



PREVENTIVE CONTROLS FOR HUMAN FOOD FOOD FACILITY TYPE AND APPLICABLE REGULATIONS TABLE

| FOOD FACILITY TYPE | APPLICABLE REGULATIONS |
|---|--|
| Food facility not qualifying for any exemption under 117 | 117 Subpart A (117.4 Qualified Individual training) 117 Subpart B (GMPs) 117 Subpart C (Preventive Controls) 117 Subpart F (Recordkeeping) 117 Subpart G (Supply-Chain) |
| Qualified Facility (QF) - very small business averaging less than \$1 million sales of human food per year during three-year period. Adjusted for inflation. Includes subsidiaries and affiliates. Must submit attestation to FDA per modified requirements outlined in subpart D 117.201 | 117 Subpart A (117.4 Qualified Individual training) 117 Subpart B (GMPs) 117 Subpart D (117.201 modified requirements for QF) 117 Subpart E (Withdrawal of QF exemption) 117 Subpart F (Qualified Individual training records) |
| Warehouse solely storing unexposed packaged food. If such a warehouse is storing unexposed packaged food that is refrigerated for safety, then Subpart D also applies. | 117 Subpart A (117.4 Qualified Individual training) 117 Subpart B (GMPs) 117 Subpart D (117.206 modified requirements for unexposed packaged food refrigerated for safety) 117 Subpart F (Qualified Individual training records) |
| Facility solely engaged in storage of raw agricultural commodities (RAC) intended for further distribution or processing (e.g. grain elevators) Exempt from 117. See next column→ (NOTE: Exemption from 117 does not apply to facility storing RAC fruits and vegetables.) | FD & C Act 117.5(k)(1)(iii) Exemption from Subpart B (GMPs) 117.5(j) Exemption from Subpart C (preventive controls) and Subpart G (supply-chain) Not subject to Subpart A 117.4 (Qualified Individual Training) and Subpart F (QI training records) because of the exemptions from subparts B, C, and G |
| Facility solely engaged in storage of RAC fruits and vegetables (e.g. produce warehouse) Off-farm packaging, packing, and holding of RAC produce (e.g. packing house) Any on-farm activities subject to the Produce Rule (21 CFR Part 112) are exempt from 117. | 117 Subpart A (117.4 Qualified Individual training) 117 Subpart B (GMPs)* 117 Subpart C (Preventive Controls) 117 Subpart F (Recordkeeping) 117 Subpart G (Supply-Chain) *Either 117 subpart B (GMPs) or applicable requirements for packing and holding RAC produce in 21CFR 112 (produce rule) can be used at off-farm facility (packing house) |



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| <p>Farm mixed-type facility: establishment that engages in both activities that are exempt from food facility registration (e.g. a farm) and activities that require the establishment to be registered (e.g. a food manufacturer).</p> <p>A farm mixed-type facility is exempt from Subpart C (preventive controls) and Subpart G (supply-chain) depending on the size of the operation and the products.</p> <p>See next column →</p> | <p>117 Subpart A (117.4 Qualified Individual training) 117 Subpart B (GMPs) 117 Subpart F (Qualified Individual training records)</p> <p>117.5(g)(3) lists 23 low-risk packing or holding activity/food combinations that are exempt from subparts C and G on a farm-mixed type facility that is a small or very small business</p> <p>117.5(g)(4) lists 27 low-risk manufacturing/ processing activity/food combinations that are exempt from subparts C and G on a farm-mixed type facility that is a small or very small business</p> <p>*Farm-mixed type facility loses exemption from Subparts C and G if it manufactures, processes, packs or holds any food product which is not identified as low-risk in 117.5(g)(3) and (h)(3) or if facility is a large business</p> |
| <p>Seafood processor</p> | <p>117 Subpart A (117.4 Qualified Individual training) 117 Subpart B (GMPs) 117 Subpart F (Qualified Individual training records) 123 Seafood HACCP Regulation</p> |
| <p>Juice Processor</p> | <p>117 Subpart A (117.4 Qualified Individual training) 117 Subpart B (GMPs) 117 Subpart F (Qualified Individual training records) 120 Juice HACCP Regulation</p> |
| <p>Low-Acid Canned Food (LACF) Processor</p> <p>Control of microbiological hazards such as <i>C. botulinum</i> are covered by 113 LACF regulation. Control of chemical hazards, physical hazards, and pathogenic heat-stable toxin formation that could occur before LACF thermal process (<i>S. aureus</i>, <i>B. cereus</i>) are covered by 117 preventive controls.</p> | <p>117 Subpart A (117.4 Qualified Individual training) 117 Subpart B (GMPs) 117 Subpart C (for all hazards except microbiological hazards covered by thermal process) 117 Subpart F (Recordkeeping) 117 Subpart G (Supply-Chain) 108.35 Thermal Processing of low-acid foods packaged in hermetically sealed containers 113 LACF Regulation (for microbiological hazards covered by thermal process)</p> |



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| <p>Acidified Food Processor</p> <p>All hazards, including microbiological hazards, must be controlled as part of the facility's food safety plan subject to 117 subparts C and G</p> | <p>117 Subpart A (117.4 Qualified Individual training) 117 Subpart B (GMPs) 117 Subpart C (Preventive Controls) 117 Subpart F (Recordkeeping) 117 Subpart G (Supply-Chain) 108.25 Acidified Foods 114 Acidified Food Regulation</p> |
| <p>Bottled Water</p> | <p>117 Subpart A (117.4 Qualified Individual training) 117 Subpart B (GMPs) 117 Subpart C (Preventive Controls) 117 Subpart F (Recordkeeping) 117 Subpart G (Supply-Chain) 129 Bottled Water Regulation 165.110 Bottled Water Standards</p> |
| <p>Infant Formula</p> | <p>117 Subpart A (117.4 Qualified Individual training) 117 Subpart B (GMPs) 117 Subpart C (Preventive Controls) 117 Subpart F (Recordkeeping) 117 Subpart G (Supply-Chain) 106 Infant Formula Regulation 107 Infant Formula Requirements</p> |
| <p>Alcoholic Beverages</p> <p>117.5(i)(1) exempts alcoholic beverages from 117 subparts C & G if they are at a facility required to register under the BT Act and obtain permits from Department of Treasury</p> | <p>117 Subpart A (117.4 Qualified Individual training) 117 Subpart B (GMPs) 117 Subpart F (Qualified Individual training records)</p> |
| <p>Interstate Travel Facilities</p> <p>If an interstate travel facility is required to register as a food facility under the BT Act then it is subject to 117 (e.g. airline caterers)</p> <p>If it meets definition of retail establishment then it does not have to register and is not subject to 117</p> | <p>117 Subpart A (117.4 Qualified Individual training) 117 Subpart B (GMPs) 117 Subpart C (Preventive Controls) 117 Subpart F (Recordkeeping) 117 Subpart G (Supply-Chain)</p> |



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| <p>Eggs (Shell eggs are raw agricultural commodity)</p> <p>Exemptions from 117. See next column→</p> | <p>118 Production, Storage, and Transportation of Shell Eggs</p> <p>Farms (e.g. on-farm production of shell eggs and egg packing houses within “farm” definition) are exempt from registration thus exempt from subpart C (preventive controls) and subpart G (supply-chain)</p> <p>117.5(k)(1)(i): Farms are exempt from subpart B GMPs</p> <p>117.5(k)(1)(iii): Establishments solely engaged in holding or transportation of shell eggs (RAC) are exempt from subpart B GMPs</p> <p>117.5(j): Facilities solely engaged in storage of shell eggs (RAC) intended for further distribution or processing are exempt from subpart C (preventive controls) and subpart G (supply-chain)</p> <p>Not subject to Subpart A 117.4 (Qualified Individual Training) and Subpart F (QI training records) because of the exemptions from subparts B, C, and G</p> |
| <p>Dietary Supplements</p> <p>117.5(e) exempts facilities manufacturing, processing, packing or holding dietary supplements in compliance with 21 CFR 111 from 117 subparts C (preventive controls) and G (supply-chain)</p> <p>*Firms that make dietary supplement ingredients will need to comply with full Part 117</p> | <p>117 Subpart A (117.4 Qualified Individual training beyond what is in 111 regarding personnel qualification requirements)</p> <p>117 Subpart B (GMPs)</p> <p>*When a requirement in 117 subpart B GMPs is not specified in 21 CFR Part 111 because it is an uncommon occurrence for dietary supplements, then the requirement in 117 subpart B will apply to dietary supplements.</p> <p>111 Dietary Supplement Regulation</p> |