CALIFORNIA DEPARTMENT OF FOOD & AGRICULTURE

Milk and Dairy Food Safety Branch

Report for Fiscal Year 2017/2018

The Branch Mission

The Milk and Dairy Food Safety Branch (MDFS) protects California's consumers by ensuring that milk and milk products are safe, wholesome, meet all state and federal standards, and are properly labeled. To fulfill this mission, MDFS conducts regulatory food safety activities at all sectors of the dairy industry from farm to table, including inspections of dairy farms, bulk milk pickup tankers, milk processing plants, industry milk testing laboratories and manufacturers of single service dairy containers. MDFS also collects samples of milk, milk products, products resembling milk products and water supplies for laboratory testing to ensure compliance with bacterial and compositional requirements, responds to consumer complaints and food safety incidents, and initiates impounds and product recalls to protect public health as warranted. In addition, sanitation ratings by MDFS personnel who have been trained and evaluated by the U.S. Food and Drug Administration (FDA) certify milk supplies and milk plants for federal approval to ship Grade-A dairy products in interstate commerce.

Regulatory Responsibilities FY 17/18

Grade A Dairy Farms*	1327
Manufacturing Grade Dairy Farms**	61
Milk Products Plants	639
PRMP – (Products Resembling Milk Products) Plants	34
Pasteurizer Units Tested Quarterly	474
Soft-serve (Semi-frozen) Dessert Establishments***	8533
Limited Manufacturers (Restaurants making ice cream)	548
Bulk Milk Pickup Tanker Trucks	1194
Licensed Bulk Milk Sampler and Weighers (Farm Pickup)	2058
Bulk Milk Tanker Wash Stations (Free-standing)	11
Licensed Limited Sampler and Weighers (Plant Personnel)	910
Single Service Container Manufacturing Plants	27
FDA-listed Milk Testing Laboratories	10
Approved Drug Residue Screening Labs	88
Approved Drug Residue Confirming Labs	28
Certificates of Free Sale and Sanitary Origin	3033

* 806 farms inspected by county Approved Milk Inspection Service (AMIS)
** 20 farms inspected by county AMIS

*** 3,546 soft-serves inspected by county AMIS

Dairy Farm Inspection

California is the number one dairy producing state in the country providing over 20% of the nation's total milk supply. Statewide, as of June 30, 2018 there were 1322 cow dairies, 53 goat dairies, 10 sheep dairies and 3 water buffalo dairies producing milk that was processed into a variety of dairy products for consumers not only in California but throughout the United States and around the world.

Of the 1,388 total dairy farms, 562 were inspected directly by MDFS. The balance was inspected by county operated Approved Milk Inspection Services under MDFS supervision. Dairy farms are inspected by official sanitation scoring occurring at least once every six months. Inspections involve detailed on-site assessments of dairy farm surroundings, milking barns, and milking equipment for proper maintenance and cleanliness and for compliance with all state and federal sanitation standards. Recording thermometers verify proper milk cooling, storage time and cleaning temperatures for farm bulk milk tanks, and are checked for accuracy regularly by MDFS and maintained under regulatory seal. MDFS also reviews plans and approves construction for new dairy farms or new equipment installations. Samples of bulk milk are collected from each farm and tested for antibiotic residues and for compliance with regulatory limits on bacteria and somatic cell counts. Milk is restricted in use or excluded from the market as necessary. Samples of well-water and re-circulating chiller water are also routinely collected for bacterial testing.

MDFS DAIRY FARM INSPECTION FY 17/18

607 Farms

Activity	Number Completed
Sanitation Inspections	1557
Farm Bulk Milk Tank Samples Collected	4589
Water Samples Collected	1069

Bulk Milk Tanker Inspection

Approximately 13 million gallons of milk, or about 2,000 tanker truck-loads, are transported from dairy farms in California every day. All bulk milk tankers that carry milk from dairy farms to milk processing plants are inspected annually by MDFS for proper maintenance, cleanliness, and sanitary design, and upon successful completion of the inspection are issued a permit to operate in California. Bulk milk tanker drivers that pick up milk from dairy farms require a sampler and weigher's (S&W) license issued by MDFS, undergo field proficiency evaluations by MDFS inspection personnel, and complete an on-line refresher course required for S&W license renewal. These activities help to ensure that milk is handled in a sanitary manner, that the samples taken for payment purposes are representative of the milk in the farm bulk tank, and that the amount of milk the producer is paid for is measured accurately. MDFS is also responsible for conducting annual inspections of, and issuing permits to, commercial facilities that wash and sanitize bulk milk tanker trucks.

BULK MILK TANKER INSPECTIONS FY 17/18

Activity	Number Completed
Tanker Truck Sanitation Inspections	1194
Tanker Wash Station Inspections	11
Sampler and Weigher Field Proficiency Evaluations	1062
On-line Sampler and Weigher Refresher Course	770
New Driver S&W Exams Administered	511

Milk Processing Plant Inspection

Facilities that receive, process or package milk and dairy products must be licensed and inspected by MDFS. Six hundred thirty-nine (639) milk product plants were licensed and inspected regularly by MDFS in FY 17/18. Licensed milk products plants are inspected and officially scored for compliance with food safety standards four times per year. MDFS reviews and approves any new construction, remodeling or new equipment installations. Raw dairy ingredients and finished dairy products are collected and analyzed for compliance with applicable bacterial and compositional standards. Soft-serve frozen dessert facilities are also licensed and inspected by MDFS to ensure products served to consumers are safe and wholesome and comply with bacterial limits. Milk or milk products which are manufactured, handled or kept in an insanitary place, or are impure, unwholesome, adulterated or mislabeled may be impounded or condemned by MDFS and thus prevented from entering the marketplace. Samples of water in use at milk processing facilities are collected for bacterial testing. All pasteurizer equipment installed statewide is inspected upon installation, and all the public health controls are tested and placed under regulatory seal initially and every 90 days to ensure proper pasteurization of the milk. Anyone wishing to operate pasteurization equipment in California must first be licensed by passing a written, practical and oral examination given by MDFS. Milk plant laboratories responsible for screening all incoming milk for antibiotic residues prior to processing are routinely inspected and evaluated for competency. MDFS is also responsible for responding to consumer complaints and any investigation of a milk products plant linked to the contamination of dairy products or a food-borne illness outbreak.

MILK PRODUCT PLANT INSPECTION FY 17/18

Activity	Number Completed
Sanitation Inspections	5062
Pasteurization Equipment Inspections	2371
Raw Ingredient Samples Collected	1314
Finished Product Samples Collected	8525
Water Samples Collected	646
Sanitation Ratings for FDA compliance	53
Evaluations of Industry Milk Testing Labs	59
Dairy Container Manufacturer Inspections	25

Laboratory Regulation

In addition to its sanitary inspection responsibilities, MDFS has an important role in the regulation of industry laboratories that conduct testing of milk for purposes of safety, quality or producer payments. This includes oversight of mandatory bulk milk tanker load testing for antibiotic residues prior to processing, administering exams for milk tester- and technician licenses, conducting FDA Interstate Milk Shipper (IMS) laboratory ratings, overseeing and coordinating split sample proficiency testing, and managing the MDFS Fluid Milk Testing Program.

The Branch administers a calibration program that ensures labs testing milk components for payment purposes meet accuracy and precision requirements in California regulations. In FY 17/18, 58 labs received samples for the calibration of their infra-red instruments used to test raw milk and finished fluid products for fat, protein, lactose, solids not fat (SNF) and total milk solids. Seven of these labs test raw milk in California for purposes of payment to dairy producers. The remaining 51 labs were production plants that used the MDFS split samples to calibrate infra-red instruments for purposes of in-process standardization of their dairy products to ensure they meet California requirements for milkfat and other components. Industry technicians who test incoming raw milk and finished products for compliance with State and Federal bacterial standards also participate in an annual split sample program administered by the State. The technicians are evaluated by MDFS on every method they are licensed to conduct, and their performance must meet Federal guidelines. In addition to oversight of basis of payment related testing, 49 labs received annual split samples of milk to verify industry analysts can accurately detect antibiotics in raw milk prior to processing and exclude such milk from human food use. Testing facility employees are also trained and evaluated regularly by our FDA-certified Laboratory Evaluation Officers (LEO's) to ensure that they are following correct procedures.

In FY 17/18, the MDFS Branch conducted oversight of antibiotic residue testing by 1319 approved industry analysts at 124 facilities in CA, 57 licensed industry technicians that test milk for compliance with bacterial standards, and 47 licensed milk testers that test milk for components used as a basis of payment to producers.

Interstate Milk Shipper Ratings

The oversight of California's Grade-A dairy products, such as fluid milks, creams, yogurts, etc., that are shipped in interstate commerce is the sole responsibility of MDFS as a member of the cooperative state-federal program of the National Conference on Interstate Milk Shipments (NCIMS). Milk regulatory agencies from all 50-states and the U.S. Trust territory of Puerto Rico are members of the NCIMS and enforce the requirements of the FDA's Pasteurized Milk Ordinance (PMO). Compliance with the regulatory requirements of the PMO is a state level responsibility and necessary for federal approval for California to ship its dairy products in interstate commerce. Ensuring that dairy farms and milk processors are properly licensed and inspected is a critical part of compliance with FDA's requirements under the PMO.

MDFS staff that have been trained and certified by FDA conduct Interstate Milk Shipper (IMS) Ratings at IMS listed dairy farms, processing plants, laboratories and single service facilities. Ratings are based on compliance with the requirements of the PMO.

IMS-Listed Facilities FY 17/18*

Type	Number
Dairy Farm BTU**	30
Single Service	28
Milk Product Plants	74
Laboratories	36

* Facilities are IMS rated once every 24 months
** A BTU is a group of dairy farms in a defined geographic area.

Foodborne Pathogen Monitoring and Response

MDFS routinely collects samples of raw milk sold for direct consumption for purposes of foodborne pathogen monitoring, including for the presence of *Campylobacter jejuni*, *E. coli* O157:H7, *Salmonella enterica*, and *Listeria monocytogenes*. The Branch also routinely tests dry milk powders and other dried milk products for *Salmonella spp*. MDFS responds to potential links of foodborne illness with dairy products by conducting food safety inspections at implicated facilities, including sampling and pathogen testing

of products and equipment surfaces in the manufacturing environment as warranted. When necessary, MDFS orders mandatory recalls of adulterated milk products under the quarantine authority of the State Veterinarian and partners with the California Department of Public Health regarding foodborne illness outbreak investigations and epidemiologic analyses pertaining to dairy products. Foodborne illness clusters occurring in multiple states, and any associated dairy product recalls in interstate commerce, are investigated and implemented in close cooperation with the U.S. FDA.

Investigative Services Unit

The Investigative Services Unit (ISU) of MDFS is responsible for enforcing the milk products plant licensing requirements of the Food and Agricultural Code and resolves criminal, civil and administrative matters associated with illegal unlicensed operations through appropriate prosecutorial and judicial venues. Persons manufacturing, freezing, or processing milk or any product of milk must obtain a license from MDFS. Licensed facilities must meet specific sanitary design, construction and hygienic operational standards, and are subject to regular inspection to ensure that milk products are safe for consumers. Unlicensed facilities often operate under insanitary conditions that can contaminate milk products with bacteria that cause human illness and sometimes death. Section 35283 of the Food and Agricultural Code specifies that any person who intentionally manufactures or processes for resale any milk product in a facility not licensed by CDFA, or provides milk to any person for the manufacturing or processing of any milk product for resale unless that person is licensed by CDFA, is guilty of a felony. Investigative activities are dedicated to the prevention of foodborne illnesses associated with unlawful domestic manufacturing, distribution of dairy food products from unlicensed sources and importation of illicit foreign products into the domestic market that present suspected public health risks through pathogenic contamination.

ISU partners with local law enforcement agencies, county health departments, the California Department of Public Health, the FDA and the US Department of Agriculture (USDA) in their efforts. ISU also provides critical outreach and education to local public health departments and law enforcement agencies. In FY 17/18, ISU investigated 53 cases of illegal manufacturing and/or sale of dairy products in California.

ISU CASES INVESTIGATED FY 17/18

Case Type	Number of Cases
New investigations	53
Closed with a warning	20
Closed with insufficient evidence	7
Referred to other agencies	7
Resulting in criminal prosecution	3

Science and Policy Unit

The Science and Policy Unit is involved in dairy product and products resembling milk products label review, monitoring of fluid milk basis-of-payment testing, State central laboratory oversight, and technical process reviews. Additionally, this unit is responsible for coordination with FDA for Food Safety Modernization Act (FSMA) implementation, developing training for field staff, integrating the FDA Manufactured Food Regulatory Program (MFRP) Standards into the existing program and developing a cooperative agreement to regularly perform inspections for FDA.

In FY 17/18, the unit reviewed 1,405 labels, and responded to hundreds of requests for labeling guidance documents. This activity ensures that product labels are in compliance with state and federal regulations, and are not misleading to consumers. New companies requesting a label review are given a "Welcome Packet" that provides the required information on retail food product labels and how to submit them to the Branch.

The Unit also reviews proposals from the industry for extended periods of continuous processing to ensure product safety while promoting the efficient use of energy and water by California's dairy plants. Extended run proposals are evaluated for their ability to maintain equipment cleanliness and continued compliance with applicable state and federal microbiological standards. The Science and Policy Unit reviewed nine extended run proposals in FY 17/18.

New in FY 2017/18

<u>Limited Frozen Manufacturing Permits</u>

The manufacture and sale of frozen desserts at the retail level is an innovative and evolving sector of the industry, with businesses seeking to safely make frozen desserts using proprietary recipes and sales approaches that were not consistently allowable under the licensing scheme described in the Food and Agricultural Code. Licenses are issued by MDFS for various types of businesses that handle or manufacture milk and milk products, including but not limited to frozen dairy products and desserts. Licensed premises range from complex facilities that receive,

pasteurize, and process milk and other ingredients into frozen desserts for broad wholesale distribution, to simple retail food facilities that only sell soft-serve frozen desserts in cones or cups directly to consumers from a freezing device.

Each of these licenses or permits is associated with specific but varying sanitary requirements and allowable manufacturing and distribution activities, and evolved in statute over the last 25 years as business needs changed in the frozen dessert manufacturing industry at the direct to consumer level. The licensing approach could be confusing to businesses and local public health as the frozen dessert sector continued to expand and innovate.

Assembly Bill AB 1486, passed by the Legislature and signed by the Governor on July 31, 2017, simplified licensing and required entities that manufacture hard frozen or semi-frozen dairy products for the use of any patron, guest, or employee to obtain a new ***Limited Frozen Manufacturing Permit***, replacing the former limited manufacturing permit and limited packing permit, and allowed more manufacturing and packaging activities by these entities. The MDFS Branch worked with industry and the bill's author to establish a licensing system that allowed businesses greater flexibility in the on-premises manufacture and sale of frozen desserts, while continuing to ensure the protection of public health through ongoing requirements for sanitary work areas and observance of good manufacturing practices under inspection by the Department.

AB 1486 based licenses and sanitary requirements on whether frozen dessert products were made for purposes of wholesale distribution to off-site locations, or strictly for purposes of on-premises sale directly to consumers. The new limited frozen manufacturing permit allows facilities to make frozen desserts from pre-pasteurized dairy ingredients, whether from scratch or from a complete mix purchased from a milk products plant, for serving consumers directly on the same premises up to 7,500 gallons per year. The new permit also authorizes packaging of manufactured frozen dessert products for on-premises sale only, provided they are properly labeled. No wholesale distribution or off-site sale is allowed, and use of raw dairy ingredients is prohibited.

Provisions for the new limited frozen manufacturing permit were effective January 1, 2018.

Implementation of Standardized Training Program

As part of an ongoing self-assessment under the national Manufactured Foods Regulatory Program Standards, the MDFS Branch developed and implemented a standardized training program for all field inspection personnel. The training consists of on-line and classroom based instruction to ensure continued development and maintenance of core competencies in public health and food safety important to protecting consumers and serving the dairy industry. Subject areas include, but are not

limited to, inspection practices, Hazard Analysis and Critical Control Point (HACCP) systems, microbiological control, pasteurization technology, foodborne illness investigations and communication skills. In addition, all field personnel, supervisors and managers in the Branch completed federally approved Preventive Controls Qualified Individual (PCQI) training required by the federal Preventive Controls for Human Food Rule for writing or revising industry Food Safety Plans. Milk processing plants must develop and maintain these plans to address potential hazards to food safety as mandated by the Food Safety Modernization Act (FSMA).

Completion of the above training not only promotes the professional development of MDFS inspection personnel, but also provides prerequisite training for conducting inspections of milk plants under contract with the U.S. Food and Drug Administration (FDA). Maintaining skills and abilities pertinent to FDA's implementation of FSMA across all food commodities including dairy products, allows the effective leveraging of MDFS expertise and resources under the national integrated food safety system. This enables MDFS to provide efficient services to the industry by avoiding redundant inspections by multiple agencies at dairy processing facilities, and to effectively protect public health.

To support the above training efforts, the MDFS Branch secured $75,996 in federal grant funds in FY 17/18.