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EFSA receives alternative article 13.1 claims assessment model

By Lorraine Heller, 07-Jul-2009

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Food industry associations have banded together to present the European Food Safety Authority (EFSA) with an alternative model for assessing article 13.1 health claims.

Published by the European Federation of Associations of Health Product Manufacturers (EHPM), the model is based on the European Union's nutrition and health claims regulation and follows the fundamental understanding that under this regulation, [article 13.1](#) claims need to be assessed differently from [article 14](#) claims.

So far, EFSA has stuck by its position that it will apply the same assessment criteria to all health claims, be they generic (article 13) or relating to children's and disease reduction claims (article 14).

Flying in the face of the law

However, trade groups have repeatedly criticized this stand, saying that applying the same criteria across the board is against "the original intention of the law".

Article 13.1 claims include those linking vitamin, mineral and herbal extract consumption with health maintenance and are therefore, industry argues, more difficult to substantiate using the 'gold standard' approach which favours pharmaceutical intervention trials. Instead, trade groups claim the regulation was intended to respect national-level generic claims that are often based on generally-accepted scientific evidence

"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."

New model

The model, prepared in collaboration with the trade groups European Responsible Nutrition Alliance (ERNA) and the European Botanical Forum (EBF), addresses how the totality of the evidence and weighing this evidence needs to be considered for judging if claims are based upon generally accepted scientific evidence.

It also analyses the key elements of the scientific assessment of article 13 list claims, including:

- The extent to which 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
- The extent to which the specific study group(s) in which the evidence was obtained is representative
- Whether the wording of the claim reflects the scientific evidence

To access the model, click [here](#).

Tools to follow the rules

"We're not asking them to change the rules, but to follow the intentions of the regulation, and we're giving them the tools to do this," Lorène Courrège, EHPM director of regulatory affairs, told NutraIngredients.com.

She said the trade groups hope this model can be used to form a basis for discussion for a stakeholder meeting they hope will be held about article 13.1 claims.

The meeting they have called for would bring together EFSA, the European Commission, and member states to address clarification issues on the 13.1 claims assessment process – in much the same way as the meeting held by EFSA last month on [article 13.5](#) claims (based on emerging and proprietary science) and article 14 claims (children's health and development and disease reduction).

However, despite the fact that the general industry consensus from last month's meeting was that EFSA appeared "set in its ways" and "inflexible", Courrège said there are positive signs for an article 13.1 meeting.

"We have to continue to push but we're getting positive feedback because people [EFSA and member states] are realizing how difficult it is to address the clarification issues," she said.

But even if such a meeting were to be welcomed by all parties, it remains uncertain who would take responsibility for organizing it, as EFSA says it is

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