Health claims
Where are we now and where are we going?

IGOR PRAVST
Nutrition institute, Ljubljana, Slovenia
Member of AgroFOOD industry hi-tech's Scientific Advisory Board

Igor Pravst

In the last few years the regulation of health claims has been one of the top food-related themes discussed in Europe. At a time when we are approaching the inclusion of general function health claims in the Community Register, it is worthwhile asking where we are now and where we are going. One thing is certain: regulation of health claims in the EU was required. The protection of the consumer against misleading claims along with harmonisation of the European market have been key issues in need of addressing (1), but we should also not forget other objectives of Regulation 1924/2006 on nutrition and health claims made on foods. The regulation targets functional foods, a concept which emerged in Japan about 20 years ago to reduce the escalating health care costs with a category of foods offering potential health benefits, although from a different perspective. At the same time as Japan, the USA created a regulation to enable the use of health claims on food labels. Some EU member states were also at the frontier of such developments at the time, but the European Union as a whole was lagging far behind. It was decided that the use of pre-approved evidence-based health claims on food labels would serve us best and in the ensuing time there has been a focus on creating a list of approved claims. While the idea of functional foods to promote health has not been questioned, the regulation of health claims still significantly varies between continents. In this issue you can find some nice examples of this in the paper by *Dolan and Chaumont* (2).

The European Food Safety Authority (EFSA) is responsible for the scientific assessment of health claims and has almost finished most of the work related to general function health claims regarding foods or food constituents other than botanicals. Those receiving favourable opinions are currently in the procedure at the European Commission to finalise the wordings of the claims and conditions of use. The positions of member states are not yet harmonised and it is hard to expect that claims will be included in the Community Register before 2012. When this happens and after the transitional period of 6 months, the era of the use of unsubstantiated health claims will start to draw to a close. *Pauquai* addresses this in his commentary in this issue (3).

When looking at the list of health claims which have received the EFSA's positive opinion, we can obtain a rough picture of what we can expect in the Community Register. Although some member states are actively fighting some of these claims the majority will probably be authorised. About a year ago it was clear that essential nutrients would be a clear winner of the process (1) and this has not changed. In cases where a well-established consensus among scientists exists on the biological role of a nutrient, the EFSA relied on that consensus and confirmed the cause-and-effect relationship without reviewing the primary scientific studies. Most favourable opinions are therefore related to vitamins, minerals and certain other essential nutrients (i.e. proteins, essential fatty acids). In most cases, the proposed condition of use is to include at least 15 percent of the RDA of vitamin/mineral per 100g/ml of final product to enable the use of health claims for such a nutrient. This will enable products which are a source of at least one such nutrient to communicate health claims even in cases where there is no deficiency in the population. The consumer will recognise such a nutrient as a health added value and there are concerns that such claims might enable consumers to be legally misled. While the authorisation of such health claims may pose a risk of misleading the consumer, there are also cases where concerns related to public health arise. Such an example is a claim concerning phosphorus and its role in the maintenance of normal bone. The intake of phosphorus easily exceeds the recommendations and a bigger intake might have adverse effects for bone health (4). Therefore, both health and ethical concerns arise as to whether such claims should be allowed, even though science is not yet clear on this issue. A useful solution in such cases would be to authorise claims with more specific conditions of use.

When critically discussing the current situation I must also mention an important part of the legislation which has not yet been implemented. Foods promoted with claims may be perceived by consumers as having a health advantage over other foods and this may encourage consumers to make choices which directly influence their total intake of individual nutrients in a way which would run counter to scientific advice. The regulation aims to avoid a situation where claims 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 with the introduction of nutrient profiles. These should have been established by a deadline of January 2009. Yet we are in mid-2011 and it is not even clear if profiles will be implemented at all (5). What does this mean for the consumer? Producers will maintain the power to stimulate the consumption of foods with a poor nutritional status. In relation to this, the alarming potential of a chloride health claim to stimulate the consumption of sodium was discussed recently (5). With these shortcomings in the regulation we must count on the producers and their commitment to serve the consumer.

These issues are an indication that we are still far from the target – even if we only consider claims with positive opinions. The situation for producers applying for health claims (for non-essential ingredients) is even harder. Yet, there is still some room for optimism. The first specific dietary fibres have received favourable opinions in relation to the maintenance of normal cholesterol levels, the reduction of post-prandial glycaemic response and reduction of intestinal transit time. In addition, some other non-essential foods or food constituents have been getting onto the positive list in recent batches. A detailed examination of all the concerns raised by the EFSA in its published opinions, together with some additional advice about expectations related to the scientific substantiation of health claims, should result in the improved quality of clinical testing for bioactive components and functional foods. In relation to this, you can read a review covering clinical testing designs by *Demonty* in this issue (6). At the end, hopefully, producers will have an idea of how to perform clinical trials to show the beneficial effect and consumers will receive even better products and fair instructions for how to use them. But it must be made clear to us all – simple enrichment with some vitamins and minerals will not bring us toward universal healthy foods, even though many health claims will be authorised. Food research must continue at the highest possible level.

REFERENCES AND NOTES

1. I. Pravst, *AgroFood Industry hi-Tech*, **21(4)**, pp. 4-6 (2010).
2. L.C. Dolan et al., *AgroFOOD industry hi-tech*, **22(4)**, pp 5-7 (2011).
3. T. Pauquai, *AgroFOOD industry hi-tech*, **22(4)**, pp 8-9 (2011).
4. I. Pravst, *Food Policy*, (2011). In press (doi:10.1016/j.foodpol.2011.05.005).
5. F.P. Cappuccio et al., *Brit. J. Nutr.*, (2011). In press (doi:10.1017/S0007114511002856).
6. I. Demonty, *AgroFOOD industry hi-tech*, **22(4)**, pp 10-13 (2011).

EFSA PUBLISHES FIFTH SERIES OF EVALUATIONS OF 'GENERAL FUNCTION' HEALTH CLAIMS

On 30 June 2011 EFSA's NDA panel (1) finalised the evaluation of all 'general function' health claims (2) due to be adopted by that date. With the publication of this fifth series of scientific opinions, EFSA adds an additional 536 claims to the 2,187 claims published to date. The European Commission and Member States will then consider EFSA's scientific advice in deciding on the possible authorisation of such claims for food products. EFSA is liaising closely with the European Commission and stands ready to provide any further support which could be required in the assessment of 'general function' health claims. Of the 536 claims evaluated in this latest series, favourable outcomes include the relation between specific dietary fibres and blood cholesterol; cereal fibre and bowel function; carbohydrate-electrolyte drinks and endurance performance; low sodium and blood pressure; dietary fibre and reduced increase in blood glucose after meals; melatonin and sleep onset and very low calorie diet in relation of body weight. Other claims in this series received unfavourable evaluations because NDA Panel experts concluded that they were not sufficiently specific, such as claims on "women's health" or "mental energy", or that they referred to food categories which were considered to be too broad, such as "fruits and vegetables", "dairy products", to be linked to specific effects. Other claims were unfavourably assessed because they were not supported by any relevant studies in humans. Such studies are central to the establishment of a cause and effect relationship between the food or substance concerned and the beneficial health effect claimed.

References and Notes

1. EFSA Panel on Dietetic Products, Nutrition and Allergies.
2. 'General function' claims defined under Article 13.1 of the Regulation (EC) No 1924/2006 on nutrition and health claims made on food include: The role of a nutrient/substance in growth, development and the functions of the body; psychological and behavioural functions; slimming and weight control or reduction of hunger, increase of satiety or the reduction of available energy from the diet. These claims do not include those related to children's development or health or disease risk reduction.
3. Out of the 4,637 claims submitted to EFSA by the European Commission between July 2008 and March 2010, the European Commission asked EFSA to evaluate 2,758 claims by June 2011, 331 claims were withdrawn and 1,548 claims on "botanicals" have been placed on hold by the Commission pending further consideration on how to proceed with these.

Timeline of publications of EFSA's evaluations in this area:

- 1st October 2009, 521 health claims addressed in 94 opinions
- 25th February 2010, 416 health claims covered in 31 opinions
- 19th October 2010, 808 health claims, addressed in 75 opinions
- 8th April 2011, 442 health claims, addressed in 63 opinions
- 30th June 2011, 536 health claims, addressed in 73 opinions
- July 2011, 35 health claims addressed in 5 opinions

EFSA RECEIVES ORIGINAL STUDIES ON ASPARTAME IN ITS PUBLIC CALL FOR DATA

The European Food Safety Authority (EFSA) has launched a public call for data on the artificial sweetener aspartame (E 951) for consideration in a full re-evaluation to be completed in 2012 as requested by the European Commission. Among data so far received are 112 original studies submitted to support the request for authorisation of aspartame in Europe in the early 1980s. The public call for data, which runs until 30 September 2011, was launched to ensure that EFSA's first full risk assessment of the safety of aspartame will be the most thorough and up-to-date yet. To complete its evaluation, EFSA is asking for all available scientific and technical data – published, unpublished and newly generated – related to aspartame in food and drinks and as a table-top sweetener. EFSA has carried out a substantial body of work on aspartame over the years and has regularly reviewed new studies published on the substance. Had any evidence been found that would have led EFSA's experts to reconsider the previous risk assessments by the Scientific Committee on Food (SCF) and to review the Acceptable Daily Intake (ADI), then they would have done so. EFSA has so far not carried out a full re-evaluation of the safety of aspartame. In May 2011, EFSA accepted a request from the European Commission for the re-evaluation of the artificial sweetener in 2012. Due to EFSA's scientific cooperation efforts, particularly with its partners in EU Member States, on-going liaison with the European Commission, international partners and its stakeholder dialogue, EFSA can draw on a well-established network to ensure that all the relevant data are considered. This network helps to disseminate news of the call and identify

sources of data and scientific literature. EFSA's partners can also provide advice and assistance to scientists, researchers and other interested parties to help them identify the data that could support EFSA's forthcoming evaluation and its robustness. Following the public call for data, a document summarising the relevant data available will be prepared. These data will then be considered for the risk assessment.

News edited by
GAYLE DE MARIA
AgroFOOD industry hi-tech
gayle@teknoscienze.com