

Parma, 12 June 2008

## **Guidance to submit the full-text of references quoted in the Article 13 List of health claims**

Concerning the consolidated list of health claims cf. Article 13 of Regulation 1924/2006/EC – which will be submitted to EFSA for scientific evaluation, EFSA would very much appreciate receiving the related references according to the below-mentioned guidance:

### **1) Which citations to submit.**

ONE electronic copy (PDF file) of each citation in the article 13 list of health claims (EFSA will take care of dealing with copyright issues if additional copies are needed), except for the ones listed below:

- a) General nutrition textbooks cited to substantiate health claims on vitamins, minerals and macronutrients.
- b) National and international dietary and nutrient recommendations.
- c) Publications from national and international bodies on the evaluation of health claims made on foods.
- d) Publications freely available in the web for which only a web link is provided in the Article 13 list.

### **Please note that:**

- a) Journal abstracts and articles published in newspapers, magazines, newsletters or handouts that have not been peer-reviewed should not be provided.
- b) Books or chapters of books for consumers or the general public should not be provided.
- c) If available, published systematic reviews, pooled analyses or meta-analyses of observational studies investigating the relationship between the consumption of the food/constituent and the health relationship should be provided. If the systematic review, pooled analysis or meta-analysis is directly relevant to the health claim applied for, the individual studies need not be provided.

### **2) How to label electronic, full-text copies**

Electronic copies (individual PDF files) should be submitted in CD-ROM (please do not send e-files by e-mail to EFSA), labelled with the last name of the first author, the journal, and the publication year, as in the example below:

- Baker et al. British Journal of Nutrition, 2008

For books and monographs, PDF files should be labelled indicating the editor(s), the book title and the publication year, as follows:

- Garrow et al (eds). Human Nutrition and Dietetics, 2000

Should the electronic, full-text copy for a citation not be available, please provide the full citation in a MS Word file as follows:

- For journal articles:

Alderman, G. and Stranks, M.H., 1967. The iodine content of bulk herd milk in summer in relation to estimated dietary iodine intake of cows. *J. Sci. Food Agric.* 18, 151-153.

➤ For book chapters:

Mock, D.M., 1999. Biotin. In: Shils, M.E.; Olson, J.A.; Shike, M. and Ross, A.C. (eds): *Modern Nutrition in Health and Disease*, 9th edition. Baltimore; Williams & Wilkins, pp 459-466.

➤ For books:

Shils M.E.; Olson, J.A.; Shike, M. and Ross, A.C. (eds), 1999: *Modern Nutrition in Health and Disease*, 9th edition. Williams & Wilkins, Baltimore.

### 3) **How to cluster electronic copies in CD-ROMs and how to label CD-ROMs**

Each CD-ROM should contain all references cited for a given health claim (i.e. for each nutrient/substance-health relationship), and the CD-ROM should be labelled with the name of the nutrient/substance, the health relationship and the stakeholder coding (SHC) number (if available), as in the example below:

➤ Ref. for Article 13: Calcium and blood pressure (SHC: 56)

If no stakeholder coding number is available, please refer to the nutrient and claimed effect only.

### 4) **Paper Copies**

Only if possible, each PDF file could be accompanied by its paper copy, organised in the same way as CD-ROMs, i.e. each folder containing all paper copies of references cited for a given health claim labelled with the name of the nutrient/substance, the health relationship and the stakeholder coding number (if available), as in the example below:

➤ Ref. for Article 13: Calcium and blood pressure (SHC: 56)

If no stakeholder coding number is available, please refer to the nutrient and claimed effect only.

### 5) **Timeframe**

In order to ensure that EFSA is able to start the scientific evaluation of the Article 13 list of health claims on time, all the material above should be sent to EFSA **possibly by the end of July 2008.**

However, EFSA will welcome late submissions **until 15 September 2008.**

Please note that electronic copies of citations already sent to EFSA by food business operators in March/April 2008 do not need to be re-sent.

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**Thank you very much in advance for your cooperation!**