EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Director General

Brussels,
SANCO/E4/NG/lb

Your Excellency,

Subject: Further Assessment of certain Health Claims subject to Article 13(1) of Regulation (EC) No 1924/2006

I am writing in relation to the further assessment that is to be made available for certain categories of health claims subject to Article 13(1) of Regulation (EC) No 1924/2006[1] (hereinafter 'the Regulation').

Article 13(3) of the Regulation requires consultation of the European Food Safety Authority (EFSA) before a decision can be taken to adopt the Union list of permitted health claims. Due to the incomplete nature of the data submitted with certain of these claims, EFSA could not provide a conclusive assessment in relation to their scientific substantiation. When the Standing Committee on the Food Chain and Animal Health, General Food Law section met on 22 February 2010, its members agreed that as risk managers they would not be able to take a final decision on whether or not to include these claims in the list of permitted health claims and a further assessment should therefore be considered.

The two categories of claims for which EFSA's assessment is considered as not conclusive are:

- Claims on micro-organisms which EFSA considered as insufficiently characterised to proceed with the assessment of the evidence. When the lists of claims were being compiled, it was clear to Member States and subsequently to stakeholders that in order to establish the scientific substantiation of claims, the subject of the claim (a food category, a food or one of its constituents) must be properly characterised. For all claims where the subject of the claim is insufficiently characterised, this condition has not been met and the claim cannot be substantiated. However, in the case of claims on micro-organisms, the constituents of a food were, in most cases, characterised at a very specific level as advised by Member States. Nevertheless, it was claimed that it was not generally known that in order to have a reliable identification for a scientific assessment micro-organisms need to be characterised at strain level by genotypic identification of the strain using appropriate methodology. When it came to make the assessment of the evidence, EFSA noticed that this level of characterisation was not

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[1] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. (OJ L 404, 30.12.2006, p.9)

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respected in the majority of submissions for claims relating to micro-organisms and therefore considered that the data provided was not sufficient to characterise the micro-organisms in question. For this reason the Commission feels it is justified to make a distinction between micro-organisms and other claims where the subject of the claim is not sufficiently characterised, and allow the submission of more specific evidence for a further assessment for claims on micro-organisms only.

- Claims for which EFSA concluded that "*the evidence provided is insufficient to establish a cause and effect relationship*" during their initial assessment. This conclusion, contrary to the cases where EFSA concluded that *"a cause and effect relationship has not been established"* indicates that the provision of *additional* evidence might prove sufficient to substantiate the claim. As the evidence substantiating the claims when the national lists were being compiled and submitted pursuant to Article 13(2) of the Regulation was provided prior to 31 January 2008, it is judged appropriate to allow any new evidence that emerged subsequently to be taken into account in the evaluation of these claims.

After consideration in the working group on health claims, the further assessment is to be conducted as an extension to the current process described in Article 13(2) and 13(3) of the Regulation. Since the original collection of health claims for submission under Article 13(2) was the sole responsibility of Member States, Member States will continue to be responsible for submission of additional data. However, the process has since moved on and Member States wanted a single agreed approach. Most of those Member States responsible for the claims qualifying for the further assessment met on 14 April to agree the modalities of the submission of data. Absent Member States were updated in writing following the meeting.

Modalities for the collection and submission of data for claims qualifying for the further assessment

Member States will take responsibility for the claims for which they originally submitted all or the majority of sub-entries, as reported on the consolidated list[2]. Responsibility for claims with equal numbers of sub-entries was agreed between relevant Member States present at the ad hoc meeting of 14 April. Claims for which no Member State is willing to take the responsibility will be removed from the list and will not be submitted to EFSA for further assessment.

In order to facilitate submission of new data, Member States will need to ensure that for each claim for which they are responsible an industry coordinator is appointed, through which submissions will be channeled, and that this is communicated to all other Member States involved. If, for any reason, that Member State's stakeholders will not coordinate the additional data, the claim will not progress; however if other interested parties in another Member State want to take on this role, the responsible Member State should make this possible. My services will help to facilitate this and publicise which claims will not be submitted to EFSA due to lack of interest by industry stakeholders.

Member States shall ensure that industry co-ordinators will have taken into account to the maximum all interested parties in one or more Member States involved before submitting the data.

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[2] http://www.efsa.europa.eu/en/ndaclaims13/docs/art13claims.zip

Member States will have the responsibility to "validate" submissions. Validation would consist of checking submissions to ensure data is presented in the required format and that there is new and pertinent data, i.e. data not previously submitted. For claims on micro-organisms this would require *as a minimum* the data to characterise strains and possibly to demonstrate the cause and effect relationship between that characterised strain and the claimed effect. For claims where EFSA concluded that evidence is "insufficient", additional data to allow EFSA to further weigh the evidence is required.

Claims for which no new and pertinent data is submitted will not be submitted to EFSA for further assessment.

Format

Data submitted should be structured in accordance with guidance, developed in agreement with EFSA, in order to increase the chances of a positive outcome of the assessment.

As the purpose of the further assessment is to allow claims which are in the process to be fully assessed, Member States shall inform stakeholders that the health relationship originally submitted to EFSA should not be modified to change the claim. Equally, Member States should inform stakeholders that only one claim per ID number may be submitted, so if the original submission had several example wordings, this will not be converted into more than one claim. Additional claims, which are not under the scope of the process of further assessment, would have to be submitted pursuant to Article 13(5) of the Regulation.

Timing

Three months is usually foreseen for technical exercises such as the submission of new data, but given the administrative burden of coordination between stakeholders in different Member States and that the summer break will fall within this period, the period for the submission of new data will open on 1 June and will close on 30 September 2011.

Member States will have until the 31 October to complete their validation of submissions and administrative checks and forward the submissions to the Commission services. Time will be allocated in the claims working group meetings (July, September and October), if required by national experts, to discuss any problematic submissions in due time. In exceptional circumstances and taking into account how many submissions might eventually go for the further assessment, consideration may be given to duly justified requests for a very limited extension.

My services will make available to the appropriate service in the Member State a table showing the claims for which they will take responsibility, a table showing the status of eligible claims (when they will not progress for a further assessment and the reason why), and the aforementioned guidance for the format for submission of data in the further assessment.

Yours sincerely,

Paola Testori Coggi