



EHPM Comments on EFSA's Draft Frequently Asked Questions (FAQ) related to EFSA assessment of health claims applications

June 8, 2009

We would like to thank EFSA for the opportunity to provide comments on this FAQ in view of the June 15 technical meeting with stakeholders.

We find the opportunity for such a dialogue is essential in view of the complexities and uncertainties regarding the assessment of health claims and regret it comes at a very late stage. We would hope that in the very near future, such dialogue is continued in particular in the context of the assessment of article 13.1 claims to clarify a number of issues and resolve them as early as possible in the process.

1. General Comments

The FAQ only addresses questions relating to the applications for article 14 and 13.5 claims. As EFSA has repeatedly indicated that the same scientific principles would underline the assessments done for all health claims, including article 13.1 claims which require a different assessment than that applied to article 14 claims according to the Regulation, we believe the FAQ and discussion of the Technical Meeting should also consider questions that are relevant to article 13.1 claims. We have therefore included relevant questions also applicable to article 13.1 claims as part of our comments below.

Although we believe the FAQ is a useful instrument to address important questions, we regret that it does not provide much more information than what is already available from Regulation 353/2008 as well as from the pre-submission and applications guidance.

We believe a number of very important & concrete questions on the scientific assessment process should be discussed at the meeting in particular:

- detailed guidance on the number and design of human intervention studies, including their duration, and their need in accordance with the type of claim and its strength.
- The issue of relevance of the evidence drawn from population with pre-clinical or clinical conditions



- The value of other sources of evidence such as observational or epidemiological evidence, as well as animal or in vitro data or evidence from history and tradition of use for botanicals
- The criteria to include or exclude studies from consideration as not pertinent to the claimed effect
- How do EFSA experts take into account in their assessment the proportionality between the amount and type of evidence required and the claimed effect: For example, it would make sense that a disease risk reduction claim would need a different strength of evidence than a more mundane function claim based on a long accepted body of scientific evidence.
- How do EFSA experts takes into account the need to weigh the evidence provided and assess the extent to which a cause & effect is established and how is it concretely reflected in its opinions so far?
- What has EFSA put in place in practice to ensure that the assessment of article 13 claims is different from that of article 14 claims, as required by the Regulation

2. Specific Comments on the FAQ

Overview of the main issues addressed by the NDA panel

Line 45: The Regulation does not refer to the establishment of a cause & effect for any health claims and it would be good to have more clarification on how EFSA interpret these terms. Some concrete examples would be beneficial as what is meant would differ according to the claim made, for example a maintenance claims would not seek to demonstrate the same type of cause & effect relationship as a disease risk reduction.

Line 41: the assessment referring to “the extent to which” a cause & effect is established is undermined by line 48 stating “ if” the cause effect is considered established. The latter does not provide the flexibility required by the Regulation and term of references in the case of article 13.1 claims. It is not clear why such process, that conditions the consideration of other elements (line 49 to 55) to the positive establishment of a cause-effect, is foreseen.

The extent to which should a food/constituent be characterized



Line 62/63: would benefit from more details of what exactly is meant by "sufficiently defined and characterised": some examples would also be useful –For example, it would seem sufficient that the characterisation is limited to the elements of the product that are relevant for the claim and not encompass all elements. For example, what is considered as an appropriate test for characterising a strain of pro-biotics?

Line 69: "characteristics considered pertinent to the claimed effect" is very general - more specifics would be helpful

Line 76/77: It is not clear why for specific formulation or combination products, a detailed rationale/evidence should be provided for each constituent in addition to the evidence already demonstrating that the formulation or combination has the effect sought. This seems to be a superfluous requirement.

Line 79 refers to providing "the preparation procedure". If the preparation procedure has no relevance to the effect claimed, why should it be required? If a different preparation procedure is used to obtain the same constituent, and thus with the same effect, the claim would surely still be valid. If such level of details is required, how will the dividing lines between two preparations be drawn and how will these be communicated?

How should the claimed effect be shown to be beneficial to human health

Line 98: The Regulation does not specify that the health effect have to be testable and measurable and we believe it would not be proportionate to apply such requirement to all claims. In particular, for many claims that describe the **role** of a nutrient or other substance in the growth, development or functions of the body, it is not possible to measure a specific effect as the number of validated surrogate biomarkers is discouragingly low and therefore the evidence would not provide a quantitative measure. It is however possible to assess the totality of the evidence, not relying solely on human intervention trials, to evaluate the plausibility and strength of the health relationship. A number of general maintenance claims indeed do not describe a measurable effect but in analogy to public health recommendations, the plausibility of a cause-effect relationship will be determined by the level of the totality of the evidence underlying the health-relationship.

Line 105: we are happy to see that EFSA does allow for the possibility of maintenance or improvement claims, as there has been some confusion as to whether maintenance claims were accepted or not, especially in the context of request for clarification requested by EFSA for article 13.1



claims. However we believe it is important to ascertain if there is a difference in the data required for this two types of claims and also consider the case of contribution claims where the effect claimed is that the product contributes to the dietary intake and thus the effect is reached also by the consumption of other dietary sources.

What is a risk factor for the development of a human disease

It would be good to have some reference to the multifactorial factors of diseases, for context.

Line 111 & 112: We fully support the reference to the WHO classification of diseases but believe that it would be better for consumer understanding to refer to common names of diseases instead of using the medical and latin terminology.

What are pertinent studies for the substantiation of a claim

It would be beneficial to understand what is considered as “ pertinent’ studies and what is meant by “from which scientific conclusions can be drawn” and that clear criteria for the inclusion or exclusion of studies are given as well as examples.

We regret that the title of this section already restrict the data for consideration to studies, as the NHCR does indicate that health claims are substantiated by generally accepted scientific evidence and that the totality of the evidence should be assessed, which can encompass different type of supportive data, that can range from human clinical studies to observational or epidemiological evidence, animal and in vitro trials, recommendations and assessment from other scientific bodies or health authorities (e.g. WHO, national food safety agencies such as AFSSA) or even evidence from history & tradition of use in the case of botanical ingredients.

We would welcome a discussion on the role of supportive evidence. For example, operators sometimes do not want to publish results of studies they have conducted to preserve their proprietary data protection rights, so what is the value given to unpublished study results as compared to peer-reviewed studies?

Line 159 to 161: we would like to have clarification as to whether studies carried out with people with clinical or pre-clinical conditions that present measurable parameters that are out of normality or even no longer physiological are considered as suitable for the substantiation of a health claim. We note that it is current practice in nutrition research to use different type of study designs and target groups, including the above as part of the evidence of a health benefit.



Line 164 to 168: this focuses essentially on the need for human studies and this in our opinion does not reflect the requirement to take into account the totality of the evidence and weigh it, as other sources of evidence, such as animal or in vitro studies, as well as observational or epidemiological data can also provide other supportive evidence. It is the assessment of all the evidence that would allow EFSA to provide an opinion indicating the extent to which a health relationship is substantiated by the data provided. Every type of evidence, including RCTs, have inherent flaws and much of what we already know about human nutrition and health and the knowledge that underpins national and international dietary & health recommendations is based on epidemiological evidence. This demonstrates the need to take into account all sources of evidence and not focus only on human studies in all cases.

What is the totality of available scientific data

Line 170: Same remark as paragraph above: it would be beneficial to understand what is considered as “pertinent” studies and what is meant by “from which scientific conclusions can be drawn” and that clear criteria for the inclusion or exclusion of studies are given as well as examples.

Line 175: We welcome the fact that EFSA would look at all available data, even if not included in the application, but we believe that should this be the case, there should be an opportunity for the applicant to be informed of the external data used so that he may comment on this if relevant.

We regret the lack of details of this section that does not provide the detailed information on the different sources and nature of evidence, beside human studies, that an applicant may use in support of their claim. In particular, we see is no mention in the FAQ of the consideration of observational or epidemiological evidence, nor evidence drawn from history of use, which is generally accepted as evidence of effect of botanicals, for example for Traditional Herbal Medicinal Products.

How does the NDA Panel decide whether a claim is substantiated

Line 185 to 187: Same remark as above, we regret that the focus is on the need for human studies, and only mentions animal or in vitro studies but does not seem to consider other type of sources of evidence such as observational or epidemiological evidence.

When does EFSA request supplementary information from the applicant

Line 194: the time limit specified by EFSA is not detailed and we believe



that a clear discussion and understanding of what is a reasonable period of time to respond, especially for SMEs that have limited resources, would be beneficial. This could take place within a structured dialogue with the applicants.

On what basis does EFSA proposes wordings for claims

Line 203- 205: How does EFSA ensure that the scientific wording relating to the health relationship can translate into an understandable claim for the consumer in practice? Does the applicant have an opportunity to discuss EFSA's proposed wording ?

How does EFSA treat proprietary data

Line 216-218: Can EFSA provide more details or examples of what is considered as data “ essential for the scientific assessment”. Will the applicant be informed prior to the release and will he have the opportunity to dialogue in case he considers such data as confidential?

3. Issues not addressed

Transparency & consultation of stakeholders

In view of the many issues encountered by all parties in the clarification of the article 13.1 list, we believe that it has become necessary for all, including stakeholders to enter into a constructive dialogue and for EFSA to provide explanation as to how the different assessment of article 13.1, claims as compared to article 14 ones is envisaged, in accordance with the requirements of the Regulation.

We believe the technical meeting can provide the opportunity to address these issues and would welcome the opportunity to discuss these. If not possible on June 15, we re-iterate our call to establish such a dialogue urgently before EFSA proceeds with the adoption of its first opinions at the end of July to ensure an equal treatment to all article 13.1 claims.

Procedural issues

We regret that the FAQ does not address any procedural issues in particular:

- the process and timing for a dialogue with applicants to resolve issues before EFSA Panel delivers its final opinion
- reasonable timing allowed for additional information to be provided by the applicant



We believe a clear lay out of such procedures in the FAQ would be of benefit to all parties.

Guidance to SMEs

The Regulation foresees that EFSA will make available appropriate technical guidance and tools especially for SMEs (recital 33). However, to date, the guidance made available are not addressing specific issues for SMEs.

How is EFSA considering addressing this requirement?

Would EFSA consider possible to establish a pre-validation or experts service to help operators, in particular SMEs, in the establishment of their dossiers: for example, it would be useful for operators to know if the protocol for the clinical study is considered appropriate or the food is sufficiently characterized.

Next Steps for FAQ & Comments

It is not clear either what will be the fate of this FAQ and outcome of discussions from the Technical meeting. Will the FAQ be revised and become part of the guidance to applicants? How will the comments received be taken into account?

An additional question is how does EFSA takes into account comments provided by any stakeholder on its opinions after they have been published (as foreseen by the Regulation) and may these lead to a revision of the opinions where appropriate