



Manufactured Food Establishment Inspection Report

Facility Information

| | | | | | | | |
|---|--|--------------------|---|---|---------------------|--------------------------------|--|
| LEGAL NAME | | | DBA OR NEW BUSINESS NAME | | | | |
| | | | | | | | |
| FACILITY TYPE | | | | | | FEI NUMBER | |
| <input type="checkbox"/> Butter Manufacturer | <input type="checkbox"/> Frozen Dessert Manufacturer | | <input type="checkbox"/> Bottled Soft Drink Plant | | | | |
| <input type="checkbox"/> Butter Distributor | <input type="checkbox"/> Frozen Dessert Distributor | | <input type="checkbox"/> Bottled Soft Drink Distributor | | | PERMIT NUMBER | |
| <input type="checkbox"/> Cheese Manufacturer | <input type="checkbox"/> Ice Manufacturer | | <input type="checkbox"/> Bottled Water Plant | | | | |
| <input type="checkbox"/> Cheese Distributor | <input type="checkbox"/> Ice Distributor/Warehouse | | <input type="checkbox"/> Bottled Water Distributor | | | | |
| PHYSICAL ADDRESS (INCLUDING CITY AND ZIP CODE) | | | | | | | |
| | | | | | | | |
| PHONE NUMBER | | | | TOP MANAGEMENT OFFICIAL NAME/TITLE | | | |
| | | | | | | | |
| EMAIL ADDRESS | | | | TOP MANAGEMENT OFFICIAL PHONE NUMBER | | | |
| | | | | | | | |
| NUMBER OF EMPLOYEES AT LOCATION | | | PERCENT OF PRODUCT | | | GROSS ANNUAL FOOD SALES | |
| Full Time | Part Time | Seasonal/Temporary | Wholesale | Retail | Interstate Incoming | Interstate Outgoing | |

Corporate Information

| | | | | | | | |
|---|--|--|--|--|--|--|--|
| NAME OF CORPORATE ENTITY | | | | CORPORATE PHONE NUMBER | | | |
| | | | | | | | |
| PHYSICAL ADDRESS (INCLUDING CITY AND ZIP CODE) | | | | | | | |
| | | | | | | | |
| NUMBER OF EMPLOYEES AT CORPORATE LOCATION | | | | CORPORATE GROSS ANNUAL FOOD SALES | | | |
| | | | | | | | |

Inspection Information

| | | | | | | | | |
|--|------------------------------------|---------------------------------------|------------------------------------|-------------------|----------------|-----------------|-----------------|-------------------------------------|
| INSPECTION TYPE (CHOOSE ALL THAT APPLY) | | | | START DATE | TIME IN | END DATE | TIME OUT | FOLLOW UP |
| <input type="checkbox"/> Routine | <input type="checkbox"/> Follow Up | <input type="checkbox"/> Reinspection | <input type="checkbox"/> Complaint | | | | | <input type="checkbox"/> No |
| <input type="checkbox"/> Audit | <input type="checkbox"/> Contract | <input type="checkbox"/> Training | <input type="checkbox"/> Joint | | | | | <input type="checkbox"/> Yes: _____ |

Biosecurity / Bioterrorism Act and Documentation

| | | | |
|--|------------------------------|-----------------------------|-----------------------------|
| IS THE FACILITY A REGISTERED FOOD FACILITY WITH FDA? | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> NA |
| BIOTERRORISM (BT) REGISTRATION REQUIREMENTS DISCUSSED WITH MANAGEMENT? Renewals occur every other year, beginning on October 1 and ending on December 31 (in even years) (Registration Link) | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> NA |
| WERE THE REQUIRED FDA FACT SHEETS OFFERED TO THE FACILITY? | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> NA |

Product Code Information

| | |
|--|--|
| DURING THE INSPECTION, THE FACILITY WAS MANUFACTURING/DISTRIBUTING THE FOLLOWING PRODUCTS | |
| | |
| | |

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

| CHECK | 21 CFR PART 117, SUBPARTS APPLICABLE TO FACILITY* | COMMENTS |
|--------------------------|---|----------|
| <input type="checkbox"/> | Subpart A: General Provisions | |
| <input type="checkbox"/> | Subpart B: Current Good Manufacturing Practice | |
| <input type="checkbox"/> | Subpart C: Hazard Analysis and Risk-Based Preventive Controls | |
| <input type="checkbox"/> | Subpart D: Modified Requirements | |
| <input type="checkbox"/> | Subpart F: Requirements Applying to Records that Must be Established and Maintained | |
| <input type="checkbox"/> | Subpart G: Supply-Chain Program | |

*Modernized GMP Inspection for a facility not required to register as a food firm with the FDA: Subparts A, B, F

*Limited Scope Inspection for a facility that has received a Qualified Facility Exemption from the FDA: Subparts A, B, D, E, F

*Inspection for a facility solely engaged in the storage of refrigerated unexposed packaged foods when temperature controls are necessary to prevent pathogen growth): Subparts A, B, D, F

*Full Scope Preventive Controls Inspection for a facility that has not received a Qualified Facility Exemption from the FDA: Subparts A, B, C, F, G

IN - In Compliance, OUT - Out of Compliance, NA - Not Applicable, CV - Consecutive Violation

| General Provisions (§117 Subpart A) | IN | OUT | NA | CV |
|--|-------------------------------------|--------------------------|--------------------------|--------------------------|
| A1- Qualifications of all individuals [§117.4(a-c)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| A2- Records [§117.4(d)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Current Good Manufacturing Practice (Subpart B, R. 61-32, R. 61-36) | IN | OUT | NA | CV |
| PERSONNEL | | | | |
| B1 - Disease control [§117.10(a)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Cleanliness | | | | |
| B2 - Wearing outer garments suitable to the operation [§117.10(b)(1)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B3 - Maintaining adequate personal cleanliness [§117.10(b)(2)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B4 - Hand washing and sanitizing [§117.10(b)(3)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B5 - Jewelry and other objects [§117.10(b)(4)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B6 - Maintaining gloves [§117.10(b)(5)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B7 - Wearing effective hair restraints [§117.10(b)(6)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B8 - Storing clothing or other personal belongings in a designated area [§117.10(b)(7)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B9 - Confining eating food, chewing gum, drinking beverages, or using tobacco [§117.10(b)(8)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B10 - Taking any other necessary precautions to protect against allergen cross-contact and contamination [§117.10(b)(9)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| PLANT AND GROUNDS | | | | |
| Grounds | | | | |
| B11 - Premises free of litter and debris; potential pest harborage removed; grass cut; equipment properly stored [§117.20(a)(1)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B12 - Maintaining roads, yards, and parking lots [§117.20(a)(2)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B13 - Adequately draining areas that may contribute contamination to food or provide a breeding place for pests [§117.20(a)(3)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B14 - Operating systems for waste treatment and disposal in an adequate manner [§117.20(a)(4)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B15 - Exclude pests, dirt, and filth from grounds not under the operator's control [§117.20(a)(5)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Plant construction and design | | | | |
| B16 - Equipment and storage of materials provides adequate space for maintenance and sanitary operations [§117.20(b)(1)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B17 - Adequate food safety controls and operating practices: location, time, partition, air flow systems, etc. [§117.20(b)(2)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B18 - Adequate precautions to protect food in outdoor bulk vessels [§117.20(b)(3)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B19 - Floors, walls, and ceiling of suitable construction, clean and in good repair [§117.20(b)(4)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B20 - Lighting adequate; adequate protection from glass breakage [§117.20(b)(5)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B21 - Rooms and equipment vented as required; ventilation equipment properly located and filtered [§117.20(b)(6)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B22 - All outer openings effectively protected against entry of flies and rodents. [§117.20(b)(7)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B23 - Separate room or area in filling room for mixing ingredients (i.e., syrup/blend room) [R.61-32(IX)(B)(1)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B24 - Separate room for filling and sealing containers (i.e., filling/bottling room) [R.61-32(IX)(B)(2)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B25 - Ice processed and packaged in rooms used exclusively for ice for human consumption [R.61-32(IX)(B)(3)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B26 - BUTTER facilities must comply with Rooms and Compartments requirements in 7 CFR 58 [R.61-36(VII)(C)(1)(a)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B27 - CHEESE facilities must comply with Rooms and Compartments requirements in 7 CFR 58 [R.61-36(VII)(C)(1)(b)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| SANITARY OPERATIONS | | | | |
| B28 - General maintenance [§117.35(a)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B29 - Substances used in cleaning and sanitizing [§117.35(b)(1)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B30 - Storage of toxic materials [§117.35(b)(2)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B31 - Pest control [§117.35(c)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B32 - Sanitation of food-contact surfaces [§117.35(d)(1-3)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B33 - Sanitation of non-food-contact surfaces [§117.35(e)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B34 - Storage and handling of cleaned portable equipment and utensils [§117.35(f)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| SANITARY FACILITIES AND CONTROLS | | | | |
| B35 - Water supply [§117.37(a), R.61-32(IX)(A)(3)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B36 - Approved water supply source and testing for Qualified Facilities [R.61-32(IX)(A)(1), R.61-36(VII)(C)(7)(a-b)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B37 - Water purification systems approved and properly operated [R.61-32(IX)(A)(2)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B38 - Carbonated water conveyed in approved stainless steel or equal food-grade piping [R.61-32(IX)(A)(4)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B39 - Water storage and cooling tanks made of noncorrosive material, properly covered; air vents filtered, clean, and dust-free inside and out; inlet and outlet arranged to prevent contamination during filling and emptying [R.61-32(IX)(A)(5)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Plumbing | | | | |
| B40 - Carry adequate quantities of water to required locations throughout the plant [§117.37(b)(1)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B41 - Properly convey sewage and liquid disposable waste from the plant [§117.37(b)(2)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B42 - Avoid constituting a source of contamination or creating an unsanitary condition [§117.37(b)(3)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B43 - Floor drainage adequate [§117.37(b)(4)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B44 - No cross connections, backflow or back-siphonage [§117.37(b)(5)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B45 - Sewage disposal [§117.37(c)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B46 - Toilet facilities [§117.37(d)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B47 - Hand-washing facilities [§117.37(e)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B48 - Rubbish and offal disposal [§117.37(f)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| EQUIPMENT AND UTENSILS | | | | |
| B49 - Equipment and utensils are designed to be cleanable and are properly maintained [§117.40(a)(1)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

| Current Good Manufacturing Practice (Subpart B, R. 61-32, R. 61-36) | IN | OUT | NA | CV |
|---|-------------------------------------|--------------------------|--------------------------|--------------------------|
| B50 - Equipment is designed, constructed, and used to avoid adulteration of food with contaminants [§117.40(a)(2)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B51 - Equipment has been installed in a way that facilitates cleaning of equipment and adjacent spaces [§117.40(a)(3)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B52 - Food contact surfaces are made of corrosion, resistant, and non-toxic material [§117.40(a)(4)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B53 - Food contact materials are nontoxic, designed for intended use, and compatible with cleaning compounds [§117.40(a)(5)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B54 - Food contact surfaces are maintained to protect food from allergens cross-contact and contamination [§117.40(a)(6)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B55 - Seams on food-contact surfaces [§117.40(b)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B56 - Equipment properly installed and maintained [§117.40(c)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B57 - Holding, conveying, and manufacturing systems design and construction [§117.40(d)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B58 - Freezer and cold storage temperature device [§117.40(e)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B59 - Instruments and controls are accurate, precise, and adequately maintained [§117.40(f)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B60 - Compressed gases [§117.40(g)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B61 - BUTTER facilities must comply with Equipment and Utensils requirements in 7 CFR 58 [R.61-36(VII)(C)(1)(a)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B62 - CHEESE facilities must comply with Equipment and Utensils requirements in 7 CFR 58 [R.61-36(VII)(C)(1)(b)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| PROCESSES AND CONTROLS | | | | |
| General | | | | |
| B63 - All operations must be conducted with adequate sanitation principles [§117.80(a)(1)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B64 - Food properly protected during all steps of processing [§117.80(a)(2)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B65 - Overall sanitation under the supervision of competent individuals [§117.80(a)(3)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B66 - All reasonable precautions taken to prevent product contamination [§117.80(a)(4)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B67 - Testing conducted where necessary to identify sanitation failures, cross-contact, or contamination [§117.80(a)(5)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B68 - Weekly total coliform monitoring and quarterly rinse/swab tests on bottled water containers and closures [R.61-32(VIII)(B)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B69 - Source water analyzed annually for chemical contaminants; every four years for radiologic contaminants [R.61-32(VIII)(C)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B70 - Yearly chemical, physical, and radiological testing [R.61-32(VIII)(D)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B71 - Adulterated food rejected or properly treated [§117.80(a)(6)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Raw materials and other ingredients | | | | |
| B72 - Are inspected, segregated, or handled as necessary to ensure that they are clean and ready for use [§117.80(b)(1)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B73 - Do not contain levels of microorganisms that may produce food poisoning or other disease [§117.80(b)(2)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B74 - Susceptible to contamination with aflatoxin or natural toxin comply with regulations before use [§117.80(b)(3)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B75 - In compliance with FDA regulations for natural or unavoidable defects if susceptible to contamination [§117.80(b)(4)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B76 - Protected from cross-contact, contamination, or adulteration. Materials designated as rework are labelled [§117.80(b)(5)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B77 - Frozen materials are kept frozen, or thawed appropriately [§117.80(b)(6)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B78 - Liquid and raw materials stored in bulk form are protected from allergen cross-contact or contamination [§117.80(b)(7)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B79 - Food allergens and rework with allergens are identified as an allergen. Stored to prevent cross-contact [§117.80(b)(8)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B80 - Raw milk and milk products are from Grade A domestic sources, or approved by the Department [R.61-36(VII)(A)(1)(a)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B81 - Only use of approved flavoring ingredients after pasteurization [R.61-36(VII)(B)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B82 - BUTTER ingredients conform to the Quality Specifications for Raw Material in 7 CFR 58 [R.61-36(VII)(A)(3)(b)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B83 - CHEESE ingredients conform to the Quality Specifications for Raw Materials in 7 CFR 58 [R.61-36(VII)(A)(2)(d)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Manufacturing operations | | | | |
| B84 - Equipment, utensils, containers in adequate condition; equipment taken apart as needed for cleaning [§117.80(c)(1)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B85 - Potential for microbial growth, allergen cross-contact, food contamination and deterioration is minimized [§117.80(c)(2)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B86 - Food is held at temperatures that minimize the growth of undesirable microorganisms [§117.80(c)(3)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B87 - Adequate measures taken to destroy or prevent microorganism growth; conditions prevent adulteration [§117.80(c)(4)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B88 - Work-in-progress (WIP), and rework minimize allergen, contaminations, and the growth of microorganisms [§117.80(c)(5)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B89 - Finished food and food on conveyors are protected from cross-contact and contamination [§117.80(c)(6)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B90 - Equipment, utensils, and containers are constructed, handled, and maintained in a manner that protects against allergen cross-contact and contamination [§117.80(c)(7)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B91 - Adequate measures are taken to protect against metal or other physical contamination [§117.80(c)(8)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B92 - Food, raw materials, and ingredients that are adulterated are disposed of or reconditioned appropriately [§117.80(c)(9)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B93 - Processing steps (ex: washing, trimming, etc.) performed in a manner to protect food [§117.80(c)(10)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B94 - Heat blanching controls minimize growth of microorganisms, are cleaned, and sanitized as required [§117.80(c)(11)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B95 - Batters and similar preparations are treated and maintained to prevent contamination and cross-contact [§117.80(c)(12)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B96 - Filling, assembling, packaging, protect against allergens, contamination, and microorganisms [§117.80(c)(13)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B97 - Dry mixes that rely on water activity control are processed to maintain a safe moisture level [§117.80(c)(14)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B98 - Food that rely on pH control are monitored and maintained at a pH of 4.6 or below [§117.80(c)(15)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B99 - Ice is made of water in accordance with §117.37(a) [§117.80(c)(16)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B100 - BUTTER facilities comply with Operations and Operating Procedures requirements in 7 CFR 58 [R.61-36(VII)(C)(1)(a)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B101 - CHEESE facilities comply with Operations and Operating Procedures requirements in 7 CFR 58 [R.61-36(VII)(C)(1)(b)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| WAREHOUSING AND DISTRIBUTION | | | | |
| B102 - Storage and transportation [§117.93] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| HOLDING AND DISTRIBUTION OF HUMAN FOOD BY PROUDCTS FOR USE AS ANIMAL FOOD | | | | |
| B103 - Held under conditions that will protect against contamination[§117.95(a)(1-3)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B104 - Labeling [§117.95(b)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B105 - Examination of shipping containers and bulk vehicles [§117.95(c)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

| Current Good Manufacturing Practice (Subpart B, R. 61-32, R. 61-36) | IN | OUT | NA | CV |
|--|-------------------------------------|--------------------------|--------------------------|--------------------------|
| DEFECT ACTION LEVELS | | | | |
| B106 - Utilize quality control operations [§117.110(a)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B107 - Mixing of food [§117.110(b)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| SOUTH CAROLINA REGULATION 61-32 | | | | |
| B108 - Each type of bottled water must meet the specific standards and limits applicable to it under 21 CFR 165 [R.61-32(IV)(A)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B109 - All soft drink and bottled water products are labeled according to the requirements in 21 CFR 101 [R.61-32(VI)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B110 - All packaged ice products are labeled according to the requirements in 21 CFR 101 [R.61-36(VI)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B111 - Developed and maintained procedures to notify regulatory officials, consumers, and for a product recall [R.61-32(XIII)(B)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Bulk Water for Bottled Water Plants | | | | |
| B112 - Bulk water source approved, bulk water transported and handled in an approved manner [R.61-32(IX)(C)(1)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B113 - Means and transportation of bulk water is approved. Bulk tanks, hoses, pumps, and connections are sanitized. Source water treated with a disinfectant prior to transportation [R.61-32(IX)(C)(2)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B114 - Tank are sealed except during operation or cleaning; Cleaning and sanitizing records are maintained; Pumps, hoses, etc. are capped and protected from contamination when not used; Manhole is not used to fill tank [R.61-32(IX)(C)(3)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B115 - Water contact surfaces are smooth, impervious, nonabsorbent, corrosion resistant, and nontoxic [R.61-32(IX)(C)(4)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B116 - Bulk water is not dispensed to consumers directly [R.61-32(IX)(C)(5)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Returnable Containers and Container Closures | | | | |
| B117 - Returnable containers properly washed, rinsed, and sanitized by an approved method [R.61-32(IX)(D)(1)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B118 - Metal and glass containers shall be exposed to a minimum of 3% alkali solution for no less than 5 minutes at a temperature no less than 130°F [R61-32(IX)(D)(2)(a)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B119 - Metal and glass containers shall be rinsed of all caustic soda with potable water [R61-32(IX)(D)(2)(b)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B120 - Polycarbonate containers are cleaned with approved non-caustic detergents at proper concentrations [R61-32(IX)(D)(3)(a)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B121 - A sanitizing rinse with appropriate chemicals using approved temperature/time/concentration follow the cleaning cycle for polycarbonate containers [R61-32(IX)(D)(3)(b)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B122 - Returnable container washer records properly maintained [R.61-32(IX)(D)(4)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B123 - Single-service containers are safe, manufactured from food-grade materials [R.61-32(IX)(E)(1)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B124 - Single-service containers are properly packaged and stored prior to filling [R.61-32(IX)(E)(2)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B125 - Single-service containers are inverted, rinsed, and treated by filtered compressed air or vacuumed [R.61-32(IX)(E)(3)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B126 - Returnable containers properly inspected prior to filling [R.61-32(IX)(F)(1)(a)] & [R.61-32(IX)(F)(2)(a)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B127 - Defective returnable bottles destroyed; destruction of bottles conducted in an approved manner [R.61-32(IX)(F)(1)(b)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B128 - Electronic inspectors operating properly; Inspectors periodically rotated to non-inspection work [R.61-32(IX)(F)(1)(c)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B129 - Returnable bottles of proper design for easy inspection [R.61-32(IX)(F)(1)(d)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B130 - Unclean metal canisters are returned to the washer or moved to a storage area for unclean canisters [R61-32(IX)(F)(2)(b)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B131 - Container closures safe, manufactured from food-grade materials, not reused [R.61-32(IX)(G)(1)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B132 - Container closures properly packaged and stored prior to use [R61-32(IX)(G)(2-3)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B133 - Contaminated container closures discarded [R61-32(IX)(G)(3)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B134 - Unused container closures are resealed in their original container or stored in an approved container [R61-32(IX)(G)(4)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B135 - Only new container closures shall be used [R61-32(IX)(G)(5)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Filling and Sealing | | | | |
| B136 - Containers shall be filled and sealed by approved mechanical equipment [R61-32(IX)(H)(1)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B137 - Filling equipment has shields for glass; machinery is stopped and cleaned when glass breaks [R61-32(IX)(H)(2)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B138 - No person or clothing comes into contact with the container or equipment during operations [R61-32(IX)(H)(3)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B139 - Imperfectly sealed containers and their contents are discarded [R61-32(IX)(H)(4)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| SOUTH CAROLINA REGULATION 61-36 | | | | |
| B140 - Each cheese type must meet the standards and limits applicable to it under 21 CFR 133 Subpart B [R.61-36(VII)(A)(2)(e)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B141 - Manufactured grade dairy products are labeled according to the requirements in 21 CFR 101 [R.61-36(IV)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| B142 - Developed and maintained procedures to notify regulatory officials, consumers, and for a product recall [R.61-36(XII)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Hazard Analysis and Risk-Based Preventive Controls - 21 CFR Part 117, Subpart C | IN | OUT | NA | CV |
| FOOD SAFETY PLAN | | | | |
| C1 - Requirement for a food safety plan [§117.126(a)(1-2)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C2 - Contents of a food safety plan [§117.126(b)(1-7)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C3 - Records [§117.126(c)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C4 - Additional requirements applying to the food safety plan [§117.310] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| HAZARD ANALYSIS | | | | |
| C5 - Requirement for a hazard analysis [§117.130(a)(1-2)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C6 - Hazard identification [§117.130(b)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C7 - Hazard evaluation [§117.130(c)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| PREVENTIVE CONTROLS | | | | |
| C8 - Identify and implement preventive controls [§117.135(a)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C9 - Written [§117.135(b)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C10 - Process controls [§117.135(c)(1)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

| Hazard Analysis and Risk-Based Preventive Controls - 21 CFR Part 117, Subpart C | IN | OUT | NA | CV |
|---|-------------------------------------|--------------------------|--------------------------|--------------------------|
| C11 - Food allergen controls [§117.135(c)(2)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C12 - Sanitation controls [§117.135(c)(3)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C13 - Supply-chain controls [§117.135(c)(4)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C14 - Other controls [§117.135(c)(6)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| PROCESS PREVENTIVE CONTROLS & MANAGEMENT COMPONENTS | | | | |
| C15 - Identify (Written) [§117.135(a)(1), §117.135(b), §117.170(d)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C16 - Appropriate (Adequate) [§117.135(c)(1), §117.145(a-b), §117.150(a), §117.165(b), §117.170(d)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C17 - Implement [§117.135(a)(1), §117.145(a), §117.150(a), §117.165(b)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C18 - Record review [§117.165(a)(4)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C19 - Validation [§117.160(a), §117.160(b)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C20 - Implementation records [§117.190(a), §117.145(c)(1), §117.150(d), §117.155(b)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| ALLERGEN PREVENTIVE CONTROLS & MANAGEMENT COMPONENTS | | | | |
| C21 - Identify (Written) [§117.135(a)(1), §117.135(b), §117.170(d)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C22 - Appropriate (Adequate) [§117.135(c)(2), §117.145(a-b), §117.150(a), §117.165(b), §117.170(d)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C23 - Implement [§117.135(a)(1), §117.145(a), §117.150(a), §117.165(b)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C24 - Record review [§117.165(a)(4)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C25 - Implementation records [§117.190(a), §117.145(c)(1), §117.150(d), §117.155(b)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| SANITATION PREVENTIVE CONTROLS & MANAGEMENT COMPONENTS | | | | |
| C26 - Identify (Written) [§117.135(a)(1), §117.135(b), §117.170(d)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C27 - Appropriate (Adequate) [§117.135(c)(3), §117.145(a-b), §117.150(a), §117.165(b), §117.170(d)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C28 - Implement [§117.135(a)(1), §117.145(a), §117.150(a), §117.165(b)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C29 - Record review [§117.165(a)(4)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C30 - Implementation records [§117.190(a), §117.145(c)(1), §117.150(d), §117.155(b)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| OTHER PREVENTIVE CONTROLS & MANAGEMENT COMPONENTS | | | | |
| C31 - Identify (Written) [§117.135(a)(1), §117.135(b), §117.170(d)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C32 - Appropriate (Adequate) [§117.135(c)(6), §117.145(a-b), §117.150(a), §117.165(b), §117.170(d)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C33 - Implement [§117.135(a)(1), §117.145(a), §117.150(a), §117.165(b)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C34 - Record review [§117.165(a)(4)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C35 - Implementation records [§117.190(a), §117.145(c)(1), §117.150(d), §117.155(b)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| RECALL PLAN | | | | |
| C36 - Written [§117.139(a)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C37 - Procedures and Responsibility [§117.139(b)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| SUPPLY CHAIN PREVENTIVE CONTROLS & MANAGEMENT COMPONENTS | | | | |
| C38 - Corrective actions and corrections in accordance with §117.150 [§117.140(b)(1)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C39 - Review of records in accordance with §117.65(a)(4) [§117.140(b)(2)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C40 - Reanalysis in accordance with §117.170 [§117.140(b)(3)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| CORRECTIVE ACTIONS AND CORRECTIONS | | | | |
| C41 - Corrective action in the event of an unanticipated food safety problem [§117.150(b)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C42 - Corrections [§117.150(c)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| VERIFICATION | | | | |
| C43 - Verification activities [§117.155(a)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| REANALYSIS | | | | |
| C44 - Reanalysis frequency [§117.170(a)-(c)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| C45 - Reanalysis done by PCQI [§117.170(e)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| REQUIREMENTS APPLICABLE TO A PREVENTIVE CONTROLS INDIVIDUAL AND A QUALIFIED AUDITOR | | | | |
| C46 - PCQI training records [§117.180(d)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

| Modified Requirements - 21 CFR Part 117, Subpart D | IN | OUT | NA | CV |
|--|-------------------------------------|--------------------------|--------------------------|--------------------------|
| MODIFIED REQUIREMENTS THAT APPLY TO A QUALIFIED FACILITY | | | | |
| D1 - Attestations to be submitted [§117.201(a)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| D2 - Frequency of determination of status and submission [§117.201(c)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| D3 - Notification to consumers [§117.201(e)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| D4 - Records [§117.201(f)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| MODIFIED REQUIREMENTS THAT APPLY TO A FACILITY SOLELY ENGAGED IN THE STORAGE OF UNEXPOSED PACKAGED FOOD | | | | |
| D5 - Implementation of temperature controls [§117.206(a)(1-4)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| D6 - Records [§117.206(a)(5)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

| Requirements Applying to Records that Must be Established and Maintained - 21 CFR Part 117, Subpart F | IN | OUT | NA | CV |
|---|-------------------------------------|--------------------------|--------------------------|--------------------------|
| F1 - General requirements applying to records [§117.305] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| F2 - Requirements for record retention [§117.315] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| F3 - Requirements for official review [§117.320] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

| Supply-Chain Program - 21 CFR Part 117, Subpart G | IN | OUT | NA | CV |
|---|-------------------------------------|--------------------------|--------------------------|--------------------------|
| G1 - Establish and Implement [117.405(a), 117.405(b), 117.405(c)(1)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| G2 - Supply-chain assurance [§117.410(c)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| G3 - Supplier approval [§117.415(a)(1), 117.420(a)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| G4 - Written procedures for receiving raw materials and other ingredients [§117.420(b)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| G5 - Conducting supplier verification activities for raw materials and other ingredients [§117.430] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| G6 - Records [§117.475(c), 117.405(c)(2), 117.420(a), 117.415(a)(2), 117.420(b)(3)] | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

| Remarks |
|---|
| <p style="font-size: 100px; opacity: 0.5; transform: rotate(-45deg);">DRAFT</p> |

DRAFT

DHEC Inspector Name

DHEC Inspector Signature

Phone Number

Name of Person in Charge at Facility

Facility's Person in Charge Signature

Phone Number or E-Mail

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
DHEC FORM 4405

Instructions for Completing

1. Provide the firm's legal name and DBA/New Business Name if applicable.
2. Mark the appropriate box(es) for the type of facility.
3. Provide the facilities FEI and Permit Number.
4. Provide the establishment's physical address, including the city and zip code.
5. Provide the firm's phone number and email address.
6. Provide the Top Management Official's Name/Title and their phone number.
7. Provide the number of employees at facility location broken down by:
 - Full Time, Part Time, Seasonal/Temporary.
8. Provide the Percent of product sales broken down by:
 - Wholesale, Retail, Interstate Incoming, Interstate outgoing
9. Provide the facility gross annual food sales.
10. Provide corporate information, which includes name of corporate entity, corporate phone number, physical address (including city and zip code), number of employees, and gross annual food sales.
11. Provide inspection information, which includes inspection type, start date of inspection, start time of inspection, and follow up details.
12. Mark the appropriate boxes for biosecurity/bioterrorism act and documentation.
13. Provide the Product Code Information for products being made during the inspection.
14. Mark the appropriate boxes for the 21 CFR 117 Subparts that are applicable based on the facility type and leave comments if necessary.
15. Check IN or OUT, and if necessary CV, for observations during the inspection. Depending on the facility type inspected, NA may also be appropriate
 - IN = In Conformance
 - OUT = Out of Conformance
 - CV = Consecutive Violation
 - NA = Not Applicable
16. Provide remarks if needed.
17. Provide inspector printed name, inspector signature, and DHEC phone number (including area code).
18. Form should be signed by the owner/representative. Include the printed name of the owner/representative and the phone number or email to contact them.
19. Provide end date of inspection and end time of inspection on first page.

Retention schedule for this form is: 11697- Dairy/Soft Drink Facility File.