



**Food and Agriculture
Organization of
the United Nations**



**World Health
Organization**

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**CL 2015/28-MMP
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TO: Codex Contact Points
Interested International Organisations

FROM: Secretariat, Codex Alimentarius Commission,
Joint FAO/WHO Food Standards Programme
00153 Roma, Italia

SUBJECT: **Request for comments at Step 3 on the proposed draft Standard for Dairy
Permeate Powders**

DEADLINE: **31 December 2015**

COMMENTS:	To: Codex Contact Point for New Zealand Ministry for Primary Industries Wellington New Zealand email: CodexNZ@mpi.govt.nz	Copy to: Secretariat Joint FAO/WHO Food Standards Programme Viale delle Terme di Caracalla 00153 Rome, Italy email : codex@fao.org
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BACKGROUND

1. The 38th session of the Codex Alimentarius Commission (CAC38) approved new work on a standard for dairy permeate powders¹. The Commission agreed to establish an Electronic Working Group (eWG,) led by Denmark, to prepare a proposed draft standard for subsequent circulation at Step 3. The eWG was open to all members and observers and worked in English only (REP15/CAC paras 90-91). The report of the eWG is in Annex II.
2. Based on the comments submitted at Step 3, New Zealand, as host country of CCMMP, will determine whether there is a need to hold the PWG agreed to by CAC38, or if the proposed draft standard is ready to be advanced in the Step process.

REQUEST FOR COMMENTS

3. Codex members and observers are invited to submit comments at Step 3, as directed above, on the proposed draft Standard for Dairy Permeate Products (Annex I).
4. Comments should be submitted through the Codex Contact Point or recognized international organizations having observer status with the Codex Alimentarius Commission. Comments should be in accordance with the general guidance for the provision of comments (Annex III) and presented in Word file to facilitate their analysis and compilation.

¹ For reference see project document ([CX/CAC 15/38/6 Annex 1](#))

PROPOSED DRAFT CODEX 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, whey², cream³ 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 permeate⁴.

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

Safe and suitable processing aids; including acidity regulators used to improve process efficiency such as flux rates and preventing fouling in product streams.

Seed lactose⁵ in the manufacture of pre-crystallized products.

3.3 Composition

Criteria	Dairy permeate powder	Whey permeate powder	Milk permeate powder
Minimum lactose, anhydrous ^(a)	76.0% (m/m)	76.0% (m/m)	76.0% (m/m)
Maximum milk protein ^(b)	7.0 (m/m)	7.0 (m/m)	5.0 (m/m)
Maximum milk fat	1.5 (m/m)	1.5 (m/m)	1.5 (m/m)
Maximum ash	14.0 (m/m)	12.0 (m/m)	12.0 (m/m)
Maximum moisture ^(c)	5.0 (m/m)	5.0 (m/m)	5.0 (m/m)

(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.

n.s. = not specified.

² Definition of *whey*, see *Standard for Whey Powders* (CODEX STAN 289-1995)

³ Definition of *cream*, see the *Standard for Cream and Prepared Creams* (CODEX STAN 288-1976)

⁴ Definition of *milk permeate*, see *Standard for Milk Powders and Cream Powder* (CODEX STAN 207-1999)

⁵ Definition of *lactose*, see the *Standard for Sugars* (CODEX STAN 212-1999)

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 water 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

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 of Food Additives* in food category [to be established] are acceptable for use in foods conforming to this standard.

Functional Class	Dairy permeate powder	Whey permeate powder	Milk permeate powder
Stabilizers	÷	÷	÷
Firming agents	÷	÷	÷
Emulsifiers	÷	÷	÷
Anti-caking 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):

INS no.	Name of additive	Maximum level
Anticaking agents:		
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

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.

Where appropriate in the country of sale, the name may be replaced by the designation **lactose rich deproteinized _____ powder**, the blank being filled with the term **dairy**, **whey** or **milk**, as appropriate to the nature of the product.

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 are intended to be forwarded to CCMAS for incorporation in STAN 234:

Provisions	Method	Principle	Type
Lactose, anhydrous	ISO 5765-1/2 IDF 79-1/2 Dried milk, dried ice-mixes and processed cheese -- Determination of lactose content	Enzymatic methods	II
Milkfat	ISO 1736 IDF 009:2008 - Dried milk and dried milk products - Determination of fat content	Gravimetry (Röse-Gottlieb)	I
Milk protein	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	To be determined		

* Moisture content excluding the crystallized water bound to lactose

REPORT OF THE ELECTRONIC WORKING GROUP ON THE PROPOSED DRAFT STANDARD FOR DAIRY PERMEATE POWDERS

1. A total number of 18 member countries and 1 non-governmental observer organization⁶ registered to participate in the working group. A list of participating members and observers is set out in Annex 1.
2. A 1st draft of the standard was circulated for comments to all participants in August 2015. Responses were received from 5 member countries and 1 observer organization.
3. The chair reviewed all the comments received and amended the draft standard accordingly.
4. A proposed draft standard for circulation at Step 3 was prepared.
5. This final report and the proposed draft standard were submitted to the CCMMP in October 2015.

Summary of the review

6. The number of comments received from the members of the eWG on the 1st draft standard was limited indicating a general support to the outline of the draft standard. The comments received have been reviewed section by section and the rationales for amendments to the first draft are given below.

Description

7. One comment concerned the mentioning of cream in indent (a). Despite cream is probably not used as raw material today and the amount available for permeate production will be limited, it makes sense to mentioning it as the permeate extracted from cream will be of similar composition as milk permeate. Inclusion of the specific term “cream permeate” is not relevant and the name of such a product will be dairy permeate powder.
8. A couple of editorial comments on indent (b) and on the definition on whey permeate powder have been inserted.
9. A number of comments related to the removal of the reference to membrane filtration in the description of whey permeate powder. One member suggested the removal of the whole second sentence while another argued the need for a definition of whey permeate. In conclusion, the key part of the description of whey permeate has been retained whereas reference to membrane filtration has been removed.
10. Several members recommended the removal of the second sentence of the description of milk permeate powder. This recommendation has been followed as milk permeate is already defined in CODEX STAN 207-1999.

Permitted ingredients

11. One member recommended, and this recommendation has been followed, that acidity regulators be mentioned as an example of a suitable processing aid and provided the technological justification as follows.

In the separation of the components of whey into dairy permeate processors take advantage of the inherent molecular properties of the components. The two critical properties are size of the molecules (or micelles) and net surface charge.

- *In the case of membrane separation, both of these properties can be reversibly modified by changing the pH of the solvent environment (water). For example, adjusting the pH of whey protein closer to pH 5.0 causes the proteins to self-assemble into globular aggregates which are larger in size than whey proteins in solution at a pH of 7.0. In this state, they can be separated from other components more readily based on size. Since this aggregation is fully reversible, adjusting the pH back to 7.0 returns the protein to its original state.*
- *In the case of ion exchange separation, adjusting the pH promotes the adherence of whey protein to the resin material so that other components can be rinsed away. A second adjustment then promotes the release of the protein from the resin so it can be collected in a pure form for drying. Again, since the effect of pH on protein is fully reversible, adjusting the pH to 7.0 after these process steps returns the protein to its original conformation.*

⁶ Argentina, Australia, Austria, Canada, China, Denmark (chair), France, Germany, Greece, India, Ireland, Japan, Netherlands, New Zealand, Norway, Spain, Switzerland, Uruguay, USA and International Dairy Federation.

Manipulation of size and charge of proteins has further benefits for process efficiency beyond separation of protein from whey (and its co-products). Manipulation of pH can improve flux rates and preventing fouling in product streams. As such, many products derived from cheese whey are likely to have undergone an adjustment in pH at some point in their manufacture using food grade acids and bases

Composition

12. One member suggested a maximum limit for lactose to distinguish these products from the commodity designated lactose (CODEX STAN 212-1999). The concern that "lactose" may be marketed as dairy permeate powders seems to be very theoretical as the market price of products designated lactose is higher than the market prices for permeate powders.

13. The suggestion of several members to change the maximum limit for moisture to 5% has been followed in order to obtain consistency with other dried milk product standards.

14. The varying suggestions of some members to change the maximum limits for ash and milk protein respectively were carefully considered and resulted in differentiating between the 3 product categories as seen in the table below. The rationale for lowering the maximum milk protein level in milk permeate powder relates to the fact that the technology is limited to ultrafiltration as specified by the definition of milk permeate in CODEX STAN 207-1999.

Food additives

15. As pointed out by one of the members, the *General Standard for Food Additives* (GSFA) does not provide (a) specific category(ies) for dairy permeate powders. Considering the nature of these products, it will be appropriate to consider these products within the GSFA Table 2 Category 1.5 [milk powder and cream powder and powder analogues (plain)]. A possibility is to establish a new subcategory 1.5.3 [dairy permeate powder (plain)] for products covered by this standard.

16. Several members have identified the need for additives. Consequently and in accordance with the project document, technologically justified functional classes have been included in a table and a list of appropriate individual additives within these classes has been provided for later submission to CCFA for the inclusion in the GSFA. Taking into account the conclusion on acidity regulators as a processing aid (see para 11) two functional classes of food additives (anti-caking agents and sequestrants) were suggested by members. Technological justification has been provided only for one of these classes (anti-caking agents) and therefore, only this class has been included in the table in the draft standard. One member suggested to compare the additive provisions with those allowed for in CODEX STAN 207-1999. However, several of the functional classes listed for milk powders are justified because of the fat content of these products. Since dairy permeate powders are almost fat free these additive classes seem not to be justified for dairy permeate powders. The differences to milk powders in this regard have been clarified by including the classes permitted for other dried milk products in the table as "not technologically justified". Editorial amendment of the text prior to the table has been made.

17. One member provided a list of specific anticaking agents based upon those currently specified in the GSFA for milk powders and dried whey. This list has been inserted in the draft standard with amendments to enable further consideration, but at the end of the drafting process the list will be removed from the standard and transferred to the CCFA for inclusion in the GSFA. The following changes to the list provided have been made:

- On the request of another member, additional anticaking agents listed in Table 3 of the GSFA has been included as well (INS 470(i) and INS 470(ii)).
- INS 553 has not been included as it is "group additive" encompassing both 553(i) and 553(iii) but also INS 553(ii) (magnesium trisilicate) which has not been evaluated by JECFA. Labelling

18. On the recommendation of a member, a reference to the Codex Stan 1 has been inserted. Two members provided comments on alternate designation. One argued that - even though the product primarily consists of lactose - the products will not be declared as lactose in the list of ingredients but as permeate powder - a term that many consumers do not understand. Accordingly, and as recommended by that member, the alternate name has been changed into "lactose rich deproteinized _____ powder". Another member requested that any other name permitted by national legislation should be mentioned as alternate names. This request has not been followed as it would nullify the entire objective of a Codex commodity standard which is to link specific designations to specific characteristics (e.g. description, composition, etc).

Methods of sampling and analysis

19. The year of publication of the methods have been removed in accordance with CCMAS decision. For lactose, IDF has recommended ISO 5765-1/2 | IDF 79-1/2 instead of ISO 22662|IDF 198 (HPLC method). With regard to ash content, IDF is currently considering the following methods and intends to submit additional information at a later stage: USP29 NF 281, AOAC 930.30-1930 and NMKL 173:2005.

20. One member requested that AOAC methods equivalent to ISO/IDF standards should be listed. This issue was debated at the 9th CCMMP Session and the following was concluded (para 61 of ALINORM 10/33/11):

The Committee reviewed the proposed AOAC methods listed in Appendix 3 of CX/MMP 10/9/6 and agreed to include all AOAC methods that were equivalent to IDF/ISO methods, not to include AOAC methods suggested for Type I for which precision figures were not available, which were outdated or were not equivalent to IDF/ISO methods; and to include, but separately from IDF/ISO methods, several AOAC methods proposed for Type III where no IDF/ISO methods were available and Type IV for which precision figures were not available, or because they were not equivalent to IDF/ISO methods.

21. The necessary documentation for including AOAC methods in accordance with the above is still lacking and should be provided to enable further consideration.

Recommendation

22. It is recommended to note that the work of the eWG has been accomplished with this report and that a proposed draft standard for Dairy Permeate Powders has been developed.

23. It is recommended that the proposed draft standard for Dairy Permeate Powders be circulated for comments at Step 3.

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.