

COMMENTS
on the 4th, 5th and 6th batch of EFSA opinions and
the risk management decisions taken on the basis of the EFSA opinions, in
particular the establishment of the Union Register of rejected claims

30 January 2012

European Commission
Mr Basil Mathioudakis
Unit E4 – Food Law, Nutrition and Labelling
Health & Consumer Protection DG

200 Rue de la Loi
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Cc DG ENTR

Re: Comments on the 4th, 5th and 6th batch of EFSA opinions and the risk management decisions taken on the basis of the EFSA opinions, in particular the establishment of the Union Register of rejected claims

Dear Mr Mathioudakis,

As representative organizations of the European food supplements and functional ingredients market, we have commented jointly on the first three series of EFSA opinions covering the Article 13 list of claims. With this letter we would like to share our comments on the last three batches of opinions published in the course of 2011 and on the decision to establish a Union Register of rejected claims on the basis of these EFSA opinions.

Scientific methodology should be changed for the sake of innovation

We have indicated repeatedly, we do not believe the approach adopted by EFSA for the assessment of article 13 claims is in line with the proportionality foreseen by the Nutrition and Health Claims Regulation (NHCR) as laid down in Recital 26. It is seriously detrimental for our capacity to innovate and compete on a global market.

We therefore continue to request that this methodology is modified and made more appropriate for nutritional research. We would like to ask the European Commission (EC) what steps it has taken to discuss the consequences of the implementation of this legislation with DG Research, DG Enterprise and Industry, DG Trade and with EFSA. We would be interested to hear from the EC how the outcome of the implementation is promoting and protecting innovation in the area of foods, one of the NHCR's main objectives.

ERNA has been invited to a meeting in Parma in the course of February to discuss the scientific aspects of the process with EFSA. We have suggested that EFSA also invites the EC to participate to this meeting and would be delighted if the EC accepts this invitation.

Including rejected claims in the Union Register is not appropriate

We have understood the EC intends to include all claims for which the assessment is finalized in a Union Register of rejected claims. Given shortcomings of EFSA's assessment procedure the way in which EFSA has assessed claims, the reasons invoked for a large number of claims and a complaint that is currently under consideration by the European Ombudsman, **we believe it is not justified nor defensible that rejected claims are included in the Union Register. They should be put on hold together with the claims in the "exceptional" assessment process until this issue is clarified and resolved. We therefore ask the European Commission to abstain from publication of a Union Register of rejected article 13.1 claims till the above issues are fully resolved.**

We appreciate the difficult process the article 13 list process has gone through because of the lack of clarity and guidance on many aspects. We have also welcomed and supported the many efforts the EC has undertaken to try and solve many issues. We nevertheless believe that a number of claims for which evidence is available are now close to rejection because of the approach taken. We therefore would call upon your help and support to find a solution for these claims and would propose the following for your consideration:

- *Claims that have received a negative or insufficient opinion after assessment of the evidence submitted and for which an article 13.5 dossier is submitted or under preparation.*

Although not a requirement, some companies have introduced an article 13.5 submission or are in the stage of preparation of such a dossier. We believe that claims for which there has been submitted a validated dossier under article 13.5 before the end of the transition period foreseen should remain on hold until a decision is taken in the framework of the application.

- *Claims that relate to foods and substances (judged insufficiently characterized by EFSA or subject to negative opinions for other reasons) which have been assessed by other organisations with a diverging outcome.*

Also these claims should remain on hold until EFSA has provided clarity on the reasons for the divergent outcome of their assessment, as it is obliged to do in accordance with Article 30 of its founding Regulation (EC) No 178/2002.

- *Claims that have been judged by EFSA to be general and non-specific.*

Such claims should not be considered for any form of rejection as they are explicitly allowed under the provisions of Article 10.3 of the NHCR.

A proportionate and workable transition period is needed

Remaining uncertainty and the massive number of rejected claims foreseen, make it difficult, if not impossible for companies to effectuate the necessary changes to product composition and labeling within the short 6 months transition period foreseen. The outcome of the discussions by the Member States during the meeting of the Working group on claims of 23 January makes it plainly clear how many interpretation issues are still under discussion and the way the Member States disagree. This does not create the legal certainty needed for companies to apply the Regulation and initiate label changes and product reformulation

Given the long shelf life of food supplements, **we urge for a transition period of 24 months** (which is still shorter than the shelf life of many products). During such transition period it should be granted to sell stocks that had been labelled or put on the market before the entry into application of the implementing Regulation.

We note that Article 28.1 of the original Regulation foresaw a 24 month transition period for foods placed on the market or labelled prior to the date of application of the NHCR. For the application of nutrient profiles, a transition period of 24 months was also judged acceptable. Given the delayed finalization of the Article 13 list and the difficulties and lack of clarity accompanying the establishment of the various lists, **we call for an equivalent transition period of 24 months to enable companies to implement the various measures that will be decided and for which today much clarity still needs to be achieved.**

We hope that you will treat our comments in this letter and annex with due consideration, in view of developing solutions that are workable and implementable by our members and respect the objectives of the legislation.

We remain as always at your disposal for further clarification.

With kind regards,



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Chair ERNA



Peter Van Doorn
Chair EHPM



Michel Donat
Chair EBF

Annex

Annex: Detailed comments

Introduction

As representative organizations for the European food supplements and functional ingredients sector, ERNA, EHPM and EBF have commented jointly on the first three series of EFSA opinions covering the Article 13 list of claims.^{1,2,3}

These comments showed that many claims have received a negative opinion because of the discrepancy that has become clear between the way in which the information has been compiled by our concerted federation effort and the way in which EFSA has used this information for the assessment.⁴

We have also noted that while the scientific evidence for a large part of the submissions was of poor quality, at least a number of claims have not received a positive opinion because of the approach for scientific assessment adopted by EFSA.

As we have indicated repeatedly, we do not believe this approach is in line with the proportionality foreseen by the Nutrition and Health Claims Regulation (NHCR) as laid down in Recital 26. It is an approach that is not appropriate for nutritional research and leads to a medicalisation of food. It is one of the elements why the NHCR fails to achieve its various objectives (see ERNA report on the implementation of the NHCR).⁵

Based on our analysis, we have developed and proposed a model for a more proportionate assessment of Article 13 claims, which we shared with the EC and EFSA.⁶ However, despite these efforts, we have unfortunately not seen that these comments have been taken into account so far.

Need for a change in the scientific assessment methodology

We acknowledge that the European Commission has taken a number of important and useful initiatives within the limits of its power to remediate and clarify a number of issues. We have welcomed in particular:

¹ Joint ERNA-EHPM-EBF Response and comments in relation to the request for clarification from EFSA on certain article 13 entries. Letter to the EC sent on 18 May 2009. Available on-line at www.erna.org

² Joint ERNA-EHPM-EBF comments in relation to the first batch of article 13.1 claims opinions. Letter sent to the EC on 15 October 2009. Available on-line at www.erna.org

³ Joint ERNA-EHPM-EBF comments in relation to the first batch of article 13.1 claims opinions. Letter sent to the EC on 15 October 2009. Available on-line at www.erna.org

⁴ Richardson DP, Binns NM, Viner P. (2007) Guidelines for an evidence-based review system for the scientific justification of diet and health relationships under Article 13 of the new European legislation on nutrition and health claims. Food Science and Technology Bulletin: Functional Foods 3 (8) 81–95

⁵ ERNA. Nutrition and Health Claims in the EU. Regulation EC (No) 1924/2006. An review of the consequences of implementation. September 2011. Available on-line at www.erna.org

⁶ ERNA. Model for the assessment of article 13.1 health claims in the framework of the EU Nutrition and Health Claims Regulation in relation to the terms of reference. June 2009. <http://www.erna.org/UserFiles/Claims%20Model%20Final.pdf>

- The possibility that was offered to provide new evidence or clarification in relation to a number of health claims (insufficiently characterized probiotics and claims that received an insufficient opinion from EFSA).
- The removal of botanicals from the process to reflect on a number of issues and eliminate the inconsistency between medicinal and food law.
- The correction of the batch-wise publication of decisions on the article 13 list.
- The further reflection on how to use data from studies in patients for the substantiation of health claims.

However, the fundamental issue of the scientific assessment approach for ‘function claims’ (article 13), leading to the vast majority of rejections has not been appropriately addressed yet. This will not only result in few accepted claims for other substances, but also limit the chances of success once such claims would be resubmitted under the authorisation process of article 13.5.

From our analysis of claims opinions that were published by EFSA as part of its 4th, 5th and 6th batch of opinions, published respectively on 8/4/11, 30/6/11 and 28/7/11 it is clear that the points we have already expressed in previous comments remain valid.

The principal findings can be summarized as follows:

- Except for essential nutrients (vitamins and minerals), the role of which in the body is well established, general information on the role of a substance in the body has not been accepted. Instead, proof of improvements of physiological functions upon supplementation in a healthy population is needed. This discrepancy is not justifiable. It has led to few claims for other substances having received positive opinions in the EFSA assessment process.
- The fact that much of the information for many claims has not been presented in a way that was acceptable to EFSA, has also led to many unfavourable opinions for formalistic reasons without the evidence having been assessed. Mainly caused by a lack of clarity and guidance on the format of the article 13.1 list this led to information being that did not enable EFSA to investigate a claim to the same level of detail as an application for authorisation under Articles 13.5 and 14.
- Many individual submissions and a number of omnibus opinions have been published as part of the last three batches with inconclusive EFSA opinions. These are opinions in which the scientific evidence has not been assessed because of a number of reasons, including:
 - Insufficiently characterized foods/food components
 - General and non-specific health benefit

- Claims outside of the scope of Art 13.1 (e.g. regarded as Art 14 claims, nutrition claim, etc)
- Claims that for other reason are not considered to comply with criteria of the claims Regulation (e.g. excess consumption, non-beneficial health relationship, medicinal claim, etc).

The number of claims that received a negative opinion for these reasons was roughly 1/3rd of all submissions (1,013 IDs) covered by the 4th, 5th and 6th batches combined. This clearly illustrates the lack of useable information relating to characterization of the food/food component and claimed effect in a large part of the submissions, despite these having been accepted by Member States and EC and further information being submitted during the process.

e.g. The lack of clarity of the requirements have still resulted in hundreds of submissions being judged inadequate by EFSA, with as a consequence that the evidence has not been considered.^{7,8,9,10}

- The assessment was not started from the health relationship, that was, for the sake of consumer understanding often worded in general terms, but from very specific effects, often selected out of the list of example wording or obtained in the further clarification process. In the article 13 list claims were formulated explicitly in a general way, as a health relationship, in the supposition that EFSA would establish the extent to which a health claim would be acceptable and delimit the boundaries of the health effect (as it has done for vitamins and minerals). This is not what EFSA did.

⁷ Scientific Opinion on the substantiation of health claims related to flavonoids and ascorbic acid in fruit juices including berry juices (ID 1186); flavonoids from citrus (ID 1471); flavonoids from *Citrus paradisi* Macfad. (ID 3324, 3325); flavonoids (ID 1470, 1693, 1920); flavonoids in cranberry juice (ID 1804); carotenoids (ID 1496, 1621, 1622, 1796); polyphenols (ID 1636, 1637, 1640, 1641, 1642, 1643); rye bread (ID 1179); protein hydrolysate (ID 1646); carbohydrates with a low/reduced glycaemic load (ID 476, 477, 478, 479, 602) and carbohydrates which induce a low/reduced glycaemic response (ID 727, 1122, 1171); alfalfa (ID 1361, 2585, 2722, 2793); caffeinated carbohydrate-containing energy drinks (ID 1272); and soups (ID 1132, 1133) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(4):2082. [38 pp.]. doi:10.2903/j.efsa.2011.2082.

⁸ Scientific Opinion on the substantiation of health claims related to: anthocyanidins and proanthocyanidins (ID 1787, 1788, 1789, 1790, 1791); sodium alginate and ulva (ID 1873); vitamins, minerals, trace elements and standardised ginseng G115 extract (ID 8, 1673, 1674); vitamins, minerals, lysine and/or arginine and/or taurine (ID 6, 1676, 1677); plant-based preparation for use in beverages (ID 4210, 4211); *Carica papaya* L. (ID 2007); “fish protein” (ID 651); acidic water-based, non-alcoholic flavoured beverages containing calcium in the range of 0.3 to 0.8 mol per mol of acid with a pH not lower than 3.7 (ID 1170); royal jelly (ID 1225, 1226, 1227, 1228, 1230, 1231, 1326, 1328, 1329, 1982, 4696, 4697); foods low in cholesterol (ID 624); and foods low in *trans*-fatty acids (ID 672, 4333) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(4):2083.

⁹ Scientific Opinion on the substantiation of health claims related to vitamins, minerals and omega-3 fatty acids (ID 1, 2, 3, 4, 5, 7, 10, 11, 12, 111, 112, 168, 173, 174, 179, 184, 201, 210, 217, 362, 372, 717, 1464, 1515, 2872, 2874, 3094, 3095, 4279, 4280, 4281, 4282, 4284, 4285, 4286, 4287, 4289, 4291, 4292, 4708) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(4):2077.

¹⁰ Scientific Opinion on the substantiation of health claims related to various foods/food constituents and “immune function/immune system (ID 573, 586, 1374, 1566, 1628, 1778, 1793, 1817, 1829, 1939, 2155, 2485, 2486, 2859, 3521, 3774, 3896), “contribution to body defences against external agents” (ID 3635), stimulation of immunological responses (ID 1479, 2064, 2075, 3139), reduction of inflammation (ID 546, 547, 641, 2505, 2862), increase in renal water elimination (ID 2505), treatment of diseases (ID 500), and increasing numbers of gastro-intestinal microorganisms (ID 762, 764, 884) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(4):2061.

- The level of product characterisation required was not considered in relation to the claimed benefit but focused in many cases on very specific compounds in the food rather than the food as such.

e.g. ID 1104, 1222, 1600, 1601, 1707, 1935, 2004, 2005: Camellia sinensis (L.) Kuntze (tea) is not sufficiently characterised but L-theanine is. ID 1310, 2657, 1108, 2640, 1110, 1119, 1120, 1121, 1275, 1117, 2812, 2814, 1274, 3280, 1118, 1273, 2813: Camellia sinensis (L.) Kuntze (tea) is not sufficiently characterised but catechins in green tea (including EGCG) are. Claims for tea or green tea as such are therefore not possible under the EFSA approach.^{11,12}

This makes it difficult - if not impossible - to assess general information relating to food components but also to foods, groups of foods or even specific diets. This is in contrast to methodologies followed by other organizations that are capable to identify health benefits for such foods. Claims for foods as such have only been accepted in few cases where the identification of a specific compound has not been required.

e.g. ID 1155, 1157: a notable example of the acceptance of a claim for a specific food without the need for the identification of a more specific food compound is the claim walnuts and improvement of endothelium-dependent vasodilation.¹³ This claim has been accepted for authorization.

- For the assessment EFSA focused on very specific health effects. We note that even quite precise health relationships (e.g. relating to liver function, gastro-intestinal health, etc) are also considered to be general and non-specific by EFSA. We also note that this is in sharp contrast with opinions on vitamins and minerals that are expressed in similar terms, e.g. contributes to the maintenance of the immune function, etc.

e.g. ID 1723, 1725, 1729: maintenance of the normal function of the nervous system, maintenance of the normal function of the immune system and contribution to normal energy-yielding metabolism are claims that are favourably assessed for vitamins and minerals but judged insufficiently characterized for other substances.¹⁴

¹¹ Scientific Opinion on the substantiation of health claims related to L-theanine from *Camellia sinensis* (L.) Kuntze (tea) and improvement of cognitive function (ID 1104, 1222, 1600, 1601, 1707, 1935, 2004, 2005), alleviation of psychological stress (ID 1598, 1601), maintenance of normal sleep (ID 1222, 1737, 2004) and reduction of menstrual discomfort (ID 1599) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(6):2238.

¹² Scientific Opinion on the substantiation of health claims related to *Camellia sinensis* (L.) Kuntze (tea), including catechins in green tea, and improvement of endothelium-dependent vasodilation (ID 1106, 1310), maintenance of normal blood pressure (ID 1310, 2657), maintenance of normal blood glucose concentrations (ID 1108), maintenance of normal blood LDL-cholesterol concentrations (ID 2640), protection of the skin from UV-induced (including photo-oxidative) damage (ID 1110, 1119), protection of DNA from oxidative damage (ID 1120, 1121), protection of lipids from oxidative damage (ID 1275), contribution to normal cognitive function (ID 1117, 2812), “cardiovascular system” (ID 2814), “invigoration of the body” (ID 1274, 3280), decreasing potentially pathogenic gastro-intestinal microorganisms (ID 1118), “immune health” (ID 1273) and “mouth” (ID 2813) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(4):2055.

¹³ Scientific Opinion on the substantiation of health claims related to walnuts and maintenance of normal blood LDL-cholesterol concentrations (ID 1156, 1158) and improvement of endothelium-dependent vasodilation (ID 1155, 1157) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(4):2074

¹⁴ Scientific Opinion on the substantiation of health claims related to copper and reduction of tiredness and fatigue (ID 272), maintenance of the normal function of the nervous system (ID 1723), maintenance of the normal function of the immune system (ID 1725) and contribution to normal energy-yielding metabolism (ID 1729) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(4):2079.

e.g. ID 1949: Maintenance of normal muscle function has been considered to be general and non-specific in relation to taurine, but has been accepted for protein and a number of vitamins and minerals.¹⁵

- The way in which the assessments are done makes it almost impossible to succeed with a maintenance claim if there is no data supporting an improvement, although the terms of reference on the article 13.1 list (TOR) recognise that there are health effects both referring to the maintenance of a function and to an improvement of a function. We believe a distinction between maintenance and improvement is essential and would allow for claims of different strengths to coexist.

e.g. ID 1779, 2020: A classical example of the above is the fact that claim for lutein for the maintenance of eye health was not accepted because EFSA insisted looking at improvements in vision. The claimed effect however was clearly explained in the submission to be protection of the eye from the harmful effects of free radicals, which is something altogether completely different.¹⁶

e.g. ID 906 The claimed effect related to “gastro-intestinal health and from the example of wording is clear this relates to the activity of the substance as probiotic. Nevertheless, the effects were judged not sufficiently defined as they addressed several effects. It was not possible to establish the effect which is the target for the claim, while it was the sum of the effects that should have been considered as support for the more general gastro-intestinal health claim.¹⁷

- For some claimed effects, specifically those relating to the maintenance of certain physiological functions, EFSA has not been able to set conditions of use and this is almost automatically taken by the EC to reject the claim.

This appears not justified. Conditions of use can always be set to the best judgment possible. We note that for vitamins and minerals a significant quantity has been set at 15% of RDA as specified for nutrition claims. In these cases EFSA applies a mere regulatory limit that is not based on scientific judgment. We do not see why this would not be possible for other claims. In addition, we observe that the NHCR does not explicitly require conditions of use, although we agree that conditions of use are very useful for legal certainty and enforcement. We believe efforts should be undertaken by the EC, in case conditions of use need to be set, to define these to the best judgment possible. We feel that a rejection of a claim purely on the basis that no conditions can be set is therefore not justified.

¹⁵ Scientific Opinion on the substantiation of health claims related to taurine and “immune system protection” (ID 611), “metabolism processes” (ID 613), contribution to normal cognitive function (ID 1659), maintenance of normal cardiac function (ID 1661), maintenance of normal muscle function (ID 1949) and delay in the onset of physical fatigue during exercise (ID 1958) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(4):2035.

¹⁶ Scientific Opinion on the substantiation of health claims related to lutein and protection of DNA, proteins and lipids from oxidative damage (ID 3427), protection of the skin from UV-induced (including photo-oxidative) damage (ID 1605, 1779) and maintenance of normal vision (ID 1779, 2080) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(4):2030.

¹⁷ Scientific Opinion on the substantiation of health claims related to *Lactobacillus rhamnosus* ATCC 53103 (LGG) and “gastro-intestinal health” (ID 906) and maintenance of tooth mineralisation (ID 3018) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(6):2233

*e.g. ID 646, 1224, 1238, 1339: EFSA considered that no single condition of use can be set because of the great variation in individual tolerances to lactose of lactose intolerant individuals. In this case an arbitrary condition of use could be set, specifying a maximum amount of lactose (e.g. 2 g/100g) accompanied with a labeling requirement that individuals suffering from lactose intolerance will need to adapt their lactose intake to their individual tolerance.*¹⁸

*e.g. ID 670, 2902: Fat contributes to normal absorption of fat-soluble vitamins. No conditions of use could be established. This is obvious as the claimed effect is a statement of fact. It could be questioned whether such statements would need to fall under the scope of the NHCR. In such case no condition of use should be established or an arbitrary value could be chosen, as is the case with vitamins and minerals (15% of RDA).*¹⁹ (It is noted that this claim was explicitly refused to be authorized for another reason: because it was judged to be contrary to nutritional policy.)

We would offer our assistance to contribute to the development of conditions of use where such would be judged desirable.

- The fact that evidence obtained in or relevant for a healthy population should be presented, may look logic but also introduces a limiting factor for the assessment of the role a food component plays in the maintenance of a certain physiological function. The totality of the available evidence and the weighing of this evidence obviously need to include all data relating to the physiological function, including data obtained in subjects in which the function is disturbed, such as populations with clinical or pre-clinical conditions. Not considering such evidence in the assessment presents a considerable limitation.
- We observe that while the TOR makes reference to qualified language for the wording of a claim, this is only used in rare occasions by EFSA. In such cases EFSA has not identified the strength of evidence in a systematic way, which makes the justification for the qualified language difficult to understand.

*e.g. ID 4663 EFSA proposed wording: “Chitosan may contribute to maintaining normal blood cholesterol levels”.*²⁰

*e.g. ID 646, 1224, 1238, 1339: “Consumption of lactose in amounts exceeding individual tolerances may lead to the occurrence of symptoms of lactose intolerance in lactose intolerant individuals; consumption of foods with reduced amounts of lactose may help to decrease gastro-intestinal discomfort caused by lactose intake in lactose intolerant individuals”.*¹⁸

¹⁸ Scientific Opinion on the substantiation of health claims related to foods with reduced lactose content and decreasing gastro-intestinal discomfort caused by lactose intake in lactose intolerant individuals (ID 646, 1224, 1238, 1339) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(6):2236.

¹⁹ Scientific Opinion on the substantiation of health claims related to fats and “function of the cell membrane” (ID 622, 2900, 2911) and normal absorption of fat-soluble vitamins (ID 670, 2902) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(6):2220.

²⁰ Scientific Opinion on the substantiation of health claims related to chitosan and reduction in body weight (ID 679, 1499), maintenance of normal blood LDL-cholesterol concentrations (ID 4663), reduction of intestinal transit time (ID 4664) and reduction of inflammation (ID1985) pursuant to Article 13(1) of Regulation (EC) No1924/2006. EFSA Journal 2011;9(6):2214.

*e.g. ID 463, 464, 563, 618, 647, 1182, 1591, 2907, 2921, 4300: “Frequent consumption of sugars contributes to tooth demineralisation. Consumption of foods/drinks containing <name of sugar replacer> instead of sugar may help maintain tooth mineralisation by decreasing tooth demineralization”.*²¹

We strongly feel that grading of the evidence and qualified language are essential for consumer information and innovation based on emerging science. Other organizations do apply this and the NHCR does not explicitly reject it. The fact that it is not applied in all assessments should be a matter for discussion between the legislator and the scientific assessor. This is a fundamental aspect that needs to be corrected.

In summary, the assessment methodology applied by EFSA to the article 13 list leads to a restrictive view of the kind of claims that are accepted and the food components that are sufficiently characterized. The same approach is taken for the assessment of the article 13 claims as for applications for authorisation under article 13.5 or 14. This is in breach of recital 26 of the NHCR that requires explicitly a different type of assessment.

No justification for establishing a Union Register of rejected article 13 claims

The positive list of accepted article 13.1 claims was adopted by the Standing Committee on 5 December. In the light of our analysis of all article 13 claims assessed so far, we believe it is not appropriate and justified to include all claims that have received a negative EFSA opinion and not put on hold in a Union Register of rejected claims based on the outcome of the EFSA assessment for various reasons.

Firstly, we observe that the NHCR does not foresee/allow that the EC formally rejects claims under the procedure of the article 13.1 list. It is only mandated to take a decision on the positive list, i.e. on the claims it decides to adopt. This is coherent with the principle that any claim that is not included in the article 13 list, is not allowed anyway. We believe that the inclusion of these claims in the Register could be seen as an act that goes beyond the powers conferred to the EC and could be challenged. Including claim in the Register of rejected claims would only be acceptable by means of a legal decision, which is not foreseen by the NHCR.

In addition, many negative opinions (approx 30% of all 2760 IDs) are the consequences of formalities and not of the assessment of the scientific data. We believe it would not be appropriate to include such claims in a register as rejected, because this would lead to Member States refusing during the validation stage resubmission under the article 13.5 or 14 procedures when the same data are presented.

Further suggestions on how to deal with specific types of claims are presented below.

²¹ Scientific Opinion on the substantiation of health claims related to the sugar replacers xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose and polydextrose and maintenance of tooth mineralisation by decreasing tooth demineralisation (ID 463, 464, 563, 618, 647, 1182, 1591, 2907, 2921, 4300), and reduction of post-prandial glycaemic responses (ID 617, 619, 669, 1590, 1762, 2903, 2908, 2920) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(4):2076.

Claims for which the evidence has not been considered supportive of a cause and effect relationship.

For those claims for which the evidence has been rejected on the basis of an assessment (approx. 50% of all submissions), the negative opinion might be the consequence of either poor data or of the inappropriate methodology.

We acknowledge that for many claims the evidence that was provided in the article 13 process was poor and that many negative opinions are justified. We regret however that also a number of claims with good evidence are among the claims that received negative opinions. This is a consequence by the methodology chosen and the fact that EFSA has decided not to grade the evidence and thus only provides yes/no opinions. Given that the appropriateness of this approach is currently under investigation by the European Ombudsman, we would plead to put these claims on hold until the decision of the investigation is made public, in order not to damage products that have been on the market in many Member States, with claims that have not been challenged before.

In addition, to help the further assessment process, we propose that companies could be given an opportunity to comment on the reason given by EFSA for the rejection of the submitted evidence.

Also, although not a systematic requirement, applicants may have submitted an application under the procedure of article 13.5.

It would be legitimate to keep such claims on hold until a decision is taken on the basis of the submission where a valid application has been submitted before the end of the transition period for the application of the positive list of article 13 claims.

Claims for which the evidence has been judged insufficient

We appreciate that claims that have received an opinion from EFSA that the evidence is insufficient to establish a cause and effect relationship between intake of the food/food component and the health effect have been accepted in a process for further assessment. We have noted that for some of these claims, additional information has been submitted and that these claims have now been put on hold until the outcome of the assessment by EFSA of the newly provided data.

The EC and EFSA have, in the context of this further clarification process, expressed on several occasions that they would favour companies submitting an application for authorization under the terms of article 13.5. This possibility has been taken by some companies and others are in the process of developing such applications.

We feel it would be legitimate to also keep on hold until a decision is taken claims that have not been approved in the article 13 process because of an insufficient opinion but for which a valid article 13.5 dossier has been introduced.

In addition, we note that the possibility for further assessment has only been offered for two specific categories of claims: Those that received an insufficient EFSA opinion and those relating to insufficiently characterized micro-organisms. As we have pointed out in the past, this is a quite arbitrary limitation. Although there were good reasons to select these claims for this process, there were also good reasons for some other claims (e.g. those that were rejected because evidence obtained in patients was not accepted by EFSA, those that have been assessed by other organizations with a different outcome than EFSA, products other than micro-organisms not sufficiently characterized, etc.).

For those claims the submission of an application under article 13.5 is the only possibility offered. It is therefore justified to put these claims on hold when a valid application has been submitted.

Claims that are too non-specific or general to be assessed.

There are many claims for which EFSA has judged that the claimed effect is not sufficiently defined to be able to be assessed. This is a direct consequence of the mismatch between the format of the article 13 submissions and EFSA's expectations that have been made clear only after all submissions had been introduced.

e.g. ID 1207: It cannot be disputed that the claim that water is a “basic requirements of all living things”. It would be aberrant to reject such a claim since it is explicitly allowed as a non-specific claims under the NHCR.²²

It should be noted that under Article 10.3 of the NHCR reference to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being may be made if accompanied by a specific approved health claim. This is precisely the reason invoked by EFSA to justify its judgment that claims must be specific.

Since claims that are general and non-specific are explicitly allowed by the NHCR, they cannot be considered as rejected and cannot be included in the Union Register of rejected claims.

In addition, we note that some very specific effects that are established also have been considered as general and non-specific which we feel is not appropriate and should not be used as a reason to reject this claim.

e.g. ID 488, 4670: A claim relating to linoleic acid as a molecule precursor regulating cell functions (prostaglandins, leucotrienes) was considered non-specific while it is a statement of fact referring to an established function of linoleic acid.²³

²² Scientific Opinion on the substantiation of health claims related to water and maintenance of normal physical and cognitive function (ID 1102, 1209, 1294, 1331), maintenance of normal thermoregulation (ID 1208) and “basic requirement of all living things” (ID 1207) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(4):2075. [16pp.]. doi:10.2903/j.efsa.2011.2075.

²³ Scientific Opinion on the substantiation of health claims related to linoleic acid and “molecule precursors regulating cell functions (prostaglandins, leucotrienes)” (ID 488, 4670), maintenance of normal blood LDL-cholesterol concentrations (ID 2899) and protection of the skin from UV-induced damage (ID 3659) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(6):2235.

Claims for food or food component that are not sufficiently characterized.

For quite a number of claims, EFSA has judged that on the basis of the evidence assessed the food constituent that is the subject of the claim is not sufficiently characterised for a scientific assessment. This is the consequence of the assessment approach chosen.

e.g. ID 531: The subject of the claim was omega 3 and omega 6 fatty acids and their contribution to normal cognitive function. EFSA has interpreted this to mean docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA) and gamma-linolenic acid (GLA) and has looked for evidence of a mixture of these fatty acids, which obviously was not the intention of the submission.²⁴

e.g. ID 1140, 1141, 1191, 1193, 1194, 1815, 1816, 2713, 1266, 1202, 424, 430, 432, 725, 1433, 1362, 1481, 2844, 2845, 1159, 1160, 1318, 4678, 4679, 2029, 2365, 1514, 1711, 461, 2191, 2157, 2556, 1125, 1288, 1370, 2638, 2796, 766, 767, 768, 769, 770, 771, 772, 804, 848, 849, 2922, 3092, 347, 1952, 1146, 1147, 458, 459, 470, 471, 654, 1277, 1278, 1279: These opinions list many claims the substance of which is judged not sufficiently characterized, despite some of them being very precise (e.g. honey, α -lactalbumin, apple polyphenols, rye flour, etc.). The reason is not always clear.^{25,26}

Other organizations, including WHO/FAO and the World Cancer Research Fund have applied a different type of scientific assessment, but of an equally rigorous scientific standard.²⁷ This methodology applied ‘grading’ of the evidence. They have been able to reach conclusions on foods and food components that EFSA has judged not sufficiently characterized. This is an apparent inconsistency for which we have not yet received an adequate explanation from EFSA.

e.g. ID 1212, 1213, 1214, 1217, 1218, 1219, 1301, 1425, 1426, 1427, 1428, 1429, 1430: The diet-health relationships of intake of fruit and vegetables or fruit and vegetable rich diets has not been assessed because the fruit and vegetables are judged insufficiently characterized. The consensus by other organizations has simply been ignored.²⁸

²⁴ Scientific Opinion on the substantiation of health claims related to docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA) and gamma-linolenic acid (GLA) and contribution to normal cognitive function (ID 532) and maintenance of normal bone (ID 642, 697, 1552) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(6):2224.

²⁵ Scientific Opinion on the substantiation of health claims related to: dairy products (ID 1140, 1141, 1191), raw or processed food products of animal origin, plus bread and panification products (ID 1193, 1194), herbal yeast plasmolysate (ID 1815, 1816), apple polyphenols (ID 2713), rye flour (ID 1266), tomato juice (ID 1202), whey protein and alphalactalbumin (ID 424, 430, 432, 725, 1433) and “brocco shoots”, “broccoli sprout powder” and “*Brassica oleracea* var. *italica* (broccoli)” (ID 1362, 1481, 2844, 2845), honey (ID 1159, 1160, 1318, 4678, 4679), and *Cucurbita pepo* L. (pumpkin) seed and seed extracts (ID 2029, 2365) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(6):2243.

²⁶ Scientific Opinion on the substantiation of health claims related to: a combination of millet seed extract, L-cystine and pantothenic acid (ID 1514), amino acids (ID 1711), carbohydrate and protein combination (ID 461), *Ribes nigrum* L. (ID 2191), *Vitis vinifera* L. (ID 2157), *Grifola frondosa* (ID 2556), juice concentrate from berries of *Vaccinium macrocarpon* Aiton and *Vaccinium vitis-idaea* L. (ID 1125, 1288), blueberry juice drink and blueberry extracts (ID 1370, 2638), a combination of anthocyanins from bilberry and blackcurrant (ID 2796), inulin-type fructans (ID 766, 767, 768, 769, 770, 771, 772, 804, 848, 849, 2922, 3092), green clay (ID 347, 1952), foods and beverages (low in energy, energy-free and energy-reduced) (ID 1146, 1147), and carbohydrate foods and beverages (ID 458, 459, 470, 471, 654, 1277, 1278, 1279) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(6):2244.

²⁷ World Health Organization/Food and Agriculture Organization (WHO/FAO) 2002. Diet, Nutrition and the Prevention of Chronic Diseases. WHO Technical Report Series 916

²⁸ Scientific Opinion on the substantiation of health claims related to fruits and/or vegetables (ID 1212, 1213, 1214, 1217, 1218, 1219, 1301, 1425, 1426, 1427, 1428, 1429, 1430) and to the “Mediterranean diet” (ID 1423) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(6):2245.

e.g. ID 744, 745, 746, 748, 749, 753, 803, 810, 855, 1415, 1416, 4308, 4330: Dietary Fiber has been judged to be non sufficiently characterized. The World Health Organization/Food and Agriculture Organization (WHO/FAO) report of 2003 on Diet, Nutrition and the Prevention of Chronic Diseases, submitted as part of the evidence, concluded that the available evidence for an effect of dietary fiber on body weight regulation and the prevention of obesity was convincing based on epidemiological evidence and the results from two meta-analyses of randomised controlled trials (RCT) assessing the effects of mixed, “soluble” and “insoluble” types of fiber on body weight compared to low-fiber diets both ad libitum and during energy restriction. This report further indicates that increased intake of dietary fiber has a probable beneficial effect on the reduction of type 2 diabetes and cardio-vascular disease. It is therefore not defensible that EFSA cannot reach conclusions on such important effects for public health.²⁹

e.g. ID 831, 832, 833, 1126, 1268, 1269, 1270, 1271, 1431: The same holds true for whole grain, covering an equally important recommendation for public health that is not considered because of the difficulty of EFSA to characterise what whole grain is.³⁰

In addition, we note that in some cases EFSA has interpreted the level of characterization in relation to the scientific evidence. We observe that in most cases it has only done so to focus on very specific food compounds, reducing possibilities for claims to compounds rather than to foods as such. Also this could have been done in a different way.

We therefore believe it justified that a case-by-case assessment takes place to identify if the EFSA interpretation has been justified. This could be identified from comments from submitters. In case divergent views can be identified with opinions issued by other recognized scientific bodies or statements by recognized opinion leaders in the field, a new but appropriate assessment, as the NHCR intended in recital 26, for these claims should be requested and EFSA should address in detail the reasons for the divergence of opinion, as it is obliged to do in accordance with Article 30 of its founding Regulation (EC) No 178/2002. These claims should be put on hold and not be included in the Union Register of rejected claims until such assessment has been performed.

Claims that have been judged out of the scope in the EFSA opinion

The fact that claims have been accepted in the process of the article 13 list and been sent to EFSA for assessment and now are judged to fall out of the scope of the process is a clear demonstration of the lack of clarity during the process. Furthermore, some of the interpretations on which such judgment has been based have only been established during the process itself.

²⁹ Scientific Opinion on the substantiation of health claims related to dietary fibre (ID 744, 745, 746, 748, 749, 753, 803, 810, 855, 1415, 1416, 4308, 4330) pursuant to Article 13(1) of Regulation (EC) No 1924/2006 EFSA Journal 2010;8(10):1735

³⁰ Scientific Opinion on the substantiation of health claims related to whole grain (ID 831, 832, 833, 1126, 1268, 1269, 1270, 1271, 1431) pursuant to Article 13(1) of Regulation (EC) No 1924/2006 EFSA Journal 2010;8(10):1766

We believe it does not fall into EFSA's competence to make a judgment on whether a claim falls under the scope or not. Instead, EFSA should have assessed the evidence and left the decision to the risk manager who asked for the opinion in the first place.

We feel it is not acceptable to include such claims in the Union Register of rejected claims as the submitters had the reasonable expectation that the claims would be assessed during the process, and no indication has been given as to why this was not the case until the opinion has been published. These claims should be put on hold and the submitters allowed to follow appropriate alternative procedures for a new assessment of their claim.

- *Claims relating to children's development and health.*

A number of claims have not been assessed because EFSA has judged they would need to fall under an application for authorization of article 14. We would note that such is not an appropriate reason not to assess the evidence and reach a conclusion. In such cases it comes to the EC to withdraw the claim from the procedure and inform the submitter of the administrative requirements it should apply instead. This has not happened.

e.g. ID 574: The claimed effect as expressed in the examples of wording: "Omega-3 fatty acids are essential for growth and development" was considered to fall under children's development and health and was not assessed. This interpretation is challengeable.³¹

The fact that some claims were judged to be children's claims is largely because of the lack of clarity on the definition. Some clarity was only provided in the EC guidance of 17 December 2007, barely a month before the deadline for Member States to submit their lists into the process and effectively after deadlines given to industry by most Member States to provide information for submissions in the list. The fact that during the further process, the Member States and EC have failed to identify the potential problems with these claims and remove them from the process, indicates that the guidance was not very helpful in this respect anyway.

We therefore believe that it is not justified to include these claims in the Union Register of rejected claims. They should be put on hold to be given a chance for resubmission under the appropriate procedures.

Furthermore, we question the legal soundness of including in the Union Register of rejected claims based on an assessment according to the article 13 procedure of claims that fall out of the scope of article 13 altogether.

- *Claims for a target population which is not considered representative of the general healthy population and claims about treatment of disease.*

³¹ Scientific Opinion on the substantiation of health claims related to n-3 polyunsaturated fatty acids (n-3 PUFAs) and "nutrient tasks and interactions" (ID 574), increase in calcium absorption leading to an increase in calcium retention (ID 606), and maintenance of normal bone (ID 607) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(6):2242.

We acknowledge that claims that refer to the treatment of disease fall out of the scope of the NHCR and remain prohibited for foodstuffs. However, we believe this judgment should not be done by EFSA but by the risk manager. In addition, the interpretation of what is a disease treatment claim should be considered in an appropriate way and take into consideration the jurisprudence of the Court of Justice of the European Union (CJEU).

In some cases EFSA has interpreted the claimed effect as medicinal effect despite the submission clearly mentioning the health effect.

e.g. ID 3588, 221: In both cases the claimed effect related to contribution to maintain a healthy prostate but given that ‘prostate function was not sufficiently defined, this has been changed into treatment of prostate cancer.’^{32,33}

In addition, we note that in many cases food interventions will accompany medical interventions. People on high cholesterol will often be advised to take phytosterol/stanol enriched foods in addition to their medical treatment. People on antibiotic therapy will often be advised to take yoghurt or pre/probiotic products in addition to regularize intestinal flora. A judgment of whether an effect of a food or food component is related to the treatment of a disease or can be considered as a beneficial physiological effect therefore needs to be nuanced and taken on a case-by-case basis. Not accepting such contributions would undermine clinical practice.

e.g. ID 1469: This may point to the usefulness of probiotic effects in patients with inflammatory bowel conditions. These effects should be considered valid physiological effects even though they occur in a specific patient group. Dietary management should be able to be assessed under the rules of the NHCR. There is no general requirement that such effects must be limited to the general population.’³⁴

Another aspect we have highlighted in the past is the too narrow interpretation of reductions of disease risk claims. The refusal of EFSA to consider evidence that is not relating directly to the reduction of a risk factor is not appropriate from a legal nor public health perspective. If a food component is capable of reducing the risk of a certain disease as evidenced by a reduced incidence of disease episodes or incidence, in the absence of knowledge on the risk factors that are influenced, such claims should be acceptable for the sake of public health. It has been remarked that reduction of disease risk claims must relate to a significant reduction of a ‘risk factor’. However, what is a ‘risk factor’ is not defined in the NHCR. The concept of ‘risk factor’ has been interpreted by EFSA as being a factor associated with the risk of a disease, and which may serve as a predictor for the development of that disease. This exclusively relates to physiological factors that

³² Scientific Opinion on the substantiation of health claims related to soy isoflavones and protection of DNA, proteins and lipids from oxidative damage (ID 1286, 4245), maintenance of normal blood LDL-cholesterol concentrations (ID 1135, 1704a, 3093a), reduction of vasomotor symptoms associated with menopause (ID 1654, 1704b, 2140, 3093b, 3154, 3590), maintenance of normal skin tonicity (ID 1704a), contribution to normal hair growth (ID 1704a, 4254), “cardiovascular health” (ID 3587), treatment of prostate cancer (ID 3588), and “upper respiratory tract” (ID 3589) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(7):2264.

³³ Scientific Opinion on the substantiation of health claims related to boron and prevention and treatment of prostate cancer (ID 221), maintenance of normal thyroid function (ID 222) and contribution to normal cognitive function (ID 223) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(6):2209.

³⁴ Scientific Opinion on the substantiation of health claims related to *Bifidobacterium animalis* ssp. *lactis* Bb-12 and immune defence against pathogens (ID 863), decreasing potentially pathogenic gastro-intestinal microorganisms (ID 866), “natural immune function” (ID 924), reduction of symptoms of inflammatory bowel conditions (ID 1469) and maintenance of normal blood LDL-cholesterol concentrations (ID 3089) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(4):2047.

(potentially) may be beneficially altered by diet and that are independent predictors of disease risk with an acceptable biological plausibility.

This is very limited. In the interest of public health a broader interpretation is not only possible, but would be appropriate. We have not seen proper justification why nutritional factors or dietary behaviour cannot be acceptable as a risk factor for the development of a disease.

- EFSA has indicated that dietary behaviour (e.g. diets with a low content of a specific category of foods or nutrients) would not be acceptable as a risk factor in this context as the beneficial alteration of the factor (increased consumption of a specific category of foods or nutrients) is not a beneficial physiological effect as required by the Regulation. We believe this is irrelevant for the purpose of defining what is a risk factor. Dietary behaviour is marked by particular low or high intake of specific foods/food components, which are shown to have a beneficial nutritional or physiological effect.
- EFSA has also rejected claims for which the evidence shows that an intervention with a food component directly results in a decrease of disease episodes or incidence, without evidence of the reduction of a risk factor. Such decision does not fall to EFSA, it is not acceptable from a public health perspective and it goes contrary to the NHCR's intention. It has been argued that this is because the NHCR requires a risk factor to be present. However, where a food component is shown to directly reduce the risk of disease incidence, it is likely that the action is mediated through effects on external, physiological or genetic factors that act as risk factors for the disease. The fact that the risk factor is not known should not warrant that the effect is not accepted. It might be the food component itself that could be the risk factor (e.g. low dietary folate intake and neural tube defect) or the food (obviously if intake of a food is shown to lead to a reduction of disease incidence, lack of intake is associated to an increased risk of the disease). This would be coherent with the fact that for a health effect it is not explicitly required that the biological mechanism is known. For a reduction of disease risk claim, it should also not be a requirement that the risk factor is known if a direct effect on disease episodes or incidence is demonstrated.
- *Claims considered as nutrition claims*

For a small number of claims submitted under the article 13 procedure, EFSA has considered in its opinion that they refer to the content of a nutrient and therefore are nutrition claims. The fact that such claims have been included is also an illustration of the lack of clear guidance and interpretation.

Also in this case the decision on the status of a claim falls to the EC and when a claim is now considered as a nutrition claim, the appropriateness of allowing the claim under the procedure foreseen by Article 8.2. In the mean time, to continue provide legal certainty, the claims should be put on hold and not be included in the Union Register of rejected claims.

Claims relating to health effects that have not been considered as beneficial

For a number of claims, EFSA has judged in its opinion that the claimed effect is not a beneficial physiological effect per se, but needs to be linked to a beneficial physiological or clinical outcome. Some of these judgments may appear strange and benefit from discussion with experts in the field.

e.g. ID 345: EFSA considered that the neutralisation of gastric acid is not a beneficial physiological effect for the general population. We feel many people with heartburn would disagree.³⁵

e.g. ID 701: For L-glutamine, increasing gut protein synthesis and decreasing gut permeability have not been considered as beneficial physiological effect per se. They would need to be linked to a beneficial physiological or clinical outcome.³⁶

e.g. ID 781, 785: Increasing numbers of gastro-intestinal microorganisms is not considered as a beneficial physiological effect. Decreasing potentially pathogenic gastro-intestinal microorganisms, might be a beneficial physiological effect.^{37,38} Experts may not particularly agree with this judgment.

In some cases, effects have even been refused in the article 13 process because they are not considered as functions of the body.

e.g. ID 345, 2660, 4296: Maintenance of the normal appearance and elasticity of the skin. This does not relate to changes in skin function and thus to a function of the body.^{35,39}

From a legal point of view, it can be questioned if such claims would then fall within the scope of the NHCR and it can be argued that their inclusion in the Union Register of rejected claims would not be appropriate.

³⁵ Scientific Opinion on the substantiation of health claims related to silicon and protection against aluminium accumulation in the brain (ID 290), “cardiovascular health” (ID 289), forming a protective coat on the mucous membrane of the stomach (ID 345), neutralisation of gastric acid (ID 345), contribution to normal formation of collagen and connective tissue (ID 287, 288, 333, 334, 335, 1405, 1652, 1718, 1719, 1945), maintenance of normal bone (ID 287, 335, 1652, 1718, 1945), maintenance of normal joints (ID 1405, 1652, 1945), maintenance of normal appearance and elasticity of the skin (ID 288, 333), and contribution to normal formation of hair and nails (ID 334, 1652, 1719) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(6):2259.

³⁶ Scientific Opinion on the substantiation of health claims related to L-glutamine and growth or maintenance of muscle mass (ID 719, 722, 3185), faster restoration of muscle glycogen stores after strenuous exercise (ID 434, 699, 701, 723, 1569), skeletal muscle tissue repair (ID 721), maintenance of normal neurological function (ID 662, 700), increased attention (ID 700, 1570), improvement of working memory (ID 700, 1570), maintenance of defence against pathogenic gastro-intestinal microorganisms (ID 452), gut protein synthesis (ID 701), decreasing gut permeability (ID 701), and stimulating immunological responses (ID 1568) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(6):2225.

³⁷ Scientific Opinion on the substantiation of health claims related to fructo-oligosaccharides (FOS) and decreasing potentially pathogenic gastro-intestinal microorganisms (ID 781), pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(6):2222.

³⁸ Scientific Opinion on the substantiation of health claims related to polydextrose and changes in bowel function (ID 784), changes in short chain fatty acid (SCFA) production and/or pH in the gastro-intestinal tract (ID 784), decreasing potentially pathogenic gastro-intestinal microorganisms (ID 785) and reduction of gastro-intestinal discomfort (ID 784) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(6):2256.

³⁹ Scientific Opinion on the substantiation of health claims related to gamma-linolenic acid (GLA) and maintenance of normal blood LDL-cholesterol concentrations (ID 2661, 4452, 4453), maintenance of normal blood pressure (ID 2662), reduction of menstrual discomfort (ID 495, 640, 1773, 1775), contribution to normal cognitive function (ID 1770), maintenance of the barrier function of the skin (ID 499, 591, 639, 676, 1554, 2003, 2065), “function of the cell membrane” (ID 1769), maintenance of normal structure, elasticity and appearance of the skin (ID 2660, 4296), and “anti-inflammatory properties” (ID 4454) pursuant to Article 13(1) of Regulation (EC) No 1924/2006.

Claims relating to botanicals

We acknowledge the efforts undertaken by the EC to seek clarification for the particular situation of botanicals and preserve the coherency between the treatment of botanicals under food and medicinal law. We appreciate that this is not an easy exercise and welcome that claims for botanicals are put on hold.

However, we have noted some incoherencies in the claims that are now scheduled for rejection and those that are put on hold. This is mainly the consequence of a lack of clear definition of botanical.

We have understood that claims are put on hold if they relate to plants, plant parts or derivatives of plants that are not conventionally used as foods (so other than plants commonly used as fruit and vegetables, fruit juice (including concentrated and extracts)). Also if the claim related to a specific component in the plant (e.g. polyphenols, caffeine, etc.) or when the plant is used as a source of a nutrient (e.g. source of essential fatty acids, vitamins or minerals, the submissions have not been considered as 'botanicals'.

Nevertheless, the fact that a number of claims for botanicals falling under these categories have already been assessed before botanicals have been removed, leads to inconsistencies that should be considered.

e.g. A claim on Rosa canina fruit ID 3680, 3681 (standardised to 3% rosasin and 1% salidroside) is on hold whereas the claim made on black currant ID 2750 (standardised at 7% of anthocyanosides) is in the proposed for rejection.

e.g. it is in line with the criteria that substances such as anthocyanins from bilberry and blackcurrant fruits (ID 2796) and isoflavones from soya (ID3588-3589....) are proposed for rejection, however, lignan from Flaxseed husk extract (ID 1807, 1808, 1809) is on hold.

There are also some ID's missing from the lists altogether, e.g. for guarana (ID 2103, 2063, 2375).

We would therefore think it useful to organize a formal consultation to address such abnormalities and have clarity on what is put on hold and what not and for what reasons.

Claims relating to formulated foods or branded products

Some article 13 submissions concern formulated foods, e.g. foods that contain mixtures of nutrients or food components. This is possible under the terms of the NHCR. However, in case that data submitted does not relate to evidence with the actual product, it is legitimate that claims for the individual components are considered instead. Claims for formulated foods should only be part of the article 13 process and as a consequence be included in the

positive list with accepted claims or in the Union list of rejected claims if the data submitted have been obtained with the product itself.

If a claim for a formulated food or mixture of food compounds has received a negative EFSA opinion on the basis of an assessment of the effects of the individual components, such a claim should not be included as such in the Union Register of rejected claims.

Other claims issues / Statements of fact

For some claims, it does not appear to be clear how they should be considered, as health claims? Nutrition claims? Non-beneficial claims? General claims? Statements of fact?

This include e.g.

- References to improved bioavailability or improved absorption
- Looking at the status of a nutrient in the body
- Referring to the supply of a nutrient (e.g. claim on DHA and maternal requirement)

We strongly believe a pragmatic approach must be taken relating to such and other examples of wording. If they refer to a statement of fact (e.g. a measure that is backed by analytical or other verification or a statement to the effect that a food component is a structural constituent of an organ or body structure), such claims should not be considered as health or nutrition claims requiring authorization but as statements of fact. Such statements of fact can be easily controlled by enforcement. They are useful and often needed to describe and provide information on accepted health effects. Statements of fact for food components have been mentioned in many EFSA opinions and are not considered as health claims per se.

Statements of fact are out of the scope of the NHCR and should be accepted to be made in conformity with general principles of labelling and advertising. The evidence underlying the validity of these statements should be kept on file for the purpose of control authorities. In particular the explicit mention of a statement of fact in an EFSA opinion should be sufficient reason for its acceptance.

We would also note that if a statement of fact has the form of a “contains” claim and is mentioned in commercial communications for other than nutrition or health-related purposes (e.g. for texture or taste) it is a “content” claim that falls out of the scope of the NHCR. If it is mentioned for a nutrition or health related purposes but does not implicate a health effect in itself it is a nutrition claim. This is confirmed in the EC 14 December 2007 guidance document which mentions that a “contains” claim for which in the naming of the substance or category of substances there is only factual information and no description or

indication of a functionality or an implied effect on health, such claims are to be considered as nutrition claims.⁴⁰

Both “content” and nutrition claims should therefore also not be included in the Union register of rejected claims.

Conclusion

In summary, the above indicates clearly that there are numerous reasons to **abstain from the creation of a Union Register of rejected article 13.1 claims.**

Not only is there no legal basis to establish such a rejected list, many claims that are scheduled for inclusion have not received a negative opinion on the basis of a scientific assessment but as a result of formalistic reasons that have prevented this assessment to be effectuated. In addition, the currently pending complaint to the European Ombudsman about the fundamental questions if the assessment methodology applied is justified in light of the provisions of the NHCR. This alone justifies plainly that such claims are put on hold and appropriate solutions are sought to minimize inappropriate consequences of the implementation of the article 13 list.

As indicated in the letter, it is also most urgent to consider an appropriate, proportionate and sufficiently long transition period of 24 months.

⁴⁰ Guidance on the implementation of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods. Conclusions of the Standing Committee on the food chain and animal health. 14 December 2007. http://ec.europa.eu/food/food/labellingnutrition/claims/guidance_claim_14-12-07.pdf