

*PRESS RELEASE*

## **Fundamental reappraisal of claims process needed says industry**

11 April 2011

The European Commission should undertake a discussion of the specificities and limitations of nutritional research and reappraise the claims evaluation process before rejecting claims based on EFSA opinions, three industry associations have said.

Commenting jointly on the fourth batch of claims opinions published by the European Food Safety Authority (EFSA) last week, European associations EHPM, ERNA and EBF said that continued reliance in the assessment process on criteria which are unfeasible and inappropriate for the majority of claims, is contributing to the high number of negative EFSA opinions.

The groups stated that on initial evaluation of the latest batch of opinions, trends have remained consistent in EFSA's assessment criteria as compared to the third batch published last year, despite weaknesses in the approach.

EHPM, ERNA and EBF again highlighted these weaknesses last month in a letter to Basil Mathioudakis, head of the European Commission's food law unit.

These weaknesses include the discrepancy between the way in which the information has been compiled and presented and the way in which EFSA is carrying out its assessments; EFSA's almost exclusive reliance on randomised controlled trials demonstrating measurable and meaningful improvements of health (also called the pharmaceutical approach); and the way in which the claims legislation is being interpreted, which the groups believe is unduly restrictive making it impossible to acknowledge and assess a number of health effects.

They further addressed EFSA's focus on isolated food components, which they said often do not exist in isolation, rather than on foods; the expectation that evidence should show improvement rather than maintenance of physiological functions; the fact that the approach is biased towards effects on reductions of disease risk factors, leaving many more general health effects unaddressed; and the lack of no visible consideration of existing consensus and views or opinions of leading experts in the various research fields.

The groups urged the European Commission not to take decisions to prohibit claims on the basis of negative EFSA opinions, but to allow these claims to be resubmitted for evaluation based on an alternative and more appropriate approach to consider the totality and a weighing of the evidence to provide a balanced view on the strength, consistency and plausibility of health benefits of food components.

“The EFSA approach has a number of weaknesses preventing the recognition of the health importance of many food components, and we remain concerned about the high number of unfavourable opinions relating to claims on other substances,” said Patrick Coppens, ERNA Secretary General. “It has now been widely recognised that the implementation of the claims legislation is a learning process and that consequences only become fully clear as the process progresses. While we appreciate the serious and professional way that the Commission has considered many of these issues, we are observing a mounting concern by the scientific community, which may ultimately affect the credibility of the European system. Many claims, for example, are receiving negative EFSA opinions because the format used to submit them is not consistent with the format adopted by EFSA to assess them. This is the result of no guidance being available for industry on the submission of claims, and as a consequence EFSA has rejected many claims without assessing the evidence.”

“The outcome of the process conveys to the public a message that the information provided by the European industry is of poor quality, while much of it is in fact the result of the process and the mismatch of what has been provided with expectations that only later became clear,” Peter Van Doorn, EHPM Chairman said. “We strongly believe that a number of rejections are not justified. In many cases a full consideration of the totality of the evidence and an approach based on nutritional science would be able to arrive at more differentiated conclusions as a basis for the possible acceptance of certain claims.”

**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 [lorenecourge@ehpm.be](mailto:lorenecourge@ehpm.be), tel + (32) 2 209 11 45, or visit [www.ehpm.org](http://www.ehpm.org)
3. The European Responsible Nutrition Alliance (ERNA) works with industry, consumer and regulatory bodies to tackle scientific and regulatory issues.
4. To contact ERNA email [secretariat@erna.be](mailto:secretariat@erna.be), tel (+32) 2 209 11 50, or visit [www.erna.org](http://www.erna.org)
5. The European Botanical Forum (EBF) is the European-wide organisation dedicated to addressing scientific and regulatory aspects of botanicals and botanical ingredients as foodstuffs. EBF strives to contribute to an optimal safety and appropriate labelling of those products and to secure a free and sustainable access to those products for European consumers using them for health purposes.
6. To contact the European Botanical Forum email [info@botanical-forum.be](mailto:info@botanical-forum.be), tel (+32) 2 209 11 50, or visit [www.botanicalforum.eu](http://www.botanicalforum.eu)
7. The letter with Joint comments addressed to Mr. Mathioudakis is available online at: <http://www.erna.org/Position-Papers.aspx>
8. The EFSA opinions on the article 13 list are available online at: <http://www.efsa.europa.eu/cs/Satellite>