

November 2012

Interested Parties

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Dear Colleagues,

**Update from the European Commission's Working Group meeting on
nutrition and health claims, 12 November 2012**

**Article 13 claims 'on hold' – discussion of draft list of some claims
proposed for authorisation**

The Commission presented an amended version of a draft annex listing claims to be authorised (attached to the email with this letter).

Alpha-cyclodextrin

Regarding the conditions of use (COU), a question was asked as to whether the beneficial effect was limited to foods containing at least 50g starch consumed with 5g alpha-cyclodextrin or whether it would be achieved by, for example, a product containing 10g starch and 1g alpha-cyclodextrin.

Caffeine – three claims related to endurance exercise

The main comments on these claims related to concerns about safety at the levels required to achieve the claimed benefit.

Caffeine – two claims relating to alertness and concentration

The restriction on use of these claims had been changed from 'may only be used on foods targeting adults' to 'shall not be used for foods targeting children'.

*Docosahexaenoic acid (DHA) / Eicosapentanoic acid (EPA)- claims for
maintaining normal blood triglycerides and normal blood pressure*

In response to a question about whether the claims for 'maintenance of normal blood triglyceride levels' and 'maintenance of normal blood triglyceride concentrations' are the same, it was explained that the subject of the first is DHA alone and the COU require a product to provide a daily intake of 2g DHA plus some EPA. By contrast, the subject of the second claim 'DHA + EPA' and the COU require a product to provide 2g DHA and EPA together.

There were no comments on the *prunes* claim.

Fructose

Some Member States (MS) are concerned that this claim might encourage excess consumption of sugar, contrary to public health recommendations;

others consider that the warning about the effects of very high consumption of fructose should be reinstated.

Glycaemic carbohydrates

Several MS asked how 'glycaemic carbohydrates' were defined and thought the term would not be useful to consumers or to enforcement authorities. Several MS are concerned that this claim might encourage consumption of sugar in excess of national dietary guidelines.

L-arginine and L-tyrosine

These claims have been dropped from the annex because it does not seem possible to set COU.

It's likely that a draft Regulation will be put to Standing Committee on 10 December, possibly for a vote.

Discussion of recent European Food Safety Authority (EFSA) opinions on individual applications for health claims

Cocoa flavanols help maintain the elasticity of blood vessels, which contributes to [normal] / [healthy] blood flow (EFSA-Q-2012-00002)

The subject of discussion was a document setting out alternative wordings and several COU to consider. Those MS that spoke seemed to favour claim wording that would refer to 'normal' blood flow than 'healthy' blood flow. EFSA confirmed that, based on the evidence it had assessed, the claim could only be used for cocoa flavanols in dark chocolate or cocoa powder (in beverages) as such, and not for chocolate or cocoa powder incorporated in other foods; the COU may be amended to make this clear.

Calcium / calcium + vitamin D may reduce the loss of bone mineral density in post-menopausal women. Low bone mineral density is a risk factor in the development of osteoporotic bone fractures (EFSA-Q-2009-00940 and 2008-721)

The subject of discussion for these claims was also a document setting out alternative claim wordings and several COU to consider however there was no clear consensus among those MS that expressed views.

Discussion of draft Commission guidance on the specific conditions for health claims in Article 10 of Regulation 1924/2006

Article 10.2.b. of Regulation 1924/2006 requires the label of a food bearing a health claim to provide information about the 'quantity of the food and the pattern of consumption required to obtain the claimed beneficial effect'. In the case of most vitamin / mineral claims (e.g. 'calcium is needed for the maintenance of normal bones') the COU require a food bearing a claim to contain at least 15% of the recommended daily allowance (RDA) but it's not evident to the consumer that the beneficial effect is provided by 100% RDA which is assumed to be consumed as part of a balanced diet. There was a discussion about whether the Art 10.2.b requirement is fulfilled by the mandatory nutrition information which would state the quantity of the vitamin / mineral, and the %RDA, in the food.

One view was that all that would be needed to tell consumers about the quantity of food and pattern of consumption required would be the [%] RDA and the

Article 10.2.a statement about the importance of a varied and balanced diet and a healthy lifestyle. Another view was that there should be label text to clearly explain that 100% RDA was required to receive the beneficial effect. There was strong reaction against this for various reasons e.g. that the amount required would depend on an individual consumer's vitamin / mineral status; that consumers could not be expected to add up their vitamin / mineral intake from foods consumed over the course of a day; and that such text could mislead consumers into thinking they had to consume large amounts of foods bearing the claim which might lead to excess vitamin / mineral consumption. There was no obvious conclusion to the discussion.

Article 10.3 of the Regulation requires a non-specific health claim to 'be accompanied by' a specific, authorised health claim. MS would like the guidance to say what this means however this is under discussion in the context of implementing Regulation 1169/2011 on food information to consumers (FIC) so it will not be defined in this guidance for now.

It's possible that the draft guidance will be put to Standing Committee in December.

Discussion of a draft Commission Regulation amending Regulation 608/2004 on the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and / or phytostanol esters
Regulation 608/2004 requires the labelling of foods and food ingredients with added plant sterols and / or plant stanols to include a statement that the product is intended exclusively for people who want to lower their blood cholesterol level; the purpose is to ensure that such products are consumed by the target group only. However, there are now two problems with the wording: 1) it is potentially misleading for consumers when read together with the recently- authorised health claims for these ingredients ('contribute to the *maintenance* of normal blood cholesterol levels') and 2) it could itself be perceived as a health claim which may not be appropriate on products containing these ingredients at levels below that required to make an authorised health claim.

The Commission had proposed amending the mandatory statement to 'this product is not intended for people who do not [need / want] to [regulate / control] their blood cholesterol level'. There was concern that the double negative might be confusing for consumers but it was explained that the double negative was intended to ensure that the statement was seen as a warning and could not mistaken for a claim.

Once the amendment to 608/2004 is in place the FIC will be amended via a delegated act. If phytosterols are approved as food additives, products containing negligible levels will not be subject to this mandatory labelling statement and that issue will be dealt with in the appropriate legal instrument at that time.

Discussion of generic descriptors

MS were asked to come to the next meeting with examples of terms that might be regarded as generic descriptors.

Next working group meeting

There will not be a meeting in December.

Yours faithfully,

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