

COMMENTS
in relation to the second batch of article 13.1 claims opinions

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European Commission
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Health & Consumer Protection DG

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Cc DG ENTR

Re: Comments to the second Batch of EFSA opinions as published on 26 February

Dear Mr Mathioudakis,

We herewith take the opportunity to provide you with our comments in relation to the second batch of EFSA opinions relating to the article 13 list. We have observed that the comments we have made in relation to the first batch of EFSA opinions have been seriously considered by the EC and we would like to express our respect and gratitude for this.

We are disappointed to see on the contrary that EFSA has not changed its approach in any way despite our constructive comments and calls for discussion.

In this letter we have addressed a number of specific and general comments in relation to the second batch of EFSA opinions that was published on 26 of February 2010.

We observe that from the 413 claims only 50 have been taken from the CIAA-EHPM-ERNA-EBF list, which is a limited number that does not allow us to draw general conclusions in relation to the level of evidence submitted by others for the majority of the claims in this batch. Nevertheless, the fact that of these 50 claims only 4 (for 1 vitamin and 1 mineral) have been approved is of grave concern. It confirms the trend that was apparent for the first batch and on which we have already commented broadly in various communications we have shared with your services.

In the present comments, we will not reiterate our concern on the consequences for research and development, nor for consumer choice and information which we extensively covered in our response to the first batch of opinions and which remain very pertinent also now.

The present comments are essentially of a scientific nature. They relate to the reasons underlying the disproportionately high number of negative claims opinions and illustrate that

the way in which EFSA assesses health claims is not appropriate for food research. If this is not acknowledged and reconsidered, it will lead to the rejection of most, if not all of the remaining 600 entries from our list. You can understand the disproportionate economic consequences if this were to happen.

That the EFSA approach is disproportionate and not adapted to food research is clear and obvious from the following observations:

- EFSA addresses all claims by the same principles that are adopted for the extreme end of the claims spectrum: reduction of disease risk claims with an exclusive focus on the reduction of validated end points or biomarkers, that serve as risk factors to human diseases (cholesterol, bone loss, oral pH, etc).
- The health relationships assessed positively to date by EFSA under any of the procedures for substances other than essential nutrients, all relate to the reduction of these disease-linked parameter. No single claim relating to the contribution of a certain substance to health has received a favourable opinion yet.
- The totality of the evidence is not considered and weighted to assess the plausibility of the claimed effect. In fact, in the opinions all sorts of reasons are invoked to consider scientific evidence as not pertinent and approvals and authoritative statements of other respected organisations are ignored.
- This approach applied to foods is therefore similar to the one applied to pharmaceutical products. It leads to an unwanted medicalisation of food and a narrowing of the borderline between foods and medicinal products.
- The difference between the three procedure of the law (art 13.1, art 13.5 and art 14) have completely vanished. The requirements are the same, the assessment is the same and even the way the decisions are taken and the time needed are the same. Proportionality is gone.

Food supplements are concentrated forms of substances intended to supplement the diet. It is imperative that the role of these substances and the contribution they can have for health can be communicated to the consumer, without them being turned into medicinal products. The adopted approach by the EFSA scientists makes such communication impossible.

We therefore would like to ask the EC to assess if the way EFSA performs its assessments is in line with the principles of the Regulation and the expectations of the EC as expressed in the terms of reference as it clearly fails to qualify the level of evidence underlying a health effect by an assessment of the totality of the evidence and weighing it. EFSA still has more than 3000 claims to assess. It would be irresponsible to let them continue and spend public money without first having a fundamental assessment in the light of the experience now gained. The necessity of a time-out and intermediate evaluation of the process has become ever more legitimate and has reached a stage where it becomes unavoidable.

We therefore clearly call upon the EC not to proceed with any adoption of decisions before a fundamental discussion has been carried out with the scientists involved on the level of evidence that is feasible and acceptable for food claims and the methodology used to assess the totality of the evidence available.

We hope the EC can take these comments on board to try and remedy the issues that currently make the claims Regulation unable to meet its primary goals: to protect consumers against

misleading claims, legal security and fair competition for operators and promotion and protection of innovation in this field.

As always, we offer our constructive help to achieve this objective.

With kind regards,

EHPM – ERNA – EBF

Annex

ANNEX

1. General observations drawn from the second batch of EFSA opinions

The experience with the Opinions gathered until now shows that the applied methodology is not capable to address health effects of food components and should be readjusted.

We have analysed in detail the opinions for the claims coming from our list in order to identify the reasons for EFSA's rejections (See part 2: specific observations). Our findings are unsettling and call for an immediate reappraisal of the methodology used.

This analysis corroborates our views that the way EFSA assesses the claims is not appropriate for foodstuffs and will lead to the approval of few if any of the remaining entries, other than vitamins and minerals from our list.

This stems from the following observations:

1.1. All claims appear to be assessed according to principles adopted for the extreme end of the claims spectrum: reduction of disease risk claims. Only claims relating to the reduction of a disease-linked parameter have been approved to date.

An analysis of the claims (other than vitamins and minerals for which the approval is based almost entirely on textbook knowledge) that have received a positive opinion to date clearly shows that the only positive effects accepted are:

- Lowering or maintenance of cholesterol levels, where maintenance is only acceptable if the substance also has a lowering effect. Cholesterol is an accepted risk factor for cardiovascular disease. It both covers article 13 and article 14 submissions, but in both cases the evidence required is clearly reduction of disease claim type of evidence showing a decrease in cholesterol level.
- Maintenance of blood pressure was only accepted because the substances (EPA and DHA) were shown to be able to decrease blood pressure. Despite this being an article 13 submission, it clearly supposed the availability of reduction of disease risk claim type of evidence showing a decrease in blood pressure.
- Decreasing platelet aggregation, which is linked to circulation and therefore cardiovascular disease. Although this was an article 13.5 submission, it was the only one that was approved because of the availability of reduction of disease risk claim type of evidence demonstrating a reduction of platelet aggregation.
- Reducing bone loss, clearly a risk factor for osteoporosis and therefore reduction of disease risk type of evidence required.
- Plaque acid neutralization, tooth mineralization, reduction of oral dryness and reduction of dental plaque, all clearly involved as risk factors in the development of caries and therefore approved because of the existence of reduction of disease risk type of evidence.

The only function claims approved that would not fall under reduction of disease risk type of evidence relates to the approved claim that lactase splices lactose, the role of melatonin in subjective feelings of jetlag and the energy reduction properties of meal-replacers. These are not really health claims in relation to physiological functions. The lactose claim is not even a health claim but a statement of fact and we understand that some Member States question if such a statement would fall under the scope of the Regulation in the first place.

These examples show that EFSA applies to all claims the type of assessment and the level of scientific evidence expected for the extreme end of the claims spectrum, i.e. reduction of disease risk claims, for all function claims. This is not only inappropriate because normal functions of the body can benefit from the intake of certain food components without showing a decrease or increase of a parameter. It is also plainly impossible for many health contributions to show improvements of health within the boundaries of normality in the way EFSA expects. Requiring normalization of aberrant parameters leans very closely to medicinal products. The expectation of such effects leads to a clear medicalisation of foods.

We believe EFSA should consider and weigh the totality of the evidence available to judge upon the plausibility of the claimed effect, and not expect only to see proof of measurable effects on endpoints or validated biomarkers that serve as disease-linked risk factors. The current approach effectively reduces all claims to reduction of disease risk claims.

1.2. The adopted approach ignores the proportionality that was included in the law and makes claims referring to a contribution to health actually impossible.

The approach adopted by the scientists result in a situation that the Claims legislation is not fulfilling its legitimate expectation. We see that despite the fact that the Claims Regulation contains three procedures which were also intended to reflect the different strengths of the various claims, what has remained today is only one procedure in terms of assessment: the most elaborate one.

- Article 13 was intended to cover longstanding health effects on the functions of the body, based on generally accepted scientific evidence.
- Article 13.5 was intended to provide incentives for companies to have a fast-track procedure for function claims based on newly developed scientific evidence and/or including a request for the protection of proprietary data.
- Article 14 was to cover reductions of disease risk claims, not allowed prior to the claims regulation and expected to be subject to a full and elaborate procedure as the message conveyed to the consumer is very strong.

Reality now is that, because of the EFSA adopted process for assessing claims, all claims are now reduced to article 14 claims. The evidence expected is the same, the assessment is the same, and even the way of discussing, approving or rejecting them is the same. It takes as long to approve a functional health claim as it takes to approve a reduction of disease risk claim, despite the explicit provision of a fast-track procedure for the function claims.

We believe it is therefore imperative and appropriate for the EC to call for a time-out and assess with EFSA from the experience gained if the result of the process is still in line with what the Regulation has intended and where not, to make the necessary readjustments.

1.3. The approach leads to a clear medicalisation of foodstuffs which we do not believe is coherent with what the claims Regulation intended

The current pharmaceutical-style approach is not appropriate for food claims and is pushing foodstuffs further into the medicinal field. It will damage the image of food components and the role they can play for the maintenance of health. They effectively eradicate most of the possibilities for communicating health effects of food/food supplements to consumers. These consequences should now be seriously considered in a structural way.

Foodstuffs and food ingredients are not medicinal products requiring a dose-response effect to benefit health. They are eaten in the context of a diet and the expectations of the potential benefit to health have to be assessed in a realistic way. Food supplements are not medicinal products intended to prevent, treat or cure disease. They are intended to supplement the diet with food components that can help maintain the body in optimal health. It is essential that such communication is able to continue reach consumers.

It is in the interest of all, industry and consumers alike to keep this clear distinction between both types of products, food and medicinal products, within their respective frameworks. The way the scientific assessment is performed in the framework of the claims Regulation is seriously undermining this difference.

Both frameworks would need to be coherent and provide for proportionality in relation to the effects of both as communicated to the consumer. This means contribution to the maintenance of health for food and prevention, treatment and cure of diseases for medicines. It is clear that as a consequence of the current approach, it is easier to license a medicinal product than it is to get a food claim approved. We note in particular that for traditional botanical products no proof of efficacy is required under medicinal rules whereas no single botanical product has as yet succeeded in getting food claim approval.

We call upon the EC to consider the consequences of the current process in the broader light of the EU legislative frameworks for foodstuffs and medicinal products to reduce the medicalisation of foods as well as the increasing banality of medicinal products.

1.4. The terms of reference of the EC are not followed by EFSA for the assessment of the article 13 list as EFSA does not qualify the extent to which a claimed effect may be plausible.

It is strange to observe that of the claimed effects that have been assessed, EFSA considers that the vast majority are or may indeed be beneficial for human health, while at the same time it does not agree that these effects are supported by any of the food components

concerned. This means that the contribution that food can play to health is effectively reduced to a handful of possibilities as listed above (i.e. effects on cholesterol, bone loss, teeth protection and blood pressure). Taking into consideration the current knowledge of contributions food components can have on health and which have been taught at schools and other educational institution for decades worldwide, this represents a gross simplification.

You may recall that we have developed a model for the assessment of article 13.1 claims, taking the Terms of Reference to EFSA as the basis. These terms of reference require EFSA to comment on the extent to which a number of conditions have been fulfilled. We have described in detail how the assessment of function claims can be done in this way, based on experience and current practice in the Member States.

We see that EFSA does not apply these principles and does not provide the EC with sufficient information in its opinions to ascertain the extent to which the scientific substantiation covers the claimed effect. This makes rejection of most claimed effects unavoidable.

To our disappointment, we have never been offered a chance of discussing this model with any of the EFSA scientists. We observe still today that there is no possibility for a dialogue. Furthermore, the second batch of EFSA opinions makes clear that EFSA takes fundamental decisions in relation to the application, by selecting certain claimed effects, while not considering others and by judging that certain claimed effects are too vague or non-specific, beneficial or not, without having made public the criteria it is applying.

We feel sorry that we have to repeat over again to you and your service our comments and remarks in this respect, but you must consider that EFSA has never in the past and does still today not allow any discussion on its dogmatic approach. We are aware of the workshop EFSA will organize on 1 June and have submitted our registration to be among the 250 participants. We do not know how much discussion will be possible, but have observed that the event of 16 June 2009 (with only 100 participants) has been largely disappointing in terms of possibilities for fundamental discussion. We are of the opinion that the problem is far more fundamental than can be addressed in one day with such an audience.

We believe the EC should urgently take the initiative to discuss the way in which EFSA implements the Regulation. EFSA is working under your mandate, so you have the possibility to do so. We feel it is irresponsible to continue to spend (read: waste) public money continuing with all these assessments with the foregone conclusion that almost everything will be rejected in the end with the risk that the assessments will need to be redone anyway if companies are forced to reintroduce data in the authorization procedure. No need to say that the capacity to resubmit will be reserved to a handful of big companies with a clear commercial interest in only certain substances.

We are therefore forced to call upon the EC to consider the appropriateness of the approach of EFSA in the light of the terms of reference and not to proceed with decisions process until this has been validated. The necessity of a time-out and intermediate evaluation of the process has become ever more legitimate and has reached a stage where it becomes unavoidable.

2. Specific comments relating to selected opinions from the second batch of EFSA opinions.

2.1. Main conclusions of our analysis of the opinions of the second batch of EFSA opinions.

The main conclusions of our assessment show that:

- The EFSA approach is not adapted to assess claims in relation to the contribution of a substance can have on the maintenance of health.
- Claims are often not accepted because of assumptions or presumptions made by EFSA prior to the assessment
 - o E.g. that a claimed effect is too general or a-specific (e.g. protection of skin from premature ageing)
 - o E.g. that the claim concerns a certain claimed effect where it may not be (e.g. maintenance of normal vision where the claimed effect is eye health based mainly on the protection of the eye against oxidative stress)
- Claims are often not accepted because EFSA ignores sources of available support.
 - o E.g. EFSA does not consider approvals by other recognized organisations (e.g. AFSSA in the case of lutein)
 - o E.g. EFSA does not consider that a food has a specific effect despite its composition. (e.g. no cause-effect relationship has been accepted between acerola or rosehip and protection of DNA against oxidative damage, whereas such a claim is accepted for Vitamin C and both fruits contain significant quantities of vitamin C)
 - o E.g. EFSA only considers animal and in vitro studies as supportive evidence when human intervention trials have already shown an effect, in which case the supportive evidence is of minor importance anyway. (e.g. antioxidative properties on blood plasma or markers form lipid peroxidation)
- EFSA still has problems assessing claims, the subject of which is defined by a functional effect (e.g. carbohydrates with a low glycemic index). It is clear that such claims are perfectly assessable as the effect is well defined and measurable.

We question if according to the responsibilities assigned by the Claims Regulation if it comes to EFSA to make these judgments, and if so we wonder what the criteria are that are used. In order to be predictive and legally sound, companies should be able to judge according to these same criteria, which is currently not the case.

2.2. We would call upon EFSA not to publish ‘mass’ opinions combining multiple substances but be clear and specific on each submitted health effect.

EFSA has published five of such mass opinions covering an important number of separate claim entries from the register (including for probiotics, anti-oxidants, glycemic index, joint health and blood glucose).

Furthermore, we observe that for many of the entries included in the opinion, the full submission has not been considered, i.e. the claimed effect is reduced to the one that EFSA assumes to reflect the meaning and accepts as having a beneficial effect, which is then the one covered by the opinion.

We wonder if this degree of freedom that EFSA permits itself can be reconciled with the case-by-case assessment it has indicated as part of its methodology.

We would like to object to those kinds of ‘mass’ opinions that EFSA issued in relation specific groups of health effects. These do not allow the rationale of the EFSA reasoning to be scrutinized in detail as the information that lead to the opinion on the individual submission is very limited and tends to be too generalized or not contained at all. It makes an analysis of the arguments virtually impossible for individual claims.

We call for the opinions to be far more transparent in their reasoning and argumentation. In particular where claimed effects are judged to be too general or not beneficial, the reasoning behind this judgment and the criteria used to reach this conclusion are not transparent.

2.3. We see a clear discrepancy between the way EFSA considers health benefits of essential nutrients as compared with non-essential substances, which is not defensible.

We believe it is inconceivable that, first and second batch taken together, of the 149 claims from our industry list only claims relating to essential nutrients (vitamins, minerals and essential fatty acids have been approved). Only one claim for a functional substance (lactase (sic)) and no single claim relating to a functional substance or botanical has received a positive opinion despite the health effects of these substances being accepted and claimed on products on the market for decades in the Member States. On the contrary, EFSA has delivered negative opinions or regarded as insufficiently substantiated claims for a number of important well-established substances including glucosamine, chondroitine, alpha-lipoic acid, lutein, etc.

An example for the differences in EFSA approach is that in the opinion on Vitamin C and protection of DNA, proteins and lipids "The Panel considers that protection of DNA, proteins and lipids from oxidative damage **is beneficial to human health**" whereas in its opinion relating to EGCG (main antioxidant polyphenolic compound in green tea (ON 1463) and all other antioxidants (ON 1489) "The Panel considers that protection of DNA, proteins and lipids from oxidative damage **may be a beneficial physiological effect.**" Such discrepancies may be caused by the lack of clear criteria but show above all a different attitude towards essential nutrients compared to substances which are not (yet) regarded as essential. It leads to positive recognition of the protective effects against oxidation for Vitamin C, Zinc, Copper, Manganese and Selenium, but not to a similar effect of any of the other substances covered by the current batch of EFSA opinions.

The most striking difference is that for essential nutrients, almost all claims are formulated to contribute to a certain physiological function, whereas this is not considered by EFSA for non-essential nutrients, despite the fact that many of these claims are phrased in a similar way in their submission.

This is also reflected by the conditions of use proposed, specifying that for essential nutrients like alpha linolenic acid or vitamins a quantity as low as 15% of the RDA is sufficient to claim the effect, i.e. to contribute to the function, whereas for other substances and botanicals an effective dose must be present.

This is a fundamental flaw in the assessment approach by EFSA which we strongly believe is not scientifically justified for many of the food components covered. Furthermore such claims are essential for food supplements, the intention of which is to supplement the diet with these food components and need to be able to indicate the contribution these components have for health. Such communication is made impossible because of the dual approach by EFSA.

This discrepancy in the assessments between essential nutrients and other substances is not scientifically justifiable in many cases. We call upon the EC to ask EFSA for a clear justification of this approach and invite the scientists to discuss this in the broader discussion on the scientific principles and the application of the terms of reference.

2.4. The lutein claim as a critical benchmark example

As we have expressed, we are very concerned by the way in which EFSA performs the assessment of claimed effects in a rather pharmaceutical way, which makes it very hard for food ingredients to obtain a positive opinion. This is clearly exemplified by the opinion on lutein, which we see as a critical benchmark example of how difficult it is to gain approval.

Our scientific experts are the ones leading the scientific underpinning of lutein, which is without doubt, apart from vitamins and minerals, one of the best researched substances with beneficial physiological effects in the world. The evidence underlying the beneficial effect on eye health is very substantial and acknowledged by many researchers in the field. From the regulatory perspective, claims related to eye health have been approved by French Administration after a positive assessment of AFSSA and recently also acknowledged for health products by Health Canada. It must therefore be considered as a good example to judge if the EFSA approach is appropriate for food ingredients.

It cannot be denied that in an ideal world it may be possible to elaborate the ideal research strategy to demonstrate an effect on an end point or validated biomarker and support the biological mechanism by experimental evidence, to meet the expectations now exemplified by EFSA. However, this is perhaps feasible for new ingredients that affect biomarkers or risk factors for human diseases that can be favorably modified by dietary interventions. And for these situations an application for authorization can be made under the authorization procedure that has been provided for specifically this situation.

It may however not be proportionate, nor appropriate to expect this for claims that relate to the effects of food components that have been accepted for decades, in particular where these claimed effects have been approved by other organisations or at least have never been challenged. In such cases, as the terms of reference of the EC clearly acknowledge, all types of scientific studies may not be available, since they have not been requested as substantiating

proof before. In such cases EFSA is supposed to judge upon the plausibility of the claimed effect based on an assessment of the available evidence submitted and a reasoned opinion must be given stating the strengths and weaknesses of this assessment. It is too simplistic to reject everything if it is not supported by well-conducted double blind randomized intervention trials when there is supportive evidence from authoritative sources, experimental, animal and/or observational evidence, which have served as sufficient evidence for national allowance of these claims prior to the EU claims Regulation.

These aspects are clearly illustrated by the lutein opinion where EFSA:

- took the decision only to assess one specific claim on vision, and ignore other claimed effects including the one assessed and approved by AFSSA;
- attributes a disproportionate weight to human intervention studies as compared to the evidence from epidemiological and experimental findings
- does not consider the highly plausible antioxidative and blue light filter effect as sufficiently proven or beneficial because of the lack of human intervention studies on markers of those functions without considering the practicalities and the fact that such studies are not possible or could be considered unethical.

As with earlier comments, we consider that it is easy for a claims assessor to reject a claimed effect because of the failure to meet the theoretically ideal criteria the assessor has adopted, if no requirement exists to recommend or advise applicants on the requirements that would satisfy it. Concretely, if EFSA does not accept a claim related to lutein because of the lack of appropriate intervention trials, we would be very obliged if EFSA could indicate how the a change in macular pigment in healthy people and eye function needs to be demonstrated to satisfy their expectations, considering that it is absolutely not clear how the maintenance of a healthy vision can be demonstrated in a healthy population. Furthermore it was EFSA's choice to select vision as the end point for the lutein claim whereas the evidence chosen was not intended to show that increasing of macular density will lead to improved sight.

Another observation that merits consideration is the fact that the number of appointed external experts is apparently very limited and does not always cover the specialization required for the various fields to be covered in the assessment of claims by EFSA. As far as we can see this is certainly the case for the claim relating to lutein where experts in ophthalmology are apparently not involved and in those related to the various substances exerting anti-oxidant effects, where it is not clear in how far the world experts in anti-oxidant research have been involved.

One important element for the lutein claim is that it has received an approval from another respected organization notably the French AFSSA. The entry in the CIAA/ERNA/EHPM/BF (Entry No 403, EFSA ID 1604) clearly mirrored the claimed effect approved by AFSSA as specified in the health relationship "eye health" and the example wording of the claim (protection of retina and lens from oxidation). However, EFSA assumes a different claimed effect. i.e. maintenance of normal vision which is significantly different from the original entry. It may be that this was the main reason that lead to the EFSA's negative opinion and if this was the case we would clearly request this entry is resubmitted and that the original claimed effect is verified by EFSA in the light of the evidence provided.

We note however that the EFSA opinion already contains statements relating to the positive impact on the maintenance of eye health as EFSA confirms that lutein does increase macular pigment optical density (MPOD) and that there is consistent epidemiological evidence between dietary and blood lutein measures and age-related maculopathy or age-related macular degeneration (“ARM” and “AMD,” respectively) or cataract incidence.

We therefore are of the opinion that the EFSA opinion, taken together with the AFSSA opinions would be sufficient for the EC to approve a lutein claim with regard to the maintenance of eye health, along the lines of the claim approved by the French authorities, i.e., “helps protect the retina and lens from oxidation”.

Finally, we would also like to highlight that article 30 of the General Food Law Regulation, explicitly states that EFSA identifies a substantive divergence over scientific issues between its own assessment and that of a Member State body, EFSA and the national body shall be obliged to cooperate with a view to either resolving the divergence or preparing a joint document clarifying the contentious scientific issues and identifying the relevant uncertainties in the data. Despite the EFSA opinion on lutein clearly being at odds with the one issued by AFSSA, we are not aware of any explanation from EFSA to explain their different conclusions.

2.5. Antioxidant claims as a second example

We note that EFSA has delivered negative opinions on all claims relating to anti-oxidant properties and to protection of DNA, fats and proteins against oxidation (except for some vitamins and minerals contained in the first batch of opinions). This opinion has sparked concern as anti-oxidative properties have been acknowledged as important beneficial effects for public health and are well understood by consumers. Although we cannot vouch for the justification for all food components included in this opinion, it includes a number of substances for which the non-acceptance of the evidence at least seems remarkable. These include green tea, grape seed extract, acerola, rose hip, amongst others. We would like to highlight some elements from this opinion that require further clarification:

We have difficulties understanding the reasons invoked by EFSA to not assess certain claims. This applies notably to the claimed effect: “Protection of cells from premature aging (ID 1468, 2832)“

The opinion states that the claimed effects are “antioxidant activity” and “antioxidant properties” and that proposed wordings include “protect cells from premature aging”, “antioxidant containing foods support of healthy aging”.

EFSA declines to assess the claimed effect because: “No definition has been provided of “premature aging” or of “healthy aging” in relation to the antioxidant properties of foods. The Panel considers that this claimed effect is general and non-specific and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.”

We are of the opinion that both claims referring to anti-oxidative activity and premature aging of body cells are clear and understandable effects and that it should be perfectly possible to

assess the scientific substantiation based on the totality of the evidence provided. We would like this to be considered as a fundamental question and would expect a motivated argumentation why such an effect cannot be assessed.

We are surprised by the attitude of EFSA to ignore the value of the anti-oxidative potential of many substances. This applies notably to the claimed effect: “Antioxidant activity, antioxidant content, and antioxidant properties” (ID 570, 1285, 1315, 1468, 1797, 1805, 1808, 1833, 1850, 1969, 1971, 1988, 1989, 2020, 2021, 2049, 2060, 2132, 2475, 2673, 2800, 2817, 2823, 2832, 2855, 2866)

The opinion states that the claimed effects are “antioxidant activity/content” and/or “antioxidant properties”. The Panel assumes that these claimed effects refer to the capacity of food/food constituents to scavenge free radicals and/or to their reducing capacity. The Panel considers that claims made on the antioxidant capacity/content or properties of food/food constituents based on their capability of scavenging free radicals in vitro refer to a property of the food/food constituent measured in model systems, and that the information provided does not establish that this capability exerts a beneficial physiological effect in humans as required by Regulation (EC) No 1924/2006. The Panel considers that no evidence has been provided to establish that having antioxidant activity/content and/or antioxidant properties is a beneficial physiological effect.

We would like to highlight that these refusals are contrary to what is currently generally recommended and even expressed in general public health recommendations regarding the consumption of fruit and vegetables.

Furthermore we would question the coherence between this EFSA approach and the opinion expressed by the Standing Committee that a claim referring to the content of anti-oxidants should not be considered as a nutrition claim but as a health claim, if EFSA explicitly denies considering this property as a health effect. The conclusion we would need to draw from this that a claim relating to the content of anti-oxidants is neither a nutrition claim, nor a health claim and would therefore fall outside the scope of the Regulation. We really wonder if the EC is going to reject and prohibit a claim to the effect that fruit and vegetables and juices contain anti-oxidants, given the excellent consumer understanding of such claim?

The only claims relating to anti-oxidative properties that are therefore assessed by EFSA are the ones relating to the protection of DNA, proteins and lipids from anti-oxidative damage (ID 1200, 1229, 1243, 1256, 1257, 1258, 1260, 1264, 1321, 1367, 1439, 1445, 1679, 1706, 1867, 1878, 1880, 1921, 1934, 1940, 1941, 1957, 1966, 1999, 2025, 2043, 2059, 2061, 2083, 2087, 2090, 2125, 2136, 2144, 2151, 2154, 2156, 2181, 2188, 2193, 2263, 2321, 2511, 2641, 2653, 2654, 2668, 2734, 2795, 2835, 2849, 2854, 2857, 3166, 3167, 3168, 3169, 3174, 3175, 3176, 3177, 3183, 3200, 3212, 3216, 3232, 3241, 3256, 3269, 3277, 3290, 3297, 3299, 3307, 3315, 3316, 3337, 3349, 3353, 3356, 3362, 3374, 3383, 3386, 3400, 3406, 3409, 3412, 3418, 3423, 3437, 3444, 3448, 3454, 3456, 3460, 3469, 3484, 3485, 3494, 3505, 3507, 3520, 3524, 3541, 3549, 3571, 3593, 3597, 3606, 3646, 3652, 3662, 3678, 3679, 3701, 3705, 3712, 3729, 3767, 3780, 3786, 3790, 3797, 3800, 3813, 3815, 3816, 3817, 3822, 3824, 3825, 3828, 3836, 3838, 3839, 3849, 3854, 3856, 3888, 3899, 3916, 4007, 4150, 4163)

EFSA does not consider references that address potential health effects of dietary antioxidants in general, or of food/food constituents other than those for which the specific claims are proposed, and/or claimed effects other than the protection of body cells and molecules from oxidative damage, as it is of the opinion that no scientific conclusions can be drawn from these references for the substantiation of the claimed effect. Nevertheless these references provide support for the plausibility of a useful effect of dietary anti-oxidants and should not be simply ignored.

EFSA states that no human studies which investigated the effects of the food(s)/food constituent(s) on reliable markers of oxidative damage to body cells or to molecules such as DNA, proteins and lipids have been provided in relation to any of the health claims evaluated in this opinion. The main problem here is of course that it is very difficult, if not impossible to perform such studies in humans.

This is of particular relevance since EFSA rejects even intervention studies in humans which investigate the effects of the food(s)/food constituent(s) on the overall antioxidant capacity of plasma assessed by different methods, for the simple reason that the evidence provided in these studies does not predict the occurrence of an effect of the food(s)/food constituent(s) on the protection of body cells and molecules from oxidative damage. Furthermore, EFSA considers that the evidence provided in the animal and in vitro studies submitted is not sufficient to predict the occurrence of an effect of the food(s)/food constituent(s) on the protection of body cells and molecules from oxidative damage in vivo in humans. The Panel considers that while effects shown in animal and in vitro studies may be used as supportive evidence, human studies are required for substantiation of a claim. Finally claims supported by references to human studies on MDA/TBARS/oxidation lag time of LDL particles ex vivo as the only markers of lipid peroxidation, either alone or in combination with animal and/or in vitro studies are also not accepted.

We strongly believe that for the assessment of anti-oxidative effects the requirement of in vivo human research is disproportionate and that evidence from ex vivo, in vitro and animal studies should be given a stronger weight.

Anti-oxidative effects are important properties of many substances, the consumption of which has been advocated for the maintenance of health. This kind of health message is also very well understood by the consumer. The disappearance of such communication may have serious consequences for public health.

3. Additional reflections

3.1. EFSA approach to assess the benefit of an effect- learnings from the risk-benefit opinion consultation

We would also like to draw the attention of the EC to the discussion on risk-benefit assessment EFSA has recently submitted for consultation (consultation open until 15 April 2010). We observe that in this document for the first time, EFSA has proposed an approach for the assessment of benefit (that is mirroring the approach for risk assessment). It does not however explain this methodology in detail and we feel this is a serious flaw as we consider this approach to benefit assessment inappropriate. Furthermore, it is inconceivable that such

an important discussion starts at a moment EFSA is in the middle of applying already this methodology without having had a proper and detailed consultation before.

We would therefore ask, in the same light as we have done in the past, that this opportunity is taken to have a fundamental discussion on how to assess health benefits of foods and we would call upon the EC to help coordinate this discussion.

3.2. Opportunity for submitting further evidence

We appreciate the possibility that the EC is currently discussing with the Member states in relation to the submission of further clarification on probiotic claims and those claims that have been judged insufficiently substantiated. We also appreciate the discussion in relation to botanicals and data obtained in patients groups. We refer to the questions we have addressed in relation to these activities and look forward to hear how we can assist in this process to achieve its objectives.

We trust that the clarification process that is currently under discussion will allow companies to respond with comments and would not lead to a situation where additional data would need to be provided by the submission of an article 13.5 dossier. This would only benefit some bigger companies and therefore not respect the proportionality introduced by the article 13.1 procedure.

Furthermore, we sincerely hope that the EC is willing to take the comments we have made in this letter on board, and calls for a time-out to take the time to reassess the process with the scientists involved, the Member States and the stakeholders, before any further decisions are taken. This is of the utmost importance for the further survival of the food supplements sector, consisting mainly of SME's that otherwise will be denied essential communication on their products.

4. Conclusion

The opinions of the 2nd batch show clearly that EFSA has not changed its approach despite our comments and calls for discussion. The approach that is characterised by sole reliance on human intervention trials demonstrating increases or decreases of disease-related endpoints or biomarkers, a narrow and rigid way for selecting pertinent data, the lack of addressing and weighing of all the evidence available, is clearly only appropriate for medicinal effects or selected reduction of disease risk claims. It is disproportionate when applied to function claims that are intended to contribute to health and will simply not pass the EFSA assessments.

The approach not only ignores the proportionality that was included in the law and makes claims referring to a contribution to health impossible. It leads to an unmistakable medicalisation of foods and puts a serious question mark over the role that Europe will play in future in the field of nutritional research and may lead a whole food market to revert to other means of communication and marketing of their products.