

European Heart Network' position on Article 13.1 health claims

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Relevant to public health

From the early stages of the development of the health and nutrition claims regulation (claims regulation), EHN has argued that the paramount principle for the regulation should be the protection and promotion of public health.

Whilst the public health principle may not be explicitly set out in the claims regulation, it is clearly in the premises of it, as included in certain recitals, and it is, of course, clearly set out in the EU's governing Treaty (art. 168).

EHN considers that the majority of claims in the working document on the establishment of the list of permitted health claims under the claims regulation's article 13.1 are not relevant. Let it be clear, EHN is not questioning EFSA's scientific substantiation, merely pointing out that whereas EFSA examined the science behind the proposed claims, it was not requested to look at the public health relevance of them.

For example, in terms of reducing the burden of cardiovascular diseases, a main lever is to reduce intake of saturated fat and replace it with polyunsaturated fat – without increasing total fat intake. A claim, such as *Chitosan contributes to the maintenance of normal blood cholesterol*, may distract from the main public health message which is to consume less foods that are high in saturated fat. Instead people may be persuaded that by eating food that contains Chitosan they will achieve the same result. This is, of course, provided that they understand the claim.

Another example is the question of claims for vitamins and minerals for which there are no deficiencies in the general EU population. If there is no general deficiency or no dietary intake is required for the substance for which the claim is made, EHN considers that there is no public health relevance for such a claim. In fact, they would seem to be contrary to the general principles of the claims regulation as set out in its Article 3. Should subgroups of the population suffer from a deficiency in one or more vitamins, minerals or substances, such deficiencies should be diagnosed by a medical professional who is in a position to advise on the best sources of these nutrients in foods – they should not rely on claims on food packaging to help them tackle their deficiencies.

The question of deficiencies or inadequate intake has been recognised by EFSA in many of its opinions, stating that “The evidence provided does not establish that inadequate intake of

(nutrient) leading to impaired function of the above health relationships occurs in the general EU populations”.

To the extent that a claim lacks public health relevance, it is highly likely to be misleading.

Damaging to public health

In addition to the issues highlighted above, EHN is seriously concerned about the potential approval of claims that contradict general dietary recommendations and thwart large-scale interventions, at national and EU levels, to reduce the intake of the nutrients or substances for which claims have been substantiated.

In particular, we refer to the claim that *Sodium contributes to the maintenance of normal muscle function*. It is a fact that populations across the EU have too high an intake of sodium which is a concern for public health because of the risks of hypertension and strokes. A similar argument can be applied to a claim such as *Fat contributes to the normal absorption of fat-soluble vitamins*, where intake is generally too high in the EU populations leading also to high intakes of saturated fat. It is noticeable that in both cases, EFSA has not proposed any conditions of use.

Consumer understanding and truthfulness of claims

Reviewing the working document on the establishment of the list of permitted health claims, the majority of proposed claims are very difficult to understand. This is due to the fact that the terminology used is often very scientific and complex (e.g. Betaine contributes to normal homocysteine metabolism).

The claims regulation clearly states that claims used must be understood by the average consumer. EHN appreciates the challenge of developing wording for claims which reflects the scientific advice from EFSA while at the same time ensuring consumer understanding of these claims. However, it is our view that the wording of claims must be such that people can understand them. EHN is not in favour of leaving it up to the food business operators to choose the wording. In order for a health claim to be approved and put on a positive list of health claims, evidence that the average consumer understands them must be provided.

Under the claims regulation, the use of nutrition and health claims must not be false or misleading. For certain maintenance claims (blood cholesterol, blood pressure and blood sugar), EFSA has indicated that, in fact, a slight reduction in levels was observed in the studies of the effects of the nutrient. However, even if such reductions generally would not have any negative implications for health, reductions in blood pressure could potentially be harmful for people who have low blood pressure, without being aware of it. Again, claims that indicate *maintenance* when the outcome is, in fact, *reduction*, do not comply with the claims regulation’s general principle of being true (Article 3).

Nutrient Profiles

The development of nutrient profiles is central to the claims regulation as the profiles which are established will ultimately be used to define which foods are permitted to bear a claim. Without

these profiles, the claims which are in the positive list can appear on any foods. It is essential that robust, scientifically validated profiles are established before the end of the transition period following the adoption of the positive list in order to prevent consumers from being misled about the qualities of a food through the use of claims.