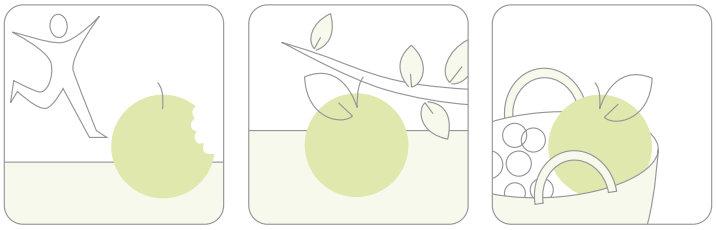
EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

Directive 90/496/EEC on Nutrition Labelling for Foodstuffs: Discussion Paper on Revision of Technical Issues



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Discussion Paper on Revision of Technical Issues

Directorate E - Safety of the food chain

May, 2006

Council Directive 90/496/EEC on Nutrition Labelling of Foodstuffs provides for the possibility of amending specific aspects of the legislation via the Standing Committee procedure. Whilst the Commission continues to reflect on some of the more fundamental issues related to the revision of this Directive, it has been decided that it would be timely to make use of this procedure to address some of these aspects (which can be considered under the broad heading of 'technical issues'). This paper identifies the technical issues to be considered, summarises the comments received from the 2003 consultation on revision of the Nutrition Labelling Directive, and highlights other work which might be relevant to discussions on how the legislation might be amended.

The Health and Consumer Protection Directorate General is keen to obtain the views of stakeholders on how these technical issues might be addressed and is issuing this discussion paper as part of the consultation process. Responses should reach the dedicated e-mail box SANCO-TECHNICAL-ISSUES@ec.europa.eu by 14 July 2006. They may include general comments but should otherwise be structured to match the sections in this text and the specific questions on which the Commission seeks comments.

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Introduction

1. Council Directive 90/496/EEC on Nutrition Labelling of Foodstuffs provides for the possibility of amending specific aspects of the legislation via the Standing Committee procedure. Whilst the Commission continues to reflect on some of the more fundamental issues related to the revision of this Directive, it has been decided that it would be timely to make use of this procedure to address some of these aspects (which can be considered under the broad heading of 'technical issues'); particularly as they may be an important and necessary support for other related Community legislation in force or proposed, such as the directives on food supplements and dietetic foods and the regulatory proposals currently under discussion regarding *nutrition and health claims made on foods* and the *addition of vitamins and minerals and of certain other substances to foods*.

2. This paper identifies the technical issues to be considered, summarises the comments received from the 2003 consultation on revision of the Nutrition Labelling Directive[1] and highlights other work which might be relevant to discussions on how the legislation might be amended.

3. It should be emphasised that only those issues which the Directive provides for can be amended via the Standing Committee procedure and, therefore, can be dealt with at this time.

4. The Health and Consumer Protection Directorate-General is keen to obtain the views of stakeholders on how these technical issues might be addressed and is issuing this discussion paper as part of the consultation process. Responses should reach the dedicated e-mail box SANCO-TECHNICAL-ISSUES@ec.europa.eu by 14 July 2006. They may include general comments but should otherwise be structured to match the sections in this text and the specific questions on which the Commission seeks comments.

[1] http://ec.europa.eu/food/food/labellingnutrition/nutritionlabel/index_en.htm

Reference Values for Vitamins and Minerals

Background

Current Legislation

5. The Annex to the Nutrition Labelling Directive (90/496/EEC) lists vitamins and minerals which may be declared on the nutrition label, their recommended daily allowances (RDAs), and specifies what is a 'significant amount' (15% of the RDA per 100g or 100ml). Article 1, paragraph 4(a) of the Directive allows for **changes to the list of vitamins, minerals and their recommended daily allowances** to be adopted via the Standing Committee procedure.

Responses to the 2003 Consultation

6. Relevant comments are:

- General agreement on the need to bring the annex up to date and to take account of the lists of vitamins and minerals in Directive 2001/15/EEC (*on substances that may be added for specific nutritional purposes in foods for particular nutritional use*) and Directive 2002/46/EEC (*on the approximation of the laws of the Member States relating to food supplements*).
- Some comments that 10% would be more appropriate than 15% as a 'significant amount', or that it should be brought into line with CODEX (5% of the recommended intake of the population concerned).
- A number of requests for 'significant amount' to be reduced for products with high liquid content.
- A number of comments about the need to have consistency/harmonisation in the way that vitamins are named on the nutrition label.
- Some requests to have RDAs for different populations - especially children.

Proposal on the Addition of Vitamins and Minerals and of Certain Other Substances to Foods.

7. It should be noted that a proposal *for the addition of vitamins and minerals and certain other substances to foods* is currently under consideration by the European Parliament and the Council. The lists of vitamins and minerals contained within this proposal include many more nutrients than the ones listed in the Annex of Directive 90/496/EEC.

Scientific Committee on Food

8. The Scientific Committee for Food (SCF) published an opinion on the *Revision of Reference Values for Nutrition Labelling* on the 5 March 2003[2]. This sets out Reference Labelling Values (RLVs)[3] for adults and for children aged 6 months to

[2] http://ec.europa.eu/food/fs/sc/scf/out171_en.pdf

[3] The term "Reference Labelling Value (RLV)" was proposed by the SCF in its 1992 report on *Nutrient and Energy Intakes for the European Community*; the purpose being to highlight that the RLV was derived specifically for use with nutrition labelling.

4 years. The SCF report covers all of the vitamins and minerals listed in Directive 2001/15/EEC (foods for particular nutritional use), Directive 2002/46/EEC (food supplements), and in the draft proposal on the addition of vitamins and minerals. Annex 1 provides a comparison between the figures proposed by the SCF and those in the current Annex to the Nutrition Labelling Directive.

9. For adults, a comparison of the values recommended by the SCF against those currently in the Annex indicates;

- Increases in values for 6 vitamins and minerals – folates; vitamins B_{12}, C, E; calcium; magnesium.
- Decreases in values for 7 vitamins and minerals – niacin; biotin; vitamins B_1, B_2, B_6; phosphorous; zinc.
- Values for 5 vitamins and minerals remain the same – vitamins A, D; pantothenic acid; iron; iodine.
- Values set for 10 new vitamins and minerals – vitamin K; potassium; sodium; chloride; copper; selenium; manganese; chromium; molybdenum; fluoride.

Codex

10. The *Codex Guidelines on Nutrition Labelling* (CAC/GL 2-1985 (Rev.1 – 1993)) provide Nutrient Reference Values (NRVs) for 14 vitamins and minerals to be used for labelling purposes. These NRVs are the same as the RDAs in the current Annex to the Nutrition Labelling Directive.

11. A discussion paper on *The Proposals for Addition of Revised Nutrient Reference Values for Labelling Purposes* was presented at the 27th Session of the Codex Committee on Nutrition and Foods for Special Dietary Purposes (CCNFSDU) in Bonn, Germany in November 2005. The Committee agreed to continue development of the paper.

European Food Safety Authority

12. In January 2005, the Commission asked the European Food Safety Authority (EFSA) to review advice on dietary intakes, highlighting that the scientific advice on recommended nutrient intakes is important as the basis of Community action in the field of nutrition. For vitamins and minerals, EFSA was asked to review the SCF recommendations on micronutrients in the light of new scientific evidence and advise on the population reference intakes. EFSA has indicated that this task will take some time, with a potential completion date of post 2010 being estimated.

Questions on which the Commission seeks comments

- Are the values in the SCF opinion on the *Revision of Reference Values for Nutrition Labelling* an acceptable basis for updating the Annex to the Nutrition Labelling Directive?
- Are there concerns about any of the values in the SCF opinion?
- Is there a need to have values for different population groups in the Annex?
- Is there a need for consistency/harmonisation in the naming of vitamins on the nutrition label? Are there any examples where this has caused a problem?
- Is there a need to change the figure for what constitutes a significant amount?[4]
- In view of the fact that other terms are being used for labelling purposes (guideline daily amounts, reference labelling values), is the term 'recommended daily amount' still acceptable?[4]

[4] Whilst this issue can be discussed in relation to revision of the technical issues, it is not certain that it will be possible to make changes via the Standing Committee procedure.

Nutrient Definitions

Background

Current legislation

13. Article 1, paragraph 4 of the Nutrition Labelling Directive provides definitions for a number of nutrients that are used in nutrition labelling. In paragraph 4(j), it is noted that 'fibre' **means the material to be defined according** to Standing Committee procedure **and measured by the method of analysis to be determined in accordance with that procedure**.

Responses to the 2003 Consultation

14. Relevant comments are:

- General agreement that a definition for fibre, along with a defined method, was required.
- Some comments that in changing the definition for fibre there would be a need to change the definition for carbohydrate.
- Some requests for work on further definitions around fats/fatty acids and vitamins/minerals. Also the need for harmonisation of definitions across the various pieces of legislation.[5]

CODEX

15. At its 27th session the CCNFSDU made further progress on moving towards an agreed definition for fibre (considering this within the discussions on the *Guidelines for the Use of Nutrition Claims: Draft Table of Conditions for Nutrient Contents*[6]). The latest definition, which was returned to Step 6 for further comment and discussions at the next session of the Committee, states that:

"Dietary fibre means carbohydrate polymers with a degree of polymerisation (DP) not lower than 3 which are neither digested nor absorbed in the small intestine. A degree of polymerisation not lower than 3 is intended to exclude mono- and disaccharides. It is not intended to reflect the average DP of a mixture. Dietary fibre consists of one or more of:

- *Edible carbohydrate polymers naturally occurring in the food as consumed,*
- *carbohydrate polymers, which have been obtained from food raw material by physical, enzymatic or chemical means,.*
- *synthetic carbohydrate polymers."*

[5] The Standing Committee procedure set out in the Directive only allows for a definition to be set for fibre. Discussions on definitions of other nutrients will need to wait for the more fundamental revision of the Nutrition Labelling Directive.

[6] http://www.codexalimentarius.net/web/archives.jsp?lang=en - Alinorm 06/29/26 Report of the 27th Session of the Codex Committee on Nutrition and Foods for Special Dietary Purposes, paragraphs 14-28 and Appendix III.

16. It should be noted that in the draft Codex guidelines the definition is linked to text on the properties of dietary fibre and to a footnote providing further information on dietary fibre derived from plant origin. The full text is given in Annex 2.

Questions on which the Commission seeks comments

- Are the current Codex discussions a suitable basis for setting down a definition of fibre in the Nutrition Labelling Directive?
- Are there any concerns about this definition and how it might be incorporated into the Directive? For example, how should the issue of the footnote be dealt with?

Energy Conversion Factors

Background

Current Legislation

17. Article 5, paragraph 1 of the Nutrition Labelling Directive provides energy conversion factors for a range of nutrients (carbohydrates, polyols, protein, fat, alcohol and organic acids). Paragraph 2 notes that **amendments to these conversion factors can be made** via the Standing Committee procedure, **as can additions for substances which belong to or are components of one of the categories of nutrients listed in paragraph 1**; the purpose being to more precisely calculate the energy value of foods.

18. The Standing Committee procedure was used in 2003 to introduce a conversion factor for salatrims (Directive 2003/120/EEC).

Responses to the 2003 Consultation

19. Relevant comments are:

- A number of requests to introduce an energy conversion factor for fibre.
- Comment that there were problems/inconsistencies with conversion factors used in the Nutrition Labelling Directive and those for a number of PARNUTS directives.
- Reference made to an FAO/WHO workshop and how this could provide guidance for future development of energy conversion factors.

CODEX & FAO/WHO

20. Conversion factors in the current CODEX *Guidelines on Nutrition Labelling* (CAC/GL 2-1985 (Rev.1 – 1993)) are in line with those in the Nutrition Labelling Directive, although the latter also includes values for polyols and salatrims. Whilst there have been discussions within the CCNFSDU over recent years, there is no clear timetable for when further work on energy conversion factors will be taken forward.

21. The FAO/WHO workshop on *Food Energy – methods of analysis and conversion factors* was held in Rome, 3-6 December 2002[7]. The report, published in 2003, highlighted that there is a major need to rationalise and harmonise methods of food analysis and energy conversion factors. The outcome of the workshop was a list of recommended methods of food analysis, from the most desirable based on current science to those approaches considered acceptable given current realities. For food energy conversion factors, the preferred factors are integrated into the recommendations, based on the analytical methods used.

[7] http://www.fao.org/documents/show_cdr.asp?url_file=/docrep/006/y5022e/y5022e00.htm

Questions on which the Commission seeks comments

- Is there any need to amend the current energy conversion factors in the Nutrition Labelling Directive?
- Is there any need to add to the current energy conversion factors in the Nutrition Labelling Directive? For example, is a conversion factor for fibre required or for erythritol (following the SCF opinion of 2003[8])?

[8] http://ec.europa.eu/food/fs/sc/scf/out175_en.pdf

Tolerances for nutrient declaration

Background

Current Legislation

22. The Nutrition Labelling Directive stipulates that **the definition of tolerable margins between values declared on labelling and those obtained by official controls should be determined following the Standing Committee procedure**. The task of setting tolerable margins for the declaration of nutrient content for food supplements was also identified as a priority during the discussions that led to the adoption of Directive 2002/46/EC on food supplements.

Responses to the 2003 Consultation

23. Relevant comments are:

- General agreement that tolerances should be defined at Community level in order to avoid trade barriers and ensure consumer protection.
- Highlighted that some Member States already have guidelines in place setting tolerances for nutrition labelling declarations.
- Some comments that it may be necessary to discuss sampling and analytical methods and whether these need to be specified in legislation.
- Comments that tolerances should be set for different foodstuffs to take into account factors such as raw material variation, food matrix, processing and storage. Tolerances may also need to be defined for specific nutrients in order to reflect issues of stability (especially for some vitamins).
- Important that the existence of tolerances should not lead to the requirement for individual laboratory testing to derive nutritional values for labelling purposes. Current legislation allows the use of food composition tables to derive such values and this should continue to be the case.

CODEX

24. The *Codex Guidelines on Nutrition Labelling* (CAC/GL 2-1985 (Rev.1 – 1993)) state in the section **3.5** T**olerances and Compliance** that;

- *Tolerance limits should be set in relation to public health concerns, shelf-life, accuracy of analysis, processing variability and inherent lability and variability of the nutrient in the product, and, according to whether the nutrient has been added or is naturally occurring in the product.*
- *The values used in nutrient declaration should be weighted average values derived from data specifically obtained from analyses of products which are representative of the product being labelled.*
- *In those cases where a product is subject to a Codex standard, requirements for tolerances for nutrient declaration established by the standard should take precedence over these guidelines.*

Member States' Approaches

25. Some Member States have provided guidance on tolerances for nutrient declarations, (examples from Denmark and the UK are set out in Annex 3). For macronutrients, both examples follow a similar general approach, with the acceptable level of tolerance decreasing as the level of the macronutrient in a product increases. The actual guideline figures are different, but not dissimilar. For example, for a product that declares 25% fat, the Danish tolerance will be ±15% and the UK ±20%.

26. For added vitamins and minerals, the Danish guidance allows 80-150% of the declared value (to take into account the loss of nutrient over time). It also notes the importance of the actual nutrient content being within tolerance limits during the whole shelf life period, and that if there are minimum and maximum limits prescribed in legislation then the analysed amount must not exceed these. The UK takes a different approach, providing tolerances for water soluble vitamins and minerals (+100% or -50% of the declared value) and oil soluble vitamins (±30%).

Canadian Approach

27. It is interesting to contrast the Danish and UK guidance with that provided by the Canadian authorities for enforcement[9]; the latter being produced to accompany the legislation passed in 2003 that will require most prepackaged foods in Canada to bear a Nutrition Facts table. Whilst the acceptable tolerance is basically similar, i.e. ±20%, the actual guidance is much more prescriptive, being based on a sound statistical framework. The purpose being to ensure the industry has a high probability of a label declaration being within the tolerance, whilst the consumer would have an equally high probability that that the label declaration accurately reflects the nutrient content of the food. This statistical approach takes into account nutrient variability in foods as well as method variability. Annex 4 summarises the Canadian system, which in addition to setting tolerances also provides rounding rules for nutrient declarations and specifies methods of analysis.

Questions on which the Commission seeks comments

- What are the important factors to take into account in setting tolerances for nutrient declarations?
- Is a 'simple' (e.g. UK/Danish approach) or 'complex' (e.g. Canadian) system preferred? What are the benefits and disadvantages of each?
- Should different tolerances be set for different product categories? In particular, how should the issue of adding overages for some vitamins to take account of losses during long-term storage be dealt with?
- How should products with inherent variability or seasonal variation, such as fresh meat, be dealt with?

[9] http://www.inspection.gc.ca/english/fssa/labeti/nutricon/nutricone.pdf

ANNEX 1

Comparison of Reference Labelling Values

	Nutrition Labelling Directive	SCF Report 2003 Adults	SCF Report 2003 Children (6 months to 4 years)
Vitamins			
B_1 Thiamine (mg)	1.4	1.1	0.5
B_2 Riboflavin (mg)	1.6	1.4	0.7
Niacin (mg)	18	16	7
B_6 (mg)	2	1.4	0.7
Folates (µg)	200	400	125
B_{12} (mg)	1	2.5	0.8
C (mg)	60	80	45
A (µg retinol equivalents)	800	800	400
D (µg)	5	5	7
E (mg)	10	12	5
K (µg)	-	75	12
Pantothenic acid (mg)	6	6	3
Biotin (µg)	150	50	10
Minerals			
Calcium (mg)	800	1000	550
Phosphorous (mg)	800	700	550
Potassium (mg)	-	2000	1000
Sodium (mg)	-	600	400
Chloride (mg)	-	800	500
Iron (mg)	14	14	8
Zinc (mg)	15	10	5
Copper (mg)	-	1.0	0.5
Iodine (µg)	150	150	80
Selenium (µg)	-	55	20
Magnesium (mg)	300	375	80
Manganese (mg)	-	2.0	1.2
Chromium (µg)	-	40	20
Molybdenum (µg)	-	50	25
Fluoride (mg)	-	3.5	0.7

ANNEX 2

Definition and properties of dietary fibre
(extract from report of the 27th session of the CCNFSDU)

"Definition:

Dietary fibre means carbohydrate polymers[1] with a degree of polymerisation (DP) not lower than 3 which are neither digested nor absorbed in the small intestine. A degree of polymerisation not lower than 3 is intended to exclude mono- and disaccharides. It is not intended to reflect the average DP of a mixture. Dietary fibre consists of one or more of:

- Edible carbohydrate polymers naturally occurring in the food as consumed,
- carbohydrate polymers, which have been obtained from food raw material by physical, enzymatic or chemical means,.
- synthetic carbohydrate polymers.

Properties:

Dietary fibre generally has properties such as:

- Decrease intestinal transit time and increase stools bulk
- fermentable by colonic microflora
- Reduce blood total and/or LDL cholesterol levels
- Reduce post-prandial blood glucose and /or insulin levels.

With the exception of non-digestible edible carbohydrate polymers naturally occurring in foods as consumed where a declaration or claim is made with respect to dietary fibre, a physiological effect should be scientifically demonstrated by clinical studies and other studies as appropriate. The establishment of criteria to quantify physiological effects is left to national authorities.

[1] When derived from a plant origin, dietary fibre may include fractions of lignin and/or other compounds when associated with polysaccharides in the plant cell walls and if these compounds are quantified by the AOAC gravimetric analytical method for dietary fibre analysis : Fractions of lignin and the other compounds (proteic fractions, phenolic compounds, waxes, saponins, phytates, cutin, phytosterols, etc.) intimately "associated" with plant polysaccharides are often extracted with the polysaccharides in the AOAC 991.43 method. These substances are included in the definition of fibre insofar as they are actually associated with the poly- or oligo-saccharidic fraction of fibre. However, when extracted or even re-introduced into a food containing non digestible polysaccharides, they cannot be defined as dietary fibre. When combined with polysaccharides, these associated substances may provide additional beneficial effects. "

ANNEX 3

Examples of Member States' Guidance on Tolerances for Nutrition Declarations[10]

Denmark

The following limits, including analytical uncertainty, regarding macronutrients are at the moment used as guidance in Denmark:

Nutrient	**Content**	**Tolerance**
Protein Carbohydrate Fat Sugars Polyols Dietary fibres Starch	≤ 10 g per 100 g 10 – 40 g per 100 g ≥ 40 g per 100 g	+/- 1,5 g +/- 15 % +/- 6 g
Fatty acids (sum of saturated, monounsaturated and polyunsaturated)	0,5 – 3,5 g per 100 g ≥ 3,5 g per 100 g	+/- 0,5 g +/- 15 %
Na	in general	+/- 15 %
Cholesterol	in general	+/- 25 %

For naturally occurring vitamins and minerals a tolerance of +/- 25%, exclusive analytical uncertainty, calculated at a 99% confidential level.

For added vitamins and minerals we have experienced from many years of analytical control of food supplements and foods for special dietary purposes, a necessity to accept asymmetrical margins of tolerance. In dialogue with manufacturers and analytical experts, we have accepted a tolerance of 80 – 150 % for added vitamins and minerals, exclusive analytical uncertainty calculated at a 95% confidence level. The loss of nutrient over time is one of the arguments for accepting asymmetrical tolerance limits. It is important that the actual nutrient content is within tolerance limits during the whole shelf life period. More narrow limits could be discussed concerning minerals. If legislation prescribes minimum and maximum values for addition of nutrients, the analysed amount must not exceed these limits.

[10] provided as part of Member States' comments to the Commission's 2003 consultation on revision of the Nutrition Labelling Directive.

United Kingdom

A. For Major Parameters: Protein, Fat, Carbohydrates (including sugars) and Dietary Fibre

Declared Values	*Recommended Tolerance*
More than 5%	+/- 20% of the declared value
More than 2% and less than 5%	+/- 30% of the declared value
Less than 2	Use discretion based on the specific individual circumstances

Note 1 : For Fibre note the figure is for the AOAC method.
Note 2 : For values above 5% seasonal/natural variability should be considered for meat, for example, this could include species or breed of animal.
Note 3 : For wholemeal cereal products and saturated fats higher tolerances may apply

B. For Vitamins and Minerals (note these tolerances apply only to non-liquid foods)

Type of Nutrient	*Recommended Tolerance*
Water Soluble Vitamins, i.e. B Vitamins Group and minerals	+100% or -50% of the declared value
Oil Soluble Vitamins, i.e. A, D, E	+/- 30% of the declared value

Note 1 : For certain heat treated products, e.g. confectionery, vitamin losses are compensated for by adding overages, so + 100% would be acceptable.

ANNEX 4

Sampling Plan and Tolerances From Canadian Food Inspection Agency – Nutrition Labelling Compliance Test

Sample is 3 composite sub-samples of 4 consumer units randomly selected from a lot

Class	*Description*	*Nutrients*	*Acceptance Criterion 1,[1,2] sub-sample*	*Acceptance Criterion 2 Tolerances[1,2]*	*Acceptance Criterion 3, 99% confidence interval[4]*
Class1 (min)[3]	added nutrients (e.g. added Vitamin C).	added vitamins, mineral nutrients, amino acids	each sub-sample ≥50% declared nutrient value	≥declared nutrient value	$\left(\frac{s \times 0.4344}{\bar{x}}\right) \leq 0.1$
Class ll (min)[3]	a naturally occurring nutrient that is declared in the Nutrition Facts table and/or for which a health or nutrient content claim is made.	protein, polyunsaturated fatty acids, omega 3 fatty acids, omega 6 fatty acids, mono-unsaturated fatty acids, carbohydrate, starch, fibre, soluble fibre, insoluble fibre, potassium, vitamins and minerals	each sub-sample ≥50% declared nutrient value	≥80% declared nutrient value	does not apply
Class ll (max)[3]	a naturally occurring nutrient declared in the nutrition facts table and/or for which a health or nutrient content claim is made.	Calories, fat, saturated fat, *trans* fat, cholesterol, sodium, sugars, sugar alcohols	≤150% declared nutrient value	≤120% declared nutrient value	does not apply

[1] Tolerances are one-sided. Nutrient content may vary within good manufacturing practices, either above declared value, where a minimum is required, or below declared value, where a maximum is required, and provided there is no risk to health and the label is not misleading.
[2] Tolerances are based on declared nutrient value and applied to pre-round value.
[3] (min) - where minimum level required; [3](max) - where maximum level required
[4] s = standard deviation $\bar{X}$ = mean value