Mad about the Food Supplements

"Nahrungsergänzungsmittelverordnung" – The German implementation of Directive 2002/46/EC and its national peculiarities

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"If I could employ a little magic that would finally destroy this stream that pains me and enchains me, but I can't" (Noël Coward)

Like all other Member States of the European Union, Germany had to implement the Food Supplements Directive 2002/46/EC into national law. The author presents the relevant German ordinance and its most important provisions. He points out minor deviations from the wording of the directive and explains the particular problems caused by the peculiarities of the national "additives" definition. His main emphasis is on the interpretation of the legal term "food supplement" and such products' lawful ingredients. The author also deals with essential labelling elements and the issue of notification. He concludes with some practical recommendations to foreign food operators wishing to import food supplements into Germany.

I. Introduction

Everyone who remembers the birth of Food Supplements Directive 2002/46/EC on 10 June 2002[1] may recollect that Art. 15 of the directive obliged all member states to comply with the directive as of 1 August 2003 at the latest. The German legislator was in no such hurry. Although recent national plans to regulate food supplements and fortified foodstuffs date back to 1997 and a respective German draft ordinance was already put forward on 15 October 1999,[2] i.e. well before the European directive was proposed, Germany was unable to meet the deadline: it took until 13 May 2003 for the relevant Federal Ministry of Consumer Protection, Food and Agriculture ("Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft" as it was then officially called)[3] to release a first draft of an implementation ordinance. But the second chamber of the German legislation, the Federal Council ("Bundesrat") needed until 13 March 2004 to convert that draft into an official legislative bill. This was finally passed by the Federal Ministry with some alterations on 24 May 2004 and subsequently published in the Federal Statutes Gazette ("Bundesgesetzblatt") a few days later.[4] The German Food Supplements Ordinance is officially called "Verordnung über Nahrungsergänzungsmittel" (Ordinance on Food Supplements), bears the official shortened title "Nahrungsergänzungsmittelverordnung" and is officially abbreviated "NemV". When the ordinance finally came into force on 28 May 2004 it solved the temporary problems of the previous months when food supplement manufacturers had to resort to the unimplemented European directive in order to use substances otherwise not permitted in Germany. However, the national ordinance also causes some new problems.

A growing number of articles in German legal publications has accompanied the draft as well as the final ordinance.[5] As with all German imple-

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1 OJ L 183/51 of 12.7.2002.

2 Bergmann, ZLR 2000, 653, 655.

3 The new Government changed its name within days of entering office on 22 November 2005, BGBl. I 2005, 3197 of 25 November 2005; it is now officially called Federal Ministry of Food, Agriculture and Consumer Protection (This is not a joke!).

4 BGBl. I 2004, 1011 of 27 May 2004.

5 To name but a few: Hahn/Hagenmeyer/Teufer, StoffR 1/2006; Delewski/Fuhrmann, ZLR 2005, 645; Mahn, ZLR 2005, 529; Meisterernst, StoffR 2005, 54, also published in Erbersdobler/Meyer, Functional Food, Vol. II, Chapter 3.4; Hagenmeyer/Hahn, WRP 2004, 1445; Hagenmeyer/Hahn, ZLR 2003, 417; Gerstberger, ZLR 2003, 295; Bergmann, ZLR 2000, 653.

mentations of European law, there are some minor deviations from the wording of the directive. In addition to the obvious inaccuracies of the directive itself, these deviations create relatively wide ranges of possible interpretations. The German peculiarities of the "additives" definition (which comprises nutrients and makes them subject to authorisation) inject a touch of madness into the current legal situation. One might of course ask which law is not mad to some extent. But that is not the question here. Let's get mad about the food supplements!

II. Sec. 1 NemV: What is a food supplement?

Sec. 1 NemV implements Art. 2 of the directive into German law. According to this directive food supplements within the meaning of the ordinance have to meet three essential criteria. They are foodstuffs which must

- be intended to supplement the general diet,
- be a concentrate of nutrients or other substances with a nutritional or physiological effect, alone or in combination, and
- be brought onto the market in dose form.

As in Art. 2 para. b of the directive the term nutrients within the meaning of the ordinance is confined by definition to vitamins and minerals pursuant to Sec. 1 para. 2 NemV. Additionally this provision makes it clear that trace elements are comprised of the minerals. The three individual criteria give rise to some further considerations.

1. Supplementation of general diet

In order to identify what can supplement a general diet, one has first of all to address the issue of diet and nutrition.[6] From the beginning of mankind until the late 20th century food was primarily considered to supply the human organism with all substances necessary for survival, i.e. in order to avoid malnutrition and the pertaining diseases. Only over recent decades have medical and nutritional sciences discovered and shown that foodstuffs can also contribute to maintain physical and mental well-being and capacity in a beneficial way; this includes long-term health. Nutrition and diet do in fact cover more aspects than was generally accepted in the past. This is important to know against the background of German court decisions even by the Federal Court of Appeal ("Bundesgerichtshof"),[7] which still perceive the human diet as the contribution of nutrients to cover energy and substance related requirements of the human organism. Accordingly diet comprises carbohydrates, fats and proteins as energy supply as well as minerals, vitamins and water. However, since mere survival can only be a minimum goal of nutrition in Germany today, a broader interpretation of the concept of nutrition should be promoted.[8] Only if the courts accept that the long term goals of human nutrition must be optimum health and quality of life can scientific research results also obtain their proper place in the legal world. This is even more so as the prevention of diseases can actually be managed by an appropriate nutrition in a comparatively large number of cases.

In view of the fact that the European legislator appreciates the benefits of an adequate and varied diet which can "under normal circumstances provide all necessary nutrients for normal development and maintenance of a healthy life" (Rec. 3 of Directive 2002/46/EC), theoretically there should not be any need for food supplements. However, the European legislator also accepts the following: "Surveys show that this ideal situation is not being achieved for all nutrients and by all groups of the population across the Community" (loc. cit.). It can be concluded therefore that an inadequate diet is a "normal" state of affairs and should thus also be the correct interpretation of the legal term "general diet" in Sec. 1 para. 1 No. 1 NemV. In any event, foodstuffs for particular nutritional uses (Parnuts) as defined by Directive 1999/21/EC must be excluded from the scope of a "general diet" by definition, since they are obviously not meant to be part of a "normal" range of food.

It is true that the implementation of Art. 2 of the directive into German law neither in any way explains what a "general diet" is, nor how, particularly by what kind of food, it can be supplemented. However, if one takes into account the significance of nutrition and the European legislator's intention, the purpose of food supplements becomes apparent: food supplements shall potentially supplement a "general diet" in such a way as to pro-

6 This issue has been comprehensively dealt with from a nutritional and food scientist's perspective by Hahn, ZLR 2001, 1.

7 Recently: BGH, WRP 2004, 1024, 1025 – Sportlernahrung II.

8 This has been convincingly proposed by Hahn, loc. cit.

mote a healthy life beyond mere survival. They serve an optimum development and function of the human organism over and above what average groups of the population achieve by their diets which often lack adequacy with respect to their nutrient supply.

2. Concentrate of nutrients or other substances

Concentrates by definition are enriched substances. Hence one might assume that food supplements have to consist of substances which are enriched or concentrated in a particular way. That, however, is not the case. Otherwise for example vitamins or unsaturated fatty acids could not be used for the manufacture of food supplements since they can neither be concentrated nor enriched. A look into the original English version of Art. 2 para. b of the directive makes it clear that concentrates within the meaning of Sec. 1 para. 1 no. 2 NemV must be the same as "concentrated sources". That is to say the characteristic nutrient or other substance as such is decisive, be it actually concentrated or merely extracted, separated, isolated, condensed, reduced or otherwise intensified. In any event, concentrates must comply with the German additives definition, an issue which will be addressed later on.

3. Dose form

The statutory criterion of a dose form pursuant to Sec. 1 para. 1 No. 3 NemV is specified in detail in that provision as in Art. 2 para. 1 of the directive. Both give the same examples – a rather medieval way of legislation which had already been overcome in Germany in the late 19th century. Since the examples are given in the legal provisions themselves, all products appearing as capsules, pastilles, tablets, pills etc. can be classified as food supplements without question. Whether a merely separable form is also comprised, e.g. a powder tin with a measuring cup, cannot be unambiguously drawn from the wording of the relevant provision itself. It has to be assumed, however, that powders or liquids, which the consumer, following dosage instructions, can convert into dose form himself, must also be included. This can also be drawn from the fact that drop dispensing bottles are expressly mentioned by the legislator, too. Furthermore it should be noted that the dose form by nature must be small. That is to say it should not be bigger than bite-size. Snack bars or 0.2 litre cans will therefore not amount to food supplements.

III. Sec. 3 NemV: What substances may be used

The incomplete European regulation of authorised substances creates particular problems in Germany. As provided by Art. 2 of the directive, Sec. 1 para. 1 no. 2 NemV mentions "nutrients" as well as "other substances with nutritional or physiological effect." While the former category is expressly confined to vitamins and minerals (including trace elements) pursuant to Sec. 1 para. 2 NemV, the latter category collides extensively with the wide German "additives" definition.

1. Nutrients

Following Art. 4 para. 1 and the two annexes of the directive, Sec. 3 para. 1 and 2 NemV authorises the particular vitamins and minerals listed in enclosure 1 NemV in the particular forms specified in enclosure 2 NemV. Both enclosures of the German ordinance are identical with the corresponding annexes of the directive. At the same time Sec. 3 para. 3 NemV expressly forbids the use of any other vitamins and minerals than those listed in enclosure 2 NemV. As a consequence such substances must not be separately added as ingredients in the manufacture of food supplements. Nevertheless they may be contained in other ingredients, provided those other ingredients are lawful. For example a number of oils derived from certain plants contain Vitamin E forms which are not listed in annex 2 of the directive. However, these oils are, and remain, lawful ingredients of food supplements in Germany even if they contain Gamma Tocopherols or Tocotrienols which cannot be used as ingredients as such. Regarding the authorised vitamins and minerals listed in enclosure 2 NemV, the purity criteria, if any, of the relevant EC directives must be observed pursuant to Sec. 3 para. 4 NemV. That is to say, for example, Calcium Carbonate or Calcium Gluconate may only be used if they conform with the specifications codified in

the European Directives 95/40/EC and 96/77/EC. Vitamins and minerals not meeting these specified purity criteria are caught by the statutory ban in Sec. 3 para. 3 NemV and may therefore not be employed for food supplements.

2. Other substances with nutritional or physiological effect

At a first glance the category of other substances with nutritional or physiological effect appears to be less regulated, because no specific demands on their use are established by the European directive. However, these substances cause most problems under German law, because they are governed by the statutory ban on unauthorised additives. One has to know in this respect that the German legal additives definition has always deviated from the European definition in such a way that it did not only pertain to substances used for technological purposes, but also to substances used for nutritional or dietetic purposes. Any material added to a foodstuff for either of these reasons was an additive by definition and thus subject to authorisation.

In spite of the sometimes heavy criticism of this incongruity of European and German law[9] the new German Food and Feedstuffs Act ("Lebensmittel- und Futtermittelgesetzbuch – LFGB") continues this confusion. Although it purports to restrict the term additives to substances used for technological purposes only now, it puts substances used for other than technological purposes into the same legal position (merely without calling them additives). Once a substance is caught in the trap of Sec. 2 para. 3 LFGB it is not likely to be authorised and must therefore not be used as a food supplement ingredient.

The only general exemption German law allows pursuant to the same provision is for natural substances which according to consumer perception are predominantly used for their taste or their nutritive capacities. As a consequence, cocoa powder remains a non-additive, even if it is employed in an individual case as a food colour; similarly egg yolk does not become an additive merely because one can use it as an emulsifier. However, a large number of substances particularly of plant origin are not known for their nutritive capacities to the German consumer. As long as that is the case, they cannot be used in food supplements. Only plant extracts which are generally known for their nutritive properties may escape the statutory additives ban.[10] As this classification is dependent on consumer perception, it is open to interpretation and thus cause of constant litigation. It can be predicted with some certainty that this type of cases will continue to crowd the legal gazettes also after the NemV has entered into force as before. Recent examples of substances under the scrutiny of German courts in such a context are red rice,[11] mushroom powder,[12] St. John's wort,[13] lycopin,[14] various Asian plant powders,[15] green tea extract,[16] and soy isoflavons.[17]

To err on the safe side it is possible in principle to apply for an individual or for a general exemption. The former is available pursuant to Sec. 68 LFGB to domestic manufactures and distributors and rarely granted in practice. The latter is available in accordance with Sec. 54 LFGB for cross border trade of food supplements lawfully on the market elsewhere in the European Union so as to allow for the principle of free movement of goods (which is of course entrenched in Art. 28 of the EC Treaty). In both cases the applicant has to show that his product does not present a potential hazard to human health (the statutory prerequisites are tailored after Art. 30 of the EC Treaty). Applications must currently be filed with the Federal Office for Consumer Protection and Food Safety (see below). Over the past years a number of general exemptions have been granted for food supplements deviating from German law with respect to the particular nutrients contained.[18] They have also covered amino acids

9 To name but a few: Schroeter, ZLR 2005, 104; Büttner/Hahn, GRUR 2004, 815; Meisterernst, StoffR 2004, 212; Hagenmeyer, StoffR 2004, 150; Meisterernst/Schneider, DLR 2004, 302; Meyer, ZLR 2004, 21; Meyer, DLR 2004, 18; Girnau, ZLR 2003, 677; Meyer/Preuß, WRP 2003, 675; Meisterernst, PharmaR 2003, 202; Schroeter, ZLR 2003, 731; Preuß, ZLR 2000, 962; Gorny, ZLR 1999, 19.

10 Hahn/Hagenmeyer/Teufer, StoffR 1/2006; Gerstberger, ZLR 2003, 295.

11 Niedersächsisches OVG Lüneburg, ZLR 2005, 143; Nordrhein-Westfälisches OVG Münster, ZLR 2000, 74.

12 Niedersächsisches OVG Lüneburg, ZLR 2005, 126.

13 BGH, WRP 2004, 1481 and OLG München, ZLR 2001, 885.

14 OLG Karlsruhe, ZLR 2003, 729.

15 Niedersächsisches OVG Lüneburg, ZLR 2003, 371.

16 Hessischer VGH Kassel, ZLR 2002, 504.

17 OLG Hamburg, ZLR 2002, 75.

18 A list of all general exemptions is published on the internet by the Ministry for Agriculture of Lower Saxony: http://www1.ml.niedersachsen.de/47a/.

which pursuant to German law are classified as additive-like substances subject to authorisation, too.

3. Maximum amounts

Of course there is no provision for maximum amounts of nutrients or other substances in the German food supplements ordinance. This would clearly be in breach of European law, because no such amounts have yet been decreed by the European legislator. Nevertheless the criteria laid down in Art. 5 para. 1 of Directive 2002/46/EC must already be observed in Germany, too. That is to say that safety aspects regarding consumer health must be respected. In order to obtain some kind of orientation as to how much of a particular substance a manufacturer may use for an individual food supplement, guidance can be gained from two scientific pamphlets published by the Federal Institute for Risk Assessment ("Bundesinstitut für Risikobewertung – BfR").[19] These give recommendations for some of the authorised vitamins and minerals but also advocate not using others in spite of the fact that they are permitted by law. Since the publication has no force in law, higher amounts of vitamins and minerals may be used, provided scientifically acknowledged upper limits of safe intake are not exceeded.[20] Furthermore the narrow borderline between food supplements and medical products pursuant to German drug law must not be overstepped. This line is drawn by German courts relying on the concept of consumer perception. The German Federal Court of Appeal has ruled that an informed and understanding consumer will not perceive a product as medical if it has no pharmacological effect in the concrete dosage.[21] Since it is unclear what a pharmacological effect is and from what dosage it might be achieved the borderline remains regularly unclear.[22] Only individual court decisions qualify as border posts and can serve as orientation marks.[23] As a rule of thumb it can be said that the lower a dose of a substance in a food supplement, the less likely the product is to be classified as a drug.

IV. Sec. 4 NemV: How to label food supplements

The compulsory labelling elements contained in Sec. 4 NemV complement those which all food labels must bear pursuant to the German Food Labelling Ordinance ("Lebensmittel-Kennzeichnungsverordnung – LMKV") which in turn implements the European Food Labelling Directive 2000/13/EC. But for some details they largely correspond with the respective demands of Art. 6 of the Food Supplements Directive.

1. Name of the product

The name under which food supplements in Germany must be brought onto the market is prescribed in Sec. 4 para. 1 NemV as "Nahrungsergänzungsmittel". Other more informative names like "Vitamin C tablets" or "Fish oil capsules" may still be used additionally but cannot replace this compulsory product name. It goes without saying that the term "Nahrungsergänzungsmittel" is reserved exclusively for the category of food supplements and must not be labelled on other foodstuffs which do not meet the statutory requirements pursuant to Sec. 1 NemV.

2. Characteristic substances

In addition to the product name Sec. 4 para. 2 no. 1 NemV demands that the names of the categories of nutrients or characteristic substances must also be indicated. It is recommended that this indication should go together with the product name so that it becomes clear to the consumer what kind of food

19 Domke/Großklaus/Niemann/Przyrembel/Richter/Schmidt/Weißenborn/Wörner/Ziegenhagen, BfR Wissenschaft 3/2004 and 4/2004 („Verwendung von Vitaminen in Lebensmitteln" and „Verwendung von Mineralstoffen in Lebensmitteln", Toxikologische und ernährungsphysiologische Aspekte; Teile 1 und 2).

20 An alternative list published by Hagenmeyer/Hahn, ZLR 2003, 417, 429-438; supporting Doepner/Hüttebräuker, ZLR 2004, 429, 444 Fn. 58; unconvincingly critical Meisterernst, StoffR 2005, 54, 63.

21 BGH, GRUR 2000, 528; GRUR 2002, 910; WRP 2004, 1024; WRP 2004, 1277; WRP 2004, 1481.

22 E.g. Schulze/Parzeller/Roebel, StoffR 2005, 235; Meyer/Reinhart, WRP 2005, 1437; Gröning, WRP 2005, 709; Hahn/Hagenmeyer, ZLR 2003, 707.

23 E.g. OLG Karlsruhe, ZLR 2005, 120; OLG Köln, ZLR 2005, 109; OLG Köln, ZLR 2004, 94; Nordrhein-Westfälisches OVG Münster, ZLR 2003, 585; OLG Stuttgart, ZLR 2003, 497; KG Berlin, ZLR 2003, 94; KG Berlin, ZLR 2002, 759; Nordrhein-Westfälisches OVG Münster, ZLR 2001, 858.

supplement is being offered. Since categories suffice the mere mentioning of "vitamins" or "minerals" is lawful. Further details as to which individual vitamins or minerals are contained in the product can be drawn from the ingredients list and the nutrient table.

3. Recommended daily amount

Sec. 4 para. 2 no. 2 NemV establishes the obligation to label a recommended daily amount in portions of the product. This is important not only with respect to maximum amounts of nutrients or other substances with nutritional or physiological capacities, but also with respect to the relevant nutrition information which must relate to this daily dose.

4. Warning

Pursuant to Sec. 4 para. 2 no. 3 NemV a warning not to exceed the stated recommended daily dose is compulsory as envisaged by Art. 6 para. 3 lit. c of the directive. It appears that the German legislator did not really trust food manufacturers to fully comply with this obligation. Hence the provision contains a prescribed wording: "Die angegebene empfohlene tägliche Verzehrsmenge darf nicht überschritten werden" (The indicated recommended daily dose must not be exceeded). Since European law does not mention this or any other wording, the German provision cannot be cogent in this respect either. Consequently Sec. 4 para. 2 NemV contains a somewhat hidden proviso which allows to deviate by giving a similar warning. Obviously this proviso devalues the obligation to use the prescribed wording; in fact the statutory formulation therefore merely amounts to a recommended wording. Nevertheless it has to be noticed that the German legislator is quite serious about the warning, since he perceives the recommended daily dose as a maximum amount.[24] In practice this can lead to absurd situations, if one imagines for example a vitamin C chewing tablet with a content of 60 mg Vitamin C and a recommended daily dose of one tablet. In view of a safe tolerable upper intake level of 600 mg even a regular consumption of five such tablets per day should not normally present any harm to human health. It is for this reason that additional labelling as to the safety of excess consumption of a product ought to be lawful provided the information is true.

5. Deterring indication

Seemingly in line with the demand of the directive, Sec. 4 para. 2 no. 4 NemV obliges the manufacturer to indicate that food supplements should not be used as a substitute for a varied diet. In the German provision, however, the word "varied" has been additionally supplemented with the term "well balanced". Since European law prevails, it is sufficient to phrase the indication along the lines of the directive. A particular wording is not prescribed. It should also be noted that the indication must not specifically relate to the product in question but merely to food supplements in general.

6. Storage indication

Sec. 4 para. 2 no. 5 NemV demands a particular storage indication, namely that the product should be stored out of the reach of small children. It is of course questionable how long a child can be perceived as small and how far such a child's potential reach may be. The necessity of the obligation is even more questionable if compared to the absence of similar obligations on e.g. spirit bottles or tobacco products.

7. Nutrition labelling

The complicated issue of nutrition or substance labelling as provided for in Art. 8 of the European Directive is implemented into German law in Sec. 4 para 3 NemV. This provision obliges food manufacturers to label the amount of nutrients or other substances with nutritional or physiological effects per daily dose upon the basis of an analysis of the product. It can be assumed that no chemical laboratory analysis has to be conducted in order to comply with this duty. A mere calculation upon the basis of data obtained from suppliers or generally known values is also permissible. It should be noted in this respect that the provision is not restricted to nutri-

24 This is obvious from the official reasons pertaining to the bill, BR-Drucks. 248/04 of 30 March 2004, p. 15.

ents added as ingredients but refers to actual contents of substances in a food supplement. Hence minerals or vitamins naturally contained in other ingredients, particularly additives, must also be taken into account. For example the Vitamin A amount must comprise Beta-Carotene if used as a food colour and the Calcium amount has to include Calcium Phosphate if used as an additive for technological purposes. This follows from the fact that the special nutrition labelling for food supplements is meant to inform the consumer about the amount of a particular substance he will take in upon consumption. After all, the human metabolism does not distinguish between substances taken in as "active" ingredients and substances employed for technological reasons only.

Additionally Sec. 4 para. 3 NemV makes it compulsory to indicate percentages of recommended daily allowances as listed in the annex to the European Nutrition Labelling Directive 90/496/EEC (which is otherwise not applicable to food supplements pursuant to its Art. 1 para. 3). It is generally known that these values are disputed and differ from current recommendations given by national societies of nutrition.[25] Nevertheless the compulsory percentages must be calculated upon the basis of those values. In individual cases this may lead to consumer deception, but that is a problem of the design of the statutory provisions.

8. Advertising ban

Sec. 4 para 4 NemV pronounces the special food supplements advertising ban. Neither the labelling nor the advertising of foodstuffs must contain an indication which states or implies that the supply of adequate quantities of nutrients in general is not possible with a varied and well balanced diet. In view of the general ban on misleading advertising contained in Art. 2 para. 1 of the European Food Labelling Directive 2000/13/EC, which is implemented into German law in Sec. 11 LFGB, the additional advertising ban in the food supplements ordinance appears futile. Perhaps the German legislator would have done better not to separately implement the respective provision of Art. 7 of the Food Supplements Directive. However, in practice this should not make much difference, since unlawful claims remain unlawful regardless of Sec. 4 para 4 NemV.

V. Sec. 5 NemV: How to notify food supplements

Pursuant to Sec. 5 para. 1 NemV anyone intending to put a food supplement onto the German market, be it as manufacturer or as importer, has to notify the Federal Office for Consumer Protection and Food Safety ("Bundesamt für Verbraucherschutz und Lebensmittelsicherheit – BVL", Diedersdorfer Weg 1, 12277 Berlin-Marienfelde) prior to the first marketing at the latest. The notification procedure is comparatively easy if one merely follows the statutory requirements. The notifying operator has therefore got to write a letter to the Federal Office, tell them who he is and that he intends to bring a particular food supplement onto the market. Furthermore he has to attach a label of the relevant product. That is all. The Federal Office would like to obtain additional information from food operators subject to the notification duty. It has therefore designed a particular three-page form for notification purposes which is also available on its website. However, there is no obligation to make use of this form. If a food supplement has already been notified to another authority in another member state, this authority must also be mentioned in the notification pursuant to Sec. 5 para. 2 NemV. It is neither necessary to file a copy of the earlier notification nor to submit a translation of any kind.

In this notification procedure the Federal Office merely functions as a letter box. In accordance with the federal system it has no inherent power to supervise or to control. Food control is the exclusive task of the 16 German Federal States which carry out the relevant functions through their local food authorities. Consequently the Federal Office has to duplicate the notification documents pursuant to Sec. 5 para. 3 NemV and pass them on to the Federal Ministry and all regional ministries. Only

25 E.g. Deutsche Gesellschaft für Ernährung/Österreichische Gesellschaft für Ernährung/Schweizerische Gesellschaft für Ernährungsforschung/Schweizerische Gesellschaft für Ernährung, Referenzwerte für die Nährstoffzufuhr, Frankfurt 2000; British Nutrition Foundation, Nutrient Requirements and Recommendations 2004, currently available on the foundation's website: http://www.nutrition.org.uk/upload/Nutritient%20 Requirements%20and%20recommendations%20pdf(1).pdf; National Research Council, Recommended Dietary Allowances, 10th ed. Washington D.C. 1989; Food and Nutrition Board/ Institute of Medicine, Dietary Reference Intakes, Washington D.C. 1997/1998.

the competent local food control authority may then take samples or measures if that seems necessary.

VI. Sec. 6 NemV: Sanctions

It is a criminal offence pursuant to Sec. 6 para. 1 NemV, punishable with imprisonment of up to one year or a relevant fine, to use unauthorised nutrients in contravention of Sec. 3 para. 1 NemV. Furthermore the legislator purports to make the marketing of a food supplement without the compulsory warning, as prescribed by Sec. 4 para. 2 No. 3 NemV, a similar criminal offence pursuant to Sec. 6 para. 2 NemV. However, since Sec. 4 para. 2 NemV also allows similar wordings, the offence can only be committed by failing to put any adequate warning on the label. The contravention of other labelling requirements is not subject to any specific sanctions, nor is a failure to comply with the notification duty punishable. Nevertheless competitors or certain associations may still take such breaches of legal obligations to court.

VII. Conclusion

The main problem for foreign food operators wishing to import food supplements into Germany is probably the composition of their products. Labelling and notification can usually be carried out without much difficulty. If foreign supplements are merely composed of vitamins or minerals listed in the annexes of the European Food Supplements Directive 2002/46/EC, the products have the best chance to survive a critical examination by German food control authorities, provided the amounts of nutrients for daily consumption are not excessive and the preparations are not perceived as drugs by the consumer because of the way they are presented. If, however, other substances are being employed as ingredients, it is advisable to obtain premarketing advice on the legality of the food supplements in Germany. Otherwise the inclined foreign food operator may well experience certain subliminal madness which is quite familiar to German food law practitioners – the magic to destroy it has not yet been found.