

GOOD MANUFACTURING PRACTICES

Code of GMP Compliance:

Plant employees
Store and Office Personnel
Visitors

I. PURPOSE

Penn State Berkey Creamery has been a significant contributor of dairy foods to Penn State University for over 140 years. Our success comes from establishing and continually earning consumer trust and loyalty. The employees of Penn State Berkey Creamery have gained consumer trust by providing consistent, high quality, dairy food products. This trust has provided us with opportunities from which the Berkey Creamery employees have continued to benefit. Employees taking pride in their work and maintaining strict adherence to the good manufacturing practices (GMP) listed on the following pages will allow us to maintain our customer satisfaction and loyalty.

We operate a dairy food manufacturing plant, the products of which will be consumed by our students, faculty, staff, and friends of the University. Therefore, it is necessary to establish and maintain clear standards of personal hygiene, dress, grooming, appearance, and conduct reasonably related to the needs of a dairy food plant.

The practices listed apply to all employees and visitors. The rules listed are consistent with good manufacturing practice regulations administered by the Food and Drug Administration (FDA). These materials have been taken from 9 Code of Federal Regulations (CFR), 21 CFR, Pasteurized Milk Ordinance (PMO), local and state regulations. These practices refer to all plant operating and warehouse areas unless otherwise stated.

II. SCOPE

Management is responsible for assuring each individual employed by Penn State Berkey Creamery is familiar with, and complies with the GMP program outlined in this policy. Good manufacturing practices are guidelines to assure that products are manufactured and stored under safe and sanitary conditions. GMP guidelines are established to satisfy regulatory requirements as well as to maintain the high quality standards of our products to our customers. Therefore, these standards are subject to change as a result of Berkey Creamery improvements or changes in state or federal regulatory requirements.

III. DEFINITIONS

1. GMP – Good manufacturing practices
2. Processing area – Any area in which ingredients/materials are received and product is produced and packaged or prepared.
3. Operating area – Any area of the dairy manufacturing plant. This includes, but is not limited to, the warehouse, coolers, freezers, processing, receiving, and shipping areas, case dock and bottle room.
4. Storage area – Any areas in which ingredients, packaging materials or finished goods are stored.

5. Cooler area – Any area utilized for the storage of packaged product or ingredients and its ambient temperature is maintained at or below 45°F.
6. Production personnel – Any employee who will normally come into near proximity to ingredients or product, including management.
7. Visitor – Any person not directly employed by The Pennsylvania State University, or a student enrolled at The Pennsylvania State University.

IV. POLICY

A. Personnel

The wearing of all types of jewelry (i.e. earrings, watches, rings, neck chains, etc.) is strictly prohibited in all plant operating areas. The only exceptions to this rule are a wedding ring without sets, and a medical alert necklace/bracelet, which must be worn under the appropriate outer garment.

Wash and dry hands thoroughly before starting work and after each absence from the work area. All persons must wash and dry their hands after visiting restrooms, eating, smoking, and/or any other times when hands have become soiled or contaminated.

Hairstyles on all employees shall be of a nature that they appear neat, trimmed or fully restrained to a degree that would give a neat, clean and sanitary appearance as becoming a food plant. Hair and beard restraints are required throughout processing areas. These restraints must be Berkey Creamery issued and completely cover employee's hair and beard. Appropriate hair covering shall be of a tight mesh and be worn in such a manner as to contain all facial hair. All beards and other facial hair, such as muttonchops, must be covered by a beard restraint and conform to government regulations and good manufacturing practices. Side burns, unless covered by a beard restraint, shall be of uniform width throughout their length and be well trimmed to avoid the appearance of being bushy. Side burns shall not extend below the bottom of the earlobe. Facial hair that requires a covering is any visible growth. Access to all processing areas is strictly prohibited unless proper hair covering is in place.

A mustache not covered by a beard guard will be permitted if it is kept neat, well trimmed and does not extend below the corners of the mouth or over the edge of the upper lip.

Cleanliness of body and clothing is required. Fingernails are not to have polish on them, and must be kept clean and neatly trimmed.

Exposed, unwrapped product, as well as packaging materials and equipment which contacts exposed product shall not be handled with:

1. Injured or bandaged hands unless protected by gloves. Gloves must be maintained in an intact, clean and sanitary condition, and changed frequently.

2. Cuts and open sores on fingers unless they are covered by a band-aid with a finger cot or glove.

Avoid use of hands which may result in contamination of food products. Such practices include:

1. Touching of the face, adjusting glasses, wiping forehead, placing fingers on or in mouth, nose or ears.
2. Scratching the head or body
3. Handling products for taste testing in an unsanitary manner.
4. Reaching in to ice cream ingredient containers and consuming pieces of cookies, candies, nutmeats, etc.

Good hygiene must be practiced at all times. Chewing tobacco, trimming fingernails, spitting, use of snuff, chewing gum and open blowing of the nose in the production area or any area exposed to products or packaging materials are examples of poor hygiene which produce unsanitary and undesirable conditions.

Smoking and tobacco usage of any type are not permitted in any area of the facility. Smoking is permitted in designated areas only and employees must wash their hands before returning to the processing area.

Employees shall not hold toothpicks, matchsticks, or similar objects in their mouth while performing their assigned duties. Pencils or other objects held behind the ears are forbidden.

The consumption of food or beverages is strictly prohibited in all plant operating areas. This includes the chewing of gum, candy, soft drinks, cough drops, and breath mints. It is prohibited to store food of any type in employee lockers. Employee lunches must be stored in designated areas only.

Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesions (including boils, sores, or infected wounds), or any other abnormal source of microbial contamination by which there is a reasonable possibility of product, product contact surfaces, or product packaging materials becoming contaminated, will be excluded from any operations which may result in such contamination until the condition is corrected. Personnel are instructed to report any such health conditions to their supervisor.

If an employee knows that he/she is affected by, or is a carrier of, a communicable disease, he/she may not work in any area in which there is a possibility of a food or food ingredient being contaminated or a reasonable possibility of the disease being transmitted to other employees.

An employee should vacate the processing area during periods of excessive coughing or sneezing until it ceases.

Medication, cough drops, etc. must be stored in personal lockers; they may not be transported or stored in operating areas.

B. Clothing

Berkey Creamery issued uniforms must be worn in all operating areas. Shirts should be completely buttoned to the next to the last button from the top to ensure that no torso body hair is exposed. Only long pants (i.e. below the bottom of the calf) are permitted in the plant. Shorts are not permitted. Office and laboratory personnel that spend more than 5% of a workday in the processing area must be covered by a lab coat.

Clothing of whatever nature, including that supplied by the Berkey Creamery, shall not be tattered or unkempt in keeping with the atmosphere expected in a dairy food plant.

Where clothing may become soiled rapidly, and employees are exposed to open product, disposable or plastic aprons should be worn over Berkey Creamery issued uniforms and changed frequently for added protection against product contamination.

Employees engaged in the handling of open foods will not be permitted to keep wearing apparel, not actually in use, in any work area where they or others are so engaged.

To prevent articles from falling into product, do not carry pens, pencils, thermometers, glasses, tools, etc., in shirt or coat pockets above the belt or waistline.

Shoes shall be of sturdy construction to afford some impact protection. Only low heel shoes are permitted. Shoe types prohibited are canvas, nylon, sandals, open heels, open toes, deep grooved soles (1/4 inch or more). It is preferable that all employees use Shoes for Crews® slip resistant soled shoes.

Gloves used for handling food and food contact packaging supplies must be intact and in a sanitary condition.

General Plant and Processing Areas

We are extremely proud of the Berkey Creamery's reputation. All of us must cooperate to maintain and improve the high regard in which our consumers hold our products.

Littering or practices that cause poor housekeeping or other unsanitary conditions are prohibited. All refuse must be placed in covered trash containers labeled accordingly. Food and beverages are to be consumed in designated areas only.

Use of food containers (i.e. cartons, bottles, jugs, etc.) for drinking cups, storage of oils, grease or anything other than actual product is strictly prohibited unless appropriately marked.

Lockers are to be maintained clean and free of trash and/or soiled clothing.

Hearing protection is required in designated areas. Several types of hearing protection are available. (See supervisor.)

Safety glasses, goggles, or shields must be worn when handling hazardous materials (i.e. cleaning chemicals, petroleum products, etc.). Eyewash and emergency shower facilities are available for use when necessary.

All exterior doors throughout the plant must remain closed at all times. They must be self-closing and tight fitting. It is not permissible to prop doors open, allowing dirt, insects, and other contaminants to enter. In addition, rest room doors must remain closed to ensure hygiene notices are visible to those exiting the rest rooms.

Protect all product areas from contamination by removing areas of peeling paint, rust, etc., on a continual basis.

When not in use, all water hoses must be neatly coiled and stored on hangers. (Note: Hose body and/or nozzle must not be in contact with the floor.) Water should not be allowed to run when not in use.

Non work related reading material of any type including newspapers, magazines, and books are prohibited in all working areas.

Employees are expected to keep their work areas and equipment clean, neat, and orderly and practice good housekeeping at all times.

C. Storage and Handling of Ingredients and Products

Store all items off the floor on pallets, slip-sheets or racks except where other storage is authorized by management personnel.

Do not use dirty or broken pallets. Remove damaged pallets for repair. Store pallets in areas free from extraneous matter such as bird, insect and rodent contamination. Pallets stored outside are to be cleaned and sanitized prior to use. Plastic pallets are for use in the processing area only.

Maintain bagged product in a neat and orderly manner.

Ensure that the outer surfaces of ingredient bags are clean before removal to a processing area.

D. Process and Product Integrity

Vigilance and good judgment must prevail at all times to prevent product contamination.

If present, strip outer coverings off ingredient containers prior to use.

Seal and identify contents of partially used ingredient containers. These materials should be used as soon as possible.

Remove the labels from empty ingredient containers and store them covered or inverted off the floor.

Cover and seal partially used packaging material when not in use. Packaging material may not be used for anything other than product.

Do not store product or ingredient containers adjacent to containers for waste product or non-product waste.

Bulk ingredients are to be stored in sanitary containers with the appropriate liners.

Exposed product, packaging materials and equipment which contacts exposed product shall not be handled with injured or bandaged hands unless protected by gloves. Cuts and open sores on fingers must be covered by a band-aid with a finger cot or rubber glove.

Exercise extreme care to prevent product from falling on the floor. Where production line failures necessitate product to be temporarily stacked off or removed from a line, the product must be protected from contamination.

Exercise care when moving product. Avoid damage to product or packaging through careless and/or improper handling.

Avoid over-stacking of product, use dividers as required.

Sitting on ingredients or packaging material is prohibited in all working areas.

Do not sit or stand on product shipping cases.

Use of glass in any area of the plant other than the lab or the office is strictly prohibited.

All piping, including product and cleaned-in-place, must be disconnected from holding tanks when it is not in use. All product piping must be capped whenever it is not being used to prevent contamination.

Before the contents of a milk can are emptied into the balance tank for reprocessing, sanitize the exterior to prevent contamination. Always transfer products for reprocessing into milk cans first.

All hoses and air lines must be maintained neatly coiled with the nozzle off the floor to prevent contamination.

E. Receiving and Shipping

Products must be handled with care to prevent damage and exposure to adverse conditions.

Unloading procedure:

1. Carefully inspect all incoming product for evidence of rodent or other infestation, damage, or objectionable odors of any kind prior to transferring to storage. If there is any evidence of contamination, document the findings and report it to your supervisor immediately. Do not unload until inspection is completed.
2. Isolate damaged materials. Label it accordingly and notify management.
3. Temperature checks on all refrigerated materials must be performed per product specifications.
4. Inspect all carriers for cleanliness and lack of objectionable odors during and after unloading.
5. When unloading bulk materials, dome openings shall be adequately screened to prevent contamination. Screening devices must allow sufficient airflow into the tank to permit the normal unloading of product.
6. All ingredient containers must be properly identified with a code date and a lot number

Loading procedure:

1. If product requires refrigeration, check temperature of the carrier before loading and be sure that it is at the specified temperature. Do not load unless specified temperatures are met.
2. Prior to loading tankers, inspect tank interior for cleanliness and absence of offensive odors. Look for damage or defects to interior surfaces. Check condition of all fittings and valves.
3. Follow a stock rotation program to assure that the oldest product is shipped first. Alert management when product nears the end of its shelf life. No product with less than five days of code remaining may be shipped to the dining halls or other eateries on the University Park Campus.

F. Product Codes

Coding is an important function of plant personnel and must be continually monitored.

All product code dates must be on the package, easily visible and clearly legible.

Employees responsible for code date printing must continually monitor the quality of the package, code date, and code printing.

Illegible code date printing or deviations that occur while filling product must be reported to management immediately.

G. Sanitation

Sanitation standard operating procedures (SSOP's) must be in place and strictly followed to assure product integrity. SSOP's, with documentation, include, but are not limited to; cleaning, gasket, o- ring, and check-valve replacements, chemical titration, training logs, etc. See Bonnie Ford if you have questions about our SSOP's and SOP's.

A written color-coded brush/bucket program is in place and must be followed.

Wash and dry hands thoroughly before starting work and after each absence from the work area.

Sanitize hands frequently in designated areas.

Do not use equipment aids with wooden handles.

Material handling equipment (i.e. scoops, carts, lifts, etc.) must be kept clean, covered and well maintained.

Follow all cleaning procedures explicitly. Eye protection (i.e. safety glasses, goggles, or shield) must be worn when handling chemicals.

All chemical containers must be properly labeled, especially secondary-use containers.

The constituents of all cleaning and sanitizing chemicals must be FDA and/or USDA approved and/or meets other applicable laws and regulations for food plant use.

During cleaning procedures, all clean parts, pipes, etc. must be stored off the floor on a cart, mat, etc. Should a part come in contact with the floor it must be re-cleaned and sanitized prior to use.

Do not splash water from the floor on clean equipment. All ponding or standing water should be squeegeed to the nearest drain.

Equipment must be thoroughly cleaned after each use and at least once each day used (material in storage tanks can be held for no longer than 72 hours).

All equipment must be inspected prior to reassembly.

Clean and replace product contact gaskets as necessary.

Clean, sterilized screens must be placed on fillers each time the filler is used.

Avoid excessive use of lubricants on equipment to prevent product contamination. All lubricants must be food grade. Lubricants must be stored in non-production areas when not in use.

All cleaning equipment (i.e. cleaning aids, personal protective equipment, chemicals, etc.) must be stored in non-production areas when not in use.

Store production-cleaning equipment must be separate from floor cleaning equipment. Equipment used for cleaning drains should be separate, properly identified, and stored in an isolated area.

Floor drains should be free of all debris with no evidence of any offensive odors. All drains must be cleaned and sanitized on a regular basis. Only black bristle brushes may be used to clean floor drains.

Drain traps should remain flooded and covers intact and in good repair.

Record Keeping

Processing records are maintained and continually monitored.

Identify and sign all temperature control charts. Highlight and explain any deviations and/or abnormalities on the chart. Mistakes must be initialed and crossed through with a single line. Do not erase or attempt to use whiteout.

Lot identification number of all raw materials must be recorded on batch sheets to enable tracing of finished goods from receiving to production, packaging and distribution.

H. Quality Control

Bonnie Ford maintains final decision-making authority in all matters pertaining to quality. Products of questionable quality will be red-tagged until further testing is completed.

Our processors and laboratory director are responsible for proper record keeping. All data should be recorded in ink and clearly legible. Records are stored in the laboratory.

All deviations from standard must be reported immediately to the machine operator, processor, laboratory director, or management.

I. Maintenance

The exterior of the building must be in good repair.

Maintain building areas and equipment in a sanitary condition.

Building grounds (i.e. weed control, litter removal, etc.) must be properly maintained at all times.

The building should be insect and bird proof with tight fitting, self-closing doors.

There may be no cracks or holes in the building structure where pests could enter. Screen window openings to prevent entrance of pests.

Maintain the required 18" open floor area for rodent control with a painted stripe or angle iron.

Provide a physical barrier between the garbage dump area and the plant.

Parking areas, including Berkey Creamery vehicles, must be maintained as dust and contaminant free as possible.

There should be no standing or pooled water that may become a source of contaminants.

All tools, parts, nuts, bolts, screws and other materials used in the repair of equipment must be confined to the immediate work area. When a repair has been completed, all tools, discarded parts, and refuse must be removed from the area prior to starting equipment.

Whenever in the course of repairing machinery that a product contact surface has been handled, exposed, or otherwise contaminated, the supervisor on duty must be notified and all necessary procedures must be followed to ensure proper cleaning and sanitizing of those areas.

Use of non-approved materials such as electrical/duct tape, string or wire, etc. for temporary repair of equipment is prohibited.

J. Utilities

Facility is equipped with adequate ventilation to circulate clean, fresh air throughout the plant.

Steam introduced into product or coming in contact with food surfaces must be culinary grade.

Provide water at a suitable temperature and under good pressure for utensil cleaning and equipment sanitation.

Water used in sanitation, cleaning, or any other purpose that comes in contact with food surfaces must be potable and of sanitary quality.

Ensure that proper back flow prevention devices exist between systems carrying water for processing, wastewater and CIP circuits.

Provide adequate floor drains for removal of discharge water from cleaning procedures.

Provide adequate lighting to all plant operating areas, especially where product is examined during processing, filling, packaging, and where equipment and utensils are cleaned.

All light bulbs and fixtures must comply with safety codes to prevent food contamination in case of breakage. All open bulbs must be plastic coated to prevent shattering if broken. Fluorescent fixtures where bulbs are exposed must have safety shields and proper end caps.

K. Visitor Rules

Visitors, as well as regulatory personnel must adhere to all plant rules and comply with sanitation and safety regulations.

Authorized personnel admitted to processing areas shall conform to the same rules and/or regulations as operations personnel. If an exception appears to be necessary, the laboratory director or manager shall be contacted for proper clearance.

Visitors unable to remove jeweled rings shall wear tape and a rubber glove over the ring as a protective restraint.

All contractors working in the plant must comply with GMP policies.

VISITORS NON-DISCLOSURE AGREEMENT

_____ of _____
(Print Name) (Berkey Creamery)

Agrees not to disclose any information regarding the operations and/or procedures he/she observes during his/her visit to PENN STATE BERKEY CREAMERY.

PENN STATE BERKEY CREAMERY shall be held harmless in the event of an injury, or injury related incident, which may occur as a result of your visit to this facility.

Signature

Date

GMP TRAINING

Employee Acknowledgement

I the undersigned acknowledge that I have received a copy of, and have been instructed in Good Manufacturing Practices (GMP) as required by the Food and Drug Administration (FDA). The topics covered in the GMP Manual included, but were not limited to:

- GMP Definitions
- Personal Hygiene
- Employee Practices
- Sanitation
- Quality Control
- Record Keeping

Employee's Signature

Date

PENN STATE BERKEY CREAMERY
Company Name

Department Manager or Supervisor

NOTE: This acknowledgement shall be read and signed by the employee. An authorized Berkey Creamery manager or department supervisor shall countersign the acknowledgement and place it in the employee's personnel file.