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


DEADLINE: 20 May 2016

BACKGROUND
1. The Proposed Draft Standard for Dairy Permeate Powders, prepared by an electronic working group led by Denmark, was circulated for comments by Circular Letter CL 2016/2-MMP.
2. The comments received in response have been analysed by the New Zealand as secretariat 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 proposed Draft Standard for Dairy Permeate Powders is attached as Appendix 2 (for information purposes). It is intended that an analysis of replies to this CL together with the proposed draft Standard will be presented to the Commission through the CCEXEC for consideration.

REQUEST FOR COMMENTS
3. Comments are hereby requested on, on the following recommendations, which are based on the conclusions set out in Appendix 1:
   - **Support** the advancement of the proposed Draft Standard for Dairy Permeate Powders to Step 5;
   - **Agree** that CCMMP will continue to work by correspondence to consider the issue of the use of anticaking agents and report the outcomes to the 40th session of the CAC; and
   - **Note** that the provisions relating to food additives, food labelling and methods of analysis will require the endorsement by the relevant horizontal committees.

4. Governments and international organizations wishing to provide comments should do so in writing **preferably by e-mail** to the above addresses before **20 May 2016**.
ANALYSIS OF RESPONSES TO CL 2016/2-MMP (COMMENTS AT STEP 3)

This report analyses the comments received at Step 3 on the Proposed Draft Standard for Dairy Permeate Powders (DPP) and makes recommendations based on the analysis. Comments were requested in CL 2016/2-MMP, and responses were received from 6 member states, 1 member organization and 1 observer organisation. The comments in English, French and Spanish are available at ftp://ftp.fao.org/codex/meetings/CCMMP/ccmmp11/Comments in reply to_CL2016-2-MMPCompilationE.pdf.

SPECIFIC COMMENTS

1. SCOPE
No comments were received.

2. DESCRIPTION
One country (Egypt) requested that a suitable drying procedure should be included since drying of lactose-rich liquids is critical with respect to lactose crystallization. Another country (Colombia) suggested improvements to the wording of the Spanish version of the standard.

One country (Egypt) proposed that cream and sweet buttermilk should not be used as a source as they are not sufficiently rich in lactose. Another country (Colombia) proposed that any type of buttermilk containing lactose should be allowed, not only sweet buttermilk, and that the phrase “similar raw materials” should be deleted.

Observations by the Chair:
Drying technology varies and will develop with time and need not be specified in the standard.

Sweet buttermilk (buttermilk resulting from making butter from unfermented cream, i.e. “sweet” cream) has a similar lactose content to skim milk. Cream is defined as having minimum 10% milkfat and the lactose content of such cream is sufficiently high for producing dairy permeate powder.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Raw materials
See comments under 2.

3.2 Permitted ingredients
No comments were received.

3.3 Composition
One country (Colombia) proposed that the maximum milk protein in milk permeate powder should be 7%, to align with the other products, and queried the maximum ash level in DPP.

One country (USA) supported the inclusion of nitrogen content levels equivalent to the protein levels. IDF recommended that the nitrogen content levels should replace the protein contents, and noted consequential amendments in the standard.

Observations by the Chair:
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.

The proposal of IDF to remove the protein specifications while retaining specifications for nitrogen should be further considered at the next stage.

4. FOOD ADDITIVES
One country (Colombia) proposed that the section on Food Additives should be replaced by a reference to the additives permitted in Food Category 01.8.2 (Dried whey and whey products, excluding whey cheeses) of the General Standard for Food Additives (GSFA).

1 Canada, Colombia, Egypt, European Union and its member states, India, Switzerland, United States of America, IDF.
Some countries considered that anticaking agents should be permitted in each of the product categories. They noted that the GSFA allows the use of anticaking agents in Food Category 01.8.2 and milk powders, that some end uses of DPP might require the use of anticaking agents, and that cost considerations will ensure they are used only when necessary. They supported 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.

On the other hand the EU Member States (EUMS) and Switzerland 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. The EUMS therefore proposed replacing the entire section 4.1 with a sentence that would read: "No additives are permitted in the products covered by this standard".

One country (Egypt) pointed out that antioxidants are not necessary in DPP. However the table in section 4.1 already notes that antioxidants are not technologically justified.

One country requested that bone phosphate (INS no. 542) should be deleted from the list of additives since dairy products are generally perceived as vegetarian in India.

Observations by the Chair:
No consensus has yet been achieved on this section. It needs to be considered further. The entire section is retained in square brackets.

4.2. PROCESSING AIDS

One country (Egypt) proposed that “substances changing the pH” should be replaced by “acidity regulator”.

Another country (India) did not support the use of hydrochloric acid as a processing aid, and proposed the inclusion of a range of other acidifying agents.

IDF suggested that the section on processing aids should be allocated a separate section (section 5) since processing aids do not function as food additives.

Observations by the Chair:
As processing aids are not additives, the terms used for functional additives classes cannot be used. Hydrochloric acid is the only acid listed as an example. Removing it from the list will leave only alkalis in the list.

As processing aids are not food additives, allocating them a separate section can be considered.

5. CONTAMINANTS
No comments were received.

6. HYGIENE
No comments were received.

7. LABELLING

7.1 Name of the food

One country (India) asked to reinstate the following text as the second paragraph in section 7.1:

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.

India noted that the name of the product should indicate the true nature of the product and should be commonly understandable, but that many consumers do not understand the term “permeate”.

Observations by the Chair:
The wording suggested by India was considered earlier by the eWG, but it was removed in the most recent draft upon the request of member countries. The target users of the products covered by this Standard are food manufacturers and not consumers. Food manufacturers using the products have sufficient food technology knowledge to understand the terms used in the standardized name.
7.2 Labelling of non-retail containers

One country (India) noted that the name and address of the manufacturer or packer should never be replaced by an identification mark, in order to protect traceability.

Observations by the Chair:

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.

8. METHODS OF ANALYSIS AND SAMPLING

No comments were received.

CONCLUSIONS

Comments at Step 3 have raised a number of points on the proposed draft standard that will need further consideration.

The major point of issue concerns the use of anticaking agents, on which opinion remains divided as to whether they are technologically justified or not. This issue was considered by the electronic working group, and 3 options were suggested for resolving the issue. The comments at Step 3 indicate that some countries support one of these options, i.e. the insertion of an exclusionary footnote as noted under section 4 above, while others remain of the view that the standard should not permit the use of anticaking agents. Based on these comments there may be a need to seek further comments from members on the technological justification for the use of anticaking agents.

RECOMMENDATIONS

Based on the above it is recommended that members:

1. Support the advancement of the proposed Draft Standard for Dairy Permeate Powders to Step 5;
2. Agree that CCMMP will continue to work by correspondence to consider the issue of the use of anticaking agents and report the outcomes to the 40th session of the CAC; and
3. Note that the provisions relating to food additives, food labelling and methods of analysis will require the endorsement by the relevant horizontal committees.
Appendix 2

PROPOSED DRAFT STANDARD FOR DAIRY PERMEATE POWDERS
(N16-2015)
(for information)

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\(^3\), 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

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

\(^a\) 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

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\(^2\) 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)
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 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.]

<table>
<thead>
<tr>
<th>Functional Class</th>
<th>Dairy permeate powder</th>
<th>Whey permeate powder</th>
<th>Milk permeate powder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stabilizers</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Firming agents</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Emulsifiers</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Anticaking agents</td>
<td>[X]</td>
<td>[X]</td>
<td>[X]</td>
</tr>
<tr>
<td>Antioxidants</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

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):

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

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.

5. 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:

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

*) 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