EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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GUIDANCE DOCUMENT FOR COMPETENT AUTHORITIES FOR THE CONTROL OF COMPLIANCE WITH EU LEGISLATION ON:

Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004
and
Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling of foodstuffs
and
Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements

with regard to the setting of tolerances for nutrient values declared on a label

IMPORTANT DISCLAIMER

"This Document has no formal legal status and, in the event of a dispute, ultimate responsibility for the interpretation of the law lies with the Court of Justice of the European Union"

Note

This document is an evolving document and will be updated to take account of the experience of the competent authorities or of information provided

1. INTRODUCTION

Tolerances for nutrition labelling purposes are important as it is not possible for foods to always contain the exact nutrient levels labelled, due to natural variations and variations from production and during storage. However, the nutrient content of foods should not deviate substantially from labelled values to the extent that such deviations could lead to consumers being misled.

This document has been drawn up by mutual agreement between the Commission services and the representatives of the Member States. The guidelines given in this document cannot be regarded as official interpretation of the legislation, this being the exclusive reserve of the judicial authorities, i.e. the national courts and the Court of Justice of the European Union.

After reaching agreement on this guidance document, Member States are reminded that all controls carried out to verify the compliance with the relevant labelling requirements, taking into account the described tolerances, shall be accounted for in the Multi-annual national control plans, as required by Article 41 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[1] (hereinafter: Regulation (EC) No 882/2004). Member States also have to report back yearly to the Commission on the results of such controls according to Article 44 of Regulation (EC) No 882/2004. In the latter context, Member States are encouraged to provide the Commission with the number of tests performed, the food categories tested, the results of the tests compared with the values that were controlled and the decisions taken, e.g. measures taken in case the measured value was outside the tolerance of the declared value. Based on the experiences gained the Commission and the Member States can discuss and agree on future modifications of the guidance document. Stakeholders will be consulted accordingly.

The Commission recommends that a pragmatic and proportionate approach should be followed for the adaptation of official controls on the basis of this EU guidance on tolerances. Therefore, it could be accepted that for a certain period of time a smooth transition applies which should end at the latest on 13 December 2014. Economic operators should be informed accordingly. Also, Member States that had already national provisions on tolerances in place before this guidance was published may consider to apply a smooth transition to controls of products labelled prior to and during such a transition period

1.1 Scope of this guidance

This document (hereinafter: 'this guidance') has been prepared to provide guidance to Member States' control authorities and food business operators on the tolerances for nutrition labelling purposes. Tolerances mean the acceptable differences between the nutrient values declared on a label and those established in the course of official controls, in relation to the 'nutrition declaration' or 'nutrition labelling' as described in Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers[2]; Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs[3]; and in relation to the nutrition labelling of food supplements, as described in Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements[4].
This guidance is, in general, also applicable for the nutrition labelling of foods under Regulations (EC) No 1925/2006/EC of the European Parliament and the Council on the addition of vitamins and minerals and of certain other substances to foods[5] and No 1924/2006 of the European Parliament and of the Council of 20

[1] OJ L 165, 30.4.2004, p. 1–141
[2] OJ L 304, 22.11.2011, p. 18
[3] OJ L 276, 6.10.1990, p. 40
[4] OJ L 183, 12.7.2002, p. 51
[5] OJ L 404, 30.12.2006, p. 26

December 2006 on nutrition and health claims made on foods[6]. Guidance on such tolerances is given in sections 3 and 4 of this document.

Levels of nutrients and other substances in foods are measured by Member States' control authorities in order to control the compliance with levels of nutrients and other substances specified in the conditions of use for nutrition claims as listed in the Annex to Regulation (EC) No 1924/2006 and for health claims as authorised via implementing measures of the Regulation. Tolerances for such controls are specified in section 5 of this document.

Levels of vitamins and minerals added to foods as regulated by Regulation (EC) No 1925/2006/EC are measured by Member States' control authorities in order to control the compliance with levels of nutrients declared in the nutrition labelling. Tolerances for such controls are specified in section 5 of this document.

This guidance does not cover tolerances around the declared value for levels of vitamins and minerals added to foods when the addition is mandatory according to national provisions as described in Article 11 of Regulation (EC) No 1925/2006. Furthermore, this guidance does not cover tolerances around the declared values for foods regulated by Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses[7]

1.2 The legislative framework related to control of nutrient values declared on a label

Article 17 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[8] (General Food Law) provides that Member States have the responsibility to enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by feed and food business operators at all stages of production, processing and distribution. For that purpose, Member States shall maintain a system of official controls and other activities as appropriate to the circumstances.

Article 3 of Regulation (EC) No 882/2004 provides that Member States shall ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency, so as to achieve the objectives of that Regulation taking into account:

- identified risks associated with animals, feed or food, feed or food businesses, the use of feed or food or any process, material, substance, activity or operation that may influence feed or food safety, animal health or animal welfare;
- feed or food business operators' past record as regards compliance with feed or food law or with animal health and animal welfare rules;
- the reliability of any own checks that have already been carried out; and
- any information that might indicate non-compliance.

Official controls shall be applied, with the same care, to exports outside the Union, to the placing on the market within the Union and to introduction from third countries. Member States shall also take the necessary measures to ensure that products intended for dispatch to another Member State are controlled with the same care as those intended to be placed on the market in their own territory.

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[6] OJ L 404, 30.12.2006, p. 9
[7] OJ L 124, 20.5.2009, p. 21

[8] OJ L 31, 1.2.2002, p. 1

As regards the control of nutrient values declared on a label, in addition to the above mentioned general control provisions, three legislative texts are concerned:

- **Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers**
- **Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs**
- **Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements**

Regulation (EU) No 1169/2011 will apply from 13 December 2014 and at the same time Directive 90/496/EEC will be repealed.

Without prejudice to specific provisions in the different pieces of legislation, rules about nutrition labelling of one or more of the three pieces of legislations mentioned above apply also to Regulation (EC) No 1924/2006/EC, Regulation (EC) No 1925/2006 and to Directive 2009/39/EC.

Directive 90/496/EEC and Regulation (EU) No 1169/2011 indicate that the energy and nutrient content should be labelled as the 'average value', which means the value that best represents the amount of the nutrient which a given food contains, and allows for natural variability of foodstuffs, seasonal variability, patterns of consumption and other factors which may cause the actual value to vary. The declared values shall, according to the individual case, be average values based on:

a) the manufacturer's analysis of the food;

b) a calculation from the known or actual average values of the ingredients used;

c) a calculation from generally established and accepted data.

2. GENERAL PRINCIPLES

The actual amount of a nutrient in a product may vary compared to the value declared on a label due to factors such as the source of values (values derived from literature and calculated by recipe instead of analysis), the accuracy of analysis, the variation in the raw materials, the effect of processing, nutrient stability and storage conditions and storage time.

2.1 Tolerances and food safety issues

The factor of food safety is to be taken into account when setting tolerances for added vitamins and minerals to food including food supplements. Excessive intakes of vitamins and minerals may result in adverse effects and it is therefore necessary to set maximum amounts for them when they are added to foods or present in food supplements. Provisions for establishing maximum amounts for vitamins and minerals are included in Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods and in Directive 2002/46/EC on food supplements. The tolerance range around a declared value may extend above the maximum amount of vitamins or minerals added to foods or present in food supplements harmonised at EU level according to the provisions in Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods and according to the provisions in Directive 2002/46/EC on food supplements. In this case, the maximum amount has priority over the tolerance range around the declared value and would therefore limit the upper end of the tolerance around the declared value.

In the absence of harmonised rules on maximum amounts in foods and food supplements Member States may establish national rules in compliance with Articles 34 and 36 of the Treaty on the Functioning of the European Union. However, in doing so, they should also follow the criteria laid down in Regulation (EC) No 1925/2006 and Directive 2002/46/EC. In case the tolerance range around a declared value extends above the maximum amount established by Member States as national rules, in compliance with Articles 34 and 36 of the Treaty on the Functioning of the European Union for which Member States should also follow the criteria laid down in Regulation (EC) No 1925/2006 and Directive 2002/46/EC, the current practice of handling such issues before this guidance document was agreed may be maintained.

As soon as harmonised rules on maximum amounts in foods and food supplements for vitamins and minerals have been established in the EU legislation, it should be considered whether this guidance document needs to be revised.

2.2 Compliance over shelf life

The measured value should be within the tolerances around the declared value during the entire shelf life.

2.3 Application of tolerance ranges of section 3 and section 5.2 of this guidance

Tolerances for nutrition labelling purposes are important as it is not possible for foods to always contain the exact levels of energy and nutrients that are labelled, due to natural variations and variations from production and during storage. However, the nutrient content of foods should not deviate substantially from labelled values to the extent that such deviations could lead to consumers being misled. The declared values should, according to the individual case, be average values and based on

a) the manufacturer's analysis of the food;

b) a calculation from the known or actual average values of the ingredients used; or

c) a calculation from generally established and accepted data.

Regardless of how nutrition declarations are derived, food business operators should act in good faith to ensure a high degree of accuracy of those nutrition declarations. In particular, declared values should approximate to the average values across multiple batches of food and should not be established at either extreme of a defined tolerance range. For nutrients where consumers are generally interested in reducing their intakes (such as fats, sugars and salt/sodium), the declared values should not be established at the lower tolerance range whilst the measured or calculated average value would be higher than this declared value. Also, for nutrients where consumers are generally interested in higher levels, the declared values should not be established at the higher tolerance range whilst the measured or calculated average value would be lower than this declared value.

2.4 Aspects to be taken into account when the measured value is outside the tolerance for the declared value

If the value measured is outside the tolerance for the declared value this should be subject to a specific assessment to decide whether some action/measures should be taken. The following aspects should, for example, be taken into account in this consideration:

a) the nutrient in question
b) the extent of the deviation
c) the nature of the deviation (overestimation or underestimation) in relation to the nutrient concerned
d) natural high variation of the nutrient, including seasonality
e) particular high degradation rates of nutrients in some food matrices
f) particular high analytical variability of nutrients in a specific food matrix
g) particular low homogeneity of a product leading to particular high variation of nutrient content in a product that is not offset by the sampling procedure
h) compliance of the majority of samples from the lot with the tolerance range, if such data is available
i) validity of the manufacturer's process for establishing the declared nutrient value
j) how the self-monitoring of the company functions in general
k) previous problems or previous sanctions against the company

These aspects will also influence the degree of sanctions if they are considered necessary, whether it should be, for example, extended guidelines, warnings, enforcement notice or fines.

Manufacturers may be asked to provide the rationale justifying deviation from tolerances and details on the particular reasons appearing.

3. TOLERANCES FOR THE NUTRITION DECLARATION ON FOODS OTHER THAN FOOD SUPPLEMENTS

For the nutrition declaration of nutrients for which a nutrition or health claim is made according to Regulation 1924/2006/EC, as well as for added vitamins and minerals according to Regulation 1925/2006/EC different tolerances may apply which are specified in section 5.

The tolerance values listed include the uncertainty of measurement associated with a measured value. Therefore, no further allowance for uncertainty of measurement has to be made when deciding whether a measured value is compliant with the declared value.

Table 1: tolerances for foods other than food supplements including measurement uncertainty

	Tolerances for foods (includes uncertainty of measurement)
Vitamins	**+50%** -35%**
Minerals	**+45% -35%**
Carbohydrate, Sugars, Protein, Fibre	**<10 g per 100 g: ±2 g 10-40 g per 100 g: ±20% >40 g per 100 g: ±8 g**
Fat	**<10 g per 100 g: ±1.5 g 10-40 g per 100 g: ±20% >40 g per 100 g: ±8 g**
Saturates, Mono-unsaturates, Polyunsaturates	**<4 g per 100 g: ±0.8 g ≥4g per 100 g: ±20%**
Sodium	**<0.5 g per 100 g: ±0.15 g ≥0.5 g per 100 g: ±20%**
Salt	**<1.25 g per 100 g: ±0.375 g ≥1.25 g per 100 g: ±20%**

** for vitamin C in liquids, higher upper tolerance values could be accepted

Example 1:

- A food product with a nutrition declaration of sugars of 8.5 g and no claim made about its sugar content
- According to the rounding guidelines of section 6 this equals to 8.45 to 8.54 g sugars /100 g
- Lower tolerance: lower value (8.45) minus lower tolerance for sugars from section 3 which is 2 g; 8.45 – 2 = 6.45 g/100 g; according to the rounding guidelines of section 6 the lower bound tolerance will be 6.5 g/100 g
- Upper tolerance: upper value (8.54) plus the upper tolerance for sugars from section 3 which is 2 g; 8.54 + 2 = 10.54 g/100 g; according to the rounding guidelines of section 6 the upper bound tolerance will be 11 g/100 g
- If official control finds a sugar content:
  - within the range of 6.5 to 11 g/100 g this product is found to be within the tolerance range according to the criteria laid down in section 3;
  - between the declared value (8.5 g) and the upper tolerance limit, control of compliance with section 2.3 should be considered

- that is outside the range of 6.5 to 11 g/100 g, section 2.4 should be considered which gives examples of aspects to be taken into account when the measured value is outside the tolerance for the declared value

4. TOLERANCES FOR VITAMINS AND MINERALS IN FOOD SUPPLEMENTS

Tolerance for vitamins and minerals in food supplements are set including all factors for variation: tolerance values listed include the uncertainty of measurement associated with a measured value. Therefore, no further allowance for measurement uncertainty has to be made when deciding whether a measured value is compliant with the declared value.

Table 2: Tolerances for food supplements including measurement uncertainty

	Tolerances for supplements (includes uncertainty of measurement)
Vitamins	**+50%** -20%**
Minerals	**+45% -20%**

** for vitamin C in liquids, higher upper tolerance values could be accepted

Example 2:

- A food supplement with a nutrition declaration of folic acid of 125 µg per unit and no claim made about its folic acid content
- According to the rounding guidelines of section 6 this equals to 124.5 to 125.4 µg folic acid per unit
- Lower tolerance: lower value (124.5) minus lower tolerance for vitamins from section 4 which is 20% (20 % of 124.5 = 24.9); 124.5 – 24.9 = 99.6 µg per unit and according to the rounding guidelines of section 6 the lower bound tolerance will be 99.6 µg per unit
- Upper tolerance: upper value (125.4) plus the upper tolerance for vitamins from section 4 which is 50% (50% of 125.4 = 62.7); 125.4 + 62.7 = 188.1 µg per unit and according to the rounding guidelines of section 6 the upper bound tolerance will be 188 µg per unit
- If official control finds a folic acid content:
  - in the range of 99.6 to 188 µg per unit, this product is found to be within the tolerance range according to the criteria laid down in section 4;
  - that is outside the range of 99.6 to 188 µg per unit, section 2.4 should be considered which gives examples of aspects to be taken into account when the measured value is outside the tolerance for the declared value.

5. TOLERANCES FOR CONTROLLING THE COMPLIANCE OF LEVELS OF NUTRIENTS AND OTHER SUBSTANCES WITH LEVELS SPECIFIED IN REGULATION 1924/2006/EC AND FOR CONTROLLING THE LEVELS OF VITAMINS AND MINERALS WHEN ADDED TO FOODS ACCORDING TO REGULATION 1925/2006/EC

This section applies to nutrients and other substances for which a nutrition or health claim is made according to Regulation 1924/2006/EC, and it applies to added vitamins and minerals according to Regulation 1925/2006/EC.

Member States' control authorities measure the levels of nutrients and other substances in foods in order to control the compliance of products using nutrition or health claims with the levels of nutrients and other substances specified in the conditions of use for such claims. The conditions of use of nutrition claims are set in the Annex to Regulation (EC) No 1924/2006 on nutrition and health claims and the conditions of use of health claims are set in the implementing measures authorising health claims. Examples of such nutrient levels specified in the Annex to Regulation (EC) No 1924/2006 are the fat level for a 'low fat' claim, the vitamin or mineral level for a 'source of' claim or the levels specified for different substances in the conditions of use for health claims. All permitted nutrition and health claims with the conditions for their use are published in the Union Register of nutrition and health claims[9].

Furthermore, levels of vitamins and minerals added to foods as regulated by Regulation (EC) No 1925/2006/EC are measured by Member States' control authorities in order to control the compliance with levels of vitamins and minerals declared in the nutrition declaration.

Irrespective of whether the provisions under 5.1, 5.2, 5.3 or 5.4 are applied, levels should not exceed maximum amounts for vitamins and minerals harmonised at EU level, according to the provisions in Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods and in Directive 2002/46/EC on food supplements. In the absence of harmonised rules on maximum amounts in foods and food supplements Member States may establish national rules in compliance with Articles 34 and 36 of the Treaty on the Functioning of the European Union. However, in doing so, they should also follow the criteria laid down in Regulation (EC) No 1925/2006 and Directive 2002/46/EC. In case the tolerance range around a declared value extends above the maximum amount established by Member States as national rules, in compliance with Articles 34 and 36 of the Treaty on the Functioning of the European Union for which Member States should also follow the criteria laid down in Regulation (EC) No 1925/2006 and Directive 2002/46/EC, the current practice of handling such issues before this guidance document was agreed may be maintained.

5.1 The declared values for the nutrients or other substances for which claims are made are the same as the level of nutrients or other substances specified in the conditions of use for such claims
or
the declared values for the vitamins and minerals added to foods are the same as the minimum levels of the vitamins and minerals that are required to be present in the food according to the provisions in Regulation (EC) No 1925/2006

In order to ensure that consumers are not misled by nutrition and health claims, especially when the claimed nutritional and/or physiological effect is achieved with a certain amount of a nutrient or other substance for which the claim is made, a tolerance that includes only the measurement uncertainty[10] is applied to one side of the declared level of the nutrients or other substances specified in the conditions of use of the claim. To the other side of the declared levels a tolerance that is wider than the measurement uncertainty can be

[9] http://ec.europa.eu/nuhclaims/

[10] Measurement uncertainty is determined for each analysed value

accepted. The levels of nutrients and other substances for the use of nutrition and health claims can be minimum or maximum levels. In case only a maximum but no minimum level is specified, for deviations to the maximum side only the measurement uncertainty is applied while deviations to the minimum side can be accepted within the tolerance range indicated in table 3 ('side 1 of tolerance' or 'side 2 of tolerance' respectively), below. In case only a minimum but no maximum level is specified, for deviations to the minimum side only the measurement uncertainty is applied while deviations to the maximum side can be accepted within the upper tolerance range indicated in table 3 ('side 1 of tolerance' or 'side 2 of tolerance' respectively).

For vitamins and minerals, for deviations to the minimum side only the measurement uncertainty is applied, while deviations to the maximum side can be accepted within the upper tolerance range indicated in table 3 ('side 1 of tolerance'); Furthermore, levels of vitamins and minerals added to foods as regulated by Regulation (EC) No 1925/2006/EC are measured by Member States' control authorities in order to control the compliance with levels of vitamins and minerals declared in the nutrition declaration. To the lower side, meaning below the declared values of the vitamins or minerals added to foods, a tolerance that only includes the measurement uncertainty is applied, while above the declared values deviations from the declared value can be accepted within the upper tolerance indicated in table 3 ('side 1 of tolerance').

Table 3: tolerances for foods and food supplements for controlling the compliance of levels of nutrients and other substances with levels specified in Regulation 1924/2006/EC and for controlling the levels of vitamins and minerals when added to foods according to Regulation 1925/2006/EC

	Tolerances for foods and food supplements	
	Side 1 of tolerance (includes uncertainty of measurement to the side specified, + or -)	**Side 2 of tolerance**
Vitamins	**+50%****	**– measurement uncertainty**
Minerals	**+45%**	**– measurement uncertainty**
Carbohydrate*, **Protein*,** **Fibre***	**<10 g per 100 g: +4g** **10-40 g per 100 g: +40%** **>40 g per 100 g: +16g**	**– measurement uncertainty** **– measurement uncertainty** **– measurement uncertainty**
Sugars*	**<10 g per 100 g: -4g** **10-40 g per 100 g: -40%** **>40 g per 100 g: -16g**	**+ measurement uncertainty** **+ measurement uncertainty** **+ measurement uncertainty**
Fat*	**<10 g per 100 g: -3g** **10-40 g per 100 g: -40%** **>40 g per 100 g: -16g**	**+ measurement uncertainty** **+ measurement uncertainty** **+ measurement uncertainty**
Saturates*	**<4 g per 100 g: -1.6 g** **≥4g per 100 g: -40%**	**+ measurement uncertainty** **+ measurement uncertainty**
Mono-unsaturates*, **Polyunsaturates***	**<4 g per 100 g: +1.6 g** **≥4g per 100 g: +40%**	**- measurement uncertainty** **- measurement uncertainty**
Sodium	**< 0.5 g per 100 g: -0.3 g** **≥0.5 g per 100 g: -40%**	**+ measurement uncertainty** **+ measurement uncertainty**
Salt	**<1.25 g per 100 g: -0.75 g** **≥1.25 g per 100 g: -40%**	**+ measurement uncertainty** **+ measurement uncertainty**

*Not applicable to sub-categories

** for vitamin C in liquids, higher upper tolerance values could be accepted

Example 3:

- A food product with added vitamin C and a claim 'source of vitamin C' that does not contain naturally occurring vitamin C
- Conditions of use for the claim: 15% of daily reference intake (80 mg) per 100 g = 12 mg vitamin C/100 g
- Nutrition declaration of the product: vitamin C: 12 mg/100 g
- According to the rounding rules of section 6 this equals to 11.5 to 12.4 mg vitamin C /100g

Case 1) Official control finds a vitamin C content of 9.6 mg/100 g, the associated measurement uncertainty is ± 1.92 mg/100 g (a specific measurement uncertainty of 20% is assumed for this analysis): 9.6 + 1.92 = 11.52; this product is found to be within the tolerance range according to the criteria laid down in section 5.1

Case 2) Official control finds a vitamin C content of 9.5 mg ± 1.9 mg/100 g (a specific measurement uncertainty of 20 % is assumed for this analysis): the value is outside the lower tolerance range according to the criteria laid down in section 5.1 and section 2.4 should be considered which gives examples of factors to be taken into account when the measured value is outside the tolerance for the declared value.

Case 3) Official control finds a vitamin C content of 17 mg/100 g which is within the upper tolerance range according to the criteria laid down in section 5.1; the upper tolerance equals the upper value (here 12.4 mg) plus the upper tolerance for vitamin C from table 3 which is 50%; (50 % of 12.4 = 6.2); 12.4 +

6.2 = 18.6 mg/100 g and according to the rounding guidelines of section 6 the upper bound tolerance will be 19 mg/100 g

Case 4) Official control finds a vitamin C content of 23 mg/100 g which is outside the upper tolerance range according to the criteria laid down in section 5.1 (see case 3); section 2.4 should be considered which gives examples of factors to be taken into account when the measured value is outside the tolerance for the declared value

Example 4:

- A food product with a 'reduced fat' claim, the fat content of the similar product is 40 g
- Conditions of use for the claim: at least a 30% reduction of fat compared to a similar product
- Nutrition declaration of the product: fat: 28 g/100 g
- According to the rounding rules of section 6 this equals to 27.5 to 28.4 g fat /100 g

Case 1) Official control finds a fat content of 29 g/100 g, the associated measurement uncertainty is ± 0.87 g/100 g (a specific measurement uncertainty of ± 3 % is assumed for this analysis); this product is found to be within the tolerance range according to the criteria laid down in section 5 since the found value minus the associated measurement uncertainty is within the acceptable range of the declared value; 29 - 0.87 = 28.13 g/100 g and according to the rounding guidelines of section 6 the upper bound tolerance will be 28 g/100 g

Case 2) Official control finds a fat content of 30 ± 0.9 g/100 g (a specific measurement uncertainty of ± 3 % is assumed for this analysis); the value is outside the upper tolerance since the found value minus the associated measurement uncertainty is outside the acceptable range of the declared value: 30 – 0.9 = 29.1 g/100 g and according to the rounding guidelines of section 6 the upper bound tolerance will be 29 g/100 g and section 2.4 should be considered which gives examples of factors to be taken into account when the measured value is outside the tolerance for the declared value.

Case 3) Official control finds a fat content of 20 g/100 g which is within the lower tolerance range according to the criteria laid down in section 5; the lower tolerance equals the lower value (here 27.5 g) minus (according to information provided in Table 3) 40 % of 27.5 which equals 11 g; 27.5 – 11 = 16.5 g/100 g, rounded to 17 g/100 g;

Case 4) Official control finds a fat content of 16 g/100 g which is outside the lower tolerance range according to the criteria laid down in section 5 (see case 3); section 2.4 should be considered which gives examples of factors to be taken into account when the measured value is outside the tolerance for the declared value.

5.2 The declared values for the nutrients or other substances for which claims are made exceed the minimum levels or are below the maximum levels specified in the conditions of use for such claims to an extent, that if the tolerances from table 1 (for foods other than food supplements) or table 2 (for food supplements) are applied around these declared values, the overall tolerance range would not overlap with the levels of nutrients or other substances specified in the conditions of use for such claims

or

the declared values for the vitamins and minerals added to foods exceed the minimum levels of vitamins and minerals that are required to be present in the food according to the provisions in Regulation (EC) No 1925/2006 to an extent, that if the tolerances from table 1 are applied around these declared values, the overall tolerance range would not overlap with the minimum levels of vitamins and minerals that are required to be present in the food according to the provisions in Regulation (EC) No 1925/2006

In this case, the tolerance values from table 1 for foods other than food supplements and the tolerance values from table 2 for food supplements apply.

Example 5:

- A food product with added vitamin C and no claim

- Minimum amount of vitamin C to be provided in 100 g of the product: 15% of daily reference intake (80 mg) per 100 g = 12 mg vitamin C/100 g
- Nutrition declaration of the product: vitamin C: 24 mg/100 g
- According to the rounding rules of section 6 this equals to 23.5 to 24.4 mg vitamin C /100g
- If the tolerances for vitamin C from table 1 are applied (-35% +50%), this would lead to a lower tolerance: lower value (23.5) minus 35%; (35% of 23.5 = 8.225 mg) = 15.275 mg/100 g and according to the rounding guidelines of section 6 the lower bound tolerance will be 15 mg/100 g; this value is above the minimum level required in the product (12 mg/100 g), therefore the provisions explained in 5.2 apply, the tolerances from table 1 are applied.
- Upper tolerance: upper value (24.4) plus the upper tolerance for vitamin C from table 1, section 3 which is 50% (50% of 24.4 = 12.2 mg) = 36.6 mg/100 g and according to the rounding guidelines of section 6 the upper bound tolerance will be 37 mg/100 g
- If official control finds a vitamin C content:
  - in the range of 15 to 37 mg/100 g this product is found to be within the tolerance range according to the criteria laid down in 5.2;
  - between the declared value and the lower tolerance range, control of compliance with section 2.3 should be considered;
- - that is outside the range of 15 to 37 mg/100 g, section 2.4 should be considered which gives examples of aspects to be taken into account when the measured value is outside the tolerance for the declared value.

5.3 The declared values for the nutrients or other substances for which claims are made exceed the minimum levels or are below the maximum levels specified in the conditions of use for such claims to an extent, that if the tolerances from table 1 (for foods other than food supplements) or table 2 (for food supplements) are applied around these declared values, the overall tolerance range would overlap with the levels of nutrients or other substances specified in the conditions of use for such claims
or
the declared values for the vitamins and minerals added to foods exceed the minimum levels of vitamins and minerals that are required to be present in the food according to the provisions in Regulation (EC) No 1925/2006 to an extent, that if the tolerances from table 1 are applied around these declared values, the overall tolerance range would overlap with the minimum levels of vitamins and minerals that are required to be present in the food according to the provisions in Regulation (EC) No 1925/2006

In this case, if a nutrition and health claim is made for nutrients or other substances, a tolerance range of the overall magnitude specified under 'side 1 of tolerance' in table 3 is applied to the minimum levels or the maximum levels of the nutrients or other substances for which claims are made as specified in the conditions of use for such claims.

For vitamins and minerals added to foods as regulated by Regulation (EC) No 1925/2006/EC, a tolerance range of the overall magnitude specified under 'side 1 of tolerance' in table 3 is applied to the minimum levels of the vitamins and minerals required to be present in the food according to the provisions in Regulation (EC) No 1925/2006.

The tolerance range described in 5.3 includes the uncertainty of measurement associated with a measured value. Therefore, no further allowance for uncertainty of measurement has to be made when deciding whether a measured value is compliant with the declared value.

Example 6:
- A solid food product with a 'low in sugars' claim
- Conditions of use for the claim: maximum 5 g of sugars per 100 g

- Nutrition declaration of the product: sugars: 4.1 g/100 g
- According to the rounding rules of section 6 this equals to 4.05 to 4.14 g sugars /100 g
- If the tolerances for sugars from table 1 are applied (± 2 g), this would lead to an upper tolerance: upper value (4.14) plus 2 g = 6.14 g/100 g and according to the rounding guidelines of section 6 the upper bound tolerance will be 6.1 g/100 g; the tolerance range from table 1 would overlap with the maximum level of 5 g sugars per 100 g according to the conditions for the claim made. Therefore, the provisions explained in 5.3 apply, the overall magnitude specified in side 1 of tolerance table in table 3 (-4 g) is applied to the maximum level of sugars specified in the conditions for the claim (5 g). According to the rounding guidelines of section 6 the upper bound tolerance will be 5.0 g and the lower bound tolerance will be 1.0 g.
- If official control finds sugars content:
- - in the range of 1.0 to 5.0 g/100 g this product is found to be within the tolerance range according to the criteria laid down in 5.3;
- - that is outside the range of 1.0 to 5.0 g/100 g, section 2.4 should be considered which gives examples of aspects to be taken into account when the measured value is outside the tolerance for the declared value.

5.4 A claim is made for nutrients or other substances which specifies a level that exceeds the minimum levels or is below the maximum levels specified in the conditions of use for such claims

In order to ensure that consumers are not misled by nutrition and health claims, in this case, the provisions of 5.1 apply.

Example 7:

- A food product with a claim 'high in fibre, contains 12 g of fibre per 100g', it contains only 2 g of fibre per 100 kcal
- Conditions of use for the claim: minimum 6 g of fibre / 100 g
- Nutrition declaration of the product: fibre: 12 g/100 g
- According to the rounding rules of section 6 this equals to 11.5 to 12.4 g fibre /100g
- In the claim a level of fibre is specified that exceeds the minimum level specified in the conditions of use for such a claim (6 g/100 g). Therefore, the provisions explained in 5.4 apply, which means 5.1 applies.

Case 1) Official control finds a fibre content of 9.6 g/100 g, the associated measurement uncertainty is ± 1.92 g/100 g (a specific measurement uncertainty of 20% is assumed for this analysis), 9.6 + 1.92 = 11.52 g, the measurement uncertainty can explain that the value found is below the value declared; this product is found to be within the tolerance range according to the criteria laid down in section 5.1

Case 2) Official control finds a fibre content of 8.1 g ± 1.62 g/100 g (a specific measurement uncertainty of 20 % is assumed for this analysis), 8.1 + 1.62 = 9.72 g: the value is outside the lower tolerance range according to the criteria laid down in section 5.1 and section 2.4 should be considered which gives examples of factors to be taken into account when the measured value is outside the tolerance for the declared value.

Case 3) Official control finds a fibre content of 14.5 g/100 g which is within the upper tolerance range according to the criteria laid down in section 5.1; the upper tolerance equals the upper value (here 12.4 g) plus the upper tolerance for fibre from table 3 which is + 40% ; (40 % of 12.4 = 4.96); 12.4 + 4.96 = 17.36 g/100 g and according to the rounding guidelines of section 6 the upper bound tolerance will be 17 g/100 g

Case 4) Official control finds a fibre content of 18.1 g/100 g which is outside the upper tolerance range according to the criteria laid down in section 5.1 (see case 3); section 2.4 should be considered which gives examples of factors to be taken into account when the measured value is outside the tolerance for the declared value.

6. ROUNDING GUIDELINES FOR NUTRITION DECLARATIONS FOR FOODS

Rounding guidelines are among the factors that influence the setting of tolerances, including the number of significant figures or decimal places in order not to imply a level of precision which is not true. The guidance on the rounding of the declared values should be taken into account when estimating whether the value that was determined during the analysis of the control authority is within tolerance limits.

For example, based on the rounding guidance, a declared value for protein of 12 g (no claim about protein made) could represent a value derived from calculation or analysis of between 12.4 g and 11.5g.

- The margins of tolerance should be applied to the upper and lower bounds of the values that could be rounded to the declared value, in this example 12.4g and 11.5 g.
- In this case the tolerance identified in section 3 would be ±20%, this gives a tolerance on the upper side calculated from 12.4g plus 20% making a total of 14.88g, rounded to 15g.
- If the analysed amount is found to be 15 g, this would be regarded as being within the tolerance, 16 g is not.

Another aspect of rounding rules are the amounts of nutrients which can be regarded as negligible and can be therefore declared as '0' or as '<x g' as indicated in table 4 giving values for 'x' for the specific nutrients. Alternatively, 'contains negligible amounts of …' could be labelled.

Table 4: Rounding guidelines for the nutrient declaration in nutrition labelling of foods

Nutritional element	Amount	Rounding
Energy		to nearest 1 kJ/kcal (no decimals)
Fat*, Carbohydrate*, sugars*, Protein*, fibre*, polyols*, starch*	≥10 g per100 g or ml	to nearest 1 g (no decimals)
	<10 g and > 0.5 g per 100 g or ml	to nearest 0.1 g
	no detectable amounts is present or concentration is ≤ 0.5 g per 100 g or ml	"0 g" or "<0.5 g" may be declared
Saturates*, Mono-unsaturates*, Polyunsaturates*	≥10 g per 100 g or ml	to nearest 1 g (no decimals)
	<10 and > 0.1 g per 100 g or ml	to nearest 0.1 g
	no detectable amounts is present or concentration is ≤ 0.1 g per 100 g or ml	"0 g" or "<0.1 g" may be declared
Sodium	≥1 g per 100 g or ml	to nearest 0.1 g
	<1 g and > 0.005 g per 100 g or ml	to nearest 0.01 g
	no detectable amounts is present or concentration is ≤ 0.005 g per 100 g or ml	"0 g" or "<0.005 g" may be declared
Salt	≥1 g per 100 g or ml	to nearest 0.1 g
	<1 g and > 0.0125 g per 100 g or ml	to nearest 0.01 g
	no detectable amounts is present or concentration is ≤ 0.0125 g per 100 g or ml	"0 g" or <0.01 g" may be declared
Vitamins and minerals	vitamin A, folic acid, chloride, calcium, phosphorus, magnesium, iodine, potassium	3 significant figures
	All other vitamins and minerals	2 significant figures

*Not applicable to sub-categories