

## To Interested Parties

18 October 2006

CPD/0093

## UK LIST OF CLAIMS

### PROCESS FOR THE COMPILATION OF CLAIMS UNDER ARTICLE 13 OF THE EUROPEAN REGULATION ON NUTRITION AND HEALTH CLAIMS MADE ON FOOD.

Dear Sir or Madam,

It is a requirement of the European Regulation on nutrition and health claims made on food that Member States submit to the Commission a list of health claims which fall under Article 13 of the Regulation. This will form the basis of the Community list of permitted claims. You will find enclosed details of the UK process for the compilation of this list and of how you should go about submitting claims.

#### Background

The Regulation will require nutrition and health claims on food to be authorised and added to the list of permitted claims. Such a list of nutrition claims has already been drafted, but the list of health claims is yet to be compiled. Under the Regulation there are different mechanisms by which health claims can be included on the permitted list. Claims based on newly developed scientific evidence, disease risk reduction claims and claims which refer to children's development and health will need to be accompanied by a dossier of information in justification of the claim, for assessment by the European Food Safety Authority (EFSA). For other claims, which fall under Article 13 of the Regulation, a full dossier will not be required. Rather, Member States will have one year, following entry into force of the Regulation, to compile these claims and submit them, together with conditions of use and references to relevant scientific justification, to the

Commission. There will then be a two-year period during which EFSA will assess the claims and Standing Committee will adopt the final list.

### **UK list**

There are a number of health claims made on products in the UK, for which there is currently no requirement for authorisation and listing, but which must not mislead consumers and must therefore be substantiated by science. The Article 13 list will help ensure there is a smooth transition to the new requirements for these claims. It will be the Food Standards Agency that is responsible for compiling this list of claims and we are now inviting you to submit eligible claims to the list. The accompanying annexes include further details about which claims are within the scope of this list and therefore eligible, guidance on scientific evidence, and a template to be used when submitting claims. At a recent meeting, the European Commission explained that it would help compilation of the European list if Member States submitted claims in a standard format, and most Member States felt the attached table would be suitable. Likewise, to aid the Agency in compiling the UK list of claims, we would ask that you use this template when submitting claims to us. The template in Annex 3 includes an example claim, with further example claims on our website. Annex 1 describes eligible health claims, and Annex 2 gives guidance on filling in the table and what scientific evidence is likely to be appropriate. It is important that you read this before submitting your claim to ensure that the information you provide is sufficient.

### **Timing**

While Member States have 12 months following entry into force of the Regulation to compile their lists, we will be setting a target date for claims to be submitted to us at the ninth month. This will allow the Agency time to compile and finalise the list before it is forwarded to the Commission. Any claims submitted after the target date may be considered for inclusion, but, depending on resources, we cannot guarantee that these will be submitted to the Commission within the 12 month deadline. It will therefore be in your interests to submit claims by the target date. At this time we do not know exactly when the Regulation will be published, but once we do we will write to you with the exact dates.

## **Assessing claims**

The Agency will aim to avoid duplication of claims included on the final list. It will not be conducting a scientific assessment, as it is EFSA's responsibility to check and validate the scientific substantiation of the health claims submitted. However, if the references you have included as justification are clearly insufficient, we will not include the claim in the UK list. For more information on appropriate references please see Annex 2.

## **Alternative means of authorisation**

You must also be aware that if a claim fails to meet the requirements of Article 13, either due to the nature of the claim or insufficient supporting scientific evidence, that claim will no longer be permitted to be used on food following adoption of the Community list unless you submit it for authorisation via another route. Disease risk reduction claims and claims referring to children's development and health should be submitted via Article 14. Claims based on new or emerging science should be submitted via Article 13(5). In both cases the claim will need to be submitted together with a dossier of supporting evidence. For further information on submitting claims via this process please contact the Agency directly.

## **Transition to the Community list**

The list of health claims submitted to the Agency will be made available on our website at the following address: [www.food.gov.uk/foodlabelling/ull/claims/](http://www.food.gov.uk/foodlabelling/ull/claims/) and will be up-dated regularly, so as to allow you to check whether the claims you wish to make have been submitted. However, this list does not represent claims approved by the Agency or claims that would comply with the current legislation. During transition to adoption of the Community list, claims within the scope of Article 13 can continue to be made but it will be your responsibility to ensure your claims comply with existing legislation.

## **Supporting claims already listed**

If you feel it necessary, you will be able to submit further information in support of a claim already on the list (e.g. additional references or conditions for use). This information should be sent to the Agency; we would ask that you make it clear that the information you are submitting is in support of a claim already submitted.

All claims should be submitted to Sarah Paterson at the Agency at the following e-mail address: [nutritionandhealthclaims@foodstandards.gsi.gov.uk](mailto:nutritionandhealthclaims@foodstandards.gsi.gov.uk). Claims can also be submitted to the following postal address:

Sarah Paterson  
Room 115b  
Food Standards Agency  
Aviation House  
125 Kingsway  
London  
WC2B 6NH

Yours sincerely

Noel Griffin  
Claims and Fortification Unit

## Annex 1

### Claims eligible to be submitted to the UK list of health claims

To be eligible for the UK list the claim must describe or refer to:

- The role of a nutrient or other substance in growth, development and the functions of the body; or
- Psychological and behavioural functions; or
- Slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or the reduction of the available energy from the diet. This will not apply to claims which are required, by law, to be made on foods for particular nutritional uses.

And be based on generally accepted scientific evidence and be well understood by the average consumer.

*You are reminded that the following health claims cannot be submitted via this process, as there are specific mechanisms for their authorisation:*

- *Claims based on new or emerging science;*
- *Claims which state, suggest or imply that consumption significantly reduces a risk factor in the development of a human disease; and*
- *Claims which directly refer to children's development and health.*

## **Annex 2**

### **How to fill in the Template**

The following notes will help you fill in the template in Annex 3 and enable you to submit claims for the UK list. A sample claim has been included to help you, with further examples on the Agency's website at the following address:  
**[www.food.gov.uk/foodlabelling/ull/claims/](http://www.food.gov.uk/foodlabelling/ull/claims/)**

You may also wish to consult this list to check that the claim you plan to submit has not already been included.

#### **Column 1 – Food category, Food, Food component.**

To include the food category, food or food component (nutrient or other substance) to which the claim refers, for example folate (folic acid).

#### **Column 2 – Health Relationship**

To include the benefit the food category, food or food component in column 1 has on health. For example, for folate this might read “developing neural tube”.

#### **Column 3 – Suggested Conditions of use**

This should include any additional information needed to help the claim's use in a responsible manner. For example, levels that should be present to justify the claim (15% of the RDA or a different level where appropriate or where no RDA exists), warning statements on possible safety issues etc. For folate this would include a requirement for a significant amount to be present in a portion of the product (15% of the RDA in 100 grams/millilitres) and a requirement that a warning statement be included which conveys that there is a risk that excess folate consumption may mask B12 deficiency. In certain cases it may also be necessary to consider the frequency of consumption needed to achieve the claimed health benefit. For example if the food or food component must be consumed at the required level for at least a two week period before there is any benefit to health, a statement to this effect should be included on the product so as not to mislead consumers. By filling in this column, it is possible to suggest suitable conditions of use and give EFSA further details upon which to make an assessment. The conditions

of use in the final Community list will take into account EFSA's advice and be for Member States to agree.

#### **Column 4 – Nature of evidence**

This should include a brief description of each reference included in column 5 and is intended to aid EFSA in assessing the references submitted. For example if the reference is to an expert opinion or report given by EFSA or the UK's Scientific Advisory Committee on Nutrition (SACN), is a systematic review, a randomised controlled trial (RCT), observational epidemiological study (e.g. cohort or case control), or an animal study, this should be highlighted in this column.

#### **Column 5 – References**

It will ultimately be for EFSA to offer an opinion on whether a claim has sufficient supporting evidence and is based on generally accepted science. The Agency is therefore not in a position to give detailed guidance on the required scientific substantiation for the claims submitted. However, there follows some general advice and recommendations on sources of information and good practice. It is also important to note that if no supporting evidence is submitted in justification of the claim we will not be able to include it in the UK list, as EFSA will not be able to make an assessment.

References should be sufficient to convince EFSA that there is scientific justification for the claim and must be to information that is in the public domain, which has been peer reviewed. While there is no requirement for a specific number of references to be supplied, the totality of the science and the balance of evidence must be represented, and one reference may be insufficient to do this, however quality will have more importance than quantity. There is no requirement as to the particular nature of the science to be referenced, but science can be of varying quality and where the science is weak (for example poorly designed single studies or insufficient subjects studied), this would be unlikely to convince EFSA. When looking for convincing evidence, you should consider: inclusion of a reference to a recent EFSA opinion or the opinion of a national or international scientific committee, such as SACN, IOM, WHO; recent systematic reviews or meta analyses; Cochrane reviews; and reputable peer-reviewed journals, taking care to reflect the totality of the science. Ideally references to peer-reviewed journals should

relate to well-defined randomised controlled human studies, either human intervention studies or human observational studies with a large cohort. Animal based studies or theoretical studies are likely only to be useful as supporting evidence, for example to provide evidence for a biological mechanism of action where good quality human evidence also exists. Similarly, care should be exercised over reliance on single textbook references. It would be advisable to list the source reference to the supporting scientific evidence rather than the textbook.

The references you include must include the following information:

- Authors
- Date
- Title
- Journal
- Journal number and page reference
- Wherever possible website addresses should be included.

To further guide you in providing substantiation for your claim you may wish to look at the following:

- The Codex Committee on Nutrition and Foods for Special Dietary Uses are currently looking at the scientific basis of health claims. Although this is still under discussion, the most recent version can be found at the following website address: [ftp://ftp.fao.org/codex/ccnfsdu28/nf28\\_07e.pdf](ftp://ftp.fao.org/codex/ccnfsdu28/nf28_07e.pdf). This is a useful 'quick start' guide, and should be read with other information, such as the JHCI code or PASSCLAIM.
- The Joint Health Claims initiative (JHCI) represents consumers, enforcement and industry in the UK and has established a Code of Practice for health claims made on food. The JHCI also offers industry advice on making claims and has previously approved claims, necessitating an assessment of the scientific substantiation. Within its code the JHCI talks about scientific substantiation of claims and the nature of evidence. A copy of the code can be accessed at the following website address: <http://www.jhci.org.uk/info/code.pdf>

- The results of a European project looking at a process for the scientific assessment of claims made on foods (PASSCLAIM) are available through the European Journal of Nutrition. This is comprehensive and extensive and a valuable source of information. Further information can be found at the following website address and in particular you should consider the documents under “publications”:  
<http://europe.ilsa.org/activities/ecprojects/PASSCLAIM/>
- The Advertising Standards Authority is an independent body that is responsible for the self-regulation of the advertising industry via codes of practice for advertisers. The codes of practice are the responsibility of the Committee on Advertising Practice, which has produced help notes on substantiation for health, beauty and slimming claims. A copy of the help notes can be accessed at the following website address:  
[www.asa.org.uk/NR/rdonlyres/5976764C-69F4-4DB9-A18B-B5F9203AF7EE/0/health\\_beauty\\_slimming\\_claims.pdf](http://www.asa.org.uk/NR/rdonlyres/5976764C-69F4-4DB9-A18B-B5F9203AF7EE/0/health_beauty_slimming_claims.pdf)

## **Column 6 – Example wording**

The example wording should reflect claims currently used. The wording in this column will only be an example and will not represent an exhaustive list of claims.

## **Separate Sheet**

A separate sheet is not a requirement, but can be included, where appropriate, with relevant background information. This could include showing the hierarchy of relevant evidence or additional information about the evidence, such as the nature of the evidence, sources etc, which may assist EFSA.