

United States Department of Agriculture
Agricultural Marketing Service | National Organic Program
Document Cover Sheet

<https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned>

Document Type:

National List Petition or Petition Update

A petition is a request to amend the USDA National Organic Program's National List of Allowed and Prohibited Substances (National List).

Any person may submit a petition to have a substance evaluated by the National Organic Standards Board (7 CFR 205.607(a)).

Guidelines for submitting a petition are available in the NOP Handbook as NOP 3011, National List Petition Guidelines.

Petitions are posted for the public on the NOP website for Petitioned Substances.

Technical Report

A technical report is developed in response to a petition to amend the National List. Reports are also developed to assist in the review of substances that are already on the National List.

Technical reports are completed by third-party contractors and are available to the public on the NOP website for Petitioned Substances.

Contractor names and dates completed are available in the report.

Petition for Removal - §205.606 (w) Whey Protein Concentrate from National List

- **Nonorganic agricultural substances allowed in or on processed products labeled as “organic” (§205.606).**

1. Substance Name

(w) Whey protein concentrate.

2. Petitioner and Manufacturer Information

Rumiano Cheese Company
511 9th Street
P.O. Box 305
Crescent City, CA 95531
(707) 465-1535

3. Intended or Current Use

Muscle Building and Weight Loss. Whey Protein Concentrate is used as an Ingredient, and can be found in formula, muscle recovery drinks, cereals, cake, pancake and waffle mixes, chocolate bars, candies, nougat, baked goods, meat and deli products.

4. Intended Activities and Application Rate

Raw milk from dairy cows is picked up from local dairies on company owned milk trucks and delivered to the cheese manufacturing plant.

5. Manufacturing Process

Raw Milk Receiving

- **Critical Control Point #1** - Milk Antibiotic Screening
- Raw Milk Storage – Silos
- **Critical Control Point #2** – HTST Milk Pasteurization
- Filter
- Cream Separator
 - Cream Tank Storage for Butter Making

Butter Making

- **Critical Control Point #3** – Cream Storage - Vat Pasteurization
 - Churn
 - Salt
 - Package in Polybag and Box
 - Metal Detector
 - Refrigerated Storage

Cheesemaking

- Pasteurized Milk into Cheese Vat
- Add Enzymes and Microbial Coagulant
- Cheese to Drain Table
 - Whey to Storage Tank (see Whey Protein Concentrate 80%)
- Salt
- Into Blockformer Towers
- Package into Polybag and Vacuum Seal
- Metal Detector
- Package into Box and Weigh
- Apply Description Label
- Metal Detector
- Refrigerated Storage

Whey Protein Concentrate 80%

- **Critical Control Point #4** – Whey HTST Pasteurization
- Filter
- Ultra-Filtration – Protein Concentrate to Storage Tank
 - Permeate to Filtration Reverse Osmosis
- Protein Concentrate to Pre-Heater
- High Pressure Pump
- Box Dryer
- Sifter Powder Hopper
- Metal Detector
- Packaging – Bag and Sealer Machine
- Dry Storage

6. Ancillary Substances

During the cheesemaking process microorganisms are added to the milk in the form of cheese starter culture, and microbial coagulant. Salt is used as a flavoring and natural preservative. Whey is the byproduct of cheesemaking and is pasteurized prior to becoming Whey Protein Concentrate, which will deactivate any enzymes from the cheesemaking process. Whey Protein Concentrate is created by Ultra Filtration and has Protein, Fat, Lactose, Moisture, Ash, and pH.

7. Previous Reviews

National Organic Program (NOP); Sunset 2017 Amendments to the National List

E. Comments Received on Proposed Rule AMS-NOP-16-0052; NOP-16-03

AMS received seven public comments from ingredient manufacturers, organic handlers, and a trade association on the proposal to remove the following three substances from the National List: Turkish bay leaves, inulin-oligofructose enriched, and **whey protein concentrate**. These substances are listed in section 205.606 of the National List, which allows nonorganic forms to be used in organic products when organic forms are not commercially available. Removing these substances from the National List would mean that only organic forms of these ingredients could be used in organic products.

AMS received public comment opposing the removal of whey protein concentrate from the National List. **Whey protein concentrate** is used as an ingredient in various products including bakery, confectionary, processed meat, infant formula, and dairy products. Public comments submitted indicated that **whey protein concentrate** is essential to organic processed products and is not commercially available in organic form at this time.

In consideration of the new information presented in public comments, AMS has determined that nonorganic forms of Turkish bay leaves, inulin-oligofructose enriched, and **whey protein concentrate** are essential to organic production and handling and should remain on the National List. The USDA organic regulations may allow the use of nonorganic substances that are not commercially available in organic form, quality, or quantity, and are necessary to organic handling. As with other substances in section 205.606 of the National List, organic handlers are permitted to use the nonorganic substance only if the organic substance is not commercially available. Handlers will need to demonstrate, and certifiers will need to verify, that the organic substance is not available in the form, quality or quantity needed. Further, any member of the public may petition to remove an agricultural substance from the National List if an organic substance becomes commercially available.^[3]

National Organic Program (NOP); Sunset 2017 Amendments to the National List

Whey Protein Concentrate

The USDA organic regulations include an exemption on the National List for **whey protein concentrate**, allowed as an ingredient in or on processed products labeled as “organic” in § 205.606(y) as follows: **whey protein concentrate**. In February 2007, **whey protein concentrate** was petitioned for addition to § 205.606 for use as an ingredient in or on organic processed products. In April 2007, the NOSB recommended adding **whey protein concentrate** to the National List in § 205.606. AMS accepted the NOSB's recommendation and **whey protein concentrate** was added to the National List on June 27, 2007 (72 FR 35137). As required by OFPA, the NOSB recommended the renewal of **whey protein concentrate** during their 2012 sunset review. The Secretary accepted the NOSB's recommendation and published a notice renewing the whey protein concentrate exemption on the National List on June 6, 2012 (77 FR 33290). Subsequently, the exemption for **whey protein concentrate** on the National List was considered during the NOSB's 2017 sunset review. Two notices of the public meetings on the 2017 sunset review with request for comments were published in **Federal Register** on March 12, 2015 (80 FR 12975) and September 8, 2015 (80 FR 53759). The purpose of these notices was to notify the public that the **whey protein concentrate** exemption discussed in this proposed rule would expire on June 27, 2017, if not reviewed by the NOSB and renewed by the Secretary.

During their 2017 sunset review deliberation, the NOSB considered written comments received prior to and during the public meetings on all substance exemptions included in the 2017 sunset review. These written comments can be viewed at <https://www.regulations.gov> by searching for the document ID numbers: AMS-NOP-15-0002 (April 2015 public meeting) and AMS-NOP-15-0037 (October 2015 public meeting). The NOSB also considered oral comments received during these public meetings. The NOSB's recommendation on whey protein concentrate is available on the NOP Web site at <http://www.ams.usda.gov/nop>. During their sunset review of **whey protein concentrate** the NOSB considered a **whey protein concentrate** technical report that were requested by and developed for the NOSB in 2015. This technical report is available for review in the petitioned substance database on the NOP Web site, <https://www.ams.usda.gov/rules-regulations/organic/national-list>.

Public comments on **whey protein concentrate** received by the NOSB during their 2017 Sunset review indicated that **organic whey protein concentrate** sources are available to organic processors. Based upon these comments, the NOSB determined that the exemption for **whey protein concentrate** in § 205.606(y) is no longer necessary or essential for organic handling/processing. From this determination, the NOSB recommended the removal of **whey protein concentrate** from § 205.606(y) from the National List at their October 2015 public meeting. AMS accepts the NOSB's recommendation on removing **whey protein concentrate** from the National List. This

proposed rule would amend National List § 205.606 by removing the substance exemption for **whey protein concentrate** listed in § 205.606(y). This amendment is proposed to be effective on the current sunset date for **whey protein concentrate**, which is June 27, 2017.

8. **Regulatory Authority**

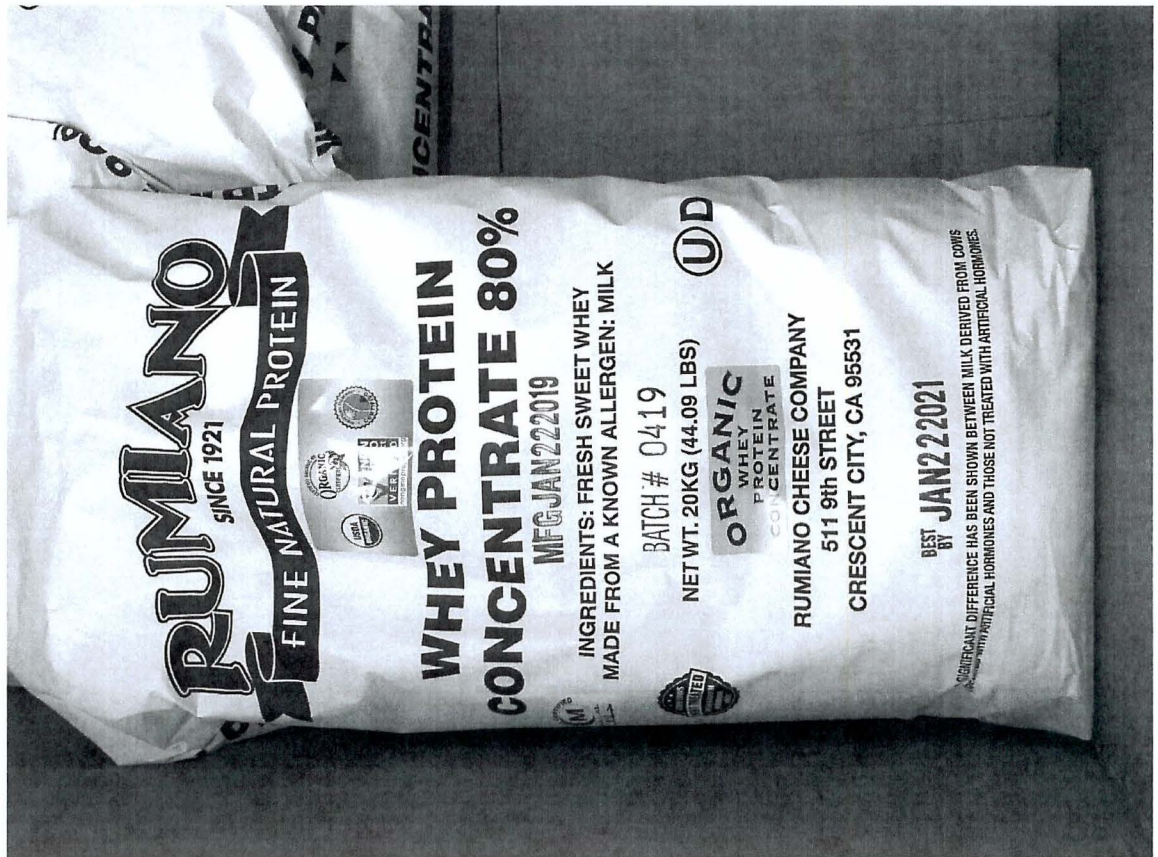
EPA Registration is not required.

USDA NOP Number 6220007851

Food Ingredient

9. **Chemical Abstracts Service (CAS) Number and Product Labels**

No CAS Number



**Organic Whey Protein Concentrate 80%
Specifications**

Chemical Specifications

Specification	Typical
Protein-dry basis (NX 6.38) >80.0%	82.5%
Moisture 4.0~5.5%	5.20%
Ash 2.0~4.0%	2.7 %
Fat 4.0~7.0%	5.00%
Lactose 4.0~7.0%	4.00%
pH (5% solution) 6.00~7.20	6.30%

Typical Microbiological Specifications

Standard Plate Count max 20,000 CFU/gram	<10 CFU/gram
Coliform/E. Coli <10 CFU/gram	<10 CFU/gram
Salmonella 25 grams	negative
Staphylococcus aureus 25 grams	negative
Yeast and Mold max 50 CFU/gram	<10 CFU/gram

Physical Specifications

Flavor	Clean, Bland
Color	Light to Light
Cream	
Texture Granular	Free flowing,

Packaging Specifications

20-kilogram bags (44.092 pounds) in a 3-ply poly-lined, square bottom, heated-sealed white Kraft bag, 40 bags (800 kilo grams) palletized on standard Heat-treated GMA 40 X 48 exchangeable pallets

Storage-Shelf Life

Shelf life is 2 years when the product is stored below 25°C and below 65% humidity. Best by date on each bag, 2 years from date of manufacture.

Coding

Date of manufacture and Batch Number (week of production and last two digits of the year, i.e. Batch #

0119 is produced 1st week of 2019), Plant #06-2384, Product of USA, Kosher (Orthodox Union, O U dairy), rBST Free, certified Organic by Organic Certifiers, American Humane Certified, NON-GMO Project Verified, Halal (Islamic Food and Nutrition Council of America), WIT Chinese Organic Certified, and European Union Conformance Compliant.

Label Statement

Organic Whey Protein Concentrate 80%

Revised: February 26, 2019

Rumiano Cheese Company

P.O. Box 305, Crescent City, CA 95531 and P.o. Box 863, Willows, CA 95988 www.rumianocheese.com

10. Physical and Chemical Properties

- a) Can create dust and/or flammable dust if handled improperly. Use in ventilated areas.
- b) No Data. No component of this product is present at levels greater than or equal to .1% as identified as probable, possible or confirmed human carcinogen by IARC, ACGIH, NTP and OSHA. RTECS is not available.
- c) Incinerate or dispose of in landfill, no hazard restrictions.
- d) No components that are considered hazardous and no occupational exposure limits. Areas of use require dust removal and adequate ventilation. Not toxic but safety glasses are recommended. Dusk masks are recommended if area is not well ventilated.
- e) Not toxic but large amounts should not be flushed down drains.

11. Safety Information

ORGANIC Whey Protein Concentrate 80%

SAFETY DATA SHEET

Revision Date: January 4, 2019

1. Product and Company Information:

- Product Name: Organic Whey protein Concentrate 80%
- Product Uses: Food Ingredient
- Manufacturer: Rumiano Cheese Company
- In Case of Emergency Contact: 1-707-465-1535

2. Hazzard Identification:

- Substance Classification: Not a hazardous substance or mixture by OSHA Hazard Communication Standard
- GHS Label Elements: Not a hazardous substance
- Signal Word: None
- Hazards not covered by GHS: Can create dust and/or flammable dust if handled improperly. Use in ventilated areas.
- OSHA TWA: Irritant Particulate- 15 mg/m³ total dust
- OSHA TWA: Irritant Particulate- 10 mg/m³ total dust

3. Compositional Information of Ingredients:

- Substance: Mixture
- Chemical Name: Whey Protein Concentrate
- CAS Number: Not Available

Component	Typical Amount	Hazard Status
Protein	80 %	None
Lactose	7%	None
Fat	5%	None
Moisture	5%	None
Ash	3.5%	None

4. First Aid Measures:

- Inhaled: Minimize inhalation. If breathing problems occur consult a doctor.
- Skin Contact: Wash with clean water.
- Swallowed: Product is fit for human consumption as food.
- Eye Contact: Wash eyes thoroughly with clean water.

5. Fire Fighting Measures:

- Fire Extinguishing: Carbon dioxide, dry chemical, foam or water spray.
- Hazards of Combustion: Non-combustible material. Any fine powder can be a fire risk keep way from open flame. Any fine particulate dust can explode if the proper mix of powder and air is achieved, keep away from open flame.
- Advice for first responders: Wear appropriate protection for the observed conditions.

6. Accidental Release Measures:

- Personal Precautions, Emergency procedures: Powder is not toxic and can be swept up with a broom and dustpan. Water can be used to wash and dissolve and flush a spill away. Collected material can be disposed of in common solid waste bins.
- Environmental Issues: Large amounts of powder should not be flushed into storm drains or waterways as it is high in BOD and can cause harm to small fish.
- Method and Materials for containment: Food grade product so safe to store in any readily available container. Noncorrosive so plastic, cardboard or paper is safe storage material.

7. Handling and Storage:

- Safe Handling: Use a dust mask if handling in confined area. Always handle in well ventilated areas.
- Safe Storage Conditions: Store at ambient temperature, no special temperatures or conditions required. Stable at ambient temperatures.

8. Exposure Controls and Personal Protection:

- Workplace Control Parameters: No components that are considered hazardous and no occupational exposure limits.
- Engineering Controls: Areas of use require dust removal and adequate ventilation.
- Eye / face protection: Not toxic but safety glasses are recommended.
- Respiratory protection: Dust masks are recommended if area is not well ventilated.
- Environmental Protection: Not toxic but large amounts should not be flushed down drains.

9. Stability and Reactivity:

- Reactivity: No Data available
- Chemical Stability: Stable under ambient conditions
- Hazardous Reaction: No Data Available
- Conditions to Avoid: Extreme heat and open flame
- Incompatible Materials: Strong Oxidizing agents and open flame
- Hazardous Decomposition Products: Hazardous decomposition products are not produced

10. Disposal Considerations:

- Incinerate or dispose of in landfill, no hazard restrictions.

Physical and Chemical Properties:

- Physical State: Solid
- Appearance: White to cream color free flowing powder
- Odor: Bland to slight dairy smell
- pH: 6.2 to 6.7
- Vapor Pressure: No Data
- Boiling Point: No Data
- Melting Point: No Data
- Flash Point: No Data
- Evaporation Rate: No Data
- Flammability: May form combustible dust if mixed with air
- Bulk Density: 250 kg/m³
- Density: No Data
- Viscosity: No Data
- Solubility: Soluble in water at ambient temperature

- Corrosion Rate: No Data
- Decomposition Temperature: No data
- Auto-ignition Temperature: 460 ° C
- Partition Coefficient: No Data
- Explosive Properties: May form combustible dust concentrations with air
- Oxidizing Properties: No Data

11. Toxicological Information:

- Acute Toxicity: No Data
- Inhalation: No Data
- Dermal: No Data
- Eye Damage: No Data
- Respiratory or skin Sensation: No Data
- Germ Cell Mutagenicity: No Data
- Carcinogenicity: No component of this product is present at levels greater than or equal to .1% as identified as probable, possible or confirmed human carcinogen by IARC, ACGIH, NTP and OSHA.
- Reproductive Toxicity: No Data
- Specific Target Organ Toxicity: Single exposure or repeated exposure no data available.
- Aspirational Hazard: No Data
- Additional Information: RTECS not available.

12. Ecological Information:

- Toxicity: No Data
- Persistence and degradability: No Data
- Bio accumulative Potential: No Data
- Mobility in Soil: No Data
- Results of PBT and vPvB Assessment: No Data
- Other Adverse Effects: No Data

13. Transport Information:

- Proper Shipping Name: Whey Protein Concentrate
- DOT, IMDG, and IATA: Not dangerous goods

14. Regulatory Information:

- SARA 302 Components: This product does not contain any chemical compounds that require SARA Title III, Section 302 reporting.
- SARA 313 Components: This product does not contain any chemical compounds that require SARA Title III, Section 313 reporting.
- SARA 311 and SARA 312: No known SARA hazards.
- Massachusetts Right to Know: Contains no chemical components on the Massachusetts Right to Know list.

- Pennsylvania Right to Know: Contains no chemical components on the Pennsylvania Right to Know list.
- New Jersey Right to Know: Contains no chemical components on the New Jersey Right to Know list.
- California Prop 65: Contains no chemical components on the California Prop 65 list.

15. **Other Information:**

- **HMIS Rating:**
 - Health Hazard: 0
 - Chronic Health Hazard: 0
 - Flammability: 0
 - Physical Hazard: 0
- **NFPA Rating:**
 - Health Hazard: 0
 - Fire Hazard: 0
 - Reactivity Hazard: 0

Prepared by Rumiano Cheese Company, Crescent City, CA 95531, (707) 465-1535. This information is provided to the best of our knowledge and Rumiano Cheese Company does not assume any legal responsibility for its use or reliance upon this data. Customers are encouraged to conduct their own test.

Rumiano Cheese Company
P.O. Box 305, Crescent City, CA 95531 and P.O. Box 863, Willows, CA 95988 www.rumianocheese.com

12. **Research Information**

What is whey protein?

Whey protein is a collection of proteins found in whey, a byproduct of cheesemaking. When a coagulant (usually renin) is added to milk, the curds (casein) and whey separate; whey protein is the water-soluble part of milk. As a supplement, it's sold as dry powders with various levels of processing that affect how concentrated a source of protein they are and how fast they're absorbed.

What are the benefits of whey protein?

It's a high quality, well-absorbed source of protein that's very useful for hitting targeted daily protein goals. Its benefits extend to the benefits of increased protein intake in general, such as augmenting muscle gain in conjunction with resistance training, limiting muscle loss during low-calorie diets, and modestly limiting fat gain during periods of excessive calorie intake. These effects aren't exclusive to whey protein but it will likely be more effective than most other protein sources per gram.

What are whey protein's side effects and drawbacks?

Whey does not harm the liver or kidneys, but it can exacerbate pre-existing damage. People with damaged livers or kidneys should exercise caution when increasing protein intake quickly without the guidance of a doctor.

Organic Whey Protein Concentrate has been commercially available from Rumiano Cheese Company since January 31, 2011. It is also made by several manufacturers around the world and therefore is available in enough volumes as an organic ingredient. **Whey Protein Concentrate should be removed from the National list.**

13. Petition Justification Statement

Removing Nonorganic produced Whey Protein Concentrate from the list of Nonorganic substances ALLOWED to be used in Organic Products.

H. Removal of a Nonorganically Produced Agricultural Substance from the National List (7 C.F.R. §205.606)

1. The difference between Organic Whey Protein Concentrate and Nonorganic Whey Protein Concentrate is that Organic Whey Protein Concentrate originates from Organic milk as a byproduct of the Organic Cheese making process. Also, the cheese making processes are identical except organically approved ingredients such as coagulants, cheese cultures, and spices and color if used, are used in the production of making organic cheese and byproduct Organic Whey Protein Concentrate.
2. There are sufficient numbers of manufacturers of organic cheese in all areas of the United States and World, which could produce additional volumes of Organic Whey Protein Concentrate if there were a higher demand for the Organic Whey Protein Concentrate, as opposed to permitting Nonorganic Whey Protein Concentrate to be substituted at a lower cost than Organic Whey Protein Concentrate. Eliminating the use of Nonorganic Whey Protein Concentrate would certainly increase demand for the Organic Whey Protein Concentrate and stimulate production. Using organic milk is substantially more costly than Nonorganic milk and the allowing of Nonorganic Whey Protein Concentrate to be substituted for Organic Whey Protein Concentrate deprives organic cheese manufacturers of an additional income stream with which to increase payments to organic dairy farmers.

3. All regions of the United States are currently engaged in organic cheese manufacturing.

Top Key Players

- Unilever (Netherlands),
- Eden Foods, Inc. (US),
- Danone (France),
- The Kroger Co. (US),
- Aurora Organic Dairy (US),
- The Lactalis Group (France),
- Fonterra Co-operative Group (New Zealand),
- The White Wave Foods Company (US),
- Purity Foods, Inc. (US)
- Organic Valley (US)

The current number of organic cheese makers and the volume of organic milk being converted to organic cheese is retarded due to the allowed use of non-organic whey protein being allowed and substituted for organic whey protein thus depriving these cheese manufactures and ultimately their organic dairymen an additional source of revenue for their organic whey protein concentrate. Furthermore, if nonorganic whey protein is not removed from the Nonorganically Produced Agricultural Substance from the National List, it should be specified as to what percentage or type of whey protein concentrate is allowed i.e. WPC-34%, WPC-80%.

Organic Cheese is identified as a healthy and natural organic source for multiple nutrients such as Protein, Zinc, Calcium, Vitamins and others. The consumption of organic cheese minimizes the exposure to toxins and pesticides that are often associated to conventional farming practices.

Cheese manufacturers are innovating new flavors by combining various flavoring ingredients, such as herbs and spices. Moreover, the introduction of various forms of organic cheese, such as spreads, blocks, and slices, help in the wider acceptability of organic cheese. The market is expected to grow at a healthy rate during the forecast period, owing to the growing awareness among consumers about the nutritional value of cheese.

<https://www.marketwatch.com/press-release/organic-cheese-market-comprehensive-study-2019-business-statistics-leading-players-review-impressive-growth-product-category-and-forecast-to-2023-2019-09-05>