FOOD STANDARDS AGENCY UPDATE FOLLOWING DISCUSSIONS IN COMMISSION WORKING GROUP ON REGULATION (EC) 1924/2006 ON NUTRITION AND HEALTH CLAIMS, 14 DECEMBER 2009

Amendments to Nutrition Claims Annex

"Now X% less" reformulation claim

The Commission introduced its latest proposal which requires at least a 15% reduction in the claimed nutrient and allows this claim to also be used for sugars, but invited Member States (MS) to comment on whether this claim should be added at all.

Some MS spoke against the reformulation claim, considering it would have the same meaning to consumers as the "reduced" claim already in the Annex. The Commission said it would check the legality of authorising a claim that is so similar to one already in the Annex.

Although most other MS seemed to be in favour of allowing a reformulation claim in principle, several raised concerns about how the one year period in which the claim could be used would be enforced, that a 10 or 15% reduction was not significant and would be difficult to enforce when taking into account tolerances and that sugar should not be included in the claim as it is only the associated energy reduction that is beneficial to health. There was some support for a suggestion that the product label could be required to state the date the reformulated product was first placed on the market to make it easier to enforce the one year period of use. Many MS preferred the proposed 15% reduction over 10%, although some raised technical and consumer acceptability issues as reasons to favour 10%.

"No added salt"

One MS asked for a "no added salt" claim to be considered for addition to the Annex as consumers find this useful in helping them to distinguish between different products and it supports public health messaging encouraging consumers to choose lower salt options. A couple of MS were also in favour of adding this claim and no MS spoke against it. The Commission will consider whether to include this claim in its proposal.

"Source of/high in energy"

A couple of MS asked for clarification about whether these claims could be used in future and whether they were considered beneficial to the general population but there was no further discussion.

"Source of/high in omega-6"

A couple of MS asked for specific omega-6 claims to be added to the Annex but the Commission was reluctant to consider this claim as some MS had previously indicated concerns with over-consumption of omega-6 compared to omega-3.

Introduction of specific criteria for "very low sodium" and "sodium free" claims on waters

The Commission said that MS representatives from the Commission working group on waters legislation had been consulted about these claims and the only comment received was that threshold levels should be rounded to the nearest whole number. One MS felt the criteria to make a "sodium free" claim on water should be reduced to 0.1 mg sodium per litre.

Introduction of specific criteria for supplements

Some MS asked for specific conditions of use to be introduced for supplements, for example by setting a daily dose rather than an amount that must be present per 100g or

100kcal, but the Commission did not consider this a priority. MS were invited to suggest specific proposals for such conditions of use.

Article 13(5) and 14 health claim applications
There were no questions or comments on two positive opinions EFSA recently adopted on claims that "iodine contributes to the normal growth of children" and "iron contributes to normal cognitive development of children".

There was lots of discussion on setting conditions of use and appropriate wording for the children's claims about docosahexaenoic acid (DHA) alpha-linolenic acid (ALA) and brain and eye/visual development. The intention seems to be to allow the claim on all foods containing the required level of DHA and not to restrict it to follow-on formulae and maternal supplements as per the original claim applications, and MS discussed whether the conditions of use should refer to a specific amount of DHA per 100g/kcal of food or to the percentage of the energy value of the food that is provided by DHA. MS were keen to ensure that the wording of the claims allowed consumers to make a clear distinction between eye and visual development, and brain and cognitive development. Due to a lack of time for full discussion the Commission asked MS to submit written comments.

Article 13 health claims
The Commission gave feedback on the ad hoc working group meeting. It said it would now not be able to propose legislative measures to authorise claims until February when the new Commission is fully in place.

Claims falling outside the scope of Article 13
The Commission reported that 37 claims identified as out of scope would be withdrawn unless MS could justify why they should remain in the A13 process. The Commission said it would not specifically inform stakeholders which claims had been withdrawn but EFSA will publish an updated list of claims undergoing authorisation on its website in due course.

Product specific claims
The Commission said MS should check whether claims are product specific by assessing whether the food component, wording of the claim, or references refer to a specific product. There is no opportunity to amend claims to remove product specific wording or references at this stage. In response to a question from one MS, the Commission said that claims not undergoing authorisation could not benefit from any transition period once the first batch of A13 claims is adopted – so businesses should be advised to re-submit these claims under Article 13(5) as soon as possible.

EFSA opinions on Article 13 claims to date
Discussion focused on those claims where EFSA's opinion states a lack of evidence for deficiency in Europe. EFSA explained that it had only mentioned a lack of deficiency of a nutrient in its opinions where the panel was sure there was no deficiency in the EU, but even then there may be deficiencies in some population sub-groups. However, for some substances, like folic acid, there is a known deficiency for one claimed effect but not others – in this case EFSA's opinion didn't mention lack of deficiency for that nutrient (regardless of the claimed effect being considered) as it would be very difficult and time-consuming to do. There are also some health effects that are never dependent on dietary intake e.g. calcium and blood clotting. The Commission said this indicated less emphasis should be placed on EFSA's comments that there is a lack of deficiency of some nutrients as this was not core to EFSA's assessment. However, a number of MS wanted further consideration to be given to conditions of use for these claims and favoured the introduction of a disclaimer stating that no deficiency exists or that the

claims is only valid for people who have a deficiency. Some MS wanted claims to be disallowed altogether for nutrients where there is no deficiency.

A couple of MS had previously raised concerns that the word "normal" could be misleading (e.g. "contributes to normal function of the immune system") as it implies risk of abnormal bodily functions if the food is not eaten. It was accepted that this may be a linguistic issue and the majority of MS seemed to be in favour of the word "normal" remaining in the wording of claims as this best reflects EFSA's opinion.

EFSA reaction on clarification on A13 claims provided by MS
The Commission reported that no clarification had been provided for 621 of the 2145 claims for which EFSA had requested further information earlier this year. EFSA reported that the clarification provided for many of the remaining claims was not helpful and in some cases made it even harder for it to identify what to assess. In some cases many different health relationships had been submitted in place of just one e.g. "heart health" was changed to "maintains normal cholesterol, blood pressure, inflammatory response, triglycerides and brain health". EFSA will put all of these claims in one opinion and state that it cannot establish what to evaluate. There was a lot of support for this from MS, who saw no other way forward for these claims and did not think that asking for more clarification was likely to be fruitful. One MS pointed out that it was important to ensure claims where lots of different health relationships had been proposed by different MS during the clarification exercise hadn't been mistakenly consolidated into one claim by the Commission earlier on in the A13 process. The Commission said it is possible that some claims may need to be split into several different ones but said it would discuss this with EFSA to ensure what it sends to EFSA is clear.

Guidance
Guidance on MS' admissibility check of Article 13(5) and 14 claims
The Commission asked whether MS would be prepared to check the novel status of foods before submitting applications although there is no legal requirement to do so. There was no consensus as some MS thought that it should be possible for novel food applications to be submitted in parallel with claims applications but other MS disagreed.

Guidance on use of authorised health claims
The Commission asked whether MS thought it should be possible to split authorised claims e.g. only mention reduction of cholesterol in the claim rather than going on to talk about reduced risk of heart disease, or use consumer-friendly wording on the front of pack and the technical scientific wording supported by EFSA on the back. Again, there was no consensus amongst MS so this will be considered further.

Next meeting: 15 January 2010