

FORTIFICATION

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21st August 2019

Overview of UK fortification product regulations

UK product regulations over view guidance to compliance with European Regulations (1)

Fortification is the method of adding nutrients or substances with a nutritional or physiological effect to enhance the nutritional profile of a product.

Fortification can be achieved via mandatory fortification such as the requirement in breads and flours (Bread and Flour Regulations 1998) or voluntary fortification by food manufactures. Fortification cannot be added to unprocessed foods/consumables such as fruit, vegetables, meat, poultry, eggs or fish. Vitamins and minerals cannot be added to alcoholic beverages with an alcohol content of 1.2% or above (with the exception of traditional tonic wines that require added minerals where additional regulations apply).

There is no requirement to register or licence voluntarily fortified foods in the UK, but it is however the responsibility of the manufacture, importer or retailer to ensure the fortification is compliant with regulations and with the Food Standards Agency (FSA) standards.

Regulations for fortified foods are covered under Regulation 1925/2006, with Annex I of the regulation listing the micronutrients that can be added to the processed foods. Annex II lists the sources of those micronutrients that can be used.

The regulation permits only the vitamins and minerals listed in Annex I to be added to foods and these must be in a bio-available form selected from the Annex II. Vitamins and minerals not listed in the Annex I & I cannot be voluntarily added to food.

Annex I & II are regularly updated via the Commission Regulation (EC) 1170/2009, (EC) 1161/2011 and (EC) 119/2014. These regulations also include additional substances that can be used in the process of fortifying foods under Annex III listing prohibited substances (see appendix 1).

Quantity of nutrients added

To ensure that the added fortification is beneficial to health, the regulation requires that the final food product contains a significant amount of the bio-available vitamins and/or minerals. Directive 90/496/EEC defines that a 'significant amount' is defined as 15% of the recommended daily amount (RDA) per 100g/100ml. The amount applies to the total level of the vitamin or mineral including amounts already occurring in the food product.

Table 1; mineral nutrient values for the UK (2).

Age	Ca mg/d	P mg/d	Mg mg/d	Na mg/d	K mg/d	Cl mg/d	Fe mg/d	Zn mg/d	Cu mg/d	Se ug/d	I ug/d
50+ years male	700	550	300	1600	3500	2500	8.7	9.5	1.2	75	140
50+ years female	700	550	270	1600	3500	2500	8.7	7	1.2	60	140
Pregnancy	700	550	270	1600	3500	2500	14.85	7	1.2	60	140
0-4 months breastfeeding	550	440	50	1600	3500	2500	14.85	13	2	75	140
4+ months breastfeeding	550	440	50	1600	3500	2500	14.85	10	2	75	140

Table 2; mineral nutrient values for the UK (2).

Age	Thiamine mg/d	Riboflavin mg/d	Vitamin B6 mg/d	Vitamin B12 ug/d	Folate mg/d	Vitamin C mg/d	Vitamin A ug/d	Vitamin D ug/d	Niacin mg/d
19-50 years male	1	1.3	1.4	1.5	200	40	700	10	17
50+ years male	0.9	1.3	1.4	1.5	200	40	700	10	16
19-50 years female	0.8	1.1	1.2	1.5	200	40	600	10	13
50+ years female	0.8	1.1	1.2	1.5	200	40	600	10	12
Pregnancy	1	1.4	1.2	1.5	100	50	100	20	12
0-4 months breastfeeding	1	1.6	1.2	3.5	160	70	950	20	14

4+ months breastfeeding	1	1.6	1.2	3.5	160	70	950	20	14
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However, the 15% lower limit is not applicable to foods where micronutrients are added to foods to restore a level of vitamins or minerals that were present prior to processing, but again the micronutrients used to restore the levels still must comply with requirements in Regulation 1924/2006.

In addition to setting minimum amounts the regulation also holds provisions that require the EC to set or guide maximum levels to ensure adverse effects of over consumption are avoided. The upper safe limits have been established by the scientific risk assessment of each nutrient based on accepted scientific data, considering the varying degrees of sensitivity and of different groups of the population (3,4,5).

As in the minimum levels of nutrient content the maximum levels are that of the nutrient values naturally found in the product and added via fortification.

Table 3; Upper safe limits and guide limits of nutrient values (3,4,5).

Nutrient	IOM upper safe limit	EVM estimated safe upper limit (SUL)	SCF/EFSA estimated safe upper limit (SUL)	EVM Guide limits (GL)
Biotin	Not est.	2.07mg/d	3000ug/d	900mg/g
Folic acid	1000ug/d	0.99mg/d	1000ug	1000ug/d
Niacin	35mg/d	307mg/d	Not est. 10mg/d (Free nicotinic acid) 900mg/d (Nicotinamide)	Not est. 17mg/d (Free nicotinic acid) 500mg/d (Nicotinamide)
Pantothenic acid	Not est.	560mg/d	Not est.	200mg/d
Riboflavin (B2)	Not est.	103mg/g	Not est.	40mg/d
Thiamine (B1)	Not est.	303mg/d	Not est.	100mg/d
B6	100mg/d	104mg/d	25mg/d	Not est.
B12	Not est.	3mg/d	Not est.	2000ug/d
C	2000mg/d	3160mg/d	Not est.	Not est.
A	3000mg/d	8450ug/d	Not est.	1500ug/d
D	50ug/d	0.02mg/d	100ug/d	25ug/d
E	1000mg/d	690mg/d	3000mg/d	540mg/d
K	Not est.	0.27mg/d	Not est.	1000mg/d
Iodine	1100mg/d	0.95mg/d	600ug/d	500mg/d
Manganese	11mg/d	18mg/d	Not est.	Not est.
Molybdenum	2000mg/d	0.56mg/d	600ug/d	Not est.
Zinc	40mg/g	77mg/d	25mg/d	Not est.
Calcium	2500mg/d	4500mg/d	2500mg/d	1500mg/d
Magnesium	350mg/d	1400mg/d	250mg/d	400mg/d
Phosphorous	4000mg/d	320mg/d	Not est.	250mg/d
Potassium	Not est.	4600mg/d	Not est.	3700mg/d
Sodium	Not est.	Not est.	Not est.	Not est.
Iron	45mg/d	44mg/d	Not est.	17mg/d

Mandatory fortification in the UK

Bread and flour Regulations 1998 Under the UK Bread and Flour Regulations 1998 (FLR) industry is required to add certain nutrients (i.e iron, calcium, thiamine and niacin) to all wheat flour (except wholemeal flour) at the milling stage of processing. This legislative requirement was introduced in the 1950's in order to restore the iron, thiamine and niacin lost in the milling process to the minimum levels known to be present in flour of 80% extraction rate¹. From 1940 until the end of food rationing in Britain in 1954, legislation enforced the milling of flour up to 80% extraction or higher in order to make full use of the nutritional value of the wheat grain. In 1953 controls on the milling of white flour were lifted and bread could again be made from flour of approximately 70% extraction rate and it was considered that restoration of nutrients removed by milling was required in order to maintain the nutritional value of a staple food. The addition of calcium was introduced in the 1940s as a

means of providing more calcium in the diet at a time when dairy products were scarce and the phytate content of high extraction flour used in the wartime loaf inhibited absorption of calcium. Details of the nutrients and levels added are summarised below (6).

Table 4; mandatory nutrients and levels to be added to wheat flour (except wholemeal flour) as set out in the Bread and Flour Regulations 1998 (6).

Nutrient	Amount per 100g flour	Form
Ca	235-390mg [94-156mg Ca]	Calcium carbonate
Fe	≥1.65mg	Any or a combination of; <ul style="list-style-type: none"> • Ferric ammonium citrate • Green ferric ammonium • Ferrous sulphate • Iron powder
Thiamine	≥0.24mg [0.21mg thiamine]	Thiamine hydrochloride
Niacin	≥1.60mg	Nicotinamide or nicotinic acid

Except self-raising flour which contains ≥0.2% Ca

Table 5; Composition of white flour with or without added nutrients (6)

Food	Ca	Fe	Thiamine	Niacin
Wheat flour (white) with added nutrition	96	1.9	0.28	1.7
Wheat flour (white) without added nutrition	15	1.5	0.10	0.7
Difference	81	0.4	0.18	1.0

Mandatory fortification has been lifted from The Spreadable Fats (Marketing Standards) and the Milk and Milk Products (Protection of Designations). Regulations 2008 has been revoked and it is no longer a criminal offence to sell unfortified margarine (7). Currently discussions are undergoing to evaluate the fortification of vitamin D in UK product food products.

Enforcement

The enforcement of the food law in the UK is the responsibilities of the local authorities, Trading Standards and Environmental Health. Trading Standards and Environmental Health officers or any authorised officer of local authority can initiate legal proceedings in the connection of a product that is deemed to breach regulation.

Food labelling

The labelling of the fortified product must comply with food labelling law listing the energy, macronutrient and micronutrient content detailing the vitamin and minerals added to the product. The labelling must not mislead the consumer about the nutritional benefit of the product and all claims made about the vitamins or minerals must comply with the conditions set out in the Regulation (EC) No 1924/2006 on nutrition and health claims.

References

1. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/204310/Fortified_Food_SI_guidance_DH_151111_-_FINAL.pdf
2. https://www.nutrition.org.uk/attachments/article/234/Nutrition%20Requirements_Revised%20Oct%202016.pdf
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4. <https://cot.food.gov.uk/sites/default/files/vitmin2003.pdf>
5. <https://www.slideshare.net/Adrienna/nutrient-risk-assessment-and-upper-intake-levels-eu2105>
6. <https://www.fob.uk.com/wp-content/uploads/2017/01/FS25-Flour-Fortification.pdf>

7. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/287673/margarine-fortification-sum-resp-201403.pdf

Appendix 1

ANNEX I Vitamins and minerals which may be used in the manufacture of food supplements

1. Vitamins	2. Minerals
Vitamin A (µg RE)	Calcium (mg)
Vitamin D (µg)	Magnesium (mg)
Vitamin E (mg a-TE)	Iron (mg)
Vitamin K (µg)	Copper (µg)
Vitamin B1 (mg)	Iodine (µg)
Vitamin B2 (mg)	Zinc (mg)
Niacin (mg NE)	Manganese (mg)
Pantothenic acid (mg)	Sodium (mg)
Vitamin B6 (mg)	Potassium (mg)
Folic acid (µg) (*)	Selenium (µg)
Vitamin B12 (µg)	Chromium (µg)
Biotin (µg)	Molybdenum (µg)
Vitamin C (mg)	Fluoride (mg)
	Chloride (mg)
	Phosphorus (mg)
	Boron (mg) Silicon (mg)

(*) Folic acid is the term included in Annex I of Commission Directive 2008/100/EC of 28 October 2008 amending Council Directive 90/496/EEC on nutrition labelling for foodstuffs as regards recommended daily al

ANNEX II Vitamin and mineral substances which may be used in the manufacture of food supplements

A. Vitamins 1.	B. Minerals
VITAMIN A	ammonium molybdate (molybdenum (VI))
• (a) retinol	boric acid
• (b) retinyl acetate	calcium acetate
• (c) retinyl palmitate	calcium bisglycinate
• (d) beta-carotene	calcium carbonate
2. VITAMIN D (a) cholecalciferol	calcium chloride
• (b) ergocalciferol	calcium citrate malate
3. VITAMIN E (a) D-alpha-tocopherol	calcium fluoride
• (b) DL-alpha-tocopherol	calcium gluconate
• (c) D-alpha-tocopheryl acetate	calcium glycerophosphate
• (d) DL-alpha-tocopheryl acetate	calcium hydroxide
• (e) D-alpha-tocopheryl acid succinate	calcium lactate
• (f) mixed tocopherols (*)	calcium L-ascorbate
• (g) tocotrienol tocopherol (**)	calcium L-lysinate
4. VITAMIN K	calcium L-pidolate
• (a) phyloquinone (phytomenadione)	calcium L-threonate
• (b) menaquinone (***)	calcium malate
5. VITAMIN B1	calcium oxide
• (a) thiamin hydrochloride	calcium pyruvate
• (b) thiamin mononitrate	calcium salts of citric acid
• (c) thiamine monophosphate chloride	calcium salts of orthophosphoric acid
• (d) thiamine pyrophosphate chloride	calcium succinate
6. VITAMIN B2 (a) riboflavin	calcium sulphate
• (b) riboflavin 5'-phosphate, sodium	choline-stabilised orthosilicic acid
7. NIACIN	chromium (III) chloride
• (a) nicotinic acid	chromium (III) lactate trihydrate
• (b) nicotinamide	chromium (III) sulphate
• (c) inositol hexanicotinate (inositol hexaniacinate)	chromium nitrate
8. PANTOTHENIC ACID	chromium picolinate
• (a) D-pantothenate, calcium	copper (II) oxide
• (b) D-pantothenate, sodium	copper bisglycinate
• (c) dexpanthenol	copper L-aspartate
• (d) pantethine	copper lysine complex
•	cupric citrate
9. VITAMIN B6	cupric gluconate
• (a) pyridoxine hydrochloride	cupric sulphate
• (b) pyridoxine 5'-phosphate	B. Minerals

• (c) pyridoxal 5'-phosphate	ammonium molybdate (molybdenum (VI))
• 10. FOLATE (a) pteroylmonoglutamic acid	boric acid
• (b) calcium-L-methylfolate	calcium acetate
11. VITAMIN B12	calcium bisglycinate
• (a) cyanocobalamin	calcium carbonate
• (b) hydroxocobalamin	calcium chloride
• (c) 5'-deoxyadenosylcobalamin	calcium citrate malate
• (d) methylcobalamin	calcium fluoride
12. BIOTIN	calcium gluconate
• (a) D-biotin	calcium glycerophosphate
13. VITAMIN C	calcium hydroxide
• (a) L-ascorbic acid	calcium lactate
• (b) sodium-L-ascorbate	calcium L-ascorbate
• (c) calcium-L-ascorbate (****)	calcium L-lysinate
• (d) potassium-L-ascorbate	calcium L-pidolate
• (e) L-ascorbyl 6-palmitate	calcium L-threonate
• (f) magnesium L-ascorbate	calcium malate
• (g) zinc L-ascorbate	calcium oxide

calcium pyruvate	manganese L-aspartate
calcium salts of citric acid	manganese pidolate
calcium salts of orthophosphoric acid	manganese sulphate
calcium succinate	potassium bicarbonate
calcium sulphate	potassium carbonate
choline-stabilised orthosilicic acid	potassium chloride
chromium (III) chloride	potassium citrate
chromium (III) lactate trihydrate	potassium fluoride
chromium (III) sulphate	potassium gluconate
chromium nitrate	potassium glycerophosphate
chromium picolinate	potassium hydroxide
copper (II) oxide	potassium iodate
copper bisglycinate	potassium iodide
copper L-aspartate	potassium lactate
copper lysine complex	potassium L-pidolate
cupric citrate	potassium malate
cupric gluconate	potassium molybdate (molybdenum (VI))
cupric sulphate	potassium salts of orthophosphoric acid
ferric ammonium citrate	selenious acid sodium selenate
ferric diphosphate (ferric pyrophosphate)	selenium enriched yeast (****)
ferric saccharate elemental iron (carbonyl + electrolytic + hydrogen reduced)	silicic acid (*****)
ferric sodium diphosphate	silicon dioxide
ferrous bisglycinate	sodium bicarbonate
ferrous carbonate	sodium borate
ferrous citrate	sodium carbonate
ferrous fumarate	sodium chloride
ferrous gluconate	sodium citrate
ferrous lactate	sodium fluoride
ferrous L-pidolate	sodium gluconate
ferrous phosphate iron (II) taurate	sodium hydrogen selenite
cupric carbonate	
ferrous sulphate	sodium hydroxide
L-selenomethionine	sodium iodate
magnesium acetate	sodium iodide
magnesium acetyl taurate	sodium lactate
magnesium bisglycinate	sodium molybdate (molybdenum (VI))
magnesium carbonate	sodium monofluorophosphate
magnesium chloride	sodium salts of orthophosphoric acid
magnesium gluconate	sodium selenite
magnesium glycerophosphate	zinc acetate
magnesium hydroxide	zinc bisglycinate
magnesium lactate	zinc carbonate
magnesium L-ascorbate	zinc chloride
magnesium L-lysinate	zinc citrate
magnesium L-pidolate	zinc gluconate
magnesium malate	Zinc lactate
magnesium oxide	zinc L-ascorbate
magnesium potassium citrate	zinc L-aspartate

magnesium pyruvate	zinc L-lysinate
magnesium salts of citric acid	zinc L-pidolate
magnesium salts of orthophosphoric acid	zinc malate
magnesium succinate	zinc mono-L-methionine sulphate
magnesium sulphate	zinc oxide
magnesium taurate	zinc picolinate
manganese ascorbate	zinc sulphate
manganese bisglycinate	
manganese carbonate	
manganese chloride	
manganese citrate	
manganese gluconate	
manganese glycerophosphate	

(*) alpha-tocopherol < 20 %, beta-tocopherol < 10 %, gamma-tocopherol 50-70 % and delta-tocopherol 10-30 % (**) Typical levels of individual tocopherols and tocotrienols:

- 115 mg/g alpha-tocopherol (101 mg/g minimum),
- 5 mg/g beta-tocopherol (< 1 mg/g minimum),
- 45 mg/g gamma-tocopherol (25 mg/g minimum),
- 12 mg/g delta-tocopherol (3 mg/g minimum),
- 67 mg/g alpha-tocotrienol (30 mg/g minimum),
- < 1 mg/g beta-tocotrienol (< 1 mg/g minimum),
- 82 mg/g gamma-tocotrienol (45 mg/g minimum), — 5 mg/g delta-tocotrienol (< 1 mg/g minimum),

(***) Menaquinone occurring principally as menaquinone-7 and, to a minor extent, menaquinone-6. (****) May contain up to 2 % of threonate.

(*****) Selenium-enriched yeasts produced by culture in the presence of sodium selenite as selenium source and containing, in the dried form as marketed, not more than 2,5 mg Se/g. The predominant organic selenium species present in the yeast is selenomethionine (between 60 and 85 % of the total extracted selenium in the product). The content of other organic selenium compounds including selenocysteine shall not exceed 10 % of total extracted selenium. Levels of inorganic selenium normally shall not exceed 1 % of total extracted selenium.

(*****) In the form of gel.'

Annex III and prohibited substances; https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/791727/uk-register-of-vitamins-minerals-and-certain-other-substances.pdf