

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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**CL 2016/2-MMP**  
**February 2016**

**TO:**

Codex Contact Points  
Interested International Organizations

**FROM:**

Secretariat, Codex Alimentarius Commission  
Joint FAO/WHO Food Standards Programme  
Viale delle Terme di Caracalla, 00153 Rome, Italy

**SUBJECT:**

**Request for comments at Step 3 on the Proposed Draft Standard for Dairy Permeate Powders**

**DEADLINE:**

**31 March 2016**

**COMMENTS:**

**To:**

Codex Contact Point for New Zealand  
Ministry for Primary Industries  
Wellington  
New Zealand  
email: [CodexNZ@mpi.govt.nz](mailto:CodexNZ@mpi.govt.nz)

**Copy to:**

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Joint FAO/WHO Food Standards Programme  
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## BACKGROUND

1. Circular Letter CL 2015/28-MMP invited comments on the Proposed Draft Standard for Dairy Permeate Powders, prepared by an Electronic Working Group led by Denmark.
2. Comments were received from five member countries, one member organization and one observer organization. Two member countries responded but did not have any comments.
3. Based on a review and analysis of comments (attached in Appendix II) the proposed draft standard has been revised. The only outstanding issue where consensus has not been achieved at this stage is whether to permit anticaking agents. Possible solutions on this issue are outlined under Section 4 of Appendix II.

## FURTHER STEPS

4. In view of the level of consensus on the proposed draft Standard, New Zealand, as chair of the Committee on Milk and Milk Products, does not see the need for a physical working group meeting.
5. Based on the comments received to this Circular Letter, New Zealand will make a determination with regard to the advancement of the proposed draft standard in the Step process.

## REQUEST FOR COMMENTS

6. Comments at Step 3 are hereby requested on the Proposed Draft Standard for Dairy Permeate Powders (Appendix I).
7. Governments and international organizations wishing to provide comments should do so in writing **preferably by e-mail** to the above addresses and through their Codex Contact Points before **30 April 2016**. Comments should be in accordance with the general guidance for the provision of comments (Appendix III) and presented in Word file to facilitate their analysis and compilation.

**PROPOSED DRAFT STANDARD FOR DAIRY PERMEATE POWDERS**  
**(N16-2015)**  
**(at Step 3)**

## 1. SCOPE

This Standard applies to dairy permeate powders, in conformity with the description in Section 2 of this Standard, intended for further processing and/or as ingredient in other foods.

## 2. DESCRIPTION

**Dairy permeate powders** are dried milk products characterized by a high content of lactose:

- a) manufactured from permeates which are obtained by removing, through the use of membrane filtration, and to the extent practical, milk fat and milk protein, but not lactose, from milk, whey<sup>1</sup>, cream<sup>2</sup> and/or sweet buttermilk, and/or from similar raw materials, and/or
- b) obtained by other processing techniques involving removal of milk fat and milk protein, but not lactose, from the same raw materials listed under (a) and resulting in an end-product with the same composition as specified in section 3.3.

**Whey permeate powder** is the dairy permeate powder manufactured from whey permeate. Whey permeate is obtained by removing whey protein, but not lactose, from whey.

**Milk permeate powder** is the dairy permeate powder manufactured from milk permeate<sup>3</sup>.

## 3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

### 3.1 Raw materials

**Dairy permeate powders:** Milk permeate, whey permeate, cream permeate, sweet buttermilk permeate and/or similar lactose-containing milk products

**Whey permeate powder:** Whey permeate

**Milk permeate powder:** Milk permeate

### 3.2 Permitted ingredients

Seed lactose<sup>4</sup> in the manufacture of pre-crystallized products.

### 3.3 Composition

Criteria	Dairy permeate powder	Whey permeate powder	Milk permeate powder
Minimum lactose, anhydrous <sup>(a)</sup> (m/m)	76.0%	76.0%	76.0%
Maximum milk protein <sup>(b)</sup> (m/m)	7.0% (=1.1% N)	7.0% (=1.1% N)	5.0% (=0.8 % N)
Maximum milk fat (m/m)	1.5%	1.5%	1.5%
Maximum ash (m/m)	14.0%	12.0%	12.0%
Maximum moisture <sup>(c)</sup> (m/m)	5.0%	5.0%	5.0%

(a) Although the products may contain both anhydrous lactose and lactose monohydrate, the lactose content is expressed as anhydrous lactose. 100 parts of lactose monohydrate contain 95 parts of anhydrous lactose.

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

(c) The moisture content does not include the water of crystallization of the lactose.

In accordance with the provision of section 4.3.3 of the *General Standard for the Use of Dairy Terms* (CODEX STAN 206-1999), the dairy permeate powders covered by this standard may be modified in composition to meet the desired end-product composition, for instance, partial demineralization. However, compositional modifications beyond the minima or maxima specified above for lactose, milk protein, milk fat, ash and moisture

<sup>1</sup> Definition of *whey*, see *Standard for Whey Powders* (CODEX STAN 289-1995)

<sup>2</sup> Definition of *cream*, see the *Standard for Cream and Prepared Creams* (CODEX STAN 288-1976)

<sup>3</sup> Definition of *milk permeate*, see *Standard for Milk Powders and Cream Powder* (CODEX STAN 207-1999)

<sup>4</sup> Definition of *lactose*, see the *Standard for Sugars* (CODEX STAN 212-1999)

are not considered to be in compliance with the Section 4.3.3 of the *General Standard for the Use of Dairy Terms*.

#### 4. FOOD ADDITIVES

[4.1 Only those functional classes indicated in the table below may be used for the product categories specified. Within each class, and where permitted according to the table, only those individual additives used in accordance with Tables 1 and 2 of the *General Standard for Food Additives* in food category [to be established] are acceptable for use in foods conforming to this standard.]

<b>Functional Class</b>	<b>Dairy permeate powder</b>	<b>Whey permeate powder</b>	<b>Milk permeate powder</b>
Stabilizers	÷	÷	÷
Firming agents	÷	÷	÷
Emulsifiers	÷	÷	÷
Anticaking agents	[x]	[x]	[x]
Antioxidants	÷	÷	÷

X = The use of additives belonging to the class is technologically justified

÷ = The use of additives belonging to the class is not technologically justified

**[List of individual additives (to be submitted to CCFA for inclusion in the GSFA):**

<b>INS no.</b>	<b>Name of additive</b>	<b>Maximum level</b>
<b>Anticaking agents:</b>		
170(i)	Calcium carbonate	10,000 mg/kg singly or in combination
460i	Microcrystalline cellulose (cellulose gel)	
460ii	Powdered cellulose	
470i	Salts of myristic, palmitic and stearic acids with ammonia, calcium, potassium and sodium	GMP
470ii	Salts of oleic acid with calcium, potassium and sodium	GMP
504(i)	Magnesium carbonate	10,000 mg/kg singly or in combination
530	Magnesium oxide	
542	Bone phosphate	4,400 mg/kg
551	Silicon dioxide, amorphous	10,000 mg/kg singly or in combination
552	Calcium silicate	
553i	Magnesium silicate, synthetic	
553iii	Talc	
900a	Polydimethylsiloxane	10 mg/kg
1442	Hydroxypropyl distarch phosphate	10,000 mg/kg

#### 4.2 Processing aids

Safe and suitable processing aids may be used including substances\* changing the pH to improve process efficiency such as flux rates and preventing fouling in product streams.

The processing aids used in products covered by this standard shall comply with the *Guidelines on Substances used as Processing Aids* (CAC/GL 75-2010).

\*) Examples include hydrochloric acid, calcium hydroxide, potassium hydroxide and sodium hydroxide.

#### 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 Food and Feed* (CODEX STAN 193-1995).

The milk used in the manufacture of the raw materials 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 Food and Feed* (CODEX STAN 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 product covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the *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 and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CAC/GL 21-1997).

## 7. LABELLING

In addition to the provisions of the *General Standard for the Labelling of Prepacked 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

The name of the food shall be **dairy permeate powder**. Products complying with the relevant descriptions in Section 2 may be named **milk permeate powder** and  **whey permeate powder**, respectively.

### 7.2 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 Prepackaged Foods* (CODEX STAN 1-1985), 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 packer may be replaced by an identification mark, provided that such a mark is clearly identifiable with the accompanying documents.

## 8. METHODS OF SAMPLING AND ANALYSIS

See CODEX STAN 234-1999.

*The table below is intended to be forwarded to CCMAS for incorporation in CODEX STAN 234:*

Provisions	Method	Principle	Type
Lactose, anhydrous	ISO 22662   IDF 198:2007 - Milk and milk products - Determination of lactose*	HPLC (high-performance liquid chromatography)	II
Milkfat	ISO 1736   IDF 009:2008 - Dried milk and dried milk products - Determination of fat content	Gravimetry (Röse-Gottlieb)	I
Milk protein (nitrogen)	ISO 8968-1   IDF 020-1:2014 - Milk and milk products - Determination of nitrogen content - Part 1	Titrimetry, Kjeldahl principle and crude protein calculation; Protein content is 6.38 multiplied by the total Kjeldahl nitrogen determined	I
Moisture**	ISO 5537   IDF 026:2004 - Dried milk - Determination of moisture content	Gravimetry (drying at 87°C)	I
Ash	NMKL 173:2005 – Ash, gravimetric determination in foods AOAC 930.30-1930 - Ash of Dried Milk	Gravimetry (ashing at 550 °C )	IV

\*) Test portion size with dairy permeates powders to be between 0.200 g and 0.260 g instead of about 0.300 g.

\*\*\*) Moisture content excluding the crystallized water bound to lactose

## Appendix II

**REVIEW AND ANALYSIS OF COMMENTS AT STEP 3 ON THE PROPOSED DRAFT STANDARD ON DAIRY PERMEATE POWDERS (CL 2015/28-MMP)**

1. This report is a summary and analysis of comments<sup>5</sup> received from Argentina, Canada, EU, India, Peru, USA and IDF on the Proposed Draft Standard for Dairy Permeate Powders at Step 3 in response to CL 2015/28-MMP. Costa Rica and Switzerland did not have any comments.

**SECTION 2 - Description**

2. One country noted that membrane filtration may not be the only technology used to obtain dairy permeate, and suggested simplifying the description to remove mention of membrane filtration thereby eliminating the need for b).

3. It is recommended that the suggestion is not followed as it has no practical consequences, and other members have specifically endorsed the current wording.

4. Another country suggested eliminating the reference to cream as this product is not rich in lactose and is not used as a raw material in permeate production.

5. It is recommended that the suggestion is not followed. It is noted that the minimum milk fat content of cream is 10%. The lactose content of the non-fat fraction of lower-fat creams is sufficiently high for producing DPP.

**SECTION 3.2 – Permitted ingredients**

6. Several suggestions were made in regard to processing aids.

7. One comment recommended moving the reference to processing aids by adding the title “Processing aids” under section 4, Food additives, for the sake of clarity and in accordance with the provisions of the Procedural Manual.

8. Two comments recommended replacing the term “acidity regulator” with “substances changing the pH”, in order to avoid confusion with a functional class of food additives, and another comment recommended listing such substances.

9. A further comment recommended clarifying the Spanish translation of the sentence, “preventing fouling in product streams” to read, “obstrucciones en el caudal del producto” (in English, “obstructions in product streams”).

10. It is recommended that these comments should be followed, except that the listing of substances changing the pH should not result in a closed list. The following text is suggested under section 4:

**Processing aids**

Safe and suitable processing aids may be used including substances\* changing the pH to improve process efficiency such as flux rates and preventing fouling in product streams. (The final phrase to read in Spanish, “obstrucciones en el caudal del product.”)

The processing aids used in products covered by this standard shall comply with the *Guidelines on Substances used as Processing Aids* (CAC/GL 75-2010).

\*) Examples include hydrochloric acid, calcium hydroxide, potassium hydroxide and sodium hydroxide.

**SECTION 3.3 - Composition**

11. One comment noted that the proposed draft does not clearly differentiate the products being covered in the standard from lactose, which is of concern with respect to product identity and related issues during its trade. Theoretically, it would be possible to sell lactose in the name of whey permeate powder. Possible amendments were suggested.

12. It is recommended that these suggestions are not followed as there appear to be no practical trade implications. The market price of lactose is higher than that of whey permeate powder, so the risk of lactose complying with CODEX STAN 212 being traded under the name “whey permeate powder” is insignificant.

<sup>5</sup> Comments are available at [ftp://ftp.fao.org/codex/meetings/ccmmp/ccmmp11/Comments\\_in\\_replies\\_to\\_CL\\_2015\\_28.pdf](ftp://ftp.fao.org/codex/meetings/ccmmp/ccmmp11/Comments_in_replies_to_CL_2015_28.pdf).

13. IDF reported that it is currently investigating whether it would be more appropriate to replace maximum limits for milk protein with maximum limits for nitrogen contents, as this limit refers to a residual from processing rather than to a nutritional quality. The investigation addresses technological arguments as well as the consequences for trade practices. IDF recommended that, in the meantime, the equivalent nitrogen content be added to the protein specifications (the values being the existing limits for max. protein divided by the factor 6.38).

14. It is recommended that IDF's proposal should be followed. The table of composition would read as follows:

Criteria	Dairy permeate powder	Whey permeate powder	Milk permeate powder
Minimum lactose, anhydrous <sup>(a)</sup> (m/m)	76.0%	76.0%	76.0%
Maximum milk protein <sup>(b)</sup> (m/m)	7.0% (=1.1% N)	7.0% (=1.1% N)	5.0% (=0.8 % N)
Maximum milk fat (m/m)	1.5%	1.5%	1.5%
Maximum ash (m/m)	14.0%	12.0%	12.0%
Maximum moisture <sup>(c)</sup> (m/m)	5.0%	5.0%	5.0%

#### SECTION 4 – Food additives

15. One country recommended that the functional classes that are not permitted should be removed from the table.

16. However the table as currently formulated provides useful information as regards functional classes of additives usually used in powdered milk products. It is recommended that this suggestion not be followed.

17. The member organization was of the view no food additives should be used for dairy permeate products and that the use of anticaking agents is neither justified nor necessary for their manufacture. By applying the right technology to lactose crystallization, dairy permeate powders can be produced without the need to use any food additives. However other countries supported the ability to use anticaking agents in dairy permeate powders. One country suggested incorporating an exclusionary footnote to identify when anticaking agents are not appropriate, such as when these powders are used in the manufacture of infant formula.

18. There is no consensus at this stage on the use of anticaking agents. Consequently, text relating to anticaking agents is placed in square brackets for further comment.

19. A possible solution may be one of the following options:

- Insertion of an exclusionary footnote to identify when anticaking agents are not appropriate, such as when these powders are used in the manufacture of infant formula;
- Excluding the use of anticaking agents from one or more categories of the three products;
- Use is restricted to where anticaking agents are permitted by national legislation in the country of sale.

#### Section 7.1 – Name of the food

20. One country proposed alternative wording, "Where appropriate in the country of sale, if the designation does not correspond specifically to dairy, whey or milk powder permeates, then it may be replaced by another equivalent designation, according to the nature of the product."

21. It is recommended that this suggestion is not followed as it would nullify the entire objective of a Codex commodity standard which is to combine link specific designations to specific characteristics (e.g. description, composition, etc.).

22. The EUMS proposed that the second paragraph of this subsection should be deleted, and that the name of the products should be in accordance with the products as described in section 2 of this Standard.

23. Considering that any alternative names will weaken the impact of the standard in trade, it is recommended that the proposal is followed.

#### Section 7.2 – Labelling of non-retail containers

24. One country considered that the name and address of the manufacturer or packer should not be replaced by an identification mark, as all of this information is required on the packaging for reasons of traceability.

25. It is recommended that this suggestion is not followed as the wording of 7.2 is a standard wording applied in all Codex standards for milk products.

## SECTION 8 – Methods of sampling and analysis

### Determination of lactose:

26. One country suggested a different method for determining lactose is needed as the enzymatic method contains a substantial margin of error that would not allow for differentiating a dairy permeate from a lactose in those cases where the lactose content of the permeate is around 95%. They recommended the reference HPLC method ISO 22662|IDF 198:2007.

27. IDF agreed, noting that this method is considered applicable with Dairy Permeate Powders provided that the test portion is adapted to between 0.200 and 0.260 g in order to bring the amount of lactose within the measurement range of the method.

### Determination of ash:

28. IDF recommended that the NMKL 173 method be chosen.

### Equivalent AOAC methods:

29. One country recommended that several AOAC methods should be listed. IDF reported that they had assessed relevant AOAC methods to determine whether they are equivalent to the methods already identified. No equivalent AOAC methods existed for lactose, milk fat, nitrogen or moisture. However AOAC 930.30-1930 is equivalent to the NMKL method.

30. Taking into account the comments submitted, the following revised table on methods of analysis is proposed:

Provisions	Method	Principle	Type
Lactose, anhydrous	ISO 22662 IDF 198:2007 - Milk and milk products - Determination of lactose*	HPLC (high-performance liquid chromatography)	II
Milkfat	ISO 1736 IDF 009:2008 - Dried milk and dried milk products - Determination of fat content	Gravimetry (Röse-Gottlieb)	I
Milk protein (nitrogen)	ISO 8968-1   IDF 020-1:2014 - Milk and milk products - Determination of nitrogen content - Part 1	Titrimetry, Kjeldahl principle and crude protein calculation; Protein content is 6.38 multiplied by the total Kjeldahl nitrogen determined	I
Moisture**	ISO 5537 IDF 026:2004 - Dried milk - Determination of moisture content	Gravimetry (drying at 87°C)	I
Ash	NMKL 173:2005 – Ash, gravimetric determination in foods AOAC 930.30-1930 - Ash of Dried Milk	Gravimetry (ashing at 550 °C )	IV

\*) Test portion size with dairy permeate powders to be between 0.200 g and 0.260 g instead of about 0.300 g.

\*\*\*) Moisture content excluding the crystallized water bound to lactose.

**Appendix III****GENERAL GUIDANCE FOR THE PROVISION OF COMMENTS**

In order to facilitate the compilation and prepare a more useful comments document, Members and Observers, which are not yet doing so, are requested to provide their comments under the following headings:

- (i) General Comments
- (ii) Specific Comments

Specific comments should include a reference to the relevant section and/or paragraph of the document that the comments refer to.

When changes are proposed to specific paragraphs, Members and Observers are requested to provide their proposal for amendments accompanied by the related rationale. New texts should be presented in underlined/bold font and deletion in ~~striketrough font~~.

In order to facilitate the work of the Secretariats to compile comments, Members and Observers are requested to refrain from using colour font/shading as documents are printed in black and white and from using track change mode, which might be lost when comments are copied/pasted into a consolidated document.

In order to reduce the translation work and save paper, Members and Observers are requested not to reproduce the complete document but only those parts of the texts for which any change and/or amendments is proposed.