



EHPM develops alternative model for article 13.1 claims assessment

3 July 2009

European trade organisation EHPM has published a model for the assessment of article 13.1 claims in a call for the authorities to help re-assess the article 13 process currently underway.

The model, which has been developed in conjunction with trade organisations ERNA, and the European Botanical Forum (EBF) is based on the European Union's nutrition and health claims regulation, the terms of reference and legal opinions, and has been scientifically reviewed.

The model, which has been sent to the European Commission and EFSA, addresses the different missions assigned to EFSA for the assessment of article 13.1 and article 14 claims, and shows that based on the format of the article 13.1 list it is impossible for EFSA to investigate a claim to the same level of detail as an application for an article 14 authorisation.

“The nutrition and health claims regulation makes it clear that there should be a different type of assessment for claims submitted for inclusion in the article 13.1 list and applications for authorisation under article 14,” said EHPM Chairman Peter van Doorn. “Both EFSA and the Commission continue to say that there is no distinction possible as to the criteria and level of scientific evidence. Our model shows that the application of the regulation's provisions and the terms of reference will automatically result in a different assessment criteria for article 13.1 claims than that required for article 14 claims.”

The model is an extensive document that analyses in detail the essential elements of the scientific assessment of article 13 list claims, such as to what extent the substance is sufficiently characterised or the claimed effect is beneficial for health; the extent to which a cause-effect relationship is established or whether the effect on the function is significant in relation to the quantity of the food; to what extent the specific study group(s) in which the evidence was obtained is representative; and whether the wording of the claim reflects the scientific evidence.

“It describes the elements we took on board when we started the compilation of the industry list, in the absence of official guidance,” said EHPM Director of Regulatory Affairs Lorène Courrège. “We now see that EFSA has stepped up these requirements and requested further information on half of the claims that have been submitted. This clearly indicates that there is a fundamental difference of understanding and we want to be able to discuss all aspects before the assessments proceed.”



The model also specifically addresses how, in line with the regulation's requirements for article 13.1 claims, the totality of the evidence and weighing this evidence needs to be considered for judging if claims are based upon generally accepted scientific evidence.

Ms Courrège said: "Rejecting claims because the level of information is not as detailed as that which would be required for article 14 claims would be irresponsible, as the law does not require this level of detail for article 13.1. It would oblige companies to re-submit their files under the authorisation procedure, which is not feasible for many SMEs and was not the intention of the law."

She added: "The principles of the EHPM, ERNA, EBF model are in line with the international guidance that Codex Alimentarius has just adopted on the scientific substantiation of health claims. Our approach will help to achieve the balance between the two main purposes of the law – that permitted claims are truthful and not misleading to the consumer, and that a stimulating environment for innovation is created that enables equal opportunities for all businesses, both large and small."

ENDS

Notes to Editor:

1. The European Federation of Associations of Health Product Manufacturers (EHPM) was created in 1975, working to provide consumers with safe, science-based, high quality products as well as accurate and helpful information about their nutritional value and use.
2. To contact EHPM email lorenecourrege@ehpm.be, tel + (32) 2 209 11 45, or visit www.ehpm.org