

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 21 CFR Part 117	117 subpart A (§117.4 Qualifications of Individuals) 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, including subsidiaries and affiliates. <u>Notes</u> Exemptions from 117 subparts C and G §117.5(a) Must submit attestation to FDA per modified requirements outlined in subpart D §117.201	117 subpart A (§117.4 Qualifications of Individuals) 117 subpart B (GMPs) 117 subpart D (§117.201 modified requirements for QF) 117 subpart E (Withdrawal of QF exemption) 117 subpart F (Food safety and food hygiene training records)
Warehouse solely storing unexposed packaged food <u>Notes</u> Exemptions from 117 subparts C and G §117.7 If such a warehouse is storing unexposed packaged food that is refrigerated for safety, then subpart D also applies.	117 subpart A (§117.4 Qualifications of Individuals) 117 subpart B (GMPs) 117 subpart D (§117.206 modified requirements for unexposed packaged food refrigerated for safety) 117 subpart F (Food safety and food hygiene training records)
Facility solely engaged in storage of raw agricultural commodities (RAC) intended for further distribution or processing (e.g., grain elevators). <u>Notes</u> Exemptions from 21 CFR Part 117 §117.5(k)(1)(iii) Exemption from subpart B (GMPs) §117.5(j) Exemption from subpart C (preventive controls) and subpart G (supply-chain) if RACs are <u>not</u> fruits or vegetables Not subject to subpart A §117.4 (Qualifications of Individuals) and subpart F (Food safety and food hygiene training records) because of the exemptions from subparts B, C, and G.	FD&C Act

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Facility solely engaged in storage of RAC fruits and vegetables (e.g., produce warehouse). <u>Notes</u> Exempt from 117 subpart B § 117.5(k)(1)(iii) Exemption from subpart B (GMPs) Enforcement discretion from PC requirements - Enforcement discretion policy of January 2018 Not subject to § 117.4 (Qualifications of Individuals) and subpart F (Food safety and food hygiene training records) because of the exemptions from subpart B and the enforcement discretion from subparts C and G.	FD&C Act
Off-farm packaging, packing, and holding of RAC produce (e.g., packing house) <u>Notes</u> Enforcement discretion from PC requirements Enforcement discretion policy of January 2018 § 117.8 Applicability of subpart B	117 subpart A (§ 117.4 Qualifications of Individuals) 117 subpart B (GMPs)* 117 subpart F (Recordkeeping) *Either 117 subpart B (GMPs) or applicable requirements for packing and holding RAC produce in 21 CFR Part 112 (produce rule)
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). <u>Notes</u> Small and very small farm mixed-type facility are exempt from subpart C (preventive controls) and subpart G (supply-chain) if they only perform certain activities on certain products. Exemption from 117 subparts C and G for small or very small farm mixed-type facilities: § 117.5(g)(3) lists the 23 low-risk packing or holding activity/food combinations § 117.5(h)(3) lists the 27 low-risk manufacturing/processing activity/food combinations	117 subpart A (§ 117.4 Qualifications of Individuals) 117 subpart B (GMPs) 117 subpart C (preventive controls) 117 subpart F (Recordkeeping) 117 subpart G (Supply-Chain) If farm mixed-type facility is a small or very small business and does only activity/food combinations listed as low-risk under § 117.5(g)(3) or (h)(3), then the following apply: 117 subpart A (§ 117.4 Qualifications of Individuals) 117 subpart B (GMPs) 117 subpart F (Food safety and food hygiene training records)
Seafood processor <u>Notes</u> Exemption from 117 subparts C and G § 117.5(b)	117 subpart A (§ 117.4 Qualifications of Individuals) 117 subpart B (GMPs) 117 subpart F (Food safety and food hygiene training records) 21 CFR Part 123 Seafood HACCP Regulation

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Juice Processor <u>Notes</u> Exemption from 117 Subparts C and G §117.5(c)	117 subpart A (§117.4 Qualifications of Individuals) 117 subpart B (GMPs) 117 subpart F (Food safety and food hygiene training records) 21 CFR Part 120 Juice HACCP Regulation
Low-Acid Canned Food (LACF) Processor <u>Notes</u> Exemption from 117 subparts C and G §117.5(d) Control of microbiological hazards such as <i>C. botulinum</i> are covered by 21 CFR Part 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 21 CFR Part 117.	117 subpart A (§117.4 Qualifications of Individuals) 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 21 CFR Part 113 LACF Regulation (for microbiological hazards covered by thermal process)
Acidified Food Processor <u>Notes</u> All hazards, including microbiological hazards, must be controlled as part of the facility's food safety plan subject to 117 Subparts C and G.	117 subpart A (§117.4 Qualifications of Individuals) 117 subpart B (GMPs) 117 subpart C (Preventive Controls) 117 subpart F (Recordkeeping) 117 subpart G (Supply-Chain) §108.25 Acidified Foods 21 CFR Part 114 Acidified Food Regulation
Bottled Water	117 subpart A (§117.4 Qualifications of Individuals) 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
Infant Formula	117 subpart A (§117.4 Qualifications of Individuals) 117 subpart B (GMPs) 117 subpart C (Preventive Controls) 117 subpart F (Recordkeeping) 117 subpart G (Supply-Chain) 21 CFR Part 106 Infant Formula Requirements 21 CFR Part 107 Infant Formula Regulation

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Alcoholic Beverages <u>Notes</u> Exemptions from subparts C and G §117.5(i)(1) exempts alcoholic beverages if they are at a facility required to register under the BT Act and obtain permits from Department of Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) §117.5(i)(2) exempts prepackaged food at such a facility if ≤ 5% of the overall sales of the facility	117 subpart A (§117.4 Qualifications of Individuals) 117 subpart B (GMPs) 117 subpart F (Food safety and food hygiene training records)
Interstate Travel Facilities <u>Notes</u> If an interstate travel facility is required to register as a food facility under the BT Act, then it is subject to 21 CFR Part 117 (e.g., airline caterers). If it meets definition of retail establishment then it does not have to register and is not subject to 21 CFR Part 117.	If an interstate travel facility is required to register as a food facility under the BT Act (e.g., airline caterers, commissaries that also manufacture ice): 117 subpart A (§117.4 Qualifications of Individuals) 117 subpart B (GMPs) 117 subpart C (Preventive Controls) 117 subpart F (Recordkeeping) 117 subpart G (Supply-Chain) Commissaries solely engaged in the storage of unexposed packaged food, some of which requires refrigeration for safety: 117 subpart A (§117.4 Qualifications of Individuals) 117 subpart B (GMPs) 117 subpart D (§117.206 Modified requirements) 117 subpart F (Recordkeeping) Commissaries solely engaged in the storage of unexposed packaged food that does not require refrigeration for safety: 117 subpart A (§117.4 Qualifications of Individuals) 117 subpart B (GMPs) 117 subpart F (Food safety and food hygiene training records)

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Eggs (Shell eggs are raw agricultural commodity) <u>Notes</u> 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 program) § 117.5(k)(1)(i): Farms are exempt from subpart B GMPs Off-farm egg warehouse § 117.5(k)(1)(iii): Establishments solely engaged in holding or transportation of shell eggs (RAC) are exempt from subpart B GMPs § 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) Not subject to subpart A (§ 117.4 Qualifications of Individuals) and subpart F (Food safety and food hygiene training records) because of the exemptions from subparts B, C, and G.	21 CFR Part 118 Production, Storage, and Transportation of Shell Eggs
Dietary Supplements <u>Notes</u> Exemption from 117 subparts C and G § 117.5(e) exempts facilities manufacturing, processing, packing, or holding dietary supplements in compliance with 21 CFR Part 111 from Part 117 subparts C (preventive controls) and G (supply-chain) Facilities that make <u>dietary ingredients</u> will need to comply with all of 21 CFR Part 117 unless another exemption applies.	117 subpart A (§ 117.4 Qualifications of Individuals beyond what is in 111 regarding personnel qualification requirements) 117 subpart B (GMPs)* 117 subpart F (Food safety and food hygiene training records) *When a requirement in Part 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.