

March 2001

# DAIRY PRODUCTS

## Imports, Domestic Production, and Regulation of Ultra-filtered Milk



G A O

Accountability \* Integrity \* Reliability

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Abbreviations

AMS Agricultural Marketing Service  
FDA Food and Drug Administration  
MPC milk protein concentrates  
USDA U.S. Department of Agriculture



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United States General Accounting Office  
Washington, DC 20548

March 5, 2001

### Congressional Requesters

Milk is primarily composed of protein, fat, lactose, water, minerals, and vitamins. The ultra-filtration process for milk, developed in the 1970s, removes most of the fluid components, leaving a high concentration of milk protein that allows cheese and other manufacturers to produce their products more efficiently. Ultra-filtered milk is also a common ingredient in high-protein sports drinks, energy bars, and nutrition supplements. It comes in two forms: (1) a dry powder, which is currently all imported and (2) a thick liquid, referred to as “wet,” which is produced domestically. Dry ultra-filtered milk imports enter the United States under the U.S. Customs Service’s broader classification of milk protein concentrates, which includes similar products made by other processes, such as blending nonfat dry milk with highly concentrated milk proteins. U.S. milk producers have expressed concern that imported ultra-filtered milk may displace domestically produced milk used to make cheese.

For regulatory purposes, cheese products fall into two broad categories—standardized and nonstandardized cheese. The Food and Drug Administration (FDA) regulates certain cheeses—such as cheddar or mozzarella—through its “standards of identity” regulations to ensure that they meet specifications for ingredients and characteristics. (See app. I for a list of standardized cheeses and related cheese products.) FDA officials stated that ultra filtration of milk is an acceptable in-plant procedure during the manufacture of cheese. However, the use of ultra-filtered milk as a starting ingredient to make cheese is not allowed by FDA’s “standards of identity” regulations. In 1996, FDA allowed an exception to its standard for a pilot project producing ultra-filtered milk on a farm in New Mexico for shipment to one cheese plant in Minnesota. FDA does not specify the ingredients and characteristics of nonstandardized cheese products, such as pizza cheese. Producers of nonstandardized cheese products may use wet or dry ultra-filtered milk as ingredients.

To address U.S. dairy producers’ concerns about the use of ultra-filtered milk, you requested that we provide information on (1) trends in ultra-filtered milk imports, including federal trade restrictions on these imports; (2) the use of domestically produced ultra-filtered milk in U.S. cheese making; and (3) FDA’s and the states’ efforts to enforce FDA’s standards of identity regulations, particularly the use of ultra-filtered milk in cheese production. To obtain this information, we interviewed officials and

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obtained data from FDA; the U.S. Department of Agriculture (USDA); the U.S. Customs Service; industry trade associations; domestic and foreign dairy companies; and agricultural academicians. We also obtained information from state officials in Vermont and Wisconsin about their efforts to inspect cheese-making plants and the extent to which they coordinate their efforts with FDA.

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## Results in Brief

No specific data on the amount of ultra-filtered milk imports exists because these imports fall under the broader U.S. Customs Service's classification of milk protein concentrates. However, milk protein concentrate imports grew rapidly from 1990 to 1999—from 805 to 44,878 metric tons—and nearly doubled between 1998 and 1999. Six countries—New Zealand, Ireland, Germany, Australia, the Netherlands, and Canada—accounted for 95 percent of the imports in 1999. Exporters of milk protein concentrates face few U.S. import restrictions: no quotas limiting the import quantity, low duties, and a broadly defined classification under which these products are imported that includes concentrates of any type if they contain 40- to 90-percent milk protein. FDA believes the milk protein concentrates pose minimal safety risks.

Similarly, there is little data on the amount and use of domestically produced wet ultra-filtered milk in U.S. cheese-making plants. According to USDA and state sources, a total of 22 dairy plants nationwide and 4 large dairy farms in New Mexico and Texas produce wet ultra-filtered milk. The plants primarily produce and use the ultra-filtered milk in the process of making cheese. The four farms transport their product primarily to cheese-making plants in the Midwest, where most is used to make standardized cheeses.

FDA relies on its own inspections, and those it contracts with 37 states, to enforce its standards of identity regulations. In addition to these federally funded inspections, some states conduct their own inspections of cheese plants for compliance with standards of identity requirements under state law. In fiscal year 1999, FDA and state contract inspectors reported no violations surrounding the use of imported ultra-filtered milk or milk protein concentrates in making standardized cheese. FDA inspected nine cheese plants in fiscal year 1999 for compliance with food labeling and economic regulations, which generally would include the standards of identity for cheese. None of these inspections were done exclusively to check for compliance with standards of identity for cheese. Similarly, states conducting inspections on FDA's behalf in fiscal year 1999 did not exclusively monitor compliance with standards for cheese. In 2000,

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Vermont state inspectors found that two cheese plants were using imported milk protein concentrates to make standardized cheeses in violation of federal and state regulations. The state issued warning letters, and the plants discontinued this practice.

We provided a draft of this report to FDA for its review and comment. FDA generally agreed with the draft and provided some specific comments, which we have incorporated where appropriate.

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## Background

Ultra-filtration technology separates the components of milk according to their size by passing milk under pressure through a thin porous membrane. Specifically, ultra filtration allows the smaller lactose, water, mineral, and vitamin molecules to pass through the membrane, while the larger protein and fat molecules—key components for making cheese—are retained and concentrated.<sup>1</sup> (See app. II for further explanation of ultra filtration and its use in the cheese-making process.) Although ultra-filtration equipment is expensive, it creates an ingredient well suited for making cheese and other food products requiring a high milk protein content. In addition, the removal of water and lactose reduces the volume of milk, and thereby lowers its transportation and storage costs. All ultra-filtered milk imported into the United States in 2000 was in a dry powder form.

The U.S. Customs Service's milk protein concentrates classification includes processed milk products containing between 40 percent and 90 percent protein. Imported powdered milk products with less than 40 percent protein are usually classified as nonfat dry milk and are subject to a tariff-rate quota that limits the amount that can be imported at a low tariff rate. In addition to ultra-filtered milk products, the milk protein concentrate classification includes concentrates made through other processes, such as blending nonfat dry milk with highly concentrated proteins. These products are often tailored to a specific use in products requiring a protein ingredient.

FDA's standards of identity regulations permit cheese manufacturers under the "alternate make" provisions to use ultra filtration as an acceptable procedure during the cheese-making process. Consequently, milk that has been ultra-filtered as an integral part of the cheese-making

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<sup>1</sup>Depending on the intended use of the ultra-filtered milk product, the fat in whole milk may be removed before filtration.

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process is acceptable as a component of a standardized cheese, according to FDA. In 1999 and 2000, organizations representing cheese makers petitioned FDA to amend its cheese standards to expand its definition of milk to include wet ultra-filtered milk. The industry petitioners requested permission to use wet ultra-filtered milk from external sources as an ingredient in standardized cheeses because it would increase the efficiency of cheese manufacturing and would explicitly recognize filtered milk products as interchangeable with other forms of milk. One of the industry petitioners, who had also asked FDA to allow the use of the dry ultra-filtered milk in standardized cheeses, later withdrew this part of the request when U.S. milk producers raised concerns that increased imports might displace domestic milk products. FDA has not yet acted on the petitions.

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## U.S. Imports of Milk Protein Concentrates, Including Dry Ultra-filtered Milk, From 1990 Through 1999

Specific data on U.S. imports of ultra-filtered milk do not exist because these imports are included in the broader classification of milk protein concentrates.<sup>2</sup> Milk protein concentrate imports increased 56-fold from 1990 to 1999. In 1999, they came primarily from New Zealand, Ireland, Germany, Australia, the Netherlands, and Canada. Milk protein concentrates are used as ingredients in cheese, frozen desserts, bakery products, and sports and other nutritional supplement products. The United States has no quota restrictions on milk protein concentrate imports, and duties are low. FDA officials told us that these imports pose little food safety risk and therefore receive minimal monitoring.

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## Milk Protein Concentrate Imports Rose Rapidly During the 1990s

U.S. milk protein concentrate imports grew from 805 metric tons in 1990 to 7,288 metric tons in 1995 to 44,878 metric tons in 1999 (see fig. 1). Imports almost doubled in 1999 alone. The volume of imported milk protein in these concentrates was approximately equivalent to 0.8 percent to 1.8 percent of the total U.S. production of milk protein in 1999.<sup>3</sup> The estimate's range reflects the fact that imported milk protein concentrates may

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<sup>2</sup>The classification number 0404.90.10 in the *Harmonized Tariff Schedule of the United States, Annotated* is intended for nonfat varieties of milk protein concentrate, U.S. Customs Service officials said. No imports were reported in classification number 0404.90.30, which is for milk protein concentrates made from whole milk, i.e., including fat.

<sup>3</sup>This estimate is based on USDA's National Agricultural Statistics Service's estimate that U.S. dairy farms produced 162.7 billion pounds of milk in 1999 and assumes that, on average, about 3 percent of milk is true protein and that the protein reported in milk protein concentrates is true protein.

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contain between 40-and 90-percent protein. The U.S. Customs Service does not collect data on the protein percentage of milk protein concentrate imports.

**Figure 1: Trend in Milk Protein Concentrate Imports to the United States for Six Major Exporting Countries and Others, 1990-1999**

Quantity in metric tons

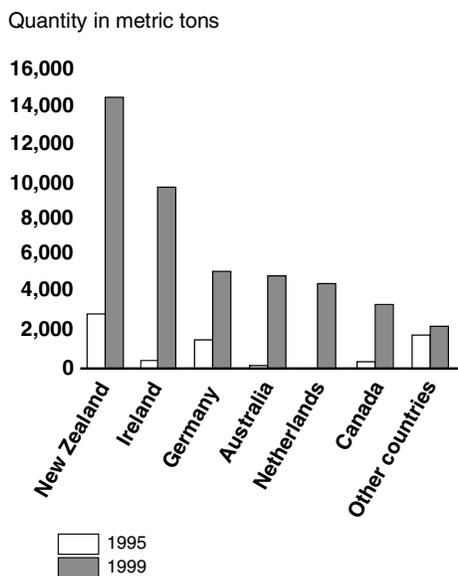


Source: Import quantities as compiled by the U.S. Census Bureau from the U.S. Customs Service data.

The total number of countries exporting milk protein concentrates to the United States grew from 4 to 16 from 1990 to 1999. (See app. III.) Australia was the only country to export milk protein concentrates in each of the 10 years. Figure 2 shows the growth in imports for each major exporter and other countries from 1995 to 1999. The share of imports among the six largest exporting countries rose from 75 to 95 percent during this 5-year period. Although the U.S. Customs Service does not categorize its data on

milk protein concentrate imports according to the manufacturing process used, representatives of Australian and New Zealand exporters assured us that their milk protein concentrate exports were all made using ultra filtration. Conversely, Canadian government officials said all of their country's milk protein concentrate exports to the United States are made by blending milk proteins.

**Figure 2: Comparison of Milk Protein Concentrate Imports, 1995 vs. 1999**



Source: Import quantities as compiled by the U.S. Census Bureau from U.S. Customs Service data.

U.S. and foreign industry executives told us that U.S. milk protein concentrate imports rose rapidly in recent years primarily because of (1) the relationship between the U.S. and international prices of milk protein, especially nonfat dry milk, and (2) the growth of the U.S. nutritional foods industry and many other new products using milk protein concentrates. According to these executives, international milk prices were below U.S. milk prices in recent years, giving U.S. dairy food manufacturers a financial incentive to substitute imported milk protein concentrates for domestic milk in products such as nonstandardized cheese. This price differential primarily stimulated U.S. imports of milk protein concentrates having lower percentages of protein—between 40 and 56 percent. More recently, U.S. demand for these milk protein concentrates has decreased, according to an Australian exporter, because the international price of milk protein is near the U.S. price.

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The strong growth of the U.S. nutritional foods industry has created new demand for high-protein milk protein concentrates that are 70- to 85-percent protein. Representatives of Australia and New Zealand exporters told us that this industry grew out of extensive research and development to create nutritional supplements for athletes, the elderly, and health conscious individuals. Milk protein concentrates provide an important source of protein in these nutritional products. Because high-protein milk protein concentrates are often customized for use in specific end products, their producers and exporters can sell them at higher prices than the equivalent amount of domestic milk protein, the exporters said. Despite their higher prices, the demand for these specialized high-protein products in the United States is strong. Industry executives noted that high-protein milk protein concentrate imports have not displaced domestic milk supplies because they are filling the growing demand for new nutritional products. In addition, a trade association representative and an academic expert noted that economic disincentives have prevented U.S. production of dry milk protein concentrates.

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### Imported Milk Protein Concentrates Are Used in Many Food Products

Federal agencies and industry trade associations do not collect data on U.S. companies' use of imported milk protein concentrates because this information is considered proprietary. According to milk protein concentrate exporters, U.S. cheese, frozen dessert, bakery, and nutritional foods industries primarily use the dry milk protein concentrate imports. In particular, dry milk protein concentrates containing lower levels of protein—42 to 56 percent—can be added to the raw milk used to make cheese, ensuring a consistent composition regardless of the seasonal variations in milk. Various concentrations of milk protein are also used in ice cream<sup>4</sup> and other frozen desserts, bakery and confection products, and nonstandardized cheese. Milk protein concentrates containing higher protein levels—70 to 85 percent—are chiefly used in sport-, adult-, and hospital-nutrition products. Concentrates containing 90-percent protein are especially useful for manufacturers seeking lactose- and sugar-free claims for their products, according to a major exporter. (See app. IV for more details on the composition and uses of dry milk protein concentrate imports provided by some exporters.)

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<sup>4</sup>FDA's standard of identity regulations for ice cream specifically provide for the use of milk protein concentrate as an ingredient (see 21 C.F.R., part 135).

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## Exporters of Milk Protein Concentrates to the United States Face Few Restrictions

The U.S. Customs Service and FDA share responsibility for monitoring milk protein concentrate imports for compliance with trade or food safety requirements. Unlike nonfat dry milk imports, which have less than a 40 percent protein content, the United States does not use a tariff-rate quota to restrict the quantity of milk protein concentrate imports. The United States imposes a duty of \$0.0037 per kilogram<sup>5</sup> on all milk protein concentrate imports except Canadian imports, which are duty-free under the North American Free Trade Agreement. The milk protein concentrates classification, which is intended to include all nonfat dry milk powder containing between 40 and 90 percent protein regardless of its method of production, allows a broad range of milk protein concentrates to enter the United States, according to the U.S. Customs Service.<sup>6</sup>

FDA and USDA's Food Safety and Inspection Service are responsible for ensuring that imported food products are safe, wholesome, and properly labeled.<sup>7</sup> FDA and USDA work with the U.S. Customs Service to ensure the safety of imported food products by monitoring and testing samples of imported foods. Customs uses a computer system containing information provided by the milk protein concentrate importers and FDA-developed screening criteria to determine which shipments may be automatically released and which should be subjected to inspection or laboratory testing.<sup>8</sup> Products such as milk protein concentrates, which are believed to pose minimal safety risks, are frequently released automatically. FDA annually inspects or conducts laboratory analyses on less than 2 percent of all types of imported food shipments. FDA officials told us that they have little concern about the safety of dry milk protein concentrates because the products are treated with heat during pasteurization and drying, which kills pathogens.

In addition to screening milk protein concentrate imports, the United States has agreements with Australia, Belgium, Denmark, France, Ireland, the Netherlands, New Zealand, Norway, and Sweden regarding dry milk

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<sup>5</sup>Duties would be higher for countries that do not have normal trade relations; however, the United States does not import milk protein concentrates from any of these countries.

<sup>6</sup>Milk protein concentrates are classified in section 0404.90.10 of Chapter 4 of the *Harmonized Tariff Schedule of the United States, Annotated*.

<sup>7</sup>USDA's Food Safety and Inspection Service has jurisdiction over meat, poultry, and some egg products, while FDA regulates all other foods.

<sup>8</sup>See *Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable* (GAO/RCED-98-103, April 30, 1998) for more details.

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and milk protein imports. The agreements are to ensure that these countries adhere to FDA's food safety regulations, thereby minimizing the need for FDA to inspect these imports. No country has reached a broader agreement with the United States that their entire food safety system is equivalent to the United States thus enabling FDA to apply fewer resources to screening their imports. Dairy products, including milk protein concentrate products, will be subject to a not-yet-implemented "veterinary equivalency agreement" with the European Union and its 15 member countries. This agreement would provide a framework for the future equivalence of the European Union.

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## Ultra-filtered Milk Produced in the United States and Used in Standardized Cheeses

Many U.S. cheese plants produce and use wet ultra-filtered milk to make standardized and nonstandardized cheeses, according to industry executives. However, federal and industry sources could not provide data on the amount of wet ultra-filtered milk produced domestically or on its use. USDA and state officials told us that 22 dairy manufacturing plants nationwide and 4 large dairy farms in New Mexico and Texas have the capacity to make wet ultra-filtered milk. Most of the ultra-filtered milk is used within the dairy manufacturing plants to make cheese, although some is transported to other plants for use. The milk concentrated at on-farm ultra-filtration plants is transported mainly to cheese plants in the Midwest to make standardized cheese or other products.

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## Government and Industry Do Not Collect Data on Ultra-filtered Milk Production

Data are not routinely collected on the amount of ultra-filtered milk produced by U.S. cheese plants or other food processors for internal use or for shipment elsewhere, according to USDA and FDA officials and industry executives. USDA's Agricultural Marketing Service (AMS) staff, which oversees the administration of milk marketing in 11 regions across the United States, collects data on the intended use of the milk but not on intermediate products, such as ultra-filtered milk, that are often produced and used in making cheese. Similarly, AMS staff said that ultra-filtered milk produced in one plant for use in another is included with other bulk milk products and not tracked separately.

Trade association executives told us that they have no data on the amount of wet ultra-filtered milk U.S. dairy manufacturing plants produced and used. Trade association staff said that manufacturers would probably not respond to a request for such data because the information is considered proprietary and because of concern surrounding the petitions to use wet ultra-filtered milk now before FDA. Executives involved with the relatively

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new on-farm production of ultra-filtered milk provided overall annual production data, which are discussed below.

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### Ultra Filtration of Milk Is Part of the Cheese-making Process in Many Plants

Many U.S. cheese-making plants have adopted ultra filtration of milk as part of the cheese-making process under the provisions in FDA's standards of identity regulations allowing for "alternate make" procedures for many of the standardized cheese and related cheese products. The "alternate make" procedures accommodate innovation by allowing these standardized cheeses to be made by any procedure that produces a finished cheese having the same physical and chemical properties as the cheese prepared by the traditional process. Filtration removes the liquid components of milk that would otherwise be removed in the traditional process when whey is separated from cheese curd. Proponents of ultra filtration state that the cheese produced is also nutritionally equivalent. The goal of ultra-filtered milk producers is to create the ideal combination of milk solids (i.e., protein and fat) for the particular style of cheese.

AMS' milk marketing staff provided a list of milk processing plants that have ultra-filtration equipment for milk in the 47 states covered at least in part by federal milk market orders.<sup>9</sup> Three states—California, Alaska, and Hawaii—are not covered by federal regulation. We contacted officials in California—a large dairy state that regulates its dairy industry separately—to acquire similar information. The 48 states reported a combined total of 22 dairy manufacturing plants with ultra-filtration equipment for milk. AMS and California officials reported that at least five of these plants transported a portion of their ultra-filtered milk product to other plants. They further stated that it was possible for cheese makers to use their ultra-filtration equipment to concentrate the whey byproduct from the cheese-making process rather than to concentrate the milk entering the cheese-making process. AMS officials said that, to the extent they were aware, the transportation of ultra-filtered milk between manufacturing plants typically involved transfers between facilities of the same company.

The American Dairy Products Institute and the National Cheese Institute of the International Dairy Foods Association have petitioned FDA to amend its standards of identity for cheese to include wet ultra-filtered milk

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<sup>9</sup>The federal milk market orders are a system of regulation administered by AMS that aims to benefit producers and consumers by establishing and maintaining orderly marketing conditions and assuring adequate supplies of milk.

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in the definition of milk allowed in standardized cheese. According to the American Dairy Products Institute, ultra-filtration makes cheese manufacturing more efficient using new technology and may benefit consumers if cost savings are passed on. It also allows more efficient movement of milk from areas with an excess of fluid milk to areas with an insufficient supply, the American Dairy Products Institute said. The National Cheese Institute noted that the “alternate make procedure,” already included in the regulations for some of the standardized cheeses, provides a legal basis for the use of filtered milk in the manufacture of standardized cheese. However, the institute wants to see the standards amended to explicitly recognize ultra-filtered milk in the standards’ definition of milk. By explicitly recognizing ultra-filtered milk as milk for cheese manufacturing, FDA would allow manufacturers to use ultra-filtered milk in the standardized cheeses that do not include “alternate make procedure” provisions. The National Cheese Institute states that the greater use of ultra-filtered milk would help manage seasonal imbalances in the milk supply in various regions and in the demand for cheese. The institute said the lower hauling costs for filtered milk have enabled cheese makers to buy milk from distant regions and meet their needs for manufacturing, especially when regional milk supplies are disrupted by adverse conditions. FDA said it has exercised enforcement discretion on ultra-filtered milk, and has not enforced the standards of identity against cheese plants that use wet ultra-filtered milk produced outside of their plants.

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### On-Farm Ultra Filtration Opens Distant Markets to Southwestern Dairies

In 1996, T.C. Jacoby & Co., a St. Louis broker of dairy products, requested that FDA allow the use of ultra-filtered milk from an on-farm ultra-filtration plant in New Mexico to Bongards Creamery of Bongards, Minnesota, to make cheddar cheese. The broker also raised the issue of how to label the cheese to indicate the ultra-filtered milk ingredient in the final cheese product. FDA responded that the ultra-filtered milk could be used by Bongards to make cheddar cheese as long as the cheese was nutritionally, physically, and chemically the same as cheese produced traditionally. FDA allowed the label of the cheddar cheese to state that “milk” was an ingredient, provided that the cheddar cheese manufactured from it is equivalent. FDA allowed a pilot project for one farm and one cheese plant. The joint venture involving Jacoby & Co. subsequently expanded its production of ultra-filtered milk to three additional farms and its sales to manufacturers in Idaho, Illinois, Iowa, Minnesota, North Dakota, Ohio, Pennsylvania, South Dakota, and Wisconsin. FDA is considering the petitions but has taken no action to revise its standards of identity to reflect this use of ultra-filtered milk.

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The joint venture's dairy, Select Milk Producers Inc., ultra-filters unheated whole raw milk on three farms in New Mexico and one in Texas. The process reduces the volume and weight of the whole milk the dairy starts with and reduces transportation costs for shipping it to manufacturers. The joint venture, which first sold wet ultra-filtered milk in 1997, reported sales of approximately 150 million pounds of ultra-filtered milk in 2000, mainly for making standardized cheeses.

On-farm ultra filtration of milk removes two-thirds of the liquid components of the milk—mainly water—to greatly reduce the costs to transport the ultra-filtered milk to market. For example, company officials noted one shipment for which the costs were reduced from \$4.50 per hundredweight of milk to \$1.20 for the remaining filtered milk. They added that this cost advantage is justified only for long-distance hauling, however, because the capital costs for installing ultra-filtration equipment are high. (See app. V for the composition of the various concentrates of wet ultra-filtered milk.)

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## FDA and State Entities Cooperate to Conduct a Limited Number of Cheese Plants Inspections

FDA relies on its own inspections and those conducted by the states under contract or partnership agreements to enforce its standards of identity regulations in about 1,000 cheese-making plants across the country. In fiscal year 1999, FDA inspected nine cheese-making plants for compliance with food labeling and economic regulations, which include checking compliance with the standards of identity for cheese. None of these inspections were done exclusively to monitor for compliance with standards of identity, and data indicating the number of these inspections that actually covered the standards of identity were not available. Similarly, the states conducting inspections on FDA's behalf did not exclusively inspect for the identity standards for cheese. In fiscal year 1999, FDA and state inspectors reported no violations for the use of imported ultra-filtered milk or milk protein concentrates to make standardized cheese. In addition, states conduct their own inspections of cheese plants for compliance with standards of identity requirements under state law. For example, in 2000, Vermont inspectors found two cheese plants using imported milk protein concentrates to make standardized cheeses in violation of federal and state regulations. Vermont issued warning letters and the plants discontinued this use.

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## FDA Performs Few Cheese Standards Inspections

FDA reported that its own inspections of cheese-making plants for compliance with FDA's food labeling and economic regulations, which include the standards of identity for cheese, are relatively infrequent. In

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fact, they accounted for 9 of the total 499 domestic inspections for composition, standards, labeling, and economics regulations in all types of food manufacturing plants during fiscal year 1999. FDA said none of the nine inspections in cheese plants was done specifically to check for compliance with standards of identity on cheese. FDA also said that the agency devoted 0.7 staff year during fiscal year 1999 to FDA's food labeling and economic regulations for cheese.

However, FDA reported that its inspectors and state inspectors working for FDA in fiscal year 1999, inspected about 300 of approximately 1,000 cheese-making plants throughout the United States for a variety of other purposes. FDA inspected 108 plants on its own. FDA officials said that states inspected 65 cheese plants under partnership agreements, 125 cheese plants under 37 contracts, and 2 under both a state partnership and contract. Overall, FDA reported inspections of about 3,500 of about 22,000 food manufacturing plants in fiscal year 1999.

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## FDA and States Cooperate to Monitor Food Safety

To increase the number of inspections of food manufacturing firms, FDA has contracts or forms partnerships with state agencies to help carry out monitoring responsibilities relating to food safety and quality. FDA provides its compliance policies and inspection guidelines to state inspectors and sometimes conducts joint inspections with state inspectors. In addition, states such as Wisconsin and Vermont have adopted FDA's cheese standards of identity as their own standards under state law.

In fiscal year 2000, FDA had contracts with 37 states to cover food inspections. Under these contracts, FDA paid states to conduct and report on food inspections of all types. State officials then inspected locations under the state or FDA authority. The number of completed inspections to check for compliance with the standards of identity for cheese, however, was not available. Officials at Wisconsin's Department of Agriculture, Trade, and Consumer Protection told us they worked closely with FDA on contracted inspections, meeting annually with FDA officials to plan and coordinate their inspection efforts to avoid duplication. At these meetings, FDA provides state authorities with a list of the dairy establishments for Wisconsin inspectors to visit during the year. In addition, for each inspection done under its contract with FDA, Wisconsin inspectors complete a FDA inspection report describing the inspection results. Wisconsin officials reported that they did 82 inspections under the contract with FDA in fiscal year 1999 and 62 in fiscal year 2000.

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Wisconsin officials told us that the state had 142 cheese-making plants in 1999 that produced many types of cheese. Wisconsin dairy inspectors check cheese plants for safety and sanitation, food composition and labeling regulations—including standards of identity—and to collect product samples. Wisconsin officials said their inspectors make on-site visits to cheese plants on a semiannual basis, taking a total of 36 samples each year for laboratory analysis of microbes, moisture content, and comparison of ingredients with FDA and Wisconsin standards. Wisconsin estimated that it expended 3.1 and 2.8 staff years in fiscal years 1999 and 2000 respectively, on routine inspections of cheese plants, not including nonroutine and contract inspections. State officials did not have the data to estimate the time spent specifically on standards of identity.

FDA and the states also have 15 partnership agreements related to FDA's regulation of dairy products. Under these partnerships, FDA and the states (or food-related organizations) collaborate on such efforts as training inspectors and sharing test results. FDA does not fund activities carried out by states under its partnership agreements, and the states bear the responsibility for handling any violations.

In addition to these efforts, the states conduct their own inspections under state law, which can include the standards of identity. For example, both Vermont and Wisconsin routinely inspect plants for compliance with state laws and regulations, and both have adopted FDA's standards of identity as part of their states' food safety and quality laws.

Vermont officials told us that the state has no formal working relationship, such as a partnership or a contract, with FDA relating to dairy inspections. However, Vermont's dairy inspectors coordinate with FDA on dairy matters. Vermont officials stated that about 2.0 staff years are used annually to inspect about 40 dairy plants, 28 of which are cheese making. Vermont's officials inspect the dairy plants for sanitation and cheese standards of identity and to collect samples. Tests of samples for microbes and animal drugs are done about once a month at the larger dairy plants. The inspectors visit the dairy plants on a quarterly basis and the larger plants about 20 times per year, according to Vermont officials.

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## FDA and the States Report Few Violations of Cheese Standards of Identity

FDA and the two states we contacted—Vermont and Wisconsin—report few violations of FDA's cheese standards of identity. In fiscal year 1999, FDA reported that no violations involving the use of ultra-filtered milk in standardized cheese in federal and the contracted state inspections. Likewise, Wisconsin officials told us that they had found no cheese

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standards of identity violations relating to the use of ultra-filtered milk in cheese in the past few years. They did report a December 2000 incident in which a cheese plant was found to be using milk protein concentrate in nonstandardized ricotta cheese. While the use of the ingredient was not a violation of state or federal standards, the product's label did not identify the ingredient as required by law. The plant stopped using the milk protein concentrate until the label could be corrected, state officials reported.

In 2000, Vermont inspectors found two cheese plants using imported milk protein concentrate to make cheeses covered by FDA's standards of identity in violation of federal and state law. Vermont officials wrote letters to the plants warning that this ingredient was not permitted by the standards. Vermont officials said the plants discontinued its use and the cases were closed.

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## Agency Comments

We provided FDA with a draft of this report for its review and comment. FDA generally agreed with the report and provided some specific comments, which we have incorporated into the report as appropriate. FDA's comments and our responses are in appendix VI.

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## Scope and Methodology

To identify the trends in ultra-filtered milk imports into the United States between 1990 and 1999, we obtained data compiled by the U.S. Census Bureau from the U.S. Customs Service on annual imports of milk protein concentrates, which includes ultra-filtered milk. To identify any quantity, tariff, or other trade restrictions applicable to imported ultra-filtered milk, we reviewed the U.S. Harmonized Tariff Schedule and interviewed USDA, Customs, and FDA officials and representatives of domestic and foreign dairy trade associations and reviewed relevant reports and publications. To identify the uses of dry ultra-filtered milk and milk protein concentrates in the manufacture of cheese and other products in the United States, we obtained information from trade association representatives, domestic and foreign company executives, and federal officials.

To identify the use of domestically produced ultra-filtered milk in the manufacture of cheese and other food products in the United States, we reviewed relevant FDA standards of identity and other regulations and available published reports. We also interviewed USDA officials; California, Vermont, and Wisconsin state officials; trade association representatives; company executives; and academicians.

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To identify FDA's and state agencies' efforts to enforce the federal standards of identity regulations, particularly the use of ultra-filtered milk in cheese production, we interviewed officials of USDA, FDA, Wisconsin, and Vermont regarding the extent of their activities and amount of staff resources used to monitor the standards. We conducted our review from August 2000 through February 2001 in accordance with generally accepted government auditing standards.

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We are sending copies of this report to the congressional committees with jurisdiction over dairy products; the Honorable Ann M. Veneman, Secretary of Agriculture; the Honorable Dr. Bernard Schwetz, Acting Commissioner of the Food and Drug Administration; the Honorable Charles W. Winwood, Acting Commissioner, U.S. Customs Service; the Honorable Mitchell E. Daniels, Jr., Director of the Office of Management and Budget; and other interested parties. We will make copies available to others on request.

If you have any questions about this report, please contact me or Richard Cheston, Assistant Director, at (202) 512-3841. Key contributors to this report were Diana P. Cheng, Jonathan S. McMurray, John P. Scott, and Richard B. Shargots.



Lawrence J. Dyckman  
Director, Natural Resources  
and Environment

---

*List of Requesters*

The Honorable Joe Skeen  
House of Representatives

The Honorable David R. Obey  
House of Representatives

The Honorable Tammy Baldwin  
House of Representatives

The Honorable Russell D. Feingold  
United States Senate

The Honorable James M. Jeffords  
United States Senate

The Honorable Herb Kohl  
United States Senate

# Appendix I: Cheeses and Related Cheese Products Covered by FDA's Standards of Identity Regulations

Table 1 below shows the cheeses and related cheese products by section number covered by the Food and Drug Administration's (FDA) Standards of Identity regulations (21 C.F.R., Part 133, Subpart B). Because these regulations do not identify ultra-filtered milk as an approved ingredient, manufacturers of standardized cheeses and related cheese products cannot use ultra-filtered milk that is produced outside the cheese-making plant. (FDA has allowed an exception to this for a pilot project producing ultra-filtered milk on a farm in New Mexico for use in a Minnesota cheese plant.) If milk protein concentrates are used in a cheese product, then the product cannot bear the name of a standardized product, which is listed below. However, milk protein concentrates can be used as ingredients for nonstandardized cheese products not listed, such as feta cheese and pizza cheese. FDA also has standards of identity for many other product types, including milk and cream, frozen desserts, bakery, macaroni and noodles, and frozen vegetables.

**Table 1: Cheeses and Related Cheese Products Covered by FDA's Standards of Identity Regulations**

Section	Cheese
133.102	Asiago fresh and asiago soft cheese
133.103	Asiago medium cheese
133.104	Asiago old cheese
133.106	Blue cheese
133.108	Brick cheese
133.109	Brick cheese for manufacturing
133.111	Caciocavallo siciliano cheese
133.113	Cheddar cheese
133.114	Cheddar cheese for manufacturing
133.116	Low sodium cheddar cheese
133.118	Colby cheese
133.119	Colby cheese for manufacturing
133.121	Low sodium colby cheese
133.123	Cold-pack and club cheese
133.124	Cold-pack cheese food
133.125	Cold-pack cheese food with fruits, vegetables, or meats
133.127	Cook cheese, koch kaese
133.128	Cottage cheese
133.129	Dry curd cottage cheese
133.133	Cream cheese
133.134	Cream cheese with other foods
133.136	Washed curd and soaked curd cheese
133.137	Washed curd cheese for manufacturing
133.138	Edam cheese

**Appendix I: Cheeses and Related Cheese Products Covered by FDA's Standards of Identity Regulations**

<b>Section</b>	<b>Cheese</b>
133.140	Gammelost cheese
133.141	Gorgonzola cheese
133.142	Gouda cheese
133.144	Granular and stirred curd cheese
133.145	Granular cheese for manufacturing
133.146	Grated cheeses
133.147	Grated American cheese food
133.148	Hard grating cheeses
133.149	Gruyere cheese
133.150	Hard cheeses
133.152	Limburger cheese
133.153	Monterey cheese and Monterey jack cheese
133.154	High-moisture jack cheese
133.155	Mozzarella cheese and scamorza cheese
133.156	Low-moisture mozzarella and scamorza cheese
133.157	Part-skim mozzarella and scamorza cheese
133.158	Low-moisture part-skim mozzarella and scamorza cheese
133.160	Muenster and munster cheese
133.161	Muenster and munster cheese for manufacturing
133.162	Neufchatel cheese
133.164	Nuworld cheese
133.165	Parmesan and reggiano cheese
133.167	Pasteurized blended cheese
133.168	Pasteurized blended cheese with fruits, vegetables, or meats
133.169	Pasteurized process cheese
133.170	Pasteurized process cheese with fruits, vegetables, or meats
133.171	Pasteurized process pimento cheese
133.173	Pasteurized process cheese food
133.174	Pasteurized process cheese food with fruits, vegetables, or meats
133.175	Pasteurized cheese spread
133.176	Pasteurized cheese spread with fruits, vegetables, or meats
133.178	Pasteurized neufchatel cheese spread with other foods
133.179	Pasteurized process cheese spread
133.180	Pasteurized process cheese spread with fruits, vegetables, or meats
133.181	Provolone cheese
133.182	Soft ripened cheeses
133.183	Romano cheese
133.184	Roquefort cheese
133.185	Samsoe cheese
133.186	Sap sago cheese
133.187	Semisoft cheeses
133.188	Semisoft part-skim cheeses
133.189	Skim milk cheese for manufacturing
133.190	Spiced cheeses

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**Appendix I: Cheeses and Related Cheese  
Products Covered by FDA's Standards of  
Identity Regulations**

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<b>Section</b>	<b>Cheese</b>
133.191	Part-skim spiced cheeses
133.193	Spiced, flavored standardized cheeses
133.195	Swiss and emmentaler cheese
133.196	Swiss cheese for manufacturing

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# Appendix II: Use of Ultra Filtration in the Cheese-making Process

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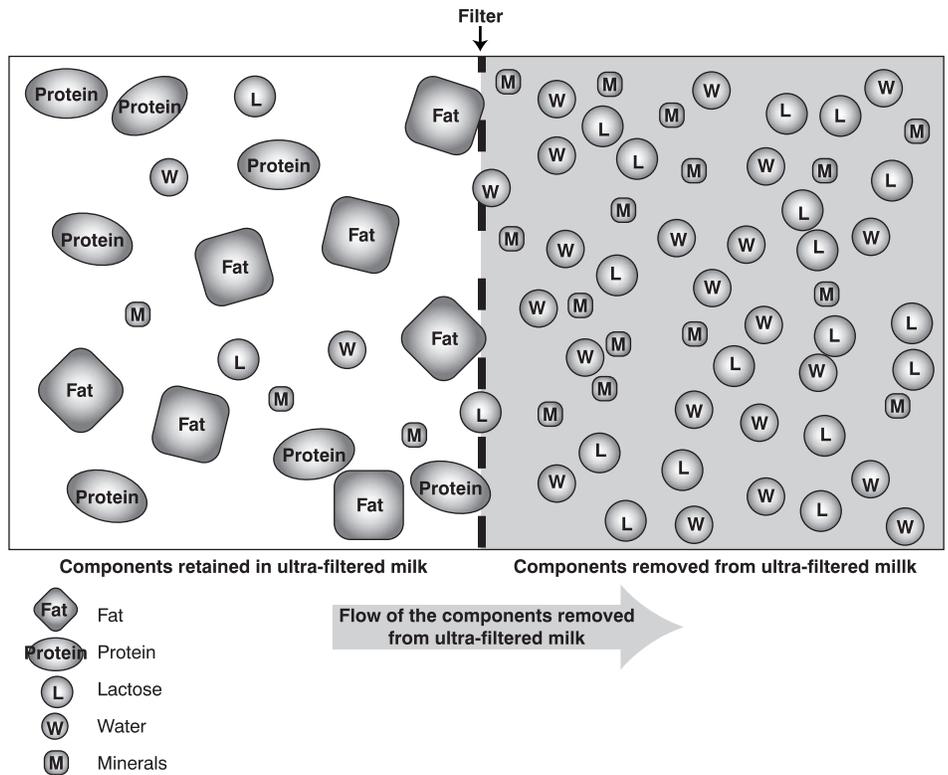
Cheese making combines an ancient art with scientific knowledge to manufacture uniform products by removing water and retaining the desirable solids in milk. Prior to making cheese, cheese makers test the quality of the milk. Then they may adjust for seasonal variations in the composition of milk, specifically milk proteins, to ensure that uniform milk is used to manufacture consistent cheese throughout the year. Traditionally, cheese makers use nonfat dry milk or liquid condensed milk as the chief ingredient to adjust the milk proteins but these have limitations due to the lactose content in these forms of milk. Ultra-filtered milk provides cheese makers with an alternative product for this purpose.

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## The Process of Ultra Filtration

Ultra-filtered milk concentrates the proteins by removing the water and lactose in milk, permitting greater efficiency in cheese making. Because the starting ingredients contain less liquid, the volume of whey (primarily water, lactose, whey proteins, and minerals) removed during cheese making is reduced and less effort and time are spent to expel the liquid from the cheese curds leading to its transformation into cheese. Figure 3 is a simplified diagram of the ultra-filtration process that enlarges a portion of the process to show how milk components are separated.

Figure 3: The Concept of Ultra Filtration



In ultra filtration, a filter (membrane with minute pores) retains the larger molecules (fat and protein) and allows the smaller molecules (water, lactose, and some minerals) to pass through. Although vitamins are a component in milk, they are not shown in the figure because they are found within the fat and water components.<sup>1</sup> Ultra filtration is not 100-percent efficient because some milk flows parallel to the filter pushed by pressure and not all of the milk comes in contact with the filter. Therefore, wet ultra-filtered milk will contain some water, lactose, and minerals.

Because of practical limitations on the amount of ultra-filtered milk that can be used in making cheese, ultra-filtered milk is normally used to supplement skim or whole milk used to make cheese. Cheese-making experts said that the majority of cheese vats in U.S. plants are not

<sup>1</sup>Milk fat holds the fat-soluble vitamins (A, D, E, and K). The water-soluble vitamins are the B complex (i.e., riboflavin, thiamin, and niacin) and C vitamins.

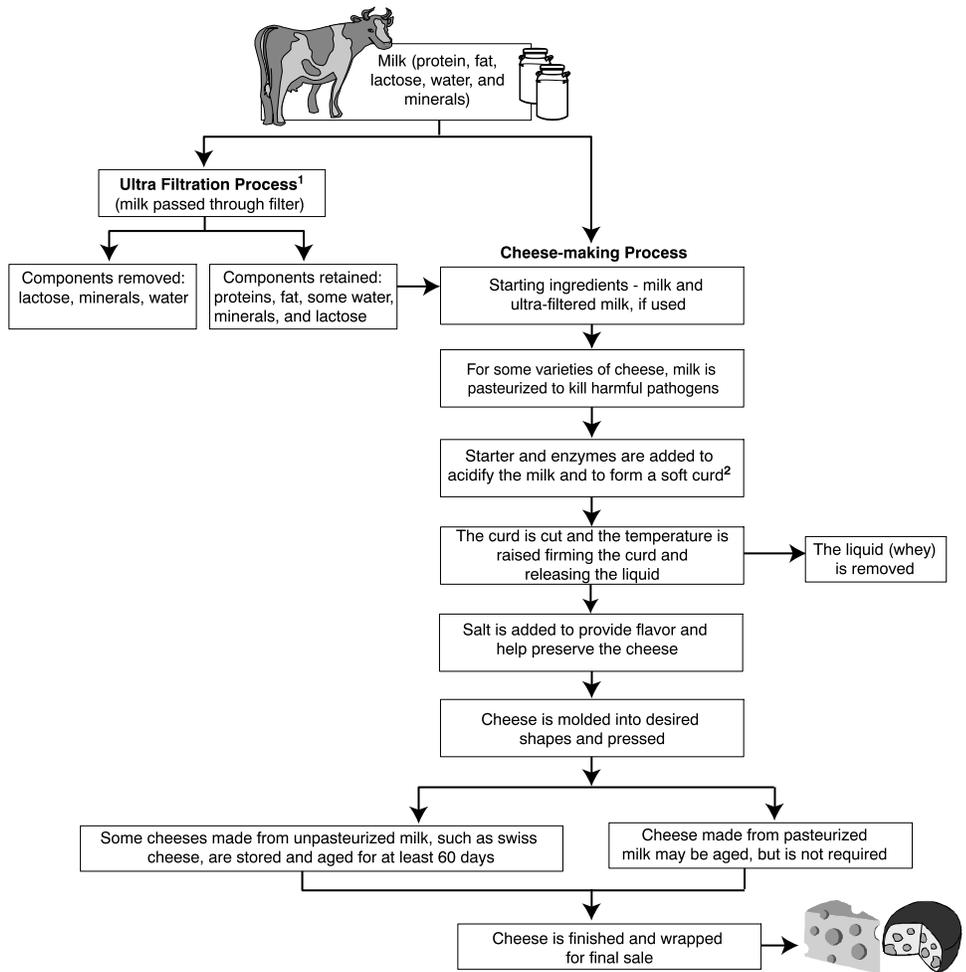
designed to use only ultra-filtered milk, which is thicker than skim or whole milk. A high proportion of ultra-filtered milk would cause the equipment to malfunction. In addition, because highly concentrated ultra-filtered milk is not nutritionally equivalent to fluid milk, it could not be used as the sole ingredient in cheese. If cheese were made entirely from ultra-filtered milk, its texture, composition, and other characteristics would be different from cheese made traditionally. Although experts believe that these limitations can be addressed, the limitations currently prevent cheese makers from making cheese entirely from ultra-filtered milk at a concentration greater than “2X” in which half of the water is removed leaving twice as many solids (fat and protein) as compared to whole milk.

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## The Cheese-making Process

Figure 4 shows a flowchart of the cheese-making process. Ultra-filtered milk can be used to maintain consistent levels of fat and protein components in the raw milk used to make cheese, ensuring that cheese quality is the same throughout the year. It can also be used in larger quantities to increase the total solids (fat and proteins) in the raw milk, resulting in larger yields. Cheese making involves transforming milk proteins into solid lumps (curds), separating the curds' solids from the liquid (whey), shaping or pressing these curds into molds, and aging the shaped curds.

Figure 4: The Cheese-making Process



<sup>1</sup>Ultra-filtered milk can be used to supplement the fat and proteins in milk or to ensure that the components of milk for making cheese are consistent.

<sup>2</sup>Curds consist mainly of milk proteins that solidify in the process and become the foundation for the final cheese product.

# Appendix III: U.S. Imports of Milk Protein Concentrates by Country, 1990-1999

Table 2 shows U.S. imports of milk protein concentrates between 1990 and 1999. Between 1990 and 1994, U.S. imports of milk protein concentrates increased 15-fold, and the number of suppliers grew from 4 countries to 11 countries. From 1995 to 1999, U.S. imports of milk protein concentrates increased 6-fold. Over the 10-year period, U.S. imports of milk protein concentrates increased 56-fold. Australia is the only country that exported milk protein concentrates to the United States in each year during this 10-year period.

**Table 2: U.S. Imports of Milk Protein Concentrates by Country, 1990-1999**

Quantity in metric tons										
	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999
<b>North America</b>										
Canada	488	0	0	65	990	340	1,303	1,016	1,957	3,420
<b>South America</b>										
Argentina	0	0	0	0	0	218	163	36	0	0
<b>European Union</b>										
Sweden	45	0	1,171	3,491	3,492	722	703	663	39	98
Denmark	0	0	0	0	0	61	18	14	92	80
United Kingdom	0	0	422	0	369	0	20	0	19	66
Ireland	0	0	59	0	0	525	3,103	3,922	7,305	9,775
Netherlands	0	494	202	94	34	24	0	26	912	4,560
Belgium-Luxembourg	0	0	0	0	0	0	58	0	20	19
France	0	0	5	193	0	5	44	306	0	339
Germany	0	0	1,445	851	3,617	1,407	1,881	1,175	1,445	5,261
Austria	0	17	0	292	181	36	48	0	0	0
Spain	0	0	0	21	892	408	153	0	0	0
Italy	0	0	0	0	0	0	0	20	0	0
<b>Other Western Europe</b>										
Switzerland	0	0	0	0	0	0	0	0	0	52
<b>Eastern Europe</b>										
Hungary	17	0	369	0	170	153	162	168	395	416
Poland	0	0	20	470	331	237	700	519	2,720	875
Estonia	0	0	0	0	0	0	0	60	180	300
Lithuania	0	0	0	0	0	0	20	100	19	49
<b>Africa</b>										
Republic of South Africa	0	0	0	0	0	0	0	0	224	0
<b>Asia</b>										
Taiwan	0	0	0	0	0	0	0	0	112	0
<b>Oceania</b>										
Australia	255	238	85	342	455	152	1,036	1,141	2,246	4,967
New Zealand	0	373	158	0	1,477	3,000	4,905	7,831	11,243	14,601
<b>Total</b>	<b>805</b>	<b>1,122</b>	<b>3,936</b>	<b>5,819</b>	<b>12,008</b>	<b>7,288</b>	<b>14,317</b>	<b>16,997</b>	<b>28,928</b>	<b>44,878</b>

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**Appendix III: U.S. Imports of Milk Protein  
Concentrates by Country, 1990-1999**

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Note: One metric ton is equal to 2,204.6 pounds or 1,000 kilograms.

Source: Imports reported for classification number 0404.90.10 of the *Harmonized Tariff Schedule of the United States, Annotated*, as compiled by the U.S. Census Bureau from the U.S. Customs Service data.

# Appendix IV: Types, Composition, and Suggested Uses of Dry Milk Protein Concentrates

Table 3 provides a general overview of the milk protein concentrate (MPC) products made from skim milk and their suggested uses, as provided by their distributors. It is not a comprehensive list because the uses for milk protein concentrate are reportedly expanding and developing, and only a few of the exporters we contacted opted to provide this information. Milk protein concentrates are typically described by their approximate protein content expressed as a percentage. For example, MPC 42 contains 42 percent protein based on dry weight. The other components in the product vary depending on its producer and customization of the products to meet customer specifications.

**Table 3: Types, Composition, and Suggested Uses of Dry Milk Protein Concentrates**

Product	Producer/distributor (MPC country of origin)	Composition <sup>a</sup> (percent)	Suggested uses <sup>b</sup>
MPC 42	Murray Goulburn Co-operative Co. Limited (Australia)	42.0 protein 2.0 fat 8.0 ash 45.5 lactose	Frozen deserts, nonfat dry milk replacement, bakery and confection applications, and cheese milk standardization.
	The Milky Whey, Inc. (Europe and New Zealand)	42.0 protein 1.0 fat 7.5 ash 45.5 lactose	
MPC 50	Murray Goulburn Co-operative Co. Limited (Australia)	49.8 protein 1.5 fat 8.0 ash 35.5 lactose	Frozen deserts, nonfat dry milk replacement, bakery and confection applications, and cheese milk standardization.
MPC 56	NZMP (North America) Inc. (New Zealand)	56.0 protein 1.2 fat 8.0 ash 31.0 lactose	Frozen deserts, nutritional beverage powders, bakery and confection applications, nonstandardized cheese products, and cheese milk standardization.
	Murray Goulburn Co-operative Co. Limited (Australia)	55.8 protein 1.5 fat 8.5 ash 30.5 lactose	
MPC 70	NZMP (North America) Inc. (New Zealand)	71.0 protein 1.0 fat 7.0 ash 17.0 lactose	Sports nutrition drinks and bars, aged care products, hospital rehabilitation products, and pasteurized process cheese products.
	Murray Goulburn Co-operative Co. Limited (Australia)	69.8 protein 2.0 fat 8.5 ash 15.5 lactose	
MPC 75	Murray Goulburn Co-operative Co. Limited (Australia)	74.8 protein 2.0 fat 8.5 ash 10.5 lactose	Sports nutrition drinks and bars, aged care products, and hospital rehabilitation products.

**Appendix IV: Types, Composition, and Suggested Uses of Dry Milk Protein Concentrates**

<b>Product</b>	<b>Producer/distributor (MPC country of origin)</b>	<b>Composition<sup>a</sup> (percent)</b>	<b>Suggested uses<sup>b</sup></b>
MPC 80	Murray Goulburn Co-operative Co. Limited (Australia)	79.8 protein 2.5 fat 8.5 ash 5.5 lactose	Sports nutrition drinks and bars, aged care products, and hospital rehabilitation products.
MPC 85	Murray Goulburn Co-operative Co. Limited (Australia)	84.8 protein 2.5 fat 8.5 ash 0.5 lactose	Sports nutrition drinks and bars, aged care products, and hospital rehabilitation products.
MPC 90	NZMP (North America) Inc. (New Zealand)	86.7 protein 1.6 fat 7.1 ash 1.0 lactose	Products with a lactose- and sugar-free claim, nutritional foods, beverages, and frozen deserts.

Note: While the producers or distributors offer these MPC products, they did not state whether all are currently exported to the United States.

<sup>a</sup>The fat and ash levels listed are maximum levels; protein is listed at a minimum level; and lactose is given as an approximate value. Ash is an industry term for minerals, such as calcium and phosphorous.

<sup>b</sup>Producers stated that the exact uses for each product are dependent on the manufacturing processes and the characteristics of the protein and minerals contained in the particular MPC product.

Sources: Murray Goulburn Co-operative Co. Limited, Australia; NZMP (North America) Inc.; and The Milky Whey, Inc.

# Appendix V: Types and Composition of Wet Ultra-filtered Milk

Table 4 provides the composition of various concentrations of wet ultra-filtered milk made from whole milk.<sup>1</sup> The composition of ultra-filtered milk depends on the composition of the raw milk, which may vary depending on the season in which the milk was produced.<sup>2</sup> Because ultra filtration removes liquids and concentrates the protein and fat components of milk, the table indicates the degree to which solids are concentrated. For example, in a “2X” concentration, half of the water is removed leaving twice as many solids (i.e. fat and protein) compared with whole milk.

**Table 4: Types and Composition of Wet Ultra-filtered Milk**

Concentration of ultra-filtered milk products	Composition of ultra-filtered whole milk products (percent) <sup>a</sup>
1.5X	4.48 protein 5.51 fat 0.95 ash 4.59 lactose
2 X	5.97 protein 7.34 fat 1.18 ash 4.41 lactose
2.5X	7.47 protein 9.18 fat 1.40 ash 4.23 lactose
3 X	8.96 protein 11.01 fat 1.63 ash 4.04 lactose
3.5X	10.45 protein 12.85 fat 1.86 ash 3.86 lactose
4 X	11.94 protein 14.68 fat 2.09 ash 3.68 lactose

<sup>a</sup>These percentages are based on the weight in the resulting concentrate.

Source: Northeast Dairy Foods Research Center, Cornell University.

<sup>1</sup>Ultra-filtered milk can also be made from skim milk.

<sup>2</sup>These calculations were made assuming the following whole milk composition (in percents): 2.9862 for true protein; 3.6700 for fat; 0.7159 for ash; and 4.7776 for lactose. True protein is the measurement of the protein content only and does not contain any non-protein nitrogen, which is of no value in making cheese.

# Appendix VI: Comments From the Food and Drug Administration



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

February 16, 2001

Mr. Lawrence J. Dyckman  
Director, Resources, Community,  
and Economic Development Division  
Food and Agricultural Issues  
United States General Accounting Office  
441 G Street, Northwest, Room 2T23  
Washington, DC 20548

Dear Mr. Dyckman:

Please find the enclosed comments from the Food and Drug Administration on the GAO draft report entitled, Dairy Products: Imports, Domestic Production, and Regulation of Ultra-filtered Milk (GAO-01-326).

Sincerely,

A handwritten signature in black ink, appearing to read "Theresa Mullin".

Theresa M. Mullin Ph.D., Director  
Evaluation Staff  
Office of Planning  
Office of Policy, Planning, and Legislation

Enclosure

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**Appendix VI: Comments From the Food and  
Drug Administration**

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FOOD AND DRUG ADMINISTRATION COMMENTS ON THE GENERAL ACCOUNTING  
OFFICE DRAFT REPORT ENTITLED, DAIRY PRODUCTS: Imports, Domestic Production,  
and Regulation of Ultra-Filtered Milk GAO/01-326

The Food and Drug Administration (FDA) welcomes this report and appreciates the opportunity to review the General Accounting Office's (GAO) draft report, and provide comments. FDA generally agrees with the report and has the following general comments for consideration regarding this draft report.

GENERAL COMMENTS

See comment 1.

1. On Page 3, in the last paragraph, GAO implies that an "alternate make" procedure allows the use of alternate ingredients. That is not accurate. FDA suggests replacing the first sentence in its entirety with the following two sentences, "FDA standards of identity give cheese manufacturers permission under the "alternate make" provisions to use ultra-filtration as an acceptable procedure during the cheese making process. Consequently, milk that has been ultra-filtered as an integral part of the cheese making process has been acceptable as a component of a standardized cheese."

See comment 2.

2. In footnote 3 on page 4 and elsewhere in the draft document, GAO continues to use a percent of protein figure that FDA has identified to be incorrect. According to most sources in the literature on milk composition, the correct figure is on the order of 3.5 percent rather than GAO's current estimate of only 3 percent. The technical difference between the 3.5 percent number and the 3.0 percent number is inclusion of all nitrogen (a component of protein) in the 3.5 percent number and exclusion of nitrogen in the 3.0 percent number. Milk contains both protein and non-protein nitrogen. Thus, use of the 3.0 percent underestimates the protein level in milk products by approximately 16 percent. Using the 3.0 percent number will cause GAO's statistics to be wrong. If GAO calculates pounds of protein imported using the 3.5 percent number and compares it to domestic protein using the number 3.0 percent (page 4), the result is an "apples to oranges" comparison. The result is that the volume of imported protein expressed as a percentage of total U.S. production in 1999 will be artificially inflated. For the sake of complete accuracy, FDA strongly urges GAO to correct this error.

See comment 3.

3. Page 11, first paragraph, last sentence. Because FDA does not withhold enforcement, we exercise enforcement discretion, we offer the following suggestion: insert "exercise enforcement discretion" in place of "withhold enforcement".

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## GAO's Comments

The following are GAO's comments on the Food and Drug Administration's written response to our draft report dated February 2, 2001.

1. We have substituted these sentences as suggested.
2. We have added language to the footnote and to appendix V to explain that we are referring to the amount of "true" protein in whole milk, which is approximately 3 percent. While some sources in literature cite the higher value of "crude" protein, we feel "true" protein is the best value to use in our example. According to academic experts, the total or "crude" protein in milk that FDA refers to is estimated from measuring the total nitrogen content of milk. The total amount of nitrogen comes from both protein and non-protein sources. The experts noted that the measurement of "crude" protein is inaccurate because test equipment does not measure the amount of non-protein nitrogen precisely. By testing for "true" protein only, which electronic testing equipment can accurately detect, this measurement error is corrected. In addition, USDA's AMS, in its 1999 decision on milk market order reform, stated that the use of total or "crude" protein measurement overstates the amount of protein in milk by the amount of non-protein nitrogen, which has little or no effect on dairy product yields. Therefore, AMS decided that milk should be priced under federal milk orders on the basis of its true protein content.
3. We have revised the sentence as suggested.



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