Department of Health

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Interested Parties

Dear Colleagues,

Update from the European Commission's Working Group meeting on health claims, 18 March 2013

Exchange of views on a draft Commission Regulation setting the rules for applications for authorisations of generic descriptors
Member States (MS) were reminded that traditionally-used generic descriptors are terms that consumers no longer perceive as implying a health benefit. There was general agreement that the granting of generic descriptors must not be a route for re-applying for non-authorised health claims.

The document under discussion – the draft Regulation setting the rules for applications for generic descriptors – is circulated with this letter. The main points of the discussion are set out below.

Comments in relation to Part A of the Annex:

- Paragraph 1 should make it clear that a dossier should only be submitted via one MS
- In Paragraph 3 it would be useful if the summary of an application was sent to other MS when they were informed. Other MS where the generic descriptor was traditionally used should be informed by the receiving MS before validation. The text will not define 'without delay' in order to give MS some flexibility.
- Paragraph 6: All MS concerned with an application will have to provide their opinions within 6 weeks.
- Paragraph 8: It was suggested that a food business or trade association putting together an application should be required to advertise the fact in order to facilitate co-operation and to ensure that the application included all the available, relevant information – in a process similar to that for further assessment of health claims.

Comments in relation to Part B of the Annex:

- Paragraph 3, the Regulation on Food Information to Consumers requires mandatory information to be in the local language but generic descriptors, being voluntary, could be used in their traditional language even in other MS.

- Paragraph 4, the wording of the 2nd point could be expanded to clarify that the information should be detailed enough to define the products concerned and to distinguish them from others. Would it be useful to define 'class' in this context?
- Paragraph 5, definition of traditional use: it was agreed that it would be appropriate to relate traditional use to a cut-off date e.g. 25 years before 2007 (the date of application of the NHCR) or 1997 (used in the novel foods regime) rather than to a time period alone however, no date was agreed.
- Paragraph 6, evidence relating to consumer understanding: it could be useful to indicate what quality and quantity of information would be needed and how it should be assessed.

We would welcome your comments on the text of the document, please send them to me (vivien.lund@dh.gsi.gov.uk) by Tuesday 26 March.

Individual health claim applications submitted under Article 13(5) or Article 14 of the NHCR before 14/12/2012 and which are still under assessment by EFSA or under consideration by the Commission

The Commission's lists of these claims are circulated with this letter. The claims are permitted on the market whilst awaiting decisions, provided their use complies with all the relevant provisions of food law, and if they are rejected they will be given 6 months' transition to allow businesses to adapt.

MS discussed whether claims on the market should only be allowed to continue to be used if they were exactly the same as those under consideration (in terms of the conditions of use and the substance that is the subject of the claim) or whether there was any flexibility. Referring to the Article 13 botanical claims on hold, it was suggested that a claim could be allowed on the market now if it was for the same plant part as mentioned in the corresponding 'on hold' claim but that there could be some flexibility for the 'dose'. There seemed to be agreement that this was a reasonable approach.

Article 13.1 health claim: carbohydrates contribute to the maintenance of normal brain function

A few MS reiterated previous suggestions for setting conditions of use (COU) but there was still no agreement. The claim may be considered again at standing committee in April.

Individual applications for calcium and vitamin D (Q-2008-721 & Q-2009-940 related to the risk of osteoporotic bone fracture and Q-2010-01233 related to the risk of falling)

These claims require daily intakes of 1200mg calcium / 20micrograms vitamin D. It had been agreed that foods bearing the claims should provide the total daily amount required above the recommended daily intake (i.e. 400mg calcium or 15micrograms vitamin D) and MS discussed whether the claims should be limited to food supplements or not. Most MS that spoke were in favour of allowing them on food supplements and on other foods. However, there was no agreement on whether a food with a claim would be required to provide the

400mg calcium or 15micrograms vitamin D in a quantified portion or in the amount consumed in a day so this will be considered further.

Implementation of Regulation 432/2012
The Commission reminded MS that Regulation 432/2012 does not include a sell-through provision.

Health claims referring to the rate or amount of weight loss
MS were made aware of a website linking certain foods to personalised predictions of weekly weight loss based on BMI. The Commission reminded MS that Article 12(b) of the NHCR prohibits health claims referring to a rate or amount of weight loss.

Next meeting: no date fixed yet.

Yours faithfully,

Dr Vivien Lund

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