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(54) Title: LIQUID NUTRITIONAL COMPOSITIONS WITH IMPROVED OXIDATIVE STABILITY

(57) Abstract: A nutritional composition in the form of an oil-in-water emulsion contains about 0.5 to 50 wt.% protein, about 0.1 to 25 wt.% fat, about 0.1 to 50 wt.% carbohydrate, and about 50 to 95 wt.% water. At least 40 wt.% of the protein in the composition is cold water soluble. In addition, at least 50 wt.% of the cold water soluble protein in the composition is derived from a cold water soluble milk protein concentrate containing at least 50 wt.% cold water soluble protein.

LIQUID NUTRITIONAL COMPOSITIONS WITH IMPROVED OXIDATIVE STABILITY

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims priority to and any benefit of U.S. Provisional Application No. 61/780,043, filed March 13, 2013, the entire content of which is incorporated herein by reference.

FIELD

The present disclosure relates to nutritional compositions. More particularly, the present disclosure relates to nutritional compositions having improved oxidative stability.

BACKGROUND

WO 2001/41578 describes a process for substantially increasing the cold water solubility of dried milk protein concentrates (MPC) and the use of the cold water-soluble milk protein concentrates (CS-MPCs) so obtained in the manufacture of cheese. WO 2004/057971 describes a process for denaturing the whey proteins found in the CS-MPCs of WO 2001/41578 for improved cheese manufacture. U.S. 2010/0021595 teaches that the modified CS-MPCs of WO 2004/057971 will improve the emulsion stability of certain solid and liquid nutritional compositions. The disclosures of each of these references is incorporated herein in their entireties.

SUMMARY

It has now been found that the CS-MPCs described in these documents will significantly retard the oxidative degradation of the polyunsaturated fatty acids found in a wide variety of different nutritional compositions which are in the form of oil-in-water emulsions.

Accordingly, this disclosure provides a nutritional composition in the form of an oil-in-water emulsion containing about 0.5 to 50 wt.% protein, about 0.1 to 25 wt.% fat, about 0.1 to 50 wt.% carbohydrate, and about 50 to 95 wt.% water, wherein at least 40 wt.% of the protein in the composition is cold water soluble and further wherein at least 50 wt.% of the

protein in the composition is derived from a cold water soluble milk protein concentrate in which at least 50 wt.% of the protein therein is cold water soluble.

Preferably, at least 60 wt.% of the protein in the composition is derived from a cold water soluble milk protein concentrate in which at least 65 wt.% of the protein therein is cold water soluble.

DETAILED DESCRIPTION

Definitions

For the purpose of this document, the following terms have the following meanings unless context dictates otherwise:

"Fat" and "oil" as used herein are used interchangeably to refer to lipid materials derived or processed from plants or animals. These terms also include synthetic lipid materials so long as such synthetic materials are suitable for oral administration to humans. As well known, such materials are normally composed of mixtures of fatty acid triglycerides, which mixtures may also contain fatty acid diglycerides and monoglycerides and even some free fatty acids.

"Retort packaging" and "retort sterilizing" are used interchangeably herein and refer to the common practice of filling a container, most typically a metal can or other similar package, with a liquid nutritional composition and then subjecting the liquid-filled package to the necessary heat sterilization step to form a sterilized, retort packaged, liquid nutritional product.

"Aseptic packaging" refers to the manufacture of a packaged product without reliance upon the above-described retort packaging step, wherein the liquid nutritional composition and package are sterilized separately prior to filling, and then are combined under sterilized or aseptic processing conditions to form a sterilized, aseptically packaged, liquid nutritional product.

"Shelf stable" refers to a liquid nutritional composition that remains commercially stable after being packaged and then stored at 18-24° C for at least 3 months.

"Total protein" in connection with the amount of protein in a particular composition means all the protein in that composition.

All percentages, parts and ratios as used herein, are by weight of the total composition, unless otherwise specified. All such weights as they pertain to listed ingredients are based on the active level and, therefore, do not include solvents or by-products that may be included in commercially available materials, unless otherwise specified.

All references to singular characteristics or limitations of the present disclosure shall include the corresponding plural characteristic or limitation, and vice versa, unless otherwise specified or clearly implied to the contrary by the context in which the reference is made.

All combinations of method or process steps as used herein can be performed in any order, unless otherwise specified or clearly implied to the contrary by the context in which the referenced combination is made.

The compositions of this disclosure may also be substantially free of any optional or selected ingredient or feature described herein. In this context, "substantially free" means that the selected nutritional composition contains less than a functional amount of the optional ingredient, typically less than 1%, including less than 0.5%, including less than 0.1%, and also including zero percent, by weight of such optional or selected ingredient.

In addition, the compositions of this disclosure may comprise, consist of, or consist essentially of the recited elements, as described herein.

The present disclosure relates nutritional compositions in the form of an oil-in-water emulsion containing about 0.5 to 50 wt.% protein, about 0.1 to 25 wt.% fat, about 0.1 to 50 wt.% carbohydrate, and about 50 to 95 wt.% water, wherein at least 40 wt.% of the protein in the composition is cold water soluble and further wherein at least 50 wt.% of the protein in the composition is derived from a cold water soluble milk protein concentrate in which at least 50 wt.% of the protein therein is cold water soluble. In certain embodiments, a powder or concentrate which, when diluted with water, yields a nutritional composition containing about 0.5 to 50 wt.% protein, about 0.1 to 25 wt.% fat, about 0.1 to 50 wt.% carbohydrate, and about 50 to 95 wt.% water, wherein at least 40 wt.% of the protein in the composition is cold water soluble and further wherein at least 50 wt.% of the protein in the composition is derived from a cold water soluble milk protein concentrate in which at least 50 wt.% of the protein therein is cold water soluble.

Product Form

The technology described in this disclosure applies to nutritional compositions which are oil-in-water emulsions when ready to be consumed. In addition, this technology also applies to products such as powders and concentrated liquids which can be readily converted into oil-in-water emulsions by the simple addition of water. So, for example, this technology applies to ready-to-feed liquids, concentrated liquids, liquids derived from nutritional powders (reconstituted liquids), the powders themselves, solids, semi-liquids, and semi-solids.

Such products are very well known and, when in a ready-to-consume condition, contain an appropriate balance of macronutrients (protein, fat and carbohydrate), micronutrients (*e.g.*, vitamins and minerals) and water. Generally, they contain about 0.5 to 50 wt.% protein, about 0.1 to 25 wt.% fat, about 0.1 to 50 wt.% carbohydrate, and about 50 to 95 wt.% water. Specific examples of such products, when in a ready to be consumed condition, include nutritional liquids such as nutrition shakes, yoghurts, soups, whipped toppings, coffee whiteners, etc.

The technology of this disclosure is particularly applicable to nutrition shakes, *i.e.*, liquid nutritional compositions having a consistency, flavor and overall desirable sensory characteristics resembling those of common every-day milk shakes. Such products are well-known and widely-available in a number of different types, including those especially formulated for promoting muscle growth, those especially formulated to provide balanced nutritional supplements for normal adults, those especially formulated for diabetic adults and those formulated especially for children (*e.g.*, ages 1 to 6) both as supplements as well as sole source foodstuffs. Specific examples of such products include the Ensure®, Glucerna®, Myoplex® and Pediasure® line of nutrition shakes available from Abbott Nutrition of Columbus, Ohio, the Muscle Milk® line of nutrition shakes available from CytoSport, Inc. of Benicia, California, and the Resource® line of health shakes available from Nestle, S.A. of Vevey, Switzerland.

As well appreciated in the art, the relative amounts of macronutrients in these compositions can vary significantly depending on type. *See*, the following Tables 1 to 4, which illustrate these variations:

Table 1
Nutrition Shakes-Muscle Building Formulations
Macronutrient Breakdown

	wt.%, based on entire composition			Calorie %		
	Protein	Carbs	Fat	Protein	Carbs	Fat
Operative	3-20	0.5-15	1-10	35-75	5-40	5-40
Desirable	5-15	1-10	0.3-5	45–70	10–35	10-35
More Desirable	6-10	2-6	0.5-2	40–65	15–30	15–30
Especially Desirable	6-10	3-5	0.7-1.5	54–58	21–25	19-23

Table 2
Nutrition Shakes-Balanced Adult Supplement
Macronutrient Breakdown

	wt.%, based on entire composition			Calorie %		
	Protein	Carbs	Fat	Protein	Carbs	Fat
Operative	0.5-15	10-30	0.5-10	2-30	30-90	6-45
Desirable	1.4-8.5	11-25	1-7	6-25	40-80	10-40
More Desirable	2-7	13-24	1.5-6	10-20	45-75	15-35
Especially Desirable	2.9-5.8	14-20	2-5	12-17	50-70	20-31

Table 3
Supplement for Diabetics
Macronutrient Breakdown, wt.%

	wt.%, based on entire composition			Calorie %		
	Protein	Carbs	Fat	Protein	Carbs	Fat
Operative	0.5-15	5-35	0.5-20	10-40	20-70	15-55
Desirable	1-10	7-20	0.7-15	12-35	30-60	20-45
More Desirable	2-7	8-15	1-10	15-30	35-55	25-40
Especially Desirable	3-5	9-12	1.5-5	18-25	40-50	30-35

Table 4
Nutrition Shakes-Children's Drink
Macronutrient Breakdown

	wt.%, based on entire composition			Calorie %		
	Protein	Carbs	Fat	Protein	Carbs	Fat
Operative	0.5-10	4-40	1-25	2-40	30-80	15-55
Desirable	0.7-7	6-30	1.2-20	4-30	40-70	20-45
More Desirable	1-6	8-20	1.5-15	7-20	45-65	25-40
Especially Desirable	2-4	10-15	2-7	10-15	50-60	30-35

Carbohydrates

Any carbohydrate or source thereof which is suitable for use in making oral nutritional products, and which is otherwise compatible with the other ingredients, can be used to make the nutritional compositions of this disclosure. Specific examples include maltodextrin (and specifically low DE Maltodextrin such as DE10 maltodextrin), corn maltodextrin, sucromalt, maltitol, maltitol powder, glycerine, glucose polymers, corn syrup, corn syrup solids, rice-derived carbohydrates (e.g., tapioca dextrin), isomaltulose, sucrose, extra fine white sugar, glucose, fructose, lactose, high fructose corn syrup, honey, sugar alcohols (e.g., maltitol, erythritol, sorbitol), artificial sweeteners (e.g., sucralose, acesulfame potassium, stevia), fructooligosaccharides, soy fiber, corn fiber, guar gum, konjac flour, polydextrose, digestion resistant maltodextrin (*e.g.*, Fibersol-2), and combinations thereof.

Normally, the carbohydrate component of the compositions of this disclosure will contain both starches and sugars. If so, the amount of sugar in nutritional compositions especially formulated for promoting muscle growth in adults may desirably represent about 1% to about 20%, about 3% to about 10%, or even about 4% to about 8%, by weight, of the total amount of carbohydrates in the composition. Similarly, the amount of sugar in nutritional compositions especially formulated to provide balanced nutritional supplements for normal adults, as well as for diabetic adults, may desirably represent about 10% to about 35%, about 15% to about 30%, or even about 20% to about 25%, by weight, of the total amount of carbohydrates in the composition. In addition, the amount of sugar in nutritional compositions especially formulated for children (e.g., ages 1 to 16), both as supplements as well as sole source foodstuffs, may desirably represent about 30% to about 70%, about 40%

to about 65%, or even about 50% to about 60%, by weight, of the total amount of carbohydrates in the composition.

Fat

Any fat or source thereof that is suitable for use in oral nutritional products and is compatible with the other ingredients in the nutritional compositions of this disclosure can be used as the fat of these compositions. Non-limiting examples include coconut oil, fractionated coconut oil, soy oil, corn oil, olive oil, safflower oil, high oleic safflower oil, MCT oil (medium chain triglycerides), sunflower oil, high oleic sunflower oil, palm and palm kernel oils, palm olein, canola oil, marine oils, cottonseed oils, and combinations thereof.

In this regard, many nutritional compositions commonly contain a variety of long chain polyunsaturated fatty acids (LC-PUFAs) as part of the lipid component of the overall nutrient system. In this context, "long chain" means a fatty acid whose acyl chain contains 13 to 28 carbon atoms. Specific examples include omega-3 (n-3) fatty acids such as alpha-linolenic acid (C18:3n-3), stearidonic acid (C18:4n-3), eicosapentaenoic acid (C20:5n-3), docosapentaenoic acid (C22:5n-3), and docosahexaenoic acid (C22:6n-3), and omega-6 (n-6) fatty acids such as linoleic acid (Cl8:2n-6), gamma-linolenic acid (C18:3n-6), eicosadienoic acid (C20:2n-6), arachidonic acid (C20:4n-6), and di-homo-gamma-linolenic acid (C20:3n-6). A growing body of evidence now suggest that diets containing sufficient amounts of certain LC-PUFAs may be beneficial for maintaining overall health, and may also be helpful for treating or preventing a variety of human diseases or afflictions. Certain LC-PUFAs have been shown to be beneficial in the prevention and/or management of cardiovascular disease, rheumatoid arthritis, depression, Alzheimer's, ulcers, cancer, hyperactivity, asthma, or other diseases or conditions responsive to anti-inflammatory effects.

These LC-PUFAs, and especially the omega-3 (n-3) and omega-6 (n-6) fatty acids, however, tend to be more sensitive to oxidation than many other ingredients commonly found in nutritional formulas. Due to their chemical structure, exposure to heat and atmospheric levels of oxygen can cause a series of chemical reactions about their carbon-carbon double bonds resulting in free radical formation. These free radicals can continue to

break down the LC-PUFAs in an auto-oxidative process, which results in the development of undesirable off-flavors and odors and the eventual degradation of the beneficial polyunsaturated fatty acids. These LC-PUFAs are especially susceptible to oxidation when subjected to elevated temperatures during processing or storage.

Oxidative stability has become especially challenging when formulating a nutritional liquid containing the relatively high concentrations of polyunsaturated fatty acids often needed to obtain a therapeutic response. Allowing even some oxidation in these products often results in a highly objectionable flavor and aroma, the characteristics of which are often described as fishy or otherwise having a rancid flavor or smell, depending upon the particular polyunsaturated fatty acid used in the formulation.

As indicated above, it has been determined that cold water soluble milk protein concentrates (CS-MPCs) such as those described in WO 2001/41578, WO 2004/057971 and U.S. 2010/0021595, improve the oxidation stability of the PUFAs found in a wide variety of different liquid nutritional compositions, whether in glyceride or free acid form. While this recognition is significant regardless of the particular type of fat used in a given nutritional composition, it is particularly significant in nutritional compositions whose fat content is based on relatively large proportions of LC-PUFAs, especially the n-3 and n-6 LC-PUFAs, as these compounds are especially susceptible to oxidative degradation.

Thus, this invention is especially useful in connection with nutritional compositions containing as little as 0.01 wt.% LC-PUFAs, based on the weight of the entire nutritional composition. Nutritional compositions in which the concentration of LC-PUFAs is $\geq$ 0.1 wt.%, $\geq$ 0.5 wt.%, $\geq$ 1 wt.%, $\geq$ 2 wt.%, $\geq$ 5 wt.%, $\geq$ 10 wt.%, $\geq$15 wt.%, and even $\geq$ 20 wt.%, are more interesting. Nutritional compositions in which the concentration of n-3 and/or n-6 LC-PUFAs is $\geq$ 0.01 wt.%, $\geq$ 0.1 wt.%, $\geq$ 0.5 wt.%, $\geq$ 1 wt.%, $\geq$ 2 wt.%, $\geq$ 5 wt.%, $\geq$ 10 wt.%, $\geq$15 wt.%, and even $\geq$ 20 wt.%, are especially interesting.

Proteins

A wide variety of different proteins supplied from a wide variety of different protein sources are commercially available. All can be used in preparing the nutritional compositions of this disclosure.

Examples of different proteins that can be used for this purpose include (1) milk proteins (*i.e.*, casein and whey) derived from a variety of different mammals including cows, sheep, goats, horses, buffalos, camels, and so forth; (2) other animal proteins available from a wide variety of non-mammals including fish, chicken and other fowl including the eggs of such non-mammals; and (3) vegetable proteins derived from a wide variety of different vegetables including soy, pea, wheat, rice, corn, and so forth.

Examples of the sources used to supply these proteins include the milk, meat, egg or vegetable itself. More commonly, however, the sources used to supply these proteins will be formed from some type of commercially-available extract or concentrated product of these materials. Unfortunately, there is no standard definition for these products in this industry. Therefore, for the purposes of this disclosure, the following meanings will be used:

"Milk protein concentrate" (MPC) and "milk protein isolates" (MPI) are products in which a substantial amount of the water and fat in whole milk have been removed. MPIs are further characterized in that a significant portion of the lactose has also been removed. As a result, the concentration of milk proteins in an MPI is normally greater than that found in a typical MPC, although this is not always the case.

For the purposes of this disclosure, therefore, MPC will be understood to be a generic term, which includes MPI as a specie thereof. Thus, MPC will be understood to refer to a milk protein product in which greater than 55% of the non-fat solids in the product are milk proteins, with the ratio of casein to whey proteins in the product being between 98:2 and 50:50. More commonly, more than 75 wt.% of the non-fat solids in the product are milk proteins, with the ratio of casein to whey proteins being between 90:10 and 70:30, even most typically between 90:10 and 80:20.

Milk protein isolates (MPIs) will be understood to mean a type of MPC in which at least 85 wt.% of the non-fat solids in the product are milk proteins, the lactose content is 5 wt.% or less, the fat content is less than 3 wt.%, the ash content is 8 wt.% or less, and the water content is less than 6 wt.%. Commercially available MPIs typically contain about 85-90 wt.% (or more) protein, about 2-5 wt.% lactose, minimal fat (*i.e.*, 1-3 wt.%) and about 5-6 wt.% water.

In addition to MPCs and MPIs, milk proteins are also available in the form caseinates, micellar casein, whey isolates or concentrates, non-fat dry milk, and condensed

skim milk. Casein separates from milk when milk is curdled; a process commonly carried out in the manufacturing of cheese, and is commonly called caseinate, having lost its typical micellar structure. Casein is most commonly bound to calcium (Ca^{2+}) and sodium (Na^{+}) since all of these ions are found naturally in milk or even potassium (K^{+}) or magnesium (Mg^{2+}), and tend to stick to the casein during the extraction process. Nutritionally, these compounds are basically interchangeable.

Micellar casein refers to casein in the form of native micelles. It is a high quality milk protein and naturally occurring in milk in a concentration of about 2.6 g/100 ml. It is concentrated by a process that does not, or does not substantially denature the casein proteins and it is marketed as Micellar Casein Isolate (MCI). Fresh skim milk is subjected to a microfiltration process, in much the same process used to concentrate whey protein, to produce a pure, substantially undenaturated milk protein with its native structure. The resulting material contains between 90% and 95%, preferably more than 95% by weight of micellar casein, the rest mainly being whey protein and other non-protein nitrogen and other constituents, such as lactose and inorganic salts, in particular calcium phosphate.

Whey protein is commercially available as liquid whey or in powder form as whey protein isolate (WPI) or whey protein concentrate (WPC). All have an elevated whey/casein ratio relative to whole milk. WPC is normally produced by membrane filtration. It is rich in whey proteins, but also contains other components such as fat, lactose and glycomacroprotein (GMP), a casein-related non-globular protein. In contrast, WPI consists primarily of whey proteins with minimal amounts of fat and lactose. WPI usually requires a more rigorous separation process such as a combination of microfiltration and ultra-filtration or ion exchange chromatography. It is generally understood that WPI refers to a mixture in which at least 90 weight % of the solids are whey proteins. A WPC is understood as having a percentage of whey proteins between the initial amount in the by-product (about 12 weight %) and a WPI. In particular, sweet whey, obtained as a by-product in the manufacturing of cheese, acid whey, obtained as a by-product in the manufacturing of acid casein, native whey, obtained by milk microfiltration, or rennet whey, obtained as a by-product in the manufacturing of rennet casein, are also available as commercial sources of milk proteins.

The vegetable proteins useful in the nutritional compositions of this disclosure will also typically be supplied from some sort of commercially-available concentrated product.

For example, soy protein can be divided into different categories according to its production method. For the purposes of this disclosure, "soy protein concentrate" (SPC) will be understood to be a generic term referring to products which are basically soybean without the water soluble carbohydrates and which contain about 60 to 90 wt.% or more soy protein. More commonly, these products contain 60 to 85 wt.% soy protein, and even more typically 70 to 80 wt.% soy protein. Meanwhile, "soy protein isolate" (SPI) will be understood to mean a type of SPC which contains about 85 to 90 wt.% protein. SPI is the most refined form of soy protein and is mainly used in meat products to improve texture and eating quality. Textured soy protein (TSP) is made from soy protein concentrate by giving it some texture. TSP is available as dry flakes or chunks. It will keep its structure when hydrated. Hydrated textured soy protein chunks have a texture similar to ground beef. It can be used as a meat replacement or can be added to meat. Textured soy protein contains about 70 wt.% protein.

The portion of soy protein which is cold water soluble (*i.e.*, soluble in water at 20° C) in a typical soy protein source can vary widely. Typical soy protein sources can include as little as 5 wt.% cold water soluble protein and as much as 50 wt.% cold water soluble protein, based on total protein. Protein sources in which the portion of water soluble protein is $\geq$ 5 wt.%, $\geq$ 10 wt.%, or even $\geq$ 20 wt.%, of total protein are interesting, as are protein sources in which the portion of water soluble protein is $\leq$ 40 wt.%, $\leq$ 30 wt.%, $\leq$ 20 wt.%, $\leq$ 15 wt.%, or even $\leq$ 10 wt.%, of total protein.

Pea protein is also available in the form of pea protein concentrates (PPC) and pea protein isolates (PPI). For the purposes of this disclosure, PPC will be understood to refer to concentrated pea protein products containing 60 to 90 wt.% pea protein. Meanwhile, PPI will be understood to refer to a PPC which contains 80 to 90 wt.% pea protein. These PPCs and PPIs typically exhibit one or more of the following attributes: (1) poured bulk density, as measured by gravimetry, of about 0.4 Kg/L; (2) a pH in a 10% solution of water of about 7; (3) a residue on a 70 mesh screen as measured by sieving of a maximum of 10% by weight; (4) a carbohydrate concentration of about 3 grams per 100 grams of intact pea protein; (5) a fat concentration of about 6 grams per 100 grams of intact pea protein; and/or (6) an ash concentration of about 4 grams per 100 grams of intact pea protein. These pea proteins can be derived from a variety of different pea species including *pisum sativum*,

green peas, cowpeas, chickpeas and field peas. *Pisum sativum* is generally preferred. One suitable commercially available intact pea protein concentrate that can be used to make the nutritional compositions of this disclosure and which is based on *pisum sativum* is NUTRALYS® F85F pea protein isolate (about 83% by weight intact pea protein), available from Roquette Freres, Lestrem France. Another source for intact pea protein based on *pisum sativum* is Cosucra Groupe Warcoing of Warcoing, Belgium. A description of pea protein sources suitable for use in certain embodiments of the nutritional composition of this disclosure can be found in commonly assigned application SN 61/615,624, SN 61/615,632, and SN 61/615,644, all filed on March 26, 2012.

All of these protein sources can be used to supply the proteins contained in the nutritional compositions of this disclosure. However, it is desirable that at least about 50 wt.% of the protein in these nutritional compositions be supplied from one or more milk protein concentrates (MPC), as this type of protein source is known to provide a desirable combination of physical properties (*e.g.*, viscosity, lack of graininess, short term emulsion stability, long term emulsion stability, etc.) and hedonic properties (*e.g.*, aroma, color, flavor, sweetness, thickness, mouthfeel, aftertaste, and overall liking) in the nutritional compositions in which it is used. Nutritional compositions in which at least about 55 wt.%., or even at least about 60 wt.%, of the proteins are derived from milk protein concentrates are more interesting.

It will also be understood that the protein sources described above are sources of intact protein. That is to say, these protein sources have not been subjected to a treatment whose primary purpose is to hydrolyze unhydrolyzed proteins. Accordingly, in the context of this document, "intact protein" will be understood to mean a protein which is unhydrolyzed, while a "source of intact protein" will be understood to mean a protein source which has not been subjected a treatment whose primary purpose is to hydrolyze unhydrolyzed proteins.

In addition to the sources of intact protein mentioned above, sources of hydrolyzed protein, i.e., sources which have been subjected a treatment whose primary purpose is to hydrolyze unhydrolyzed proteins, can also be used to supply some of the proteins in the nutritional compositions of this disclosure. If so, the amount of hydrolyzed proteins supplied to the nutritional compositions of this disclosure from these sources should not

exceed 20 wt.% of total protein. More desirably, the amount of hydrolyzed proteins supplied to the nutritional compositions of this disclosure from these sources should not exceed 10 wt.% , 5 wt.%, or even 3 wt. %, of total protein. Nutritional compositions containing no hydrolyzed proteins from these protein sources are even more interesting.

Cold Water-Soluble Milk Protein Concentrate

In accordance with the technology of this disclosure, a substantial portion of the proteins in the nutritional compositions of this disclosure are cold water-soluble milk proteins which have been supplied from a cold water-soluble milk protein concentrate (CS-MPC). In accordance with this technology, it has been found that the oxidative stability of nutritional compositions in the form of oil-in-water emulsions, especially those containing LC-PUFAs, can be significantly and inexpensively improved by including these cold water-soluble milk proteins in these compositions.

Milk protein concentrates in which a substantial portion of the proteins therein are cold water soluble are described, for example, in the above-noted WO 2001/41578, WO 2004/057971 and U.S. 2010/0021595. Basically, they are made by a process in which the calcium ions in a concentrated whole milk product in which at least 40% of the non-fat solids are milk proteins are removed by (1) cation exchange using an ion exchanger charged substantially with a single species of monovalent cation, or (2) acidification to pH 4.6-7 with subsequent dialysis and/or ultrafiltration and/or diafiltration, or (3) by the addition of a chelating or sequestering agent to bind a portion of the calcium ions therein, or (4) a combination of these methods. Depending on how the process is carried out, modified protein concentrates are obtained in which some, and in some instances essentially all, of the proteins therein are cold water soluble (*i.e.*, soluble in water at 20° C). Using this technology, modified MPCs can be produced in which the proportion of proteins which are cold water soluble (soluble in water at 20° C) represent from as little as 5 wt.% or less up to essentially all of the total amount of proteins in the MPC.

Such MPCs in which the portion of proteins which are cold water soluble represent at least 40 wt.% of total proteins are especially useful in formulating the nutritional compositions of this disclosure. Particular commercially-available examples of these products include Fonterra MPC 4861 and Fonterra MPC 4862, available from Fonterra

Cooperative Group Limited, Auckland, New Zealand. MPC 4861 contains about 66-70 % cold water soluble proteins as a percentage of total proteins, while MPC 4862 contains about 99 % or more cold water soluble protein.

MPCs made by any other technique or approach and which also contain at least 40 wt.% cold water soluble proteins based on total proteins can also be used.

For ease of description, these MPCs, *i.e.*, MPCs in which at least 40 wt.% of the total amount of proteins in the MPC are soluble in water at 20° C, are referred to in this disclosure as "cold water soluble milk protein concentrates" (CS-MPCs). CS-MPCs in which at least 50 wt.%, at least 60 wt.%, at least 70 wt.%, at least 80 wt.%, at least 90 wt.%, and even at least 95 wt.%, of the total amount of proteins in the MPC are cold water soluble are especially useful in making the nutritional compositions of this disclosure.

As further discussed below, the nutritional compositions of this disclosure are formulated so that at least 40 wt.% of total proteins in the composition are cold water soluble. For economic reasons, most proteins used in commercial nutritional compositions are derived from protein sources which contain mixtures of different proteins, not single isolated proteins. Therefore, as a practical matter, determining what proportion of the proteins in a nutritional composition made in accordance with this disclosure are water soluble will not be made by direct analysis of these proteins. Rather, this determination will made by measuring the amounts of water soluble proteins in the different protein sources that are used to prepare this composition and then calculating the total amount of water soluble proteins in the compositions so obtained.

For the purpose of determining the proportion of the proteins in a particular protein source which are cold water soluble as a percentage of the total proteins, the following analytical test can be used: The protein source to be tested is suspended in water at room temperature at a concentration of 1% w/w. The sample so obtained is then centrifuged for 90 minutes at 31,000 x g at 20° C. The amount of soluble protein in the supernatant is then determined by reversed phase HPLC and size exclusion HPLC. Soluble protein is taken as the total soluble protein in the supernatant divided by the total solids in the suspension before centrifugation.

In accordance with the technology of this disclosure, oil-in-water nutritional compositions are formulated so that at least 40 wt.% of the proteins in the composition are

cold water soluble. In certain embodiments, the amount of proteins in the composition which are cold water soluble is at least 50 wt.%, at least 60 wt.%, at least 70 wt.%, at least 80 wt.%, or even at least 90 wt.%, of total proteins. As indicated above, it has been found that by following this approach, the oxidative stability of the lipids contained in these nutritional compositions can be significantly improved.

In further accordance with the technology of this disclosure, at least 50 wt.% of the total amount of protein in these compositions is derived from one or more CS-MPCs in which at least 50 wt.% of the protein therein is cold water soluble. In certain embodiments, at least 60 wt.% of the protein in the composition is derived from a CS-MPC in which at least 65 wt.% of the protein therein is cold water soluble. In certain embodiments, the portion of the proteins in these CS-MPCs which are cold water soluble may represent at least 60 wt.%, at least 70 wt.%, at least 80 wt.%, or at least 90 wt.%, of the total protein in these CS-MPCs. CS-MPCs in which essentially all proteins are cold water soluble are especially interesting. In further accordance with the technology of this disclosure, it has also been found that nutritional compositions having a desirable combination of physical and hedonic properties, especially viscosity, emulsion stability, flavor, texture, mouth-feel and overall liking can be obtained relatively inexpensively by following this approach.

Other sources of cold water soluble proteins, *i.e.*, sources other than the CS-MPCs mentioned above, can be used to supply some of the cold water soluble proteins of the nutritional compositions of this disclosure. For example, caseinates or sources of hydrolyzed proteins can be used for this purpose. However, there is little, if any, economic advantage in doing so. Accordingly, the amount of cold water soluble proteins in the nutritional compositions of this disclosure which are supplied by these CS-MPCs will normally be $\geq$ 60 wt.%, $\geq$ 70 wt.%, $\geq$ 80 wt.%, $\geq$ 90 wt.%, or even $\geq$ 95 wt.%, of the total amount of cold water soluble proteins in these compositions. Desirably, all or essentially all of the cold water soluble proteins in these nutritional compositions will be supplied from these CS-MPCs.

In one embodiment of this disclosure, this technology is used in formulating nutritional compositions, especially liquid nutritional compositions, in which a significant portion of the fat content of the composition is composed of LC-PUFAs, especially n-3 and n-6 LC-PUFAs, as these lipids are especially vulnerable to oxidative degradation. In such

compositions, the amount of LC-PUFAs is desirably ≥ 0.01 wt.%, ≥ 0.1 wt.%, ≥ 0.5 wt.%, ≥ 1 wt.%, ≥ 2 wt.%, ≥ 5 wt.%, ≥ 10 wt.%, ≥15 wt.%, and even ≥ 20 wt.%, based on the weight of the composition as a whole. In certain embodiments, the nutritional composition comprises long chain polyunsaturated fatty acids and the long chain polyunsaturated fatty acids are omega-3 long chain polyunsaturated fatty acids, omega-6 long chain polyunsaturated fatty acids, or a mixture thereof.

In another embodiment, the technology of this disclosure is used in formulating liquid nutritional compositions in which a substantial majority (75 wt.% or more) of the protein content is based on the combination of milk proteins and vegetable proteins, most commonly soy proteins. In certain embodiments of these compositions, the amount of vegetable proteins typically ranges between about 10 to 45 wt.%, more commonly 15 to 40 wt.%, or even 20 to 32 wt.% of the total protein in the nutritional composition, while milk proteins usually constitute from about 45 to 90 wt.%, more commonly 60 to 85 wt.% or even 68 to 80 wt.% of the total protein in the nutritional composition. This combination is desirable because it makes for a relatively inexpensive product which still exhibits a desirable combination of flavor, odor, texture (viscosity), mouth feel and other hedonic properties. This combination is widely used in making nutrition shakes.

In yet another embodiment, the technology of this disclosure is used for formulating liquid nutritional compositions in which the protein content of the composition is composed of the combination of milk proteins, intact soy proteins and intact pea proteins. *See,* WO 2010/126362 A1, the disclosure of which is incorporated herein by reference. As described therein, the cost of producing nutritional compositions generally and nutrition shakes in particular can be reduced even further by using pea protein as part of the vegetable protein of the composition. Moreover, provided that the proteins are selected in a certain way, this reduction in cost can be accomplished without adversely affecting the other desirable hedonic and other properties of the compositions being modified.

So, for example, WO 2010/126362 A1 suggests that desirable nutritional compositions containing intact vegetable proteins in amounts as high as 40 wt.% of total proteins can be achieved if intact pea protein represents > 25 to 90 wt.% of total intact vegetable protein and, in addition, the amount of casein represents about 60 wt.% (35/65) of total milk proteins. Accordingly, in certain embodiments of the nutritional composition

described herein, intact pea protein represents > 25 to 90 wt.% of total intact vegetable protein in the composition, and the amount of casein represents about 60 wt.% of the total milk protein in the composition.

In certain embodiments, the technology of this disclosure is used for formulating liquid nutritional compositions which comprise intact vegetable proteins and milk protein. In certain embodiments, the intact vegetable proteins (*e.g.*, intact pea protein, intact soy protein) may be present in amounts as high as 35 wt.%, 40 wt.%, 50 wt.%, or 55 wt.% or more of the total protein. In certain embodiments, the nutritional composition comprises intact pea protein, intact soy protein, and milk protein. In certain embodiments, the nutritional composition is formulated such that: (a) the combined amount of intact pea protein and intact soy protein represents about 35 to 55 wt.% of total protein; (b) the amount of intact pea protein represents 14 to 90 wt.% of the combined amount of intact soy protein and intact pea protein; (c) the amount of milk protein represents about 40 to 65 wt.% of total protein; and (d) at least 80 wt.% of the milk protein in the composition is supplied in the form of a cold water soluble milk protein concentrate having a ratio of whey protein to casein of 0.375 or less, more typically about 10/90 to 25/75, even more typically about 20/80.

In certain other embodiments, the nutritional composition is formulated such that: (a) the combined amount of intact pea protein and intact soy protein represents about 38 to 52 wt.% of total protein; (b) the amount of intact pea protein represents 14 to 90 wt.% of the combined amount of intact soy protein and intact pea protein; (c) the amount of milk protein represents about 48 to 62 wt.% of total protein; and (d) at least 90 wt.% of the milk protein is supplied in the form of a cold water soluble milk protein concentrate containing about 75 to 83 wt.% protein.

In certain embodiments, the pea protein in the composition is supplied in the form of a pea protein concentrate (PPC) containing 78 to 90 wt.% pea protein, while the soy protein in the composition is supplied in the form of a concentrated soy protein product (CSPP) containing 60 to 90 wt.% soy protein. Moreover, in certain embodiments, the amount of pea protein concentrate used to formulate the nutritional composition represents 25 to 70 wt.% of the combined amounts of pea protein concentrate and concentrated soy protein product used, while the amount of milk protein concentrate plus added casein (if any) used to

formulate the nutritional composition represents about 50 to 65 wt.% of the total amount of milk protein concentrate, casein, pea protein concentrate and concentrated soy protein product used.

By formulating the nutritional compositions with the CS-MPCs of this disclosure, nutritional compositions can be obtained which not only (a) are less expensive to produce and (b) still exhibit desirable hedonic and other properties, (c) but also exhibit superior oxidative stability as well. And, this is especially so if these compositions also contain elevated amounts of LC-PUFAs as mentioned above, *i.e.*, LC-PUFAs in the amount of ≥ 0.01 wt.%, ≥ 0.1 wt.%, ≥ 0.5 wt.%, ≥ 1 wt.%, ≥ 2 wt.%, ≥ 5 wt.%, ≥ 10 wt.%, ≥15 wt.%, and even ≥ 20 wt.%, based on the weight of the composition as a whole.

EXAMPLES

The following working examples are provided to illustrate nutritional compositions of this disclosure, including their relationship to control examples made in accordance with conventional technology:

Control Example A

A vanilla flavored nutrition shake in the form of an aqueous oil-in-water emulsion having a viscosity of approximately 15 cps, which was especially formulated to provide balanced nutritional supplements for normal adults, was formulated to contain 3.5 wt.% protein, 16 wt.% carbohydrate and 2.4 wt.% fat.

The protein component of this composition was formulated using a conventional commercially-available milk protein concentrate containing 22 wt.%, based on total protein, of cold water soluble milk protein, and a conventional commercially-available soy protein concentrate containing 37 wt.%, based on total protein, of cold water soluble protein. Enough of these protein sources were used to produce a final product containing 42 g/L milk protein and 4.4 g/L soy protein, resulting in a total concentration of cold water soluble protein of 24 wt.% based on total protein.

Example 1

Control Example A was repeated except that the conventional commercially-available milk protein concentrate was replaced with an equal amount of Fonterra MPC 4862, a cold water soluble milk protein concentrate containing 99+% cold water soluble protein based on total protein. The total concentration of cold water soluble protein in the product ultimately obtained was 94 wt.% ,based on total protein, representing a 392% increase in cold water soluble protein relative to Control Example A.

Control Example B

Control Example A was repeated, except that the nutrition shake was formulated to be chocolate flavored and to contain 3.5 wt.% protein, 16 wt.% carbohydrate and 2.4 wt.% fat. In addition, enough of these protein sources were used to produce a final product containing 37 g/L milk protein and 9.3 g/L soy protein, resulting in a total concentration of cold water soluble protein of 25 wt.% based on total protein.

Example 2

Control Example B was repeated except that the conventional commercially-available milk protein concentrate was replaced with an equal amount of Fonterra MPC 4861, a cold water soluble milk protein concentrate containing about 70% cold water soluble protein based on total protein. The total concentration of cold water soluble protein in the product ultimately obtained was 63 wt.%, based on total protein, representing a 252% increase in cold water soluble protein relative to Control Example B.

Control Example C

Control Example A was repeated, except that the nutrition shake was formulated to contain 3.5 wt.% protein, 16 wt.% carbohydrate and 2.4 wt.% fat. In addition, a whey protein concentrate containing 96 wt.% cold water soluble protein was used to provide 3.5 g/L of additional whey protein to the product ultimately obtained. while enough milk protein concentrate and soy protein concentrate were used to provide 48 g/L milk protein (from this concentrate) and 17 g/L soy protein. The total concentration of cold water soluble protein in this product was 29 wt.% based on total protein.

Example 3

Control Example C was repeated except that the conventional commercially-available milk protein concentrate was replaced with an equal amount of Fonterra MPC 4862, a cold water soluble milk protein concentrate containing about 99+% cold water soluble protein based on total protein. The total concentration of cold water soluble protein in the product ultimately obtained was 84 wt.%, based on total protein, representing a 290% increase in cold water soluble protein relative to Control Example C.

Although only a few embodiments of the nutritional compositions of this disclosure have been described above, it should be appreciated that many modifications can be made without departing from the spirit and scope of the technology described in this disclosure. All such modifications are intended to be included within the scope of this disclosure, which is to be limited only by the following claims:

What is claimed is:

1. A nutritional composition in the form of an oil-in-water emulsion containing about 0.5 to 50 wt.% protein, about 0.1 to 25 wt.% fat, about 0.1 to 50 wt.% carbohydrate, and about 50 to 95 wt.% water, wherein at least 40 wt.% of the protein in the composition is cold water soluble and further wherein at least 50 wt.% of the protein in the composition is derived from a cold water soluble milk protein concentrate in which at least 50 wt.% of the protein therein is cold water soluble.

2. The nutritional composition of claim 1, wherein at least 60 wt.% of the protein in the composition is derived from a cold water soluble milk protein concentrate in which at least 65 wt.% of the protein therein is cold water soluble.

3. The nutritional composition of claims 1 or 2, wherein at least 60 wt.% of the protein in the composition is cold water soluble.

4. The nutritional composition of any of claim 3, wherein at least 80 wt.% of the protein in the composition is cold water soluble

5. The nutritional composition of any of the preceding claims, wherein the composition contains $\geq$ 0.1 wt.% long chain polyunsaturated fatty acids.

6. The nutritional composition of claim 5, wherein composition contains $\geq$ 1 wt.% long chain polyunsaturated fatty acids.

7. The nutritional composition of claim 6, wherein composition contains $\geq$ 5 wt.% long chain polyunsaturated fatty acids.

8. The nutritional composition of any one of claims 5 to 7, wherein the long chain polyunsaturated fatty acids are omega-3 long chain polyunsaturated fatty acids, omega-6 long chain polyunsaturated fatty acids, or a mixture thereof.

9. The nutritional composition of any of the preceding claims, wherein from about 10 to 45 wt.% of the total protein in the composition is derived from vegetable protein, and from about 45 to 90 wt.% of the total protein in the composition is derived from milk protein.

10. The nutritional composition of claim 9, wherein from about 20 to 32 wt.% of the total protein in the composition is derived from vegetable protein, and from about 68 to 80 wt.% of the total protein in the composition is derived from milk protein.

11. The nutritional composition of any of the preceding claims, wherein the protein content of the composition is composed of the combination of milk protein, intact soy protein, and intact pea protein.

12. The nutritional composition of claim 11, wherein intact pea protein represents > 25 to 90 wt.% of total intact vegetable protein in the composition, and the amount of casein represents about 60 wt.% of total milk protein in the composition.

13. The nutritional composition of claim 11, wherein (a) the combined amount of intact pea protein and intact soy protein in the composition represents about 35 to 55 wt.% of total protein, (b) the amount of intact pea protein in the composition represents 14 to 90 wt.% of the combined amount of intact soy protein and intact pea protein, (c) the amount of milk protein in the composition represents about 40 to 65 wt.% of total protein, and (d) at least 80 wt.% of the milk protein in the composition is supplied in the form of a cold water soluble milk protein concentrate having a ratio of whey protein to casein of 0.375 or less.

14. The nutritional composition of claim 13, wherein (a) the combined amount of intact pea protein and intact soy protein represents about 38 to 52 wt.% of total protein, (b) the amount of intact pea protein represents 14 to 90 wt.% of the combined amount of intact soy protein and intact pea protein, (c) the amount of milk protein represents about 48 to 62 wt.% of total protein, and (d) at least 90 wt.% of the milk protein is supplied in the form of a cold water soluble milk protein concentrate containing about 75 to 83 wt.% protein.

15. The nutritional composition of claims 13 or 14, wherein the pea protein in the composition is supplied in the form of a pea protein concentrate containing 78 to 90 wt.% pea protein, while the soy protein in the composition is supplied in the form of a concentrated soy protein product containing 60 to 90 wt.% soy protein.

16. The nutritional composition of claim 15, wherein the amount of pea protein concentrate used to formulate the nutritional composition is 25 to 70 wt.% of the combined amounts of pea protein concentrate and concentrated soy protein product used, while the amount of milk protein concentrate plus added casein, if any, used to formulate the nutritional composition is about 50 to 65 wt.% of the total amount of milk protein concentrate, casein, pea protein concentrate and concentrated soy protein product used.

17. The nutritional composition of any of the preceding claims, wherein at least 60 wt.% of the protein in the composition is derived from a milk protein concentrate.

18. A powder or concentrate which, when diluted with water, yields the nutritional composition of claim 1.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2014/026188

A. CLASSIFICATION OF SUBJECT MATTER
INV. A23L1/305 A23L1/30 A23L1/29 A23C9/20
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A23L A23C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, BIOSIS, FSTA, PAJ, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2013/017553 A1 (GROUPE LACTALIS [FR]; MORGAN FRANCOIS [FR]; BONHOMME CECILE [FR]; MATH) 7 February 2013 (2013-02-07) page 1, lines 2-6 page 2, lines 3-4 page 3, line 11 - page 5, line 26 page 6, lines 3-5, 20-24 examples 1,2 table 1	1-18

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 June 2014	25/06/2014

Name and mailing address of the ISA/	Authorized officer
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INTERNATIONAL SEARCH REPORT

International application No
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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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