Whey Protein Concentrate (WPC)

Handling

Identification of Petitioned Substance

Chemical Names:
Whey Protein Concentrate (WPC), WPC 34, WPC 55, WPC 80

Other Name:
Whey, proteins, Designer Whey, Milk basic protein, Whey powders (permeate), Sweet whey Acid whey, Demineralized whey products, Bioactive proteins/Whey fractions, Reduced lactose whey

Trade Names:
Whey Protein Concentrate, WPC, WPC 34, WPC80
CAS Number: 91082-88-1 **(**Guidechem, 2015)

EINECS (EC#):293-803-2

Summary of Petitioned Use

Currently, whey protein concentrate (WPC) is listed on USDA's National Organic Program's (NOP) National List of allowed ingredients for use in or on processed products labeled organic.

This falls under the following section:

> §205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."
>
> Only the following nonorganically produced agricultural products may be used as ingredients in or on processed products labeled as "organic," only in accordance with any restrictions specified in this section, and only when the product is not commercially available in organic form.
>
> (z) Whey protein concentrate.

The Organic Foods Production Act (OFPA), 7 U.S.C. 6501 et seq., authorizes the establishment of the National List of allowed and prohibited substances. Exemptions and prohibitions granted under the OFPA are required to be reviewed every 5 years by the National Organic Standards Board (NOSB). The NOSB requested a technical evaluation report for WPC. WPC is scheduled to sunset on June 27, 2017.

Characterization of Petitioned Substance

Composition of the Substance:

There is approximately 3.6% protein in liquid bovine milk. This protein fraction is composed of 20% whey and 80% casein. Whey is the liquid substance obtained by separating the coagulum from milk or cream in cheese making. In its raw liquid form, whey is composed of naturally occurring macronutrients-i.e., water (93%) protein (0.8%), fat (0.3%), lactose (4.8%) and minerals-referred to as ash (0.5 %). Whey is the collection of globular proteins isolated from the liquid fraction (micronutrients) that are biologically active-beta (β) - lactoglobulin, alpha (α)-lactalbumin, glycomacropeptide, bovine serum albumin, immunoglobulins, lactoferrin and lactoperoxidase. The liquid whey becomes the starting material for whey protein concentrate (WPC). Ultrafiltration, evaporation and drying are used to produce commercial

ingredients with 34 to 80% protein content in the dry product. Additional steps are needed to make whey protein isolates (WPI) that have greater than 90% protein content.

Table 1. Proximate Composition of Whey

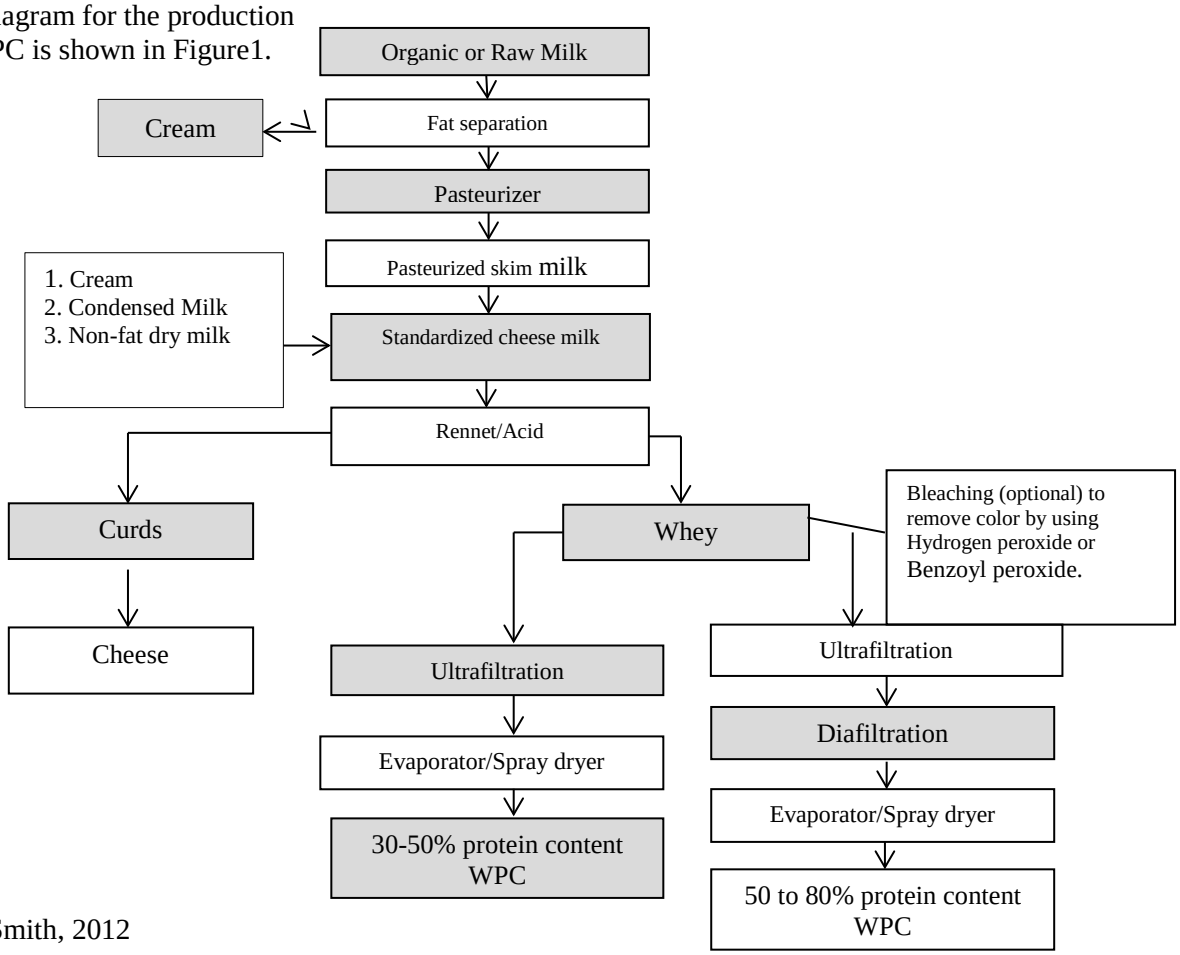
Component	% concentration
Total solids	6.0-7.0
Water	93.0
Fat	0.3
Phospholipid	0.12
Whey protein	0.8
β-Lactoglobulin	0.32
α-Lactalbumin	0.12
Immunoglobulins	0.06
Bovine serum albumin	0.04
Proteose-peptone	0.07
Lactoferrin	0.003
Lactoperoxidase	0.002
Glycomacropeptide	0.13
Lactose	4.9
Minerals	0.5
Calcium	0.05
Phosphorous	0.04
Potassium	0.15

Source: Smith, 2012.

Source or Origin of the Substance:

A process flow diagram for the production of cheese and WPC is shown in Figure1.

Figure 1.



Source: Smith, 2012

Whey, by definition from 21 U.S. Code of Federal Regulations (CFR) §184.1979a, is the liquid substances obtained by separating the coagulum from the milk or cream in cheese making. The milk is often standardized before cheese making in order to optimize the protein (casein) to fat ratio. This is accomplished by adding protein solids (i.e., condensed skim milk and non-fat dry milk NFDM) to the standardized cheese milk (SCM) in order to improve cheese (compositional) quality and production yields. Rennet (animal –derived) or chymosin preparation (fermentation-derived) 21 CFR § 184.1685 calcium chloride (21 CFR184.1193), and dairy cultures are added to the SCM. These nonorganic substances are allowed as ingredients in or on processed products labeled as organic (7 CFR §205.605). The casein coagulates in the presence of rennet or (lactic) acid to form the cheese curd. The pH of the cheese milk drops from 6.7 to 5.3 which causes the casein protein to coagulate and form a curd. The curd traps most of the lactose, fat, and ash. The liquid whey protein that remains is further processed into a variety of commercial ingredients from dried whey (13 percent protein) to whey protein concentrates (25 to 89 percent protein) and whey protein isolates (greater than 90 percent protein). One pound of cheese produces nine pounds of liquid whey protein. In high moisture fresh cheeses such as cottage cheese (where a portion of the original raw milk is returned to the cheese as cream dressing) the ratio may be as low as 6:1 (Burrington, 2012b., Etzel, 2004., Brown, 2014., and Walstra et al., 1999).

Properties of the Substance:

Whey is the soluble fraction of milk, rich in proteins, minerals and lactose that are separated from casein during the manufacture of cheese or casein (Table 1). This separation is usually accomplished by acidification to pH 4.5-4.8 or through the action of rennet, a casein-coagulating enzyme preparation. In acid coagulation, the pH is lowered either by microbial fermentation of the milk sugar lactose into lactic acid or by direct addition of organic (lactic) acids. The fermentation route is most often used in the production of cottage cheese and other fresh cheeses, and is referred to as acid whey. In contrast, sweet wheys are obtained in manufacture of cheddar, mozzarella and other hard cheeses using rennet coagulation to form the curd. Since enzymatic clotting of milk by rennet occurs at pH 6.0 or higher, the lactic acid content of freshly obtained sweet whey is low and is controlled by pasteurization and refrigeration. In addition, rennet whey contains glycomacropeptide, which is cleaved from kappa (k)-casein by chymosin to initiate precipitation of the caseins forming curd (Foegeding et al., 2011).

The main constituents of the cheese whey are β-lactoglobulin and α-lactalbumin, two globular proteins that account for 70-80 percent of total whey protein. Minor protein components include immunoglobulin, bovine serum albumin, glycomacropeptide (rennet whey), lactoferrin, lactoperoxidase and numerous and endogenous enzymes. The level and amount present is dependent on the milk source (e.g., animal husbandry, feed, stage of lactation), whether standardized cheese milk (SCM) was used to improve cheese compositional quality, and the type of whey (acid or sweet) used.

Whey proteins are widely used as food ingredients for their nutritional properties (Morr et al., 1993). Whey protein has a biological value (BV) that exceeds that of egg protein (by 15 percent) and other high protein foods (meat, soy and casein). BV is the measure of a food's protein quality compared to that of egg protein, which has the maximum biological value of 0.9–1.00 (defined as the ratio of nitrogen retained/nitrogen lost in a single source) (Segen, 2012). Smithers, 2012 reported that whey is a source for 20 amino acids and all nine essential amino acids (i.e., leucine, isoleucine, and valine, ≥ 20 percent w/w). These amino acids are believed to play a role in as metabolic regulators in protein and glucose homoeostasis and lipid metabolism. In addition, whey contains sulfur amino acids (i.e., methionine and cysteine) (Smithers, 2008) which serves as an antioxidant and in carbon metabolism.

Also, WPC is used as a food ingredient because of its functional properties. Morr et al., 1993 defines protein functional properties as those physiochemical changes that influence the structure appearance, texture, viscosity, mouthfeel or flavor retention of the food product. Whey proteins can be used in a number of products because of these functional properties and desirable sensory characteristics. These include bakery, confectionary, processed meat and infant formula, and dairy products (Onwalata et al, 2004). The functionality of whey protein depends on the chemical and physicochemical properties of their

three dimensional protein structure including the shape (molecular unfolding and rearrangement), bonding of the sulfhydryl groups, amino acid composition, molecular weight, polypeptide chain flexibility, and surface hydrophobicity. External factors that influence functional properties include protein concentration, pH, temperature, ionic strength, and type of ions present and the influence of other available food components (Farrell et al., 2004 and Morr et al.,1993).

The functionality of WPC depends on the total whey protein not the individual fractions. However, Chatterton et al., 2006 reported that β-lactoglobulin showed excellent gelling, foaming and emulsifying properties while α-lactalbumin some emulsifying properties but poor gelling ability. In addition, researchers have indicated that there are no uniform set of standards for these products in food systems due to their inherent compositional variability and different processing conditions used in cheese making and producing WPC (Morr et al., 1993, Jovanovic et al., 2005).

The chemical and properties of whey proteins are summarized in Table 2.

Table 2. Chemical and physicochemical properties of whey proteins.

Whey Protein fractions	Molecular mass (kg/mol)	Isoelectric point	Concentration In liquid whey (g/l)	Number of amino acids	Temperature of denaturation °C
β-lactoglobulin	18	5.4	3.2	162	78
α-lactalbumin	14	4.4	1.2	123	62
bovine serum albumin	66	5.1	0.4	582	64
immunoglobulin	≥145	5-8	0.7	-	72
glycomacropeptide	8.6	≤ 3.8	1.5	64	-
Lactoferrin	77	7.9	0.1	700	-
lactoperoxidase	78	9.6	0.03	612	-

Source: Madureira et al., 2007, Mollea et al., 2013, Morr et al., 1993, and Farrell et al., 2004 and Bryant et al., 1998.

The liquid whey is then concentrated by ultrafiltration (UF). UF membranes with varying pore sizes separate whey's larger-molecular-weight proteins and residual fats (retentate) from their smaller-molecular-weight lactose , minerals, soluble salts and non-protein nitrogen are removed with the permeate.

Diafiltration (DF) is commonly applied to help remove additional lactose and soluble minerals. The liquid whey protein fractions are further concentrated by evaporation prior to spray-drying in order to improve the physical properties of the powder.

The most important commercial whey protein products are whey protein concentrates (WPCs) with protein levels ranging from 34% to 85%. Whey protein isolate (WPI) contains at least 90% protein on a dry weight basis (w/w) and contains little fat, lactose and mineral content (Morr et al., 1993). The principal fractions (%) of whey protein (dry matter basis) and their biological functions and benefits are listed in Table 3.

Table 3. Percent of Whey protein fractions found in WPC.

Whey Protein fraction	WPC %	WPI %	Biological functions and benefits
β-lactoglobulin	50 to 60	44 to 69	Acts as a transport protein for desirable lipophilic compounds such as tocopherol and vitamin A.
α-lactalbumin	12 to 16	14 to 15	Modulates the synthesis of lactose in the mammary gland. Added to infant formulas and to products for individuals with limited

			or restricted protein intakes.
glycomacropeptide	15 to 21	2 to 20	Reduces gastric secretion, inhibition of platelet aggregation, suppress appetite via stimulation of the pancreatic hormone cholecystokinin release. Acts as prebiotic and has immunomodulatory actions.
Bovine serum albumin	3 to 5	1 to 3	Associated with its lipid binding properties and mediates lipid oxidation.
Immunoglobulins	5 to 8	2 to 3	Provides disease protection to newborns through passive immunity.
Lactoferrin	<1	-	Antimicrobial properties, iron binding characteristics and inhibition of free radicals
Lactoperoxidase	<1	-	Identified as an antimicrobial agent

Source: Burrington, 2013, and U.S. Dairy Export Council, 2004.

Specific Uses of the Substance:

Whey proteins are well known for their high nutritional value and versatile functional properties in food products (de Wit, 1998). In food systems, whey protein contributes to the functional characteristics of a food product. These characteristics and functional benefits for yogurt are listed in Table 4.

Table 4. Whey protein functional characteristics for yogurt.

Functionality	**Characteristics**	**End results**
Water binding and viscosity	Whey protein molecular structure begins to unfold and form aggregates (denaturation) in solution.	Increases viscosity, and affects the mouthfeel and texture of the yogurt.
Nutritional enrichment	Possess high-quality proteins — all the amino acids required for a healthful diet — in a readily digestible form. Whey products are high in calcium content and rich in thiamin, riboflavin, pantothenic acid and other nutrients.	Contributes to healthful image-label friendly ingredients. A natural source of essential amino acids, calcium, and bioactive proteins.
Gelation	Whey components form non-reversible gels under denaturation (at 70° C or higher influenced by pH and salts).	Gels bind large quantities of water and non-protein compounds. Improves mouthfeel and texture.
Dairy flavor	The natural flavors of	Bland in flavor

	milk.	
Solubility	Soluble at all pH levels, temperature, protein concentration, and ionic conditions. If denatured, insoluble at pH 5	Can be used as an ingredient in a wide range of food system applications.

Source: US Dairy Export Council, 2004, Smithers, 2008, and Morr et al., 1993.

Approved Legal Uses of the Substance:

National Organic Program:

Currently, WPC is listed on USDA National Organic Program's (NOP) National List of allowed ingredients for use in or on processed products labeled organic.

This falls under the following section:

> §205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."

Food and Drug Administration (FDA):

FDA has designated WPC as Generally Recognized as Safe (GRAS) ingredient. Specifically:

21 CFR §184.1979a. (1) Whey is the liquid substance obtained by separating the coagulum from milk, cream, or skim milk in cheese making. Whey obtained from a procedure, in which a significant amount of lactose is converted to lactic acid, or from the curd formation by direct acidification of milk, is known as acid whey. Whey obtained from a procedure in which there is insignificant conversion of lactose to lactic acid is known as sweet whey.

21 CFR § 184.1979c. Whey protein concentrate. (a) Whey protein concentrate is the substance obtained by the removal of sufficient nonprotein 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. The acidity of whey protein concentrate may be adjusted by the addition of safe and suitable pH-adjusting ingredients. (b) The whey protein concentrate meets the following specifications: (1) the analysis of whey protein concentrate, on a dry product basis, based on analytical methods in the referenced sections of "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th ed. (1980).
(i) Protein content, minimum 25 percent.
(ii) Fat content, 1 to 10 percent.
(iii) Ash content, 2 to 15 percent.
(iv) Lactose content, maximum 60 percent.
(v) Moisture content, 1 to 6 percent.
(vii) Titratable Acidity, variable.
(2) Limits of impurities are: Heavy metals (as lead). Not more than 10 parts per million (0.001 percent.
(3) The whey protein concentrate shall be derived from milk that has been pasteurized, or the whey protein concentrate shall be subjected to pasteurization techniques or its equivalent before use in food.
(c) The whey protein concentrate may be used in food in accordance with good manufacturing practice as indicated in 184.1(b) (1). (d) The percent of protein present on a dry product basis, i.e., "whey protein concentrate (__% protein)," shall be declared on the label of the package sold to food manufacturers. The percent of protein may be declared in 5-percent increments, expressed as a multiple of 5, not greater than the actual percentage of protein in the product, or as an actual percentage provided that an analysis of the product on which the actual percentage is based is supplied to the food manufacturer.

(e) The presence of whey protein concentrate in a finished food product shall be listed as "whey protein concentrate".

Action of the Substance:

Whey is the soluble fraction of milk, rich in proteins, minerals and lactose that are separated from casein during the manufacture of cheese or casein (Table 1). This separation is usually accomplished by acidification to pH 4.5-4.8 (20°C) or through the action of rennet, a casein-coagulating enzyme preparation.

The liquid whey is called “sweet whey” (pH greater than or equal to 5.6) if it comes from rennet coagulated cheese production or “acid” whey (pH less than or equal to 5.1) if it originates from cottage cheese production. Whey proteins can perform a number of technical functions in food products. They possess solubility over a wide pH range, even near their isoelectric point, create viscosity through water binding, form gels, emulsify, bind fat, facilitate whipping, foaming and aeration, enhance color, flavor and texture, and bring with them numerous nutritional advantages.

For example, high solubility over a wide range of pH makes WPCs a good candidate for a sport beverage or meal-replacement beverage. WPC can also be used as a replacement for other protein ingredients (i.e., soy, egg, milk and meat proteins), modified starches and hydrocolloids gums. In their native state, whey proteins are highly soluble and perform emulsification and whipping functions in a food application. They have no flavor on their own and are compatible with dairy, bakery and meat analog products. They give firmness texture and facilitate retention of moisture during processing and cooking. In baked goods, whey proteins are used to enhance crust browning, bread flavor and crumb structure. They impart a smooth mouthfeel and mild in flavor. Finally, they are a source for high nutritional-quality proteins which makes them particularly useful in sports nutrition. They have an excellent metabolic efficiency and are easily digested. They have the highest concentration of branched chain amino-acids (BCAAs), are a good source of sulphur-containing amino-acids that maintains antioxidant levels in the body, contain glutamine and high levels of arginine and lysine that may stimulate growth hormone release and an increase in muscle mass (Sodini et al., 2005, Walstra et al. 1999, Brown, 2014).

In January 2006, the NOP received a petition to add whey protein concentrate (35% Protein) to section 205.606 of the National List as a non-organically produced agricultural product to meet their specifications for the manufacturing frozen yogurt products as a fat replacer. The petitioner stated their inability to locate an adequate of domestic supply of organic WPC (35% protein).

The legal definitions for yogurt, low-fat yogurt and nonfat yogurt are specified in the Standards of Identity listed in the CFR, in 21 CFR §131.200, 21 CFR §131.203, and 21 CFR§ 131.206, respectively.

The CFR description for yogurt is a food produced by culturing one or more of the optional dairy ingredients specified in paragraph (c) of this section with a characterizing bacterial culture that contains the lactic acid-producing bacteria, *Lactobacillus bulgaricus* and *Streptococcus thermophilus.* One or more of the other optional ingredients specified in paragraphs (b) and (d) of this section may also be added. When one or more of the ingredients specified in paragraph (d)(1) of this section are used, they shall be included in the culturing process. All ingredients used are safe and suitable. Yogurt, before the addition of bulky flavors, contains not less than 3.25 percent milkfat and not less than 8.25 percent milk solids not fat, and has a titratable acidity of not less than 0.9 percent, expressed as lactic acid. The food may be homogenized and shall be pasteurized or ultra-pasteurized prior to the addition of the bacterial culture. Flavoring ingredients may be added after pasteurization or ultra-pasteurization. To extend the shelf life of the food, yogurt may be heat treated after culturing is completed, to destroy viable microorganisms.

(b) Vitamin addition (optional).
(c) Optional dairy ingredients. Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.

(d) Other optional ingredients. (1) Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food: Provided, That the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present shall not be decreased as a result of adding such ingredients.

Since WPC is a dairy ingredient, it can be labeled as a natural ingredient. As reported by Sodini et al., 2005, WPC could be used as a possible supplement to improve the functional properties (i.e., water holding capacity, gel firmness and viscosity) of yogurt. However, current CFR regulations, as mentioned above, limit WPC use as an optional (secondary) ingredient. The regulations state that solids come from the optional dairy ingredients (Cream, milk, partially skimmed milk, or skim milk, used alone or in combination) in order to increase milk solids (protein) nonfat content to the required 8.25% level. Therefore, limiting the use of WPC as a primary ingredient in yogurt.

Combinations of the Substance:

Whey is co-product of cheese making and casein manufacture in the dairy industry (Solak et al., 2012). The composition of whey products varies according to the milk source, type of cheese, the methods of production, purification and concentration, and manufacturing process (Harper, 2004, Solak et al., 2012).

In cheese processing, there are two basic types of whey. Acid whey is obtained from a process in which either a significant amount of lactose is converted to lactic acid or from curd formation by direct acidification of milk (cottage cheese). Sweet whey is derived from the manufacture of rennet-produced cheeses. Most commercial whey ingredients are made from sweet whey, which is a coproduct of cheese varieties like cheddar and mozzarella. The fresh liquid whey is concentrated by evaporation, ultrafiltration prior to spray drying (Figure 1). Rennet, calcium chloride, and dairy cultures are added to the standardized cheese milk (SCM). These nonorganic substances are allowed as ingredients in or on processed products labeled as organic (7 CFR §205.605).

Status

Historic Use:

Whey was discovered 3,000 years ago when calves stomachs were used to transport milk. Through the action of the naturally occurring enzyme chymosin found in calves' stomachs, the milk coagulated during storage and transport, resulting in curds and whey (Smithers, 2008). Historically, whey (lactoserum) was considered as a medicinal cure for a number of human ailments in the 17th and 18th centuries (Smithers, 2008). Until recently, whey was considered a waste product from cheese manufacturing, rarely used as a food product and discarded either as a waste stream or for use as animal feed and fertilizer (Chegini et al., 2013). In most jurisdictions, environmental regulations now prevent disposal of untreated whey on agricultural land or discharging in municipal sewage system or surface water. Whey composition (high solids, lactose and salt content) makes disposal practices a problem (Smithers, 2008).

With recent advances in technology, as well as increasing awareness of the environmental and financial costs of whey disposal, the dairy industry have found it profitable to process whey into high value added protein products for use as ingredients in food systems. Whey proteins are generally recognized as safe (GRAS) by FDA and are considered label-friendly ingredient (Bryant et al., 1998). WPC, which range in protein from 25 to 90 percent, contribute to the flavor, texture and nutritional quality found in bakery and dairy products, infant formulas and sports bars.

In 2013, US production of whey protein concentrates (25-90% protein solids) and isolates (>90% protein solids) totaled approximately 576 million pounds (NASS, 2014). Total production of dry whey products (for human and animal) totaled 961 million pounds for this time period.

In January 2006, the NOP received a petition to add whey protein concentrate (35% Protein) to § 205.606 of the National List as a nonorganically produced agricultural product to meet their specifications for the manufacturing frozen yogurt products as a fat replacer.

The petitioner stated that processors capable of manufacturing WPC powder are instead choosing to manufacture whey powder. "Most whey is processed into either whey powder, which is used in dry cheese powders, or demineralized whey powder, which is used in organic infant formulas and organic protein bars. The processing yield for whey powder is higher than for WPC which is produced through a multiple step process. The process of producing WPC results in lactose which can be recovered and sold." The petitioner also stated that the "market for organic WPC is still relatively small resulting in proportionately small processing runs for organic WPC. The quantity of lactose recovered from processing of organic WPC is too small to make recovery economically feasible. This in combination with other losses associated with small processing runs and lower processing yield creates an economic disincentive for processors to produce WPC."

In addition, the petitioner needed to receive documentation that the milk supply used to manufacturer WPC was free from recombinant Bovine Growth Hormone (rBGH), a synthetic form of growth hormone injected into cows to increase growth rates and milk production.

Organic Foods Production Act, USDA Final Rule:

Currently, Whey Protein Concentrate (WPC) is listed on USDA National Organic Program's (NOP) National List of allowed ingredients for use in or on processed products labeled organic.

This falls under the following section:

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> Only the following nonorganically produced agricultural products may be used as ingredients in or on processed products labeled as "organic," only in accordance with any restrictions specified in this section, and only when the product is not commercially available in organic form.
>
> (z) Whey protein concentrate.

International

- **Canada** - Canadian General Standards Board Permitted Substances List – CAN/CGSB-32.311-2006 Amended June 2011

http://www.tpsgc-pwgsc.gc.ca/ongc-cgsb/programme-program/normes-standards/internet/bio-org/permises-permitted-eng.html

WPC is not on the permitted substance list for processing and handling of organic food.

- **CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)**

www.fao.org/docs/eims/upload/230124/CXG_032e.pdf

WPC is not on the permitted substance list for processing and handling of organic food.

- **European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008**

www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5085368

Article 28:
Use of certain non-organic ingredients of agricultural origin in processing food

For the purpose of Article 19(2) (c) of Regulation (EC) No 834/2007, non-organic agricultural ingredients listed in Annex IX to this Regulation can be used in the processing of organic food.
3. ANIMAL PRODUCTS
− whey powder 'herasuola' (To stay in Annex IX of Reg. (EC) No. 889/2008 due to shortage in quantity and/or quality)

- **Japan Agricultural Standard (JAS) for Organic Production**—
  http://www.ams.usda.gov/nop/NOP/TradeIssues/JAS.html

Standards and Individual Procedures for Judging Compliance of Substances Listed in Appendices 1 and 2 of Japanese Agricultural Standards for Organic Plants: Notice 1180, August 2009

WPC is not on the permitted substance list for processing and handling of organic food.

- **The International Federation of Organic Agriculture Movements (IFOAM)**
  http://www.organic-standards.Info/en/documents standards state in

Chapter 7 PROCESSING AND HANDLING
Ingredients
General Principle
Organic processed products are made from organic ingredients.
Requirements:
7.2.1) All ingredients used in an organic processed product shall be organically produced except for those additives and processing aids that appear in Appendix 4.
Regional or other exception
In cases where an ingredient of organic origin is commercially unavailable in sufficient quality or quantity, operators may use non-organic raw materials, provided that:
a. they are not genetically engineered or contain nanomaterials , and
b. the current lack of availability in that region is officially recognized or prior permission from the control body is obtained.

WPC is not on the permitted substance list for processing and handling of organic food.

Evaluation Questions for Substances to be used in Organic Handling

Evaluation Question #1: Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).

Whey is the soluble fraction of milk, rich in proteins, minerals and lactose that are separated from casein during the manufacture of cheese or casein (Table 1). This separation is usually accomplished by acidification to pH 4.5-4.8 or through the action of rennet, a casein-coagulating enzyme preparation. In acid coagulation, the pH is lowered either by microbial fermentation of the milk sugar lactose into lactic acid or by direct addition of organic (lactic) acids. The fermentation route is most often used in the production of cottage cheese and other fresh cheeses, and is referred to as acid whey. In contrast, sweet wheys are obtained in manufacture of cheddar, mozzarella and other hard cheeses using rennet coagulation to form the curd. Since enzymatic clotting of milk by rennet occurs at pH 6.0 or higher, the lactic acid content of freshly obtained sweet whey is low and is controlled by pasteurization and refrigeration. In addition, rennet whey contains glycomacropeptide, which is cleaved from kappa (k)-casein by chymosin to initiate precipitation of the caseins forming curd (Foegeding et al., 2011).

The main constituents of the cheese whey are β-lactoglobulin and α-lactalbumin, two globular proteins that account for 70-80 percent of total whey protein. Minor protein components include immunoglobulin, bovine serum albumin, glycomacropeptide (rennet whey), lactoferrin, lactoperoxidase and numerous and endogenous enzymes. The level and amount present is dependent on the milk source, (animal husbandry, feed, stage of lactation), whether SCM was used to improve cheese compositional quality, and the type of whey (acid or sweet) used.

WPC is typically produced using an ultrafiltration process. After the ultrafiltration process, the concentrated liquid whey passes through an evaporator and a spray dryer to remove all but 4-5 % of the water. WPC is often referred to in conjunction with its level of protein concentration. The processing method of choice is commercial-scale ultrafiltration and diafiltration with semipermeable membranes. These have molecular weight cut-off limits of 1000 to 300,000 Daltons (Da) for fractionating whey protein from the low-molecular-weight compounds such as lactose, minerals, non-protein nitrogen and vitamins.

Whey from Cheddar cheese production is one of the most common fluid whey sources. Cheddar cheese is largely colored with annatto which is a GRAS pigment from the tropical shrub Bixa orellana, used to give the Cheddar cheese its characteristic yellowish-orange natural color. Annatto has been used in dairy products since the 1800s to standardize the color of cheese, which varies due to seasonal feed variations in the milk (Kang et al., 2010). According to 21 CFR §73.30 annatto extract may be used for coloring foods as long as good manufacturing practices (GMP) are employed. Annatto is comprised of two carotenoid pigments, oil soluble bixin and water soluble norbixin (Kang et al., 2010). Studies suggest that norbixin (water-soluble) is able to bind with β-casein or β-lactoglobulin to form a stable complex that prevents easy removal of the annatto. This colorant is not all retained in the cheese; approximately 20 percent of annatto added to cheese milk passes into whey, which is highly undesirable visual in appearance (Burrington, 2012).

As a result, whey is often bleached to remove the yellow color. Hydrogen peroxide (HP) and benzoyl peroxide (BP) are two bleaching agents currently approved by FDA for bleaching whey (Burrington, 2012, and Kang, et al., 2010) and are generally recognized as safe (GRAS).

HP (H_2O_2) is a clear, colorless liquid with a slightly pungent odor. HP decomposes to oxygen and water during bleaching Residual hydrogen peroxide must be removed from whey and cheese milk physically or by the addition of catalase according to 21 CFR §184.1366 and 21 CFR §133.113. Catalase converts hydrogen peroxide into oxygen and water. Catalase use must not exceed 20 ppm and must be sufficient to remove any residual hydrogen peroxide. As hydrogen peroxide is a GRAS substance, the maximum treatment level for bleaching annatto-colored whey using hydrogen peroxide is 0.05% (<500 ppm) of the whey (Kang et al., 2010 and Listiyani et al., 2011).

BP ($C_{14}H_{10}O_4$) is a colorless, crystalline solid permitted for use in removing color in whey products that are not used for infant formula. Like hydrogen peroxide, benzoyl peroxide is also a GRAS substance and can be used to bleach dairy ingredients. Unlike hydrogen peroxide, benzoyl peroxide has no limitation on usage rates in foods other than current GMP rules. BP will breaks down to water-soluble benzoic acid (BA) when it reacts with annatto or carotenoid pigments during bleaching process.

Although BA is listed as GRAS, it has been reported to give adverse health effects, such as skin and eye irritation, asthma, metabolic acidosis, and convulsions (Listiyani et al., 2011). Many Asian and European countries consider BA harmful (Kang et al., 2010). Benzoic acid levels in dried whey ingredients are a concern in the Asian market and could hinder exporting whey powder that is bleached with BP. China and Japan has banned BP as a bleaching agent in whey (Fox et al., 2013).

Sieber et al. (1995) reported that BA occurs naturally in many foods such as dairy products, nuts, fruits, and vegetables. In fermented dairy products, it is produced from hippuric acid in milk during fermentation and, therefore, cultured dairy products, such as yogurt and smear-ripened cheeses contain some BA (Sieber et

al., 1995). In yogurt, BA was detected at various levels between 12 to 47 mg/kg (plain yogurt) and between 5 to 39 mg/kg in fruit yogurt (Sieber et al., 1995).

When whey is bleached, off-flavors can develop in the spray dried powder and could result in detectable off flavor in the finished food products when used as an ingredient. Lipid and protein oxidation are a primary source of off-flavors (cardboard, fatty, cabbage) in dried whey products (Burrington 2012). Croissant et al., (2009) reported that when applied to liquid whey, BP bleaching resulted in fewer lipid oxidation products and off flavors compared with HP. Another recent study demonstrated that fat content in liquid whey did not impact bleaching efficacy using HP (250 or 500 mg/kg) or BP (50 or 100 mg/kg) but that temperature of bleaching had a large influence on HP bleaching (but not BP) activity in fluid whey (Listiyani et al., 2011 and Kang et al., 2012).

Fluid whey can be bleached prior to ultrafiltration step (Figure 1) as long as the whey is not held between 7^0 and 63^0 C for more than 2 hours. Holding longer could be interpreted as a preservation step for microbiological control and is prohibited by Federal (USDA) regulation.

Evaluation Question #2: Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)). Discuss whether the petitioned substance is derived from an agricultural source.

Currently, WPC is listed on NOP's National List as a nonorganically produced agricultural product allowed for use in or on processed products labeled as "organic."

Whey protein is one of the two major groups of proteins found in milk and is a by-product of cheese-making. Raw whey is composed of naturally occurring macronutrients – protein, fat, minerals, lactose and water as well as micronutrients that are biologically active, β-lactoglobulin and α-lactalbumin, two globular proteins that account for 70-80 percent of total whey protein. Minor protein components include immunoglobulin, bovine serum albumin, glycomacropeptide (rennet whey), lactoferrin, lactoperoxidase and numerous and endogenous enzymes.

Membrane filtration is a cold temperature processing method (under pressure 30-150psi) that allows for the production of high protein finished whey where the protein remains intact and is not treated with chemical reagents. Membrane ultrafiltration uses a filter with different pore sizes (0.01 to 0.1 microns) which allows minerals, non-protein nitrogen and lactose in raw whey to pass through and retains (retentate) the whey proteins and small amount of fat (with a molecular weight of 1,000 to 300,000 Da). While the process concentrates the proteins, membrane filtration does not change the profile of naturally occurring whey proteins. In some cases, an extra filtration step will be required (diafiltration) to remove additional lactose and minerals from pre-concentrated whey to produce WPC up to 80% protein (See Figure 1). In addition, the same ultrafiltration technology is being used in home water filtration systems to remove bacteria, cysts and remove certain heavy metals.

Microfiltration can also be used initially to partially separate (pore size generally spans 0.1 to 1 microns) casein and whey protein (with a molecular weight of 200,000- 1 million Da) or remove fat from the pasteurized fluid whey (Smith, 2013).

Evaluation Question #3: If the substance is a synthetic substance, provide a list of non-synthetic or natural source(s) of the petitioned substance (7 CFR § 205.600 (b) (1)).

Whey protein is created by a naturally occurring biological process (see historic uses). WPC is listed on NOP's National List as a nonorganically produced agricultural product allowed for use in or on processed products labeled as "organic."

Evaluation Question #4: Specify whether the petitioned substance is categorized as generally recognized as safe (GRAS) when used according to FDA's good manufacturing practices (7 CFR § 205.600 (b) (5)). If not categorized as GRAS, describe the regulatory status.

Whey protein concentrate is GRAS affirmed at 21 CFR §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.

Evaluation Question #5: Describe whether the primary technical function or purpose of the petitioned substance is a preservative. If so, provide a detailed description of its mechanism as a preservative (7 CFR § 205.600 (b) (4)).

Whey is the soluble fraction of milk, rich in proteins, minerals and lactose that are separated from casein during the manufacture of cheese or casein. The most important commercial whey protein products are whey protein concentrates with protein levels (total solids) ranging from 34% to 85%. Whey proteins are well known for their high nutritional value and versatile functional properties in food products (de Wit, 1998). As described in the petition, WPC is not acting as a preservative.

Evaluation Question #6: Describe whether the petitioned substance will be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law) and how the substance recreates or improves any of these food/feed characteristics (7 CFR § 205.600 (b)(4)).

In food systems, whey protein contributes to the functional characteristics of a food product. These characteristics and functional benefits for yogurt are listed in Table 4. WPC is a nutrient-dense, high-quality animal-based protein that can used to enrich numerous food products. WPC improves texture, enhances flavor and color, and water holding capacity of various processed dairy and bakery products, beverages, and sports and nutritional products. The most important commercial whey protein products are whey protein concentrates (WPCs) with protein levels ranging from 34% to 85 %(Morr et al., 1993).

Sodini et al., 2005 reported that the replacement of skim milk powder by WPC on textural and physical properties of yogurts has been studied by various researchers. They found contradictions in the scientific literature as to the effects of WPC on the water holding capacity, firmness, and viscosity of the yogurts. They attributed these contradictions to the composition of the e commercial whey used in the studies, how the yogurts were fortified prior to fermentation, and the methods used to measure the physical and rheological properties.

Burrington, 2012b, reported that heat stability is the ability of proteins to survive heat processing without detrimental changes such as excessive turbidity, increased viscosity, phase separation, or precipitation or gelation. β-lactoglublin and α-lactalbumin are the major whey proteins responsible for the heat stability characteristics of ingredients found in WPC. These globular proteins, account for 70-80 percent of total whey protein. Heat denaturation (above 80^0 C) of whey protein involves the unfolding of the protein structure, followed by aggregation, which includes protein-protein interactions that are covalent (not reversible) and noncovalent (possibly reversible) and changes to the functional properties of the food system (Bryant et al., 1998, Fuente et al., 2002). For a yogurt product, this coagulation would impact the viscosity and texture of the product (Tamime et al, 1999).

This type of processing does not affect the nutritional value of the whey protein.

Evaluation Question #7*:* Describe any effect or potential effect on the nutritional quality of the food or feed when the petitioned substance is used (7 CFR § 205.600 (b) (3)).

Whey proteins are widely used as food ingredients for their nutritional properties (Morr et al., 1993). Whey protein has a biological value (BV) that exceeds that of egg protein (by 15 percent) and other high protein foods (meat, soy and casein). BV is the measure of a food's protein quality compared to that of egg protein, which has the maximum biological value of 0.9–1.00 (defined as the ratio of nitrogen retained/nitrogen lost in a single source) (Segen, 2012). Smithers, 2012 reported that whey is a source for 20 amino acids and all nine essential amino acids (i.e., leucine, isoleucine, and valine, ≥ 20 percent w/w). These amino acids are believed to play a role in as metabolic regulators in protein and glucose homoeostasis and lipid metabolism. In addition, whey contains sulfur amino acids (i.e., methionine and cysteine) (Smithers, 2008) which serves as an antioxidant and in carbon metabolism.

Evaluation Question #8: List any reported residues of heavy metals or other contaminants in excess of FDA tolerances that are present or have been reported in the petitioned substance (7 CFR § 205.600 (b) (5)).

No food safety reports were found regarding heavy metal or other types of contamination in WPC. However, the July 2010, "Consumer Reports" reported their findings of an investigation regarding the need to supplement diets with additional protein drinks. Fifteen ready–to–drink and powdered protein supplements were purchased in retail stores or online, and were tested for their toxic heavy metal content (arsenic, cadmium, lead and mercury). Based upon an intake of 3 servings per day, 3 of the products were found to contain levels of heavy metals in excess of the safe overall daily intakes proposed by the U.S. Pharmacopeia (USP). Whey protein isolate (greater than 90% protein content) was one of the ingredients mentioned in the report.

Evaluation Question #9: Discuss and summarize findings on whether the manufacture and use of the petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).

Until recently, whey was considered a waste product from cheese manufacturing, rarely used as a food product and discarded either as a waste stream (earthen seeping pits) or for use as animal feed and fertilizer (Chegini et al., 2013). A typically cheese making operation produces one pound of cheese and nine pounds of liquid whey protein (Brown, 2014). In 2007, Ghaly et al. 2007, reported that 7.76×10^{10} pounds of liquid whey was produced domestically from cheese operations. In most jurisdictions, environmental regulations now prevent disposal of untreated whey on agricultural land or discharging in municipal sewage system or surface water. Whey composition (high solids, lactose and salt content) makes disposal practices a problem (Smithers, 2008, Ghaly et al., 2007).

Rodenberg, 1998 reported that the five day biochemical oxygen demand (BOD_5) is a measure of the organic pollutant concentration in the wastewater, and is proportional to the amount of milk or whey lost to the sewer. Normal dairy production plant wastewater is in the range of 2000 to 3000 mg/l which is 10 times the strength of domestic sewage. The BOD_5 can go much higher if a milk spill occurs and the pH can fluctuate widely if spent cleaning in place chemicals are discharged as well. Rodenberg, 1998 also stated that dairies manage their wastewater discharge to avoid upsetting their biological treatment process or a publicly owned treatment system.

With recent advances in technology, as well as increasing awareness of the environmental and financial costs of whey disposal, the dairy industry have found it profitable to process whey into high value added protein products for use as ingredients in food systems (Hutchinson et al., 2003). Whey proteins are generally recognized as safe (GRAS) and are considered label-friendly ingredient (Bryant et al., 1998).

Zehr et al. 1997 reported that 80% of the energy used at a typical cheese making operation is devoted to processing whey powder or concentrate. Falling-film type evaporation systems are used to concentrate whey liquid. To fully dry the whey to a powder form, condensed whey from an evaporator is fed to a spray dryer. Both of these processes are highly energy intensive due to the thermal energy required.

Evaluation Question #10: Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)).

Given the long history of human consumption of dairy products and milk in general, there is little toxicological concern to human health or animals. The scientific literature for WPC did not indicate any adverse effects associated with ingesting concentrated milk proteins.

Evaluation Question #11: Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).

The legal definitions for yogurt, low-fat yogurt and nonfat yogurt are specified in the Standards of Identity listed in the CFR, in 21 CFR §131.200, 21 CFR §131.203, and 21 CFR§ 131.206, respectively.

The type of organic milk used depends on the type of yogurt – whole milk yogurt, low-fat milk for low-fat yogurt, and skim milk for nonfat yogurt. Other dairy ingredients are allowed in yogurt to adjust the composition, such as cream to adjust the fat content, and nonfat dry milk powder to adjust the solids/protein content. Stabilizers (i.e., alginates (carrageenan), gelatin, gums (locust bean, guar), pectin and starch) may also be used in yogurt to improve the body and texture by increasing firmness and preventing separation of the whey (syneresis). These substances can be used as for low fat and fat free yogurt (Tamime et al. 1999). Also, these same stabilizers (substances) are allowed as ingredients in or on processed products labeled as organic (7 CFR and §205.606). The fortified milk is homogenized, heated to 90 °C for 10 min, cooled to the fermentation temperature (42 °C) and inoculated with a starter culture.

After inoculation, the process differs depending on the kind of yogurt produced. In the case of set yogurt, the inoculated milk is filled into consumer cups and incubated to the desired pH (4.5), then cooled to 4 °C without disturbing the curd. In the case of stirred yogurt, the inoculated milk is filled into a tank where the fermentation occurs. After fermentation, the gel is broken, and then the yogurt is pumped through a fine mesh, cooled and finally packaged into cups.

Traditionally, nonfat dry milk or skim milk powders are used to fortify the milk before fermentation.

Evaluation Question #12: Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).

The ingredients listed below are considered all natural (non-synthetic) substances that may be used in place of the WPC.

The legal definitions for yogurt, low-fat yogurt and nonfat yogurt are specified by FDA's Standards of Identity in the CFR, in sections 21 CFR §131.200, 21 CFR §131.203, and 21 CFR §131.206, respectively The CFR contains a list of the permissible dairy ingredients allowed for use in yogurt (i.e., cream, milk, partially skimmed milk, or skim milk, used alone or in combination. Other optional ingredients include concentrated skim milk, non-fat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the non-fat solids content of the food: Provided, that the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present shall not be decreased as a result of adding such ingredients.
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Evaluation Information #13: Provide a list of organic agricultural products that could be alternatives for the petitioned substance (7 CFR § 205.600 (b) (1)).

In the original petition submitted to NOP, the petitioner stated their inability to locate an adequate domestic supply of organic WPC (35% protein) to meet their specifications for the manufacturing frozen yogurt products. At present, no public or private organizations are collecting organic WPC production data.

As for alternatives for the petitioned substance, the ingredients listed in the CFR are permissible dairy ingredients allowed for use in yogurt (i.e., cream, milk, partially skimmed milk, or skim milk, used alone or in combination. Other optional ingredients include concentrated skim milk, non-fat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the non-fat solids content of the food: Provided, that the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present shall not be decreased as a result of adding such ingredients.

All these ingredients are commercially available as organic.

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