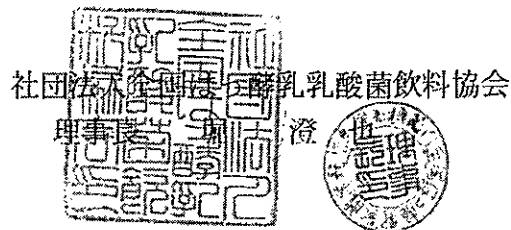


厚生労働大臣
舛添要一殿

はっ酵乳協21発第3号
平成21年4月10日



乳等省令に殺菌タイプ発酵乳（仮称）の追加の要望

1. はじめに

乳及び乳製品の成分規格等に関する省令（以下乳等省令という）の別表二の（三）「乳製品の成分規格並びに製造及び保存の基準」中に「(23) 発酵乳」の規格基準が設定されているが、殺菌タイプ発酵乳は規格化がなされていない。

一方、国際食品規格（コーデックス規格）には、その適用範囲の中で「発酵乳類とは、加熱処理発酵乳、濃縮発酵乳及びこれらの製品からなる複合乳製品をいう」と規定され、外国ではすでに市場に流通している。（別添資料参照）

2. 要望の理由

発酵乳製品にバリエーションを持たせ、発酵乳市場の拡大、発展等を図る。

3. 発酵乳の成分規格等の変更について

- (1) 乳等省令別表二の（三）中、(24) 乳酸菌飲料（無脂乳固形分3%以上のもの）の「1 成分規格」に定める「ただし書き」を(23) 発酵乳の「1 成分規格」中に追加する。
- (2) 乳等省令第7条第2項「三 乳製品」のルに「殺菌した発酵乳」を追加する。

以上

CODEX STANDARD FOR FERMENTED MILKS**CODEX STAN 243-2003****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**

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

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 Stragisto (strained yoghurt), Labneh, Ymer and Ylette.

2.3 FLAVOURED FERMENTED MILKS

Flavoured Fermented Milks are composite milk products, as defined in Section 2.3 of the Codex General Standard for the Use of Dairy Terms (CODEX STAN 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 therefrom, 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.

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;
- Sodium chloride; and
- Non-dairy ingredients as listed in Section 2.3 (*Flavoured Fermented Milks*).
- Gelatine and starch in:
 - fermented milks heat-treated after fermentation;
 - flavoured 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 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 labeling.

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 (CODEX STAN 192-1995), additional additives may be present in the flavoured fermented milks as a result of carry-over from non-dairy ingredients.

Additive class	Fermented Milks		Fermented Milks Heat Treated After Fermentation	
	Plain	Flavoured	Plain	Flavoured
Colours	-	X	-	X
Sweeteners	-	X	-	X
Emulsifiers	-	X	-	X
Flavour enhancers	-	X	-	X
Acids	-	X	X	X
Acidity regulators	-	X	X	X
Stabilizers	X ¹	X	X	X
Thickeners	X ¹	X	X	X
Preservatives	-	-	-	X
Packaging gases	-	X	X	X

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

¹ = Use is restricted to reconstitution and recombination and if permitted by national legislation in the country of sale to the final consumer.

Acidity regulators, colours, emulsifiers, packaging gases and preservatives listed in Table 3 of the General Standard for Food Additives (CODEX STAN 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(+))	2000 mg/kg as tartaric acid
335(i)	Monosodium tartrate	
335(ii)	Disodium tartrate	
336(i)	Monopotassium tartrate	
336(ii)	Dipotassium tartrate	
337	Potassium sodium tartrate	
355	Adipic acid	1500 mg/kg, as adipic acid
356	Sodium adipate	
357	Potassium adipate	
359	Ammonium adipate	

INS No.	Name of Additive	Maximum Level
Colours		
100(i)	Curcumin	100 mg/kg
101(i)	Riboflavin	300 mg/kg
101(ii)	Riboflavin 5'-phosphate, sodium	
102	Tartrazine	300 mg/kg
104	Quinoline yellow	150 mg/kg
110	Sunset yellow FCF	300 mg/kg
120	Carmines	150 mg/kg
122	Azorubine	150 mg/kg
124	Ponceau 4R	150 mg/kg
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)	Chlorophyllins, copper complexes, sodium and potassium salts	
143	Fast green FCF	100 mg/kg
150b	Caramel II - caustic sulfite process	150 mg/kg
150c	Caramel III - ammonia process	2000 mg/kg
150d	Caramel IV - sulfite ammonia process	2000 mg/kg
151	Brilliant black (Black PN)	150 mg/kg
155	Brown HT	150 mg/kg
160a(i)	beta-Carotene (synthetic)	100 mg/kg
160e	beta-apo-8' Carotenal	
160f	beta-apo-8' Carotenoic acid, methyl or ethyl ester	
160a(iii)	beta-Carotenes (<i>Blakeslea trispora</i>)	
160a(ii)	Carotenes, vegetable	600 mg/kg
160b(i)	Annatto extracts, bixin-based	20 mg/kg as bixin
160b(ii)	Annatto extracts, norbixin-based	20 mg/kg as norbixin
161b(i)	Lutein from <i>Tagetes erecta</i>	150 mg/kg
161h(i)	Zeaxanthin	150 mg/kg
163(ii)	Grape skin extract	100 mg/kg
172(i)	Iron oxide, black	100 mg/kg
172(ii)	Iron oxide, red	
172(iii)	Iron oxide, yellow	
Emulsifiers		
432	Polyoxyethylene (20) sorbitan monolaurate	3000 mg/kg
433	Polyoxyethylene (20) sorbitan monooleate	
434	Polyoxyethylene (20) sorbitan monopalmitate	
435	Polyoxyethylene (20) sorbitan	
436	Polyoxyethylene (20) sorbitan	
472e	Diacetyltartaric and fatty acid esters of glycerol	10000 mg/kg
473	Sucrose esters of fatty acids	5000 mg/kg
474	Sucroglycerides	5000 mg/kg
475	Polyglycerol esters of fatty acids	2000 mg/kg
477	Propylene glycol esters of fatty acids	5000 mg/kg
481(i)	Sodium stearoyl lactylate	10000 mg/kg
482(i)	Calcium stearoyl lactylate	10000 mg/kg
491	Sorbitan monostearate	5000 mg/kg
492	Sorbitan tristearate	
493	Sorbitan monolaurate	
494	Sorbitan monooleate	
495	Sorbitan monopalmitate	
900a	Polydimethylsiloxane	50 mg/kg
Flavour Enhancers		
580	Magnesium gluconate	GMP
620	Glutamic acid (L+)-	GMP
621	Monosodium glutamate, L-	GMP
622	Monopotassium glutamate, L-	GMP
623	Calcium glutamate, D1-L-	GMP
624	Monoammonium glutamate, L-	GMP
625	Magnesium glutamate, D1-L-	GMP
626	Guanylic acid, 5'-	GMP
627	Disodium guanylate, 5'-	GMP
628	Dipotassium guanylate, 5'-	GMP

INS No.	Name of Additive	Maximum Level
629	Calcium guanylate, 5'-	GMP
630	Inosinic acid, 5'-	GMP
631	Disodium inosinate, 5'-	GMP
632	Dipotassium inosinate, 5'-	GMP
633	Calcium inosinate, 5'-	GMP
634	Calcium ribonucleotides, 5'-	GMP
635	Disodium ribonucleotides, 5'-	GMP
636	Maltol	GMP
637	Ethyl maltol	GMP
Preservatives		
200	Sorbic acid	1000 mg/kg as sorbic acid
201	Sodium sorbate	
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		
170(i)	Calcium carbonate	GMP
331(iii)	Trisodium citrate	GMP
338	Orthophosphoric acid	1000 mg/kg, singly or in combination, as phosphorus
339(i)	Monosodium orthophosphate	
339(ii)	Disodium orthophosphate	
339(iii)	Trisodium orthophosphate	
340(i)	Monopotassium orthophosphate	
340(ii)	Dipotassium orthophosphate	
340(iii)	Tripotassium orthophosphate	
341(i)	Monocalcium orthophosphate	
341(ii)	Dicalcium orthophosphate	
341(iii)	Tricalcium orthophosphate	
342(i)	Monoammonium orthophosphate	
342(ii)	Diammonium orthophosphate	
343(i)	Monomagnesium orthophosphate	
343(ii)	Dimagnesium orthophosphate	
343(iii)	Trimagnesium orthophosphate	
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	
542	Bone phosphate	
400	Alginate acid	GMP
401	Sodium alginate	GMP
402	Potassium alginate	GMP
403	Ammonium alginate	GMP
404	Calcium alginate	GMP
405	Propylene glycol alginate	GMP
406	Agar	GMP
407	Carrageenan and its sodium, potassium, ammonium, calcium and magnesium salts (including furcelleran)	GMP
407a	Processed <i>Eucheuma</i> seaweed	GMP
410	Carob bean gum	GMP
412	Guar gum	GMP

INS No.	Name of Additive	Maximum Level
413	Tragacanth gum	GMP
414	Gum arabic	GMP
415	Xanthan gum	GMP
416	Karaya gum	GMP
417	Tara gum	GMP
418	Gellan gum	GMP
425	Konjac flour	GMP
440	Pectins	GMP
459	Beta-cyclodextrin	5 mg/kg
460(i)	Microcrystalline cellulose	GMP
460(ii)	Powdered cellulose	GMP
461	Methyl cellulose	GMP
463	Hydroxypropyl cellulose	GMP
464	Hydroxypropyl methyl cellulose	GMP
465	Methyl ethyl cellulose	GMP
466	Sodium carboxymethyl cellulose	GMP
467	Ethyl hydroxyethyl cellulose	GMP
468	Cross-linked carboxymethyl cellulose	GMP
469	Sodium carboxymethyl cellulose, enzymatically hydrolyzed	GMP
470(i)	Salts of myristic, palmitic and stearic acids with ammonia, calcium, potassium and sodium	GMP
470(ii)	Salts of oleic acid (calcium, potassium and sodium)	GMP
471	Mono- and di- glycerides	GMP
472a	Acetic and fatty acid esters of glycerol	GMP
472b	Lactic and fatty acid esters of glycerol	GMP
472c	Citric and fatty acid esters of glycerol	GMP
508	Potassium chloride	GMP
509	Calcium chloride	GMP
511	Magnesium chloride	GMP
1200	Polydextrose	GMP
1400	Dextrins, roasted starch	GMP
1401	Acid treated starch	GMP
1402	Alkaline treated starch	GMP
1403	Bleached starch	GMP
1404	Oxidized starch	GMP
1405	Enzyme treated starch	GMP
1410	Mono starch phosphate	GMP
1412	Distarch phosphate	GMP
1413	Phosphated distarch phosphate	GMP
1414	Acetylated distarch phosphate	GMP
1420	Starch acetate	GMP
1422	Acetylated distarch adipate	GMP
1440	Hydroxypropyl starch	GMP
1442	Hydroxypropyl distarch phosphate	GMP
1450	Starch sodium octenyl succinate	GMP
1451	Acetylated oxidized starch	GMP
Sweeteners¹		
420	Sorbitol and sorbitol syrup	GMP
421	Mannitol	GMP
950	Acesulfame potassium	350 mg/kg
951	Aspartame	1000 mg/kg
952	Cyclamates	250 mg/kg
953	Isomalt	GMP
954	Saccharin	100 mg/kg
955	Sucralose	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	Maltitol (including maltitol syrup)	GMP
966	Lactitol	GMP
967	Xylitol	GMP

¹ The use of sweeteners is limited to milk-and milk derivative-based products energy reduced or with no added sugar.

INS No.	Name of Additive	Maximum Level
968	Erythritol	GMP

5. CONTAMINANTS

The products covered by this standard shall comply with the maximum limits for contaminants and the maximum residue limits for pesticides and veterinary drugs established by the Codex Alimentarius Commission.

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 Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969), the Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 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 for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997).

7. LABELLING

In addition to the provisions of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985) and the General Standard for the Use of Dairy Terms (CODEX STAN 206-1999), the following specific provisions apply:

7.1 NAME OF THE FOOD

7.1.1 The name of the food 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 Fermented milks to which only nutritive carbohydrate sweeteners have been added, may be labeled as “sweetened _____”, the blank being replaced by the term “Fermented Milk” or another designation as specified in Section 7.1.1. 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.

7.1.5 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

Information required in Section 7 of this Standard and Sections 4.1 to 4.8 of the General Standard for the Labelling of Pre-packaged Foods, 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.

8. METHODS OF SAMPLING AND ANALYSIS

See CODEX STAN 234-1999.