

PERSONNEL – Qualification & Training			Yes/No/NA
1.	§117.4(a)	Did you ensure that all individuals engaged in manufacturing, processing, packing, or holding food are qualified to perform their assigned duties?	
2.	§117.4(c)	Did you ensure that supervisory personnel have the education, training, or experience (or a combination thereof) necessary to supervise the production of clean and safe food?	
3.	§117.4(b)	Did you train employees in the principles of food hygiene and food safety?	
4.	§117.4(d)	Do you have and maintain records documenting training of qualified individuals?	
5.	§117.305	Do your training records meet general record requirements (facility name/address, trainer sign/date, accurate, legible, etc.)?	
6.	§117.315	Did you retain training records for at least 2 years after they were prepared?	
PERSONNEL – Employee Health & Hygienic Practices			Yes/No/NA
7.	§117.10(a)	Does management take all reasonable measures and precautions to ensure disease control by excluding employees who by supervisory observation or medical examination appear to be ill or have open lesions or other abnormal source of microbial contamination?	
8.	§117.10(a)	Are employees instructed to report health conditions that might contaminate food, food product surfaces or food packaging materials to their supervisor?	
9.	§117.10(b)(1)	Do employees protect against contamination of food and allergen cross-contact by properly wearing suitable outer garments, hair nets, beard coverings, etc.?	
10.	§117.10(b)(2)	Do employees maintain adequate personal cleanliness?	
11.	§117.10(b)(3)	Do employees wash hands thoroughly before work and after each absence from their work station?	
12.	§117.10(b)(4)	Do employees remove unsecured jewelry and other objects that might fall into food?	
13.	§117.10(b)(5)	Are gloves used for food handling made of an impermeable material and maintained in a clean sanitary condition?	
14.	§117.10(b)(6)	Do employees properly wear effective hair restraints (hair and beard covers, etc.)?	
15.	§117.10(b)(7)	Do employees store clothing or other personal belongings away from areas where food is exposed or where equipment or utensils are washed?	
16.	§117.10(b)(8)	Do employees confine eating, drinking, gum chewing, and use of tobacco to areas where food is not exposed or equipment and utensils are not washed?	
17.	§117.10(b)(9)	Do employees protect against allergen cross-contact and against contamination with microorganisms or other foreign substances such as perspiration, cosmetics, medicines, etc.?	
FACILITY & GROUNDS			Yes/No/NA
18.	§117.20(a)	Are the grounds about your plant under your control kept in a condition that will protect against the contamination of food?	
19.	§117.20(a)(1)	Are areas within the vicinity of the plant kept free from litter and waste with grass and weeds trimmed?	
20.	§117.20(a)(2)	Are roads, yards and parking lots maintained to prevent sources of contamination?	
21.	§117.20(a)(3)	Is there adequate drainage of outside areas that may contribute to contamination?	
22.	§117.20(a)(4)	Are systems for waste treatment and disposal operated in a manner to protect against contamination?	
23.	§117.20(a)(5)	Are steps taken to prevent potential sources of food contamination where bordering grounds not under the control of the facility are not maintained?	
24.	§117.20(b)	Are the plant buildings and structures of suitable size, construction, and design to maintain sanitary operations and to produce safe food?	
25.	§117.20(b)(1)	Does the plant building(s) provide sufficient space for placement of equipment and storage of materials to permit maintenance of sanitary operations and production of safe food?	

FACILITY & GROUNDS (cont.)			Yes/No/NA
26.	§117.20(b)(2)	Are food processing areas effectively separated (i.e. location, time, partition, etc.) from other operations which may cause contamination of food being processed or allergen cross-contact?	
27.	§117.20(b)(3)	Are there proper precautions to protect food in outdoor bulk vessels?	
28.	§117.20(b)(4)	Are floors, walls and ceilings constructed to facilitate adequate cleaning and repair?	
29.	§117.20(b)(4)	Does drip or condensate from fixtures, ducts and pipes cause or potentially cause contamination of food, food contact surfaces or food packaging materials?	
30.	§117.20(b)(4)	Are aisles and working spaces unobstructed and of adequate width to permit employees to perform their jobs and protect against contamination of food by clothing or personal contact?	
31.	§117.20(b)(5)	Is there adequate lighting in all hand-washing and toilet areas, and dressing and locker rooms?	
32.	§117.20(b)(5)	Is there adequate lighting in all areas where food is processed, packed, or stored and where utensils and equipment are cleaned?	
33.	§117.20(b)(5)	Are food products and processing areas protected against contamination from breakage of light bulbs and other glass fixtures?	
34.	§117.20(b)(6)	Is air quality and ventilation or other control systems adequate to prevent contamination by dust, odors, vapors (including steam and noxious fumes) and/or other airborne substances?	
35.	§117.20(b)(6)	Are fans and other air blowing equipment located in a manner to prevent allergen cross-contact and contamination of food, food contact surfaces and food packaging materials?	
36.	§117.20(b)(7)	Are doors, windows and other openings protected by adequate screening or other protection to eliminate entry by insects, rodents and other pests?	
SANITARY OPERATIONS			Yes/No/NA
37.	§117.35(a)	Are buildings, physical facilities, fixtures, etc. kept clean and in a good state of repair?	
38.	§117.35(a)	Are cleaning and sanitizing of utensils and equipment performed in a manner to protect against contamination and allergen cross-contact?	
39.	§117.80(c)(1)	Are equipment and utensils properly cleaned and sanitized and, as necessary, equipment are taken apart for thorough cleaning?	
40.	§117.35(b)(1)	Are cleaning compounds and sanitizing agents free from microorganisms and used in a safe and effective matter?	
41.	§117.35(b)(2)	Are cleaning compounds, sanitizing agents, pesticide chemicals and other hazardous materials identified, kept in original containers and stored separate from raw materials?	
42.	§117.35(c)	Are the processing areas maintained free of insects, rodents, and other pests?	
43.	§117.35(c)	Are effective measures taken to exclude pests from processing areas?	
44.	§117.35(c)	Are insecticides and rodenticides used and stored so as to prevent contamination of food, food contact surfaces and food-packaging material?	
45.	§117.35(d)	Are all utensils and equipment food-contact surfaces cleaned and sanitized at intervals frequently enough to protect against allergen cross-contact and contamination of food?	
46.	§117.35(d)(1)	Are food-contact surfaces used for manufacturing or holding low-moisture food dry and in a sanitary condition at the time of use?	
47.	§117.35(d)(2)	In wet processing, are food contact surfaces cleaned and sanitized before use and after any interruption during which contamination could occur?	
48.	§117.35(d)(3)	Are single-service articles (paper cups, towels, etc.) stored, handled, dispensed, used and disposed of in an appropriate manner?	
49.	§117.35(e)	Are non-food-contact surfaces of equipment cleaned at intervals frequently enough to protect against allergen cross-contact and contamination of food, food contact surfaces and food-packaging materials?	
50.	§117.35(f)	Are cleaned and sanitized portable equipment with food-contact surfaces and utensils stored in a manner that protects them from contamination (e.g. splash, dust, etc.)?	

SANITARY FACILITIES & CONTROLS			Yes/No/NA
51.	§117.37(a) & §117.80(b)(1)	Is the facility's water supply from approved source and of adequate quantity and quality for its intended uses?	
52.	§117.37(a)	Are the water temperature and pressure maintained at suitable levels for intended use?	
53.	§117.37(b)	Is the plumbing adequately sized, designed, installed and maintained in a manner to prevent contamination?	
54.	§117.37(c)	Is the sewage disposal system adequate?	
55.	§117.37(d)	Are adequate toilet facilities provided, equipped and maintained clean and in good repair?	
56.	§117.37(e)	Are adequate hand-washing facilities provided where appropriate (convenient, equipped, running water at a suitable temperature, etc.)?	
57.	§117.37(f)	Is all refuse properly conveyed, stored, protected where necessary from pests and disposed of in an adequate manner?	
EQUIPMENT & UTENSILS			Yes/No/NA
58.	§117.40(a)(1)	Are all plant equipment and utensils designed to be adequately cleanable and properly maintained?	
59.	§117.40(a)(2)	Is equipment designed and used in a manner that precludes contamination with lubricants, fuel, contaminated water, metal fragments, and other contaminants?	
60.	§117.40(a)(3)	Is equipment installed and maintained so as to facilitate the cleaning of equipment and adjacent areas?	
61.	§117.40(a)(4) and (5)	Are food-contact surfaces of equipment made of corrosion-resistant, non-toxic and durable material?	
62.	§117.40(a)(6)	Are food-contact surfaces and utensils properly maintained to protect food?	
63.	§117.40(b)	Are seams on food-contact surfaces smoothly bonded or otherwise maintained to minimize accumulation of dirt, organic matter, etc.?	
64.	§117.40(c)	Are the non-food-contact surfaces of equipment in the food handling areas constructed that it can be kept in a clean and sanitary condition?	
65.	§117.40(d)	Are holding, conveying and manufacturing systems designed in a way to be maintained in a clean and sanitary condition?	
66.	§117.40(e)	Are freezers and cold storage compartments fitted with appropriate temperature measuring and/or recording devices to accurately show the compartment temperature?	
67.	§117.40(f)	Are instruments and controls for measuring, regulating, or recording temperature, pH, water activity, acidity, etc. accurate, maintained (i.e. calibrated), and adequate in number?	
68.	§117.40(g)	Are compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment treated in such a way to protect food from unlawful indirect additives?	
PROCESSES & CONTROLS			Yes/No/NA
21 CFR 117.80(a)- General.			Yes/No/NA
69.	§117.80(a)(1)	Are all operations conducted in accordance with adequate sanitation principles?	
70.	§117.80(a)(2)	Is there an appropriate quality control operation employed to ensure that food is suitable for human consumption and that food packaging material is safe and suitable?	
71.	§117.80(a)(3)	Are the facility sanitation functions under the supervision of a competent individual(s)?	
72.	§117.80(a)(4)	Are all reasonable precautions taken to ensure that production procedures do not contribute to allergen cross-contact and contamination from any source?	
73.	§117.80(a)(5)	Are chemical, microbial, or extraneous material testing procedures used when necessary to identify sanitation failures or possible allergen cross-contact and food contamination?	
74.	§117.80(a)(6)	Is any adulterated food (within the meaning of PA Food Safety Act) either rejected or treated/processed to eliminate the contamination?	

PROCESSES & CONTROLS (cont.)

21 CFR 117.80(b)- Raw materials and other ingredients			Yes/No/NA
75.	§117.80(b)(1)	Are raw materials and other ingredients inspected, segregated or otherwise handled as necessary to ascertain they are clean and suitable for processing into food?	
76.	§117.80(b)(1)	Are raw materials and other ingredients stored in such a way to prevent allergen cross-contact, contamination or deterioration of food?	
77.	§117.80(b)(1)	Are raw materials washed or cleaned as necessary to remove soil or other contamination?	
78.	§117.80(b)(1)	If water is reused for washing, rinsing or conveying food, is it maintained at such quality to prevent allergen cross-contact or increasing the contamination level of food?	
79.	§117.80(b)(2)	Are raw materials or other ingredients that contain levels of microorganisms that may render the food injurious to public health pasteurized or otherwise treated?	
80.	§117.80(b)(3) & (4)	Do raw materials and other ingredients comply with FDA regulations, guidelines, and defect action levels for poisonous or deleterious substances?	
81.	§117.80(b)(5)	Are raw materials and other ingredients, including rework, held in bulk or in containers designed to protect against allergen cross-contact and against contamination?	
82.	§117.80(b)(5)	Are raw materials held at temperature and humidity levels that prevent food from becoming adulterated?	
83.	§117.80(b)(5)	Are materials scheduled for rework identified as such?	
84.	§117.80(b)(6)	Are frozen raw materials and other ingredients kept frozen?	
85.	§117.80(b)(6)	Is thawing done in a manner that prevents raw materials and other ingredients from becoming adulterated?	
86.	§117.80(b)(7)	Are liquid or dry raw materials and other ingredients that are received and stored in Bulk held in a manner that protects against allergen cross-contact and against contamination?	
87.	§117.80(b)(8)	Are allergen-containing raw materials, other ingredients and rework identified and held in a manner that prevents allergen cross-contact?	

PROCESSES & CONTROLS (cont.)

21 CFR 117.80(c)- Manufacturing operations			Yes/No/NA
88.	§117.80(c)(2)	Are food processing conditions and parameters controlled and monitored as are necessary to minimize the potential for microbial growth, allergen cross-contact and/or contamination?	
89.	§117.80(c)(3)	Are foods that can support the rapid growth of microorganisms (TCS foods) held at temperatures to prevent its adulteration during processing, packing and holding?	
90.	§117.80(c)(4)	Are measures that are taken to destroy or prevent microbial growth (i.e. lethality treatment, formulation, etc.) adequate to prevent food from being adulterated (process validation)?	
91.	§117.80(c)(5)	Is work-in-progress handled in a manner that protects against allergen cross-contact, contamination, and microbial growth?	
92.	§117.80(c)(6)	Are effective measures taken to protect finished product from allergen cross-contact and contamination by raw materials, other ingredients or refuse?	
93.	§117.80(c)(6)	Are food transported by conveyor protected against allergen cross-contact and contamination?	
94.	§117.80(c)(7)	Are equipment, containers, and utensils used to process food constructed, handled, and maintained, during production, in a manner that protects against allergen cross-contact and contamination?	
95.	§117.80(c)(8)	Are adequate measures taken to protect against inclusion of metal or other extraneous material in food (example: use of traps, sieves, metal detectors, magnets, etc.)?	
96.	§117.80(c)(9)(i)	Are food, raw materials and other ingredients that are adulterated disposed of in a manner to protect other food from contamination?	
97.	§117.80(c)(9)(ii)	When reconditioning of adulterated food is done, is a proven effective method used, or is the reconditioned food re-examined for adulteration?	

PROCESSES & CONTROLS (cont.)			
21 CFR 117.80(c)- Manufacturing operations			Yes/No/NA
98.	§117.80(c)(10)	Are mechanical manufacturing steps (i.e. washing, peeling, cutting, drying, etc.) performed so as to protect food against allergen cross-contact and against contamination?	
99.	§117.80(c)(10)	Are food protected from contaminants that may drip, drain, or be drawn into the food?	
100.	§117.80(c)(11)	Is heat blanching, when used, performed in an effective manner to prevent growth and contamination by thermophilic microorganisms?	
101.	§117.80(c)(12)	Are batters, breading, and other similar preparations treated or maintained in a manner that protects against allergen cross-contact, contamination, and microbial growth?	
102.	§117.80(c)(13)	Are filling, assembling, and packaging operations adequately performed to prevent allergen cross-contact, contamination and microbial growth?	
103.	§117.80(c)(14)	Are foods that rely principally on the control of water activity (aw) for preventing microbial growth processed and maintained at a safe moisture level?	
104.	§117.80(c)(15)	Are foods that rely principally on the control of pH for preventing microbial growth monitored and maintained at pH 4.6 or below?	
105.	§117.80(c)(16)	Is ice (when used) manufactured from potable water and stored and handled in a sanitary manner?	
WAREHOUSING & DISTRIBUTION			Yes/No/NA
<i>(see more FSMA Sanitary Transportation requirements if your facility is subject to the rule in 21 CFR 1 Subpart O)</i>			
106.	§117.93	Are finished products stored and transported under conditions that prevent contamination of the food, allergen cross-contact, and deterioration of the food and the container?	
107.	§117.93	Are finished products and containers clearly labeled to identify contents and the presence of any allergens?	
108.	§117.93	Are transportation vehicles properly designed, maintained and kept in sanitary conditions? Are they cleaned to remove potential contaminants from prior loads?	
109.	§117.93	Are products returned from distribution assessed for food safety, properly handled and disposed?	
Holding and Distribution of Human Food By-Product for Use as Animal Food (HFBUAF)			Yes/No/NA
110.	§117.95(a)(1)	Are containers and equipment used for HFBUAF before distribution designed, constructed of appropriate material, cleaned, and maintained to protect against contamination?	
111.	§117.95(a)(2) & (3)	Are by-products held for distribution properly identified and held in a manner to protect against contamination from sources such as trash?	
112.	§117.95(b)	Are labels that identify the by-products affixed to or accompany these HFBUAF products when distributed?	
113.	§117.95	Are shipping containers and bulk vehicles used for distribution examined prior to use to protect against contamination during transportation?	
DEFECT ACTION LEVELS			Yes/No/NA
<i>For examples of defect action levels that may render food adulterated, see the Handbook which can be accessible at: https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/SanitationTransportation/ucm056174.htm</i>			
114.	§117.110(a) & §117.80(b)(4)	Are quality control operations in place to ensure natural or avoidable defects are reduced to the lowest level currently feasible?	
115.	§117.110(b)	Is food, containing natural or unavoidable defects above current defect action levels prohibited from being mixed with other lots of food?	