

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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**CL 2016/46-MMP**  
**November 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: Analysis of Responses to CL 2016/25-MMP: Draft Standard for Dairy Permeate Powders**

**DEADLINE:** **23 December 2016**

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

1. The Draft Standard for Dairy Permeate Powders was circulated for comments at step 6 by Circular Letter CL 2016/25-MMP.
2. The comments received in response have been analysed by the New Zealand as host government of the Committee on Milk and Milk Products (CCMMP), and their report and recommendations of the Chair of the Committee are attached as *Appendix 1*. The report includes some specific recommendations to the Spanish language version of the draft standard to address the comments and suggestions from Spanish speaking countries. The Draft Standard for Dairy Permeate Powders has been revised in accordance with the recommendations and is attached as *Appendix 2* (for information purposes).
3. It is intended that an analysis of responses to the recommendations presented in paragraph 3 of this CL together with the Draft Standard will be presented to the Commission through the CCEXEC for its consideration.

## REQUEST FOR COMMENTS

4. Comments are hereby requested on the following recommendations, which are based on the conclusions set out in Appendix 1:
  - **Note** the revised Draft Standard for Dairy Permeate Powders presented in Appendix 2, and in particular the provisions regarding the use of anticaking agents;
  - **Support** the advancement of the Draft Standard to Step 8;
  - **Note** that the provisions relating to food additives (including establishment of a food category), food labelling and methods of analysis will require the endorsement of the relevant horizontal committees.
5. Governments and international organizations wishing to provide comments should do so in writing **preferably by e-mail** to the above addresses before **23 December 2016**.

## ANALYSIS OF RESPONSES TO CL 2016/25-MMP (COMMENTS AT STEP 6)

This report analyses the comments received at Step 6 on the Draft Standard for Dairy Permeate Powders (DPP) and makes recommendations based on the analysis. Comments were requested in CL 2016/25-MMP, and responses were received from 16 member states, 1 member organization and 1 observer organization<sup>1</sup>. A late response was also expected from another observer organization (IDF), but in the event IDF stated they were not able to answer at this point of time. However a follow-up to their comments at step 3 is noted below.

The comments are available in [English](#), [French](#) and [Spanish](#).

### SPECIFIC COMMENTS

#### 1. SCOPE

No comments were received.

#### 2. DESCRIPTION

One country proposed that dairy permeate powders should be described as “dried products” rather than “dried milk products”. However it is important to retain the term “milk products” in the definition in order to maintain a link to “milk products” as defined in the *General Standard for the Use of Dairy Terms* (CODEX STAN 206-1999) (GSUDT).

One country proposed changing “content of lactose” to “concentration of lactose”. The word “content” is considered satisfactory.

Some countries expressed concern at the phrase “similar raw materials” because they considered it is ambiguous and could lead to misinterpretation with reference to the origin of the raw material. They proposed to delete the phrase or to replace “similar” with “dairy”. However dairy permeate powders are described as “milk products” hence raw materials must be consistent with the definition of milk product in the GSUDT. A reference to the GSUDT could be added to the term “milk products” for clarity.

One country proposed a new description of the manufacturing process of dairy permeate powders that differed significantly in the description of separation technology, raw materials and the use of pH adjusting ingredients and that introduced new terms “diafiltration” and “dairy product solids”. It is recommended that the definition not be used. This country also proposed to include information on the application and functionality of dairy permeate powders. However this information is not appropriate for inclusion in a Codex commodity standard.

Several countries commented on the wording of the Spanish version of the description, which uses the term “productos de leche en polvo”, which fails to use the term “productos lácteos” as used in the GSUDT, and also could be misunderstood as meaning that dairy permeate powders are made from milk powder (leche en polvo).

If the term “productos lácteos” is used, the terms “permeado de suero en polvo” and “permeado de leche en polvo” are consistent and can be retained.

#### Observations by the Chair:

It is recommended that, in order to use terminology consistent with the GSUDT, the Spanish and French versions of the first paragraph should read as follows:

**Los permeados lácteos en polvo** son productos lácteos (en polvo) caracterizados por un contenido elevado de lactosa:

**Les poudres de perméat laitier** sont des produits laitiers séchés qui se caractérisent par leur forte teneur en lactose

A footnote referring to the *General Standard for the Use of Dairy Terms* should be added to the term “milk products”.

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<sup>1</sup> Argentina, Bolivia, Canada, Colombia, Costa Rica, Cuba, European Union Member States, India, Iran, Norway, Paraguay, Peru, Philippines, Switzerland, Thailand, Trinidad and Tobago, USA and ARSO.

### 3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

#### 3.1 Raw materials

One country expressed concern at the phrase “similar raw materials”, for the same reason as given in section 2. The same response applies.

One country proposed to include descriptions of whey permeate and milk permeate. However permeates are described adequately in section 2.

One country commented on the Spanish wording of the product names “permeado de suero en polvo” and “permeado de leche en polvo”. As noted above, these are consistent and can be retained.

#### Observation by the Chair:

No changes are needed in this section.

#### 3.2 Permitted ingredients

One country commented that the term “seed lactose” would be clearer in Spanish as “cristales de lactosa” rather than “productos de lactosa”.

#### Observation by the Chair:

It is recommended that the Spanish version of the second paragraph should read:

Cristales de lactosa<sup>5</sup> en la elaboración de productos precristalizados.

#### 3.3 Composition

One country proposed a maximum of 7.0% protein (1.1% nitrogen) in milk permeate powder. Many views have been expressed as regards the maximum protein content of the three product categories. The current values are the result of a compromise among the various views.

In comments at step 3, IDF proposed to remove the protein specifications while retaining specifications for nitrogen as this limit refers to a residual from processing rather than to a nutritional quality. IDF considered technological arguments as well as the consequences for trade practices. It was noted that this should be further considered at the next stage.

It is noted that this change triggers several consequential changes:

- Footnote (b) in Section 3.3: To be deleted
- Last paragraph of section 3.3: “*milk protein*” to be replaced with “*nitrogen*”
- Section 8: Method “*Milk protein (nitrogen)*” to be replaced with “*Nitrogen*” and the principle to read “*Titrimetry, Kjeldahl principle and crude protein calculation; Protein content is 6.38 multiplied by the total Kjeldahl nitrogen determined*”

#### Observations by the Chair:

It is recommended to follow IDF’s proposal.

### 4. FOOD ADDITIVES

One country proposed that the section on Food Additives should be replaced by a reference to the additives permitted in the *General Standard for Food Additives* (CODEX STAN 239-2003) (GSFA). Reference to GSFA will be achieved during the process of alignment. In the meantime additives should be listed.

Some countries considered that anticaking agents should be permitted in each of the product categories. They noted that the GSFA and commodity standards allow the use of anticaking agents in some milk products, and end uses (such as use in high humidity conditions) of DPP might require the use of anticaking agents, that cost considerations will ensure they are used only when necessary, and that permission would allow for future innovation.

Some countries proposed the 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. However one country noted that the GSFA already includes a provision precluding such use (see Section 4.3 of the GSFA).

On the other hand other countries were of the view that no food additives should be used for the products covered by this Standard, and in particular that the use of anticaking agents is neither technologically justified nor necessary in the production of DPP using normal manufacturing methods. They were however open to information on technological justification.

Several countries noted that some additives are not listed in the GSFA or are considered a possible health risk. However all the additives listed are considered appropriate for dairy permeates, have been evaluated for safety and have appropriate maximum levels or are specified as GMP.

#### Observations by the Chair:

Opinions are divided on the use of anticaking agents. Some countries consider anticaking agents are not necessary and should not be permitted because there is no technological justification, but others consider they should be permitted and have provided technological justification. The justifications that have been provided are:

- to minimize clumping under high humidity conditions
- anti-caking agents are permitted in Codex standards for other dairy powders (e.g. *Codex Standard for Milk and Cream Powders* – CODEX STAN 207-1999 and *Codex Standard for Whey Powders* – CODEX STAN 289-1995) and in Food Category 01.8.2 Dried whey and whey products, excluding whey cheeses, as per the GSFA
- lactose, the main ingredient of permeates, is hygroscopic, so permeates may compact during their useful life, which increases their hydration time at the moment of using them, gives rise to longer processes that have an impact on productivity, and can create problems in the manufacture of the products where they are used and even quality problems in end products.

It is proposed therefore that anticaking agents should be permitted. In addition it is proposed that the table of functional classes should be simplified by listing only anticaking agents, since it is understood that no other functional classes are permitted.

In order to be consistent with the GSFA a footnote should be added to indicate that dairy permeate powders containing anticaking agents should not be used as ingredients in food category 13.1 - Infant formulae, follow-up formulae, and formulae for special medical purposes for infants, and 13.2 - Complementary foods for infants and young children.

## **4.2. PROCESSING AIDS**

One country recommended that calcium hydroxide, potassium hydroxide and sodium hydroxide should be included in the table of food additives, if they are needed. However these substances have a technological purpose during processing rather than in the food, hence they are classified as processing aids in this standard.

#### Observations by the Chair:

No change is recommended.

## **5. CONTAMINANTS**

One country noted that it would be difficult for importing countries to analyse contaminants in milk used in the manufacture of raw material.

#### Observations by the Chair:

No change is recommended.

## **6. HYGIENE**

No comments were received.

## **7. LABELLING**

### **7.1 Name of the food**

Two countries commented on the wording of the product names in the Spanish version. It is recommended that the names should be consistent with those used in section 2, Description.

Some countries proposed to specify possible alternative names, or to specify that the country of sale may use an equivalent designation. The main concern is that consumers may not be aware that the term “permeate powder” in ingredients lists will refer to products primarily used as a source of lactose considering that lactose content will not be declared as such. The name “lactose-rich deproteinized \_\_\_\_ powder”, the blank being filled with the term dairy, whey or milk, as appropriate to the nature of the product, was suggested as an alternative where appropriate in the country of sale.

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 regard to the specific proposal for an alternative name, it is noted that other products with a high lactose content, such as skim milk powder and whey powder, are frequently used as ingredients in foods without a reference to their lactose content. Furthermore, the wording of an alternative name should avoid any suggestion that it might be a label claim; however the terms “lactose-rich” and “deproteinized” might be understood as such.

#### Observations by the Chair:

It is recommended that, in the Spanish version, the first paragraph should read:

La denominación del alimento deberá ser **permeado lácteo en polvo**. Los productos que cumplan con las descripciones pertinentes de la Sección 2 podrán denominarse **permeado de leche en polvo** y **permeado de suero en polvo**, respectivamente.

It is noted that Section 7.1 cross-references only Section 2, whereas many other standards for milk products refer also to the compositional section 3.3. Accordingly it is recommended also to insert a cross reference to Section 3.3.

### **7.2 Labelling of non-retail containers**

One country considered that the lot identification, name and address of the manufacturer or packer should not be replaced by an identification mark, in order to facilitate traceability. However the wording included in the draft standard is standard wording used by the CCMMP in all milk product standards, based on “Format for Codex Commodity Standards” in the Codex Procedural Manual. Traceability requirements relate to various types of records and information and are not restricted to labelling. Traceability principles are considered to be already covered by the general references in section 6.

#### Observations by the Chair:

No change is recommended.

## **8. METHODS OF ANALYSIS AND SAMPLING**

One country recommended that the terms “milkfat” and “milk protein” should be simply “fat” and “protein”, since the methods of analysis do not identify that the source is milk. However the terms are used to align with 3.3.

Another country commented that the footnote regarding moisture content should use the term “water of crystallisation”. It is agreed that the wording should be consistent with footnote (c) (now footnote (b)) in 3.3.

#### Observations by the Chair:

It is recommended to amend the footnote marked \*\* to read “Moisture content excluding the water of crystallization of lactose.”

It is also recommended that the wording of the section should be updated to follow current Codex practice.

## **RECOMMENDATIONS**

Based on the above it is recommended that members:

1. **Note** the revised Draft Standard for Dairy Permeate Powders presented in Appendix 2, and in particular the provisions regarding the use of anticaking agents;
2. **Support** the advancement of the Draft Standard to Step 8;
3. **Note** that the provisions relating to food additives (including establishment of a food category), food labelling and methods of analysis will require the endorsement of the relevant horizontal committees.

**DRAFT STANDARD FOR DAIRY PERMEATE POWDERS  
(N16-2015)**

**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<sup>1</sup> 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>2</sup>, cream<sup>3</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>4</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>5</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 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 <sup>(b)</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) The moisture content does not include the water of crystallization of the lactose.

<sup>1</sup> Definition of *milk product*, see *General Standard for the Use of Dairy Terms* (CODEX STAN 206-1999)

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

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

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

<sup>5</sup> 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 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>
Anticaking agents <sup>(a)</sup>	<b>X</b>	<b>x</b>	<b>x</b>

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

(a) Dairy permeate powders containing anticaking agents should not be used as ingredients in food category 13.1 - Infant formulae, follow-up formulae, and formulae for special medical purposes for infants, and 13.2 - Complementary foods for infants and young children.

*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
460(i)	Microcrystalline cellulose (cellulose gel)	
460(ii)	Powdered cellulose	
470(i)	Salts of myristic, palmitic and stearic acids with ammonia, calcium, potassium and sodium	GMP
470(ii)	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	
553(i)	Magnesium silicate, synthetic	
553(iii)	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 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<sup>6</sup>

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:*

<b>Provisions</b>	<b>Method</b>	<b>Principle</b>	<b>Type</b>
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

<sup>6</sup> The listing of methods of analysis and sampling will be removed when the standard is adopted by CAC.



<b>Provisions</b>	<b>Method</b>	<b>Principle</b>	<b>Type</b>
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 water of crystallization of lactose.