

Tolerances for Nutrient Values Declared on a Food or Drink Label

In December 2012 the European Commission Health and Consumers Directorate General published a “Guidance Document for Competent Authorities for the Control of Compliance with EU Legislation on ... the Setting of Tolerances for Nutrient Values Declared on a Label” ([the EC Guide](#)). Its aim was to provide advice on calculating acceptable differences between levels of nutrients and other substances declared on a label and those established in the course of official controls in relation to ‘nutrition declaration’ or ‘nutrition labelling’ as described in [Regulation EU 1169/2011](#); and to control compliance with the conditions of use for nutrition claims as listed in the Annex to [Regulation EC 1924/2006](#).

The EC Guide was addressed to control authorities and food business operators; its comprehensiveness and the complexity of its rules make comprehension and application somewhat difficult in places. We have produced this simplified guidance to help food business operators set tolerances which may differ from the EC Guide, but will be compatible with it. That is, tolerance ranges calculated using this simplified guidance will be wholly contained in tolerance ranges calculated according to the EC Guide, but may be slightly narrower.

This guidance is restricted to setting tolerances on declared nutrient values. For help with labelling issues in general and nutrient labelling in particular, please contact our legislation team at regulatoryadvice@campdenbri.co.uk or visit our website at www.campdenbri.co.uk/services/legislation-advice-service.php

For help with nutritional analytical issues, contact David Miles at david.miles@campdenbri.co.uk, or see our website at www.campdenbri.co.uk/services/nutritional-analysis.php

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1. Introduction

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:

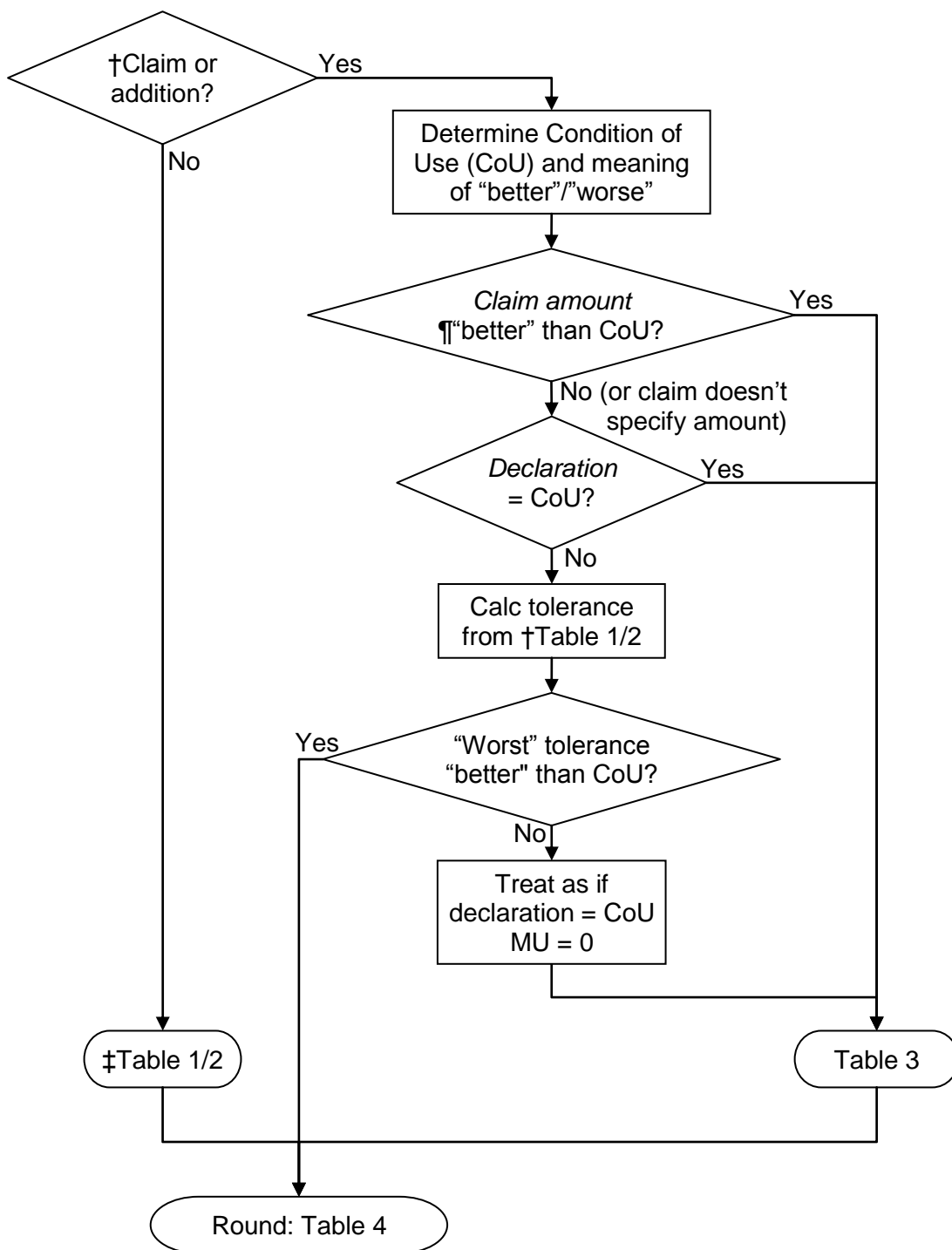
- a) analysis of the food;
- b) calculation from the known or actual average values of the ingredients used; or
- c) calculation from generally established and accepted data.

Analysis is usually the best way of arriving at a declared value. We can help with analysis or calculation, see www.campdenbri.co.uk/services/nutritional-analysis.php.

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.

A flow diagram (section 2) shows the steps in calculating tolerance ranges, and supplementary tables (sections 3-5) provide required information. Section 6 gives worked examples of the application of this guidance to example circumstances taken from the EC Guide. In this guidance the first reference to official documents is an active hyperlink to an appropriate website; Section 7 lists these internet addresses.

2. Flow diagram (see worked examples in Section 6)



† "Claim" is fully defined by Regulation EC 1924/2006, but may loosely be thought of as a representation (written or graphic) which:

- a) is not legally required, and
- b) implies benefits to nutrition or health.

Additions of vitamins and minerals are regulated by [Regulation \(EC\) No 1925/2006](#). Such claims and additions are subject to Conditions of Use described in section 3.

‡Table 2 for food supplements, Table 1 for other foods.

¶The meaning of “better” depends on the nutrient. Either:

- “Better” is less (e.g. fat); conditions of use give maximum levels.
- “Better” is more (e.g. protein); conditions of use give minimum levels.

Table 3 in section 4 indicates the direction of “better” for a range of nutrients

3. Conditions of use

Nutrition claims are only permitted as laid out in the annexes to Regulation (EC) No 1924/2006. A more readable list of permitted claims and their conditions of use is in the [European Union Register of Nutrition claims](#). Some examples of conditions of use are shown in Figure 1 below.

Vitamins and/or minerals may only be added to foods as permitted by Regulation (EC) No 1925/2006. The [Community Register on the addition of vitamins and minerals](#) lists permitted vitamins, minerals, and formulations, and gives conditions of use. Currently the only level-related condition of use on added vitamins and minerals is “a significant amount” as defined in EU law. This is currently defined in the annex of [Directive 90/496/EEC](#). From 13 December 2014 the identical table in Annex XIII of the Food Information to Consumers [Regulation \(EU\) No 1169/2011](#) will apply. These lead to values shown in Figure 2 below.

Figure 1: Examples of claim conditions of use; adapted from Regulation (EC) No 1924/2006

Nutrient	Claim	CoU /100g (solids)
Vitamins, Minerals	Source, Contains	≥ “significant amount”
	High	≥ 2 x “significant amount”
Protein	Source	≥ 12% of energy
	High	≥ 20% of energy
Fibre	Source	≥ 3 g
	High	≥ 6 g
Sugars	Low	≤ 5 g
	Free	≤ 0.5 g
Fat	Low	≤ 3 g
	Free	≤ 0.5 g
Saturates	Low	≤ 1.5 g
	Free	≤ 0.1 g
Sodium, Salt	Low	≤ 0.12 g Na
	Very low	≤ 0.04 g Na
	Free	≤ 0.005 g Na
Energy	Low	≤ 40 kcal
	Reduced	reduced by at least 30%
	Free	≤ 4 kcal

**Figure 2: Vitamin and mineral “significant amounts”:
adapted from Directive 90/496/EEC and Regulation (EU) No 1169/2011**

Nutrient	Significant amount	Nutrient	Significant amount
Vitamin A (µg)	120	Potassium (mg)	300
Vitamin D (µg)	0.75	Chloride (mg)	120
Vitamin E (mg)	1.8	Calcium (mg)	120
Vitamin K (µg)	11.25	Phosphorus (mg)	105
Vitamin C (mg)	12	Magnesium (mg)	56.25
Thiamin (mg)	0.165	Iron (mg)	2.1
Riboflavin (mg)	0.21	Zinc (mg)	1.5
Niacin (mg)	2.4	Copper (mg)	0.15
Vitamin B6 (mg)	0.21	Manganese (mg)	0.3
Folic acid (µg)	30	Fluoride (mg)	0.525
Vitamin B12 (µg)	0.375	Selenium (µg)	8.25
Biotin (µg)	7.5	Chromium (µg)	6
Pantothenic acid (mg)	0.9	Molybdenum (µg)	7.5
		Iodine (µg)	22.5

4. Tolerance tables

Table numbers correspond to those in EC Guide.

Tables 1 & 2: No claim or addition

	Nutrient	Declared g per 100g	Tolerance	
Table 2: Supplements	[†] Vitamins		-20%	+50%
	Minerals		-20%	+45%
	[†] Vitamins		-35%	+50%
	Minerals		-35%	+45%
Table 1: Not supplements		<10	-2 g	+2 g
	Carbohydrate, Sugars, Protein, Fibre	10-40	-20%	+20%
		>40	-8 g	+8 g
		<10	-1.5 g	+1.5 g
	Fat	10-40	-20%	+20%
		>40	-8 g	+8 g
		<4	-0.8 g	+0.8 g
	Saturates. Mono-unsaturates, Polyunsaturates	≥4	-20%	+20%
		<0.5	-0.15 g	+0.15 g
	Sodium	≥0.5	-20%	+20%
		<1.25	-0.375	+0.375
	Salt	≥1.25	-20%	+20%

NOTES: [†] For vitamin C in liquids, higher upper tolerance values could be accepted

Make no allowance for measurement uncertainty (MU) other than shown. MU is usually that of the official control; food business operators will often 'play safe' and take MU = 0

Table 3: With claim or added vitamins/minerals

Nutrient	Declared or Claimed g per 100g	Tolerance		Better is:
[†] Vitamins			+50%	
Minerals			+45%	
	<10	-MU	+4 g	more >
[‡] Carbohydrate, Protein, Fibre	10-40		+40%	
	>40		+16 g	
	<10	-4 g		
[‡] Sugars	10-40	-40%		
	>40	-16 g		
	<10	-3g	+MU	less <
[‡] Fat	10-40	-40%		
	>40	-16g		
	<4	-1.6 g		
[‡] Saturates	≥4	-40%		
	<4			
[‡] Mono-unsaturates, Polyunsaturates	≥4	-MU	+1.6 g +40%	more >
	<0.5	-0.3g	+MU	less <
Sodium	≥0.5	-40%		
	<1.25	-0.75g		
Salt	≥1.25	-40%		

NOTES: [†] For vitamin C in liquids, higher upper tolerance values could be accepted

[‡] Not applicable to sub-categories

Make no allowance for measurement uncertainty (MU) other than shown. MU is usually that of the official control; food business operators will often 'play safe' and take MU = 0

5. Rounding Rules

Table 4: Rounding rules (0.5 rounds to 1.0)

	Nutrient	g per 100g	Rounding
Vitamins	Vit A, folic acid		3 sig figs
	others		2 sig figs
Minerals	Cl, Ca, P, Mg, I, K		3 sig figs
	others		2 sig figs
† Fat, Carbohydrate, Sugars, Protein, Fibre, Polyols, Starch		≤0.5	declare 0 or <0.5
		0.5 - 10	nearest 0.1 g
		≥10	nearest 1 g
† Saturates. Mono-unsaturates, Polyunsaturates		≤0.1	declare 0 or <0.1
		0.1 - 10	nearest 0.1 g
		≥10	nearest 1 g
Sodium		≤0.005	declare 0 or <0.005
		0.005 - 1	nearest 0.01 g
		≥1	nearest 0.1 g
Salt		≤0.0125	declare 0 or <0.01
		0.0125 - 1	nearest 0.01 g
		≥1	nearest 0.1 g
Energy			nearest 1kJ/kcal

NOTE: † Not applicable to sub-categories

6. Worked examples

Example circumstances (but not the working) are taken from the EC Guide; example numbers follow the EC Guide; § indicates EC Guide section numbers.

Numbers such as 1) 2) ... indicate steps through the flow diagram starting at “1) Claim or addition?” and continuing to a maximum of nine steps.

Example 1; §3

- A food product with a nutrition declaration of sugars of 8.5 g and no claim made about its sugar content.

- 1) Claim or addition? NO
- 2) Table 1/2
 - Not supplement, so Table 1
 - Sugar, Declared <10; tolerance -2g:+2g
 - 8.5g [-2g:+2g] = 6.5g:10.5g
- 3) Round: Table 4.
 - Sugar
 - 6.5g is in range 0.5 - 10; nearest 0.1g: **6.5g**
 - 10.5g is in range ≥10; nearest 1g: **11g**

If an official control finds a sugar content in the range 6.5-11g, the product is within the tolerance range

Example 2; §4

- A food supplement with a nutrition declaration of folic acid of 125 µg per unit and no claim made about its folic acid content.

- 1) Claim or addition? NO
- 2) Table 1/2
 - Supplement, so Table 2
 - Vitamins; tolerance -20%:+50%
 - 125 µg [-20%:+50%] = 100.0µg:187.5µg
- 3) Round: Table 4.
 - folic, 3 sig figs
 - 100.0µg: **100µg**
 - 187.5µg: **188µg**

If an official control finds a folic acid content in the range 100-188µg, the product is within the tolerance range

Example 3; §5.1

- A food product with added vitamin C and a claim 'source of vitamin C' that does not contain naturally occurring vitamin C.
- Nutrition declaration of the product: vitamin C: 12 mg/100 g.
- A specific measurement uncertainty of 20% is assumed for this analysis.

- 1) Claim or addition? YES
- 2) Determine CoU and meaning of “better”
 - Table: Examples of claim conditions of use
Vitamins; Source; \geq “significant amount”
 - Table: “Significant amounts” for vitamins and minerals
Vitamin C (mg) 12
so CoU = 12, “better” = “more”
- 3) Claim amount better than CoU? NO (claim doesn't specify amount)
- 4) Declaration = CoU? YES
- 5) Table 3
 - Vitamins; tolerance -MU:+50% = -20%:+50%
 - 12mg [-20%:+50%] = 9.6mg:18mg
- 6) Round: Table 4
 - Vitamins; others; 2 sig figs
 - 9.6mg: **9.6mg**
 - 18mg: **18mg**

If an official control finds a vitamin C content in the range 9.6-18mg, the product is within the tolerance range

Example 4; §5.1

- A food product with a 'reduced fat' claim, the fat content of the similar product is 40 g.
- Nutrition declaration of the product: fat: 28 g/100 g.
- A specific measurement uncertainty of $\pm 3 \%$ is assumed for this analysis

- 1) Claim or addition? YES
- 2) Determine CoU and meaning of "better"
 - follow links to find "reduction in content is at least 30 % compared to a similar product"
 - $40\text{g} - 30\% = 28\text{g}$
 - so CoU = 28, "better" = "less"
- 3) Claim amount better than CoU? NO (claim doesn't specify amount)
- 4) Declaration = CoU? YES
- 5) Table 3
 - Fat, Declared 10-40; tolerance $-40\%:+\text{MU} = -40\%:+3\%$
 - $28 [-40\%:+3\%] = 16.8\text{g}; 28.84\text{g}$
- 6) Round: Table 4
 - Fat;
 - 16.8 is in range ≥ 10 ; nearest 1g: **17g**
 - 28.84 is in range ≥ 10 ; nearest 1g: **29g**

If an official control finds a fat content in the range 17-29, the product is within the tolerance range

Example 5; §5.2

- A food product with added vitamin C and no claim.
- Nutrition declaration of the product: vitamin C: 24 mg/100 g.

- 1) Claim or addition? YES
- 2) Determine CoU and meaning of “better”
 - CoU on added vitamins is “a significant amount”
 - Table: “Significant amounts” for vitamins and minerals
Vitamin C (mg) 12so CoU = 12, “better” = “more”
- 3) Claim amount better than CoU? NO (claim doesn’t specify amount)
- 4) Declaration = CoU? NO
- 5) Calc tolerance from Table 1/2
 - Not supplement, so Table 1
 - Vitamins; tolerance -35%:+50%
 - 24mg [-35%:+50%] = 15.6mg:36mg
- 6) “Worst” tolerance “better” than CoU?
worst (least) tolerance = 15.6 is better (more) than CoU = 12 so YES
- 7) Round: Table 4
 - Vitamins; others; 2 sig figs
 - 15.6mg: **16mg**
 - 36mg: **36mg**

If an official control finds a vitamin C content in the range 16-36mg, the product is within the tolerance range

Example 6; §5.3

- A solid food product with a 'low in sugars' claim.
- Nutrition declaration of the product: sugars: 4.1 g/100 g.

- 1) Claim or addition? YES
- 2) Determine CoU and meaning of “better”
 - Table: Examples of claim conditions of use
 - Sugars; Low; $\leq 5\text{g}$
 - so CoU = 5, “better” = “less”
- 3) Claim amount better than CoU? NO (claim doesn't specify amount)
- 4) Declaration = CoU? NO
- 5) Calc tolerance from Table 1/2
 - Not supplement, so Table 1
 - Sugars; Declared <10 ; tolerance $-2\text{g}; +2\text{g}$
 - $4.1\text{g} [-2\text{g}; +2\text{g}] = 2.1\text{g}; 6.1\text{g}$
- 6) “Worst” tolerance “better” than CoU?
worst (highest) tolerance = 6.1g is worse (more) than CoU = 5 so NO
- 7) Treat as if declaration = CoU (=5) MU = 0
- 8) Table 3
 - Sugars; Declared <10 ; tolerance $-4\text{g}; +\text{MU} = -4\text{g}; +0$
 - $5\text{g} [-4\text{g}; +0] = 1\text{g}; 5\text{g}$
- 9) Round: Table 4
 - Sugars
 - 1 is in range 0.5-10; nearest 0.1g: **1g**
 - 5 is in range 0.5-10; nearest 0.1g: **5g**

If an official control finds a sugar content in the range 1-5g, the product is within the tolerance range

Example 7; §5.4

- 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.
- Nutrition declaration of the product: fibre: 12 g/100 g.
- A specific measurement uncertainty of 20% is assumed for this analysis.

- 1) Claim or addition? YES
- 2) Determine CoU and meaning of “better”
 - Table: Examples of claim conditions of use
Fibre; High; $\geq 6\text{g}$
so CoU = 6, “better” = “more”
- 3) Claimed amount better than CoU YES
- 4) Table 3
 - Fibre; Claim 10-40; tolerance -MU:+40% = -20%:+40%
 - 12g [-20%:+40%] = 9.6g:16.8g
- 5) Round: Table 4
 - Fibre
 - 9.6 is in range 0.5-10; nearest 0.1g: **9.6g**
 - 16.8 is in range ≥ 10 ; nearest 1g: **17g**

If an official control finds a fibre content in the range 9.6-17g, the product is within the tolerance range

7. Internet addresses of official documents

[EC Guide](#)

http://ec.europa.eu/food/food/labellingnutrition/nutritionlabel/guidance_tolerances_december_2012.pdf

[Regulation \(EU\) No 1169/2011](#)

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011R1169:EN:NOT>

[Regulation \(EC\) No 1924/2006](#)

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R1924:EN:NOT>

[Regulation \(EC\) No 1925/2006](#)

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R1925:en:NOT>

[European Union Register of Nutrition claims](#)

http://ec.europa.eu/food/food/labellingnutrition/claims/community_register/nutrition_claims_en.htm

[Community Register on the addition of vitamins and minerals](#)

http://ec.europa.eu/food/food/labellingnutrition/vitamins/comm_reg_en.pdf

[Directive 90/496/EEC](#)

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990L0496:en:NOT>

[Regulation \(EU\) No 1169/2011](#)

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011R1169:EN:NOT>