Technical meeting between EFSA, the Commission and Member States on assessment of Article13.3 health claims, 6 October 2009

This note summarises the questions posed by MS and answers given by members of EFSA's panel on Nutrition, Dietetic Products and Allergies (NDA) and the Commission. It should be read in conjunction with the briefing document published by EFSA before the meeting (http://www.efsa.europa.eu/cs/BlobServer/Event_Meeting/NDA_briefing_%20doc_Art_13_claims.pdf?ssbinary=true) .

EFSA will publish a short note of the meeting in due course.

Q: How did the NDA panel weigh evidence of function for vitamins/minerals where the DRV is not well established from evidence in humans?

A: If there is an evidence base of need for an essential nutrient then we would look for evidence of the specific function in question.

Q: One possible outcome of an assessment is 'The evidence provided is insufficient to establish a cause and effect relationship between the consumption of the food/constituent and the claimed effect.' What do you mean by 'insufficient evidence'?

A: This varies, in some cases it may be that there's limited evidence of cause and effect together with emerging evidence; in others it may be to do with the balance of positive and negative evidence. In the published opinions the panel has tried to describe how the evidence has been used as the basis for conclusions.

Q: Are there any differences between the assessments for Art 13.5 & 14 claims and those for Art 13.1 claims?

A: The terms of reference for assessment of each type of claim were given to the NDA panel by the Commission; they are almost identical. There is a lot of overlap between the types of claims applied for under 13.5 / 14.1 and 13.1 and if the panel had used different criteria for assessment this would have led to anomalies in outputs. There is no convincing argument as to why the assessments should be different.

Q: Where evidence comes from studies on patients how have you extrapolated the results to the target (normal) population?

A: This is considered on a case-by-case basis. If we understand the mechanism of the claimed effect in patients then we may be able to judge whether there would also be the same effect in healthy people. In considering claims the panel has separated the nature of the evidence from the type of claim e.g. evidence of lowering LDL

cholesterol could support a disease risk reduction claim but also a 'maintenance of cholesterol' claim.

Q: Can you comment on EFSA's opinions on glucosamine?

A: All of the studies on the effect of glucosamine on joints were carried out on patients with osteoarthritis and, in this case, it is not correct to extrapolate the same effect to the general population with healthy joints.

Q: In early opinions, the panel did not say much about how it had weighed evidence; will this change?

A: The panel accepts this criticism and has tried to say more in 13.5 opinions. We have not always commented on 'the extent to which…' if there was either very strong evidence or a lack of evidence (since this didn't seem necessary) but we've tried to comment where the evidence was more finely balanced.

Q: In some opinions the panel has said a claimed effect 'might be beneficial' and in others an effect is 'beneficial'. What's the difference?

A: There may not be much difference, this assessment simply allows the panel to proceed to the next stage of the assessment process; then something that was earlier judged as 'might be beneficial' may, in particular circumstances, be judged 'beneficial'.

Q: Has the panel considered that the applications may not contain references that point to negative as well as positive evidence?

A: Yes, we did have some concerns about this but all NDA panel members are experts and we have access to additional experts on the panel working groups (WG); the panel therefore does use data in addition to those submitted if they're pertinent to the claimed effect. We are reasonably confident that we will pick it up if the evidence provided is incomplete but we acknowledge that this is a weakness in the system.

Q: What are the working groups?

A: The NDA panel has working groups (WG) on gut and immune system; cardiovascular health, oxidative stress; bone, dental health, connective tissue; weight management, satiety, physical performance, glucose control; mental health, CNS, vision; characterisation of botanicals; miscellaneous. The WGs prepare the first drafts of the panel's opinions.

Q: Where EFSA has said that a 13.1 application cannot be assessed because more information is needed, can more information now be submitted?

A: No. A new application, including the additional information, would need to be made (under Art 13.4 of 1924/2006 or under 13.5 if proprietary data are involved).

Q: What information does the panel need for characterisation of botanicals?

A: Information should include: the scientific name, part used, preparation procedure.

Q: For herbals, how does the panel consider evidence of traditional use?

A: During negotiations on 1924/2006 there was a lot of debate on whether to include reference to tradition of use for herbals and a decision was made to omit it (negotiations on the Traditional Herbal Medicines Directive were underway at that time). Since 1924/2006 is silent on this it may mean that it's not excluded. There's a danger of proceeding to make the level of evidence required for substantiation of a claim on food higher than for a medicine.

Q: The panel looked at textbooks when considering claims for botanicals; what were these?

A: The panel looked at, and accepted, medical textbooks and monographs, and references in monographs, for evidence of the claimed effect. In general there is very little literature on the use of herbals in foods. The panel has a WG looking at characterisation of botanicals and this has greatly increased the number of botanicals that could be characterised. The panel is looking for scientific evidence of effect but traditional use appears to be mostly based on long-standing beliefs and, in general, this would not be regarded as 'generally accepted scientific evidence'.

Q: How do you distinguish between botanicals in Traditional Herbal Medicinal Products and the associated medicinal claims and similar claims on botanicals in foods?

A: The panel is only assessing non-medicinal claims. Medicinal claims were weeded out early on.

Q: Did the NDA panel communicate with the European Medicines Agency on 'borderline' claims?

A: Yes and the panel will continue to co-operate in future.

Q: Can the panel give more information about what it needs for characterisation of a food/constituent?

A: The panel needs information on the food/constituent characteristics that may influence the specific physiological effect that is the basis for the claim. This may include: source; physical/chemical properties; matrix; composition, including nutrient content. Analysis should be with sound, standardised analytical methods performed in competent laboratories (GLP/ISO). The panel also needs information on consistency of the final product for those characteristics pertinent to the claimed effect; on batch-to-batch stability; and on details on manufacturing process (GMP).

Q: How do you know if the food matrix influences the claimed effect?

A: The NDA panel looked at the references supplied in support of the claim. If there's no evidence of a matrix effect in the references then this will not be included in the assessment.

Q: How will the panel deal with Glycaemic Index (GI) claims?

A: The panel cannot substantiate a claim if the food/constituent in question is characterised solely on the basis of the claimed effect e.g. 'non-cariogenic', 'low GI', antioxidant'. The panel can, however, assess the effect of a food characterised by its effect on the blood glucose and can then decide if the effect is beneficial to the proposed target group.

Q: Have any claims been rejected on the grounds that they were not beneficial?

A: Yes, for example 'eliminates water from the body' which we felt was not beneficial to the general population.

Q: How does the panel deal with claims about foods/constituents with no independent role in the claimed effect?

A: This can be difficult; in some cases a beneficial effect is claimed where a substance with an adverse effect is substituted by a substance without that effect e.g. lowering of serum cholesterol when saturated fatty acids are replaced by monounsaturated fatty acids.

Q: When will EFSA update the claims database on its website?

A: Later this year and will include timelines for remaining claims.

Q: When will EFSA publish more opinions on Art 13.1 claims?

A: EFSA intends to publish several series of opinions throughout 2010 and 2011.

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