

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

FOOD FACILITY TYPE	APPLICABLE REGULATIONS
<p>Food facility not qualifying for any exemption under 21 CFR Part 117.</p>	<p>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)</p>
<p>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.</p> <p><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</p>	<p>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)</p>
<p>Warehouse solely storing unexposed packaged food.</p> <p><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.</p>	<p>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)</p>
<p>Facility solely engaged in storage of raw agricultural commodities (RAC) intended for further distribution or processing (e.g., grain elevators).</p> <p><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.</p>	<p>FD&amp;C Act</p>

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<p>Facility solely engaged in storage of RAC fruits and vegetables (e.g., produce warehouse).</p> <p><u>Notes</u></p> <p>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.</p>	<p>FD&amp;C Act</p>
<p>Off-farm packaging, packing, and holding of RAC produce (e.g., packing house).</p> <p><u>Notes</u></p> <p>Enforcement discretion from PC requirements Enforcement discretion policy of January 2018 § 117.8 Applicability of subpart B</p>	<p>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)</p>
<p><b>Farm mixed-type facility:</b> 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><u>Notes</u></p> <p>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</p>	<p>If farm mixed-type facility is a large business OR does any activity/food combination <u>not</u> 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 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)</p>
<p><b>Seafood processor</b></p> <p><u>Notes</u></p> <p>Exemption from 117 subparts C and G § 117.5(b)</p>	<p>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</p>



FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

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<p><b>Juice Processor</b></p> <p><u>Notes</u> Exemption from 117 subparts C and G §117.5(c)</p>	<p>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</p>
<p><b>Low-Acid Canned Food (LACF) Processor</b></p> <p><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.</p>	<p>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)</p>
<p><b>Acidified Food Processor</b></p> <p><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.</p>	<p>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</p>
<p><b>Bottled Water</b></p>	<p>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</p>
<p><b>Infant Formula</b></p>	<p>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</p>

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<p><b>Alcoholic Beverages</b></p> <p><u>Notes</u></p> <p>Exemptions from subparts C and G</p> <p>§ 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)</p> <p>§ 117.5(i)(2) exempts prepackaged food at such a facility if ≤ 5% of the overall sales of the facility</p>	<p>117 subpart A (§ 117.4 Qualifications of Individuals)</p> <p>117 subpart B (GMPs)</p> <p>117 subpart F (Food safety and food hygiene training records)</p>
<p><b>Interstate Travel Facilities</b></p> <p><u>Notes</u></p> <p>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).</p> <p>If it meets definition of retail establishment then it does not have to register and is not subject to 21 CFR Part 117.</p>	<p><b>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):</b></p> <p>117 subpart A (§ 117.4 Qualifications of Individuals)</p> <p>117 subpart B (GMPs)</p> <p>117 subpart C (Preventive Controls)</p> <p>117 subpart F (Recordkeeping)</p> <p>117 subpart G (Supply-Chain)</p> <p><b>Commissaries solely engaged in the storage of unexposed packaged food, some of which requires refrigeration for safety:</b></p> <p>117 subpart A (§ 117.4 Qualifications of Individuals)</p> <p>117 subpart B (GMPs)</p> <p>117 subpart D (§ 117.206 Modified requirements)</p> <p>117 subpart F (Recordkeeping)</p> <p><b>Commissaries solely engaged in the storage of unexposed packaged food that does not require refrigeration for safety:</b></p> <p>117 subpart A (§ 117.4 Qualifications of Individuals)</p> <p>117 subpart B (GMPs)</p> <p>117 subpart F (Food safety and food hygiene training records)</p>

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<p><b>Eggs</b> (Shell eggs are raw agricultural commodity)</p> <p><u>Notes</u></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 program)</p> <p>§117.5(k)(1)(i): Farms are exempt from subpart B GMPs Off-farm egg warehouse</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 Qualifications of Individuals) and subpart F (Food safety and food hygiene training records) because of the exemptions from subparts B, C, and G.</p>	<p>21 CFR Part 118 Production, Storage, and Transportation of Shell Eggs</p>
<p><b>Dietary Supplements</b></p> <p><u>Notes</u></p> <p>Exemption from 117 subparts C and G</p> <p>§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)</p> <p>Facilities that make <u>dietary ingredients</u> will need to comply with all of 21 CFR Part 117 unless another exemption applies.</p>	<p>117 subpart A (§117.4 Qualifications of Individuals beyond what is in 111 regarding personnel qualification requirements)</p> <p>117 subpart B (GMPs)*</p> <p>117 subpart F (Food safety and food hygiene training records)</p> <p>*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.</p>