

NUTRITION AND HEALTH CLAIMS REGULATION Article 13.1 health claims list

REASONS WHY ENVI MEMBERS SHOULD OBJECT TO THE PROPOSED HEALTH CLAIMS LIST ON 9TH FEBRUARY 2012



The principal aims of this MEP information pack are four-fold:

- 1. To provide ENVI members with detailed reasons why, in the view of the Alliance for Natural Health International (ANH-Intl) following years of research and evaluation of opinions, it would be inappropriate to support the passage of the existing form of the Article 13.1 health claims list into EU law (pages 3–4)
- 2. The information in this pack appeals to ENVI members to support an objection to the proposed measure, so exercising the Parliament's right of veto according to the 'regulatory procedure with scrutiny' (RPS). The ENVI internal deadline for objection is 9th February 2012
- 3. The pack also provides reasons why the proposed Article 13.1 list, in its present form, is inappropriate for European citizens and consumers (pages 5–6)
- 4. Finally, the pack includes background about ANH-Intl, a leading non-governmental science- and law-based campaign organisation focusing on natural and sustainable healthcare (page 6).

Personnel from ANH-Intl will be visiting the European Parliament in the coming days and are in the process of booking meetings. Please email info@anh-europe.org or telephone +44 (0)1306 646 600 should you be interested in discussing the proposal for the Article 13.1 health claims list.

For further information, go to:

http://anh-europe.org/health-claims-veto-2012

or search 'health claims' at ANH-Intl's European website, www.anh-europe.org.

Thank you.

JUSTIFICATIONS FOR VETO

1. Allowing only 222 authorised, 'general function' health claims, while rejecting some 2,500 other health claims, contravenes the intended purpose of the Regulation.

While the Regulation aims to disallow misleading claims to the consumer, the removal of the majority of scientifically supported health claims from the marketplace will limit consumers' ability to make informed nutritional choices (Recitals 1, 9 and 10). Such information is of vital significance to consumers at a time when diet- and lifestyle-related diseases are seen to represent the main burden on healthcare systems.

2. EFSA's scientific opinions, which have led to rejection of 92% of the 2,758 health claims that have been evaluated, do not correspond with the state-of-the-art findings of nutritional science.

Nutritional science has evolved over recent decades through the interpretation of molecular, biochemical, epidemiological, observational and clinical data. Major reasons for such a high rejection rate of evaluated health claims are: the over-reliance on data from human clinical (intervention) studies; the exclusion of other sources as primary evidence; and the need for studies to relate only to healthy, as opposed to diseased, populations. The 92% rejection rate occurs against a background of ample evidence of health benefits for many thousands of foods and food ingredients, e.g. prunes and bowel function, probiotics and gastrointestinal health, glucosamine and joint health.

3. Mandating the proposed list, while also prohibiting claims that have not received positive opinions by EFSA, contravenes the European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR) that is referenced in the Treaty on the Functioning of the European Union (TFEU).

The ECHR asserts that EU action "shall be directed towards improving public health [and] preventing physical and mental illness and diseases". It also states that "such action shall cover the fight against the major scourges, by promoting...health information and education..." (Article 168, ECHR). The removal of so much health information associated with commercial products therefore contravenes these and other provisions, including EU citizens' right to information and education (Article 168, ECHR).

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4. Committing the existing list into European law is premature, given that botanicals and probiotics have been separated from the main list of 'general function' (Article 13.1) health claims.

The Regulation envisages the passage of a single Community list of authorised 'general function' health claims (Article 13.3). Around 1,500 proposed health claims for botanicals and probiotics have been separated from the 2,758 claims that have completed evaluation by EFSA. This separation creates disproportionality, given that claims for the outstanding group will be subjected to national rules, while those from the main group will be harmonised EU-wide within six months of publication of the Community list. Further disproportionality will result if botanicals and probiotics are evaluated by EFSA against criteria which are different from those of the main group.

5. While large food corporations and their trade associations support the passage of the proposed list into European law, small- to medium-sized enterprises and their representative associations have consistently opposed key provisions.

Transnational food corporations have been the primary stakeholder group supporting the evaluation methods used by EFSA to assess health claims. Small-to-medium-sized enterprises (SMEs), in contrast, have consistently voiced objections to what are deemed inappropriate scientific methods of evaluation that fail to recognise the importance of specific foods and food ingredients in maintaining and managing health and wellbeing. A regime that favours large corporations will skew product supply as well as research and innovation, with transnational companies being the main winners, and health-conscious consumers and SMEs the main losers.

 There has been no adequate, relevant consumer-orientated research to evaluate the impact of the imposition of a narrow range of authorised 'general function' health claims relating to commercial foods and food ingredients.

The purpose of the Regulation is, among other things, "to protect all consumers from misleading claims" (Recital 16) on commercial food products and food ingredients, and to ensure consumers are given "the necessary information to make choices in full knowledge of the facts" (Recital 9). However, prior to the imposition of the Article 13.1 list, there has been no attempt to evaluate consumer behaviour in a marketplace with so few health claims, or one in which the same small clutch of claims are repeated on a diverse range of commercial food or food supplement products. Additionally, the long-term effect of a highly restricted health claims environment on product development and availability, and the consequent effect on consumer choice and public health, have also not been evaluated.

REASONS WHY PROPOSED HEALTH CLAIMS LIST IS NOT IN THE INTEREST OF EUROPEAN CITIZENS AND CONSUMERS

1. Millions will be prevented from taking control of their health through diet and lifestyle.

The public needs information about the health benefits of foods in order to make informed choices relating to diet and lifestyle. Chronic, degenerative diseases like cancer, heart disease, obesity and diabetes are recognised by international health authorities and the scientific community as being caused largely by inappropriate diets and lifestyles. A lack of information will increase the risks of these diseases.

2. The negative impact on future generations will be even greater than on the current generation, which already understands the links between diet and lifestyle, and health and wellbeing.

Many of us have learned about the health benefits of foods, herbs and natural health products because the companies making or selling the products have been able to communicate openly about scientific findings that relate to their products. Future generations will not have this advantage. Consequently, they will find it much harder to make healthy food choices and will have less understanding of how specific foods or ingredients can support the optimum function of their bodies.

3. The drastic reduction of health information in the marketplace will discriminate against lower socio-economic groups wanting the best for their families.

The population groups that will be most severely affected will be the poorest and least educated – those with less time available or lacking the knowledge needed to make appropriate food choices. These groups currently suffer most from diet- and lifestyle-related diseases, placing the greatest burden on healthcare systems. In an age when obesity-related diseases are rampant, it is particularly disconcerting that information on foods and food ingredients that help support weight loss will be so lacking.

4. Large corporations will be the primary beneficiaries.

The large food corporations have sufficient resources to undertake the human clinical (intervention) studies needed to establish causal relationships between consuming a food or food ingredient and a specific health benefit. This relationship must be shown in healthy people for a health claim to be authorised. These kinds of studies were designed for pharmaceutical products, and are less relevant and appropriate for foods and nutrients with which

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humans have evolved over millennia.

5. Freedom of speech and fundamental rights will be infringed.

The inability of food or food supplement producers to communicate freely to the public and reference published scientific studies infringes commercial free speech. While it is right that misleading claims are disallowed, the vast majority of health claims that will need to be removed following the imposition of the list are not misleading; they simply do not meet the inappropriate and unnecessarily stringent criteria required by the European institutions for authorisation of claims.

6. The proposed regime will stifle innovation.

Many smaller companies will have little incentive to innovate given the very onerous requirements for authorised health claims that will become their only option for communicating the benefits of their products to consumers. Historically, small companies have been the main innovators in the health food sector and these restrictions will result in business closures, increased unemployment and unnecessary economic hardship.

ABOUT ALLIANCE FOR NATURAL HEALTH INTERNATIONAL

Alliance for Natural Health International is a non-governmental organisation dedicated to protecting and promoting natural and sustainable healthcare using the tools of 'good science' and 'good law'. It is an international alliance of consumers, practitioners, doctors, scientists and lawyers, as well as specialist natural health enterprises, all with a common goal of optimising human health using, as far as possible, approaches that are compatible with human physiology and our genetic backgrounds. The World Health Organization, and other leading health authorities, have confirmed that the major burdens on healthcare systems the world over are now caused by largely preventable, chronic diseases. Since prevention of these diseases needs to be mediated largely through dietary and lifestyle changes, the EU's Nutrition and Health Claims Regulation, and in particular its power to authorise and ban health claims, is of vital significance to European citizens' ability to make informed choices over the foods and ingredients consumed.

ANH-Intl was established by sustainability scientist, Robert Verkerk PhD, in 2002, and Dr Verkerk remains its executive and scientific director.

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