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## Safe upper intake levels for vitamins and minerals

This document provides an overview of the safe upper intake levels for vitamins and minerals established by the following Expert Groups: Scientific Committee on Food (SCF), US Institute of Medicine (IOM), UK Expert Group on Vitamins and Minerals (EVM), Joint FAO/WHO Expert Committee on Food Additives (JECFA) and a Danish Expert Group.

The tolerable upper intake level levels (UL) established by SCF are based on evaluations of possible adverse health effects of individual micronutrients at intakes in excess of dietary requirements and are based on the principles of scientific risk assessment. Similarly, IOM defines the UL levels as the highest level of daily nutrient intake, that is likely to pose no risk of adverse health effects to almost all individuals in the general population.

EVM established two different types of safe upper intake levels, the Guidance level (GL) and the safe upper level (SUL). The determination of SUL or GL entails the determination of doses of vitamins and minerals, that potentially susceptible individuals could take daily on a life-long basis, without medical supervision in reasonable safety. SUL levels were established for vitamins and minerals, for which good data was available regarding both nature and frequency of adverse effects detected at different levels of intake. For vitamins and minerals, where the EVM considered the data inadequate to set a SUL, GLs were given instead. It should however be noted, that GLs are based on very limited data, and are less secure than SULs.

The Danish Expert Group recommends the use of the UL values set by SCF/EFSA, but for vitamins and minerals without a recommended UL value the Danish Expert Group refers to the GL levels established by the EVM.

In the case of Vitamin B1, Vitamin C and  $\beta$ -carotene, for which no safe upper intake levels have been proposed by other Expert Groups, The Danish Expert Group established temporary guidance levels (TGL) based on safety evaluations of the limited data available from human studies. These are intended to be used in the same way as the GLs established by the EVM, and should be re-evaluated whenever new knowledge about the safety of the vitamins and minerals becomes available.

The figures shown in the table below only applies to adults, and it should be noted, that the corresponding safe upper intake levels for children are lower for most vitamins and minerals. This is important to keep in mind, since safety must be assured for all age groups. The levels proposed for children have been copied from (2) and included in Appendix A.

**Tolerable upper intake levels (ULs), Safe upper levels (SULs), Guidance levels (GLs) and Temporary guidance levels (TGLs) for intake of vitamins and minerals.**

	SCF/EFSA (UL)	IOM (UL)	EVM <sup>i</sup> (GL)	EVM <sup>1</sup> (SUL)	JECFA	Danish Expert Group <sup>ii</sup> (TGL)
Biotin (µg)	- <sup>r [iii]</sup>	- <sup>r</sup>	900	-		
Folate (µg)	-	1000 <sup>l</sup>	-	-		
Folic acid (µg)	1000 <sup>[iv]</sup>	-	1000	-		
Niacin (mg)	-	35 <sup>l</sup>	-	-		
Nicotinic acid (mg)	10 <sup>s [v]</sup>	-	17	-		
Nicotinamide (mg)	900 <sup>s [vi]</sup>	-	500 <sup>n</sup>	-		
Pantothenic acid (mg)	- <sup>r [vii]</sup>	- <sup>r</sup>	200	-		
Vitamin B2 (mg)	- <sup>r [viii]</sup>	- <sup>r</sup>	40	-		
Vitamin B1 (mg)	- <sup>r [ix]</sup>	- <sup>r</sup>	100 <sup>k</sup>	-		50
Vitamin B6 (mg)	25 <sup>u [x]</sup>	100	-	10 <sup>n</sup>		
Vitamin B12 (µg)	- <sup>r [xi]</sup>	- <sup>r</sup>	2000	-		
Vitamin C (mg)	- <sup>r [xii]</sup>	2000	- <sup>p</sup>	- <sup>p</sup>		1000
Vitamin A (µg)	3000 <sup>a [xiii]</sup>	3000	1500 <sup>m</sup>	-		
β-carotene (mg)	- <sup>r [xiv]</sup>	- <sup>i</sup>	-	7 <sup>h</sup>		5
Vitamin D (µg)	50 <sup>[xv]</sup>	50 <sup>g</sup>	25	-		
Vitamin E (mg)	300 <sup>b [xvi]</sup>	1000 <sup>f</sup>	540 <sup>t</sup>	-		
Vitamin K (µg)	- <sup>r [xvii]</sup>	- <sup>r</sup>	1000	-		
Sodium (mg)	- <sup>r [xviii]</sup>		- <sup>x</sup>	- <sup>x</sup>		
Chloride (mg)	- <sup>r [xix]</sup>		- <sup>x</sup>	- <sup>x</sup>		
Potassium (mg)	- <sup>r [xx]</sup>		3700	-		

	SCF/EFSA (UL)	IOM (UL)	EVM <sup>i</sup> (GL)	EVM <sup>1</sup> (SUL)	JECFA	Danish Expert Group <sup>ii</sup> (TGL)
Calcium (mg)	2500 [xxxi]	2500	1500	-		
Phosphorous (mg)	- r [xxii]	4000	250	-		
Magnesium (mg)	250 <sup>y</sup> [xxiii]	350 <sup>z</sup>	400 <sup>aa</sup>	-		
Iron (mg)	- t [xxiv]	45	17 <sup>v</sup>	-	50	
Zinc (mg)	25 [xxv]	40	-	25		
Copper (mg)	5 <sup>d</sup> [xxvi]	10	-	10 <sup>n</sup>		
Iodine (µg)	600 <sup>c</sup> [xxvii]	1100	500	-		
Selenium (µg)	300 [xxviii]	400	-	450		
Manganese (mg)	- r [xxix]	11	4	-		
Chromium (mg)	- r [xxx]	- r	10 <sup>e</sup>	-		
Molybdenum (µg)	600 [xxxii]	2000	- p	- p		
Fluoride (mg)	7 <sup>w</sup> [xxxiii]	10	- <sup>o</sup>	-		
Boron (mg)	10 <sup>j</sup> [xxxiiii]	20	-	9.6 <sup>n</sup>		
Cobalt (mg)			1.4 <sup>n</sup>	-		
Nickel (µg)	- r	1000	- q	- q		
Tin (mg)	- r [xxxiv]		13 <sup>n</sup>	-		
Vanadium (mg)	- r [xxxv]	1.8	- p	- p		
Silicon (mg)	- r [xxxvi]	- r	-	1500 <sup>n</sup>		

- a. The UL does not apply for postmenopausal women, here SCF recommends a maximum intake of 1500µg
- b. The UL does not apply for subjects with blood coagulation defects caused by vitamin K deficiency or by malabsorption or due to therapy with anticoagulants.
- c. The UL established for iodine does not apply to populations with iodine deficiency disorders or individuals who are being treated with iodine under medical supervision.
- d. The UL does not apply during pregnancy or lactation because of inadequate data relating to this critical life stage
- e. The value applies to trivalent chromium only

- f.  $\alpha$ -Tocopherol
- g. Cholecalciferol
- h. The SUL value does not apply to smokers or subjects exposed to asbestos.
- i. UL could not be established for  $\beta$ -carotene because of inconsistent data and could not be set for other carotenoids because of a lack of suitable data.
- j. The UL only applies to the intake of boron in the form of boric acid and borates. It should be noted, that EFSA/SCF has been asked to reconsider the UL value for boron
- k. The GL is only applicable to the water-soluble forms of thiamin.
- l. The UL's for niacin and folate apply to forms obtained from supplements, fortified foods or a combination of the two.
- m. It should be noted, that data from NDNS indicates, that 9% of men and 4% of women between the age 19-64 years, have retinol intakes exceeding GL. For people aged 65 years and over, 11% of men and 10% of women are considered to exceed GL through their daily diet.
- n. The value refers to a 60 kg adult
- o. Fluoride was excluded in the study, as supplements are only available as licensed medicines.
- p. Insufficient data to establish either SUL or GL
- q. Due to high prevalence of nickel sensitivity no SUL or GL for nickel has been established.
- r. The available data are insufficient to establish UL
- s. The UL value for niacin (nicotinic acid and nicotinamide) is not applicable during pregnancy or lactation because of inadequate data relating to this critical life stage. The ULs do not apply to the use of nicotinic or nicotinamide under clinical supervision for the treatment of hypercholesterolaemia and hyperlipidaemias or reducing the risk of the development of
- t. ~~Anders~~ cannot be established for iron (including haem iron) based on increased risk of chronic diseases such as cardiovascular disease, diabetes and cancer, due to the lack of convincing evidence of a causal relationship between iron intake or stores and chronic diseases.
- u. UL does not apply to individuals taking vitamin B6 under medical supervision
- v. The GL does not apply to individuals with an increased susceptibility to iron overload, via a mechanism of unregulated (increased) absorption from the diet, associated with the homozygous haemochromatosis genotype.
- w. For persons of 15 years and older
- x. No SUL or GL value has been established for sodium chloride, because there appears to be a graded response across doses that include the current estimated intake in the UK.
- y. The UL is established for readily dissociable magnesium salts (e.g., chloride, sulphate, aspartate, lactate) and compounds like MgO in nutritional supplements, water, or added to food and beverages. UL does not include Mg normally present in foods and beverages.
- z. The UL for magnesium represents intake from pharmacological agents only and does not include intake from food and water.
- æ. The GL only applies to supplemental magnesium, since reported adverse effects are not associated with magnesium in food.

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<sup>i</sup> Expert Group on Vitamins and Minerals. (2003) Safe upper levels for vitamins and minerals, UK, Food Standards Agency Publications

<sup>ii</sup> Rasmussen, S. E., Andersen, N.L., Dragsted, L. O., Larsen, J. C. (2006) A safe strategy for addition of vitamins and minerals to foods, European journal of nutrition, 45, p. 123-135

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- iii Opinion adopted 26 September 2001
  - iv Opinion adopted 19 October 2000
  - v Opinion adopted 17 April 2002
  - vi Opinion adopted 17 April 2002
  - vii Opinion adopted 17 April 2002
  - viii Opinion adopted 22 November 2000
  - ix Opinion adopted 11 July 2001
  - x Opinion adopted 19 October 2000
  - xi Opinion adopted 19 October 2000
  - xii Opinion adopted 28 April 2004 by the NDA Panel
  - xiii Opinion adopted 26 September 2002
  - xiv Opinion adopted 19 October 2000
  - xv Opinion adopted 4 December 2002
  - xvi Opinion adopted 4 April 2003
  - xvii Opinion adopted 4 April 2003
  - xviii Opinion adopted 21 April 2005
  - xix Opinion adopted 21 April 2005
  - xx Opinion adopted 22 February 2005 by the NDA Panel
  - xxi Opinion adopted 4 April 2003
  - xxii Opinion adopted 1 July 2005
  - xxiii Opinion adopted 26 September 2001
  - xxiv Opinion adopted 19 October 2004 by the NDA Panel
  - xxv Opinion adopted 5 March 2003

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<sup>xxvi</sup> Opinion adopted 5 March 2003

<sup>xxvii</sup> Opinion adopted 26 September 2002

<sup>xxviii</sup> Opinion adopted 19 October 2000

<sup>xxix</sup> Opinion adopted 19 October 2000

<sup>xxx</sup> Opinion adopted 4 April 2003

<sup>xxxi</sup> Opinion adopted 19 October 2000

<sup>xxxii</sup> Opinion adopted 22 February 2005

<sup>xxxiii</sup> Opinion adopted 8 July 2004 by the NDA Panel

<sup>xxxiv</sup> Opinion adopted 6 July 2005

<sup>xxxv</sup> Opinion adopted 19 February 2004 by the NDA Panel

<sup>xxxvi</sup> Opinion adopted 28 April 2004 by the NDA Panel

## Appendix A

### Tolerable upper levels of vitamins and minerals for different age groups, established by the SCF

Micronutrient	UL <sup>e</sup>	Age 1-3 years	Age 4-6 years	Age 7-10 years	Age 11-14 years	Age 15-17 years	Adults
Vitamin A (µg)	SCF	800	1100	1500	2000	2600	3000 <sup>g</sup>
Vitamin D (µg)	SCF	25	25	25	50	50	50
Vitamin E (mg)	SCF	100	120	160	220	260	300 <sup>h</sup>
Niacin (mg) <sup>a</sup>	SCF	150	220	350	500	700	900 <sup>f</sup>
Vitamin B <sub>6</sub> (mg)	SCF	5	7	10	15	20	25
Folic acid (µg) <sup>b</sup>	SCF	200	300	400	600	800	1000
Calcium (mg) <sup>c</sup>	SCF	2500 <sup>c</sup>	2500	2500	2500	2500	2500
Magnesium (mg) <sup>d</sup>	SCF	65 <sup>d</sup>	250	250	250	250	250

Zinc (mg)	SCF	7	10	13	18	22	25
Copper (mg)	SCF	1	2	3	4	4	5 <sup>f</sup>
Iodine (µg)	SCF	200	250	300	450	500	600 <sup>i</sup>
Selenium (µg)	SCF	60	90	130	200	250	300

<sup>a</sup> The ULs only apply for nicotinamide. <sup>b</sup> Does not include dietary folate from natural sources. <sup>c</sup> The SCF does not recommend an age-differentiation of the UL for calcium. <sup>d</sup> The UL only applies for magnesium supplements and for magnesium present in water. No UL was established by the SCF in 2001 for children under 4 years due to insufficient data. The UL for this age group was established by the US Institute of Medicine in 2003. <sup>e</sup> The SCF tolerable upper intake level. <sup>f</sup> The UL for adults does not apply during pregnancy or lactation. <sup>g</sup> The UL for adults does not apply for postmenopausal women, here the SCF recommends a maximum intake of 1500µg. <sup>h</sup> The UL does not apply for subjects with blood coagulation defects caused by vitamin K deficiency or by malabsorption or due to therapy with anticoagulants. <sup>i</sup> The UL established for iodine does not apply to populations with iodine deficiency disorders.

**Upper tolerable intake level (UL), Guidance levels (GLs) or temporary guidance levels (TGLs) for intake of vitamins and minerals, for which no UL has been established by the SCF**

Micronutrient	UL/GL/TGL <sup>b</sup>	Age 1-3 years	Age 4-6 years	Age 7-10 years	Age 11-14 years	Age 15-17 years	Adult men	Adult women
β-carotene	TGL <sup>b</sup>	5	5	5	5	5	5	5
Vitamin K (µg)	GL, EVM <sup>c</sup>	270	370	500	670	870	1000	1000
Thiamin (mg)	TGL <sup>b</sup>	15	20	25	34	42	50	50
Riboflavin (mg)	GL, EVM <sup>c</sup>	12	16	22	29	37	43	43
Vitamin B <sub>12</sub> (µg)	GL, EVM <sup>c</sup>	530	730	1000	1330	1730	2000	2000
Panthenic acid (mg)	GL, EVM <sup>c</sup>	55	75	100	135	175	200	200
Biotin (µg)	GL, EVM <sup>c</sup>	270	370	500	670	870	1000	1000

Vitamin C (mg)	TGL, NDA <sup>b,d</sup>	270	370	500	670	870	1000	1000
Phosphorus (mg)	UL, IOM <sup>e</sup>	3000	3000	3000	4000	4000	4000	3500 <sup>g</sup>
Iron (mg)	TGL, JECFA <sup>f</sup>	10	14	20	30	40	50	50

<sup>a</sup> The SCF and other international expert committees may have evaluated these micronutrients, although no tolerable upper intake level (UL) could be established. GLs are obtained from other expert panels (see specific references for each micronutrient), and TGLs are suggested by the authors of (2); <sup>b</sup> The basis for establishing the TGL is discussed in (2); <sup>c</sup> The GL established by EVM is used; <sup>d</sup> No UL was established by the NDA, but the TGL is based on the statement that ‘supplemental daily doses of vitamin C up to about 1g, in addition to normal dietary intakes, are not associated with adverse gastrointestinal effects,’ <sup>e</sup> The US Institute of Medicine established a UL for phosphorus in 2003; <sup>f</sup> The PMTDI at 50 mg/day established by JECFA is used to derive TGLs for children of all ages. For consistency, the bodyweight groups used by the SCF, are also used for extrapolation for iron; <sup>g</sup> The UL for women is set for pregnant women.