

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

15 October 2009

In this paper we take the opportunity to comment on the first batch of article 13.1. opinions published by EFSA on 1 October 2009

First of all, it should be noted that quite a number of opinions now published by EFSA are not related to the list that has been elaborated by us. We cannot therefore vouch for the appropriateness of the claimed effects and submitted references of these entries and would like to stress they are not representative of our combined efforts.

However, the approach as has now become apparent for the first time can be projected on our submissions that are scheduled to be published in further batches of opinions. And it leads us to express our serious concern about a number of aspects that we would like to highlight below.

PART 1: SUMMARY OF THE ANALYSIS

We would therefore ask the EC and the Member States to consider the following questions which relate both to procedural and scientific aspects.

1. Questions on Procedural Matters

1.1. Why has EFSA not asked for further data for these claims as compared to others?

For those claims that EFSA is unable to assess because of insufficient information, the approach seems arbitrary and it should be assessed what criteria have been used to discriminate between entries that were sent back for comments at an earlier stage and those that were not. If no justifiable reasons are given, we would strongly insist that all submitters are given the same opportunity to provide the necessary clarification and that EFSA reassesses its opinions in the light of the information received before any decisions are taken. We anticipate that this will be the case with many botanicals and therefore would ask again to have a fundamental discussion on the requirements that EFSA is expecting. In this respect we remind you of our letter of 18 May 2009 highlighting the unclarity in the EFSA request for clarification and the many inconsistencies that he had identified, our letter of 29 June 2009 in which we communicated to the EC a model explaining a number of concerns and indicating a way forward and our letter of 8 June 2009 to Commissioner Vassiliou asking for a constructive dialogue on these issues. We can only observe and deplore that unfortunately our request for such dialogue remains unanswered and would like to ask what the status is of the

claims for which clarification has been requested and provided as well of those that had gone missing during the process.

1.2. Why has EFSA not published its requirements for characterization of micro-organisms at a time when companies could have provided the necessary information?

We wonder if the EC and Member States find it acceptable that EFSA publishes clarification on how micro-organisms should be characterized and at the same time rejects submissions without giving the submitters any chance to clarify their entries? We believe an opportunity should be given to all industry submitters of micro-organism claims to correct and supplement any information in line with the now published guidance.

1.3. Why has no formal opportunity been provided so far to all stakeholders to discuss the art. 13.1. approach and the principles adopted by the scientists ?

We observe that many claims are now rejected as a direct consequence of a number of principles adopted by scientists without any discussion with interested parties including industry submitters of claims to their Member State authorities. We wonder how it can be maintained that this approach can be justified to fit with the commitment both by the EC and EFSA for transparency and involvement of stakeholders, especially given the potentially important impact on the market and consumer choice.

2. Questions on Scientific Elements

2.1. Can the EC and the Member States express their position on the non-acceptance by EFSA of studies in patients and provide arguments for this position?

We observe that EFSA only appears to accept studies done in a healthy population to substantiate health effects and dismisses studies in clinical conditions as substantiating evidence. On this basis all claims relating to joint health have been rejected. This kind of scientific substantiation underlying these health effect has been well accepted by national authorities (e.g. Belgium, Italy). Non-acceptance of such data as part of the totality of the evidence greatly jeopardises the chances of receiving positive opinions for most of the other substances. It is debatable whether feasible and realistic studies could be conducted that would satisfy this EFSA criterion. Before any decisions are taken, we would be very interested to know from the EFSA scientists what studies should be conducted and what parameters they would find acceptable to show an effect on maintenance of health of the substances concerned so that the feasibility of such approach can be assessed. Also their views on the criteria to define appropriate target populations would be useful.

2.2. Can the EC indicate how it is going to consider the potential consequences and impact of any measure to remove these claims/products from the market?

Firstly, we would be interested to know how products can remain on the market and be safely used if appropriate information on their intended use is no longer permitted? Removal of such information would effectively deny consumers the possibility to make informed choices. In particular we would like to ask whether it is justified and proportionate that the products are removed from the market on the basis of a purist approach of scientists with the consequence that consumers may have no other choice other than to use medicinal products intended for disease states. If they want to take a supplement for the good functioning of their disease-free joints or other functions of their body, the only other alternative would be to risk obtaining supplies from unregulated sources – the supply of which would surely flourish under such circumstances. We are also interested to know how the EC and Member States are going to consider the impact on sales and competition as well as on consumer safety from unregulated channels such as the internet?

Finally, we would like to stress that any decisions that will be taken to remove claims from the market will have economic consequences in terms of recall of products and loss of business for thousands of companies. We would therefore call upon the EC to justify such decisions appropriately on the basis of sound arguments and legitimate reasons and balance what is practically achievable against the theoretical scientific principles that have never been disclosed to nor open for discussion during the whole process leading to the adoption of the opinions. We believe a quantitative and qualitative impact assessment and a through discussion of these principles are the absolute minimum legitimate expectations before any decision is taken.

2.3. Can the EC indicate how it intends to request EFSA to explain apparent inconsistencies in its scientific assessments and proposals for conditions of use of the different groups of claims?

In particular the different treatment of essential nutrients versus non-essential substances is a remarkable observation, where reference textbooks play an important role for the one and not at all for the other, where the emphasis is on the existence of acceptable original research papers, without any apparent reason other than that EFSA focuses on the merit of supplementation to improve bodily functions rather than on the role the substances play in growth, development and the functions of the body.

We would question if it is appropriate that claims for other substances are systematically considered in relation to the effect of increased intake to improve a bodily function, rather than in the framework of homeostasis. Also we would like to understand why in some cases very different conditions of use were proposed for comparable claims for essential (% of the RDA) vs. non-essential nutrients (effective dose).

We would like to ask the EC how the EFSA approach on this aspect fits with the terms of reference and if and how it can provide for a fundamental discussion on this approach?

2.4. Will EC request EFSA to explain the difference between sufficient and insufficient evidence and can EC and the Member States express their position on how to take the

decisions on those claims which are backed by evidence which is not regarded as conclusive by EFSA?

We would be interested to know how EFSA made clear the extent to which there is evidence for a claim which has been classified as insufficient and also how the EC and Member States, based on the information provided by EFSA, will be able to decide if the supporting evidence is sufficient to allow for a claim with proportionate wording, conditions of use and/or target population.

2.5. What is the opinion of the EC on the accepted evidence to substantiate claims in relation to botanicals?

Finally, we observe that EFSA uses reference text books to characterize the substances, but does not use these same text books to validate the accompanying indications. EFSA also appears to reject evidence from authoritative sources and monographs thereby effectively refuting the whole market of botanical food supplements. We wonder what the position of the EC and the Member States is in relation to this approach in the light of proportionality?

3. Batch-wise publication of the list and transition periods

In addition we reiterate that the batch-wise publication of opinions and subsequent decisions has a distorting effect on competition and would like to ask that this is balanced by sufficiently long transition periods, including the possibility to, at least, sell stocks that have been labelled and put on the market (given that shelf life for most supplement products is 2-3 years).

We would also like to highlight that a batch-wise publication may also require multiple reformulations and label changes to be in conformity with the conditions of use and the new requirements. This is not only the case for products containing substances with approved claims, but also for many food supplements that are combination products containing a number of substances. These substances may be subject to claims that feature in different batches of opinions resulting in ingredients becoming already illegal now while another ingredient, assessed next year, may only become illegal at a later date.

We would appreciate that the following elements are considered by the EC and the Member States:

- To ask EFSA to consider, as the terms of reference require, the totality of the evidence, including reference textbooks, monographs, authoritative statements, etc., and not only rely on a standard that solely focuses on improvements of functions based on increased intake of the substances.
- To provide for an opportunity for companies to come back with additional information for those entries for which such an opportunity has not yet been provided.

- To consider as part of the totality of the evidence also data originating from studies in clinical conditions and to express to the EC the nature and quality of these data in a more detailed way than is currently the case.
- To clearly indicate to EFSA that for botanicals it has to consider the totality of the evidence, including text book evidence and proof of traditional use.

We would also invite the EC and the Member States:

- To carefully consider the relevance of the EFSA opinion and the selective application of certain principles as a basis for decisions with a huge economic and social impact.
- To consider in particular the consequences of the removal of a great many well-established products from the market for consumer behaviour, stemming from the lack of information on appropriate use of products that can no longer communicate on their intended use and the likely impact of a shift of the market to unregulated channels as the internet.
- To carefully consider both the way in which the batch-wise publication of opinions by EFSA and the consequent legislative decisions apparently contradict the legal requirements of the legislation and the distortion it will create in the market between companies.
- To underpin any legislative decisions with a quantitative and qualitative impact assessment.
- To provide for a transition period that is proportionate to the effect of the decision taken.

A more detailed analysis of the arguments is given in Part 2.

PART 2: DETAILED ANALYSIS

1. Questions on Procedural Matters

1.1. Why has EFSA not asked for further data for these claims as compared to others?

We observe that many claims have been rejected because of insufficient data, especially in relation to the characterization of the substances. Although this appears to be justified in a number of cases, we are nevertheless surprised and puzzled by the procedure followed by EFSA and especially the reason why no further clarification has been requested before such opinions are adopted.

EFSA has returned to the EC and the Member States more than 2000 claims requesting clarification in the course of 2009. As you recall, our industry federations have helped provide such clarification where necessary but have also raised the many inconsistencies we had observed with similar claims that had not be returned for clarification. We now see that EFSA rejects certain claims because of the same reason it has requested clarification for others. We fail to see the reasons or criteria EFSA has used to justify this difference and can only conclude that the approach seems arbitrary. The consequences are however serious as the conclusion that there is no cause-effect relationship between the substance and the claimed effect is mainly the consequence of the insufficient characterization of the substance and not of the underlying evidence.

As this approach is likely to discriminate against certain claims (and therefore companies), we would appreciate if this can be investigated to see if the process was conducted using clear criteria and does not result in companies being treated unequally.

If not, we would appreciate that equal rights are given to all and that companies are given a fair chance to provide still the necessary clarification for EFSA to be able to reassess its opinions where appropriate.

1.2. Why is EFSA only publishing its requirements for characterization of micro-organisms together with the negative opinions and not at a point where companies could have provided the necessary information?

One concrete illustration of the consequences of not being able to submit clarification is the opinion relating to ‘non-characterised micro-organisms’ in which EFSA published for the first time the criteria it deems necessary to provide a sufficient characterization of micro-organisms and at the same time rejects claimed effects for those micro-organisms that have not been characterized in accordance with these criteria.

We observe that amongst the claims returned for clarification earlier this year there was none concerning the lack of characterisation of micro-organisms and, as far as we are aware, no further request has come to us to provide clarification on this aspect at another moment. In particular the criteria now published have not been divulged to a broad audience before and

come to a surprise as at the technical meeting EFSA organized on 15 June it responded to a question specifically on this issue that it had no intention to publish guideline on the characterization of micro-organisms.

In addition, apart from publishing these criteria to allow companies to verify their submission and provide the necessary clarification, EFSA already formulates the opinion that for the strains concerned no cause and effect relationship can be established, mainly because of this lack of sufficient characterization, in the same opinion. It appears thereby to put all companies concerned before a 'fait accompli' by preventing effectively that the necessary clarification can still be submitted in line with the criteria proposed.

We feel it is unacceptable that such clarification is only provided now, in an opinion that at the same time rejects the existence of a cause-effect relationship, given that such criteria have not been published before and that such request for clarification has not been included in the batch of claims returned to the EC for further clarification earlier this year.

We would respectfully ask the EC how it can justify the situation in which the companies concerned will not be allowed to have the chance to respond with the necessary information in line with the criteria now published by EFSA?

We would strongly insist that this right is granted and that EFSA is requested to reassess the opinions where appropriate taking into consideration the submitted information, before any decision to withdraw the claims from the market is taken. This is especially relevant also since a number of claims relating to probiotic products are still in the process and would effectively benefit from a competitive advantage compared to claims for products that are already removed from the market at this stage.

1.3. What are the reasons why the EFSA's approach to evaluating article 13.1 claims has not been discussed with a broad range of stakeholders given the number of claims that have received negative opinions solely on the basis of principles adopted by EFSA scientists without that have not been disclosed and the relevance and consequences of which have not been discussed with interested stakeholders?

The example given above on micro-organisms is a clear illustration that companies making claims in the market today are denied the necessary possibility to provide and discuss their current justification with the scientific assessor. We can only observe and deplore that until today, there has been no formal opportunity for such stakeholders to discuss with risk managers and EFSA scientists any aspects relating to the criteria EFSA scientists have chosen to adopt and the approach they take towards the substantiation of article 13.1 health claims. The single first instance that EFSA has chosen to present and discuss its approach in an official way is, as far as we are aware, at a meeting they organized on 6 October and which was limited to the EC and the Member States. This is at a moment when their first opinions have already been published which effectively reduces any chance of correcting or modifying the approach where appropriate.

In addition, the timing of this meeting - only 3 working days after the publication of the first batch, covering 523 claims in 94 opinions (a total of more than 1.000 pages) - made it

impossible for attendees to scrutinize the opinions in detail and raise specific questions. We are not aware of the outcome of the meeting, as we were not invited to attend, but it is clear that the conditions under which the meeting took place were less than optimal for the EC and the Member States to have enabled a fundamental discussion on the aspects of the EFSA approach in relation to the article 13.1 list. We, in any case, were not in a position to convey our analysis on the published opinions in time for it to be addressed during the meeting.

We have however given input via the Member States on the briefing document that was published.

We must observe that also in this case, although EFSA has already been working on the article 13.1 submission for months and had already adopted the now published opinions back in July, this document was only published on the website (we believe on 25 September as we were not officially notified of its publication) 4 working days before the deadline for comments and 6 working days before the actual meeting. This is totally insufficient for the Member States to request feed back from the stakeholders and conduct a thorough assessment of the paper. In addition we have observed that the briefing paper is formulated in very broad terms, the relevance of which can only be addressed when taken in combination with the published opinions for a thorough appraisal.

Our federations have repeatedly asked for a fundamental discussion on the approach towards the article 13.1 list and until today this has been consistently denied. We have both presented the criteria and modus operandi for the compilation of our industry list of claims (including presentations to the Ad Hoc Working Group in July 2006; at the EFSA Claims Conference in November 2006; and at further meetings with DG SANCO and EFSA in the course of 2007) and shared with the EC, the Member States and EFSA our contribution to such discussion under the form of a model (in our opinion, far more detailed and focused than the EFSA briefing paper) taking the terms of reference as the basis for the scientific assessment. We have no indication that this document has ever been officially tabled or discussed by EFSA, nor at one of the Member States' working group meetings. We can only strongly deplore this fact and observe that a number of the issues we have indicated and requested a discussion on, are now apparent in the published opinions.

As a stakeholder, closely concerned by the outcome of this process, we would appreciate that the EC provides clarity on how this approach can be justified to fit with the commitment both by the EC and EFSA for transparency and involvement of stakeholders?

We reiterate that we remain open for such a discussion of the approach and would be obliged if the EC and Member States would assess the conformity of the EFSA approach in relation to the terms of reference, current practice and proportionality, in the full acknowledgement of the potential serious economic consequences of decisions to be taken on the basis of inappropriate application of the law and, in particular, avoidance of the requirement to subject article 13.1 submissions to a different type of assessment. In particular the following scientific aspects may be of relevance in this respect.

2. Questions on Scientific Elements

The sheer number of article 13.1. submissions has unavoidably lead to a chaotic article 13.1. list and we appreciate the work that both EC and EFSA have undertaken to bring order in this process. We regret that our joint industry effort that has resulted in 776 well-established health-relationships was swamped by the more than 44,000 submissions sent in by the Member States, including many very poor submissions.

We also welcome the fact that EFSA uses all the data in the entry to interpret the claimed health effect where the health relationship seems to be too vague or the substance not sufficiently characterized. However we observe that EFSA does not do this always in a consistent way and inevitably may not have always adopted the most appropriate interpretation.

Furthermore, we are seriously concerned that most claims relating to substances other than vitamins and minerals have been rejected for various reasons. The arguments used by EFSA to justify the acceptance of claims for vitamins and minerals give a strong impression that such claims are acceptable because the substances are considered to be essential nutrients and recommended daily allowances have been established. Whilst for essential nutrients it is easy to determine the consequences of deficiencies and thereby derive nutrient functions, EFSA appears to take a far more restrictive attitude towards the totality of the evidence for other substances.

2.1. Can the EC and the Member States express their position on the non-acceptance by EFSA of studies in patients and provide arguments for such position?

A major concern for our sector is the refusal by EFSA to accept results in study populations other than the target population (often the general population according to EFSA's own definition), as for example claims for substances such as glucosamine, chondroitin and others in relation to the maintenance of joint health. It should be stressed that this is an important and well-established segment of the market with a considerable number of companies marketing products containing these substances and millions of consumers using these products for more than two decades. The scientific substantiation underlying the effect of the products has been well accepted and has not been challenged by national authorities prior to the claims Regulation coming into force. In fact a number of Member States, including Belgium and Italy have specifically accepted such effects.

We therefore believe the refusal by EFSA on these grounds should at least be addressed with due consideration and the reasons for not accepting the role of these substances for healthy joints should be closely investigated before any decisions are taken.

We would like to stress that the rejection is the result of the criteria that have been adopted by scientists without having assessed the consequences or the availability of any alternatives and that these scientists have consistently refused to submit these criteria to public discussion. While it can be appreciated that trials in patients with clinical conditions cannot always be considered conclusive for the effects of dietary components in normal people, this does not mean that such studies do not give appropriate supportive evidence of the usefulness of such

substances for public health while taken as part of the totality of the evidence. We strongly believe that by disregarding this kind of evidence, EFSA seriously undermines the potential for substantiation of health effects for food components in itself. It is all very well for a scientist to say that such evidence is not pertinent to the claimed effect, but given that most accepted biomarkers are indicators of a disease state in the first place and that designing trials in the healthy population to show an effect of an intervention on a normal function as compared to a healthy control group with sufficient statistical power is extremely difficult if not impossible, we would be very interested to hear from the same scientists what kind of intervention trials should be conducted and what parameters or kind of evidence they would find acceptable to show an effect on maintenance of health of the substances concerned.

We believe that if EFSA cannot give an indication that would be feasible and realistic in practice, it is neither legitimate nor proportionate to disregard the current situation and the limitations of scientific research inherent to this issue because of purely theoretical considerations. **We would be grateful if the EC could ask EFSA to provide clarification in concrete terms on what research they would in practice accept to substantiate that there is indeed a relationship between the intake of the substances now rejected and the maintenance of healthy joints or other normal functions of the body.**

The same holds true for other rejected effects, such as the one relating to the role of beta-carotene and skin health. In this case two effects were mentioned (UV protection and immune function) and we note that EFSA only evaluated the UV protection claim. None of the references for immune function was considered in the opinion.

We would also like to mention that we observe that the application of this criterion not to accept data from population groups with clinical conditions is not being applied correctly and consistently by EFSA. We note that the intended population is not always indicated in the submissions (this is not a prerequisite of the claims list). We appreciate that EFSA makes assumptions in relation to the target population while assessing the claim and that this is not always an easy judgment. In most cases, especially where this is not clearly deductible from the evidence submitted, EFSA has assumed that the target population is the general population. Although such an assumption may seem logical, it may often be too broad and inappropriate.

It must be observed that neither the terms of reference nor the Regulation itself explicitly require EFSA to judge the scientific evidence only for the general population. This is plainly obvious from the fact that claims on foods for particular nutritional uses (which are clearly not intended for the general population) fall under its scope.

In addition, we observe that in some cases EFSA has narrowed down the target population, as is the case with the health relationships related to cholesterol, where the target population is considered to be people with normal or mildly elevated blood cholesterol concentrations. Elevated cholesterol level may be a trait of the normal population (unfortunately) but it is definitely a condition that may also be considered pathological and is treated with medicinal products also. We wonder why EFSA has not considered in the same way conditions like stiffness of the joints and mild joint pain, which are health conditions for which people have until now used supplements like glucosamine, chondroitin, etc. Does this mean that in future

the only option for these people will be to revert to medicinal products used to treat osteoarthritis?

2.2. Can the EC indicate how it is going to consider the potential consequences and impact of any measure to remove these claims/products from the market?

In this respect we would therefore request the EC and the Member States to reflect on the consequences of any decision that would force manufacturers to remove all these claims on such products from the market, which would result in falling sales and removal of the products from the market. **In particular we would like to ask whether it is justified and proportionate that the products are removed from the market on the basis of a theoretical approach of scientists with the consequence that consumers will have no other choice than to use medicinal products intended for disease states if they would want to take a supplement for the good functioning of their joints.** We believe it is appropriate and warranted to have a fundamental discussion on this before any decisions are taken.

Furthermore, we ask the EC and Member States also to consider two additional elements in the case they would make decisions that would result in the removal of all these products from the market.

The first one is, as the EC has frequently stated, that legally speaking the removal of the claim does not mean that products containing these substances have to be withdrawn from the market also when they are marketed without any health-related communication. This may result in a situation where consumers will find these products on the market without any useful information, leading to potential incorrect use, as a direct consequence of the decision taken by the EC and Member States.

The second is that consumers may continue to search for such products and will still be able to purchase them in uncontrollable ways via internet or other channels that potentially bypass legal enforcement

We would therefore ask the EC if and in what way they will consider these potentially negative consequences in their arguments to withdraw or not the said claims on the market based upon the theoretical scientific opinion?

Finally, we would also enquire if the EC is intending to support any measure to restrict consumer choice based upon these opinions with an appropriate and well conducted impact assessment, addressing both qualitative and quantitative aspects of the market and consumer expectations and if not, what reasonable arguments it has for not doing so, given the huge impact this measure will have on the market? This is in particular also relevant in view of the evaluation the Regulation imposes by virtue of article 27 requesting the EC to present by 19 January 2013 a report on the evolution of the market, consumer understanding and the impact of dietary choices.

We are currently assessing the impact from an economic point of view for our sector.

2.3. Will the EC request EFSA to explain apparent inconsistencies in its scientific assessments and proposals for conditions of use of the different groups of claims?

In the first batch of opinions published by EFSA we observe important differences between the way in which claims relating to vitamins and minerals and claims relating to other substances have been scientifically assessed.

For vitamin and mineral claims, it goes without saying that we are very pleased with the fact that EFSA has delivered positive opinions on most of the vitamin and mineral claims included in the list, most of which have been entries from the industry list. We therefore very much support any measure by the EC to allow all claims that are subject to a positive opinion on food products and that the observations by EFSA for a number of nutrients that there is no established inadequate intake of the nutrient leading to impaired function of the mentioned health relationships in the general EU population will not be considered a reason for not adopting the claims.

We observe that for most claims relating to vitamins and minerals EFSA has considered the totality of the evidence as the terms of reference request. We observe an important reliance on general sources of information including authoritative statements and textbook knowledge. We even observe that certain claims are approved without references submitted because the effect is apparently well recognised.

This is in strong contrast with claims for other substances, including beta-carotene, where the requirements for scientific justification seem far more demanding. EFSA apparently abandons the reliance on general sources of scientific information to look specifically for intervention trials to demonstrate the benefits of supplementation with the substance. It seems that if a substance is not an essential nutrient, proof must be delivered that ingestion of this substance improves a bodily function, rather than contributes to its well-functioning. EFSA thereby ignores the function of the substance in the body in relation to a health effect and makes it virtually impossible to support health effects by the scientific evidence that is available. This is one of the elements we have flagged up in our model but which has until now been impossible to discuss with any of the parties involved in the claims assessments. **We would like to ask the EC how the EFSA approach on this aspect fits with the terms of reference and if and how it can provide for a fundamental discussion on this approach?**

Likewise we observe that the definition of the conditions of use is not always consistent. For example, while for the claim on the maintenance of normal blood cholesterol levels for alpha-linolenic acid 15% of the proposed labelling reference intake is proposed, for a maintenance of normal concentrations of triglycerides claim for DHA and EPA the effective dose is required although there are labelling reference intake values established as well.

2.4. Will the EC request EFSA to explain the difference between sufficient and insufficient evidence and can the EC and the Member States express their position on how to take the decisions on those claims, which are backed by evidence, which is not regarded as conclusive by EFSA?

We note that EFSA has considered the nature and quality of the data in their opinions. However, the information provided is often too limited to appreciate precisely the way in which the evidence has been weighed, especially in those cases where data have been dismissed without any explanation about the nature of these data. This makes it difficult not only for the EC to appreciate exactly the quality of the data but also for other scientists to appreciate the flaws in their research that led EFSA to dismiss their data. We note that criticism is raising in the scientific community from other scientists and see this as indicative that the EFSA approach is refuting decades of scientific findings from research centres all over Europe and internationally and that the criteria used by EFSA are indeed ignoring what is practically feasible in the field of food research. It has been highlighted that this may even result in a significant drop in research funding as the requirements may be simply not feasible to be met, a fact that has not been seriously considered yet by the EC and would certainly warrant closer investigation.

We feel that, given the impact of the EFSA opinions on scientific research and business development, EFSA has the obligation to be far more precise in its opinions. In particular, the distinction that is now being made between ‘no cause-effect relationship’ and ‘insufficient data to establish a cause-effect relationship’ fails completely in enabling the EC to appreciate the level of evidence that is underlying the individual claims as it does not truly indicate the extent to which a cause and effect relationship is established as requested in the terms of reference. We note that EFSA has decided not to use a system of grading of the evidence as is applied by others. We strongly regret this as it significantly reduces the information available for the EC and Member States to fully appreciate the level of evidence available. We feel it would be appropriate still for the EC and Member States to request EFSA to grade at least the opinions on claims that they have judged to be insufficiently supported by the scientific evidence available.

We would like to enquire if and how the EC is going to differentiate between claims that are rejected because of lack of evidence and those with insufficient evidence, and in particular how the EC and the Member States, based on the information provided by EFSA, will be able to decide if the supporting evidence is sufficient to allow for a claim with proportionate wording, conditions of use and/or (restricted) target population.

2.5. What is the opinion of the EC on the accepted evidence to substantiate claims in relation to botanicals?

A critical group of products are those that consist or contain botanicals. We should first of all stress that the vast majority of the botanicals that are subject of this first batch of opinions were not submitted by us or our members and in general appear to be of very poor quality. We therefore do not dispute the correctness of the majority of the rejections.

However, the analysis of the published opinions provides us with some reasons of concern that may be relevant for the majority of the claims for botanicals introduced on our list.

We notice that EFSA takes serious efforts to characterize a botanical using standard reference books, where such characterization has not been sufficiently detailed in the original list entry. This can only be welcomed. However, since the terms of reference requests EFSA to consider

the totality of the evidence we wonder why EFSA subsequently bases its opinion on the validity of the claimed effect only on the references provided in the list (which are often of poor quality or not even accessible) and not use the same reference textbooks to clarify and address also the health relationship. We note that such textbooks are valuable sources of information on the acknowledged effects of botanicals and represent in many cases the general consensus of botanical experts that exist. In parallel with the way in which EFSA has assessed the claims for vitamins and minerals, sufficient weight should be given for this kind of evidence to substantiate health-effects of botanicals. **We would ask if the EC will request EFSA for the reason why it has not done so for those botanicals it has succeeded in characterizing using these reference books.**

We feel it must also be reiterated that the list has been compiled without any guidance from the EC or EFSA as to what would constitute sufficient and acceptable evidence. Many of the health-effects described for botanicals stem from acknowledged textbooks and monographs, a list of which was attached to the industry list. We cannot but observe now that such evidence is discarded by the EFSA scientists.

Indications for the traditional use of plants such as *Fraxinus excelsior* recognised by reputable organisations such as the French AFSSAPS have been rejected by EFSA for no clear reason, except for a mention that ‘the references cited did not provide any scientific data that could be used to substantiate the claimed effect’. We can therefore deduce that EFSA does not consider reference textbooks and monographs as scientific data and in all cases dismisses such evidence. We believe this is unacceptable given the facts that these references are currently accepted by Member States, are part of the totality of the evidence and that these sources of evidence are considered expressions of generally accepted scientific evidence. This is confirmed by a legal opinion we have commissioned in this respect, the content of which we would welcome discussion with the EC.

We are extremely concerned that if this kind of evidence is disregarded by EFSA, no botanical claims will be able to get a positive opinion. We believe this would be inappropriate given the current practice in the market with the support of the Member States. It would also be disproportionate and not in line with the requirements of the Regulation as such evidence is definitely part of the totality of the evidence EFSA is requested to review. If recognized textbook knowledge is acceptable to substantiate claimed effects for minerals and vitamins, it should also be acceptable for botanicals. We fail to see the point that these text books are used to characterize in detail the botanicals if the associated health effects are disregarded.

We also have noticed that not all references that have been submitted and sent to EFSA in reply to their request in 2008 are included in the database of references that is published on the EFSA website. This is for instance the case with information provided by the Dutch NPN relating to isoflavones (NPN masterfiles) and the larger meta-analyses, which they were based on. This is also relevant for the reference books we have included as references for botanicals as annex to our industry submission. We have the impression that this list of references has gone missing and would like clarification that it has indeed been included in the list that has been submitted to EFSA.

We would also like to express a word of caution. The article 13.1 claims list is a list with claims that are generally accepted. EFSA clearly indicates it has no guarantee that all the

references that are relevant have been included. However we would like to remark that EFSA itself has clearly indicated that it would not accept additional references, so we have been refused the opportunity to submit additional references on entries where we have identified gaps in the references. Secondly, EFSA has indicated that it would use additional references it is aware of, where relevant, even if such references are not included in the submitted list. We now observe that EFSA has not used the reference text books at hand to complete the evidence that has been submitted and we would appreciate if the EC could ask EFSA to provide justifiable grounds for this.

As a final note to our comments in relation to botanicals, we avoid concluding that the way in which EFSA considers proof in relation to botanicals and certain other substances as described above has very negative consequences for the continued existence of food supplements under food law. In fact, it is clear that the EFSA approach will effectively refute most if not all health effects that are currently used for food supplements. We believe the distinction between food and medicinal use is not an issue that falls under the remit of EFSA. We are also not clear what the aim is of meetings that we believe to take place between EFSA and EMEA in this respect.

It should be noted that in the light of the EFSA approach, the requirements for the substantiation of health effects for food products need more proof than for certain medicinal products. In particular as traditional herbal medicinal products need no scientific proof at all to show efficacy. **We would respectfully ask the EC and the Member States to consider the relevance of the EFSA approach as a justified basis to reject most botanical food supplements indications in the light of the principle of proportionality.** Also in this respect we have commissioned a legal opinion that we would be glad to discuss with the EC and Member States.

When we started the elaboration of the list and explained our intention and way of working to the EC and Member States we have made it clear that substantiation of the health-effects of botanicals is largely based on monographs and reference textbooks describing traditional use of plants and products. Traditional use means that the effects of a substance are plausible on the basis of longstanding use and experience. It is a well-established concept that is accepted as sufficient for the substantiation of medicinal effect of the so-called ‘traditional herbal medicinal products’, but it is not exclusive to medicinal products. The notion of traditional use is of equal value for the support of botanical health claims.

EFSA needs to consider that the non-acceptance of traditional use is an artificial way of discrediting one sector against another one and may result forcing health products to fall under medicinal law. Since they do not comply with the requirements of medicinal law they will therefore be effectively be removed from the market. We strongly feel such regulatory decisions should not result from the opinions of the scientific risk assessor because this would result in a situation that would be in breach with the application of the current legal framework for these products in the EU.

Furthermore, our entries, substantiated on that basis have been adopted by the Member States and included in the list that is sent to EFSA. **We would therefore like to receive a clear position by the EC on the validity of such substantiation in view of the fact that no objection has been raised at any stage of the process and the clear observation that EFSA now refuses to take this into consideration, with no alternative being available.**

Give the serious consequences of the non-acceptance of traditional use as part of the totality of the evidence for health claims, while neither the Terms of Reference nor the Regulation itself specifically mention this aspect - and therefore not specifically prevent it from being considered - we would appreciate to have a clear indication from the EC how it will consider this aspect and its consequences when approving or rejecting claims.

3. Additional remarks

3.1. Batch-wise approach

To conclude we would like to reiterate that the batch-wise publication of the EFSA opinions in itself is a measure that breaches the equal treatment of companies as it creates a greatly distorted playing field. We appreciate the efforts the EC has undertaken to make this clear to EFSA, unfortunately to no avail. We now observe that the EC is going to take decisions also in a batch-wise way, thereby ignoring the very arguments it has brought to EFSA to avoid such measures being taken.

We appreciate that from a consumer perspective, unjustified claims should be prohibited. However, given the background expressed in our arguments, we do not believe that the criteria that EFSA is using gives sufficient grounds for the rejection of a number of these claims, especially when claims that have yet to be assessed will be allowed to continue on the market. We do not believe the Regulation allows a batch-wise establishment of the list and would like to ask the EC to carefully assess the legal basis for taking the management steps proposed.

3.2. Transition period

We also appreciate that the EC is contemplating a transition period for rejected claims of 6 months.

Given that food supplements have a shelf life of 2-3 years, such a transition period in essence can only be achieved by a recall of the products. We would therefore ask the EC to carefully reflect, in the light of the arguments in this paper and the fact that the use of a rejected claim does not entail a safety risk, on the reasons for the rejection of claims that are a substantial and well-established part of the market and trusted by numerous consumers.

We would also ask the EC to consider whether a transition period of 6 months is appropriate for products carrying claims relating to positive EFSA opinions where, as a result of the decision adopted, changes in the labelling would be required.

Finally, the batch-wise publication of opinions and decisions will not only have a distorting effect on competition but is also likely to require multiple reformulations and label changes to be in conformity with the conditions of use and the new requirements for many products. This is not only the case for products containing substances with approved claims, but also for many food supplements that are combination products containing a number of substances.

These substances may be subject to claims that feature in different batches of opinions resulting in ingredients being rejected now while other ingredients, assessed next year, may only be rejected at a later date. These consequences could be attenuated by a sufficiently long transition period.

For the reasons above a proportionate measure would be that any transition period is accompanied by a provision allowing that products that have already been put on the market can remain on the market until stocks are sold.