

ARTICLE 13.1 HEALTH CLAIMS UNDER REGULATION (EC) NO 1924/2006

EDA Argumentation Paper on Dairy Health Claims

Ü Introduction

Regulation 1924/2006 was introduced in an effort to harmonise legislation on nutrition and health claims across Europe. There are a variety of different types of health claims included in the regulation which require scientific substantiation by EFSA. The processes by which article 13 and 14 claims are submitted for substantiation are different. However, the evaluation criteria developed by the EFSA for the adjudication of the different types of claims require the same high level of scientific evidence for article 13 and 14 claims (with a focus on clinical studies), and the strength of the scientific evidence is not graded within an official Evidence-based Rating System, which would take into account all types of conclusions and consider their relative weight. In evaluation, EFSA is looking for:

- A cause and effect between the food or food substance and health.
- The claimed effect to be well defined and the food or food constituent to show a benefit.
- The food/food constituent to be well characterised.
- The quantity of the food/food constituent to be relevant to a balanced diet.
- The claim wording to reflect the science.
- The appropriate terms and conditions of use.

As a result, each application is examined on a case by case basis.

Ü EDA would like to discuss with EFSA the following technical issues which impede the passing of health claims:

Merging process

By 31 January 2009, the Commission had received more than 44,000 article 13.1 health claims from the national lists of Member States. These were consolidated into a list of 4,000 health claims (main entries covering several similar but not identical claims) and passed on to EFSA for evaluation. EFSA requires that science be specific to the claim as one of their criteria for a positive opinion but it is hard to see how consolidating 44,000 into 4,000 will allow any of the science submitted to remain specific enough for EFSA approval. This 'merging' process will undoubtedly have affected the relevance of the scientific studies to the wording of the claims and could mean claims are less likely to receive a favourable opinion. This could be a particular problem for food-related claims. For example, claim 1239 on "Dairy and blood pressure" merges claims that are actually quite different from each other. One claim concerns a "diet rich in low-fat dairy products", another claim is about dairy products in a diet rich in fruits and vegetables, and again another includes also proteins in the claim. The scientific studies are undoubtedly different and specific for each case.

Characterisation of foods and food groups

EFSA panel members have publically stated during the "EFSA technical meeting with applicants on recent developments on article 14 health claims applications" (held in Brussels, 15 June 2009) the difficulty they have in defining food groups and the difficulties they will have in adjudication of food based health claims.

One of the problems with this is that the scientific evidence which has been built up over the years and would be considered consensus science consists, in its majority, of studies which were carried out to look at the effect of a food or food substance on a specific endpoint and were concerned with the end result and not with defining and characterising foods. How milk, cheese or dairy is defined were not considerations in scientific studies looking, for instance, at dairy and bone health. However, characterisation and being able to show good characterisation from the literature is something that the EFSA is now looking for, which means that much of the scientific evidence gathered over decades will not be favourably viewed by the EFSA. This will give a competitive advantage to those with the capital to conduct their own clinical trials as opposed to those mainly using the already available information in the scientific literature. As a result of EFSA's apparent inability to characterise foods, EFSA has indicated that general food group claims - among them dairy claims - should be considered as claims that are based on new scientific evidence and therefore undergo the 13.5/14 claims evaluation procedure.

Another point about characterisation is that EFSA sometimes evaluates only one part of the claim and gives a negative opinion on truncated information. EDA is therefore concerned that some claims might be rejected for the wrong reasons. To illustrate this, the example of the claim 1143 / 2976 on “Yoghurt cultures (live) and lactose digestion” can be given. The first request of EFSA about probiotics is the characterisation of the strain. Indeed, the current state of evidence suggests that probiotic effects are strain specific. However, in the “Guidelines for the Evaluation of Probiotics in Food” FAO/WHO acknowledge that “a possible exception is the ability in general of *S. thermophilus* and *L. delbrueckii* ssp. *bulgaricus* to enhance lactose digestion in lactose intolerant individuals. In this case, or in other cases where there is suitable scientific substantiation of health benefits that are not strain specific, individual strain identity is not critical”. EDA is of the opinion that this demonstrates that the evaluation should not only take into account the characterisation but also the whole context of the claim, especially in the case of probiotics.

Scientific evaluation criteria

The EFSA provided two negative opinions for articles 14 health claims on dairy products related to children developments and health (dairy and body weight, dairy and dental health) arguing that the scientific evidence provided did not include intervention studies that specifically examine a cause and effect relationship. Those two health claims have therefore recently been rejected by the Commission and Member States.

Science available for dairy food health claims contrasts with the evaluation criteria applied by the EFSA for the scientific assessment - independent whether for article 13.1 or 13.5/14 health claims - as the health relationship for generic dairy foods are often similar and referring to the whole population. Intervention clinical studies - the “golden standard” - are difficult to perform with generic foods to prove a causal relationship. It is necessary to look at the totality of the data available. The quality level of science should always be the same but the nature of the evidence could be different and epidemiological studies e.g. observational, prospective etc. should also be taken into account for the scientific evaluation. The evaluation criteria should form a framework for the scientific assessment on a case-by-case basis that allows the consideration of the specificities of each health claim, the nature of the food or substance that is claimed on and the scientific evidence required.

Ü Potential implications of negative EFSA opinions for dairy health claims

Generic messages on dairy consumption and health which rely on scientific evidence as it has been built up over generations might be prohibited following a negative EFSA opinion and subsequent rejection by the Commission and Member States. This is in contradiction with dietary guidelines in place in all EU Member States promoting daily consumption of nutrient-rich dairy foods as part of a healthy and balanced diet. The rejection of health claims on generic dairy foods and prohibition to communicate about the health benefits of dairy food consumption in general might have an unforeseen impact on the nutrient intake and worsen the nutrition and health status of the EU population.

Ü Conclusion

The dairy sector is looking for the possibility to continue to inform the consumer about the health benefits of dairy products and the importance of dairy as part of a healthy and balanced diet. Therefore, EDA would be pleased to discuss those technical issues which we think are relevant for the EFSA to consider when assessing the scientific evidence available for article 13 claims on general health benefits of dairy products submitted to the EFSA.

Dairy health claims concerned

- Dairy and bone health (No. 1138)
- Dairy and weight loss (No. 1139)
- Milk and dental health (No. 1142)
- Yoghurt cultures (live) and lactose digestion (No. 1143 / 2976)
- Dairy and blood pressure (No. 1239)
- Hard cheese (calcium rich) and dental health (No. 1304)