

The specificities of food supplements in relation to exposure assessment

20 March 2024



FOOD SUPPLEMENTS

Directive 2002/46/EC

Definition

“ ‘food supplements’ means **foodstuffs** the purpose of which is to **supplement the normal diet** and which are **concentrated sources of nutrients or other substances with a nutritional or physiological effect**, alone or in combination, **marketed in dose form**, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in **measured small unit quantities** ”

Labelling

Notification

THE SPECIFICITIES OF FOOD SUPPLEMENTS

“ **concentrated sources of nutrients or other substances** with a nutritional or physiological effect, alone or in combination “



Supplements have no common composition

“ marketed in dose form, namely forms such as **capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders** “



Supplements have no common format

“ designed to be taken in **measured small unit quantities** “



Supplements are taken in small quantities

Label must mention:

- **the portion of the product recommended for daily consumption**



The daily dose is indicated on the label

Typical weights of food supplements used in EFSA

Solid forms (Tablets – Hard gel / soft gel capsules – chewable forms)

Tablets (F): **0.2 g**
Tablets/capsules (Vit B9/B12/Vit D): **0.3 g**
Tablets/capsules (Algae): **0.3 g**
Tablet (Vitamins only/Yeast-based): **0.4 g**
Capsules (Zn): **0.4 g**
Tablets/capsules (Multi-Vitamins/Vit C+Zn) : **0.5 g**
Tablets/capsules (Vit A/Vit E/Cr/Cu/EnzQ10): **0.6 g**
Tablets/capsules/chewable tablets (probiotics): **0.6 g**
Chewable tablets (Vit C): **0.6 g**
Tablets/capsules (Fe/Se/K/Carotenoids/Fibres): **0.7 g**
Tablets/Capsules (Botanicals): **0.7 g**
Tablets/capsules (Vit C/Bee products/Minerals/Amino acids/Lecithin): **0.8 g**
Tablets/capsules, chewable forms (Mixed): **0.95 g**
Tablets/capsules (Vitamins+Minerals): **1.0 g**
Capsules (Fatty acids): **1.0 g**
Capsules/Tablets (Mg/Glucosamine): **1.3 g**
Chewable tablets (Vitamins+-Minerals): **1.3 g**
Chewable Tablets (Ca+Vit D): **1.6 g**
Tablets/chewable tablets (Ca): **1.7 g**
Effervescent tablets: **4 g** (dilutable form)

Solid forms (Powder)

Powder (probiotics): **2.0 g**
Fibres (Teaspoon): **5.0 g**
Powder (Bee products): **5.0 g**
Powder sachets (fibres): **14 g**
Powder scoop (Protein/amino acids): **28 g**

Liquids:

Drops: 0.04 g
Liquid (teaspoon): 5 ml

Internal report on the quantification of food supplements units to be used in the assessment of dietary exposure

European Food Safety Authority (EFSA),
Sofia Ioannidou, Rita Sousa

**Vast majority of supplement
forms has a weight of < 2 g**

**Only powder form supplements
have a higher unit weight**

EXPOSURE ASSESSMENT: PHOSPHATES

SCIENTIFIC OPINION



ADOPTED: 4 June 2019*
doi: 10.2903/j.efsa.2019.5674

Re-evaluation of phosphoric acid–phosphates – di-, tri- and polyphosphates (E 338–341, E 343, E 450–452) as food additives and the safety of proposed extension of use

EFSA Panel on Food Additives and Flavourings (FAF),
Maged Younes, Gabriele Aquilina, Laurence Castle, Karl-Heinz Engel, Paul Fowler,
Maria Jose Frutos Fernandez, Peter Fürst, Rainer Gürtler, Trine Husøy, Wim Mennes,
Peter Moldeus, Agneta Oskarsson, Romina Shah, Ine Waalkens-Berendsen, Detlef Wölfe,
Peter Aggett, Adamasco Cupisti, Cristina Fortes, Gunter Kuhnle, Inger Therese Lillegaard,
Michael Scotter, Alessandra Giarola, Ana Rincon, Alexandra Tard and Ursula Gundert-Remy

Table 7: Summary of dietary exposure to phosphates (E 338–341, E 343, E 450–452) from their uses as food additives for food supplements consumers only, in children, adolescents, adults and the elderly (minimum–maximum across the dietary surveys in mg P/kg bw per day)

	Children (3–9 years)	Adolescents (10–17 years)	Adults (18–64 years)	The elderly (≥ 65 years)
• Mean	15–89	8–23	6–22	10–24
• 95th percentile	38–112	21–26	20–99	24–83

bw: body weight.

For the *food supplements consumers only*, mean exposure to phosphates (E 338–341, E 343, E 450–452) from their uses as food additives ranged from 275 mg P/person per day for children to 1,541 mg P/person per day for the elderly. The 95th percentile of exposure to phosphates (E 338–341, E 343, E 450–452) ranged from 753 mg P/person per day for adolescents to 7,292 mg P/person per day for adults. The Panel noted the high levels for food supplements compared to therapeutic use (see

Conclusion: Phosphorus exposure from food supplements exceeds the proposed ADI of 2800 mg/day (adult)

P95 phosphorus intake (adolescents): 7292 mg per day
Corresponds to > 16 g of P₂O₃
Corresponds to > 40 g of dicalcium phosphate

EXPOSURE ASSESSMENT: CALCIUM CARBONATE

SCIENTIFIC OPINION



ADOPTED: 20 June 2023
doi: 10.2903/j.efsa.2023.8106

Re-evaluation of calcium carbonate (E 170) as a food additive in foods for infants below 16 weeks of age and follow-up of its re-evaluation as food additive for uses in foods for all population groups

EFSA Panel on Food Additives and Flavourings (FAF),
Maged Younes, Gabriele Aquilina, Laurence Castle, Gisela Degen, Karl-Heinz Engel,
Paul J Fowler, Maria Jose Frutos Fernandez, Peter Fürst, Rainer Gürtler, Trine Husøy,
Melania Manco, Wim Mennes, Peter Moldeus, Sabina Passamonti, Romina Shah,
Ine Waalkens-Berendsen, Matthew Wright, Detlef Wölflé, Birgit Dusemund, Alicja Mortensen,
Dominique Turck, Karlien Cheyns, Eric Gaffet, Katrin Loeschner, Jan Mast, Manuela Mirat,
Anna Undas, Stefania Barmaz, Agnieszka Mech, Ana Maria Rincon, Camilla Smeraldi,
Alexandra Tard and Ursula Gundert-Remy

Table 9: Intake of calcium per person (mg/day) for adolescents, adults, the elderly from: a) uses of calcium carbonate (E 170) as a food additive; b) uses of calcium carbonate as a source of calcium in foods; c) the sum of food additive (E 170) use and sources of calcium and; d) use of calcium carbonate as a source of calcium in food supplements (consumers only scenario)

	Adolescents (10–17 years)				Adults (18–64 years)				The elderly (≥ 65 years)			
	Mean		p95		Mean		p95		Mean		p95	
	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max
a) For consumers' only of food supplements (number of consumer)	421 (n = 110)	3,202 (n = 80)	1,289 (n = 110)	9,762 (n = 80)	432 (n = 21)	2,432 (n = 66)	1,738 (n = 246)	10,553 (n = 66)	309 (n = 10)	3,530 (n = 6)	1,569 (n = 143)	7,184 (n = 87)

n: number of consumers for the exposure scenario of consumers' only of food supplements.

Conclusion: Exposure to calcium in consumers only of food supplements is greatly exceeding the Tolerable Upper Intake Level (UL) and may be of concern given the known adverse effects of high-dose calcium

P95 calcium intake (adults): 10553 mg per day (n = 66)
Corresponds to > 25 g of calcium carbonate
Corresponds to > 40 g of dicalcium phosphate

**Such intakes would require 20-50
tablets or capsules of food
supplements per day which is
unrealistic**

REASONS TO EXPLAIN THIS OVERESTIMATION

- ➡ The lack of detail of the dietary survey database**
- ➡ The maximum use level without considering the supplement format**
- ➡ The application of the maximum use level to all food supplements**

ANALYSIS MADE POSSIBLE BY:

Two post-adoption teleconferences:

- Post-adoption teleconference of 4 July 2019 on the opinion relating to the re-evaluation of phosphates as food additives.
- Post-adoption teleconference of 19 September 2023 on the opinion relating to the re-evaluation of calcium carbonate as food additive.

New data collection on phosphates in the context of the EC Call for Data

1. DIETARY SURVEY DATA

In dietary surveys, intake of food supplements is not measured on the basis of weight but on the basis of the daily recommended intake as indicated on the label.

This information is translated into units of weight for the purpose of the EFSA Comprehensive Food Consumption Database using the weights as indicated in the internal report.



Typical weights of food supplements used in EFSA
Solid forms (Tablets – Hard gel / soft gel capsules – chewable forms)
Tablets (F): 0.2 g
Tablets/capsules (Vit B9/B12/Vit D): 0.3 g
Tablets/capsules (Algae): 0.3 g
Tablet (Vitamins only/Yeast-based): 0.4 g
Capsules (Zn): 0.4 g
Tablets/capsules (Multi-Vitamins/Vit C+Zn) : 0.5 g
Tablets/capsules (Vit A/Vit E/Cr/Cu/EnzQ10): 0.6 g
Tablets/capsules/chewable tablets (probiotics): 0.6 g
Chewable tablets (Vit C): 0.6 g
Tablets/capsules (Fe/Se/K/Carotenoids/Fibres): 0.7 g
Tablets/Capsules (Botanicals): 0.7 g
Tablets/capsules (Vit C/Bee products/Minerals/Amino acids/Lecithin): 0.8 g
Tablets/capsules, chewable forms (Mixed): 0.95 g
Tablets/capsules (Vitamins+Minerals): 1.0 g
Capsules (Fatty acids): 1.0 g
Capsules/Tablets (Mg/Glucosamine): 1.3 g
Chewable tablets (Vitamins+-Minerals): 1.3 g
Chewable Tablets (Ca+Vit D): 1.6 g
Tablets/chewable tablets (Ca): 1.7 g
Effervescent tablets: 4 g (dilutable form)
Solid forms (Powder)
Powder (probiotics): 2.0 g
Fibres (Teaspoon): 5.0 g
Powder (Bee products): 5.0 g
Powder sachets (fibres): 14 g
Powder scoop (Protein/amino acids): 28 g
Liquids:
Drops: 0.04 g
Liquid (teaspoon): 5 ml

- ➡ P95 intake strongly biased towards weight of powders
- ➡ Wide range between lowest and highest reported P95
- ➡ Low number of subjects (P95 calcium exposure: 66 people)

Adults (18–64 years)
6–22
20–99

1. DIETARY SURVEY DATA

FSE survey:

- Mean and median weight of the food supplements: 1 - 1.5 g per unit.
- Out of 902 products, only 8 had a daily intake weight of more than 5 g (max: 6.5 g).

Weight distribution of food supplement intake (mg/day) – (Calculated as weight of one unit x number of units indicated as daily dose)			
	Range	Mean	Median
Weight (mg/day)	110 - 6500	1252	1084



Dietary survey data expressed in terms of weight creates bias towards powders which are not representative of supplements and overestimate intake

EXAMPLE



DAILY DOSE OF VITAMINS

Cedevita is a food supplement and a source of 9 vitamins: C, E, B1, B2, B3, B5, B6, B9, B12. One serving contains 50% of recommended daily intake of vitamins.

Instructions for preparation

Up to 4 tablespoons of powder (38g) in 500 ml of cold water.

2. REPORTED USE LEVELS

The exposure assessment is calculated with the highest reported use level.

Example: Phosphates

- Highest reported use level: 832600 mg/kg E341(ii) (343031 mg/kg P_2O_5)
 - Product: 180 mg weight tablet; consumption: 1 per day
 - Contribution to the daily phosphorus intake: 27 mg per day
- Second highest reported level: 831500 mg/kg E341(ii) (342578 mg/kg P_2O_5)
 - Product: 800 mg weight tablet; consumption: 1 per day
 - Contribution to the daily phosphorus intake : 120 mg per day

➔ This is far below the P95 estimated intake of phosphorus of > 7 g per day

2. REPORTED USE LEVELS

FSE survey:

- When actual intake is considered, the maximum contribution to P intake: 680 mg/d.
- Only 3 out of 902 products contribute more than 200 mg/d.

Range of use levels for Phosphates (mg/kg) and corresponding contribution of P (mg/day)			
Use levels	Phosphorus intake	Mean Phosphorus contribution	Median Phosphorus contribution
0.0023 - 349177	0.0000006 – 680	20	3

- ➡ This is well below the ADI.
- ➡ This is well below the national maximum levels: e.g. 1600 mg/day in Belgium.
- ➡ This is well below the maximum level for P of the FSE model: 1700 mg/day.

3. PROPORTION OF SUPPLEMENTS CONTAINING THE ADDITIVE

For the exposure assessment it is assumed that all food supplements contain the food additive at the highest reported use level.

MINTEL GNPD database:

- **Only 9.9% of food supplements have phosphates listed on the label.**
- **Only 6.5% of food supplements have calcium carbonate listed on the label.**

CONCLUSIONS AND RECOMMENDATIONS

Intake assessment for food supplements is grossly overestimated because of:

- ➡ the limitations of the intake database that result in incorrect representation of food supplements intake**
- ➡ The use of the highest reported use level to all food supplements indiscriminately which does not consider the actual products and the proportion of supplements in which the additives are used**

For food supplements, the label recommended daily intake is a far more sensitive measure for exposure assessment than weight.

Intake assessment based on modeling or intake scenarios would result in a far more accurate indication of potential maximum exposure.

Information about daily intake is available from food supplement notifications.

THANK YOU

www.foodsupplementseurope.org

