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Current Status of Health Claims in the European Union

The "Regulation on Nutrition and Health Claims Made on Foods" and related best practices

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Current Status of Health Claims in the European Union

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1. Introduction

After a long and difficult discussion between the individual Member States of the European Union and European institutions, the Regulation on nutrition and health claims made on foods ("NHCR 1924/2006") was published on 18 January 2007[1]. It has been in force since 1 July 2007.

NHCR 1924/2006 covers nutrition (Art. 2, para. 2(4)) and health claims (Art. 2, paras. 2(5) and (6)) on food labels and in advertisements.

Since the entry into force of this regulation, every health claim is "prohibited with a right of permission" (Art. 10, para. 1) which represents a legal paradigm shift, and furthermore, each claim must undergo a costly and time-consuming official authorisation procedure (Arts. 13, 15, and 18). In the case of health claims, generally accepted scientific information must be presented as evidence that the presence, absence, or decreased presence of a substance to which the claim refers has a positive nutritional-physiological effect.

paradigm shift

2. Scope

Art. 14 of NHCR 1924/2006 allows for the possibility of approval of so- called "risk reduction claims" (such as "Plant sterols demonstrably reduce cholesterol levels. High cholesterol is a risk factor of coronary heart disease"[2]. Nevertheless, **disease-related claims** are prohibited under Art. 7, para. 3 of the Food Information to Consumers Regulation (FIC) 1169/2011.

In circumstances where a **special provision** applies pertaining to the regulation of specific nutrition and health claims, for example

1 Corrigendum to Reg. (EC) No 1924/2006 on nutrition and health claims made on foods (OJ L 12/3, 18.1.2007).

2 Commission Reg. (EC) Nr. 983/2009 (OJ L 277/3, 22.10.2009).

those for food products that are intended for special nutritive purposes[3], mineral water, drinking water[4], and dietary supplements[5], the special provision takes precedence over NHCR 1924/2006.

allergies

The classification of claims that convey the reduction of a health risk in the form of **allergies and intolerances** such as "lactose-free", "no milk protein added", or "gluten-free" is unclear. A claim's relationship to health in the sense of Art. 2, para. 2(5) NHCR 1924/2006 is certainly indisputable (see also the Regulation's recital 22), but a benefit in the form of a nutrition or physiological effect would not be linked to this due to the addition of a substance (standard profile under Art. 2, paras. 2(3) and (4)); on the contrary, the food does not develop any negative effect from the extraction of a substance. However, for the European Court of Justice (or ECJ, for short), the term "health claim" also includes any statement that correlates the absence or reduced presence of negative or harmful effects otherwise associated with or linked to consuming the food[6].

Claims regarding reduced risk of allergy to milk proteins are explicitly regulated in Directive 2006/141 from 22.12.2006 on infant formulae and follow-on formulae[7]. Standards for the production and labelling of foods suitable for people with a gluten intolerance are addressed in the FIC 1169/2011[8].

3. Nutrition claims

Nutrition claims are statements that explain, suggest, or even only indirectly express that a food has special positive nutritional properties, and specifically, because of the energy that they do or do not provide (in terms of caloric value) in increased or decreased amounts, and/or the nutrients (such as vitamins) or other substances (for example, "contains lycopene") that they do or do not contain in increased or decreased amounts (Art. 2, para. 2(4)).

3 e.g. Directive 2006/141 from 22.12.2006 on infant formulae and follow-on formulae (OJ L 401/1, 30.12.2006) regulating health claims about the reduction of milk protein allergies.

4 Directive 98/83/EC from 3.11.98 on the quality of water intended for human consumption (and additionally, Germany's "Potable Water Regulation" or *Trinkwasserverordnung*).

5 Directive 2002/46/EC (and additionally, the German "Nutrition Supplements Regulation" or *Nahrungsergänzungsmittelverordnung*).

6 ECJ, 6.9.2012, C-544/10, Deutsches Weintor eG, recital 35.

7 Directive 2006/141 from 22.12.2006 on infant formulae and follow-on formulae (OJ L 401/1, 30.12.2006).

8 Commission Delegated Regulation (EU) No 1155/2013 amending FIC 1169/2011 (L 306/7, 16.11.2013).

Nutrition claims may only be made when they appear in the Annex of NHCR 1924/2006 (like "low energy") and fulfill the specifications therein prescribed (Art. 8, para. 1), which are in line with international regulations such as the "Guidelines on Nutrition and Health Claims" of the Codex Alimentarius. Therefore the claim "low carb," which is not listed in the Annex, is prohibited[9].

Information about the properties of a food does not constitute a "claim" in the sense of Art. 2, para. 2(1) of Regulation (EC) No. 1924/2006 as long as no particular property of the food is expressed more prominently than others, rather, only objective information is given about the quality or the properties of the type or category to which the food belongs. The declaration "Energy & Vodka" is therefore not a claim in the sense of Art. 2, para. 2(1) NHCR, because the term "Energy" refers to a property of the food, namely, an invigorating and stimulating effect, which from the perspective of a reasonably well-informed, observant, and circumspect average consumer, that is, the model consumer described in Recital 16 of NHCR 1924/2006, is common to all energy drinks[10].

Energy & Vodka

4. Health claims

A "health claim" is any declaration (Art. 2, para. 2(1)) that states, suggests, or even indirectly expresses that a relationship exists between a food category, a food, or one of its constituents, and health (Art. 2, para. 2(5)).

The definition of the term contains no explanation as to whether a claim must include a direct or perhaps indirect correlation, nor the required intensity nor duration of the correlation. Under these circumstances the ECJ[11] interprets the word "relationship" broadly, even though constitutional law principles would allow for a narrower interpretation of the term on account of the already-restrictive nature of the prior authorisation of claims requirement[12]. The term "health claim" not only includes implications of improved health

9 High Regional Court (Oberlandesgericht or OLG) Hamburg, 24.4.2014, 3 W 27/14.

10 German Federal Court of Justice (Bundesgerichtshof or BGH), 9.10.2014, I ZR 167/12 – Energy & Vodka.

11 ECJ, 6.9.2012, C-544/10, Deutsches Weintor eG; "*bekömmlich*" or "wholesome", ECJ, 18.7.2013, C-299/12 – Green Swan Pharmaceuticals.

12 BGH WRP 2011, 344 = Erbersdobler/Meyer, Functional Food Vol. II, Law 5.2.22 – Gurktaler Kräuterlikör; Federal Administrative Court (Bundesverwaltungsgericht or BVwG) WRP 2011, 103, appeal under the EU Charter of Fundamental Rights.

conditions thanks to the consumption of a given food[13], but also encompasses any connection drawn between consuming the food and an absence or decrease in negative or harmful effects otherwise linked to consumption, i.e. the mere continuation of good health conditions despite consuming a potentially harmful food. Moreover, according to the ECJ the term "health claim" pertains not only to the effects of sporadically consuming a certain amount of a particular food (effects that normally might be temporary or transitional), but also to the effects of repeated, regular, or even frequent consumption of the food.

A health claim can therefore also arise when, in the understanding of the average consumer, which naturally is influenced by certain expectations and prior knowledge, a connection is drawn between a component of a food and the health of the consumer[14], such as in "prebiotic"[15] or "with prebiotic fibres", but not in the case of made-up words such as "combibiotic"[16]. The German Federal Court of Justice (Bundesgerichtshof or BGH) stretched this principle too far: it held that the slogan "as important as a glass of milk"[17] bore a connection to the (supposedly) "wide-spread opinion […] that children and youths should drink a glass of milk everyday because of its health-promoting effects (especially on account of its mineral content), and that, in turn, the positive effect of a 'daily glass of milk' would also be attributed to the advertised product with which it is equated".

prebiotic

5. Specific health claims

Art. 13, para. 1 and Art. 14 NHCR 1924/2006 list the five types of permissible and required specific health claims. These are

- Claims about the significance of a nutrient (Art. 2, para. 2(2)) or other substance (Art. 2, para. 2(3)) for g**rowth, development, and bodily functions**, as in "prevents natural hair loss"[18].
- Claims related to **psychological and behavioral functions**

13 ECJ, GRUR 2012, 1161 = Erbersdobler/Meyer, Functional Food Vol. II, Law 5.1.20 – Deutsches Weintor; BGH, Judgment from 5.12.2012, I ZR 36/11 – Monsterbacke; BGH I ZR 5/12, 17.1.2013 – Vitalpilze.

14 BGH WRP 2011, 344 – Gurktaler Kräuterlikör.

15 BGH ZR 178/12, 26.2.2014 – Praebiotik; EU Commission, Guidance on the Implementation of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods, version produced by the permanent committee on 14.12.2007.

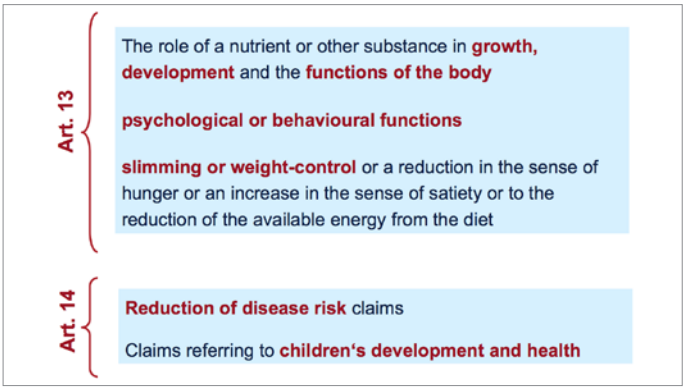
16 OLG Frankfurt LRE 66, 189 = WRP 2013, 1382.

17 BGH ZR 36/11, 5.12.2012 – Monsterbacke.

18 BGH I ZR 5/12, 17.1.2013 – Vitalpilze.

(subparagraph b), as in "relaxed and strong throughout the day - RESCUE® - The Original Bach® Flower Remedy - also for use in emotionally agitating situations, for example at work"[19].

- Claims about **slimming or weight controlling** properties of a food as well as the reduction of appetite, an increased feeling of satiety, or a reduced energy (i.e. caloric) uptake due to the ingestion of a given food (subparagraph c); however, the claim "easy to digest and satisfying" does not constitute an "increase in the sense of satiety" that would be prohibited by Art. 13, para. 1(c).



Reg. 1924/2006 – 5 Specific Health Claims

- Claims related to **children's development and health** (Art. 14). Claims about infant formulae and follow-on formulae as regulated in Directive 2006/141/EC as well as cereal-based foods and other baby foods as regulated in Directive 2006/125/EC are always "as such" claims under Art. 14 NHCR 1924/2006, the EU Commission has explained in its interpretation guidelines[20]. Art. 14 does not cover all claims that (only) pertain to children, rather, only the claims exclusively aimed at children (such as "Lecithin enhances your child's learning and concentration abilities", "Calcium is good for children's growth") in which children are expressly named or depicted in a product's labelling or advertising[21].
- Claims about the **reduction of a risk of disease** (Art. 2, para. 2(6); Art. 14), like "high cholesterol is a risk factor for coronary heart disease" (authorised under Regulation (EU) No 1048/2012 from 8.11.2012) or "chewing gum with up to 100% of its sweetener

19 Regional Court (Landesgericht or LG) Bielefeld, 27.8.2013, 15 O 59/13.

20 EU Commission, Guidance on the Implementation of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods, version produced by the permanent committee on 14.12.2007.

21 Public notice published by the German Federal Ministry for Consumer Protection and Food Safety (BVL), Federal Gazette (*Bundesanzeiger* or BAnz) No 235 from 14.1.2006.

from xylitol is proven to reduce dental plaque. Severe plaque is a risk factor for the development of cavities in children" (authorised under Regulation (EU) No 1024/2009 from 29.10.2009). To date only very few "risk reduction claims" have been authorised.
The difference between "risk reduction claims" and health claims of the catch- all aspect of Art. 13, para. 1(a) is often very slight; general claims, for example related to cholesterol levels, are cases under Art. 13; by contrast, indications of the effect of reducing cholesterol levels fall under Art. 14 (such as "plant sterols demonstrably reduce cholesterol levels. High cholesterol is a risk factor of coronary heart disease")[22].

6. Unspecific health claims, "health-related well-being"

Under Art. 10, para. 3 NHCR 1924/2006, "Reference[s] to general, non-specific benefits of the nutrient or rood for overall good health or health-related well-being" is only permissible "if accompanied by an [authorised] specific health claim". The NHCR 1924/2006 does not explain what amounts to a claim of "health-related well-being". The German Federal Court of Justice pointed out one limitation criteria that is difficult to give effect in practice: in its view, unspecific health claims are for example those which assert that consuming the food supports or increases health-related well-being, such as "for optimal performance support" or "increases endurance and performance"; specific claims, on the other hand, would be those that express or suggest the "promotion of bodily functions"[23]. Claims specifically related to "performance" must be those authorised in Regulation (EU) No 432/2012 such as "Carbohydrate-electrolyte solutions contribute to the maintenance of endurance performance during prolonged endurance exercise" or "Pantothenic acid contributes to normal mental performance"[24].

well-being

Unspecific claims about "**health-related well-being**" include for example "very good for your organism", "helps the body release stress", "cleanses the body", "contributes to a balanced metabolism", "helps you maintain a body that feels good"[25], and "vitalising".

22 Regulation (EC) No 983/2009 (OJ L 277/3, 22/10/2009); EU Commission, Guidance on the Implementation of Reg. 1924/2006, SANCO/2007/E4/SCOFAH 15.10.2007.

23 BGH I ZR 5/12, 17.1.2013 – Vitalpilze.

24 Authorised under Regulation (EU) No 432/2012 from 16/5/2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health (OJ L 136/1, 25.5.2012).

25 Commission Regulation on Nutrition and Health Claims: Myths and Misunderstandings, MEMO/03/188, 1.10.2003.

In accordance with Art. 10, para. 3 NHCR 1924/2006, the strength of a specifically authorised (as under Regulation 432/2012) health claim formulation for a given food's labels and/or advertisements may be amplified with claims that vary from the exact prescribed wording as long as the advertising message does not deviate in content and in particular is not misleading. Special claims from the lists of permitted health claims should furthermore maintain a certain relationship to the link with the food's general benefits. The broader this reference is cast, as in for example "for good health", the more accompanying claims from permissible health claims lists may be joined by reference. One example from a paper on "General Principles on Flexibility of Wording for Health Claims" by experts from some of the Member States (from December 2012) is "good for your skin – X contributes to the maintenance of normal skin". So as not to mislead consumers, food companies are obligated to establish the link between the reference to the general, non-specific benefits of the food and the accompanying special authorised claim[26].

good for

Note that a supplemental claim beyond the authorised indication would be inconceivable: the authorised claim "copper contributes to normal energy yielding metabolism" may not be expanded to read "copper contributes to the normal breaking down of fats in fat tissue"[27]. Use of the subjunctive is cautious in authorisation (or to be precise, the corresponding recommendation of the European Food and Safety Authority or EFSA), thus, permitted claims should not be rewritten with relation to success, instead of "choline contributes to normal liver function" not "choline demonstrably reduces the accumulation of fats in the liver"; the claim "vitamin C contributes to the protection of cells from oxidative stress" may not be supplemented with the name of the organ where this process occurs (i.e., the liver).

Since the NHCR 1924/2006 only covers claims about "health-related well-being" but not claims about "general well-being", claims such as "has a positive effect on your well-being" are permitted as long as they are not misleading in the context of the advertisement. The Commission named further examples of non-specific claims not prohibited by the regulation in a press release (quite an uncommon occurrence, incidentally) on 1.10.2003, such as "Red Bull gives you wings", "Haribo makes children happy", and "As valuable as a small steak"[28].

26 Commission Implementing Decision of 24.1.2013 adopting guidelines for the implementation of specific conditions for health claims laid down in Article 10 of Regulation (EC) No 1924/2006 (OJ L 22/25, 5.1.2013).

27 Experts of the Member States, "General Principles on Flexibility of Wording for Health Claims" (December 2012), with reference to the EFSA Journal; 7(9): 1211.

28 Commission Regulation on Nutrition and Health Claims: Myths and Misunderstandings, MEMO/03/188, 1.10.2003.

7. Right of permission

7.1 Registration procedure

The Member States were called upon to submit lists of health claims to the European Commission with relation to

- "growth, development, and the functions of the body" (Art. 13, para. 1(a))
- "psychological and behavioural functions" (Art. 13, para. 1(b)), or
- "slimming or weight-control" (Art. 13, para. 1(c)),

together with the relevant conditions and references to corresponding scientific justification (Art. 13, para. 2 "collection procedure").

The Commission was notified of over 40,000 health claims, which clearly came as a surprise to it. However, of these claims the Com-

Art. 13 Community list

mission forwarded only about 10,000 to the controlling authority EFSA; the other 30,000 or so were tossed into the trash without the Commission giving the hitherto constitutionally required transparent and objective legal justification for why it did so. EFSA sorted the health claims that were forwarded to it by objective criteria (available for perusal in database form online) and was able to show that especially because of duplicates, only 4,637 unique health claims were submitted for evaluation, and of those approximately 1,500 were for botanicals (plants and plant extracts). By 2012 EFSA had evaluated 2,758 of the claims, which they then published in six tranches. 222 of these health claims were authorised in Regulation 432/2012[29] as a (partial) Community list of permitted claims; those

29 Regulation (EU) No 432/2012 from 16.5.2012 establishing a list of permitted health claims made on foods (OJ L 136/1, 25.5.2012) (updated many times)

that were not approved were published in an online list as "not authorised/rejected". This list is continuously expanded; however, to date there are only about 300 authorised health claims.

7.2 Authorisation procedure

Art. 13, para. 5 procedure

In addition to the so-called "collection procedure" of Art. 13, para. 3, it is possible to initiate a formal authorisation procedure (Art. 13, para. 5). A food business operator contemplating the use of a health claim not listed in the relevant (partial) Community list can apply for the claim to be added (Art. 13, para. 5 and Art. 18).

Art. 14 cases

An individual authorisation under Arts. 15 through 17 and Art. 19 NHCR 1924/2006 is required for claims involving the reduction of disease risk and/or the "development and health of children" (Art. 14). EFSA has issued a guideline for authorisation procedures of such claims[30].

Data privacy

Information shared in the course of the authorisation process carries a guaranteed right of privacy for five years. Sharing should nevertheless be limited reasonably, because any peer-reviewed studies an application to EFSA requires in accordance with Art. 15, para. 3(c) are likely to be published widely in professional journals accessible to anyone.

8. Scientific requirements for health claims

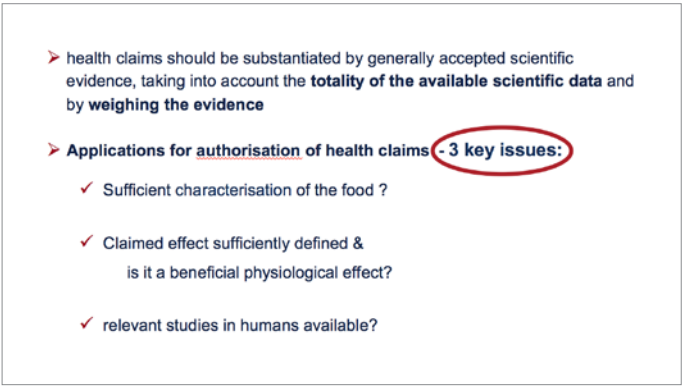
NHCR 1924/2006 contains no standards for the scientific requirements of health claims. In Arts. 5 and 6 NHCR, the singular statement on the topic is practically meaningless: "Nutrition and health claims shall be based on and substantiated by generally accepted scientific evidence" (Art. 6, para. 1).

scientific evidence

In hindsight, taking into account the very numerous official statements of the control authority EFSA on individual health claims as well as additional Guidance documents EFSA has published, it has become fairly clear what EFSA's requirements for health claims are. Both in the initial collection procedure as well as among new applications under Art. 13, para. 5 and Art. 14, health claims have

30 Scientific and technical guidance for the preparation and presentation of an application for authorisation of a health claim; EFSA Journal 2011;9 (5): 2170

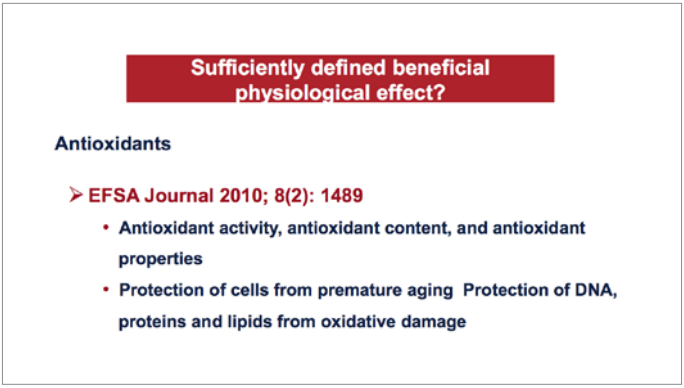
been rejected frequently for failure to answer **three key questions** from EFSA. The three key questions are:



Applications for authorisation of health claims

- Is the food sufficiently characterised?
- Is the claimed effect adequately defined and is it a beneficial physiological effect?
- Are there appropriate human studies that substantiate the effect?

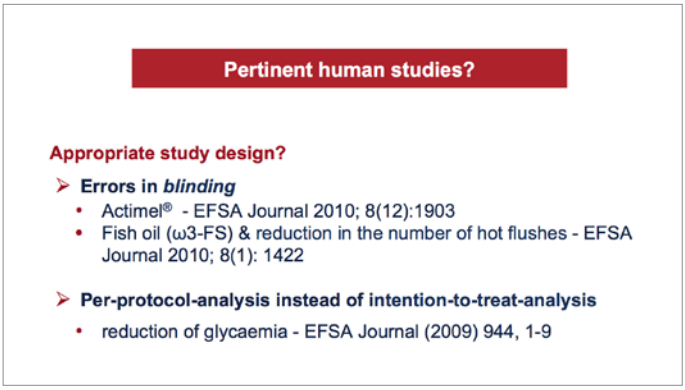
Most rejected applications fail due to the dearth of adequate scientific studies in support of the application. By now it is well-known that randomised placebo-controlled **human studies** (RCTs) are necessary in order to substantiate the pursued health claims. Animal studies may of course lend support to an application, but will not in any case be sufficient evidence for a successful application on their own.



EFSA: Applications for Antioxidants

Indeed there are several important factors to include when designing an RCT. For example, the food subject of the study must be tested under the same conditions and used in the same way as the context of the health claim pursued presumes. This was not possible in the application of Uroval®, a nutritional supplement with a fixed combination of cranberry extract (100 mg with 10% proanthocyanidinen) and mannitol (300 mg). Its application included no studies whatsoever of the exact combination contained in the product, rather only studies on "cranberry extracts"[31], not defined more specifically than that. Danone submitted 65 references for Actimel®, not a single one of them of the product itself (Lactobacillus casei and yoghurt cultures), nor even any studies conducted with the same strain of bacteria used as an ingredient[32]. EFSA did not consider these inadequate studies when evaluating the applications.

The usage of appropriate **endpoints** (biomarkers) is also a mandatory prerequisite for studies EFSA will consider. In studies submitted in support of an application for a children's chocolate product, for example, endpoints were used that could not possibly have substantiated the applied-for health effects of calcium and influence upon growth; rather, the endpoints selected for study were calcium-resorption among lactose intolerant people, effects with respect to glucose metabolism or blood pressure, and others[33].



EFSA: Applications for Authorisation

Additionally essential to an acceptable study design is proper **blinding**; if for example a fish taste and smell is only discernible by the verum group but not the placebo group, the blindness of the study is no longer valid[34]. Also the **duration** of the study must be

31 EFSA Journal 2009; 7(12): 1421.
32 EFSA Journal 2010; 8(12): 1903.
33 EFSA Journal 2009; 940: 1–8.
34 EFSA Journal 2010; 8(1): 1422.

- **Provide sufficient characterization and specification of food.**
- **Only submit claims if their formulations comply with those of the "beneficial physiological effects" accepted by the EFSA so far.**
- **Use only study populations and markers which have already been previously characterized as appropriate by the EFSA for the respective claim.**
- **Consider all information in the guidelines for the respective claim which include clear specifications.**

Chances of Approval for Applications

adjusted to match the effect under evaluation; thus, a study aimed at showing a positive effect on bone mineralisation may not last a mere 12 weeks, rather, should last at least 2-3 years[35]. Furthermore the study population should be selected as to reflect the product target population; for a children's chocolate product application, EFSA did not consider numerous studies submitted that had been conducted on adults[36].

EFSA has retrospectively compiled its official positions to date in the form of the following guidance documents on particular claims of effects:

guidance

- Guidance on the scientific requirements for health claims related to gut and immune function (EFSA Journal 2011; 9(4): 1984)
- Guidance on the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health (EFSA Journal 2011; 9(12): 2474)
- Guidance on the scientific requirements for health claims related to appetite ratings, weight management, and blood glucose concentrations (EFSA Journal 2012; 10(3): 2604)
- Guidance on the scientific requirements for health claims related to bone, joints, and oral health (EFSA Journal 2012; 2702)
- Guidance on the scientific requirements for health claims related to neurological and psychological functions (EFSA Journal 2012; 2816)
- Guidance on the scientific requirements for health claims related to physical performance (EFSA Journal 2012; 2817).

35 EFSA Journal 2009; 7(9): 1270.

36 EFSA Journal 2009; 940: 1–8.

9. Labelling requirements

9.1 Wording

Authorised health claims for a particular food should be reproduced verbatim on the label and/or in the advertisement as composed in the regulation in effect. NHCR 1924/2006 itself does not demand the verbatim use of claims as published in the Community list; also recital 9 of Regulation (EU) No 432/2012 establishing a (partial) Community list states that deviating from the formulation would be allowed as long as the claim would have the "same meaning from a consumer perspective".

It is nevertheless inadvisable to deviate from the expressly permitted wording in the regulation. Practice shows that deviation from the official wording can trigger (at least) discussion with (if not complaints or warnings from) third parties like government agencies or competitors, whether the or not a different relationship to health or indication than the permitted one results.

Experts of the Member States also affirm a practically strict adherence to health claims as officially published in the "General Principles on Flexibility of Wording for Health Claims" (from December 2012). In that publication, the verbs "contributes", "plays", and "supports" may not be replaced with the stronger formulations "stimulates" and "optimises", such as in "X contributes to the normal function of the immune system" or "X optimises the normal function of the immune system". Exchanging the adjective "normal" for other words like "demanding" or "compromised immune system" is impermissible because – unlike the authorised formulations – the effect is described in context characterised by strain or stress.

flexibility

Furthermore the authorised health claim always must relate to the substance itself and not to the product that includes the substance as a whole: the "General Principles on Flexibility of Wording for Health Claims" (December 2012) mention in this regard that "X contributes to the normal function of the immune system" is permissible; whereas "Y contributes to the normal function of the immune system. Y contains X" is prohibited because the link to the authorised substance is not presented clearly and unambiguously.

9.2 Mandatory labelling requirements

Health claims may only be present when accompanied by certain information as mandated under Art. 10, para. 2:

- "a statement indicating the importance of a varied and balanced diet and a healthy lifestyle" (Art. 10, para. 2(a)), as well as
- "the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect" (Art. 10, para. 2(b)); and
- as the case may be, also an appropriate warning under Art. 10, paras. 2(c) and (d) NHCR 1924/2006.

These requirements are compulsory since the enactment of NHCR 1924/2006, independent of the creation of the Community list and the transition period allowed under Art. 28, paras. 5 and 6[37].

9.3 Nutrition labelling

Nutrition labelling of foods for which nutrition and/or health claims are asserted is mandatory unless the claims are advertisements not specific to the product (Art. 7, NHCR 1924/2006 in accordance with Art. 49 FIC 1169/2011). The relevant information requirements for energy value and the amounts of fat, saturated fats, carbohydrates, sugar, protein, and salt are listed in Art. 30, para. 1 FIC 1169/2011. For nutrition or health claims about a nutrient named in Art. 30, para. 2 of FIC 1169/2011 (simple unsaturated fats, polyunsaturated fats, polyhydric alcohols, starches, dietary fibres, as well as the vitamins and minerals listed in Annex XIII Part A, Number 1), the amount of the nutrient must be stated in accordance with Art. 31 to 34 FIC 1169/2011. For substances that are the subject of a nutrition or health claim but do not appear in the nutrition label, the amount of the substance must be declared in accordance with Arts. 31, 32, and 33 FIC 1169/2011 in the same field of view as the nutrition label. Individually adapted units of measurement must be used in stating the amount of each substance present (Art. 7, para. 2 NHCR 1924/2006 in accordance with Art. 49 FIC 1169/2011).

10. Conditions of use

Art. 16, para. 4(c) and Art. 17, para. 5 NHCR 1924/2006 envision that the approved use of a health claim may be bound by "special conditions for use". EFSA avails itself of the European Commission in this area. For example, Wrigley's authorised health claim for a sugar-free chewing gum, "Sugar-free chewing gum helps reduce tooth demineralisation. Tooth demineralisation is a risk factor in the development of dental caries" must be accompanied by recommended consumption indications: "the beneficial effect is obtained with chewing of 2-3 g of sugar-free chewing gum for 20 minutes, at

37 ECJ, 10.4.2014, C-609/12, Request for a preliminary ruling sought by the BGH, decision from 5.12.2012.

least three times per day after meals"[38]. The claim approved for Unilever "Plant sterols have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease" must be accompanied by the information that "the beneficial effect is obtained with a daily intake of at least 2 g plant sterols"[39].

Regulation (EU) No 432/2012[40] establishing a (partial) list of permitted health claims also envisions diverse conditions for their use, such as

conditions

- **Standard profiles** for foods, such as "the claim may only be used for water that satisfies the requirements of Directives 2009/54/EC and/or 98/83/EC"
- **Use limitations**, such as "the claim may not be used for chloride derived from natrium chloride"
- **Minimum amounts** with regard to vitamins and minerals; additionally, specific claims like "the claim may be used only for food which is at least a source of ALA as referred to in the claim SOURCE OF OMEGA 3 FATTY ACIDS as listed in the Annex to Regulation (EC) No 1924/2006"
- **Compulsory notices**, like "the claim may be used only for foods targeting adults performing high intensity exercise"
- **Requirements of further information**, such as "a daily intake in excess of 4 g may significantly increase blood cholesterol levels"
- **Warnings**, such as a "warning of choking to be given for people with swallowing difficulties or when ingesting with inadequate fluid intake - advice on taking with plenty of water to ensure substance reaches stomach".

11. Traditional claims

Claims reported by the EU Commission as "traditional" may be used without an authorisation procedure under Arts. 13 through 18. Such traditional claims are obligated only to give notification but not seek authorisation in accordance with Art. 1, para. 4. Applications for the use of "generic descriptors" in the sense of Art. 1, para. 4 must be drafted and submitted in accordance with the rules set forth in Annex of Regulation (EC) No 907/2013[41]; additionally required is "relevant bibliographical or otherwise verifiable evidence demonstrating the presence on the market of the class of foods or

38 Commission Reg. 665/2011 from 11.7.2011 (OJ L 182/5, 12.7.2011).

39 Commission Reg. 983/2009 from 21.10.2009 (OJ L 277/3, 22.10.2009).

40 Reg. (EU) No 432/2012 from 16.5.2012 (OJ L 136/1, 25.5.2012)

41 Reg. (EU) No 907/2013 setting the rules for applications concerning the use of generic descriptors (denominations) (OJ L 251/7, 21.9.2013).

beverages with the generic descriptor over at least a 20-year period in the Member State(s) prior to the date of entry into force of this Regulation". Until the enactment of Regulation 907/2013, traditional descriptors were permissible due to of a lack of procedural rules[42].

Recital 5 of the Regulation names two not very illustrative examples for claims under para. 3: "digestive" and "cough drops". It is unclear what, other than these examples specifically named in Recital 5, could count as traditional claims.

12. Pharmaceuticals

Melatonin

Also on the Community list of permitted health claims are claims for substances that may be used because of pharmacological effects they (can) produce, like activated charcoal, lactulose (albeit also conceivable as a dietetic), melatonin[43], and *Monascus purpureus* (red yeast rice). The Community list anticipates two claims for melatonin: "Melatonin contributes to the alleviation of subjective feelings of jet lag" and "Melatonin contributes to the reduction of time taken to fall asleep". Between 0.5 and 1 grams of melatonin should be taken shortly before going to sleep. The basis of this indication is a meta-analysis of controlled intervention studies on humans.[44]

Cases such as that of melatonin are unacceptable failures of the system; the authorisation of a health claim for pharmaceuticals as though the claim is for a food should be constitutionally and legally barred. It is well-known that during the consultation procedure leading up to the enactment of Regulation (EU) No 432/2012, Germany (correctly) insisted that the Community list exclude any possible authorisation of pharmaceutical products under NHCR 1924/2006. It is of little consolation that Recital 17 of Regulation (EU) No 432/2012 allows the Member States to reserve authorisation (Any decision on a health claim in accordance with Regulation (EC) No 1924/2006 such as inclusion in the list of permitted claims referred to in Article 13(3) thereof does not constitute an authorisation to the marketing of the substance on which the claim is made, a decision on whether the substance can be used in foodstuffs, or a classification of a certain product as a foodstuff").

42 Orientation enactment of the Austrian Federal Ministry for Health, Family, and Youth, GZ BMGFJ-75 100/0018-IV/B7/2007, ***Ernährung***/Nutrition, 2007, 333.

43 German Federal Ministry for Pharmaceuticals and Medicinal Products (BfArM), Letter to the BVL, 20.9.2011.

44 EFSA Journal 2010; 8(2): 1467 and 2011; 9(6): 2241.

13. Complete prohibitions

The prohibition of health claims with right of permission is flanked by several complete prohibitions. Art. 12 NHCR 1924/2006 contains three types of banned claims that are impermissible as such and ineligible for authorisation:

- Claims which suggest that health could be affected by not consuming the food (Art. 12(a))
- Claims which make reference to the rate or amount of weight loss (Art. 12(b)), such as "five kilograms in two weeks"; otherwise advertisements purporting slimming effects may be allowed (Art. 13, para. 1(c));
- Claims which make reference to recommendations of individual doctors or health professionals and other associations not referred to in Art. 11 (Art. 12(c)).

14. Transitional rules

NHCR 1924/2006 foresees transitional rules in order to enable food business operators to adapt their activities properly to the legal framework in due time and also to be able to sell off "old" products. With the enactment of Regulation (EU) No 432/2012 from 16.5.2012 however, the European Commission ratified – contrary to the requirement of Art. 13, para. 3 NHCR 1924/2006 – only a partial list of permitted health claims[45]. The transitional period in Art. 28, para. 5 is valid with the enactment of Regulation (EU) 432/2012 only for laws that are "on hold", such as in the case of health claims from the collection procedure that have not yet been authorised or rejected (Art. 13, para. 3); the substances affected by this rule require further testing, primarily "botanical substances" (plants and herbs or plant extracts)[46]. Health claims that were not part of the collection procedure and thus are new require authorisation under Art. 13, para. 5 NHCR 1924/2006; the privilege of Art. 28, para. 5 is thus not applicable in these cases.

on hold

Such "on hold" health claims may however only be used "provided that they comply with this Regulation and with existing national provisions applicable to them" (Art. 28, para. 5). Assuming that the EU legislature has issued a fundamental prohibition on the use of nutrition and health claims, the user of such a claim must

45 Reg. (EU) No 432/2012 from 16.5.2012 (OJ L 136/1, 25.5.2012) (updated many times)

46 Summarised in a "Supporting Working Document" of the Standing Committee of the Food Chain and Animal Health, 12.6.2013, Agenda Item B.1, SANCO/11074/2013.

therefore present, and in the event of conflict also prove, the authorisation of the claim[47]. In this case, the claimant must submit properly randomised and placebo-controlled double-blind studies that have withstood the peer-review process in the appropriate professional field[48]; the demonstration of adequate scientific evidence does not have to be based on human studies however. The claim "on hold", or more specifically, the effect related to it, cannot have become subject to a general scientific debate[49]. Sufficient scientific verification can be based upon a single work, as long as its methods and results are convincing.[50]

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47 BGH I ZR 5/12, 17.1.2013 – Vitalpilze.

48 BGH I ZR 5/12, 17.1.2013 – Vitalpilze.

49 BGH I ZR 23/07 – Vorbeugen mit Coffein „Alpezin".

50 BGH I ZR 23/07 – Vorbeugen mit Coffein „Alpezin".

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