

# The specificities of food supplements in relation to exposure assessment

20 March 2024

#### Official Journal of the European Communities DIRECTIVE 2002/46/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL or 10 June 2002 on the approximation of the laws of the Member States relating to food supplements There is a wide range of nutrients and other ingredients There is a wide range of nutrients and other ingredients that might be present in food supplements including, but that might be present in food supplements including, but the problem of the control of that might be present in 1000 supplements including out not limited to, vitamins, minerals, amino acids, essential fatty acids (three and various plants and herbal petracts). not limited to, vitamins, minerals, amino acids, essenti. fatty acids, fibre and various plants and herbal extracts. PARLIAMENT AND THE COUNCIL OF THE As a first stage, this Directive should lay down specific ard to the Treaty establishing the European , and in particular Article 95 thereof, As a first stage, this Directive should lay down specific rules for vitamins and minerals used as ingredients of rules for vitamins and minerals used as ingrequents of food supplements. Food supplements containing vitamins or minerals as well as other ingredients should also have in conferently with the energific rules on vitamins and the inconferently with the energific rules on vitamins and mins or minerals as well as other ingredients should also be in conformity with the specific rules on vitamins and minerals laid drawn in this Direction. geard to the proposal from the Commission (\*), regard to the opinion of the Economic and Social ittee (\*). ue in conformity with the specific reminerals laid down in this Directive. $_{ m log}$ in accordance with the procedure laid down in Article of the Treaty $^{(2)}$ , Specific rules concerning numerits, outer than vitamins and minerals, or other substances with a nutritional or and minerais, or other substances with a nutritional or physiological effect used as ingredients of food supplements about the laid dearen of a latter state about the pnysiological effect used as ingredients of 100d supplier ments should be laid down at a later stage, provided that advantage and agreementage entoutific data about them Appropriate scientific data about them appropriate scientific data account inter-Until such specific Community rules. become available. Until such specific Community rules are adopted and without prejudice to the provisions of the Treaty national value concerning nutrinosis or other There is an increasing number of products marketed in the Community as foods containing concentrated are adopted and without prejudice to the provisions of the Treaty, national rules concerning nutrients or other substances with nutritional or physiological effect used to the provision of the foods containing concentrated the Community as 1000s containing concentrated sources of nutrients and presented for supplementing the intake of three nutrients from the normal diet substances with nutritional or physiological effect used as ingredients of food supplements, for which no Community specific rules have been adopted, may be annitiable. sources or nutrients and presented for supplement intake of those nutrients from the normal diet. Those products are regulated in Member States by differing national rules that may impede their free movediffering national rules that may impede their free move-ment, create unequal conditions of competition, and thus home a direct impact on the functioning of the internal ment, create unequal conditions of competition, and thus have a direct impact on the functioning of the internal market it is therefore necessary to alter Community have a direct impact on the functioning of the internal market. It is therefore necessary to adopt Community rules on those products marketed as foodstuffs. Only vitamins and minerals normally found in, Unly vitamins and minerals normally found in, and consumed as part of, the diet should be allowed to be consumed as part of, the diet should be allowed to be consumed as part of, the diet should be allowed to be consumed as part of the diet should be allowed to be consumed as part of the diet should be allowed to be consumed as part of the diet should be allowed to be consumed as part of the diet should be allowed to be consumed as part of the diet should be allowed to be consumed as part of the diet should be allowed to be consumed as part of the diet should be allowed to be consumed as part of the diet should be allowed to be consumed as part of the diet should be allowed to be allowed to be consumed as part of the diet should be allowed to be al consumed as part of, the diet should be allowed to be present in food supplements although this does not mean that their presence therein is necessary Control An adequated and varied diet could, under normal circumstances previde all narraes are missions. present in lood supplements although this does not mean that their presence therein is necessary. Continuous versy as to the identity of those nutrients that could be avoided. Therefore, it is notentially arise should be avoided. An adequate and varied diet could, under normal circumstances, provide all necessary nutrients for normal devaluations and maintaining of Ladden in the country of the coun circumstances, provide all necessary nutrients for normal development and maintenance of a healthy life in quantities which more those models had a provided the control of development and maintenance of a healthy life in quanti-ties which meet those established and recommended by potentially arise should be avoided. Therefore, it is appropriate to establish a positive list of those vitamins and minerals. ties which meet those established and recommended by generally acceptable scientific data. However, surveys show that this ideal situation is not being achieved for generally acceptable scientific data. However, surveys show that this ideal situation is not being achieved for show that this ideal situation of the nonstation across all outsignts and by all occurse of the nonstation across. show that this ideal situation is not being achieved for all nutrients and by all groups of the population across Consumers, because of their particular lifestyles or for other macrone may change to annulaments their instance. Consumers, because of their particular litestyles or for other reasons, may choose to supplement their intake of compensation and the supplemental compensation of th the Community. There is a wide range of vitamin preparations and There is a wide range of vitamin preparations and mineral substances used in the manufacture of food nuneral substances used in me manufacture of food supplements currently marketed in some Member States outer reasons, may cnoose to supplement t some nutrients through food supplements supplements currently marketed in some Member States that have not been evaluated by the Scientific Committee on Found and consequently and not included in the most In order to ensure a high level of protection for consuthat have not been evaluated by the Scientilic Committee on Food and consequently are not included in the positive liter. These should be enhanted to the European in order to ensure a nign jeyel of protection for consu-nces and facilitate their choice, the products that will be nest on to the market must be eafe and bear adequate frood and consequently are not included in the post-lists. These should be submitted to the European mers and nacunate their choice, me products that will be put, on to the market must be safe and bear adequate tive lists. These should be submitted to the European Food Safety Authority for urgent evaluation, as soon as appropriate files are presented by the interested parties. (2) Ol C 14, 161, 2001, p. 42. Parliament of 14 February 23 December of 19 Opinion of the European Parliament of 19 Security 19 Opinion of the European 126, 10, 2001, p. 126, 2002, p. 1) and Decision of May 2002. 2001 (Ol C 90 E, 164, 2002, Council Decision of 30 May 2002. Parliament of 13 March 2002. Council Decision of 30 May 2002. (1) Of C311 E, 31.10.2000, p. 207 and C180 E, 26.6.2001, p. 248. Of C14, 16.1.2001, p. 42. Of C14, 16.1.2001, p. 42. Operating of the European Parliament of

## **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 daily dose is indicated on the label

the portion of the product recommended for daily consumption

#### Typical weights of food supplements used in EFSA Solid forms (Tablets - Hard gel / soft gel capsules - chewable forms) Tablets (F): 0.2 q 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 q 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 q 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 q Tablets/chewable tablets (Ca): 1.7 g Effervescent tablets: 4 g (dilutable form) Solid forms (Powder) Powder (probiotics): 2.0 q 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



Risk Assessment and Scientific Assistance (RASA) Department Evidence Management Unit (DATA)

Internal Report

27 July 2018

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 Wölfle,
Peter Aggett, Adamasco Cupisti, Cristina Fortes, Gunter Kuhnle, Inger Therese Lillegaard,
Michael Scotter, Alessandra Giarola, Ana Rincon, Alexandra Tard and Ursula Gundert-Rem

**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  $P_2O_3$ 

Corresponds to > 40 g of dicalcium phosphate

#### **EXPOSURE ASSESSMENT: CALCIUM CARBONATE**

#### efaJOURNAL

#### 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 Wölfle, 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
)	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)		10,553 (n = 66)		3,530 (n = 6)		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 reevaluation 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 q 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)

(18-64 years)

**Adults** 

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<sub>2</sub>O<sub>5</sub>)
  - 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<sub>2</sub>O<sub>5</sub>)
  - 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 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

