Surprisingly "cheap" Health Claims for Food Supplements – By Courtesy of EFSA*

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Many producers of food supplements deplore the strict assessment practice of EFSA. They fear that soon they will not be able to market their products any longer. If, however, one looks at the current draft of a first Regulation on the authorisation of certain health claims, it will be possible to make lots of "cheap" claims without great effort. This is because the pertaining EFSA opinions suggest recipes which open up unimagined perspectives for food advertising. The authors of this article reveal the secrets of these recipes and show how they can be used for marketing food supplements. First they sketch the regulatory background and the general problems (I.); then they present the draft Regulation together with the pertaining scientific opinions (II.). Thereafter, they propose several model recipes which allow the use of "cheap" health claims (III.). In some critical comments they show practical consequences of the envisaged authorisations (IV.) before concluding with a brief assessment (V). The authors suspect that neither legislators nor EFSA have asked for the partly absurd results to which the instant analysis must lead. However, the strange consequences of the current authorisation practice have to be accepted until better and more sensible rules as well as an adequate scientific assessment procedure are available.

I. Background and Problems

1. Problems of the Authorisation Proceedings

The gigantic problem which legislators have caused not only to food business operators with Regulation (EC) No. 1924/2006 on nutrition and health claims (NHCR) is widely lamented[1] – with justification! The Regulation's regulatory approach is exceedingly oversized; moreover, it remains extremely unclear with respect to many details. The complicated authorisation proceedings and especially the largely intransparent and also inconsistent assessment practice of the European Food Safety Authority (EFSA) create enormous bureaucratic difficulties. In practice this leads to previously unimaginable problems for the advertising of foodstuffs[2]. Furthermore, the Regulation also obstructs science

* This is an adapted version of the authors' parallel publication "Die 'geheimen' Rezepturen der EFSA" (EFSA's 'secret' recipes) in StoffR 6/2010 to which the readers should refer when looking for more detailed model recipes of low cost food supplements allowing as many "cheap" claims as legally possible.

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1 Cf. e.g. essentially *Loosen*, „Chronik eines angekündigten Scheiterns", in Festschrift für Michael Welsch, 2010, p. 279 seq. with several references; cf. also *Schwinge*, „Bekömmliches Lebensmittel trifft unbekömmliches Gesetz", ZLR 2010, 370 seq. as well as *Domeier*, „Wo verläuft die Grenze zwischen gesundheitsbezogenen Angaben und solchen, die sich auf das allgemeine Wohlbefinden beziehen?", 3. Euroforum Newsletter „Nahrungsergänzungsmittel", 2010, pp. 17–18; cf. finally *Meisterernst*, „Ein Lernprozess?", WRP 2010, pp. 481 et seq.

2 Cf. *Sandner/Turowski*, „Steigende regulatorische Anforderungen behindern das Wachstum des OTC-Gesundheitsmarktes", 3. Euroforum Newsletter „Nahrungsergänzungsmittel", 2010, pp. 14–16.

because one can already see that studies[3] sponsored by industry no longer aim at scientific progress but rather have to be aimed at "proving" a certain relationship. An even more distinct "publication bias" [4] is the logical consequence of this development: Positive studies with desired results are being published, negative results are systematically withheld because in the course of weighing "the totality of the available scientific data" within the meaning of Recital 17 of the Regulation they could become obstacles during authorisation proceedings for health claims. Producers of food supplements are particularly concerned by the complex regulatory requirements for the authorisation of such claims. This is because their products hardly taste, they have no appetising appearance and it is not in any way appealing to consume for example vitamin or mineral products – not to mention cod liver oil capsules or plant extract tablets. Thus, food supplement advertising is dependent on the possibility of emphasising health benefits or health related effects of such products[5].

Anyone having conducted or accompanied authorisation proceedings for health claims knows that costs and value are in no acceptable relation, at least not for small and medium sized enterprises. Often, the necessary investment cannot be mastered financially, especially against the background of the completely unclear chances of success of applications for the authorisation of health claims[6]. The conduct of the necessary studies involves monetary expenses[7], the collection of the necessary documents is difficult and expensive, the proceedings can take several years – contrary to the legislators' intentions –, and the chances of success are slim. One of the main reasons for this gloomy perspective is that the scientific assessment of applications by EFSA is and remains very strict and intransparent[8]. Instead of the evidence based evaluation demanded by the legislators, many opinions of EFSA reveal a more eminence based approach[9] which does not really show which criteria have guided the members of the NDA panel. Certain reasons for rejection cannot even be understood from the perspective of a critical science. Some damaging consequences of negative opinions as to the reputation of individual food business operators, however, cannot be credited to EFSA. The fact that defined relations or effects are not perceived as scientifically substantiated by EFSA is occasionally reported in a false and distorted manner by the media and interpreted in such a way that there are no relations and effects at all so that the products in question are generally and comprehensively discredited[10].

It cannot come as a surprise therefore that many producers of food supplements fear dangers for the marketing of their products. If they have no authorised claims they can hardly sell their supplements. Retail enterprises are of course not interested in products of which not even consumers know why they should swallow them. Not least for that reason, many enterprises urgently look for ways to avoid the strict requirements of the NHCR as far as possible[11].

3 Especially university research is largely dependent on support from industry – not only in Germany. Currently public funds are not even sufficient to sustain minimal requirements for the maintenance of teaching.

4 "Publication bias" is a term for the fact that "positive" study results as such which show significant or desired effects are preferred for publication in scientific journals whilst "negative" results remain unpublished. The main reasons are that "positive" studies can be published more easily and are more likely to be accepted by journals, but also that negative studies do not reach the publication process; cf. in this context *Hopewell/Loudon/Clarke/Oxman/Dickersin*, Cochrane Database Syst Rev. 2009 Jan 21;(1):MR000006: "Trials with positive findings are published more often, and more quickly, than trials with negative findings".

5 Cf. also *Hagenmeyer*, „Aktuelle Werbestrategien für Nahrungsergänzungsmittel und ihre Bewertung durch die Rechtsprechung", StoffR 2009,pp. 56 et seq.

6 The Commission's obligation to "assist" small and medium enterprises pursuant to Article 15 para. 5 NHCR does not appear to work in practice.

7 Cf. *Hahn/Teufer*, „Zur wissenschaftlichen Absicherung von Wirkaussagen für Lebensmittel", ZLR 2008, pp. 663 et seq.

8 Cf. also in detail *Hahn/Hagenmeyer*, „Sind die wissenschaftlichen Stellungnahmen der EFSA hinreichend gesichert?", 3. Euroforum Newsletter „Nahrungsergänzungsmittel", 2010, pp. 5–6.

9 Notworthy is e.g. EFSA's following comment towards an applicant when rejecting arguments: "...the claim is for a function ... for which there is consensus among scientific experts as to its substantiation and EFSA has therefore used *authoritative* scientific sources to support substantiation", cf. http://ec.europa.eu/food/efsa/comments/efsa_reply_q2009_485.pdf.

10 Cf. for example (last visited on 24.10.2010): http://www.bild.de/BILD/ratgeber/telegramm/ratgeber-telegramm,rendertext=14388432.html "Probiotic yoghurts are a rip-off. Examinations by the 'European Food Safety Society' [sic!] have shown that probiotic yoghurts do not keep what is promised in their marketing. Food supervisory has therefore decided that these 'health lies' cannot be used any longer for marketing the products".

11 Proposals i.a. by *Gerstberger/Hegele*, „Ohne Health Claims zum Produkterfolg", 3. Euroforum Newsletter „Nahrungsergänzungsmittel", 2010, pp. 9–10.

2. Possible Marketing of Food Supplements

The most simple way has so far been the resort to nutrition claims[12]. Pursuant to Article 8 in conjunction with the Annex of NHCR claims such as "source of Vitamin C" or "contains Calcium" are merely demanding that the advertised foodstuff contains a "significant amount" of the nutrient in question pursuant to Nutrition Labelling Directive 90/496/EEC, i.e. 15 % of the "recommended daily amount" according to the Annex of that Directive – in the two examples this would be 12 mg Vitamin C and 120 mg Calcium, respectively. However, this does not mean a lot to a consumer if he does not know how to benefit from these substances[13]. Furthermore, nutrient claims are particularly difficult to justify for substances which are not expressly regulated in the Annex of NHCR, namely substances other than vitamins and minerals. This is because the nutrition claim "source of [nutrient or other substance]" may only be made where the product complies with all the applicable provisions of the Regulation, i.e. especially Article 5, para. 1 NHCR which i.a. demands a "significant quantity" of the advertised substance, without, however, mentioning particular criteria for the type of significance other than that it must be "established by generally accepted scientific evidence".

In spite of the justified depression in the food supplement trade, there is hope! Especially the first lot of "positive" scientific opinions published by EFSA allows manufacturers of vitamin and mineral products new and surprisingly affordable opportunities, almost like a playground, which hardly anyone had thought of – surely EFSA itself the least of all. Vitamins and minerals have been privileged by European food legislation for years[14]. This is probably because one believes to know them, they are perceived as comprehensively researched and for some of these substances, supplies below the recommendation levels of expert groups have been well documented[15] – so that health claims can even support occasionally welcome additional intakes of those substances. Vitamins and minerals obviously enjoy higher esteem than other substances with EFSA, too. This can be drawn from those scientific opinions which have recently been compiled in a draft of a first general Regulation for authorisation by the European Commission[16]. Should this Regulation enter into force as planned, unimagined new advertising possibilities would present themselves especially for suppliers of food supplements with vitamins and minerals. Small amounts of these nutrients – which is remarkable from a scientific perspective – will then justify a plethora of comparatively "cheap" health claims without particularly difficult conditions having to be met for the marketing of fortified foodstuffs. This becomes clear if one has a closer look at the scientific assessments and the pertaining draft Regulation.

II. EFSA Opinions on Vitamins and Minerals together with Planned Draft Authorisation

1. EFSA Opinions

The EFSA opinions concerned assess approximately 50 health claims almost exclusively regarding vitamins and minerals pursuant to the relevant consultation procedure. Pursuant to Article 13, para. 3 NHCR, the European Commission should have published a Community list of all permitted health claims by 31 January 2010 "at the latest". This, however, has not been achieved, especially because EFSA with its 21 member NDA panel has not been able to scientifically assess more than 4,600 claims submitted by the Commission pursuant to Article 13, para. 2 NHCR. In fact, the badly paid and overworked members of the NDA panel cannot be envied for their Sisyphus work. This is especially because they have to evaluate all proposals as demanded by the legislators at the highest scientific

12 Cf. also *Zechmeister*, „Verkannt und unterschätzt? – Chancen bei der Verwendung nährwertbezogener Angaben in der Werbung", ZLR 2009, pp. 677 et seq.

13 A nutrient claim does not have to be a health claim in this context at the same time only because the emphasis of a particular nutritive quality can also signify a special health benefit; cf. *Meisterernst*, WRP 2010, 481, 485 as well as *Hagenmeyer*, WRP 2010, pp. 492 (493–494).

14 Cf. the Annexes of Food Supplements Directive 2002/46/EC as well as Fortification Regulation (EC) No. 1925/2006; both in the version of Regulation (EC) No. 1170/2009; cf. with respect to other substances than vitamins and minerals in food supplements also *Schwinge*, „Andere Stoffe in Nahrungsergänzungsmitteln", ZLR 2009, pp. 117 et seq.

15 Cf. by way of example for the situation in Germany (last visited on 24.10.2010): http://www.was-esse-ich.de/uploads/media/NVSII_Abschlussbericht_Teil_2.pdf.

16 Draft Commission Regulation on the authorisation of certain claims made on food, other than those referring to the reduction of disease risk and to children's development and health, SANCO/10656/2010 Rev. 3.

level[17]. What that level is, however, can neither be answered by the legislators nor by EFSA until today[18]. Apparently the assessors of EFSA themselves, contrary to those assessed, do not suffer from this fact; this can be concluded from the authority's behaviour: Even justified and reasoned criticism regarding certain opinions is generally rejected in a largely stereotype manner, for example, "In conclusion, having taken into account the comments raised by the applicant we wish to reiterate the overall conclusion of the Panel, i.e. that the information provided is insufficient to establish a cause and effect relationship..."[19]. To put it mildly: Detailed criticism is kindly accepted, the "long arm" of the authority, however, lets it "recoil"[20], be it justified or not[21].

The fact that EFSA's work does not advance as envisaged by the legislators has now also come to the Commission's attention which therefore intends to publish partial lists with health claims corresponding to EFSA's evaluation progress[22]. This intention is also visible from Recital 7 of the planned Regulation which acknowledges that the assessment of all the health claims will require "at least two more years of work". Since EFSA – as of 1 October 2009 – has first dealt with health related effects of vitamins and minerals, the first Regulation for authorisation is intended to regulate health claims concerning these nutrients.

2. Draft Authorisation Regulation

The current draft Regulation allows altogether 51 health claims for 11 vitamins and 10 minerals – each upon the basis of a "cause and effect relationship"[23] attested by EFSA and mentioned in Recital 8 of the Regulation. These claims are listed in the Regulation's Annex by order of substances. Essentially, they are "contributes to"-claims expressing the general participation of the substance in question in a certain bodily function. The conditions for use of the respective claims mentioned in the Annex in line with Recital 9 of the Regulation deserve particular attention. Accordingly, it is compulsory – upon the basis of the scientific assessments by EFSA – that the products claimed contain a "significant amount" of the nutrient in question in accordance with Nutrition Labelling Directive 90/496/EEC. Thus, the relevant health claims have to meet exactly the same criteria as the above mentioned nutrient claims pursuant to Article 8 in conjunction with the Annex of NHCR (see above I. 2.). In other words: A food supplement which because of its content of Calcium may be marketed with the nutrient claim "contains Calcium" can in future also be advertised with the claim "Calcium contributes to the maintenance of normal teeth and bone structures"; a product "with Vitamin C" can for example also bear the claim "contributes to the normal function of the immune system".

3. Health Claims for Vitamins and Minerals

For illustrative purposes, all these health claims awaiting authorisation are sorted subsequently in the order of their health relation (1st column). The table also lists the vitamins and minerals which justify the claim in question (2nd column) as well as the necessary minimum amounts of those nutrients, i.e. exactly 15 % of the relevant "recommended daily amount" (3rd column).

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17 Cf. Recital 23 NHCR; this reads: "Health claims should only be authorised for use in the Community after a scientific assessment of the *highest possible standard*".

18 Most of all, there are no transparent evidence criteria, cf. also *Hahn/Teufer*, ZLR 2008, p. 666.

19 http://ec.europa.eu/food/efsa/comments/efsa_reply_q2009_485.pdf, identical for example http://ec.europa.eu/food/efsa/comments/Q-2008-667-reply.pdf, almost identical also http://ec.europa.eu/food/efsa/comments/efsa_reply_q2008_106.pdf.

20 A reason could be that EFSA gives opinions which can amount to a massive market intervention but there are no legal means against the authority's publications.

21 Of course EFSA's reasons for rejections are plausible in many cases and justified from a scientific perspective where there are no studies concerning the population in question or obvious flaws restrict the validity of studies.

22 European Commission, Note for the attention of the Advisory Group on the Food Chain, Animal and Plant Health, "Model on progressive adoption of the Community list of health claims", 16.10.2009.

23 This is a connection between a substance (cause) and a certain body function (effect). Consequently, EFSA does not demand a direct relation, it can also be indirect and therefore further reaching. Thus, Vitamin C is a cofactor of the enzyme Dopamine-β-monooxygenase (direct effect) which is joined into the synthesis of the two neurotransmitters Adrenaline and Noradrenaline (indirect effect) which are essential for the maintenance of the normal function of the nervous system. For reasons of this causal link EFSA recognises that "a cause and effect relationship has been established between the dietary intake of Vitamin C and normal function of the nervous system"; cf. http://www.efsa.europa.eu/de/scdocs/doc/1226.pdf. It would therefore be only consequent to also positively assess applications for authorisations of the following claims: "Vitamin C is necessary for the activity of the enzyme Dopamine- β-monooxygenase" and "Vitamin C is necessary for the formation of the neurotransmitters Adrenaline and Noradrenaline".

Health relation ("contributes to [maintenance of] normal ...")	Nutrient (or other substance)	Necessary amount (15 % RDA or other amount)
acid-base balance	Zinc	1.5 mg
blood calcium concentrations	Vitamin D	0.75 µg
blood cholesterol concentrations	Alpha-linolenic Acid (ALA)	0.3 g (2 g)
	Linoleic Acid (LA)	1.5 g (10 g)
	Beta-glucans	(3 g)
	Glucomannan	(4 g)
blood clotting	Calcium	120 mg
	Vitamin K	11.25 µg
blood formation	Folate	30 µg
blood pressure	Eicosapentaenoic Acid (EPA)/ Docosahexaenoic Acid (DHA)	0.45 g (3 g)
blood vessels	Vitamin C	12 mg
(maintenance of normal) bone	Vitamin D	0.75 µg
	Phosphorus	105 mg
	Zinc	1.5 mg
	Magnesium	56.25 mg
	Calcium	120 mg
	Manganese	0.3 mg
	Vitamin K	11.25 µg
bone function	Vitamin C	12 mg
cartilage	Vitamin C	12 mg
cell differentiation	Vitamin A	120 µg
cell division	Vitamin B_{12}	0.375 µg
	Vitamin D	0.75 µg
	Iron	2.1 mg
	Zinc	1.5 mg
	Magnesium	56.25 mg
	Folate	30 µg
cell membranes	Phosphorus	105 mg
cognitive function	Iron	2.1 mg
	Zinc	1.5 mg
connective tissues	Copper	0.15 mg
digestive enzymes	Calcium	120 mg
electrolyte balance	Magnesium	56.25 mg
energy-yielding metabolism	Copper	0.15 mg
	Biotin	7.5 µg
	Vitamin B_{12}	0.375 µg
	Thiamin	0.165 mg
	Pantothenic Acid	0.9 mg
	Phosphorus	105 mg
	Iron	2.1 mg
	Niacin	2.4 mg
	Iodine	22.5 µg
	Magnesium	56.25 mg
	Vitamin C	12 mg
	Manganese	0.3 mg
	Calcium	120 mg
eyes	Vitamin A	120 µg
	Zinc	1.5 mg
fertility and reproduction	Zinc	1.5 mg
gum	Vitamin C	12 mg
hair	Biotin	7.5 µg
	Copper	0.15 mg
heart	Thiamin	0.165 mg
homocysteine metabolism	Folate	30 µg
hormonal activity	Vitamin B_6	0.21 mg
immune system	Vitamin B_{12}	0.375 µg
	Vitamin B_6	0.21 mg
	Vitamin A	120 µg
	Iron	2.1 mg
	Zinc	1.5 mg
	Vitamin C	12 mg
	Copper	0.15 mg
	Folate	30 µg
	Selenium	8.25 µg
iron absorption	Vitamin C	12 mg
iron metabolism	Vitamin A	120 µg

Health relation ("contributes to [maintenance of] normal ...")	Nutrient (or other substance)	Necessary amount (15 % RDA or other amount)
iron transport	Copper	0.15 mg
(breaking down) lactose	Lactase	
macronutrient metabolism	Biotin	7.5 µg
mental performance	Pantothenic Acid	0.9 mg
metabolism of fatty acids	Zinc	1.5 mg
metabolism of Vitamin A	Zinc	1.5 mg
mucous membranes	Vitamin A	120 µg
	Niacin	2.4 mg
	Biotin	7.5 µg
muscle function	Magnesium	56.25 mg
muscle function and neurotransmission	Calcium	120 mg
nerve function	Magnesium	56.25 mg
nervous system	Thiamin	0.165 mg
	Vitamin B_6	0.21 mg
	Vitamin C	12 mg
	Biotin	7.5 µg
	Copper	0.15 mg
	Niacin	2.4 mg
(reduction of) oral dryness	Sugar-free chewing gum	
(protection of cell constituents from) oxidative damage	Zinc	1.5 mg
	Vitamin C	12 mg
	Copper	0.15 mg
	Manganese	0.3 mg
	Selenium	8.25 µg
oxygen transport	Iron	2.1 mg
(tissue growth during) pregnancy	Folate	30 µg
protein and glycogen metabolism	Vitamin B_6	0.21 mg
protein synthesis	Magnesium	56.25 mg
red blood cell formation	Vitamin B_6	0.21 mg
	Vitamin B_{12}	0.375 µg
	Iron	2.1 mg
skin	Biotin	7.5 µg
	Vitamin A	120 µg
	Niacin	2.4 mg
	Iodine	22.5 µg
	Vitamin C	12 mg
	Copper	0.15 mg
spermatogenesis	Selenium	8.25 µg
(synthesis and metabolism of) steroid hormones, vitamin D and some neurotransmitters	Pantothenic Acid	0.9 mg
teeth	Vitamin D	0.75 µg
	Phosphorus	105 mg
	Magnesium	56.25 mg
	Vitamin C	12 mg
	Sugar-free chewing gum	
	Calcium	120 mg
	Fluoride	0.525 mg
thyroid	Iodine	22.5 µg
	Selenium	8.25 µg
triglyceride concentrations	Eicosapentaenoic Acid (EPA)/ Docosahexaenoic Acid (DHA)	0.45 g (2-4g)

A closer look at the table leads to interesting results. There are a number of claims which may be made for several substances. These are especially claims regarding bone structure, cell division, energy yielding metabolism, immune system, nervous system, cell protection, skin and teeth. In such cases, manufacturers can thus vary, sometimes even between mineral and vitamin. If, for example, a health claim regarding "blood clotting" shall be made, minimum amounts of either 120 mg Calcium or alternatively 11.25 µg of Vitamin K would suffice. Of course, lower amounts of substances also facilitate different galenics which may be appealing for limited capacities of food supplements regarding different types of consumption units.

It is also interesting that the Commission intends to allow claims for cell protection for a number of nutrients upon the basis of EFSA assessments. In

the past, the advertising claim "protection of cells from oxidative damages" has regularly been banned as illness related at least by competent courts in Germany[24]. Other health relations, for example regarding iron metabolism, shall be authorised for several nutrients in different shades, for example for Vitamin A regarding "iron metabolism", for Vitamin C regarding "iron absorption" and for Copper regarding "iron transport". Similar distinctions also apply to claims regarding blood, bones and cells. Accordingly, one can influence special aspects of product marketing through a choice of ingredients, not only with respect to health claims as such but also to special aspects of the health benefits in question. This feature shall be explained in some more detail by way of possible model recipes (see below III.).

At first, however, it should be pointed out that in the meantime further positive opinions have been published by EFSA regarding vitamins, minerals and some other substances on 25 February 2010 and on 19 October 2010. These assessments have not yet been compiled in a draft Regulation by the Commission but it is foreseeable that they will be authorised in a similar manner at some stage. For completeness sake, these new opinions have been listed here[25] in the same manner as in the previous table:

Health relation ("contributes to [maintenance of] normal ...")	**Nutrient (or other substance)**	**Necessary amount (15 % RDA or other amount)**
amino acid metabolism	Molybdenum	7.5 µg
amino acid synthesis	Folate	30 µg
blood cholesterol	Plant sterols and plant stanols	0,8 g
(fasting) blood concentrations of triglycerides	Docosahexaenoic Acid (DHA)	2 g
blood glucose concentrations	Trivalent chromium	6 µg
blood pressure	Potassium	300 mg
brain function	Docosahexaenoic Acid (DHA)	250 mg
carbohydrate metabolism	Zinc	1.5 mg
cardiac function	Mixed long-chain n-3 polyunsaturated fatty acids (n-3 LCP-UFA), namely Docosahexaenoic Acid (DHA) in combination with Eicosapentaenoic Acid (EPA) and, for ID 703, with Docosapentaenoic Acid (DPA)	250 mg
(regulation of normal) cell division and differentiation	Calcium	120 mg
cognitive and neurological function	Iodine	22.5 µg
(formation of) connective tissue	Manganese	0.3 mg
digestion by production of hydrochloric acid in the stomach	Chloride as Na-, K-, Ca-, or Mg-salt	120 mg
(protection of) DNA, proteins and lipids from oxidative damage	Riboflavin	0.21 mg
	Vitamin E	1.8 mg
energy-yielding metabolism	Riboflavin	0.21 mg
	Vitamin B_6	0.21 mg
(reduction in) gastrointestinal transit time	Lactulose	10 g
hair	Selenium	8.25 µg
	Zinc	1.5 mg
homocysteine metabolism	Vitamin B_6	0.21 mg
	Vitamin B_{12}	0.375 µg
(function of the) immune system and inflammatory response	Vitamin D	0.75 µg
macronutrient metabolism	Trivalent Chromium	6 µg
	Zinc	1.5 mg
metabolism of iron	Riboflavin	0.21 mg

24 Thus expressly Berlin Court of Appeal, ZLR 2000, p. 88 with critical case note *Mettke* as well as Berlin Court of Appeal, ZLR 1993, p. 549 and Berlin Court of Appeal, ZLR 1993, p. 482; cf. also *Zipfel/Rathke*, Lebensmittelrecht, C 102, § 12 LFGB marginal 20.

25 The list concentrates primarily on claims regarding vitamins and minerals as well as some other substances which are of significance in food supplements in general and which can be used in dose form designed to be taken in measured small unit quantities as envisaged by Article 2 lit. a) of Directive 2002/46/EC.

Health relation ("contributes to [maintenance of] normal ...")	Nutrient (or other substance)	Necessary amount (15 % RDA or other amount)
muscle function	Vitamin D	0.75 µg
muscular and neurological function	Potassium	300 mg
nails	Selenium	8.25 µg
	Zinc	1.5 mg
(function of the) nervous system	Riboflavin	0.21 mg
neurological and psychological functions	Vitamin B_{12}	0.375 µg
protein synthesis	Zinc	1.5 mg
psychological functions	Biotin	7.5 µg
	Folat	30 µg
	Magnesium	56.25 mg
	Thiamin	0.165 mg
	Vitamin B_6	0.21 mg
	Niacin	2.4 mg
	Vitamin C	12 mg
red blood cells	Riboflavin	0.21 mg
regeneration of the reduced form of vitamin E	Vitamin C	12 mg
skin	Zinc	1.5 mg
skin and mucous membranes	Riboflavin	0.21 mg
(serum) testosterone concentrations	Zinc	1.5 mg
(reduction of) tiredness and fatigue	Folat	30 µg
	Iron	2.1 mg
	Magnesium	56.25 mg
	Niacin	2.4 mg
	Pantothenic Acid	0.9 mg
	Riboflavin	0.21 mg
	Vitamin B_6	0.21 mg
	Vitamin B_{12}	0.375 µg
	Vitamin C	12 mg
vision	Docosahexaenoic Acid (DHA)	250 mg
	Riboflavin	0.21 mg

III. Model Recipes and Claims

The currently planned authorisation of health claims (table 1) as well as the authorisations to be expected upon the basis of the new positive EFSA opinions (table 2) make it possible to distil a number of model recipes for food supplements. Upon the basis of such authorisations, it would be permitted to use the claims as long as the products in question contained the necessary amounts of vitamins and minerals.

If one has a look at the "OTC" market and the large group of popular "indications" with which nutrient preparations are currently marketed[26], the subsequent EFSA-compatible model recipes may appeal to suppliers of food supplements[27]. It is always recommendable in this context to use 12 mg Vitamin C as well as 1.5 mg Zinc. These nutrients appear to be EFSA's main favourites: Their benefits cover almost everything, especially as Vitamin C[28] and Zinc[29] have a number of effects other substances do not have, and thus justify comparatively many health claims. That is why Vitamin C in particular should only be excluded from food supplement recipes in exceptional circumstances; if the

26 Cf. *Hofbauer*, Aktuelle Entwicklungen und Trends im Markt der Gesundheitsmittel und Nahrungsergänzungsmittel, Vortragsfolien, Euroforum „Nahrungsergänzungsmittel"-Jahrestagung, 21./22.1.2010.

27 Regarding the manifold and uncontested effects of vitamins and minerals, reference is made to standard nutrition science and nutrition medicine textbooks – also beyond the claims assessed by EFSA, e.g. *Hahn*, Nahrungsergänzungsmittel, 2. Aufl. 2006; *Hahn/Stöhle/Wolters*, Ernährung – physiologische Grundlagen, Prävention, Therapie, 2. Aufl. 2006; *Leitzmann et al.*, Ernährung in Prävention und Therapie, 3. Aufl. 2009; *Biesalski/Bischoff/Puchstein* (Hrsg.), Ernährungsmedizin, 4. Aufl. 2010.

28 The following health relations have been positively assessed for Vitamin C by EFSA: normal function of the immune system; maintain the normal function of the immune system; during and after intense physical exercise; normal collagen formation and the normal function of bones, teeth, cartilage, gums, skin and blood vessels; normal energy-yielding metabolism; normal function of the nervous system; protection of cell constituents from oxidative damage; increase non-haem iron absorption; reduction of tiredness and fatigue; contribution to normal psychological functions; regeneration of the reduced form of Vitamin E.

29 The following health relations have been positively assessed for Zinc by EFSA: normal function of the immune system; maintenance of normal bone; maintenance of normal vision; normal acid-base metabolism; normal cognitive function; normal DNA synthesis and cell division; normal fertility and reproduction; normal metabolism of fatty acids; normal metabolism of Vitamin A; protection of cell constituents from oxidative damage; maintenance of normal skin; contribution to normal protein synthesis; maintenance of normal serum testosterone concentrations; contribution to normal carbohydrate metabolism; maintenance of normal hair; maintenance of normal nails; contribution to normal macronutrient metabolism.

mere volume of 12 mg Vitamin C causes problems with respect to galenics, 1.5 mg Zinc will usually be the suitable alternative. A further large range of health claims is also permitted when using 120 mg Calcium[30].

It should be noted in this context that the following recipes, in spite of the fact that they will be legitimate by law and upon the basis of EFSA's opinions, may still lead to products with questionable nutritional benefits and with claims which might well have been perceived as misleading in the past. Thus, one may ask whether better and especially more sensible food supplements will still be marketed in future although "cheaper" 15 % RDA alternatives allow the same claims.

1. Immune System/Common Cold

It is well known that vitamins and minerals are of central significance for the immune function[31]. Hence, it can scarcely be a surprise that such relations have been recognised by EFSA. A "normal function of the immune system" may thus not only be advertised when using 12 mg Vitamin C, also 0.375 µg Vitamin B_{12}, 0.21 mg Vitamin B_6, 120 µg Vitamin A, 2.1 mg Iron, 1.5 mg Zinc, 30 µg Folic Acid or 8.25 µg Selenium justify this claim. Suppliers could use the authorisation of the health claim also as a welcome additional statement for other food supplements containing those nutrients. Thus, wherever one of these substances is contained in the subsequent recipe, beneficial effects on the immune system can also be mentioned.

2. Eyes/Vision

Food supplements supporting healthy vision are currently often marketed as line extensions to foods for special medical purposes for the dietary management of "age related eye disease" which in turn have to be labelled with this mandatory indication pursuant to national implementations of Article 4 para. 4 lit. a) of Directive 1999/21/EC[32]. Such a compulsory labelling element would of course not qualify as a claim pursuant to Article 1, para. 5 and Article 2, para. 2, No. 1 NHCR. The essential nutrients of such products have also been positively assessed for health claims by EFSA. Thus, 120 µg Vitamin A and 1.5 mg Zinc justify the advertising of a relation to "normal vision", as do 250 mg DHA and 0,21 mg Vitamin B_2 (Riboflavin) pursuant to the most recent scientific opinions.

3. Digestion/Metabolism

120 mg Calcium allow claiming a "normal function of digestive enzymes". 10 g Lactulose, which can be put easily in a sachet portion, contribute to the "reduction in gastrointestinal transit time". A normal "macronutrient metabolism" can be advertised upon the basis of 7.5 µg Biotin, 6 µg Trivalent Chromium or 1.5 mg Zinc. Additionally the "normal metabolism of fatty acids" as well as the "normal metabolism of carbohydrates" may be claimed for food supplements with the required content of 1.5 mg Zinc, which makes Biotin and Trivalent Chromium look superfluous by comparison. 7.5 µg Molybdenum maintain a "normal amino acid metabolism", 30 µg Folic Acid even a "normal amino acid synthesis". A "normal cysteine synthesis"[33] is sustained by 0.2 mg Vitamin B_6. The enzyme Lactase can also contribute to splitting lactose[34].

4. Skin/Hair/Nails

Health claims regarding "normal hair" and "normal skin" may be made for food supplements containing 7.5 µg Biotin or 0.15 mg Copper. "Normal hair" as well as "normal nails" can be advertised upon the basis of 1.5 mg Zinc or 8.25 µg Selenium. Alternatively, the claim regarding skin can be justified with 12 mg Vitamin C or 1.5 mg Zinc, respectively, or else with 120 µg Vitamin A, 2.4 mg Niacin or 22.5 µg Iodine, which, however, do not really make sense in the recipe because of the additional claims possible for Vitamin C and Zinc.

30 The following health relations have been positively assessed for Calcium by EFSA: normal blood clotting; normal energy-yielding metabolism; normal muscle function and neurotransmission; normal function of digestive enzymes; maintenance of normal bones and teeth, regulation of normal cell division and differentiation.

31 For an up-to-date overview cf. e.g. *Ströhle/Hahn*, MMW-Fortschr. Med. Originalien III, 151, 2009, pp. 133–141.

32 Cf. also *Hagenmeyer*, DLR 2009, pp. 78 (87).

33 It is unlikely that consumers can appreciate this claim (cf. also below IV. 2.). This raises the question whether the significance of cysteine can be explained in a manner that would not require authorisation pursuant to NHCR.

5. Muscles/Bones/Joints

Health effects on a "normal bone function" and "normal cartilage function" may be claimed for food supplements with 12 mg Vitamin C. An additional emphasis on the maintenance of a "normal bone structure" is justified by the use of 0.75 µg Vitamin D, 105 mg Phosphorus, 1.5 mg Zinc, 56.25 mg Magnesium, 120 mg Calcium, 0.3 mg Manganese or 11.25 µg Vitamin K.

Advertising the maintenance of a "normal muscle function" requires 56.25 mg Magnesium or 0.75 µg Vitamin D. For the claim "normal muscular and neurological function" 300 mg Potassium are required. Currently, there are several food supplements on the market containing Magnesium which mention this particular effect. However, it is unclear why food supplements for normal muscle function should contain Magnesium in the future, since the alternative use of 120 mg Calcium allows a more comprehensive claim of a contribution to "normal muscle function and neurotransmission". The advertising of "the maintenance of normal connective tissue function" requires an additional amount of 0.15 mg Copper, of "normal formation of connective tissue" 0.3 mg Manganese.

From a marketing perspective, Glucosamine and Chondroitin are not needed for bones because EFSA has rejected claims applications for "maintenance of joints and reduction of inflammation" as well as "reduced rate of cartilage degeneration and reduced risk of development of osteoarthritis" with respect to healthy joints[35]. However, these substances may of course be added to such a product, albeit without a substance related claim.

6. Bladder/Reproduction

According to EFSA, no vitamin or mineral supports a normal function of the bladder. However, a contribution to "normal fertility and reproduction" can be claimed upon the basis of 1.5 mg Zinc. Furthermore, 0.21 mg Vitamin B_6 allows the additional claim of "regulation of hormonal activity". 30 µg Folic Acid supports "tissue growth during pregnancy" and the claim of a contribution to "normal spermatogenesis" requires 8.25 µg Selenium; it could be interesting in this context not only for fertility that 1.5 mg Zinc is also significant for the maintenance of "normal serum testosterone concentrations". Thus, Zinc and Vitamin B_6 should be contained in a fertility food supplement in any event.

7. Blood/Circulation

More or less attractive claims on "blood" demand the use of different vitamins and minerals. A "normal blood clotting" may be claimed for foodstuffs containing 120 mg Calcium or 11.25 µg Vitamin K. The advertising of "normal blood vessels" is justified upon the basis of 12 mg Vitamin C. And the presentation of "normal blood formation" is maintained by 0.21 mg Vitamin B_6, 0.375 µg Vitamin B_{12} or 2.1 mg Iron. If only the "formation of red blood cells" shall be advertised, one can alternatively resort to 0.21 mg Vitamin B_2.

An upgrading of the advertising to the "normal heart function" requires 0.165 mg Thiamine or 250 mg mixed long-chain polyunsaturated fatty acids in the recipe. The addition of the already mentioned 2.1 mg Iron also justifies a contribution to the "normal oxygen transport". Furthermore, 30 µg Folic Acid has an effect on a "normal homocysteine level". From a marketing perspective, the already mentioned claim on "protection of cell constituents from oxidative damage" (s.a. II. 3.) may also be attractive; it is justified upon the basis of 12 mg Vitamin C as well as 1.5 mg Zinc, 0.15 mg Copper, 0.3 mg Manganese or 8.25 µg Selenium.

The use of EPA and DHA in amounts recognised as a "source" within the meaning of the Annex of NHCR (i.e. in "significant quantities") allows claiming a "contribution to normal triglyceride concentrations" in the blood as well as mentioning a support of "normal blood pressure". It is interesting to note that the conditions of use of the claim demand additional information to the consumer that the beneficial effect is obtained with the daily intake of

34 http://www.efsa.europa.eu/de/scdocs/scdoc/1236.htm; this cannot surprise!

35 http://www.efsa.europa.eu/de/scdocs/scdoc/1264.htm as well as http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753820_1211902983270.htm; the essential reason for this negative assessment is that there are no studies in the healthy general population (the target population of the health claim) but only data gained with patients suffering from osteoarthritis.

2–4 g/d and 3 g/d of the fatty acids[36], respectively. It is also noteworthy that 0.8 g Phytosteroles or Phytostanoles may be promoted to contribute to the "normal blood cholesterol level". Finally, presenting "normal cholesterol concentrations in blood" is also possible for food supplements containing 2 g of Alpha Linolenic Acid or 10 g Linolenic Acid[37]; but 3 g Beta Glucans or 4 g Glucomannan allow this claim, too. In case lower amounts of EPA and DHA are used, i.e. less than 2-4 g or 3 g per recommended daily dose, the additional information must be labelled!

8. Sedation/Sleep/Concentration

Health claims on a "normal cognitive function" may be made for food supplements containing either 2.1 mg Iron or 1.5 mg Zinc. The "normal mental performance" is supported by 0.9 mg Pantothenic Acid, "normal cognitive and neurologic function" by 22.5 µg Iodine.

56.25 mg Magnesium suffice for the advertising of a "normal nervous function". The "normal nervous system" may be marketed with contents of 12 mg Vitamin C, 0.165 mg Thiamine, 0.21 mg Vitamin B_6, 7.5 µg Biotin, 0.15 mg Copper, 2.4 mg Niacin or 0.21 mg Riboflavin.

EFSA has confirmed several relations of nutrients contributing to "normal psychological functions": 7.5 µg Biotin, 30 µg Folic Acid, 56.25 mg Magnesium, 2.4 mg Niacin, 0.165 mg Thiamine, 0.21 mg Vitamin B_6 or the almost compulsory 12 mg Vitamin C justify this health claim. Noteworthy and surely interesting for marketing is also a large number of nutrients which contribute to a "reduction of tiredness and fatigue": 30 µg Folic Acid, 2.1 mg Iron, 56.25 mg Magnesium, 2.4 mg Niacin, 0.9 mg Pantothenic Acid, 0.21 mg Riboflavin, 0.21 mg Vitamin B_6, 0.375 µg Vitamin B_{12} and of course also 12 mg Vitamin C allow the presentation of such effects. However, no generally recognised benefits of vitamins and nutrients on sleep and sedation have been recognised by EFSA.

9. Teeth/Gums

The almost compulsory 12 mg Vitamin C permit the marketing of "normal tooth function" and "normal gum function". The tooth claim is also justified when using 0.75 µg Vitamin D, 105 mg Phosphorus, 56.25 mg Magnesium, 120 mg Calcium or 0.525 mg Fluoride; however, these nutrients do not allow the marketing of positive effects on the gums.

10. Special Recipes

The range of potential model recipes could still be extended. However, the examples mentioned, be they sensible or not, should suffice to make the principle clear. On this basis, one can summarise: The positive EFSA opinions and the ensuing future authorisations of health claims allow combinations of product concepts up to the most absurd preparations. Indeed, it is irrelevant for such food supplements whether they make sense from a nutritional point of view; only the authorised claims matter. A food supplement could actually be marketed with almost all the above mentioned claims if it merely contained the following preferred nutrient combination: 12 mg Vitamin C, 120 mg Calcium, 1.25 mg Zinc and 0.15 mg Copper.

Such a preparation could support concentration and nerves as well as bones and muscles, it would be beneficial to digestion and fertility, maintain psychological functions, reduce tiredness and fatigue and it might also support the immune system. All these health effects could thus be advertised accordingly – at surprisingly cheap costs for the manufacturer of the supplement. The product could be marketed with claims on-pack as well as through other media individually or in combination, and the core recipe would at the same time allow the establishment of a large product portfolio. Individual items of the portfolio could be fortified with other substances, even those for which no authorised health claims are available, e.g. glucosamine and chondroitin or L-carnitine. The essential nutrient combi-

36 This approach is surprising and shows the inconsistency of EFSA's procedure. In fact, EFSA recognises a positive health effect – as with vitamins and minerals – although there is no evidence for the dosages in question by way of human studies. Other than in cases of vitamins and minerals consumers have to be advised, however, that the dosage in question has no benefit. Upon the basis of this method, other health claims would also have to be acknowledged by EFSA.

37 This claim can be used in this form without restrictions if the amounts of fatty acids mentioned are contained. Alpha-linolenic Acid has to be contained at least in a "source of" amount of this nutrient, Linoleic Acid is necessary in amounts of 1.5 g. In these instances, however, it has to be indicated that the beneficial effect only appears with a consumption of 2 g or 10 g, respectively, of the fatty acids.

nation would even allow the marketing of a daisy extract – with implicit approval by the highest competent scientific body in Europe[38].

IV. Legal and Scientific Assessment

1. Food and Unfair Competition Law Aspects

The legal situation which is created by the planned Authorisation Regulation is comparatively simple in principle. The stipulations of the draft connect with Article 10 NHCR, the essential ban on health claims[39]. Pursuant to Article 10, para. 1 NHCR, health claims are "prohibited unless they comply with the general requirements in Chapter II and ... are authorised in accordance with this Regulation and included in the lists of authorised claims provided for in Articles 13 and 14". Article 1 of the new Regulation accordingly authorises the health claims set out in the Regulation's Annex in compliance with the conditions mentioned there and also envisages that the claims shall be included into the Union list of permitted claims pursuant to Article 13, para. 3 NHCR.

With the express authorisation and the parallel inclusion in the Union list, the health claims in question meet the most important requirements of Article 10, para. 1 NHCR. As this stipulation also refers to Chapter II of NHCR, food supplements have to comply with the criteria of Article 5 NHCR, especially the individual demands of Article 5, para. 1 NHCR. However, since the new authorisations are based on EFSA opinions, most of these conditions will be met. The "generally accepted scientific evidence" pursuant to Article 5, para 1 lit. a) and b) NHCR for a "beneficial nutritional or physiological effect" relating to the content of a "significant quantity" is present in the pertaining EFSA opinions – for 15 % of the "recommended daily amount" of the relevant vitamins and minerals. The criterion of Article 5, para. 1 lit. d) NHCR, namely that the "quantity of the product that can reasonably be expected to be consumed" supplies "a significant quantity of the nutrient" is essentially met by food supplements because of the mandatory indication of the "portion of the product recommended for daily consumption" pursuant to Article 6, para. 3 lit. b) of Food Supplements Directive 2002/46/EC. Furthermore, it should go without saying that nutrients are "available to be used by the body" in food supplements as demanded by Article 5, para. 1 lit. c) NHCR because this is an essential criterion of this particular type of foodstuff; otherwise the relevant vitamin and mineral forms in question would not be authorised pursuant to Article 4, para. 1) in conjunction with Annex 2 of Directive 2002/46/EC nor could they "supplement the normal diet" with "nutrients or other substances" pursuant to Article 2, lit. a) of the Directive.

It should be noted that Article 2 of the new Regulation allows a further use of claims assessed until 1 October 2009, but not authorised pursuant to Article 1, for an additional six months after the entry into force of the Regulation. This feature once again extends the transition period of Article 28, para. 5 NHCR for health claims within the meaning of Article 13, para. 1 lit. a) NHCR which have got a negative evaluation by EFSA. The reason for this extension is mentioned in Recitals 12 and 13 of the draft Regulation: Food business operators shall get an opportunity to adapt to the change of the legal situation against the background of the delayed authorisation of health claims. Whilst this motivation is understandable, it is at least problematic from a systematic legal perspective and under the rule of law[40]. Scientifically insufficiently substantiated claims on health effects have always been illegal pursuant to Article 2, para. 1 lit a) (i) and (ii) of Labelling Directive 2000/13/EC and of course this ban also applies during the statutory transition period of Article 28, para. 5 NHCR[41]. Although the negative opinions in issue have been known since 1 October 2009, one may still perceive the statutory extension of – non-existing – transition periods as useful, especially because food supplements normally have a longer durability than many other foodstuffs. However, it may well be doubted whether the proposed extension of time for unproven health benefits will be recognised by the competent courts in spite of the general ban on misleading advertising.

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38 Cf. also *Hagenmeyer/Hahn/Teufer*, „Das Gänseblümchen wird entblättert", StoffR 2006, p. 2.

39 Cf. only *Meisterernst/Haber*, Health & Nutrition Claims, Art. 10 VNGA marginal 3.

40 Cf. also *Meisterernst*, WRP 2010, pp. 481 (489).

41 Cf. in this context *Hagenmeyer*, „Das ‚Survival' der ‚Claims'", StoffR 2007, pp. 201, 206 and 207–208; dissenting *Meisterernst*, WRP 2010, pp. 481 (490).

2. Assessment of Marketing Opportunities

With a view at the type and manner of advertising, a glance at Article 5, para. 2 NHCR appears interesting; this stipulation, in line with Recital 16 of the Regulation, establishes the condition that "the average consumer can be expected to understand the beneficial effects as expressed in the claim"[42]. This statutory requirement raises the question if and how far food business operators may deviate from the wordings of the claims envisaged to be authorised. Whether claims regarding the "homocysteine level", "spermatogenesis", "cysteine synthesis", "triglyceride concentration" or even the "normal function of the immune system and healthy inflammatory response" can meet the criterion may well be doubted with good reason. And which consumer will be able to understand advantages of Vitamin C with a view to an increased intake of "non-haem iron"[43]? Such a claim can only be fully appreciated if it is accompanied by an additional explanation that foodstuffs contain different types of iron, that non-haem iron dominating in food of plant origin is more difficult to metabolise and that this type of iron can be better absorbed by the human digestion in the presence of Vitamin C.

The Commission has in fact taken notice of that problem also with respect to health claims for vitamins and minerals. This can be seen from Recital 10 of the planned Regulation which mentions that not only the wordings listed in the Annex of the Regulation but also wordings having "the same meaning for consumers ... should be subject to the same conditions of use indicated for the authorised health claims". Against the background of the requirement of intelligibility pursuant to Article 5, para. 2 NHCR, this can only mean that food business operators may paraphrase authorised claims within the frame of the same meaning. The claims listed in the Annex of the new Regulation can thus be simplified as long as they remain fully understandable for average consumers or become understandable as long as the advertised beneficial effect is not distorted. However, no extension of the meaning of an authorised claim will be permitted. Because of these obstacles some health claims will probably not survive in practice in spite of their authorisation. Yet, a restriction of a claim's meaning should be lawful in principle: For example, it is not necessary to promote the "cognitive and neurological function" to which 22.5 µg Iodine contribute; marketing measures may merely claim one of these aspects.

Since most consumers still do not know about the compulsory authorisation of health claims, not to mention (details of) the requirement of the scientific evaluation by EFSA and the pertaining criteria, it must be allowed to refer to positive EFSA opinions in food advertising. This may be done by way of footnotes or additions to the authorised claims in brackets mentioning that a particular health benefit is a generally recognised product quality which has been positively assessed by the highest competent scientific instance. With a view of the general ban on misleading advertising pursuant to Article 2, para. 1 lit. a) of Directive 2000/13/EC, such statements must not create the false impression, EFSA had examined the product itself. Furthermore, it would be unlawful to suggest the existence of a positive EFSA opinion as a special characteristic although this would also be true for all similar foodstuffs; but this would require a presentation of an EFSA evaluation in a deceptive manner as a peculiarity of the advertised foodstuff[44]. A matter of fact presentation of product characteristics generally unknown to consumers, however, should not breach the law[45]. Furthermore, advertising may of course also refer to product related studies within the context of an authorised health claim as long as such references do not exceed the scope of the relevant authorisation.

Another privilege of food supplements should be mentioned in this context which follows from the compulsory labelling element pursuant to Article 6, para. 3 lit. a) of Directive 2002/46/EC. Accordingly, "names of categories of nutrients or other substances which are characteristic for the product or an indication for the characterisation of these nutri-

42 Cf. *Zipfel/Rathke*, Lebensmittelrecht, C 111, Art. 5 VNGA marginal 24.

43 This claim also shows the doubtful approach of EFSA. The authors are not aware of data confirming an increased iron absorption through a consumption of 12 mg Vitamin C. Therefore, such a claim would have to fall short of the ban on misleading advertising pursuant to Article 2 para. 1 lit. a) of Directive 2000/13/EC because it suggests a health effect which is not proven for the dosage in question.

44 Cf. *Zipfel/Rathke*, Lebensmittelrecht, C 102, § 11 LFGB marginal 215.

45 Cf. *Meyer/Streinz*, LFGB/BasisVO (Auszüge), § 11 LFGB marginal 110.+

ents or other substances" have to be labelled on-pack. Additionally, Article 8, para. 1 of the Directive demands the indication of the "amounts of nutrients or other substances with nutritional or physiological effect present in the product". It follows that the above mentioned model recipes can be extended with respect to such "characteristic ingredients" even where those substances are not subject matter of a health claim. This is because Article 2, para. 2 No. 1 NHCR expressly excludes mandatory labelling elements from the statutory definition of the term "claim". Hence, compulsory indications of substances not mentioned in the Annex of NHCR, i.e. especially "other substances" than vitamins and minerals, do not always have to meet the requirements of Article 5 NHCR. In such cases, it has not to be shown that the presence of another substance to which a claim relates has "a beneficial nutritional or physiological effect" in the foodstuff. For example, a food supplement containing 12 mg Vitamin C may be marketed with a "joint"-health claim and at the same time contain Glucosamine and Chondroitin as characteristic ingredients – as long as the claim does not refer to the latter substances (s.a. III. 5.). The same applies e.g. to L-carnitine supplements which in order to justify the claim "contributes to the maintenance of a normal energy metabolism" a fortified with 0.375 µg Vitamin B_{12}, 0.21 mg Vitamin B_6, 0.165 mg Thiamine or 0.21 mg Riboflavin.

3. Scientific Aspects

The intended authorisation of health claims is even more problematic from a scientific perspective especially with a view to the purpose of the NHCR. This is obvious not only from the first lot of EFSA opinions published on 1 October 2009, but also from the further opinions published in the meantime on 25 February 2010 and 19 October 2010. EFSA employs a two-tier procedure. In a first step, the authority examines whether the claimed effect is beneficial for human health. For example, it has put forward that a "normal immune function" or a "normal vision" meet this criterion. The formation of collagen is also perceived as beneficial; and since collagen serves as a structural component of blood vessels, cartilage, bones and skin, effects of a nutrient, namely Vitamin C, are accepted as effects on the relevant body structures[46]. In a second step, the NDA panel examines the question to what extent the relation between the nutrient and the alleged health benefit is substantiated from a scientific point of view.

The corresponding EFSA opinions essentially accept claims which relate to well established effects of vitamins and minerals. Hence, they cannot really surprise from a scientific perspective. A glance at the pertaining physiological-biological processes makes this clear because such relations actually exist. Well-known metabolism characteristics as well as the fact that the absence of the relevant substances leads to defined symptoms are sufficient for EFSA to find a cause-effect-relationship. Specific studies showing proof of an effect or a defined dose-response-relationship appear to have been less important. It is especially surprising that the nutrients under examination have well-known physiological-biochemical effects but the claimed health benefits can hardly be proven for the respective dosage. This is why – as EFSA phrases it – they only "contribute" to the relevant health function.

This can be demonstrated with an example of an opinion on health claims regarding Vitamin C: The biochemical fact that Vitamin C participates in reactions of the collagen biosynthesis as a cofactor and that scurvy as a Vitamin C malnutrition disease especially shows clinical symptoms of collagen biosynthesis lead to EFSA's acceptance of a corresponding health benefit of this vitamin. The same applies to the effects of Vitamin C on the nervous system since this nutrient participates in the formation of neurotransmitters. Such a procedure is acceptable from a scientific perspective and in most cases corresponds with the demands of the NHCR because the functions are evident and highly plausible. Methodically adequate human studies (for example by way of targeted deficiency experiments) would not be possible in many cases.

But EFSA has also recognised the already mentioned and biochemically also plausible increase of non-haem Iron through Vitamin C in spite of the authority's following assessment: "Although the clinical effects of Vitamin C intake in raising haemoglobin concentrations when administered with iron are modest, inorganic (non-haem) Iron absorption is increased by 1.5 to 10 fold depending on iron status, the dose of Vitamin C and the test

46 Cf. http://www.efsa.europa.eu/de/scdocs/doc/1226.pdf.

meal. Vitamin C is administered with Iron in clinical practice to increase the absorption of the latter". In other words: There is no indication that the amount of 12 mg Vitamin C per day which is perceived as necessary for the health claim, has a provable effect on the Iron intake. A "modest" effect of a nutrient in a dosage for which no proof can be shown is thus acknowledged as the main basis of a positive EFSA opinion in this case and consequently the later authorisation of a health claim.

Similarly surprising are claims regarding a "reduction of tiredness and fatigue" by Vitamin C and a number of other nutrients. EFSA first maintains that "reduction of tiredness and fatigue is a beneficial physiological effect". Furthermore, the NDA panel opines the scientific substantiation "provided by consensus opinions/reports from authoritative bodies and reviews shows that weakness and fatigue are among the symptoms of Vitamin C deficiency" und "symptoms respond to Vitamin C supplementation"[47]. In other words: The deficiency of mere symptoms confirms the conclusion that the nutrient contributes to the reduction of tiredness and fatigue. However, it can be doubted with good reasons whether such a claim corresponds with the purpose of the NHCR and especially Article 5, para 1 lit. b) (i) NHCR. This is because it can neither be shown that already the "significant quantity" of 12 mg Vitamin C has this effect nor is the wording of the health claim suitable to protect consumers from deception. On the contrary: It suggests – in spite of the auxiliary "contributes to" – that the consumption of low amounts of Vitamin C (and also other nutrients) has a proven health benefit which in fact is not present in this form. Until so far, such a claim would probably have being classified as deceptive within the meaning of Article 2, para 1 lit. a) of Directive 2000/13/EC.

Contrary to that, EFSA does not see a connection between Vitamin C and "normal vision". Apparently, the authority applies a far stricter standard here. Essentially, it comes to this conclusion because intervention studies concerning a relation between Vitamin C supply and cataract risk are inconsistent, although many, but of course not all, observational studies imply such a correlation[48].

These few examples may show that EFSA's approach is highly critical, especially as it lacks a minimum of scientifically essential transparency and consistency. Obviously, the authority employs variable standards and positively assesses cause-effect-relations – contrary to the intentions of the NHCR – where precise dosages cannot be proven; whilst in other cases a doubtful measure of evidence is accepted which, however, is not concretely defined. Hence, there is no uniform assessment practice for all substances which could allow sensible health claims for scientifically convincing recipes.

For this reason, it appears unavoidable to reach a legal clarification by the competent courts upon the basis of applications for health claims with scientifically unjustified rejections. A leading case might help to reveal how the statutory requirements for the authorisation of health claims have to be met. The current – inconsistent – assessment practice of EFSA cannot be the proper applicable standard. It would be interesting to see whether and how far the present practice would survive a ruling by the European Court of Justice.

V. Conclusion and Outlook

How can the food industry defend well against the authorisation procedure for health claims and its current application by the European Commission and EFSA? Perhaps one has to hoist the legislator by his own petard. It has to be doubted whether the currently envisaged authorisations of health claims can "ensure a high level of protection for consumers and ... facilitate their choice" as intended pursuant to Recital 1 of the NHCR. One can rather conclude once again that the NHCR and EFSA's opinions as a basis for the authorisation of health claims are a bureaucratic monster[49] which unnecessarily binds enormous capacities all over Europe and generates huge costs that at the end of the day have to be borne by consumers. The Regulation is also clearly impeding innovation and makes the development of foodstuffs having to rely on health claims a hardly calculable risk. Who can predict whether submitted data will convince a small panel in Parma if it is not even clear which standards the scientists

47 Cf. http://www.efsa.europa.eu/de/scdocs/doc/1815.pdf.

48 EFSA is labouring under the false conclusion that intervention studies as such have a higher quality; regarding an evidence based approach for the assessment of nutritional relations as well as potential criteria cf. *Ströhle/Hahn*, Akt. Ernährunsmed. 35 (2010), in print.

49 Thus *Hagenmeyer* passim.

there apply and when (!) they decide – not to mention the lack of opportunities to communicate with the authority?

Thus, suppliers of food supplements, but also other food business operators, can only try to make creative use of the imminent Union list of authorised health claims. Scientific aspects and questions of a sensible product composition can lose their significance when new food supplements are being conceived. A look at the lists of the "cheap" future health claims introduced in this article could become the decisive criterion for manufacturers who are primarily interested in selling their products. The resulting marketing measures would be lawful and legitimate by courtesy of EFSA, but also necessary – at worst in self-defence!