CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

E

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

CL 2017/3-MMP

January 2017

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 2016/46-MMP: Draft Standard for Dairy Permeate Powders**

DEADLINE: **31 March 2017**

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

BACKGROUND

1. The Draft Standard for Dairy Permeate Powders was circulated for comments by Circular Letter CL 2016/46-MMP, noting provisions regarding the use of anticaking agents and requesting comments on a recommendation to support the advancement of the Draft Standard to Step 8.

2. The comments received in response have been analysed by New Zealand as host government of the Committee on Milk and Milk Products (CCMMP), and their report and revised recommendations of the Chair of the Committee are attached as *Appendix 1*. The recommendations involve a significant amendment to the Draft Standard, which has been revised in accordance with comments received and is attached as *Appendix 2* (for information purposes).

3. The provisions relating to food additives, food labelling and methods of analysis will require the endorsement of the relevant horizontal committees.

4. The intent of this CL is to gauge support for adoption of the draft Standard at Step 8. Based on the replies received to this CL, the Chair of the Committee will make a final recommendation for consideration by CAC40 and CCEXEC73.

REQUEST FOR COMMENTS

5. Comments are hereby requested on whether the revised Draft Standard for Dairy Permeate Powders presented in Appendix 2 is ready for adoption at Step 8.

Appendix 1

ANALYSIS OF RESPONSES TO CL 2016/46-MMP

This report analyses the comments received on the recommendations set out in CL2016/46-MMP regarding the Draft Standard for Dairy Permeate Powders (DPP) and makes revised recommendations based on the analysis. Comments were requested in CL 2016/46-MMP, and responses were received from 9 member states, 1 member organization and 1 observer organization[1].

The comments are available in English, French and Spanish.

ftp://ftp.fao.org/codex/meetings/CCMMP/ccmmp11/Comments-in-reply-to_CL2016-46-MMP_CompilationE.pdf

SPECIFIC COMMENTS

Comments regarding the recommendations as a whole

Four countries (Canada, Costa Rica, Cuba and Switzerland) supported the recommendations as a whole.

Comments in regard to the use of anticaking agents

Three countries (Canada, Colombia and India) agreed with permitting the use of anticaking agents.

Colombia repeated its initial rationale that 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.

As additional support, Colombia noted that in the process of obtaining dairy permeate powders (milk permeate, whey permeate, cream permeate, sweet buttermilk permeate), up to 5% of amorphous lactose, which is hygroscopic, may form, even if pre- and post-crystallization of lactose are combined. A dairy permeate powder contains more lactose than whey powder (category 01.8.2), so it is more likely to contain amorphous lactose. In addition, some areas in the tropics are quite humid, with temperatures that may reach over 40°C in storage areas, possibly giving rise to a rubbery product and, at the end of the product's useful life, to lumps of product which have an impact on productivity.

In its comments, India noted that anticaking agents were allowed in food category 01.8.2 (dried whey and whey products, excluding whey cheeses), as per the GSFA. They are also permitted in milk powders. India further noted that where dairy permeate powders are intended to be used in infant formula, manufacturers will conform to the provisions of Section 4.3 of the *General Standard for Food Additives* on Carry-Over of Food Additives into Foods. India also commented that cost considerations would ensure that anticaking agents would be used only where extremely necessary.

Two countries (Ecuador and USA), the European Union Member States (EUMS) and International Dairy Federation (IDF) considered there was no technological justification for the dairy permeate powders covered by the standard.

The IDF provided detailed information in regard to the types of permeates covered by the standard and consequently the need or not for the use of anticaking agents, and supplied supporting references. In particular they note that the standard limits the sources of permeates to non-fermented sources (e.g. milk, milk concentrate, whey from rennet coagulated milk, sweet buttermilk, cream), and excludes permeates from highly acidified sources such as acid whey (as defined by CODEX STAN 289-1995) and whey from some relatively high acid cheeses (e.g. quark, cottage cheese) and permeates obtained by concentrating fermented milks (e.g. buttermilk, concentrated yoghurt).

The IDF technical comments acknowledge that for dried products obtained from the latter sources it can be difficult to maintain product stability during storage and distribution, and in this case anticaking agents may be needed.

On the other hand in the case of the dairy permeate powders covered by the standard, product stability can be maintained by controlling the fraction of non-crystalline, amorphous lactose, thus eliminating the need for anticaking agents. In contrast to crystalline lactose, amorphous lactose is quite hygroscopic, especially in combination with relative high air humidity, elevated temperatures and pressure, and as a result, such a product can readily reach glass transition, resulting in a so-called rubbery state. The closer to glass transition or rubbery state, the stickier the powder gets. However, optimization of drying and packaging processes has

[1] Argentina, Canada, Colombia, Costa Rica, Cuba, Ecuador, European Union Member States, India, Switzerland, USA and IDF.

replaced former usage of anticaking agents for these products, Manufacturers achieve stable products by applying well-known technology as follows:

- Using appropriate packaging material;
- Ensuring that packaging and decanting (depackaging) operations are carried out under conditions that ensure that the glass transition temperature (T_g) of the lactose is not exceeded, e.g. through controlling water activity (a_w), relative air humidity (%RH) and cooling powder well below the glass transition temperature (T_g) before packaging;
- Keeping the fraction of amorphous lactose below 25%, e.g. through pre-crystallization of lactose prior to drying and/or post crystallization after primary drying. Up to 95% crystallization can be achieved using a combination of pre- and post-crystallization;
- Avoiding mixing particles with different initial humidity and temperature;
- Minimizing temperature variation within and between silos or bags.

The IDF also noted that:

- Storage stability of dairy permeate powders mainly relates to the form in which lactose is present in the product. In this regard, dairy permeate powders are similar to lactose. Anticaking agents are not permitted in lactose (see CODEX STAN 212-1999 and GSFA food category 11.1.4).
- Storage stability of milk powders and other milk products with relatively lower lactose contents are less related to the form in which lactose is present. Therefore, it is not entirely correct, as stated in the Analysis of Responses to CL 2016/25-MMP, to refer to the permitted use of anticaking agents in milk powders and whey powders as a technical justification for their use in dairy permeate powders made from non-fermented/non-acidified sources.

The IDF requested that the entire text within section 4.1 be replaced with the following text:

> "The use of food additives is not technically justified for dairy permeate powders covered by this standard."

Ecuador was of the view that, based on the precautionary principle regarding public health, anticaking agents must not be allowed in milk permeate powders, since there are no Codex analytical methods to analyse the presence and quantity of these additives in infant formula and related products.

Observations by the Chair

Opinion remains divided on the issue of use of anticaking agents with some members continuing to support the proposal to allow the use of anticaking agents. However it is now apparent that a significant number of countries are opposed to the proposal to allow the use of anticaking agents in the manufacture of dairy permeate powders. The International Dairy Federation (IDF) has in particular noted 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 is now proposed to delete the provision relating to use of anticaking agents, and replace it with a new section 4.1 as proposed by IDF, except using the words "not permitted" rather than "not technically justified".

Comments in regard to advancement to Step 8

Canada supported advancement of the standard to Step 8. The EUMS, USA and IDF also supported advancement, on condition that the use of anticaking agents is not permitted.

Comments in regard to referral to horizontal committees for endorsement

Canada agreed that sections of the proposed standard will need referral to the relevant horizontal committees. The IDF suggested that if their proposed wording for section 4.1 were incorporated, the Draft Standard would not need prior endorsement by the Committee on Food Additives.

Observations by the Chair

Endorsement of section 4 by CCFA would still be required. Since section 4.1 would not permit the use of additives, an amendment to the *General Standard for Food Additives* will be needed to distinguish dairy permeate powders from other dairy products in which food additives are permitted. Furthermore section 4.2 contains provisions concerning processing aids which come under the purview of CCFA.

Comments on other matters

Sections 2, Description, and 3.1, Raw materials

Colombia proposed the deletion of the terms 'similar raw materials' from section 2(a) and 'similar lactose-containing milk products' from section 3.1 in order to avoid the use of raw materials that may be misleading to the consumer.

Observations by the Chair

This issue was raised in previous comments (CL 2016/25-MMP). However as noted in the analysis presented in CL 2016/46-MMP, dairy permeate powders are clearly described as milk products. However to improve clarity and avoid any ambiguity a footnote reference to the definition of milk product in the *General Standard for the Use of Dairy Terms* (GSUDT) was added to Section 2 in response to previous comments on this issue.

Section 3.3, Composition

Colombia proposed that the maximum milk protein content of milk permeate powder should be increased to 7.0% (= 1.1% N), since the value must be the same as, or above that of the other permeates, which is 7.0.

Observations by the Chair

Again, this issue was raised in previous comments (CL 2016/25-MMP). However as noted in the analysis presented in CL 2016/46-MMP, 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.

Section 4, Food Additives

Argentina noted a correction to the Spanish version of the Draft Standard.

Colombia asked for clarification of the reason why the other additives that were not between brackets, that is, firming agents, emulsifiers and antioxidants, were omitted in the table.

Observations by the Chair

The correction noted by Argentina is not needed in the Revised Draft in Appendix 2.

In regard to other additives, it was noted in the analysis presented in CL 2016/46-MMP that the table of functional classes should be listed by listing only anticaking agents, since it was understood that no other functional classes were permitted.

Section 7.1, Name of the food

India proposed that the following text should be reinstated as the second paragraph in the section 7.1 of the standard:

> *'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 provides several reasons, in summary:

- The name "dairy/whey permeate powder" does not reflect true nature of the product, which is its "lactose rich" nature.
- It would not be appropriate to base the name of the product in a Codex standard on a particular technology.
- The product will primarily be used as a source of lactose in the products but will not be declared as such.
- Important Codex standards allow for alternative names as appropriate in the country of sale (e.g. CODEX STAN 207 for milk and cream powders; CODEX STAN 243 for fermented milks; CODEX STAN 288 for creams and prepared creams etc.).
- The requested provision for alternative terminology does not prevent use of the names 'whey permeate powder' or 'dairy permeate powder', where these are well understood by the consumer and the industry.
- The proposed terminology is not inconsistent with the *Guidelines for Nutrition and Health Claims* (CAC/GL 23) in regard to lactose content and protein content.

Observations by the Chair

This issue was raised in previous comments (CL 2016/25-MMP). In response it was noted in the analysis presented in CL 2016/46-MMP that 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 in regard to provisions for alternative names which are permitted for some milk products, that such names had an established usage on the international market before the Codex standard was established (e.g. low fat milk powder). However for the products covered by this standard there appear to be no well-established alternative names used internationally.

Section 7.2, Labelling of non-retail containers

Ecuador proposed that the second sentence of this section should read: "However, lot identification, and the name and address of the manufacturer or packer may be ~~replaced~~ **supplemented** by an identification mark …", in order to maintain product traceability.

Observations by the Chair

This issue was raised in previous comments (CL 2016/25-MMP). In response it was noted in the analysis presented in CL 2016/46-MMP that 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.

Appendix 2

DRAFT STANDARD FOR DAIRY PERMEATE POWDERS (REVISED)

(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[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], 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.