CHARACTERISTICS AND COMMON VULNERABILITIES INFRASTRUCTURE CATEGORY: AGRICULTURAL PROCESSING FACILITIES – MILK PROCESSING

Protective Security Division
Department of Homeland Security

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Preventing terrorism and reducing the nation's vulnerability to terrorist acts requires understanding the common vulnerabilities of critical infrastructures, identifying site-specific vulnerabilities, understanding the types of terrorist activities that likely would be successful in exploiting those vulnerabilities, and taking preemptive and protective actions to mitigate vulnerabilities so that terrorists are no longer able to exploit them. This report characterizes and discusses the common vulnerabilities of agricultural processing facilities that produce milk products.

FACILITY CHARACTERISTICS

Characterization of the Industry

This section provides basic information about the structure of the industry. Figure 1 shows milk production in the United States. Figure 2 shows the distribution of production by state. The top five states of California, Wisconsin, New York, Pennsylvania, and Minnesota account for 52% of total U.S. milk production. The top 10 states, which also include Idaho, Michigan, New Mexico, Washington, and Texas, account for more than 70% of total milk production. Of all dairy products, fluid milk enters and leaves the distribution channel most rapidly. Cream and butterfat can be extracted from whole fluid milk to produce a variety of other dairy products: reduced-fat milk and higher-butterfat products such as butter, cheese, cottage cheese, cream cheese, and ice cream. Value-added products, such as flavored yogurts, yogurt drinks, and nutritional and sports beverages, have shorter product life cycles. Dairy products and their derivatives are also often used as ingredients for remanufacturing (e.g., whey, nonfat dry-milk solids, cheeses). Most dairies that produce whole and reduced-fat milk for retail sale also produce many of the value-added products mentioned.The consumption of milk products (as both fluid milk and processed products) per capita varies widely, with highs occurring in Europe and North America and lows occurring in Asia. In 2001, per-capita consumption in the U.S. diet was significant: 587.2 pounds of dairy products, 207.5 pounds of fluid whole milk and cream, 4.5 pounds of butter, 30 pounds of cheese, and 16.1 pounds of ice cream (U.S. Department of Agriculture [USDA] Marketing Service).

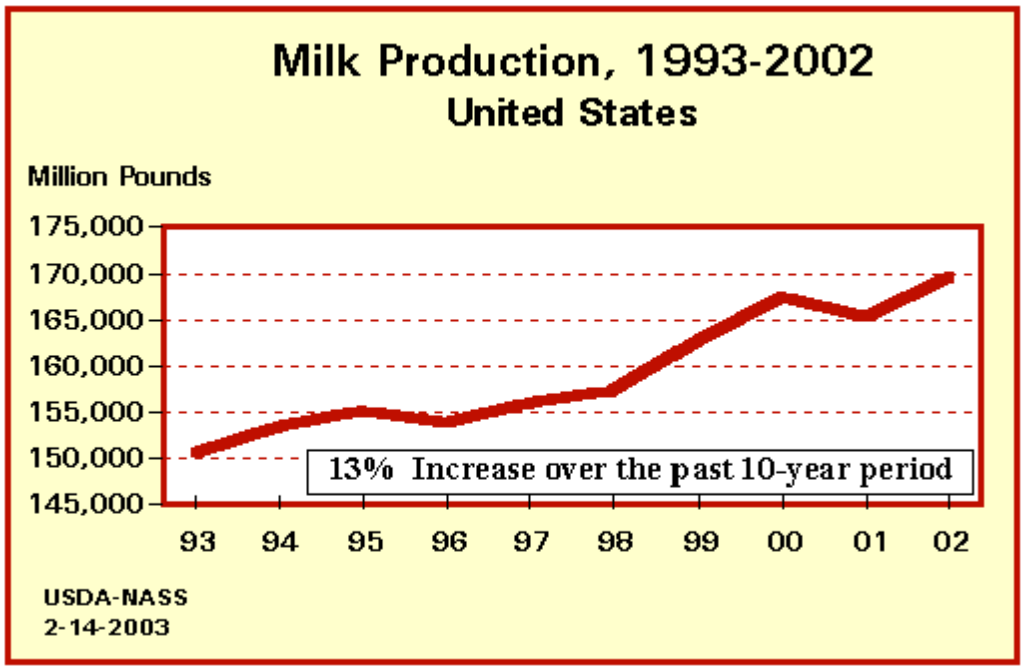
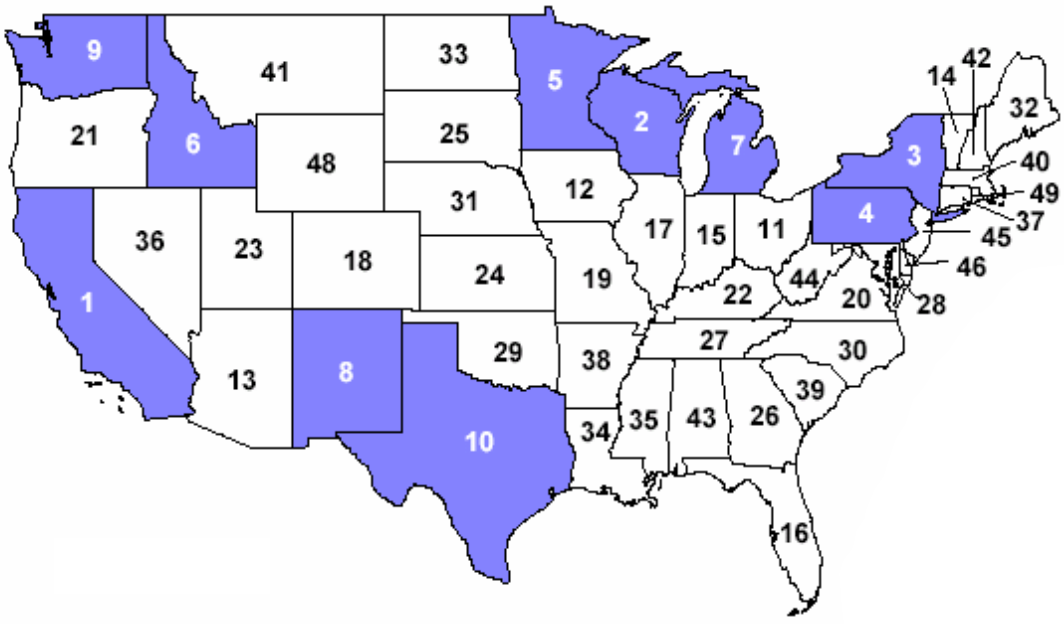


Figure 1 U.S. Milk Production



The USDA uses the following terminology to characterize participants in the industry:

- *Marketing Area.* A marketing area is an area designated in the provisions of a federal milk order, within which the handling of milk is regulated by the order. Generally, the size of the marketing area is determined by the sales territory of competing handlers.

- *Producer.* A producer is usually any dairy farmer who sells milk to a pool handler. Producers must produce milk in compliance with Grade A inspection requirements, and their milk must either be received at a pool plant or diverted to a nonpool plant for the account of a pool handler. Producer-handlers are not producers.

- *Handler.* A handler is an individual, partnership, corporation, association, or other business unit that is subject to the provisions of an order. A handler can be an operator of a plant that is approved by a duly constituted regulatory agency for the handling of Grade A milk. A handler also can be a milk distributor or a broker. A cooperative association that does not operate a plant can be a handler.

- *Pool Handler.* A pool handler is a handler that is subject in full to the provisions of the order. A pool handler can be an operator of a plant that meets the minimum performance standards included in each order (i.e., a pool plant). Such plants include distributing plants, plants primarily engaged in processing packaged fluid milk products, and supply plants (i.e., plants primarily engaged in producing manufactured dairy products). A cooperative association that does not operate a plant can be a pool handler. A milk distributor or broker cannot be a pool handler.

- *Receipts of Milk.* Receipts of milk come principally from producers. The volume of milk that is reported as received by handlers from producers includes all such milk, regardless of where it may be sold. Milk identified as that received from producers for a given market may come directly from nearby producers or from producers associated with a supply plant that, although it may be located several hundred miles from the marketing area, is pooled on the market. Producer milk also may include milk that is diverted by a pool plant operator to another pool plant or to a nonpool plant.

Handlers regulated under federal milk orders process about 75% of all the milk marketed in the United States. Table 1 shows the number or plants operating under federal milk orders. The USDA identifies four basic classes of milk use:

- Class I: Fluid milk products (products intended to be used as a beverage);
- Class II: Cream products, cottage cheese, ice cream, and other food uses;
- Class III: Hard and spreadable cheeses; and
- Class IV: Butter and dried milk products.

Table 1 Federal Milk Order Plants, 2003

State	Distributing Plants	Supply Plants
Alabama	5	0
Arizona	3	1
Arkansas	5	1
Colorado	9	2
Connecticut	3	0
Delaware	2	0
Florida	12	0
Georgia	4	0
Idaho	5	0
Illinois	16	5
Indiana	10	1
Iowa	6	15
Kansas	2	0
Kentucky	8	1
Louisiana	7	1
Maine	3	0
Maryland	3	1
Massachusetts	4	1
Michigan	15	0
Minnesota	14	10
Mississippi	2	4
Missouri	4	2
Montana	1	0
Nebraska	3	0
New Hampshire	1	0
New Jersey	6	0
New Mexico	1	2
New York	20	3
North Carolina	6	0
North Dakota	1	1
Ohio	14	1
Oklahoma	3	0
Oregon	10	5
Pennsylvania	22	5
Rhode Island	1	0
South Carolina	5	0
South Dakota	1	3
Tennessee	9	1
Texas	20	4
Utah	7	0
Vermont	2	3
Virginia	6	1
Washington	8	3
West Virginia	1	0
Wisconsin	11	61
Total	**301**	**138**

Source: USDA.

Common Facility Characteristics

Figure 3 shows the flow through a typical milk processing plant. The configuration varies from plant to plant, depending on the output product stream, production capacity, production line requirements, and design and layout of the facilities and equipment. Because of the variety of both continuous and batch-style product-handling steps, many diary product manufacturing practices and procedures cannot be described in this document. Examples are included to provide information on a variety of techniques that are used to produce several different products, including whole and fat-reduced retail fluid milk, butter, cream, cheeses, ice cream, and yogurt products. For fluid milk, there are process access points that could be targeted by an adversary. For process applications other than packaged fluid milk — including products such as butter, cottage cheese, yogurt, and ice cream — there are a greater number of product access points at which a contaminant could intentionally be added into the manufacturing stream. Furthermore, in a milk processing facility, the cleaning and sanitation of assembled (clean-in-place) and disassembled (clean-out-of-place) equipment parts occur routinely. Insider opportunities exist to not adequately clean some equipment, substitute wrong parts or reinstall parts incorrectly into the process line, or introduce an odorless and tasteless contaminant that is not analytically tested for in finished products.

Raw fluid milk is collected from individual dairy farms where dairy cattle are fed and milked and where milk is temporarily stored until transport. The raw milk is delivered to the processing plant by truck. Figure 4 shows a milk-gathering truck that is unloading at a dairy. Human access to stored ingredients and packaging material and the process of adding ingredients and vitamins to milk products and product derivatives create the greatest opportunity for intentional contamination with biological or chemical agents.

The incoming tanker milk delivered to the processing/production facility is routinely tested. If it is below 40°F, the delivery is rejected. In addition, raw milk received at the plant is routinely checked for additional quality and safety factors, including biological, chemical, and physical contaminants: odors, temperature, appearance, acidity, bacterial counts, drug residues, antibiotics, herbicides, and pesticides. Measures of product quality, such as the amount of solids, lactose, protein, and butterfat in the milk, are also taken. A lab technician may perform a taste test on every shipment of milk. If any abnormalities are detected, the entire shipment of milk is rejected. These off-loading and analytical sampling procedures, in addition to providing important quality and safety checkpoints, can also create human access points and opportunities to intentionally introduce contamination. If the milk is accepted, it is pumped into raw milk storage tanks, which can hold several hundred thousand gallons of milk. Figure 5 shows raw milk storage silos. Because the milk from many different sources is combined into these large tanks, any contamination that escapes initial detection by the lab technicians' qualitative and quantitative analytical testing can affect a large volume of raw milk.

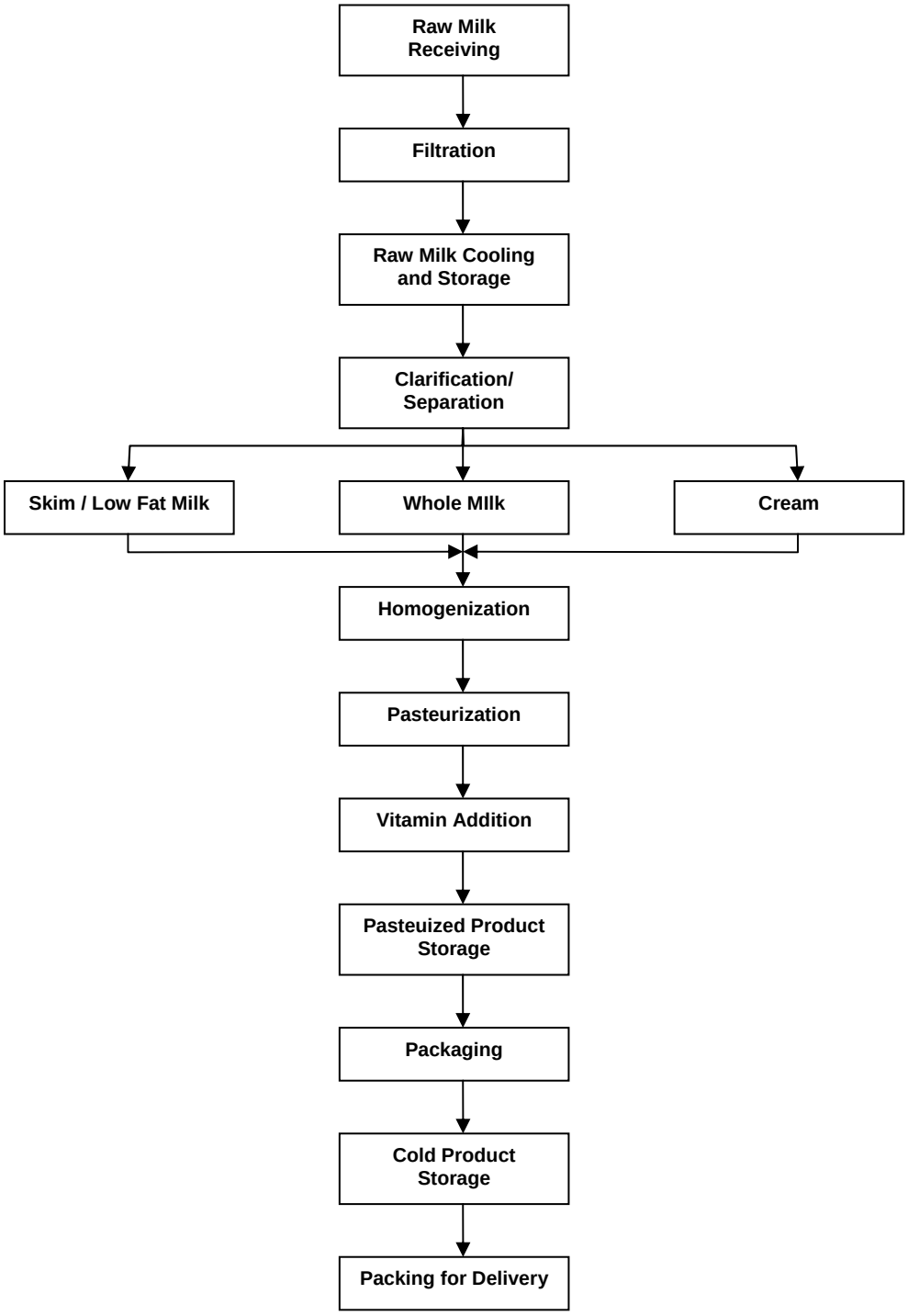


Figure 3 Process Flow for a Typical Milk Processing Plant

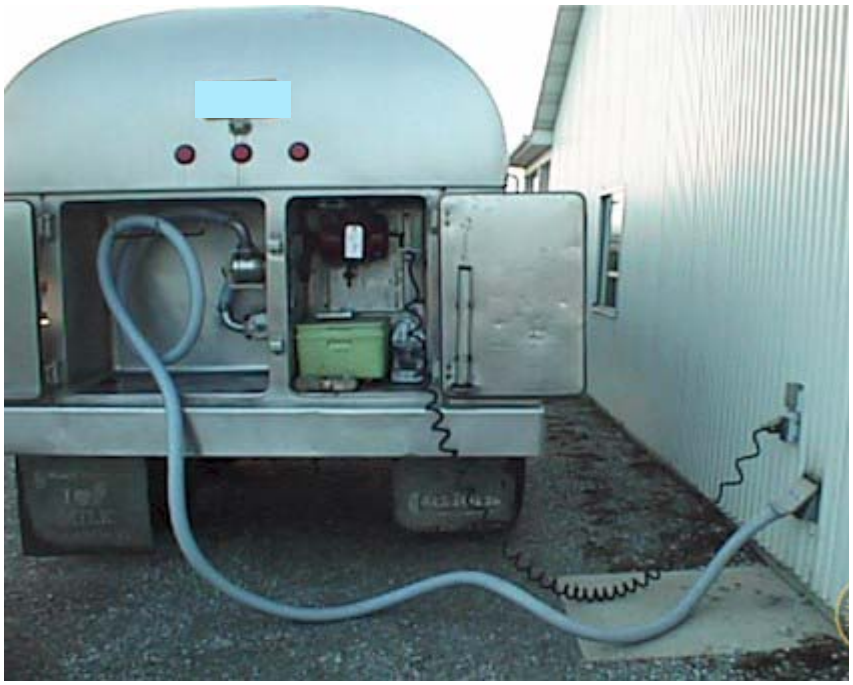


Figure 4 Unloading of a Milk-gathering Truck

Figure 5 Storage Silos for Raw Milk

When the raw milk is ready for processing, the first step may be to use a clarifier to separate out foreign substances (i.e., nonmilk solids such as dirt, epithelial cells, bacteria sediment, and sludge). If the general quality of the raw milk is good, then a separate clarifier stage is not included, and only a separator is used.

A milk *separation* process is designed to separate the cream from the skim milk. A separator centrifuge consists of disks stacked together and separated by a small gap or separation channel. Milk is introduced at the outer edge of the disk stack. Under the influence of centrifugal force, the fat globules (cream), which are less dense than the skim milk, move inward through the separation channels toward the axis of rotation. The skim milk moves outward and leaves the unit through a separate outlet. Figure 6 shows a separator. Standardized streams of milk with various fat contents can be produced by adjusting the mixture of cream and skim milk at the separator.

Milk is an oil-in-water emulsion, with the fat globules dispersed in a continuous skim milk phase. If raw milk were left to stand, the fat would rise and form a cream layer. *Homogenization* is a mechanical treatment of the fat globules in milk that is brought about by passing milk under high pressure (2000 pounds per square inch [psi] or higher) through a tiny orifice, which results in a decrease in the average diameter and an increase in the number and surface area of the fat globules and thus more dispersion. The net result, from a practical view, is a much reduced tendency for creaming of fat globules. Figure 7 shows a homogenizer.

Pasteurization is designed to heat the raw milk to a temperature that is high enough that when it is held for a required minimum time, it will kill or inactivate certain (but not all) microorganisms (common pathogenic and nonpathogenic bacteria, yeast, molds, and viruses) and disable certain enzymes, while minimizing the effects on taste. Milk is pasteurized by heating the fluid to a minimum of 145°F (62.8°C) for half an hour or 163°F (72.8°C) for 15 seconds. Figure 8 shows the design for a continuous-plate heat-exchanger pasteurizer and a photo of a tube-in-tube continuous heating and cooling pasteurizer. For any method of heat treatment employed, federal and state regulations require that milk must be pasteurized within 72 hours of milking.

Ultrahigh-temperature (UHT) pasteurization completely sterilizes the dairy product and is designed to render it free of microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution. In this case, a thermal process referred to as “aseptic” is applied to separately sterilize the product, package, filling. and packaging system by heat, hot water, and/or chemical agents, with all components being brought together in a presterilized “sterile zone” for filling and package sealing. It is used to created shelf-stable “boxes of milk” that can be stored without refrigeration, allowing extended dairy-product shelf life. In UHT pasteurization, the temperature of the milk is raised to about 285°F (141°C) for 1 or 2 seconds, thereby sterilizing the milk. The milk is cooled down in a closed system and “aseptically” filled and sealed in plastic containers (e.g., fluid milk, coffee creamer). Equipment access and improper opening of presterilized sections of this system during operation can potentially cause process failure and product spoilage.

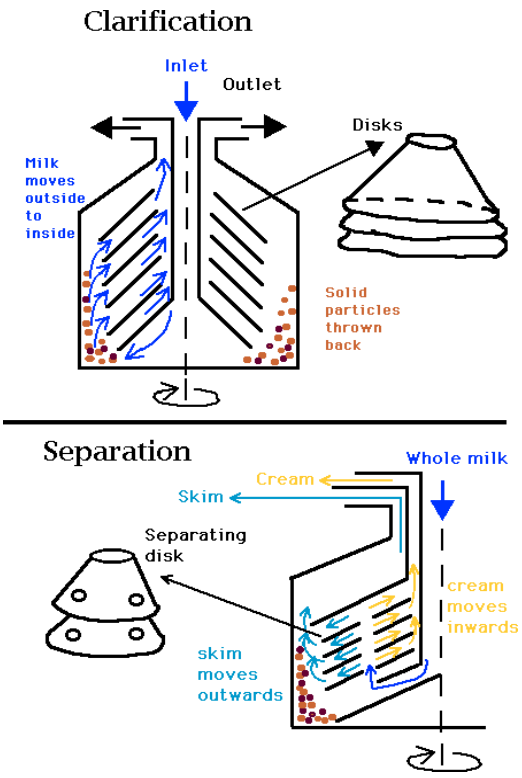


Figure 6 Milk Separator Centrifuge

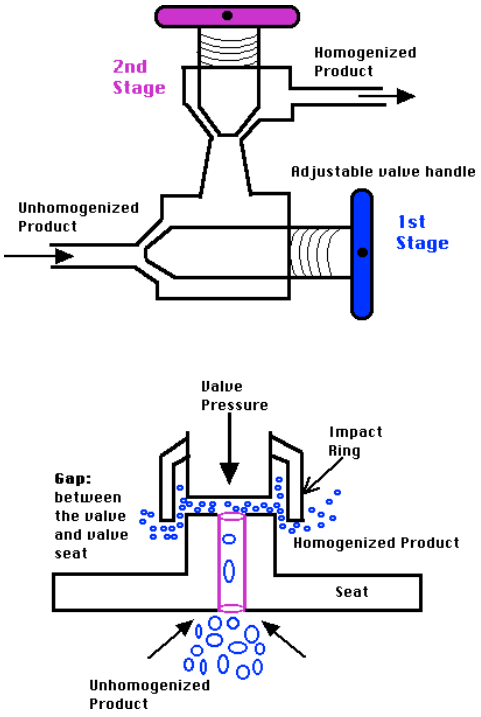
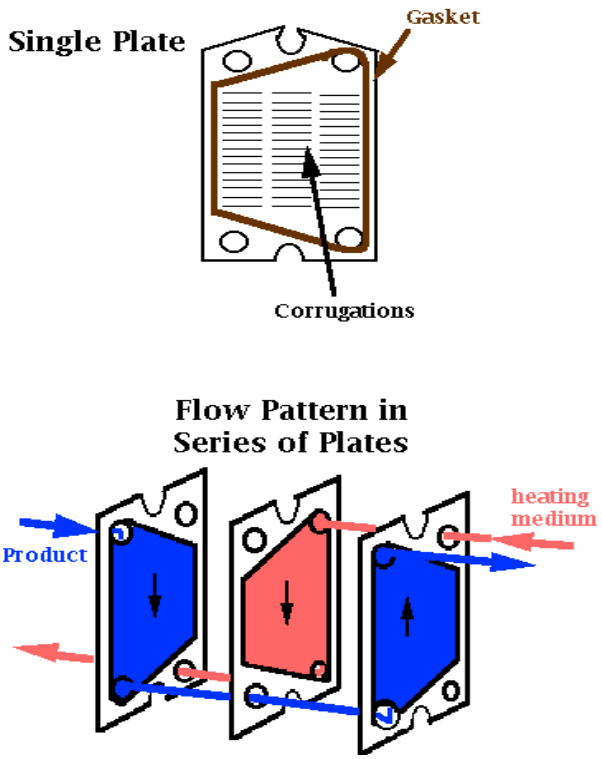


Figure 7 Homogenizer



Continuous Plate Heat Exchanger in a Pasteurizer

Continuous Flow (Tube-In-Tube) Heat Exchanger in a Pasteurizer

Figure 8 Pasteurizers

Because vitamins are degraded by thermal treatment, selected products may have vitamins added after pasteurization. Fortification vitamins A and D are the most common additions. The product is then moved to holding tanks that are used only for pasteurized products. It is after pasteurization and before packaging of the fluid milk that opportunities arise for biological or chemical contaminants to be added that would later move into the food supply.

Products are then packaged. Figure 9 shows a filler machine for gallon milk jugs. The packaged products are held in cold storage until they are packed for delivery. In most facilities, there are no routine analytical checks for determining biological or chemical contaminants introduced prior to distribution.

Figure 9 Machine for Filling Milk Jugs

Butter

Butter is produced from the separation of butterfat from the whole milk product. The butter-making process involves a number of stages (Figure 10). The continuous butter maker has become the most common type of equipment used.

Cream can either be supplied by a fluid milk dairy or separated from whole milk by the butter manufacturer. If cream is separated by the butter manufacturer, the whole milk is preheated to the required temperature in a milk pasteurizer before being passed through a separator. The cream is cooled and led to a storage tank, where the fat content is analyzed and adjusted to the desired value, if necessary. The skim milk from the separator is pasteurized and cooled before being pumped to storage. It is usually destined for concentration and drying.

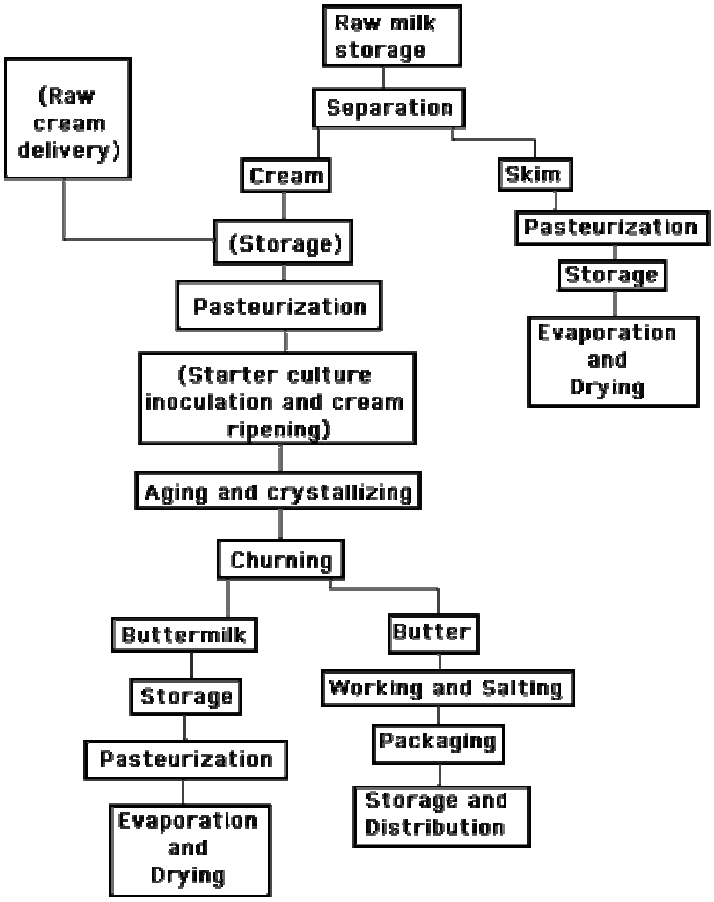


Figure 10 Typical Process Flow: Milk into Cream, Butter, and Butterfat

From the intermediate storage tanks, the cream goes to pasteurization at a temperature of 95^{o}C or higher. The high temperature is needed to destroy enzymes and microorganisms that would impair the keeping quality of the butter. The cream is then churned. Churning splits the cream into two fractions: butter and buttermilk. In traditional churning, the machine stops when the butter grains have reached a certain size. The buttermilk is drained off and recovered. After draining, the butter is worked into a continuous fat phase containing a finely dispersed water phase. Butter may be open to the introduction of biological or chemical contaminants before it is wrapped, put in cartons, and cased for distribution.

Cheeses

The basic processes or manufacturing steps described in Figure 11 are used to produce most cheeses. However, no two cheese varieties are produced by exactly the same method. The details of each step are varied to yield characteristics and qualities unique to each cheese. Today most cheese production is mechanized and automated, which results in greater production efficiency and an improved product of uniform quality. This helps to limit, but does not eliminate, human access points where contamination could be introduced during routine production.

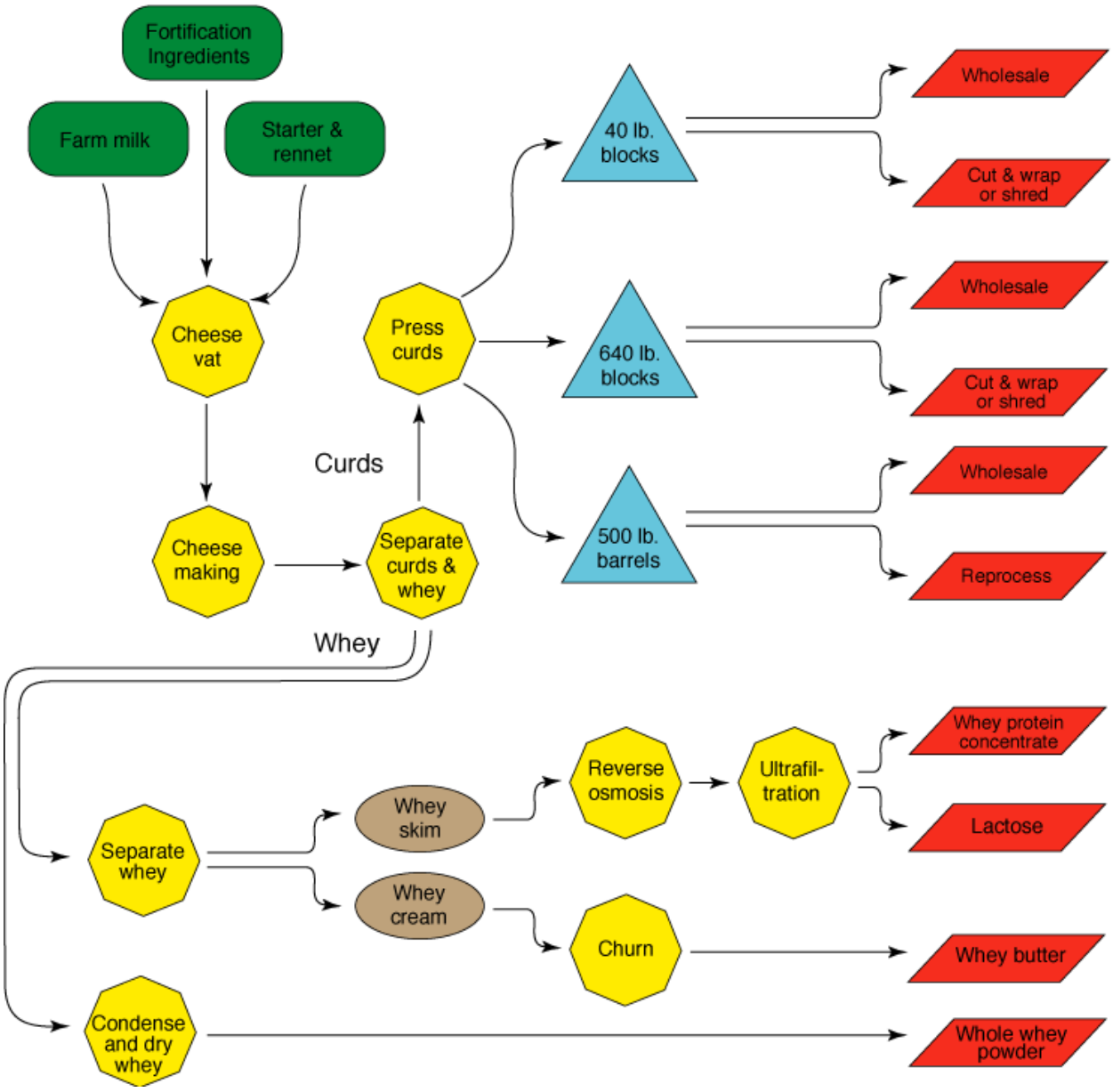


Figure 11 Typical Process Flow for Cheese Production

The making of cheese is essentially a dehydration of milk, resulting in a sixfold to twelvefold concentration of milk proteins (caseins), fat, and minerals. The manufacturing processes differ depending on the type of cheese desired, but the cheeses are often prepared in open vats by employees with tools and utensils for stirring and pressing the product.

For some cheeses, such as unripened cheeses, the acid coagulation of milk involves the addition of a culture of lactic-acid-producing bacteria (starter culture) to warm the milk to create “curd.” The specific starter culture depends on the type of cheese being produced. The combination of coagulation temperature, starter culture, coagulating enzyme, and acid produced create the desired cheese quality. According to federal definitions and standards, salt may be added to milk

to accelerate enzyme coagulation and cheese firmness. Antimicrobial agents (e.g., sorbic acid) may be added to prevent mold growth. Curd particles are then cut into various sizes, depending on the type of cheese produced. Liquid whey is then separated from the curds, and additional time is allowed for lactic acid production.

Salting improves the flavor, texture, and appearance of cheese. It slows the fermentation of lactic acid after desirable levels have been achieved by suppressing the growth of undesirable micro-organisms and controlling the moisture content of the final cheese. The salt contents of most varieties of cheese vary from about 1% (cottage and cream cheeses) to about 5% (Parmesan and Roquefort).

Pressing achieves the characteristic shape of the cheese by compacting the texture, extruding free whey from the curds, and completing curd knitting. This step involves confining the curds for fixed periods to a constricted metal form or cloth bag. External weights or presses may be applied. The operation occurs in an open environment.

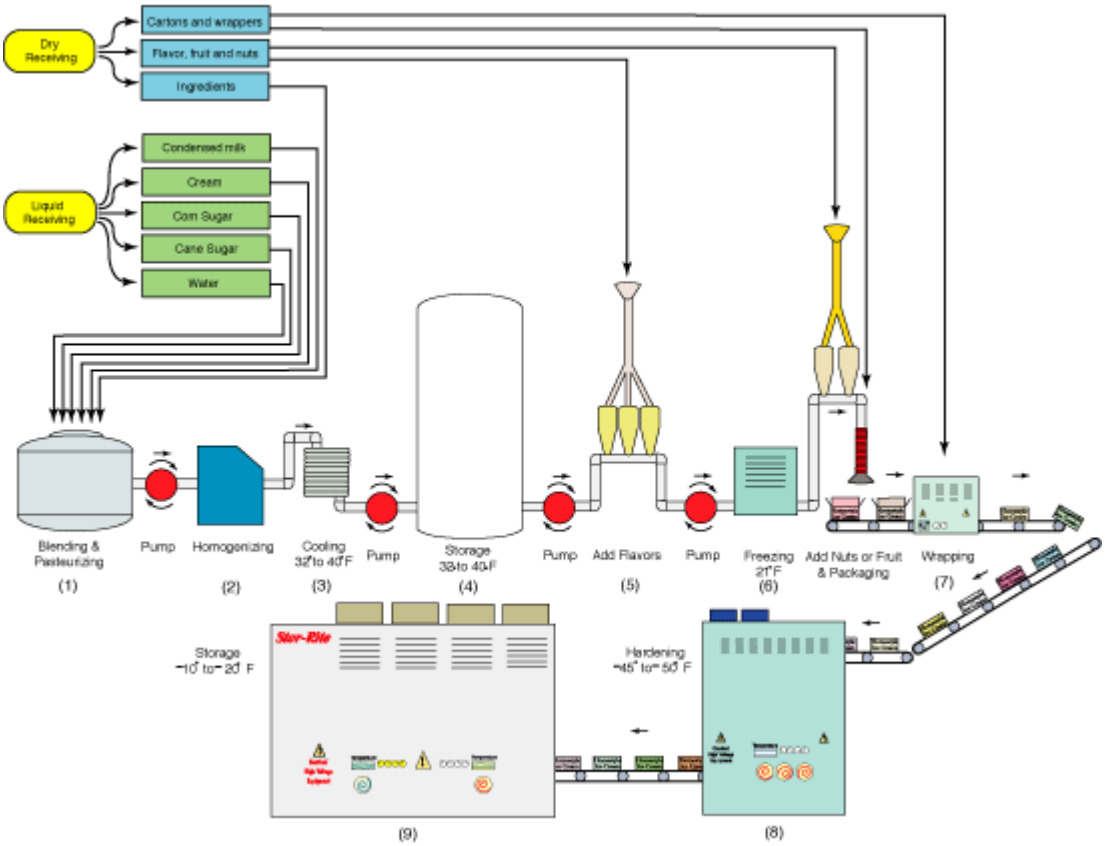
Ripened or cured cheeses (e.g., cheddar) are purposely exposed to a specified temperature- and humidity-controlled environment for a specified length of time. Remaining beneficial bacteria and enzymes transform the fresh curd into a cheese with a specific flavor, texture, and appearance. Uncured or soft-body fresh cheeses (e.g., cottage, cream, Neufchatel) are generally ready for immediate consumption following curd collection. Hard cheeses are additionally held to control the ripening rate. The nature and extent of cheese ripening are influenced by the types and concentrations of ripening agents, temperature and humidity, presence of salt, and treatment of the cheese surface. The changes during ripening are selectively brought about by enzymes or microorganisms in or on the cheese curd.

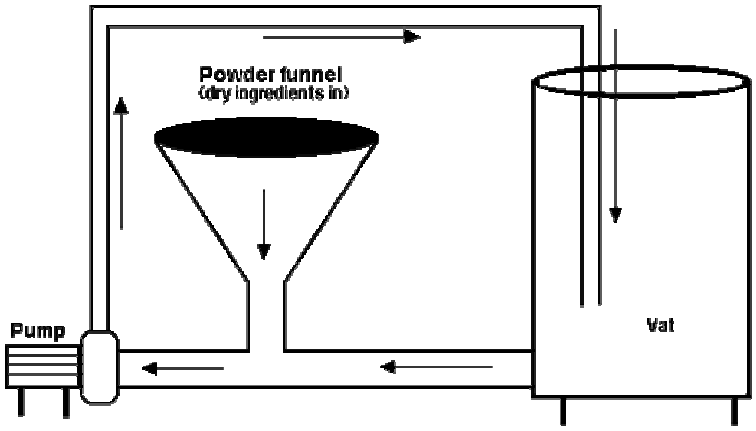
Ice Cream

The basic steps in manufacturing ice cream are shown in Figure 12. The addition of dry ingredients (e.g., nuts, fruit) to the ice cream blend creates an opportunity for contaminating biological or chemical agents to be intentionally added.

Other Dairy Products

Useful enzymes, microorganisms, flavorings, stabilizers, and thickeners may be routinely added to pasteurized fluid milk to create other value-added dairy products such as yogurt. The process requires additional manufacturing steps and product conditioning that make use of large vats, some open to the environment to allow fermentation. Lactose (milk sugar) is used as a nutritional source for the useful microorganisms, which are naturally present or added. This results in lactic acid, which yields the desired texture and taste of many dairy products. In addition, other complementary ingredients (e.g., shell nuts, jams, whole fruit) may be routinely added to the final product. These steps may provide avenues for the intentional introduction of contaminants.





Simple hopper device for incorporating dry ingredients into recirculating liquids

Figure 12 Typical Process Flow for Ice Cream Production

Standards

Milk processing plants are regulated by a cooperative network of federal, state, and local health inspectors operating under a combination of federal and state authority. Regulations and standards are in place to ensure the quality and safety of dairy products. Enforcement mechanisms include detention or embargo of products and civil or criminal penalties for distributing adulterated products or interfering with enforcement of standards. In practice, daily regulation of the industry depends to a considerable extent on cooperative federal/state/industry programs and voluntary compliance by the industry. Milk processing plants are also subject to environmental and workplace safety rules, in the same manner as are other industries.

Public Health Regulations

Federal Authority. The Federal Food, Drug and Cosmetic Act (FFDCA; 21 U.S.C. 301 et seq., as amended) provides authority for the Food and Drug Administration (FDA) to regulate food, drugs, medical devices, and cosmetics in interstate commerce. The FFDCA prohibits the "introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded" (21 U.S.C. 301). It also prohibits a number of ancillary actions, such as receipt of adulterated or misbranded goods, forgery of approval documents, failure to keep required records, and failure to allow authorized inspections. Penalties include imprisonment and fines. Enforcement powers were recently expanded by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188, hereafter referred to as the Bioterrorism Preparedness Act). The FDA's food and drug regulations are contained in Title 21, Parts 1-1299, of the *Code of Federal Regulations* (CFR).

Enforcement powers granted to the FDA include the following:

- *Inspection of Facilities and Records*. Section 704 of the FFDCA (21 U.S.C. 374) provides authority for the FDA to conduct inspections of factories, warehouses, establishments, and vehicles and of all pertinent equipment, finished and unfinished materials, containers, and labeling therein where food, drugs, devices, or cosmetics are manufactured or held. Case law has established that this authority includes the right to take samples for analysis. Until recently, this authority did not include a general authority to examine records. However; the Bioterrorism Preparedness Act closed that gap, and now inspectors can request and copy any records deemed necessary in order to establish that foods are not adulterated, subject to certain limitations as to notice and reasonableness (P.L. 107-188, Sec. 414).

- *Administrative Detention of Products*. Under the Bioterrorism Preparedness Act, "An officer or qualified employee of the Food and Drug Administration may order the detention, in accordance with this subsection, of any article of food that is found during an inspection, examination, or investigation under this Act . . . if the officer or qualified employee has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals." Such detention must be approved by a senior FDA official and may not exceed 30 days in length (P.L. 107-188, Sec. 303).

- *Embargo or Seizure of Products*. The FFDCA provides for permanent embargo or seizure of adulterated or misbranded products. However, this authority must be exercised by a federal court. A request for embargo or seizure of product originating with an FDA district office goes through the FDA Headquarters Office of Chief Counsel to the Department of Justice (DOJ). DOJ then petitions the relevant U.S. District Court for an order of embargo or seizure to be carried out by federal marshals.

- *Prosecution*. The FDA can recommend that persons be criminally prosecuted for violations of the FFDCA. Recommendations for prosecution go through the FDA Headquarters Office of Chief Counsel, to the DOJ, and to a federal district attorney to initiate court action.

State Authority. In each state, state and local officials have some type of jurisdiction over the food and drug establishments located within their state or local boundaries, regardless of the interstate movement or origin of the products involved. Some states divide the responsibility for food, drugs, etc., among various agencies within the state.

State authority to regulate dairies and dairy processing facilities is a function of state law. Many state laws are based on uniform or model codes, so that the variations from state to state are minimized. For general regulation of the food industry, many states have enacted the basic Uniform Food, Drug, and Cosmetic Bill, and others have adopted at least a part of it. Most states without this bill have laws based on the federal 1906 Food and Drug Act. Most larger cities have their own ordinances and regulations.

In addition, each state has established rules specifically for milk and milk products. These rules also derive from uniform codes. The Grade A Pasteurized Milk Ordinance (PMO) has been adopted by all states. It regulates the production, processing, and sale of products such as fluid milk, yogurt, and cottage cheese. Its rules not only cover milk, from the cow to the consumer, but also cover the cow itself and its health. Grade A standards are recommended by the National Conference on Interstate Milk Shipments (NCIMS), which is composed of voting representatives from state and local regulatory agencies and of nonvoting representatives from the dairy industry and FDA. As a general rule, the FDA accepts the NCIMS recommendations and incorporates them into the revised PMO. The state regulator (which is usually either the State Department of Agriculture or the State Health Department) adopts the PMO standards as a minimum and, in many cases, requires more stringent standards. The FDA has also established Standards of Identity for dairy products, which must be maintained by the processor.

The PMO provides for the licensing and inspection of dairy farms, milk transportation vehicles, and milk processing plants. It sets standards for pasteurization, testing, bacterial counts, sanitation procedures, and many other aspects of milk product safety. By its terms, the PMO applies to milk and milk products. The definition of milk products in the PMO does not include infant formula, ice cream, butter, or cheese. Those items are regulated separately. Also, some milk that is intended for processing into products and that does not have to meet Grade A standards is regulated separately. Non-Grade-A milk is often referred to as “milk for manufacturing purposes” and is the subject of separate criteria under state law or regulation. For

example, in Nebraska, such milk is regulated under the Nebraska Manufacturing Milk Act (Nebraska Revised Statutes Sections 2-3913 – 2-3946). That act sets out detailed sanitary requirements for testing manufacturing milk and sets standards for bacterial counts, sediment, and drug and pesticide residues as well as sanitation standards for facilities that handle the manufacturing of milk.

The National Sanitation Foundation (NSF) issues "3-A Sanitary Standards" for dairy processing equipment. These standards are referred to for Grade A milk products, and they specify equipment materials, equipment design, and the cleanability of such processing equipment. The standards are accepted and implemented by regulatory agencies and the industry. The USDA Marketing Service also acknowledges these standards.

Officials at the state and local level generally have enforcement authority equal to or greater than that of FDA officials for enforcing public health rules at dairy facilities within their jurisdiction. Laws in each state provide enforcement authority as necessary to protect public health and safety, including authority to embargo and/or prevent the sale or shipment of milk products suspected of adulteration. Details on which officials may issue enforcement orders and procedures for hearings and finalization of orders vary from state to state.

Federal/State Roles and Cooperation. Under the FFDCA, federal officials have direct jurisdiction only over products that travel in interstate commerce (i.e., products shipped from one state to another) and products imported to the United States from overseas. Products produced and consumed within one state (which is the case for many dairy items) are regulated only by the cognizant state authority. However, the FDA and the states cooperate extensively on enforcing food safety. Under federal-state memoranda of understanding (MOUs), federal officials may be empowered to enforce state standards, and vice versa. Such MOUs may provide for splitting the inspection workload among federal, state, and local inspectors and may also provide for joint inspection activities. At present, the FDA has MOUs with 42 states and the District of Columbia.

Environmental and Workplace Safety Regulations

In addition to being subject to public health regulations designed to ensure dairy product safety, dairy farms and processing facilities are also subject to environmental and workplace safety regulations, including limits on the following:

- Air emissions from process units and risk management planning (Clean Air Act);
- Toxic Release Inventory reporting and emergency planning in coordination with the Local Emergency Planning Committee (Emergency Planning and Community Right-to-Know Act of 1986, expanded by the Pollution Prevention Act of 1990);
- Waste and wastewater management, including wastewater discharges to water courses (Resource Conservation and Recovery Act [RCRA], Clean Water Act) and underground injection wells (Safe Drinking Water Act [SDWA]);
- Water withdrawal and treatment and protection of sole-source aquifers (SDWA); and
- Remediation of contaminated properties (RCRA, Comprehensive Environmental Response, Compensation, and Liability Act).

Processing facilities also have to comply with employee safety and occupational health requirements under the Occupational Safety and Health Act.

Environmental and occupation health regulations are most often enforced by state personnel under a state program that has been approved by the U.S. Environmental Protection Agency (EPA) or Occupational Safety and Health Administration (OSHA). However, federal approval of state programs is done state-by-state and is specific to each program. For example, in a given state, the state environmental agency may have approval to enforce state standards for air emissions but not for hazardous waste. Where the federal government has not approved a state program, standards are administered by the EPA or OSHA directly.

CONSEQUENCE OF EVENT

There are two main categories of potential consequences of a successful attack on a facility:

1. Contamination of fluid milk and
2. Contamination of milk products.

Successful contamination of fluid milk can have serious public health consequences, since the product moves through the distribution and consumption stages very quickly. The shelf life of fluid milk is short compared to the shelf life of other food products; fluid milk is bought and used by consumers in short time periods. This leads to the potential for a rapid spread of any contaminated product.

Fluid milk is consumed by all segments of the population from infants to the elderly. Health impacts from contamination could reach a wide range of people, including those with limited ability to recover from an induced illness.

Some milk products such as cheese and ice cream have longer shelf lives and more limited consumption patterns than does fluid milk. Health impacts from the contamination of these products would be confined to a smaller group. Moreover, the longer times between production and consumption allow for response actions (e.g., product recall) to be implemented more effectively.

For both fluid milk and milk products, any contamination event would have serious consequences even beyond the direct health impacts. Loss of consumer confidence in a particular brand or product as a result of a contamination event, or even a contamination scare, could pose significant economic burdens on the companies involved in its production. Loss of revenue and the costs of carrying out a significant product recall could bankrupt small milk processors.

Because of the widespread consumer use of milk and milk products, any contamination event would place a severe burden on governmental and private sector health, law enforcement, and regulatory resources (e.g., hospital care, physician care, laboratory testing) to deal with the incident. If an attack on the milk and milk product supply were coupled with simultaneous

attacks on other health-related infrastructures, the system might be hard pressed to manage the event effectively.

COMMON VULNERABILITIES

Critical infrastructures and key assets vary in many characteristics and practices relevant to specifying vulnerabilities. There is no universal list of vulnerabilities that applies to all assets of a particular type within an infrastructure category. Instead, a list of common vulnerabilities has been prepared, based on experience and observation. These vulnerabilities should be interpreted as possible vulnerabilities and not as applying to each and every individual facility or asset. Many chemical facilities have instituted security vulnerability assessment protocols, site prioritization processes, and risk-based approaches to improving security performance, including provisions to increase security measures during heightened threat conditions. The security improvements implemented by dairy products companies under such protocols may mitigate certain vulnerabilities listed below. The vulnerabilities listing consider the issues within the physical perimeter boundaries of milk processing and production facilities. The majority of vulnerabilities that are present inside dairy processing facilities result from inadequate perimeter protection, undetected incoming contaminated raw materials and packaging, and unauthorized human access to allow for inside crimes of opportunity.

Exhibit 1 Economic and Institutional Vulnerabilities	
Economic and institutional vulnerabilities are those that would have extensive national, regional, industry-wide consequences if exploited by a terrorist attack.	
1	Generally, high production, high consumption, widespread consumer product exposure, limited-shelf-life food products, and high market turnover create conditions for significant and rapid impacts from a contamination incident.
2	Just-in-time production environment and low inventories create conditions for rapid movement of a contaminated product.
3	An incident can result in a loss of consumer confidence and damage to trust in a product or brand. This could have significant economic consequences on a company.
4	A contamination incident can result in the loss of export opportunities and/or loss of confidence in import suppliers.
5	Dealing with a contamination incident can place significant burdens on governmental and private-sector public health, law enforcement, and regulatory resources (e.g., hospital care, physician care, laboratory testing).

Exhibit 2 Site-Related Vulnerabilities

Site-related vulnerabilities are conditions or situations existing at a particular site or facility that could be exploited by a terrorist or terrorist group to do economic, physical, or bodily harm or to disable or disrupt facility operations or other critical infrastructures.

Access and Access Control	
1	Public roads may be in close proximity to critical assets (e.g., storage tanks) or entrance points, allowing easy access by outsiders..
2	Facilities may be located in remote, rural, or semi-rural locations.
3	Rail lines adjacent to or through large milk processing facilities make it difficult to define and protect the facility perimeter.
4	Railcar storage may be located in or near a facility.
5	The contents of railcars are not always known to facility owners.
6	Hazardous and toxic cleaning and sanitizing chemicals are loaded/unloaded at milk processing facilities.
7	Facilities typically use contract guard services, and turnover rates in the guard force are high.
8	Trucks are typically not inspected, and it would be difficult to ensure that no contaminants are brought into the facility.
9	Heavy truck traffic may come through a milk processing facility. Inspections to verify cargo, driver identification, and bill of lading are not always conducted.
10	Trucks carrying toxic and hazardous chemicals (e.g., ammonia) may enter the facility. On-site escort may be informal.
11	Ammonia tanks and critical assets near the perimeter fence line may not be protected by barriers or other hardening equipment.
12	Many facilities use contract guard services. Guard staff are sometimes inadequately trained, unarmed, or otherwise inadequate. Company security departments are often understaffed.
13	Enclosure of critical facilities or assets may by incomplete or inadequate.
14	Dairy facilities typically employ only a limited use of signs posted to deter vehicles or pedestrians from entering the facility premises.
15	Camera surveillance typically does not cover all critical assets.
16	Lighting may be inadequate (e.g., too little, poorly spaced, or improperly directed).
17	Entrances to critical assets within the facility (e.g., control rooms) may not have controlled access. Once someone is on site, that person often has access anywhere throughout the milk processing facility.
18	Access identification may not be required or may not be adequately enforced.
19	Employee and visitor parking may exist next to critical buildings.
Operational Security	
	(Continued on next page.)

20	Plant password facilities, equipment, and information access are still active to some terminated employees.
21	Background checks conducted on employees and contractor personnel are typically limited. Some states or even union contracts limit the use of background investigations.
22	There is limited coordination with local, state, and federal agencies on roles/responsibilities in protecting dairy processing facilities.
23	Terminated or fired employees often gain re-access to facilities via friends and coworkers.
24	Radiological agents (gamma-emitting sources) in laboratory equipment may be unsecured and accessible by unauthorized intruders or plant workers.
25	Lists of milk processing locations are readily available through many public sources.
Process Control	
26	Security may be lacking around servers and control rooms.
27	There is a potential for intruders to hack into process control through a remote enterprise network.
28	There is a potential for a controller to cause an undesirable process event.
29	Passwords to critical assets are not routinely changed.
30	Testing for the presence of contaminants is not always carried out throughout the process.
Emergency Planning and Preparedness	
31	Contingency plans are not always formalized or exercised.
32	Emergency operation center backup facilities may not be in place.
33	On-site aboveground pipelines can be attacked.
34	Nontraditional fires/explosions can be created that cause additional challenges to first responders.
35	Coordination of emergency plans with industry neighbors and the local, state, and federal government.
Hazardous and Toxic Chemicals	
36	Large storage tanks and clearly marked hazardous chemical tanks are easily identifiable from outside the facility perimeter.
37	Many different types of hazardous and flammable chemicals are stored, processed, and transported.
38	Several toxic chemicals (e.g., ammonia) pose large loss-of-life scenarios if released.
Other System Operation Considerations	
39	Critical pipelines (e.g., natural gas, potable water, on-site pipelines), manifolds, and valves are often aboveground within the dairy facility premises.
40	Unsecured, belowground or aboveground fuel tanks can be contaminated with foreign material.

Exhibit 3 Interdependent Vulnerabilities

Interdependency is the relationship between two or more infrastructures by which the condition or functionality of each infrastructure is affected by the condition or functionality of the other(s). Interdependencies can be physical, geographic, logical, or information-based.

General	
1	Testing for contaminants introduced through ingredients received from outside the plant is not always carried out.
Natural Gas	
2	Loss of natural gas may reduce or shut down dairy processing facility operations.
3	Although most natural gas pipelines are underground, valves and other aboveground equipment are visible and detectable.
4	Natural gas rights-of-way are identified by signs.
5	Loss of gas service, even for a short time, may result in deterioration and/or contamination of milk products due to bacterial growth.
Water	
6	Loss of water supply can shut down a dairy processing facility because it does not have steam or other process or fire-fighting resources.
7	Water from rural dairy processing facilities may come from contaminated wells.
8	Most milk processing facilities have one source of water supply. Contamination of the water supply could impact facility operations.
9	Large quantities of chlorine are stored on site for water purification plant sanitation.
Electric Power	
10	Electric substations are generally unmanned and remote.
11	Electric substations are easily identified by entry and exit of large high-voltage wires.
12	Although usually enclosed by a fence, critical equipment at electric substations can be easily identified from off site.
13	Electric substations are usually surrounded by property of third parties, over which the utility has little or no control or with which it may have little or no cooperation.
	Loss of electric power, even for a short period of time, may result in deterioration and/or contamination of milk products due to bacterial growth.
Telecommunication	
14	Handheld radios may be critical to milk processin facility operations. Disruption of communications could shut down a facility.
15	Frequencies can be scanned by adversaries to determine operating conditions, location of employees, on-going activities, etc.
	(Continued on next page.)

16	Communication with first responders is crucial to react in a timely manner to incidents. Jamming or other methods can be used to disrupt communication channels.
17	Telecommunications rely on a public switched network. Telephone congestion occurs during emergencies.

OTHER INFORMATION

Industry Activities to Decrease Vulnerabilities

International Issues

Foreign firms and imports (e.g., soft cheeses from France and Mexico and hard cheeses from Italy), under the Bioterrorism Preparedness Act, must register their facilities with U.S. agents under the registration provisions of the FDA interim final rule (IFR).

Ongoing Food Security Activities

Collaborative work is underway to develop a threat assessment and guidance document and distribute it to members of the industry, International Dairy Foods Association, American Dairy Association, FDA Center for Food Safety and Applied Nutrition (CFSAN), USDA Animal and Plant Health Inspection Service (APHIS), U.S. Department of Transportation Volpe Research Center, and Conference on Interstate Milk Shippers.

CFSAN Guidance

On July 11, 2003, the FDA CFSAN issued security guidance designed to aid operators of dairy farms, bulk milk transportation operations, bulk milk transfer stations, and fluid milk processing facilities. The guidance identifies preventive measures to minimize the risk that fluid milk will be subject to tampering or other malicious, criminal, or terrorist actions. The introduction to the guidance cautions that it does not establish legally enforceable responsibilities and that not all of the recommendations may be appropriate or practical for every facility.

The FDA recommends that operators of dairy farms, bulk milk transportation operations, bulk milk transfer stations, and fluid milk processing facilities consider implementing security measures.

The list is divided into the following categories: management, human element, facility, and operations. Some items on the list apply to only certain types of facilities, as indicated.

Management

- Conducting an initial assessment of the adequacy of food security procedures and operations, which is recommended to be kept confidential.
- Developing a security management strategy to prepare for and respond to tampering and other malicious, criminal, or terrorist actions, both threats and actual events, including identifying, segregating, and securing affected product.
- Developing a product recall strategy.
- Providing training in food security awareness to encourage all staff to be alert to any signs of tampering or other malicious, criminal, or terrorist actions or areas that may be vulnerable to such actions and to report any findings to management. The training may also encourage staff to be alert to the presence of unidentified or unknown individuals or individuals who are in areas to which they have not been designated access and to directly question such individuals or report them to management.
- Providing appropriate supervision to all staff with access to raw and pasteurized milk storage, vitamin supplement receiving and storage, and milk processing and packaging areas of the facility, including cleaning, maintenance, and quality control staff; seasonal, temporary, contract, and volunteer staff; and especially, new staff. The supervision may include watching for unusual or suspicious behavior by staff (e.g., staff who, without an identifiable purpose, stay unusually late after the end of their shift, arrive unusually early, access files/information/areas of the facility outside the areas of their responsibility; remove documents from the facility; ask questions on sensitive subjects; bring cameras to work).
- Conducting routine security checks of the raw and pasteurized milk storage, vitamin supplement receiving and storage, and milk processing and packaging areas of the facility for signs of tampering or malicious, criminal, or terrorist actions or checks of areas that may be vulnerable to such actions.
- Alerting appropriate law enforcement and public health authorities about any threats of or suspected tampering or other malicious, criminal, or terrorist actions. The FDA may be contacted through its 24-hour emergency number, 301-443-1240, or through a local FDA District Office. FDA District Office telephone numbers are listed at http://www.fda.gov/ora/inspect_ref/iom/iomoradir.html.
- Reviewing, at least annually, the effectiveness of the food security plan by using knowledgeable in-house or third-party staff, and revising the program accordingly, which we recommend be kept confidential.

Human Element

- Obtaining and verifying work references, addresses, and phone numbers of all staff with access to raw and pasteurized milk storage, vitamin supplement receiving and storage, and milk processing and packaging areas of the facility, including cleaning, maintenance, and quality control staff and seasonal, temporary, contract, and volunteer staff.
- Having a criminal background check performed by local law enforcement or by a contract service provider for the above-listed staff, except if such staff are under direct supervision when they access the above-listed areas.

- Limiting access to raw and pasteurized milk storage, vitamin supplement receiving and storage, and milk processing and packaging areas of the facility to those staff who need to enter because of their job functions and only during appropriate work hours.
- Preventing staff from bringing personal items (e.g., lunch containers, purses) into raw and pasteurized milk storage, vitamin supplement receiving and storage, and milk processing and packaging areas of the facility.
- Being alert for atypical staff health conditions that staff may voluntarily report and absences that could be an early indicator of tampering or other malicious, criminal or terrorist actions (e.g., an unusual number of staff who work in the same part of the facility reporting similar symptoms within a short time frame), and reporting such conditions to local health authorities.
- Accompanying all visitors.

Facility

- Securing doors (including freight loading doors, when not in use and not being monitored, and emergency exits), windows, roof openings/hatches, vent openings, ventilation systems, utility rooms, loft areas, trailer bodies, tanker trucks, and bulk storage tanks, to the extent possible.
- Inspecting bulk unloading equipment and pumps in the receiving area before use.
- Monitoring the security of the premises.
- [Dairy Farms]: Locking or sealing, with serially numbered seals, all entrances to the milk house or all entry ports on the bulk milk tank, from the time the bulk milk tank is washed until the time it is emptied, except when it is under direct, visual supervision. (Remember to first make arrangements with the state regulatory agency that will ensure that the regulatory agency, rating agency, and FDA continue to have ready access to the milk house and milking operation for routine inspections, Grade A IMS ratings, and FDA check ratings, when applicable.)

Operations

Vitamin Supplements and Laboratory Supplies [Fluid Milk Processing Facilities]

- Using only known, appropriately licensed or permitted (where applicable) sources for vitamin supplements.
- Establishing delivery schedules for vitamin supplements; not accepting unexplained, unscheduled deliveries or drivers; and investigating delayed or missed shipments.
- Supervising off-loading of incoming vitamin supplements, laboratory reagents, and positive controls, to include off-hour deliveries.
- Reconciling the product and amount received with the product and amount ordered and the product and amount listed on the invoice and shipping documents.
- Investigating shipping documents with suspicious alterations.
- Inspecting incoming vitamin supplements for signs of tampering, contamination, or damage (e.g., abnormal powders, liquids, stains, or odors, evidence of resealing) or “counterfeiting” (e.g., inappropriate or mismatched product identity, labeling, or product lot coding or specifications).

- Storing vitamin supplements, laboratory reagents, and positive controls in a secure location.
- Keeping track of vitamin supplements, laboratory reagents, and positive controls and investigating any missing or extra stock outside a predetermined normal range of variability.

Labeling [Fluid Milk Processing Facilities]

- Storing product labels in a secure location and destroying outdated or discarded labels.

Raw Milk [Bulk Milk Transfer Stations and Fluid Milk Processing Facilities]

- Accepting only those incoming tanker loads of raw milk for which all openings were either locked or sealed, with a serially numbered seal, from the time the tanker was last washed until the load is delivered. Exception may be provided for incoming loads for which a thorough investigation demonstrates that there is a verified, reasonable explanation for a deviation. Seals or locks need not be in place during those times that the tanker is under the direct, visual supervision of the driver.
- Using only known, reputable transportation companies.
- Establishing delivery schedules for raw milk; not accepting unexplained, unscheduled deliveries or drivers; and investigating delayed or missed shipments. We recommend that driver identification include the name of the transportation company.
- Supervising off-loading of incoming milk.
- Reconciling the amount received with the amount listed on the shipping documents.
- Verifying that operators of bulk milk transfer stations that supply raw milk adhere to the preventive measures listed in this guidance.
- Locking or sealing, with serially numbered seals, every tanker from the time it is last washed until the time the load of milk is delivered to the bulk milk transfer station or fluid milk processing facility. Seals or locks need not be in place during those times that the tanker is under the direct, visual supervision of the driver.

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