The European Community (EC) welcomes the new Draft Recommendations on the Scientific Basis of Health Claims.

The EC acknowledges the importance of defining common standards for the evaluation of the scientific substantiation of health claims and broadly supports the content of the draft Recommendations and the principles it is laying down, with the following proposed changes to specific aspects of the text:

As a general point the EC believes that the Guidelines for the Substantiation of Health Claims should reflect the following principles, and considers that these principles are reflected in the proposed draft Annex:

- foods or food constituents should be sufficiently characterised to substantiate claims made on them;
- in case of a claimed health effect that cannot be measured directly, relevant validated biomarkers may be used;
- data and rationale that the constituent for which the health claim is made is in a form that is available to be used by the human body should be provided where applicable;
- methodological quality of each type of study should be assessed;
- the systematic review shall demonstrate the claimed effect by taking into account the totality of the available evidence and by weighing the evidence.

The EC has the following specific comments on the draft Annex:
2 – DEFINITIONS

Paragraph 3 – the EC considers that the term "related substances" is not clear as it could be interpreted as meaning the substance is directly associated with a nutrient in the food whereas the intention is to cover substances that can have a physiological effect. Therefore, it is proposed that the term should be changed to "other substances".

3 - SUBSTANTIATION OF HEALTH CLAIMS

Paragraph 5 (a) - The EC would like clarification on the intention of the initial step in the process of substantiation of health claims, namely "Identify the criteria for substantiation and other policies for health claims" as it is not clear whether these issues are already covered by the Guidelines for Use of Nutrition and Health Claims and the associated Annex on substantiation of health claims which is currently under consideration.

Paragraph 5 (d) – It is suggested to replace the word "studies" by "scientific data" at the end of the sentence. The new wording would be consistent with paragraphs 9, 10, 11 and 12 in Section 3.3. - Consideration of the evidence. The substantiation of a health claim shall take into account the totality of the available data, and, by weighing the evidence, shall demonstrate the claimed effect. It is proposed that the paragraph should be amended as follows:

"(d) Identify and categorise all relevant studies scientific data."

Paragraph 7 (a) – It is proposed that under this point it should be indicated that the authoritative statements should be recognised by an expert scientific body. It is proposed that the paragraph should be amended as follows:

"(a) ‘Nutrient function’ claims may be substantiated based on generally accepted authoritative statements by recognised expert scientific bodies that have been verified and validated over time."

Paragraph 7 (b) – The drafting of the paragraph can be improved by adding the word "competent" in the last sentence as follows:

"Evidence-based dietary guidelines prepared or endorsed by an authoritative competent body and meeting high scientific standards may also be used."

Paragraph 9 - It is suggested to delete the words "including the analytical methods applied" in the first sentence of paragraph 9 as the second sentence includes a reference to analytical methods applied and the EC considers that analytical methods need to be considered on a case-by-case basis. For example, when a food or a food category is subject to a claim, the food can be sufficiently characterised without referring to analytical methods. Analytical methods are more relevant for food constituent based claims. Concerning claims on food categories, the reference to analytical method is also less pertinent. It is proposed that the paragraph should be amended as follows:

"The scientific data should provide adequate characterization of the food or food constituent considered as responsible for the health effect, including the analytical methods applied. Where applicable, the characterization includes a summary of the
studies undertaken on production conditions, batch-to-batch variability, analytical procedures, results and conclusions of the stability studies, and the conclusions with respect to storage conditions and shelf-life."

**Paragraph 10** – The EC supports the use of the wording "available to be used by the body" to include the cases where other mechanisms of actions than intestinal absorption are involved. The food matrix can have a significant influence on the activity or release of the food constituent and therefore any information relevant to assess and determine the conditions for the food matrix to ensure the claimed effect have to be provided, which is well reflected in the last sentence.

**Paragraph 12** – The EC strongly supports the principle that the systematic review should take into account the totality of the available evidence, and shall demonstrate the claim effect by weighing the evidence. A simple correlation is not sufficient and a cause and effect relationship has to be established between consumption and claimed effect. Quantity of food and pattern of consumption to obtain the claimed effect have also to be achievable through a normal diet, and the population group studied should be representative of the population targeted by the claim. All these important principles are well reflected in the wording of this paragraph.

**Paragraph 12 (b)** – The EC considers that the wording of this paragraph could make it explicit that the examples apply where appropriate. Therefore, the following drafting of the paragraph can is proposed:

"(b) a cause and effect relationship is established between consumption of the food or food constituent and the claimed effect in humans (such as, where appropriate, the strength, consistency, specificity, dose-response, and biological meaningfulness plausibility of the relationship)."

**Paragraph 13** - To be more consistent with the wording used in the Guidelines for Use of Nutrition and Health Claims, it is proposed to replace "government" by "competent authorities".

### 5 - RE-EVALUATION

**Paragraph 17** - The re-evaluation of the claim scientific basis should only be conditioned to the emergence of significant new evidence. A periodical review would lead to unnecessary re-evaluations when no new data have to be assessed, without providing any benefit compared with a re-evaluation conditioned to significant new evidence. Therefore the words "periodically or" should be deleted. The paragraph should be amended as follow:

"Health claims should be re-evaluated periodically or following the emergence of significant new evidence that has the potential to alter previous conclusions about the relationship between the food or food constituent and the health effect."