



JOINT FAO/WHO FOOD STANDARDS PROGRAMME
EXECUTIVE COMMITTEE OF THE CODEX ALIMENTARIUS COMMISSION
Seventieth Session
WHO Headquarters, Geneva, Switzerland
30 June - 3 July 2015

CRITICAL REVIEW FOR THE ELABORATION OF CODEX STANDARDS AND RELATED TEXTS

PROPOSALS FOR THE ELABORATION OF NEW STANDARDS AND RELATED TEXTS

BACKGROUND

1. A list of proposals to elaborate new standards and related texts is contained in **Table 1**, including the reference to the project document in the relevant report. Project documents 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**.
2. The Executive Committee is invited to make recommendation to the Commission as to whether or not to undertake new work in the light of the *Strategic Plan 2014-2019* and the *Criteria for the Establishment of Work Priorities and for the Establishment of Subsidiary Bodies*.

CONCLUSION AND RECOMMENDATIONS

3. Project documents and proposals for new work submitted by various Committees generally comply with requirements described in the Procedural Manual and the *Criteria for the Establishment of Work Priorities and for the Establishment of Subsidiary Bodies*.
4. **CCEXEC is invited to recommend that CAC38 approves all new work proposals, with the exception of the following proposals for which specific recommendations are made:**

- Definition on Biofortification (CCNFSDU)

Recommendation: Request CCNFSDU to (i) better clarify the purpose of developing such a definition, its relationship with other Codex texts, the gaps that it would address and how the definition will be used in Codex; and (ii) revise the project document, in particular: Section 1 "Purpose and Scope of the Standard" and Section 6 "Relation between the proposal and other existing Codex documents" and, in particular, clarify how the proposed definition will be used in Codex and consequentially where it would be best placed.

Regional Standard for Dried Meat (CCAFRICA)

Recommendation: Request CCAFRICA to (i) better clarify the problem that the proposed new work is addressing (e.g. hygiene measures for dried meat, quality provisions) and the gaps in existing Codex texts that the new work would address; and (ii) revise the project document, in particular Section 3 "Its relevance and timeliness"; Section 5 (a) "Volume of production and consumption in individual countries and volume and patterns of trade between countries"; Section 5 (b) "Diversification of national legislation and apparent resultant or potential impediments to regional trade" and Section 7 "Information on relation between the proposal and other existing Codex texts".

5. **CCEXEC is also invited to recommend** (if new work on a Regional Standard for Fermented Cooked Cassava Based Products is approved) **that CAC38, requests CCAFRICA to take into account other Codex texts such as the *Standard for Gari* (CODEX STAN 151-1989) and the *Code of Practice for the Reduction of Hydrocyanic Acid (HCN) in Cassava and Cassava Products* (CAC/RCP 73-2013).**

TABLE 1: PROPOSALS FOR NEW WORK²

Committee on Food Import and Export Inspection and Certification Systems (21 st Session, 13-17 October 2014)	Timeframe		Output Codes	Scientific Advice	Explanatory Notes
	Reference and project document	Target Year			
Principles and/or Guidelines for the Exchange of Information (including questionnaires) between Countries to Support Food Import and Export	<u>REP15/FICS</u> , para. 28, App. III	2019	1.4	Not required	CCFICS19 and CCFICS 20 supported the work to address the issue of the burden of multiple questionnaires. Two rounds of EWGs consultations and informal workshops were held to develop a better understanding of the issue and scope of work. There was general agreement by CCFICS21 to advance the work based on the scope of work contained in the document.
Guidance for Monitoring the Performance of National Food Control Systems	<u>REP15/FICS</u> , para. 36, App. IV	2019	1.4	Any relevant expert advice will be taken into account	CCFICS19 and CCFICS 20 started the discussions and this was also followed by discussions through a EWG and two informal workshops to gain better understanding of the issues. There was support for the work by CCFICS21, noting the need to limit the scope to self evaluation of a country's food control system and develop general guidance in this area. The Committee also noted that there had not been enough time to gain ample experience with the implementation of <i>Principles and Guidelines for National Food Control Systems</i> (CAC/GL 82-2013), but that several countries had already started working on monitoring their national food control systems and that it would be useful to have a consistent framework and understanding of the terminology used in this regard.
<i>Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations</i> (CAC/GL 19-1995) (Revision)	<u>REP15/FICS</u> para. 46, App. V	2019	1.4	Any relevant expert advice will be taken into account	CCFICS21 generally supported the proposal for new work as it is intended to update the document to address gaps as competent authorities needed a comprehensive document for use in emergency situations. The revision will also consider the previous recommendations with regards to the appropriateness of the inclusion of feed in this document as well as relevant guidance produced by FAO and WHO, EMPRES and INFOSAN.
<i>Guidelines for the Exchange of Information between Countries on Rejections of Imported Food</i> (CAC/GL 25-1997) (Revision)	<u>REP15/FICS</u> , para. 54, App. VI	2019	1.4	Any relevant expert advice will be taken into account	CCFICS21 supported the proposal to revise the guidelines to address animal feeding but also noted that this was not possible without a more complete revision. The revision will take into consideration other Codex texts and consideration of

² "Target Year": the year by which the text is to be adopted at Step 8, as agreed by the Commission on the basis of the project document (from 2004 onwards), or the date specified by the Committee, where applicable.

"Output Codes": the following codes are used: 1.1: Review and develop Codex standards and related texts for food safety; 1.2: Review and develop Codex standards and related texts for food quality; 1.3: Review and develop Codex standards and related texts for food labelling and nutrition; 1.4: Review and develop Codex standards and related texts for food inspection and certification, and methods of sampling and analysis.

Explanatory Notes: includes specific issues only for relevant provisions and the status of endorsement when applicable. There are no comments when no specific problems exist as regards the criteria mentioned in the Critical Review or other related issues.

Committee on Food Import and Export Inspection and Certification Systems (21 st Session, 13-17 October 2014)	Timeframe		Output Codes	Scientific Advice	Explanatory Notes
	Reference and project document	Target Year			
					issues like exchange of information and other identified challenges. Although there were some concerns that the proposal had been developed only during the session the Committee acknowledged that it was important to proceed with the review in a timely manner to ensure that the Guideline can achieve its purpose of providing adequate guidance to competent authorities on the exchange of information on rejected food/feed.

Comments by the Chairperson/host country:

The Committee is submitting four proposals for new work, as you will note by the explanatory notes there has been a lot of preparatory work done by the Committee and informally to ensure that the members are ready to commence new work in these areas. Australia as the host country will continue to support the work of this committee through the use of both electronic and physical working groups, workshops and seminars. Whilst we acknowledge first priority should be given to working electronically the use of the time between sessions of the committee can be maximised by including where possible opportunities for physical face to face discussions.

The Committee will also need to examine in the future whether there is a role for it in respect of the obligations for members in respect of the new Trade Facilitation Agreement and its implementation.

Committee on Nutrition and Food for Special Dietary Uses (36 th Session, 24-28 November 2014)	Timeframe		Output Codes	Scientific Advice	Explanatory Notes
	Reference and project document	Target Year			
Definition on Biofortification	REP15/NFSDU, para. 165, App. VII	2016	1.3	None required	This work entails the development of a harmonized definition for biofortification to bring clarity to the subject of biofortification for possible inclusion in the <i>General Principles for the Addition of Essential Nutrients to Foods</i> (CAC/GL 9-1987) or other Codex texts. The project document needs to provide more information on: Section 1 "Purpose and Scope of the Standard" and in particular to clarify how this proposed work relates to Codex work and the gaps that it would address; Section 6 "Relation between the proposal and other existing Codex documents" and in particular clarify how the proposed definition will be used in Codex and consequentially where it would be best placed.
NRV-NCD for EPA and DHA Long Chain Omega-3 Fatty Acids	REP15/NFSDU, para. 191, App. IX	2016	1.3	Available scientific advice identified in discussion paper	

Comments by the Chairperson/host country:

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FAO/WHO Coordinating Committee for Africa (21 st Session, 27-30 January 2015)	Timeframe		Output Codes	Scientific Advice	Explanatory Notes
	Reference and project document	Target Year			
Regional Standard for Dried Meat	<u>REP15/AFRICA</u> , para. 62, App. II	2019	1.1/1.2	None required	<p>During CCAFRICA21, the Codex Secretariat said that: dried meat was produced in most countries of the world and it might be difficult to define a product standard covering all different production processes; it was important for the project document to focus on the problem that should be addressed which seemed to be mainly hygiene issues and proposed that the CCAFRICA could consider requesting CCEXEC in its critical review process how to most appropriately address the issues related to dried meat production and trade (e.g. a code of hygienic practice or a standard).</p> <p>CCAFRICA agreed to refocus the project document on the development of a regional standard and to propose the new work to CAC38.</p> <p>The project document needs to provide more information on:</p> <p>Section 3 “Its relevance and timeliness” in particular the problem that the proposed new work intends to address (e.g. hygiene measures for dried meat; quality provisions) and whether these problems are related to products traded in the African region only;</p> <p>Section 5 (a) “Volume of production and consumption in individual countries and volume and patterns of trade between countries” and in particular provide data on volume of trade for this product;</p> <p>Section 5 (b) “Diversification of national legislation and apparent resultant or potential impediments to regional trade” and in particular existence of diverse national legislation and information on impediments to trade;</p> <p>Section 7: “Information on relation between the proposal and other existing Codex texts” in particular with texts such as <i>Code of Hygienic Practice for Meat</i> (CAC/RCP 58-2005), <i>Guidelines for the Control of Campylobacter and Salmonella in Chicken Meat</i> (CAC/GL 78-2011) and <i>Guidelines for the Control of Taenia Saginata in Meat of Domestic Cattle</i> (CAC/GL 85-2014) in order to avoid duplication.</p>
Regional Standard for Fermented Cooked Cassava Based Products	<u>REP15/AFRICA</u> , para. 64, App. III	2019	1.1/1.2	JECFA would need to determine the ADI for the hydrogen cyanide content.	When developing the regional standard, CCAFRICA will need to take into account other Codex texts such as <i>Standard for Gari</i> (CODEX STAN 151-1985) and the <i>Code of Practice for the Reduction of Hydrocyanic Acid (HCN) in Cassava and Cassava Products</i> (CAC/RCP 73-2013).

FAO/WHO Coordinating Committee for Africa (21 st Session, 27-30 January 2015)	Timeframe		Output Codes	Scientific Advice	Explanatory Notes
	Reference and project document	Target Year			
Regional Standard for Shea butter	<u>REP15/AFRICA</u> , para. 66, App. IV	2019	1.2	-	
Regional Standard for <i>Gnetum</i> Spp Leaves	<u>REP15/AFRICA</u> , para. 67, App. V	2019	1.2	It would be desirable to undertake further analysis of bitterness of some <i>Gnetum</i> varieties	
<u>Comments by the Chairperson/host country:</u> Comments received after 20 May will be compiled in CX/EXEC 15/70/4 Add.1.					

Committee on Fats and Oils (24 th Session, 9-13 February 2015)	Timeframe		Output Codes	Scientific Advice	Explanatory Notes
	Reference and project document	Target Year			
Addition of Palm Oil with High Oleic Acid (OxG) to the <i>Standard for Named Vegetable Oils</i> (CODEX STAN 210-1999) (Revision)	<u>REP15/FO</u> , para. 89, App. VI	2019	1.2	Available	
- 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)	<u>REP15/FO</u> , para. 87, App. VI	2017	1.2	None identified	
Revision of the Limit for Campesterol to the <i>Standard for Olive Oils and Olive Pomace Oils</i> (CODEX STAN 33-1981) (Revision)	<u>REP15/FO</u> , para. 118, App. VIII	2017	1.2	None identified	
<u>Comments by the Chairperson/host country:</u> Comments received after 20 May will be compiled in CX/EXEC 15/70/4 Add.1.					

Committee on Contaminants in Foods (9 th Session, 16-20 March 2015)	Timeframe		Output Codes	Scientific Advice	Explanatory Notes
	Reference and project document	Target Year			
Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Spices	<u>REP15/CF</u> , para. 143, App. VIII	2018	1.1		This work will take into account relevant Codex texts such as those developed by CCFH e.g. <i>Code of Hygienic Practice for Spices and Dried Aromatic Herbs</i> . All relevant information necessary to proceed with the development of the COP has been identified through the elaboration of discussion papers prior to taking a decision to recommend new work. This work will support establishment of MLs for mycotoxins in spices.

Committee on Contaminants in Foods (9 th Session, 16-20 March 2015)	Timeframe		Output Codes	Scientific Advice	Explanatory Notes
	Reference and project document	Target Year			
Comments by the Chairperson/host country: Comments received after 20 May will be compiled in CX/EXEC 15/70/4 Add.1.					

Committee on Food Additives (47 th Session, 16-20 March 2015)	Timeframe		Output Codes	Scientific Advice	Explanatory Notes
	Reference and project document	Target Year			
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)	<u>REP15/FA</u> , para. 92, App. XI	2016 /2017	1.1/1.2	None identified	
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)	<u>REP15/FA</u> , para. 164, App. XIV	2016 /2017	1.1/1.2	None identified	
Comments by the Chairperson/host country: Comments received after 20 May will be compiled in CX/EXEC 15/70/4 Add.1.					

Committee on Pesticide Residues (47 th Session, 13-18 April 2015)	Timeframe		Output Codes	Scientific Advice	Explanatory Notes
	Reference and project document	Target Year			
Establishment of Codex schedules and priority list of pesticides for evaluation by JMPR	<u>REP15/PR</u> , para. 158, App. XII	Ongoing work	1.1	JMPR ongoing	The approval of the Codex schedules and priority list of pesticides for evaluation by JMPR constitutes the Steps 1/2/3 in the development of Codex MRLs for pesticides. It is done in close collaboration with the FAO and WHO JMPR Secretariats to ensure sustainability and availability of scientific advice for the compounds proposed for evaluation / re-evaluation.
Comments by the Chairperson/host country: Support.					

Committee on Residues of Veterinary Drugs in Foods (22 nd Session, 27 April – 1 May 2015)	Timeframe		Output Codes	Scientific Advice	Explanatory Notes
	Reference and project document	Target Year			
Priority List of Veterinary Drugs requiring Evaluation or re-evaluation by JECFA	REP15/RVDF, para. 112, App. VIII	ongoing work	1.1	JECFA	Some of the substances in the Priority List have been included in an additional Call for Data for the 81 st JECFA (November 2015)
<p><u>Comments by the Chairperson/host country:</u> This priority list represents one of the best interactions with the JECFA Secretariats to put forward on the priority list only those drugs where dossiers are ready for submission to JECFA and to look at future possible drugs for the priority list to enable JECFA plan for future work. As the Chair, I was very impressed with the work the Committee did in this session to really partner with JECFA to plan work.</p>					

Committee on Milk and Milk Products (working electronically)	Timeframe		Output Codes	Scientific Advice	Explanatory Notes
	Reference and project document	Target Year			
Standard for Dairy Permeate Powders	See Annex 1	2017	1.2	None is required	The report of the CCMMP EWG on new work on the Standard for Dairy permeate products is attached as Annex 2.
<p><u>Comments by the Chairperson/host country:</u> As agreed by the 37th session of the CAC, an electronic working group (EWG) led by Denmark and New Zealand, has been working on the revision of the draft Project Document for the development of a Codex Standard for Dairy Permeate Powders. Some 25 countries, 1 member organization and 3 non-governmental organizations participated in the EWG. The revised project document accurately reflects the comments and feedback submitted by members of the EWG. Significant amendments were made to broaden the scope of the standard to include a wider range of permeate products on the market – hence the amended title, Dairy Permeate Powders. Substantive changes were also made to include more information on trade, international and regional market potential and the amenability of these products to standardisation. As chair and host government of CCMP, New Zealand believes that the Project Document meets the Commission's criteria for new work and recommends its approval.</p>					

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.

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.

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>

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

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.

Data provided by the International Dairy Federation (IDF) (Figures in metric tonnes)	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.

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 permeates 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.

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

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

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 carcinogenicity⁶. 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.

Amenability of the commodity to standardization⁸

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 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.

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.

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.

- *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.

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.

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

Annex 2**DAIRY PERMEATE POWDERS: REPORT OF THE ELECTRONIC WORKING GROUP****Introduction**

1. Denmark submitted a proposal for new work on a standard for whey permeate powder to the 69th Session of the CCEXEC. The 37th CAC endorsed the recommendation of the CCEXEC and established a EWG, led by Denmark and co-chaired by New Zealand, and working in English only, to revise the project document for submission through the Committee on Milk and Milk Products (CCMMP) at the 38th Session of the Commission and the CCEXEC 70.
2. A total number of 25 member countries, 1 member organization (EU) and 3 non-governmental observer organizations registered to participate in the working group.¹
3. A 1st draft of the revised project document was sent for comments to all participants in September 2014. Responses were received from 8 member countries, 1 member organization (EU) and 2 observer organizations.
4. The chair and the co-chair reviewed all the comments received and amended the draft project document.
5. A 2nd draft of the project document was circulated for comments to all participants in December 2014. Responses were received from 9 member countries. The 2nd draft project document was widely supported by the EWG members with the result that the draft was subject to minor amendments only.
6. The final report and the project document were submitted to the CCMMP at the end of March 2015.

Summary of discussionsThe scope of the standard

7. From the comments received, it turned out that there was a need for extending the scope to include other permeate products rich in lactose. Consequently, the scope of the project document has been extended to Dairy Permeate Powders as a descriptor for generic products, having in common that they are manufactured by drying permeates and similar products obtained from lactose-containing liquid raw materials such as milk, cream, sweet buttermilk and/or whey, and with the sub-categories milk permeate powder and whey permeate powder. This will allow for a broader spectrum of permeate powders while ensuring that more narrow provisions are established for specific permeate powders such as whey permeate powder and milk permeate powder. The extended scope includes milk permeate powder and whey permeate powder as well as mixes of permeates of different origins under the umbrella heading "dairy permeate powder".
8. One member expressed concerns as to whether this approach may lead to the use of, for example, whey permeate powder (rather than or in addition to milk permeate) as a means to standardize the protein content of milk powder and cream powder, sweetened condensed milk and evaporated milks. This concern will be addressed in the standard by the inclusion of specific definitions of whey permeate powder and milk permeate powder, the latter being based on the definition of milk permeate as it appears in the three milk product standards mentioned. By doing so there will be no risk that permeates other than milk permeate will become acceptable ingredients in these products.
9. Another member has requested to include only milk permeate and whey permeate as raw materials (thus excluding sweet butter milk, cream, etc.) for dairy permeate powder. However, this request has not been followed, as the broader scope included in the project document has been generally supported by the EWG because such scope takes into consideration future market developments for permeate powders made from already available and appropriate liquid raw materials with significant lactose contents.
10. A member suggested that it should be possible to produce whey permeate powder from a mix of whey permeate and milk permeate. However, this suggestion has not been followed because comments from other members indicate that such an approach could not be generally supported. Nevertheless, this could be further discussed during the drafting of the standard.
11. Finally, consideration has also been given to including other whey based products such as whey protein concentrates and whey protein isolates within the scope. However, these products were not included as they are different in nature from permeate powders and not characterized by high lactose content.

Relevance and Timeliness

12. On the request of the EWG members, the description of the relevance and timeliness of the standard for dairy permeate powders has been clarified thus providing further details on history and trade issues supporting the need to establish a Codex standard covering the identity, composition, labelling and quality that will apply as a reference in trade.

¹ Argentina, Australia, Austria, Brazil, Canada, European Union France, Germany, India, Indonesia, Iran, Ireland, Japan, Republic of Korea, Lithuania, Mexico, Netherlands, New Zealand, Norway, Poland, Russia, Spain, Switzerland, Thailand, United Kingdom, United States of America, European Whey Products Association, International Alliance of Dietary/Food Supplement Associations, International Dairy Federation.

Main aspects to be covered

13. The EWG supported a suggestion to address in the standard product modifications such as partial demineralization. A suggestion to change the name "Dairy Permeate Powders" into "Lactose rich deproteinized dairy powders" has not been followed because such a name is too distinct from the well-established trade names. However, such a name could be considered as an alternative name during the drafting of the labelling section of the standard.

Assessment against criteria

14. The International Dairy Federation has kindly provided data on the production and trade in dairy permeate powders.

15. The EWG noted the existing trade in related products manufactured from the same raw materials using similar materials but traded under different names. It is proposed that difficulties in continuing trade with such products, if any, be brought up for consideration during the drafting of the standard.

16. With regard to the description of the market potential, more details on the nutritional benefits have been included.

17. A considerable part of the discussion in the EWG was devoted to which compositional requirements should be specified in the standard. There is a consensus to include specifications for minimum lactose content and for maximum content of protein, milk fat, ash and water, but the EWG did not conclude on detailed limits. Compositional requirements will be one of the essential elements of the standard. When the drafting of the standard begins, it would be appropriate to present requirements in a table format.

18. With regard to additives, it has been included in the revised project document that the intent is to identify the technologically justified functional classes, and to develop a list of appropriate individual additives within these classes for submission to CCFA for the inclusion in the GSFA.

19. Consideration has been given to the inclusion of this new group of products into the existing standard for whey powders, rather than establishing a separate standard. However, the change in scope, i.e. to aim for a standard for dairy permeate powders, makes it inappropriate to incorporate them into the standard for whey powders.

Recommendation

20. It is recommended to note that the work of the EWG has been accomplished with a general consensus on the project document on dairy permeate powders.

21. It is recommended that the report and the project document be submitted for endorsement at the 38th CAC with a view to start the drafting of a standard for dairy permeate powders as outlined in the project document.