2002 establishing the European Food Safety Authority. For this reason the PPE-DE Group also rejects this amendment outright.

For all the reasons I have outlined, I can have no truck whatsoever with the proposal to reject the common position that is made in Amendment No 7.

Finally, a few words on the campaign which all Members of Parliament have been forced to endure in the last few weeks and months; this is a campaign through which a single producer and dealer of vitamin products has been pursuing interests of a purely economic nature.

(Applause)

The company behind this campaign is engaging in image-making at the expense of the sick. It is breeding anxiety among consumers and exploiting their distress for its own ends. I sympathise with all those people who have been taken in by the scaremongering and utterly specious arguments that have emanated from the company concerned. It is clearly not the case that we seek to prohibit vitamin therapies by means of this directive on food supplements or that we are trying to curtail access to natural treatment methods. What the directive does prohibit, and rightly so, is any attempt to mislead consumers by making exaggerated claims about the curative or preventive powers of vitamins and minerals. This directive gives consumers in Europe the support of a legal framework that attaches great value to product safety and responsible labelling without restricting the range of products on shop and supermarket shelves. In short, it is a legal regime that combines free circulation of goods with a high level of protection. After talks with many organisations – industrial associations as well as consumer associations – I am more convinced than ever that this directive points in the right direction.

(Applause)

Oomen-Ruijten (PPE-DE). – *(NL)* Mr President, allow me to start by thanking the rapporteur, Mrs Müller, not only on her sound report but also on the tenacity she has displayed.

The issue we are debating today has caused a huge stir. As we know, there are different traditions, as well as do's and do not's in Europe. Like the United States, Great Britain and the Netherlands have, in fact, very flexible legislation whereby, once registered, all vitamins and minerals can be freely bought, sold and used.

However, there are also products, certain vitamins and minerals, that are not without risk. In Germany, another Member State, rules are very strict. Food supplements are only available on prescription and at the chemist. This is sufficient reason, also as far as the European citizens are concerned, to start to harmonise the internal market. This harmonisation should be subject to two criteria: firstly, the indication of a recommended daily intake as a guideline to the consumer and secondly, the establishment of a definitive list of permitted products. Products not yet on the European list will be permitted if their file has been submitted to the independent scientific committee for testing.

Honest European businesses are satisfied with this directive, unlike cowboys such as one Mathias Rath, who, just across the German border in the Netherlands, runs a very lucrative business using his own products. Adoption of this European legislation will ensure that his trade, which is primarily aimed at Germany, will fizzle out because consumers will be able to buy safe vitamins and minerals at the chemist or the supermarket anywhere in Europe.

I am also inundated with an incredible number of e-mails, thousands of e-mails and letters. Rath drove the anxious citizen to action with false arguments, no less. Let me be quite clear: nothing is being taken away from the consumer. There is a 30-month period during which businesses can prove that their products are indeed safe, and I will continue to monitor the scientific committee with regard to registration. I am pleased that Europe is calling an end to a practice which is only aimed at excessive profiteering on the backs of many people who are seriously ill.

Corbey (PSE). – (NL) Mr President, Commissioner, I should first of all like to congratulate Mrs Müller on her consistent, expert and tenacious approach. Her work currently has great significance. The food supplements market is growing fast. Food supplements can make a positive contribution to health. Anyone who can afford it is keen to buy good health. However, it is obvious that quality is not always guaranteed. We must therefore separate the chaff from the wheat. The consumer is entitled to a safe product and sound information.

In the field of food supplements, large industrial interests are at stake. We have already gathered this from the thousands of e-mails, four books, video cassettes and postcards in support of the cause of the producers. In the magazine 'The Rapporteur', the vitamin lobby campaign was described as counter-productive. If only! Unfortunately, a number of fellow MEPs, mainly from the liberal and green groups, have fallen for this lobby.

I recently received 35 letters from anxious consumers. I did not receive them directly but via the industry, which immediately makes one wonder. The letters were written by people who said that they benefited from taking multi-vitamin tablets and that they had heard that the European Parliament would ban them henceforth. A clear example of misinformation. Multi-vitamin tablets can still be taken. Only when they contain substances or compounds which do not feature on the extensive list must the manufacturer prove that they are safe. Is that too much to ask?

Anyone who claims that hardly any damage has occurred involving food supplements to date is probably right. However, their use has so far been restricted. Only latterly has the market grown and do high-dose tablets appear in the shops. Safety must be the main concern. Producers have 18 months in which to demonstrate that their products are safe. This appears to me to be sufficient time, but I have no problem with extending this period to 24 months.

The directive is of huge importance, and it is futile to regulate safety for each Member State individually. We do not do this for food either. With regard to food supplements, there is currently no internal market, but many different, national rules. We must set up this internal market for food supplements. In my personal opinion, the internal market is a great good, provided, however, that it prescribes common standards at a high level, which is where this directive comes in. The Commission has laid down a solid foundation for the establishment of maximum safety levels for vitamins and minerals, and that also forms the basis for consumer confidence. I would urge you to vote for this directive.

Ries (ELDR). – (FR) Mr President, Commissioner, the consumption of vitamins and other food supplements by our society is a genuine trend rather than a fashion. The market that this generates is huge. The considerable lobbying that has been carried out on this issue is proof of this, if it were needed.

Let us turn directly to the main question which is niggling a number of my fellow Members who oppose this directive and that is should we legislate? I have no hesitation in saying 'no' and I have at least three reasons for this.

First of all, the proposal for a directive provides a specific response to a reality, namely the lack of an internal market, which has damaging repercussions both for the economic actors in this sector and for consumers. By way of example, it is currently virtually impossible for a vitamin manufacturer based in the UK to export and place his products on the market in Belgium or in France, for instance.

Secondly, it is useful, even so, to recall the two major battles waged at first reading regarding the inclusion of substances with psychological effects – fibres and plant extracts, in particular – and the essential labelling standards to enable consumers to make an informed choice. Parliament made its view heard.

I would add, and this is my third point, that no high-quality food supplement, regardless of its ingredients, will be banned under this directive. I stress the point that we must stop brandishing the prospect of bans and of a Europe that castrates. Manufacturers will have three and a half years, depending on our vote, to submit their dossier and prove that their products which are not currently listed in the Annex are safe, and if a ban has to be imposed eventually, it would therefore be placed on doubtful substances. Anyhow this is the least of our problems, as far as I am concerned.

Since I am speaking of the purely health-related aspect of this matter, I would also like us to stop saying that vitamin abuse poses no danger. This is wrong, simply wrong! We must say that excessive consumption of all fat-soluble vitamins such as A, K, E and D are problematic, and, to give another example, excess vitamin A has known harmful teratogenic effects and

can result in foetus malformation. We can allow political opposition to this directive therefore, but in no case can we allow scientific falsehoods to go unchallenged.

To sum up, and for all the aforementioned reasons, we are dealing with flexible and balanced legislation which takes into account the interests of consumers, manufacturers and distributors and which lays a basis for the harmonisation that is necessary in this sector. The majority of my colleagues in the Group of the European Liberal, Democrat and Reform Party will vote in favour of this very good report by Mrs Müller and I too would like to congratulate her.

(Applause)

McKenna (Verts/ALE). – I believe this directive is an unacceptable assault on the right of citizens to choose how they look after their health and well-being. Huge numbers of EU citizens choose to take supplements to reduce the possibility of their falling ill and needing to seek medical advice to obtain prescribed drugs. People should have the right to opt for a healthy approach, rather than waiting for disease to set in and then having to resort to pharmaceutical drugs, many of which have dangerous side effects.

I am not surprised that the pharmaceutical industry is supporting this directive, since it plays right into their hands and means more business for them. Products which have been widely and safely used for many years in several EU Member States are being restricted without any health and safety justifications. I believe this is lawnmower harmonisation at its best, where everything is chopped down to the lowest common denominator.

Consumers should be free to choose their own level of potency and nutrients, provided that they are safe and appropriately labelled. Availability of supplements should not be restricted for any reason other than safety. This proposal is profoundly flawed, in that it is based on the old-fashioned research which relies on RDAs of vitamins and minerals. For the past fifty years, RDAs have formed the basis of conventional nutritional wisdom. However, according to many reports which I have read on this issue, RDAs are set far too low and should be revised upwards. Instead, legislators should rely on the upper safe limits, which are a much better device. For example, the RDA for vitamin B6 is just 2 mg while the upper safe limit is 200 mg. Two studies published in the *New England Journal of Medicine* in 1993 demonstrated that taking supplements containing 100 IU of vitamin E for at least two years reduced the risk of heart disease in both men and women by approximately 40%. Despite this, the RDA for Vitamin E remains a measly 10 IU.

I believe that countries with a restrictive policy should relax it, but not on the condition that we tighten our system and restrict the access of our consumers in our countries to vitamin and food supplements.

(Applause)

Sjöstedt (GUE/NGL). *(SV)* Mr President, two different types of argument have been put forward for this directive. The first concerns public health, the second harmonisation of the internal market.

I consider that the public health arguments are weak. There is no major public health problem from people overdosing on vitamins and minerals. Nor will the risk of overdose disappear with this directive.

If we really want to make a vigorous contribution to public health, we should possibly address the subjects of alcohol, tobacco or something else rather than the area covered by this directive. The fact is too that the EU is not allowed to introduce harmonisation on public health issues. This is clearly stated by the Treaties. There is also a risk that consumers who use certain dosages of particular preparations will find this more difficult once this directive has entered into force.

The real motivation behind the directive is harmonisation, in other words the opportunity to be free to sell everywhere. This is not a strong argument in my opinion. In my view, sometimes other considerations must be more important than a free market.

I consider that, in areas such as this, different EU countries should be allowed to have different rules – more liberal or more restrictive – depending on the wishes of the voters. I consider that supranational rules should only be used to combat real supranational common problems. This is not the case here.

We have witnessed a furious and quite unpleasant lobbying campaign. Its methods and its content have been counter-productive. Several of the arguments put forward against the proposal have been exaggerated and sometimes also incorrect.

Parts of this proposal are positive, such as the requirement for declarations of contents. On the whole, there are, however, no strong arguments for implementing the far-reaching harmonisation proposed. There is also a risk that the system which has been drawn up will benefit major industrial interests at the expense of small enterprises.

(Applause)

Fitzsimons (UEN). – The directive which is before us today has two principal key objectives: first, to harmonise national legal provisions on food supplements so as to reduce and eliminate considerable problems facing the free movement of food supplements; second, to establish an appropriate level of consumer protection in the use of food supplements in the European Union Member States.

To achieve these two objectives, it is necessary, as the rapporteur has said, to appropriately define what food supplements are; it is necessary to put in place a scientific assessment of all the ingredients and their minimum and maximum doses; it is necessary also to outline the key criteria for requirements with regard to consumer protection; and of course, the quality of standards has to be looked into as well.

The protection of the European Union's 370 million consumers is of paramount importance. Under the Amsterdam Treaty, Parliament has the power of codecision with the Council in the area of consumer protection and public health matters. I have always supported the need for improved labelling provisions so as to ensure that the consumer information is transparent and effective. The fact of matter is this: we live in an internal market where there is free movement of goods, services, persons and capital. We need to guarantee the safety of our food chain from farm to table. It is important that we have the framework proposal to put in place uniform systems for the full certification of food supplements. If there is any possible likelihood of endangering public health by means of the implementation of any particular proposal, one must always veer on the side of caution, and I compliment the rapporteur on her report.

Blokland (EDD). – *(NL)* Mr President, there are no known cases of serious, harmful effects that have been caused by consuming vitamins and minerals that fall within the present directive. In contrast, we all know that in the European Union, half a million people die prematurely from the effects of smoking every year. It is therefore astonishing that minerals and vitamins will soon be subject to stricter legislation than tobacco.

In the report, producers of food supplements are being met halfway by extending the period of approval from one and a half years to three years. This does not solve anything for the, mostly small, companies, since the required tests are too costly. This will lead to a ban on food supplements which have been sold legally in certain Member States without any problems for many years.

Since permitted quantities in tablets have in many cases been reduced, this will mainly have the effect that consumers will end up buying larger quantities of tablets in order to consume the same levels.

However, I have more fundamental objections. Since different regions of the European Union have different eating habits and eating cultures, the need for food supplements varies greatly. I have come to the conclusion that it is impossible to draw up European legislation in this area to suit these different cultures.

At first reading, the PPE-DE Group called for a referral back of Mrs Müller's report because it contravenes the Treaty. This was met with little support at the time. Meanwhile, it is my understanding that the support for rejecting this legislation has grown considerably. I therefore hope that there will be a sufficient number of Members who have the courage to reject the Council's common position. Many consumers share this hope. Given the numerous reactions, this is a considerable problem for many consumers. I should like to hand you the many thousands of signatures that have been collected for this purpose.

(Applause)

Jackson (PPE-DE). – Mr President, this is a bad directive. I do not say that on the basis of any emotion or the fact that Doctor Rath has lobbied me. Oddly enough I have not received many e-mails, so my machine has not been stuffed full of e-mails from Doctor Rath or anybody else. I do not know why that is, but I am very quick with the delete button.

I do believe this is a very bad directive, not in its intention but in its method. It is designed, as everybody has said, to bring about a common market in food supplements. It may well bring

that about, but in doing so the risk is – and there is a risk – that some products currently on the market in some countries will cease to be available.

I, like many British MEPs, have received many letters from people in the region that I represent. These are not circular letters that they have just signed, they are letters that they have written themselves. The people who write them fear that they will no longer be able to buy over 300 food supplements that their good health depends on.

We do not need to go into why this fear has arisen and who stirred it up, if anybody has stirred it up. The fact of the matter is that the Commission has created a situation, by bringing forward the directive in this form, that has given people reason to voice and to have such fears. I have no quarrel with the German Members or with the rapporteur. She has done a valiant job. They are standing up for the system they have in place. They believe our – British, in this instance – more liberal system may allow unsafe products onto the market. We contend that consumers should be able to exercise as wide a choice as possible and that there is no evidence that products on our market are unsafe. Where is the evidence that they are unsafe? Why should we have to prove that they are safe when people buy them every day and believe that their health depends on them?

I say to Commissioner Byrne: be careful. This directive tries to reconcile very different national approaches to allowing these products onto the markets and it fails in that attempt at reconciliation. Small businesses have been allowed too little time to submit the required safety dossier on their products. We may put that right tomorrow, but why, Commissioner Byrne, is it that there is no cost impact assessment on small businesses in this directive? When it came forward two years ago there was no cost impact assessment attached.

Just as important, we need to have the whole process of reviewing what there is on the market much more out in the open. It should not be done by secret committees. MEPs on the Committee on the Environment, Public Health and Consumer Policy will insist that we are much better informed on this, so that we can keep track of what is happening on behalf of our anxious constituents. We hope that we will be able to block any heavy-handed attempt to deprive people of the products they know and continue to need.

Roth-Behrendt (PSE). – (DE) Mr President, I must confess to being quite astonished! We are speaking about products that are on the market today and are asking why we need to provide evidence of their safety! I can tell you why: because it has to be done for every last bit of artificial colouring that goes into your *Uncle Joe's Mintballs* and for every preservative that is added to jam, and because we have always resolutely proclaimed in this forum that consumer safety is important. For this reason a product cannot be deemed marketable unless it can be proved safe and harmless. This is surely easy to demonstrate for any product that has already been on the market for some time.

Moreover, I must also express my astonishment at the references to divergent systems. I do not know what you are talking about. I understood neither Mrs Oomen-Ruijten's reference to these divergences nor Mrs Jackson's. In Germany you can go into any drugstore at all, into any supermarket, and you will be perfectly free to buy vitamins, calcium or whatever you want in various different dosages. I have nothing against that. Nor do I object to these products remaining freely obtainable. I do wish, however, to see the introduction of a maximum dose – yes, a maximum dose is something I do want to see. People like myself, for example, who have the misfortune to suffer from kidney stones, must not take too much Vitamin C, because it crystallises. People like me must also be careful with calcium, and we have to know these things. This is why labelling is needed; this is why safety is paramount.

Anyone who stands up today like Patricia McKenna and says that the adoption of this directive would force products off the market is misleading people. I take no pleasure in saying this, Patricia, because our opinions often concur. It is not true that a single safe product will disappear from today's market. All manufacturers must be able to demonstrate the safety of their products. Every single manufacturer must be able to do that. For each and every product we buy – for all our cosmetics, our pharmaceutical products, our artificial sweeteners – we expect proof of safety. And are we now saying that we do not expect the same for food supplements? Surely food manufacturers will then come along to us and say, 'Why must we prove that our muesli bars are safe?' And they would be right to do so. They would then be exempted in future too. At that point they could start making their products with genetically modified organisms and whatever else. Why should anyone then have to demonstrate the safety of any product?

Goodness knows that I have been involved for long enough in matters of consumer protection in this House. I believe my reputation goes before me in that respect. I tell all the people who call me that none of the products they can now buy will be taken off the market. I shall ensure that they are informed in future about any product they buy and whether it is safe. It makes no difference to me whether the evidence has to be produced within 24 or 30 months, but the evidence must be produced.

I congratulate Mrs Müller on her excellent report, which will have my unreserved support tomorrow.

(Applause)

President. – Mr Blokland, I had a quick look at the list you gave me and I thought it best to pass it on to the Chairman of the Committee on Petitions, who can give you a response. You will, of course, receive another response regarding the outcome of the document you entrusted to me as well.

Davies (ELDR). – Mr President, last year in Britain alone, 5 000 people died from overdosing on alcohol. They drank themselves to death in one session. Yet I do not see a directive before us to require alcohol to be submitted to all sorts of safety tests, or for bottles of Guinness or Strasbourg wine to carry the strongest possible health warnings. So why on earth are the manufacturers of food supplements being told that they must jump through a series of expensive hoops, which may be so costly as to drive some of them out of business, in order to keep their products on the market?

My colleague, Frederick Ries, says that not all vitamins are safe, but of course you can kill yourself on anything if you eat enough of it. You can stuff yourself with baked beans until you die, but unlike alcohol or most pharmaceutical products, vitamin and food supplements do not have a track record of killing people. On the contrary, I, like Mr Blokland, have a stack of letters which testify that many do a great deal of good.

This directive, therefore, is like taking a sledgehammer to crack a nut! Better labelling would have been sufficient to provide such protection as is needed, but perhaps that would not have been enough to satisfy the big drug companies, which are seeking to control a lucrative market.

I remember the Commissioner telling us not long ago that under his regime we would have less interference of the kind which angers many European citizens for no good reason. However, when it comes to Brussels proving that it wants to treat people like an interfering nanny, this directive really does take the biscuit.

(Applause)

Schörling (Verts/ALE). *(SV)* I will begin by distancing myself from the very aggressive campaign which we Members and, especially, the rapporteur Mrs Müller have faced while debating this issue. Naturally, everyone has the democratic right to argue for what they believe in and to attempt to influence decision-makers and decisions but, in this case, matters have gone beyond the limits of what is acceptable.

I am one of those who would like to reject the common position. This is not because I always have to be against regulation or harmonisation in the area of public health but because, in this particular case, I consider that it is neither desirable nor necessary to harmonise national legislation. Just as Mr Blokland said, different countries have very different traditions and, as far as I know, no one has ever died from taking vitamins and minerals.

The problem with the directive is partly Article 5, which concerns establishing the maximum daily intake. The European Parliament will have no insight whatsoever into, or influence upon, how this is determined. What, however, is most likely is that it will be done using the committee procedure.

Another problem is the appendix which states which vitamins and minerals are to be permitted as food supplements. The opportunity of small companies and manufacturers to make their influence felt in the market worries me considerably in that respect. Many companies and products will disappear and, most importantly of all, consumer choice will thus be limited.

We are currently exposed to stress and to a number of environmental poisons and chemicals, which means that a varied and healthy diet is not always sufficient to ensure that we keep healthy and well. We need vitamin and mineral supplements, sometimes in high doses, to be

able to balance the functions of the body. Good knowledge of nutrition, Mr President, could also prevent illness in all contexts.

We should encourage people to take care of themselves and take responsibility for their own health. This directive sends out the wrong signals.

Fiebiger (GUE/NGL). – *(DE)* Mr President, obtaining food supplements as health products from the Internet is not encouraged by this report. I well understand the life stories of the individuals who are concerned by this directive, but my own experiences tell me something different. In my opinion, substances that are used to treat and alleviate the symptoms of serious illnesses, of illnesses that may not yet be curable at the present time, should be covered by legislation on medicinal products and have nothing to do with the consumption of foodstuffs. In other words, products with pharmaceutical ingredients which are advertised as possessing medicinal powers must be subject to licensing as medicinal products.

The aim of the directive is to harmonise maximum permissible quantities of active ingredients throughout the 15 Member States and to improve national conditions on the basis of criteria relating to the harmlessness of products to human health as a preventive measure of consumer protection. The national food and pharmaceuticals industries are vying for an extremely lucrative market in foodstuffs enriched with active ingredients.

A new type of food product is being advertised here, and the advertisements often focus on additional health- and performance-enhancing qualities, sometimes proven but often imputed, of these products. I believe that it is important and that it befits our responsibility to ensure that the line between medicinal and food products does not become blurred or negotiable. In this expanding market, the pharmaceuticals and foodstuffs industries will move heaven and earth to enrich food products with additives which are not naturally found in those products. The report is based on transparency, disclosure and safety for consumers. For this reason I support it. The directive will never absolve patients and consumers, however, from the imperative obligation to read the small print: 'If in doubt, please consult your doctor or pharmacist'. This is why scientists and researchers have a legal entitlement to improve this common position.

Titford (EDD). – Mr President, circulating the streets of Strasbourg this morning was a mobile advertising hoarding asking this Parliament how it could ignore the wishes of 450 million voters. The obvious answer is 'very easily': it has been doing it for years. And if this Parliament accepts the common position on this directive it will prove my point. It is a totally unnecessary intrusion into the freedoms of millions of people. Never have I received so many communications from ordinary people asking me to reject it. The Commission is entirely wrong to assert that lobby groups are scaremongering. As far as I can see the pressure is coming from ordinary people who are very worried by this proposal. It is those ordinary people whose interests are under threat. Accordingly I will be voting for the UEN Amendment No 7, calling for the rejection of the common position. I urge every Member of this House to do likewise.

Nisticò (PPE-DE). – *(IT)* Mr President, I would like to start by thanking Mrs Emilia Müller, and Mr Corbey and Mrs Roth-Behrendt too, for the courage they have displayed, despite the immense, absurd amount of pressure to which they have been constantly subjected by people with no scientific knowledge and no integrity. I would like to inform Commissioner Byrne that, in order to speed up the adoption of this directive, I have withdrawn an excellent amendment which sought to ensure the safety of consumers, particularly, in that it specified that all food supplements should be prepared according to good manufacturing practice. This amendment was intended to ensure that food supplements are prepared in such a way as to guarantee not just the highest quality of ingredients but also their innocuousness when taken repeatedly over long periods of time.

I therefore call upon Commissioner Byrne to deliver a formal undertaking to the effect that the provisions of the regulations to be drawn up stipulating that food supplements must meet high quality and safety standards in order to prevent small artisans – or health quacks, even – from marketing low quality, potentially dangerous products, will be made clearer and more explicit. In view of Parliament's clear, great responsibility in matters of the citizens' health, we must be highly focused in our work in order to ensure that all the individual Member States of the European Union are provided with rules making high standards of quality and safety a priority.

One last plea to Commissioner Byrne: in calling for this new documentation we should request that it be differentiated according to the composition of certain products, for this would reduce the expenditure for small and medium-sized businesses considerably.

Whitehead (PSE). – Mr President, it is not every day we have to congratulate a rapporteur for sheer civil courage in standing up to one of the most unscrupulous lobbies of our time. I do not believe that I have seen anything like it before. Like most of us, she has been accused of being a stooge of the pharmaceutical industry, of being ignorant and insensitive. We should say to those who made these accusations that we cannot be bought in this House and that we cannot be bullied either.

We owe our constituents our judgement, and mine is that for all its flaws and deficiencies, the directive is one that should be commended, with amendments, to those many people who are frightened and nervous, who depend on these food supplements to preserve their health, and some of whom even believe it is a matter of life or death. They fear this directive because they have been told that these products will be banned, that testing will be prohibitive, and that what remains will be swallowed up in a restrictive and prescriptive regime. We owe it to them to make certain that is not the case, and shallow populist rhetoric is not the way to do it. We need to make certain that small producers can come forward and be reassured that it will not be a costly and prohibitive process. Time after time, we see that this is ignored in directives. It has been ignored in the PPP directive.

The people who have the greatest need of our protection now are the small producers and we should help them. They should be able to register their product for simple and cost-effective evaluation. It should be a positive list which is rapidly expanded, with maximum dosages linked to real needs and not to outmoded daily allowances.

People such as Mr Davies have said: 'well, we have not done this for alcohol'. My God, we have tried! We know what lobby it is that stops us doing this on alcohol, which stops us having the labelling that is necessary. Two wrongs do not make a right. We have to look at this directive in terms of the way in which it will be interpreted. The more people make claims about their health, the more we see that this needs a safety evaluation. You cannot have the one without the other. If you make the claims, you must expect to see them tested, but they should be tested fairly, simply and in a cost-effective way to leave a regime of light-touch and user-friendly practices. That is what my country has had and I believe we can keep it. It is also possible to fit that in to the framework of this directive.

(Applause from the left)

Ahern (Verts/ALE). – Mr President, I believe that this directive represents a terrible infringement of our right to these products. Commissioner Byrne, your proposal, if implemented, could remove hundreds of vitamin and mineral supplements from our shelves, in the UK and Ireland in particular. These products are safe and have been accessible to consumers for years. But instead of going for a scientific safety assessment, the directive is based on an outmoded Recommended Daily Allowance dating back to the Second World War. This directive will force consumers to purchase these products on the Internet, where there are no controls. Is this what you really want? Consumers will not forgo these products.

I believe that this directive is an own goal. The European Commission has stated that its goal is the extension of the internal market. However, many Member States have put national interests first and lobbied to keep their markets closed. This is because the liberal regime in Ireland, the UK and the Netherlands is not acceptable to other Member States such as Germany and France. This means that products that are safe and widely available will be withdrawn from the market. The only criterion for taking products off the market should be one of safety.

As I said, this is an own goal and we will end up importing products from the US via the Internet. Is this really what you want?

Arvidsson (PPE-DE). (SV) Mr President, the EU's internal market is a fundamental pillar of European cooperation. It has given Europe free trade, competitiveness and welfare. There is however no need, in terms of the market, for uniform rules on the sale of vitamins and minerals.

Member States have different traditions in this area. In Sweden, as in the UK and Ireland, individuals can buy many preparations with strengths up to the maximum recommended daily

intake over the counter. This tradition must be respected and take precedence over the requirement for uniform rules.

What is really behind the proposal to regulate the sale of vitamin and mineral supplements at EU level? Opponents shift the blame onto the pharmaceutical industry on the grounds that it wants to sell more tablets. Those in favour of the regulation also point the finger at the pharmaceutical industry, but in this case as being opposed to the proposal because it wants to see even higher volumes of sales. I personally believe both sides are wrong.

I have not encountered any lobbyists from the pharmaceutical industry on this issue. The main driving force behind the eagerness for regulation is instead an overprotective mentality among EU civil servants and politicians.

Naturally, it is inappropriate to overdose on vitamins and minerals, but there is a huge margin between overdose and harmful levels. With the help of information on the bottles, most people are able to manage their daily vitamin intake themselves. We should trust individuals to do so.

I myself am a dialysis doctor and have seen many cases of poisoning. I have seen two young women poisoned by nutmeg and an older man suffering from severe nicotine poisoning, but I have never met anyone with vitamin or mineral poisoning. Kidney stone patients have to be very careful about taking much more than just vitamin C and calcium. It is Mrs Roth-Behrendt's doctor whose job it is to tell her what she should be careful of. Doctors have more important things to do than prescribe vitamins and minerals in higher doses than those accepted as food supplements.

de Roo (Verts/ALE). – (NL) Mr President, today, we are debating the vitamin directive at second reading. I must say that I am pro-European and in favour of harmonisation, but not in this manner.

I am pleased that the majority of the Committee on the Environment, Public Health and Consumer Policy are willing to grant producers of vitamin tables 36 months instead of 18 months in order to prove that their products are safe. While this is not a problem for large pharmaceutical producers, it does cause problems for small businesses, especially financially. In principle, it is wrong that they should have to prove that their products are safe while these may have been on the Dutch, British and Irish markets for dozens of years.

I am in favour of proving the safety of new vitamin tablets, but not of the old tablets. The Commission, the majority of the Council and Mrs Roth-Behrendt are saying, in fact, that all the old tablets are unsafe. This is why I shall be voting for rejection of the common position.

(Applause)

Bowis (PPE-DE). – Mr President, Commissioner, for 60 years we have had two traditions in Europe and had no significant health problems. As long as we have acceptance of the upper safe limit, consumer choice should prevail. Millions of people in Europe have bought vitamins and minerals of their choice. Not only have they had no problems, but their health and well-being have benefited. Now we are faced not with a health measure but with a single-market measure which threatens to omit 300 items on this list from the 'positive' list of items available. These 300 items are currently legally and safely on sale in the shops of my country and yours, Commissioner. They are not oddball items – they are things based on boron, calcium, copper, iron, manganese, potassium, selenium, zinc and so on. If these items fail in 18 short months to get the scientific committee's approval or to get their dossier in, then they will come off the market. That is not a problem for large manufacturers, but it is a very serious problem for the small ones. The cost and time to them may be prohibitive, and if items go off the market, then it is the consumer who will suffer. If they do go off the market they may, as we have heard, go abroad, go offshore or appear on the Internet, at some risk to the consumer.

What we need, Commissioner, is a simplified procedure for the items that have been omitted so that they can come onto the list quickly, and for that we need the 36-month timescale.

However, may I say also that Emilia Müller has suffered one of the worst assaults by people outside this Parliament that any Member has had to put up with. It is one thing to be e-mailed; it is one thing to be lobbied; it is one thing to be mass-lobbied; but to endure threats of violence, bullying and harassment as she and her family have is something which this Parliament will not accept. I say that to whoever is doing it outside: lay off, because we will not allow our fellow Member to suffer in that way. She has more integrity in her little finger than those people have in the whole of their bodies and I demand, Mr President, that you

suggest to the President of this Parliament that this matter be referred to the Legal Affairs Committee, with a view to seeing how a Member of Parliament under that sort of assault can be protected and allowed to do her job properly as a Member of this Parliament, as a rapporteur and as someone for whom we have great affection and respect.
(Applause)

President. – I too fully condemn this sort of behaviour and I will certainly inform the President. I do not know whether the President will decide to refer the case to the Committee on Legal Affairs but, in any case, I agree that something has to be done. There is a great difference between all the pressure and lobbies and being subjected to threats and abuse.

Korhola (PPE-DE). – (FI) Mr President, firstly I would like to express my sincere thanks to the rapporteur, Emilia Müller, who has attended to her task in difficult circumstances. Many of us have been pestered and obstructed to an unreasonable degree by those who have masqueraded as philanthropists and defenders of the sick. I have had thousands of messages a day sent to my own private e-mail address, sometimes as many as 8 000 unnecessary messages in one day. It is not really any longer a matter of public opinion when one and the same person sends 900 messages on the same day. That is simply criminal harassment. I can just imagine what it has been like for Mrs Müller!

Parliament should explore, not just in this case but especially in preparation for any future situation, practices of national parliaments that would guarantee Members' inviolability, safety and right to work in peace. All this harassment, with people being urged to express their opinions, has been absolutely pointless. It has seemed to be more of an unscrupulous marketing campaign on the part of a private business, which did not even intend to influence the work of Parliament. Presumably the party that got the campaign off the ground also knew that alternative treatments and vitamin cures and treatments are not banned or prevented in the EU. A simple thought has many times crossed my mind: the means is the message. If the means to lobby us has been so unscrupulous, it is hard to be convinced of the sincerity of the issue that lies behind it.

The two main purposes of the directive are, on the one hand, the approximation of national laws so that a single market for food supplements can be created, and, on the other, to establish an appropriate level of consumer protection in all Member States. For that reason, with this directive there should be an appropriate definition of food supplements, a scientific assessment of all ingredients should be carried out, requirements relating to consumer information and labelling should be specified, quality standards should be developed, and an adequate monitoring system should be guaranteed. All this should be totally acceptable to the honest players and even directly to their advantage.

Whilst the directive will help guarantee access to the markets for all manufacturers, Parliament has been especially keen to take account of the problems of small manufacturers. For that reason, Parliament wishes to extend, by way of its own compromise proposal, the eighteen-month deadline proposed in the Council's common position to 30 months.

If these conditions are met I see no reason to reject the common position.

Flemming (PPE-DE). – (DE) Mr President, what has happened to Mrs Müller should actually have repercussions. The word 'duress' occurs to me, as a lawyer. I am full of admiration for her, and I shall most certainly be supporting the common position.

I also feel, however, that this position touches the limits of moral acceptability. You see, I come from a country where vitamins are still available in pharmacies only. When anyone goes into a chemist's shop and buys vitamins, the chemist will say, 'Don't take too much, and please read the enclosed instruction leaflet'. It will cause great confusion in my country if that all changes. It will create the impression that vitamin supplements are really quite harmless after all. This is not the case. Vitamins have side-effects. The impact, of course, is not immediate. It is like when you drink too much. Not until you come staggering out of the pub do you begin to feel the effects on your health. It may have tasted good, but it will catch up with you at some point.

We are far more aware than we were ten years ago that vitamins do indeed have adverse effects. I really do find it irresponsible to set them loose on consumers in this way. To tell you the truth, Mrs McKenna, I am deeply disappointed. I thought you would be encouraging us to eat oranges, lemons, bananas, curly kale and other health foods. No, you are recommending

artificial substances to us, substances that are simply mass-produced by an industry where many people earn great fortunes. I fail to understand your thinking.

(Applause)

Byrne, Commission. – Mr President, I would like to express my satisfaction at the outset at the progress that has been made on this proposal for a directive on food supplements.

First of all, the objective of this legislation – and I must emphasise this – is not to ban food supplements. It has to do with maximum safety levels. I regret very much that I have to disagree with my friend Mr Bowis, for whose opinions I have the utmost respect, when he says that the position at the moment is that there are upper safe limits. That really is not the position. This will be the position after this legislation comes into place. That is the purpose of the exercise. This exercise will be based on scientific evidence and scientific evaluation.

It also dismays me to some extent to hear people in this House – also for whom I have enormous respect – express the view that this legislation is motivated by, of all things, lobbying of the pharmaceutical industry. That is a slander. It is absolutely wrong. It is unfair to say that I or the people who work for me would be motivated by such things. But sometimes people who make these allegations are the ones who are inordinately concerned about the role of industry. But what about the role of industry that profits from this piece of legislation not going through? What about that? Have they questioned themselves to determine whether they have been subjected to such a degree of lobbying from that industry that they have themselves been duped by that industry and tried to tar the Commission and those who advocate the passing of this legislation with a brush in a way that I find quite reprehensible?

The subject is not an easy one. We currently have very different attitudes, rules and practices among Member States. These impede the free circulation of food supplements within the European Union, and can deprive consumers from access to a wide range of these products.

So the case for harmonisation is obvious and is strong. I believe that the vast majority of stakeholders share that view. You will not, therefore, be surprised that I cannot support the views of those who propose, with Amendment No 7, to reject the common position.

A substantial number of Members of Parliament and of the Commission have been subjected to an orchestrated and misleading campaign against the adoption of this directive. This campaign has only been waged by those who do not share the general European interest.

I should also emphasise to Mr Blokland and others who make reference to being lobbied by consumers who have written letters, that may be the case. I suspect they may very well be people who have been seriously misled by those who profit by this legislation not going through the system.

(Applause)

The consumer organisations who are there to look after the best interests of consumers have not been misled. They are in favour of this legislation. BEUC has come out and said that it supports this legislation.

This is a strong endorsement, in my view, rather than anecdotal accounts of individual consumers who, in my opinion, have probably been misled by the statements made by many which are simply untrue. They have misrepresented the aims of the directive, used misleading arguments and misled consumers. This was made clear during the debate in the Committee on the Environment, Public Health and Consumer Policy.

Mrs Müller has done an excellent job as rapporteur. Her contribution to the advancement of the draft directive has been invaluable. I sincerely congratulate her and thank her. I would also like to acknowledge the responsible and very constructive role of Mrs Corbey, as shadow rapporteur.

The common position provides a very good framework for the regulation of food supplements in the European Union. It is designed to ensure that a very wide range of such products is available to consumers. The underlying criterion for a single market in food supplements is safety: adequate and appropriate labelling designed to inform consumers. Of course, these products must be used in the context of a diversified diet and in line with manufacturers' instructions.

The deadline for preparing dossiers for the evaluation of substances that are already on the market is an important issue. I have listened carefully to the concerns expressed, concerning small and medium enterprises, that a period of 18 months for the preparation of evaluation dossiers may be too short.

If that were to be the only amendment to the common position, I would be prepared to consider an extension of the period mentioned. I can, therefore, accept any one of

Amendments Nos 1, 3, 4 or 5 that relate to this point, provided that this would contribute to the adoption of the common position without further changes.

I have also taken careful note of the interventions with regard to good manufacturing practice for food supplements, which is the subject of Amendment No 2. I would like to reiterate what I said at first reading. The adoption of principles of good manufacturing practice by legally binding measures for specific categories of products is not appropriate in the case of foodstuffs. This already exists in relation to foodstuffs in many pieces of horizontal legislation. I am happy to take comfort from Mr Nisticò's contribution on the basis that he is certainly one of the MEPs I know here who is a scientist himself. He supports this legislation. He has asked me to take careful note of the risks to ensure the elimination of low-quality products when this framework legislation goes through the system. I am happy to say that will be taken into account.

The vast majority of these principles are covered by horizontal legislation, particularly in the directives on hygiene and control. These will apply also to the manufacture of food supplements. In the draft directive, we are referring specifically to the issue of purity criteria for the vitamins and minerals to be used. We have improved the relevant provisions following your amendment at first reading. We also foresee adopting specific technical rules with regard to the margins of tolerance for the amounts of vitamins and minerals declared to be present in food supplements. We believe that these rules are important for ensuring the quality of these products.

I am firmly of the view that this array of horizontal and specific rules fully covers all concerns expressed that these products should be manufactured to high-quality standards. I cannot, therefore, accept Amendment No 2 to adopt provisions on GMPs for food supplements. However, I reiterate that I will give priority to adopting the technical rules on margins of tolerance mentioned in Article 9(1).

Amendment No 6 refers to the criteria that will be used for setting the maximum levels for vitamins and minerals in food supplements. This point was the most difficult one to reconcile in the Council. The text of Article 5 is now carefully balanced. It is my belief that any disruption would jeopardise the whole proposal.

Finally, Amendment No 8 proposes an addition to the text that concerns principles for the functioning of the Standing Committee on the Food Chain and Animal Health and of the Scientific Panels of the European Food Safety Authority. I believe that these issues are adequately covered in the recently adopted general food law. They should not, therefore, be repeated in this specific directive. For this reason I cannot accept Amendment No 8. But I repeat and emphasise that the role of the European Food Safety Authority in this area will be of paramount importance and that this work will be done by independent scientists. The evaluation of that work by the Board of the European Food Safety Authority will be done in a fully transparent way – indeed, in public.

In conclusion, the Commission considers that the common position as such is satisfactory on all substantial points. The Commission would be ready to accept a technical modification of the common position to extend the period mentioned in Article 4.6.b. as in one of the amendments – Amendment No 1, 3, 4 or 5 – if that would help the adoption of the directive at second reading. The Commission cannot accept Amendments Nos 2, 6 and 8 and certainly does not support Amendment No 7, that calls for the rejection of the common position.

President. – Thank you Commissioner.

The debate is closed.

The vote will take place tomorrow at 12 noon.