

Health claims

An opportunity for science

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The year 2012 will be remembered by the European food industry for a long time. Following the acceptance of Regulation (EU) No 432/2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health in May, thousands of unsubstantiated health claims on foods will become illegal on 14 December 2012. The food industry is investing to harmonise all relevant labelling and is measuring the 'economic damage' in millions of euros. Yet, at the same time, food products are being reformulated. Unfortunately, in many cases the goal of such reformulation is not to create better functional foods, but simply to enable the use of authorised health claims. Another problem is health claims for botanicals for which scientific evaluations have been put "on hold". These are in a privileged position compared to other food ingredients with unsubstantiated claims.



THE REFORMULATION OF FUNCTIONAL FOODS OR HOW TO ADD A PINCH OF VITAMIN

Health claims in the EU have been regulated to protect the consumer against misleading claims and to harmonise the European market. In addition, to avoid a situation where claims could mask the overall nutritional status of a food product and confuse consumers when trying to make healthy choices in the context of a balanced diet, the regulation introduced nutrient profiles. It was expected that this would call for extensive reformulations to enable the use of existing claims on some foods, particularly in the direction of reducing saturated fats, sugar and salt content. But since nutrient profiles have not been implemented (1, 2), there is no need for this. Nevertheless, a different kind of reformulation has commenced. Many functional ingredients have ended up without permitted health claims and most labels of functional foods have come into question. In many cases, whole brands could become illegal. To resolve this, the industry has launched a wave of reformulations to enable the use of authorised health claims – to add (a pinch of) vitamin and start using health claims about their role in body functions. Vitamins and minerals have been the winners of the health claims substantiation process and it was a logical solution of the industry to use them to enable its claims and brands. Did you know that vitamin C contributes to the normal functioning of the immune system, to maintaining the normal functioning of the immune system during and after intense physical exercise, to normal collagen formation (for the normal functioning of blood vessels, bones, teeth, cartilage, gums and skin), to a normal energy-yielding metabolism, to the normal functioning of the nervous system, to normal psychological function, to the reduction of tiredness and fatigue, to the protection of cells from oxidative stress, to the regeneration of the reduced form of vitamin E and that it increases iron absorption? Imagine a product containing vitamin C and the possibilities for health claims on the basis of these 15 authorised health claims and being aware that general, non-specific claims are also possible if accompanied by a specific health claim. The objective of the legislator when accepting the Regulation on nutrition and health claims made on foods in 2006 was to ensure the effective functioning of the internal market whilst providing a high level of consumer protection, but I am not sure if the above mentioned practices are what we have expected from the regulation.

BOTANICALS: FOOD OR MEDICINE?

Botanicals are plant and herbal substances with a long tradition of being used in both food and medicine. As a medicinal product, botanicals can be registered using a simplified traditional use registration and sold as Traditional Herbal Medicinal Products (THMP). For such products, there is no requirement for clinical trials on the effectiveness of the product, although products must have sufficient safety data and their production must comply with Good Manufacturing Practices (GMP). On the contrary, when botanicals are used as food supplements, there is no special requirement regarding manufacturing practices other than for foods alone, although the final product should be safe for use and labelled in line with the legislation pertaining to food, including the regulation on health claims.

Health claims must be substantiated by scientific evidence of the highest possible standard and traditional use is not accepted as sufficient evidence. In the scientific assessments of the European Food Safety Authority (EFSA) a number of health claims applications for botanicals have therefore received negative opinions. In September 2010, the Commission decided it was not possible to continue with the assessment of health claims for botanicals and the EFSA was asked to discontinue its assessment of claims for botanicals with the result that these, together with a number of already assessed botanicals, have been put on hold (3). Currently, two possible solutions for these claims have been floated. One is to continue the scientific evaluations by applying the same criteria and standards as for other food ingredients. In practice, this would mean negative opinions for the vast majority of claims made for botanicals. The other solution is to adopt a regulation and establish different rules that recognise their traditional use. In this case, the use of botanicals in the EU market would also have to be harmonised because there are major differences among the member states concerning how products containing botanicals are classified.

AN OPPORTUNITY FOR SCIENCE

In the past the industry financed a number of very expensive trials were often not performed using standards that would enable the successful substantiation of health claims. The process of scientifically evaluating health claims is a steep learning curve and important lessons can be learned from the existing opinions. In addition, the EFSA has made available its guidance on the scientific requirements for health claims related to the most common functions. Recently, two additional guides were published, one covering functions of the nervous system, including psychological functions (4) and the other concerning health claims related to physical performance (5). It has been shown that relevant human intervention studies are critically important for the proper substantiation of a health claim, and that many negative opinions could also be connected with some basic errors which might be avoided. I will finish with the same ending as one year ago: Simple enrichment with some vitamins and minerals will not bring us toward universal healthy foods. Food research must continue at the highest possible level.

REFERENCES AND NOTES

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