

**Draft Guidance Document for the Preparation and Presentation of
the Application for Authorisation of Health Claims
17 June 2007**

Comments by ERNA (European Responsible Nutrition Alliance)¹

ERNA welcomes these guidance notes and especially the transparent way in which EFSA submits these guidance notes to a public consultation. Although the time provided for comments is short, we understand the time pressure on EFSA to be ready before the Regulation enters into application on July 1st. Nevertheless, we strongly regret that not more time is devoted to discuss these guidelines with industry, other stakeholders and the international scientific community. Guidelines for the substantiation of health claims are currently under discussion at Codex Alimentarius Committee on Nutrition and Foods for Special Dietary Uses and may be binding for the European Union in cases of international trade. These developments are not considered.

Furthermore, these guidance notes are so tremendously important because they will determine the future way of working for any company that wants to come to the market with a new claim. They will most probably also be the basis for article 18 submissions and will in that respect determine the workability of the EU claims approval system. It would have been good that there was an opportunity to include experience gathered in the compilation of the article 13 list by our association in close cooperation with CIAA, EHPM and EBF into the document, as well as experience gathered by national claims approval systems. Indeed, the guidance notes could be tested with examples that have been introduced already in order to get experience on what is achievable and what not. One example is the yes or no section (lines 838 and following) where clearly questions are listed that in many cases cannot be answered with a straight yes or no.

These guidance notes are complex and tedious to comply with and do not consider in any way the specificities of small and medium sized enterprises (SME's). However, despite the intention that the guidelines are considered to be a living document where experience will be gathered over time, they will have to be approved in one way or another by a regulatory decision under article 25 of the Regulation, which will turn them in quite a static and final document.

We therefore regret that no more time is given for proper discussions with representatives of industry and other stakeholders and testing to make these guidelines simpler and more easy to comply with for SME's.

As a matter of principle we also strongly deplore that we have not been formally invited to attend the consultation on 11/06 in Parma, despite our high relevance and expertise in the

¹ The European Responsible Nutrition Alliance is representing the major European food supplement manufacturers and suppliers. It was established in 1998 and is striving for a common European approach towards food supplements that reflects the interests of both consumers and industry. Recent achievements include the development of a Risk Management Model for the Setting of Maximum Levels of Vitamins and Minerals in Food Supplements and a number of scientific fact sheets on vitamins, minerals and other substances. ERNA is also coordinating the establishment of an EU wide list of claims under article 13 of the Claims Regulation, together with CIAA, EHPM and EBF. For more information see: www.erna.org.

field of claims and our leading role in the compilation of the EU wide article 13 list, together with CIAA, EHPM and EBF. We were fortunate that another invited party was happy to accept us in their delegation, but would want that in future EFSA recognises our expertise in this field and includes us directly in further discussions.

Comments

The general tendency of the guidance notes is very detailed and puts an important emphasis on the presentation of the data. It is clear that the application is intended to contain all relevant scientific data - both data in favour of the claim as non-supportive data – to limit the work of EFSA to do additional research. However asking such degree of detail leads to a number of reflections that should be considered before the document is finalised and endorsed.

- The Claims Regulation 1924/2006 is quite specific in detailing the requirements for submissions. Article 15.3 specifies that:
“The application shall include the following:
 - (a) the name and address of the applicant;
 - (b) the nutrient or other substance, or the food or the category of food, in respect of which the health claim is to be made and its particular characteristics;
 - (c) a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out with regard to the health claim and any other material which is available to demonstrate that the health claim complies with the criteria provided for in this Regulation;
 - (d) where appropriate, an indication of the information which should be regarded as proprietary accompanied by verifiable justification;
 - (e) a copy of other scientific studies which are relevant to that health claim;
 - (f) a proposal for the wording of the health claim for which authorisation is sought including, as the case may be, specific conditions for use;
 - (g) a summary of the application.”

We note that the EFSA requirements go far beyond these basic requirements and would like to ask if there is sufficient legal basis to require such level of detail.

- The legal basis of the guidance notes is given as articles 15.4 of the Regulation. It is peculiar that article 15.5, which especially imposes upon the Commission, in close cooperation with the Authority, to make available appropriate technical guidance and tools to assist food business operators, in particular SMEs, in the preparation and presentation of the application for scientific assessment, is not even considered. Although the guidance notes can be considered as technical guidance, there are no specificities included that make the submission of an application more manageable for SME's. Quite on the contrary, the level of detail requested will make the application a tedious and laborious task. This is especially important for SME's that often lack the necessary resources to engage in such work. In particular those companies that depend on investments in innovation through scientific research for their survival will need to hire still extra expertise to make a valid submission.
- The complexity of the data required may be warranted for the evaluation of reduction of disease risk claims where the substantiation should be sufficiently detailed and complete. However, article 14 covers not only reduction of diseases risk claims but also claims relating to children's development and health. Evidence for such claims may range from basic text book knowledge to clinical intervention studies and in many cases it would not be necessary to submit all information requested to arrive at a positive opinion. This is even the case for quite a number of reduction of disease risk claims, especially those

relating to the intake of nutrients and foods, which are based primarily on observational and epidemiologic evidence, the totality of which has lead expert panels, like WHO to conclude on validity of the relationship. In such cases where a scientific evaluation has already been carried out by other expert panels, there should be allowance for a more simplified application, requiring only the appropriate and more proportionate data. In particular, the requirement to supply summaries of all non-human data is not justified in relation to the (little) strength of evidence they provide.

- The current format of the submission is apparently developed to cover claims at the extreme end of the spectrum, namely those for specific products of ingredients with data coming from multiple human intervention studies. In particular many of the requirements from Part 1.4.4. to 2.3 will not be applicable, or known to the applicant or even appropriate, as they will probably only apply to the very few finished consumer goods for which claims submissions may be made. Some examples:
 - Target populations and conditions of use are only applicable to some finished products
 - Consumer labelling, brochures, advertising will not be known to the applicant of an ingredient as this will be dependent of all other users of the claim.
 - Consumer studies/understanding is only applicable for final marketers of products
 - Information on the manufacturing process or stability depend on the final food matrix in which an ingredient is used. Such information will in most cases not be available to the applicant.
 - Food quality is not an appropriate criterion in the context of claims. It is covered by other regulations and is subject to the responsibility of the ultimate food producers. GMP is not even used in food manufacturing, so it cannot be a criterion.
 - What analytical data should be provided in case the subject of the claim is a food of food category (e.g. banana's or fruits)?
 - Bioavailability is a measure that depends on the food matrix, often not known to the applicant of a claim for an ingredient and is also depending on inter-individual and inter-population variability. It is advisable that EFSA provides further information about how it interprets the term 'bioavailability' and what scientific evidence it would find acceptable. For many bioactive components there are few or no data on bioavailability or whether the substances reaches the target site. Clarification is needed on what happens if there are no data. In case of nutrient compounds allowed by EU legislation for the use in foodstuff, in general, no bioavailability data should be required.

The guidance note makes it clear that when entries are not completed, argumentation as to the reason why should be provided. However the omission of data that are requested but are redundant in the case of a specific application should not lead to refusal of the file or undue delay. We feel this should be clearly indicated in the guidance.

- Although the guidance is referring to the article 14 procedure and the mandate does not cover article 18 applications, it is expected that the same rules will apply since both are covered by article 15.3 of the Regulation. It is therefore important that the guidance notes already take into consideration the specificities of applications under article 18. In this respect it is still very debatable if the interpretation of EFSA on the application of the article 18 procedure is legally sound. Our legal interpretation contradicts the statement

that the procedure can only be applied after the establishment of the article 13 list. If such proves to be correct, applications could already be expected to be introduced from July 1st and the same guidance may therefore apply.

- EFSA requests also quite some information that is not required by the Regulation and that may not be available at the time a submission is made. In particular when the subject of the application is a general substance or food or category of foods, the final claim will be available for all operators to use. The applicant therefore cannot have information on the different food matrices or foods that will be subject of the claim, nor on content, bioavailability, etc. It should be noted that general conditions of use are subject to article 5 of the Regulation and fall under the obligations of the food business operator. Although general conditions of use can form part of the conditions for using the claim, these conditions should be restricted to those that are essential for the substantiation of the claim.
- The same issue applies when a dossier is submitted by an ingredient manufacturer. In this case, information such as manufacturing details of the final foods, bioavailability and analytical data on the final food are unknown to the applicant and should not be requirements for approval.
- The application should contain examples of the wording. The role of EFSA should however be limited to the verification that the proposed wording is in line with the scientific substantiation of the claim. It is not possible to be more specific as the formulation of the claim and the understanding by the consumer are intrinsically linked and are tested once the final product concept is developed. In most cases this will be after the claim is approved and thus all conditions of the claim are known. Communication will also be adapted to the specific consumer as it is known that understanding in many cases depends on cultural and regional factors. When EFSA includes in its opinion a proposed wording for the claim, the necessary flexibility for alternative wordings should be taken into consideration and specified.
- In the field of food supplements, the intended use that is communicated to the consumer is considered as a claim. This is an essential part of the product presentation, rather than something that is used for promotional purposes. This intended use now has to be approved through one of the different procedures the Regulation specifies. In most cases it concerns claims that have been used in domestic markets during decades in full conformity with national law. It should be appreciated that the submission of applications is an important additional burden of work that companies have to engage in. Undue complexity and delays are therefore to be avoided at all cost.
- In line 241, it is requested to provide information as to whether the quantity for ingestion can reasonably be achieved by a balanced diet. However, there is no definition of what is understood as a balanced diet, nor does this take into consideration intake from enriched food and food supplements. Food supplements are specifically intended to supplement the diet. In some cases this may result in intakes that are higher than those via the normal diet. Furthermore, the dosage for a claimed effect might well be above that achieved by a balanced diet, but easy to achieve via enrichment or supplementation. Furthermore, depending on the different sources of a food component in the diet, a reasonable quantity could be either the quantity delivered by the product when the product is the sole source

of the food component in the diet, or a significant contribution if the claim is the result of the combined intake of all sources from the diet

- We would also like to emphasise the importance of traditional use as a valid piece of information in the case of botanicals. This is fully recognised as valid substitute for intervention data in the approval process for medicinal products in the field of traditional herbal medicinal products. It would be disproportionate that such data would not be valid in the field of food research, especially in relation to herbal infusions and botanical food supplements. It would make the rules for the approval of medicinal products easier than those for food products. Nevertheless, we don't see any recognition of the value of traditional evidence and its place in the hierarchy of scientific evidence in the guidance notes. Acceptance of this is of the absolute highest importance for the continued acceptance of the use of botanicals in foods, herbal tea's and food supplements.
- EFSA indicates that the document is meant as a living document and will be continuously updated based on changing scientific environment and experience gained. We would like to point out that this may prove difficult as the guidance needs a comitology decision under art 15.4 of the Regulation. This may stifle the live character of the guidance.
- Confidentiality. In line 852 EFSA states that the summary of the application should not contain parts which are considered to be confidential as it will be published on the EFSA Website following receipt of the application from a National Competent Authority of a Member State. However, the summary of the application (line 861-940) requires so much information on 'health claim particulars', 'consumer understanding', 'food characteristics' and 'scientific substantiation' that it is unlikely that any company or researcher could retain much of either the confidentiality/proprietary nature of the diet and health relationship or the nature of the claim to be used. Although line 275 states that the application itself cannot be confidential, the application summary needs to be kept to an absolute minimum, in keeping with the requirements of the legislation. The public availability of the information proposed by EFSA could undermine the drive for innovation for European companies to compete in a global market for foods with health claims. European industry and researchers would be substantially disadvantaged if global competitors seize the information and initiative to develop a similar food or food component with either a health or disease risk reduction claim. Furthermore, the procedure for rejection of a health claim under Article 20 needs clarification, as publication of this information could be a significant disincentive and be potentially commercially damaging.
- A final comment concerns the timings as proposed by EFSA in its pre-guidance notes. It is clear that EFSA's interpretation of article 16.1 is rather broad: "In giving its opinion, the Authority shall respect a time limit of five months from the date of receipt of a valid application' EFSA does not consider the time needed to check the validity of the application and inform the EC and the Member States as falling under the five month period. Nor does it included in this the time needed for publishing the opinion after approval and sending it to the EC. These elements are introducing a non-specified time variable in the procedure which we do not believe is justified under the provisions of the Regulation.