

# Milk and Dairy Food Safety Branch

## 2015 Annual Report



### **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 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.

### **2015 Regulatory Responsibilities**

Grade A Dairy Farms*	1,467
Manufacturing Grade Dairy Farms**	49
Milk Products Plants (Grade-A)	76
Milk Products Plants (Non Grade-A; Cheese, Frozen, etc.)	485
Pasteurizer Units Tested Quarterly	418
Soft-serve (Semi-frozen) Dessert Establishments***	8,145
Limited Manufacturers (Restaurants making ice cream)	122
Bulk Milk Pickup Tanker Trucks	1,808
Licensed Bulk Milk Sampler and Weighers (Farm Pickup)	2,300
Bulk Milk Tanker Wash Stations (Free-standing)	9
Licensed Limited Sampler and Weighers (Plant Personnel)	585
Single Service Container Manufacturing Plants	27
FDA-listed Milk Testing Laboratories	36
Approved Drug Residue Screening Labs	74
Approved Drug Residue Confirming Labs	25
Certificates of Free Sale and Sanitary Origin	3,641

\* 892 farms inspected by county Approved Milk Inspection Service (AMIS)

\*\* 17 farms inspected by county AMIS

\*\*\* 3,194 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 December 31, 2015 there were 1,438 cow dairies, 61 goat dairies, 15 sheep dairies and 2 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 1,516 total dairy farms, 607 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.

<b><u>MDFS DAIRY FARM INSPECTION 2015</u></b>	
<b>607 Farms</b>	
<b><u>Activity</u></b>	<b><u>Number Completed</u></b>
Sanitation Inspections	1,553
Farm Bulk Milk Tank Samples Collected	4,644
Water Samples Collected	1,336

### ***Bulk Milk Tanker Inspection***

Approximately 13 million gallons of milk, or about 2000 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 2015**

<b><u>Activity</u></b>	<b><u>Number Completed</u></b>
Tanker Truck Sanitation Inspections	1,261
Tanker Wash Station Inspections	9
Sampler and Weigher Field Proficiency Evaluations	645
On-line Sampler and Weigher Refresher Course	547
New Driver S&W Exams Administered	472

### ***Milk Processing Plant Inspection***

Facilities that receive, process or package milk and dairy products must be licensed and inspected by MDFS. Five hundred sixty-one (561) milk products plants were licensed and inspected regularly by MDFS in 2015. 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.

<b><u>MILK PRODUCT PLANT INSPECTION 2015</u></b>	
<b><u>Activity</u></b>	<b><u>Number Completed</u></b>
Sanitation Inspections	4,304
Pasteurization Equipment Inspections	2,015
Raw Ingredient Samples Collected	1,190
Finished Product Samples Collected	11,342
Water Samples Collected	697
Sanitation Ratings for FDA compliance	116
Evaluations of Industry Milk Testing Labs	63
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 2015, 54 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 47 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, 77 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 2015, the MDFS Branch conducted oversight of antibiotic residue testing by 710 approved industry analysts at 82 facilities in CA, 50 licensed industry technicians that test milk for compliance with bacterial standards, and 52 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.

<b><u>IMS-Listed Facilities 2015*</u></b>	
<b><u>Type</u></b>	<b><u>Number</u></b>
Dairy Farm BTU**	28
Single Service	28
Milk Product Plants	75
Laboratories	37

\* 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.

In 2015, there were three (3) recall orders issued by MDFS (1 recall of pasteurized cheeses associated with *Listeria monocytogenes*, and 2 recalls of raw fluid milk products due to *Campylobacter jejuni*), and one voluntary recall coordinated by FDA of aged raw milk cheese due to *Listeria monocytogenes*.

### ***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 2015 ISU investigated 72 cases of illegal manufacturing and/or sale of dairy products in California.

**ISU CASES INVESTIGATED 2015**

<b><u>Case Type</u></b>	<b><u>Number of Cases</u></b>
New investigations	72
Closed with a warning	32
Closed with insufficient evidence	12
Referred to other agencies	5
Resulting in criminal prosecution	6

***Science and Policy Unit***

The Science and Policy Unit is involved in dairy product label review, fluid milk payment testing, State central laboratory oversight, and technical process reviews. Additionally, this unit is responsible for coordination with FDA liaisons 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 2015, the unit reviewed 620 labels, 4 extended run processing proposals and 3 pasteurizer equivalent water treatment proposals. Additionally, in response to a temporary standard petition from the industry, branch staff promulgated a regulation to define, and establish labeling requirements for, Ultra-Filtered Milk products in California.

New regulations related to FSMA will challenge the branch to provide regulatory oversight under an integrated state-federal food safety system including training of field staff, updating inspection reports and score cards, and providing information and resources to industry for compliance. Additionally, the branch plans to move forward in achieving conformance with the FDA MFRP Standards for purposes of entering into a cooperative agreement with FDA that will help reduce redundant multiple agency inspections of licensed facilities by leveraging MDFS resources and expertise. These national MFRP standards require inspection staff to complete additional coursework and field training, uniform score sheets and reports for inspections, and a branch audit program for continuous improvement to promote uniform prevention, intervention, and response activities for manufactured foods across the country.