



FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

# 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 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></p> <p>Exemptions from 117 Subparts C and G</p> <ul style="list-style-type: none"> <li>• 117.5(a)</li> </ul> <p>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></p> <p>Exemptions from 117 Subparts C and G</p> <ul style="list-style-type: none"> <li>• 117.7</li> </ul> <p>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></p> <p>Exemptions from 117</p> <ul style="list-style-type: none"> <li>• 117.5(k)(1)(iii) Exemption from Subpart B (GMPs)</li> <li>• 117.5(j) Exemption from Subpart C (preventive controls) and Subpart G (supply-chain) if RACs are <u>not</u> fruits or vegetables</li> </ul> <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>FD&amp;C Act</p>

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

FOOD FACILITY TYPE	APPLICABLE REGULATIONS
<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</p> <ul style="list-style-type: none"> <li>117.5(k)(1)(iii) Exemption from Subpart B (GMPs)</li> </ul> <p>Enforcement discretion from PC requirements</p> <ul style="list-style-type: none"> <li>Enforcement discretion policy of January 2018</li> </ul> <p>Not subject to 117.4 (Qualifications of Individuals) and Subpart F (Food safety and food hygiene training records) because of the exemptions from subparts 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</p> <ul style="list-style-type: none"> <li>Enforcement discretion policy of January 2018</li> </ul> <p>117.8 Applicability of subpart B</p>	<p>117 Subpart A (117.4 Qualifications of Individuals) 117 Subpart B (GMPs)*</p> <p>117 Subpart F (Recordkeeping)</p> <p>*Either 117 subpart B (GMPs) or applicable requirements for packing and holding RAC produce in 21 CFR 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.</p> <p>Exemption from 117 Subparts C and G for small or very small farm mixed-type facilities:</p> <ul style="list-style-type: none"> <li>117.5(g)(3) lists the 23 low-risk packing or holding activity/food combinations</li> <li>117.5(h)(3) lists the 27 low-risk manufacturing/processing activity/food combinations</li> </ul>	<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:</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>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:</p> <p>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</p> <ul style="list-style-type: none"> <li>117.5(b)</li> </ul>	<p>117 Subpart A (117.4 Qualifications of Individuals) 117 Subpart B (GMPs) 117 Subpart F (Food safety and food hygiene training records) 123 Seafood HACCP Regulation</p>



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

FOOD FACILITY TYPE	APPLICABLE REGULATIONS
<p><b>Juice Processor</b></p> <p><u>Notes</u></p> <p>Exemption from 117 Subparts C and G</p> <ul style="list-style-type: none"> <li>• 117.5(c)</li> </ul>	<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>120 Juice HACCP Regulation</p>
<p><b>Low-Acid Canned Food (LACF) Processor</b></p> <p><u>Notes</u></p> <p>Exemption from 117 Subparts C and G</p> <ul style="list-style-type: none"> <li>• 117.5(d)</li> </ul> <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 Qualifications of Individuals)</p> <p>117 Subpart B (GMPs)</p> <p>117 Subpart C (for all hazards except microbiological hazards covered by thermal process)</p> <p>117 Subpart F (Recordkeeping)</p> <p>117 Subpart G (Supply-Chain)</p> <p>108.35 Thermal Processing of low-acid foods packaged in hermetically sealed containers</p> <p>113 LACF Regulation (for microbiological hazards covered by thermal process)</p>
<p><b>Acidified Food Processor</b></p> <p><u>Notes</u></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 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>108.25 Acidified Foods</p> <p>114 Acidified Food Regulation</p>
<p><b>Bottled Water</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>129 Bottled Water Regulation</p> <p>165.110 Bottled Water Standards</p>
<p><b>Infant Formula</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>106 Infant Formula Regulation</p> <p>107 Infant Formula Requirements</p>

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

FOOD FACILITY TYPE	APPLICABLE REGULATIONS
<p><b>Alcoholic Beverages</b></p> <p><u>Notes</u></p> <p>Exemptions from Subparts C and G</p> <ul style="list-style-type: none"> <li>• 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)</li> <li>• 117.5(i)(2) exempts prepackaged food at such a facility if ≤ 5% of the overall sales of the facility</li> </ul>	<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 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><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>

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

FOOD FACILITY TYPE	APPLICABLE REGULATIONS
<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> <ul style="list-style-type: none"> <li>• 117.5(k)(1)(i): Farms are exempt from subpart B GMPs</li> </ul> <p>Off-farm egg warehouse</p> <ul style="list-style-type: none"> <li>• 117.5(k)(1)(iii): Establishments solely engaged in holding or transportation of shell eggs (RAC) are exempt from subpart B GMPs</li> <li>• 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)</li> </ul> <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>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> <ul style="list-style-type: none"> <li>• 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)</li> </ul> <p>Facilities that make <u>dietary ingredients</u> will need to comply with all of 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 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>