



GRAS Notice (GRN) No. 504

<http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/default.htm>

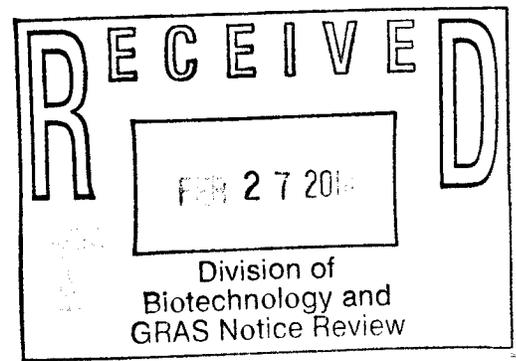
Original Submission

ORIGINAL SUBMISSION

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GRN000504



Writer's Direct Access  
**Richard F. Mann**  
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February 19, 2014

**Via U.S. Postal Service**

Moraima J. Ramos Valle, M.S.  
Consumer Safety Officer  
Division of Biotechnology and GRAS Notice Review (HFS-225)  
Office of Food Additive Safety  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Pkwy  
College Park, MD 20740

**Re: GRAS Notification for Concentrated Milk Proteins: Milk Protein Concentrate (MPC) and Milk Protein Isolate (MPI)**

Dear Ms. Ramos Valle:

We respectfully submit the attached GRAS Notification on behalf of our clients, the American Dairy Products Institute (ADPI) and the U.S. Dairy Export Council (USDEC), for the concentrated milk proteins: milk protein concentrate (MPC) and milk protein isolate (MPI) for use as food ingredients for functional or nutritional purposes in multiple food applications.

Per your instructions, we are submitting three (3) hard copies of the GRAS Notification and FORM FDA 3667.

We look forward to the Agency's review of this submission and we would be happy to provide you with any further information you may need.

Sincerely,

(b) (6)

Richard F. Mann

Enclosure

**FDA USE ONLY**

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration  
**GENERALLY RECOGNIZED AS SAFE  
(GRAS) NOTICE**

GRN NUMBER	DATE OF RECEIPT
ESTIMATED DAILY INTAKE	INTENDED USE FOR INTERNET
NAME FOR INTERNET	
KEYWORDS	

Transmit completed form and attachments electronically via the Electronic Submission Gateway (see Instructions); OR Transmit completed form and attachments in paper format or on physical media to: Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835.

**PART I – INTRODUCTORY INFORMATION ABOUT THE SUBMISSION**

1. Type of Submission (Check one)

New       Amendment to GRN No. \_\_\_\_\_       Supplement to GRN No. \_\_\_\_\_

2.  All electronic files included in this submission have been checked and found to be virus free. (Check box to verify)

3a. For New Submissions Only: Most recent presubmission meeting (if any) with FDA on the subject substance (yyyy/mm/dd): 2013/11/21

3b. For Amendments or Supplements: Is your amendment or supplement submitted in response to a communication from FDA? (Check one)  
 Yes If yes, enter the date of communication (yyyy/mm/dd): \_\_\_\_\_  
 No

**PART II – INFORMATION ABOUT THE NOTIFIER**

<b>1a. Notifier</b>	Name of Contact Person Dan Meyer/Veronique LaGrange	Position Dir. of Technical Services/Sr. VP, Strategy & Insig
	Company (if applicable) American Dairy Products Institute (ADPI) /U.S. Dairy Export Council (USDEC)	
	Mailing Address (number and street) 126. N. Addison Avenue/2101 Wilson Boulevard, Suite 400	
	City Elmhurst/Arlington	

State or Province IL/VA	Zip Code/Postal Code 60126/22201	Country United States of America
Telephone Number (202) 434-4229	Fax Number (202) 434-4646	E-Mail Address dmeyer@adpi.org/vlagrange@usdec.org

<b>1b. Agent or Attorney (if applicable)</b>	Name of Contact Person Richard F. Mann	Position Partner
	Company (if applicable) Keller and Heckman LLP	
	Mailing Address (number and street) 1001 G Street NW, Suite 500W	

State or Province District of Columbia	Zip Code/Postal Code 20001	Country United States of America
Telephone Number (202) 434-4229	Fax Number (202) 434-4646	E-Mail Address mann@khlaw.com

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**PART III – GENERAL ADMINISTRATIVE INFORMATION**

1. Name of Substance

Milk protein concentrate (MPC) and milk protein isolate (MPI)

2. Submission Format: (Check appropriate box(es))

- Electronic Submission Gateway  Electronic files on physical media with paper signature page  
 Paper  
If applicable give number and type of physical media

3. For paper submissions only:

Number of volumes 1

Total number of pages 22

4. Does this submission incorporate any information in FDA's files by reference? (Check one)

- Yes (Proceed to Item 5)  No (Proceed to Item 6)

5. The submission incorporates by reference information from a previous submission to FDA as indicated below (Check all that apply)

- a) GRAS Notice No. GRN \_\_\_\_\_  
 b) GRAS Affirmation Petition No. GRP \_\_\_\_\_  
 c) Food Additive Petition No. FAP \_\_\_\_\_  
 d) Food Master File No. FMF \_\_\_\_\_  
 e) Other or Additional (describe or enter information as above) \_\_\_\_\_

6. Statutory basis for determination of GRAS status (Check one)

- Scientific Procedures (21 CFR 170.30(b))  Experience based on common use in food (21 CFR 170.30(c))

7. Does the submission (including information that you are incorporating by reference) contain information that you view as trade secret or as confidential commercial or financial information?

- Yes (Proceed to Item 8)  
 No (Proceed to Part IV)

8. Have you designated information in your submission that you view as trade secret or as confidential commercial or financial information (Check all that apply)

- Yes, see attached Designation of Confidential Information  
 Yes, information is designated at the place where it occurs in the submission  
 No

9. Have you attached a redacted copy of some or all of the submission? (Check one)

- Yes, a redacted copy of the complete submission  
 Yes, a redacted copy of part(s) of the submission  
 No

**PART IV – INTENDED USE**

1. Describe the intended use of the notified substance including the foods in which the substance will be used, the levels of use in such foods, the purpose for which the substance will be used, and any special population that will consume the substance (e.g., when a substance would be an ingredient in infant formula, identify infants as a special population).

MPC and MPI will be used as food ingredients in a variety of food categories.

The level of incorporation depends on the specific type of MPC or MPI (described with respect to protein content in the GRAS Notification), as well as the food category in which the ingredient is used. Intended uses, applications, and levels of incorporation are detailed in Table 4 of the GRAS Notification.

Depending on the food category in which MPC and MPI are used, these substances are intended to serve as emulsifiers, flavor enhancers, flavoring agents, formulation aids, humectants, stabilizers and thickeners, and sources of high-quality protein.

Foods containing MPC and MPI will be consumed by the general population, i.e., adults and children (1 year and older).

2. Does the intended use of the notified substance include any use in meat, meat food product, poultry product, or egg product? (Check one)

- Yes  No

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**PART V – IDENTITY**

**1. Information about the Identity of the Substance**

	Name of Substance <sup>1</sup>	Registry Used (CAS, EC)	Registry No. <sup>2</sup>	Biological Source (if applicable)	Substance Category (FOR FDA USE ONLY)
1	Milk protein concentrate (MPC)				
2	Milk protein isolate (MPI)				
3					

<sup>1</sup> Include chemical name or common name. Put synonyms (*whether chemical name, other scientific name, or common name*) for each respective item (1- 3) in Item 3 of Part V (*synonyms*)

<sup>2</sup> Registry used e.g., CAS (*Chemical Abstracts Service*) and EC (*Refers to Enzyme Commission of the International Union of Biochemistry (IUB), now carried out by the Nomenclature Committee of the International Union of Biochemistry and Molecular Biology (IUBMB)*)

**2. Description**

Provide additional information to identify the notified substance(s), which may include chemical formula(s), empirical formula(s), structural formula(s), quantitative composition, characteristic properties (*such as molecular weight(s)*), and general composition of the substance. For substances from biological sources, you should include scientific information sufficient to identify the source (*e.g., genus, species, variety, strain, part of a plant source (such as roots or leaves), and organ or tissue of an animal source*), and include any known toxicants that could be in the source.

Milk Protein Concentrate (MPC) and Milk Protein Isolate (MPI) are substances obtained by the partial removal of non-protein constituents (lactose and minerals) from skim milk such that the finished dry product contains 42% or more protein by weight (for MPC) or 90% or more protein by weight (for MPI). Several different MPC and MPI products are commercially available, each of which is identified by a number that represents the protein content of the product, e.g., MPC42 contains 42% protein by weight. MPC and MPI may be produced by filtration (Microfiltration, Ultrafiltration & Diafiltration), dialysis, or by any other safe and suitable process in which all or part of the lactose may be removed. The concentrated milk proteins are made available for commercial purposes as a free flowing, off-white to light tan colored powder.

**3. Synonyms**

Provide as available or relevant:

1	Collectively referred to as "concentrated milk proteins"
2	
3	

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**PART VI – OTHER ELEMENTS IN YOUR GRAS NOTICE**  
(check list to help ensure your submission is complete – check all that apply)

- Any additional information about identity not covered in Part V of this form
- Method of Manufacture
- Specifications for food-grade material
- Information about dietary exposure
- Information about any self-limiting levels of use (which may include a statement that the intended use of the notified substance is not-self-limiting)
- Use in food before 1958 (which may include a statement that there is no information about use of the notified substance in food prior to 1958)
- Comprehensive discussion of the basis for the determination of GRAS status
- Bibliography

**Other Information**

Did you include any other information that you want FDA to consider in evaluating your GRAS notice?

Yes  No

Did you include this other information in the list of attachments?

Yes  No

**PART VII – SIGNATURE**

1. The undersigned is informing FDA that ADPI and USDEC

(name of notifier)

has concluded that the intended use(s) of Milk protein concentrate (MPC) and milk protein isolate (MPI)

(name of notified substance)

described on this form, as discussed in the attached notice, is (are) exempt from the premarket approval requirements of section 409 of the Federal Food, Drug, and Cosmetic Act because the intended use(s) is (are) generally recognized as safe.

2.  ADPI and USDEC (name of notifier) agrees to make the data and information that are the basis for the determination of GRAS status available to FDA if FDA asks to see them.

ADPI and USDEC (name of notifier) agrees to allow FDA to review and copy these data and information during customary business hours at the following location if FDA asks to do so.

Keller and Heckman LLP, 1001 G Street NW, Suite 500W, Washington, DC 20001  
(address of notifier or other location)

ADPI and USDEC (name of notifier) agrees to send these data and information to FDA if FDA asks to do so.

OR

The complete record that supports the determination of GRAS status is available to FDA in the submitted notice and in GRP No.

(GRAS Affirmation Petition No.)

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3. Signature of Responsible Official,  
Agent, or Attorney

(b) (6)

Printed Name and Title

Richard F. Mann, Partner

Date (mm/dd/yyyy)

02/19/2014

## PART VIII – LIST OF ATTACHMENTS

List your attached files or documents containing your submission, forms, amendments or supplements, and other pertinent information. Clearly identify the attachment with appropriate descriptive file names (or titles for paper documents), preferably as suggested in the guidance associated with this form. Number your attachments consecutively. When submitting paper documents, enter the inclusive page numbers of each portion of the document below.

Attachment Number	Attachment Name	Folder Location (select from menu) (Page Number(s) for paper Copy Only)
	Cover letter to Moraima Ramos-Valle	N/A
	GRAS Notification for Concentrated Milk Proteins: Milk Protein Concentrate (MPC) and Milk Protein Isolate (MPI)	Pages 1-18

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**OMB Statement:** Public reporting burden for this collection of information is estimated to average 150 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, Room 400, Rockville, MD 20850. (Please do NOT return the form to this address.). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

**GRAS Notification for Concentrated Milk  
Proteins: Milk Protein Concentrate (MPC) and Milk  
Protein Isolate (MPI)**

Prepared for: U.S. Food and Drug Administration  
Office of Food Additive Safety (HFS-200)  
Center for Food Safety and Applied Nutrition  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

Prepared by: Keller and Heckman LLP  
1001 G Street, NW  
Suite 500W  
Washington, DC 20001

Date: February 19, 2014

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## **Figures**

Figure 1	Manufacturing Process Flow Chart
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## **Appendices**

Appendix 1	Five-batch analysis on MPC70 and MPI
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## **I. Introduction**

Keller and Heckman LLP submits the enclosed information on behalf of our clients, the American Dairy Products Institute (ADPI) and the U.S. Dairy Export Council (USDEC), in support of this notification that the concentrated milk proteins: milk protein concentrate (MPC) and milk protein isolate (MPI) are generally recognized as safe (GRAS) for use in multiple food applications. As detailed below, these products are manufactured using very similar processes. We refer to these products collectively as “concentrated milk proteins” throughout the document, unless otherwise specified.

The concentrated milk proteins are intended for use as food ingredients for functional or nutritional purposes in the following foods, which are intended for consumption by adults and children (1 year and older): Meal Replacements and Meal Supplements; Powdered Nutritional Beverages; Nutritional Bars; Milk Products (including dairy beverages); Yogurt and Fermented Milk Products; Non Standardized Cheese Products; Spreads, Dips, and Cream Substitutes; Frozen Dairy Desserts and Mixes; Desserts and Mousses; Confections (including chocolate confections); Snack Foods; Coatings and Fillings; Salad Dressings; and Soups, Soup Mixes, and Sauces. In each food category, the concentrated milk proteins will be used where permitted, and within limits permitted, by existing standards of identity or any other applicable regulations. This GRAS Notification does not cover the use of the concentrated milk proteins in infant formula or in meat/poultry products.

We submit information in the following areas:

- The identity and specifications for the concentrated milk proteins;
- The manufacturing process for the concentrated milk proteins;
- The intended uses and an estimation of consumption of the concentrated milk proteins; and
- Supportive evidence from the long history of safe use of milk and milk protein as food.

It is our expectation that FDA will concur that the information presented fully supports the determination that the concentrated milk proteins as produced by the members of ADPI and USDEC are GRAS for use as food ingredients.

## **II. Administrative Information**

### **A. Claim Regarding GRAS Status**

ADPI and USDEC have determined that concentrated milk proteins – milk protein concentrate (MPC) and milk protein isolate (MPI) – are GRAS for use in a variety of food categories based on scientific procedures in accordance with 21 C.F.R. § 170.30(b) and in conformance with the guidance issued by FDA under proposed 21 C.F.R. § 170.36, 62 Fed. Reg. 18938 (Apr. 17, 1997). The analytical data, published studies, and information that are the basis

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for this GRAS determination are available for FDA review and copying at reasonable times at Keller and Heckman LLP, 1001 G Street, NW, Suite 500W, Washington, DC 20001, or will be sent to FDA upon request.

B. Name and Address of the Notifiers

American Dairy Products Institute	and	U.S. Dairy Export Council
126 N. Addison Avenue		2101 Wilson Boulevard, Ste 400
Elmhurst, IL 60126		Arlington, VA 22201

All communications on this matter are to be sent to Counsel for the Notifiers:

Richard F. Mann  
Keller and Heckman LLP  
1001 G Street, NW  
Suite 500W  
Washington, DC 20001  
Telephone: (202) 434-4229  
Facsimile: (202) 434-4646  
Email: mann@khlaw.com

C. Common or Usual Name of GRAS Substance

The common or usual names for the GRAS ingredients are “milk protein concentrate (MPC)” and “milk protein isolate (MPI),” referred to collectively in this document as “concentrated milk proteins.”

D. Intended Use of GRAS Substance

The concentrated milk proteins will be used as food ingredients in a variety of food categories at levels up to those outlined in **Table 4**. Depending on the food category in which the concentrated milk proteins are used, these substances are intended to serve as: emulsifiers, flavor enhancers, flavoring agents, formulation aids, humectants, stabilizers and thickeners, texturizers, and sources of high-quality protein. Foods containing the concentrated milk proteins will be consumed by the general population (adults and children).

E. Self-Limiting Levels of Use

The use of the concentrated milk proteins as food ingredients is limited by the level that can technically be added to a given food without jeopardizing its quality and consumer acceptability.

**III. Product Identity and Specifications**

The concentrated milk proteins will be marketed under the following names: milk protein concentrate (MPC) and milk protein isolate (MPI). These products have similar compositions with different levels of protein, fat, and carbohydrate. The products share the same

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microbiological characteristics, and they are manufactured using very similar processes, as detailed further below.

A. Product Identification

Milk Protein Concentrate (MPC) and Milk Protein Isolate (MPI) are substances obtained by the partial removal of non-protein constituents (lactose and minerals) from skim milk such that the finished dry product contains 42% or more protein by weight (for MPC) or 90% or more protein by weight (for MPI). Several different MPC and MPI products are commercially available, each of which is identified by a number that represents the protein content of the product, e.g., MPC42 contains 42% protein by weight. MPC and MPI may be produced by filtration (Microfiltration, Ultrafiltration & Diafiltration), dialysis, or by any other safe and suitable process in which all or part of the lactose may be removed. The manufacturing techniques employed to concentrate protein and to remove non-protein constituents from milk are based primarily on the use of membrane filtration technologies, as listed in 21 C.F.R. § 177.2910 (“Ultra-filtration membranes”). All membrane materials employed in the production of concentrated milk proteins comply with applicable food-contact regulations, and the use of such technologies complies with cGMP for food (21 C.F.R. Part 110). The concentrated milk proteins are made available for commercial purposes as a free flowing, off-white to light tan colored powder.

B. Product Specifications

**Tables 1 and 2** provide typical composition and microbiological and lead specifications for various concentrated milk proteins and their test methods.

**Table 1. Typical Product Specifications for Concentrated Milk Proteins**

	<b>MPC42</b>	<b>MPC56</b>	<b>MPC70</b>	<b>MPC85</b>	<b>MPI</b>	<b>Test method</b>
<b>Protein %</b>	40.0 - 44.0	54.0 - 58.0	68.0 - 72.0	83.0 - 87.0	90.0 - 94.0	AOAC 991.20 or Standard Methods 15.131
<b>Fat %</b>	0.8 - 1.2	0.9 - 1.3	1.0 - 1.4	1.2 - 1.6	0.3 - 0.7	AOAC 989.05 or Standard Methods 15.086
<b>Lactose %</b>	45.0 - 49.0	30.0 - 34.0	16.0 - 20.0	1.0 - 5.0	0.5 - 1.2	Standard Methods 15.091 or by difference
<b>Ash %</b>	6.2 - 6.8	6.5 - 7.1	6.5 - 7.1	6.3 - 6.9	5.1 - 5.7	AOAC 945.46 or Standard Methods 15.041
<b>Moisture %</b>	3.2 - 3.8	3.8 - 4.4	3.7 - 4.3	3.5 - 4.1	3.0 - 3.6	AOAC 927.05 or Standard Methods 15.111

**Table 2. Typical Microbiological and Lead Specifications for Concentrated Milk Proteins<sup>1</sup>**

<b>Parameter</b>	<b>Specification</b>	<b>Test method</b>
Standard Plate Count	< 30,000 cfu/g	AOAC 989.10
<i>Coliform</i>	< 10 cfu/g	AOAC 989.10
<i>E coli</i>	< 10 cfu/g	AOAC 989.10
<i>Salmonella</i>	Neg/375 g	AOAC 2003.09
Yeast and Molds	< 50 cfu/g	AOAC 997.02
<i>Listeria monocytogenes</i>	Neg/25 g	AOAC 997.03
<i>Staphylococcus aureus</i>	< 10 cfu/g	AOAC 2003.08
Lead	< 1 ppm	FSNC(ICP-OES)

Five-batch analysis was performed on MPC70 and MPI (Appendix 1).

#### **IV. Manufacturing Process**

**Figure 1** provides a step-by-step illustration of the manufacturing process, which we also describe in detail below.

The concentrated milk proteins are manufactured from skim milk in accordance with current Good Manufacturing Practices (cGMP) for food (21 C.F.R. Part 110). The manufacture of the concentrated milk proteins typically does not involve organic solvents or enzymes, although some manufacturers may use low levels of the enzyme lactase in the production process. When lactase is used, the enzyme preparation complies with the GRAS affirmation regulation in 21 C.F.R. § 184.1388 (“Lactase enzyme preparation from *Kluyveromyces lactis*”). The source organism is the nonpathogenic, nontoxicogenic yeast *Kluyveromyces lactis*. Lactase is a naturally-occurring human enzyme used in the digestion of lactose in milk. When lactase is used in the production of concentrated milk proteins, the enzymes are rendered inactive during the drying process.

Manufacturers have significant flexibility with respect to the use of additives and ingredients in concentrated milk protein production. The food additives and ingredients that may be utilized in the manufacturing process for concentrated milk proteins are all either approved food additives or GRAS for their food applications and used in accordance with cGMP. Lecithin, potassium chloride, and sodium chloride are examples of three ingredients appropriately used in the production of commercial forms of concentrated milk proteins. For example, lecithin is used in the production of instantized ingredients. Lecithin is listed in 21 C.F.R. § 184.1400 as GRAS for use in food generally with no limitation other than cGMP. Sodium chloride (salt, NaCl) or potassium chloride (KCl) may be added in very small quantities during the diafiltration process to improve solubility of the final product. Salt is a common food ingredient and a GRAS

<sup>1</sup> All methods follow the Standard Methods for the Examination of Dairy Products.

substance (i.e., in 21 C.F.R. § 182.1). Potassium chloride is affirmed in 21 C.F.R. § 184.1622 as GRAS for use in food generally with no limitation other than cGMP.

To ensure pathogen control and compliance with regulatory limits in the finished product, the milk used to manufacture concentrated milk proteins is pasteurized in accordance with the provisions of the Pasteurized Milk Ordinance (PMO) at a minimum temperature of 145°F for a minimum time of 30 minutes or any other combination of time and temperature that satisfies PMO requirements. Alternatively, the concentrated milk proteins may be pasteurized in liquid form later in the manufacturing process, prior to spray drying.<sup>2</sup> Any other pasteurization process that is (or may come to be) recognized and accepted by FDA as being equally efficient as thermal pasteurization for the control of pathogens in milk may be employed for this purpose.

**Table 3. Pasteurization Temperature vs. Time**

<b>Temperature</b>	<b>Time</b>
63°C (145°F)	30 minutes
72°C (161°F)	15 seconds
89°C (191°F)	1.0 second
90°C (194°F)	0.5 seconds
94°C (201°F)	0.1 seconds
96°C (204°F)	0.05 seconds
100°C (212°F)	0.01 seconds

The manufacturing techniques employed to concentrate protein and to remove non-protein constituents from milk are based primarily on the use of membrane filtration technologies, as listed in 21 C.F.R. § 177.2910 (“Ultra-filtration membranes”). All membrane materials employed in the production of concentrated milk proteins comply with applicable food-contact regulations, and the use of such technologies complies with cGMP for food (21 C.F.R. Part 110). Semi-permeable membranes used in the production of concentrated milk proteins typically are rated at 10kDa to 300kDa Molecular Weight Cut-off (MWCO). Based on the combination of this membrane pore size and the fluid dynamics of processing a dairy stream such as skim milk, the effect is a concentration of fat, true protein, and any other large particles in the stream (suspended solids, extraneous material, bacteria, spores, etc.). The components that freely pass through the membrane are water, lactose, ash, and non-protein nitrogen (NPN). The result is a protein-enriched, lactose- and ash-reduced, concentrated milk protein. Depending on the level of concentration (or alternatively, the extent of the removal of lactose and ash relative to protein), the higher the protein level of concentrated milk proteins.

The raw material (skim milk) is circulated along a semi-permeable membrane in a pressure-driven process. The membrane is permeable to low molecular weight constituents (sugars, minerals, and other low molecular weight components) that pass through and form a permeate stream. High molecular weight constituents (protein and fat) are preferentially retained by the membrane and become components of the retentate stream. Two distinct semi-permeable

<sup>2</sup> Figure 1 does not depict the pasteurization step.

membrane processes are now employed as core technologies in the manufacture of concentrated milk proteins: ultrafiltration and microfiltration. Ultrafiltration facilitates the concentration of milk protein by the removal of low molecular weight constituents, such as lactose, minerals, and non-protein nitrogen components. Microfiltration includes a further fractionation step made possible through the physical partitioning of casein protein from whey protein.<sup>3</sup> Manufacturers may make small modifications to the casein/whey ratio when such modifications can improve functionality (for example, better heat stability or emulsification capability) or meet particular nutritional needs (for example, slow vs. fast proteins for nutritional beverages). The adjustment is minor and does not constitute a significant change in the nature of the product.

Sufficient lactose and minerals are removed into the permeate until the desired protein content is reached in the retentate stream. A diafiltration step may be included, wherein water is added to dilute the retentate in order to facilitate the removal of further quantities of minerals and lactose. Diafiltration is required for the production of MPI, and it is optional for any MPC product with a protein content exceeding 65%.

As indicated above, microfiltration may be used to affect changes in the partition of protein components between the retentate and permeate streams, thereby facilitating moderate adjustments to the ratio of casein to whey protein present in the finished product. Ancillary physical separation techniques may also be employed to optimize functional and compositional attributes of the finished product.

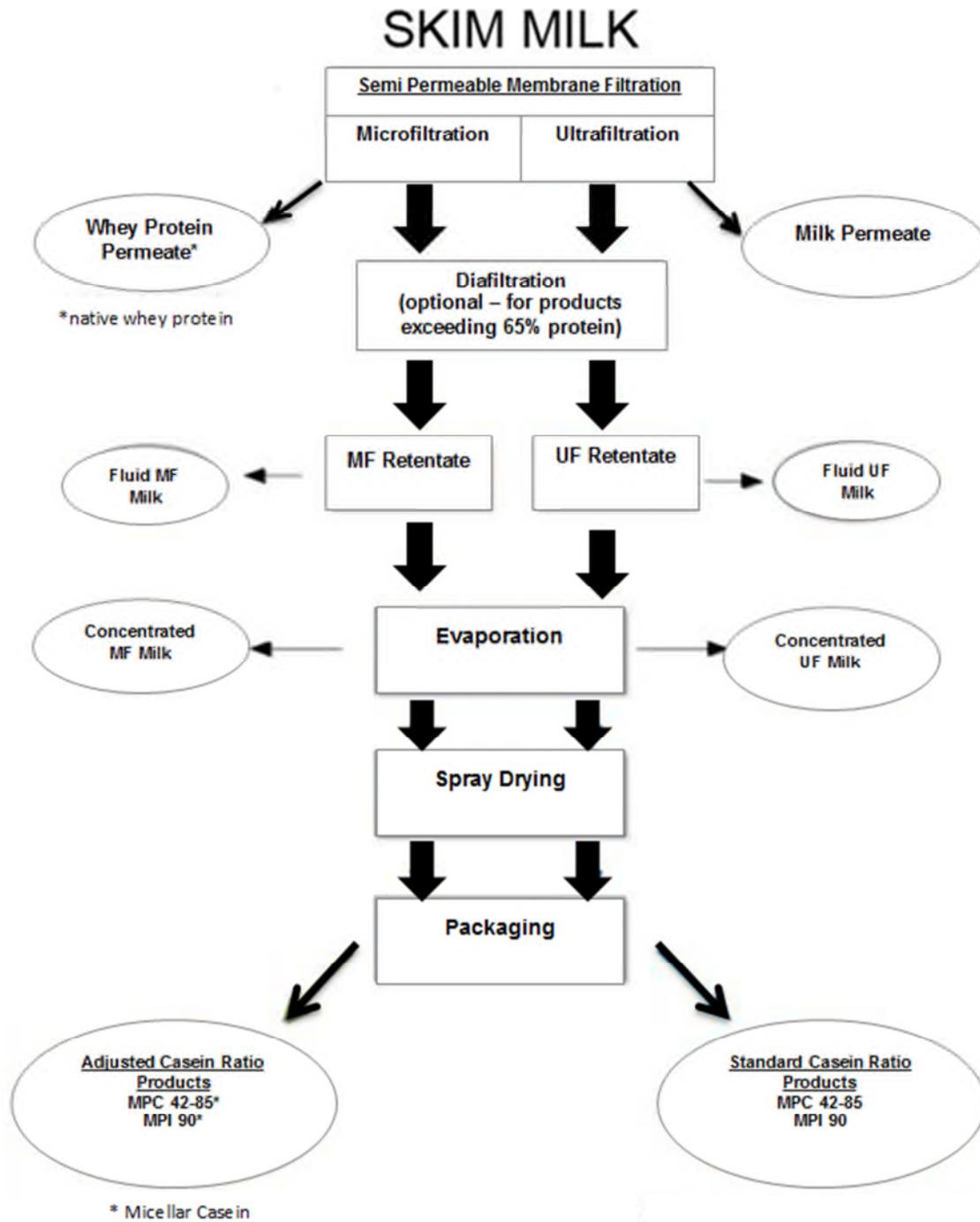
When the retentate has reached its target protein content, it is removed from the filtration system. Further processing steps include an optional evaporative concentration stage in which moisture is removed to increase the solids content of the product stream. Following evaporation (or without this processing step, depending on the particular manufacturing circumstance), the product stream may be dried and packaged using normal dairy drying techniques.

Concentrated milk protein finished products may be obtained by removing the product stream from the process at the completion of various stages, such as the filtration stage, concentration stage, or drying stage. The resulting products may be identified as fluid, concentrate, or dried versions of concentrated milk protein, respectively. For purposes of this GRAS Notification, the MPC and MPI products are obtained after the drying stage, in dry form.

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<sup>3</sup> Ultrafiltration captures essentially all the casein and whey proteins contained in the raw material stream, resulting in a casein-to-whey ratio in the finished products equivalent to that of the original milk, generally a value of 80:20. Such products are described as Standard Casein Ratio (SCR) products, and their production is depicted on the right side of Figure 1. Microfiltration enables the partial separation of casein and whey protein, resulting in two protein streams, compared to ultrafiltration's single stream. Upon the completion of processing, the finished product from the retentate has a modified casein-to-whey protein ratio, such as 92:8, versus 80:20. Such products are described as Adjusted Casein Ratio (ACR) products, and their production is depicted on the left side of Figure 1. ACR products are not materially different from SCR products.

Figure 1. Manufacturing Process Flow Chart



## V. Consideration of Potential Contaminating Materials

### A. Pesticide Residues

Milk Protein Concentrate (MPC) and Milk Protein Isolate (MPI) are tested regularly for the presence of pesticides such as organophosphorous and organosulfur, carbamate, organonitrogen, halogenated pesticides, and phenylurea herbicides. The results show that no pesticides have been detected in the products.

### B. Melamine

MPC and MPI are tested regularly to verify absence of melamine. The results show that melamine is not present in these products. All equipment used in the manufacture of these products and their packaging materials are melamine free. The analytical method for melamine detection follows FDA LIB 4421 Melamine and Cyanuric Acid Residues in Infant Formula using LC-MS/MS.<sup>4</sup>

### C. Other Contaminants

The raw milk used in the production of concentrated milk proteins is produced in accordance with good agricultural practices, and as such, meets applicable state and federal regulations. Further, concentrated milk proteins meet regulatory limits on veterinary drug residues, polychlorinated biphenyls (PCBs), and pesticides.

The milk used for the production of concentrated milk proteins is tested regularly for any potential contaminants. Procedures for sampling, analysis, and reporting are presented in the PMO.<sup>5</sup> The document states “industry shall screen all bulk milk pickup tankers, regardless of final use, for Beta lactam drug residues. Additionally, other drug residues shall be screened for by employing a random sampling program on bulk milk pickup tankers when the Commissioner of the FDA determines that a potential problem exists as cited in [Section 6 of the PMO]. The random bulk milk pickup tanker sampling program shall represent and include, during any consecutive six (6) months, at least four (4) samples collected in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. Samples collected under this random sampling program shall be analyzed as specified by FDA.” The industry follows PMO guidelines with respect to monitoring for contaminants during the production of concentrated milk proteins.

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<sup>4</sup> FDA Laboratory Information Bulletin LIB No. 4421 *Volume 24, October 2008* Determination of Melamine and Cyanuric Acid Residues in Infant Formula using LC-MS/MS, available at: <http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm071637.htm> (last accessed on January 27, 2014).

<sup>5</sup> FDA, Grade “A” Pasteurized Milk Ordinance (2011), at Appendix N (“Drug Residue Testing and Farm Surveillance – Industry Responsibilities – Monitoring and Surveillance”).

## VI. Nutrition – Protein Identification and Digestibility

The concentrated milk protein manufacturing process utilizes physical separation processes that simply concentrate the milk proteins and do not result in any substantive alteration to the chemical character of the milk constituents. Thus, the concentrated milk proteins are as nutritious as milk itself and the protein digestibility is essentially equivalent to that of milk. The value of the protein digestibility-corrected amino acid score (PDCAAS) for cow's milk has been shown to be 121, higher than that for egg (118), beef (92), soy (91) or wheat (42).<sup>6</sup> Since MPC and MPI are derived from cow's milk using only physical separation processes, the PDCAAS for MPC and MPI is expected to be similar to that of cow's milk.

The nutritional utilization of milk proteins has been studied in both animals and humans.<sup>7</sup> It has been shown that milk proteins are of particularly excellent nutritional value in humans with a true digestibility and a net postprandial protein utilization of 95-96% and 74%, respectively.<sup>8</sup>

## VII. Basis for GRAS Determination

### A. Regulatory Status of Milk Protein Products

Several substances that are similar to concentrated milk proteins have already been affirmed as GRAS or have been the subject of GRAS Notifications. Milk proteins are classified under two major groups: whey proteins (20%) and caseins (80%).<sup>9</sup> Whey proteins are the soluble proteins that remain when milk coagulates. Caseins are more hydrophobic proteins that exist in milk as casein micelles. Like the GRAS substances described below, the concentrated milk proteins that are the subject of the current GRAS Notification are manufactured through physical separation techniques. Therefore, the constituents of the final products, MPC and MPI, are no different in substance than the other milk protein products described below. Due to the similarities between concentrated milk proteins and the substances described below, FDA's

<sup>6</sup> Schaafsma G. The Protein Digestibility-Corrected Amino Acid Score. *J Nutr* 2000; 130:1865S-1867S (internal citations omitted).

<sup>7</sup> Cook BB, Morgan AF, Singer B, Parker J. The effect of heat treatment on the nutritive value of milk proteins. II. Rat growth studies with casein and lactalbumin and their lactose derivatives. *J Nutr* 1951;44:63-81; Gilani GS, Sepehr E. Protein digestibility and quality in products containing antinutritional factors are adversely affected by old age in rats. *J Nutr* 2003;133:220-5; Rutherford SM, Moughan PJ. The digestible amino acid composition of several milk proteins: application of a new bioassay. *J Dairy Sci* 1998; 81:909-17; Bos C, Gaudichon C, Tome D. Nutritional and physiological criteria in the assessment of milk protein quality for humans. *J Am Coll Nutr* 2000;19(suppl):191S-205S; Gaudichon C, Mahe S, Benamouzig R, et al. Net postprandial utilization of [15N]-labeled milk protein nitrogen is influenced by diet composition in humans. *J Nutr* 1999;129:890-5.

<sup>8</sup> Bos C, Mahe S, Gaudichon C, et al. Assessment of net postprandial protein utilization of 15N-labelled milk nitrogen in human subjects. *Br J Nutr* 1999;81:221-6; Bos C, Metges CC, Gaudichon C, et al. Postprandial kinetics of dietary amino acids are the main determinant of their metabolism after soy or milk protein ingestion in humans. *J Nutr* 2003;133:1308-15; Gausseres N, Mahe S, Benamouzig R, et al. [15N]-labeled pea flour protein nitrogen exhibits good ileal digestibility and postprandial retention in humans. *J Nutr* 1997;127:1160-5; Morens C, Bos C, Pueyo ME, et al. Increasing habitual protein intake accentuates differences in postprandial dietary nitrogen utilization between protein sources in humans. *J Nutr* 2003;133:2733-40.

<sup>9</sup> Milk Composition and Nutritional Value, available at: [http://babcock.wisc.edu/sites/default/files/de/en/de\\_19.en.pdf](http://babcock.wisc.edu/sites/default/files/de/en/de_19.en.pdf) (last accessed on January 27, 2014).

acceptance of the GRAS status of the following substances has direct implications for the GRAS status of MPC and MPI.

Whey protein concentrate is GRAS affirmed at 21 C.F.R. § 184.1979(c). The regulation states that whey protein concentrate is the substance obtained by the removal of sufficient non-protein constituents from whey so that the finished dry product contains not less than 25 percent protein. Whey protein concentrate is produced by physical separation techniques such as precipitation, filtration, or dialysis. As with whey, whey protein concentrate can be used as a fluid, concentrate, or dry product form.

In GRAS Notice No. GRN000037, FDA had no questions regarding the GRAS determination of “whey protein isolate” for use in high-energy food and beverage products such as yogurts, pudding, ice cream, margarine, and mayonnaise. Similarly, also in GRAS Notice No. GRN000037, FDA had no questions regarding the GRAS determination of “dairy product solids” for use in a variety of foods and in the production of alcohol and organic chemicals, galactose and glucose syrups, and sugar and corn syrup replacers. Both whey protein isolate and dairy product solids are manufactured using physical separation techniques involving the application of membrane filtration systems and optional dialysis to process whey.<sup>10</sup>

In GRAS Notice No. GRN000052, FDA had no questions regarding the GRAS determination of “whey mineral concentrate” for use as a source of calcium in fortified beverages, fortified foods, and enriched dairy products. Whey mineral concentrate is produced by subjecting pasteurized fluid whey to a precipitation and membrane separation process, followed by purification and drying. The resulting concentrate is a free-flowing white powder that is soluble at acid pH.<sup>11</sup>

According to a Select Committee on GRAS Substances (SCOGS) opinion, enzymatically hydrolyzed casein is included on a list of substances that FDA presumes to be GRAS.<sup>12</sup> The Select Committee concluded that “[t]here is no evidence in the available information on enzymatically hydrolyzed casein that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when it is used as a nutrient in special dietary foods at levels that are now current or that might reasonably be expected in the future.”<sup>13</sup>

In GRAS Notice No. GRN000011, FDA had no questions regarding the GRAS determination of a “mixture of calcium casein peptone and calcium phosphate (CCP-CP)” for

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<sup>10</sup> FDA Response to GRN000037, available at: <http://www.fda.gov/food/ingredientspackaginglabeling/gras/noticeinventory/ucm154133.htm> (last accessed on January 27, 2014).

<sup>11</sup> FDA Response to GRN000052, available at: <http://www.fda.gov/food/ingredientspackaginglabeling/gras/noticeinventory/ucm153729.htm> (last accessed on January 27, 2014).

<sup>12</sup> Select Committee on GRAS Substances (SCOGS) Opinion: Enzymatically hydrolyzed casein. SCOGS-Report Number: 37b, ID Code: 9000-71-9, Year: 1980, available at: <http://www.fda.gov/food/ingredientspackaginglabeling/gras/scogs/ucm261282.htm> (last accessed on January 27, 2014).

<sup>13</sup> *Id.*

use as a texturizer in chewing gum at a level not to exceed 5%.<sup>14</sup> CCP-CP is produced by the enzymatic hydrolysis of casein to form casein peptone, which is then complexed with amorphous calcium phosphate to form a calcium casein peptone-calcium phosphate complex. Casein peptones have been GRAS affirmed for the direct addition to human foods at 21 C.F.R. § 184.1553.

Finally, in GRAS Notice No. GRN 000196, FDA did not object to the determination that “bovine milk basic protein fraction (BMBPF)” is GRAS for use in cottage cheese, imitation milk (including rice and soy milk), juice, meal replacement bars and drinks, milk, processed cheese, salad dressing, and yogurt at levels of up to 40% in some of the applications. BMBPF is produced from pasteurized bovine skim milk that is applied to a cation exchange chromatographic column, removing acid milk proteins and lactose. The basic proteins remaining on the column are eluted from the resin using sodium chloride. The resulting eluate is concentrated and dialyzed to produce BMBPF solids. These BMBPF solids are then crushed and packaged.<sup>15</sup>

The GRAS Affirmations and Notices above exhibit FDA’s confidence in the safety of these milk-derived ingredients. Similar to the milk-derived ingredients above, concentrated milk proteins are produced using physical processes that do not present any safety concerns that have not already been addressed in the existing, favorably-reviewed GRAS Affirmations and Notices discussed above.

## B. Safety Overview

### 1. Human Consumption of Milk Protein

The raw material used in the manufacture of concentrated milk protein is skim milk. Milk and products derived from milk, such as whey and casein, have a long history of safe consumption by humans at all ages in the form of fluid milk, in dried form (i.e., milk powder), or as milk-derived ingredients.

### 2. Purification of Concentrated Milk Protein

Concentrated milk protein is manufactured using safe and well-characterized physical separation techniques that are analogous to the processes employed in the manufacture of the whey protein concentrate and whey protein isolate products described above. Such physical separation processes do not cause substantive alterations to the chemical character and safety-related properties of the constituents. The food additives that may be utilized in the manufacturing process for concentrated milk protein are all either approved food additives or GRAS food ingredients for these applications and are used in accordance with food cGMP (21

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<sup>14</sup> FDA Response to GRN000011, available at: <http://www.fda.gov/food/ingredientspackaginglabeling/gras/noticeinventory/ucm154906.htm> (last accessed on January 27, 2014).

<sup>15</sup> FDA Response to GRN000196, available at: <http://www.fda.gov/food/ingredientspackaginglabeling/gras/noticeinventory/ucm154673.htm> (last accessed on January 27, 2014).

C.F.R. Part 110). The manufacturing process does not generate, concentrate, or introduce any potential toxicants. As a result, the concentrated milk proteins are as safe as milk itself.

### 3. Safety Studies on Concentrated Milk Protein

Given the long history of human consumption of milk, milk and milk proteins are of little toxicological concern to humans or animals. With the exception of particularly sensitive populations – namely milk-allergic and lactose-intolerant individuals, whom we address below – we are not aware of adverse effects associated with consumption of concentrated milk proteins. In addition, a literature search does not yield any reported adverse effects.

### 4. Allergenicity of Milk Protein

An allergy to milk is among the eight most common food allergies.<sup>16</sup> Because the substances are chemically identical, milk and concentrated milk proteins will produce similar incidences of protein allergy when consumed. All concentrated milk protein ingredients will clearly include “milk” as part of the common or usual name of the ingredient. This will indicate that that the product contains milk protein and will inform those consumers who are allergic to milk and satisfy food allergen labeling requirements.

### 5. Lactose Intolerance

Lactose intolerance is the inability or insufficient ability to digest lactose, a sugar found in milk and milk products. Lactose intolerance is caused by a deficiency of the enzyme lactase, which is produced by the cells lining the small intestine. Lactase breaks down lactose into two simpler forms of sugar called glucose and galactose, which are then absorbed into the bloodstream. People with lactose intolerance may feel uncomfortable 30 minutes to 2 hours after consuming milk and milk products. Symptoms range from mild to severe, based on the amount of lactose consumed and the amount a person can tolerate. Common symptoms include abdominal pain, abdominal bloating, gas, diarrhea, and nausea.<sup>17</sup>

Research indicates that most people with lactose intolerance are able to consume the amount of lactose in up to 2 cups of milk a day if taken with meals, one at breakfast and the other at dinner. Other dairy foods, such as aged cheese and yogurts are also well-tolerated because lactose is converted to lactic acid by select microorganisms during the making of the products.<sup>18</sup>

The percentage of lactose is inversely related to the protein content of the concentrated milk protein. As shown in Table 1, the percentage of lactose in concentrated milk protein products is 47.0%, 32%, 18%, 3.2%, and 0.8% for MPC 42, MPC 56, MPC 70, MPC 85, and MPI 90, respectively. These levels are lower than the level of lactose in Nonfat Dry Milk, which

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<sup>16</sup>“Eight major foods or food groups – milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans – account for 90 percent of food allergies.” Pub. L. 108-282, title II § 202(1)(2)(A) (Aug. 2, 2004).

<sup>17</sup> Lactose Intolerance, National Digestive Diseases Information Clearinghouse (NDDIC), available at: <http://digestive.niddk.nih.gov/ddiseases/pubs/lactoseintolerance/> (last accessed on January 27, 2014).

<sup>18</sup> National Dairy Council, Handbook of Dairy Foods and Nutrition 6 (3rd ed. 2006).

is around 49.0-52.3%.<sup>19</sup> Therefore, we do not anticipate any unique impact on lactose sensitive populations.<sup>20</sup>

C. Estimated Consumption of Concentrated Milk Protein Derived From Proposed Food Uses

The typical proposed food uses of concentrated milk proteins in food are provided in **Table 4.**

**Table 4. Typical Levels of Incorporation for MPC and MPI**

Food Category	Application <sup>21</sup>	Function	MPC42 Level of Incorp. grams/100 grams as is	MPC56 Level of Incorp. grams/100 grams as is	MPC70 Level of Incorp. grams/100 grams as is	MPC80 Level of Incorp. grams/100 grams as is	MPC85 Level of Incorp. grams/100 grams as is	MPI90 Level of Incorp. grams/100 grams as is
Nutritional Products	Meal Replacements and Meal Supplements	Emulsification, heat stability, source of high quality protein, flavor	5-10%	5-10%	5-10%	5-10%	5-10%	5-10%
	Powdered Nutritional Beverages	Source of high quality protein, organoleptic appeal	Up to 50%	Up to 50%	50-80%	50-80%	50-80%	50-90%
	Nutritional Bars	Source of high quality protein, cohesiveness, flexibility, chewiness control	5-10%	5-10%	5-10%	5-10%	5-10%	5-10%
Dairy and Dairy Based Products*	Milk Products (including dairy beverages)	Sedimentation stability, protein enrichment, mouthfeel	5-15%	5-15%	5-15%	5-15%	5-15%	5-15%
	Yogurt and Fermented Milk Products	Texturizing thickener	< 5%	< 5%	< 5%	< 5%	< 5%	< 5%
	Non Standardized Cheese Products	Texturizing thickener, fat stabilization	1-10%	1-10%	1-10%	1-10%	1-10%	1-10%
	Spreads, Dips and Cream Substitutes	Mouthfeel, fat replacement	1-10%	1-10%	1-10%	1-10%	1-10%	1-10%

<sup>19</sup> The Really BIG List of Lactose Percentages, available at: [http://www.stevecarper.com/li/list\\_of\\_lactose\\_percentages.htm](http://www.stevecarper.com/li/list_of_lactose_percentages.htm) (last accessed on January 27, 2014).

<sup>20</sup> Additional information on lactose intolerance can be found in the scientific status report from the National Dairy Council, available at: <http://www.nationaldairyCouncil.org/Research/ResearchSummaries/Pages/LactoseIntolerance.aspx> (last accessed on January 27, 2014).

<sup>21</sup> The use of MPC and MPI in infant formula and in meat/poultry products is outside the scope of this GRAS Notification.

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	Frozen Dairy Desserts and Mixes*	Stabilization, emulsification	1-10%	1-10%	1-10%	1-10%	1-10%	1-10%
<b>Sugar Based Products</b>	Desserts and Mousses	Foaming, reduction of lactose content	<5%	<5%	<5%	<5%	<5%	<5%
	Confections (including chocolate confections)*	Source of lactose, mouthfeel, dairy flavor	1-10%	1-10%	1-10%	NA	NA	NA
	Snack Foods	Flavor carrier, dairy flavor, texture	1-10%	1-10%	1-10%	NA	NA	NA
	Coatings and Fillings	Flavor carrier, dairy flavor, texture	1-10%	1-10%	1-10%	NA	NA	NA
<b>Dressings</b>	Salad Dressings	Emulsification, flavor	<5%	<5%	<5%	<5%	<5%	<5%
<b>Other</b>	Soups, Soup Mixes, and Sauces	Reduction of stabilizer, dairy flavor, creaminess	2-10%	2-10%	2-10%	2-10%	2-10%	2-10%

\* Where, and within limits permitted by, existing standards of identity or any other regulations

The total 2010 domestic market for milk protein concentrate (MPC) (all protein levels) and milk protein isolate (MPI) was estimated to be 77,608 metric tons, which is  $77.608 \times 10^6$  kilograms.<sup>22</sup> The total population of the United States is about 310 million people. The mean daily consumption of concentrated milk protein per capita is as follows:

$$77.608 \times 10^6 \text{ (kg/year)} \times 10^3 \text{ (g/kg)} \div 310 \times 10^6 \text{ (persons)} \div 365 \text{ (days/year)} = 0.686 \text{ g/person/day}$$

We conservatively assume that the protein content of the concentrated milk protein comprises 90% of the product. The mean daily protein intake from concentrated milk protein per capita would thus be:

$$0.686 \text{ g/person/day} \times 90\% = 0.62 \text{ g/person/day}$$

If we assume that the entire amount of concentrated milk protein produced in the United States is consumed by only 10% of the population (“eaters-only”), the daily consumption of concentrated milk protein per capita for the eaters-only population would be 6.86 g/person/day and the daily protein intake from concentrated milk protein per capita would thus be 6.2 g/person/day. **Table 5** provides recommendations by the National Institutes of Health (NIH) regarding the consumption of milk and the corresponding consumption of milk protein.<sup>23</sup>

<sup>22</sup> U.S. Dairy Export Council, Milk Protein Concentrate Markets: Production, Market and Manufacturers (July 2012).

<sup>23</sup> National Institutes for Health – Office of Dietary Supplements; National Institute of Child Health and Human Development, available at: [http://ods.od.nih.gov/Health\\_Information/Dietary\\_Reference\\_Intakes.aspx/](http://ods.od.nih.gov/Health_Information/Dietary_Reference_Intakes.aspx/) (last accessed on January 27, 2014).

**Table 5. Recommendations for Milk Intake**

Male and Female Age Groups	Number of 8 ounce cups per Day	Milk Protein Equivalent grams/daily
1-3 years	1-2	8-16
4-8 years	2-3	16-24
9-18 years	4	32
19-50 years	3	24
51+ years	3	24

The recommended daily protein intake from milk ranges between 5.6 and 32 grams per day, depending on age cohort. In addition, FDA has established a Daily Reference Value (DRV) of 50 g/day for protein for adults and children aged 4 or older.<sup>24</sup> The Institute of Medicine (IOM) has established a Recommended Dietary Allowance (RDA) for protein of 56 g/day for adult males and 46 g/day for adult females.<sup>25</sup> The estimated daily protein intake from concentrated milk protein is approximately 0.62 g/person/day, which is a fraction of the recommended protein intake. Even considering the eaters-only population, which provides the most conservative estimate of consumption, the daily protein intake from concentrated milk protein of 6.2 g/person/day is far less than the recommended protein intake described above.

Most of the population's protein intake is derived from, and will continue to be derived from, unprocessed foods, including meat, poultry, fish, and legumes. Moreover, for those processed foods to which the concentrated milk proteins will be added, there are competitive products on the market. Thus, the addition of these concentrated milk protein ingredients will simply serve as a replacement for these other competitive protein sources and will not increase consumer exposure to protein. Therefore, we do not realistically expect that the actual consumption of foods containing concentrated milk protein products will contribute to a significant portion of total protein intake.

#### D. Directions for Labeling

For any food containing MPC or MPI products, the label will bear a statement indicating that the product has been derived from a milk source to satisfy allergen labeling requirements.

<sup>24</sup> FDA Guidance for Industry: A Food Labeling Guide, Calculate the Percent Daily Value for the Appropriate Nutrients, available at: <http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm064928.htm> (last accessed on January 27, 2014).

<sup>25</sup> Dietary Reference Intakes (DRIs): Recommended Dietary Allowances and Adequate Intakes, Total Water and Macronutrients. Food and Nutrition Board, Institute of Medicine, National Academies, available at: [http://www.iom.edu/Activities/Nutrition/SummaryDRIs/~//media/Files/Activity%20Files/Nutrition/DRIs/5\\_Summary%20Table%20Tables%201-4.pdf](http://www.iom.edu/Activities/Nutrition/SummaryDRIs/~//media/Files/Activity%20Files/Nutrition/DRIs/5_Summary%20Table%20Tables%201-4.pdf) (last accessed on January 24, 2014).

## **VIII. Summary of Basis for GRAS Determination**

ADPI and USDEC have determined that concentrated milk proteins, milk protein concentrate (MPC) and milk protein isolate (MPI), are Generally Recognized as Safe (GRAS) based on the following:

- The fact that concentrated milk proteins are manufactured under current good manufacturing practices (cGMP) for food (21 C.F.R. Part 110) and meet appropriate food grade specifications.
- That potential contaminants such as pesticides and heavy metals are either absent (not detected) or below toxicological and regulatory limits.
- The digestibility and nutritional quality of the concentrated milk proteins.
- The intended uses and the estimated consumption of the concentrated milk proteins.
- The proper labeling of the products; and
- Supportive evidence from the long history of safe use of milk and milk protein as food.

## **IX. Conclusion**

Based on the documentation provided in this GRAS Notification, and as discussed above, ADPI and USDEC have concluded that milk protein concentrate (MPC) and milk protein isolate (MPI) are GRAS via scientific procedures for use in a variety of foods and beverages.

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## Appendix 1

### Five-batch analysis on MPC70 and MPI

**Table 1. Batch Analysis for MPC70**

Parameter	Batch 1	Batch 2	Batch 3	Batch 4	Batch 5
Water	4.96	4.31	4.90	4.51	4.27
Protein* <sup>o</sup>	70.42	70.73	70.41	71.08	70.80
Fat	0.61	1.27	0.59	1.04	1.08
Minerals	7.22	7.06	7.22	7.06	7.18
Carbohydrate	16.79	17.47	16.88	16.31	16.69
Standard Plate Count	2,500 cfu/g	1,000 cfu/g	1,200 cfu/g	1,000 cfu/g	2,200 cfu/g
<i>Coliform</i>	<10 cfu/g				
<i>E coli</i>	<10 cfu/g				
<i>Salmonella</i>	Neg/375 g				
Yeast and Molds	9 cfu/g	9 cfu/g	9 cfu/g	12 cfu/g	5 cfu/g
<i>Listeria monocytogenes</i>	Neg/25 g				
<i>Staphylococcus aureus</i>	<10 cfu/g				

\* In dry matter

<sup>o</sup> N x 6.38

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**Table 2. Batch Analysis for MPI**

<b>Parameter</b>	<b>Batch 1</b>	<b>Batch 2</b>	<b>Batch 3</b>	<b>Batch 4</b>	<b>Batch 5</b>
Water	5.7	5.4	4.7	4.4	5.3
Protein* <sup>o</sup>	92.6	91.9	90.3	92.1	91.6
Fat	0.7	1.2	1.2	1.1	1.3
Minerals	6.6	6.8	6.8	7.0	6.5
Carbohydrate	0.1	0.07	1.5	0.05	0.7
Standard Plate Count	2,400 cfu/g	500 cfu/g	24,000 cfu/g	500 cfu/g	9,800 cfu/g
<i>Coliform</i>	<10 cfu/g				
<i>E coli</i>	<10 cfu/g				
<i>Salmonella</i>	Neg/375 g				
Yeast and Molds	<10 cfu/g				
<i>Listeria monocytogenes</i>	Neg/25 g				
<i>Staphylococcus aureus</i>	<10 cfu/g				

\* In dry matter

<sup>o</sup> N x 6.38

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