CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5 **CX/CAC 17/40/3 Add1**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

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FINAL ADOPTION OF CODEX TEXTS[1]

1. In accordance with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts, the following texts are submitted to the Commission for adoption:

- Draft standards and related texts submitted at Step 8;
- Draft standards and related texts submitted at Step 5 of the Accelerated Procedure (Step 5A);
- Proposed draft standards submitted at Step 5 with the recommendation of the subsidiary body concerned for the omission of Steps 6 and 7 (Step 5/8).
- Other standard and related texts.

2. Comments submitted in accordance with the Procedures for the Elaboration of Codex Standards and Related Texts are contained in CX/CAC 17/40/4.

Standards and related texts submitted for adoption

Codex body	Standard and Related Texts	Reference	Job No.	Step
CCMMP	Standard for dairy permeate powders (draft)	See Annexes 1 and 2	N16-2015	8

[1] This document compiles the standard submitted by Codex Committee on Milk and Milk Products.

Annex 1

Report on the Draft Standard for Dairy Permeate Powders

Prepared by New Zealand (host country of CCMMP)

1. CAC39 adopted the Draft Standard for Dairy Permeate Powders at step 5 and advanced it to Step 6 noting that technical comments should be resubmitted at Step 6 for consideration by the relevant committees (REP16/CAC, para. 79 and Appendix IV). Comments at step 6 were requested by CL 2016/25-MMP.

2. The responses to the Circular Letter were reported and analysed, resulting in proposals for amendment of the Draft Standard. CL 2016/46-MMP requested comments on the advancement of the amended Draft Standard to step 8 and the endorsement of horizontal provisions.

3. Responses to this Circular Letter revealed continuing differences of opinion on the issue of use of anticaking agents in the manufacture of dairy permeate powders. Some members continued to support the use of anticaking agents, but a significant number of countries were opposed to their use. The International Dairy Federation (IDF) provided technical advice, noting that for the types of permeate powders covered by the standard it is possible to ensure product stability without the use of anticaking agents. On the basis of this clarification it was proposed to delete the provision relating to use of anticaking agents

4. CL 2017/3-MMP provided an analysis of these responses and requested comments on whether the revised version of the Draft Standard was ready for adoption at step 8. Responses were received from 10 member states, 1 member organization and 1 observer organization[2]. The comments are available at http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-703-11%252FWD%252FComments-in-reply-to_CL2017-3-MMP_CompilationX.pdf (in the original language only).

5. Six members (Australia, Ecuador, Mexico, Paraguay, Peru and USA) and the EUMS supported advancing the standard to step 8, one of these (Peru) on condition that the standard does not allow the use of anticaking agents. Two countries (Cuba and Switzerland) had no further comments on the Draft Standard.

6. One country (India) did not support advancement to step 8, since the Draft Standard does not allow for the use of anticaking agents. They commented that removal of the provision for anticaking agents has the potential to create non-tariff barriers to the trade of the countries, especially those developing countries that may in future intend to manufacture dairy permeate powders, as they will find it difficult to manufacture/store a good quality product without use of anticaking agents. In their view the standard appears to favour those countries that are currently able to manufacture permeate powders without the use of anticaking agents. However according to the information provided by IDF[3], sourced from countries that manufacture dairy permeate powders, stability of products within the scope of the standard can be easily maintained and that anticaking agents are therefore not needed. In that case there appears to be no risk of a non-tariff barrier because of inability to manufacture products without the use of anticaking agents.

7. India also commented that the Draft Standard does not provide for the use of alternative names for the product. However the names in the draft standard have been discussed extensively, and are the best terminology for products produced by the "reference" technology, membrane filtration. Alternative names appear not to be necessary in the standard, since countries may specify alternative names consistent with the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985). In addition it can be noted that for the products covered by this standard there appear to be no well-established alternative names used internationally.

8. Australia and IDF recommended amendments to make it clear that the standard does not cover permeate powders made using acid whey as a raw material. This is an important point, since the question of whether or not there is a need to use anticaking agents depends largely on the type of whey used as raw material. Currently the definition of "whey" used as raw material is made only through a footnote referring to the *Standard for Whey Powders* (CODEX STAN 289-1995). It would be preferable to explicitly exclude acid whey, and it is therefore recommended that section 2(a) should be amended to read:

> 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 **(excluding acid whey)**, cream and/or sweet buttermilk, and/or from similar raw materials, and/or

[2] Australia, Colombia, Cuba, Ecuador, European Union, IDF, India, Mexico, Paraguay, Peru, Switzerland and USA
[3] See CL 2017/3-MMP, Appendix 1, Analysis of Responses to CL 2016/46-MMP

9. Two countries (Colombia and Peru) recommended amendments intended to ensure that the “similar raw materials” mentioned in section 2(a) of the standard would be milk products. However this protection is already provided by the chapeau in section 2 where dairy permeate powders are defined as “milk products” with a footnote referring to the *General Standard for the Use of Dairy Terms* (GSUDT). The GSUDT states:

> ***Milk product*** is a product obtained by any processing of milk, which may contain food additives, and other ingredients functionally necessary for the processing.

10. One country (Colombia) requested a technical justification for maintaining different values for the maximum nitrogen content between dairy permeate powders, whey permeate powders and milk permeate powders.

11. Permeate powders are characterized by their lactose content, whereas nitrogen, ash and milk fat could be described as “impurities”, as they are unnecessary but unavoidable carry-over according to the technology used and further treatment. The nitrogen content of permeate powders is in the form of free amino acids and relatively high proportions of nitrogen moieties such as urea, purine bases and creatine.

12. Many views have been expressed as regards the compositional specifications for the three product categories. The current values are the result of a compromise among the various views and are generally supported by countries. The values aim at distinguishing between categories obtained from milk permeate, where the only raw material permitted is milk and the only technology permitted is ultrafiltration (as defined in STAN 207), and the other two product categories, where various raw material sources as well as processing technologies other than ultrafiltration are permitted. These differences in the nature of the three product categories impact the maximum ranges while still allowing for acceptable product performance.

13. The highest nitrogen level specified (1.1%) was chosen as it corresponds to the lowest minimum level for whey powder (see STAN 289).

14. IDF requested that the rules regarding no. 4.2 "Processing Aids" could formally be transferred to number 3.2 "Permitted Ingredients". However according the Procedural Manual the current placing is the correct one.

Recommendation

15. It is recommended that CAC adopt the draft Standard for Dairy Permeate Powders with the amendment noted in paragraph 8 above (see Annex 2).

Annex 2

DRAFT STANDARD FOR DAIRY PERMEATE POWDERS

(N16-2015)

(for adoption at Step 8)

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[1] 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[2] (excluding acid whey), cream[3] 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[4].

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[5] in the manufacture of pre-crystallized products.

3.3 Composition

Criteria	**Dairy permeate powder**	**Whey permeate powder**	**Milk permeate powder**
Minimum lactose, anhydrous[(a)] (m/m)	76.0%	76.0%	76.0%
Maximum nitrogen (m/m)	1.1%	1.1%	0.8 %
Maximum milk fat (m/m)	1.5%	1.5%	1.5%
Maximum ash (m/m)	14.0%	12.0%	12.0%
Maximum moisture[(b)] (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) The moisture content does not include the water of crystallization of the lactose.

[1] Definition of *milk product*, see *General Standard for the Use of Dairy Terms* (CODEX STAN 206-1999)
[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, nitrogen, milk fat, ash and moisture 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 The use of food additives is not permitted for dairy permeate powders covered by this standard.

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 and compositions in Section 3.3 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[6]

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

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
Nitrogen	ISO 8968-1 | IDF 020-1:2014 - Milk and milk products - Determination of nitrogen content - Part 1	Titrimetry, Kjeldahl principle	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 water of crystallization of lactose.

[6] The listing of methods of analysis and sampling will be removed when the standard is adopted by CAC.