

Dietary Supplements

A Guide through the Opinion Jungle



How harmful are dietary supplements?

This question may surprise you. How could dietary supplements be harmful? Regular reports issued by the media make assertions such as this one, and some even claim that dietary supplements can result in death. As an expert association dealing with this category of foods we feel competent to bring some clarity to the discussion of the diverse views on dietary supplements. We hope that our comments make sense, even if we have to go into some detail.

Vitamin trials with negative results

The starting point for many (if not all) media reports on the dangers of supplements is that the major vitamin trials have, for the most part, produced disappointing results, and even evidence of harmful effects in some cases. Without exception, the media reports always refer to the same vitamin trials. However, the inexperienced reader is given the impression that these are new scientific discoveries.

Scientific research is, however, very complex, much too complex to be properly discussed in a balanced way in simple newspaper articles. So we would like to explain why many of these studies do not provide conclusive information on dietary supplements.

- They were carried out on people who were ill or exposed to a high health risk (e.g. smokers and asbestos workers), so they cannot be regarded as trials of preventive measures.
- They mainly used isolated micronutrients, such as individual vitamins. However, in nature these substances are found in combination with many other vitamins and nutrients. It is now known that the interaction of nutrients contributes significantly to their health benefits.¹
- Finally, the vitamins were often given in very high doses in these studies (many times the amounts that are usually ingested with a healthy diet; see also "About the risks of dietary supplements" on page 6).

In this context, it is striking that even positive results are presented in a uniformly negative way. An example is the SU.VI.MAX study, carried out in over 13,000 adults in France², which showed that in **men** taking a combination of vitamins and minerals had a reduced risk of cancer by 31% while the overall mortality rate was reduced by 37% after 7.5 years of intake. However, more often than not, reports only mention that there was no effect in **women** - so that the study is mostly represented in a negative fashion. But the explanation is relatively simple: the women were better supplied with these nutrients from the start (they had higher blood levels of these nutrients) - in fact, their blood levels were about the same as in the men after the men had taken the supplements!

¹ This is referred to as „nutrient synergy“

² SU.VI.MAX Study (see References)

The statement that dietary supplements are superfluous or even harmful is therefore untenable. When micronutrients are in short supply, as is often the case in the European population, dietary supplements may have important health benefits. However, in later sections we will deal with some aspects of possible risks of certain supplements in a nuanced way.

What are dietary supplements?

As the name suggests, dietary supplements are food products that supplement our regular diet. These supplements are necessary, not only because many nutrients are present in insufficient amounts in our normal diet, but because the body may require a higher concentration of nutrients in certain situations. To meet the body's nutritional needs, concentrated mixtures of nutrients can be beneficial. Vitamin and mineral mixtures were the most popular forms of nutritional supplements for many years. In recent years, this range has been complemented by a huge number of other nutrient concentrates, such as fish oil products, prebiotics and probiotics³, various plant substances⁴ and many others. Law in Europe extensively regulates supplements. For example, there are rules as to which substances are allowed in dietary supplements, what quantity of a nutrient can still be regarded as a foodstuff and therefore different from a pharmaceutical product, and what advertising claims may be made for dietary supplements. Some of these regulations apply uniformly across the whole of Europe⁵, while others (such as maximum levels) are regulated at the national level.

Dietary supplementation with bioactive substances in the natural matrix

In our teachings on prevention we recommend, along with the Harvard School of Public Health (HSPH), dietary supplementation with preparations containing physiological doses (also in persons without visibly apparent deficiency symptoms or who are not classified as being in a special risk group). The HSPH was the first major institution to do major work on placing prevention and health promotion on a solid scientific footing. For over 40 years now, the HSPH has been publishing nutrition studies with the largest sample size and longest duration worldwide. So far, 48 HSPH scientists have been awarded a Nobel Prize.

Many slight deficiencies remain subclinical for years, but damage that is minor at first can accumulate and induce many other dysfunctions in a kind of domino effect, finally leading to clinically manifest diseases.

Complacency is not justified by the fact that obtaining a ready supply of nutrients is easier in our society today than ever before. Despite the availability of good nutritional information, the diet of a large part of the population is insufficient, for partly understandable reasons. Even during pregnancy, when women consciously wish to improve their diet, dietary deficiencies can be observed in a relatively large proportion of cases. According to the WHO, such nutrient deficiencies are not only observed in developing countries, but are also on the increase in the industrialized world [*Declaration of the WHO 2001/2002. Bradley 2002*].

I see the greatest need for supplementation in the food group fruits and vegetables (in which all diet studies show the worst and most prevalent deficiencies in all population groups). A dietary supplementation based on fruit and vegetables with a natural matrix of nutrients is preferable to a preparation containing nothing but a multivitamin mixture. What we look for in particular is whether the efficacy of a product has been confirmed in scientific studies conducted by reputable universities and research institutions.



*Visiting Professor Werner Seebauer, MD, Director of Preventive Medicine
Institute for Transcultural Health Sciences,
Viadrina Europe University, Frankfurt/Oder,
Germany*

³ These are products that either contain beneficial gut bacteria or encourage their growth.

⁴ Also referred to as 'botanicals'

⁵ DIRECTIVE 2002/46/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements

Dietary supplements from a paediatric cardiologist's perspective

Correct functioning of the **cardiovascular system** (blood pressure, cardiac function, blood coagulation system) is closely tied to the presence of antioxidants and micronutrients.

Nutritional reports from Austria, Germany and Switzerland (as well as other European countries) clearly document a deficient intake of important micronutrients.

The cause of this deficiency is not so much a lack of knowledge of the effects of these micronutrients but rather changed lifestyles characterized by stress, the fast pace of life and convenience-oriented living.

High-quality dietary supplements (controlled production, carefully selected ingredients such as omega-3 fatty acids, antioxidants and secondary plant substances, in physiological amounts, with proven scientific efficacy) can make an important contribution.

According to the above-mentioned nutritional reports, even the diet of **children and adolescents** does not fully meet the health needs of a young and growing body in most cases.

The deficiencies most recorded involve vitamin D and folic acid, followed by other important micronutrients.

Here as well, lifestyle would appear to be the main cause since the media and schools are relatively effective in disseminating general knowledge about a healthy and balanced diet.

High-quality dietary supplements, as described above, can also make a valuable contribution on a day-to-day basis. Besides ensuring a basic supply of nutrients, they can help promote a positive sense of awareness and possibly even changes in behaviour.



*Assoc. Prof. Gerald Tulzer, MD,
Paediatric Cardiologist
Director of the Paediatric Cardiac Centre,
Linz, Austria
Member of the ENA board*

How safe are dietary supplements

One of the most important aspects of legislation on dietary supplements is safety. One needs to be sure that these products have no harmful effects, even if they are taken for many years. In our view, the legal basis for this is well developed. The result is that any products from reputable companies and sources that are approved for sale in Europe can be regarded as safe. Nonetheless, even pharmaceutical products from dubious sources may be suspect (such products are often sold on the Internet), and this is unfortunately true for dietary supplements as well. However, this is obviously not an argument against dietary supplements in general - it's more a reason to buy such products from reputable suppliers.

On the basis of current legislation we can therefore say that general statements claiming dietary supplements are harmful are not tenable.

Not harmful, but useless?

We have already shown (above) that dietary supplements are beneficial if used properly. Reports from the European Food Safety Authority (EFSA) on food products have made headlines in the past (and will no doubt continue to do so even more frequently in future). As part of new legislation for the promotion of food products within the European Union⁶, the EFSA has compiled scientific assessments of such products, including many dietary supplements. Of the thousands of applications regarding health claims, 70-80% were rejected by the EFSA due to negative assessments (i.e., the EFSA did not consider that a health benefit was proven for these applications). Doesn't that show that such products are useless?

Certainly not! Let us explain this briefly.

⁶ REGULATION (EC) No 1924/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 20 December 2006 on nutrition and health claims made on foods

- These applications are for a very large number of food products; only some of these are dietary supplements.
- In fact, vitamins and minerals, the products that get most of the headlines, received the most positive assessments by EFSA.
- Many of the EFSA's negative assessments are not shared at all by some distinguished scientists - so they are clearly contrary to some well-established expert opinions.
- Many of the negative assessments were due to technical errors in the application, not because the products had no benefit.

Benefits of dietary supplements

Two key questions

What are the benefits of dietary supplements? A key question here is the **amount** of these nutrients that people ingest in their normal diet. Collection of such data is not as easy as one would wish, and the results of such studies are always somewhat inaccurate. However, there are general results from which one can draw concrete conclusions. Some examples of critical nutrients can be found in the table alongside.

Another key question is whether there are particular **population groups** that don't receive enough micronutrients or which have greater needs than average. Such groups are listed in the table alongside.

Isn't a normal diet enough?

It is often argued that the food supply is very good nowadays, and that nutritional supplements are quite unnecessary if one eats a balanced diet. We agree with this statement in principle. But, as one might say: „If only there was no ‚if‘.“ And the fact is that in practice, not everyone eats a *balanced diet*. And even here there are obvious deficits - the recommendations to eat at least five servings of fruit and vegetables a day, or to eat saltwater fish at least once a week illustrate the problem. Surveys show quite clearly that only a small percentage of the population actually follows these recommendations, in spite of campaigns that have been running for years like "five-a-day".

Critical Nutrients

Nutrients widely undersupplied

- Vitamin D
- Folate

Nutrients partly undersupplied

- Vitamin E
- Vitamin C
- Iron (in specific risk groups)
- Iodine (supply mainly through iodised table salt)
- Zinc
- Calcium
- Magnesium
- Selenium
- Omega 3 fatty acids (EPA, DHA)

Critical foodstuffs

- Fruits and vegetables (depending on different surveys only a maximum of 15% of the population meets the recommendation)
- Saltwater fish (rich source of omega 3 fatty acids)

Risk groups for some nutrients

- Infants and adolescents
- Pregnant and nursing mothers
- Women of reproductive age
- People on diets
- Elderly
- Chronically diseased people (e.g. diabetics)
- Users of some drugs
- Smokers
- Athletes involved in intensive activities

This discrepancy between dietary recommendations and people's actual dietary habits is the reason for the insufficient intake and the critical population groups shown above.

Rational dietary supplements

The tables on page 5 provide an overview. We differentiate between nutrients that are regarded as being generally useful, and those for which interesting and promising scientific data are available.

Wide use of iodine (in most countries covered with iodised table salt), folic acid, vitamin D, omega 3 fatty acids (fish oil and other sources) and also to some extent fruit and vegetable concentrates⁷ appears to be justified. For **certain situations** and **specific target groups**, minerals such as calcium, magnesium, iron, zinc and possibly selenium may be useful.

An often-discussed topic is supplementation with so called **antioxidants**. Well known antioxidants are the vitamins A, C, and E, but especially rich and diverse in this regard are fruits and vegetables with countless phytochemicals that act as antioxidants and protect against harmful free oxygen radicals (please read the expert opinion on page 8).

There is also valid scientific evidence for **substances** such as pre-and probiotics, glucosamine and chondroitin, certain amino acids, plant sterols and stanols, and certain fibres.

This list just gives a few important examples, and is not intended to be comprehensive.

Risks of taking dietary supplements

Even if we acknowledge the obvious benefits of such products, we still need to recognise that some of the points in the negative statements about dietary supplements are valid. The problem with these media reports is the one-sided and simplistic way in which they are written.

The dose makes the difference

As indicated in the section on vitamin trials (see page 2) certain rules have to be followed with dietary supplements, otherwise negative effects may occur.

As Paracelsus said centuries ago: „It is the dose that makes things poisonous“⁸. This applies to almost everything we may take in. Even drinking excessive quantities of water can result in death (not by drowning, but actually by drinking too much water). It is well known that certain vitamins can even have exactly the opposite effect at high doses⁹. This may help to explain why studies of smokers who were given large quantities of beta-carotene¹⁰ reported negative results in relation to cancer risk.

⁷ There are many scientific studies for these products, in contrast to countless other products, which gives us enough evidence so that we are able to take a concrete position towards this specific form of dietary supplementation.

⁸ Phillipus Theophrastus Bombastus von Hohenheim Aureolus, called Paracelsus, in his *Third Defensio*, 1538

⁹ Anti-oxidants (vitamins that can neutralise some harmful effects of oxygen) in high doses may also become pro-oxidants, so that the vitamins themselves generate harmful oxygen radicals.

¹⁰ The most important studies are the ATBC and CARET trials (see References).

Establishment of so-called “tolerable upper intake levels” (UL) for vitamins and minerals is important in this context. This means daily quantities that can be consumed regularly without any risk of harm (see adjacent table).

These ULs are not suitable for determining the amount of a nutrient in a dietary supplement, but only provide an indication which quantities of nutrients should not be exceeded per day. These levels, however, are so high that it is difficult to exceed them by taking dietary supplements as defined on page 3.

In this connection we would like to mention foods that are fortified with vitamins and minerals. By consuming this kind of foods (like fortified juices, breakfast cereals, etc.) on a regular basis and in high amounts one may easily lose control over the nutrients ingested. Here dietary supplements with clearly defined amounts of nutrients may be preferred.

Nutrient	UL
Vitamin A (µg)	800
Vitamin B1 (thiamine) (mg)	50
Vitamin B2 (riboflavin) (mg)	200
Vitamin B3 (niacin) (mg)	900
Vitamin B6 (pyridoxine) (mg)	25
Folate (µg)	1000
Vitamin B12 (cobalamin) (µg)	3000
Vitamin C (mg)	2000
Vitamin D (µg / IU)	50 / 2000
Vitamin E (mg)	300
Iron (mg)	45
Selenium (µg)	300
Iodine (µg)	600
Calcium (mg)	2500
Magnesium (mg)	250
Zinc (mg)	25

“Tolerable Upper Intake Level (UL)”, Scientific Committee on Food (SCF) of the European Community and US Food and Nutrition Board (FNB) of the Institute of Medicine.

Nutrients in nature are hardly ever found in pure form.

A problem, which has already been addressed on page 2 in the section on “trials”, is the administration of single nutrients. This is the usual practice in medicine and pharmaceutical research, where one normally combats diseases with single substances. It was thought that this principle could also be used with nutrients, and major vitamin trials were planned and conducted accordingly. It was reasoned that a diet rich in fruit and vegetables could reduce the risk of certain diseases. Blood tests also showed that people with high blood levels of certain substances, such as beta-carotene, were less likely to suffer from these diseases. The “logical” thing to do was to administer beta-carotene at higher doses, in the hope of achieving the same effect (but the result of this is well known by now - see above).

Although we now know that this approach does not work (the interrelationships between biological systems are much more complex than one might imagine), we currently see a somewhat similar „logic“, not with vitamins, but with phytochemicals. Products containing phytochemicals derived from sources such as green tea, grapes etc. are sold as „botanicals“, often (as used to be the case with vitamins) at doses much higher than would ever be reached in a normal diet. This can be a problem, especially if highly concentrated extracts and high doses of single compounds are involved. Comprehensive safety information on these substances is not yet available, so it is still impossible to assess what effects they might have. However, several reports of adverse effects are already under discussion.

Antioxidant supplementation

The subject of dietary supplementation with antioxidants is a “two-edged sword” since there are study data supporting both positive and negative effects. In principle, however, it can be stated that antioxidant supplementation is necessary when the basic diet does not supply sufficient antioxidants. This recommendation for supplementation is further reinforced when other factors such as mental and physical stress or unfavourable environmental conditions such as air pollution, heat, cold, etc. are also involved. In most of the studies, antioxidant supplementation also has positive health-related effects in chronic inflammatory diseases.

In selecting a certain antioxidant preparation, however, there must be clear scientific evidence that the relevant product exerts antioxidant effects in the human body. Preparation use should follow the study report recommendations regarding dosage and target group.



Assoc. Prof.
Manfred Lamprecht,
PhD, Sport Physiologist
Centre for Physiological
Medicine, Medical University,
Graz, Austria
Member of the ENA board

How good are synthetic nutrients?

There is no single answer to this question. There are vitamins (such as vitamin C) where there is virtually no chemical difference between the synthetic and natural forms, so that their effects are essentially identical. But we have to keep in mind that in nature vitamin C always is accompanied by other substances with usually synergistic effects.

However, the situation with vitamin E is quite different. Vitamin E is not a substance with just a single unique structure. For example, the synthetic vitamin E that was used in large trials was a mixture of left- and right-handed forms¹¹; however, in nature it only occurs as the right-handed form¹². The question is: what does the body do with the form that it can't use? There is no clear answer to this question, and some critics suggest that it could be harmful. More recently, it has become possible to synthesise the naturally occurring form of vitamin E, and most commercial products only contain this form.

Another issue is that vitamin E occurs naturally not only as alpha-tocopherol, but also as beta, gamma and delta forms. And as well as the tocopherols, there are also tocotrienols (and even other versions) - again in four different forms. This means that vitamin E occurs naturally

in at least 16 different forms, although only one of these is present in most dietary supplements. It is obvious that the natural forms are preferable, and the trend is to use these forms¹³.

In a nutshell

How harmful are dietary supplements? This was our opening question. To answer this question in short: dietary supplements that contain single and isolated nutrients and in high doses, should be regarded sceptically. Our review of critical media reports suggests they only discuss such products. However, one should not “throw the baby out with the bathwater” and judge the whole issue on the basis of a few dubious examples. To illustrate this with another example, if one applied this logic to cars, one would not allow them as a form of transport - they are much too dangerous.

We would like to follow the opinion of the Harvard School of Public Health: “A daily multivitamin is a good nutrition insurance policy. Some extra vitamin D may add an extra health boost.”¹⁴

¹¹ all-rac-alpha-tocopherol

¹² RRR-alpha-tocopherol

¹³ unfortunately the use of natural substances often causes legal challenges

¹⁴ source: <http://www.hsph.harvard.edu/nutritionsource/what-should-you-eat/vitamins/>

Omega-3 fatty acids

Fish oil supplements contain the omega-3 fatty acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). Fish oils come from the flesh of some fish species and from the livers of other species. Fish oils are not pure omega-3 but contain several other fatty acids. They also contain fat-soluble vitamins (Vitamins A, D and E); liver oils (e.g. cod liver oil) have more of vitamins A and D than fish body oils. Standard fish oils are about 30% EPA and DHA. Fish oil concentrates have a higher content than this. The likelihood of fish oils from reputable sources containing significant levels of contaminants is low since the processing of fish oils for use in supplements removes contaminants if they are present in the starting oil. Fish oil supplements have been used in a large number of trials in humans, many demonstrating positive effects on physiological functions, disease biomarkers and clinical outcomes. Omega-3 fatty acids have received several positive opinions from the European Food Safety Authority (EFSA).

There is a need for pregnant and nursing women to supply DHA to their baby to support brain and eye growth and development.

Intakes of EPA and DHA among adults in European countries are often quoted to average about 200 mg per day. However, these numbers represent the average intake of the small number of individuals who consume oily fish regularly and the large number of individuals who do not eat this kind of fish. An Australian study reported a median intake of EPA plus DHA of 30 mg per day (Meyer et al., 2003). Recommendations for intake of EPA plus DHA to assure optimal health are typically in the range of a minimum of 200 to 500 mg per day. The FAO/WHO recommendation for adults is at least 250 mg EPA plus DHA per day (FAO/WHO, 2010), a recommended intake mirrored by EFSA (EFSA, 2010). Such intakes can be achieved by regular use of fish oil supplements. However, higher intakes may be needed to influence some functions, such as inflammation.



*Prof. Philip C. Calder, PhD, Professor of Nutritional Immunology
Faculty of Medicine, University of Southampton, UK
Member of the ENA board*

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My personal mix

The subject of dietary supplementation quickly, and usually intensively, leads to discussion. The sometimes very high expectations consumers have of such products, on the one hand, and the often highly emotive and dismissive reporting in the media, on the other hand, generate a climate that is not conducive to calm and considered reflection.

This is why I often simply limit myself to telling people which dietary supplements I personally use, based on current scientific understanding. My personal mix essentially includes a dietary supplement based on fruit and vegetable juices including folic acid, a daily dose of vitamin D and a fish oil product. We must not forget, however, that prevention goes far beyond just swallowing dietary supplements. I therefore, of course, also set store by eating well on a diet high in plants, doing regular exercise and maintaining a healthy mental balance in everyday life (an aspect which is, unfortunately, often overlooked in a materialistic world).



*Peter Prock,
MD, Physician for Preventive Medicine and Scientific Advisor
President of the ENA, Basel, Switzerland*

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info@enaonline.org, www.enaonline.org

Editor in Chief:

Dr Peter Prock, ENA

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