



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

38th Session, CIGG,

Geneva, Switzerland, 6-11 July 2015

PROPOSALS FOR THE ELABORATION OF NEW STANDARDS AND RELATED TEXTS

A list of proposals to elaborate new standards and related texts is presented below, including the reference of the project document in the relevant report. Projects document which were not included in the report and were finalised after the session of the relevant Committee are attached to the present document as **Annexes**. The Commission is invited to decide whether or not to undertake new work in each case, taking into account the critical review conducted by the Executive Committee, and to decide which subsidiary body or other body should undertake the work. The Commission is invited to consider these proposals in the light of its *Strategic Plan 2014-2019* and the *Criteria for the Establishment of Work Priorities and for the Establishment of Subsidiary Bodies*.

Codex Body	Text	Reference and project document
CCFICS	Principles and/or guidelines for the exchange of information (including questionnaires) between countries to support food import and export	REP 15/FICS paras 28 and 29, Appendix III
CCFICS	Guidance for monitoring the performance of National Food Control Systems	REP 15/FICS paras 36 and 37, Appendix IV
CCFICS	<i>Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations</i> (CAC/GL 19-1995) (Revision)	REP 15/FICS paras 46 and 47, Appendix V
CCFICS	<i>Guidelines for the Exchange of Information between Countries on Rejections of Imported Food</i> (CAC/GL 25-1997) (Revision)	REP 15/FICS paras 54 and 55, Appendix VI
CCNFSDU	Definition on Biofortification	REP 15/NFSDU paras 164 and 165, Appendix VII
CCNFSDU	NRV-NCD for EPA and DHA long chain omega-3 fatty acids	REP 15/NFSDU para. 191, Appendix IX
CCAFRICA	Regional Standard for dried meat	REP 15/AFRICA para. 61, Appendix II
CCAFRICA	Regional Standard for fermented cooked cassava based products	REP 15/AFRICA para. 63, Appendix III
CCAFRICA	Regional Standard for Shea butter	REP 15/AFRICA para. 65, Appendix IV

Codex Body	Text	Reference and project document
CCAFRICA	Regional Standard for <i>Gnetum</i> Spp leaves	REP 15/AFRICA para. 66, Appendix V
CCFO	Addition of Palm Oil with High Oleic Acid (OxG) to the <i>Standard for Named Vegetable Oils</i> (CODEX STAN 210-1999) (Revision)	REP15/FO Para. 89, Appendix VI
CCFO	Revision of Fatty Acid Composition and Other Quality Factors of Peanut Oil to the <i>Standard for Named Vegetable Oils</i> (CODEX STAN 210-1999) (Revision)	REP15/FO Para. 97 , Appendix VII
CCFO	Revision of the Limit for Campesterol to the <i>Standard for Olive Oils and Olive Pomace Oils</i> (CODEX STAN 33 – 1981) (Revision)	REP15/FO Para. 118, Appendix VIII
CCCF	Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Spices	REP 15/CF paras 143, Appendix VIII
CCFA	Food category 01.1 “Milk and dairy-based drinks” and its sub-categories of the <i>General Standard for Food Additives</i> (CODEX STAN 192-1995) (GSFA) (Revision)	REP15/FA para. 92, Appendix XI
CCFA	Sections 4.1.c and 5.1.c of the <i>General Standard for the Labelling of Food Additives When Sold as Such</i> (CODEX STAN 107-1981) (Revision)	REP15/FA para. 164, Appendix XIV
CCPR	Establishment of Codex schedules and priority list of pesticides for evaluation by JMPR	REP15/PR Para. 175, Appendix XII
CCRVDF	Priority List of Veterinary Drugs requiring Evaluation or re-evaluation by JECFA	REP15/RVDF para. 112, Appendix VIII
CCMMP	Standard for Dairy Permeate Powders	see Annex 1 of this document

PROJECT DOCUMENT:**CODEX STANDARD FOR DAIRY PERMEATE POWDERS**

Prepared by an Electronic Working Group led by Denmark and co-chaired by New Zealand

1. THE PURPOSE AND THE SCOPE OF THE STANDARD

The Standard will address the identity, compositional quality and safety of powders made from dairy permeates intended as ingredients in food.

Dairy permeate powders are a group of milk products which are characterized by a high concentration of lactose and have in common that they have been manufactured by drying permeates or similar products, obtained by removing, to the extent practical, milk fat and milk protein from lactose-containing liquid raw materials such as milk (skimmed, partially skimmed and whole), cream, sweet buttermilk and/or whey. Depending on the raw material used, dairy permeate powders are usually designated *milk permeate powder*, *whey permeate powder* or *dairy permeate powder*.

Whey permeate powder is the dairy permeate powder obtained from whey permeate. Whey permeate is obtained by removing, for instance by a mechanical process (e.g. membrane filtration) or by heat induced precipitation, milk proteins from whey. Whey is defined by the *Standard for Whey Powders* (CODEX STAN 289-1995) as a milk product resulting from the manufacture of cheese and/or of casein.

Milk permeate powder is the dairy permeate powder obtained from milk permeate. Milk permeate is defined by standards for *Milk Powders and Cream Powders* (CODEX STAN 207-1999), *Blend of Evaporated Skimmed Milk and Vegetable Fat* (CODEX STAN 250-2006), *Blend of Skimmed Milk and Vegetable Fat in Powdered Form* (CODEX STAN 251-2006), *Blend of Sweetened Condensed Skimmed Milk and Vegetable Fat* (CODEX STAN 252-2006), *Evaporated Milks* (CODEX STAN 281-1971) and *Sweetened Condensed Milks* (CODEX STAN 282-1971) as a milk product obtained by removing milk proteins and milk fat from milk, partly skimmed milk, or skimmed milk by ultrafiltration.

2. ITS RELEVANCE AND TIMELINESS

Dairy permeate powders were introduced in the 1970s and 1980s as membrane filtration technology developed. However, the introduction was not successful because the product was very hygroscopic (the proportion of amorphous lactose was too high), and the emerging market was largely replaced by lactose powders. Since then, powder drying technology has developed and it is now possible to control the crystallization process thus making “free flowing” powders. There is now a growing volume of production and a large number of food businesses involved in manufacture, trade and use of these products

However no single, internationally-agreed definition or designation for labelling has been established for these products, which can lead to unfair trading practices and consumers being misled, e.g. as regards to how dairy permeate powders are referenced in the list of ingredients of other foods. The absence of an international standard for this type of product also creates problems for trade with countries that only permit imports of products for which a compositional standard exists (either in their national legislation or as a Codex standard).

Another issue in trade in dairy permeate powders relates to the fact that similar products are already in use as ingredients in animal feed. This situation has led to a reluctance in some markets to recognize food grade dairy permeate powders as appropriate and safe ingredients in food. This has resulted in import restrictions in some countries and/or in incorrect marketing of these products as “lactose” or “whey powder”. The non-existence of international standards is also a factor in the reluctance to accept dairy permeate powders in food aid products¹.

Due to the above restrictions, it is necessary to establish a Codex standard covering the identity, composition, labelling and quality that will apply as a reference in trade.

A Codex standard for dairy permeate powders would also contribute to the protection of consumers' health as the standard will address food additives and reference appropriate Codex food safety documents.

¹ Many dairy ingredient specifications for products intended for food aid, as provided by UNICEF and World Food Programme refer to existing Codex standards (i.e. milk powders, lactose, whey powders)*. Examples include Lipid-based Nutrient Supplements (LNS-LQ and LNS-MQ) at the WFF website:
<http://foodqualityandsafety.wfp.org/specifications;jsessionid=BCEEF351C1966A0C7565463C44D4AFBB>

3. THE MAIN ASPECTS TO BE COVERED

The standard will be a commodity standard following the format of other Codex milk product standards developed by the Committee on Milk and Milk Products. This involves the establishment of a product definition for the overarching product *dairy permeate powder* and definitions for the more specific products *milk permeate powder* and *whey permeate powder*. Further, the standard will include specification of essential composition and quality factors, food additives, and labelling. Appropriate product modifications, e.g. partial demineralization, will be addressed. Food safety will be addressed through references to relevant Codex standards, guidelines and codes of practice.

4. AN ASSESSMENT AGAINST THE CRITERIA FOR THE ESTABLISHMENT OF WORK PRIORITIES

General criterion

The standard aims at ensuring fair trade practices through the establishment of product identity, composition and designations and at providing consumer protection through inclusion of references to the appropriate Codex standards for food safety and labelling.

Criteria applicable to commodities

a) *Volume of production and consumption in individual countries and volume and pattern of trade between countries*

Dairy permeate powder is produced in at least three geographical regions of the world in amounts exceeding 540,000 metric tonnes (see the table below). The data are presented by region in order not to expose data from individual companies.

<i>Data provided by the International Dairy Federation (IDF) (Figures in metric tonnes)</i>	2013		2014	
	Production	Exports	Production	Exports
North America				
Milk permeate powder	24,948	10,433	24,993	10,497
Whey permeate powder	464,937	251,293	470,335	256,428
Latin America				
Milk permeate powder	0	0	0	0
Whey permeate powder	22,570	17,982	23,730	18,119
Europe				
Milk permeate powder	1,500	800	1,650	850
Whey permeate powder	202,720	148,800	212,300	150,500
Oceania				
Milk permeate powder	0	0	0	0
Whey permeate powder	0	0	0	0
Asia				
Milk permeate powder	0	0	0	0
Whey permeate powder	0	0	0	0
In total	716,675	429,308	733,008	436,394

It is emphasized that the above data provided does not give the complete information on production and trade as it has not been possible to retrieve data from all countries that are manufacturing dairy permeate powders. Regarding consumption data on Dairy permeate powders, such data are not available.

The global volume of production, trade and consumption of dairy permeate powders justify the establishment of an international standard.

b) *Diversification of national legislation and apparent resultant or potential impediments to international trade*

No national standards are currently available, but trade standards exist or are in development.

There is a wide range of dairy permeate powders of varying composition and quality currently traded in the international market. This diversity and the absence of a clearly defined international standard covering essential composition and quality parameters are not conducive to the further growth and development of international trade in these products. The absence of a clearly defined standard for this class of products has

resulted in sales of dairy permeate powders under other inappropriate dairy designations (such as Whey Powder and Lactose).

Some related products exist that are manufactured from whey or milk using similar technology but are sold under different names². These products have lower contents of lactose and higher contents of protein and salts as compared to dairy permeate powders. Difficulties in continuing trade in such products, if any, can be brought up for consideration during the drafting of the standard.

c) *International or regional market potential*

Dairy permeate powders are used as ingredients in other foods (e.g. dairy products, bakery products, snacks, beverages, desserts, ice creams, confectionery, etc.), mainly for its sweetening and flavour enhancing ability. Dairy permeate powders provide nutritional benefits compared to other sweetening foods, which is due to its natural content of calcium, phosphorus, magnesium and potassium.

So far, increased sales of dairy permeate powders have been driven partly by slightly lower prices than whey powder and lactose, and partly because of their sensory benefits, i.e. less bitter/metallic taste than whey powder (lower content of bitter nitrogenous compounds) and more bulky and milky taste when added to other foods (e.g. chocolate, bakery) than can be obtained by using lactose.

Lactose has been shown to have a growth promoting effect in weanling piglets and a beneficial prebiotic effect leading to increased growth of lactobacilli and bifidobacteria in the colon^{3,4}. In humans a prebiotic effect of lactose has been observed in adults with lactase deficiency and is indicated in premature infants with immature lactase activity as well as in term infants⁵. Lactose may have a similar prebiotic effect in malnourished children with secondary lactose deficiency. Adding lactose to food for moderately malnourished children would increase the energy density and likely improve the palatability of food aid. Compared to sucrose, which is currently used to increase energy density in some food aid products, lactose has a lower cariogenicity⁶. Finally lactose may enhance mineral absorption in infants and young children.

The mineral package of permeates contains mainly growth promoting minerals (K, Mg, P and Zn)⁷ and calcium. Overall the amount of these minerals, as well as the relative nutrient-to-nutrient ratios in permeates, are considered relevant for incorporation in food for moderately malnourished children as long as the recommendations for daily nutrient intake in this population are taken into account.

Due to these benefits, the market for dairy permeate powders, both in tonnage and in applications in a variety of foods, is growing.

The growing market for milk protein concentrates (e.g. whey protein concentrate) increases the amount of permeates available for drying into permeate powders. Thus, the supply potential of the remaining milk solids to produce dairy permeate powders is high.

It is expected that the standard will contribute positively to further developing the market and trade in dairy permeate powders.

d) *Amenability of the commodity to standardization*⁸

The commodity is amenable to Codex standardization. This is demonstrated by the nature of the parameters intended to be standardized; they include the same well-known types of components as are addressed by Codex standards for other dried milk products (i.e. lactose, protein, milk fat, ash and moisture).

The main compositional parameter in dairy permeate powders is lactose, which is the component characterizing the product.

Other milk constituents such as milk protein and organic salts are unavoidable and acceptable components of the product, the content of which will be determined by the raw material and the protein removal method used. The organic salts consist of milk constituents (calcium phosphates, calcium citrates, chlorides). Where

² For example “dairy product solids”, under an ADPI specification.

³ Ito M, Kimura M. Influence of Lactose on Faecal Microflora in Lactose Maldigestors. *Microb Ecol Health Dis* 1993; 73–76

⁴ Szilagyi, A. et al. Differential impact of lactose/lactase phenotype on colonic microflora. *Can J Gastroenterol* 2010; 24: 373–379

⁵ Coppa GV, Zampini L, Galeazzi T, Gabrielli O. Prebiotics in human milk: a review. *Dig. Liver Dis.* 2006 Dec; 38, Suppl 2: S291 – S294

⁶ Bowen WH, Lawrence RA. Comparison of the cariogenicity of cola, honey, cow milk, human milk and sucrose. *Pediatrics.* 2005; 116, 921-927

⁷ K. Fleisher Michaelsen et al..Cow’s milk in Treatment of moderate and severe under nutrition in low-income countries. In *Milk and Milk Products in Human Nutrition*, p. 99-111. Karger Medical and Scientific Publishers, 2011

⁸ The term “standardization” refers to the establishment of a Codex commodity standard and not to the standardization of product constituents to meet compositional specifications.

Whey is the basis, residues of the salts formed during microbiological fermentation of cheese milk (e.g. lactate, propionate, citrate, depending on the cultures used) will also be present. The salts are of the same types that are present in whey powder. Whey permeate powder produced from acid whey will also contain the salts arising during precipitation of caseins. Further treatment can minimize contents of the mentioned components (e.g., demineralization).

The nitrogen content of permeate powders, calculated as "protein", consists of free amino acids and relatively high proportions of nitrogenous compounds such as urea, purine bases and creatine. Specification of a minimum limit for protein in the standard will not be appropriate as protein does not characterize the products, and they are not intended to be marketed as containing significant amounts of protein.

Consequently, it is appropriate to specify only a maximum content of protein.

The compositional balance between lactose, milk protein and salts of the individual dairy permeate powders is determined by the raw material and protein removal method used.

The standard will address composition requirements for the following components:

- A minimum limit for lactose, e.g. 76% (m/m) expressed as anhydrous lactose;
- Maximum levels for milk protein (e.g. less than 7%), milk fat and ash;
- No minimum limits for milk protein, milk fat and ash are required as they do not constitute characterizing parameters for the identity of dairy permeate powders;
- A maximum level for water for reasons of maintaining safety and quality during storage, e.g. 5% moisture, including the water of crystallization of the lactose.

With regard to additives, the intent is to identify the technologically justified functional classes. A corresponding list of appropriate individual additives belonging to these functional classes can be included or submitted to the Committee on Food Additives for inclusion in the General Standard for Food Additives.

e) Coverage of the main consumer protection and trade issues by existing or proposed general standards

Currently, the Codex Alimentarius does not include any Codex standards covering the identity of dairy permeate powder.

Dairy permeate powders are milk products that differ from the two other lactose-containing milk products covered by Codex commodity standards, i.e.

- *Lactose* defined as the fully concentrated isolate of lactose is covered by Standard for Sugars (CODEX STAN 212-1999), and
- *Whey powders* defined as dried whey or dried acid whey are covered by *Standard for Whey Powders* (CODEX STAN 289-1995).

Consideration has been given to the inclusion of dairy permeate powder into the existing *Standard for Whey Powders* (CODEX STAN 289-1995). However, dairy permeate powders are distinct from whey powders in terms of raw materials used, manufacturing, composition and usage. Consequently, it is proposed to develop a separate standard for dairy permeate powders.

There will be no overlap in scope between a commodity standard for dairy permeate powders and the two existing standards for whey powders and sugars respectively.

f) Number of commodities which would need separate standards indicating whether raw, semi-processed or processed

The work will cover a group of well-defined commodities. Due to its specific characteristics, no other existing Codex commodity standard covers or can be extended to cover dairy permeate powders. Consequently, it is necessary to establish a separate standard for dairy permeate powders.

g) Work already undertaken by other international organisations in this field and/or suggested by the relevant international intergovernmental body(ies)

The European Whey Products Association has undertaken preparatory work to obtain agreement on the compositional requirements of whey permeate powder. The American Dairy Products Institute (ADPI), which is a trade association representing the dairy ingredients industry, including the majority of manufacturers and marketers of dairy permeate powder in the U.S, is also active in this field.

5. RELEVANCE TO THE CODEX STRATEGIC OBJECTIVES

Establishment of a Codex standard for dairy permeate powders is in line with the CODEX strategic objectives as follows:

- It reinforces the Codex Alimentarius as being the preeminent international food standards-setting body to protect the health of consumers and ensure fair practices in the food trade.
- It meets the specified Goal 1 of the Strategic Plan 2014-2019 to establish international food standards that address current and emerging food issues, and in particular, activity 1.2.2 – “Develop and revise international and regional standards as needed, in response to needs identified by Members and in response to factors that affect food safety, nutrition and fair practices in the food trade”.

6. INFORMATION ON THE RELATION BETWEEN THE PROPOSAL AND OTHER EXISTING CODEX DOCUMENTS

The standard will be used in conjunction with all existing and relevant Codex standards. It will take into account the provisions of *General Standard for the Use of Dairy Terms* (CODEX STAN 206-1999), the *General Principles of Food Hygiene* (CAC/RCP 1-1969), the *Code of Hygienic Practice for Milk and Milk Products* (CAC/RCP 57-2004), *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CAC/GL 21-1997), the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985), the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995) and the *General Standard for Food Additives* (CODEX STAN 192-1995).

7. IDENTIFICATION OF ANY REQUIREMENT FOR AND AVAILABILITY OF EXPERT SCIENTIFIC ADVICE

None is required.

8. IDENTIFICATION OF ANY NEED FOR TECHNICAL INPUT TO THE STANDARD FROM EXTERNAL BODIES SO THAT THIS CAN BE PLANNED FOR

None is required.

9. THE PROPOSED TIME-LINE FOR COMPLETION OF THE NEW WORK.

Agreement to initiate new work on a standard for dairy permeate powders by the CAC	July 2015
Circulation of a Proposed Draft Standard for comments at Step 3	September 2015
Consideration by the CCMMP at Step 4	Early 2016
Adoption at step 5 or 5/8 (depending on progress) by the CAC	July 2016
Consideration of the draft Standard at Step 7 by the CCMMP, if required	Early 2017
Adoption of the Standard by the CAC	July 2017