Assessment and Management of Health Claims in Europe 9 Years after the Adoption of the Regulation

Ambroise Martin
Chair of the Panel on Dietetic Products, Nutrition and Allergy (NDA Panel) of the European Food Safety Authority (EFSA)

Summary The European regulation 1924/2006 foresees that any nutrition or health claim should be assessed by EFSA and authorised by the European Commission and the Member States (with scrutiny by the European Parliament and the Council), the outcomes of which are published in the EU Register of Nutrition and Health Claims. Since 2007, EFSA has evaluated 230 dossiers submitted under Article 13.5 or Article 14. In addition, out of the 44,000 ‘general function claims’, defined under Article 13.1, proposed by Member States, a list of 4,637 claims was compiled, EFSA completed evaluation of 2,849 of them, and published the results in 365 opinions, providing the basis for a list of 229 permitted health claims. For maintaining consistency over time and scientific areas, EFSA developed a systematic approach (for food characterisation, effect characterisation and scientific substantiation). Pertinent human studies of sufficient quality are central for the substantiation; any other study type can be used as supportive. This approach is summarized in 6 guidance documents. These guidance documents are revised progressively, which includes systematic submission to public consultation.

Key Words claims, regulation, assessment, guidance

The European regulation 1924/2006 (1) was adopted in December 2006 in order to improve the free movement of foods within the European market; it introduced two major changes in the management of nutrition and health claims in European countries: the first was the need for an authorisation from the European Commission (after scrutiny by the European Parliament and the Council) after a favourable scientific assessment performed by the European Food Safety Authority (EFSA) before any claim can be used on food labels; the second was the need for a food to comply with a nutrient profile before a claim can be made for it. To date, the second requirement has not yet been implemented due to the difficulties for reaching an agreement between the European Member States on a nutrient profile system; the first requirement has been fully in force since December 2012, after the adoption and the publication in the European Register of the initial list of permitted health claims (http://ec.europa.eu/nuhclaims/).

Different Types of Claims
“General function claims” are defined by and known as article 13.1 claims: they were collected by EU Member states from interested stakeholders and compiled by the services of the European Commission; since they were considered as being based on well-established evidence, no dossier was required and EFSA was provided only with a table including the name of the food, the health relationship and examples of wording, together with a list of supportive scientific references. The Commission received more than 44,000 claims: the cleaning of this big database (eliminating duplicates, medicinal claims, vague claims, and others) took almost one year and resulted in a list of 4,367 claims transmitted to EFSA in June 2008; during this period, EFSA defined the general principles for assessment and the general structure of all the claim opinions. EFSA completed the evaluation of 2,849 of these “general function claims” (331 claims were withdrawn and 1,548 claims on “botanicals” have been placed on hold by the European Commission), and published the results in 365 opinions, providing the basis for a list of 229 health claims authorised by the European Commission in June 2012.

Though the scientific assessment should theoretically provide similar results throughout the world, indeed the precise regulatory context leads sometimes to different outcomes (2). A first example is given by the absence of the possibility to define “qualified claims” (i.e. claims including in their wording some form of grading of the supportive evidence) in the European regulation, so that only a “yes or no” answer for the existence of a cause and effect relationship between the food and the claimed effect is generally given by EFSA; even in the rare cases where the evidence was considered as insufficient, the final outcome remains binary: authorisation or non-authorisation of the proposed claim. The second example is the legal absence of product-specific claims in Europe, according to article 17.5 of the regulation, where it is stated that “health claims included in the lists provided for in Articles 13 and 14 may be used, in conformity with the conditions applying to them, by any food business operator, if they are not restricted for use in accordance with the provisions of Article 21”. Article 21 refers to the protection of proprietary data which in
practice allows restricting the use of the claim to the applicant for which EFSA recognised that the favourable outcome could have not been reached without the study/ies claimed as proprietary (which means that the results of the study/ies were not yet published at the date of submission of the dossier).

**Scientific Assessment**

Three major issues are addressed in all the claim opinions: characterisation of the food, characterisation of the effect and of the target population, and substantiation of the claim.

Food characterisation is a critical point that led to a lot of negative opinions for article 13.1 claims and was also frequently neglected in the first dossiers received: a sufficient characterisation (in relation to the claimed effect) should be provided for assessing the relevance of the studies/papers submitted for substantiation, for defining conditions of use and for allowing any other business operator to use the claim in accordance with these conditions of use. Characterisation can be done very precisely in the case of single molecules or can use a combination of characteristics (such as preparation process and standardization on a representative molecule) for complex foods. For microorganisms where the strain specificity of the effect is consensually recognized, the genomic characterisation is required. For a combination of food/substances, each part of the combination should be sufficiently characterised. For “innovative” foods, reproducibility of the process and stability of the food over time should also be considered. Finally, sufficient characterisation is needed for objective control of claims by public authorities.

The effect should be sufficiently characterised so that its beneficial character for health can be assessed and so that it can be efficiently measured by the use of validated techniques (clinical, physical, biological or other quantitative measurements, including questionnaires). Thus, the modification of a biological or clinical parameter, even significant statistically, is not sufficient if the relevance of this modification for a health benefit is not ascertained. In this field, scientific evaluation can always been done, but some decisions are under the remit of risk managers (Member States and European Commission), such as cosmetic claims (where a beneficial effect for health is questionable) or claims addressing side effects of drugs (by definition consumed by diseased people); authorising claims on probiotics that would decrease the risk of antibiotic-associated diarrhoea are an example of this type of extra-scientific issues.

In this assessment, the Panel considers not only the argumentation of the applicant but also guidelines developed at the national or international levels by scientific societies or authoritative bodies, as far as they have been elaborated in an up-to-date and transparent way. By default, the target population for the claim is the healthy general population (from children above 3 y of age to very elderly); however, a claim can target a restricted subgroup of population which can easily recognize itself as concerned by the claim, such as physically active people, postmenopausal women or people who want to maintain a normal weight or a normal blood cholesterol level. Because European regulation still prohibits any claim that states that a food can prevent, treat or cure a disease, the reduction in the risk of a disease cannot be the subject of a claim, but only the beneficial modification of a risk factor. From the dossiers submitted until now, only LDL-Cholesterol and blood pressure have been recognized by the NDA Panel as well-established risk factors. For the other potential risk factors, the concomitant modification of the factor and of the disease risk by consumption of the food must be demonstrated, preferably in the same studies. There is no formal request for conducting studies in European populations, but the possibility of extrapolation to European subjects of the results conducted in non-European subjects may be sometimes required, on a case-by-case basis.

**Scientific Substantiation of the Claim**

For many generic claims on essential nutrients, it was considered that a lot of well-established functions have already been assessed by many other authoritative bodies and are consensually reported in most of the textbooks, so that coming back to original studies would have been a waste of time and effort. Therefore, the work of the Panel focused on non-well-established functions of non-essential and essential nutrients, which imposed the careful analysis of the relevant scientific studies.

The selection of the pertinent studies (out of a transparent and comprehensive literature search) for substantiating a claim is totally dependent on the characteristics assessed in the two previous steps. In the light of recital 23 of the regulation, stating “Health claims should only be authorised for use in the [EU] Community after a scientific assessment of the highest possible standard”, the Panel considered human studies of sufficient quality to be central for claim substantiation: animal studies cannot accurately predict the occurrence of an effect in humans and the application of high standards was considered as the only way to limit arbitrariness in the relatively short time assessment of such a huge number of claims. Since “A claim should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence” according to recital 17 of the regulation, there is no prefixed number or type of studies which should be submitted.

The quality of a study can only be assessed if there is a reporting of good quality, so that scientific conclusions can be drawn. Many published papers do not meet the high quality of reporting recommended by international consensus (see recent guidelines in http://www.equator-network.org). In particular, poor statistical reporting is a very frequent concern (not specific to NDA applications) that led EFSA to develop specific guidelines on this issue (http://www.efsa.europa.eu/en/efsajournal/doc/3908.pdf). Any uncertainty in the interpretation of submitted data leads the Panel to apply the stop-the-clock procedure, organised according to the
Guidance Documents

Early in the process (2007), the Panel issued general guidelines on the structure and content of dossiers submitted for claim assessment; in addition, based on the experience gained during 3 y of intensive claim assessments, the NDA Panel adopted and published in 2011 and 2012 (after a public consultation) 6 guidance documents, covering the vast majority of the areas addressed by generic claims or specific applications: gut and immune function/antioxidants, oxidative damage and cardiovascular health/appetite ratings, weight management and blood glucose concentrations/bone, joints, skin and oral health/nervous system, including psychological functions/physical performance. These guidance documents provide positive lists of claims, for which target populations, study populations and relevant biomarkers have already been favourably assessed, so that they no longer deserve any justification for being used in new applications. However, these lists are also open lists, so that any new function or risk factor, new target or study population and new supportive relevant biomarker(s) can be proposed. In this way, it is more important to understand the rationale behind the proposed analyses than to look for “magic recipes”. The reading of the guidance documents together with the corresponding opinions is needed for such an understanding.

In order to improve the assistance to applicants, and beyond all the large amount of information already available on the EFSA website (http://www.efsa.europa.eu/en/nda/ndaguidelines.htm) and in the EFSA Journal, the Panel recently undertook an update of these guidance documents, using a new process including two public consultations: it must be pointed out that generally claims represent a unique combination of a food, of a health relationship and its suggested wording, and of a target population; therefore, it is quite impossible to decide in advance what could be acceptable for any combination, or toavour an a priori assessment of a given combination.

Conclusion

The assessment of such a number of claims in a constrained timeframe constituted a major challenge for scientists in EFSA. The “severity” of the global outcome has frequently been criticised though it may also be asserted that scientific rigor is a condition for the long-term credibility of the claim system for the consumer and may be an incentive for innovation as well as for improvement in the quality of research and its reporting in the nutrition area. Beyond the scientific assessment, the full story highlights the importance of the regulatory context and of the distinction between assessment and management. Moving towards a more harmonised approach around the world will likely require more efforts on the regulatory side than on the scientific assessment where a common scientific language already exists.

REFERENCES