Demarcation of Medicinal Products and Food in the European Union – Focus: Food Supplements

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Abbreviations

AMG	Arzneimittelgesetz
BfR	Bundesinstitut für Risikobewertung
BGH	Bundesgerichtshof
BVL	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
DGE	Deutsche Gesellschaft für Ernährung
EC	European Community
ECJ	European Court of Justice
EEC	European Economic Community
EFSA	European Food Safety Authority
EMEA	European Medicines Agency
EU	European Union
GMO	Genetically Modified Organisms
KG	Kammergericht
LMBG	Lebensmittel- und Bedarfsgegenständegesetz
NemV	Nahrungsergänzungsmittelverordnung
NRW	Nordrhein Westfalen
OLG	Oberlandesgericht
OTC	Over the Counter
OVG	Oberverwaltungsgericht
SCF	Scientific Committee on Food
VG	Verwaltungsgericht

1 INTRODUCTION

Medicinal products and foodstuffs are two categories of products which are governed by completely different regulations. In fact, at EU level two different departments are responsible for these products in the European Commission. Medicinal products belong to the DG Enterprise whereas foodstuffs belong to DG Health and Consumer Protection.

For the marketing of both product groups, different prerequisites have to be fulfilled. Medicinal products for example have to undergo a marketing authorisation procedure and can only be marketed if and when the marketing authorisation is granted, while foodstuffs do not need a marketing authorisation.
Therefore, a differentiation between medicinal products and foodstuffs is essential. However, yet there are products which are not so easy to classify because of their ambivalent ingredients (e.g. vitamins and minerals), their presentation or their area or usage.
Some foodstuffs which are often involved in demarcation disputes between foodstuffs and medicinal products include:

- Novel Foods and Novel Foods Ingredients according to Regulation (EC) No 258/97[1], e.g. new substances containing, consisting of, or produced from GMOs.
- Foodstuffs for particular nutritional uses according to Directive 98/398/EEC[2], *which are foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability,* e.g. food for infants, special diets, etc.
- Food Supplements according to Directive 2002/46/EC[3], i.e. *foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities*
- Dietary Foods for special medical purposes according to Directive 1999/21/EC[4], a *category of foods for particular nutritional uses specially processed for formulated and intended for the dietary management of patients and to be used under medical supervision. […]*

Until 2002, a harmonised definition was only available for medicinal products. Foodstuffs were only defined on a national level in the Member States. Therefore, different classifications of products in the Member States were possible; this led to trade problems for manufacturers and suppliers which wanted to import a product legally marketed as a foodstuff in one Member State into another Member State, if the latter classified the product as a medicinal product.
On the other hand, different classifications of a product on national level developed between manufacturers and competitors or authorities.
These classification problems were often clarified by the national jurisdiction or the European Court of Justice.
In 2002, a harmonised definition for foodstuffs was introduced with Regulation (EC) No. 178/2002[5]. A harmonised definition for food supplements was also published with Directive 2002/46/EC.[3]

In the following, first the classification between foodstuffs in general and medicinal products up until 2002 is discussed. Secondly, the classification after the introduction of the

harmonised foodstuff definition is discussed – with a primary focus on food supplements as a subgroup of food supplements often affected by demarcation problems.
The definition and jurisdiction are taken into account in this discussion. As regards national jurisdiction, only German decisions were considered.

2 CONSEQUENCES OF A CLASSIFICATION AS MEDICINAL PRODUCT OR FOODSTUFF

Foodstuffs and medicinal products are two different groups of products regulated by two different legal areas in EU law. Food supplements are a subgroup of foodstuffs.
As the effects of foodstuffs and medicinal products can overlap the demarcation between the groups is not always easy. The products with a "dual-use" -character are also called "borderline" products, as they are often in a grey zone between foodstuffs and medicinal products.
Some products even can be foodstuffs or medicinal products, such as vitamins or minerals. Nevertheless, the classification of a product as a foodstuff or a medicinal product has major consequences for the product's marketing strategy.

2.1 Marketing authorisation

In order to market a medicinal product, a marketing authorisation is needed. The relevant authority of the Member States grants this marketing authorisation. The application must be submitted to the authorities of each single Member State of the EU or, in special cases, (unlikely in the case of borderline products), to the EMEA.
In order to prove the quality, efficacy and safety of the product detailed information and data have to be submitted with this application. Essential (pivotal) studies have to be undertaken, especially where safety and efficacy are concerned. – for known active ingredients safety and efficacy can also be verified bibliographically if sufficient literature is available. Hence the development of a medicinal product is expensive and takes a long time. After all studies have been carried out and the application has been submitted to the authorities the marketing authorisation procedure starts. This procedure should take no longer than 210 days[6]. In practice, it takes between 1.5 and more than 3 years before marketing authorisation is granted.
Foodstuffs do not require any marketing authorisation. They can be marketed as soon as the development is finalised. An authority does not check the quality and safety before the product is launched. Samples are collected and tested according to a monitoring program by the authorities.[5]
In the case of foodstuffs and medicinal products, the person who markets the product has responsibility for the safety of the product.

If a product marketed as a foodstuff is classified by the relevant authority or by a ruling as a medicinal product, the vendor would be selling a medicinal product without marketing authorisation at that point of time. This is illegal. The product must be taken from the market directly. The vendor must reckon with a penalty if he continues to market the product without marketing authorisation.

In short, foodstuffs can be launched on the market directly after development. For medicinal products, a marketing authorisation procedure must be undergone; this is expensive, as the product cannot be sold for a lengthly period.

Incorrect classification by the vendor can lead to withdrawal of the product from the market and a fine.

2.2 Prices

In general, prices for foodstuffs such as food supplements are lower than prices that can be achieved with medicinal products which are often supplied only via pharmacies or drugstores. People seem to spend more money on a medicinal product than on a food supplement.

2.3 Advertising, promotion

Advertising for medicinal products is subject to strict rules as laid down in Title VIII of Directive 2001/83/EC[6]. The advertising of foodstuffs is not so strictly regulated and leaves more scope for the supplier/manufacturer. In the case of foodstuffs, misleading the consumer is strictly prohibited. Advertising which claims to the consumers that the product is a medicinal product is not allowed[7].
In short, the framework for possible advertising is much wider for foodstuffs/food supplements than for medicinal products.

2.4 Free movement of goods

In the Treaty[8] of the European Community, the free movement of goods is one of the most important issues.

Article 28 (ex Article 30)
Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States.

Article 30 (ex Article 36)
The provisions of Articles 28 and 29 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on ground of […] the protection of health and life of humans, animals or plants; […]

The different classification of medicinal products and foodstuffs in the individual Member States leads to problems with regard to imports from one Member State to another. Because there is no marketing authorisation, products legally marketed in one Member State cannot be imported to another where the same product is classified as a medicinal product.
Marketing of a "dual-use" -product in the EU can therefore be a major challenge for a vendor. Accordingly, a harmonised classification in the EU is of great importance.

2.5 Growing health market

The health market is growing rapidly and the number of borderline products is rising, with the result that classification is becoming more and more important.
It seems that people's health awareness is increasing. Unfortunately, this does not lead to better nutrition but to the consumption of an increasing number of food supplements.

All things considered, harmonisation is important to improve the free trade of goods on the one hand and to secure the protection of health on the other hand. Therefore, a harmonised classification of medicinal products and foodstuffs/food supplements and harmonised regulations for labelling and advertising become necessary.

3 DEMARCATION BEFORE 2002

3.1 Regulations and definitions

Before 2002 there was only a harmonised definition for medicinal products in the EU. Foodstuffs were only defined at national level. The valid definition for medicinal products was contained in Directive 65/65/EC,[9] which was then assimilated into Directive 2001/83/EC[10]:

Any substance or combination of substances presented for treating or preventing disease in human beings.

Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product.

The first group of medicinal products can be called "presentation medicinal products", as the definition focuses on the presentation of the products. The second group are the "function medicinal products".

In Germany, the definition for foodstuffs is contained in Article 1 of the LMBG[11]:
According to the purpose of this Regulation, foodstuffs are substances that are intended to be consumed by humans in an unchanged, prepared or processed form except substances that are predominately intended to be consumed for other purposes than nutrition or consumption.

This German definition explicitly contains the nutrition or consumption purpose. This criterion was important for national classification in Germany.

The demarcation was mostly decided by national courts or the ECJ due to different decisions in the Member States and different classifications by the manufacturer and competitors, - a summary of the most important judgements relevant to the demarcation is provided in the following chapters.

3.2 National German Decisions

BGH I ZR 209/92 – "Garlic capsules" – 19 January 1995[12]
In this process a previous judgement from the Landgericht Düsseldorf (4 November 1992) in which a "garlic capsule" product was classified as a food supplement was revised.
The product had no indications or health claims on its package. "Food supplement" and "for spicing" were labelled.
Nevertheless, for the following reasons the BGH classified the product as a medicinal product:

- For the classification not only the product itself must be taken into consideration. A large number of competitors marketing and advertising garlic products must be considered. These competitors market garlic capsules as medicinal products. Therefore, it is known that garlic includes ingredients that can reduce blood pressure and cholesterol and thus prevent arteriosclerosis.
- For the customer products in capsule form are generally medicinal products and only in exceptional cases food supplements.

Hence the customer has the implication that a garlic product in capsule form has a pharmacological effect even if it is not stated in the labelling.

- The use of blisters for packaging and the dosage recommendation are further facts indicating the product is a medicinal product.
- According to BGH, garlic capsules contain no nutrients that serve the development or preservation of the human body, as opposed to e.g. vitamins. Therefore, a nutritional purpose is missing and classification as a foodstuff is impossible.
- Capsules are an unusual form for a garlic product intended for seasoning meals. Such products are usually granules, garlic salt or garlic oil in bottles, in addition to fresh garlic itself.

In short, according to all listed reasons the BGH stated that the customer would use the capsules not for nutritional or consumption purposes but in order to prevent arteriosclerosis. This BGH judgement had a great impact. Up to now, all garlic capsule products have been classified as medicinal products in Germany.

OVG NRW 23 B 2280/96 – "saturation capsules" – Decision of 02 January 1997[13]

Capsules containing ingredients that swell in the stomach were classified as medicinal products in the transition period for the implementation of the German medicinal devices regulation as they have no nutrition or consumption purpose. The product in question was originally labelled as a food supplement.
The supply with minerals and vitamins played a minor role in the view of the OVG. Additionally, the contained proteins were excreted indigested and the effect of fibre was not the major purpose of the product. The major purpose was to stop hunger. Therefore, the product influenced the condition and functions of the body and had to be classified as a medicinal product.
Besides this, the presentation (capsules form, package leaflet, and dosage recommendations) and the supply via a health service, the high price and the distribution through pharmacies indicated that the product is a medicinal product.

Bayerischer Verwaltungsgerichtshof 25 CS 96.3855 – "shark cartilage powder" – Decision of 13 May 1997[14]

An earlier decision that classified shark cartilage powder as a medicinal product was revised for the following reasons:
According to AMG[15] foodstuffs are exempted from the definition of a medicinal product. Because of the AMG[15] definition, a product is a foodstuff, if an averagely well-informed consumer does not get the impression that the purpose of the product is healing. Shark cartilage powder has no pharmacological effect. The product was not presented as a medicinal product but as a food supplement. The high prices of the product and the fact that it was distributed through pharmacies were no evidence for a medicinal product, even though these issues had a strong association with medicinal products.

OLG Hamm 4 U 131/97 – "Powder with probiotic cultures" – Judgement of 2 October 1997[16]
The court classified a powder with probiotic cultures intended to be mixed with fluids as a medicinal product. According to the OLG, the external form – bottles with packages leaflet and dosage recommendations- and the promotion of the products were clear evidence. In the promotion, health claims such as "treating", "therapy" and "regulation of immune reactions" were included. The dosage recommendation stated a doubling of the dosage in the first 4 weeks and a recommendation for intake in the evening before sleep. These recommendations were not typical of foodstuffs according to the court.
Therefore, the OLG concluded that the product is undoubtedly a medicinal product with the purpose of supplying the intestinal flora with bacteria.

OLG München 29 U 4085/97 – "Gingko-biloba" – Decision of 16 October 1997[17]
In this decision the OLG classified honey wine with 10 % milled leafs of the Gingko tree as a medicinal product due to the fact that the consumer will gain this impression knowing that several other products with Gingko biloba (even as extracts) and similar names were marketed as medicinal products. Additionally, the external form (ampoules) and the dosage recommendation indicated this to the consumer.

VG Düsseldorf 16 L 1708/99 – "Pu-Erh-Tea capsules" – Decision of 13 August 1999[18]
Hanseatische Oberlandesgericht Hamburg 3 U 173/99 – " Pu-Erh-Tea capsules" – Judgement of 4 May 2000[19]
In 1999, Pu-Erh-Tea capsules were classified as a medicinal product by the VG Düsseldorf. According to the court, a product in capsule form could not have a consumption purpose, as swallowing of capsules give no consumption. Additionally, a nutritional purpose could not be seen. The promotion that the product is suitable for slimming indicated to the consumer that he is taking in a medicinal product. This was strengthened by the external form and dosage recommendation.
One year later, the Hanseatische Oberlandesgericht Hamburg classified Pu-Erh-Tea capsules as foodstuffs because of a missing pharmacological effect. A tea concentrate was not usual for a foodstuff, but not excluded. Even a consumption value could not be excluded. According to the court "consumption" had to be seen in a wider sense, including the neutral "intake". The published claims that the product could influence body shape do not necessarily indicate that the product is a medicinal product.

BGH I ZR 97/98 – "L-Carnitine" – Judgement of 10 February 2000[20]
In this decision regarding a product containing 500 mg Carnitine, the BGH stated that the decisive factor for the demarcation is the predominant purpose for an averagely well-informed, attentive and judicious consumer according to objective characteristics.
BGH criticised that a former judgement failed to indicate whether the product containing 500 mg Carnitine had an objective purpose of a medicinal product in the view of the consumer. In general, a judicious consumer would not assume that a product presented as a food supplement is a medicinal product if the recommended dosage had no pharmacological effect.
The BGH also confirmed that a declaration as "dietary food" is no sole evidence to classify a product as a foodstuff and that the external form "capsule", the packaging in "blisters" and the distribution through pharmacies is no sufficient indication for a medicinal product.
In summary, the product was classified as a foodstuff.

BGH 2 StR 374/00 – "Vitamins" – Judgement of 25 April 2001[21]
Foodstuffs containing three times more vitamins than the recommended daily DGE (Deutsche Gesellschaft für Ernährung) amount have always been classified as medicinal products in Germany. In case 2 StR 374/00, BGH stated that for the classification the complete product must be assessed. A general classification because the recommended daily amount is exceeded three times is not possible. Furthermore, the court announced that the external capsule or tablet form, the packaging or the intake recommendations are not sufficient evidence for a medicinal product as they are also usual for food supplements

Hanseatisches Oberlandesgericht 3 U 013/01 – "Soya isoflavones" – Judgement of 31 May 2001[22]
According to the court, a soya isoflavone product (vegetable estrogens) was classified as a food supplement. Disorders during the menopause need not directly be an ailment. A product recommended for disorders in the menopause can be a food supplement. The major purpose for an averaged well-informed consumer is important.
In this case the product was clearly presented as a food supplement. The form "capsule" was not an indication for a medicinal product according to the court. Soya isoflavones can be and are consumed with the normal diet in the same amount. The court also pointed out that the pharmacological effect itself is a difficult factor for demarcation.

Hessischer Vewaltungsgerichtshof 11 TZ 3006/01 – "Green Tea Capsules" – Judgement of 17 December 2001[23]
According to the court Green Tea Capsules were food stuffs for the following reasons:
Firstly, the average well-informed consumer does not get the impression that this is a medicinal product just because the product is marketed in capsules form.
Secondly, products that are consumed for their stimulating effect, such as tea, coffee, etc., serve consumption. As green tea may have stimulating effects if taken in capsule form, a consumption purpose could not be denied according to the court.

BGH I ZR 273/99 – "Nutrition for sportsmen" – Judgement of 11 July 2002[24]
In this case a judgement was revised in which several products for the nutrition of sportsmen were classified as medicinal products because they were advertised in a catalogue as being capable of building up muscles. According to BGH, the pharmacological effect and the presentation of the package must also be taken into account. For classification, the purpose from an objective point of view is important. The products cannot be classified as a group in general, but must be assessed product by product.

3.3 ECJ Decisions

Some important judgements of the ECJ have reflected developments in the demarcation between foodstuffs and medicinal products. Some of these judgements do not only cover the demarcation between foodstuffs and medicinal products but also between cosmetic and medicinal products. Nevertheless, these decisions have also influenced the foodstuff/medicinal product demarcation. A selection of important decisions is presented in the following.

C-227/82 – "van Bennekom" – Judgement of 30 November 1983[25]

In this judgement, the ECJ stated some important opinions with major influence on future national and ECJ decisions regarding demarcation.

- The ECJ quoted that there are two different groups of medicinal products covered by the former Directive 65/65/EC[9]: those based on the criterion of "presentation" and those based on the criterion of "function". "Presentation" must be seen in very broad terms according to the ECJ. *Whenever any averagely well-informed consumer gains the impression, which, provided it is defined, may even result from implication, that the product in question should, regard being had to its presentation have an effect such as described by the first part of the community definition.*
  That means that even if the manufacturer does not explicitly label the product as a medicinal product, the product would have to be classified as such.

- The external form of a product, such as capsule, tablet or pill, cannot be the sole or conclusive evidence. But it can serve as evidence that the manufacturer has the intention of marketing the product as a medicinal product. In national German judgements, external forms typical of medicinal products such as tablets, pills, capsules, powders, etc., were seen as evidence for a medicinal product. [12,13]

- *The classification of a vitamin as a medicinal product must be carried out case by case, having regard to the pharmacological properties of each such vitamin to the extent to which they have been established in the present state of scientific knowledge.*
  The ECJ emphasises the important role of the pharmacological property of each constituent of the product.

- In 1983, only the definition of medicinal products was harmonised by the European Union. Foodstuffs were only defined nationally. Because of this absence of harmonisation *it is for the Member States [---] to decide what degree of protection of health and life of humans they intend to ensure, having regard however to the requirements of the free movement of goods within the community.* The ECJ stated here that as long as no harmonisation is in force national courts have to judge in the case of demarcation problems with the background of health protection. This also means that different national decisions are possible in the Member States. A product legally marketed as a foodstuff in a Member State could be prevented from being imported to another Member State for health protection reasons if it did not come under the foodstuff definition of this Member State and is regarded as a medicinal product there.

C-369/88 – "Delattre" – Judgement of 21 March 1991[26]

- As in the "van Bennekom" decision[25], the pharmacological property of a product is an important factor for the demarcation between foodstuffs and medicinal products. Additionally, the ECJ emphasised again the important role of national decisions in the Member States and the possibility of different decisions in these.
  In order to decide whether that product is to be categorized as a medicinal product or as a foodstuff, it is necessary to have regard to its pharmacological properties. The fact that such a product is classified as a foodstuff in one Member State does not preclude its being treated as a medicinal product in the State concerned if it possesses the relevant characteristics.

- *A product may be regarded as being presented as a medicinal product if its form and the manner in which it is packaged render it sufficiently similar to a medicinal product and, in particular, if on its packing and in the information provided with it reference is made to research by pharmaceutical laboratories, to methods or substances developed by medical practitioners or even to testimonials from medical practitioners recommending the qualities of the product. A statement that the product is not medicinal is persuasive evidence which the national court may take into consideration but is not in itself conclusive.*

- *It is for the national authorities to determine, subject to judicial review, whether or not, having regard to its composition, the risks which its prolonged consumption may entail or its side-effects and, more generally, all of its characteristics, a product presented as counteracting certain conditions or sensations, […].*

C-60/89 – "Monteill and Samanni" – Judgement of 21 April 1991[27]

This judgement dealed with the demarcation between medicinal products and cosmetic products.

- According to this judgement the product had to be classified as a "presentation medicinal product" when it is presented for treating or preventing disease. *That classification is necessary in view of the aim of protecting public health pursued by both Directives, since the legal rules applicable to proprietary medicinal products are more rigorous than those applicable to cosmetic products in view of the particular dangers which the former may present to public health and cosmetic products generally do not.* In food law and cosmetic law, precautions and controls are implemented. The protection of public health is an important aspect of the foodstuff and medicinal product regulation system. It is not admissible to market foodstuffs or cosmetic products that are dangerous to public health. Therefore, risks and side effects should not be used to classify a product as a medicinal product. Otherwise there is no difference between a medicinal product and an unhealthy foodstuff or cosmetic product.[28,29]

- For the classification as a "function medicinal product" *account must be taken of the adjuvant also entering into the composition of the product, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks its use may entail.* The composition plays and has always played an important role in the classification of a product as a medicinal product.

C-107/97 – "Rombi" – Judgement of 18 May 2000[30]

In France, an L-Carnitine product was classified as a normal foodstuff by a regional court whereas the manufacturer declared his product to be a foodstuff for particular nutritional uses. In addition to Directive 89/398/EEC[31], a national law was in force in France, which permits L-Carnitine products as an additive for nutritional purposes only for the manufacture of foodstuffs and foodstuffs intended for particular nutritional uses for infants and young children in small doses. The addition of L-Carnitine to normal foodstuffs was prohibited in France.

According to ECJ

- *food supplements such as those at issue in the main proceedings, which contain L-Carnitine in high doses and which are marketed on the basis that they are suitable for*

a particular nutritional purpose, fall within the scope of this Directive unless the national court establishes that they are not suitable for the nutritional purposes that the manufacturer claims they are or that they do not fulfil the particular nutritional requirements of one of the categories of persons referred to in Article 1 (2) (b) (i) and (ii) of the Directive.

- *Member States can maintain in force after the transposition of Directive 89/398/EEC*[31] *prior national legislative provisions such as those at issue in the main proceedings which apply to additives authorised in the manufacture of foodstuffs intended for particular nutritional uses, even if those provisions are based on a classification other than that used in Directive 89/398/EEC*[31].
- *It is for the national court to decide whether the rules on the free movement of goods within the Community have any application to an activity such as that at issue in the main proceedings.*

Even if this judgement does not deal with the demarcation of foodstuffs and medicinal products, it clearly shows how much importance the ECJ attaches to national decisions of Member States.

C-387/99 – "Vitamins – Germany" – Judgement of 29 April 2004[32]

Even if this judgement is dated April 2004, it must be seen in the light of the regulations in force in 1999 when the application was made.
Vitamin and mineral preparations which are lawfully produced or marketed as food supplements in other Member States and which contain three times more vitamins and minerals that the daily amount recommended by the DGE are classified as medicinal products in Germany.
The European Commission declared that Germany has failed to fulfil its obligations under Article 30 of the EC Treaty[8] because of this.
The general rule of classifying all vitamin preparations as medicinal products if they contain more than three times the recommended daily amount regardless of the vitamin in their composition is criticised. As a consequence, vitamin preparations that are not capable of "restoring, correcting or modifying human physiological functions could be classified as medicinal products that need a marketing authorisation for trade". For the ECJ, the German practice is unreasonable, as it is not based on a case-by-case analysis but on a general systematic approach. This is a barrier to trade in the EU and an infringement of Article 30 of the EC Treaty[8].

C-150/00 – "Vitamins – Austria" – Judgement of 29 April 2004[33]

As in the judgement in case C-387/99[32] the ECJ made his decision in another vitamin case.
The ECJ declared that *by automatically classifying as medicinal products vitamin preparations or preparations containing minerals lawfully manufactured or marketed as food supplements in other Member States if they contain either more vitamins, other than vitamins A, C, D, or K, or minerals other than those in the chromate group, than the simple daily amount of those nutrients, or vitamins, A, D or K, regardless of content, the Republic or Austria failed to fulfil its obligations under Article 28 EC.*

3.4 The German Guidance Document[34]

Because of the grey area between foodstuffs and medicinal products, the Arbeitsgemeinschaft Lebensmittelchemischer Sachverständiger der Länder and BgVV (Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedizin) published a guidance document[34] for demarcation in Germany based on law, legal comments, national and EU cases and the experience of experts.

According to this guidance document, the following issues should be checked in particular:

- the purpose stated by the manufacturer
- classification as a foodstuff possible from a scientific point of view with reference to the definitions in § 1 LMBG[11] and § 2 AMG[15]
- the general impression of consumers
- a product that is a medicinal product from an objective point of view cannot be classified as a foodstuff only because it is labelled as "not a medicinal product"
- the general impression of consumers can change over time

A catalogue with test characteristics / questions and examples of answers and conclusions is also presented:

No.	Characteristic / Question	Examples of answers and conclusions
1	What is the name under which the product is sold?	foodstuff: name defined in laws or directives medicinal product: marketing authorisation, registration
2	What are the components?	foodstuff: substances that usually serve the purpose of nutrition or consumption medicinal product: overwhelming medicinally used herbal components or chemically defined active ingredients
3	What is the quantitative composition?	foodstuff: essential nutrients in amounts relevant from the nutritional and physiological point of view (lower than three times the daily dose) medicinal products: doses with pharmacological, therapeutic effect; composition comparable to already approved medicinal products
4	What is the main purpose according to the manufacturer?	foodstuff: nutrition, consumption, refreshment, particular nutritional use (athletes, pregnant women, breast-feeding women) medicinal products: activation of defence system, strengthening of the immune system, protection against infections and other health claims
5	What does the patient information leaflet / package leaflet say?	foodstuff: to consume, eat, drink medicinal product: take, use, three times daily, cure
6	What does the package/ presentation look like?	foodstuff: food supplements are now often marketed in forms not typical of foodstuffs. A typical foodstuff labelling is not definite evidence for a foodstuff. medicinal product: tablets, capsules, dragées,

		ampoules, drops, medicinal bottles. The Pharma.-Zentralnummer is not evidence of a medicinal product.
7	Is there accompanying information /promotion material / press articles?	foodstuff: nutrition information; information about fulfilment of demand, nutritional or consumption value medicinal product: reference to health professionals, letters of gratitude, cures, curing or prevention of health damage through environmental influences, slowing down of ageing processes
8	What is the distribution channel?	medicinal product: exclusive distribution through pharmacies, practitioners or alternative practitioners, direct distribution

This guidance document summarizes the criteria used by German experts for the demarcation of foodstuffs and medicinal products.

4 DEMARCATION IN THE CURRENT REGULATION

4.1 Regulations and definitions

4.1.1 Foodstuffs

An EU legal definition for **foodstuffs** is given in the basic food Regulation (EC) No 178/2002[5] for the first time. This Regulation is directly binding in all member states of the EU.
According to Article 1 of this Regulation the definition is as follows:

For the purpose of this Regulation, 'food' (or 'foodstuff') means any substance or product, whether processed, partially processed, intended to be, or reasonably expected to be ingested by humans.
'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directive 80/778/EEC and 98/83/EC.
'Food' shall not include:

- *(a) feed;*
- *(b) live animals unless they are prepared for placing on the market for human consumption;*
- *(c) plants prior to harvesting;*
- *(d) medicinal products within the meaning of Council Directive 65/65/EEC and 92/73/EEC;*
- *(e) cosmetics within the meaning of Council Directive 76/768/EEC;*
- *(f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC;*
- *(g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971;*
- *(h) residues and contaminants*

The definition is very general: substances or products intended to be ingested by humans. There is no specific purpose defined such as nutrition or consumption as it is for example in the German definition of LMBG[11]. Instead of a purpose, a number of products are mentioned which belong to foodstuffs and another group of products are listed which clearly do not belong to foodstuffs. These non-food products include medicinal products as contained in Directive 65/65/EEC[9] which is in the meantime codified in Directive 2001/83/EC[10].

By this definition, any changes to the definition of medicinal products always directly influence the definition of foodstuffs. The definition of medicinal products is laid down in a Directive which has to be implemented in national law. As this definition is part of the foodstuff definition of a directly binding regulation, the definition of a medicinal product gets a form of regulation status.

Because of the close connection between the foodstuff and medicinal product definition, consideration of the legal definition of medicinal products is necessary.

4.1.2 Medicinal products

The definition for **medicinal products** is given in Directive 2001/83/EC[10]. This Directive has currently been amended by Directive 2004/27/EC[35]. Directive 2004/27/EC[35] has to be implemented in national law by the member states by 30 October 2005.

With Directive 2004/27/EC[35] two changes for the distinction between food and medicinal products were implemented.

First of all the definition of medicinal products was changed.
According to recital No 7 in the preamble of Directive 2004/27/EC[35] the definitions were modified to *avoid any doubt as to the applicable legislation when a product whilst fully falling within the definition of a medicinal product, may also fall within the definition of other regulated products. This definition should specify the type of action that the medicinal product may exert on physiological functions* taking into account so called borderline products.

Secondly a new regulation was implemented in Article 2 paragraph 2:
In case of doubt, where, taking into account all its characteristics, a product may fall within the definition of a "medicinal product" and within the definition of a product covered by other community legislation the provisions of this Directive shall apply.
The reasons for this new paragraph are also given in recital No 7 in the preamble:
With the same objective of clarifying situations, where a given product comes under the definition of a medicinal product but could also fall within the definition of other regulated products, it is necessary 'in case of doubt' to state explicitly which provisions have to be complied with. Where a product comes clearly under the definition of other product categories, in particular food, food supplements, medicinal devices, biocides or cosmetics, this Directive should not apply.

Medicinal products can be divided into two groups according to their definition: "presentation medicinal products" and "function medicinal products" as mentioned before.
"Presentation medicinal products" are those defined in Article 1 paragraph 2 a and "function medicinal products" are those defined in Article 1 paragraph 2 b.

Of course the division into these two groups is not clear-cut and a product can be a "presentation" and a "function" medicinal product

"Presentation medicinal products"

Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; [6]

The definition for a medicinal product relating to presentation was changed slightly with Directive 2004/27/EC[35].
"As having properties" was added to the definition.

"Function medicinal products"

The definition of "function medicinal products" was completely changed. The former wording:

Any substance or combination of substances which may be administered to human beings with a view to making a medicinal diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product.

was replaced by the following wording

Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medicinal diagnosis.

The most important difference is the specification of *the type of action that the medicinal product may exert on physiological functions* as was explained in recital No 7.
"Pharmacological", "immunological" and "metabolic" are also part of the definition of a medicinal product according to Article 1 (2a) of Directive 93/42/EC[36].

Article 2 (2)

This paragraph is new in the Directive for medicinal products as mentioned above. If a product fulfils the definition of a medicinal product and of another product group such as foodstuffs and there is a case of doubt, the product falls under the terms of Directive 2001/83/EC[6].

Implementation in national law – example Germany

The amended definition of medicinal products of Directive 2004/27/EC[35] is not implemented in the current draft of the 14 amendment of AMG[37]. Neither is the "doubt regulation" of article 2 (2) of the Directed part of it.

4.1.3 Special Focus – Food Supplements

Before 2002, no legal or common definition for a food supplement was available. At national level, only vague definitions could be found influenced by national judgement decisions. A common legal definition and regulations for food supplements were therefore necessary.

Food supplement Directive

Content:

The Directive for **food supplements** was published in 2002: Directive 2002/46/EC[3]. This Directive had to be implemented in national law by the member states by 31 July 2003. With this Directive a partial harmonisation of the free movement for food supplements has been achieved.

The reason why the EU legislator implemented this Directive is given in the points for consideration. According to item 2, food supplements *are regulated in Member States by differing national rules that may impede their free movement, create unequal conditions of competition, and thus have a direct impact on the functioning of the internal market. It is therefore necessary to adopt Community rules on those products marketed as foodstuffs.* So the main reason for this Directive is the harmonisation of the free movement of goods, in this case food supplements. The second reason is protection of the consumer. This is laid down in item 5: *In order to ensure a high level of protection for consumers and facilitate their choice, the products that will be put on the market must be safe and bear adequate and appropriate labelling.*[3]

The Directive only deals with pre-packaged food supplements marketed and presented as foodstuffs, see Article 1. Like Regulation (EC) No. 178/2002[5], the Directive does not apply to medicinal products defined by Directive 2001/83/EC[6]. This rules out the possibility of one product being a food supplement and a medicinal product.

According to Article 2 (a) of this Directive the definition for a food supplement is as follows:

'food supplements' mean foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities. [3]

Nutrients themselves are defined in Article 2(b). At the moment only vitamins and minerals are falling under this definition. It is foreseen that this definition should not be static but be amended in future - point for consideration no. 8: *Specific rules concerning nutrients, other than vitamins and minerals, or other substances with a nutritional or physiological effect used as ingredients of food supplements should be laid down at a later stage, provided that adequate and appropriate scientific data about them become available.* [3]

The EU legislator intended to allow only vitamins and minerals for food supplements that are normally found in human diet, see recital No. 9 in order to avoid controversial decisions being made by the member states due to different interpretation of which vitamins and minerals are covered the legislator implemented positive lists. In these lists only vitamins and minerals are

listed which have been evaluated by the Scientific Committee on Foods. The allowed vitamins and minerals are listed in Annex I of the Directive; the allowed forms of these are listed in Annex II. At the moment 13 vitamins and 15 minerals are listed in Annex I, in summary 32 vitamin forms and 80 mineral forms in Annex II. These positive lists are not static but should be amended in future. According to Article 4 (8) the Commission shall submit a report on the advisability of establishing specific rules that include, where appropriate also the amendment of other nutrients or substances with nutritional or physiological effect. Article 4 also regulates the purity criteria. Purity criteria for substances listed in Annex II shall be adopted by a procedure laid down in Article 13 (2). If purity criteria for these substances are specified for their use in the manufacture of foodstuff for purposes other than those covered by Directive 2002/46/EC[3], those shall apply according to Article 13 (3).
Vitamins and minerals not listed in Annex 1 and forms not listed in Annex II that are marketed in at least one food supplement in the Community on 12 July 2002 and have not been given an unfavourable opinion by EFSA can be cleared by Member States to be marketed in their territory until 31 December 2009. A dossier supporting the use of the substance must be submitted to the Commission by the Member States by 12 July 2005 in order to claim this right. On the other hand Member States are allowed to ban or restrict the trade in food supplements containing vitamins and minerals not listed in Annex I or forms not listed in Annex II in their national territory according to Article 4 (7).
More detailed information about the submission of the technical dossier for the safety evaluation is provided in an administrative guidance document published by the Commission.[38]

Directive 2002/46/EC[3] also defines maximum levels for vitamins and minerals see Article 5. For the implementation of these maximum levels the daily portion recommended by the manufacturer, upper safe levels from a scientific risk assessment and the intake from other dietary sources have to be taken into account. If appropriate additional minimum amounts shall be set.
Tolerated upper intake levels have been published by the Scientific Committee on Food (SCF) for

- β-carotene, vitamin B6, vitamin B12, folate, manganese, selenium, molybdenum (October 2000)
- vitamin B2 (November 2000)
- vitamin B1 (July 2001)
- biotin, magnesium (September 2001)
- pantothenic acid, nicotinic acid, nicotinamide (April 2002)
- iodine, preformed vitamin A (retinol and retinyl esters) (September 2002)
- vitamin D (December 2002)
- zinc, copper (March 2003)
- calcium, vitamin E, vitamin K, chronium (April 2003)[39]

Opinions of the Scientific Panel on Dietatic products, Nutrition and Allergies are also available for

- Tolerated upper intake level of fluoride (adopted 22 February 2005)
- Tolerated upper intake level of potassium (adopted 22 February 2005)[40]

Defined maximum levels based on these tolerated upper intake levels for the vitamins and minerals in food supplements have not been established yet.

Rules regarding labelling, presentation and advertising are contained in Articles 7 to 9 of Directive 2002/46/EC[3]. The term “food supplement” must be used. Further regulations in

addition to Directive 2000/13/EC[7] including warnings, statements and name, amount per portion, etc., are listed.
According to Article 6 (2) no attribution to the property of preventing, treating or curing a human disease or reference to such properties is allowed.
For labelling, presentation and advertising, more specific rules for implementation are foreseen but not yet implemented.

Regarding nutrition and health claims on food a proposal for an EU regulation was published in 2003.[41] This proposal covers permitted nutrition claims that are listed in an Annex. This list is not static and can be amended. For health claims no list is foreseen. These should only be authorised after a scientific assessment carried out by the EFSA. The authorisation procedure for health claims is laid down in Chapter IV of the proposal.

Article 10 of Directive 2002/46/EC[3] enables the Member States to implement a national notification procedure in their territory to facilitate efficient monitoring of food supplements. Germany took this opportunity and introduced a notification procedure in the Nahrungsergänzungsmittelverordnung[42] – national implementation of Directive 2002/46/EC[3].

In the case of new or reassessed information about a food supplement endangering human health, the Member States have the possibility of suspension or restriction in their territory. In this case the Commission and the other Member States have to be informed about the reasons for this decision. The Commission will then consider amendments to the Directive or the implementation of Community acts.

The Directive had to be implemented in national law by the Member States by 31 July 2003. That means from 1 August 2003 for all food supplements fulfilling the requirements of Directive 2002/46/EC[3] permission to trade must have been implemented. From 1 August 2005, trade with food supplements that do not comply with the Directive is prohibited in the EU.

Implementation in national law – example Germany

In Germany the Directive 2002/46/EC[3] was implemented in national law with the Regulation: „Verordnung über Nahrungsergänzungsmittel und zur Änderung der Verordnung über vitaminisierte Lebensmittel"[42] (NemV) dated 24 May 2004. This means implementation took place nearly one year after the expiry of the implementation deadline given in the Directive. Some Articles of the Directive were not implemented into NemV because of lacking necessity. So is Article 6 (2) that prohibits properties of preventing, treating or curing a human disease not implemented in NemV[42]. As the content of this article is already laid down in the German Food Law (LMBG)[11] a special article in NemV[42] is not necessary.
The definition for food supplements was not transferred word for word. Instead of "normal diet", the German legislator chose the expression "common diet". According to Hagenmeyer/Hahn.[43] this affects the meaning of the definition.
As mentioned above, the German legislator made use of the capability of implementing a notification procedure for food supplements. From 28 May 2004, when the NemV came into force all food supplements introduced for the first time have to be reported to the relevant authority BVL (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit).

According to Directive 2002/46/EC[3], **trade** with food supplements that do not comply with the Directive is prohibited in the EU from **1 August 2005 at the latest**. Here the German legislator specified a more generous deadline. It is possible to **manufacture and trade** with food supplements in accordance with the regulations valid before the NemV came into force by **30 November 2005**. This is not in accordance with Directive 2002/46/EC[3].

Unlike the EU, where today only tolerated upper limits for some vitamins and minerals from the SCF are available, the German Bundesinstitut für Risikobewertung (BfR) has published possible maximum levels for vitamins and minerals[44]. These maximum levels take into account tolerated upper intake levels, recommended daily portions and daily intake of the substances.

Current developments:

On 5 April 2005 the opinion of the Advocate General at the European Court of Justice (ECJ) for the joint cases C-154/04 and C-155/04 was introduced[45].
The claimants in the cases are Europe-wide federations of manufactures, wholesalers, distributors, retailers and consumers of food supplements. The claimants applied to the referring court for leave to commence proceedings for judicial review of the Food Supplement regulations in October 2003. The responsible UK court stayed the proceedings and referred a question to the ECJ for a preliminary ruling.

The question is if Articles 3 (marketing of food supplements in the Community only if compliance with Directive 2002/46/EC[3]), 4 (1) (only vitamins and minerals listed in Annex 1 and forms in Annex 2 allowed for manufacture) and 15 (b) (prohibition of trade for products not complying with Directive 2002/46/EC[3] from 1 August 2005) of Directive 2002/46/ EC[3] are **invalid** because of an inadequate legal basis, infringement of EC Treaty[8] Articles, subsidiary, proportionality, infringement of the principles of equal treatment.

In the view of the General Advocate the Directive in its present form is seriously deficient in three aspects (principle of proportionality):
1) There is no mention, in the text of the Directive itself, of the substantive norm which the Commission must follow as a guiding principle and no standard for assessing whether the Commission has remained within the limits of its legal powers.
2) It is not clear whether the Directive allows private parties to submit substances for evaluation within a view to having them included in the positive lists.
3) On the supposition that private parties are indeed able to submit substances for an evaluation with a view to inclusion in the positive lists, there is no clear procedure for this purpose which provides minimum guarantees for protecting those parties interests.

The General Advocate comes to the conclusion that Directive 2002/46/EC[3] is invalid. The Directive infringes the principle of proportionality because of a lack of appropriate and transparent procedures for its application.

A decision of the ECJ is expected this summer. In former cases the ECJ followed mostly the opinion of the General Advocate. Therefore, it is likely that the ECJ will declare the Directive invalid.

In the following some cases since the 2002 are summarised in order to see how ECJ and/or national cases judged since the implementation of Regulation (EC) No. 178/2002[5] and Directive 2002/46/EC[3].

4.2 National German Decisions

BGH I ZR 34/01 – "L-Carnitine" – Judgement of 11 July 2002[46]
In this case dealing with the classification of products for muscle building BGH emphasised that with the implementation of Regulation (EC) No. 178/2002[5] no changes to the judgement of BGH I ZR 97/98 of 10 February 2000[20] are necessary. The classification as a foodstuff is in accordance with the jurisdiction of the ECJ according to the court.

KG 5 U 76/02 – "L-Carnitine + Vitamin C" – Judgement of 24 September 2002[47]
The judgement here classified a product containing 1000 mg Carnitine and 180 mg Vitamin C in ampoules as a "function medicinal product". According to the judgement, the predominant purpose based on objective characteristics for an averagely well-informed, attentive and judicious consumer is decisive for the classification. Products intended for consumption are medicinal products if and when the medicinal purpose predominates. If the purpose is of equal value, the product is a foodstuff. In cases of doubt, the product should be classified as a foodstuff.
The court stated further that for the classification of a medicinal product the pharmacological effect of the recommended dosage is the decisive basic parameter.
In the present case, the applicant submitted an expert report that declared a pharmacological effect for the product. 1 g Carnitine has a therapeutic effect according to the expert.
Hence the judgement classified the product as a medicinal product.

OLG Cologne 6 U 140/02 – "Glucosaminsulphate I" – Judgement of 3 January 2003[48]
Two products containing 250 and 500 mg glucosaminsulphate (recommended daily amount 750 or. 1000 mg) were classified as medicinal products. According to the court, the consumer has the impression that these products are medicinal products. The internet advertisement used words such as "therapeutically effect", "patient", therapy", "placebo", "adverse effect" etc.. The court also concluded that the products have a pharmacological effect, as the Aufbereitungsmonographie[49] states a pharmacological effect. The neutral presentation of the products themselves and the declaration "food supplement" refuted the impression of a medicinal product.

OLG Stuttgart 2 U 19/00 – "Carnitine" – Judgement of 13 February 2003[50]
In another Carnitine judgement, the court classified two different Carnitine products.
A drink with 1000 mg Carnitine was classified as a foodstuff and a special tube with 12 ml liquid containing 1200 mg Carnitine was classified as a medicinal product. The predominant purpose is the criterion for demarcation, in the view of the court. A dose with an amount several times more than the daily requirement is not evidence of a medicinal product. The court emphasised that the form of the product alone is not evidence. Nevertheless, the tubes used are usual for medicinal products. According to the court, the purpose of the 1200 mg product is an unnatural muscle building that is associated with health risks. Therefore, the product must be classified as a medicinal product.

OVG Münster 13 A 1977/02 – "Lactobact. omni FOS" – Decision of forwarding the case to ECJ of 7 May 2003[51]

In this case a product containing bacteria cultures that was legally marketed as a novel food in another Member State and classified as a medicinal product by the German authorities had to be examined. The OVG decided to forward 16 questions to the ECJ for clarification. As the new foodstuff regulation is already in force and the food supplement Directive published, the responses of ECJ will have a great impact on future demarcation and could solve certain problems, depending on the interpretation and distinction of the different rules. The OVG would like to have a classification of this special product and wants to know if this classification is binding on all Member States. If the ECJ denies the classification because it sees the decision to be made by the single Member States OVG has further questions. Hence the ECJ should give a definition for "pharmacological effect" and should declare if the objective purpose is not essential for demarcation anymore but the fact that products fulfilling the definition of foodstuffs and medicinal products must be seen only a medicinal products. In the meantime the opinion of the General Advocate has become available. See under ECJ decisions; case C-211-03[58].

BGH I ZR 275/01 – "Nutrition for sportsmen" – Judgement of 6 May 2004[52]

A group of muscle building products containing e.g. Carnitine and Creatine was classified as doping preparations and therefore medicinal products in a former judgement. The BGH revised this judgement. In the opinion of the BGH a muscle building and cell volume extending effect does not always prove a medical purpose.
It is also possible that such products serve the fulfilment of special physiological needs and nutrition requirements of special groups like athletes. Hence the products could also be foodstuffs for particular nutritional use.
According to the BGH nutrition for sportsmen cannot only serve a particular purpose if it refills lacks after maximum performances. It is also possible that these foodstuffs support the ability to achieve maximum performances.
Therefore, the BGH gave the case back to the relevant court for reassessment.

OLG Cologne 6 U 136/02 – „ Glucosaminsulphate II" – Judgement of 26 May 2004[53]

A product containing 300 mg glucosaminsulphate and other ingredients in capsules was classified as a food supplement by the court for the following reasons:

- The product is clearly presented as a food supplement: food supplement is mentioned on the package, a consumption recommendation is given, not a dosage recommendation, the internet advertisement only refers to regeneration of cartilage etc.
- Glucosaminsulphate is a natural component of the body that is also consumed with the normal diet. There are no studies proving a pharmacological-therapeutically effect in the recommended amount.

OVG NRW 13 A 320/30 – Doubt regulation Decision of 15 June 2004[54]

If a product meets the definition of a medicinal product and a foodstuff (food supplement in particular), earlier judgements declared that the product should be classified as a foodstuff as long as the medical purpose does not predominate. [47]
With the new Article 2 of Directive 2001/83/EC, this classification is no longer possible. In cases of doubt, the product now has to be classified as a medicinal product.

OVG NRW stated that a product containing Chrome (III) Picolat would be classified as a medicinal product when Article 2 (2) of amended 2001/83/EC[6] comes into force. Because of its composition and presentation, it clearly falls under the "doubt regulation" of Article 2 (2). Therefore, the court judged the question of whether Chrome (III) Picolat is permissible in combination with foodstuffs as being of no significance because the old regulation was soon to be phased out.

OLG Karlsruhe 6 U 31/04 – "GELITA CH alpha" – Judgement of 23 June 2004[55]
In this case, a decision had to be made as to whether the advertising and packaging of a product containing Gelatine and Collagen hydrolisate presents the product as a medicinal product.
According to OLG the presentation does not give the impression that the product is a medicinal product. "Food supplement" is clearly indicated on the packaging. The advertising claim that the product should be used to counteract stress and strain resulting from ageing etc. cannot be interpreted as indication of a concrete disease. Age is not a disorder and stress and strain resulting from ageing is therefore not necessarily an ailment either. The effects of the food supplement are proven by the literature presented.

OVG Niedersachsen 11 ME 12/04 – "Mushroom Powder Capsules" – Decision of 8 July 2004[56]
Capsules containing mushroom powder were classified as food supplements for the following reasons. For such a product a common objective view has not yet been established. Therefore, the presentation by the manufacturer/supplier has to be considered. The presentation does not justify classification as a medicinal product. Information containing health claims has only been given to health professionals. The brochures will additionally be revised. On the other hand, experts state that the nutritional and physiological effects of the product are predominant.

OVG Niedersachsen 11 ME 303/03 – "Red Rice Capsules" – Decision of 29 September 2004[57]
Red Rice capsules were classified as a medicinal product as the common objective purpose is not nutrition, consumption, taste or odour value. The product contained Monacolin K as an active ingredient which is identical with Lovastatin (a pharmaceutical active ingredient). The vitamins play only a secondary role in the view of the court. Therefore, the capsules cannot be classified as a food supplement in terms of Directive 2002/46/EC[3].

4.3 ECJ Decisions

Joint cases C-211/03, C-299/03, C-316-03, C-317-03, C-318-03 – "HLH, Orthica" – Opinion of the General Advocate of 3 February 2005[58]
Several questions have been forwarded to the ECJ by OVG North Rhine-Westphalia regarding the demarcation of foodstuffs and medicinal products. The opinion of the General Advocate has since been published. According to this opinion, no answer is provided as to how the products in question should be classified. Classification has to be carried out by the national court. The following factors must be considered in connection with the decision:

- the pharmacological characteristic of the product in terms of the current scientific knowledge
- the way in which the product is used
- the extent of its dispersal
- the degree to which the consumer is familiar with the product
- the possible risk accompanied with usage

The General Advocate is against a too wide interpretation and usage of the medicinal product definition.
If a product is dissolved in water or yoghurt, it is not significant for the classification.
According to the General Advocate the pharmacological effect of a product is a factor that must be considered by assessing the question as to whether a product has essential influence on metabolism and whether it can influence the function of the body and hence in accordance with Article 1 (1) No. 2 (2) of Directive 2001/83/EC[6], can be used to restore, correct or modify physiological functions. Risks through usage of the product are points of views that can be taken into account by the demarcation. But they are not decisive. Additionally, there should at least be a proven therapeutically effect. This therapeutic effect must always be assessed together with risks connected with usage of the product.
Regarding the definition of the term "pharmacological effect", the General Advocate states that the term is not defined in law but is familiar in ECJ jurisdiction in connection with Article 1 No. 2 of Directive 2001/83/EC[6]. What matters is whether the product is a "function medicinal product". That means that it can be used to make a medical diagnosis or to restore, correct or modify physiological functions in humans.
According to the General Advocate, products that are covered by both definitions – medicinal products and foodstuffs – must be classified as medicinal products because products falling under the definition of medicinal products are clearly exempted from the definition of Regulation (EC) No. 178/2002[5]. This fact is now also embodied in Article 2 (2) of Directive 2004/27/EC[35].

If a product is classified as a foodstuff in one Member State and, because of a potential risk, as a medicinal product in another Member State, the procedure defined in Regulation (EC) No. 178/2002[5] should be initiated in order to find an agreement between the relevant Member States and the Commission.
There is no provision for direct questions regarding a demarcation problem or a matter of a scientific nature from national courts to the EFSA and these are therefore not possible. On the other hand, expert reports from EFSA are not binding for a national court but should be treated as evidence and considered in the decision.

5 IMPACT ON DEMARCATION

In the following chapters an overview is given of the impact the new foodstuff regulation, food supplement Directive and the new definitions of medicinal products have on the demarcation, taking into consideration the judgements already ratified. There is also a discussion of which criteria are left for the demarcation as a result of the new regulations and past judgements.

5.1 Impact of the new regulations on the demarcation

5.1.1 Foodstuff Regulation (EC) No. 178/2002[5]

With the foodstuff Regulation a definition of foodstuffs was implemented. But what influence has this new definition on the demarcation between foodstuffs and medicinal products? According to Köhler two basic statements can be derived from the definition of foodstuffs in Article 1:

- A product is either a foodstuff or a medicinal product. Both together are not possible due to the direct exclusion of medicinal products from the foodstuff definition.
- The medicinal product status is more specific than the foodstuff status

The demarcation between foodstuffs and medicinal products can therefore no longer be different. In the event of different interpretations in the Member States, the ECJ has to pronounce a final decision.[29]

In summary, the implementation of the basic foodstuff Regulation is an important step in the unification of the demarcation between foodstuffs and medicinal products as an EU-wide valid definition is now available. Therefore, demarcation should also be unified in future. Because of the wide definition and the absence of a defined purpose the implementation of the definition does not simplify the distinction between foodstuffs and medicinal products.

5.1.2 Medicinal products Directive 2001/83/EC[10] amended through Directive 2004/27/EC[35]

With the amendment of Directive 2001/83/EC[6] the definition of medicinal products was changed as described before. In the following the influence of the changes is discussed for "presentation" and "function medicinal products". Furthermore, the impact of the new regulation of Article 2 (2) is discussed.

"Presentation medicinal products":

According to Pfortner [59] in the presentation of a product itself indications are contained that the manufacturer of the product wants to market this product as a medicinal product. In practise, these indications can be found only in the labelling. The result of the objectification in the definition of "presentation medicinal products" could be interpreted that only criteria unquestionably coming from the manufacturer are used as basis for the demarcation and not advertisements, etc. issued by third parties[59].
Klaus[60] states that the definition was not significantly modified.
In summary, the change of the definition of "presentation medicinal products" will not basically influence the demarcation.

"Function medicinal products":

The term "pharmacological" was as mentioned before, a very important criterion for the demarcation in the legal practice of ECJ[25, 26].
The reason to include "pharmacological", "immunological" and "metabolic" in the definition was that all foodstuffs also modify the physiological functions in human beings. Therefore, all foodstuffs fell under the definition of a "function medicinal product". The term "physiological functions" alone was insufficient for the demarcation of foodstuffs and medicinal products.

But is the more specific definition of the amended Directive more helpful for the demarcation?

The term "pharmacological" is not defined in the medicinal products or foodstuff regulations. According to Pfortner[59] it should be possible to use the definitions for "pharmacological", "immunological" and "metabolic" given in the Guidance Document for medicinal devices[61] here also because both items of legislation are closely related.
As this makes sense, a look at these questions could help to answer the question:

"Pharmacological"
is understood as an interaction between molecules of the substance in question and a cellular constituent, usually referred to as a receptor, which either results in a direct response, or which blocks the response to another agent. Although not a completely reliable criterion, the presence of a dose-response correlation is indicative of a pharmacological effect.
A pharmacological effect as a criterion has always been a problem in past judgements regarding demarcation.[62,63]

"Immunological"
is understood as an action in or on the body by stimulation and/or mobilisation of cells and/or products involved in a specific immune reaction.
The intake of foodstuffs can strengthen and therefore influence the immune system.

"Metabolic"
is understood as an action which involves an alteration, including stopping, starting or changing the speed of normal chemical processes participating in and available for, normal body function
Foodstuffs have a metabolic effect. They participate in the metabolism of the body and therefore always affect the normal chemical processes in the body.

In summary the changes in the definitions do not solve the problem of demarcation of foodstuffs and medicinal products.

Article 2 (2)
Klaus[60] remarks that because of the wideness of the medicinal product definition a lot of foodstuffs fall under this definition. The danger could be seen in single interpretations by Member States, as Article 2 (2) leaves room for interpretation. Pfortner[59] points out that it would be better to see Article 2 (2) in the light of recital No 7 in the preamble. When a product clearly comes under the definition of other product categories, Directive 2001/83/EC[6] shall not apply.

According to the Opinion of the General Advocate in the joint cases C-211/03, C-299/03, C-316-03, C-317-03, C-318-03[58] a product that is covered by both definitions – medicinal products and foodstuffs – must be classified as medicinal products as products falling under the definition of medicinal products are clearly exempted from the definition of Regulation (EC) No. 178/2002[5]. Article 2 (2) now summarises the same fact in the medicinal product law.

In past decisions products falling under both definitions were seen as foodstuffs as long as the medical purpose did not predominate (more than 50 percent). With Article 2 (2) the latest this changed.

5.1.3 Food supplement Directive 2002/46/EC[3]

With Directive 2002/46/EC[3] food supplements are defined for the first time in the EU.
As only vitamins and minerals fall under the definition of the Directive Klügel/Delewski[64] conclude with reference to recital No. 7 that the regulations of the Directive only apply for food supplements containing only/as well as vitamins and/or minerals. Rehmann[65] comes with reference to the same point of consideration to another opinion. Because of the changes carried out between the last and a former version of this point of consideration he concludes that the unspecific aspects of the Directive such as labelling etc., laid down in Article 6 to 12 should also apply for food supplements which do not contain vitamins and minerals.
The wording of this point of consideration: *As a first stage, this Directive should lay down specific rules for vitamins and minerals used as ingredients of food supplements. Food supplements containing vitamins or minerals as well as other ingredients should also be in conformity with the specific rules on vitamins and minerals laid down in this Directive.*
The different interpretations focus on "specific rules". Rehmann[65] differs between specific rules and unspecific rules such as labelling and monitoring whereas Klügel/Delewski[64] sees the whole Directive under "specific rules".

In summary, Directive 2002/46/EC[3] is an important step in the harmonisation procedure of food supplements in the EU and therefore important for the free trade in the EC domestic market.
A legal definition for food supplements was implemented for the first time, the nutritional and physiological effect was stated and the dose forms for food supplements are listed.

Many of the regulations in Directive 2002/46/EC[3] have to be put in more concrete terms by additional rules that have to be implemented. As long as no maximum/minimum levels for nutrients and or substances with nutritional effect have been established a secure legal demarcation between food supplements and medicinal products seems to stay difficult.

At the moment the validity of Directive 2002/46/EC[3] is insecure and will be clarified in near future (possibly in summer 2005) [43].
If the ECJ follows the opinion of the General Advocate[43] and declares that Directive 2002/46/EC[3] is invalid considerable amendment will be necessary or a completely new Directive will have to be drawn up. This would have a major impact on the harmonisation of the regulations regarding food supplements and therefore also on the demarcation of food supplements and medicinal products.

5.2 Criteria for demarcation – which can be used with regard to current definitions and past judgements

In chapter 3.4, criteria for demarcation of a guidance document published by German experts were introduced. In the following, criteria used for demarcation are summarised and discussed on the basis of past judgements and current regulations.

5.2.1 Criteria regarding the presentation of the product

External form
The external form played an important role in the past. Forms such as capsules, tablets, ampoules etc. were not always seen a sole evidence but as an indication for a medicinal

product[12, 13, 25]. The external form also became usual for food supplements. Therefore, this criterion rightly lost its impact for demarcation in the legislation. Today forms such as capsules, tablets and ampoules are part of the food supplement definition of Directive 2002/46/EC. Hence, this criterion cannot be used for the demarcation any longer.

Packaging and package information leaflets

Packaging and package information leaflets were seen as evidence for medicinal products in the past[12, 13, 16]. They are now also common for food supplements. Even recommendations such as "3 times daily" as stated in the German guidance document or other consumption modalities do not indicate a medicinal product any more. If the packaging or package information leaflet contains a description that clearly assigns a pharmacological effect to the product, this could be significant for the demarcation with regard to "presentation medicinal products".

In the view of the ECJ, specific information on the packaging or in the package information leaflet e.g. *if reference is made to research by pharmaceutical laboratories, to methods or substances developed by medical practioners or even to testimonials from medical practitioners commending the qualities of the product*[26] could be an indication of a medicinal product. In some cases *a statement that the product is not medicinal is persuasive evidence which the national court may take into consideration but is not in itself conclusive*[26].

Price and distribution

The price and the distribution channel played a role in the former demarcation process. A high price and distribution exclusively through pharmacies was seen as evidence or a powerful indication of a medicinal product[13, 14, 34]. Today many food supplements are exclusively or additionally distributed through pharmacies whereas OTC medicinal products are available in supermarkets and drugstores. The prices for food supplements are not always significantly lower than medicinal products (or even higher) – trying to convince the consumer by means of the price to buy a high-quality product. This means neither the price nor the distribution channel can be effectively used for demarcation.

Risks and adverse effects

It is prohibited to market products with a risk to public health, whether they are medicinal products or foodstuffs. According to Mühl[28], the only difference lies in the procedures used to determine these risks. In food legislation, a precaution principle and market controls are provided for. In medicinal products legislation, a control before marketing is carried out by applying a marketing authorisation procedure. Hence, health protection is a key factor in both regulations. Therefore, Mühl[28] states that risks and adverse reactions should play no role in the demarcation.

The possible risk involved in usage is on the other hand one of the issues that should be considered in view of the current opinion of the General Advocate[58]. That means that the ECJ wishes to retain this issue as a possible indication for classification.

Advertising

Advertising is another factor in the presentation of the product. With foodstuffs, it is prohibited firstly to mislead the consumer according to Article 8 of Regulation (EC) No. 178/2002[5] and secondly to attribute the property of preventing, treating or curing a human disease according to Article 2 No 1 (b). According to Mühl[28] misleading advertisement and the classification of medicinal According to Mühl[28], misleading advertising and the

classification of medicinal products must be strictly separated. He also states that advertising should be used for classification only in those cases where it is an unambiguous "presentation" of a medicinal product. In other cases advertising cannot be implicitly used for classification.

Summary

The literature discusses how to handle the demarcation between foodstuffs and "presentation medicinal products".
Köhler[29] points out the problem of presentation, examining the information of a product that is given by the manufacturer of the product itself and of information that is related to the product by third parties. He says that it is justified in the first case to classify the product as a medicinal product. In the second case he suggests classifying the product to fall under food law and the misleading prohibition regulations of that law.
Klaus[60] states that the *classification of medically innocuous products as medicinals based on their presentation is only justified in a few cases, since protection of the consumer against the risk of being misled and, especially, of confusing a foodstuff with a medicine has already been guarded by means of a Community wide system of labelling, presentation and advertising prohibitions, combined with the appropriate system of penalties for breaches.*

The ECJ interprets "presentation" very broadly: *Whenever any averagely well-informed consumer gains the impression, which, provided it is defined, may even result from implication, that the product in question should, regard being had to its presentation have an effect such as described by the first part of the community definition.* [25]

Therefore, classifying a product as a medicinal product or a foodstuff according to its presentation can only be carried out on a case by case basis[66].

5.2.2 Criteria regarding the function of the product

Composition, Concentration, Pharmacological effect
The composition of a product has a central influence on the classification of a product as the composition impacts the function of the product.
But how could the borderline between foodstuffs / food supplements and medicinal products be drawn with regard to their function?
"Function medicinal products" restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action according to their definition. As mentioned in chapter 5.1.2 the change of the definition with the amendment of Directive 2001/83/EC[6] is not that helpful for the demarcation as intended by the legislator.

Therefore, a more detailed glance should be taken on this issue especially on the "pharmacological effect" that played such an important part in former and current classification decisions.

Foodstuffs are the basis of the human metabolism and therefore modify naturally the physiological functions of the body. All products, which are necessary for the daily nutrition and the normal function of the human body, are clearly foodstuffs and no medicinal products as maintenance of the body cannot be seen identical to restoring[66].
That means if a product has only a nutritional and physiological effect from the current scientific knowledge it must be classified as a foodstuff.

On the other hand, Klaus[60] states: *If such a nutritional and physiological effect cannot be objectively said or cannot be given a superior status to more foods, then other criteria for the purpose of drawing a distinction must be adducted.*

The pharmacological effect is the central reason in national and ECJ judgements for the classification of a product as a medicinal product. The problem is – as mentioned before in chapter 5.1.2 – the missing definition of this term. But even if the definition of the MEDDEV[61] is used the term is hardly to distinguish and therefore not suitable for drawing the borderline between foodstuffs and medicinal products. [63]
Hence, the term should be seen in a wider meaning: if the product influences the body to a higher grade than to what could be triggered by consumption of food[28].

As mentioned before the General Advocate[58] answers the question for a definition of pharmacological effect as follows: Important is if the product is a "function" medicinal product. That means that it can be used to make a medical diagnosis or to restore, correct or modify physiological functions in human beings.

The question is now which concentration is the threshold for drawing the borderline for a single substance.
In particular cases it is not always possible to fix this threshold from the scientifically point of view[28]. A general fixation is not possible due to the latest ECJ vitamin decision [32, 33].

In summary, citing Klaus[60] with regard to the pharmacological effect: *Legal practise has shown that in cases in which pharmacological effectiveness will certainly suffice to clarify the issue from the scientific angle, this criterion is suitable, on the other hand for which a pharmacological effect depending on dose cannot scientifically be stated, this criterion is unsuitable for purpose of drawing the distinction.*

The only possibility according to Köhler[29] is the manifestation of thresholds by the legislator. This should be done on the EU basis as already foreseen in the Directive 2002/46/EC[3] for food supplements.

These thresholds that will be established for food supplements according to Directive 2002/46/EC[3] are immensely important for vitamin and mineral products but also for substances like L-Carnitine and Creatine.
Vitamins and minerals can serve in a limited dosage range a foodstuff and medicinal product purpose[29]. For some groups of individuals like athletes and breast feeding women concentrations much higher than the normal daily amount are necessary for the nutrition purpose. On the other hand, for the prevention of deficiency related diseases regular intake of clearly lower doses are afforded. That means within a certain dose range the usage as medicinal products or foodstuffs / food supplements is possible[29] – dual-use products.
For these products only the purpose according to their presentation can be drawn for the demarcation.

Physiological events are not static but influenced by hereditary predisposition and external influences. Therefore, substances important for the normal growing and development of an individual or for the need of special groups like athletes belong to the group of substances that serve the normal nutrition. That means they are foodstuffs.

In summary, the classification if a product is a medicinal product or a foodstuff according to its function can also only be carried out on a case by case basis.

5.2.3 Criteria Summary

Looking back to the German guidance document[34] in chapter 4.3 most of the questions given in the catalogue are still relevant. Exceptions are number 8 – distribution channel – and some criteria like the dose lower three times the recommended daily or the intake recommendation "three times daily".

The General Advocate gives the following criteria that should be considered in his current opinion of the joint cases mentioned before[58]

- the pharmacological characteristic of the product due to the current scientific knowledge
- the way in which the product is used
- the extent of its dispersal
- the degree to which the consumer is familiar with the product
- the possible risk accompanied with the usage

As a result the common opinion due to objective reasons regarding the product decides over the classification on a case by case basis. This common opinion is not static but can change due to new scientific knowledge or new developments of foodstuffs.

5.3 Past judgements regarding foodstuffs/food Supplements against the background of the new regulations

In the following two national German and two ECJ decisions are reviewed. The former grounds for the decisions are discussed against the background of the new regulations and an assessment is made as to whether the decisions would be the same today.

"Garlic capsules"[12]
The garlic capsules judgement was already discussed critically by Forstmann in 1995[67]. Forstmann agrees with the judgement itself but criticises the grounds stated by the court. He disagrees that products in capsule form are generally medicinal products from the point of view of the customer and are only in exceptional cases food supplements.
The capsule form has always been a typical form for food supplements such as vitamin or mineral preparations. Because of this, the external form is now directly implemented in the definition of a food supplement in 2002/46/EC[3]and therefore, as mentioned before, obsolete as regards demarcation.
BGH also stated that garlic capsules contain no nutrients to serve the development or sustenance of the human body. According to 2002/46/EC[3] food supplements contain nutrients or other substances with a nutritional or physiological effect. Therefore, under the new regulation a physiological effect is sufficient. There are substances such as fibre and secondary plant components that have no nutritional effect but are clearly foodstuffs.
It is possible to agree with BGH that capsules are usual for seasoning meals even today. But this fact alone is not a reason for classification.

Further evidence for a medicinal product according to BGH is the fact that competitors market similar products as medicinal products. Hence, the consumer has the impression that garlic capsules in general have a pharmacological effect. Forstmann[67]contradicts this view, pointing out that this would be the end of any innovation and extension of the product range of food supplements.
For the demarcation of garlic capsules the question as to whether the amount in the capsules has a pharmacological/therapeutically effect is important. According to Meisterernst[68] the amounts that the German Aufbereitungsmonographie[49] declared for medicinal products can easily be consumed with the normal diet. Hence the question arises as to whether these amounts can be used without an indication as food supplements.
This question will be answered by the ECJ in the near future, as the European Commission tabled a motion[69] against Germany. The reason for this move is that Germany classifies all garlic preparations in capsules (even with pure garlic powder) as medicinal products while they are legally marketed as foodstuffs in other EU Member States. In the view of the European Commission this is an infringement of Article 30 of the Treaty. In addition, the German position seems to demonstrate an insufficient understanding of the borderline between food supplements and medicinal products in the sense of current European legislation in the view of the European Commission.
In the case of garlic capsules, it is likely that an EU-wide harmonised classification as food supplements up to a certain amount will be the verdict, thus overriding the garlic capsule decisions in Germany.

"van Bennekom"[25]

The "van Bennekom" judgement is one of the most cited ECJ judgements in the demarcation jurisdiction.
The ECJ stated that whenever any averagely well-informed consumer gains the impression, which, provided it is defined, may even result from implication, that the product in question should, regard being had to its presentation have an effect such as described by the first part of the community definition. The impression of the consumer is still important for the demarcation. One of the criteria mentioned by the General Advocate in the current joint cases[58]s the degree to which the consumer is familiar with the product.
The court also said that the external form of a product, such as capsule, tablet or pill form, cannot be the sole or conclusive evidence. But it can serve as evidence that the manufacturer has the intention to market the product as a medicinal product. This criterion is obsolete with Directive 2002/46/EC[3] the most recent, as mentioned earlier.
The classification of a vitamin as a medicinal product must be carried out case by case according to the ECJ, having regard to the pharmacological properties of each such vitamin to the extent to which they have been established in the present state of scientific knowledge. This statement is still valid and was reiterated by the ECJ in the vitamin judgement against Germany[32]n which the general classification of vitamin and minerals in an amount three times above the DGE recommendation as medicinal products was criticised, as mentioned earlier in chapter 3.3.
In view of this lack of harmonisation, the ECJ announced that it is for the Member States to decide what degree of protection of human health and life they intend to ensure, having regard however to the requirements of the free movement of goods within the community. In the meanwhile, the definitions for foodstuffs, food supplements and medicinal products are harmonised in the EU. Therefore, the ECJ will be responsible for solving demarcation problems if agreement between the Member States in question is not possible, due account being taken of current scientific knowledge, etc..

"Delattre" [2]
The "Delattre" case is like the "van Bennekom" case[25] an often cited judgement of the ECJ. In this jugdement the ECJ emphasises the importance of the pharmacological properties of a product for the classification which is as discussed a difficult to handle but still important criteria for drawing the borderline to "function" medicinal products.
The fact that a product is classified as a foodstuff in one Member State does not preclude its being treated as a medicinal product in the State concerned if it possesses the relevant characteristics according to the ECJ. According to the current opinion of the General Advocate[56] it should be started to find an agreement between the concerned Member States and the Commission in case of different decisions in the Member States.
A product may be regarded as being presented as a medicinal product if on its packing and in the information provided with it reference is made to research by pharmaceutical laboratories, to methods or substances developed by medical practitioners or even to testimonials from medical practitioners commending the qualities of the product. This criterion is an often cited and still used important indication for a medicinal product with regard to its presentation.
The ECJ also declares in this judgement that a statement that the product is not a medicinal product is not a conclusive evidence for a foodstuff or food supplement. But the national courts could take this into consideration. This statement is part of the whole presentation and is therefore still considered today[55].

6 OUTLOOK AND CONCLUSION

Medicinal products and foodstuffs/food supplements are complementary terms. As seen before the terms cannot be seen isolated. The definitions are connected and influence one another.

With the new foodstuff Regulation (EC) No. 178/2002[5] a harmonised but only wide definition was given for foodstuffs.
Foodstuffs – even if not required by their definition – at least as a rule possess intrinsic nutritional and physiological suitability and purpose-orientation.[60]

As discussed the function and purpose of foodstuffs is important for the demarcation between foodstuffs and medicinal products. A more precise definition of foodstuffs including a purpose is therefore strongly recommended by Streinz[70].

Possible purposes to lay down in the definition could be nutrition, role for the normal function, building and maintenance of the body and consumption.

In the European Commission two different Directorates are responsible for medicinal products and foodstuffs. The demarcation problem is therefore dependant on the decisions made by two groups. Hence, a cooperation between the two Directorates when new law has to be drawn up that affect the definitions of medicinal products, foodstuffs, food supplements etc. through e.g. working groups could lead to a better result with reference to the demarcation. These working groups could also act as contacts in case of special questions by the Member States so that the ECJ must only intervene in exemptional cases.

Such working groups could also be implemented for general interpretations of law with regard to the classification e.g. through the establishment of guidelines.

Regarding food supplements defined levels for nutrients will be implemented according to Directive 2002/46/EC[3]. These levels are urgently needed for clearer demarcation in case of borderline products. BfR[44] has published maximum levels for several vitamins and minerals. These could be used as basis for the establishment of EU maximum levels by EFSA.

Borderline products are more and more often discussed on EU level. On 28 October 2004 a workshop took place on EU level[71].
This workshop was organised by the Commission with representatives of the Member States to clarify different legal provisions, listen to interested parties' concerns and problems of the new legislation, to discuss practical future solutions to avoid problems of borderline between e.g. foodstuffs and medicinal products.

One of the conclusions of this workshop was that the necessity for further action regarding borderline products. This will be considered after the following actions have been completed: legislation on nutrition and health claims, adoption of maximum levels for vitamins and minerals in food, Commission report regarding the use of substances other than vitamins and minerals in food supplements (to be prepared for 2007).
In view of the imminent invalidity declaration of Directive 2002/46/EC[3] by the ECJ, these actions described in the Directive could possibly take place later. As a result the urgently necessary considerations of the need for further action at EU level, as described by the European Commission on the workshop, could also be postponed. Hopefully, certain necessary amendments to the Directive such as maximum levels for vitamins and minerals at least will already have been implemented with the probable update of the Directive.
Another conclusion of the workshop is that in the medium terms, *the Commission will reflect on the need to prepare a communication, explaining the legal principles as well as the different ways to proceed when taking decisions concerning the classification of products*.
Guidelines for specific products are possible.
In the long term, the Commission will reflect on the creation of an overriding committee or group, competent to take decisions at Community level, on the clarification of certain products. This group shall overcome national and Community sectoral approaches and should be able to provide advice.
These conclusions by the workshop members are commendable. Unfortunately, the named timescales refer to - "medium term" and "long term" - are very imprecise.

The demarcation and development of criteria for drawing the borderline will remain with the jurisdiction in the event of future disputes.

Manufacturers should be aware that it is easier for a court to assess the presentation of a product than to assess the function, because where the function is concerned experts are normally needed.
A careful evaluation of its own product should be carried out by the manufacturer in order to avoid an incorrect classification of its product. Consultation with experts may be advisable in certain cases.

7 SUMMARY

The demarcation between foodstuffs and medicinal products has often been a problem for products with a "dual-use" -character such as certain food supplements containing e.g. vitamins or minerals. Numerous classifications had to undertaken by national courts or the European Court of Justice (ECJ).
Until 2002, most decisions were taken on national level, as there was no harmonised definition of foodstuffs. ECJ judgements emphasised the importance of the Member States in view of the absence of harmonisation, taking due account of the requirements of the free movement of goods within the community as laid down in the EC Treaty[8].

In 2002, a harmonised definition of foodstuffs was finally introduced with Regulation (EC) No. 178/2002[5]. This was an important step toward unification of the demarcation between foodstuffs and medicinal products. But because of the wide definition and the absence of a defined purpose, implementation of the definition did not solve all problems regarding demarcation.

In the same year, Directive 2002/46/EC[3] came into force; this contained a definition for food supplements for the first time. Many of the regulations in the Directive have to be expressed in more concrete terms by additional rules which have still to be implemented. At the moment there are no maximum/minimum levels for nutrients and/or substances with nutritional effect; these are important for drawing the borderline between food supplements and medicinal products e.g. for vitamins or minerals. Furthermore, the Directive covers only vitamins and minerals at present. In the near future a revision or amendment of the Directive seems probable, since the validity of the Directive is currently assessed by the European Court of Justice.

In 2004, the definition of medicinal products was amended by Directive 2004/27/EC[35] in order to make it more precise. The terms "pharmacological", "immunological" and "metabolic" were included in the part of the definition dealing with the function.
The pharmacological effect was and is a crucial factor in national and ECJ judgements for the classification of a product as a medicinal product on account to its function, even though it is hard to use e.g. because there is no legal definition of the term.

In view of the new regulations and the development of decisions made on national level and by the ECJ before and after 2002, certain criteria for classification by presentation and function can no longer be used as sole evidence, such as the external form or general concentration limits (used for vitamins, for example in Germany and Austria).

Classification of a product as a medicinal product or a foodstuff is only possible on a case by case basis. The general opinion based on objective reasons regarding the product determines the classification. This general opinion is not static but can change in response to new scientific knowledge or new developments in foodstuffs.

To determine this general opinion, the following points should be taken into account:

- the pharmacological characteristic of the product in the light of current scientific knowledge
- the way in which the product is used
- the extent of its dispersal
- the degree to which the consumer is familiar with the product

- the possible risk involved in usage

To improve the classification, the following is suggested:

- a more precise definition of foodstuffs, including a purpose
- cooperation between the two Directorates of the European Commission responsible for medicinal products and foodstuffs when new regulations are drawn up and the setting up of working groups for general interpretations of law with regard to classification e.g. through the establishment of guidelines

Initial steps in this direction have been undertaken with a workshop organised by the European Commission in October 2004.

All in all, positive steps have been undertaken and have begun to improve the demarcation between foodstuffs / food supplements and medicinal products. Further developments are urgently necessary.

At present, the demarcations between foodstuffs / food supplements and medicinal products remain a problem for special products and will therefore continue to be a matter of individual assessment in many cases.

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Hiermit erkläre ich an Eides statt, die Arbeit selbständig verfasst und keine anderen als die angegebenen Hilfsmittel verwendet zu haben.

Dachau, den _____