POSITION PAPER
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Why the Community list of 'general function' health claims must be vetoed by the European Parliament

Current situation

The Nutrition and Health Claims Regulation (NHCR; No. 1924/2006)[1] was intended to protect the public from misleading health and nutrition claims on commercial foods and food supplements, to facilitate informed consumer choice and improve the functioning of the single market (Recitals 1 and 2). The text of the NHCR mandates the compilation of a Community Register including authorised general function health claims (Recital 26, Articles 13.1 and 20) that will be permitted EU-wide. The Community Register is also intended to include a list of rejected health claims, including reasons for their rejection (Article 20).

Assessment of general function health claims by the European Food Safety Authority (EFSA) was completed in late 2011. The proposed Community list of authorised health claims includes a total of just 222 health claims, applicable to only 70 foods and food ingredients. Six months following the proposed list's adoption into EU law, only those general function health claims permitted on the Community Register will be allowed on commercial products (Article 28).

EFSA's assessment of health claims for most botanical products and probiotics was placed on hold following industry complaints over high (in excess of 95%) rates of negative opinions from EFSA. Resumption of the assessment process is contingent upon EFSA's decision on whether to amend its assessment procedure for botanical and probiotic health claims.

Problems with implementation of Article 13.1 general function health claims

The proposed implementation of the Regulation does not meet the Regulation's intent for the following reasons:

1. Legal disproportionality

Delaying authorisation of most botanical and all probiotic health claims results in disproportionality, given that the status of these claims will remain unclear as compared with claims that have been successfully evaluated and added to the Community Register of authorised claims. A small number of botanicals have been included in the proposed Article 13.1 list (e.g. various plant sources of fibre, konjac mannan, fruit pectins, plant sterols and olive oil polyphenols), yet the majority await re-evaluation. Further disproportionality occurs if botanical and probiotic health claims are subsequently authorised under a revised, more lenient assessment procedure.

2. Unequal competition

The proposed implementation of the Regulation would create unequal competition (thereby contravening Recital 9), by favouring processed foods and ingredients manufactured by large corporations over wholesome and healthy foods and food ingredients, for which costly human studies are unnecessary and inappropriate. Such foods and ingredients are often the mainstay of health food stores. Also, authorising general function health claims in successive batches provides an advantage to companies selling foods or ingredients bearing health claims that are successfully authorised in earlier, as opposed to later, batches.

3. Unclear and inappropriate assessment criteria

EFSA has more than once altered its methods of assessment of health claims since the Regulation came into force in July 2007. In 2008, for example, it decided to reject applications unless they were supported by human studies, despite this requirement not having been specified prior to the submission deadline in Member States. EFSA is currently determining whether different methods of assessment are required for botanicals and probiotics, compared with foods and food ingredients. Furthermore, EFSA has incorrectly used similar criteria for Article 13 and 14 claims; Recital 26 states specifically that these two groups of claims "should undergo a different type of assessment and authorisation". Finally, the present assessment methods do not adequately take into account plausible evidence from biochemical, observational and epidemiological studies, which greatly contribute to generally accepted knowledge of the benefits of specific foods and nutrients.

[1] *http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1924:20080304:EN:PDF.*

ANH International
The Atrium, Curtis Road, Curtis Road, Dorking, Surrey RH4 1XA United Kingdom
e: info@anh-europe.org **t:** +44 (0)1306 646 600 **t:** +44 (0)1306 646 552
www.anh-europe.org

ANH-Intl Regional Offices
EUROPE USA
anh-europe.org anh-usa.org

4. Proposed claims list does not accurately reflect nutritional science

An important aspect of the Regulation is to facilitate informed consumer choice (Recitals 1 and 9). The proposed Community Register of permitted Article 13.1 health claims principally includes vitamins and minerals, along with miscellaneous foods or food ingredients, such as various sources of plant fibre and a small number of botanical substances. Among the health claims rejected by EFSA, or that are awaiting re-evaluation by EFSA, are some of the most important nutritional constituents for human health and wellbeing. These include the very diverse range of substances found in fruits and vegetables, other than vitamins and minerals. Accordingly, the proposed list of general function health claims does not reflect the state of knowledge of nutritional science. Its implementation prior to the re-evaluation of botanicals, and especially those associated with fruit and vegetable food sources, would therefore be premature.

5. Excessively wide remit of the Regulation and its implementation

The Regulation has been implemented in such a way that well-known and generally accepted claims for a large number of foods or ingredients will be unavailable for use by food business operators, owing to their rejection by EFSA (e.g. glucosamine for joint health, cranberry juice for urinary health, lutein for vision). The Regulation applies equally to the written and spoken word, and will therefore prevent, for example, health-store retail staff from discussing such relationships with members of the public, thus impeding consumer informed choice.

6. The Commission has yet to evaluate the Regulation's impact on consumer behaviour

There has been no attempt by the Commission to evaluate how the Regulation might impact consumer behaviour and dietary choices. In addition, the Regulation requires that, by 19 January 2013 at the latest, the Commission "include an evaluation of the impact of this Regulation on dietary choices and the potential impact on obesity and non-communicable diseases" (Article 27), yet there has been no baseline study to allow the direct comparison of baseline data with those derived following the implementation of the Community Register of health claims. Such baseline data are required if a meaningful evaluation is to be undertaken by the Commission.

Solutions

1. The European Parliament should veto the existing list of 222 EFSA-approved health claims in order to temporarily halt the legislative process, to allow the implementation of the Regulation in such ways that it is legally proportionate, helps inform consumer choice and does not create conditions of unequal competition in the EU single market. The veto would thus not result in the collapse of the whole legislative system, but would delay it and reduce the likelihood of subsequent judicial review.
2. The European Parliament should resolve to request EFSA to alter its methods of assessment for general function (Article 13.1) health claims, as inferred in Recital 26. Such assessments should differ from those used for Article 14 disease risk reduction health claims and should include all plausible evidence concerning the heath benefits of the substance under consideration. This may include biochemical evidence, animal studies, and epidemiological, observational and clinical studies of both diseased and healthy humans.
3. The European Parliament should resolve that it will not accept a Community list of general function health claims until the EFSA criteria for assessment of all 4,637 claims[2] have been agreed.
4. The European Parliament should request that the Commission delays publication of the Article 13.1 list of rejected health claims on the Community Register[3] until the above stated problems associated with the Regulation's implementation and assessment have been resolved.
5. The European Parliament should also urge the European Commission to undertake a baseline study of consumer behaviour and dietary choices in a number of Member States in order to provide a baseline for comparison with data acquired subsequently (as per the requirement in Article 27).

[2] *http://www.efsa.europa.eu/en/topics/topic/article13.htm.*
[3] *http://ec.europa.eu/nuhclaims.*