

**Summary of the Responses to:
Directive 90/496/EEC on Nutrition Labelling for Foodstuffs:
Discussion Paper on Revision of Technical Issues**

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Background

On the 15th of May 2006, a public consultation was launched seeking stakeholder views on the discussion paper on the revision of technical issues of Directive 90/496/EEC on nutrition labelling for foodstuffs. The consultation closed on the 14th of July 2006.

Council Directive 90/496/EEC on Nutrition Labelling of Foodstuffs provides for the possibility of amending specific aspects of the legislation via the Regulatory Committee procedure. Whilst the Commission continues to reflect on some of the more fundamental issues related to the revision of this Directive to be done through the co-decision procedure, it was decided that it would be timely to initiate work that will address some of these aspects (which can be considered under the broad heading of ‘technical issues’) particularly as they are an important and necessary support for other related Community legislation in force, such as the directives on food supplements and dietetic foods and the regulations on nutrition and health claims made on foods and on the addition of vitamins and minerals and of certain other substances to foods. The discussion paper identified the technical issues to be considered, summarised the comments received from the 2003 consultation on the revision of Directive 90/496/EEC and highlighted other work which might be relevant to discussions on how the legislation might be amended. The discussion paper was issued as part of the consultation process in order to obtain the views of stakeholders on how these technical issues might be addressed.

Summary of responses

In the response to the Technical Issues consultation by the Commission a total of 48 contributions were received from a range of stakeholders including governmental organisations, civil society, industry sectors, professional organisations and individuals:

14 responses from EU Member States

1 response from an EFTA country

1 response from a third country

28 responses from industry associations, consumer organisations and individual companies

4 responses from individual persons

Contributions varied from concrete proposals to general remarks on the importance of such technical revisions. This summary briefly describes some of the key messages of the contributions but, however, is not reflecting all points raised.

1. Reference values for vitamins and minerals

1.1 Are the values in the Scientific Committee for Food (SCF) opinion on the Revision of Reference Values for Nutrition Labelling an acceptable basis for updating the Annex to Directive 90/496/EEC?

There is general consensus about the need to revise the reference values for nutrition labelling and complete the list of nutrients as soon as possible. The pragmatic approach in using the

values proposed by the SCF in 2003 is supported by most respondents, as those are the most recent ones at the European level and as the population reference intakes set by EFSA are expected to be available at a date past 2010. Single respondents of the industry mention the need for appropriate transition periods, as re-labelling as well as reformulation and stability testing might be required. Individual comments include the wish for values to stay in line with those recognised at Codex level, in order to facilitate trade of global players.

1.2 Are there concerns about any of the values in the SCF opinion?

Specific concerns with the proposed new values were frequently voiced by respondents and can be grouped into the following categories.

Firstly, the acceptance of the values in the SCF opinion was linked to the definition of a significant amount and the outcome of discussions on tolerances for the nutrient declarations (see below section 4). Among the nutrients mentioned here are calcium and folate, food sources being for example dairy and cereal products. For both the values recommended by the SCF are higher than the current ones with the consequence that, assuming the definition of a significant amount for content claims remained the same, some foods that are naturally a good source of these nutrients could no longer make a nutrition claim.

Secondly, some respondents, especially Member States, were concerned when the values recommended by the SCF differ from national reference values or from internationally recommended values. Apart from a perceived risk of confusing consumers by this divergence, safety concerns were voiced where more recent national reference values were lower than the proposed values from SCF .

Finally, some respondents were concerned about the proposed value for sodium and the implications of having values for iodine and fluoride when those are added to salt. There was concern about adding a value for sodium in the list based on the same principles as the other nutrients, as consumers might interpret a high percentage as a positive feature.

1.3 Is there a need to have values for different population groups in the Annex?

There was general consensus to have one value for adults for general foods and no mandatory labelling for another population group. Many respondents accepted that reference values for a special population group can be used for products specifically intended for this group, at least for children. However, the age range of 6 months to 4 years for children in the SCF opinion was agreed only by few respondents. Reasons were a lack of harmonisation with the age bands mentioned in other relevant pieces of legislation or the current practice of targeting children in other age bands by products. Further population groups mentioned by a few respondents comprised pregnant and lactating women, the elderly and sportspeople.

The possible impact of additional population groups on other regulations such as on supplements, nutrition and health claims and the addition of vitamins and minerals and certain other substances to food was highlighted together with the need to clarify how the values for additional population groups are to be used. Other respondents proposed to use the adult reference values and explain on the label that special consideration should be given in case of children, older adults, and pregnant and lactating women. Another view was that different reference values for different population groups are only relevant for food supplements and dietetic products and should be dealt with in the specific legislation.

1.4 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?

Most respondents agreed that consistency/harmonisation of the naming and units of micronutrients on the label was desirable, along with a need for consistent, harmonised definitions and conversion factors. Some respondents requested to consider harmonization of those with other areas of the world. A clear definition and conversion factors should account for different forms of micronutrients such as free and salt forms or pro-form and active forms or naturally present and synthetic forms added to a food, when bioavailability or activity differs. Some reasons mentioned were to facilitate consumer choice by giving comparable information on products across the EU and to reduce the risk that the UL could be exceeded if a substance has more than one name of which the consumer is unaware.

Despite this principal agreement, the ideas and proposals from respondents about which names should be used were very diverse. The argumentation supporting the proposals are multi-layered, including consumer understanding in different parts of Europe, already existing regulations in some Member States, problems that may be encountered by multilanguage labelling and limited pack sizes, scientific correctness.

Concerning definitions, as explained in the discussion paper, the rules set out in Directive 90/496/EEC only allow for the Regulatory Committee procedure to be applied in the case of the definition of dietary fibre.

1.5 Is there a need to change the figure for what constitutes a significant amount?

Although this question was raised in the discussion paper it was noted that it may not be possible to amend this section of Directive 90/496/EEC through the Regulatory Committee Procedure.

While the majority of respondents from both the industry and Member States saw a need to reconsider additions or changes to the figure for what constitutes a significant amount, few respondents did not see any need to change it.

Lower figures between 5 and 10% were proposed frequently, sometimes in line with Codex guidelines. Some respondents suggested that there should be different figures for solids and liquids or low energy foods. Also, the basis for some percentage figure was proposed to be either energy content or one serving size. It was mentioned that the current single pack rule leads to inconsistent use of claims. Some areas where the present system evokes problems were mentioned: electrolyte content in isotonic sports drinks and iodised or fluoridated salt.

Some respondents asked for consideration of the current figure in relation to food supplements and the setting of the minimum amounts for supplements, others asked for drafting a clearer text describing the significant amount requirements and that it refers to the food ready for consumption in case a food needs preparation.

1.6 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?

Although this question was raised in the discussion paper it was noted that it may not be possible to amend this section of Directive 90/496/EEC through the Regulatory Committee Procedure.

Different preferences and objections for the proposed terms were voiced, as well as new suggestions made or differing translation of the term into the local language. The term RDA was generally preferred as consumers were familiar with it, at least for nutritional supplements. Some respondents asked for educational campaigns to communicate its meaning to consumers. Some respondents preferred new terms such as GDA or RLV, while all terms were seen by at least one respondent as being inappropriate or misleading.

2. Nutrient definitions

2.1 Are the current Codex discussions a suitable basis for setting down a definition of fibre in Directive 90/496/EEC?

Most respondents, both from industry and from Member States, supported the introduction of a definition of dietary fibre, most considered the Codex discussions as a suitable basis. A number of respondents also agreed that a method to determine fibre should be established. One response commented that until the completion of the Codex definition, agreement should be reached at European level to have a definition and method.

Only few considered the current Codex discussions unsuitable or the text to be too complex, some proposed different definitions. Among the reasons for disagreement were the following: the small intestine digestibility should be considered a key determinant to distinguish fibre from carbohydrate; there is no precedent for basing the definition of a food component on physiological properties as compared to their chemical constituents; lack of distinction between natural and artificial sources of fibre; lack of a single method to measure fibre as defined by Codex; the Codex definition is not respecting that the concept of fibre reflects a largely unrefined plant-rich diet on which the health benefits of the dietary fibre hypothesis is based; consumers associate fibre with plant origin.

Some comments explained that when setting a definition for fibre there would be a need to change the definition of carbohydrate. One comment asked to wait for a WHO/FAO position paper on carbohydrates that will include advice on dietary fibre in order to take it into consideration.

2.2 Are there any concerns about this definition and how it might be incorporated into the Directive? For example, how should the issue of the footnote¹ be dealt with?

No general consensus was achieved on this point. While some respondents were not concerned about the inclusion of the footnote in the proposed form, other proposed to include it in an amended or simplified version or in an additional guidance document. Only few respondents perceived the footnote as being irrelevant.

3. Energy conversion factor

3.1 Is there any need to amend the current energy conversion factors in Directive 90/496/EEC?

Most respondents were in favour of amendments to the current energy conversion factors. Criteria were proposed that should be fulfilled when amending a specific energy conversion factor: when a food ingredient has an energy conversion factor based on scientific evidence,

¹ See explanation in the Discussion Paper:
http://ec.europa.eu/food/food/labellingnutrition/nutritionlabel/discussion_paper_rev_tech_issues.pdf

and that is significantly different from the one set up for the category to which it belongs; the food ingredient is not part of the nutrient categories that have been established. The level of use in a given foodstuff would need to significantly impact the total energy value of the food. Also, the need for international consistency was highlighted by some respondents.

Some respondents were not in favour of amending the current energy conversion factors, or asked to limit the amendment to a few substances such as fibre, as it was felt that adding too many new factors would lead to a complicated system of declaration, thus the burden of the amendment has to be checked and balanced against the benefit.

3.2 Is there any need to add to the current energy conversion factors in Directive 90/496/EEC? For example, is a conversion factor for fibre required or for erythritol (following the SCF opinion of 2003)?

Different substances and groups were proposed for addition, fibre being the one named most frequently. Other substances included erythritol, polydextrose, inulin/oligofructose, acacia gum, gum arabic, phytosterols, glycerol, and pulp. Energy conversion factors for these substances were proposed and evidence supporting those values supplied by some respondents. An individual respondent recommended to take into account a document published by FAO in 2003 on energy conversion factors and net metabolisable energy (NME) values.

4. Tolerances for nutrient declaration

4.1 What are the important factors to take into account in setting tolerances for nutrient declarations?

Respondents contributed a vast amount of factors to be taken into account when setting tolerances for energy and nutrient declarations. The tolerances have to be workable within the different pieces of legislation that refer to Directive 90/496/EEC. The tolerances, for example, have an impact on claims as a certain percentage of increase or decrease in nutrient is required and would be difficult to make a claim if tolerances are set very broadly.

A number of contributors have established recommendations for tolerances and proposed their adoption. Concerning the process of setting these, it was suggested by industry to establish a special multistakeholder working group.

The Commission was asked to clearly define which elements are included in the term 'tolerance' for the purposes of nutrition labelling. In general, the response was that tolerances should be based on science. Furthermore, some respondents requested to also specify official methods for sampling and analysis and to continue to accept average values.

4.2 Is a 'simple' (e.g. UK/Danish approach) or 'complex' (e.g. Canadian) system preferred? What are the benefits and disadvantages of each?

There was general consensus that a 'simple' approach is preferable. This was seen as the more cost-effective model for operators, especially for small and medium sized enterprises, but also as better enforceable by authorities. Also, this 'simple' approach is applied already in a number of Member States. It was mentioned that the increased resources required by an increasingly complex system and precise values have to be balanced with the added benefit for the consumer.

4.3 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?

The majority of respondents, including nearly all responses from industry, supported that different tolerances are required for different product categories. Among the categories mentioned were solid versus liquid products or products to which vitamins and minerals have been added versus products with naturally occurring nutrients, products containing stable versus unstable nutrients and products with different shelf-lives.

A number of Member States did not find it reasonable to have, in general, different tolerances for different product categories, but found it necessary to have different tolerances for macro- and micronutrients, to have different tolerances for low and high levels of macronutrients, or to consider special tolerances for food supplements or foods for particular nutritional use. Exceptions allowing to have different tolerances for specific foods or under specific circumstances could be accepted if supported by clear evidence.

There was general consensus that with regard to products containing added unstable nutrients, the tolerable margins should allow for overages which could guarantee the presence of the nutrient until the use-by date, while still respecting the safety levels established for each nutrient.

4.4 How should products with inherent variability or seasonal variation, such as fresh meat, be dealt with

A number of approaches to the problem of inherent variability of products were suggested: the use of weighted averages, the use of averages that take into account seasonal or variety variation assessed during a prolonged period, broad tolerances for nutrients with a high natural variation, labelling with maximum or minimum content or intervals, setting of additional, broader tolerances if those can be justified by scientific literature. Furthermore, the consumer could be informed about a high variation of the declared value of a nutrient by a suitable footnote.

On the other hand for products with a large inherent variability or seasonal variation, it should not be accepted to widen the tolerance limits infinitely, because the declared values will then be of no use for the consumer. Such products could be exempted from nutritional labelling, at least for certain nutrients.

Others Issues raised

A number of other issues were raised that did not strictly answer the questions raised in the discussion paper.

The need for more harmonisation across the various pieces of legislation was expressed frequently.

Many respondents, both from industry and Member States, asked for harmonisation of rounding rules of the values on the nutrition label.

Some respondents requested that carbohydrates, fats and various fatty acids should be defined more precisely.

Industry especially voiced concern about the timing of different pieces of legislation with an impact on reformulating and relabelling of products. Ideally, technical amendments to Directive 90/496/EEC should be adopted at the same time as the overall revision of the

legislation through the co-decision process and the setting of maximum amounts for supplements and fortified foods. This would minimise the risk of confusing consumers and imposing additional costs for relabelling and reformulation. Furthermore, reasonable transition periods were requested.

ANNEX 1

The following organisations and individuals provided comments in response to the consultation:

EU Member States – Government related:

Austria (Austrian Agency for Health and Food Safety)

Czech Republic Ministry of Agriculture

Denmark (Ministry of Family and Consumer Affairs, Danish Veterinary and Food Administration)

Estonia (Ministry of Agriculture)

Finland

France

Germany (Federal Ministry of Food, Agriculture and Consumer Protection)

Hungary (Ministry of Health)

Ireland (Department of Health and Children, Food Safety Authority of Ireland)

Lithuania (Ministry of Health)

Netherlands (Ministry of Health, Welfare and Sports)

Poland (Główny Inspektor Sanitarny)

Sweden (National Food Administration)

United Kingdom (Food Standards Agency)

EFTA Countries – Government related:

Norway (The Royal Ministry of Health and Care Services)

Non-EU /EFTA countries – Government related:

Philippines (Department of Agriculture)

Stakeholders and individuals:

AAF (Association des Amidonniers et Féculiers: European Starch Industry Association)

AESGP (Association of the European Self-Medication Industry)

BNF (British Nutrition Foundation)

Bernard Moinier (Salt and Health Consultant)

BRC (British Retail Consortium)

CIAA (Confederation of the food and drink industries of the EU)

COPA/COGECA (Committee of Professional Agricultural Organisations in the EU / General Confederation of Agricultural Co-operatives in the EU)

EDA (European Dairy Association)

EHPM (European Federation of Association of Health Product Manufacturers)

Englyst Carbohydrates

ENSA (European Natural Soyfoods Manufacturer Association)

ERNA (European Responsible Nutrition Alliance)

EuroCommerce

EU Salt

FDF (Food and Drink Federation)

FICT (Fédération Française des Industriels Charcutiers, Traiteurs, Transformateurs de Viandes)

GAM (Groupement des Associations Meunières de l'UE: European Flour Milling Association)

GSK (GlaxoSmithKline Nutritional Healthcare UK)
Geoffrey Livesey (B.Sc., Ph.D., R.P.H.Nutr.) and G. Sawar Gilani, Health Canada,
HFMA (Health Food Manufacturers' Association)
Holland&Barrett
ICGA (International Chewing Gum Association)
ISA (International Sweeteners Association)
Jean Marie Pycke (Professor, Institut Paul Lambin, Brussels)
John H. Cummings (Professor of Experimental Gastroenterology, University of Dundee)
McDonalds Europe
NPN (Natuur- en gezondheidsProducten Nederland)
OEITFL (Organisation of European Fruit and Vegetable Processing Industries)
PIE (Platform for Ingredients in Europe)
Susan McGinty (PhD student: nutritional genomics and health promotion)
SYNDIFRAIS/SYNDILAIT
TFX (The UK Campaign against Trans Fats in Food)
UNESDA (Union of European Beverages Associations)
VZBV (Verbraucherzentrale Bundesverband e.V.: Federation of German Consumer Organisations)
Wyeth Consumer Healthcare UK