

National Contributions to the Development of Nutrient Profiles for the EU Nutrition and Health Claims Regulation – the German Example*

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Summary

According to Article 4 (1) of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods, specific nutrient profiles, including exemptions, which food or certain categories of foods must comply with in order to bear claims and/or the conditions for the use of such claims with respect to nutrient profiles, shall be set until January 2009. In setting these profiles, the European Food Safety Authority shall provide scientific advice to ensure that nutrient profiles are based on scientific knowledge. As the final decision will be made by Comitology, Member States have also begun to consult their national risk assessment bodies to aid them in their decision-making.

This paper discusses the development process and the content of the German Federal Institute of Risk Assessment position paper on "Nutrient Profiles – The Precondition for Health Claims". It becomes evident that the setting of nutrient profiles is not a linear but an iterative process, which requires the involvement of all stakeholders from the outset. The significant political dimension of the decision-making process needs an approach on the national level, which in its transparency has to be equivalent to the work of European institutions such as the European Food Safety Authority or the European Commission. Any attempt not to embrace all stakeholders from the beginning or to replace scientific knowledge with subjective opinions will deprive national contributions of their full value and result in objections.

I. Introduction

Nutrient profiling is a concept aimed at categorising foods for specific purposes on the basis of their nutrient content. Critics are arguing that nutrient profiles are an attempt to classify foods into "good" and "bad", that they lack any science base and arbitrarily discriminate food categories without considering different dietary needs of individuals and the variation in dietary habits in Europe. On the contrary, advocates emphasise that nutrient profiles are supported by nutrition science and can help consumers to make informed nutritional choices. Despite this controversy, nutrient profiles are being used for various purposes both in voluntary approaches and also in legislation. Voluntary applications include for example traffic light labelling systems by individual UK retailers¹ or simple nutrition labelling schemes such as the Swedish Keyhole scheme² which is a positive labelling scheme that rewards the reformulation of products by reducing the amount of components regarded as problematic, thus making the products "healthier". Examples for mandatory regulatory provisions include the use of nutrient profiles by the UK Office of Communications (Ofcom)³, the independent regulator and competition authority for the UK communications industry, to help tighten controls on the advertising to children of foods high in saturated fat, salt or sugar, or the EU Nutrition and Health Claims Regulation⁴ (hereinafter called *Claims Regulation*). The World Health Organization has considered an even wider use of nutrient profiles for regulating nutrition and health claims, setting compositional standards for foods, reforming taxation/subsidy systems, and restricting or banning the marketing of foods in general⁵. However, the implementation of such dras-

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¹ For example see <http://www.waitrose.com/food/healthand-nutrition/howwaitrosecanhelp/trafficlightlabelling.aspx>

² The Swedish Keyhole. National Food Administration administrative provisions on the use of a particular symbol, 2004 (<http://www.slv.se>)

³ *Regulating TV advertising of food and drink to children,*

Ofcom, September 2006

⁴ *Corrigendum to Regulation (EC) No 1924/2006 of the European Parliament and the Council of 20 December 2006 on nutrition and health claims made on foods, OJ 2007 L 12/3*

⁵ *WHO Forum on Marketing of Food and Non-alcoholic Beverages to Children (2006: Oslo, Norway)*

tic measures has not received the support from the vast majority of its members and stakeholders. For the purposes of this article, the word food(s) encompasses both foods and beverages.

II. The Nutrition and Health Claims Regulation: Legal Context

The inclusion of nutrient profiles into the Claims Regulation has an interesting history. In 2001 the Directorate General for Health and Consumer Protection (DG SANCO) of the European Commission in a discussion paper took the position that "... defining what is a reasonable nutritional profile could be difficult"⁶. An in-depth analysis of the more than 90 comments from stakeholders shows that only 20 comments dealt with the topic directly⁷. 14 stakeholders clearly expressed opposition to the concept of nutrient profiles and only six clearly supported it. A draft proposal from DG SANCO for an EU regulation on claims from 2002 did not include the concept of nutrient profiles⁸. In a statement to the Committee on the Environment, Public Health and Consumer Policy (ENVI) of the European Parliament in February 2003, Commissioner David Byrne confirmed that the Commission did not intend to use the concept of nutrient profiles in a proposal for a regulation on claims⁹. Despite these renunciative statements the proposal for an EU Claims Regulation, which was published in summer 2003, did include the concept of nutrient profiles in its Article 4¹⁰. The inclusion of nutrient profiles in this proposal without sufficient prior public consultation or an impact assessment goes against the principle of transparency in the General Food Law Regulation¹¹ and the principle of the "Better Regulation" policy¹² of the EU¹³. The legislative process between the publication of the proposal and the publication of the final Claims Regulation did not substantially change Article 4. The objectives for Article 4 as stated in the recitals 10–13 of the Claims Regulation remained unchanged and state that "*the application of nutrient profiles as a criterion would aim to avoid a situation where nutrition or health claims mask the overall nutritional status of*

a food product, which could mislead consumers when trying to make healthy choices in the context of a balanced diet." Article 4 of the Claims Regulation requires that nutrient profiles have to be set by the European Commission in accordance with the Comitology procedure until 19 January 2009, preceded by relevant scientific advice from the European Food Safety Authority (EFSA) until 19 January 2008. In addition, the Commission has to carry out consultations with interested parties, in particular food business operators and consumer groups.

Early in the complex and sometimes controversial discussions on the implementation of Article 4, it became evident that the establishment of nutrient profiles cannot be managed properly with the usual linear sequence of a risk assessment from EFSA followed by a risk management decision from the European Commission. The political dimension of nutrient profiles is significantly larger than for other risk management decisions so that the process has to be reiterative and involve all relevant stakeholders from the very beginning. To this end the Commission has already established a small working group together with representatives from EFSA and the five Member States United Kingdom, France, Germany, Finland and the Netherlands. This group has already commenced working on nutrient profiles even without any scientific advice from EFSA being available. This approach can be accepted and seen as useful if the proceeding of this working group is fully transparent and will – at least for certain activities – also involve other key stakeholders such as food business operators and consumer groups. However, without an opening of this group to these stakeholders, the impact of nutrient profiles on the European single market, on innovation or consumer understanding could not be assessed properly and therefore key objectives of the Claims Regulation would not be met.

Also EFSA started already to engage in a dialogue with stakeholders, for example by organising the Conference on Nutrition and Health Claims, in Bologna, Italy, from 8–10 November 2006¹⁴. This conference attracted

⁶ Discussion Paper on Nutrition Claims and Functional Claims by DG SANCO, SANCO/1341/2001

⁷ Stakeholder comments on the Discussion Paper have been published at http://ec.europa.eu/food/food/labellingnutrition/claims/index_en.htm

⁸ Draft Proposal for Regulation of the European Parliament and of the Council on Nutrition, Functional and Health Claims Made on Foods, Working Document SANCO/1832/2002

⁹ Reported by observers to the ENVI meeting of 19 February 2003 but not recorded in minutes

¹⁰ Commission of the European Communities, Proposal for a Regulation of the European Parliament and of the Council on nutrition and health claims made on foods, Brussels, 16 July 2003, COM (2003) 424 final 2003/0165 (COD)

¹¹ See in particular Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ 2002 L31/9

¹² European Commission, Impact Assessment Guidelines, SEC (2005) 791, 15 June 2005 with March 2006 update, see http://ec.europa.eu/governance/impact/docs/key_docs/sec_2005_0791_en.pdf

¹³ For a detailed discussion see the article from Coppens, *EFFL*, 2, 2007, p. 67 ff.

¹⁴ For details see http://www.efsa.europa.eu/en/in_focus/nutrition_health.html

about 200 participants from 21 countries and its final session was even webcasted to meet the demand of many others who could not attend. This contributes to the picture of nutrient profiles being a sensitive topic with a considerable political dimension and potentially having a significant impact on the European food industry and therefore requiring a transparent process and full stakeholder involvement. As a consequence, all national activities, for example by authorities or risk assessment institutions, will have to be assessed against these requirements.

III. Approach by the German BfR and Stakeholder Dialogue

According to the Claims Regulation EFSA is the *only* risk assessment institution, which has to give scientific advice for setting nutrient profiles. No other risk assessment body has explicitly been mentioned as a source of scientific input. However, it does not come as a surprise that Member States have begun to involve their national risk assessment institutes or other scientific bodies such as nutrition societies or universities because after all Member States play a key role in establishing nutrient profiles through the Comitology procedure.

In the case of Germany the Federal Institute of Risk Assessment (BfR) issued a position paper on nutrient profiles on 12 March 2007¹⁵. It then organised a Consumer Protection Forum on 23 April 2007¹⁶, which led to an updated version of its position paper¹⁷. The fact that only the updated position paper – but not the original one any longer – is available on the BfR website, makes it difficult to impossible for the public to assess if and to which extent the BfR has taken stakeholder input at the Forum into consideration. For the sake of transparency both the original and the updated versions should be accessible, together with a rationale where and why changes have been made. In addition, the original BfR position paper did not actively ask for input from stakeholders, for example through an Internet consultation, so that the Consumer Protection Forum remained the only effective option for stakeholders to voice their opinions. In the Forum the BfR confirmed that industry or consumer representatives had not been consulted at all in the process of developing the position paper. This poses the question how the topics of food composition, role and importance of foods in the diet, categorisation of foods,

reference quantities, calculation of the profiles and the feasibility and testing of a proposed system were adequately dealt with if those who produce and consume foods were not involved. Full transparency and comprehensive active stakeholder involvement through more than one channel are common practice in stakeholder consultations from EFSA or the European Commission and should also be the standard for all national authorities or government-related institutions.

The following comments refer to the updated position paper and where applicable and useful will discuss the differences with the original paper. In its position paper the BfR states that in 2005 they were requested as part of their scientific policy advice for the Federal Government to formulate general proposals and principles for the elaboration of nutrient profiles. However, contrary to the mandate EFSA received from the European Commission and which is accessible on the Internet¹⁸, the mandate that the BfR received is not available to the public. It is therefore not possible to say if the BfR also received any “political guidance” that could have affected its final position.

IV. Detailed Discussion of the BfR Position

The BfR position paper is titled “Nutrient Profiles – The Precondition for Health Claims”. In its introduction it says that “... a nutrient profile... is to be used as the criterion... whether a food may carry a nutrition or health claim.” It continues by saying that “... nutrient profiles aim to ensure that foods bearing claims of positive effects on health do not, at the same time, contain amounts of nutrients associated with chronic diseases when consumed in excess”. With the second statement the BfR seems to equate nutrition with health claims, thus ignoring the definitions in Article 2 of the Claims Regulation. However, the updated BfR position paper now includes a short statement clarifying that nutrient profiles would also be applicable to foods, which wanted to bear nutrition claims.

The introduction to the BfR position paper also mentions that nutrient profile models that had already been developed internationally were taken into account. However, the BfR position paper falls short of saying which models were taken into account and which aspects of them¹⁹.

¹⁵ This document is not available any more on the BfR website and has been replaced with the updated version; see footnote 17

¹⁶ The programme and presentations of this Forum can be accessed at <http://www.bfr.bund.de/cd/3879>

¹⁷ http://www.bfr.bund.de/cm/245/nutrient_profiles_the_precondition_for_health_claims.pdf

¹⁸ http://www.efsa.europa.eu/en/science/nda/requests_mandates.html

¹⁹ Details about the considered models can be extracted from a presentation by R. Großklaus to a meeting of the working group “Questions of Nutrition” of the GDCh (German Chemical Society) on 12 February 2007 in Frankfurt

The BfR position paper includes twelve points, which will be discussed in the following.

1. Nutrient profiles should be formulated specifically for food categories.

In principle, this recommendation can be supported as it helps “to identify the extremes” on the market and to create incentives for innovation by setting category-specific targets that could most likely be met by reformulating products. Literature reviews of existing nutrient profiling systems have also questioned the relevance of “across the board” (i.e. horizontal) approaches and have regarded category-based approaches as more consistent.²⁰

The BfR position paper identifies the following food categories for the definition of nutrient profiles using data from the German Food Code and Nutrient Database (BLS) and the typical dietary habits of the German population. These categories are said to be used as carrier foods for fortification or are placed on the market as “children’s” foods.

- Cereal products
- Dairy products/mixed dairy products (except cheese)
- Convenience products/finished products
- Finished meat/sausage products
- Beverages/beverage powders/soft drinks/fruit juice drinks
- Sweets/confectionery

The BfR position does not elaborate on the composition of these foods specifically with regard to nutrients of a public health relevance and the dietary surveys it considered to establish their role and function in the diet. The only criteria that seem to have driven the selection is the fact that products in these categories are allegedly more often fortified or marketed as “children’s foods” (without any attempt to clarify what is meant by that). It also does not deal with the question if fortified foods could be a source of “qualifying nutrients” as mentioned in point 5 of the BfR position paper and therefore even play an exceeding positive role in the diet. Finally, the important qualifier in the original paper that the list of categories which are used as carrier foods for fortification is only based on a non-representative market survey of supermarkets and discounter outlets in Berlin, carried out by the BfR in 2005, has been

eliminated without substitution in the version of the updated paper.

Based on these points the limitation of categories which should be subject to nutrient profiles to the six mentioned above cannot be justified and omits other food categories (which may even be unprocessed) which could deliver comparable quantities of energy or nutrients of a public health relevance to the population’s diet.

Finally, the BfR paper does not explain why the categories bread and rolls, eggs and egg products, vegetarian foods, milk and cheese, coffee, tea and water (!), sugar and ice cream, which were considered suitable in principle for nutrient profiling in the original position, have been dropped in the updated version.

2. The nutrients to be considered should be selected on the basis of scientifically accepted relationships between the consumption of certain nutrients and an increased or reduced risk of the manifestation of chronic diseases.

This general statement can be supported as long as its execution remains within the scope of the Claims Regulation. For example, the BfR paper lists sugar as a “disqualifying” nutrient because of its role in the development of caries²¹. In addition to the fact that in its report WHO says that the increase of caries has come to a halt in countries with appropriate oral hygiene, caries as such is not related to overweight and obesity. It is also not necessarily related to the quantity of sugar in a food or a food category and has to be seen in the context of all consumed carbohydrates. If caries is the only argument from the BfR why sugar has been listed as a “disqualifying” nutrient, then it has gone beyond the scope of the Claims Regulation and as a consequence sugar has to be delisted again.

3. Nutrient deficiencies in the population could be considered as another important criterion.

The treatment of nutrient deficiencies as an objective of nutrient profiles is also exceeding the mandate of Article 4 of the Claims Regulation and goes beyond the legal basis of the Claims Regulation, which is exclusively based on Article 95 of the Treaty with the sole objective to ensure the functioning of the internal market.

²⁰ V. Azais-Braesco et al., *Nutrient profiling: comparison and critical analysis of existing systems*, *Public Health Nutrition*: 9(5), 613–622

²¹ *Report of the joint WHO/FAO expert consultation Diet, Nutrition and the Prevention of Chronic Diseases*, WHO Technical Report Series, No. 916, 2003

4. The use of “disqualifying” nutrients is advocated for the elaboration of nutrient profiles. “Qualifying” nutrients could also be used as a criterion, provided they occur naturally in foods.

This recommendation plays with the myth that “bad” foods may become “good” foods because of the presence of certain nutrients which in the BfR paper are called “qualifying” nutrients. If this would actually be the case, then the criterion, which requires them to occur naturally in foods, could not be substantiated. The working group confirmed that “... the nutritional-physiological value of ‘qualifying’ nutrients solely refers to intake from the natural matrix and that a transfer of the positive properties to the respective isolated nutrient form is not justified.” However, this opinion is not supported by a single reference to the scientific literature and, if true, would make large parts of the EU Regulation on the Addition of Vitamins and Minerals and of Certain Other Substances to Foods obsolete²². The lack of references to scientific evidence for this opinion violates the requirement in the last paragraph of Article 4 (1) of the Claims Regulation that nutrient profiles shall be based on scientific knowledge about diet and nutrition, and their relation to health and classifies it as purely judgmental.

5. It is proposed that the following nutrients be considered:

- **disqualifying nutrients:** total fat, saturated fatty acids, trans fatty acids, sugar and sodium/salt
- **qualifying nutrients:** fibre, folate, omega-3 fatty acids and calcium

This selection of nutrients is relevant for all age groups in the population independent of gender.

The list of the “disqualifying” nutrients is the result of a copy and paste exercise from the Claims Regulation (Article 4 [1] [a]) or the WHO Report²³. It fails to discuss the exemplary nature of the list as expressed through the words “such as” in the Claims Regulation, which would require a more in-depth analysis of the German situation. A good example are trans fatty acids for which the BfR has confirmed in a position paper from 2006 that an excessive consumption above the recommendations can only be expected in

isolated cases²⁴. Does this mean that nutrient profiles should also be used to cover extreme cases of a completely unbalanced diet?

The rationale for the list of “qualifying” nutrients is geared towards the findings of the German Nutrition Report 2004. However, it does not explain why other nutrients, such as iodine, vitamin D or iron, for which an insufficient supply at least for some population groups has been reported, have been excluded.

6. “100 g or 100 mL” of a food are proposed as the reference amounts.

The BfR argues that “... portion sizes for individual foods can vary considerably from region to region and from individual to individual and would, therefore, have to be standardised. It should be borne in mind that the nutrient profiles are not intended as information for end consumers ...” This argument is acceptable as long as the role and importance of the food (or of categories of food) and their contribution to the diet of the population in general or, as appropriate, of certain risk groups are duly considered as required by Article 4 (1) (b) of the Claims Regulation.

7. A system based on thresholds is preferable to a scoring system.

The BfR position concludes that a scoring system “... lends itself to steering individual choices of foods but not, however, to defining the composition of foods which could then serve as the precondition for the admission of advertising claims. Furthermore, the scoring system would have to operate with many exemptions as otherwise its use in practice would lead, in some instances, to nonsensical results. The simplest way of ensuring that foods have a healthy nutrient composition, for which health claims may be made, is to set thresholds for relevant nutrients bearing in mind the typical composition of products within a food category.” This concurs with the conclusions of an ILSI Europe Workshop,²⁵ which state that “... a threshold approach will be applied as the final step to define the different categories of food products.” A threshold-based approach would also be easier to apply both for food business operators and enforcement authorities.

²² Regulation (EC) No 1925/2006 of the European Parliament and the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods, OJ 2006 L 404/26–38

²³ See supra 20

²⁴ BfR position Nr. 015/2006 of 30 January 2006 Trans Fat Acids are Undesired in the Diet – and also too much

Fat; for the German version see http://www.bfr.bund.de/cm/208/trans_fettsaeuren_sind_in_der_ernaehrung_unerwuenscht_zu_viel_fett_auch.pdf

²⁵ ILSI Europe Workshop on “Nutritional Characterisation of Foods: Science-based Approach to Nutrient Profiling”, 25–27 April 2006, Mallorca (Spain); for details see <http://europe.ilsa.org/events/past/nutrientprofiling.htm>

For setting thresholds the BfR is suggesting the following three options:

8. a) Thresholds could be established in line with existing national and/or international dietary recommendations or guidelines.

This approach could be a possible starting point if it refers to European dietary recommendations, which currently do not exist. As nutrient profiles have to be set for the purpose of regulating the use of nutrition and health claims for the European Union food market, the use of national dietary recommendations or guidelines, or international ones that go beyond the EU (for example from WHO) should not be used. The references have to be valid for Europe, which means that the setting of population reference values by the European Food Safety Authority and its adaption for the use for nutrient profiles for claims would become a priority. However, the problem to translate these nutrient-based dietary recommendations or guidelines into meaningful food-based dietary recommendations or guidelines and their back-translation into thresholds for nutrient profiles still remains.

Examples for this approach cannot be found in the BfR position paper but only in a presentation delivered at the Consumer Protection Forum²⁶. The examples in this presentation show that the approach deserves further exploration as it manages to put individual foods into the context of the whole diet. However, the large variations of nutrient quantities that foods can have (for example salt in pizza or fibre in cereals) demonstrate once again that the final decisions on thresholds will contain a significant political component that will determine if the risk managers intend to cut off the extremes in all food categories from making claims or – following the good food vs. bad food mantra – make it impossible at all for a number of categories to make claims.

b) Alternatively, the thresholds for nutrition claims listed in the Annex to Regulation (EC) No 1924/2006 could be used to set maximum and minimum levels.

The proposal to align nutrient or energy thresholds with the definitions for nutrition claims in the annex of the Claims Regulation also deserves further investigations. This approach would be easy to apply both by food business operators and enforcement authori-

ties and – if done properly – provide incentives for reformulation and innovation of products.

A practical example for the category of non-alcoholic beverages could look as follows: it is normally only carbohydrates in the form of sugars (i.e. mono- and disaccharides) which non-alcoholic beverages may contain in any quantity that could contribute to the overall energy intake from the diet by consumers. Sugars have not been linked directly to the development of obesity-related chronic diseases^{27, 28, 29}. Therefore – in the context of overweight and obesity – the nutrient profile threshold should be related to the amount of energy consumed. On average, regularly sweetened beverages contain 10–13 g of sugars (i.e. 40–52 kcal) per 100 mL. In line with the annex of the Claims Regulation, “energy-reduced foods” are defined as having an energy content reduced by at least 30 % which would translate into an average of 8 g sugars (i.e. 32 kcal) per 100 mL. It could therefore be recommended to set a level of 8 g total sugars per 100 mL (which provides a maximum energy level of 32 kcal per 100 mL or 80 kcal per 250 mL serving) for non-alcoholic beverages as the level up to which these products are allowed to bear nutrition and health claims. However, such an approach would need further refinements, for example in order to consider beverages with a higher sugar/energy level but containing ingredients (such as fruit or vegetable juice, soya or cereals) that have been scientifically recognised as having a positive effect on health and which are important in the diet of the population if they are present in a beverage in an adequate quantity. Another beverage subcategory that might deserve a special exemption from this sugar/energy threshold could be beverages for particular nutritional uses such as drinks formulated to meet the expenditure of intense muscular effort, especially for sportspeople (so-called *sports drinks*).

c) Another alternative would be to set the thresholds according to a reference food from the corresponding food category.

This approach appears to be a variation of 8. b) but with the need to define a reference food. Due to the variations of foods throughout Europe – sometimes even in the same category – this method could turn out to be impractical because it would attempt to standardise the European diet in a way that does not reflect reality.

²⁶ Rolf Großklaus, *Positionspapier der BfR-Arbeitsgruppe über Nährwertprofile als Voraussetzung für Health Claims*, 3. BfR-Forum Verbraucherschutz, Berlin, 23.4.2007; for details see <http://www.bfr.bund.de/cd/9196>

²⁷ Eurodiet Core Report Nutrition & Diet for Healthy Life-

styles in Europe, 2000

²⁸ WHO Technical Report 216 Diet, Nutrition and the Prevention of Chronic Diseases, 2003

²⁹ FAO/WHO Expert Consultation on Carbohydrates in Human Nutrition, 1977

9. Foods which are major sources of qualifying nutrients but which also contain disqualifying nutrients (e.g. full cream milk contains calcium and fat) should not be denied the possibility of bearing a claim.

In principle, this is correct but has to be seen in the context of the discussion about naturally present nutrients vs. fortified foods (see also point 1 of the BfR position).

The declared objective of nutrient profiles is to "... aim to avoid a situation where nutrition or health claims mask the overall nutritional status of a food product, which could mislead consumers when trying to make healthy choices in the context of a balanced diet"³⁰ and there is no reason why this should not also apply to all foods which are major contributors of energy or nutrients one should consume less of. The mentioned full cream milk and its calcium content is a good example where a corresponding threshold for fat could result in a situation where full cream milk could not make health claims (but probably nutrition claims with a disclaimer according to Article 4 [2] [b] of the Claims Regulation) while semi-skimmed or skimmed milk could. This in turn could help to guide consumers towards milk with a reduced fat content (and therefore reduce the intake of energy and saturated fat) but still deliver calcium, which is available from all three different types of milk in comparable quantities.

10. From the scientific nutritional angle it may be appropriate to exclude certain foods from the possibility of bearing a claim.

This point is dispensable because it only repeats the provision of Article 4 (5) of the Claims Regulation. As the BfR does not provide a concrete list of foods for which this should apply, one could conclude that currently the BfR does not see a scientific reason for any food to be listed. From a regulatory point of view, the setting of nutrient profiles according to Article 4 (1) of the Claims Regulation and the establishment of a list of foods for which nutrition or health claims are to be restricted or prohibited according to Article 4 (5) are two different processes. If the scientific advice, which EFSA has to deliver by January 2008, does not clearly recommend any foods for which Article 4 (5) should be applied, then this means that currently there is no scientific basis for such a list.

11. It should be possible for unprocessed foods (primary agricultural products) to bear claims without having to specify nutrient profiles for them. This should help to counteract any shift in consumption from unprocessed foods to (highly) processed foods bearing claims.

This is the only position which has been changed compared to the original BfR position paper where it reads as follows: *It should be possible for unprocessed foods to bear claims in order to avoid a shift in consumption from unprocessed foods to (highly) processed foods bearing claims. It should be possible for certain unprocessed foods like fruit and vegetables to bear advertising claims without having to define nutrient profiles for them.*³¹

Both the original and the updated positions make the unsubstantiated assumption that unprocessed foods are superior to processed foods and should therefore be exempted from nutrient profiling. The examples of milk (see discussion on point 9) or the different fat composition of different types of meat are good indications that this generalisation cannot be supported and that also unprocessed foods have to be scrutinised with regard to their composition and the role they play in the diet.

12. Nutrient profiles should be viable and easy to apply by manufacturers and control authorities.

This position reflects the requirement of Article 4 (1) (v) of the Claims Regulation but falls short of delivering any recommendation or position about how this can be achieved. This underlines the need for a reiterative approach to the process of setting nutrient profiles (see discussion in section II) and reveals the disadvantage of not involving other stakeholders at an early stage. The mandate EFSA received from the European Commission³² includes the request for scientific advice with regard to the feasibility and testing of a proposed system. Any national contribution to EFSA's work should also provide inputs on this topic and not just refer it to the risk manager.

V. Conclusions

The BfR position paper is the first published contribution of a national government-related risk assessment institution to the establishment of nutrient profiles for the Claims Regulation. Its content is the result of

³⁰ *Recital 11 of Corrigendum to Regulation (EC) No 1924/2006 of the European Parliament and the Council of 20 December 2006 on nutrition and health claims made on foods,*

OJ 2007 L 12/3

³¹ *See supra 15*

³² *See supra 18*

almost two years of work of scientists mainly from academia but without any representation from the food industry or consumers associations. Based on a mandate, which is not publicly available, the BfR has developed a position, which includes constructive elements that deserve further exploration but also parts, which are not supported by scientific evidence, so that they appear to be judgmental and subjective.

The intransparent process of developing the original position paper and amending it to the updated paper following the Consumer Protection Forum deprive it from its full value. Nevertheless, the BfR position paper is welcome as a basis for further discussions on a national and European level. A more proactive

involvement in the future of other stakeholders such as food business operators, consumer groups and enforcement authorities could lead to a more practical and scientifically more sound position which in turn would receive broader acceptance and therefore carry more weight in the European discussions.

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