# Overview on Tolerable Upper Intake Levels as derived by the Scientific Committee on Food (SCF) and the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)

The Tolerable Upper Intake Level (UL) is the maximum level of total chronic intake of a nutrient from all sources judged to be unlikely to pose a risk of adverse health effects in humans (EFSA NDA Panel, 2022a).

Following a request from the European Commission, the Scientific Committee on Food (SCF), which was the predecessor of EFSA, started off in the year 2000 with giving scientific advice in relation to ULs for vitamins and minerals. The task was then taken over by EFSA when it became operational. As a result, EFSA and the SCF published a report of their first series of scientific opinions on ULs for vitamins and minerals in 2006 (EFSA, 2006). The report also covered trace elements such as boron, nickel, tin and vanadium.

Updates of individual scientific opinions were then carried out by the NDA Panel for calcium (2012); vitamin D (2012, 2018 (infants) and 2023); selenium, vitamin B6, folate and manganese (2023); iron, vitamin A and  $\beta$ -carotene (2024). For nutrients for which there are insufficient data on which to base the UL, the European Commission requested EFSA to provide "an indication [...] on the highest level of intake for which there is reasonable confidence on the absence of adverse effects. This is called a safe level of intake. Safe levels of intake have more limited applications than ULs as intakes above the safe levels of intake do not necessarily mean that there is a risk of adverse effects and these values cannot be used to characterise the proportion of the population at risk of adverse effects.

Other re-evaluations are on-going. This document will be updated accordingly.

This document provides an overview about the outcome of the SCF's and EFSA's scientific deliberations. The detailed reasoning for establishing individual values can be found in the related opinions of the SCF and NDA Panel.

© European Food Safety Authority, 2024

Correspondence: nif@efsa.europa.eu

Reproduction is authorised provided the source is acknowledged.



### Table 1: Tolerable Upper Intake Levels for minerals

	Unit	4-6 mo <sup>(a)</sup>	7-11 mo <sup>(b)</sup>	1-3 y	4-6 y	7-10 y	11-14 y	15-17 у	Adults	Pregnancy	Lactation	Ref
Boron	mg/d			3	4	5	7	9	10	10	10	(EFSA NDA panel, 2004b)
Calcium	mg/d	No adequat	No adequate data to derive a UL 2500 2500 2500								(EFSA NDA Panel, 2012b)	
Chloride		No adequat	No adequate data to derive a UL									(EFSA NDA panel, 2005c)
Chromium <sup>(c)</sup>		No adequat	No adequate data to derive a UL									(SCF, 2003c)
Copper <sup>(d)</sup>	mg/d	•		1	2	3	4	4	5	N	D	(SCF, 2003a)
Iodine	µg/d			200	250	300	450	500	600	600	600	(SCF, 2003b)
Iron <sup>(e)</sup>		No adequat	e data to deriv	e a UL	•							(EFSA NDA Panel, 2024a)
Manganese <sup>(f)</sup>		No adequat	e data to deriv	e a UL								(EFSA NDA Panel, 2023b)
Magnesium <sup>(g)</sup>	mg/d			ND	250	250	250	250	250	250	250	(SCF, 2001b)
Molybdenum	mg/d			0.1	0.2	0.25	0.4	0.5	0.6	0.6	0.6	(SCF, 2000a)
Nickel		No adequat	No adequate data to derive a UL								(EFSA NDA Panel, 2005b)	
Phosphorus		No adequat	No adequate data to derive a UL								(EFSA NDA panel, 2005e)	
Potassium		No adequat	No adequate data to derive a UL								(EFSA NDA panel, 2005d)	
Selenium	µg/d	45	55	70	95	130	180	230	255	255	255	(EFSA NDA Panel, 2023c)
Silicon		No adequat	No adequate data to derive a UL								(EFSA NDA Panel, 2004c)	
Sodium		No adequat	No adequate data to derive a UL							(EFSA NDA Panel, 2005f)		
Tin		No adequat	e data to deriv	e a UL								(EFSA NDA
Vanadium		No adequate data to derive a UL									Panel, 2005g) (EFSA NDA	
Zinc	mg/d			7	10	13	18	22	25	25	25	Panel, 2004d) (SCF, 2002c)
	ing/a			1-3 y	4-8 y		14 y	15-17 y	Adults	Pregnancy	Lactation	
Fluoride	mg/d			1.5	2.5		5	7	7	7	7	(EFSA NDA Panel, 2005a)

d, day; mo: month; ND: not defined; y, year

(a): i.e. from the 18<sup>th</sup> to the 26<sup>th</sup> week of life

(b): i.e. the second half of the first year of life (from the 27<sup>th</sup> to the 52<sup>th</sup> week of life)

(c): Trivalent chromium (Cr III)

(d): In 2023, the EFSA Scientific Committee established an Acceptable Daily Intake (ADI) of 0.07 mg/kg body weight copper (EFSA Scientific Committee, 2023).

(e): As there were insufficient data on which to base the UL for iron, safe levels of intakes were established (see Table 2).

(f): As there were insufficient data on which to base the UL for manganese, safe levels of intakes were established (see Table 2).

(g): Readily dissociable Mg salts (e.g. chloride, sulphate, aspartate, lactate) and compounds like MgO in food supplements, water or added to foods; does not include Mg naturally present in foods and beverages.

#### Table 2: Safe levels of intake for **minerals**

**Safe levels of intake:** For nutrients for which there are insufficient data on which to base the UL, the European Commission requested EFSA to provide "an indication [...] on the highest level of intake for which there is reasonable confidence on the absence of adverse effects. This is called a safe level of intake. Safe levels of intake have more limited applications than ULs: intakes above the safe levels of intake do not necessarily mean that there is a risk of adverse effects and these values cannot be used to characterise the proportion of the population at risk of adverse effects.

	Unit	4-6 mo <sup>(a)</sup>	7-11 mo <sup>(b)</sup>	1-3 y	4-6 y	7-10 y	11-14 у	15-17 у	Adults	Pregnancy	Lactation	Ref
Iron	mg/d	5 <sup>(c)</sup>	5 <sup>(c)</sup>	10	15	20	30	35	40	40	40	(EFSA NDA Panel, 2024a)
		4-1	2 mo	1-2 y	3-6 у	7-	13 y	14-17 у	Adults	Pregnancy	Lactation	
Manganese	mg/d		2	4	5		6	7	8	8	8	(EFSA NDA Panel, 2023b)

d, day; mo: month; ND: not defined; y, year

(a): i.e. from the 18<sup>th</sup> to the 26<sup>th</sup> week of life

(b): i.e. the second half of the first year of life (from the 27<sup>th</sup> to the 52<sup>th</sup> week of life)

(c): For children less than one year of age, safe levels of supplemental intake are given and apply to iron intakes from food supplements and fortified foods (infant and follow-on formulas are excluded).



#### Table 3: Tolerable Upper Intake Levels for vitamins

	Unit	4-6 mo <sup>(a)</sup>	7-11 mo <sup>(b)</sup>	1-3 y	4-6 y	7-10 y	11-14 y	15-17 у	Adults	Pregnancy	Lactation	Ref
Biotin		No adequate	data to derive a	a UL								(SCF, 2001a)
β-Carotene <sup>(c)</sup>		No adequate	No adequate data to derive a UL								EFSA NDA Panel, 2024	
Folate <sup>(d)</sup>	µg/d	200	200	200	300	400	600	800	1000	1000	1000	(EFSA NDA Panel, 2023a)
Niacin												(SCF, 2002a)
Nicotinamide	mg/d			150	220	350	500	700	900	Inadequa	ate data	
Nicotinic acid	mg/d			2	3	4	6	8	10	Inadequa	ate data	
Pantothenic acid		No adequate	data to derive a	a UL								(SCF, 2002b)
Vitamin A <sup>(e)</sup>	µg RE/d	600	600	800	1100	1500	2000	2600	3000	3000	3000	(EFSA NDA Panel, 2024b)
Vitamin B1		No adequate	No adequate data to derive a UL								(SCF, 2001c)	
Vitamin B12			No defined adverse effects								(SCF, 2000c)	
Vitamin B2		No adequate	No adequate data to derive a UL								(SCF, 2000b)	
Vitamin B6	mg/d	2.2	2.5	3.2	4.5	6.1	8.6	10.7	12	12	12	(EFSA NDA Panel, 2023d)
Vitamin C		No adequate	No adequate data to derive a UL							(EFSA NDA Panel, 2004a)		
Vitamin E <sup>(f)</sup>	mg/d			100	120	160	220	260	300	300	300	(SCF, 2003d)
Vitamin K		No adequate data to derive a UL								(SCF, 2003e)		
		0-6 mo	7-11 mo <sup>(b)</sup>	1-3 y	4-6 y	7-10 y	11-14 y	15-17 у	Adults	Pregnancy	Lactation	
Vitamin D	µg VDE <sup>(g)</sup> / d	25	35	50	50	50	100	100	100	100	100	(EFSA NDA Panel, 2018, 2023e)

d, day; mo, month; RE, retinol equivalents; VDE, vitamin D equivalent; y, year

(a): i.e. from the 18<sup>th</sup> to the 26<sup>th</sup> week of life

(b): i.e. the second half of the first year of life (from the 27<sup>th</sup> to the 52<sup>th</sup> week of life)

(c): Smokers should avoid consuming food supplements containing  $\beta$ -carotene. The Panel also considers that the use of supplemental  $\beta$ -carotene (i.e., in fortified foods and/or food supplements) by the general population should be limited to the purpose of meeting vitamin A requirements.

(d): ULs apply to the combined intake of folic acid, (6S)-5-methyltetrahydrofolic acid glucosamine and I-5-methyltetrahydrofolic acid calcium salts added to foods or used in food supplements, under their authorised conditions of use; do not include folate naturally present in foods and beverages.

(e): ULs apply to preformed vitamin A, i.e. retinol and retinyl esters.

(f): A review of the ULs for vitamin E is on-going.

(g): 1 µg VDE = 1 µg cholecalciferol (vitamin D3) = 1 µg ergocalciferol (vitamin D2) = 0.4 µg calcidiol monohydrate = 40 IU. This applies to calcidiol monohydrate at doses up to 10 µg/day.



## Table 4: Other nutrients

		Ref
Total fat	No adequate data to derive a UL for any age group	(EFSA NDA Panel, 2010)
Saturated fatty acids	No adequate data to derive a UL for any age group	(EFSA NDA Panel, 2010)
Proteins	No adequate data to derive a UL for any age group	(EFSA NDA Panel, 2012a)
DHA, EPA, DPA	No adequate data to derive a UL for any age group	(EFSA NDA Panel, 2012c)
Sugars	No adequate data to derive a UL for any age group	(EFSA NDA Panel, 2022b)

d, day; DHA, docosahexaenoic acid, DPA, docosapentaenoic acid; EPA, eicosapentaenoic acid

# References

- EFSA, 2006. Tolerable Upper Intake Levels for Vitamins and Minerals. European Food Safety Authority. 480 pp. Available online: <u>https://www.efsa.europa.eu/sites/default/files/efsa\_rep/blobserver\_assets/ndatolerable</u> <u>uil.pdf</u>
- EFSA NDA Panel, 2004a. Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies (NDA) a request from the Commission related to the Tolerable Upper Intake Level of Vitamin C (L-Ascorbic acid, its calcium, potassium and sodium salts and L-ascorbyl-6-palmitate). EFSA Journal, 2:59. doi: <u>https://doi.org/10.2903/j.efsa.2004.59</u>
- EFSA NDA panel, 2004b. Opinion of the Scientific Panel on Dietetic products, nutrition and allergies [NDA] related to the Tolerable Upper Intake Level of Boron (Sodium Borate and Boric Acid). EFSA Journal, 2:80. doi: <u>https://doi.org/10.2903/j.efsa.2004.80</u>
- EFSA NDA Panel, 2004c. Opinion of the Scientific Panel on Dietetic products, nutrition and allergies [NDA] related to the Tolerable Upper Intake Level of Silicon. EFSA Journal, 2:60. doi: <u>https://doi.org/10.2903/j.efsa.2004.60</u>
- EFSA NDA Panel, 2004d. Opinion of the Scientific Panel on Dietetic products, nutrition and allergies [NDA] related to the Tolerable Upper Intake Level of Vanadium. EFSA Journal, 2:33. doi: <u>https://doi.org/10.2903/j.efsa.2004.33</u>
- EFSA NDA Panel, 2005a. Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies (NDA) on a request from the Commission related to the Tolerable Upper Intake Level of Fluoride. EFSA Journal, 3:192. doi: <u>https://doi.org/10.2903/j.efsa.2005.192</u>
- EFSA NDA Panel, 2005b. Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies (NDA) on a request from the Commission related to the Tolerable Upper Intake Level of Nickel. EFSA Journal, 3:146. doi: <u>https://doi.org/10.2903/j.efsa.2005.146</u>
- EFSA NDA panel, 2005c. Opinion of the Scientific Panel on Dietetic products, nutrition and allergies [NDA] on a request from the Commission related to the Tolerable Upper Intake Level of Chloride. EFSA Journal, 3:210. doi: <u>https://doi.org/10.2903/j.efsa.2005.210</u>
- EFSA NDA panel, 2005d. Opinion of the Scientific Panel on Dietetic products, nutrition and allergies [NDA] on a request from the Commission related to the Tolerable Upper Intake Level of Potassium. EFSA Journal, 3:193. doi: <u>https://doi.org/10.2903/j.efsa.2005.193</u>
- EFSA NDA panel, 2005e. Opinion of the Scientific Panel on Dietetic products, nutrition and allergies [NDA] related to the tolerable upper intake level of phosphorus. EFSA Journal, 3:233. doi: <u>https://doi.org/10.2903/j.efsa.2005.233</u>
- EFSA NDA Panel, 2005f. Opinion of the Scientific Panel on Dietetic products, nutrition and allergies [NDA] related to the Tolerable Upper Intake Level of Sodium. EFSA Journal, 3:209. doi: <u>https://doi.org/10.2903/j.efsa.2005.209</u>
- EFSA NDA Panel, 2005g. Opinion of the Scientific Panel on Dietetic products, nutrition and allergies [NDA] related to the tolerable upper intake level of tin. EFSA Journal, 3:254. doi: <u>https://doi.org/10.2903/j.efsa.2005.254</u>
- EFSA NDA Panel, 2010. Scientific Opinion on Dietary Reference Values for fats, including saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, trans fatty acids, and cholesterol. EFSA Journal, 8:1461. doi: <u>https://doi.org/10.2903/j.efsa.2010.1461</u>
- EFSA NDA Panel, 2012a. Scientific Opinion on Dietary Reference Values for protein. EFSA Journal, 10:2557. doi: <u>https://doi.org/10.2903/j.efsa.2012.2557</u>
- EFSA NDA Panel, 2012b. Scientific Opinion on the Tolerable Upper Intake Level of calcium. EFSA Journal, 10:2814. doi: <u>https://doi.org/10.2903/j.efsa.2012.2814</u>
- EFSA NDA Panel, 2012c. Scientific Opinion on the Tolerable Upper Intake Level of eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA) and docosapentaenoic acid (DPA). EFSA Journal, 10:2815. doi: <u>https://doi.org/10.2903/j.efsa.2012.2815</u>
- EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2018. Update of the tolerable upper intake level for vitamin D for infants. EFSA Journal 2018;16(8):5365, 118 pp. doi: 10.2903/j.efsa.2018.5365

#### Summary of Tolerable Upper Intake Levels

EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens), 2022a. Guidance for establishing and applying tolerable upper intake levels for vitamins and essential minerals. EFSA Journal 2022;20(1):e200102, 27 pp. doi: 10.2903/j.efsa.2022.e200102

EFSA NDA Panel, 2022b. Tolerable upper intake level for dietary sugars. EFSA Journal, 20:e07074. doi: <u>https://doi.org/10.2903/j.efsa.2022.7074</u>

EFSA NDA Panel, 2023a. Scientific opinion on the tolerable upper intake level for folate. EFSA Journal, 21:e8353. doi: <u>https://doi.org/10.2903/j.efsa.2023.8353</u>

EFSA NDA Panel, 2023b. Scientific opinion on the tolerable upper intake level for manganese. EFSA Journal, 21:e8413. doi: <u>https://doi.org/10.2903/j.efsa.2023.8413</u>

EFSA NDA Panel, 2023c. Scientific opinion on the tolerable upper intake level for selenium. EFSA Journal, 21:e07704. doi: <u>https://doi.org/10.2903/j.efsa.2023.7704</u>

EFSA NDA Panel, 2023d. Scientific opinion on the tolerable upper intake level for vitamin B6. EFSA Journal, 21:e08006. doi: <u>https://doi.org/10.2903/j.efsa.2023.8006</u>

EFSA NDA Panel, 2023e. Scientific opinion on the tolerable upper intake level for vitamin D, including the derivation of a conversion factor for calcidiol monohydrate. EFSA Journal, 21:e08145. doi: <u>https://doi.org/10.2903/j.efsa.2023.8145</u>

EFSA NDA Panel, 2024a. Scientific opinion on the tolerable upper intake level for iron. EFSA Journal, 22:e8819. doi: <u>https://doi.org/10.2903/j.efsa.2024.8819</u>

EFSA NDA Panel, 2024b. Scientific opinion on the tolerable upper intake level for preformed vitamin A and β-carotene. EFSA Journal, 22:e8814. doi: <u>https://doi.org/10.2903/j.efsa.2024.8814</u>

EFSA Scientific Committee, 2023. Scientific Opinion on the re-evaluation of the existing healthbased guidance values for copper and exposure assessment from all sources. EFSA Journal, 21(1):7728:117. doi: <u>https://doi.org/10.2903/j.efsa.2023.7728</u>

SCF (Scientific Committee on Food), 2000a. Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Molybdenum. In: Tolerable Upper Intake Levels for Vitamins and Mineral 77-85 pp. Available online: <u>https://www.efsa.europa.eu/sites/default/files/efsa\_rep/blobserver\_assets/ndatolerable</u> <u>uil.pdf</u>

SCF (Scientific Committee on Food), 2000b. Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Vitamin B2. In: Tolerable Upper Intake Levels for Vitamins and Mineral 87-92 pp. Available online: <u>https://www.efsa.europa.eu/sites/default/files/efsa\_rep/blobserver\_assets/ndatolerable uil.pdf</u>

SCF (Scientific Committee on Food), 2000c. Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Vitamin B12. In: Tolerable Upper Intake Levels for Vitamins and Mineral 45-49 pp. Available online: <u>https://www.efsa.europa.eu/sites/default/files/efsa\_rep/blobserver\_assets/ndatolerable uil.pdf</u>

SCF (Scientific Committee on Food), 2001a. Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Biotin. In: Tolerable Upper Intake Levels for Vitamins and Mineral 99-105 pp. Available online: <u>https://www.efsa.europa.eu/sites/default/files/efsa\_rep/blobserver\_assets/ndatolerable uil.pdf</u>

SCF (Scientific Committee on Food), 2001b. Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Magnesium. In: Tolerable Upper Intake Levels for Vitamins and Mineral. 107-116 pp. Available online: <u>https://www.efsa.europa.eu/sites/default/files/efsa\_rep/blobserver\_assets/ndatolerable uil.pdf</u>

SCF (Scientific Committee on Food), 2001c. Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Vitamin B1. In: Tolerable Upper Intake Levels for Vitamins and Mineral 93-97 pp. Available online: <u>https://www.efsa.europa.eu/sites/default/files/efsa\_rep/blobserver\_assets/ndatolerable uil.pdf</u>

SCF (Scientific Committee on Food), 2002a. Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Nicotinic Acid and Nicotinamide (Niacin). In: Tolerable Upper Intake Levels for Vitamins and Mineral 121-133 pp. Available online: <u>https://www.efsa.europa.eu/sites/default/files/efsa\_rep/blobserver\_assets/ndatolerable\_uil.pdf</u>

- SCF (Scientific Committee on Food), 2002b. Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Pantothenic Acid. In: Tolerable Upper Intake Levels for Vitamins and Mineral 117-120 pp. Available online: <u>https://www.efsa.europa.eu/sites/default/files/efsa\_rep/blobserver\_assets/ndatolerable uil.pdf</u>
- SCF (Scientific Committee on Food), 2002c. Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Zinc. In: Tolerable Upper Intake Levels for Vitamins and Mineral 191-201 pp. Available online: <u>https://www.efsa.europa.eu/sites/default/files/efsa\_rep/blobserver\_assets/ndatolerable uil.pdf</u>
- SCF (Scientific Committee on Food), 2003a. Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Copper. In: Tolerable Upper Intake Levels for Vitamins and Mineral. 203-213 pp. Available online: <u>https://www.efsa.europa.eu/sites/default/files/efsa\_rep/blobserver\_assets/ndatolerable uil.pdf</u>
- SCF (Scientific Committee on Food), 2003b. Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Iodine. In: Tolerable Upper Intake Levels for Vitamins and Mineral. 135-150 pp. Available online: <u>https://www.efsa.europa.eu/sites/default/files/efsa\_rep/blobserver\_assets/ndatolerable uil.pdf</u>
- SCF (Scientific Committee on Food), 2003c. Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Trivalent Chromium. In: Tolerable Upper Intake Levels for Vitamins and Mineral. 261-271 pp. Available online: <u>https://www.efsa.europa.eu/sites/default/files/efsa\_rep/blobserver\_assets/ndatolerable uil.pdf</u>
- SCF (Scientific Committee on Food), 2003d. Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Vitamin E. In: Tolerable Upper Intake Levels for Vitamins and Mineral 243-252 pp. Available online: <u>https://www.efsa.europa.eu/sites/default/files/efsa\_rep/blobserver\_assets/ndatolerable uil.pdf</u>
- SCF (Scientific Committee on Food), 2003e. Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Vitamin K. In: Tolerable Upper Intake Levels for Vitamins and Mineral 253-259 pp. Available online: <u>https://www.efsa.europa.eu/sites/default/files/efsa\_rep/blobserver\_assets/ndatolerable uil.pdf</u>