

GENERAL PRINCIPLES ON FLEXIBILITY OF WORDING FOR HEALTH CLAIMS

These general principles were presented for the first time at an informal meeting in Brussels on 19 June 2012. Experts from 17 Member States¹ met to discuss a common approach to advising food business operators (FBOs) about flexibility of wording for health claims. The recommendations in this document only relate to the general principles over which there was broad agreement. Discussions at the meeting took place in English therefore it is possible that the examples given in this document may need to be adapted for other languages.

These recommendations were agreed by Member States' experts in December 2012.

However, note that authorities in some Member States may have developed more detailed national recommendations on flexibility of wording.

Introduction

Recital (9) of Regulation 432/2012 states: "One of the objectives of Regulation (EC) No 1924/2006 is to ensure that health claims are truthful, clear, reliable and useful to the consumer. In that respect, the wording and presentation of such claims have to be taken into account. Where the wording of claims has the same meaning for consumers as that of a permitted health claim, because it demonstrates the same relationship that exists between a food category, a food or one of its constituents and health, the claims should be subject to the same conditions of use indicated for the permitted health claims." The terms and conditions of the EU Register of nutrition and health claims made on foods ("the Register") explain that some flexibility of wording is possible provided that its aim is to help consumer understanding, taking into account factors such as linguistic and cultural variations and the target population.

The aim of this document is to set out the principles that should be respected when authorised health claims are used but the wording used is not exactly as authorised. The same principles should be respected whenever authorised claims are used in commercial communications whether in labelling, presentation or advertising and in whatever medium including on websites, radio and television.

Recommendations

In general, we recommend that FBOs stick as closely as possible to the authorised wording of health claims. This should ensure that consumers are provided with appropriate information and it should help enforcement officers judge whether claims are being used in compliance with the law.

¹ Austria, Belgium, Denmark, Finland, France, Germany, Estonia, Hungary, Ireland, Lithuania, Luxembourg, Netherlands, Norway, Poland, Portugal, Sweden, United Kingdom.

1) To ensure that adapted wording has the same meaning to the consumer as authorised wording

If the wording of a health claim is adjusted, the first principle to be respected is that the adapted wording must mean the same to a consumer as the authorised claim in the Register since this has been substantiated by scientific evidence. It is important that the adapted wording of the claim demonstrates the same relationship between a food category, a food or one of its constituents and health.

In practice, this means that a claim must not be made ‘stronger’ than the authorised claim. It is important that the health claim wording is not adapted into a medicinal claim. It is also important that the claim must not be presented such that it becomes misleading.

In the examples that follow, ‘X’ refers to a food constituent e.g. a nutrient.

For example, consider a claim “X contributes to the normal function of the immune system”. It might be justifiable to replace ‘contributes to’ such that the claim reads

“X plays a role in the normal function of the immune system” or

“X supports the normal function of the immune system” or

“X contributes to maintaining the normal function of the immune system”

but it would not be acceptable to say

“X stimulates the normal function of the immune system” or

“X optimises the normal function of the immune system”

Continuing with the same example claim, it might be justifiable to replace ‘normal function of’ so that the claim reads

“X contributes to the normal functioning of the immune system” or

“X contributes to the maintenance of a normal immune system”

Similarly for an authorised claim “X contributes to the maintenance of normal skin” it might be justifiable to adapt the wording to read

“X contributes to maintaining normal skin” or

“X contributes to supporting the maintenance of normal skin”.

However, it would not be acceptable to say

"X contributes to stimulating the normal function of the immune system" or

"X contributes to optimising the maintenance of normal skin."

Ultimately, an FBO should be able to justify that the adapted wording has the same meaning as the relevant authorised claim in the Register and that it still reflects the scientific evidence by which the authorised claim was substantiated. FBOs should also bear in mind Article 5(2) of Regulation 1924/2006 which says that health claims shall only be permitted if the average consumer can be expected to understand the beneficial effects as expressed in the claim.

2) Use of the term 'normal'

The term 'normal' appears in the English language version of many health claims authorised by Regulation 432/2012. In some cases it was part of the wording that the European Food Safety Authority (EFSA) said was justified; in other cases Member States' representatives, the European Commission and EFSA agreed that it should be included. Therefore, it should be retained in adapted wording, it should not be replaced by another term or removed. However, 'normal' does not appear in all linguistic versions of the Regulation and in some European languages words such as 'healthy' or 'proper' are used instead. In every case, the key principle is that when adapted wording is used it must mean the same to the consumer as the authorised wording because it demonstrates the same health relationship between the food category, food or one of its constituents and health.

3) Link between the claimed effect and the nutrient, substance, food or food category responsible for the effect

The terms and conditions of the Register state that health claims should only be made for the nutrient, substance, food or food category for which they have been authorised and **not for the product** that contains them. This is because the authorised claim describes the particular health relationship that EFSA said is substantiated by scientific evidence.

Take as an example the authorised health claim "X contributes to the normal function of the immune system". In relation to product Y containing the relevant amount of nutrient X it would be acceptable to say:

"X contributes to the normal function of the immune system" or

"Y contains X which contributes to the normal function of the immune system"

but not: "Y contributes to the normal function of the immune system" or

"Y contributes to the normal function of the immune system. Y contains X"

since there is no clear link made between X and the claimed effect.

Where a food product contains two constituents for which there are authorised claims, FBOs must take care not to make the claims misleading.

In the case of a product containing Vitamins B6, B12 and C, it would be acceptable to say "Mix of vitamins (Vitamin, B6, B12, C) which contribute to the reduction of tiredness, fatigue & to the normal function of the immune system". This is because the individual health relationships are evident and because all three vitamins are responsible for each of the claimed effects.

However, for a product containing DHA and EPA and the authorised health claims 'EPA and DHA contribute to the normal function of the heart', 'DHA contributes to maintenance of normal brain function' and 'DHA contributes to maintenance of normal vision' it would be misleading to claim: "DHA and EPA contribute to the normal function of the heart and to the maintenance of normal brain function and vision".

Similarly, in the case of a product containing biotin, folate and niacin, it would not be acceptable to say "Mix of vitamins which contribute to the normal function of the immune and nervous systems and to the maintenance of normal skin". This is because the individual health relationships are not evident and because it is misleading to imply that all three vitamins are responsible for each of the claimed effects.

4) Particular considerations for health claims about food supplements

Article 6(3) of Directive 2002/46/EC requires the labelling of a food supplement to state the names of the categories of nutrients or substances which characterise the product or an indication of the nature of those nutrients or substances.

Consider a food supplement called 'CARTILAGE' for which the label states:

"CARTILAGE - contains chondroitin, vitamin C
Vitamin C contributes to normal collagen formation for the normal function of cartilage".

Presented in this way, the text could be seen as implying that chondroitin, as well as vitamin C, contributes to the normal function of cartilage. However, the claim is not authorised for chondroitin therefore this presentation could be misleading.

However, if the food supplement label stated:

"Contains chondroitin and vitamin C"

CARTILAGE - Vitamin C contributes to normal collagen formation for the normal function of cartilage",

so that the joint health claim is clearly linked only to vitamin C, this could be acceptable.

In this example "Contains chondroitin and vitamin C" could be considered as meeting the requirement in Article 6(3)(a) of Directive 2002/46/EC on food supplements. Since this statement is mandatory on a food supplement, it would be exempt from the rules in Regulation EC 1924/2006 by way of Article 2(2)(1). Similarly, other mandatory labelling information such as that in the ingredients list and nutrition panel (information panel), is exempt. However, the names of the nutrient(s)/substance(s) are only required to appear once on the label to meet the requirement of Art 6(3)(a) 2002/46/EC therefore if chondroitin was emphasised on the label again such that it could be construed as a nutrition claim (for example as a 'contains' claim) this would need to be carefully considered.

This is an example that the context and overall presentation of a claim is very important. A decision about whether a claim is acceptable may need to be made on a case-by-case basis.

5) Presentation of general, non-specific health claims

Article 10(3) of Regulation 1924/2006 requires that when reference is made to general, non-specific benefits of a nutrient or food for overall good health or health-related well-being it must be accompanied by a specific, authorised Article 13 or Article 14 health claim.

So for example, if a claim were made for 'GOOD FOR YOUR SKIN' on the front of a product pack (product 'Y' which contains a substance 'X') it would be acceptable to present this as:

'GOOD FOR YOUR SKIN' - X contributes to the maintenance of normal skin' or

'GOOD FOR YOUR SKIN' - Y contains X which contributes to the maintenance of normal skin'

6) Trade mark, brand name or fancy name

If the term "Good For Your Skin" is a trade mark, brand name or fancy name the considerations set out in section 5 would also apply.

7) Reference to excerpts from EFSA opinions

It may be tempting to pick sentences or phrases from an EFSA opinion in order to adapt the wording of an authorised health claim however, this should be done with extreme caution as it could increase the risk of changing the meaning of the claim.

So for example, it would be misleading to replace the authorised Article 13(1)(a) claim "copper contributes to normal –energy yielding metabolism" with "copper contributes to the normal breaking down of fats in fat tissue" (EFSA Journal; 7(9):1211) since this could be construed as an Article 13(1)(b) slimming claim or a weight loss claim.

Some EFSA opinions include references to deficiency diseases. The adapted wording of a health claim should not include reference to symptoms of deficiency since this could at the very least make the claim misleading and could even mean that it was construed as a medicinal claim.

Thus, it would not be acceptable to amend the authorised wording "vitamin A contributes to the maintenance of normal vision" to "without an adequate level of vitamin A in the retina the function of the rods in dim light situations becomes compromised, resulting in abnormal dark adaptation (night blindness)" (EFSA Journal 2009; 7(9):1221).

In many cases, EFSA opinions consider several similar health claims / health relationships that were proposed in the initial applications; where this is the case, details of the individual proposed health claims / health relationships are listed in an annex to the opinion. When a particular health relationship is substantiated by scientific evidence the EFSA opinion clearly states the appropriate health claim wording. This does not mean that all of the health claim wordings originally proposed are validated therefore these should not be used to adapt the wording of an authorised health claim.

To illustrate this, consider the authorised health claim "vitamin C contributes to the protection of cells from oxidative stress" (EFSA Journal 2009; 7(9):1226); it would not be acceptable to replace this wording with "antioxidant vitamins and minerals act against age-accelerating free radicals" which was one of the claim wordings originally proposed.

DECEMBER 2012