

CODEX ALIMENTARIUS

INTERNATIONAL FOOD STANDARDS



Food and Agriculture
Organization of
the United Nations



World Health
Organization

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STANDARD FOR FERMENTED MILKS

CXS 243-2003

Adopted in 2003. Revised in 2008, 2010, 2018. Amended in 2022.

2022 Amendment

The following amendment was made to the text of the standard following decisions taken at the forty-fifth session of the Codex Alimentarius Commission in December 2022.

Page	Location	Text in previous version	Text in amended version
12	Section 7.3 Labelling of Non-Retail Containers	Information required in Section 7 of this Standard and Sections 4.1 to 4.8 of the <i>General Standard for the Labelling of Pre-packaged Foods</i> , and, if necessary, storage instructions, shall be given either on the container or in accompanying documents, except that the name of the product, lot identification, and the name and address of the manufacturer or packer, shall appear on the container. However, lot identification and the name and address of the manufacturer or packager may be replaced by an identification mark, provided that such mark is clearly identifiable with the accompanying documents	The labelling of non-retail containers should be in accordance with the <i>General Standard for the Labelling of Non-Retail Containers of Foods</i> (CXS 346-2021).

1. SCOPE

This standard applies to fermented milks, that is Fermented Milk including, Heat Treated Fermented Milks, Concentrated Fermented Milks and composite milk products based on these products, for direct consumption or further processing in conformity with the definitions in Section 2 of this Standard.

2. DESCRIPTION

- 2.1 *Fermented Milk*** is a milk product obtained by fermentation of milk, which milk may have been manufactured from products obtained from milk with or without compositional modification as limited by the provision in Section 3.3, by the action of suitable microorganisms and resulting in reduction of pH with or without coagulation (iso-electric precipitation). These starter microorganisms shall be viable, active and abundant in the product to the date of minimum durability. If the product is heat treated after fermentation the requirement for viable microorganisms does not apply.

Certain Fermented Milks are characterized by specific starter culture(s) used for fermentation as follows:

Yoghurt:	Symbiotic cultures of <i>Streptococcus thermophilus</i> and <i>Lactobacillus delbrueckii</i> subsp. <i>bulgaricus</i> .
Alternate culture yoghurt:	Cultures of <i>Streptococcus thermophilus</i> and any <i>Lactobacillus</i> species.
Acidophilus milk:	<i>Lactobacillus acidophilus</i> .
Kefir:	Starter culture prepared from kefir grains, <i>Lactobacillus kefir</i> , species of the genera <i>Leuconostoc</i> , <i>Lactococcus</i> and <i>Acetobacter</i> growing in a strong specific relationship. Kefir grains constitute both lactose fermenting yeasts (<i>Kluyveromyces marxianus</i>) and non-lactose-fermenting yeasts (<i>Saccharomyces unisporus</i> , <i>Saccharomyces cerevisiae</i> and <i>Saccharomyces exiguus</i>).
Kumys:	<i>Lactobacillus delbrueckii</i> subsp. <i>bulgaricus</i> and <i>Kluyveromyces marxianus</i> .

Other microorganisms than those constituting the specific starter culture(s) specified above may be added.

- 2.2 *Concentrated Fermented Milk*** is a Fermented Milk the protein of which has been increased prior to or after fermentation to minimum 5.6%. Concentrated Fermented Milks includes traditional products such as Stragis to (strained yoghurt), Labneh, Ymer and Ylette.
- 2.3 *Flavoured Fermented Milks*** are composite milk products, as defined in Section 2.3 of the *General Standard for the Use of Dairy Terms* (CXS 206-1999) which contain a maximum of 50% (m/m) of non-dairy ingredients (such as nutritive and non nutritive sweeteners, fruits and vegetables as well as juices, purees, pulps, preparations and preserves derived there from, cereals, honey, chocolate, nuts, coffee, spices and other harmless natural flavouring foods) and/or flavours. The non-dairy ingredients can be mixed in prior to/or after fermentation.
- 2.4 *Drinks based on Fermented Milk*** are composite milk products, as defined in Section 2.3 of the *General Standard for the Use of Dairy Terms* (CXS 206-1999), obtained by mixing Fermented Milk as described in Section 2.1 with potable water with or without the addition of other ingredients such as whey, other non-dairy ingredients, and flavourings. Drinks Based on Fermented Milk contain a minimum of 40% (m/m) fermented milk.

Other microorganisms than those constituting the specific starter culture(s) specified above may be added.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Raw materials

- Milk and/or products obtained from milk.
- Potable water for the use in reconstitution or recombination.

3.2 Permitted ingredients

- Starter cultures of harmless microorganisms including those specified in Section 2;
- Other suitable and harmless microorganisms (*in products covered by Section 2.4*);
- Sodium chloride;
- Non-dairy ingredients as listed in Section 2.3 (Flavoured Fermented Milks);
- Potable water (*in products covered by Section 2.4*);
- Milk and milk products (*in products covered by Section 2.4*);
- Gelatine and starch in:
 - fermented milks heat-treated after fermentation;
 - flavoured fermented milk;
 - drinks based on fermented milk; and
 - plain fermented milks if permitted by national legislation in the country of sale to the final consumer;

provided they are added only in amounts functionally necessary as governed by Good Manufacturing Practice, taking into account any use of the stabilizers/thickeners listed in Section 4. These substances may be added either before or after adding the non-dairy ingredients.

3.3 Composition

	Fermented Milk	Yoghurt, Alternate Culture Yoghurt and Acidophilus milk	Kefir	Kumys
Milk protein ^(a) (% m/m)	min. 2.7%	min. 2.7%	min. 2.7%	
Milk fat (% m/m)	less than 10%	less than 15%	less than 10%	less than 10%
Titration acidity, expressed as % lactic acid (% m/m)	min. 0.3%	min. 0.6%	min. 0.6%	min. 0.7%
Ethanol (% vol./w)				min. 0.5%
Sum of microorganisms constituting the starter culture defined in section 2.1 (cfu/g, in total)	min. 10 ⁷	min. 10 ⁷	min. 10 ⁷	min. 10 ⁷
Labelled microorganisms ^(b) (cfu/g, total)	min. 10 ⁶	min. 10 ⁶		
Yeasts (cfu/g)			min. 10 ⁴	min. 10 ⁴

(a) Protein content is 6.38 multiplied by the total Kjeldahl nitrogen determined.

(b) Applies where a content claim is made in the labelling that refers to the presence of a specific microorganism (other than those specified in section 2.1 for the product concerned) that has been added as a supplement to the specific starter culture.

In Flavoured Fermented Milks and Drinks based on Fermented Milk the above criteria apply to the fermented milk part. The microbiological criteria (based on the proportion of fermented milk product) are valid up to the date of minimum durability. This requirement does not apply to products heat-treated after fermentation.

Compliance with the microbiological criteria specified above is to be verified through analytical testing of the product through to “the date of minimum durability” after the product has been stored under the storage conditions specified in the labelling.

3.4 Essential manufacturing characteristics

Whey removal after fermentation is not permitted in the manufacture of fermented milks, except for Concentrated Fermented Milk (Section 2.2).

4. FOOD ADDITIVES

Only those additives classes indicated in the table below may be used for the product categories specified. Within each additive class, and where permitted according to the table, only those individual additives listed may be used and only within the limits specified.

In accordance with Section 4.1 of the Preamble to the *General Standard for Food Additives* (CXS 192-1995), additional additives may be present in the flavoured fermented milks and drinks based on fermented milk as a result of carry-over from non-dairy ingredients.

Additive class	Fermented Milks and Drinks based on Fermented Milk		Fermented Milks Heat Treated After Fermentation and Drinks based on Fermented Milk Heat Treated After Fermentation	
	Plain	Flavoured	Plain	Flavoured
Acidity regulators:	–	X	X	X
Carbonating agents:	X ^(b)	X ^(b)	X ^(b)	X ^(b)
Colours:	–	X	–	X
Emulsifiers:	–	X	–	X
Flavour enhancers:	–	X	–	X
Packaging gases:	–	X	X	X
Preservatives:	–	–	–	X
Stabilizers:	X ^(a)	X	X	X
Sweeteners:	–	X	–	X
Thickeners:	X ^(a)	X	X	X

^(a) Use is restricted to reconstitution and recombination and if permitted by national legislation in the country of sale to the final consumer.

^(b) Use of carbonating agents is technologically justified in Drinks based on Fermented Milk only. X The use of additives belonging to the class is technologically justified. In the case of flavoured products the additives are technologically justified in the dairy portion.

– The use of additives belonging to the class is not technologically justified.

Acidity regulators, colours, emulsifiers, packaging gases and preservatives listed in Table3 of the *General Standard for Food Additives* (CXS 192-1995) are acceptable for use in fermented milk products categories as specified in the table above.

INS no.	Name of additive	Maximum level
Acidity regulators		
334	Tartaric acid L(+)-	2 000 mg/kg as tartaric acid
335(ii)	Sodium L(+)-tartrate	
337	Potassium sodium L(+)-tartrate	
355	Adipic acid	1 500 mg/kg as adipic acid
356	Sodium adipate	
357	Potassium adipate	
359	Ammonium adipate	
Carbonating agents		
290	Carbon dioxide	GMP
Colours		
100(i)	Curcumin	100 mg/kg
101(i)	Riboflavin, synthetic	300 mg/kg
101(ii)	Riboflavin 5'-phosphate, sodium	
102	Tartrazine	
104	Quinoline yellow	150 mg/kg
110	Sunset yellow FCF	300 mg/kg
120	Carmines	150 mg/kg
122	Azorubine (Carmoisine)	
124	Ponceau 4R (Cochineal red A)	
129	Allura red AC	300 mg/kg
132	Indigotine	100 mg/kg
133	Brilliant blue FCF	150 mg/kg
141(i)	Chlorophylls, copper complexes	500 mg/kg
141(ii)	Chlorophylls, copper complexes, sodium and potassium salts	
143	Fast green FCF	100 mg/kg
150b	Caramel II – sulphite caramel	150 mg/kg
150c	Caramel III – ammonia caramel	2 000 mg/kg
150d	Caramel IV – sulphite ammonia caramel	2 000 mg/kg
151	Brilliant black (Black PN)	150 mg/kg
155	Brown HT	150 mg/kg
160a(i)	Carotene, <i>beta</i> -, synthetic	100 mg/kg

INS no.	Name of additive	Maximum level
160e	Carotenal, <i>beta</i> -apo-8'-	
160f	Carotenic acid, methyl or ethyl ester, <i>beta</i> -apo-8'-	
160a(iii)	Carotenes, <i>beta</i> -, <i>Blakeslea trispora</i>	
160a(ii)	Carotenes, <i>beta</i> -, vegetable	600 mg/kg
160b(i)	Annatto extract, bixin-based	20 mg/kg as bixin
160b(ii)	Annatto extract, norbixin-based	20 mg/kg as norbixin
160d	Lycopenes	30 mg/kg as pure lycopene
161b(i)	Lutein from <i>Tagetes erecta</i>	150 mg/kg
161h(i)	Zeaxanthin, synthetic	150 mg/kg
163(ii)	Grape skin extract	100 mg/kg
172(i)	Iron oxide, black	
172(ii)	Iron oxide, red	
172(iii)	Iron oxide, yellow	
Emulsifiers		
432	Polyoxyethylene (20) sorbitan monolaurate	3 000 mg/kg
433	Polyoxyethylene (20) sorbitan monooleate	
434	Polyoxyethylene (20) sorbitan monopalmitate	
435	Polyoxyethylene (20) sorbitan monostearate	
436	Polyoxyethylene (20) sorbitan tristearate	
472e	Diacetyltartaric and fatty acid esters of glycerol	10 000 mg/kg
473	Sucrose esters of fatty acids	5 000 mg/kg
474	Sucroglycerides	5 000 mg/kg
475	Polyglycerol esters of fatty acids	2 000 mg/kg
477	Propylene glycol esters of fatty acids	5 000 mg/kg
481(i)	Sodium stearyl lactylate	10 000 mg/kg
482(i)	Calcium stearyl lactylate	10 000 mg/kg
491	Sorbitan monostearate	5 000 mg/kg
492	Sorbitan tristearate	
493	Sorbitan monolaurate	
494	Sorbitan monooleate	

INS no.	Name of additive	Maximum level
495	Sorbitan monopalmitate	
900a	Polydimethylsiloxane	50 mg/kg
Flavour enhancers		
580	Magnesium gluconate	GMP
620	Glutamic acid, (L+)-	
621	Monosodium L-glutamate	
622	Monopotassium L-glutamate	
623	Calcium di-L-glutamate	
624	Monoammonium L-glutamate	
625	Magnesium di-L-glutamate	
626	Guanylic acid, 5'-	
627	Disodium 5'-guanylate-	
628	Dipotassium 5'-guanylate-	
629	Calcium 5'-guanylate	
630	Inosinic acid, 5'-	
631	Disodium 5'-inosinate	
632	Dipotassium 5'-inosinate	
633	Calcium 5'-inosinate	
634	Calcium 5'-ribonucleotides-	
635	Disodium 5'-ribonucleotides-	
636	Maltol	
637	Ethyl maltol	
Preservatives		
200	Sorbic acid	1 000 mg/kg as sorbic acid
202	Potassium sorbate	
203	Calcium sorbate	
210	Benzoic acid	300 mg/kg as benzoic acid
211	Sodium benzoate	
212	Potassium benzoate	
213	Calcium benzoate	
234	Nisin	500 mg/kg
Stabilizers and Thickeners		

INS no.	Name of additive	Maximum level
170(i)	Calcium carbonate	GMP
331(iii)	Trisodium citrate	GMP
338	Phosphoric acid	1 000 mg/kg, singly or in combination, as phosphorus
339(i)	Sodium dihydrogen phosphate	
339(ii)	Disodium hydrogen phosphate	
339(iii)	Trisodium phosphate	
340(i)	Potassium dihydrogen phosphate	
340(ii)	Dipotassium hydrogen phosphate	
340(iii)	Tripotassium phosphate	
341(i)	Monocalcium dihydrogen phosphate	
341(ii)	Calcium hydrogen phosphate	
341(iii)	Tricalcium orthophosphate	
342(i)	Ammonium dihydrogen phosphate	
342(ii)	Diammonium hydrogen phosphate	
343(i)	Monomagnesium phosphate	
343(ii)	Magnesium hydrogen phosphate	
343(iii)	Trimagnesium phosphate	
450(i)	Disodium diphosphate	
450(ii)	Trisodium diphosphate	
450(iii)	Tetrasodium diphosphate	
450(v)	Tetrapotassium diphosphate	
450(vi)	Dicalcium diphosphate	
450(vii)	Calcium dihydrogen diphosphate	
451(i)	Pentasodium triphosphate	
451(ii)	Pentapotassium triphosphate	
452(i)	Sodium polyphosphate	
452(ii)	Potassium polyphosphate	
452(iii)	Sodium calcium polyphosphate	
452(iv)	Calcium polyphosphate	
452(v)	Ammonium polyphosphate	

INS no.	Name of additive	Maximum level
542	Bone phosphate	
400	Alginic acid	GMP
401	Sodium alginate	
402	Potassium alginate	
403	Ammonium alginate	
404	Calcium alginate	
405	Propylene glycol alginate	
406	Agar	
407	Carrageenan	
407a	Processed eucheama seaweed (PES)	
410	Carob bean gum	
412	Guar gum	
413	Tragacanth gum	
414	Gum Arabic (Acacia gum)	
415	Xanthan gum	
416	Karaya gum	
417	Tara gum	
418	Gellan gum	
425	Konjac flour	
440	Pectins	
459	Cyclodextrin, -beta	5 mg/kg
460(i)	Microcrystalline cellulose (Cellulose gel)	GMP
460(ii)	Powdered cellulose	
461	Methyl cellulose	
463	Hydroxypropyl cellulose	
464	Hydroxypropyl methyl cellulose	
465	Methyl ethyl cellulose	
466	Sodium carboxymethyl cellulose (Cellulose gum)	
467	Ethyl hydroxyethyl cellulose	
468	Cross-linked sodium carboxymethyl cellulose (Cross-linked cellulose gum)	
469	Sodium carboxymethyl cellulose, enzymatically hydrolyzed (Cellulose gum, enzymatically hydrolyzed)	

INS no.	Name of additive	Maximum level	
470(i)	Salts of myristic, palmitic and stearic acids with ammonia, calcium, potassium and sodium		
470(ii)	Salts of oleic acid with calcium, potassium and sodium		
471	Mono- and di- glycerides of fatty acids		
472a	Acetic and fatty acid esters of glycerol		
472b	Lactic and fatty acid esters of glycerol		
472c	Citric and fatty acid esters of glycerol		
508	Potassium chloride		
509	Calcium chloride		
511	Magnesium chloride		
1200	Polydextrose		
1400	Dextrins, roasted starch		
1401	Acid treated starch		
1402	Alkaline treated starch		
1403	Bleached starch		
1404	Oxidized starch		
1405	Starches, enzyme treated		
1410	Mono starch phosphate		
1412	Distarch phosphate		
1413	Phosphated distarch phosphate		
1414	Acetylated distarch phosphate		
1420	Starch acetate		
1422	Acetylated distarch adipate		
1440	Hydroxypropyl starch		
1442	Hydroxypropyl distarch phosphate		
1450	Starch sodium octenyl succinate		
1451	Acetylated oxidized starch		
Sweeteners^(a)			
420	Sorbitol		GMP
421	Mannitol		GMP

INS no.	Name of additive	Maximum level
950	Acesulfame potassium	350 mg/kg
951	Aspartame	1 000 mg/kg
952	Cyclamates	250 mg/kg
953	Isomalt (Hydrogenated isomaltulose)	GMP
954	Saccharin	100 mg/kg
955	Sucralose (Trichlorogalactosucrose)	400 mg/kg
956	Alitame	100 mg/kg
961	Neotame	100 mg/kg
962	Aspartame-acesulfame salt	350 mg/kg on an acesulfame potassium equivalent basis
964	Polyglycitol syrup	GMP
965	Maltitols	
966	Lactitol	
967	Xylitol	
968	Erythritol	

(a) The use of sweeteners is limited to milk-and milk derivative-based products energy reduced or with no added sugar.

5. CONTAMINANTS

The products covered by this Standard shall comply with the Maximum Levels for contaminants that are specified for the product in the *General Standard for Contaminants and Toxins in Foods and Feeds* (CXS 193-1995).

The milk used in the manufacture of the products covered by this Standard shall comply with the Maximum Levels for contaminants and toxins specified for milk by the *General Standard for Contaminants and Toxins in Foods and Feeds* (CXS 193-1995) and with the maximum residue limits for veterinary drug residues and pesticides established for milk by the CAC.

6. HYGIENE

It is recommended that the products covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the *General Principles of Food Hygiene* (CXC 1-1969), the *Code of Hygienic Practice for Milk and Milk Products* (CXC 57-2004) and other relevant Codex texts such as Codes of Hygienic Practice and Codes of Practice. The products should comply with any microbiological criteria established in accordance with the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997).

7. LABELLING

In addition to the provisions of the *General Standard for the Labelling of Pre-packaged Foods* (CXS 1-1985) and the *General Standard for the Use of Dairy Terms* (CXS 206-1999), the following specific provisions apply:

7.1 Name of the food

7.1.1 The name of the products covered by Sections 2.1, 2.2 and 2.3, shall be fermented milk or concentrated fermented milk as appropriate.

However, these names may be replaced by the designations Yoghurt, Acidophilus Milk, Kefir, Kumys, Stragisto, Labneh, Ymer and Ylette, provided that the product complies with the specific provisions of this Standard. Yoghurt may be spelled as appropriate in the country of retail sale.

“Alternate culture yoghurt”, as defined in Section 2, shall be named through the use of an appropriate qualifier in conjunction with the word “yoghurt”. The chosen qualifier shall describe, in a way that is accurate and not misleading to the consumer, the nature of the change imparted to the yoghurt through the selection of the specific *Lactobacilli* in the culture for manufacturing the product. Such change may include a marked difference in the fermentation organisms, metabolites and/or sensory properties of the product when compared to the product designated solely as “yoghurt”. Examples of qualifiers which describe differences in sensory properties include terms such as “mild” and “tangy”. The term “alternate culture yoghurt” shall not apply as a designation.

The above specific terms may be used in connection with the term “frozen” provided (i) that the product submitted to freezing complies with the requirements in this Standard, (ii) that the specific starter cultures can be reactivated in reasonable numbers by thawing, and (iii) that the frozen product is named as such and is sold for direct consumption, only.

Other fermented milks and concentrated fermented milks may be designated with other variety names as specified in the national legislation of the country in which the product is sold, or names existing by common usage, provided that such designations do not create an erroneous impression in the country of retail sale regarding the character and identity of the food.

- 7.1.2** Products obtained from fermented milk(s) heat treated after fermentation shall be named “Heat Treated Fermented Milk”. If the consumer would be misled by this name, the products shall be named as permitted by national legislation in the country of retail sale. In countries where no such legislation exists, or no other names are in common usage, the product shall be named “Heat Treated Fermented Milk”.
- 7.1.3** The designation of Flavoured Fermented Milks shall include the name of the principal flavouring substance(s) or flavour(s) added.
- 7.1.4** The name of the products defined in Section 2.4 shall be drinks based on fermented milk or may be designated with other variety names as allowed in the national legislation of the country in which the product is sold. In particular, water added as an ingredient to fermented milk shall be declared in the list of ingredients¹ and the percentage of fermented milk used (m/m) shall clearly appear on the label. When flavoured, the designation shall include the name of the principal flavouring substance(s) or flavour(s) added.
- 7.1.5** Fermented milks to which only nutritive carbohydrate sweeteners have been added, maybe labelled as “sweetened _____”, the blank being replaced by the term “Fermented Milk” or another designation as specified in Section 7.1.1 and 7.1.4. If non-nutritive sweeteners are added in partial or total substitution to sugar, the mention “sweetened with _____” or “sugared and sweetened with _____” should appear close to the name of the product, the blank being filled in with the name of the artificial sweeteners.
- 7.1.6** The names covered by this Standard may be used in the designation, on the label, in commercial documents and advertising of other foods, provided that it is used as an ingredient and that the characteristics of the ingredient are maintained to a relevant degree in order not to mislead the consumer.

7.2 Declaration of fat content

If the consumer would be misled by the omission, the milk fat content shall be declared in a manner acceptable in the country of sale to the final consumer, either as (i) a percentage of mass or volume, or (ii) in grams per serving as qualified in the label, provided that the number of servings is stated.

7.3 Labelling of non-retail containers

The labelling of non-retail containers should be in accordance with the *General Standard for the Labelling of Non-Retail Containers of Foods* (CXS 346-2021).

8. METHODS OF SAMPLING AND ANALYSIS

For checking the compliance with this standard, the methods of analysis and sampling contained in the *Recommended Methods of Analysis and Sampling* (CXS 234-1999) relevant to the provisions in this standard, shall be used.

¹ As prescribed in section 4.2.1.5 of the *General Standard for the Labelling of Pre-packaged Foods* (CXS 1-1985)