



GOOD MANUFACTURING PRACTICES (GMPS) AND PREVENTIVE CONTROLS FOR HUMAN FOOD CONSUMER PROTECTION CRITERIA

The following list of criteria is based on Chapter 69.04 RCW (Revised Code of Washington) Intrastate Commerce in Food, Drugs, and Cosmetics; RCW 15.130 Food Safety & Security; and Title 21 CFR (Code of Federal Regulations) Part 101 Food Labeling; Part 117 Current Good Manufacturing Practice, Hazard Analysis, and Risked-Based Preventive Controls for Human Foods (**GMP 117**); Chapter 15.36 RCW Milk and Milk Products, 16.25 RCW Wholesome Eggs and Egg Products; 16-165 WAC (Washington Administrative Code) Food Inspections; 16-167 WAC Intrastate Commerce in Food. Other adopted statutes may also appear as detailed.

Licensing: The facility must achieve a score of ninety points or higher on the pre-licensing inspection AND follow licensing (L) criteria.

Inspection: An establishment is considered in substantial compliance with the inspection criteria if: No critical (C) violations are found, or if critical violations are found and corrected prior to completion of the inspection; and the establishment's inspection score is ninety points or above. (WAC 16-165-110,150)

NO	CATEGORIES AND CRITERIA	DEBIT
PRODUCTS		
1	RCW 15.130 - CRITICAL - Food products free from adulteration. RCW 15.130.200	C/L
PERSONNEL		
2A	GMP 117 - CRITICAL - Persons with apparent infections or communicable diseases properly restricted: 21 CFR, 117.10(a)	C/L
2B	GMP 117 - Jewelry, watches, other personal items not a source of contamination: 21 CFR, 117.10(b)(4)	1
2C	GMP 117 - Clean and adequate protective clothing and hair restraints: 21 CFR, 117.10(b)(1-2)(6)	1-2
2D	GMP 117 - Use of tobacco, eating and drinking of food and beverages and gum chewing restricted to appropriate areas: 21 CFR, 117.10(b)(8)	1
2E	GMP 117 - CRITICAL - Adequate washing and sanitizing of hands as necessary, gloves used in food handling of sanitary condition: 21 CFR, 117.10(b)(3)(5)	C/L
2F	GMP 117 - Garments and personal belongings stored appropriately, not a source of potential contamination: 21 CFR, 117.10(b)(7)	1-2
2G	GMP 117 - Employee work procedures preclude allergen cross-contact and contamination: 21 CFR, 117.10(b)(9)	1-2
9E	GMP 117 - Each individual engaged in manufacturing, processing, packing, or holding food receives training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the individual's assigned duties: 21 CFR, 117.4(b)	1
9G	GMP 117 - Record kept of required training of each individual engaged in manufacturing, processing, packing, or holding food: 21 CFR, 117.4(d), 117.301; 117.305; 117.315; 117.320; 117.330	1
GROUND'S - PLANT CONSTRUCTION & DESIGN		
3	GMP 117 - Grounds: Free from pest attractants, breeding places, harborage, excessive dust & other contaminants: 21 CFR, 117.20(a)	1
4A	GMP 117 - Suitable size & location, construction including walls, floors, ceiling, counters, shelving, other fixtures, smooth, readily cleanable and in good repair: 21 CFR, 117.20(b),(1)(4); 117.35(a)	1-5/L
4B	GMP 117 - Processes separated as required: 21 CFR, 117.20(b)(2)	1-2/L
4C	GMP 117 - No operations in domestic living or sleeping quarters (including domestic kitchens): 21 CFR, 117.20(b)(2)	L
4D	GMP 117 - Adequate light: 21 CFR, 117.20(b)(5)	1-2/L
4E	GMP 117 - Lights; glass over food protected, break proof: 21 CFR, 117.20(b)(5)	1
4F	GMP 117 - Adequate ventilation to minimize vapors, steam, noxious fumes: 21 CFR, 117.20(b)(6)	1-2/L
4G	GMP 117 - Drip or condensate from ceiling, fixtures, pipes ducts not a potential source of contamination: 21 CFR, 117.20(b)(4)	1-3
4H	GMP 117 - Screened or protected to exclude pests: 21 CFR, 117.20(b)(7)	1-2

SANITARY OPERATIONS		
5A	GMP 117 - Building, fixtures, facilities clean; including transport vehicles: 21 CFR, 117.35(a)	1-5/L
5B	GMP 117 - Cleaning operations conducted to minimize allergen cross-contact and contamination: 21 CFR 117.35(a)	1-3
5C	GMP 117 - Detergents, sanitizers, toxic materials safely used and stored: 21 CFR 117.35(b)(1)(2)	1-3
5D	GMP 117 - Detergents, sanitizers & toxic materials properly identified: 21 CFR, 117.35(b)(2)	1-2
5E	GMP 117 - CRITICAL - Product contact surfaces clean and maintained in a sanitary condition; cleaned and sanitized prior to each use or as essential: 21 CFR, 117.35(d),(2)(3); 117.80(c)(1)	C/L
5F	GMP 117 - NON-CRITICAL - Product contact surfaces clean and maintained in a sanitary condition; cleaned and sanitized prior to each use or as essential: 21 CFR, 117.35(d),(1)(3); 117.80(c)(1)	1-2
5G	GMP 117 - Non-product contact surfaces of equipment clean and maintained in a sanitary condition: 21 CFR, 117.35(e)	1-2
5H	GMP 117 - Suitable cleaning facilities provided and conveniently located: 21 CFR, 117.37	1-2/L
5I	GMP 117 - Cleaned and sanitized equipment properly stored: 21 CFR, 117.35(f)	1-2
5J	GMP 117 - CRITICAL - In use food contact equipment and utensils appropriately stored; protected from contamination between uses: 21 CFR, 117.35(f); 117.35(d)(2); WAC 16-165-130(11)	C
5K	GMP 117 - NON-CRITICAL - In use food contact equipment and utensils appropriately stored; protected from contamination between uses: 21 CFR, 117.35(f); 117.35(d)(1); 16-165-130(10)	1-2
PEST CONTROL		
6A	GMP 117 - Effective measures taken to exclude pests from the facility. No harborage/breeding areas: 21 CFR, 117.35(c)	1-2
6B	GMP 117 - Pesticides safely used and stored: 21 CFR, 117.35(c)	1-3
6C	GMP 117 - No evidence of rodents, insects, birds or other animals: 21 CFR, 117.35(c)	1-5/L
SANITARY FACILITIES AND CONTROL		
7A	GMP 117 - CRITICAL - Water used safe and of adequate sanitary quality; from approved source: 21 CFR, 117.37(a)	C/L
7B	GMP 117 - Current Satisfactory Water supply test: 21 CFR, 117.37(a); WAC 16-165-130(13)	5/L
7C	GMP 117 - Water supply sufficient in quantity for intended operations: 21 CFR, 117.37(a), (b)(1)	2/L
7D	GMP 117 - CRITICAL - No cross connections; no back-siphonage: 21 CFR, 117.37(b)(5); WAC 16-165-130(16)	C/L
7E	GMP 117 - CRITICAL - Ice from approved source: 21 CFR, 117.80(c)(16)	C/L
7F	GMP 117 - CRITICAL - Running water at suitable temperature, under pressure, in areas where foods are processed or equipment washed: 21 CFR, 117.37(a)	C/L

7G	GMP 117- Adequate floor drains and plumbing to convey wastes and sewage from plant: 21 CFR, 117.37(b)(2)(4); 117.37(c)	1-2/L
7H	GMP 117- Sewage and waste lines protected, not a source of contamination: 21 CFR, 117.37(b)(3)	1-2/L
7I	GMP 117- Adequate offal, rubbish and waste disposal. Proper holding and distribution of human food by-products for use as animal food: 21 CFR, 117.20(a)(4); 117.37(c)(f); 117.95	1-2/L
7J	GMP 117- CRITICAL - Adequate, readily accessible toilet facilities provided: 21 CFR, 117.37(d)	C/L
7K	GMP 117- Toilet facilities clean and not a potential source of contamination: 21 CFR, 117.37(d); WAC 16-165-130(19)	1-2/L
7L	GMP 117- CRITICAL - Toilet facilities not a potential source of contamination. No evidence of human defecation or urination about the premises: 21 CFR, 117.37(d)	C/L
7M	GMP 117- CRITICAL - Handwash facilities adequate and convenient, including running water at a suitable temperature: 21 CFR, 117.37(e)	C/L
7N	GMP 117- Soap and single service towels or suitable drying devices provided at hand-wash facilities. Adequate refuse receptacles provided: 21 CFR, 117.37(e)	1-2
7O	GMP 117- Readily understandable handwash signs provided at handwash facilities: 21 CFR, 117.37(e)	1
7P	GMP 117- Hand-dips provided as necessary: 21 CFR, 117.37(e); WAC 16-165-130(20)(21)	1-2
EQUIPMENT AND UTENSILS		
8A	GMP 117- Design, material & workmanship durable, readily cleanable and in good repair. Contact surfaces non-toxic & corrosion resistant: 21 CFR, 117.40(a)(1)(4)(5); 117.40(b)(c); 117.80(c)(7)	1-3/L
8B	GMP 117- Design & use preclude contamination with lubricants, fuel, contaminated water, paint, rust, compressed air/gas & other contaminants: 21 CFR, 117.40(a)(2)(6); 117.40(g)	1-3
8C	GMP 117- Freezers and cold storage units equipped with adequate thermometers: 21 CFR, 117.40(e)	1
8D	GMP 117- Equipment installed to facilitate cleaning and maintenance of equipment and adjacent spaces: 21 CFR, 117.40(a)(3)	1-2/L
PROCESSES AND CONTROLS		
9A	GMP 117- Incoming raw materials, ingredients or processed food from an approved source, in an obvious sanitary condition. Items inspected on receipt, suitable for intended use, segregated as necessary and properly stored (clean storage containers, facilities, products properly covered), frozen foods stored frozen, properly thawed; ingredients properly identified; raw materials washed or cleaned as required; ice properly handled: 21 CFR, 117.80(a)(b)(c); 117.93	1-5
9B	GMP 117- CRITICAL - Food protected from contamination in storage: 21 CFR, 117.80(b)(1-5),(7); 117.80(c)(5)(6)(7); 117.93	C
9C	GMP 117- CRITICAL - Critical control points & factors such as time, temperature, pressure, flow rate, pH, Aw, inhibitors, adequate to ensure safety of product: 21 CFR, 117.80(c)(2)(4)(14)	C/L
9E	GMP 117- CRITICAL - Overall sanitation of plant under supervision of one or more competent individuals: 21 CFR, 117.4(c), 117.80(a)(3)	C
9F	GMP 117- CRITICAL -- Complete and adequate training records of each individual engaged in manufacturing, processing, packing, or holding food. Records available for review: 21 CFR, 117.4(d); 117.301; 117.305; 117.315; 117.320; 117.330; RCW 69.07.080; RCW 15.130.420(1), 15.130.430(1)(b), 15.130.500(4)	C
9G	GMP 117- Record kept of required training of each individual engaged in manufacturing, processing, packing, or holding food: 21 CFR, 117.4(d), 117.301; 117.305; 117.315; 117.320; 117.330;	1
9J	GMP 117- CRITICAL - Required instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms must be maintained and accurate. Devices and controls must be sufficient in number for the designed use: 21 CFR, 117.40(a)(6)(f)	C/L
9K	GMP 117- CRITICAL - Required critical control point monitoring, measurements, tests, analysis on products and containers performed as required: 21 CFR, 117.80(c)(12)(15)	C
9L	GMP 117- NON-CRITICAL - Required tests not performed as required: 21 CFR 117.80(c)(15)	1
9M	GMP 117- CRITICAL - Potentially hazardous foods maintained at proper temperatures: 21 CFR, 117.80(c)(3)	C/L

9N	GMP 117- No contaminating material used, stored or transported with supplies, ingredients or processed foods: 21 CFR, 117.35(b)(2)	1-2
9O	GMP 117- Packaging material properly handled and stored: 21 CFR, 117.35(d)(3)	1-2
LABELING		
10A	GMP 117- CRITICAL - Food products misbranded, product has undeclared allergens or human sensitivity causing ingredients including sub-components: RCW 15.130.210, 300; 21 CFR 101.3(b), 101.4(a); 101.4(b)(2); 101.5	C/L
10B	GMP 117- NON-CRITICAL - Food products misbranded, including Pull Dates required for packaged products perishable within 30 days; product label fails to break down multi-component ingredients (no undeclared allergenic type ingredients): RCW 15.130.210, 300; 21 CFR 101.3(b), 101.4(a); 101.4(b)(2); 101.5	1
LICENSING		
11	CRITICAL - Producing, holding, or packaging products not approved by WSDA license or permit: Food Proc: RCW 69.07.040; RCW 15.36.041; 15.36.051; 15.36.081 Warehouse: RCW 69.10.015; Eggs: RCW 69.25.050; Spec. Poultry: RCW 69.07.103; Direct Seller: WAC 16-130-030	C
Additional Requirements for firms with sales over \$1 Million annually, averaged over past 3 years, adjusted for inflation.		
Preventive Controls (PC)		
9C	PC - CRITICAL - Process control critical limits & factors such as time, temperature, flow rate, pH, etc. adequate and appropriate to controls identified hazards; Other preventive controls (allergen, sanitation, etc.) adequate to control identified hazards; mandatory corrective action is adequate: 21 CFR, 117.135(c)(1); 117.145(a)	C/L
9E	PC - CRITICAL - Persons involved in food processing and those overseeing the food safety plan are qualified through training and/or job experience: 21 CFR, 117.3; 117.4; 117.180	C
9F	PC - CRITICAL - Complete and adequate required Food Safety Plan and related records maintained as required, including preventive controls monitoring records, training records, supply chain control records, etc. Records available for review: 21 CFR, 117.126(c); 117.140; 117.145(c)(1); 117.150(b)(1)(iii),(d); 117.155(b); 117.165(a)(4); 117.180(d); 117.190; 117.206(a)(5); 117.305; 117.315; 117.320	C
9G	PC - NON-CRITICAL - Complete and adequate required Food Safety Plan and related records maintained as required, including preventive controls monitoring records, training records, supply chain control records, etc. Records available for review: 21 CFR, 117.126(c); 117.140; 117.145(c)(1); 117.150(b)(1)(iii),(d); 117.155(b); 117.165(a)(4); 117.180(d); 117.190; 117.206(a)(5); 117.305; 117.315; 117.320	1-5
9J	PC - CRITICAL - Required critical limit monitoring devices such as thermometers, recorder/controllers, pH meters, approved, accurate and in place: 21 CFR, 117.165(a)(1)	C/L
9K	PC - CRITICAL - Implementation of Food Safety Plan with all preventive controls, monitoring procedures, other verification activities and corrective actions: 21 CFR, 117.126(a); 117.135(a)(1); 117.145(a); 117.150(a)(1),(b); 117.155(a); 117.165(a)	C
9L	PC - NON-CRITICAL - Implementation of Food Safety Plan with all preventive controls, monitoring procedures, other verification activities and corrective actions. 21 CFR, 117.126(a); 117.135(a)(1); 117.145(a); 117.150(a)(1),(b); 117.155(a); 117.165(a)	1-5
9Q	PC - CRITICAL - Food Safety Plan has been created, complete with all required elements; Required recall plan created and complete: 21 CFR, 117.126(a),(b); 117.130(a)(1),(2); 117.135(a)(1),(b),(c); 117.139(a); 117.145(a); 117.150(a)(1),(2); 117.165(b)	C
9R	PC - NON-CRITICAL - Food Safety Plan has been created, complete with all required elements; Required recall plan created and complete: 21 CFR, 117.126(a),(b); 117.130(a)(1),(2); 117.135(a)(1),(b),(c); 117.139(a); 117.145(a); 117.150(a)(1),(2); 117.165(b)	1-5

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