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Setting of tolerances for nutrient values declared on a label

Guidance For Food Supplements

January 2014

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Guidance for food supplements

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This guidance document is intended to assist food supplement companies in setting tolerances for nutrition labelling of food supplements under Directive 2002/46/EC and Regulation (EC) No 1924/2006 on nutrition and health claims made on foods. Tolerances mean the acceptable differences between the nutrient values declared on the label and those established in the course of official controls.

This guidance document presents a schematic interpretation of the European Commission guidance for competent authorities for the control of the compliances with EU legislation related to the setting of tolerances.

The guidance is divided into the following sections:

- Rounding guidelines for nutrition labelling;
- Tolerances for vitamins and minerals in supplements;
- Tolerances for controlling the compliance levels of nutrients with levels specified in Regulation (EC) No 1924/2006.

It should be used in conjunction with the European Commission Guidance published in December 2012 and available at the following link: http://ec.europa.eu/food/food/labellingnutrition/nutritionlabel/index_en.htm.

This document is a living document and will be updated to reflect the views of the competent authorities and food supplement companies.

January 2014

Rounding Guidelines for Nutrition Declaration

The rounding should be taken into account for nutrition declaration. Table 1 below summarises the rounding rules for the nutrient information of label.

Table 1. Rounding guidelines for the nutrient declaration in nutrition labelling of foods and food supplements

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

The rounding of the declared values should be taken into account when determining the tolerance limits.

Amounts of nutrients which can be regarded as negligible.

1. Can be declared as '0' ; or
2. As '<x g' as indicated in table 1 ; or
3. labelled as 'contains negligible amounts of ...' in close proximity of the nutrition declaration.

Use of significant figures: There are 3 rules on how to define how many significant figures are in a number.

Rules	Number	Significant figures
All non-zero digits are always significant	12,4	3
All zeros to the right of a significant digit are always significant	12,40	4
	0,001	1
Any zeros between 2 significant digits are significant	102	3

Tolerances: Questions and Answers

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What are tolerances?

Tolerances mean the acceptable difference between the nutrient values declared on a label and those established in the course of official controls.

What is tolerance range?

Tolerance range is the difference between the upper and lower level of the tolerances.

Why setting tolerances?

The actual amount of a nutrient may vary compared to the value declared on the label. To ensure that label information is accurate and reflects the nutrient content of the food, tolerance limits have to set. Tolerances are also important for determining if a declared value is correct in the course of official controls by authorities.

What is uncertainty of measurement?

Uncertainty of measurement is a parameter reflecting the precision and the accuracy of a measurement. It charaterises the dispersion around the measured value (e.g. 10 mg +/- 10%). The degree of uncertainty is the result of factors including the limitations of the measuring instruments, sample preparation, measurement conditions, methods of analysis, etc.

How can the declared values be defined?

The declared values should approximate the average values across different batches. The EU guidance on tolerances defines the average value as the value that best represents the amount of a 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.

Compliance over shelf life

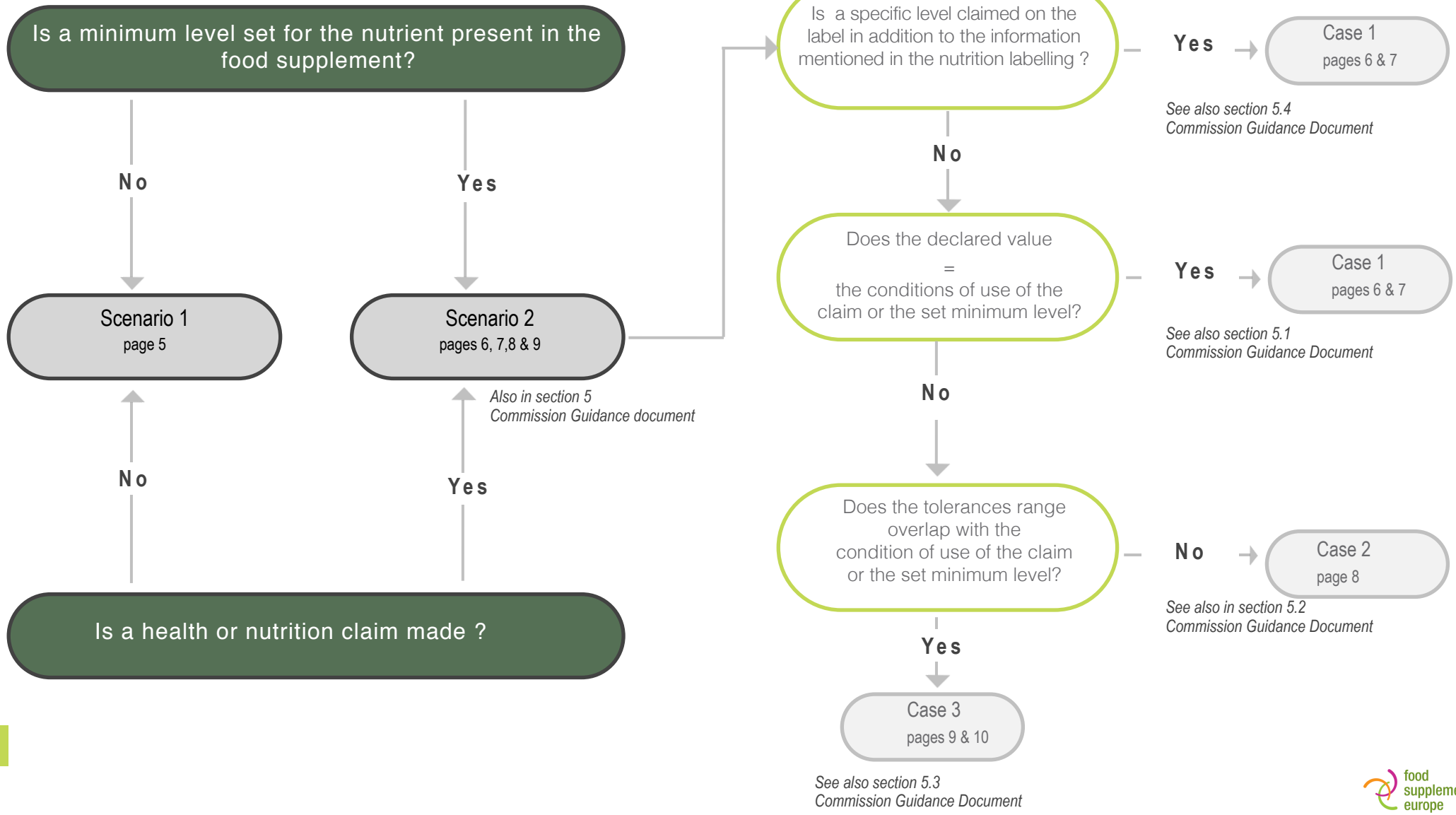
The measured value should be within the tolerances around the declared value during the entire shelf life.

Should safety be taken into account when setting tolerances?

Safety has to be taken into account when setting tolerances for vitamins and minerals. The maximun levels should not be exceeded. In other words, maximum levels for vitamins and minerals based on safety should include any tolerance. However, since national maximum levels have not always been determined on the basis of safety, in the absence of harmonised rules on maximum amounts for vitamins and minerals, national practice of handling this issue that were applied before December 2012 may be maintained.

Setting of Tolerances for Nutrient Values: Overview

This flowchart shows in which cases the setting of tolerances is applicable and to which section of this guidance document you should refer to.



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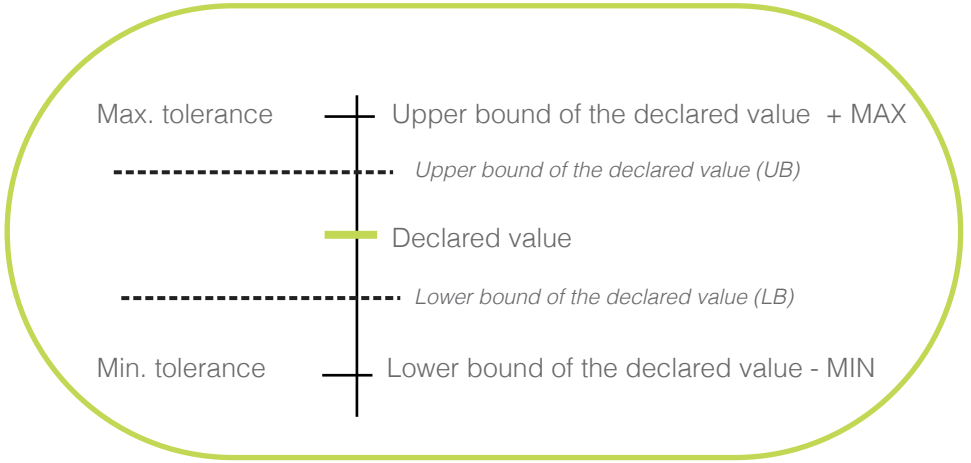
GENERAL PRINCIPLE

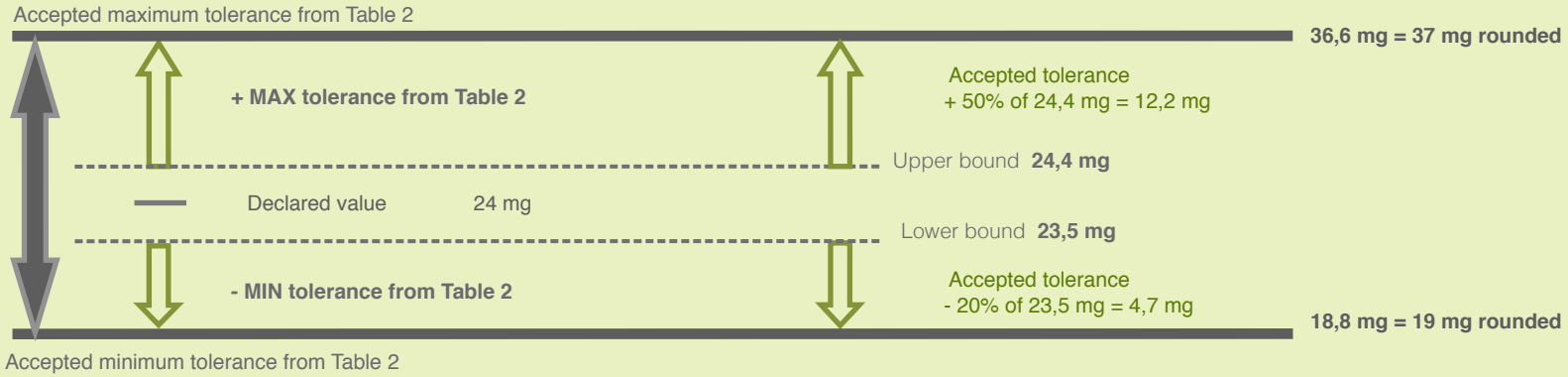
Tolerances for vitamins and minerals in food supplements include the uncertainty of measurement associated with a measured value.
No further allowance for measurement uncertainty has to be made when deciding whether a measured value is compliant with the declared value.

Table 2. Tolerances for food supplements including measurement uncertainty

	Maximum (MAX)	Minimum (MIN)
Vitamins	+50%	-20%
Minerals	+45%	-20%

For Vitamin C in liquids, higher upper tolerance values could be accepted.





Scenario 2 - CASE 1A

- Declared value equals the minimum level specified in the conditions of use of the claim **or** the set minimum value, **OR**
- When a level - exceeding the minimum level specified in the conditions of use of the claim - is made in addition to the information mentioned in the nutrition labelling

A

When a MINIMUM level is specified, either as condition of use for a claim or as a minimum level set for the addition of nutrients to food supplements,

OR

When a claim referring to a specific quantity of a nutrient - exceeding the minimum level specified in the conditions of use of the claim - is made in addition to the information mentioned in the nutrition labelling.

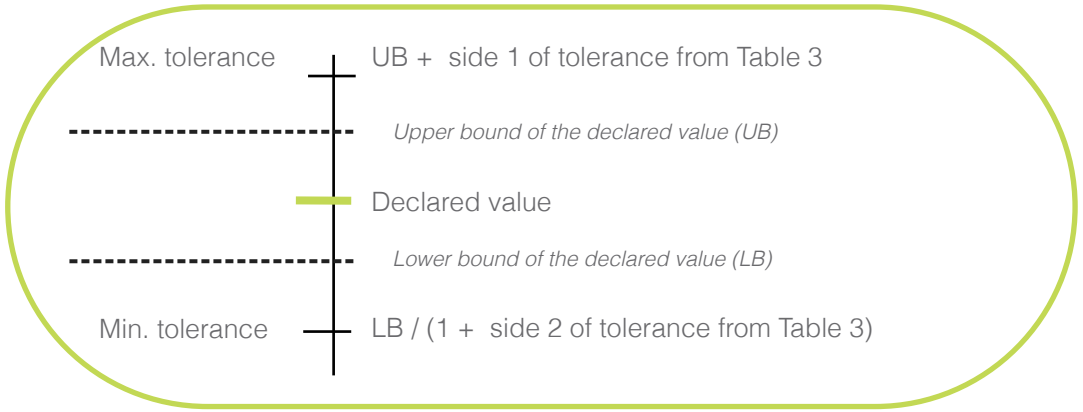
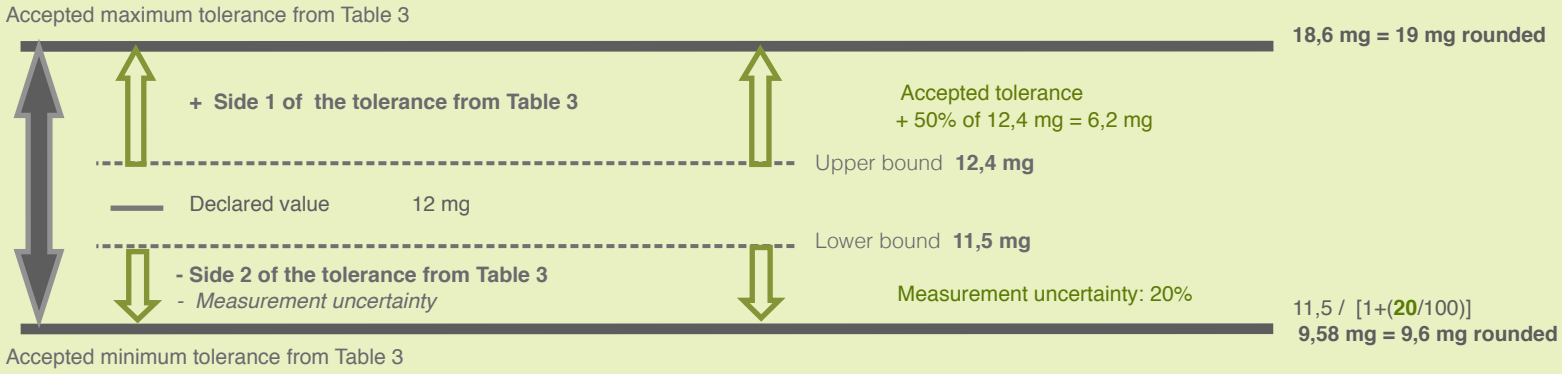


Table 3. Tolerances for food supplements for controlling the compliance of levels of nutrients with the levels specified in the Nutrition and Health Claims Regulation 1924/2006/EC

	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



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Scenario 2 - CASE 1 B

- Declared value equals the maximum level specified in the conditions of use of the claim, **OR**
- When a level - below the maximum level specified in the conditions of use of the claim - is made in addition to the information mentioned in the nutrition labelling

B

In case a MAXIMUM level is specified in the conditions of use of the claim,

OR

When a claim referring to a specific quantity of a nutrient - below the maximum level specified in the conditions of use of the claim - is made in addition to the information mentioned in the nutrition labelling.

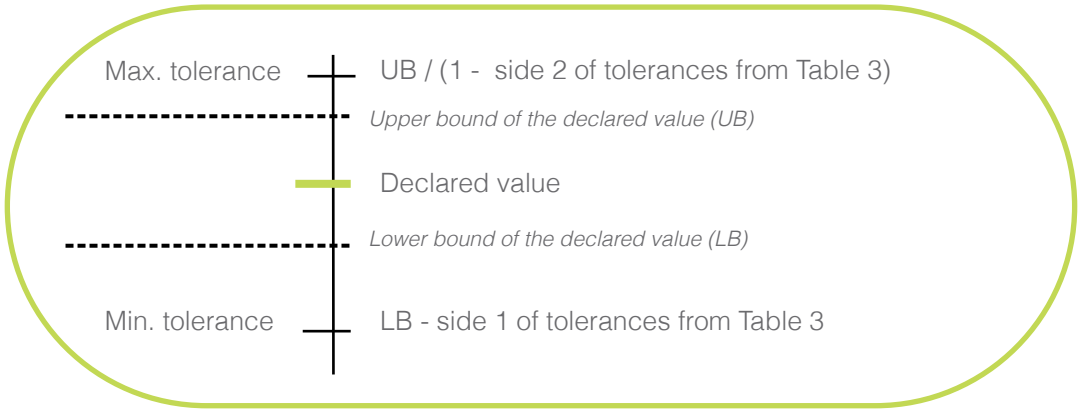
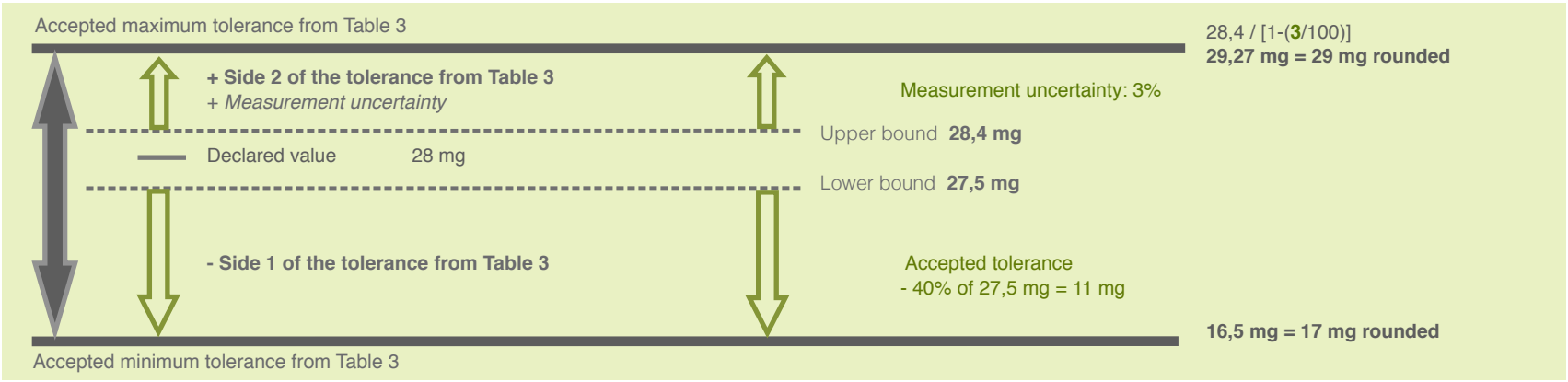


Table 3. Tolerances for food supplements for controlling the compliance of levels of nutrients with the levels specified in the Nutrition and Health Claims Regulation 1924/2006/EC

	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



28,4 / [1-(**3**/100)]
29,27 mg = 29 mg rounded

16,5 mg = 17 mg rounded

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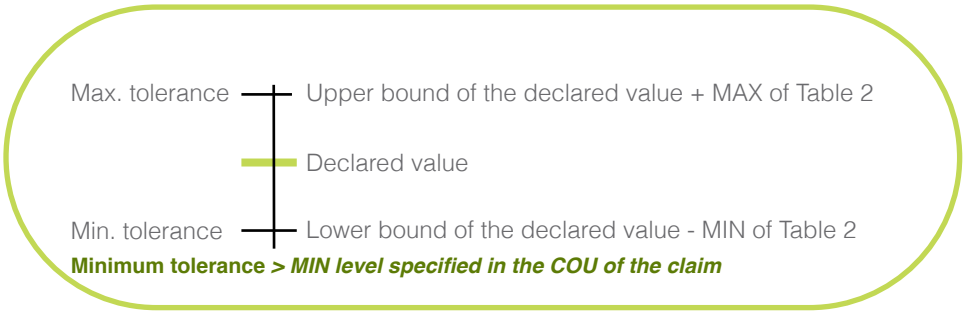
Scenario 2 - CASE 2

- Declared value different from level specified in the conditions of use of the claim, **AND**
- Tolerance range calculated according to Table 2 not overlapping with the condition of use (COU) of the claim

A Declared value exceeding the MINIMUM level specified in the COU of the claim, **AND**

Tolerances calculated according to Table 2 above the minimum level specified in the COU of the claim.

Tolerance values from Table 2 apply.



B Declared value below the MAXIMUM level specified in the COU of the claim, **AND**

Tolerances calculated according to Table 2 below the maximum level specified in the COU of the claim.

Tolerance values from Table 2 apply.

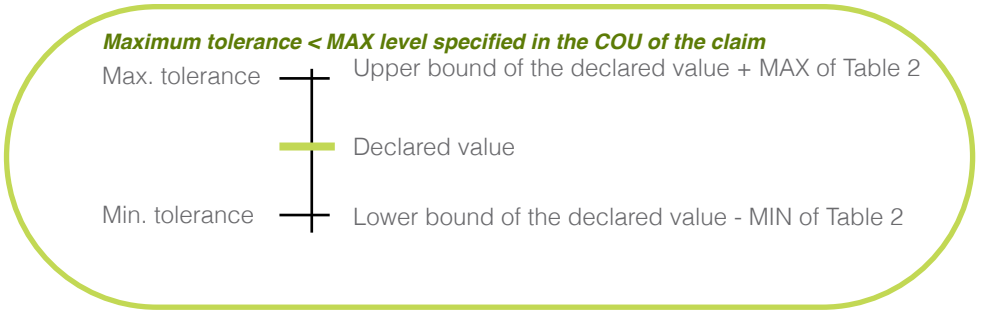


Table 2. Tolerances for food supplements including measurement uncertainty

	Maximum (MAX)	Minimum (MIN)
Vitamins	+50%	-20%
Minerals	+45%	-20%

For Vitamin C in liquids, higher upper tolerance values could be accepted.

Example for a food supplement bearing a claim 'source of vitamin C'
COU: Minimum 12 mg per day

Declared value = 24 mg / daily dose
Minimum value specified in the conditions of use of the claim: **12 mg** / daily dose

Upper bound of the declared value: 24,4 mg / daily dose
Lower bound of the declared value: 23,5 mg / daily dose

If the tolerance values from Table 2 apply:
Tolerance range = [23,5 **- 20%** ; 24,4 **+ 50%**] = [18,8 mg ; 36,6 mg] = [**19 mg** ; 37 mg] rounded
But **19 mg** > **12 mg** / daily dose

Therefore the tolerance values from table 2 apply.

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Scenario 2 - CASE 3 A

- Declared value different from the level specified in the conditions of use of the claim (COU), **AND**
- Tolerance range calculated according to Table 2 overlapping with the minimum level specified in the conditions of use of the claim

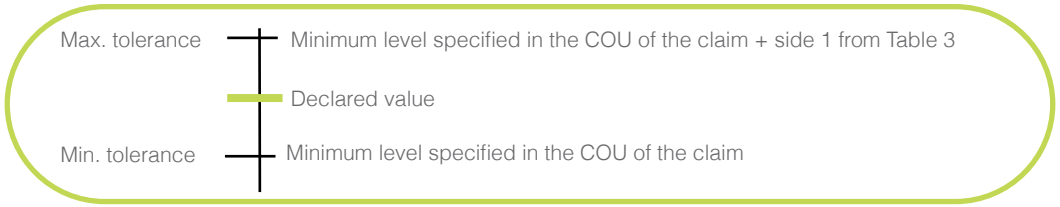
A

Declared value exceeding the MINIMUM level specified in the COU of the claim,

AND

Tolerances calculated according to Table 2 below the minimum level specified in the COU of the claim.

Tolerance values from Table 3 'side 1' apply to the minimum level specified in the conditions of use of the claim.



Example for a food supplement containing a vitamin

Declared value = 14 mg / daily dose

Minimum value specified in the conditions of use of the claim: **12 mg** / daily dose

Upper bound of the declared value: 14,4 mg / daily dose Lower bound of the declared value: 13,5 mg / daily dose

If the tolerances from Table 2 are applied:

Tolerance range = [13,5 **- 20%** ; 14,4 **+ 50%**] = [10,8 mg ; 21,6 mg] = [**11 mg** ; 22 mg] rounded.

But **11 mg** < **12 mg** / daily dose

Therefore the tolerance values from table 3 'side 1' apply to the level specified in the conditions of use of the claim:

[12 mg ; 12 mg + 50%] = [12 mg ; 18 mg] = [12 mg ; 18 mg] rounded

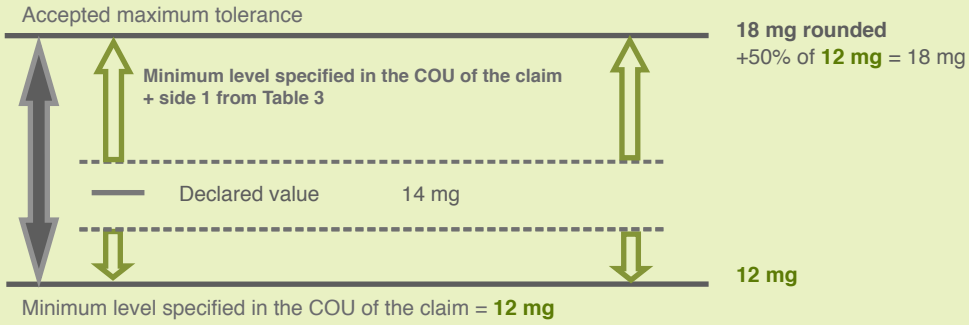


Table 2. Tolerances for food supplements including measurement uncertainty

	Maximum (MAX)	Minimum (MIN)
Vitamins	+50%	-20%
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For Vitamin C in liquids, higher upper tolerance values could be accepted.

Table 3. Tolerances for food supplements for controlling the compliance of levels of nutrients with the levels specified in the Nutrition and Health Claims Regulation 1924/2006/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

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Scenario 2 - CASE 3 B

- Declared value different from the level specified in the conditions of use of the claim (COU), **AND**
- Tolerance range calculated according to Table 2 overlapping with the maximum level specified in the conditions of use of the claim

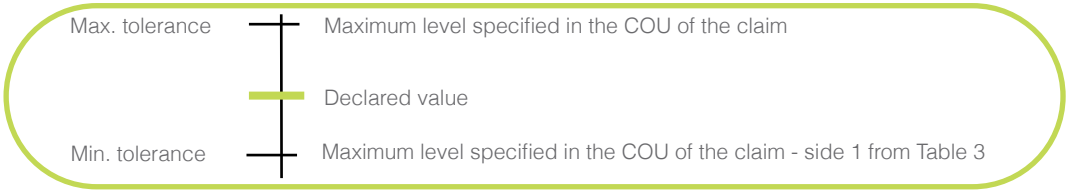
B

Declared value below the MAXIMUM level specified in the COU of the claim,

AND

Tolerances calculated according to Table 2 above the maximum levels specified in the COU of the claim.

Tolerance values from Table 3 'side 1' apply to the maximum level specified in the conditions of use of the claim.



Example for a food supplement containing a vitamin

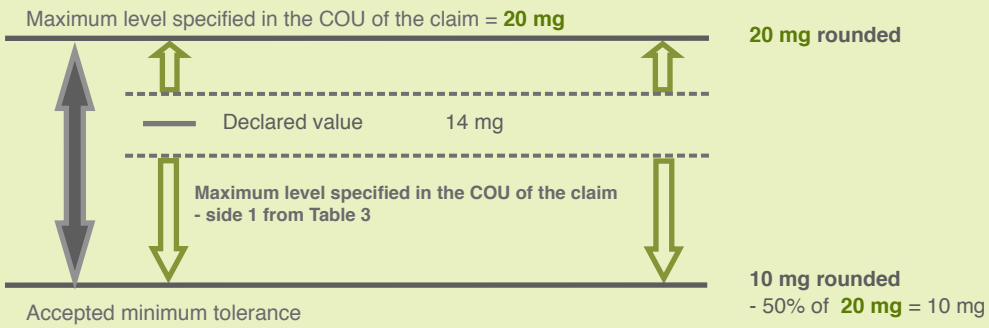
Declared value = 14 mg / daily dose
Maximum value specified in the conditions of use of the claim: **20 mg** / daily dose

Upper bound of the declared value: 14,4 mg / daily dose
Lower bound of the declared value: 13,5 mg / daily dose

If the tolerances from Table 2 are applied:
Tolerance range = [13,5 **- 20%** ; 14,4 **+ 50%**] = [10,8 mg ; 21,6 mg] = [11 mg ; **22 mg**] rounded.

But **22 mg** > **20 mg** / daily dose

Therefore the tolerance values from table 3 'side 1' apply to the level specified in the conditions of use of the claim:
[20 mg - 50% ; 20 mg] = [10 mg ; 20 mg] = [10 mg ; 20 mg] rounded



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For Vitamin C in liquids, higher upper tolerance values could be accepted.

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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**

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