

CHAPTER 1

PURPOSE AND DEFINITIONS

1- Purpose

The following rules and regulations shall be applied for the protection of public health.

THE PURPOSE OF THIS REGULATION IS TO SAFEGUARD PUBLIC HEALTH AND PROVIDE TO CONSUMERS FOOD THAT IS SAFE, UNADULTERATED, AND HONESTLY PRESENTED. THIS REGULATION ESTABLISHES DEFINITIONS; SETS STANDARDS FOR MANAGEMENT AND PERSONNEL, FOOD OPERATIONS AND EQUIPMENT AND FACILITIES; AND PROVIDES FOR FOOD ESTABLISHMENT PLAN REVIEW, LICENSE ISSUANCE, INSPECTIONS, EMPLOYEE RESTRICTION AND ENFORCEMENT. THIS REGULATION IS INTENDED TO BE THE STANDARD FOR THE DEPARTMENT AND ITS AUTHORIZED AGENTS AND EMPLOYEES, TO BE APPLIED UNIFORMLY BY ALL PARTIES.

1- Definitions

A. The following terms are defined for the purposes of the rules and regulations.

~~(1) "Asterisk"(*) means any section denoted with an * indicates it is a critical item.~~

1. "ACCREDITED PROGRAM" MEANS A FOOD PROTECTION MANAGER CERTIFICATION PROGRAM THAT HAS BEEN EVALUATED AND LISTED BY AN ACCREDITING AGENCY AS CONFORMING TO THE NATIONAL STANDARDS FOR ORGANIZATIONS THAT CERTIFY INDIVIDUALS. ACCREDITED PROGRAM DOES NOT REFER TO TRAINING FUNCTIONS OR EDUCATIONAL PROGRAMS.

~~2. _____~~

~~(2.) "Adulterated" means as stated in the Colorado Pure Food and Drug Act, section 25-5-4, C.R.S.~~

3. "ALLERGENS"-SEE MAJOR FOOD ALLERGENS DEFINITION 1-202(65).

~~(4.) "Approved" means acceptable to the Department, or its authorized agents, and employees based on a determination of with applicable, documented standards and good public health practices WITH PRINCIPLES, PRACTICES, AND GENERALLY RECOGNIZED STANDARDS THAT PROTECT PUBLIC HEALTH.~~

~~(.) "ASTERISK"(*) MEANS ANY SECTION OR PORTION THEREOF DENOTED WITH AN * INDICATES IT IS A CRITICAL ITEM.~~

6. "ASYMPTOMATIC":

⊕ MEANS WITHOUT OBVIOUS SYMPTOMS; NOT SHOWING OR PRODUCING INDICATIONS OF A DISEASE OR OTHER MEDICAL CONDITION, SUCH AS AN INDIVIDUAL INFECTED WITH A PATHOGEN BUT NOT EXHIBITING OR PRODUCING ANY SIGNS OR SYMPTOMS OF VOMITING, DIARRHEA, OR JAUNDICE.

⊕ INCLUDES NOT SHOWING SYMPTOMS BECAUSE SYMPTOMS HAVE RESOLVED OR SUBSIDED, OR BECAUSE SYMPTOMS NEVER MANIFESTED.

7. "" MEANS WATER ACTIVITY WHICH IS A MEASURE OF THE FREE MOISTURE IN A FOOD, IS THE QUOTIENT OF THE WATER VAPOR PRESSURE OF THE SUBSTANCE

- 1 DIVIDED BY THE VAPOR PRESSURE OF PURE WATER AT THE SAME TEMPERATURE,
2 AND IS INDICATED BY THE SYMBOL .
- 3 8. **"BALUT"** MEANS AN EMBRYO INSIDE A FERTILE EGG THAT HAS BEEN
4 INCUBATED FOR A PERIOD SUFFICIENT FOR THE EMBRYO TO REACH A SPECIFIC
5 STAGE OF DEVELOPMENT AFTER WHICH IT IS REMOVED FROM INCUBATION
6 BEFORE HATCHING.
- 7 (-) **"Bulk Foods"** means foods as defined in section 25-4-1302, C.R.S.
- 8 10. **"CATERING OPERATION"** MEANS A RETAIL FOOD ESTABLISHMENT THAT
9 PROVIDES A CONTRACTED, PREARRANGED NUMBER OF MEALS AND/OR FOOD
10 PRODUCTS THAT ARE PREPARED AT A LICENSED RETAIL FOOD ESTABLISHMENT
11 FOR SERVICE AND CONSUMED AT THE SAME OR ANOTHER PREARRANGED OFFSITE
12 LOCATION AND NOT AVAILABLE FOR INDIVIDUAL PURCHASE.
- 13 11. **"CERTIFIED FOOD PROTECTION MANAGER"** MEANS A PERSON IN CHARGE
14 THAT IS CERTIFIED BY AN ACCREDITED PROGRAM FOR FOOD PROTECTION.
- 15 12. **"CFR"** MEANS CODE OF FEDERAL REGULATIONS. CITATIONS IN THIS CODE TO
16 THE CFR REFER SEQUENTIALLY TO THE TITLE, PART, AND SECTION NUMBERS,
17 SUCH AS 40 CFR 180.194 REFERS TO TITLE 40, PART 180, SECTION 194.
- 18 (-) **"Clean In Place (CIP)"** means cleaned in place by the circulation or flowing by
19 mechanical means through a piping system of a detergent solution, water rinse,
20 and sanitizing solution onto or over equipment surfaces that require cleaning,
21 such as the method used, in part, to clean and sanitize a frozen dessert machine.
- 22 CIP does not include the cleaning AND SANITIZATION of equipment such as band
23 saws, CUTTING BOARDS, slicers or mixers that are subjected to in-place manual
24 cleaning without the use of an AUTOMATED CIP system.
- 25 (-) **"Commercial Design"** means ~~all~~ equipment THAT IS CERTIFIED OR
26 CLASSIFIED BY AN AMERICAN NATIONAL STANDARDS INSTITUTE
27 (ANSI) ACCREDITED CERTIFICATION PROGRAM, ~~meeting recognized~~
28 ~~commercial sanitation criteria by organizations,~~ such as the National Sanitation
29 Foundation (NSF), Underwriters Laboratories (UL) sanitation standards,
30 Environmental Testing Laboratories, Inc. (ETL) sanitation standards, Baking
31 Industry Sanitation Standards Committee (BISSC), or other comparable design
32 criteria as approved by the Department during a standardized equipment review.
- 33 15. **"COMMINGLE"** MEANS:
- 34 A. TO COMBINE SHELLSTOCK HARVESTED ON DIFFERENT DAYS OR FROM
35 DIFFERENT GROWING AREAS AS IDENTIFIED ON THE TAG OR LABEL, OR
- 36 B. TO COMBINE SHUCKED SHELLFISH FROM CONTAINERS WITH DIFFERENT
37 CONTAINER CODES OR DIFFERENT SHUCKING DATES.
- 38 (-) **"Comminuted"** means reduced in size by methods including chopping, flaking,
39 grinding, or mincing. This includes fish or meat products that are reduced in size
40 and restructured or reformulated such as gefilte fish, formed roast beef, gyros,
41 ground beef, and sausage; and a mixture of two or more types of meat which
42 have been reduced in size and combined, such as sausages made from two or
43 more meats.
- 44 (-) **"Commissary"** ~~means an approved catering establishment, restaurant, or other~~
45 ~~approved place in which food, containers, or supplies are kept, handled, prepared,~~

- 1 ~~packaged or stored.~~ MEANS A FACILITY THAT IS APPROVED BY THE DEPARTMENT
2 AS A BASE OF OPERATION FOR A TEMPORARY RETAIL FOOD ESTABLISHMENT,
3 PUSHCART, OR MOBILE FOOD ESTABLISHMENT WHERE FOOD, CONTAINERS, OR
4 SUPPLIES ARE KEPT, HANDLED, PREPARED, PACKAGED OR STORED AND IS
5 CONSTRUCTED AND OPERATED IN COMPLIANCE WITH THE RULES AND
6 REGULATIONS.
- 7 18. **"CONDITIONAL EMPLOYEE"** MEANS A POTENTIAL FOOD EMPLOYEE TO WHOM A
8 JOB OFFER IS MADE, CONDITIONAL ON RESPONSES TO SUBSEQUENT MEDICAL
9 QUESTIONS OR EXAMINATIONS DESIGNED TO IDENTIFY POTENTIAL FOOD
10 EMPLOYEES WHO MAY BE SUFFERING FROM A DISEASE THAT CAN BE
11 TRANSMITTED THROUGH FOOD AND DONE IN COMPLIANCE WITH TITLE 1 OF THE
12 AMERICANS WITH DISABILITIES ACT OF 1990.
- 13 ~~(-)"Contamination"~~ means EXPOSURE TO OR CONTACT WITH A CONTAMINANT.
14 ACTIONS THAT MAY CONTAMINATE OR CAUSE CONTAMINATION INCLUDE:
15 UNSANITARY FOOD-CONTACT SURFACES, COUGHING, SNEEZING, SPITTING,
16 UNNECESSARY HANDLING, FLOODING, DRAINING, LEAKAGE FROM OVERHEAD
17 PIPES, AND CONDENSATION. "CONTAMINANT" MEANS A SUBSTANCE, ORGANISM,
18 OR ENTITY THAT MIGHT CAUSE DISEASE OR THREATEN PUBLIC HEALTH, AND
19 INCLUDES SOIL, DUST, INSECTS, RODENTS, OTHER PESTS, AND POISONOUS OR
20 TOXIC MATERIALS. ~~to make unfit for use by the introduction or potential~~
21 ~~introduction of unwholesome or undesirable elements~~
- 22 20. **"CONFIRMED DISEASE OUTBREAK"** MEANS A FOODBORNE DISEASE OUTBREAK
23 IN WHICH LABORATORY ANALYSIS OF APPROPRIATE SPECIMENS IDENTIFIES A
24 CAUSATIVE AGENT AND EPIDEMIOLOGICAL ANALYSIS IMPLICATES THE FOOD AS
25 THE SOURCE OF THE ILLNESS.
- 26 ⊕ **"Corrosion-Resistant Materials"** means ~~those materials which maintain their~~
27 ~~original surface characteristics under prolonged contact with food, the normal use~~
28 ~~of cleaning compounds and bactericidal solutions, and other conditions of use~~ A
29 MATERIAL THAT MAINTAINS ACCEPTABLE SURFACE CLEANABILITY
30 CHARACTERISTICS UNDER PROLONGED INFLUENCE OF THE FOOD TO BE
31 CONTACTED, THE NORMAL USE OF CLEANING COMPOUNDS AND SANITIZING
32 SOLUTIONS, AND OTHER CONDITIONS OF THE USE ENVIRONMENT.
- 33 ⊕ **"Critical Control Point"** means any point in a food preparation process at which
34 loss of control might result in an unacceptable consumer health risk.
- 35 ⊕ **"Critical Item"** means a provision of these rules and regulations that, if in
36 noncompliance, is more likely than other violations to contribute to food
37 contamination, illness, or AN environmental ~~degradation~~ HEALTH HAZARD.
38 These are items denoted in these rules and regulations with an asterisk *.
- 39 24. **"CRITICAL LIMIT"** MEANS THE MAXIMUM OR MINIMUM VALUE TO WHICH A
40 PHYSICAL, BIOLOGICAL, OR CHEMICAL PARAMETER MUST BE CONTROLLED AT A
41 CRITICAL CONTROL POINT TO MINIMIZE THE RISK THAT THE IDENTIFIED FOOD
42 SAFETY HAZARD MAY OCCUR.
- 43 25. **"CROSS-CONNECTION"** MEANS ANY CONNECTION OR ARRANGEMENT,
44 PHYSICAL OR OTHERWISE, BETWEEN A POTABLE WATER SUPPLY SYSTEM AND
45 ANY PLUMBING FIXTURE OR ANY TANK, RECEPTOR, EQUIPMENT OR DEVICE, TO
46 WHICH IT MAY BE POSSIBLE FOR NON-POTABLE, USED, UNCLEAR, POLLUTED OR

- 1 CONTAMINATED WATER, OR OTHER SUBSTANCES, TO ENTER ANY PART IN SUCH
2 POTABLE WATER SYSTEM UNDER ANY CONDITION.
- 3 26. **“CROSS CONTAMINATION”** MEANS THE TRANSFER OF HARMFUL BACTERIA TO
4 FOOD FROM OTHER FOODS, SUCH AS RAW OR UNDERCOOKED ANIMAL PRODUCTS,
5 TO CUTTING BOARDS, UTENSILS, ETC. IF THEY ARE NOT HANDLED PROPERLY.
- 6 27. **“CUT LEAFY GREENS”** MEANS FRESH LEAFY GREENS WHOSE LEAVES HAVE
7 BEEN CUT, SHREDDED, SLICED, CHOPPED, OR TORN. THE TERM "LEAFY GREENS"
8 INCLUDES ICEBERG LETTUCE, ROMAINE LETTUCE, LEAF LETTUCE, BUTTER
9 LETTUCE, BABY LEAF LETTUCE (I.E., IMMATURE LETTUCE OR LEAFY GREENS),
10 ESCAROLE, ENDIVE, SPRING MIX, SPINACH, CABBAGE, KALE, ARUGULA AND
11 CHARD. THE TERM "LEAFY GREENS" DOES NOT INCLUDE HERBS SUCH AS
12 CILANTRO OR PARSLEY.
- 13 ⊕ **“Department”** means Colorado Department of Public Health and Environment,
14 or its authorized agents, and employees.
- 15 (29) **“DRINKING WATER”**
- 16 A. **“DRINKING WATER”** MEANS WATER THAT MEETS CRITERIA AS
17 SPECIFIED IN SECTION 25-1.5-2, C.R.S., *COLORADO PRIMARY DRINKING*
18 *WATER REGULATIONS*.
- 19 B. **“DRINKING WATER”** IS TRADITIONALLY KNOWN AS "POTABLE WATER."
20 C. **“DRINKING WATER”** INCLUDES THE TERM "WATER" EXCEPT WHERE
21 THE TERM USED CONNOTES THAT THE WATER IS NOT POTABLE, SUCH AS
22 "BOILER WATER," "MOP WATER," "RAINWATER," "WASTEWATER," AND
23 "NONDRINKING" WATER.
- 24 ⊕ **“Dry Storage Area”** means a room or area ~~used~~ DESIGNATED for the storage of
25 PACKAGED OR CONTAINERIZED BULK FOOD THAT IS NOT ~~non~~ potentially
26 hazardous (TIME AND TEMPERATURE CONTROL FOR FOOD SAFETY) ~~packaged or~~
27 ~~containerized food~~ and dry goods such as single-service items.
- 28 ⊕ **“Easily Cleanable”** means surfaces are readily accessible and fabricated of such
29 materials and finishes that residue can be effectively removed by normal cleaning
30 methods.
- 31 32. **“EGG”** MEANS THE SHELL EGG OF AVIAN SPECIES SUCH AS CHICKEN, DUCK,
32 GOOSE, GUINEA, QUAIL, RATITES OR TURKEY.
- 33 **“EGG”** DOES NOT INCLUDE:
- 34 A. A BALUT;
- 35 B. THE EGG OF REPTILE SPECIES SUCH AS ALLIGATOR; OR
- 36 C. AN EGG PRODUCT.
- 37 33. **EGG PRODUCT.**
- 38 A. **“EGG PRODUCT”** MEANS ALL, OR A PORTION OF, THE CONTENTS FOUND
39 INSIDE EGGS SEPARATED FROM THE SHELL AND PASTEURIZED IN A FOOD
40 PROCESSING PLANT, WITH OR WITHOUT ADDED INGREDIENTS, INTENDED
41 FOR HUMAN CONSUMPTION, SUCH AS DRIED, FROZEN OR LIQUID EGGS
- 42 B. **“EGG PRODUCT”** DOES NOT INCLUDE FOOD WHICH CONTAINS EGGS
43 ONLY IN A RELATIVELY SMALL PROPORTION SUCH AS CAKE MIXES.

- 1 ⊖ ~~“Employee” means any person working in a food establishment who transports~~
2 ~~food or food containers, who engages in food preparation or service, or who~~
3 ~~comes in contact with any food, utensils or equipment~~ THE LICENSEE, PERSON IN
4 CHARGE, FOOD EMPLOYEE, PERSON HAVING SUPERVISORY OR MANAGEMENT
5 DUTIES, PERSON ON THE PAYROLL, FAMILY MEMBER, VOLUNTEER, PERSON
6 PERFORMING WORK UNDER CONTRACTUAL AGREEMENT, AND ANY PERSON
7 WORKING IN A FOOD ESTABLISHMENT.
- 8 35. **"ENTEROHEMORRHAGIC ESCHERICHIA COLI"** (EHEC) MEANS E. COLI WHICH
9 CAUSE HEMORRHAGIC COLITIS, MEANING BLEEDING ENTERICALLY OR BLEEDING
10 FROM THE INTESTINE. THE TERM IS TYPICALLY USED IN ASSOCIATION WITH E.
11 COLI THAT HAVE THE CAPACITY TO PRODUCE SHIGA TOXINS AND TO CAUSE
12 ATTACHING AND EFFACING LESIONS IN THE INTESTINE. EHEC IS A SUBSET OF
13 SHIGA TOXIN-PRODUCING E. COLI (STEC), WHOSE MEMBERS PRODUCE
14 ADDITIONAL VIRULENCE FACTORS. INFECTIONS WITH EHEC MAY BE
15 ASYMPTOMATIC BUT ARE CLASSICALLY ASSOCIATED WITH BLOODY DIARRHEA
16 (HEMORRHAGIC COLITIS) AND HEMOLYTIC UREMIC SYNDROME (HUS) OR
17 THROMBOTIC THROMBOCYTOPENIC PURPURA (TTP). EXAMPLES OF SEROTYPES
18 OF EHEC INCLUDE: E. COLI O157:H7; E. COLI O157:NM; E. COLI O26:H11; E.
19 COLI O145:NM; E. COLI O103:H2; OR E. COLI O111:NM. ALSO SEE SHIGA
20 TOXIN-PRODUCING E. COLI.
- 21 36. **"EPA"** MEANS THE U.S. ENVIRONMENTAL PROTECTION AGENCY.
- 22 ⊖**"Equipment"** means an article used in the operation of a food establishment, such as,
23 but not limited to a freezer, grinder, hood, ice maker, meat block, mixer, oven,
24 reach-in refrigerator, range, scale, sink, slicer, stove, table, TEMPERATURE
25 MEASURING DEVICE ~~thermometer~~, or warewashing machine.
- 26 Equipment does not include items used for handling or storing large quantities of
27 packaged foods received from a supplier in a cased or overwrapped lot, such as
28 hand trucks, forklifts, dollies, pallets, racks, and skids.
- 29 38. **"EXCLUDE"** MEANS TO PREVENT A PERSON FROM WORKING AS AN EMPLOYEE IN
30 A FOOD ESTABLISHMENT OR ENTERING A FOOD ESTABLISHMENT AS AN
31 EMPLOYEE.
- 32 ⊖**"Extensively Remodeled"** means any major alteration of an existing configuration in
33 a food establishment which might affect the food operation that results in one or
34 more of the following conditions:
- 35 . Seating capacity, including service provided anywhere on the premises, is
36 increased by A MINIMUM OF 15 SEATS OR 20 percent WHICHEVER IS
37 GREATER ~~or more~~ in either a single construction project or an
38 incremental series of construction activities;
- 39 . Alterations or revisions involving retail food establishments or related
40 equipment that require a building or construction permit by local
41 building authorities. Routine maintenance, repairs or cosmetic changes
42 shall not be defined as extensive remodeling;
- 43 . Changes or alterations made in the nonpublic areas that result in a reduction or
44 increase of total space by 25 percent or more; or

1 .The facility's capabilities to handle food, EQUIPMENT, and utensils in a sanitary
2 manner have been diminished DUE TO MENU OR FOOD PROCESS CHANGE,
3 creating potentially hazardous conditions.

4 (19) ~~“Fish” means fresh or saltwater finfish, crustaceans, and other forms of aquatic~~
5 ~~animal life (including, but not limited to alligator, frog, aquatic turtle, jellyfish,~~
6 ~~sea cucumber, and sea urchin and the roe of such animals) other than birds or~~
7 ~~mammals, and includes any edible human food product derived in whole or in~~
8 ~~part from fish, including fish that has been processed in any manner.~~

9 40. **“FISH”**

10 A. **“FISH”** MEANS FRESH OR SALTWATER FINFISH, CRUSTACEANS AND
11 OTHER FORMS OF AQUATIC LIFE (INCLUDING ALLIGATOR, FROG,
12 AQUATIC TURTLE, JELLYFISH, SEA CUCUMBER, AND SEA URCHIN AND
13 THE ROE OF SUCH ANIMALS) OTHER THAN BIRDS OR MAMMALS, AND ALL
14 MOLLUSKS, IF SUCH ANIMAL LIFE IS INTENDED FOR HUMAN
15 CONSUMPTION.

16 B. **“FISH”** INCLUDES AN EDIBLE HUMAN FOOD PRODUCT DERIVED IN
17 WHOLE OR IN PART FROM FISH, INCLUDING FISH THAT HAVE BEEN
18 PROCESSED IN ANY MANNER.

19 ~~⊖~~ ~~“Food” means a raw, cooked, or processed edible substance, ice, beverage, or~~
20 ~~ingredient used or intended for use or for sale in whole or in part for human~~
21 ~~consumption.~~ MEANS A RAW, COOKED, OR PROCESSED EDIBLE SUBSTANCE, ICE,
22 BEVERAGE, OR INGREDIENT USED OR INTENDED FOR USE OR FOR SALE IN WHOLE
23 OR IN PART FOR HUMAN CONSUMPTION.

24 ~~⊖~~ **“Foodborne Disease Outbreak”** means an incident in which:

25 1-A. Two or more otherwise unrelated persons experience a similar illness
26 after ingestion of a common food; and

27 2-B. Epidemiological analysis implicates the food as the source of the illness.

28 ~~⊖~~ **“Food-Contact Surfaces”** means those surfaces of equipment and utensils with
29 which food normally comes in contact, and those surfaces from which food may
30 drain, drip, or splash back onto surfaces in contact with food. This excludes
31 ventilation hoods.

32 44. **“FOOD EMPLOYEE”** MEANS AN INDIVIDUAL WORKING WITH UNPACKAGED
33 FOOD, FOOD EQUIPMENT OR UTENSILS, OR FOOD-CONTACT SURFACES.

34 45. **“FOOD PREPARATION”** MEANS PACKAGING, PROCESSING, ASSEMBLING,
35 PORTIONING, OR ANY OPERATION THAT CHANGES THE FORM, FLAVOR, OR
36 CONSISTENCY OF FOOD, BUT DOES NOT INCLUDE TRIMMING OF PRODUCE FOR
37 DISPLAY PRIOR TO SALE.

38 ~~⊖~~ **“Food Processing Establishment”** means an establishment in which food is
39 processed, prepared, packaged, and distributed for human consumption and
40 approved by the Department. ~~This term does not include a retail food~~
41 ~~establishment, or commissary operation.~~

42 (24) ~~“Game Animal” means an animal, the products of which are food, that is not~~
43 ~~classified as domestic cattle, sheep, swine, goat, or poultry, or fish.~~

44 ~~_____~~ **“Game Animal”** includes:

1 ~~Animals, such as reindeer, elk, deer, antelope, bison, rabbit, squirrel, bear, and~~
2 ~~muskrat; nonaquatic reptiles, such as rattlesnakes; aquatic mammals; and exotic~~
3 ~~animals, such as lion, tiger, leopard, elephant, camel, antelope, anteater,~~
4 ~~kangaroo, water buffalo, species of foreign domestic cattle, such as Ankole,~~
5 ~~Gaya, Yak, and other animals approved by the Department.~~

6 ~~“Game Animal” does not include:~~

7 ~~—— Ratites such as ostrich, emu, and rhea.~~

8 47. **“GAME ANIMAL”**

- 9 A. **“GAME ANIMAL”** MEANS AN ANIMAL, THE PRODUCTS OF WHICH ARE
10 FOOD, THAT IS NOT CLASSIFIED AS LIVESTOCK, SHEEP, SWINE, GOAT,
11 HORSE, MULE, OR OTHER EQUINE IN 9 CFR 301.2 DEFINITIONS, OR AS
12 POULTRY, OR FISH.
- 13 B. **“GAME ANIMAL”** INCLUDES MAMMALS SUCH AS REINDEER, ELK, DEER,
14 ANTELOPE, WATER BUFFALO, BISON, RABBIT, SQUIRREL, OPOSSUM,
15 RACCOON, NUTRIA, OR MUSKRAT, AND NONAQUATIC REPTILES SUCH AS
16 LAND SNAKES.
- 17 C. **“GAME ANIMAL”** DOES NOT INCLUDE RATITES SUCH AS EMU, OSTRICH
18 AND RHEA.

19 ⊖ **“Ground Beef”** means meat that is derived from the voluntary striated muscle of
20 beef, with a maximum of thirty percent total fat by weight, with no water,
21 phosphates, extenders, or binders added.

22 ⊖ **“HACCP Plan”** means a written document that delineates the formal procedures
23 for following the Hazard Analysis Critical Control Point principles.

24 50. **“HANDWASHING SINK”** MEANS A LAVATORY, A BASIN OR VESSEL FOR
25 WASHING, A WASH BASIN, OR A PLUMBING FIXTURE ESPECIALLY PLACED FOR
26 USE IN PERSONAL HYGIENE AND DESIGNED FOR THE WASHING OF THE HANDS
27 AND EXPOSED PORTIONS OF THE ARMS.

28 ⊖ **“Hazard”** means a biological, chemical, or physical property that might cause an
29 unacceptable consumer health risk.

30 52. **“HEALTH PRACTITIONER”** MEANS A PHYSICIAN LICENSED TO PRACTICE
31 MEDICINE, OR IF ALLOWED BY LAW, A NURSE PRACTITIONER, PHYSICIAN
32 ASSISTANT, OR SIMILAR MEDICAL PROFESSIONAL.

33 ⊖ **“Hermetically Sealed Container”** means a container designed and intended to
34 be secure against the entry of microorganisms and to maintain the commercial
35 sterility of its contents after processing.

36 ⊖ **“Highly Susceptible Population”** means persons who are more likely than other
37 people in the general population to experience foodborne disease because they
38 are immunocompromised, preschool age children, or older adults; and they
39 obtain food at a facility that provides services such as custodial care, health care,
40 or assisted living, such as a child or adult day care center, kidney dialysis center,
41 hospital or nursing home, or nutritional or socialization services such as a senior
42 center.

43 ⊖ **“Hygroscopic”** means readily taking up and retaining moisture.

1 NOTIFICATION PROCESS SPECIFIED IN THE FOOD ALLERGEN LABELING
2 AND CONSUMER PROTECTION ACT OF 2004 (PUBLIC LAW 108-282).

3 ⊕ **“Meat”** means the flesh of animals used as food including the dressed flesh of
4 cattle, swine, sheep, or goats and other edible animals, except fish, poultry, and
5 wild game animals.

6 67. **“MECHANICALLY TENDERIZED”**

7 A. **“MECHANICALLY TENDERIZED”** MEANS MANIPULATING MEAT WITH
8 DEEP PENETRATION BY PROCESSES WHICH MAY BE REFERRED TO AS
9 “BLADE TENDERIZING,” “JACCARDING,” “PINNING,” “NEEDLING,” OR
10 USING BLADES, PINS, NEEDLES OR ANY MECHANICAL DEVICE.

11 B. **“MECHANICALLY TENDERIZED”** DOES NOT INCLUDE PROCESSES BY
12 WHICH SOLUTIONS ARE INJECTED INTO MEAT.

13 ⊕ **“mg/L”** means milligrams per liter, which is the metric equivalent of parts per
14 million (ppm).

15 ⊕ **“Mobile Retail Food Establishment”** means a retail food establishment that
16 ~~reports to and operates from a commissary and is readily moveable, is a~~
17 ~~motorized wheeled vehicle, or a towed wheeled vehicle designed and equipped to~~
18 ~~serve food~~ IS A WHEELED VEHICLE OR TRAILER THAT IS READILY MOVEABLE AND
19 DESIGNED FOR THE SERVICE OF FOOD FROM THE INTERIOR OF THE UNIT THAT IS
20 INTENDED TO PHYSICALLY REPORT TO AND OPERATE FROM A COMMISSARY FOR
21 SERVICING, RESTOCKING, AND MAINTENANCE EACH OPERATING DAY.

22 ~~(38)“Modified Atmosphere Packaging” means the reduction of the amount of oxygen~~
23 ~~in a package by mechanically evacuating the oxygen; displacing the oxygen with~~
24 ~~another gas or combination of gases; or otherwise controlling the oxygen content~~
25 ~~in a package to a level below what is normally found in the surrounding~~
26 ~~atmosphere, which is 21% oxygen. Reduced oxygen packaging includes~~
27 ~~methods that may be referred to as altered atmosphere, modified atmosphere,~~
28 ~~controlled atmosphere, low oxygen, and vacuum packaging including sous vide.~~

29 ⊕ **“Molluscan Shellfish”** means any edible species of fresh or frozen oysters,
30 clams, mussels, and scallops or edible portions thereof, except when the scallop
31 product consists only of the shucked adductor muscle.

32 71. **“NEW RETAIL FOOD ESTABLISHMENT”** MEANS A FACILITY THAT MAKES ITS
33 INITIAL APPLICATION AS A RETAIL FOOD ESTABLISHMENT, A FACILITY THAT
34 CHANGES ITS PHYSICAL LOCATION, OR WHEN THERE IS A CHANGE IN THE
35 DEPARTMENT OF REVENUE SALES TAX ID NUMBER.

36 ⊕ **“Nonfood-Contact Surfaces”** means all surfaces other than food-contact
37 surfaces.

38 73. **“NON-CONTINUOUS COOKING”**:

39 A. MEANS THE COOKING OF FOOD IN A FOOD ESTABLISHMENT USING A
40 PROCESS IN WHICH THE INITIAL HEATING OF THE FOOD IS
41 INTENTIONALLY HALTED SO THAT IT MAY BE COOLED AND HELD FOR
42 COMPLETE COOKING AT A LATER TIME PRIOR TO SALE OR SERVICE.

43 B. DOES NOT INCLUDE COOKING PROCEDURES THAT ONLY INVOLVE
44 TEMPORARILY INTERRUPTING OR SLOWING AN OTHERWISE CONTINUOUS
45 COOKING PROCESS.

- 1 74. **“NON-CRITICAL ITEM”**:
- 2 A. MEANS A PROVISION IN THIS CODE THAT IS NOT DESIGNATED AS A
- 3 CRITICAL ITEM.
- 4 B. INCLUDES AN ITEM THAT USUALLY RELATES TO GENERAL SANITATION,
- 5 OPERATIONAL CONTROLS, SANITATION STANDARD OPERATING
- 6 PROCEDURES (SSOPs), FACILITIES OR STRUCTURES, EQUIPMENT DESIGN,
- 7 OR GENERAL MAINTENANCE.
- 8
- 9 ⊕ **“Packaged”**
- 10 A.A. Means bottled, canned, cartoned, securely bagged, or securely wrapped,
- 11 whether packaged in a food establishment or a food processing plant.
- 12 B.B. **“Packaged”** does not include a wrapper, carry-out box, or other
- 13 nondurable container used to containerize food with the purpose of
- 14 facilitating food protection during service and receipt of the food by the
- 15 consumer.
- 16 ⊕ **“Person”** means a ~~natural person, partnership, association, company,~~
- 17 ~~corporation, organization, or manager, agent, servant officer, or employee of any~~
- 18 ~~of them or other legal entity~~ AN ASSOCIATION, A CORPORATION, INDIVIDUAL,
- 19 PARTNERSHIP, OTHER LEGAL ENTITY, GOVERNMENT, OR GOVERNMENTAL
- 20 SUBDIVISION OR AGENCY.
- 21 ⊕ **“Person In Charge”** means the individual present at a retail food establishment
- 22 who is responsible for the operation at the time of inspection. If no individual is
- 23 responsible, then any employed person present is the person in charge.
- 24 ⊕ **“Personal Care Items”** means items or substances that may be poisonous, toxic,
- 25 or a source of contamination which are used to maintain or enhance a person's
- 26 health, hygiene, or appearance, such as medicines, first aid supplies, cosmetics,
- 27 toiletries SUCH AS LOTION, toothpaste and mouthwash.
- 28 ⊕ **“pH”** means the measure of the degree of acidity or alkalinity of a solution.
- 29 ~~Values~~ pH between 0 and 7 indicates acidity and ~~values~~ pH between 7 and 14
- 30 indicates alkalinity. The value for pure distilled water is 7, which is considered
- 31 neutral.
- 32 ⊕ **“Physical Facilities”** means the structure and interior surfaces of a retail food
- 33 establishment including ~~attachments, such as light fixtures and heating or air~~
- 34 ~~conditioning system vents~~ FLOORS, WALLS, CEILINGS, LIGHTING, AND PREMISES,
- 35 INCLUDING, BUT NOT LIMITED TO ACCESSORIES SUCH AS SOAP AND TOWEL
- 36 DISPENSERS AND ATTACHMENTS SUCH AS LIGHT FIXTURES AND HEATING OR AIR
- 37 CONDITIONING SYSTEM VENTS.
- 38 ⊕ **“Poisonous or Toxic Materials”** means substances not intended for ingestion
- 39 and are included in four categories:
- 40 .
- 41 Cleaners and sanitizers, which include cleaning and sanitizing agents and
- 42 agents such as caustics, acids, drying agents, polishes, and other
- 43 chemicals;
- 44 .
- Pesticides, which include substances such as insecticides and
- rodenticides;

1 . Substances necessary for the operation and maintenance of the
 2 establishment such as nonfood grade lubricants and personal care items
 3 that may be deleterious to health; and

4 . Substances that are not necessary for the operation and maintenance of
 5 the establishment and are on the premises for retail sale, such as
 6 petroleum products and paints.

7 ~~(48)“Potentially Hazardous Food” means a food that is natural or synthetic and that~~
 8 ~~requires temperature control because it is in a form capable of supporting:~~

9 A. ~~The rapid and progressive growth of infectious or toxigenic~~
 10 ~~microorganisms;~~

11 B. ~~The growth and toxin production of *Clostridium botulinum*; or~~

12 C. ~~In raw shell eggs, the growth of *Salmonella enteritidis*.~~

13 — (i) ~~“Potentially Hazardous Food” includes a food of animal origin~~
 14 ~~that is raw or heat treated; a food of plant origin that is heat treated~~
 15 ~~or consists of raw seed sprouts; cut melons; and garlic in oil~~
 16 ~~mixtures that are not acidified or otherwise modified at a food~~
 17 ~~processing plant in a way that results in mixtures that do not~~
 18 ~~support growth as specified in subparagraphs 1, 2 and 3 of this~~
 19 ~~definition.~~

20 — (ii). ~~“Nonpotentially Hazardous Food” includes:~~

21 a. ~~Hard boiled eggs with shells intact which have been air~~
 22 ~~cooled;~~

23 b. ~~Foods with a water activity () value of 0.85 or less;~~

24 c. ~~Foods with a measurement of acidity (pH) of 4.6 or below;~~

25 d. ~~Foods which have been adequately commercially processed~~
 26 ~~and remain in their unopened hermetically sealed container;~~
 27 ~~and~~

28 e. ~~Food for which laboratory evidence (acceptable to the~~
 29 ~~regulatory authority) demonstrates that rapid and progressive~~
 30 ~~growth of infectious and toxigenic microorganisms, the growth~~
 31 ~~of *S. enteritidis* in eggs or the slower growth of *Clostridium*~~
 32 ~~*botulinum* cannot occur.~~

33 82. **“POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR**
 34 **SAFETY FOOD)”**

35 A. **“POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL**
 36 **FOR SAFETY FOOD)”** MEANS A FOOD THAT REQUIRES
 37 TIME/TEMPERATURE CONTROL FOR SAFETY (TCS) TO LIMIT PATHOGENIC
 38 MICROORGANISM GROWTH OR TOXIN FORMATION.

39 B. **“POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL**
 40 **FOR SAFETY FOOD)”** INCLUDES:

41 (1) A FOOD OF ANIMAL ORIGIN THAT IS RAW OR HEAT-TREATED; A
 42 FOOD OF PLANT ORIGIN THAT IS HEAT-TREATED OR CONSISTS OF

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RAW SEED SPROUTS, CUT MELONS, CUT LEAFY GREENS, CUT TOMATOES OR MIXTURES OF CUT TOMATOES THAT ARE NOT MODIFIED IN A WAY SO THAT THEY ARE UNABLE TO SUPPORT PATHOGENIC MICROORGANISM GROWTH OR TOXIN FORMATION, OR GARLIC-IN-OIL MIXTURES THAT ARE NOT MODIFIED IN A WAY SO THAT THEY ARE UNABLE TO SUPPORT PATHOGENIC MICROORGANISM GROWTH OR TOXIN FORMATION; AND

- (2) EXCEPT AS SPECIFIED IN SUBPARAGRAPH (C)(4) OF THIS DEFINITION, A FOOD THAT BECAUSE OF THE INTERACTION OF ITS AND PH VALUES IS DESIGNATED AS PRODUCT ASSESSMENT REQUIRED (PA) IN TABLE A OR B OF THIS DEFINITION:

TABLE A. INTERACTION OF PH AND AW FOR CONTROL OF SPORES IN FOOD HEAT-TREATED TO DESTROY VEGETATIVE CELLS AND SUBSEQUENTLY PACKAGED				
AW VALUES	PH VALUES			
	4.6 OR LESS	> 4.6 - 5.6	> 5.6	
≤0.92	NON-PHF*/NON-TCS FOOD**	NON-PHF/NON-TCS FOOD	NON-PHF/NON-TCS FOOD	
>0.92 - .95	NON-PHF/NON-TCS FOOD	NON-PHF/NON-TCS FOOD	PA***	
>0.95	NON-PHF/NON-TCS FOOD	PA	PA	
* PHF MEANS POTENTIALLY HAZARDOUS FOOD ** TCS FOOD MEANS TIME/TEMPERATURE CONTROL FOR SAFETY FOOD *** PA MEANS PRODUCT ASSESSMENT REQUIRED				
TABLE B. INTERACTION OF PH AND AW FOR CONTROL OF VEGETATIVE CELLS AND SPORES IN FOOD NOT HEAT-TREATED OR HEAT-TREATED BUT NOT PACKAGED				
AW VALUES	PH VALUES			
	<4.2	4.2 - 4.6	>4.6 - 5.0	>5.0
<0.88	NON-PHF*/NON-TCS FOOD**	NON-PHF/NON-TCS FOOD	NON-PHF/NON-TCS FOOD	NON-PHF/NON-TCS FOOD
0.88 - 0.90	NON-PHF/NON-TCS FOOD	NON-PHF/NON-TCS FOOD	NON-PHF/NON-TCS FOOD	PA***
>0.90 - 0.92	NON-PHF/NON-TCS FOOD	NON-PHF/NON-TCS FOOD	PA	PA
>0.92	NON-PHF/NON-TCS FOOD	PA	PA	PA
* PHF MEANS POTENTIALLY HAZARDOUS FOOD ** TCS FOOD MEANS TIME/TEMPERATURE CONTROL FOR SAFETY FOOD *** PA MEANS PRODUCT ASSESSMENT REQUIRED				

12
13

- C. "POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD)" DOES NOT INCLUDE:

- 1 (1) AN AIR-COOLED HARD-BOILED EGG WITH SHELL INTACT, OR AN
2 EGG WITH SHELL INTACT THAT IS NOT HARD-BOILED, BUT HAS
3 BEEN PASTEURIZED TO DESTROY ALL VIABLE **SALMONELLAE**;
- 4 (2) A FOOD IN AN UNOPENED HERMETICALLY SEALED CONTAINER
5 THAT IS COMMERCIALY PROCESSED TO ACHIEVE AND
6 MAINTAIN COMMERCIAL STERILITY UNDER CONDITIONS OF NON-
7 REFRIGERATED STORAGE AND DISTRIBUTION;
- 8 (3) A FOOD THAT BECAUSE OF ITS pH OR VALUE, OR INTERACTION
9 OF AND pH VALUES, IS DESIGNATED AS A NON-PHF/NON-TCS
10 FOOD IN TABLE A OR B OF THIS DEFINITION;
- 11 (4) A FOOD THAT IS DESIGNATED AS PRODUCT ASSESSMENT
12 REQUIRED (PA) IN TABLE A OR B OF THIS DEFINITION AND HAS
13 UNDERGONE A PRODUCT ASSESSMENT SHOWING THAT THE
14 GROWTH OR TOXIN FORMATION OF PATHOGENIC
15 MICROORGANISMS THAT ARE REASONABLY LIKELY TO OCCUR IN
16 THAT FOOD IS PRECLUDED DUE TO:
- 17 (A) INTRINSIC FACTORS INCLUDING ADDED OR NATURAL
18 CHARACTERISTICS OF THE FOOD SUCH AS
19 PRESERVATIVES, ANTIMICROBIALS, HUMECTANTS,
20 ACIDULANTS, OR NUTRIENTS,
- 21 (B) EXTRINSIC FACTORS INCLUDING ENVIRONMENTAL OR
22 OPERATIONAL FACTORS THAT AFFECT THE FOOD SUCH
23 AS PACKAGING, MODIFIED ATMOSPHERE SUCH AS
24 REDUCED OXYGEN PACKAGING, SHELF LIFE AND USE, OR
25 TEMPERATURE RANGE OF STORAGE AND USE, OR
- 26 (C) A COMBINATION OF INTRINSIC AND EXTRINSIC FACTORS;
27 OR
- 28 (5) A FOOD THAT DOES NOT SUPPORT THE GROWTH OR TOXIN
29 FORMATION OF PATHOGENIC MICROORGANISMS IN ACCORDANCE
30 WITH ONE OF THE SUBPARAGRAPHS (C)(1)-(4) OF THIS
31 DEFINITION EVEN THOUGH THE FOOD MAY CONTAIN A
32 PATHOGENIC MICROORGANISM OR CHEMICAL OR PHYSICAL
33 CONTAMINANT AT A LEVEL SUFFICIENT TO CAUSE ILLNESS OR
34 INJURY.
- 35 ⊕ **"Poultry"** means any domesticated bird such as chickens, turkeys, ducks, geese,
36 ~~or guineas~~ OR SQUABS and any migratory waterfowl, or game bird, such as
37 pheasant, partridge, quail, grouse, OR PIGEON. ~~or guinea, or pigeon, or squab.~~
- 38 ⊕ **"Premises"** means the physical facility, its contents, and the contiguous land or
39 property and its facilities and contents that may impact retail food establishment
40 personnel, facilities, or operations.
- 41 ⊕ **"Primal Meat Cuts"** ~~means any of various wholesale cuts into which a carcass~~
42 ~~of a food animal is divided~~ MEANS A BASIC MAJOR CUT INTO WHICH CARCASSES
43 AND SIDES OF MEAT ARE SEPARATED, SUCH AS A BEEF ROUND, PORK LOIN, LAMB
44 FLANK, OR VEAL BREAST.
- 45 ⊕ **"Private Boarding Houses"** means a house at which meals, or meals and
46 lodging, may be obtained for payment."

- 1 **"Private Boarding Houses"** does not include:
- 2 A. Hotels
- 3 B. Motels
- 4 C. Homeless shelters
- 5 D. Youth hostel
- 6 E. Other commercial facilities providing lodging and/or meals for the
- 7 indigent population whether or not there is a charge for such food and/or
- 8 lodging.
- 9 ⊕ **"Pushcart"** means ~~a non self propelled vehicle limited to serving commissary~~
- 10 ~~prepared or prepackaged food and non potentially hazardous food unless the~~
- 11 ~~equipment is commercially designed and approved to handle food preparation~~
- 12 ~~and service.~~ RETAIL FOOD ESTABLISHMENT THAT IS A NON-MOTORIZED, UNIT
- 13 DESIGNED SO FOODS ARE SERVED FROM THE EXTERIOR OF THE UNIT, AND WHICH
- 14 IS INTENDED TO PHYSICALLY REPORT TO AND OPERATE FROM A COMMISSARY
- 15 FOR SERVICING, RESTOCKING AND MAINTENANCE EACH OPERATING DAY.
- 16 88. **"Ratite"** MEANS A FLIGHTLESS BIRD SUCH AS AN EMU, OSTRICH, OR RHEA.
- 17 ⊕ **"Ready-to-Eat Food"** means food that is edible without further washing,
- 18 cooking, or additional preparation and that is reasonably expected to be
- 19 consumed in that form. READY-TO-EAT FOOD DOES NOT INCLUDE WHOLE, RAW
- 20 FRUITS AND VEGETABLES THAT ARE INTENDED FOR WASHING BY THE CONSUMER
- 21 BEFORE CONSUMPTION.
- 22 ⊕ **"Reconstituted"** means dehydrated food products recombined with water or
- 23 other liquids.
- 24 91. **"REDUCED OXYGEN PACKAGING"**
- 25 A. **"REDUCED OXYGEN PACKAGING" MEANS:**
- 26 (1) THE REDUCTION OF THE AMOUNT OF OXYGEN IN A PACKAGE BY
- 27 REMOVING OXYGEN; DISPLACING OXYGEN AND REPLACING IT
- 28 WITH ANOTHER GAS OR COMBINATION OF GASES; OR OTHERWISE
- 29 CONTROLLING THE OXYGEN CONTENT TO A LEVEL BELOW THAT
- 30 NORMALLY FOUND IN THE ATMOSPHERE (APPROXIMATELY 21%
- 31 AT SEA LEVEL); AND
- 32 (2) A PROCESS AS SPECIFIED IN SECTION (A)(1) OF THIS DEFINITION
- 33 THAT INVOLVES A FOOD FOR WHICH THE HAZARDS
- 34 CLOSTRIDIUM BOTULINUM OR LISTERIA MONOCYTOGENES
- 35 REQUIRE CONTROL IN THE FINAL PACKAGED FORM.
- 36 B. **"REDUCED OXYGEN PACKAGING" INCLUDES:**
- 37 (1) VACUUM PACKAGING, IN WHICH AIR IS REMOVED FROM A
- 38 PACKAGE OF FOOD AND THE PACKAGE IS HERMETICALLY
- 39 SEALED SO THAT A VACUUM REMAINS INSIDE THE PACKAGE;
- 40 (2) MODIFIED ATMOSPHERE PACKAGING, IN WHICH THE
- 41 ATMOSPHERE OF A PACKAGE OF FOOD IS MODIFIED SO THAT IT'S
- 42 COMPOSITION IS DIFFERENT FROM AIR BUT THE ATMOSPHERE
- 43 MAY CHANGE OVER TIME DUE TO THE PERMEABILITY OF THE

- 1 PACKAGING MATERIAL OR THE RESPIRATION OF THE FOOD.
2 MODIFIED ATMOSPHERE PACKAGING INCLUDES REDUCTION IN
3 THE PROPORTION OF OXYGEN, TOTAL REPLACEMENT OF
4 OXYGEN, OR AN INCREASE IN THE PROPORTION OF OTHER GASES
5 SUCH AS CARBON DIOXIDE OR NITROGEN;
- 6 (3) CONTROLLED ATMOSPHERE PACKAGING, IN WHICH THE
7 ATMOSPHERE OF A PACKAGE OF FOOD IS MODIFIED SO THAT
8 UNTIL THE PACKAGE IS OPENED, ITS COMPOSITION IS DIFFERENT
9 FROM AIR, AND CONTINUOUS CONTROL OF THAT ATMOSPHERE IS
10 MAINTAINED, SUCH AS BY USING OXYGEN SCAVENGERS OR A
11 COMBINATION OF TOTAL REPLACEMENT OF OXYGEN,
12 NONRESPIRING FOOD, AND IMPERMEABLE PACKAGING
13 MATERIAL;
- 14 (4) EXCEPT AS SPECIFIED IN SECTION (C), COOK CHILL PACKAGING,
15 IN WHICH COOKED FOOD IS HOT FILLED INTO IMPERMEABLE
16 BAGS WHICH HAVE THE AIR EXPELLED AND ARE THEN SEALED
17 OR CRIMPED CLOSED, THE BAGGED FOOD IS RAPIDLY CHILLED
18 AND REFRIGERATED AT TEMPERATURES THAT INHIBIT THE
19 GROWTH OF PSYCHROTROPHIC PATHOGENS; OR
- 20 (5) SOUS VIDE PACKAGING, IN WHICH RAW OR PARTIALLY COOKED
21 FOOD IS VACUUM PACKAGED IN AN IMPERMEABLE BAG,
22 COOKED, RAPIDLY CHILLED, AND REFRIGERATED AT
23 TEMPERATURES THAT INHIBIT THE GROWTH OF
24 PSYCHROTROPHIC PATHOGENS.
- 25 C. **"REDUCED OXYGEN PACKAGING"** DOES NOT INCLUDE:
- 26 (1) PLACING PRODUCT IN A BAG AND SEALING IT IMMEDIATELY
27 PRIOR TO OR AFTER, COOKING, COOLING OR REHEATING THE
28 PRODUCT AS LONG AS THE PRODUCT IS:
- 29 (A) LABELED WITH THE TIME AND DATE THE PRODUCT IS
30 PLACED IN THE BAG; AND
- 31 (B) REMOVED FROM THE BAG WITHIN 48 HOURS OF THE
32 TIME THE PRODUCT IS PLACED IN THE BAG.
- 33 92. **"REFUSE"** MEANS SOLID WASTE NOT CARRIED BY WATER THROUGH THE
34 SEWAGE SYSTEM.
- 35 93. **"RE-SERVICE"** MEANS THE TRANSFER OF FOOD THAT IS UNUSED AND RETURNED
36 BY A CONSUMER AFTER BEING SERVED OR SOLD AND IN THE POSSESSION OF THE
37 CONSUMER, TO ANOTHER PERSON.
- 38 94. **"RESTRICT"** MEANS TO LIMIT THE ACTIVITIES OF A FOOD EMPLOYEE SO THAT
39 THERE IS NO RISK OF TRANSMITTING A DISEASE THAT IS TRANSMISSIBLE
40 THROUGH FOOD AND THE FOOD EMPLOYEE DOES NOT WORK WITH EXPOSED
41 FOOD, CLEAN EQUIPMENT, UTENSILS, LINENS, OR UNWRAPPED SINGLE-SERVICE
42 OR SINGLE-USE ARTICLES.
- 43 ⊕ **"Retail Food Establishment"** means a retail operation that stores, prepares, or
44 packages food for human consumption or serves or otherwise provides food for
45 human consumption to consumers directly or indirectly through a delivery

1 service, whether such food is consumed on or off the premises or whether there is
2 a charge for such food.

3 **“Retail Food Establishment”** does not include:

- 4 . Any private home;
- 5 . Private boarding houses;
- 6 . Hospital and health facility patient feeding operations licensed by the
7 Department;
- 8 . Child care centers and other child care facilities licensed by the
9 Department of Human Services;
- 10 . Hunting camps and other outdoor recreation locations where food is
11 prepared in the field rather than at a fixed base of operation;
- 12 . Food or beverage wholesale manufacturing, processing, or packaging
13 plants, or portions thereof, that are subject to regulatory controls under
14 state or federal laws or regulations;
- 15 . Motor vehicles used only for the transport of food;
- 16 . Establishments preparing and serving only hot coffee, hot tea, instant hot
17 beverages, and nonpotentially hazardous doughnuts or pastries obtained
18 from sources complying with all laws related to food and food labeling;
- 19 . Establishments that handle only nonpotentially hazardous prepackaged
20 food and operations serving only commercially prepared, prepackaged
21 foods requiring no preparation other than the heating of food within its
22 original container or package;

23 ——— **J.J.** Farmers markets and roadside markets that offer only uncut fresh fruit
24 and vegetables for sale;

25 ——— **K.K.** Automated food merchandising enterprises that supply only prepackaged
26 nonpotentially hazardous food or drink or food or drink in bottles, cans,
27 or cartons only, and operations that dispense only chewing gum or salted
28 nuts in their natural protective covering;

29 ——— **L.L.** The donation, preparation, sale, or service of food by a nonprofit or
30 charitable organization in conjunction with an event or celebration if
31 such donation, preparation, sale, or service of food;

32 ~~1.~~(1) Does not exceed the duration of the event or celebration or a
33 maximum of fifty-two days within a calendar year; and

34 ~~2.~~(2). Takes place in the county in which such nonprofit or charitable
35 organization resides or is principally located.

36 96. **“Risk”** MEANS THE LIKELIHOOD THAT AN ADVERSE HEALTH EFFECT WILL
37 OCCUR WITHIN A POPULATION AS A RESULT OF A HAZARD IN A FOOD

38 ~~(.)~~ ——— **“Safe Materials”** means articles manufactured from or composed of materials
39 that may not reasonably be expected to result, directly or indirectly, in their
40 becoming a component or otherwise affecting the characteristic of any food. If
41 materials are food additives or color additives as defined in section 25-5-402(3)
42 or (12), C.R.S., of the “Colorado Pure Food and Drug Law”, as used, they are

- 1 “safe” only if they are used in conformity with all applicable regulations of the
2 U.S. Food and Drug Administration.
- 3 (-) **“Sanitization”** means the application of cumulative heat or chemicals on cleaned
4 food-contact surfaces that, when evaluated for efficacy, is sufficient to yield a
5 reduction of 5 logs, which is equal to a 99.999% reduction, of representative
6 disease microorganisms of public health importance.
- 7 99. **“SEALED”** MEANS FREE OF CRACKS OR OTHER OPENINGS THAT ALLOW THE
8 ENTRY OR PASSAGE OF MOISTURE OR DEBRIS.
- 9 100. **“SELF CONTAINED MOBILE RETAIL FOOD ESTABLISHMENT”** MEANS A
10 LICENSED MOBILE RETAIL FOOD ESTABLISHMENT THAT IS APPROVED TO
11 OPERATE WITHOUT A COMMISSARY, AND IS NOT CONNECTED TO FIXED UTILITIES
12 SUCH AS WATER, SEWER AND ELECTRICITY, AND IS REQUIRED TO REPORT TO AN
13 APPROVED SERVICING LOCATION FOR SEWAGE DISPOSAL AND WATER.
- 14 101. **“SERVICE ANIMAL”** MEANS ANY DOG OR MINIATURE HORSE THAT IS
15 INDIVIDUALLY TRAINED TO DO WORK OR PERFORM TASKS FOR THE BENEFIT OF
16 AN INDIVIDUAL WITH A DISABILITY, INCLUDING A PHYSICAL, SENSORY,
17 PSYCHIATRIC, INTELLECTUAL, OR OTHER MENTAL DISABILITY. OTHER SPECIES
18 OF ANIMALS, WHETHER WILD OR DOMESTIC, TRAINED OR UNTRAINED, ARE NOT
19 SERVICE ANIMALS FOR THE PURPOSES OF THIS DEFINITION. THE WORK OR TASKS
20 PERFORMED BY A SERVICE ANIMAL MUST BE DIRECTLY RELATED TO THE
21 HANDLER'S DISABILITY. EXAMPLES OF WORK OR TASKS INCLUDE, BUT ARE NOT
22 LIMITED TO, ASSISTING INDIVIDUALS WHO ARE BLIND OR HAVE LOW VISION
23 WITH NAVIGATION AND OTHER TASKS, ALERTING INDIVIDUALS WHO ARE DEAF
24 OR HARD OF HEARING TO THE PRESENCE OF PEOPLE OR SOUNDS, PROVIDING
25 NON-VIOLENT PROTECTION OR RESCUE WORK, PULLING A WHEELCHAIR,
26 ASSISTING AN INDIVIDUAL DURING A SEIZURE, ALERTING INDIVIDUALS TO THE
27 PRESENCE OF ALLERGENS, RETRIEVING ITEMS SUCH AS MEDICINE OR THE
28 TELEPHONE, PROVIDING PHYSICAL SUPPORT AND ASSISTANCE WITH BALANCE
29 AND STABILITY TO INDIVIDUALS WITH MOBILITY DISABILITIES, AND HELPING
30 PERSONS WITH PSYCHIATRIC AND NEUROLOGICAL DISABILITIES BY PREVENTING
31 OR INTERRUPTING IMPULSIVE OR DESTRUCTIVE BEHAVIORS. THE CRIME
32 DETERRENT EFFECTS OF AN ANIMAL'S PRESENCE AND THE PROVISION OF
33 EMOTIONAL SUPPORT, WELL-BEING, COMFORT, OR COMPANIONSHIP DO NOT
34 CONSTITUTE WORK OR TASKS FOR THE PURPOSES OF THIS DEFINITION.
- 35 102. **“SEWAGE”** MEANS LIQUID WASTE CONTAINING ANIMAL OR PLANT MATTER IN
36 SUSPENSION OR SOLUTION AND MAY INCLUDE LIQUIDS CONTAINING CHEMICALS
37 IN SOLUTION.
- 38 (-) **“Shellstock”** means raw, in-shell, molluscan shellfish.
- 39 104. **“SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI*”** (STEC) MEANS ANY *E. COLI*
40 CAPABLE OF PRODUCING SHIGA TOXINS (ALSO CALLED VEROCYTOTOXINS OR
41 “SHIGA-LIKE” TOXINS). EXAMPLES OF SEROTYPES OF STEC INCLUDE BOTH
42 O157 AND NON-O157 *E. COLI*. ALSO SEE ENTEROHEMORRHAGIC *ESCHERICHIA*
43 *COLI*
- 44 (-) **“Shucked Shellfish”** means molluscan shellfish that have one or both shells
45 removed.

1 ~~(.)~~ **“Single-Service Articles”** means cups, containers, lids, closures, plates, knives, forks,
2 spoons, stirrers, paddles, straws, napkins, place mats, doilies, wrapping materials,
3 toothpicks and similar articles intended for one-time, one-person CONSUMER
4 use and then discarded after use.

5 ~~(62)~~ **“Single-Use Articles”** means utensils and bulk food containers designed and
6 constructed to be used once and discarded. _____

7 107. **“SINGLE-USE ARTICLES”**

8 A. **“SINGLE-USE ARTICLES”** MEANS UTENSILS AND BULK FOOD
9 CONTAINERS DESIGNED AND CONSTRUCTED TO BE USED ONCE AND
10 DISCARDED.

11 B. **“SINGLE-USE ARTICLES”** INCLUDES ITEMS SUCH AS WAX PAPER,
12 BUTCHER PAPER, PLASTIC WRAP, FORMED ALUMINUM FOOD
13 CONTAINERS, JARS, PLASTIC TUBS OR BUCKETS, BREAD WRAPPERS,
14 PICKLE BARRELS, KETCHUP BOTTLES, AND NUMBER 10 CANS WHICH DO
15 NOT MEET THE MATERIALS, DURABILITY, STRENGTH, AND CLEANABILITY
16 SPECIFICATIONS UNDER 4-101, AND 4-201 FOR MULTUISE UTENSILS.

17 108. **“SLACKING”** MEANS THE PROCESS OF MODERATING THE TEMPERATURE OF A
18 FOOD SUCH AS ALLOWING A FOOD TO GRADUALLY INCREASE FROM A
19 TEMPERATURE OF - (-) TO - () IN PREPARATION FOR DEEP-FAT FRYING OR TO
20 FACILITATE EVEN HEAT PENETRATION DURING THE COOKING OF PREVIOUSLY
21 BLOCK-FROZEN FOOD SUCH AS SHRIMP.

22 ~~(.)~~ **“Smooth”** means:

23 ~~A.~~ A. A food-contact surface having a surface free of pits and inclusions with a
24 cleanability equal to or exceeding that of (100 grit) number 3 stainless
25 steel;

26 ~~B.~~ B. A nonfood-contact surface of equipment having a surface equal to that of
27 commercial grade hot-rolled steel free of visible scale; and

28 ~~C.~~ C. A floor, wall, or ceiling having an even or level surface with no
29 roughness, projections, perforations, pits, or inclusions that render it
30 difficult to clean.

31 ~~(64)~~ **“Subprimal Meat Cuts”** means cuts made in the retail food establishment from
32 primal meat cuts.

33 ~~(65)~~ **“Support Animal”** means a trained animal, such as a guide or service animal,
34 that accompanies a person with a disability to assist in managing the disability
35 and enables the person to perform functions that the person would otherwise be
36 unable to perform.

37 ~~(.)~~ **“Tableware”** means eating, drinking, and serving utensils for table use, such as forks,
38 knives, and spoons; including bowls, cups, serving dishes, tumblers and plates.

39 111. **“TEMPERATURE MEASURING DEVICE”** MEANS A THERMOMETER,
40 THERMOCOUPLE, THERMISTOR, OR OTHER DEVICE THAT INDICATES THE
41 TEMPERATURE OF FOOD, AIR, OR WATER.

42 112. **“TEMPORARY EVENT”** MEANS A SINGLE COMMUNITY EVENT OR CELEBRATION
43 THAT OPERATES FOR A PERIOD OF TIME OF NOT MORE THE FOURTEEN (14)

1 CONSECUTIVE DAYS AND MAY INCLUDE TOWN CELEBRATIONS, FAIRS, AND
2 FESTIVALS.

3 TEMPORARY EVENTS DO NOT INCLUDE:

4 A. REGULARLY SCHEDULED SERIES OF EVENTS AT VENUES SUCH AS
5 SPORTING ARENAS, CONCERT HALLS, FLEA MARKETS, OR FARMERS'
6 MARKETS.

7 B. EVENTS SERVICED BY LICENSED CATERERS ARE NOT CONSIDERED
8 TEMPORARY EVENTS.

9 C. SPORADIC PROMOTIONAL EVENTS SUCH AS GRAND OPENINGS ARE NOT
10 CONSIDERED TEMPORARY EVENTS.

11 ~~(.)~~ **“Temporary Retail Food Establishment”** means a food establishment that ~~operates~~
12 ~~at a fixed location for a period of time of not more than fourteen (14) consecutive~~
13 ~~days in conjunction with a single event or celebration.~~ IS LIMITED TO OPERATING
14 AT TEMPORARY EVENTS ONLY.

15 114. **“USDA”** MEANS THE U.S. DEPARTMENT OF AGRICULTURE.

16 ~~(.)~~ **“Utensil”** means A FOOD CONTACT ~~any~~ implement OR CONTAINER used in the storage,
17 preparation, transportation, DISPENSING, SALE or service of food, SUCH AS
18 KITCHENWARE OR TABLEWARE THAT IS MULTIUSE, SINGLE-SERVICE, OR SINGLE-
19 USE.

20 116. **“VARIANCE”** MEANS A WRITTEN DOCUMENT ISSUED BY THE COLORADO
21 DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT (CDPHE) THAT
22 AUTHORIZES A MODIFICATION OR WAIVER OF ONE OR MORE REQUIREMENTS
23 OF THIS CODE IF, IN THE OPINION OF CDPHE, A HEALTH HAZARD OR
24 NUISANCE WILL NOT RESULT FROM THE MODIFICATION OR WAIVER.

25 ~~(.)~~ **“Warewashing”** means the cleaning and sanitizing of ~~equipment and utensil food-~~
26 ~~contact surfaces.~~ UTENSILS AND FOOD-CONTACT SURFACES OF EQUIPMENT.

27 ~~(.)~~ **“Water Activity”** () ~~means a measure of free moisture in a food and is indicated by~~
28 ~~the symbol a_w .~~ SEE AW DEFINITION IN SECTION 1-202(7).

29 119. **“WHOLE-MUSCLE, INTACT BEEF”** MEANS WHOLE MUSCLE BEEF THAT IS
30 NOT INJECTED, MECHANICALLY TENDERIZED, RECONSTRUCTED, OR SCORED
31 AND MARINATED, FROM WHICH BEEF STEAKS MAY BE CUT.

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CHAPTER 2

MANAGEMENT AND PERSONNEL

2-1 SUPERVISION

2-101 Responsibilities

The operator shall be the person in charge or shall designate a person in charge and shall ensure that a person in charge is present at the retail food establishment during all hours of operation. ~~*The operator shall educate and monitor employees to ensure conformance to these rules and regulations.~~

*2-102 Demonstration

Based on the risks of foodborne illness inherent to the food operation, during inspections and upon request the person in charge shall demonstrate to the ~~regulatory authority~~ DEPARTMENT knowledge of foodborne disease prevention, application of the Hazard Analysis Critical Control Point principles, and the requirements of these rules and regulations. The person in charge shall demonstrate this knowledge by:

- A. Complying with these rules and regulations BY HAVING NO VIOLATIONS OF CRITICAL ITEMS DURING THE CURRENT INSPECTION ; or
- B. Being a certified food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program; or
- C. Responding correctly to the inspector’s questions as they relate to the specific food operation. The areas of knowledge include:
 - (1.) Describing the relationship between the prevention of foodborne disease and the personal hygiene of a food employee;
 - (2.) Explaining the responsibility of the person in charge for preventing the transmission of foodborne disease by a food employee who has a disease or medical condition that may cause foodborne disease;
 - (3.) Describing the symptoms associated with the diseases that are transmissible through food;
 - (4.) Explaining the hazards involved in the consumption of raw or undercooked meat, poultry, eggs and fish;
 - (5.) Stating the required temperatures and times for the safe cooking, refrigerated storage, hot holding, cooling, and reheating of ~~potentially hazardous food~~ POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD);
 - (6.) Describing the relationship between the prevention of foodborne illness and the management and control of the following:
 - (a). Cross contamination,
 - (b). Hand contact with ready-to-eat foods,
 - (c). Handwashing, and

1 ***2-103 Person in Charge**

2 The person in charge shall EDUCATE AND MONITOR EMPLOYEES to ensure that:

- 3 A. Employees are effectively cleaning their hands, by routinely monitoring the
4 employees' handwashing;
- 5 B. Employees are visibly observing foods as they are received to determine that they
6 are from approved sources, delivered at the required temperatures, protected from
7 contamination, unadulterated, and accurately presented, by routinely monitoring
8 the employees' observations and periodically evaluating foods upon their receipt;
- 9 C. Employees are properly cooking ~~potentially hazardous food~~ POTENTIALLY
10 HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD), being
11 particularly careful in cooking those foods known to cause severe foodborne
12 illness and death, such as eggs and comminuted meats, through daily oversight of
13 the employees' routine monitoring of the cooking temperatures using appropriate
14 temperature measuring devices properly scaled and calibrated as specified IN
15 SECTION 4-401 OF THESE RULES AND REGULATIONS;
- 16 D. Employees are using proper methods to rapidly cool ~~potentially hazardous foods~~
17 POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY
18 FOOD) that are not held hot or are not for consumption within 4 hours, through
19 daily oversight of the employees' routine monitoring of food temperatures during
20 cooling;
- 21 E. Employees are properly sanitizing cleaned multiuse equipment and utensils
22 before they are reused, through routine monitoring of solution temperature and
23 exposure time for hot water sanitizing, and chemical concentration, pH,
24 temperature, and exposure time for chemical sanitizing;
- 25 F. Consumers are notified that clean tableware is to be used when they return to
26 self-service areas such as salad bars and buffets as specified ~~under §~~IN SECTION
27 3-~~308~~411(A);
- 28 G. Employees ~~are minimizing~~ PREVENT bare hand contact with ready-to-eat food by
29 properly using suitable utensils such as deli tissue, spatulas, tongs, single-use
30 gloves, or dispensing equipment; and
- 31 H. Employees are properly trained in food safety as it relates to their assigned
32 duties.
- 33 I. FOOD EMPLOYEES AND CONDITIONAL EMPLOYEES ARE INFORMED OF THEIR
34 RESPONSIBILITIES TO REPORT THEIR ILLNESSES AND INFECTIONS TRANSMISSIBLE
35 THROUGH FOOD TO THE PERSON IN CHARGE, SO THAT THE PERSON IN CHARGE
36 MAY EXCLUDE OR RESTRICT ANY EMPLOYEES WHO ARE ILL, HAVE A BOIL OR
37 WOUND, AND WHEN TO NOTIFY THE DEPARTMENT OF ILLNESSES.
- 38 J. EMPLOYEES AND OTHER PERSONS SUCH AS DELIVERY AND MAINTENANCE
39 PERSONS AND PESTICIDE APPLICATORS ENTERING THE FOOD PREPARATION, FOOD
40 STORAGE, AND WAREWASHING AREAS COMPLY WITH THIS CODE;
- 41 K. CONSUMERS WHO ORDER RAW OR PARTIALLY COOKED READY-TO-EAT FOODS OF
42 ANIMAL ORIGIN ARE INFORMED AS SPECIFIED IN SECTION 3-801 OF THESE RULES
43 ARE REGULATIONS THAT THE FOOD IS NOT COOKED SUFFICIENTLY TO ENSURE ITS
44 SAFETY.
- 45

1 **2-2 EMPLOYEE HEALTH**

2 ~~*2-201 Restrictions Regarding Ill Or Otherwise Infected Employees~~

3 ~~No employee, while infected with a communicable disease that can be transmitted by~~
4 ~~foods or who is a carrier of organisms that cause such a disease or while afflicted with a~~
5 ~~boil, an infected wound on an exposed body part, or an acute respiratory infection, shall~~
6 ~~work in a retail food establishment in any capacity in which there is a likelihood of such~~
7 ~~employee contaminating food or food contact surfaces with pathogenic organisms or~~
8 ~~transmitting disease to other persons.~~

9 ~~*2-202 Reporting~~

10 ~~It shall be the responsibility of the employee to report to the person in charge when~~
11 ~~infected with or a carrier of a communicable disease or an organism that may be~~
12 ~~transmitted by food.~~

13 ~~*2-203 Exclusions~~

14 ~~The person in charge shall exclude an employee from a retail food establishment if the~~
15 ~~employee is diagnosed with an infection where there is a likelihood of such employee~~
16 ~~contaminating as specified in section 2-201 of these rules and regulations.~~

17 ~~*2-204 Removal of Exclusions~~

18 ~~The person in charge may remove an exclusion, applied under section 2-203 of these~~
19 ~~rules and regulations, with the Department's approval.~~

20 ~~*2-205 Restrictions~~

21 ~~Any employee with a pustular lesion, such as a boil or infected wound, on any exposed~~
22 ~~portions of the body shall keep such lesion covered by a dry, waterproof, durable, tight~~
23 ~~fitting bandage and a single use glove, if on the hands or wrist, that shields the wound~~
24 ~~from direct contact with food or equipment.~~

25 ***2-201 RESPONSIBILITY OF LICENSEE, PERSON IN CHARGE, AND EMPLOYEES**

26 A. THE LICENSEE SHALL REQUIRE FOOD EMPLOYEES AND CONDITIONAL EMPLOYEES
27 TO REPORT TO THE PERSON IN CHARGE INFORMATION ABOUT THEIR HEALTH AND
28 ACTIVITIES AS THEY RELATE TO DISEASES THAT ARE TRANSMISSIBLE THROUGH
29 FOOD. A FOOD EMPLOYEE OR CONDITIONAL EMPLOYEE SHALL REPORT
30 PERTINENT INFORMATION IN A MANNER THAT ALLOWS THE PERSON IN CHARGE
31 TO REDUCE THE RISK OF FOODBORNE DISEASE TRANSMISSION, , IF THE FOOD
32 EMPLOYEE OR CONDITIONAL EMPLOYEE:

- 33 1. HAS ANY OF THE FOLLOWING SYMPTOMS:
- 34 A. VOMITING,
 - 35 B. DIARRHEA,
 - 36 C. JAUNDICE,
 - 37 D. SORE THROAT WITH FEVER, OR
 - 38 E. A LESION CONTAINING PUS SUCH AS A BOIL OR INFECTED
 - 39 WOUND THAT IS OPEN AND/OR DRAINING AND IS:

- 1 (1) ON THE HANDS OR WRISTS, UNLESS AN IMPERMEABLE
2 COVER SUCH AS A FINGER COT OR STALL PROTECTS THE
3 LESION AND A SINGLE-USE GLOVE IS WORN OVER THE
4 IMPERMEABLE COVER,
- 5 (2) ON EXPOSED PORTIONS OF THE ARMS, UNLESS THE LESION IS
6 PROTECTED BY AN IMPERMEABLE COVER, OR
- 7 (3) ON OTHER PARTS OF THE BODY, UNLESS THE LESION IS
8 COVERED BY A DRY, DURABLE, TIGHT-FITTING BANDAGE;
- 9 2. HAS AN ILLNESS DIAGNOSED BY A HEALTH PRACTITIONER DUE TO:
 - 10 A. NOROVIRUS,
 - 11 B. HEPATITIS A VIRUS,
 - 12 C. SHIGELLA SPP.,
 - 13 D. ENTEROHEMORRHAGIC OR SHIGA TOXIN-PRODUCING
14 ESCHERICHIA COLI,
 - 15 E. SALMONELLA TYPHI; OR
 - 16 F. OTHER ENTERIC PATHOGEN
- 17 3. HAD A PREVIOUS ILLNESS, DIAGNOSED BY A HEALTH PRACTITIONER,
18 WITHIN THE PAST THREE (3) MONTHS DUE TO SALMONELLA TYPHI, AS
19 DETERMINED BY A HEALTH PRACTITIONER;
- 20 B. THE PERSON IN CHARGE SHALL NOTIFY THE DEPARTMENT WHEN A FOOD
21 EMPLOYEE IS:
 - 22 1. JAUNDICED, OR
 - 23 2. DIAGNOSED WITH AN ILLNESS DUE TO A PATHOGEN AS SPECIFIED IN
24 SUBPARAGRAPHS (A)(2) AND (A)(3) OF THIS SECTION.
- 25 C. THE PERSON IN CHARGE SHALL ENSURE THAT A CONDITIONAL EMPLOYEE:
 - 26 1. WHO EXHIBITS OR REPORTS A SYMPTOM, OR WHO REPORTS A
27 DIAGNOSED ILLNESS AS SPECIFIED IN SUBPARAGRAPHS (A)(1)-(3) OF
28 THIS SECTION, IS PROHIBITED FROM BECOMING A FOOD EMPLOYEE UNTIL
29 THE CONDITIONAL EMPLOYEE MEETS THE CRITERIA FOR THE SPECIFIC
30 SYMPTOMS OR DIAGNOSED ILLNESS AS SPECIFIED IN SECTION 2-203; AND
 - 31 2. WHO WILL WORK AS A FOOD EMPLOYEE IN A FOOD ESTABLISHMENT
32 THAT SERVES AS A HIGHLY SUSCEPTIBLE POPULATION AND REPORTS A
33 HISTORY OF EXPOSURE TO A COMMUNICABLE DISEASE, IS PROHIBITED
34 FROM BECOMING A FOOD EMPLOYEE UNTIL THE CONDITIONAL
35 EMPLOYEE MEETS THE CRITERIA AS SPECIFIED IN SECTION 2-203.
- 36 D. THE PERSON IN CHARGE SHALL ENSURE THAT A FOOD EMPLOYEE WHO EXHIBITS
37 OR REPORTS A SYMPTOM, OR WHO REPORTS A DIAGNOSED ILLNESS OR A HISTORY
38 OF EXPOSURE AS SPECIFIED IN SUBPARAGRAPHS (A)(1)-(3) OF THIS SECTION IS:
 - 39 1. EXCLUDED AS SPECIFIED IN 2-202 (A)-(D)(1), (E)(1), (F)(1), (G)(1),
40 (H)(1), AND IN COMPLIANCE WITH THE PROVISIONS SPECIFIED UNDER 2-
41 203(A) - (G); OR

- 1 F. IF A FOOD EMPLOYEE IS DIAGNOSED WITH AN INFECTION FROM
2 ENTEROHEMORRHAGIC OR SHIGA TOXIN-PRODUCING E. COLI, AND IS
3 ASYMPTOMATIC:
 - 4 1. EXCLUDE THE FOOD EMPLOYEE WHO WORKS IN A FOOD ESTABLISHMENT
5 SERVING A HIGHLY SUSCEPTIBLE POPULATION; OR
 - 6 2. RESTRICT THE FOOD EMPLOYEE WHO WORKS IN A FOOD ESTABLISHMENT
7 NOT SERVING A HIGHLY SUSCEPTIBLE POPULATION.
- 8 G. IF A FOOD EMPLOYEE IS DIAGNOSED WITH ANOTHER BACTERIAL ENTERIC
9 PATHOGEN AND IS ASYMPTOMATIC:
 - 10 1. EXCLUDE THE FOOD EMPLOYEE WHO WORKS IN A FOOD ESTABLISHMENT
11 SERVING A HIGHLY SUSCEPTIBLE POPULATION; OR
 - 12 2. RESTRICT THE FOOD EMPLOYEE WHO WORKS IN A FOOD ESTABLISHMENT
13 NOT SERVING A HIGHLY SUSCEPTIBLE POPULATION.
- 14 H. IF A FOOD EMPLOYEE IS ILL WITH SYMPTOMS OF ACUTE ONSET OF SORE THROAT
15 WITH FEVER:
 - 16 1. EXCLUDE THE FOOD EMPLOYEE WHO WORKS IN A FOOD ESTABLISHMENT
17 SERVING A HIGHLY SUSCEPTIBLE POPULATION; OR
 - 18 2. RESTRICT THE FOOD EMPLOYEE WHO WORKS IN A FOOD ESTABLISHMENT
19 NOT SERVING A HIGHLY SUSCEPTIBLE POPULATION.
- 20 I. IF A FOOD EMPLOYEE IS INFECTED WITH A SKIN LESION CONTAINING PUS SUCH AS
21 A BOIL OR INFECTED WOUND THAT IS OPEN OR DRAINING AND NOT PROPERLY
22 COVERED AS SPECIFIED IN SECTION 2-201(A)(1)(E), RESTRICT THE FOOD
23 EMPLOYEE.

24 ***2-203 REMOVAL, ADJUSTMENT, OR RETENTION OF EXCLUSIONS AND RESTRICTIONS**

25 THE PERSON IN CHARGE SHALL ADHERE TO THE FOLLOWING CONDITIONS WHEN
26 REMOVING, ADJUSTING, OR RETAINING THE EXCLUSION OR RESTRICTION OF A FOOD
27 EMPLOYEE:

- 28 A. EXCEPT WHEN A FOOD EMPLOYEE IS DIAGNOSED WITH AN INFECTION FROM
29 HEPATITIS A VIRUS OR SALMONELLA TYPHI:
 - 30 1. REINSTATE A FOOD EMPLOYEE WHO WAS EXCLUDED AS SPECIFIED IN
31 SECTION 2-202(A)(1) IF THE FOOD EMPLOYEE:
 - 32 A. IS ASYMPTOMATIC FOR AT LEAST 24 HOURS; OR
 - 33 B. PROVIDES TO THE PERSON IN CHARGE WRITTEN MEDICAL
34 DOCUMENTATION FROM A HEALTH PRACTITIONER THAT STATES
35 THE SYMPTOM IS FROM A NONINFECTIOUS CONDITION.
 - 36 B. REINSTATE A FOOD EMPLOYEE WHO WAS EXCLUDED AS SPECIFIED UNDER
37 SUBPARAGRAPHS 2-202(A)(2) IF THE EMPLOYEE HAS MET PARAMETERS LISTED
38 IN THE COLORADO COMMUNICABLE DISEASE MANUAL AND THE PERSON IN
39 CHARGE OBTAINS APPROVAL FROM THE DEPARTMENT.
 - 40 C. REINSTATE A FOOD EMPLOYEE WHO WAS EXCLUDED AS SPECIFIED IN 2-202(B)
41 AND (C). IF THE EMPLOYEE HAS MET PARAMETERS LISTED IN THE COLORADO
42 COMMUNICABLE DISEASE MANUAL AND THE PERSON IN CHARGE OBTAINS
43 APPROVAL FROM THE DEPARTMENT.

- 1 D. REINSTATE A FOOD EMPLOYEE WHO WAS RESTRICTED AS SPECIFIED IN 2-202(D)
2 IF THE SKIN, INFECTED WOUND, CUT, OR PUSTULAR BOIL IS PROPERLY COVERED
3 WITH ONE OF THE FOLLOWING:
- 4 1. AN IMPERMEABLE COVER SUCH AS A FINGER COT OR GLOVE AND A
5 SINGLE-USE GLOVE OVER THE IMPERMEABLE COVER IF THE INFECTED
6 WOUND OR PUSTULAR BOIL IS ON THE HAND, FINGER, OR WRIST;
- 7 2. AN IMPERMEABLE COVER ON THE ARM IF THE INFECTED WOUND OR
8 PUSTULAR BOIL IS ON THE ARM; OR
- 9 3. A DRY, DURABLE, TIGHT-FITTING BANDAGE IF THE INFECTED WOUND OR
10 PUSTULAR BOIL IS ON ANOTHER PART OF THE BODY.
- 11 E. REINSTATE A FOOD EMPLOYEE WHO WAS EXCLUDED AS SPECIFIED UNDER
12 SUBPARAGRAPHS 2-202(D)(1) OR WHO WAS RESTRICTED UNDER SUBPARAGRAPH
13 2-202(D)(2). THE FOOD EMPLOYEE SHOULD NOT BE REINSTATED UNTIL THE
14 EMPLOYEE HAS BEEN ASYMPTOMATIC FOR AT LEAST 48 HOURS AND THE PERSON
15 IN CHARGE OBTAINS APPROVAL FROM THE DEPARTMENT.
- 16 F. REINSTATE A FOOD EMPLOYEE WHO WAS EXCLUDED OR RESTRICTED AS
17 SPECIFIED IN SUBPARAGRAPHS 2-202(H)(1) OR (2) IF THE FOOD EMPLOYEE
18 PROVIDES TO THE PERSON IN CHARGE WRITTEN MEDICAL DOCUMENTATION
19 FROM A HEALTH PRACTITIONER STATING THAT THE FOOD EMPLOYEE MEETS ONE
20 OF THE FOLLOWING CONDITIONS:
- 21 1. HAS RECEIVED ANTIBIOTIC THERAPY FOR STREPTOCOCCUS PYOGENES
22 INFECTION FOR MORE THAN 24 HOURS;
- 23 2. HAS AT LEAST ONE NEGATIVE THROAT SPECIMEN CULTURE FOR
24 STREPTOCOCCUS PYOGENES INFECTION; OR
- 25 3. IS OTHERWISE DETERMINED BY A HEALTH PRACTITIONER TO BE FREE OF
26 A STREPTOCOCCUS PYOGENES INFECTION.

27 ***2- Discharges from the Eyes, Nose and Mouth***

28 Food employees experiencing persistent sneezing, coughing, or a runny nose that causes
29 discharges from the eyes, nose or mouth may not work with exposed food, clean
30 equipment, utensils, and linens, or unwrapped single-service or single-use articles.

31 **2-3 AUTHORIZED PERSONNEL**

32 Only persons necessary to the operation and maintenance of the retail food
33 establishment shall be allowed in food preparation, food storage, food equipment
34 storage, and warewashing areas.

35 **2-4 PERSONAL CLEANLINESS**

36 ***2-401** FOOD EMPLOYEES SHALL KEEP THEIR HANDS AND EXPOSED PORTIONS OF THEIR ARMS
37 CLEAN.

38 ***2- Procedure**

39 A. Food Employees shall clean their hands and exposed portions of their arms
40 INCLUDING SURROGATE PROSTHETIC DEVICES FOR HANDS OR ARMS WITH SOAP

1 AND WATER for at least 20 seconds and shall use the following cleaning
2 procedure:

- 3 (1). Vigorous friction on the surfaces of the lathered fingers, finger tips, areas
4 between the fingers, hands and arms for at least 15 seconds, followed by;
- 5 (2). Thorough rinsing under clean, running warm water; and
- 6 (3). Immediately follow the cleaning procedure with thorough drying of
7 cleaned hands and arms WITH DISPOSABLE OR SINGLE USE TOWELS OR A
8 MECHANICAL HAND DRYING DEVICE.

9 B. Food employees shall pay particular attention to REMOVING SOIL ~~the areas~~
10 underneath the fingernails during the cleaning procedure.

11 C. If approved and capable of removing the types of soils encountered in the food
12 operations involved, an automatic handwashing facility INSTALLED AND
13 OPERATED AS PER SECTION 5-208(I) may be used by food employees to clean
14 their hands.

15 ***2- When to Wash**

16 Food employees shall clean their hands and exposed portions of their arms immediately
17 before engaging in food preparation including working with exposed food, clean
18 equipment and utensils, and unwrapped single-service and single-use articles and:

- 19 A. ~~When returning to the kitchen after using the toilet room~~ BEFORE LEAVING THE
20 RESTROOM, AND AFTER RETURNING TO FOOD AND BEVERAGE PREPARATION,
21 FOOD STORAGE, EQUIPMENT STORAGE AND WAREWASHING AREAS FROM USING
22 THE RESTROOM;
- 23 B. After coughing, sneezing, using a handkerchief or disposable tissue, using
24 tobacco, eating, or drinking;
- 25 C. When switching between working with raw foods of animal origin and working
26 with ready-to-eat foods;
- 27 D. After touching bare human body parts other than clean hands and clean, exposed
28 portions of arms;
- 29 E. During food preparation, as often as necessary to remove soil and contamination
30 and to prevent cross-contamination when changing tasks;
- 31 F. Before ~~donning~~ HANDLING OR PUTTING ON single-use gloves for working with
32 food, and between removing soiled gloves and putting on clean gloves;
- 33 G. After handling soiled equipment or utensils;
- 34 H. After caring for or handling any animals;
- 35 I. After engaging in any activities that contaminate the hands; AND
- 36 J. After handling fish in aquariums, shellfish, or crustacea in display tanks.

37 ***2- Hand Sanitizers ANTISEPTICS**

38 Hand ~~sanitizers~~ ANTISEPTICS may be used in addition to but not in place of proper
39 handwashing.

1 ***2- Where to Wash**

2 Food employees shall clean their hands in a handsink or approved automatic
3 handwashing facility and may not clean their hands in a sink used for food preparation
4 or warewashing, IN A DUMP SINK, or in a utility sink or a curbed cleaning facility used
5 for the disposal of mop water and similar liquid waste.

6 ***2- Fingernail Care**

7 A. Food employees shall keep their fingernails clean, trimmed, filed and maintained
8 so the edges and surfaces are cleanable and not rough.

9 B. Unless wearing intact gloves in good repair, a food employee may not wear
10 fingernail polish or artificial fingernails when working with exposed food.

11 C. ~~This section does not apply to employees such as counter staff who serve only
12 beverages and wrapped or packaged foods, or hostesses and wait staff who
13 present a minimal risk of contaminating exposed foods, clean equipment,
14 utensils, and linens, and unwrapped single service and single use articles.~~

15 **2- Clothing**

16 Employees shall wear clean outer clothing to prevent ~~cross~~-contamination.

17 **2- Jewelry**

18 A. ~~While preparing food, food employees may not wear jewelry, including medical
19 information jewelry, on their arms and hands. This section does not apply to the
20 wearing of a single ring.~~

21 B. ~~This section does not apply to employees such as counter staff who serve only
22 beverages and wrapped or packaged foods, or hostesses and wait staff who
23 present a minimal risk of contaminating exposed foods, clean equipment,
24 utensils, and linens, and unwrapped single service and single use articles.~~

25 EXCEPT FOR A PLAIN RING SUCH AS A WEDDING BAND, WHILE PREPARING FOOD, FOOD
26 EMPLOYEES MAY NOT WEAR JEWELRY, WATCHES, OR MEDICAL INFORMATION
27 BRACELETS ON THEIR WRISTS AND HANDS OR ANY OTHER AREA OF THE ARM THAT MAY
28 INTERFERE WITH PROPER HANDWASHING OR RESULT IN CONTAMINATION OF FOOD.

29 ~~**2-408 Dressing Rooms and Locker Areas**~~

30 A. ~~If employees routinely change clothes within a retail food establishment, rooms
31 or areas shall be designated and used for that purpose. These designated rooms
32 or areas shall not be used for food preparation, food storage, food display,
33 warewashing, or storage of utensils and equipment.~~

34 B. ~~Lockers or other suitable facilities shall be provided and used for the orderly
35 storage of employee clothing and other belongings. Lockers or other suitable
36 facilities may only be located in designated dressing rooms or areas, or in food
37 storage rooms or areas containing only completely packaged food or packaged
38 single service articles.~~

1 **2-5 HYGIENIC PRACTICES**

2 ***2-501 General**

3 Employees shall maintain a high degree of personal cleanliness and shall conform to
4 good hygienic practices during all working periods. PROPER HYGIENIC PRACTICES MUST
5 BE FOLLOWED BY RETAIL FOOD EMPLOYEES IN PERFORMING ASSIGNED DUTIES TO
6 ENSURE THE SAFETY OF THE FOOD, PREVENT THE INTRODUCTION OF FOREIGN OBJECTS
7 INTO THE FOOD, AND MINIMIZE THE POSSIBILITY OF TRANSMITTING DISEASE THROUGH
8 FOOD.

9 ***2-502 Eating, Drinking, or Using Tobacco**

10 A. Except as specified in paragraph B, employees shall consume food, drink or use
11 tobacco only in designated areas. Such designated areas must be located so that
12 eating or tobacco use ~~of an~~ BY AN employee does not result in contamination of
13 food, equipment, utensils, or other items needing protection.

14 B. An employee may drink from a closed beverage container SUCH AS POP TOP
15 SPORT BOTTLES WHEN TEETH OR MOUTH ARE USED TO OPEN THE TOP, CUPS WITH
16 A LID AND A STRAW, AND CUPS WITH SNAP-ON LIDS WITH A HOLE IN THE TOP IF:

- 17 1. The container is clean;
18 2. It does not contaminate the employee's hands; and
19 3. It is stored to prevent the contamination of exposed food, clean
20 equipment, utensils, linens, unwrapped single-service and single-use
21 articles.

22 **2-503 Hair Restraints**

23 A. Except as provided under paragraph B of this section, FOOD employees engaged
24 in food preparation shall wear hair restraints, such as hats, hair coverings, HAIR
25 OR BEARD nets, or other effective means, to effectively keep hair from contacting
26 exposed food, clean equipment, utensils, and linens, and unwrapped single-
27 service or single-use articles.

28 B. This section does not apply to employees such as counter staff who serve only
29 beverages and wrapped or packaged foods, or , BARTENDERS, and wait staff who
30 present a minimal risk of contaminating exposed foods, clean equipment,
31 utensils, and linens, and unwrapped single-service and single-use articles.

32

CHAPTER 3

FOOD

3-1 CHARACTERISTICS

***3-101 General**

FOOD SHALL BE SAFE, UNADULTERATED, AND HONESTLY PRESENTED. Food shall be in sound condition, free from spoilage or contamination and shall be safe for human consumption. FOOD SHALL NOT CONTAIN UNSAFE OR UNAPPROVED FOOD OR COLOR ADDITIVES PER 21 CFR 170-186. Food shall be obtained from approved sources that comply with the applicable laws relating to food and food labeling. FOOD PREPARED OR STORED IN A PRIVATE HOME SHALL NOT BE USED, DISTRIBUTED, OR OFFERED FOR SALE. ~~Food prepared in a private home shall not be used or offered for sale.~~

3-2 SOURCES, ORIGINAL CONTAINED AND RECORDS FOR SHELLFISH AND FISH

3-201 SHELLFISH AND FISH ~~Fish and Shellfish~~

A. MOLLUSCAN SHELLFISH

MOLLUSCAN SHELLFISH SHALL BE OBTAINED FROM SOURCES ACCORDING TO LAW AND THE REQUIREMENTS SPECIFIED IN THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE, FOOD AND DRUG ADMINISTRATION, NATIONAL SHELLFISH SANITATION PROGRAM GUIDE FOR THE CONTROL OF MOLLUSCAN SHELLFISH.

B. MAINTAINING SHELLSTOCK IDENTIFICATION

*. Fresh and frozen shucked molluscan shellfish (oysters, clams, mussels or scallops) shall be received and/or repacked in non-returnable packages identified with the name and address of the original shellstock processor, shucker-packer, or repacker, and the state shellstock certification number issued according to law. Shucked molluscan shellfish shall be kept in the container in which they were received until used or sold.

Each original container of unshucked molluscan shellfish shall be identified by an attached tag, to be retained for a period of 90 days AFTER THE CONTAINER IS EMPTIED. THE TAG SHALL BE MARKED WITH THE EMPTY DATE AND, ~~that~~ the name and address of the original shellfish processor, the kind and quantity of shellfish, and the certification number issued by the State or foreign shellfish control agency, where applicable. TAGS SHALL BE STORED IN CHRONOLOGICAL ORDER FROM THE EMPTY DATE.

Shellstock from one tagged or labeled container shall not be commingled with shellstock from another container before being ordered by the consumer.

- 1 *. WHEN RECEIVED BY A FOOD ESTABLISHMENT, UNSHUCKED SHELLSTOCK
2 SHALL BE REASONABLY FREE OF MUD, DEAD SHELLFISH, AND SHELLFISH
3 WITH BROKEN SHELLS. DEAD SHELLFISH OR SHELLSTOCK WITH BADLY
4 BROKEN SHELLS SHALL BE DISCARDED.
- 5 *C. MOLLUSCAN SHELLFISH THAT ARE RECREATIONALLY CAUGHT MAY NOT BE
6 RECEIVED FOR SALE OR SERVICE.
- 7 *D. FISH THAT ARE RECEIVED FOR SALE OR SERVICE SHALL BE:
- 8 1. COMMERCIALY AND LEGALLY CAUGHT OR HARVESTED; OR
9 2. APPROVED FOR SALE OR SERVICE.
- 10 *E. RAW SHUCKED SHELLFISH SHALL BE OBTAINED IN NONRETURNABLE PACKAGES
11 WHICH BEAR A LEGIBLE LABEL THAT IDENTIFIES THE:
- 12 1. NAME, ADDRESS, AND CERTIFICATION NUMBER OF THE SHUCKER, PACKER
13 OR REPACKER OF THE MOLLUSCAN SHELLFISH; AND
- 14 2. THE "SELL BY" OR "BEST IF USED BY" DATE FOR PACKAGES WITH A
15 CAPACITY OF LESS THAN 1.89 L (ONE-HALF GALLON) OR THE DATE
16 SHUCKED FOR PACKAGES WITH A CAPACITY OF 1.89 L (ONE-HALF
17 GALLON) OR MORE.
- 18 F. MOLLUSCAN SHELLFISH, ORIGINAL CONTAINER.
- 19 1. EXCEPT AS SPECIFIED IN (B) - (C) OF THIS SECTION, MOLLUSCAN
20 SHELLFISH MAY NOT BE REMOVED FROM THE CONTAINER IN WHICH THEY
21 ARE RECEIVED OTHER THAN IMMEDIATELY BEFORE SALE OR
22 PREPARATION FOR SERVICE.
- 23 G. FOR DISPLAY PURPOSES, SHELLSTOCK MAY BE REMOVED FROM THE CONTAINER
24 IN WHICH THEY ARE RECEIVED, DISPLAYED ON DRAINED ICE, OR HELD IN A
25 DISPLAY CONTAINER, AND A QUANTITY SPECIFIED BY A CONSUMER MAY BE
26 REMOVED FROM THE DISPLAY OR DISPLAY CONTAINER AND PROVIDED TO THE
27 CONSUMER IF:
- 28 1. THE SOURCE OF THE SHELLSTOCK ON DISPLAY IS IDENTIFIED AS SPECIFIED
29 IN SECTION 3-201(A); AND
- 30 2. THE SHELLSTOCK ARE PROTECTED FROM CONTAMINATION.
- 31 H. SHUCKED SHELLFISH MAY BE REMOVED FROM THE CONTAINER IN WHICH THEY
32 WERE RECEIVED AND HELD IN A DISPLAY CONTAINER FROM WHICH INDIVIDUAL
33 SERVINGS ARE DISPENSED UPON A CONSUMER'S REQUEST IF:
- 34 1. THE LABELING INFORMATION FOR THE SHELLFISH ON DISPLAY AS
35 SPECIFIED IN SECTION 3-201(E) IS RETAINED AND CORRELATED TO THE
36 DATE WHEN, OR DATES DURING WHICH, THE SHELLFISH ARE SOLD OR
37 SERVED; AND
- 38 2. THE SHELLFISH ARE PROTECTED FROM CONTAMINATION.

~~*B. Except as specified in paragraph C of this section, before service or sale in ready-to-eat form, raw, raw marinated, lightly cooked marinated, marinated, or partially cooked fish other than molluscan shellfish shall be frozen throughout to a temperature of:~~

- ~~1. 4°F (20°C) or below for 168 hours (7 days) in a freezer; or~~
- ~~2. 31°F (35°C) or below for 15 hours in a blast freezer.~~

~~The freezing temperature and time to which the fish are subjected shall be recorded, retained and made readily available upon request at the food establishment for 90 calendar days after the time of service or sale of the fish.~~

~~— If the fish are frozen by the retail food establishment and/or supplier, a written agreement or statement from the supplier stipulating that the fish supplied are frozen to the proper temperature and for a time specified in this section may substitute for the records required.~~

~~*C. If the fish are tuna of the species *Thunnus alalunga*, *Thunnus albacares* (Yellowfin tuna), *Thunnus atlanticus*, *Thunnus maccoyii* (Bluefin tuna, Southern), *Thunnus obesus* (Bigeye tuna), or *Thunnus thynnus* (Bluefin tuna, Northern), the fish may be served or sold in a raw, raw marinated, or partially cooked ready-to-eat form without freezing as specified under paragraph B of this section.~~

3-202 PARASITE DESTRUCTION.

*A. EXCEPT AS SPECIFIED IN (B) OF THIS SECTION, BEFORE SERVICE OR SALE IN READY-TO-EAT FORM, RAW, RAW-MARINATED, PARTIALLY COOKED, OR MARINATED-PARTIALLY COOKED FISH SHALL BE:

- 1. FROZEN AND STORED AT A TEMPERATURE OF - (-) OR BELOW FOR A MINIMUM OF 168 HOURS (7 DAYS) IN A FREEZER;
- 2. FROZEN AT - (-) OR BELOW UNTIL SOLID AND STORED AT - (-) OR BELOW FOR A MINIMUM OF 15 HOURS; OR
- 3. FROZEN AT - (-) OR BELOW UNTIL SOLID AND STORED AT - (-) OR BELOW FOR A MINIMUM OF 24 HOURS.

THE FREEZING TEMPERATURE AND TIME TO WHICH THE FISH ARE SUBJECTED SHALL BE RECORDED, RETAINED AND MADE READILY AVAILABLE UPON REQUEST AT THE FOOD ESTABLISHMENT FOR 90 CALENDAR DAYS AFTER THE TIME OF SERVICE OR SALE OF THE FISH.

IF THE FISH ARE FROZEN BY THE RETAIL FOOD ESTABLISHMENT AND/OR SUPPLIER, A WRITTEN AGREEMENT OR STATEMENT FROM THE SUPPLIER STIPULATING THAT THE FISH SUPPLIED ARE FROZEN TO THE PROPER TEMPERATURE AND FOR A TIME SPECIFIED IN THIS SECTION MAY SUBSTITUTE FOR THE RECORDS REQUIRED.

B. PARAGRAPH (A) OF THIS SECTION DOES NOT APPLY TO:

- 1. MOLLUSCAN SHELLFISH;
- 2. TUNA OF THE SPECIES THUNNUS ALALUNGA, THUNNUS ALBACARES (YELLOWFIN TUNA), THUNNUS ATLANTICUS, THUNNUS MACCOYII (BLUEFIN TUNA, SOUTHERN), THUNNUS OBESUS (BIGEYE TUNA), OR THUNNUS THYNNUS (BLUEFIN TUNA, NORTHERN); OR

- 1 3. AQUACULTURED FISH, SUCH AS SALMON, THAT:
2 A. IF RAISED IN OPEN WATER, ARE RAISED IN NET-PENS, OR
3 B. ARE RAISED IN LAND-BASED OPERATIONS SUCH AS PONDS OR
4 TANKS, AND
5 C. ARE FED FORMULATED FEED, SUCH AS PELLETS, THAT CONTAINS
6 NO LIVE PARASITES INFECTIVE TO THE AQUACULTURED FISH.
7 D. IF RAW, RAW-MARINATED, PARTIALLY COOKED, OR MARINATED-
8 PARTIALLY COOKED FISH ARE SERVED OR SOLD IN READY-TO-
9 EAT FORM, AND THE FISH ARE RAISED AND FED AS SPECIFIED IN
10 SECTION 3-202(B)(3)(A)-(C), A WRITTEN AGREEMENT OR
11 STATEMENT FROM THE SUPPLIER OR AQUACULTURIST
12 STIPULATING THAT THE FISH WERE RAISED AND FED AS
13 SPECIFIED IN SECTION 3-202(B)(3)(A)-(C) SHALL BE OBTAINED
14 BY THE PERSON IN CHARGE AND RETAINED IN THE RECORDS OF
15 THE FOOD ESTABLISHMENT FOR 90 CALENDAR DAYS BEYOND
16 THE TIME OF SERVICE OR SALE OF THE FISH.
17 4. FISH EGGS THAT HAVE BEEN REMOVED FROM THE SKEIN AND RINSED.

18 **3- GENERAL SOURCES, ORIGINAL CONTAINERS AND RECORDS**

19 ***3-301 PACKAGE INTEGRITY.**

20 FOOD PACKAGES SHALL BE IN GOOD CONDITION AND PROTECT THE INTEGRITY OF THE
21 CONTENTS SO THAT THE FOOD IS NOT EXPOSED TO ADULTERATION OR POTENTIAL
22 CONTAMINANTS.

23 ***3- Hermetically Sealed Food**

24 The use, DISTRIBUTION, OR SALE of food from hermetically sealed containers that was
25 not prepared in an approved food processing establishment OR RETAIL FOOD
26 ESTABLISHMENT THAT IS APPROVED FOR THIS TYPE OF PROCESSING, is prohibited.

27 Hermetically sealed packages shall be handled so as to maintain product and container
28 integrity. Food items that are spoiled or that are in damaged containers that may affect
29 the product and those food items that have been returned to, or are being detained by, the
30 retail food establishment because of spoilage, container damage, or other public health
31 considerations shall be segregated and held in designated areas pending proper
32 disposition unless disposed of under the supervision of the ~~regulatory authority~~
33 Department.

34 ***3- Dry Milk and Dry Milk Products**

35 Dry milk and milk products used, served or offered for sale shall be made from
36 pasteurized milk and milk products.

37 ***3- Reconstitution of Dry Milk, Dry Milk Products and Non-Dairy Products**

38 Dry milk, dry milk products and non-dairy creaming, whitening, or whipping agents
39 may be reconstituted with potable water on the premises only when they will be stored

1 in sanitized, covered containers and cooled to 41°F (7°C) or below within four hours
2 after preparation.

3 Reconstituted dry milk cannot be substituted for use as a Grade A fluid milk product in
4 its final form (e.g. for drinking, over cereal, etc.).

5 ***3- Fluid Milk, Fluid Milk Products, and Frozen Dessert Mix**

6 A. Fluid milk and fluid milk products used, served or offered for sale shall comply
7 with the Colorado Grade A Pasteurized Fluid Milk and Milk Products
8 Regulation.

9 B. Only pasteurized mix from an approved licensed dairy plant may be mixed
10 and/or frozen by a counter freezer.

11 C. RAW MILK SUPPLIED TO AND HELD BY RETAIL FOOD ESTABLISHMENTS FOR
12 DISTRIBUTION TO SHAREHOLDERS SHALL MEET THE REQUIREMENTS OF SECTION
13 25-5.5-117 ET. SEQ., C.R.S.

14 1. ONLY FARMS OR DAIRIES THAT ARE PROPERLY REGISTERED WITH THE
15 DEPARTMENT MAY DISTRIBUTE RAW MILK.

16 2. ONLY AN OWNER OR SHAREHOLDER OF A COW, GOAT OR DAIRY HERD
17 MAY DISTRIBUTE RAW MILK FROM A RETAIL FOOD ESTABLISHMENT.
18 DISTRIBUTION OF RAW MILK BY MANAGEMENT OR EMPLOYEES OF A
19 RETAIL FOOD ESTABLISHMENT THAT ARE NOT OWNERS OR
20 SHAREHOLDER OF A COW, GOAT OR DAIRY HERD IS PROHIBITED.

21 3. ONLY AN OWNER OR SHAREHOLDER OF A COW, GOAT OR DAIRY HERD
22 SHALL RECEIVE RAW MILK FROM THE FARM OR DAIRY WHERE THE COW
23 OR GOAT IS LOCATED OR FROM A SHAREHOLDER OF THE SAME COW,
24 GOAT OR DAIRY HERD.

25 4. CONTAINERS USED TO HOLD RAW MILK SHALL HAVE A PROMINENT
26 WARNING STATEMENT THAT THE MILK IS NOT PASTEURIZED, IS
27 DELIVERED TO THE SHAREHOLDER WITH THE MILK OR IS DISPLAYED ON
28 A LABEL AFFIXED TO THE MILK CONTAINER.

29 5. STORAGE OF RAW MILK WITH OTHER FOOD IS PROHIBITED. RAW MILK
30 MUST BE STORED IN A SEPARATE REFRIGERATOR OR COOLER THAT IS
31 USED ONLY FOR RAW MILK AND MUST BE STORED IN A MANNER WHERE
32 IT CANNOT BE MISTAKEN FOR PASTEURIZED MILK. DISPLAY OR ACCESS
33 OF RAW MILK TO THE PUBLIC IS PROHIBITED.

34 ***3- Wild Mushrooms**

35 A. Except as specified in paragraph B of this section, mushroom species picked in
36 the wild shall be obtained from sources where each mushroom is individually
37 inspected and found to be safe by a mushroom identification expert approved by
38 the ~~regulatory agency~~ DEPARTMENT. TO BE APPROVED BY THE DEPARTMENT AN
39 INDIVIDUAL MUST

40 1. IDENTIFY WHICH COUNTY(IES) AND RETAIL FOOD ESTABLISHMENTS
41 THEY WILL SUPPLY WILD MUSHROOMS;

42 2. PROVIDE THE GENUS AND SPECIES OF THE WILD MUSHROOMS THAT WILL
43 BE SUPPLIED;

- 1 3. PROVIDE WRITTEN VERIFICATION DETAILING THEIR QUALIFICATIONS
2 THAT DEMONSTRATE THEIR ABILITY TO IDENTIFY AND PICK WILD
3 MUSHROOMS THAT ARE SAFE FOR HUMAN CONSUMPTION SUCH AS
4 EDUCATIONAL DEGREES, YEARS OF EXPERIENCE, MEMBERSHIP TO ANY
5 PROFESSIONAL ORGANIZATIONS.;
- 6 4. PROVIDE A WRITTEN LETTER OF REFERENCE FROM A SEPARATE
7 INDIVIDUAL WHO CAN VERIFY THE PICKER HAS THE EXPERTISE. THE
8 PERSON SUPPLYING THE LETTER OF REFERENCE MUST BE A RECOGNIZED
9 MYCOLOGIST WHO CAN ATTEST THE PICKER HAS THE ABILITY TO
10 IDENTIFY THE GENUS AND SPECIES OF WILD MUSHROOMS THEY INTEND
11 TO PICK;
- 12 5. MAINTAIN RECORDS FOR AT LEAST TWO (2) YEARS IDENTIFYING THE
13 BUYERS, THE TYPE OF MUSHROOM(S) RECEIVED AND THE QUANTITY
14 RECEIVED, AND;
- 15 6. SUPPLY AN INVOICE TO THE BUYER WITH EACH SHIPMENT THAT
16 IDENTIFIES:
 - 17 A. THE VARIETY OF MUSHROOM BY COMMON NAME AND GENUS
18 AND SPECIES;
 - 19 B. THE QUANTITY;
 - 20 C. THE SUPPLIERS NAME, ADDRESS, AND DATE OF PACKING.
- 21 B. This section does not apply to:
 - 22 1. Cultivated wild mushroom species that are grown, harvested, and
23 processed in an operation that is regulated by the regulatory agency that
24 has jurisdiction over the operation; or
 - 25 2. Wild mushroom species if they are in packaged form and are the product
26 of a food processing plant that is regulated by the food regulatory agency
27 that has jurisdiction over the plant.

28 ***3- MEAT, POULTRY, Game Animals and Exotic Species**

29 Game animals and exotic species may be received for sale or service provided they are
30 slaughtered and processed according to laws governing meat and poultry as determined
31 by the agency that has animal health jurisdiction and the agency that conducts the
32 inspection program.

- 33 A. MEAT AND POULTRY ARE REQUIRED TO COME FROM A USDA FSIS INSPECTED
34 FACILITY.
 - 35 1. MEATS LISTED IN THE FEDERAL MEAT INSPECTION ACT THAT REQUIRE
36 MANDATORY USDA INSPECTION INCLUDE CATTLE, SWINE, SHEEP,
37 GOATS, HORSE, MULE, OTHER EQUINE, AND ANY OTHERS AS DETERMINED
38 BY THE USDA.
 - 39 2. POULTRY LISTED IN THE POULTRY PRODUCTS INSPECTION ACT THAT
40 REQUIRE MANDATORY USDA INSPECTION INCLUDE CHICKEN, GEESE,
41 DUCK, TURKEY, GUINEAS, EMU, RATITE, OSTRICH, SQUAB (PIGEON), AND
42 ANY OTHERS AS DETERMINED BY THE USDA.

- 1 B. GAME ANIMALS INDIGENOUS TO NORTH AMERICA SUCH AS REINDEER, ELK,
2 DEER, ANTELOPE, WATER BUFFALO, BISON, RABBIT, SQUIRREL, OPOSSUM,
3 RACCOON, NUTRIA, OR MUSKRAT, AND ANY OTHERS AS DETERMINED BY THE
4 USDA SHALL GO THROUGH THE USDA VOLUNTARY MEAT INSPECTION
5 PROGRAM IN ORDER TO BE CONSIDERED AN APPROVED SOURCE. .
- 6 C. POULTRY PRODUCTS THAT ARE GAME ANIMALS ARE REQUIRED TO BE INSPECTED
7 UNDER THE USDA VOLUNTARY POULTRY INSPECTION PROGRAM. SPECIES
8 INCLUDE QUAIL, PHEASANT, DOVE, OTHER GAME BIRDS AND ANY OTHERS AS
9 DETERMINED BY THE USDA.
- 10 D. ANY OTHER GAME ANIMAL THAT IS OBTAINED FROM A RETAIL FOOD
11 ESTABLISHMENT WOULD FALL UNDER FDA INSPECTION AUTHORITY. THIS
12 WOULD INCLUDE RATTLESNAKE, BEAR, ALLIGATOR, AND ANY OTHERS AS
13 DETERMINED BY THE USDA.
- 14 E. GAME ANIMALS OBTAINED FROM STATES THAT HAVE CONTRACTS WITH THE
15 FDA OR USDA TO CONDUCT INSPECTIONS OF GAME ANIMAL FOOD PROCESSING
16 ESTABLISHMENTS ARE RECOGNIZED BY THE DEPARTMENT AS BEING AN
17 APPROVED REGULATORY AUTHORITY AND FOOD PRODUCTS RECEIVED FROM
18 THESE STATES ARE CONSIDERED AN APPROVED SOURCE.

19 FOR ADDITIONAL GUIDANCE, REFER TO THE COLORADO DEPARTMENT OF PUBLIC
20 HEALTH AND ENVIRONMENT ISSUED INTERPRETATIVE MEMO TITLED “DETERMINING
21 APPROVED SOURCE FOR MEAT, POULTRY, GAME ANIMALS, AND EXOTIC ANIMAL
22 SPECIES.”

23 ***3- Eggs**

- 24 A. Only clean INTACT, APPROVED shell eggs meeting applicable grade standards or
25 pasteurized shell, liquid, frozen or dry eggs, or pasteurized dry egg products shall
26 be used or offered for sale.
- 27 B. THE EGG CARTON MUST BE NEW, CLEAN AND PROPERLY LABELED TO INCLUDE
28 THE SUPPLIER’S NAME AND ADDRESS, EGG GRADE, SIZE AND PACK DATE. *FDA*
29 *SAFE HANDLING INSTRUCTIONS* ON THE CARTON ARE REQUIRED.
- 30 C. EGGS CAN BE OFFERED FOR SALE LOOSE OR IN A BASKET, BUT MUST HAVE AN
31 ACCOMPANYING CARD OR SIGN THAT CONTAINS THE REQUIRED LABELING
32 INFORMATION INCLUDING THE WASH AND PROCESS DATE VERSUS A PACK DATE
33 AS INDICATED ON A CARTON.
- 34 D. POOLING OF RAW SHELL EGGS IS ALLOWED ONLY IF THE EGGS ARE 41°F (5°C) OR
35 BELOW WHEN THEY ARE CRACKED AND MAINTAINED AT 41°F (5°C) OR BELOW
36 UNTIL COOKED.

37 **3- Ice**

- 38 *A. ☐ Only ice which has been manufactured from ~~potable~~ DRINKING water and
39 handled in a sanitary manner shall be used or offered for sale. Ice offered for
40 sale shall be packaged and properly labeled.
- 41 B. ☐ Ice for human consumption shall be DRAINED. ~~dispensed only by employees~~
42 ~~with scoops, tongs, or other ice dispensing utensils, or through automatic self-~~
43 ~~service, ice dispensing equipment. Ice dispensing utensils shall be stored on a~~
44 ~~clean surface or in the ice with the dispensing utensil's handle extended out of the~~

1 ~~ice. Between uses, ice transfer receptacles shall be stored in a way that protects~~
2 ~~them from contamination.~~

3 ***3- Ice Used as Exterior Coolant, Prohibited as Ingredient**

4 Ice used as a cooling medium for food storage, BEVERAGE CONTAINERS, food
5 containers or food utensils shall not be used or sold for human consumption.

6 **3- Storage or Display of Food in Contact With Water or Ice**

7 A. Packaged food may be stored in direct contact with ~~potable~~ ice or ~~potable~~
8 DRINKING water if the packaging, wrapping, or container is not subject to entry
9 of water.

10 B. Except as specified in C and D of this section, unpackaged food may not be
11 stored in direct contact with undrained ice.

12 C. Whole raw fruits and whole or cut raw vegetables, such as celery or carrot sticks
13 or cut potatoes; and tofu may be immersed in ~~potable~~ ice MADE WITH DRINKING
14 WATER. ~~or potable water.~~

15 D. Raw chicken and raw fish that are received immersed in ~~potable~~ ice MADE WITH
16 DRINKING WATER in shipping containers may remain in that condition while in
17 storage awaiting preparation, display, service, or sale.

18 ***3- Juice**

19 A. Pre-packaged juice shall be obtained pasteurized; in a sterile shelf-stable form in
20 a hermetically sealed container; or otherwise treated under an approved HACCP
21 plan as specified in 21 CFR § SECTION 120.24, (2003) to attain a 5-log reduction
22 of the most resistant microorganism of public health significance.

23 B. Juice packaged in a retail establishment and sold exclusively and directly to its
24 consumers does not have to be processed in conformance with an approved
25 HACCP plan, but if packaged shall bear the phrase: **“WARNING: This product**
26 **has not been pasteurized and, therefore, may contain harmful bacteria that can**
27 **cause serious illness in children, the elderly, and persons with weakened immune**
28 **systems”** and meet the requirements of the Federal Fair Packaging and Labeling
29 Act.

30 **3-313 WHOLE –MUSCLE, INTACT BEEF STEAKS**

31 WHOLE-MUSCLE, INTACT BEEF STEAKS THAT ARE INTENDED FOR CONSUMPTION IN AN
32 UNDERCOOKED FORM WITHOUT A CONSUMER ADVISORY AS SPECIFIED IN SECTION 3-801
33 SHALL BE:
34

35 A. OBTAINED FROM A FOOD PROCESSING PLANT THAT, UPON REQUESTED BY THE
36 PURCHASER, PACKAGES THE STEAKS AND LABELS THEM, TO INDICATE THAT THE
37 STEAKS MEET THE DEFINITION OF WHOLE-MUSCLE, INTACT BEEF, OR

38 B. DEEMED ACCEPTABLE BY THE DEPARTMENT BASED ON OTHER EVIDENCE, SUCH
39 AS WRITTEN BUYER SPECIFICATIONS OR INVOICES, THAT INDICATES THAT THE
40 STEAKS MEET THE DEFINITION OF WHOLE-MUSCLE, INTACT BEEF; AND

41 C. IF INDIVIDUALLY CUT IN A FOOD ESTABLISHMENT:

- 1 1. CUT FROM A WHOLE-MUSCLE INTACT BEEF THAT IS LABELED BY A FOOD
- 2 PROCESSING PLANT AS SPECIFIED IN PART (A) OF THIS SECTION OR
- 3 IDENTIFIED AS SPECIFIED IN PART (B) OF THIS SECTION,
- 4 2. PREPARED SO THEY REMAIN INTACT, AND
- 5 3. IF PACKAGED FOR UNDERCOOKING IN A FOOD ESTABLISHMENT, LABELED
- 6 AS SPECIFIED IN PART (A) OF THIS SECTION OR AS IDENTIFIED IN PART (B)
- 7 OF THIS SECTION.
- 8

9 **3- PROTECTION FROM CONTAMINATION AFTER RECEIVING**

10 ~~*3-301 Preventing Contamination from Hands (Effective until March 1, 2007)~~

- 11 ~~A. Food shall be prepared with minimal manual contact. This can be achieved by~~
- 12 ~~the use of suitable utensils, such as deli tissues, spatulas, tongs, or single use~~
- 13 ~~gloves. Employees shall not contact ready to eat foods with their bare hands~~
- 14 ~~when it is determined by the Department that no bare hand contact with ready to~~
- 15 ~~eat food is necessary to control pathogenic microorganisms that are transmissible~~
- 16 ~~by food.~~
- 17 ~~B. If used, single use gloves shall be used for only one task, such as working with~~
- 18 ~~ready to eat food, or with raw animal food. Single use gloves shall be used for~~
- 19 ~~no other purpose, and discarded when damaged, soiled, when interruptions occur~~
- 20 ~~in the operation, or when the task is completed.~~

21 ***3-401 Preventing Contamination from Hands (Effective March 1, 2007)**

- 22 A. Food employees shall wash their hands as specified ~~under §~~ IN SECTION 2-402 OF
- 23 THESE RULES AND REGULATIONS.
- 24 B. Food employees shall minimize bare hand and arm contact with exposed food
- 25 that is not in a ready-to-eat form.
- 26 C. Except when washing fruits and vegetables as specified ~~under §~~ IN SECTION 3- (a)
- 27 OF THESE RULES AND REGULATIONS or except as specified in (D) of this section,
- 28 food employees may not contact exposed, ready-to-eat food INCLUDING FRUITS
- 29 AND VEGETABLES with their bare hands and shall use suitable utensils such as
- 30 deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment.
- 31 D. Food employees not serving a highly susceptible population (~~“Highly Susceptible~~
- 32 ~~Population” means persons who are more likely than other people in the general~~
- 33 ~~population to experience foodborne disease because they are~~
- 34 ~~immunocompromised, preschool age children, or older adults; and they obtain~~
- 35 ~~food at a facility that provides services such as custodial care, health care, or~~
- 36 ~~assisted living, such as a child or adult day care center, kidney dialysis center,~~
- 37 ~~hospital or nursing home, or nutritional or socialization services such as a senior~~
- 38 ~~center.) may contact exposed, ready-to-eat food with their bare hands if:~~
- 39 1. Written procedures are maintained in the food establishment and made
- 40 available to the ~~regulatory authority~~ DEPARTMENT upon request that
- 41 include:
- 42 a. A listing of the ready-to-eat food categories that are touched by
- 43 bare hands;

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- b. Handwashing facilities are, equipped, maintained, are easily accessible and in CLOSE proximity to the work station(s) where the bare hand contact procedure is conducted as specified ~~under~~ § IN SECTION 5-208 (B) – (J) OF THESE RULES AND REGULATIONS;
 - c. A written employee health policy that details how the food establishment will comply with § SECTIONS 2-201, § 2-202, § 2-203, AND § 2-204. ~~§2-205 and §2-206~~ OF THESE RULES AND REGULATIONS, including health conditions upon which the food employee will not be allowed to work and acknowledgement of their responsibilities as specified ~~under~~ § IN SECTIONS 2-201 and § 2-202;
 - d. An employee training program that ~~includes~~ DOCUMENTS COMPLETION OF THE FOLLOWING TRAINING AREAS:
 - (~~i~~) (1) The risks of contacting the ready-to-eat foods with bare hands;
 - (~~ii~~) (2) Proper handwashing as specified ~~under~~ § IN SECTION 2-401 and 2-402;
 - (~~iii~~) (3) When to wash their hands as specified ~~under~~ § IN SECTION 2-;
 - (~~iv~~) (4) Where to wash their hands as specified ~~under~~ § IN SECTION 2-;
 - (~~v~~) (5) Proper fingernail maintenance as specified ~~under~~ § IN SECTION 2- A;
 - (~~vi~~) (6) Prohibition of jewelry as specified ~~under~~ § IN SECTION 2- A; and
 - (~~vii~~) (7) Good hygienic practices as related to §SECTION 2-501 and §SECTION 2-502.
- 2. Hands are washed prior to food preparation and as necessary to prevent cross contamination as specified ~~under~~ § IN SECTIONS 2-401, §2-402, 2-403 and §2- by food employees during all hours of operation when the specific ready-to-eat foods are prepared.
 - 3. In addition to the requirements specified in ~~§~~ SECTION 2- “When to Wash”, food employees contacting ready-to-eat foods with bare hands utilize two or more of the following control measures to provide additional safeguards to hazards associated with bare hand contact:
 - a. Double handwashing;
 - b. Nail brushes;
 - c. A hand antiseptic after handwashing as specified ~~under~~ § IN SECTION 2-;
 - d. Incentive programs that encourage food employees not to work when they are ill with a communicable disease that can be transmitted by foods as specified in § SECTION 2-201; or

- 1 e. Other control measures approved by the ~~regulatory authority~~
2 DEPARTMENT.
- 3 4. Corrective actions are immediately taken when subparagraphs D (1) - (3)
4 of this section are not followed. Accompanying monitoring, corrective
5 actions, and appropriate documentation are required.
- 6 E. If a food establishment is found to be in non-compliance with the requirements
7 listed in subparagraphs D (1) - (4) and a civil penalty has been issued in
8 accordance with C.R.S., §25-4-1611, as a result of this non-compliance~~t~~, OR IF A
9 CONFIRMED FOODBORNE ILLNESS IS ASSOCIATED WITH BARE HAND CONTACT
10 AND ILL EMPLOYEES, The ~~regulatory authority~~ DEPARTMENT may revoke the
11 food establishment's allowance for food employees to contact ready-to-eat foods
12 with their bare hands.
- 13 F. If the allowance for a food establishment to contact ready-to-eat foods with bare
14 hands is voluntarily discontinued by the food establishment or revoked as
15 provided for in subparagraph E, a food establishment may not reinstate bare hand
16 contact with ready-to-eat foods without prior written approval from the
17 ~~regulatory~~ DEPARTMENT.

18 **3-402 Glove Use**

- 19 *A. IF USED, SINGLE-USE GLOVES SHALL BE USED FOR ONLY ONE TASK, SUCH AS
20 WORKING WITH READY-TO-EAT FOOD, OR WITH RAW ANIMAL FOOD. SINGLE-USE
21 GLOVES SHALL BE USED FOR NO OTHER PURPOSE, AND DISCARDED WHEN
22 DAMAGED, WHEN INTERRUPTIONS OCCUR IN THE OPERATION, OR WHEN THE
23 TASK IS COMPLETED.
- 24 B. EXCEPT AS SPECIFIED IN (C) SLASH-RESISTANT GLOVES THAT ARE USED TO
25 PROTECT THE HANDS DURING OPERATIONS REQUIRING CUTTING SHALL BE USED
26 IN DIRECT CONTACT ONLY WITH FOOD THAT IS SUBSEQUENTLY COOKED AS
27 SPECIFIED IN PART 3-5 SUCH AS FROZEN FOOD OR A PRIMAL CUT OF MEAT.
- 28 C. SLASH-RESISTANT GLOVES MAY BE USED WITH READY-TO-EAT FOOD THAT WILL
29 NOT BE SUBSEQUENTLY COOKED IF THE SLASH-RESISTANT GLOVES HAVE A
30 SMOOTH, DURABLE, AND NONABSORBENT OUTER SURFACE; OR IF THE SLASH-
31 RESISTANT GLOVES ARE COVERED WITH A SMOOTH, DURABLE, NONABSORBENT
32 GLOVE, OR A SINGLE-USE GLOVE.
- 33 D. CLOTH GLOVES MAY NOT BE USED IN DIRECT CONTACT WITH FOOD UNLESS THE
34 FOOD IS SUBSEQUENTLY COOKED AS REQUIRED UNDER SECTION 3-5 SUCH AS
35 FROZEN FOOD OR A PRIMAL CUT OF MEAT.

36
37 ***3-403 Preventing Contamination When Tasting**

38
39 A FOOD EMPLOYEE MAY NOT USE A UTENSIL MORE THAN ONCE TO TASTE FOOD
40 THAT IS TO BE SOLD OR SERVED.

41 **3- General**

42 At all times, including while being stored, prepared, displayed, dispensed, packaged, or
43 transported, food shall be protected from cross-contamination between foods and from
44 potential contamination by insects, insecticides, rodents, rodenticides, other toxins,
45 probe-type price tags or probe-type identification tags, unclean equipment and utensils,

unnecessary handling, flooding, draining, overhead leakage or condensation, or other agents of public health significance. Hanging primal cuts and quarters or sides of meat, and uncut raw fruits and vegetables do not need to be over wrapped or covered. Foods in original individual packages must be over wrapped or covered if the package has been torn or broken. During transportation, including transportation to another location for service or catering operations, food shall meet the requirements of these rules and regulations relating to food protection, food storage and temperature maintenance of ~~potentially hazardous foods~~ POTENTIALLY HAZARDOUS FOODS (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD).

***3- Cross-Contamination Control**

Each time there is a change in processing between raw beef, raw pork, other raw meats, raw poultry, raw fish and molluscan shellfish or from raw to ready-to-eat foods, food-contact surfaces and utensils shall be cleaned and sanitized ~~in accordance with Chapter AS SPECIFIED IN 4-403 AND 4-, parts 4 40304 4 405 of these rules and regulations.~~ Salads and other ready-to-eat foods may also be prepared simultaneously in areas that are separated by a barrier or open space from areas used for processing potentially hazardous raw products.

~~Slash-resistant gloves used to protect hands during operations requiring cutting shall be handled in a manner which will prevent the cross-contamination between raw and ready-to-eat foods.~~

3-4046 PACKAGED AND UNPACKAGED FOOD - SEPARATION, PACKAGING, AND SEGREGATION

A. FOOD SHALL BE PROTECTED FROM CROSS CONTAMINATION BY:

1. EXCEPT AS SPECIFIED IN (C) BELOW, SEPARATING RAW ANIMAL FOODS DURING STORAGE, PREPARATION, HOLDING, AND DISPLAY FROM:

*A. RAW READY-TO-EAT FOOD INCLUDING OTHER RAW ANIMAL FOOD SUCH AS FISH FOR SUSHI OR MOLLUSCAN SHELLFISH, OR OTHER RAW READY-TO-EAT FOOD SUCH AS FRUITS AND VEGETABLES, AND

*B. COOKED READY-TO-EAT FOOD;

C. FROZEN, COMMERCIALY PROCESSED AND PACKAGED RAW ANIMAL FOOD MAY BE STORED OR DISPLAYED WITH OR ABOVE FROZEN, COMMERCIALY PROCESSED AND PACKAGED, READY-TO-EAT FOOD.

***3- Pasteurized Eggs, Substitute for Shell Eggs for Certain Recipes**

~~Raw shell eggs shall not be used as an ingredient in the preparation of uncooked, ready-to-eat menu items. Commercially pasteurized egg and egg products may be substituted for raw shell eggs in such items. Pasteurized eggs may also be substituted for raw shell eggs where holding is required for menu items such as scrambled eggs, omelets, French toast, Monte Cristo sandwiches, etc. Pooling of raw shell eggs is allowed only if the eggs are 41°F (5°C) or below when they are cracked and maintained at 41°F (5°C) or below until cooked.~~

PASTEURIZED EGGS OR EGG PRODUCTS SHALL BE SUBSTITUTED FOR RAW EGGS IN THE PREPARATION OF FOODS SUCH AS CAESAR SALAD, HOLLANDAISE OR BÉARNAISE SAUCE,

1 MAYONNAISE, MERINGUE, EGGNOG, ICE CREAM, AND EGG-FORTIFIED BEVERAGES THAT
2 ARE NOT COOKED AS SPECIFIED IN SECTION 3- (D).

3 ***3- Washing Fruits and Vegetables/Additives/Sulfites**

4 A. ~~All raw fruits and raw vegetables including those that will be cut, combined with~~
5 ~~other ingredients, or otherwise processed into food products by the retail food~~
6 ~~establishment shall first be thoroughly cleaned with potable water. Whole, raw~~
7 ~~fruits and raw vegetables intended for washing by the consumer before~~
8 ~~consumption need not be washed before sale. EXCEPT AS SPECIFIED IN (B)-(D)~~
9 ~~OF THIS SECTION AND EXCEPT FOR WHOLE, RAW FRUITS AND VEGETABLES THAT~~
10 ~~ARE INTENDED FOR WASHING BY THE CONSUMER BEFORE CONSUMPTION, RAW~~
11 ~~FRUITS AND VEGETABLES SHALL BE THOROUGHLY WASHED IN RUNNING~~
12 ~~DRINKING WATER TO REMOVE SOIL AND OTHER CONTAMINANTS BEFORE BEING~~
13 ~~CUT, COMBINED WITH OTHER INGREDIENTS, COOKED, SERVED, OR OFFERED FOR~~
14 ~~HUMAN CONSUMPTION IN READY-TO-EAT FORM. COMMERCIALY, PREWASHED~~
15 ~~RAW FRUITS AND VEGETABLES THAT ARE PREPACKAGED TO PREVENT~~
16 ~~CONTAMINATION DO NOT REQUIRE FURTHER WASHING PRIOR TO USE.~~

17 B. ~~An indirectly drained food preparation sink with an approved eighteen inch (18")~~
18 ~~46 cm) self draining drain board or alternate approved methods shall be provided~~
19 ~~to prevent cross contamination of clean raw fruits and vegetables. In~~
20 ~~establishments where vegetable preparation is limited to a few items and in~~
21 ~~limited quantity, and either single service tableware or a mechanical dishwasher~~
22 ~~is used, the three compartment sink may be used for food preparation if the sink~~
23 ~~is indirectly drained and the sink and drain board are cleaned and sanitized~~
24 ~~between changes in use. FRUITS AND VEGETABLES FROM WHICH RINDS, PEELS,~~
25 ~~HUSKS, OR SHELLS ARE NOT REMOVED BEFORE PREPARATION REQUIRE WASHING.~~

26 ~~Application of sulfiting agents to fresh fruits (except grapes) and~~
27 ~~vegetables intended for raw consumption or to a food considered to be a good~~
28 ~~source of vitamin ; .e., poultry, crab meat (except canned), mixed nuts, whole~~
29 ~~grains, whole grain flours, enriched bakery products is prohibited.~~

30 C. CHEMICALS FOR WASHING FRUITS AND VEGETABLES, CRITERIA.

31 1. CHEMICALS USED TO WASH OR PEEL RAW, WHOLE FRUITS AND
32 VEGETABLES SHALL MEET THE REQUIREMENTS SPECIFIED IN 21 CFR
33 173.315, "CHEMICALS USED IN WASHING OR TO ASSIST IN THE PEELING
34 OF FRUITS AND VEGETABLES".

35 2. OZONE AS AN ANTIMICROBIAL AGENT USED IN THE TREATMENT,
36 STORAGE, AND PROCESSING OF FRUITS AND VEGETABLES IN A FOOD
37 ESTABLISHMENT SHALL MEET THE REQUIREMENTS SPECIFIED IN 21 CFR
38 173.368 OZONE.

39 D. APPLICATION OF SULFITING AGENTS TO FRESH FRUITS (EXCEPT GRAPES) AND
40 VEGETABLES INTENDED FOR RAW CONSUMPTION OR TO A FOOD CONSIDERED TO
41 BE A GOOD SOURCE OF VITAMIN ; SUCH AS POULTRY, CRAB MEAT (EXCEPT
42 CANNED), MIXED NUTS, WHOLE GRAINS, WHOLE GRAIN FLOURS, ENRICHED
43 BAKERY PRODUCTS IS PROHIBITED.

44 E. NEW OR EXTENSIVELY REMODELED ESTABLISHMENTS WITH FOOD ITEMS THAT
45 REQUIRE WASHING SHALL HAVE A FOOD PREPARATION SINK. THE FOOD
46 PREPARATION SINK MUST BE SUPPLIED WITH BOTH HOT AND COLD RUNNING

1 WATER, MUST BE INDIRECTLY DRAINED TO SEWER AND MUST BE EQUIPPED WITH
2 AN APPROVED EIGHTEEN INCH (18") [(46 CENTIMETERS (CM)] DRAIN BOARD OR
3 AN ALTERNATE DRAIN TABLE OR WORK SPACE APPROVED BY THE DEPARTMENT.
4 IF A GARBAGE DISPOSAL IS TO BE INSTALLED AT THE FOOD PREPARATION SINK,
5 IT SHALL BE LOCATED IN THE DRAIN BOARD OF THE SINK AND MUST BE PLUMBED
6 IN ACCORDANCE WITH SECTION 5-205.

7 F. IN ESTABLISHMENTS LICENSED PRIOR TO THE EFFECTIVE DATE OF THESE
8 REGULATIONS, WHERE VEGETABLE PREPARATION IS LIMITED TO A FEW ITEMS
9 AND IN LIMITED QUANTITY, AND EITHER SINGLE-SERVICE TABLEWARE OR A
10 MECHANICAL DISHWASHER IS USED, THE THREE- COMPARTMENT WAREWASHING
11 SINK MAY BE USED FOR FOOD PREPARATION IF THE SINK IS INDIRECTLY DRAINED
12 AND THE SINK AND DRAIN BOARDS ARE CLEANED AND SANITIZED BETWEEN
13 CHANGES IN USE.

14 G. A FOOD PREPARATION SINK MAY ONLY BE USED FOR WASHING FOOD, COOLING,
15 THAWING AND OTHER FOOD PREPARATION ACTIVITIES.

16 **3- In-Use Utensils, Between Use Storage**

17 A. To avoid unnecessary manual contact with the food, suitable dispensing utensils
18 and single-service articles shall be used by employees and consumers. Consumer
19 display and self-service of bulk food shall meet the requirements of section 25-4-
20 1301 et seq., C.R.S., (See Appendix). EXCEPT AS SPECIFIED IN 5 and 6,
21 dispensing utensils shall be:

22 . Stored in the food with the dispensing utensil handle extended out of the
23 food; or

24 . Stored ON A clean and ~~dry~~ SANITIZED SURFACE, IF WASHED AND
25 SANITIZED IN ACCORDANCE WITH SECTION 4-407(C); or

26 . Stored in ~~potable running~~ CONTINUOUSLY FLOWING DRINKING water
27 SUCH as in a ~~running water~~ dipper well; or

28 . Stored at temperatures of 135°F () and above, or 41°F () and below.

29 5. UTENSILS MAY NOT BE STORED IN CRACKS AND CREVICES BETWEEN
30 EQUIPMENT.

31 6. IN-USE UTENSILS MAY NOT BE STORED IN SANITIZING OR CLEANING
32 SOLUTIONS.

33 B. ICE FOR HUMAN CONSUMPTION SHALL BE DISPENSED ONLY BY EMPLOYEES WITH
34 SCOOPS, TONGS, OR OTHER ICE DISPENSING UTENSILS, OR THROUGH AUTOMATIC
35 SELF-SERVICE, ICE DISPENSING EQUIPMENT. ICE DISPENSING UTENSILS SHALL BE
36 STORED ON A CLEAN SURFACE OR IN THE ICE WITH THE DISPENSING UTENSIL'S
37 HANDLE EXTENDED OUT OF THE ICE. BETWEEN USES, ICE TRANSFER
38 RECEPTACLES SHALL BE STORED IN A WAY THAT PROTECTS THEM FROM
39 CONTAMINATION.

40 **3- Wiping Cloths**

41 A. Cloths used for wiping food spills on food-contact surfaces shall be cleaned and
42 rinsed frequently in one of the sanitizing solutions permitted in Appendix of
43 these rules and regulations and used for no other purpose. These cloths shall be

1 ~~saturated~~ HELD BETWEEN USES IN A CLEAN, CHEMICAL SANITIZER SOLUTION AT
2 ~~with the proper concentration of sanitizing solution.~~

3 B. Cloths used for cleaning nonfood-contact surfaces shall be clean and rinsed as
4 specified in paragraph A of this section and used for no other purpose. These
5 cloths shall be HELD BETWEEN USES IN A CLEAN, CHEMICAL SANITIZER SOLUTION
6 AT ~~saturated with the proper concentration. of sanitizing solution between uses.~~

7 C. ~~Dry or moist e-~~Cloths that are used with raw foods of animal origin shall be kept
8 separate from cloths used for other purposes. ~~Moist e-~~Cloths used with raw foods
9 of animal origin shall be kept in a separate sanitizing solution.

10 D. DRY, ~~S-~~use disposable towels are permitted FOR WIPING FOOD SPILLS in lieu of
11 wiping cloths ~~or sponges~~ if discarded after each use.

12 E. Cloths used for wiping food spills on tableware, such as plates and bowls being
13 served to the consumer, shall be clean, dry, and used for no other purpose.

14 F. Sponges shall not be used in contact with ~~cleaned and sanitized or in use~~ food-
15 contact surfaces.

16 G. WET WIPING CLOTHS SHALL BE LAUNDERED DAILY.

17 H. DRY WIPING CLOTHS SHALL BE LAUNDERED AS NECESSARY TO PREVENT
18 CONTAMINATION OF FOOD AND CLEAN SERVING UTENSILS.

19 **3- Re-Use of Tableware**

20 A. EXCEPT AS SPECIFIED IN B, -use of soiled tableware ~~by self-service consumers~~
21 ~~returning to the service area for additional food~~ is prohibited.

22 B. Beverage cups and glasses ~~are exempt from this requirement~~ may be refilled
23 where filling equipment is designed to prevent cross-contamination provided
24 that ~~C. T-~~the dispensing equipment actuating lever or mechanism and filling
25 device of ~~consumer self-service~~ beverage dispensing equipment ~~shall be~~ is
26 designed to prevent contact with the lip-contact surface of glasses or cups that are
27 being refilled.

28 **3- Refilling Returnables**

29 A. A take-home OR PERSONAL food container shall not be refilled at a retail food
30 establishment with a ~~potentially hazardous food~~ POTENTIALLY HAZARDOUS FOOD
31 (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD).

32 B. Returnables refilled with food that is not potentially hazardous shall be clean.

33 C. PERSONAL TAKE-OUT BEVERAGE CONTAINERS, SUCH AS THERMALLY INSULATED
34 BOTTLES, NONSPILL COFFEE CUPS, AND PROMOTIONAL BEVERAGE GLASSES, MAY
35 BE REFILLED BY EMPLOYEES OR THE CONSUMER IF REFILLING IS A
36 CONTAMINATION-FREE PROCESS.

37 **3- Food Storage**

38 A. Containers of food shall be stored a minimum of six inches (6") [15 centimeters
39 (cm)] above the floor or stored on dollies, skids, racks, or open-ended pallets,
40 provided such equipment is easily movable, either by hand or with the use of
41 pallet-moving equipment that is on the premises and used. Such storage areas
42 shall be kept clean.

- 1 B. Pressurized beverage containers, cased food in waterproof containers such as
2 bottles or cans, milk containers in plastic crates, and waterproof, easily
3 moveable, covered containers may be stored on a floor that is clean and not
4 exposed to floor moisture.
- 5 C. Packaged food, once the container is opened in the retail food establishment prior
6 to use or retail sale, shall be kept covered. Food, whether raw or prepared, if
7 removed from the container in which it was originally packaged, shall be stored
8 in a clean, covered container, except during necessary periods of preparation OR
9 COOLING.
- 10 Primal cuts, quarters or sides of meat, or processed meats, such as country hams,
11 slab bacon, and smoked or cured sausages, may be hung uncovered or placed on
12 clean, sanitized metal racks in such a manner as to preclude contamination of any
13 food products in storage.

14 **3- Food Storage, Prohibited Areas**

15 Food may not be stored:

- 16 A. In locker areas unless the food is completely packaged;
- 17 B. In toilet rooms and their vestibules;
- 18 C. In dressing rooms;
- 19 D. In ROOMS DESIGNATED FOR garbage, RECYCLING OR COMPOSTING COLLECTION
20 rooms;
- 21 E. In mechanical rooms;
- 22 F. Under sewer lines that are not shielded to intercept potential drips;
- 23 G. Under leaking water lines, including leaking automatic fire sprinkler heads, or
24 under lines on which water has condensed;
- 25 H. UNDER OPEN STAIRWELLS;
- 26 . Under other sources of contamination; or
- 27 ~~I. In recycling rooms.~~
- 28 J. IN A PRIVATE HOME.

29 **3- Food Display**

- 30 A. Except for nuts in the shell and whole, raw fruits and vegetables that are intended
31 for hulling, peeling, or washing by the consumer before consumption, food on
32 display shall be protected from contamination by the use of packaging; food
33 shields at counters, service lines, or salad bars; display cases; or other effective
34 means of protection.
- 35 B. French style, hearth baked or hard-cruste d loaves and rolls may be considered
36 properly wrapped if contained in an open-end bag of sufficient size to enclose the
37 loaves or rolls.
- 38 C. Bulk food that is available for consumer self-dispensing shall meet the
39 requirements of section 25-4-1301 et seq., C.R.S., (See Appendix).

1 **3- Condiments, Protection**

- 2 A. Condiments shall be protected from contamination by being kept in protective
3 dispensers, in food displays THAT MEET THE REQUIREMENTS OF SECTION 3-311
4 (A) and are provided with the proper utensils, in original containers that are
5 designed for dispensing, or in individual packages or portions
- 6 B. ADDING ADDITIONAL PRODUCT BEFORE THE CONTAINER IS EMPTIED, CLEANED
7 AND SANITIZED IS PROHIBITED.

8 ***3-417 Consumer Self-Service Operations**

- 9 A. Unpackaged or unwrapped raw animal food, such as beef, lamb, pork, poultry and
10 fish shall not be offered for consumer self-service. This does not apply to
11 consumer self-service of ready-to-eat foods at buffets or salad bars that serve
12 foods such as sushi or raw shellfish, or to ready-to-cook individual portions for
13 immediate cooking and consumption on the premises such as consumer-cooked
14 meats or consumer-selected ingredients for Mongolian barbecue.
- 15 B. CONSUMER SELF-SERVICE OPERATIONS SUCH AS BUFFETS AND SALAD BARS
16 SHALL BE MONITORED BY FOOD EMPLOYEES TRAINED IN SAFE OPERATING
17 PROCEDURES.

18 ***3- Reservice**

19 Once served to a consumer, portions of leftover food shall not be served again except
20 that packaged food, other than ~~potentially hazardous food~~ POTENTIALLY HAZARDOUS
21 FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD), that is still in an unopened
22 package and is still in sound condition, may be re-served.

23 **3- DESTRUCTION OF ORGANISMS OF PUBLIC HEALTH CONCERN**

24 ***3-501 Temperature**

- 25 A. The temperature of ~~potentially hazardous foods~~ POTENTIALLY HAZARDOUS FOOD
26 (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) shall be 41°F (5°C) or below
27 or 135°F (57°C) or above, at all times, except during necessary periods of
28 preparation or as otherwise provided in this code.
- 29 B. Equipment for cooling, heating and holding food, cold and hot, shall be sufficient
30 in number and capacity to provide required food temperatures.
- 31 C. Fluid milk and milk products, molluscan shellstock, and shell eggs may be
32 received at their respective temperatures according to laws governing their
33 distribution.
- 34 D. A FOOD THAT IS LABELED FROZEN AND SHIPPED FROZEN BY A FOOD
35 PROCESSING PLANT SHALL BE RECEIVED FROZEN.
- 36 E. UPON RECEIPT, POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE
37 CONTROL FOR SAFETY FOOD) SHALL BE FREE OF EVIDENCE OF PREVIOUS
38 TEMPERATURE ABUSE.

***3-502 Cooking RAW ~~Potentially Hazardous Foods~~ POTENTIALLY HAZARDOUS FOODS (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD)**

~~Unless otherwise ordered by the immediate consumer, potentially hazardous foods~~ POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) processed within the retail food establishment shall be cooked to a uniform internal temperature of ~~140°F (60°C)~~ 135°F (57°C), except that:

A. Poultry, STUFFED RATITE, stuffed fish, stuffed meat, stuffed pasta, stuffed poultry, or stuffing containing fish, meat or poultry shall be cooked to a ~~uniform~~ MINIMUM internal temperature of at least 165°F (74°C) for 15 seconds.

B. ~~Rare roast beef and rare beef steak shall be cooked to a uniform internal temperature of at least 130°F (55°C).~~ WHOLE MEAT ROASTS INCLUDING BEEF, CORNED BEEF, LAMB, PORK, AND CURED PORK ROASTS SUCH AS HAM SHALL BE COOKED:

1. IN AN OVEN THAT IS PREHEATED TO THE TEMPERATURE SPECIFIED FOR THE ROAST'S WEIGHT IN THE FOLLOWING CHART AND THAT IS HELD AT THAT TEMPERATURE:

OVEN TYPE	OVEN TEMPERATURE BASED ON ROAST WEIGHT	
	LESS THAN 10 LBS (4.5 KG)	10 LBS(4.5 KG) OR MORE
STILL DRY	() OR MORE	() OR MORE
CONVECTION	() OR MORE	() OR MORE
HIGH	() OR LESS	() OR LESS

¹ RELATIVE HUMIDITY GREATER THAN 90% FOR AT LEAST 1 HOUR AS MEASURED IN THE COOKING CHAMBER OR EXIT OF THE OVEN; OR IN A MOISTURE-IMPERMEABLE BAG THAT PROVIDES 100% HUMIDITY.

; AND

2. AS SPECIFIED IN THE FOLLOWING CHART, TO HEAT ALL PARTS OF THE FOOD TO A TEMPERATURE AND FOR THE HOLDING TIME THAT CORRESPONDS TO THAT TEMPERATURE:

TEMPERATURE °F	IN MINUTES	TEMPERATURE °F	IN SECONDS
(54.4)	112	(63.9)	134
(55.0)	89	(65.0)	85
(56.1)	56	(66.1)	54
(57.2)	36	(67.2)	34
(57.8)	28	(68.3)	22
(58.9)	18	(69.4)	14
(60.0)	12	(70.0)	0

142 (61.1)	8		
144 (62.2)	5		
145 (62.8)	4		
¹ <i>HOLDING TIME MAY INCLUDE POST OVEN HEAT RISE.</i>			

- 1 C. A RAW OR UNDERCOOKED WHOLE-MUSCLE, INTACT BEEF STEAK MAY BE SERVED
2 OR OFFERED FOR SALE IN A READY-TO-EAT FORM IF:
- 3 1. THE FOOD ESTABLISHMENT SERVES A POPULATION THAT IS NOT A
4 HIGHLY SUSCEPTIBLE POPULATION,
- 5 2. THE STEAK IS LABELED TO INDICATE THAT IT MEETS THE DEFINITION OF
6 "WHOLE-MUSCLE, INTACT BEEF", AND
- 7 3. THE STEAK IS COOKED ON BOTH THE TOP AND BOTTOM TO A SURFACE
8 TEMPERATURE OF () OR ABOVE AND A COOKED COLOR CHANGE IS
9 ACHIEVED ON ALL EXTERNAL SURFACES.
- 10 . Eggs, pork, lamb, fish and other meats as defined in section 1-202 () shall be
11 cooked to a ~~uniform~~ MINIMUM internal temperature of 145°F (63°C) for 15
12 seconds.
- 13 E. EGGS THAT ARE NOT PREPARED IN RESPONSE TO A CONSUMER’S ORDER OR FOR
14 IMMEDIATE SERVICE SHALL BE COOKED TO 155°F (68°C).
- 15 . Ground beef AND RATITES shall be cooked to a ~~uniform~~ MINIMUM internal
16 temperature of 155°F (68°C) for 15 seconds, or to 145°F (63°C) for 3 minutes, or
17 150°F (66°C) for 1 minute, or 158°F (70°C) for less than one second.
- 18 . Game animals shall be cooked to a ~~uniform~~ MINIMUM internal temperature of °F
19 (°C) for 15 seconds EXCEPT AS SPECIFIED IN SECTION 3-502 (K) OF THESE RULES
20 AND REGULATIONS.
- 21 . Comminuted fish, meat and game animals AND BEEF INCLUDING MECHANICALLY
22 TENDERIZED OR INJECTED MEATS OTHER THAN WHOLE MUSCLE INTACT BEEF
23 STEAK, shall be cooked to a ~~uniform~~ MINIMUM internal temperature of 155°F
24 (68°C) for 15 seconds.
- 25 . Raw animal foods cooked in a microwave oven shall be:
- 26 1. Rotated or stirred throughout or midway during cooking to compensate
27 for uneven distribution of heat;
- 28 2. Covered to retain surface moisture;
- 29 3. Heated to a temperature of at least 165°F (74°C) in all parts of the food;
30 and
- 31 4. Allowed to stand covered for 2 minutes after cooking to obtain
32 temperature equilibrium.
- 33 . Fruits and vegetables that are cooked for hot holding shall be cooked to a
34 temperature of 135°F (°C).
- 35 K. UNLESS OTHERWISE ORDERED BY THE IMMEDIATE CONSUMER AND THE
36 CONSUMER IS INFORMED AS SPECIFIED IN SECTIONS 1(A)-(C) BELOW:

- 1 1. A RAW ANIMAL FOOD SUCH AS RAW EGG, RAW FISH, RAW-MARINATED
2 FISH, RAW MOLLUSCAN SHELLFISH, OR STEAK TARTARE; OR A
3 PARTIALLY COOKED FOOD SUCH AS LIGHTLY COOKED FISH, SOFT
4 COOKED EGGS, OR RARE MEAT OTHER THAN WHOLE-MUSCLE, INTACT
5 BEEF STEAKS AS SPECIFIED IN (C) OF THIS SECTION, MAY BE SERVED OR
6 OFFERED FOR SALE UPON CONSUMER REQUEST OR SELECTION IN A
7 READY-TO-EAT FORM IF:
- 8 A. AS SPECIFIED IN SECTION 3-702(A)-(C) OF THESE RULES AND
9 REGULATIONS, THE FOOD ESTABLISHMENT SERVES A
10 POPULATION THAT IS NOT A HIGHLY SUSCEPTIBLE POPULATION;
- 11 B. THE FOOD, IF SERVED OR OFFERED FOR SERVICE BY CONSUMER
12 SELECTION FROM A CHILDREN'S MENU, DOES NOT CONTAIN
13 COMMUNUTED MEAT; AND
- 14 C. THE CONSUMER IS INFORMED AS SPECIFIED IN PART 3-8
15 “CONSUMER ADVISORY” THAT TO ENSURE ITS SAFETY, THE
16 FOOD SHOULD BE COOKED AS SPECIFIED IN SECTION 3-502(A)-
17 (K) OF THIS SECTION.

18 ***3-503 Non-Continuous Cooking of Raw Animal Foods**

- 19 A. RAW ANIMAL FOODS THAT ARE COOKED USING A NON-CONTINUOUS COOKING
20 PROCESS SHALL BE:
- 21 1. SUBJECT TO AN INITIAL HEATING PROCESS THAT IS NO LONGER THAN
22 SIXTY MINUTES IN DURATION;
- 23 2. IMMEDIATELY AFTER INITIAL HEATING, COOLED ACCORDING TO THE
24 TIME AND TEMPERATURE PARAMETERS SPECIFIED FOR COOKED
25 POTENTIALLY HAZARDOUS FOOD (TIME /TEMPERATURE CONTROL FOR
26 SAFETY FOOD) IN SECTION 3-603(A) OF THESE RULES AND
27 REGULATIONS;
- 28 3. AFTER COOLING, HELD FROZEN OR COLD, AS SPECIFIED FOR
29 POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR
30 SAFETY FOOD) IN SECTION 3-501(A) OF THESE RULES AND
31 REGULATIONS;
- 32 4. PRIOR TO SALE OR SERVICE, COOKED USING A PROCESS THAT HEATS ALL
33 PARTS OF THE FOOD TO A TEMPERATURE OF AT LEAST 165°F () FOR 15
34 SECONDS;
- 35 5. COOLED ACCORDING TO THE TIME AND TEMPERATURE PARAMETERS
36 SPECIFIED FOR COOKED POTENTIALLY HAZARDOUS FOOD (TIME
37 /TEMPERATURE CONTROL FOR SAFETY FOOD) IN SECTION 3-603(A)-(C) IF
38 NOT EITHER HOT HELD AS SPECIFIED IN SECTION 3-501(A), SERVED
39 IMMEDIATELY, OR HELD USING TIME AS A PUBLIC HEALTH CONTROL AS
40 SPECIFIED IN SECTION 3-605(A)-(B) AFTER COMPLETE COOKING; AND
- 41 6. PREPARED AND STORED ACCORDING TO WRITTEN PROCEDURES
42 APPROVED BY THE DEPARTMENT THAT:
- 43 A. ARE MAINTAINED IN THE FOOD ESTABLISHMENT AND ARE
44 AVAILABLE TO THE DEPARTMENT UPON REQUEST;

- 1 B. DESCRIBE HOW THE REQUIREMENTS SPECIFIED IN (1)-(5) OF THIS
- 2 SECTION ARE TO BE MONITORED AND DOCUMENTED BY THE
- 3 LICENSEE AND THE CORRECTIVE ACTIONS TO BE TAKEN IF THE
- 4 REQUIREMENTS ARE NOT MET;
- 5 C. DESCRIBE HOW THE FOODS, AFTER INITIAL HEATING, BUT PRIOR
- 6 TO COMPLETE COOKING, ARE TO BE MARKED OR OTHERWISE
- 7 IDENTIFIED AS FOODS THAT MUST BE COOKED AS SPECIFIED IN
- 8 (4) OF THIS SECTION PRIOR TO BEING OFFERED FOR SALE OR
- 9 SERVICE; AND
- 10 D. DESCRIBE HOW THE FOODS, AFTER INITIAL HEATING BUT PRIOR
- 11 TO COOKING AS SPECIFIED IN SECTION (4) OF THIS SECTION, ARE
- 12 TO BE SEPARATED FROM READY-TO-EAT FOODS AS SPECIFIED IN
- 13 SECTION 3-406.

14 ***3- Reheating**

- 15 A. Except as specified in ~~under~~ paragraphs (B) and (C) of this section, ~~potentially~~
- 16 ~~hazardous—foods~~ POTENTIALLY HAZARDOUS FOODS (TIME/TEMPERATURE
- 17 CONTROL FOR SAFETY FOODS) that have been cooked and then refrigerated shall
- 18 be rapidly reheated within two hours to a uniform internal temperature of 165°F
- 19 (74°C) or higher before being placed in hot food storage holding units which
- 20 shall maintain product temperature at 135°F (57°C) or above at all times. Food
- 21 warmers and other hot food holding units shall not be used to reheat ~~potentially~~
- 22 ~~hazardous—foods~~ POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE
- 23 CONTROL FOR SAFETY FOOD) unless the equipment is specifically designed for
- 24 that purpose. ~~If a retail food establishment proposes to use equipment for~~
- 25 ~~reheating that is not designed for reheating, written procedures documenting use~~
- 26 ~~must be approved by the Department.~~
- 27 *B. Except as specified in paragraph (C) of this section, food reheated in a
- 28 microwave oven shall be heated to a uniform internal temperature of at least
- 29 165°F (74°C) and the food is rotated or stirred, covered, and allowed to stand
- 30 covered for 2 minutes after reheating.
- 31 *C. Ready-to-eat food taken from a commercially processed, hermetically sealed
- 32 container, or from an intact package from a food processing plant that is
- 33 inspected by the food ~~regulatory authority~~ DEPARTMENT that has jurisdiction
- 34 over the plant, shall be heated WITHIN TWO HOURS to a uniform internal
- 35 temperature of at least 135°F (60°C) for hot holding.
- 36 ~~D. Cooked and refrigerated food that is prepared for immediate service in response~~
- 37 ~~to an individual consumer order, such as a roast beef sandwich au jus, may be~~
- 38 ~~served at any temperature.~~

39 **3-505 Preparation for Immediate Service**

40 COOKED AND REFRIGERATED FOOD THAT IS PREPARED FOR IMMEDIATE SERVICE IN
41 RESPONSE TO AN INDIVIDUAL CONSUMER ORDER, SUCH AS A ROAST BEEF SANDWICH AU
42 JUS, MAY BE SERVED AT ANY TEMPERATURE.

1 **3- LIMITATION OF GROWTH OF ORGANISMS OF PUBLIC**
2 **HEALTH CONCERN**

3 **3-601 Thawing**

4 ~~Potentially hazardous foods shall be thawed:~~

5 EXCEPT AS SPECIFIED IN SUBPARAGRAPH (D) OF THIS SECTION, POTENTIALLY
6 HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) SHALL BE
7 THAWED:

8 A. Under refrigeration ~~or conditions~~ that maintains the food temperature at () or
9 ~~below~~ LESS; OR

10 B. COMPLETELY SUBMERGED UNDER RUNNING WATER:

11 1. AT A WATER TEMPERATURE OF () OR BELOW,

12 2. WITH SUFFICIENT WATER VELOCITY TO AGITATE AND FLOAT OFF LOOSE
13 PARTICLES IN AN OVERFLOW, AND

14 3. FOR A PERIOD OF TIME THAT DOES NOT ALLOW THAWED PORTIONS OF
15 READY-TO-EAT FOOD TO RISE ABOVE (); OR

16 4. FOR A PERIOD OF TIME THAT DOES NOT ALLOW THAWED PORTIONS OF A
17 RAW ANIMAL FOOD REQUIRING COOKING AS SPECIFIED IN SECTION 3-
18 502 TO BE ABOVE (), FOR MORE THAN 4 HOURS INCLUDING:

19 A. THE TIME THE FOOD IS EXPOSED TO THE RUNNING WATER AND
20 THE TIME NEEDED FOR PREPARATION FOR COOKING, OR

21 B. THE TIME IT TAKES UNDER REFRIGERATION TO LOWER THE FOOD
22 TEMPERATURE TO ();

23 C. AS PART OF A COOKING PROCESS IF THE FOOD THAT IS FROZEN IS:

24 1. COOKED AS SPECIFIED IN SECTION 3-502, OR

25 2. THAWED IN A MICROWAVE OVEN AND IMMEDIATELY TRANSFERRED TO
26 CONVENTIONAL COOKING EQUIPMENT, WITH NO INTERRUPTION IN THE
27 PROCESS; OR

28 D. USING ANY PROCEDURE IF A PORTION OF FROZEN READY-TO-EAT FOOD IS
29 THAWED AND PREPARED FOR IMMEDIATE SERVICE IN RESPONSE TO AN
30 INDIVIDUAL CONSUMER'S ORDER.

31 ~~B. Unwrapped and completely submerged under running water:~~

32 1. ~~At a water temperature of 70°F (21°C) or below, and~~

33 2. ~~With sufficient water velocity to agitate and float off loose particles in an~~
34 ~~overflow, and~~

35 3. ~~For a period of time that does not allow any thawed portions of raw~~
36 ~~animal food requiring cooking to rise above 41°F (5°C) for more than~~
37 ~~four hours including necessary periods of preparation or~~

38 *34. ~~For a period of time that does not allow thawed portions of food to rise~~
39 ~~above 41°F (5°C) for more than four hours.~~

1 ~~C. In a microwave oven only when the food will be immediately transferred to a~~
2 ~~conventional cooking process as part of a continuous operation, or when the~~
3 ~~entire, uninterrupted cooking process takes place in the microwave oven, or~~
4 ~~returned immediately to cold storage.~~

5 ~~*D. Under conditions that do not allow any portions of the food to be above 41°F~~
6 ~~(5°C).~~

7 ~~E. As part of the conventional cooking process.~~

8 **3-602 SLACKING**

9 A. FROZEN POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR
10 SAFETY FOOD) THAT IS SLACKED TO MODERATE THE TEMPERATURE SHALL BE
11 HELD:

- 12 1. UNDER REFRIGERATION THAT MAINTAINS THE FOOD TEMPERATURE AT
13 41°F (5°C) OR LESS, OR
14 2. AT ANY TEMPERATURE IF THE FOOD REMAINS FROZEN.

15 ***3- Cooling**

16 A. Cooked ~~potentially hazardous food~~ POTENTIALLY HAZARDOUS FOOD
17 (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) shall be cooled from 135°F
18 (57°C) to 41°F (5°C), or below, in 6 hours, provided that the food is cooled
19 from 135°F (57°C) to 70°F (21°C) within the first 2 hours.

20 B. ~~Potentially hazardous food~~ POTENTIALLY HAZARDOUS FOOD
21 (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) that has been prepared from
22 ingredients at ambient temperature, such as reconstituted milk and canned
23 products, shall be cooled to 41°F (5°C), or below, within 4 hours.

24 C. Fluid milk and milk products, shell eggs, and molluscan shellstock received in
25 compliance with laws regulating the respective food during shipment from the
26 supplier shall be cooled to 41°F (5°C) or below within 4 hours.

27 **3- Cooling Methods**

28 *A. Cooling shall be accomplished as required in section 3-, by using one or more of
29 the following methods based on the type of food being cooled:

- 30 1. Placing the food in shallow pans;
31 2. Separating the food into smaller or thinner portions;
32 3. Using rapid cooling equipment;
33 4. Stirring the food in a container placed in an ice water bath;
34 5. Using containers that facilitate heat transfer;
35 6. Adding ice as an ingredient; or
36 7. Other effective methods that meet the requirements of section 3- of these
37 rules and regulations.

38 B. When using food containers to cool food, food shall be:

- 39 1. Arranged in the container to provide maximum heat transfer through the
40 container walls; and

- 1 A. AS A METHOD OF FOOD PRESERVATION RATHER THAN AS A
- 2 METHOD OF FLAVOR ENHANCEMENT, OR
- 3 B. TO RENDER A FOOD SO THAT IT IS NOT POTENTIALLY
- 4 HAZARDOUS.
- 5 4. PACKAGING FOOD USING A REDUCED OXYGEN PACKAGING METHOD
- 6 EXCEPT AS SPECIFIED IN SECTION 3-607 WHERE A BARRIER TO
- 7 CLOSTRIDIUM BOTULINUM IN ADDITION TO REFRIGERATION EXISTS;
- 8 5. OPERATING A MOLLUSCAN SHELLFISH LIFE-SUPPORT SYSTEM DISPLAY
- 9 TANK USED TO STORE OR DISPLAY SHELLFISH THAT ARE OFFERED FOR
- 10 HUMAN CONSUMPTION;
- 11 6. CUSTOM PROCESSING ANIMALS THAT ARE FOR PERSONAL USE AS FOOD
- 12 AND NOT FOR SALE OR SERVICE IN A FOOD ESTABLISHMENT;
- 13 7. SPROUTING SEEDS OR BEANS;
- 14 8. OTHER SPECIALIZED PROCESSING METHODS.

15 ***3-607 ~~Modified Atmosphere~~ REDUCED OXYGEN Packaging, Criteria**

- 16 A. A retail food establishment that packages POTENTIALLY HAZARDOUS food
- 17 (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) using a ~~modified atmosphere~~
- 18 REDUCED OXYGEN packaging method shall CONTROL THE GROWTH AND TOXIN
- 19 FORMATION OF CLOSTRIDIUM BOTULINUM AND THE GROWTH OF LISTERIA
- 20 MONOCYTOGENES AND have a HACCP plan that contains the information
- 21 specified under Appendix and that:
 - 22 1. Identifies the food to be packaged;
 - 23 2. ~~Limits the food packaged to a food that does not support the growth of~~
 - 24 ~~*Clostridium botulinum* because it~~ EXCEPT AS SPECIFIED IN (B) - (D) OF
 - 25 THIS SECTION, REQUIRES THAT THE PACKAGED FOOD SHALL BE
 - 26 MAINTAINED AT () OR LESS AND MEET AT LEAST ONE OF THE
 - 27 FOLLOWING CRITERIA:
 - 28 a. Has an of 0.91 or less,
 - 29 b. Has a pH of 4.6 or less,
 - 30 c. Is a meat OR POULTRY product cured at a FOOD processing plant
 - 31 regulated by the U.S. Department of Agriculture (USDA) using a
 - 32 ~~combination of nitrites, nitrates, and salt that at the time of~~
 - 33 ~~processing consists of 120 mg/L or higher concentration of sodium~~
 - 34 ~~nitrite and a brine concentration of at least 3.50% and is received in~~
 - 35 ~~an intact package, SUBSTANCES SPECIFIED IN 9 CFR 424.21, USE OF~~
 - 36 ~~FOOD INGREDIENTS AND SOURCES OF RADIATION, AND IS RECEIVED~~
 - 37 ~~IN AN INTACT PACKAGE OR~~
 - 38 d. Is a food with a high level of competing organisms such as raw
 - 39 ~~meat or~~ raw poultry OR RAW VEGETABLES.
 - 40 3. ~~Specifies methods for maintaining food at 41°F (5°C) or below;~~
 - 41 4. ~~Describes how the packages shall be prominently and conspicuously~~
 - 42 ~~labeled on the principal display panel in bold type on a contrasting~~
 - 43 ~~background, with instructions to:~~

- 1 a) ~~Maintain the food at 41°F (5°C) or below, and~~
- 2 b) ~~Discard the food if not consumed within 14 calendar days of its~~
- 3 ~~packaging.~~
- 4 5. ~~Limits the refrigerated shelf life to no more than 14 calendar days from~~
- 5 ~~packaging to consumption, or the original manufacturer's "sell by" or~~
- 6 ~~"use by" date, whichever occurs first;~~
- 7 6. ~~Includes operational procedures that:~~
- 8 a) ~~Minimize handling of food with bare hands,~~
- 9 b) ~~Identify a designated area and the method by which:~~
- 10 i) ~~Physical barriers or methods of separation of raw foods~~
- 11 ~~of animal origin and ready to eat foods minimize cross-~~
- 12 ~~contamination, and~~
- 13 ii) ~~Access to the processing equipment is restricted to~~
- 14 ~~responsible trained personnel familiar with the potential~~
- 15 ~~hazards of the operation, and~~
- 16 iii) ~~Delineate cleaning and sanitization procedures for food-~~
- 17 ~~contact surfaces;~~
- 18 7. ~~Describes the training program that assures the individual responsible for~~
- 19 ~~the modified atmosphere packaging operation understands the:~~
- 20 a) ~~Concepts required for a safe operation,~~
- 21 b) ~~Equipment and facilities, and~~
- 22 c) ~~Procedures specified in subparagraph (A)(6) of this section and~~
- 23 ~~Appendix H.~~
- 24 B. ~~Except for fish that is frozen before, during and after packaging, a food establishment~~
- 25 ~~may not package fish using a modified atmosphere packaging method.~~
- 26 3. DESCRIBES HOW THE PACKAGE SHALL BE PROMINENTLY AND
- 27 CONSPICUOUSLY LABELED ON THE PRINCIPAL DISPLAY PANEL IN BOLD
- 28 TYPE ON A CONTRASTING BACKGROUND, WITH INSTRUCTIONS TO:
- 29 A. MAINTAIN THE FOOD AT () OR BELOW, AND
- 30 B. DISCARD THE FOOD IF WITHIN FOURTEEN (14) CALENDAR DAYS
- 31 OF ITS PACKAGING IT IS NOT SERVED FOR ON-PREMISES
- 32 CONSUMPTION, OR CONSUMED IF SERVED OR SOLD FOR OFF-
- 33 PREMISES CONSUMPTION;
- 34 4. LIMITS THE REFRIGERATED SHELF LIFE TO NO MORE THAN FOURTEEN
- 35 (14) CALENDAR DAYS FROM PACKAGING TO CONSUMPTION, EXCEPT THE
- 36 TIME THE PRODUCT IS MAINTAINED FROZEN, OR THE ORIGINAL
- 37 MANUFACTURER'S "SELL BY" OR "USE BY" DATE, WHICHEVER OCCURS
- 38 FIRST;
- 39 5. INCLUDES OPERATIONAL PROCEDURES THAT:
- 40 A. PROHIBIT CONTACTING READY-TO-EAT FOOD WITH BARE HANDS
- 41 AS SPECIFIED IN SECTION 3-302 OF THESE RULES AND
- 42 REGULATIONS,

- 1 B. IDENTIFY A DESIGNATED WORK AREA AND THE METHOD BY
- 2 WHICH:
- 3 (1) PHYSICAL BARRIERS OR METHODS OF SEPARATION OF RAW
- 4 FOODS AND READY-TO-EAT FOODS MINIMIZE CROSS
- 5 CONTAMINATION, AND
- 6 (2) ACCESS TO THE PROCESSING EQUIPMENT IS LIMITED TO
- 7 RESPONSIBLE TRAINED PERSONNEL FAMILIAR WITH THE
- 8 POTENTIAL HAZARDS OF THE OPERATION, AND
- 9 C. DELINEATE CLEANING AND SANITIZATION PROCEDURES FOR
- 10 FOOD-CONTACT SURFACES; AND
- 11 6. DESCRIBES THE TRAINING PROGRAM THAT ENSURES THAT THE
- 12 INDIVIDUAL RESPONSIBLE FOR THE REDUCED OXYGEN PACKAGING
- 13 OPERATION UNDERSTANDS THE:
- 14 A. CONCEPTS REQUIRED FOR A SAFE OPERATION,
- 15 B. EQUIPMENT AND FACILITIES, AND
- 16 C. PROCEDURES SPECIFIED UNDER SUBPARAGRAPH (A)(5) OF THIS
- 17 SECTION AND APPENDIX G.
- 18 B. EXCEPT FOR FISH THAT IS FROZEN BEFORE, DURING, AND AFTER PACKAGING, A
- 19 FOOD ESTABLISHMENT MAY NOT PACKAGE FISH USING A REDUCED OXYGEN
- 20 PACKAGING METHOD.
- 21 C. EXCEPT AS SPECIFIED IN (B) OF THIS SECTION, A FOOD ESTABLISHMENT THAT
- 22 PACKAGES POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR
- 23 SAFETY FOOD) USING A COOK-CHILL OR SOUS VIDE PROCESS SHALL:
- 24 1. IMPLEMENT A HACCP PLAN THAT CONTAINS THE INFORMATION AS
- 25 SPECIFIED IN APPENDIX G;
- 26 2. ENSURE THE FOOD IS:
- 27 A. PREPARED AND CONSUMED ON THE PREMISES, OR PREPARED
- 28 AND CONSUMED OFF THE PREMISES BUT WITHIN THE SAME
- 29 BUSINESS ENTITY WITH NO DISTRIBUTION OR SALE OF THE
- 30 PACKAGED PRODUCT TO ANOTHER BUSINESS ENTITY OR THE
- 31 CONSUMER,
- 32 B. COOKED TO HEAT ALL PARTS OF THE FOOD TO A TEMPERATURE
- 33 AND FOR A TIME AS SPECIFIED IN SECTION 3-502,
- 34 C. PROTECTED FROM CONTAMINATION BEFORE AND AFTER
- 35 COOKING AS SPECIFIED IN SECTION 3-401 THROUGH 3-406,
- 36 D. PLACED IN A PACKAGE WITH AN OXYGEN BARRIER AND SEALED
- 37 BEFORE COOKING, OR PLACED IN A PACKAGE AND SEALED
- 38 IMMEDIATELY AFTER COOKING AND BEFORE REACHING A
- 39 TEMPERATURE BELOW 57°C (135°F),
- 40 E. COOLED TO () IN THE SEALED PACKAGE OR BAG AS SPECIFIED IN
- 41 SECTION 3-503 AND:
- 42 (1) COOLED TO 34°F() WITHIN 48 HOURS OF REACHING () AND
- 43 HELD AT THAT TEMPERATURE UNTIL CONSUMED OR

- 1 DISCARDED WITHIN THIRTY (30) DAYS AFTER THE DATE OF
- 2 PACKAGING;
- 3 (2) HELD AT () OR LESS FOR NO MORE THAN 7 DAYS, AT WHICH
- 4 TIME THE FOOD MUST BE CONSUMED OR DISCARDED;
- 5 (3) COOLED TO () OR LESS WITHIN 24 HOURS OF REACHING ()
- 6 AND HELD THERE FOR NO MORE THAN 72 HOURS FROM
- 7 PACKAGING, AT WHICH TIME THE FOOD MUST BE CONSUMED
- 8 OR DISCARDED; OR
- 9 (4) HELD FROZEN WITH NO SHELF LIFE RESTRICTION WHILE
- 10 FROZEN UNTIL CONSUMED OR USED.
- 11 F. HELD IN A REFRIGERATION UNIT THAT IS EQUIPPED WITH AN
- 12 ELECTRONIC SYSTEM THAT CONTINUOUSLY MONITORS TIME AND
- 13 TEMPERATURE AND IS VISUALLY EXAMINED FOR PROPER
- 14 OPERATION TWICE DAILY,
- 15 G. IF TRANSPORTED OFF-SITE TO A SATELLITE LOCATION OF THE
- 16 SAME BUSINESS ENTITY, EQUIPPED WITH VERIFIABLE
- 17 ELECTRONIC MONITORING DEVICES TO ENSURE THAT TIMES AND
- 18 TEMPERATURES ARE MONITORED DURING TRANSPORTATION;
- 19 AND
- 20 H. LABELED WITH THE PRODUCT NAME AND THE DATE PACKAGED;
- 21 AND
- 22 3. MAINTAIN THE RECORDS REQUIRED TO CONFIRM THAT COOLING AND
- 23 COLD HOLDING REFRIGERATION TIME/TEMPERATURE PARAMETERS ARE
- 24 MET AS PART OF THE HACCP PLAN AND:
- 25 A. MAKE SUCH RECORDS AVAILABLE TO THE DEPARTMENT UPON
- 26 REQUEST, AND
- 27 B. HOLD SUCH RECORDS FOR AT LEAST 6 MONTHS; AND
- 28 4. IMPLEMENT WRITTEN OPERATIONAL PROCEDURES AS SPECIFIED IN
- 29 (A)(5) OF THIS SECTION AND A TRAINING PROGRAM AS SPECIFIED IN
- 30 (A)(6) OF THIS SECTION.
- 31 D. A FOOD ESTABLISHMENT THAT PACKAGES CHEESE USING A REDUCED OXYGEN
- 32 PACKAGING METHOD SHALL:
- 33 1. LIMIT THE CHEESES PACKAGED TO THOSE THAT ARE COMMERCIALY
- 34 MANUFACTURED IN A FOOD PROCESSING PLANT WITH NO INGREDIENTS
- 35 ADDED IN THE FOOD ESTABLISHMENT AND THAT MEET THE STANDARDS
- 36 OF IDENTITY AS SPECIFIED IN 21 CFR 133.150 HARD CHEESES, 21 CFR
- 37 133.169 PASTEURIZED PROCESS CHEESE OR 21 CFR 133.187 SEMISOFT
- 38 CHEESES;
- 39 2. HAVE A HACCP PLAN THAT CONTAINS THE INFORMATION SPECIFIED
- 40 UNDER APPENDIX G AND AS SPECIFIED IN (A)(1), (A)(3)(A), (A)(5) AND
- 41 (A)(6) OF THIS SECTION;
- 42 3. LABELS THE PACKAGE ON THE PRINCIPAL DISPLAY PANEL WITH A "USE
- 43 BY" DATE THAT DOES NOT EXCEED THIRTY (30) DAYS FROM ITS

- 1 PACKAGING OR THE ORIGINAL MANUFACTURER'S "SELL BY" OR "USE BY"
2 DATE, WHICHEVER OCCURS FIRST; AND
3 4. DISCARDS THE REDUCED OXYGEN PACKAGED CHEESE IF IT IS NOT SOLD
4 FOR OFF-PREMISES CONSUMPTION OR CONSUMED WITHIN THIRTY (30)
5 CALENDAR DAYS OF ITS PACKAGING.

6 **3-608 BREADING MIXTURES**

- 7 A. CONTAINERS OF DRY BREADING MIXTURES (CONTAINING FLOUR, CORNMEAL,
8 SPICES, ETC.) INTO WHICH RAW ANIMAL FOODS SUCH AS POULTRY AND FISH ARE
9 REPEATEDLY DIPPED, MAY BE USED FOR A TOTAL PERIOD OF UP TO 7 DAYS AND
10 STORED AT ROOM TEMPERATURE, PROVIDED THAT:
11 1. CONTAINERS ARE STORED COVERED IN A CLEAN DRY AREA OVERNIGHT
12 AND/OR WHEN NOT IN USE AS SPECIFIED IN SECTIONS 3-311 AND 3-312;
13 2. THE BREADING MIXTURE IS SIFTED AT A MINIMUM OF EVERY 4 HOURS TO
14 REMOVE EXCESS MOISTURE AND DOUGHBALLS WHILE IN USE; AND
15 3. CONTAINERS ARE COMPLETELY EMPTIED, CLEANED AND SANITIZED,
16 AND THE BREADING MIXTURES DISCARDED AT INTERVALS OF NO
17 GREATER THAN 7 DAYS.
18 B. IF THIS PROCEDURE IS USED, THE PERSON IN CHARGE MUST HAVE A SYSTEM IN
19 PLACE TO INDICATE THE DATE THE BREADING MUST BE DISCARDED.

20 **3-7 ON-PREMISES LABELING**

21 **3-701 Labeling**

- 22 A. When voluntary code date information appears on a retail food establishment or
23 manufacturers' label, it shall not be concealed or altered.
24 B. Bulk food available for consumer self-dispensing shall be prominently labeled
25 according to section 25-4-1301 et seq., C.R.S., (See Appendix).
26 C. If an unpackaged non-bulk food product is manufactured on site and sold at the
27 site where it was manufactured or sold over the counter at a different site, no
28 labeling is required. However, an ingredient label shall be made available upon
29 request.
30 IF A PACKAGED FOOD ~~the~~ product IS MANUFACTURED AND SOLD ~~distributed at a~~
31 ~~location different from the manufacturing~~ ON OR OFF SITE FOR CUSTOMER SELF
32 SERVICE, ~~as a prepackaged item~~, it must be labeled in accordance with section
33 25-5-401 et seq., C.R.S. and all labeling regulations authorized therein.
34 D. A food ingredient, such as flour, sugar, salt, spices, DRIED HERBS, POTATO
35 FLAKES, baking powder, cooking oil or vinegar, that is not stored in the original
36 package and is not readily identifiable on sight, shall be stored in a container
37 identifying it by a common name.

38 ***3-702 Special Requirements for Highly Susceptible Populations**

- 39 A. READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE
40 CONTROL FOR SAFETY FOOD) SERVED IN FACILITIES PROVIDING FOOD TO HIGHLY
41 SUSCEPTIBLE POPULATIONS SHALL ADHERE TO THE FOLLOWING DATE MARKING
42 REQUIREMENTS:

- 1 *1. EXCEPT WHEN PACKAGING FOOD USING A REDUCED OXYGEN
2 PACKAGING METHOD AS SPECIFIED IN SECTION 3-607 OF THESE RULES
3 AND REGULATIONS, AND EXCEPT AS SPECIFIED IN (4) AND (5) OF THIS
4 SECTION, REFRIGERATED, READY-TO-EAT, POTENTIALLY HAZARDOUS
5 FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) PREPARED AND
6 HELD IN A FOOD ESTABLISHMENT FOR MORE THAN 24 HOURS SHALL BE
7 CLEARLY MARKED TO INDICATE THE DATE OR DAY BY WHICH THE FOOD
8 SHALL BE CONSUMED ON THE PREMISES, SOLD, OR DISCARDED WHEN
9 HELD AT A TEMPERATURE OF 41°F () OR LESS FOR A MAXIMUM OF 7
10 DAYS.
- 11 *2. EXCEPT AS SPECIFIED IN (4)-(6) OF THIS SECTION, REFRIGERATED, READY-
12 TO-EAT, POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL
13 FOR SAFETY FOOD) PREPARED AND PACKAGED BY A FOOD PROCESSING
14 PLANT SHALL BE CLEARLY MARKED, AT THE TIME THE ORIGINAL
15 CONTAINER IS OPENED IN A FOOD ESTABLISHMENT AND IF THE FOOD IS
16 HELD FOR MORE THAN 24 HOURS, TO INDICATE THE DATE OR DAY BY
17 WHICH THE FOOD SHALL BE CONSUMED ON THE PREMISES, SOLD, OR
18 DISCARDED, BASED ON THE TEMPERATURE AND TIME COMBINATIONS
19 SPECIFIED IN (1) OF THIS SECTION AND:
- 20 A. THE DAY THE ORIGINAL CONTAINER IS OPENED IN THE FOOD
21 ESTABLISHMENT SHALL BE COUNTED AS DAY 1; AND
- 22 B. THE DAY OR DATE MARKED BY THE FOOD ESTABLISHMENT MAY
23 NOT EXCEED A MANUFACTURER'S USE-BY DATE IF THE
24 MANUFACTURER DETERMINED THE USE-BY DATE BASED ON FOOD
25 SAFETY.
- 26 *3. A REFRIGERATED, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD
27 (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) INGREDIENT OR A
28 PORTION OF A REFRIGERATED, READY-TO-EAT, POTENTIALLY HAZARDOUS
29 FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) THAT IS
30 SUBSEQUENTLY COMBINED WITH ADDITIONAL INGREDIENTS OR PORTIONS
31 OF FOOD SHALL RETAIN THE DATE MARKING OF THE EARLIEST-PREPARED
32 OR FIRST-PREPARED INGREDIENT.
- 33 4. A DATE MARKING SYSTEM THAT MEETS THE CRITERIA STATED IN (1) AND
34 (2) OF THIS SECTION MAY INCLUDE:
- 35 A. USING A METHOD APPROVED BY THE DEPARTMENT FOR
36 REFRIGERATED, READY-TO-EAT POTENTIALLY HAZARDOUS FOOD
37 (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) THAT IS
38 FREQUENTLY REWRAPPED, SUCH AS LUNCHMEAT OR A ROAST, OR
39 FOR WHICH DATE MARKING IS IMPRACTICAL, SUCH AS SOFT
40 SERVE MIX OR MILK IN A DISPENSING MACHINE;
- 41 B. MARKING THE DATE OR DAY OF PREPARATION, WITH A
42 PROCEDURE TO DISCARD THE FOOD ON OR BEFORE THE LAST
43 DATE OR DAY BY WHICH THE FOOD MUST BE CONSUMED ON THE
44 PREMISES, SOLD, OR DISCARDED AS SPECIFIED IN (1) OF THIS
45 SECTION;
- 46 C. MARKING THE DATE OR DAY THE ORIGINAL CONTAINER IS
47 OPENED IN A FOOD ESTABLISHMENT, WITH A PROCEDURE TO

- 1 DISCARD THE FOOD ON OR BEFORE THE LAST DATE OR DAY BY
2 WHICH THE FOOD MUST BE CONSUMED ON THE PREMISES, SOLD,
3 OR DISCARDED AS SPECIFIED IN (2) OF THIS SECTION; OR
- 4 D. USING CALENDAR DATES, DAYS OF THE WEEK, COLOR-CODED
5 MARKS, OR OTHER EFFECTIVE MARKING METHODS, PROVIDED
6 THAT THE MARKING SYSTEM IS DISCLOSED TO THE DEPARTMENT
7 UPON REQUEST.
- 8 5. PARAGRAPHS (1) AND (2) OF THIS SECTION DO NOT APPLY TO INDIVIDUAL
9 MEAL PORTIONS SERVED OR REPACKAGED FOR SALE FROM A BULK
10 CONTAINER UPON A CONSUMER'S REQUEST.
- 11 6. PARAGRAPH (2) OF THIS SECTION DOES NOT APPLY TO THE FOLLOWING
12 FOODS PREPARED AND PACKAGED BY A FOOD PROCESSING PLANT
13 INSPECTED BY A DEPARTMENT:
- 14 A. DELI SALADS, SUCH AS HAM SALAD, SEAFOOD SALAD, CHICKEN
15 SALAD, EGG SALAD, PASTA SALAD, POTATO SALAD, AND
16 MACARONI SALAD, MANUFACTURED IN ACCORDANCE WITH 21
17 CFR 110 CURRENT GOOD MANUFACTURING PRACTICE IN
18 MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD;
- 19 B. HARD CHEESES CONTAINING NOT MORE THAN 39% MOISTURE AS
20 DEFINED IN 21 CFR 133 CHEESES AND RELATED CHEESE
21 PRODUCTS, SUCH AS CHEDDAR, GRUYERE, PARMESAN AND
22 REGGIANO, AND ROMANO;
- 23 C. SEMI-SOFT CHEESES CONTAINING MORE THAN 39% MOISTURE,
24 BUT NOT MORE THAN 50% MOISTURE, AS DEFINED IN 21 CFR 133
25 CHEESES AND RELATED CHEESE PRODUCTS, SUCH AS BLUE,
26 EDAM, GORGONZOLA, GOUDA, AND MONTEREY JACK;
- 27 7. CULTURED DAIRY PRODUCTS AS DEFINED IN 21 CFR 131 MILK AND
28 CREAM, SUCH AS YOGURT, SOUR CREAM, AND BUTTERMILK;
- 29 8. PRESERVED FISH PRODUCTS, SUCH AS PICKLED HERRING AND DRIED OR
30 SALTED COD, AND OTHER ACIDIFIED FISH PRODUCTS DEFINED IN 21 CFR
31 114 ACIDIFIED FOODS;
- 32 9. SHELF STABLE, DRY FERMENTED SAUSAGES, SUCH AS PEPPERONI AND
33 GENOA SALAMI THAT ARE NOT LABELED "KEEP REFRIGERATED" AS
34 SPECIFIED IN 9 CFR 317 LABELING, MARKING DEVICES, AND CONTAINERS,
35 AND WHICH RETAIN THE ORIGINAL CASING ON THE PRODUCT; AND
- 36 10. SHELF STABLE SALT-CURED PRODUCTS SUCH AS PROSCIUTTO AND PARMA
37 (HAM) THAT ARE NOT LABELED "KEEP REFRIGERATED" AS SPECIFIED IN 9
38 CFR 317 LABELING, MARKING DEVICES, AND CONTAINERS.

- 1 B. A FOOD ESTABLISHMENT THAT PACKAGES POTENTIALLY HAZARDOUS FOOD
2 (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) THAT WILL BE SERVED IN
3 FACILITIES PROVIDING FOOD TO HIGHLY SUSCEPTIBLE POPULATIONS USING A
4 REDUCED OXYGEN PACKAGING METHOD AS SPECIFIED IN SECTION 3-607 SHALL
5 HAVE A HACCP PLAN THAT CONTAINS THE INFORMATION SPECIFIED UNDER
6 APPENDIX G AND THAT IS PROVIDED TO THE DEPARTMENT FOR REVIEW AND
7 APPROVAL PRIOR TO IMPLEMENTION.
- 8 C. The following foods may not be served or offered for sale in a ready-to-eat form
9 to persons in a highly susceptible population:
 - 10 1. Raw animal foods such as raw fish, raw-marinated fish, raw molluscan
11 shellfish, and steak tartare;
 - 12 2. A partially cooked animal food such as lightly cooked fish, rare meat,
13 soft cooked eggs that are made from raw shell eggs and meringue;
 - 14 3. Raw seed sprouts;~~and~~
 - 15 4. Juice that is not pasteurized or treated under an HACCP plan as specified
16 in Appendix I-G of these rules and regulations, or contains a warning
17 label as specified in Section 3-(B) of these rules and regulations;
- 18 D. FOOD MAY NOT BE RE-SERVED TO OR FROM HIGHLY SUSCEPTIBLE POPULATIONS
19 UNDER THE FOLLOWING CONDITIONS:
 - 20 1. ANY FOOD SERVED TO PATIENTS OR CLIENTS WHO ARE UNDER CONTACT
21 PRECAUTIONS IN MEDICAL ISOLATION OR QUARANTINE, OR PROTECTIVE
22 ENVIRONMENT ISOLATION MAY NOT BE RE-SERVED TO OTHERS OUTSIDE.
 - 23 2. PACKAGES OF FOOD FROM ANY PATIENTS, CLIENTS, OR OTHER
24 CONSUMERS SHOULD NOT BE RE-SERVED TO PERSONS IN PROTECTIVE
25 ENVIRONMENT ISOLATION.

26 **3-8 Consumer Advisory**

27 ***3-801 CONSUMPTION OF ANIMAL FOODS THAT ARE RAW, UNDERCOOKED, OR NOT**
28 **OTHERWISE PROCESSED TO ELIMINATE PATHOGENS.**

- 29 A. EXCEPT AS SPECIFIED IN 3-502(C) AND SUBPARAGRAPH 3-502(K)(1) AND IN 3-
30 702(A)-(D), IF AN ANIMAL FOOD SUCH AS BEEF, EGGS, FISH, LAMB, MILK, PORK,
31 POULTRY, OR SHELLFISH IS SERVED OR SOLD RAW, UNDERCOOKED, OR WITHOUT
32 OTHERWISE BEING PROCESSED TO ELIMINATE PATHOGENS, EITHER IN READY-TO-
33 EAT FORM OR AS AN INGREDIENT IN ANOTHER READY-TO-EAT FOOD, THE
34 LICENSEE SHALL INFORM CONSUMERS OF THE SIGNIFICANTLY INCREASED RISK
35 OF CONSUMING SUCH FOODS BY WAY OF A DISCLOSURE AND REMINDER, AS
36 SPECIFIED IN (B) AND (C) OF THIS SECTION USING BROCHURES, DELI CASE OR
37 MENU ADVISORIES, LABEL STATEMENTS, TABLE TENTS, PLACARDS, OR OTHER
38 EFFECTIVE WRITTEN MEANS.
- 39 B. DISCLOSURE SHALL INCLUDE:
 - 40 1. A DESCRIPTION OF THE ANIMAL-DERIVED FOODS, SUCH AS “OYSTERS ON
41 THE HALF SHELL (RAW OYSTERS),” “ UNDERCOOKED EGGS,” AND
42 “HAMBURGERS (CAN BE COOKED TO ORDER);” OR
 - 43 2. IDENTIFICATION OF THE ANIMAL-DERIVED FOODS BY ASTERISKING THEM
44 TO A FOOTNOTE THAT STATES THAT THE ITEMS ARE SERVED RAW OR

1 UNDERCOOKED, OR CONTAIN (OR MAY CONTAIN) RAW OR
2 UNDERCOOKED INGREDIENTS.

3 C. REMINDER SHALL INCLUDE ASTERISKING THE ANIMAL-DERIVED FOODS
4 REQUIRING DISCLOSURE TO A FOOTNOTE THAT STATES:

5 1. REGARDING THE SAFETY OF THESE ITEMS, WRITTEN INFORMATION IS
6 AVAILABLE UPON REQUEST;

7 2. CONSUMING RAW OR UNDERCOOKED MEATS, POULTRY, SEAFOOD,
8 SHELLFISH, OR EGGS MAY INCREASE YOUR RISK OF FOODBORNE ILLNESS;
9 OR

10 3. CONSUMING RAW OR UNDERCOOKED MEATS, POULTRY, SEAFOOD,
11 SHELLFISH, OR EGGS MAY INCREASE YOUR RISK OF FOODBORNE ILLNESS,
12 ESPECIALLY IF YOU HAVE CERTAIN MEDICAL CONDITIONS.

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CHAPTER 4

WAREWASHING, EQUIPMENT, UTENSILS, AND LINENS

4-1 MATERIALS FOR CONSTRUCTION AND REPAIR

4-101 General

All equipment, utensils and single-service articles shall be fabricated with safe materials; be of commercial design, that is certified or classified for sanitation by an American National Standards Institute (ANSI) accredited certification program or a design approved by the Department (see Appendix); fabricated for durability under conditions of normal use; and resistant to denting, buckling, pitting, chipping, and crazing. Equipment, utensils, and single-service articles shall not impart odor, color, or taste, nor in any manner contribute to the contamination of food. Equipment and utensils shall be repaired with safe materials and maintained in good repair to comply with the requirements of this code.

4-102 Equipment Requirements

All retail food establishments shall have at a minimum:

- A. Equipment and utensil washing facilities installed and operated in accordance with section 4-403 EXCEPT RETAIL FOOD ESTABLISHMENTS THAT DO NOT PREPARE FOOD, PACKAGE FOOD, OR DISPENSE UNPACKAGED FOOD OTHER THAN WHOLE, UNCUT RAW FRUITS AND VEGETABLES, AND WHOLE NUTS IN THE SHELL. ~~of these rules and regulations;~~
- B. AT LEAST ONE MANUAL h accessible to employees involved in food preparation and equipment and utensil washing in accordance with section 5- ~~of these rules and regulations;~~ and
- C. A utility facility in accordance with section 5-210 ~~of these rules and regulations.~~

4-2 DESIGN AND CONSTRUCTION

4-201 Food Contact Surfaces

Multi-use food-contact surfaces shall be:

- A. Smooth;
- B. Free of breaks, open seams, cracks, chips, pits, and similar imperfections;
- C. Free of sharp internal angles, corners, and crevices;
- D. Finished to have smooth welds and joints; and
- E. Accessible for cleaning and inspection by one of the following methods:
 - 1. Without being disassembled,
 - 2. By disassembly without the use of tools, or
 - 3. By easy disassembly with the use of only simple tools, such as mallets, screw drivers, or wrenches, that are kept in a readily accessible location near the equipment.

1 **4-202 Use Limitations**

- 2 A. Cast iron may only be used as a cooking surface which can include use in the
 3 service of food when used in an uninterrupted process from cooking through
 4 service.
- 5 B. Ceramic, china, crystal utensils, and decorative utensils, such as hand-painted
 6 ceramic or china, that are used in contact with food shall be lead-free or contain
 7 levels of lead not exceeding the limits of the following utensil categories:
 8

UTENSIL CATEGORY	DESCRIPTION	MAXIMUM LEAD mg/L
Hot Beverage Mugs, CUPS, PITCHERS	Coffee Mugs	0.5
Large Hollowware (EXCLUDING PITCHERS)	Bowls ≥ 1.1 L (1.16 QT)	1
Small Hollowware (EXCLUDING CUPS AND MUGS)	Bowls < 1.1 L (1.16 QT)	2.0
Flat Utensils TABLEWARE	Plates, Saucers	3.0

- 9
- 10 *C. Copper and copper alloys, such as brass, may not be used in contact with food
 11 that has a pH below 6 (e.g. vinegar, fruit juice, wine, CARBONATED BEVERAGE
 12 etc.)~~or used for a fitting or tubing installed between a backflow prevention
 13 device and a carbonator.~~
- 14 Copper and copper alloys may be used in contact with beer brewing ingredients
 15 that have a pH below 6 in the prefermentation and fermentation steps of a beer
 16 brewing operation such as a brewpub or microbrewery.
- 17 *D. Enamelware SHALL NOT BE USED FOR STORAGE OR PREPARATION OF ACIDIC
 18 FOODS (E.G. VINEGAR, TOMATO BASED SAUCES, JUICES, ETC.)~~is prohibited for
 19 any food contact surface.~~
- 20 *E. Galvanized metal may not be used to fabricate food-contact surfaces of
 21 equipment that is used for beverages, moist food, or hygroscopic food.
- 22 F. LINENS AND NAPKINS MAY NOT BE USED IN CONTACT WITH FOOD UNLESS THEY
 23 ARE USED TO LINE A CONTAINER FOR THE SERVICE OF FOODS AND THE LINENS
 24 AND NAPKINS ARE REPLACED EACH TIME THE CONTAINER IS REFILLED FOR A
 25 NEW CONSUMER. ~~Clean linens and napkins may be used to line containers used
 26 for the service of foods, if the linens and napkins are replaced each time the
 27 container is refilled for a new consumer.~~
- 28 G. Clean cloth gloves may be used in direct contact with food that will be
 29 subsequently cooked as required AS SPECIFIED IN PART 3-5 OF THESE RULES AND
 30 REGULATIONS, such as frozen food or a primal cut of meat.
- 31 H. Pewter ALLOYS CONTAINING LEAD IN EXCESS OF 0.05% may not be used as a
 32 food-contact surface.

- 1 I. Solder and flux containing lead in excess of 0.2%, and cadmium, antimony,
2 bismuth, or other toxic chemicals may not be used on surfaces that contact food.
- 3 J. Except as specified in paragraphs 1, 2, and 3 of this section, wood and wicker
4 may not be used as a food-contact surface.
- 5 1. Hard maple or an equivalently hard, close-grained, nonabsorbent wood,
6 provided it is not cracked, pitted or uncleanable, may be used for:
- 7 a. Cutting boards, cutting blocks, bakers' tables, bagel boards, and
8 utensils such as rolling pins, doughnut dowels, salad bowls,
9 pizza paddles, and chopsticks; and
- 10 b. Wooden paddles used in confectionery operations for pressure
11 scraping kettles when manually preparing confections at a
12 temperature of 230°F (110°C) or above.
- 13 2. Whole, uncut, raw fruits and vegetables, and nuts in the shell may be
14 kept in the original wood or wicker containers until the fruits, vegetables,
15 or nuts are used.
- 16 3. If the nature of the food requires removal of rinds, peels, husks, or shells
17 before consumption, the whole, uncut, raw food may be kept in:
- 18 a. Untreated wood or wicker containers; or
- 19 b. Treated wood containers if the containers are treated with a
20 preservative that meets the requirements specified by the
21 Department in Preservatives for Wood, 21 CFR—§ SECTION
22 178.3800, ().
- 23 K. Cutting surfaces that are scratched and scored must be resurfaced so as to be
24 easily cleaned, or be discarded when these surfaces can no longer be effectively
25 cleaned and sanitized.
- 26 ~~L. Newspapers, cloth, paper, cardboard, towels, contact paper, foil, oil cloth, or~~
27 ~~similar materials shall not be used as liners for shelves, drawers, or drain boards.~~
- 28 . Wrapping of utensils or equipment handles with absorbent or difficult-to-clean
29 material, such as string, wire or tape shall not be allowed.
- 30 M. NEWSPAPER, CLOTH, PAPER, OIL CLOTH, CARDBOARD, TOWELS AND OTHER
31 NONFOOD GRADE SURFACES, SUCH AS GROCERY BAGS OR RETAIL STORE BAGS,
32 ARE NOT APPROVED FOOD CONTACT SURFACES. THIS DOES NOT PRECLUDE THE
33 USE OF GROCERY BAGS FOR RETAIL CUSTOMERS.

34 **4-203 Nonfood-Contact Surfaces**

- 35 Nonfood-contact surfaces shall be constructed of approved materials, in good repair, and
36 be easily maintained in a clean and sanitary condition.
- 37 A. In new or extensively remodeled retail food establishments, wood interior
38 construction in walk-in cooler and freezer units shall be prohibited.
- 39 B. Unfinished wood is not acceptable in food preparation, equipment or
40 warewashing, or food storage areas other than those areas used solely as dry food
41 storage areas.

- 1 C. Surfaces of equipment or other areas, which are exposed to splash, food debris or
2 which otherwise require frequent cleaning, shall be designed and fabricated to be
3 smooth, durable, washable, free of unnecessary ledges, projections, or crevices,
4 and readily accessible for cleaning.
- 5 D. Wicker and wicker-like materials, in good repair can be used for service and
6 display of prepackaged food. Service of bread or rolls in wicker or wicker-like
7 materials is permissible if lined with dry linens or napkins, which are replaced
8 each time the container is refilled for a new customer.
- 9 E. NEWSPAPERS, CLOTH, PAPER, CARDBOARD, TOWELS, CONTACT PAPER, FOIL, OIL
10 CLOTH, OR SIMILAR MATERIALS SHALL NOT BE USED AS LINERS FOR SHELVES,
11 DRAWERS, OR DRAIN BOARDS.

12 **4-204 Clean In Place (CIP) Equipment**

- 13 A. CIP equipment shall meet the characteristics of food-contact surfaces and shall
14 be designed and constructed so that:
- 15 *1. Cleaning and sanitizing solutions circulate throughout a fixed system and
16 contact all interior food-contact surfaces; and
- 17 2. The system is self-draining or capable of being completely drained of
18 cleaning and sanitizing solutions.
- 19 B. CIP equipment that is not designed to be disassembled for cleaning shall be
20 designed with inspection access points to ensure that all interior food-contact
21 surfaces throughout the fixed system are being effectively cleaned.

22 **4-205 “V” Threads, Use Limitation**

23 “V” type threads may not be used on food-contact surfaces, except for hot-oil cooking or
24 filtering equipment.

25 **4-206 Hot-Oil Filtering Equipment**

26 Hot-oil filtering equipment shall meet the characteristics specified under food-contact
27 surfaces AS SPECIFIED IN (section 4-201) or CIP equipment AS SPECIFIED IN (section 4-
28 204) and shall be readily accessible for filter replacement and cleaning of the filter.

29 **4-207 Bearings and Gear Boxes, Leakproof**

30 Equipment containing bearings and gears requiring lubricants not made of safe materials
31 shall be designed, constructed and maintained to ensure that the lubricant cannot leak,
32 drip, or be forced into food or onto food-contact surfaces. Equipment designed to
33 receive lubrication of bearings and gears on or within food-contact surfaces shall be
34 lubricated with materials meeting the requirements of Lubricants, 21 CFR §SECTION
35 178.3570, () (see Appendix).

36 **4-208 Beverage Tubing, Separation**

37 Beverage tubing and cold-plate beverage cooling devices shall not be installed in contact
38 with stored ice. This section does not apply to cold plates that are constructed integrally
39 with an ice storage bin.

1 **4-209 Ice Units, Separation of Drains**

2 Liquid waste drain lines may not pass through an ice machine or ice storage bin.

3 **4-210 Condenser Unit, Separation**

4 If a condenser unit is an integral component of equipment, the condenser unit shall be
5 separated from the food and food storage space by a dustproof barrier.

6 ***4-211 Molluscan Shellfish Tanks**

7 ~~Molluscan shellfish life support system display tanks may only be used to display~~
8 ~~shellfish not offered for human consumption.~~

9 A. EXCEPT AS SPECIFIED IN B OF THIS SECTION, MOLLUSCAN SHELLFISH LIFE
10 SUPPORT SYSTEM DISPLAY TANKS MAY NOT BE USED TO STORE OR DISPLAY
11 SHELLFISH THAT ARE OFFERED FOR HUMAN CONSUMPTION AND SHALL BE
12 CONSPICUOUSLY MARKED SO THAT IT IS OBVIOUS TO THE CONSUMER THAT THE
13 SHELLFISH ARE FOR DISPLAY ONLY.

14 B. MOLLUSCAN SHELLFISH LIFE-SUPPORT SYSTEM DISPLAY TANKS THAT ARE USED
15 TO STORE OR DISPLAY SHELLFISH THAT ARE OFFERED FOR HUMAN CONSUMPTION
16 SHALL BE OPERATED AND MAINTAINED IN ACCORDANCE WITH AN APPROVAL
17 GRANTED BY THE DEPARTMENT OR AN APPROVED HACCP PLAN THAT:

18 1. IS SUBMITTED BY THE LICENSEE AND APPROVED AS SPECIFIED IN
19 SECTION 11-403; AND

20 2. ENSURES THAT:

21 A. WATER USED WITH FISH OTHER THAN MOLLUSCAN SHELLFISH
22 DOES NOT FLOW INTO THE MOLLUSCAN TANK,

23 B. THE SAFETY AND QUALITY OF THE SHELLFISH AS THEY WERE
24 RECEIVED ARE NOT COMPROMISED BY THE USE OF THE TANK,

25 AND

26 C. THE IDENTITY OF THE SOURCE OF THE SHELL STOCK IS RETAINED
27 AS SPECIFIED IN SECTION 3-201(B).

28 **4-212 Ventilation and Ventilation Hood Systems**

29 All rooms shall have sufficient ventilation to keep them free of excessive heat, steam,
30 condensation, vapors, obnoxious odors, smoke, and fumes. Ventilation systems shall
31 comply with applicable building department and fire prevention bureau requirements,
32 and when vented to the outside shall not create an unsightly, harmful, or unlawful
33 discharge. ~~All v~~ Ventilation systems shall comply with the ~~Uniform Mechanical~~.
34 2006 INTERNATIONAL MECHANICAL CODE (IMC). When local building and/or fire
35 departments have adopted codes equivalent or more stringent than the above, those
36 codes shall apply.

37 A. Ventilation Hood Systems. Ventilation ~~hood~~ systems shall be sufficient in
38 number, capacity, and designed and constructed according to the ~~Uniform~~
39 ~~Mechanical~~, 2006 INTERNATIONAL MECHANICAL CODE ~~section 402.4, chapter~~
40 ~~4, and sections 507 and 508, chapter 5, SECTIONS 507 AND 508~~. Ventilation ~~hood~~
41 systems and devices shall be designed to prevent grease or condensation from
42 collecting on walls and ceilings, and from dripping into food or onto food-contact

1 surfaces. HOOD filters or other grease extracting equipment shall be easily
2 removable for cleaning and replacement when not designed for in place cleaning.
3 HOOD FILTERS SHALL REMAIN IN PLACE WHENEVER THE SYSTEM IS IN
4 OPERATION.

5 B. ~~Ventilation.~~ Equipment from which aerosols, obnoxious odors, noxious fumes,
6 or vapors may originate shall be effectively vented to the outside air or vented
7 through an approved ventilation system. ~~All grease producing equipment shall~~
8 ~~be vented through a properly designed ventilation hood and grease collection~~
9 ~~system. Condensate producing equipment may be vented to the outside in~~
10 ~~mobile units and food establishments through exhaust air ducts or by flow~~
11 ~~through ventilation provided no nuisance is created.~~

12 1. TYPE I HOODS SHALL BE INSTALLED WHERE COOKING APPLIANCES
13 PRODUCE GREASE OR SMOKE SUCH AS OCCURS WITH GRILLS, FRYERS,
14 BROILERS, RANGES AND WOKS.

15 2. TYPE II HOODS SHALL BE INSTALLED WHERE COOKING OR DISH
16 WASHING APPLIANCES PRODUCE HEAT, STEAM OR PRODUCTS OF
17 COMBUSTION BUT DO NOT PRODUCE GREASE OR SMOKE. THIS INCLUDES
18 STEAMERS, PASTA COOKERS AND HIGH TEMPERATURE SANITIZING DISH
19 WASHING MACHINES. THIS DOES NOT APPLY TO UNDER-COUNTER-TYPE
20 COMMERCIAL DISHWASHING MACHINES.

21 . Intake and exhaust ducts shall be maintained to prevent the entrance of
22 dust, dirt, and other contaminating materials.

23 . In new or extensively remodeled retail food establishments, ~~all rooms,~~
24 ~~including~~ restrooms, ~~from which obnoxious odors, vapors, or fumes~~
25 ~~originate~~ shall be mechanically vented to the outside ~~unless exempted~~
26 ~~under paragraph B of this section.~~

27 C. ~~Fire Prevention Equipment and Lighting Systems.~~ EXCEPT FOR MOBILE RETAIL
28 FOOD ESTABLISHMENTS, MAKE UP AIR MUST BE FILTERED AND MECHANICALLY
29 INTRODUCED INTO THE ESTABLISHMENT AT A VOLUME EQUAL TO OR GREATER
30 THAN WHAT IS EXHAUSTED.

31 D. Fire prevention, extinguishing equipment and lighting systems shall be installed
32 in a ventilation system or hood so as to not create a cleaning problem.

33 **4-3 LOCATION AND INSTALLATION**

34 **4-301 Equipment, and Storage Cabinets, Contamination Prevention.**

35 A. The storage of cleaned and sanitized equipment, utensils, laundered linens,
36 laundered clothing and single-service and single-use articles may not be located:

- 37 1. In locker areas;
- 38 2. In toilet rooms and their vestibules;
- 39 3. In dressing rooms;
- 40 4. In garbage, RECYCLING, OR COMPOSTING rooms;
- 41 5. In mechanical rooms;

- 1 6. Under water and sewer lines that are not shielded to intercept potential
- 2 drips;
- 3 7. Under leaking automatic fire sprinkler heads, or under lines on which
- 4 water has condensed;
- 5 8. IN A PRIVATE HOME;
- 6 . UNDER OPEN STAIRWELLS; OR
- 7 . Under other sources of contamination; ~~or~~
- 8 9. ~~— In recycling rooms.~~
- 9 B. A storage cabinet used for linens or completely packaged single-service or
- 10 single-use articles may be stored in a locker area.

11 **4-302 Fixed Equipment, Spacing or Sealing**

12 Equipment, including ice makers and ice storage equipment, shall not be located under

13 sewer lines that are not shielded to intercept potential drips or under leaking water lines,

14 including leaking automatic fire sprinkler heads, or under lines on which water has

15 condensed.

16 A. Table-Mounted Equipment

- 17 1. Table-mounted equipment shall be installed to facilitate the cleaning of
- 18 the equipment and the adjacent areas.
- 19 2. Equipment that is mounted on tables or counters, unless portable, shall
- 20 be sealed to the table or counter, or elevated on legs to provide at least a
- 21 4-inch (10 cm) clearance between the table or counter, except that if no
- 22 part of the table under the equipment is more than 18 inches (46 cm)
- 23 from cleaning access, the clearance space shall be three (3) inches (8 cm)
- 24 or more; or if no part of the table under the equipment is more than three
- 25 (3) inches (8 cm) from cleaning access, the clearance space shall be two
- 26 (2) inches (5 cm) or more.
- 27 3. Equipment is portable within the meaning of THIS section ~~4-302(A)(3) of~~
- 28 ~~this code~~ if:
 - 29 a. It is small and light enough to be moved easily by one person; or
 - 30 b. Is equipped with a mechanical means of safely tilting the unit for
 - 31 cleaning; and
 - 32 c. It is table-mounted, such as powered mixers, grinders, slicers,
 - 33 tenderizers, and similar equipment; and
 - 34 d. It has no utility connection, has a utility connection that
 - 35 disconnects quickly, or has a flexible utility connection line of
 - 36 sufficient length to permit the equipment to be moved for easy
 - 37 cleaning.

38 B. Floor-Mounted Equipment

- 39 1. Floor-mounted equipment, unless easily moveable, shall be:
 - 40 a. Sealed to the floor; or

- 1 b. Elevated on sanitary legs to provide at least a 6-inch (15 cm)
 2 clearance between the floor and equipment, except that
 3 equipment may be elevated to provide at least a 4-inch (10 cm)
 4 clearance between the floor and equipment if the floor under the
 5 equipment is no more than six (6) inches (15 cm) from cleaning
 6 access;
- 7 c. Display shelving units, display refrigeration units, and display
 8 freezer units are exempt from the provisions of Paragraph 1, a
 9 and b of this section if they are installed so that the floor beneath
 10 the units can be cleaned.
- 11 2. Equipment is easily moveable if:
- 12 a. It is mounted on commercially designed wheels or casters; and
- 13 b. It has no utility connection, or has a utility connection that
 14 disconnects quickly, or has a flexible utility line of sufficient
 15 length to permit the equipment to be moved for easy cleaning.
- 16 3. Grease-Use Equipment. Grease-use equipment, in which fats and oils
 17 are utilized as the heat transfer agent or which is used in preparation of
 18 foods that produce grease, shall be installed to facilitate cleaning around
 19 and beneath the equipment by means of:
- 20 a. Rollers or casters with a utility connection that disconnects
 21 quickly, or has a flexible utility line of sufficient design and
 22 length to permit the equipment to be moved for easy cleaning; or
- 23 b. Mounted on 6 inch (15.24 cm) sanitary legs; or
- 24 c. Cantilever mounted to the wall at least 6 inches (15.24 cm)
 25 above the floor.
- 26 C. Space Between Adjoining Units
- 27 1. The space between adjoining units, and between or above a unit and the
 28 adjacent wall or ceiling, shall be closed unless exposed to seepage, in
 29 which event it shall be sealed; or sufficient space shall be provided to
 30 facilitate easy cleaning between, behind, and beside or above all such
 31 equipment. (See Figure 1 and Figure 2)
- 32 2. Space required between or behind walls or equipment shall be based on
 33 the following distances: (See Figure 1 and Figure 2)
- 34 a. When distance “A” is 2 feet (0.61 M) or less, distance “B” must
 35 be at least 6 inches (15 cm).
- 36 b. When distance “A” is over 2 feet (0.61 M) but less than 6 feet
 37 (1.8 M), distance “B” must be at least 12 inches (30 cm).
- 38 c. When distance “A” is 6 feet (1.8 M) or more, then distance “B”
 39 must be at least 18 inches (46 cm).
- 40 3. When rollers or casters are installed on equipment, the space requirements
 41 between adjoining units may not apply.

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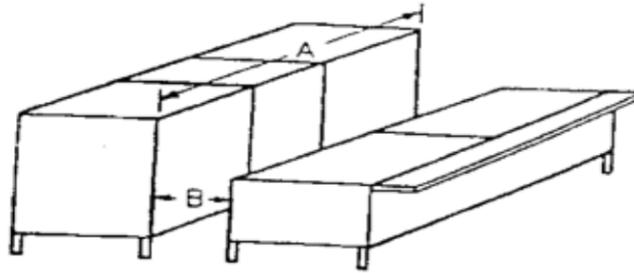


FIGURE 1

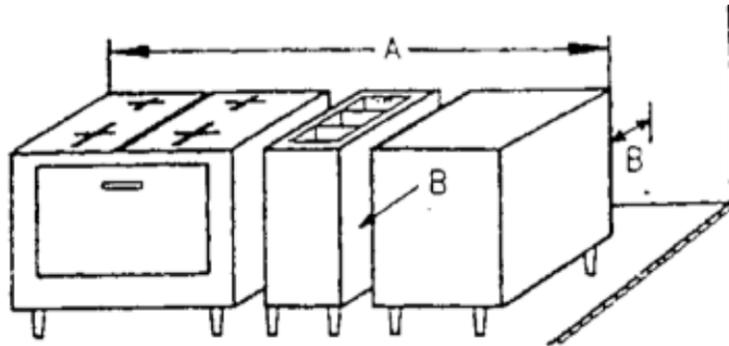


FIGURE 2

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- D. Aisles and Working Spaces. Aisles and working spaces between units of equipment and between equipment and walls shall be unobstructed and of sufficient width to permit employees to perform their duties readily without contamination of food or food-contact surfaces by clothing or personal contact. All easily moveable storage equipment such as dollies, skids, racks, and open-ended pallets shall be positioned to provide accessibility to working areas.
- E. Kick Plates, Removable. Kick plates shall be designed so that the areas behind them are accessible for inspection and cleaning by being:
 1. Removable by one of the methods specified in section 4-201(E)(1-3) of these rules and regulations or capable of being rotated open; and
 2. Removable or capable of being rotated open without unlocking equipment doors.

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**4-4 EQUIPMENT AND UTENSIL CLEANING AND SANITIZATION-
TESTING DEVICES -CLEANING FACILITIES**

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4-401 ~~Thermometers~~/TEMPERATURE MEASURING DEVICES

~~Indicating thermometers~~/TEMPERATURE MEASURING DEVICES shall be provided and used. ~~Thermometers with glass sensors and stems encased in a shatterproof coating may be used. A food product~~SURFACES OF FOOD TEMPERATURE MEASURING DEVICES THAT COME IN CONTACT WITH FOOD shall be cleaned and sanitized before use or storage.

- 1 A. ~~*Food product thermometers/~~ TEMPERATURE MEASURING DEVICES shall be
2 AVAILABLE, USED, capable of reading both hot and cold temperatures, and shall
3 have a numerical scale THAT INCLUDES THE RANGE OF (0°-220°F), printed
4 record, or digital readout in increments no greater than 2°F (1°C). ~~Food product~~
5 ~~thermometers/~~TEMPERATURE MEASURING DEVICES shall be used to determine
6 required food temperature(s) and shall be accurate to ±2°F (1°C).
- 7 B. A temperature measuring device WITH A SUITABLE SMALL DIAMETER PROBE that
8 is capable of measuring the temperature of thin masses shall be provided and
9 readily accessible to accurately measure the temperature in thin foods such as
10 meat patties and fish fillets, if this type of food is prepared.
- 11 C. Ambient air and warewashing ~~thermometers~~ TEMPERATURE MEASURING DEVICES
12 shall have a numerical scale, printed record, or digital readout in increments no
13 greater than 2°F or 1°C and shall be accurate to ±3°F (2°C).
- 14 D. Each mechanically refrigerated and each hot food storage unit storing ~~potentially~~
15 ~~hazardous food~~ POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL
16 FOR SAFETY FOOD) shall be provided with a numerically scaled indicating
17 ~~thermometer~~ TEMPERATURE MEASURING DEVICE. TEMPERATURE MEASURING
18 DEVICES ~~Thermometers~~ used to measure the air temperature of cold holding units
19 shall be conspicuously located in the upper one-third of the unit. ~~Thermometers~~
20 TEMPERATURE MEASURING DEVICES used to measure the air temperature of hot
21 food storage units shall be conspicuously located in the lower one-third of the
22 unit.
- 23 E. ~~Thermometers/~~TEMPERATURE MEASURING DEVICES shall be CHECKED AND
24 calibrated as necessary to ensure their accuracy.
- 25 F. Where it is impractical to install ~~thermometers~~ TEMPERATURE MEASURING
26 DEVICES on equipment, such as heat lamps, calrod units, or insulated food
27 transport carriers, a ~~food product~~ TEMPERATURE MEASURING DEVICE
28 ~~thermometer~~, as required in part A of this section, shall be available and used to
29 check internal food temperature.

30 **4-402 TESTING DEVICES**

- 31 A. AN APPROPRIATE TEST KIT OR OTHER DEVICE DESIGNED TO ACCURATELY
32 MEASURE THE CONCENTRATION IN PARTS PER MILLION (MG/L) OF THE
33 SANITIZING SOLUTION SHALL BE AVAILABLE AND USED.
- 34 B. WHERE CHEMICALS ARE USED TO WASH FRUITS AND VEGETABLES IN THE
35 ESTABLISHMENT, THE CHEMICALS SHALL BE PREPARED AND USED IN
36 ACCORDANCE WITH THE MANUFACTURE'S LABELED INSTRUCTIONS.
- 37 C. WHERE HEAT SANITIZATION IS USED IN MECHANICAL WAREWASHING MACHINES,
38 AN APPROPRIATE IRREVERSIBLE REGISTERING TEMPERATURE INDICATOR, SUCH
39 AS MAXIMUM READ TEMPERATURE, MEASURING DEVICE OR HEAT SENSITIVE
40 TAPE SHALL BE AVAILABLE AND USED TO VERIFY PROPER SANITIZATION AND IN
41 ADDITION TO THE MACHINE OR WATER LINE MOUNTED TEMPERATURE GAUGE.

42 ~~4-402 Sanitizing Solutions, Testing Devices~~

43 ~~A test kit or other device that accurately measures the concentration in parts per million~~
44 ~~(mg/L) of the sanitizing solution shall be available and used.~~

1 **4-403 ~~MANUAL Equipment and Utensil~~ Cleaning and Sanitization**

2 IN NEW OR EXTENSIVELY REMODELED RETAIL FOOD ESTABLISHMENTS, EQUIPMENT
3 AND UTENSIL WASHING FACILITIES IN ACCORDANCE WITH SECTION (A) OF THIS
4 SECTION SHALL BE PROVIDED FOR WASHING, RINSING, AND SANITIZING EQUIPMENT AND
5 UTENSILS.

6 . Except as specified in paragraph 3(C) of this section, a sink with at least three
7 compartments shall be provided for manually washing, rinsing, and sanitizing
8 equipment and utensils. Each compartment of the sink shall be supplied with hot
9 and cold DRINKING ~~potable~~-running water.

10 . Sink compartments shall be self-draining and large enough to accommodate
11 immersion of the largest equipment and utensils. If equipment or utensils are too
12 large for the sink compartments, a warewashing machine or alternative
13 equipment as specified in paragraph 3(C) of this section shall be used.

14 . Alternative manual warewashing equipment may be used when there are special
15 cleaning needs or constraints and the ~~regulatory authority~~ DEPARTMENT has
16 approved the use of the alternative equipment. Alternative manual warewashing
17 equipment may include:

- 18 a)1. High-pressure detergent sprayers;
- 19 b)2. Low- or line-pressure spray detergent foamers;
- 20 e)3. Other task-specific cleaning equipment;
- 21 d)4. Brushes or other implements;
- 22 e)5. Two-compartment sinks as specified ~~under~~-IN paragraph 4-D of this
23 section.

24 . A two-compartment sink may be used in an existing retail food establishment
25 only if:

- 26 a)1. The Department has approved its use; and
- 27 b)2. The nature of warewashing is limited to batch operations such as
28 between cutting one type of raw meat and another or cleanup at the end
29 of a shift, where the number of items cleaned is limited, and where the
30 cleaning and sanitizing solutions are made up immediately before use
31 and drained immediately after use. *If a detergent-sanitizer is used to
32 sanitize in a cleaning and sanitizing procedure where there is not a
33 distinct water rinse between the washing and sanitizing steps, then the
34 detergent-sanitizer shall be approved and used according to the
35 manufacturer's specifications.
- 36 e)3. A two-compartment sink may not be used for warewashing operations
37 such as where cleaning and sanitizing solutions are used for a continuous
38 or intermittent flow of kitchenware or tableware in an ongoing
39 warewashing process.

40 5.E In manual warewashing operations, a ~~thermometer~~-TEMPERATURE MEASURING
41 DEVICE shall be provided and readily accessible for frequently measuring the
42 washing and sanitizing temperatures. The temperature of the wash solution shall

1 be maintained at not less than 110°F (43°C) unless a different temperature is
 2 specified on the cleaning agent manufacturer's label instructions.

3 ~~6. Approved self draining drainboards, or utensil racks large enough to~~
 4 ~~accommodate all soiled and cleaned items that may accumulate during~~
 5 ~~hours of operation shall be provided for necessary utensil holding before~~
 6 ~~cleaning and after sanitizing. Alternate approved methods may be used~~
 7 ~~in lieu of the drainboard sizing specified according to the following:~~

	<u>Clean Drainboards</u>	<u>Soiled Drainboards</u>
8 Bar Sink	Eighteen Inches (18")	Eighteen Inches (18")
9 (46 cm)	(46 cm)	(46 cm)
10 Single Service	Twenty four Inches (24")	Twenty four Inches (24")
11 (61 cm)	(61 cm)	(61 cm)
12 Multi-use Service	Thirty six Inches (36")	Thirty six Inches (36")
13 (91 cm)	(91 cm)	(91 cm)

15 7-F. Equipment and utensils shall be pre-flushed or pre-scraped, and when necessary,
 16 pre-soaked to remove gross food particles and soil.

17 8-G. When a three-compartment sink is utilized for warewashing OR WHEN
 18 EQUIPMENT SUCH AS SLICERS, GRINDERS, KETTLES, AND MIXERS ARE CLEANED
 19 AND SANITIZED IN PLACE, the operation shall be conducted in the following
 20 sequence:

- 21 a)1. The sinks OR EQUIPMENT USED FOR WAREWASHING shall be cleaned and
 22 sanitized before use; and
- 23 b)2. Equipment and utensils shall be thoroughly cleaned in the first
 24 compartment with a hot (not less than 110°F [43°C]) detergent solution
 25 that is kept clean and at a concentration indicated on the manufacturer's
 26 label CLEAN DETERGENT SOLUTION THAT IS MIXED IN ACCORDANCE
 27 WITH THE MANUFACTURER'S LABEL and A TEMPERATURE OF AT LEAST
 28 ().
- 29 e)3. Equipment and utensils shall be rinsed free of detergent and abrasive
 30 with clean water in the second compartment; and
- 31 *d)4. Equipment and utensils shall be sanitized in the third compartment
 32 according to one of the methods included in section 4-404 (A)(10)(b-d)
 33 4-403(I)(1-4) of these rules and regulations.

34 *9 H. When pressure spray methods are utilized for cleaning and sanitizing, the
 35 equipment and utensils shall be thoroughly flushed with a detergent-sanitizer
 36 solution until the article is free of food particles and soil. The detergent-sanitizer
 37 shall be used in accordance with the manufacturer's instructions and shall be of
 38 the type that does not require a potable water rinse when used according to those
 39 instructions.

40 *10 I. The food-contact surfaces of all equipment and utensils shall be sanitized by:

- 41 a)1. Immersion for at least ½ minute in clean, hot water of a temperature of at
 42 least 170°F (77°C); or
- 43 b)2. Immersion for at least 1 minute in a clean solution containing a minimum
 44 of 50 parts per million (mg/L) and no more than 200 parts per million

- 1 (mg/L) of available chlorine as a hypochlorite and having a temperature
2 of at least 75°F (24°C); or
- 3 e)3. Immersion for at least 1 minute in a clean solution containing at least
4 12.5 parts per million (mg/L) of available iodine, having a pH range not
5 higher than 5.0, unless otherwise certified to be effective by the
6 manufacturer, and at a temperature of at least 75-68°F (°C); or
- 7 d)4. Immersion in a clean solution containing a quaternary ammonia product
8 AT A MINIMUM OF 75°F (24°C) or any other chemical sanitizing agent
9 allowed under Sanitizers, ~~21 CFR §178.1010, (2003)~~ 40 CFR 180.940
10 (2005).
- 11 e)5. Treatment with steam that is free from materials or additives other than
12 those specified in 21 CFR § SECTION 173.310, (2003) in the case of
13 equipment too large to sanitize by immersion, but in which steam can be
14 confined; or
- 15 f)6. Rinsing, spraying, or swabbing with a chemical sanitizing solution
16 containing at least the strength required for that particular sanitizing
17 solution ~~under IN section 4-4043(1A)(109)(b through d) 4-403(I)(2-4) of~~
18 ~~these rules and regulations~~ for equipment too large to sanitize by
19 immersion.
- 20 7. IF A CHEMICAL NOT SPECIFIED IN PARAGRAPHS (2)-(4) OF THIS SECTION
21 IS USED, THE LICENSEE SHALL DEMONSTRATE TO THE DEPARTMENT
22 THAT THE SOLUTION ACHIEVES SANITIZATION AND THE USE OF THE
23 SOLUTION SHALL BE APPROVED; OR
- 24 8. IF A CHEMICAL SANITIZER OTHER THAN CHLORINE, IODINE, OR A
25 QUATERNARY AMMONIUM COMPOUND IS USED, IT SHALL BE REGISTERED
26 WITH EPA AND APPLIED IN ACCORDANCE WITH THE EPA REGISTERED
27 LABEL USE INSTRUCTIONS.
- 28 *~~11~~ J. When hot water is used for sanitizing, the following equipment shall be provided
29 and used:
- 30 a)1. An integral heating device or fixture installed in, on, or under the
31 sanitizing compartment of the sink which is capable of maintaining the
32 water at a temperature of at least 170°F (77°C); and
- 33 b)2. A numerically-scaled indicating ~~thermometer~~/TEMPERATURE
34 MEASURING DEVICE, accurate to ±3°F (±2°C), located convenient to the
35 sink for frequent checks of water temperature; and
- 36 e)3. Utensil racks, baskets, or other appropriate means to permit complete
37 immersion of utensils and equipment in the hot water.
- 38 *~~12~~ K. Chemicals used for sanitization, shall not have concentrations higher than the
39 maximum permitted under Sanitizers, ~~21 CFR §178.1010, (2003)~~ 40 CFR
40 180.940 (2005).

41 **4.- Mechanical Cleaning and Sanitization**

- 42 *~~1~~.A. Cleaning and sanitizing may be done by spray-type, immersion warewashing, or
43 by any other type of machine or device if it is demonstrated that it thoroughly
44 cleans and sanitizes equipment and utensils. These machines and devices shall
45 be properly installed and maintained in good repair. Machines and devices shall

- 1 be operated in accordance with manufacturer's instructions. Utensils and
 2 equipment placed in the machine shall be exposed to all warewashing cycles.
 3 Automatic detergent dispensers, wetting agent dispensers, and liquid sanitizer
 4 injectors shall be properly installed and maintained.
- 5 . The pressure of final rinse water supplied to spray-type warewashing machines
 6 shall not be less than 15 pounds per square inch (1.05 kg per sq cm) nor more
 7 than 25 pounds per square inch (1.76 kg per sq cm) measured in the water line
 8 immediately upstream from the final rinse control valve. A 1/4 inch (6.4
 9 millimeters) Iron Pipe Size (IPS) valve shall be provided immediately upstream
 10 from the final control valve to permit checking the flow pressure of the final rinse
 11 water. In all new installations, a pressure gauge shall be provided for use with
 12 the IPS valve. This section does not apply to a machine that uses only a pumped
 13 sanitizing rinse.
- 14 3.C. Machine or water-line mounted numerically-scaled indicating ~~thermometers~~
 15 TEMPERATURE MONITORING DEVICE, accurate to $\pm 3^{\circ}\text{F}$ ($\pm 2^{\circ}\text{C}$), shall be provided
 16 to indicate the temperature of the water in each tank of the machine and the
 17 temperature of the final rinse water as it enters the manifold.
- 18 4.D. Rinse water tanks shall be protected by baffles, curtains, or other effective means
 19 to minimize the entry of wash water into the rinse water. Conveyors in
 20 warewashing machines shall be accurately timed to ensure proper exposure times
 21 in wash and rinse cycles in accordance with manufacturer's specifications
 22 attached to the machines.
- 23 5. ~~Self draining drainboards shall be provided and be large enough to accommodate~~
 24 ~~all soiled and cleaned items. Drainboards or alternate approved equipment shall~~
 25 ~~not be located and constructed in a manner that interferes with the proper use of~~
 26 ~~the warewashing facilities.~~
- 27 . Equipment and utensils shall be flushed or scraped and, when necessary, soaked
 28 to remove gross food particles and soil prior to being washed in a warewashing
 29 machine unless a pre-wash cycle is a part of the warewashing machine operation.
 30 Equipment and utensils shall be placed in racks, trays, or baskets, or on
 31 conveyors, in a way that exposes food-contact surfaces to the unobstructed
 32 application of detergent wash and clean rinse waters, and that permits free
 33 draining.
- 34 . Chemical sanitizing warewashing machines (single-tank, stationary-tank, door-
 35 type machines, and spray-type glass washers) may be used provided that:
- 36 A)1. The temperature of the wash water shall not be less than 120°F (49°C);
 37 b)2. The wash water shall be kept clean; and
 38 e)3. Chemicals added for WASHING AND sanitization purposes shall be
 39 automatically dispensed; and
 40 *d)4. Utensils and equipment shall be exposed to the final chemical sanitizing
 41 rinse in accordance with the manufacturer's specifications for time and
 42 concentration; and
 43 *e)5. The chemical sanitizing rinse water temperature shall not be less than
 44 75°F (24°C) nor less than the temperature specified by the machine's
 45 manufacturer; and

1 *~~f~~6. Chemical sanitizers shall meet the requirements specified ~~in 21 CFR~~
2 §~~178.1010, (2003)~~ 40 CFR 180.940 (2005) Sanitizing solutions AND
3 APPLIED IN ACCORDANCE WITH THE EPA REGISTERED LABEL USE
4 INSTRUCTIONS.

5 *. Hot water sanitizing warewashing machines may be used, provided that wash
6 water and pumped rinse water is kept clean and the wash solution temperature is
7 maintained at not less than the temperatures stated in this section, ~~4-403(B)(8)(a-~~
8 ~~e) 4-404(G)(1-5) of these rules and regulations.~~

9 Achieving a utensil and/or ~~equipment~~ or equipment surface temperature of
10 160°F (71°C) is an acceptable means of testing the sanitization process of a hot
11 water sanitizing warewashing machine.

12 a)1. Single-tank, stationary-rack, dual-temperature machines:

13 Wash temperature 150°F (66°C)

14 b)2. Single-tank, stationary-rack, single-temperature machine:

15 Wash temperature 165°F (74°C)

16 e)3 Single-tank, conveyor machine:

17 Wash temperature 160°F (72°C)

18 .) Multi-tank, conveyor machine:

19 Wash temperature 150°F (66°C)

20 Pumped rinse temperature 160°F (72°C)

21 e)5. Single-tank, pot, pan, and utensil washer (either stationary or moving
22 rack)

23 Wash temperature 140°F (60°C)

24 . Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures

25 In mechanical warewashing machines the temperature of the fresh hot water
26 sanitizing rinse as it enters the manifold may not be more than 194°F (90°C), or
27 less than:

28 a)1. For a stationary rack, single temperature machine, 165°F (74°C); or

29 b)2. For all other machines 180°F (82°C).

30 . All warewashing machines shall be thoroughly cleaned daily and as needed to
31 maintain them in a satisfactory operating condition.

32 . A warewashing machine shall be provided with an easily accessible and readable
33 data plate affixed to the machine which includes:

34 a)1. Temperatures required for washing, rinsing, and sanitizing;

35 b)2. Pressure required for the fresh water sanitizing rinse unless the machine
36 is designed to use only a pumped sanitizing rinse;

37 e)3. Conveyor speed required for conveyor machines or cycle time required
38 for stationary-rack machines; and

39 d)4. Required type and concentration of sanitizing solutions.

- 1 K. AFTER BEING CLEANED AND SANITIZED, EQUIPMENT AND UTENSILS SHALL NOT
 2 BE RINSED BEFORE AIR DRYING OR USE UNLESS:
- 3 1. THE RINSE IS APPLIED DIRECTLY FROM A DRINKING WATER SUPPLY BY A
 4 WAREWASHING MACHINE THAT IS MAINTAINED AND OPERATED AS
 5 SPECIFIED IN SECTIONS 4-404; AND
- 6 2. THE RINSE IS APPLIED ONLY AFTER THE EQUIPMENT AND UTENSILS HAVE
 7 BEEN SANITIZED BY THE APPLICATION OF HOT WATER OR BY THE
 8 APPLICATION OF A CHEMICAL SANITIZER SOLUTION WHOSE EPA
 9 REGISTERED LABEL USE INSTRUCTIONS CALL FOR RINSING OFF THE
 10 SANITIZER AFTER IT IS APPLIED IN A COMMERCIAL WAREWASHING
 11 MACHINE.

12 **4-405 DRAINBOARD AND DISHTABLE REQUIREMENTS**

- 13
- 14 A. DRAINBOARDS AND DISHTABLES SHALL BE SELF DRAINING AND SHALL HAVE A
 15 MINIMUM PITCH OF 1/8 INCH (3.2MM) PER FOOT (304.8MM). DRAINAGE SHALL
 16 BE DIRECTED TO WAREWASHING SINK BOWLS, PRE-RINSE SINKS, SCUPPERS OR
 17 WAREWASHING MACHINES.
- 18 B. DRAINBOARDS AND DISHTABLES SHALL BE SUPPORTED AS NEEDED TO PREVENT
 19 SAGGING AND SHALL HAVE EDGES TURNED UP AT LEAST ½ INCH (12.7MM).
- 20 C. WHEN PROVIDED ON WAREWASHING SINKS, DRAINBOARDS SHALL BE
 21 INTEGRALLY WELDED TO THE SINK BOWL(S).
- 22 D. DRAINBOARDS AND DISHTABLES SHALL BE LARGE ENOUGH TO ACCOMMODATE
 23 FOR THE STAGING OF SOILED EQUIPMENT, DISHES, GLASSES, MUGS,
 24 KITCHENWARE, TABLEWARE AND UTENSILS SO THEY MAY BE ADEQUATELY PRE-
 25 SCRAPED AND PRE-FLUSHED PRIOR TO WAREWASHING AND LARGE ENOUGH TO
 26 ACCOMMODATE THE AIR DRYING OF SANITIZED ITEMS THAT MAY ACCUMULATE
 27 DURING HOURS OF OPERATION. DRAINBOARD AND DISHTABLE’S LENGTH SHALL
 28 BE MEASURED FROM RIGHT TO LEFT.
- 29 1. DRAINBOARDS AND DISHTABLES INSTALLED ON THE ESTABLISHMENT’S
 30 PRIMARY MEANS FOR WAREWASHING SHALL BE SIZED IN ACCORDANCE
 31 WITH THE FOLLOWING:

FACILITY TYPE	SOILED DRAINBOARDS	CLEAN DRAINBOARDS
SINGLE SERVICE	TWENTY-FOUR (24) INCHES (64 CM)	TWENTY-FOUR (24) INCHES (64 CM)
MULTI-USE SERVICE WITH MANUAL WAREWASHING	THIRTY-SIX (36) INCHES (91 CM)	THIRTY-SIX (36) INCHES (91 CM)
MULTI-USE SERVICE WITH MECHANICAL WAREWASHING	FORTY-EIGHT (48) INCHES (122 CM)	FORTY-EIGHT (48) INCHES (122 CM)

- 44 2. BAR SINKS SHALL BE EQUIPPED WITH AN EIGHTEEN (18") INCH (46 CM)
 45 DRAINBOARD FOR STAGING SOILED TABLEWARE, UTENSILS, GLASSES

1 AND MUGS AND AN EIGHTEEN (18") INCH (46 CM) DRAINBOARD FOR AIR
2 DRYING SANITIZED ITEMS.

3 3. UNDER COUNTER WAREWASHING MACHINES SHALL BE PROVIDED WITH
4 DRAINBOARDS OR DISHTABLES THAT ARE LARGE ENOUGH TO
5 ACCOMMODATE STAGING OF SOILED EQUIPMENT, DISHES, GLASSES,
6 MUGS, KITCHENWARE, TABLEWARE AND UTENSILS AND LARGE ENOUGH
7 FOR AIR DRYING OF SANITIZED ITEMS. A COMMON DRAINBOARD,
8 DISHTABLE OR THE OPEN DOOR OF THE WAREWASHING MACHINE MAY BE
9 UTILIZED.

10 4. MULTI-TANK CONVEYOR WAREWASHING MACHINES EQUIPPED WITH
11 BOTH, A POWERED PRE-WASH UNIT AND A POWERED BLOWER-DRYER
12 UNIT SHALL BE EQUIPPED WITH DISHTABLES SIZED IN ACCORDANCE
13 WITH THE WAREWASHING MACHINE'S MANUFACTURE.

14 5. ALTERNATE EQUIPMENT OR METHODS, SUCH AS WALL MOUNTED
15 DRAINBOARDS, WIRE SHELVING OR BUS CARTS, MAY BE PROVIDED FOR
16 STAGING OF SOILED EQUIPMENT, DISHES, GLASSES, MUGS, AND UTENSILS
17 FOR PRE-SCRAPING AND PRE-FLUSHING PRIOR TO WAREWASHING AND TO
18 ACCOMMODATE AIR DRYING OF SANITIZED ITEMS MAY BE UTILIZED IF
19 APPROVED BY THE DEPARTMENT. ALTERNATE EQUIPMENT SHALL NOT
20 BE LOCATED OR CONSTRUCTED IN A MANNER THAT INTERFERES WITH
21 THE PROPER USE OF THE WAREWASHING FACILITIES.

22 E. EXCEPT FOR UNDER COUNTER WAREWASHING MACHINES, PRERINSE SPRAYERS
23 OR OTHER APPROVED MEANS SHALL BE PROVIDED AND USED FOR PRE-SCRAPING
24 AND PRE-FLUSHING OF SOILED EQUIPMENT, DISHES AND UTENSILS WHEN A
25 WAREWASHING MACHINE IS INSTALLED.

26 F. SCUPPERS WHEN INSTALLED SHALL TRANSVERSE THE ENTIRE FLAT SECTION OF
27 THE DRAINBOARD OR DISHTABLE TO PREVENT SOILED WATER AND DEBRIS FROM
28 DRAINING INTO THE WAREWASHING SINK BOWL OR WAREWASHING MACHINE.
29 SCUPPERS SHALL BE EQUIPPED WITH A READILY REMOVABLE STRAINERS OR
30 STRAINER BASKETS.

31 **4-406 E. Drying**

32 Unless used immediately after sanitization, all equipment and utensils shall be air-dried.
33 Towel drying shall not be permitted. Utensils that have been air-dried may be polished
34 with cloths which are maintained clean and dry.

35 ~~4-404 Food Establishments Without Cleaning Facilities~~

36 ~~Retail food establishments that do not have facilities for proper cleaning and sanitizing~~
37 ~~of utensils and equipment shall not prepare food, package food, or dispense unpackaged~~
38 ~~food other than whole, uncut raw fruits, raw vegetables, and whole nuts in the shell.~~

39 **4- Food-Contact Surfaces of Equipment and Utensils**

40 A. Equipment food-contact surfaces and utensils shall be clean to sight and touch.

41 *B. Utensils and food-contact surfaces of equipment shall be cleaned and sanitized:

42 1. ~~Except as specified in paragraph B of this section,~~ Before each use with a
43 different type of raw animal food, such as beef, fish, lamb, pork, or
44 poultry;

- 1 2. Each time there is a change from working with raw animal foods to
- 2 working with ready-to-eat foods;
- 3 3. Between uses with raw fruits or vegetables and with ~~potentially~~
- 4 ~~hazardous food~~ POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE
- 5 CONTROL FOR SAFETY FOOD);
- 6 4. At any time during the operation when contamination may have
- 7 occurred; and
- 8 5. After final use each working day.
- 9 *C. Where equipment and utensils are used for the preparation of ~~potentially~~
- 10 ~~hazardous food~~ POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL
- 11 FOR SAFETY FOOD on a continuous or production-line basis, utensils and the
- 12 food-contact surfaces of equipment shall be cleaned and sanitized at intervals not
- 13 to exceed four (4) hours.
- 14 *D. SURFACES OF UTENSILS AND EQUIPMENT CONTACTING POTENTIALLY
- 15 HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) MAY BE
- 16 CLEANED LESS FREQUENTLY THAN EVERY 4 HOURS IF:
- 17 1. UTENSILS AND EQUIPMENT SUCH AS SKILLETS, OMELET PANS AND WOKS
- 18 USED ON A PRODUCTION LINE BASIS IN CONTINUOUS USE FOR THE
- 19 HEATING/COOKING OF POTENTIALLY HAZARDOUS FOOD
- 20 (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) SHALL BE CLEANED
- 21 AND SANITIZED AFTER FINAL USE EACH WORKING DAY AND AT LEAST
- 22 EVERY 24 HOURS.
- 23 2. CONTAINERS IN SERVING SITUATIONS SUCH AS SALAD BARS, DELIS, AND
- 24 CAFETERIA LINES HOLDING READY TO EAT POTENTIALLY HAZARDOUS
- 25 FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) THAT IS
- 26 MAINTAINED AT THE TEMPERATURE SPECIFIED IN CHAPTER 3 AND ARE
- 27 INTERMITTENTLY COMBINED WITH THE ADDITIONAL SUPPLIES OF THE
- 28 SAME FOOD THAT IS AT THE REQUIRED TEMPERATURE, AND THE
- 29 CONTAINERS ARE CLEANED AND SANITIZED AT LEAST EVERY 24 HOURS.
- 30 3. UTENSILS AND EQUIPMENT USED TO PREPARE FOOD IN A REFRIGERATED
- 31 ROOM OR AREA THAT IS MAINTAINED AT ONE OF THE TEMPERATURES IN
- 32 FIGURE 3 SHALL BE CLEANED AND SANITIZED AT THE FREQUENCY THAT
- 33 CORRESPONDS TO THE AMBIENT TEMPERATURES:

<u>Temperature</u>	<u>Cleaning Frequency</u>
41°F (5.0°C) or less	24 hours
>41°F - 45°F (>5.0°C - 7.2°C)	20 hours
>45°F - 50°F (>7.2°C - 10.0°C)	16 hours
>50°F - 55°F (>10.0°C - 12.8°C)	10 hours

FIGURE 3

- 35
- 36 4. The food-contact surfaces of cooking AND BAKING UTENSILS AND
- 37 EQUIPMENT, SUCH AS GRILLS, WOKS, HOT SANDWICH PRESSES, WAFFLE
- 38 IRONS, AS WELL AS baking equipment and the cavities and door seals of

1 microwave ovens shall be cleaned at least every 24 hours AND SHALL BE
2 KEPT FREE OF ENCRUSTED GREASE DEPOSITS AND OTHER ACCUMULATED
3 SOIL. This shall not apply to hot-oil cooking equipment and hot-oil
4 filtering systems. ~~The food contact surfaces of all cooking equipment~~
5 ~~shall be kept free of encrusted grease deposits and other accumulated~~
6 ~~soil.~~

7 **4- Nonfood-Contact Surfaces**

8 Nonfood-contact surfaces of equipment, including transport vehicles, shall be cleaned as
9 often as necessary to keep the equipment free from the accumulation of dust, dirt, food
10 particles, and other debris.

11 **4- Dry Equipment Cleaning Methods**

12 Dry equipment cleaning methods, such as brushing, scraping, and vacuuming shall
13 contact only surfaces that are soiled with dry food residues that are not potentially
14 hazardous; this cleaning equipment shall not be used for any other purpose.

15 **4-5 LAUNDRY FACILITIES**

16 **4-501 Laundry Facilities**

17 A. If provided, laundry facilities shall be restricted to the washing and drying of
18 linens and work clothes used in the operation. If such items are laundered on the
19 premises, an electric or gas CLOTHES dryer shall be provided and used, except
20 that it is not necessary to provide ~~electric or gas clothes dryer~~ PROVIDED ~~given~~
21 that:

- 22 1. On-premise laundering is limited to wiping cloths intended to be used
23 moist, and
- 24 2. The laundered wiping cloths are stored in an approved sanitizing
25 solution; or
- 26 3. The laundered wiping cloths are air-dried in a laundry room or other
27 approved locations.

28 B. Laundry facilities shall not be located in food preparation areas. If located in
29 food storage areas, it shall be operated in a manner that prevents the
30 contamination of food, equipment, utensils, linens, single-service and single-use
31 articles and wiping cloths.

32 C. Soiled linens shall be kept in clean, nonabsorbent receptacles or clean, washable
33 laundry bags. Soiled linens shall be stored and transported to prevent
34 contamination of food, clean equipment, clean utensils, single-service and single-
35 use articles.

36 **4-6 EQUIPMENT AND UTENSIL HANDLING AND STORAGE**

37 **4-601 Equipment and Utensil Storage**

38 A. Cleaned and sanitized equipment and utensils shall be handled in a way that
39 protects them from contamination. Spoons, knives, and forks shall be touched
40 only by their handles. Cups, glasses, bowls, plates, and similar items shall be

1 handled without contact with inside surfaces or surfaces that contact the user's
2 mouth.

3 B. Cleaned and sanitized utensils and equipment shall be stored at least 6 inches
4 (15.24 cm) above the floor in a clean, dry location in a way that protects them
5 from contamination by splash, dust, and other means. The food-contact surfaces
6 of fixed equipment shall also be protected from contamination. Equipment and
7 utensils shall not be placed under sewer lines or water lines that are not protected
8 to intercept potential drips, including leaking automatic fire protection sprinkler
9 heads, or under lines on which water has condensed.

10 C. Utensils shall be air-dried, IN ACCORDANCE WITH SECTION 4-406, before being
11 stored or shall be stored in a self-draining position.

12 D. Glasses and cups shall be stored inverted. Other stored TABLEWARE ~~utensils~~
13 shall be covered or inverted, wherever practical. Facilities for the storage of
14 knives, forks and spoons shall be designed and used to present the handle to the
15 employee or consumer. Unless ~~tableware is~~ pre-wrapped, holders for knives,
16 forks and spoons at self-service locations shall protect these articles from
17 contamination and present the handle of the utensil to the consumer.

18 **4-602 Single-Service and Single-Use Articles**

19 A. Single-service articles shall be stored at least 6 inches (15.24 cm) above the floor
20 in closed cartons or containers which protect them from contamination. They
21 shall not be placed under exposed sewer lines or water lines, except for automatic
22 fire protection sprinkler heads that may be required by law.

23 B. Single-service articles shall be handled and dispensed in a manner that prevents
24 contamination of surfaces which may come in contact with food or with the
25 mouth of the user.

26 C. Single-service knives, forks, and spoons packaged in bulk shall be inserted into
27 holders or be wrapped PRIOR TO DISPENSING by employees who have washed
28 their hands immediately prior to sorting or wrapping the utensils. ~~Unless single-~~
29 ~~service knives, forks, and spoons are pre-wrapped or prepackaged,~~ shall be
30 provided to protect these items from contamination and present the handle of the
31 utensil to the consumer.

32 D. Single-service and single-use articles may not be reused.

33 E. Mollusk and crustacea shells may not be used more than once as serving
34 containers.

35 **4-603 Preset Tableware**

36 A. EXCEPT AS SPECIFIED IN PARAGRAPH (B) OF THIS SECTION, Tableware THAT IS
37 ~~may be~~ preset SHALL BE protected from contamination by being wrapped,
38 covered or inverted;

39 B. PRESET TABLEWARE MAY BE ~~It is~~ exposed IF Unused settings are removed when a
40 consumer is seated AND CLEANED AND SANITIZED BEFORE FURTHER USE.; ~~or~~

41 ~~2. It is exposed and unused settings are cleaned and sanitized before further use, if~~
42 ~~the settings are not removed when the customer is seated.~~

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CHAPTER 5

WATER, PLUMBING, AND WASTE

5-1 WATER SUPPLY

***5-101 General**

A. Adequate, uncontaminated, safe ~~potable~~ DRINKING water for the needs of the retail food establishment shall be provided from a source constructed, maintained, and operated according to the *Colorado Primary Drinking Water Regulations* and regulations adopted pursuant to Title 25-1.5-203 C.R.S., or

1. If the retail food establishment does not meet the definition of a public water system pursuant to ~~article 1.2.2(48)~~ of the *Colorado Primary Drinking Water Regulations*, PROMULGATED PURSUANT to 25-1.5-101, and 25-1.5-203, C.R.S., -the retail food establishment shall provide: ~~adequate treatment on a continuous basis and bacteriological samples at a minimum of once per quarter or at a frequency determined by the Department and;~~

- A. ADEQUATE TREATMENT ON A CONTINUOUS BASIS; AND
- B. BACTERIOLOGICAL SAMPLES AT A MINIMUM OF ONCE PER QUARTER OR AT A FREQUENCY DETERMINED BY THE DEPARTMENT; AND
- C. A DPD COLORIMETRIC DRINKING WATER TEST KIT CAPABLE OF TESTING FREE CHLORINE AT AN ACCURACY OF 0.1MG/LITER; AND
- D. FREE CHLORINE SHALL RANGE FROM A TRACE AMOUNT TO 4 MG/LITER (0.2 TO 1.2 MG/LITER RECOMMENDED) AT ANY FIXTURE; AND
- E. MOST RECENT REQUIRED WATER SAMPLE REPORTS SHALL BE RETAINED ON FILE AT THE RETAIL FOOD ESTABLISHMENT AND SHALL BE AVAILABLE FOR REVIEW BY THE DEPARTMENT WHEN REQUESTED; AND

2. Retail food establishments with water supplies determined to be surface water or DETERMINED TO BE under the DIRECT influence of surface water shall be required to filter their water to 1µm (micron) ABSOLUTE using National Sanitation Foundation approved equipment AND MAINTAIN A RESIDUAL DISINFECTANT CONCENTRATION to ensure inactivation and/or removal of giardia AND OTHER PARASYTIC CYSTS and viruses, ~~and maintaining a residual disinfectant concentration.~~

***5-102 System Flushing and Disinfection**

A drinking water system shall be flushed and disinfected before being placed in service after construction, repair, or modification and after an emergency situation, such as a flood, that may introduce contaminants to the system.

1 ***5-103 Bottled Drinking Water**

2 Bottled drinking water used or sold in a retail food establishment shall be obtained from
3 approved sources in accordance with Processing and Bottling of Bottled Drinking
4 Water, 21 CFR § SECTIONS 129 AND 165, ().

5 ***5-104 Transportation**

6 All ~~potable~~ DRINKING water not provided directly by pipe to the retail food
7 establishment from the source shall be transported in a bulk water transport system and
8 shall be delivered to a closed-water system. Both of these systems shall be constructed
9 and operated according to law AND OPERATED AS APPROVED BY THE DEPARTMENT.

10 ***5-105 EMERGENCY ALTERNATIVE WATER SUPPLY**

11 A. ESTABLISHMENTS INTENDING TO OPERATE WHEN THERE IS A TEMPORARY
12 INTERRUPTION OF WATER SERVICE OR AN UPSET IN THE SUPPLY OF TREATED
13 DRINKING WATER, WITH APPROVAL BY THE DEPARTMENT PRIOR TO
14 IMPLEMENTATION, THE ESTABLISHMENT MAY CONTINUE OPERATION IF THE
15 TEMPORARY WATER SUPPLY MEETS THE REQUIREMENTS OF SECTIONS 5-101,
16 5-102, 5-103, 5-104 AND 5-105 AND DRINKING WATER IS MADE AVAILABLE
17 THROUGH:

- 18 1. A SUPPLY OF COMMERCIALY BOTTLED DRINKING WATER;
- 19 2. ONE OR MORE CLOSED PORTABLE WATER CONTAINERS;
- 20 3. AN ENCLOSED VEHICULAR DRINKING WATER TANK;
- 21 4. AN ON-PREMISES DRINKING WATER STORAGE TANK; OR
- 22 5. PIPING, TUBING, OR HOSES CONNECTED TO AN ADJACENT APPROVED
23 SOURCE

24 ***5- Non-DRINKING ~~Potable~~ Water**

25 A non-DRINKING ~~potable~~ water system is permitted for air conditioning, NON-FOOD
26 equipment cooling, LANDSCAPE IRRIGATION and fire protection, and shall be installed
27 according to law. Non-DRINKING ~~potable~~ water shall not directly or indirectly contact
28 food or equipment or utensils that contact food. The piping of any non-DRINKING
29 ~~potable~~ water system shall be identified so that it is readily distinguishable from piping
30 that carries ~~potable~~ DRINKING water.

31 ***5- Pressure and Temperature**

- 32 A. Water under pressure of at least 15 pounds per square inch (psi) (1.05 kg per sq.
33 cm) at the required temperatures shall be provided to all fixtures and equipment
34 that use water.
- 35 B. HOT AND COLD WATER SHALL BE PROVIDED TO ALL SINKS.

36 ***5- Hot Water**

37 Hot water generation and distribution systems shall be sufficient to meet the peak hot
38 water demands throughout the retail food establishment. (see Appendix)

1 *5- **Steam**

2 Steam used in contact with food or food-contact surfaces shall be free from any unsafe
3 materials or additives not listed in Specific Usage Additives, 21 CFR § SECTION
4 173.310, (2003). (see Appendix).

5 **5-2 PLUMBING SYSTEM**

6 **5-201 General**

7 Plumbing shall be sized, installed, and maintained in accordance with applicable state
8 and local plumbing codes, ordinances, regulations, and standards. ~~There shall be no~~
9 ~~unprotected cross-connection between the potable water supply and any non-potable~~
10 ~~water supply, nor any sources of contamination.~~ Plumbing shall be designed and
11 constructed according to the ~~Uniform Plumbing Code~~ INTERNATIONAL PLUMBING
12 CODE. Where local building departments have adopted codes equivalent TO or more
13 stringent than the above, those codes shall apply. THE DEPARTMENT SHALL WORK IN
14 COLLABORATION WITH THE LOCAL BUILDING AND/OR FIRE DEPARTMENT WITH REGARD
15 TO ENFORCEMENT AND COMPLIANCE ACTIVITIES. PLUMBING FIXTURES SHALL BE
16 EASILY CLEANABLE AND KEPT CLEAN.

17 **5-202 Backflow**

18 A. — ~~General~~

19 ~~The potable water system shall be constructed to prevent backflow. Devices or~~
20 ~~assemblies shall be installed to prevent backflow at all fixtures or appliances.~~
21 ~~Inlets to tanks, vats, garbage disposals, troughs, fixtures and equipment with~~
22 ~~submerged inlets shall be protected by an approved vacuum breaker located on~~
23 ~~the discharge side of the last valve not less than 6 (six) inches (154.4 mm) above~~
24 ~~the overflow rim of such equipment, or with an approved air gap at the inlet.~~
25 ~~Where utilized, an air gap separation shall be a minimum vertical distance of~~
26 ~~twice the potable water outlet diameter between the outlet and the fixture's flood~~
27 ~~level rim, but shall not be less than 1 inch (25.4mm). No hose shall be attached to~~
28 ~~a potable water outlet that is not equipped with a suitable backflow prevention~~
29 ~~device. Backflow prevention devices or assemblies shall be installed for service~~
30 ~~and maintenance access. Any discharge from a backflow preventer shall be~~
31 ~~visible and discharged indirectly to the sanitary sewer.~~

32 B. ~~Backflow Prevention Device, Carbonator~~

33 ~~The potable water supply to carbonated beverage dispensers shall be protected~~
34 ~~from backflow by at least one of the following methods:~~

- 35 1. ~~An approved air gap; or~~
- 36 2. ~~A vented and screened dual check valve constructed of stainless steel or~~
37 ~~other material impervious to attack by carbonated water, specifically~~
38 ~~designed to control the backflow of carbonated water from a soda~~
39 ~~carbonator, and installed downstream of any copper or copper alloy pipe~~
40 ~~or fixture; or~~
- 41 3. ~~A reduced pressure zone backflow prevention assembly constructed of~~
42 ~~stainless steel or other material impervious to attack by carbonated water.~~

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*A. General

THE DRINKING WATER SYSTEM SHALL BE CONSTRUCTED TO PREVENT BACKFLOW. THERE SHALL BE NO UNPROTECTED CROSS-CONNECTIONS BETWEEN THE DRINKING WATER SUPPLY AND ANY NON-DRINKING WATER SUPPLY, OR ANY SOURCES OF CONTAMINATION. DEVICES OR ASSEMBLIES INSTALLED SHALL MEET THE APPROPRIATE APPLICATION FOR THE HAZARD OF THE CROSS CONNECTION TO PREVENT BACKFLOW OF A SOLID, LIQUID OR GAS CONTAMINANT INTO THE DRINKING WATER SUPPLY SYSTEM AT EACH POINT OF USE WITHIN THE RETAIL FOOD ESTABLISHMENT.

*B. BACKFLOW PREVENTION DEVICES AND INSTALLATION REQUIREMENTS

1. AN AIR GAP BETWEEN THE WATER SUPPLY INLET AND THE FLOOD LEVEL RIM OF THE PLUMBING FIXTURE, EQUIPMENT, OR NONFOOD EQUIPMENT SHALL BE AT LEAST TWICE THE DIAMETER OF THE WATER SUPPLY INLET AND MAY NOT BE LESS THAN ONE (1) INCH (25 MM).
2. AN ATMOSPHERIC VACUUM BREAKER SHALL BE LOCATED ON THE DISCHARGE SIDE OF THE LAST VALVE AND NOT LESS THAN SIX (6) INCHES (154.4 MM) ABOVE THE FLOOD RIM OF PLUMBING FIXTURE OR EQUIPMENT. A SHUTOFF VALVE DOWNSTREAM OF THE ATMOSPHERIC VACUUM BREAKER IS PROHIBITED.
3. BACKSIPHONAGE AND BACKFLOW PREVENTION DEVICES SHALL MEET AMERICAN SOCIETY OF SANITARY ENGINEERING (A.S.S.E.) STANDARDS FOR CONSTRUCTION, INSTALLATION, MAINTENANCE, INSPECTION AND TESTING FOR THAT SPECIFIC APPLICATION AND TYPE OF DEVICE.

C. APPLICATIONS

- *1. INLETS TO TANKS, VATS, GARBAGE DISPOSALS, TROUGHS, FIXTURES, WAREWASHING MACHINES AND OTHER EQUIPMENT WITH SUBMERGED INLETS SHALL BE PROTECTED BY AN APPROVED BACKFLOW PREVENTION DEVICE OR WITH AN APPROVED AIR GAP AT THE INLET.
- *2. CARBONATED BEVERAGE DISPENSERS
The DRINKING water supply CONNECTION to carbonated beverage dispensers shall be protected AGAINST backflow by at least one of the following:
 - a. An approved air gap, or
 - b. A DUAL CHECK VALVE CONSTRUCTED OF A MATERIAL NOT AFFECTED BY CARBON DIOXIDE WITH AN INTERMEDIATE VENT INSTALLED UPSTREAM OF THE CARBONATOR AND downstream of any copper and copper alloy piping or fixture, or
 - c. A reduced pressure zone backflow prevention assembly constructed of MATERIAL IMPERVIOUS TO ATTACK BY CARBON DIOXIDE, AND INSTALLED UPSTREAM OF THE CARBONATOR AND DOWNSTREAM OF ANY COPPER AND COPPER ALLOY PIPING OR FIXTURE.
3. NON-CARBONATED BEVERAGE DISPENSERS

1 THE DRINKING WATER SUPPLY CONNECTION TO NON-CARBONATED
2 BEVERAGE DISPENSERS SHALL BE PROTECTED AGAINST BACKFLOW BY
3 AT LEAST ONE OF THE FOLLOWING:

- 4 A. AN APPROVED AIR GAP, OR
- 5 B. A DUAL CHECK VALVE CONSTRUCTED OF A MATERIAL NOT
6 AFFECTED BY CARBON DIOXIDE WITH AN INTERMEDIATE VENT
7 INSTALLED DOWNSTREAM OF ANY COPPER AND COPPER ALLOY
8 PIPING OR FIXTURE,

9 *4. HOSE BIBS, SILLCOCKS, AND THREADED FAUCETS WHERE A HOSE CAN BE
10 ATTACHED SHALL BE EQUIPPED WITH A PROPER BACKFLOW PREVENTION
11 DEVICE IN ACCORDANCE WITH 5-202 B (2) AND (3). THIS PARAGRAPH
12 SHALL NOT APPLY TO WATER HEATER AND BOILER DRAIN VALVES THAT
13 ARE PROVIDED WITH HOSE CONNECTION THREADS AND THAT ARE
14 INTENDED ONLY FOR TANK OR VESSEL DRAINING, OR TO WATER SUPPLY
15 VALVES INTENDED FOR CONNECTION OF CLOTHES WASHING MACHINES
16 WHERE BACKFLOW PREVENTION IS OTHERWISE PROVIDED OR IS
17 INTEGRAL WITH THE MACHINE.

18 5. IN ALL NEW OR EXTENSIVELY REMODELED FACILITIES, A DEDICATED
19 HOT AND COLD WATER SUPPLY SHALL BE PROVIDED FOR CHEMICAL
20 DISPENSING TOWERS.

21 **5-203 Conditioning Device, Design**

22 A Water filterS, screenS, and other water conditioning devices installed on water lines
23 shall be MADE OF SAFE MATERIALS AND designed and located to facilitate disassembly
24 for periodic servicing and cleaning. A water filter element shall be of the replaceable
25 type.

26 **5-204 Grease Trap / Grease Interceptor**

27 If required by the local building, water or sanitation authority, when possible, a grease
28 trap, ~~or~~ grease interceptor, OR SOLIDS INTERCEPTOR should be located outside the
29 establishment. When installed inside the establishment, a grease trap, ~~or~~ grease
30 interceptor, OR SOLIDS INTERCEPTOR shall be located away from the food preparation
31 area and be easily accessible for cleaning.

32 **5-205 ~~Garbage~~ FOOD WASTE Grinders/GARBAGE DISPOSALS**

33 A. In new or extensively remodeled retail food establishments, FOOD WASTE
34 ~~garbage~~ grinders and/or GARBAGE DISPOSALS, if PROVIDED ~~used~~, shall be
35 installed ~~at~~ IN THE SOILED DRAINBOARD OF THE WAREWASHING SINK, FOOD
36 PREPARATION SINK, OR WAREWASHING MACHINE. ~~warewashing or food~~
37 ~~preparation sink, warewashing machine, or as an isolated unit.~~ The installation
38 will be approved under the following conditions: ~~Shall not be installed in the~~
39 ~~basin of a sink;~~

40 B-1. THE DISPOSAL be directly connected to the sanitary sewer UNLESS
41 OTHERWISE REQUIRED BY LAW; or

42 C-2. ~~If~~ WHEN installed in the drainboard of a food preparation sink, the
43 drainboard shall be equipped with an indirectly drained scupper/scrap
44 basket or similar device to prevent contamination of food-contact

1 surfaces. A second approved eighteen (18") (46 cm) self-draining drain
2 board or alternate approved shall be provided to prevent ~~cross-~~
3 contamination of food.

4 B. FOOD WASTE GRINDERS OR GARBAGE DISPOSALS MAY BE INSTALLED IN THE
5 BASIN OF THE SINK IF THE SINK IS USED SOLELY FOR THE DISPOSAL OF FOOD
6 WASTES.

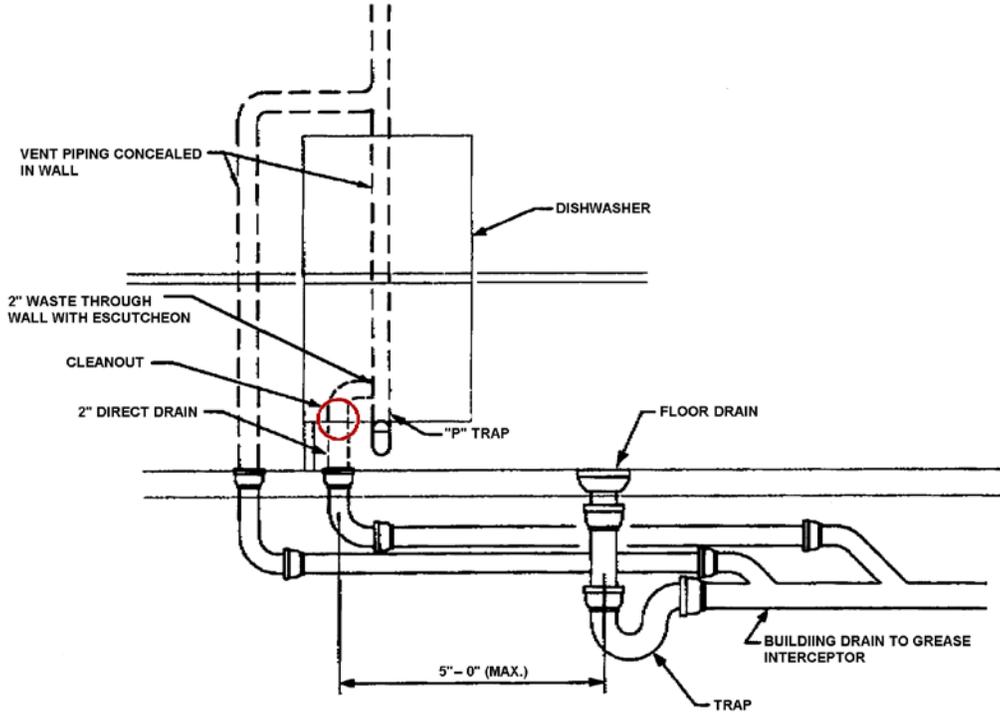
7 ***5-206 Drainage Of Equipment.**

8 A. Warewashing machines, refrigerators, walk-IN REFRIGERATORS, FREEZERS,
9 WALK-IN FREEZERS, warewashing sinks, food/vegetable preparation sinks, steam
10 kettles, potato peelers, ice bins, CONTAINERS OF ICE FOR USE IN FOOD AND
11 BEVERAGES, ~~and~~ ice machines, and similar types of equipment in which food,
12 portable equipment or utensils are placed shall be indirectly connected to the
13 waste line and shall drain into an approved receptor of such size, shape, and
14 capacity to prevent splashing or flooding. The receptor shall be readily accessible
15 for cleaning and inspection.

16 B. Warewashing sinks and dishmachines INSTALLED PRIOR TO THE EFFECTIVE DATE
17 OF THESE REGULATIONS may be directly connected to the plumbing waste
18 system provided there is a floor drain or floor sink installed within five (5) feet
19 (1.5 M) immediately downstream of the sink waste line, and the fixture shall be
20 connected on the sewer side of the floor drain or floor sink, and no other fixtures
21 are connected to the waste line. The fixture and floor drain shall be trapped and
22 vented as required by the ~~Uniform Plumbing~~ 2009 INTERNATIONAL PLUMBING
23 CODE or where local building departments have adopted codes equivalent or
24 more stringent than the above, those codes shall apply (see Figure).

25 C. In new or extensively remodeled food establishments, each walk-in refrigerator
26 used for iced products, hanging meats or which requires flushing shall either be
27 equipped with a floor drain installed only with indirect waste and discharged
28 through an air gap into an approved receptor or constructed so all parts of the
29 floor of such walk-in refrigerator shall be graded to drain to the outside of the
30 refrigerator through a waste pipe, doorway or other opening.

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FIGURE

4 **5-207 Drainage System Installation**

5 Drain lines from equipment shall not discharge LIQUID in a manner that permits the
 6 flooding of floors, or the flowing of water across working or walking areas, or into
 7 difficult-to-clean areas that create a nuisance.

8 **5-208 Handwashing Lavatory, Water Temperature, and Flow**

9 *A. \bar{z} The number of fixtures shall comply with the requirements of the plumbing
 10 code adopted by the respective local jurisdiction, or in the absence of such local
 11 requirements with the minimum plumbing fixtures listed in the Uniform
 12 Plumbing Code, table 4-1 INTERNATIONAL PLUMBING CODE.

13 *B. \bar{z} Handsinks shall be conveniently located to employees involved in food
 14 PREPARATION, FOOD DISPENSING, WAREWASHING and utensil handling.
 15 Handsinks shall be unobstructed and accessible to employees at all times and
 16 used only for handwashing. Sinks used for food preparation or for washing
 17 equipment shall not be used for handwashing. Handsinks used for toilet rooms
 18 shall be located in the toilet rooms.

19 *C. Facility SINK WATER TEMPERATURES. Each handsink shall be provided with
 20 hot (minimum of 90°F [35°C]) and cold water AT LEAST 100°F (38°C) tempered
 21 by means of a mixing valve or combination faucet. Any self-closing, slow-
 22 closing, or metering faucet used shall be designed to provide a flow of water for
 23 at least 15 seconds without the need to reactivate the faucet. ~~Steam mixing~~
 24 ~~valves are prohibited at handsinks.~~

1 *D. ~~*A supply of hand-cleansing soap or detergent shall be available at each~~
2 ~~handsink. *A supply of dispensed sanitary towels, disposable towels, or a hand-~~
3 ~~drying device providing heated air shall be conveniently located near each~~
4 ~~handsink. *Common towels are prohibited. If disposable towels are used, easily~~
5 ~~cleanable waste receptacles shall be conveniently located near the handsinks.~~

6 A SUPPLY OF HAND-CLEANSING SOAP OR DETERGENT SHALL BE AVAILABLE AT
7 EACH HANDSINK OR GROUP OF TWO (2) ADJACENT HANDWASHING SINKS. A
8 CONTINUOUS CLOTH TOWEL SYSTEM THAT SUPPLIES THE USER WITH A CLEAN
9 TOWEL, INDIVIDUAL DISPOSABLE TOWELS, OR A HAND-DRYING DEVICE
10 PROVIDING HEATED OR HIGH VELOCITY PRESSURIZED AIR SHALL BE
11 CONVENIENTLY LOCATED NEAR EACH HANDSINK OR GROUP OF ADJACENT
12 HANDWASHING SINKS.

13 *E. ~~Handsinks, soap dispensers, hand-drying devices and all related fixtures shall be~~
14 ~~kept clean and in good repair.~~

15 COMMON TOWELS ARE PROHIBITED FOR THE DRYING OF HANDS.

16 F. HAND TOWELS SHALL BE STORED TO PROTECT UNUSED TOWELS FROM
17 BECOMING CONTAMINATED.

18 G. IF DISPOSABLE TOWELS ARE USED, AN EASILY CLEANABLE WASTE RECEPTACLE
19 SHALL BE CONVENIENTLY LOCATED NEAR THE HANDSINK.

20 H. HANDSINKS, SOAP DISPENSERS, HAND-DRYING DEVICES AND ALL RELATED
21 FIXTURES SHALL BE KEPT CLEAN AND IN GOOD REPAIR.

22 *I. AUTOMATIC HANDWASHING FACILITIES:

23 1. IF THE MODEL, INSTALLATION, LOCATION, AND CONDITIONS OF USE ARE
24 APPROVED, AND THE UNIT IS CAPABLE OF REMOVING THE TYPES OF
25 SOILS ENCOUNTERED IN THE FOOD OPERATIONS INVOLVED, AUTOMATIC
26 HANDWASHING FACILITIES MAY BE SUBSTITUTED FOR HANDWASHING
27 SINKS IN A FOOD ESTABLISHMENT THAT HAS AT LEAST ONE ADDITIONAL
28 HANDWASHING SINK THAT IS EASILY ACCESSIBLE.

29 2. AN AUTOMATIC HANDWASHING FACILITY SHALL BE INSTALLED AND
30 USED IN ACCORDANCE WITH MANUFACTURER'S INSTRUCTIONS.

31 J. HANDWASHING SINK SPECIFICATIONS FOR NEW OR EXTENSIVELY REMODELED
32 ESTABLISHMENTS

33 1. THE HEIGHT OF THE SINK'S FLOOD RIM SHALL BE BETWEEN 30 INCHES
34 (76CM) AND 48 INCHES (122 CM) ABOVE THE FLOOR.

35 2. THE DIAMETER OF THE HANDWASHING SINK BASIN SHALL BE A MINIMUM
36 OF 10 INCHES (25 CM) IN ANY DIRECTION

37 3. WHEN INSTALLED IN A COUNTER TOP, HANDWASHING SINK FAUCETS
38 SHALL BE WITHIN 24 INCHES (61CM) OF THE FRONT EDGE OF THE
39 COUNTER TOP.

40 4. THE CLEARANCE BETWEEN THE FLOOD RIM OF HANDWASHING SINK AND
41 THE BASE OR UNDERSIDE OF ANY OVERHEAD CABINETS, SHELVES, OR
42 OTHER EQUIPMENT SHALL BE A MINIMUM OF 24 INCHES (61CM).

43 5. HANDWASHING SINK FAUCETS SHALL BE INSTALLED ON THE SIDE OF THE
44 SINK BASIN DIRECTLY OPPOSITE THE USER.

1 **5-209 Toilets and Urinals**

2 *A. Toilet facilities shall be installed according to law, shall be the number required
3 by law, shall be conveniently located, and shall be accessible to employees and
4 patrons.

5 B. Separate toilet facilities shall be required for each sex in establishments with
6 seating capacity in excess of ~~15-20~~ patrons or more than ~~15-20~~ employees. In all
7 new or extensively remodeled retail food establishments, these facilities shall be
8 installed to comply with the requirements of the Plumbing Code adopted by the
9 respective local jurisdictions, or in the absence of such local requirements, with
10 the minimum numbers of plumbing fixtures listed in ~~the 2000 Uniform~~
11 ~~Plumbing Code, table 4-1.~~ 2009 INTERNATIONAL PLUMBING CODE.

12 C. Separate toilet facilities are not required for each sex in places of 15 or fewer
13 seating capacity for patrons, or ~~15-20~~ or fewer employees where there is no
14 seating capacity, provided the toilet is a single occupancy facility and the door
15 can be secured from the inside.

16 ~~If a separate men's toilet room is installed and it is a single occupancy toilet~~
17 ~~room, unless otherwise required by the local jurisdiction, a urinal is not required~~
18 ~~if the total seating capacity does not exceed 100.~~

19 D. Retail food establishments with no space on the premises for consumption of
20 food by patrons are required to provide toilet facilities only for employees.
21 Patron facilities shall be available where parking is provided primarily for
22 consumption of food on the premise. In all new or extensively remodeled retail
23 food establishments where parking is provided primarily for consumption of food
24 on the premise, the number of necessary fixtures shall comply with the minimum
25 plumbing fixtures required by the Plumbing Code OR BUILDING CODE adopted
26 by the respective local jurisdiction, or in the absence of such local requirements,
27 with the numbers listed in the ~~2000 Uniform Plumbing Code, table 4-1.~~ 2009
28 INTERNATIONAL PLUMBING CODE, TABLE 403.1.

29 E. Employees and patrons may use the same toilet facility provided that patrons
30 have access to them without entering the food preparation, food storage, or
31 warewashing or utensil storage areas of the establishment.

32 F. Public toilets in multiple activity areas such as shopping centers, sports centers,
33 etc., may suffice for the use of retail food establishment patrons and employees,
34 if fixtures are provided in adequate numbers conveniently located to the retail
35 food establishment and available at all times the retail food establishment is in
36 operation.

37 G. EXCEPT WHERE A TOILET ROOM IS LOCATED OUTSIDE A FOOD ESTABLISHMENT
38 AND DOES NOT OPEN DIRECTLY INTO THE FOOD ESTABLISHMENT SUCH AS A
39 TOILET ROOM THAT IS PROVIDED BY THE MANAGEMENT OF A SHOPPING MALL, A
40 TOILET ROOM LOCATED ON THE PREMISES SHALL BE COMPLETELY ENCLOSED
41 AND PROVIDED WITH A TIGHT-FITTING AND SELF-CLOSING DOOR.

42 . Toilet facilities, including toilet fixtures and any related vestibules, shall be kept
43 clean and in good repair. A supply of toilet tissue in a permanently mounted
44 dispenser shall be provided at each toilet at all times. ~~Easily cleanable~~
45 ~~receptacles shall be provided for waste materials.~~

1 ~~Receptacles shall be emptied at least once a day, and more frequently when~~
2 ~~necessary to prevent excessive accumulation of waste material.~~

3 I. EASILY CLEANABLE TRASH RECEPTACLES SHALL BE PROVIDED. A TOILET ROOM
4 USED BY FEMALES SHALL BE PROVIDED WITH A COVERED TRASH RECEPTACLE
5 FOR SANITARY PRODUCTS. TRASH RECEPTACLES SHALL BE EMPTIED AT LEAST
6 ONCE A DAY, AND MORE FREQUENTLY WHEN NECESSARY TO PREVENT
7 EXCESSIVE ACCUMULATION OF REFUSE.

8 **5-210 Utility Facility**

9 A. In new or extensively remodeled retail food establishments, at least one
10 conveniently located utility sink or curbed cleaning facility with a floor drain and
11 hot and cold water shall be provided and used for the cleaning of mops or similar
12 wet floor cleaning tools and for the disposal of mop water or similar liquid
13 wastes.

14 B. Suitable cleaning equipment and supplies, such as high pressure pumps, hot
15 water, steam, and detergent, shall be provided as necessary for effective cleaning
16 of equipment and receptacles for refuse, recyclables, and returnables. If
17 approved by the ~~regulatory authority~~ DEPARTMENT, off-premise cleaning
18 services may be used.

19 *C. A utility sink cannot be used for food preparation or warewashing. ~~A utility sink~~
20 ~~cannot be used for handwashing in new or extensively remodeled retail food~~
21 ~~establishments.~~

22 D. DUMP SINKS

23 IN NEW OR EXTENSIVELY REMODELED ESTABLISHMENTS, BARS, JUICE BARS,
24 COFFEE BARS, DRINK STATIONS, WAIT STATIONS OR OTHER AREAS WHERE
25 SOILED DRINKING GLASSES AND MUGS ARE EMPTIED AND STAGED FOR
26 WAREWASHING, A DUMP SINK SHALL BE PROVIDED AND USED FOR THE SANITARY
27 DISPOSAL OF LIQUID DRINK WASTE, ICE AND/OR COLLECTION OF DEBRIS EMPTIED
28 FROM GLASSES AND MUGS.

29 1. DUMP SINKS SHALL BE FITTED WITH A REMOVABLE STRAINER BASKET,
30 AND SHALL BE PLUMBED WITH HOT AND COLD RUNNING WATER.

31
32 2. BLENDER STATION SINKS AND FOOD PREPARATION SINKS SHALL NOT BE
33 UTILIZED AS DUMP SINKS.

34
35 3. OTHER METHODS MAY BE USED IF APPROVED BY THE DEPARTMENT.

36 ***5-211 Sewage**

37 All sewage shall be disposed of by a sewage disposal system constructed, maintained
38 and operated according to law.

39 ***5-212 Water Reservoir of Fogging Devices, Cleaning**

40 A. A reservoir used to supply water to a device, such as a produce fogger shall be:

41 1. Installed and maintained in accordance with manufacturer's
42 specifications; and

- 1 2. Cleaned in accordance with manufacturer's specifications or according to
2 the procedures specified in paragraph B of this section, whichever is
3 more stringent.
- 4 B. Cleaning procedures shall include at least the following steps and shall be
5 conducted at least once a week:
- 6 1. Draining and complete disassembly of the water and aerosol contact
7 parts;
- 8 2. Brush-cleaning the reservoir, aerosol tubing, and discharge nozzles with
9 a suitable detergent solution;
- 10 3. Flushing the complete system with water to remove the detergent
11 solution and particulate accumulation; and
- 12 4. Rinsing by immersing, spraying, or swabbing the reservoir, aerosol
13 tubing, and discharge nozzles with at least 50 ppm (mg/L) hypochlorite
14 solution.

15 **5-3 REFUSE, RECYCLABLES, AND RETURNABLES**

16 **5-301 Containers**

- 17 A. Garbage, ~~and~~ refuse, COMPOST, AND RECYCLABLES shall be held in durable,
18 easily cleanable containers that do not leak and do not absorb liquids. Plastic
19 bags and/or wet strength paper bags shall be used to line these containers. Such
20 bags and durable plastic garbage and refuse containers shall be used for storage
21 inside the food establishment.
- 22 B. Containers stored in food preparation and utensil washing areas shall be emptied
23 when full.
- 24 C. Containers stored outside the food establishment, including dumpsters,
25 compactors, and compactor systems, shall be easily cleanable, shall be insect and
26 rodent-proof, shall be provided with tight-fitting lids, doors, or covers, and shall
27 be kept covered when not in actual use. DRAINS IN RECEPTACLES AND WASTE
28 HANDLING UNITS FOR REFUSE, RECYCLABLES AND RETURNABLES SHALL HAVE
29 DRAIN PLUGS IN PLACE. ~~Containers designed with drains, drain plugs shall be in
30 place at all times, except during cleaning.~~
- 31 D. There shall be a sufficient number of containers to hold all the garbage, ~~and~~
32 refuse, COMPOST AND RECYCLABLES that .
- 33 E. Soiled containers, including dumpsters, compactors, and compactor systems,
34 shall be cleaned at a frequency to prevent insect and rodent attraction. Each
35 container shall be thoroughly cleaned on the inside and outside in a way that does
36 not contaminate food, equipment, utensils, or food preparation areas. Suitable
37 facilities, detergent, and hot water or steam, shall be provided and used for
38 cleaning containers. Liquid waste from compacting or cleaning operations shall
39 be disposed of as sewage.

40 **5-302 Storage**

- 41 A. Garbage, ~~and~~ refuse, COMPOST AND RECYCLABLES, on the premises, shall be
42 stored in a manner to be inaccessible to insects and rodents. Cardboard or other

1 packaging material not containing garbage or food wastes need not be stored in
2 covered containers provided such materials do not create a nuisance.

3 B. INDOOR garbage or refuse storage rooms, COMPOST and recycling areas if
4 provided, shall be constructed of easily cleanable, nonabsorbent, washable
5 materials, shall be kept clean, and shall be insect and rodent resistant. These
6 areas shall be large enough to store all garbage and refuse containers.

7 C. Outside storage areas or enclosures, if provided, shall be kept clean and shall be
8 large enough to store all the garbage and refuse containers. Garbage, ~~and~~ refuse,
9 COMPOST, RECYCLING containers, dumpsters, and compactor systems located
10 outside, shall be stored on a smooth surface of nonabsorbent material, such as
11 concrete or machine-laid asphalt, that is kept clean and maintained in good
12 repair.

13 **5-303 Disposal**

14 A. Garbage, refuse, COMPOST and recyclable materials shall be removed often
15 enough to prevent the development of objectionable odors and the attraction of
16 insects and rodents.

17 B. Where garbage or refuse is burned on the premises, it shall be done by controlled
18 incineration in accordance with the law. Areas around incineration units shall be
19 kept clean and orderly.

20 **5-304 Storage Areas, Redeeming Machines, Equipment, and Receptacles, Location**

21 A. An area designated for refuse, recyclables, COMPOST, returnables and, a
22 redeeming machine for recyclables or returnables, except as specified in
23 paragraph B of this section, shall be located separate from food, equipment,
24 utensils, linens, and single-service and single-use articles, and a public health
25 nuisance is not created.

26 B. A redeeming machine may be located in the packaged food storage area or
27 consumer area of a retail food establishment if food, equipment, utensils, linens,
28 and single-service and single-use articles are not subject to contamination from
29 the machines and a public health nuisance is not created.

30 C. The location of equipment and receptacles for refuse, recyclables, COMPOST and
31 returnables may not create a public health nuisance or interfere with the cleaning
32 of adjacent space.

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CHAPTER 6

PHYSICAL FACILITIES

6-1 FLOORS

6-101 Floor Construction

- A. Floors and floor coverings in all food preparation, food storage, warewashing areas, walk-in refrigeration units, dressing rooms, locker rooms, utility sink areas, toilet rooms, garbage rooms, and around permanently installed buffets, salad bars and soft drink dispensers shall be constructed of smooth, durable, nonabsorbent AND EASILY CLEANABLE material and shall be maintained in good repair. Areas subject to spilling or dripping of grease or fatty substances shall be of grease-resistant material. Nothing in this section shall prohibit the use of anti-slip floor coverings in areas where necessary for safety reasons.
- B. Floors which are water flushed or which receive discharges of water or other fluid wastes or are in areas where pressure spray methods for cleaning are used, shall be provided with properly installed trapped drains and graded to drain. In all new establishments, floor drains and floor sinks shall be installed to be accessible for cleaning.

6-102 Floor Carpeting

Carpeting, if used as a floor covering, shall be of closely-woven construction, properly installed, easily cleanable, and maintained in good repair. Carpeting shall not be used in food preparation, warewashing, food storage, utility sink areas, or in toilet room areas where urinals or fixtures are located. Carpeting is permitted in the retail sales area provided it is maintained in good repair and kept clean.

6-103 Utility Line Installation

Exposed utility service lines and pipes shall be installed in a way that does not obstruct or prevent cleaning of the floor. In all new or extensively remodeled food establishments, installation of exposed horizontal utility service lines and pipes on the floor is prohibited.

6-104 Floor Junctures

All floors installed in food preparation, food storage and warewashing areas, and in walk-in refrigerators, dressing or locker rooms, utility sink areas, and toilet rooms, shall provide a coved juncture between the floor and wall. In all cases, the juncture between the floor and wall shall be closed and sealed.

6-105 Prohibited Floor Covering

Cardboard, newspapers, sawdust, wood shavings, granular salt, baked clay, diatomaceous earth, or similar materials shall not be used as floor coverings; however, these materials may be used in amounts necessary for immediate spot clean-up of spills or drippage on floors.

1 **6-106 Mats and Duckboards**

2 Mats and duckboards shall be designed to be removable, easily cleanable, and BE
3 maintained CLEAN AND in good repair.

4 **6-2 WALLS AND CEILINGS**

5 **6-201 Construction**

6 A. Walls, wall coverings, and ceilings shall be designed, constructed and installed to
7 be smooth, DURABLE and easily cleanable.

8 B. Except for in dry storage units, walls, including non-supporting partitions, wall
9 coverings and ceilings of walk-in refrigerating units, food preparation areas, food
10 storage areas, equipment-washing and warewashing areas shall be smooth,
11 nonabsorbent, easily cleanable, and maintained in good repair. Concrete or
12 pumice blocks used for interior wall construction in these locations shall be
13 finished and sealed to provide an easily cleanable surface. Acoustical material,
14 free of porous perforations, smooth and durable enough to be washed with a cloth
15 or sponge, may be used. Walls, including non-supporting partitions and wall
16 coverings in toilet rooms shall be smooth, nonabsorbent, and easily cleanable.
17 Porous acoustical ceilings are permitted in toilet rooms and their vestibules.

18 **6-202 Attachments, Exposed Construction**

19 A. Except as specified in paragraph C of this section, attachments to walls and
20 ceilings such as light fixtures, mechanical room ventilation system components,
21 vent covers, wall-mounted fans, decorative items, and other attachments shall be
22 easily cleanable.

23 B. Studs, joists, and rafters shall not be exposed in those areas listed in section 6-
24 201(B) of these rules and regulations. If exposed in other rooms or areas, they
25 shall be kept clean.

26 C. In consumer and backbar areas ~~where limited food preparation occurs~~ LIMITED
27 TO BEVERAGE SERVICE AND THE HEATING OF PRE-PREPARED FOODS FOR
28 IMMEDIATE SERVICE, wall and ceiling surfaces and decorative items and
29 attachments that are provided for ambiance need not meet this requirement if
30 they are kept clean.

31 D. Exposed utility service lines and pipes shall not obstruct or prevent cleaning of
32 walls and ceilings. Utility service lines or pipes shall not be unnecessarily
33 exposed on walls or ceilings in those areas listed in section 6-201(B) of these
34 rules and regulations.

35 **6-3 LIGHTING**

36 **6-301 Light Intensity**

37 A. Permanently fixed artificial light sources shall be installed to provide at least 50
38 foot candles (330–540 lux) of light on all food preparation surfaces and at
39 warewashing work levels.

40 B. Permanently fixed artificial light sources shall be installed to provide, at a
41 distance of 30 inches (76.2 cm) from the floor:

- 1 1. At least 20 foot candles (lux) of light in sales areas, AT CONSUMER
2 SERVICE AREAS SUCH AS BUFFETS AND SALAD BARS, utensil and
3 equipment storage areas, and in lavatory and toilet areas; and
4 2. At least 10 foot candles (lux) of light throughout walk-in refrigeration
5 AND FREEZER units, dry food storage areas, and in all other areas.

6 **6-302 Light Bulbs, Protective Shielding**

- 7 A. Except as specified in paragraph B of this section, light bulbs shall be shielded,
8 coated, or otherwise shatter-resistant in areas where there is exposed food, clean
9 equipment, utensils, linens, or unwrapped single-service and single-use articles.
10 B. Shielded, coated or otherwise shatter-resistant bulbs are not required in areas
11 used only for storing food in unopened packages if:
12 1. The integrity of the packages cannot be affected by broken glass falling
13 onto them; and
14 2. The packages are capable of being cleaned of debris from broken bulbs
15 before the packages are opened.
16 C. An infrared or other heat lamp shall be protected against breakage by a shield
17 surrounding and extending beyond the bulb so that only the face of the bulb is
18 exposed.

19 **6-4 OPERATION AND MAINTENANCE**

20 **6-401 Cleaning Physical Facilities**

- 21 A. Cleaning of floors, walls, and ceilings shall be done as needed, preferably during
22 periods when the least amount of food is exposed, such as after closing.
23 B. Only dustless methods for cleaning floors, walls, and ceilings shall be used, such
24 as vacuum cleaning, wet cleaning, treated dust mops, or the use of dust-arresting
25 sweeping compounds with brooms.
26 C. Floors, mats, duckboards, walls, ceilings, and attachments (e.g., light fixtures,
27 vent covers, wall and ceiling mounted fans, and similar equipment), and
28 decorative materials (e.g., signs and advertising materials), shall be kept clean.
29 ~~Mop water shall be changed frequently.~~
30 D. MOP WATER SHALL BE CHANGED AS NEEDED TO PREVENT THE
31 RECONTAMINATION OF CLEANED SURFACES.

32 **6-402 Cleaning Equipment Storage.**

33 Maintenance and cleaning tools, such as brooms, mops, vacuum cleaners, and similar
34 equipment, shall be maintained in good repair and stored in a way that does not
35 contaminate food, utensils, equipment, or linens. Maintenance and cleaning tools shall
36 be stored in an orderly manner to facilitate the cleaning of the storage area. AFTER USE,
37 MOPS SHALL BE PLACED IN A POSITION THAT ALLOWS THEM TO AIR-DRY WITHOUT
38 SOILING WALLS, EQUIPMENT, OR SUPPLIES.

39

1 **6-5 PREMISES**

2 **6-501 General**

3 A. Retail food establishments and all parts of the property used in connection with
4 operations of the retail food establishment shall be kept free of litter and shall
5 comply with local ordinances.

6 B. The outdoor walking and driving areas shall be surfaced with concrete, asphalt,
7 gravel or other materials that have been effectively treated to minimize dust,
8 facilitate maintenance, and minimize muddy conditions. These surfaces shall be
9 graded to drain and kept free of litter. Exterior surfaces of buildings shall be of
10 weather-resistant materials and shall comply with law.

11 C. Only articles necessary to the operation and maintenance of the retail food
12 establishment shall be stored on the premises.

13 **6-502 Living Areas**

14 No retail food establishment operation shall be conducted in any area used as living or
15 sleeping quarters. A retail food establishment operation shall be separated from any
16 living or sleeping quarters by complete partitioning and solid, self-closing doors, and
17 shall comply with local requirements.

18 **6-503 DRESSING ROOMS AND LOCKER AREAS**

19 A. DRESSING ROOMS OR DRESSING AREAS SHALL BE DESIGNATED IF EMPLOYEES
20 ROUTINELY CHANGE THEIR CLOTHES IN THE ESTABLISHMENT.

21 B. LOCKERS OR OTHER SUITABLE FACILITIES SHALL BE PROVIDED FOR THE
22 ORDERLY STORAGE OF EMPLOYEES' CLOTHING AND OTHER POSSESSIONS.

23 C. ANY FOOD BELONGING TO EMPLOYEES NOT STORED IN A DESIGNATED LOCKER
24 OR OTHER SUITABLE FACILITY SHALL BE STORED IN A PACKAGE OR CONTAINER
25 AND KEPT INSIDE A COVERED, LEAKPROOF CONTAINER DESIGNATED FOR THE
26 STORAGE OF EMPLOYEE FOOD AND MAINTAINED BY THE FACILITY.

27

1 **CHAPTER 7**

2 **POISONOUS OR TOXIC MATERIALS**

3 **7-1 LABELING AND IDENTIFICATION**

4 ***7-101 Identifying Information, Prominence**

5 Containers of poisonous or toxic materials and personal care items shall bear a legible
6 manufacturer's label.

7 ***7-102 ~~Name~~ WORKING CONTAINERS**

8 Working containers used for storing poisonous or toxic material, such as cleaners and
9 sanitizers taken from bulk supplies, shall be clearly and individually identified with at
10 least the name of the material.

11 ***7-103 Separation**

12 Poisonous or toxic materials shall be stored so they do not contaminate food, equipment,
13 utensils, linens, or single-service and single-use articles by:

- 14 A. Separating the poisonous or toxic materials by spacing or partitioning; and
- 15 B. Locating the poisonous or toxic materials in an area that is not above food,
16 equipment, utensils, linens, and single-service or single-use articles. Except that
17 equipment and utensil cleaners and sanitizers may be stored in warewashing
18 areas for availability and convenience if such materials are stored to prevent
19 contamination of food, equipment, utensils, linens, or single-service and single-
20 use articles.
- 21 C. Poisonous or toxic materials stored or displayed for retail sale shall be separated
22 from food and single-service articles by spacing, partitioning, or dividers. These
23 materials shall not be stored or displayed above food or single-service articles.

24 ***7-104 Restriction**

- 25 A. Only those poisonous or toxic materials required for the operation and
26 maintenance of a retail food establishment, such as for the cleaning and
27 sanitizing of equipment and utensils and the control of insects and rodents, shall
28 be allowed in a retail food establishment.
- 29 B. Paragraph A of this section does not apply to packaged poisonous or toxic
30 materials that are for retail sale.

31 ***7-105 Use of Materials**

- 32 A. Sanitizers, DISINFECTANTS, cleaning compounds, or other compounds intended
33 for use on food-contact surfaces shall not be used in a way that leaves a toxic
34 residue on such surfaces IN ACCORDANCE WITH 40 CFR 180.940 (2005).
- 35 B. Poisonous or toxic materials shall not be used in a way that contaminates food,
36 FOOD CONTACT SURFACES, equipment, ~~or~~ utensils, OR SINGLE SERVICE
37 ARTICLES, nor in a way other than in full compliance with the manufacturer's
38 labeling.

1 ***7-106 Food Containers**

2 A container previously used to store poisonous or toxic materials shall not be used as a
3 food contact surface. A container previously used to store food shall not be used as a
4 container to store toxic materials.

5 ***7-107 Chemicals for Washing Fruits and Vegetables, Criteria**

6 Chemicals used to wash whole fruits and vegetables shall meet the requirements of
7 Chemicals Used In Washing Or To Assist In The Lye Peeling Of Fruits And Vegetables,
8 21 CFR § section 173.315, ().

9 ***7-108 Boiler Water Additives, Criteria**

10 Chemicals used as boiler water additives shall meet the requirements specified in Boiler
11 Water Additives, 21 CFR § section 173.310, (2003) (see Appendix).

12 ***7-109 Drying Agents, Criteria**

13 Drying agents used in conjunction with sanitization shall be approved by the
14 Department.

15 ***7-110 Personal Medications AND COSMETICS**

16 Only those medications necessary for the health of employees shall be present in the
17 retail food establishment. Medications and cosmetics shall be stored in properly labeled
18 containers and located so that food and food-contact surfaces of equipment, utensils,
19 linens, single-service and single-use articles cannot be contaminated. Medications
20 requiring refrigeration and stored in a food refrigerator shall be properly identified,
21 double packaged and located on the lowest shelf. This paragraph does not apply to
22 medications that are stored or displayed for retail sale.

23 ***7-111 First Aid Supplies**

24 First aid supplies shall be properly labeled and stored in a way that prevents them from
25 contaminating food and food-contact surfaces, equipment, utensils, linens, single-service
26 and single-use articles.

27

1 **CHAPTER 8**

2 **INSECT, RODENT AND ANIMAL CONTROL**

3 **8-1 PREVENTION**

4 **8-101 Outer Openings, Protected**

- 5 A. Openings to the outdoors shall be protected against the entry of insects and
6 rodents by:
- 7 1. Closed, tight-fitting windows; and
 - 8 2. Solid self-closing, tight-fitting doors; or
- 9 B. If windows or doors are kept open, the openings shall be protected against the
10 entry of insects and rodents by:
- 11 1. 16 mesh to 1 inch (16 mesh to 25.4 mm) screens,
 - 12 2. Properly designed and installed air curtains to control flying insects, or
 - 13 3. Other effective means.
- 14 C. Paragraph B of this section does not apply in customer areas if flying insects and
15 other pests are absent due to the location of the retail food establishment, the
16 weather, or other limiting conditions.
- 17 D. Doors used only for delivery or emergency exit are not required to be equipped
18 with self-closing devices, but shall remain closed at all other times.
- 19 E. All foundations shall be rodent-proof. Openings between the floor and bottom of
20 outer doors, when closed, shall be no greater than one-fourth inch (1/4") (0.635
21 cm).

22 **8-102 Controlling Pests**

23 THE PRESENCE OF , rodents, and other pests shall be controlled ~~as specified in~~
24 ~~Paragraph B of this section~~ to minimize their presence ON THE PREMISES BY:

- 25 A. ~~Within the physical facility and its contents~~ ROUTINELY INSPECTING INCOMING
26 SHIPMENTS OF FOOD AND SUPPLIES; ~~and~~
- 27 B. ~~On the contiguous land or property under the control of the retail food establishment~~
28 ~~generator~~ ROUTINELY INSPECTING THE PREMISES FOR EVIDENCE OF PESTS;
- 29 *C. USING METHODS, IF PESTS ARE FOUND, SUCH AS TRAPPING DEVICES OR OTHER
30 MEANS OF PEST CONTROL AS SPECIFIED IN SECTIONS 8-103 AND 8-104;
- 31 D. ELIMINATING HARBORAGE CONDITIONS; AND
- 32 *E. Eliminating infestations
- 33 B. ~~The presence of insects, rodents, and other pests shall be controlled by:~~
- 34 1. ~~Routinely inspecting the premises for evidence of pests;~~
 - 35 2. ~~Using methods, if pests are found, such as trapping devices or~~
36 ~~extermination.~~

1 3. ~~Eliminating harborage conditions.~~

2 **8-103 Insect Control Devices, Design and Installation**

3 A. Devices used to electrocute flying insects and that may impel insects or insect
4 fragments shall be:

5 1. Designed to have escape-resistant trays; and

6 2. Installed so that:

7 a. The devices are not located over a food preparation area; and

8 b. Dead insects and insect fragments are prevented from falling on
9 or being impelled onto exposed food, clean equipment, utensils,
10 linens, and unwrapped single-service and single-use articles.

11 B. Devices used to trap insects by adherence may not be installed above exposed
12 food, clean equipment, utensils, linens, or unwrapped single-service and single-
13 use articles unless the device is designed to completely contain the trapped
14 insects.

15 ***8-104 Pesticide Application**

16 A. Only pesticides registered for application in a food establishment are permitted
17 and shall be applied according to label directions.

18 B. A pesticide shall be applied so that direct or indirect contact with food,
19 equipment, utensils, linens, and single-service and single-use articles is prevented
20 by protecting those items as follows:

21 1. Removing the items;

22 2. Covering the items with impermeable covers; or

23 3. Taking other appropriate preventive actions; and

24 4. Cleaning and sanitizing equipment and utensils after the application of a
25 pesticide.

26 C. Bait shall be contained in a covered tamper-proof bait station.

27 D. ~~ONLY NONTOXIC- SUCH AS TALCUM OR FLOUR may not be used in a retail food~~
28 ~~establishment~~ PROVIDED IT DOES NOT CONTAMINATE FOOD, EQUIPMENT,
29 UTENSILS, LINENS, SINGLE-SERVICE OR SINGLE-USE ARTICLES.

30 ***8-105 Removing Birds, Insects, Rodents, and Other Pests**

31 Birds, insects, rodents, and other pests shall be removed from control devices and the
32 premises at a frequency that prevents their accumulation, decomposition, or the
33 attraction of pests.

34 **8-106 Prohibiting of Animals**

35 A. ~~*Live animals shall be excluded from within the food establishment. This~~
36 ~~exclusion does not apply to edible fish, crustacea, shellfish or fish in aquariums.~~
37 ~~Live or dead fish bait shall be stored separately from food or food products.~~

38 ~~*Patrol dogs accompanying security or police officers shall be permitted in~~
39 ~~offices, storage areas and outside storage areas and outside establishment~~

1 premises. ~~*Sentry dogs may be permitted to run loose in outside fenced areas for~~
2 ~~security reasons. Guide and service animals accompanying blind, visually~~
3 ~~handicapped, partially deaf or otherwise disabled persons or animals training for~~
4 ~~this purpose shall be permitted in customer and office areas.~~

5 ~~*B. While on duty, persons employed in the food operational areas of a retail food~~
6 ~~establishment shall not care for or handle any pets, or patrol/sentry dogs.~~

7 *A. EXCEPT AS SPECIFIED IN (B) AND (C) OF THIS SECTION, LIVE ANIMALS MAY NOT
8 BE ALLOWED ON THE PREMISES OF A FOOD ESTABLISHMENT.

9 B. PROVIDED THAT THE CONTAMINATION OF FOOD; CLEAN EQUIPMENT, UTENSILS,
10 AND LINENS; AND UNWRAPPED SINGLE-SERVICE AND SINGLE-USE ARTICLES IS
11 CONTROLLED, LIVE ANIMALS ARE ALLOWED IN THE FOLLOWING SITUATIONS:

12 1. EDIBLE FISH OR DECORATIVE FISH IN AQUARIUMS, SHELLFISH OR
13 CRUSTACEA ON ICE OR UNDER REFRIGERATION, AND SHELLFISH AND
14 CRUSTACEA IN DISPLAY TANK SYSTEMS;

15 2. PATROL DOGS ACCOMPANYING POLICE OR SECURITY OFFICERS IN
16 OFFICES AND DINING, SALES, AND STORAGE AREAS, AND SENTRY DOGS
17 RUNNING LOOSE IN OUTSIDE FENCED AREAS;

18 3. IN AREAS THAT ARE NOT USED FOR FOOD PREPARATION AND THAT ARE
19 USUALLY OPEN FOR CUSTOMERS, SUCH AS DINING AND SALES AREAS,
20 SERVICE ANIMALS THAT ARE CONTROLLED BY THE DISABLED EMPLOYEE
21 OR PERSON. THIS DOES NOT APPLY TO INCIDENTAL FOOD CONTACT
22 SURFACES INCLUDING DINING TABLES, GROCERY CARTS AND BASKETS;

23 4. PETS IN THE COMMON DINING AREAS OF INSTITUTIONAL CARE
24 FACILITIES SUCH AS NURSING HOMES, ASSISTED LIVING FACILITIES,
25 GROUP HOMES, OR RESIDENTIAL CARE FACILITIES AT TIMES OTHER THAN
26 DURING MEALS IF:

27 A. EFFECTIVE PARTITIONING AND SELF-CLOSING DOORS SEPARATE
28 THE COMMON DINING AREAS FROM FOOD STORAGE OR FOOD
29 PREPARATION AREAS;

30 B. CONDIMENTS, EQUIPMENT, AND UTENSILS ARE STORED IN
31 ENCLOSED CABINETS OR REMOVED FROM THE COMMON DINING
32 AREAS WHEN PETS ARE PRESENT; AND

33 C. DINING AREAS INCLUDING TABLES, COUNTERTOPS, AND SIMILAR
34 SURFACES ARE EFFECTIVELY CLEANED BEFORE THE NEXT MEAL
35 SERVICE; AND

36 5. IN AREAS THAT ARE NOT USED FOR FOOD PREPARATION, STORAGE,
37 SALES, DISPLAY, OR DINING, IN WHICH THERE ARE CAGED ANIMALS OR
38 ANIMALS THAT ARE SIMILARLY CONFINED, SUCH AS IN A VARIETY STORE
39 THAT SELLS PETS OR A TOURIST PARK THAT DISPLAYS ANIMALS.

40 C. LIVE FISH BAIT SHALL BE STORED TO PREVENT CONTAMINATION OF FOOD;
41 CLEAN EQUIPMENT, UTENSILS, AND LINENS; AND UNWRAPPED SINGLE-SERVICE
42 AND SINGLE-USE ARTICLES.

43

CHAPTER 9

MOBILE RETAIL FOOD ESTABLISHMENTS AND OR PUSHCARTS

9-1 MOBILE RETAIL FOOD ESTABLISHMENT AND PUSHCARTS

9-101 General

A. Mobile retail food establishments ~~or~~ AND pushcarts shall comply with the requirements of these rules and regulations except as otherwise provided in this chapter. The Department may impose additional requirements to protect against health hazards related to the conduct ~~the~~ mobile retail food establishment OR PUSHCART and may prohibit the sale of any ~~potentially hazardous foods~~ POTENTIALLY HAZARDOUS FOODS (TIME/TEMPERATURE CONTROL FOR SAFETY FOODS). THIS MAY INCLUDE MAINTAINING RECEIPTS, LOGS, OR ANY OTHER RECORDS. If restrictions are imposed by the Department, they shall be in writing with a copy provided on the mobile unit at all times. A list of menu items prepared and/or served by the operator shall be submitted to the Department~~-,~~ AND AVAILABLE AT ALL TIMES. THE ORIGINAL RETAIL FOOD ESTABLISHMENT LICENSE SHALL BE POSTED ON THE UNIT AT ALL TIMES AS PER SECTION 11-101.

When no apparent health hazard will result, the Department may waive or modify requirements of ~~this chapter~~ THESE RULES AND REGULATIONS relating to physical facilities, except those requirements of sections 9-104, AND 9-105, ~~and 9-107 of these rules and regulations. Section 9-107(A) may be waived or modified when operating in accordance to chapter 10 of these rules and regulations.~~

B. MOBILE RETAIL FOOD ESTABLISHMENTS SHALL HAVE EQUIPMENT INSTALLED AND/OR MOUNTED, ACCORDING TO SECTION 4-302, WITHIN THE MOBILE RETAIL FOOD ESTABLISHMENT WITH THE EXCEPTION OF A GRILL AND/OR A SMOKER, APPROVED BY THE DEPARTMENT, WHICH SHALL BE ALLOWED OUTSIDE OF THE MOBILE RETAIL FOOD ESTABLISHMENT FOR COOKING OF FOOD ONLY. *ALL FOODS SHALL BE PREPARED, ASSEMBLED AND SERVED FROM WITHIN THE MOBILE RETAIL FOOD ESTABLISHMENT AND NOT FROM THE EXTERNAL PIECE OF COOKING EQUIPMENT.

*C. PUSHCARTS SHALL BE LIMITED TO COOKING APPROVED MENU ITEMS AND SERVING COMMERCIALY PREPARED OR COMMISSARY PREPARED FOOD THAT WILL RESULT IN SIMPLE ASSEMBLY. ALL ITEMS RELATED TO THE OPERATION OF THE PUSHCART SHALL BE KEPT ON THE UNIT, EXCEPT FOR THOSE ITEMS SPECIFIED IN SECTION 9-108(A).

9-102 Exemptions

Mobile retail food establishments ~~or~~ AND pushcarts are exempt from requirements for self-contained water or sewage systems, and cleaning and sanitization OF equipment under the following conditions:

A. THE MENU IS LIMITED TO COMMERCIALY PACKAGED ~~potentially hazardous food~~ POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOODS OR FOOD THAT is prepared, then packaged in individual servings,

1 transported and stored and served without further handling under conditions
2 meeting the requirements of these rules and regulations; and

3 B. Beverages served are ~~not potentially hazardous and are~~ dispensed from covered
4 urns or other protected equipment; and

5 C. The required equipment for cleaning and sanitization exists at the commissary.

6 **9-103 Single-service Articles**

7 Mobile retail food establishments ~~or~~ AND pushcarts shall provide only single-service
8 articles for use by the consumer.

9 ***9-104 Water System**

10 A. A mobile retail food establishment or a pushcart that does not meet the
11 exemptions of section 9-102 of these rules and regulations shall provide hot and
12 cold ~~potable~~ DRINKING water under pressure with sufficient capacity for food
13 preparation, utensil cleaning and sanitizing, in accordance with the requirements
14 of these rules and regulations.

15 B The water supply tank shall be designed so that it can be flushed and with a drain
16 that permits complete drainage of the tank. The ~~potable~~ DRINKING water tank
17 shall have no common interior partition with the tank holding non-potable water
18 or other liquids. The water tank overflow or vent shall terminate in a downward
19 direction and shall be located and constructed so as to prevent the entrance of
20 contaminants.

21 *C. WHEN A MOBILE RETAIL FOOD ESTABLISHMENT OR PUSH CART IS EQUIPPED WITH
22 A THREE-COMPARTMENT WAREWASHING SINK, THE WATER SUPPLY SHALL BE
23 SIZED TO ADEQUATELY FILL WAREWASHING SINKS AT LEAST ONCE EVERY FOUR
24 (4) HOURS OF OPERATION. IN ADDITION, THE MOBILE RETAIL FOOD
25 ESTABLISHMENT OR PUSH CART MUST SUPPLY THREE (3) GALLONS OF WATER TO
26 EACH HAND WASHING SINK FOR EACH HOUR OF OPERATION. WHERE OTHER
27 WATER USING FIXTURES SUCH AS TOILETS, UTILITY SINKS, FOOD PREPARATION
28 SINKS, COFFEE, ESPRESSO AND SOFT DRINK MACHINES ARE PROVIDED, THE
29 WATER SUPPLY SHALL BE SIZED IN ACCORDANCE WITH THE MANUFACTURERS
30 SPECIFICATION FOR EACH FIXTURE.

31 *D. THE WATER SUPPLY TANK FOR PUSH CARTS SHALL HAVE A MINIMUM CAPACITY
32 OF AT LEAST FIVE (5) GALLONS.

33 *E. ADEQUATE WATER PRESSURE MUST BE PROVIDED AT ALL FIXTURES AT ALL
34 TIMES. A MINIMUM FLOW RATE OF ONE (1) GALLON PER MINUTE OR THIRTY-
35 TWO (32) OUNCES PER FIFTEEN (15) SECONDS SHALL BE PROVIDED

36 F. ~~The w- Water capacity~~ SYSTEMS shall be adequate to fill the ~~three-~~
37 ~~compartment~~ WAREWASHING sink with 110°F water without interruptions
38 AND TO SUPPLY HAND SINKS WITH THREE (3) GALLONS PER HOUR OF 100°F
39 WATER AT ALL TIMES AND OTHER HOT WATER USING FIXTURES AND EQUIPMENT
40 WITH A CONTINUOUS SUPPLY OF HOT WATER. STANDARD TANK TYPE HEATING
41 SYSTEMS SHALL BE SIZED IN ACCORDANCE WITH SECTION 5-108. ~~at a minimum~~
42 ~~rate of 1 gallon per minute with reserve capacity to provide a minimum of~~
43 ~~3 gallons per hour of warm water to all handsinks at all times.~~

- 1 G. The water inlet shall be located so that it will not be contaminated by waste
2 discharge, road dust, oil, or grease, and it shall be kept capped unless being filled.
3 The water inlet shall be provided with a ~~transition~~ connection of a size or type
4 that will prevent its use for any other service. All water distribution pipes or
5 tubing shall be constructed and installed in accordance with the requirements of
6 these rules and regulations.
- 7 *H. When a mobile retail food establishment is connected to a pressurized water
8 supply, it shall be provided with approved backflow prevention devices. This
9 shall include the protection of the water source as well as protection of each
10 individual water service connection.
- 11 *I. The water supply hose and couplings shall be of a size and type compatible with
12 the water supply tank inlet fixture and shall be free of cracks and checks. Hose
13 couplings shall be constructed to permit a tight connection between the mobile
14 retail food establishment coupling and the water supply hose bib. Hose ends
15 must be capped, connected or otherwise fully protected when not ~~being~~ IN .
16 ONLY FOOD GRADE HOSES SHALL BE USED TO FILL OR TRANSFER DRINKING
17 WATER TO OR WITHIN A MOBILE RETAIL FOOD ESTABLISHMENT OR A PUSH CART.
- 18 *J. WATER SYSTEMS AND COMPONENTS SHALL BE DISINFECTED AND FLUSHED IN
19 ACCORDANCE WITH 25-1.5-2, C.R.S., *COLORADO PRIMARY DRINKING WATER*
20 *REGULATIONS*, PRIOR TO USE, IF THE MOBILE RETAIL FOOD ESTABLISHMENT OR
21 PUSH CART IS NOT IN DAILY USE.

22 **9-105 Wastewater Retention**

- 23 *A. A MOBILE RETAIL FOOD ESTABLISHMENT OR PUSH CART THAT DOES NOT MEET
24 ALL THE RESTRICTIONS OF SECTION 9-102 OF THESE RULES AND REGULATIONS
25 MUST PROVIDE A WASTE WATER RETENTION TANK. All liquid waste, except
26 drainage from clean ~~potable~~ ice MADE WITH DRINKING WATER, generated by a
27 mobile retail food establishment or pushcart shall be stored in a retention tank
28 that is at least 15 percent larger than the water supply tank. Liquid waste shall be
29 discharged from the retention tank to an approved sewage disposal system and
30 flushed as often as necessary to maintain sanitary conditions. Discharge onto the
31 surface of the ground shall be strictly prohibited. Drainage from ~~clean-potable~~
32 UNCONTAMINATED ice MADE WITH DRINKING WATER can be discharged onto the
33 surface of the ground provided it does not create a nuisance.
- 34 B. All connections on the vehicle for servicing mobile food unit waste disposal
35 facilities shall be of a different size or type than those used for supplying ~~potable~~
36 DRINKING water to the mobile food establishment. The waste WATER OUTLET
37 connection shall be located lower than the DRINKING water inlet connection to
38 prevent contamination of the ~~potable~~ DRINKING water system.
- 39 C. Liquid waste discharge piping and the ~~potable~~-DRINKING water hose shall not be
40 stored in a manner that may result in ~~cross~~-contamination.

41 ***9-106 Handwashing Facilities**

42 A mobile retail food establishment or pushcart that does not meet all the ~~restrictions~~
43 EXEMPTIONS of section 9-102 of these rules and regulations must be equipped with a
44 convenient, accessible handsink INSTALLED AS SPECIFIED IN SECTION 5-208(J) for
45 employee handwashing. The handsink must be capable of providing a hands-free,
46 continuous flow of ~~warm-water~~ 100°F WATER AS SPECIFIED IN SECTION 9-104(F). ~~The~~

1 ~~handsink must be of adequate pressure and size to facilitate proper handwashing. Soap~~
2 ~~and individually DISPENSED paper towels must also be provided AT THE HAND SINK.~~

3 ***9-107 Commissary AND SERVICING AREAS**

4 *A. The commissary is considered to be an essential part of the mobile food RETAIL
5 FOOD establishment AND PUSH CART operation. The commissary shall be
6 constructed and operated in compliance with the requirements of these rules and
7 regulations. Mobile retail food establishments and ~~or~~ pushcarts shall operate from
8 a commissary or other fixed retail food establishment and shall report every 24
9 hours (on operational days) to that location for ~~all~~ supplies, ~~and for all~~ cleaning
10 and servicing operations. ~~The mobile retail food establishment operator shall~~
11 ~~verify to the Department in writing that the mobile unit returns to the commissary~~
12 ~~every 24 hours.~~

13 THE USE OF THE PROPOSED COMMISSARY FOR EACH MOBILE RETAIL FOOD
14 ESTABLISHMENTS OR PUSHCARTS SHALL BE SUBMITTED AND APPROVED BY THE
15 DEPARTMENT. THE MOBILE RETAIL FOOD ESTABLISHMENT OR PUSH CART SHALL
16 PROVIDE AN AGREEMENT FROM THE COMMISSARY OPERATOR TO THE
17 DEPARTMENT EACH CALENDAR YEAR AND UPON CHANGE OF A COMMISSARY
18 LOCATION.

19 THE AGREEMENT SHALL SPECIFY THE MOBILE RETAIL FOOD ESTABLISHMENT OR
20 PUSH CART IS ALLOWED TO REPORT TO THE COMMISSARY DAILY, AND IS
21 ALLOWED TO USE THE FACILITY'S WAREWASHING EQUIPMENT, REFRIGERATION,
22 FOOD PREPARATION EQUIPMENT AND STORAGE AREAS AS A BASE FOR
23 OPERATION. THE AGREEMENT SHALL ALSO SPECIFY HOW AND WHERE THE
24 COMMISSARY USE LOG WILL BE MAINTAINED. THESE COMMISSARY RECORDS
25 SHALL BE MADE AVAILABLE TO THE DEPARTMENT WHEN REQUESTED.

26 B. ACCOMMODATIONS FOR A ~~mobile retail establishment~~ servicing area shall
27 be AVAILABLE WITH A DRINKING ~~provided and shall include a potable~~
28 water supply FOR THE MOBILE RETAIL FOOD ESTABLISHMENT OR PUSH
29 CART. ~~A Servicing area is an operating base location to which a mobile~~
30 ~~food establishment or transportation vehicle returns regularly for such~~
31 ~~things as~~ MAY INCLUDE vehicle and equipment cleaning, discharging liquid
32 or solid wastes, refilling water tanks, and RESTOCKING OF ice bins, and
33 ~~boarding food.~~

34 1. ~~Within this servicing area, there shall be a location provided for the flushing~~
35 ~~and drainage of liquid wastes that is separate from the location provided for~~
36 ~~potable water servicing and for the loading and unloading of food and related~~
37 ~~supplies. This servicing area will not be required where only packaged food is~~
38 ~~placed on the mobile food unit or pushcart, or where mobile food units do not~~
39 ~~contain waste retention tanks.~~

40 . Potable DRINKING water servicing equipment shall be installed according
41 to the law and shall be stored and handled to protect the water and
42 equipment from contamination, ACCORDING TO SECTION 5-101 AND 5-
43 102.

44 . The mobile retail food establishment AND PUSH CART liquid waste
45 retention tank shall be thoroughly DRAINED AND flushed ~~and drained~~
46 ~~during the servicing operation.~~ All liquid waste shall be discharged to a

- 1 sanitary sewage system in accordance with section 5-211 of these rules
2 and regulations.
- 3 3. THERE SHALL BE A LOCATION PROVIDED FOR THE FLUSHING AND
4 DRAINAGE OF LIQUID WASTES THAT IS SEPARATE FROM THE LOCATION
5 PROVIDED FOR OBTAINING DRINKING WATER AND FOR THE LOADING
6 AND UNLOADING OF FOOD AND RELATED SUPPLIES.
- 7 . WHEN SERVICING AREAS ARE PROVIDED AS PART OF THE COMMISSARY, floor
8 surfaces of the servicing area shall be constructed of a smooth, nonabsorbent
9 material such as concrete or machine-laid asphalt and shall be maintained in good
10 repair, kept clean, and be graded to drain.
- 11 5- The construction of the walls and ceilings of the servicing area is exempt from
12 the provisions of sections 6-201 and 6-202 of these rules and regulations.
- 13 . A ~~fully equipped~~, SELF-CONTAINED mobile retail food establishment ~~shall~~ IS not
14 be required to report to a ~~servicing area~~ COMMISSARY if:
- 15 1. ~~The mobile retail food establishment's potable water system and waste~~
16 ~~retention system is sufficiently sized or operated properly to serve the needs~~
17 ~~of the mobile retail food establishment and, and liquid waste is emptied only~~
18 ~~at service locations approved by the Department; and~~
- 19 2. ~~The mobile retail food establishment is capable of being maintained in a~~
20 ~~sanitary condition; and~~
- 21 1. Adequate storage areas are provided within the mobile retail food
22 establishment for food, dry goods, single service articles and cleaning
23 supplies; and
- 24 2. ~~Adequate facilities are provided for food preparation, for cleaning and~~
25 ~~sanitizing of equipment and utensils, for the storage of additional food,~~
26 ~~equipment, utensils and other supplies, and for other servicing~~
27 ~~operations; and~~ ADEQUATE FACILITIES INCLUDING HAND SINK, FOOD
28 PREPARATION SINK, WAREWASHING FACILITIES, MOP SINK, MECHANICAL
29 REFRIGERATION, AND ANY ADDITIONAL EQUIPMENT ARE PROVIDED AS
30 REQUIRED BY THE MENU.
- 31 3. ADEQUATE ACCOMMODATIONS FOR FOOD PREPARATION, STORAGE OF
32 FOOD, EQUIPMENT, UTENSILS AND OTHER SUPPLIES; AND
- 33 4. Approved arrangements and facilities are provided and used to supply
34 ~~potable~~ DRINKING water to the mobile unit AND for the disposal of
35 wastewater generated by the establishment; and
- 36 5. A written operational plan is submitted by the mobile retail food
37 establishment, which demonstrates that this process can be accomplished
38 in compliance with these rules and regulations. Review and approval of
39 this plan must include the menu and standard operating procedures for
40 the mobile unit. Once an operational plan is approved, any additions or
41 changes to the approved plan must be approved by the Department prior
42 to implementation. THE APPROVED OPERATIONAL PLAN MUST BE
43 AVAILABLE ON THE MOBILE RETAIL FOOD ESTABLISHMENT AT ALL
44 TIMES.

1 E. A MOBILE RETAIL FOOD ESTABLISHMENT IS PROHIBITED FROM ACTING AS A
2 COMMISSARY FOR ANOTHER RETAIL FOOD ESTABLISHMENT.

3 **9-108 Additional Requirements**

4 A. Spare tires, tools, and other equipment relating to the mechanical operation of the
5 vehicle shall be stored in a way that does not contaminate food, food equipment,
6 or utensils.

7 B. EXCEPT FOR SERVICE WINDOWS, ANY OPENABLE WINDOWS AND DOORS MUST BE
8 SCREENED. SERVICE WINDOWS MUST BE SELF-CLOSING.

9 C. RESTROOM FACILITIES SHALL BE AVAILABLE TO EMPLOYEES AT ALL TIMES THAT
10 THE MOBILE RETAIL FOOD ESTABLISHMENT OR PUSH CART IS IN OPERATION.

11 *D. EQUIPMENT SHALL BE ADEQUATE TO MAINTAIN POTENTIALLY HAZARDOUS
12 FOODS (TIME/TEMPERATURE CONTROL FOR SAFETY FOODS) AT REQUIRED
13 TEMPERATURES IN ACCORDANCE WITH PARTS 3-5 AND 3-6. IN ADDITION;

14 1. MOBILE RETAIL FOOD ESTABLISHMENTS SHALL UTILIZE MECHANICAL
15 REFRIGERATION TO HOLD AND SERVE POTENTIALLY HAZARDOUS FOODS
16 (TIME/TEMPERATURE CONTROL FOR SAFETY FOODS).

17 2. PUSH CARTS MAY USE NO MORE THAN TWO (2) HARD SIDED COOLERS TO
18 MAINTAIN FOOD AT REQUIRED TEMPERATURES. ONE COOLER SHALL BE
19 USED FOR ALL RAW ANIMAL FOODS AND THE OTHER COOLER FOR ALL
20 OTHER POTENTIALLY HAZARDOUS FOODS (TIME/TEMPERATURE
21 CONTROL FOR SAFETY FOODS). IF THE FACILITY NEEDS ADDITIONAL
22 REFRIGERATION SPACE, THE PUSH CART SHALL PROVIDE COMMERCIAL
23 MECHANICAL REFRIGERATION.

24 *E. MOBILE RETAIL FOOD ESTABLISHMENTS AND PUSH CARTS SHALL PROVIDE
25 ENOUGH CLEAN UTENSILS TO SATISFY THE REQUIREMENTS OF SECTION 4-
26 407(C)5.

27 F. ITEMS FOR CUSTOMER SELF SERVICE SHALL BE ADEQUATELY PROTECTED FROM
28 CONTAMINATION.

29

1 **CHAPTER 10**

2 **TEMPORARY RETAIL FOOD ESTABLISHMENTS**

3 **10-1 TEMPORARY RETAIL FOOD ESTABLISHMENTS**

4 **10-101 General**

5 A temporary retail food establishment shall comply with ~~the~~ ALL requirements of these
6 rules and regulations, except as otherwise provided in this chapter.

7 ~~A list of menu items used by the operator shall be submitted to the Department. A~~
8 TEMPORARY EVENT VENDOR APPLICATION, WHICH SHALL INCLUDE A LIST OF FOOD
9 ITEMS TO BE SOLD, SHALL BE SUBMITTED TO THE DEPARTMENT FOR EACH EVENT. THE
10 VENDOR APPLICATION SHALL BE SUBMITTED AT LEAST TEN (10) WORKING DAYS PRIOR
11 TO THE EVENT. ~~The Department may impose additional requirements to protect against~~
12 ~~health hazards related to the conduct of the temporary retail food establishment and may~~
13 ~~prohibit the sale of any potentially hazardous foods. When no apparent health hazard~~
14 ~~will result, the Department may waive or modify requirements of these rules and~~
15 ~~regulations~~ APPROVAL WILL BE BASED UPON MENU, EQUIPMENT, SETUP AND THE
16 ABILITY TO PROTECT AGAINST PUBLIC HEALTH HAZARDS.

17 MOBILE RETAIL FOOD ESTABLISHMENTS AND PUSHCARTS OPERATING AT TEMPORARY
18 EVENTS SHALL OPERATE ACCORDING TO CHAPTER 9 OF THESE RULES AND
19 REGULATIONS.

20 ***10-102 Restricted Operations**

21 ~~Only potentially hazardous foods requiring preparation limited to seasoning and cooking~~
22 ~~shall be served. The preparation or service of other potentially hazardous foods,~~
23 ~~including pastries filled with cream or synthetic cream, custards and similar products,~~
24 ~~salads or sandwiches containing meat, poultry, eggs, or fish, is prohibited unless~~
25 ~~approved, and adequate equipment and facilities are provided. This prohibition does not~~
26 ~~apply to any potentially hazardous food prepared and packaged under conditions~~
27 ~~meeting the requirements of these rules and regulations, obtained in individual servings,~~
28 ~~stored at a temperature of 41°F (5°C) or below, or at a temperature of 135°F (57°C) or~~
29 ~~above in facilities that meet the requirements of these rules and regulations, and is~~
30 ~~served directly in the unopened container in which it was packaged.~~

31 A. FOOD PREPARATION AT THE EVENT SHALL BE LIMITED TO SEASONING, COOKING,
32 ASSEMBLY OF PRE-PREPARED FOODS AND SERVICE OF PACKAGED FOODS STORED
33 AT REQUIRED TEMPERATURES.

34 B. ALL SLICING, CHOPPING, PEELING, DICING, SHREDDING AND WASHING OF
35 PRODUCE SHALL BE DONE AT AN APPROVED COMMISSARY.

36 C. FOOD AND FOOD-CONTACT SURFACES OF EQUIPMENT SHALL BE PROTECTED
37 FROM CONTAMINATION BY CONSUMERS OR OTHER SOURCES. APPROPRIATE
38 COVERINGS, PACKAGING, SHIELDS, BARRIERS, OR OTHER MEANS SHALL BE
39 PROVIDED AS NECESSARY TO PREVENT CONTAMINATION.

40 D. EQUIPMENT SHALL BE MAINTAINED AND OPERATED PER ITS INTENDED USE AND
41 DESIGN.

1 E. EQUIPMENT SHALL BE LOCATED AND INSTALLED TO FACILITATE CLEANING. NO
2 GREASE FROM GREASE PRODUCING EQUIPMENT SHALL DISCHARGE ONTO THE
3 GROUND OR INTO ANY STORM DRAINAGE SYSTEM.

4 ***10-103 COMMISSARY**

5 A. TEMPORARY RETAIL FOOD ESTABLISHMENT VENDORS SHALL OPERATE FROM A
6 COMMISSARY APPROVED BY THE DEPARTMENT AND SHALL PROVIDE A
7 COMMISSARY AGREEMENT TO THE DEPARTMENT FOR EACH EVENT. VENDORS
8 WITH LIMITED MENUS OPERATING FROM LICENSED SELF-CONTAINED MOBILE
9 UNITS IN ACCORDANCE WITH SECTION 9-107(D) MAY BE ALLOWED TO OPERATE
10 WITHOUT A COMMISSARY.

11 B. THE COMMISSARY FOR VENDORS OPERATING AT AN EVENT OF MORE THAN ONE
12 (1) DAY IN DURATION SHALL BE WITHIN 30 MINUTES OR 30 MILES OF THE EVENT.

13 C. ALL FOODS, UTENSILS, AND SINGLE USE ARTICLES SHALL BE TRANSPORTED
14 FROM THE COMMISSARY TO THE EVENT SITE IN A MANNER THAT PROTECTS THEM
15 FROM CONTAMINATION. FOOD PRODUCT TEMPERATURE SHALL BE MAINTAINED
16 AS REQUIRED IN SECTION 3-501.

17 D. THE COMMISSARY SHALL BE CONSTRUCTED AND OPERATED IN COMPLIANCE
18 WITH THE REQUIREMENTS OF THESE RULES AND REGULATIONS. TEMPORARY
19 RETAIL FOOD ESTABLISHMENTS SHALL OPERATE FROM A COMMISSARY OR
20 OTHER FIXED RETAIL FOOD ESTABLISHMENT AND SHALL REPORT AT A MINIMUM
21 OF EVERY 24 HOURS (ON OPERATIONAL DAYS) TO THAT LOCATION FOR ALL
22 SUPPLIES, ALL CLEANING, ADVANCED FOOD PREPARATION, AND SERVICING
23 OPERATIONS. THE COMMISSARY OPERATOR, AS REQUESTED BY THE
24 DEPARTMENT, SHALL VERIFY TO THE DEPARTMENT WHEN THE TEMPORARY
25 RETAIL FOOD ESTABLISHMENT REPORTS TO THE COMMISSARY.

26 1 THE AGREEMENT SHALL SPECIFY THE TEMPORARY RETAIL FOOD
27 ESTABLISHMENT IS ALLOWED TO REPORT TO THE COMMISSARY DAILY, IS
28 ALLOWED TO USE THE FACILITY'S WAREWASHING EQUIPMENT,
29 REFRIGERATION, FOOD PREPARATION EQUIPMENT AND STORAGE AREAS
30 AS A BASE FOR OPERATION. THE COMMISSARY OPERATOR SHALL
31 MAINTAIN WRITTEN DOCUMENTATION OR A LOG AS TO WHEN THE
32 TEMPORARY RETAIL FOOD ESTABLISHMENT UTILIZES THE COMMISSARY.
33 THESE RECORDS SHALL BE MADE AVAILABLE TO THE DEPARTMENT
34 WHEN REQUESTED.

35 2. TEMPORARY RETAIL FOOD ESTABLISHMENT OPERATORS SHALL
36 MAINTAIN WRITTEN RECORDS OF PURCHASES DETAILING THE SOURCE OF
37 ALL FOODS BEING HELD, STORED, OFFERED FOR SALE, SOLD AND
38 DISTRIBUTED AND EXPENSES INCLUDING RECEIPTS FOR EXPENDITURES
39 SUCH AS SERVICING OPERATIONS. THESE RECORDS SHALL BE MADE
40 AVAILABLE TO THE DEPARTMENT WHEN REQUESTED.

41 **10-104 Minimum Event Site Equipment Requirements**

42 A. EQUIPMENT FOR HEATING AND HOLDING FOOD COLD AND HOT, SHALL BE
43 SUFFICIENT IN NUMBER AND CAPACITY TO MAINTAIN FOODS AT REQUIRED
44 TEMPERATURES. EQUIPMENT UTILIZING FUEL GEL CANISTER IS PROHIBITED AT
45 OUTDOOR VENUES UNLESS APPROVED BY THE DEPARTMENT.

- 1 B. A CONVENIENTLY LOCATED HAND WASHING STATION SHALL BE PROVIDED
2 WITHIN THE TEMPORARY RETAIL FOOD ESTABLISHMENT.
- 3 C. EXTRA UTENSILS AND IN-USE FOOD CONTACT SURFACES (CUTTING BOARDS,
4 TONGS, KNIVES, ETC.) SHALL BE PROVIDED TO ALLOW SOILED ITEMS TO BE
5 REPLACED AT A MINIMUM OF EVERY FOUR (4) HOURS. WAREWASHING OF
6 EQUIPMENT AND UTENSILS SHALL BE CONDUCTED AT AN APPROVED FACILITY.
7 ONSITE WAREWASHING IS PROHIBITED UNLESS OTHERWISE APPROVED BY THE
8 DEPARTMENT.
- 9 D. A SUFFICIENT NUMBER OF SMOOTH, NON-ABSORBENT, AND EASILY CLEANABLE
10 WORK SURFACES SHALL BE PROVIDED WHERE FOOD IS BEING HANDLED.
- 11 E. COOLERS AND CONTAINERS USED TO STORE FOOD SHALL BE DURABLE, SMOOTH,
12 NON-ABSORBENT AND EASILY CLEANABLE. STYROFOAM AND SOFT SIDED
13 COOLERS ARE PROHIBITED.
- 14 F. A CLEAN TRASH RECEPTACLE SHALL BE PROVIDED.

15 ***10- Ice**

16 ~~Ice that is consumed or that contacts food shall be made under conditions meeting the~~
17 ~~requirements of these rules and regulations. Ice obtained off site shall be only in~~
18 ~~chipped, crushed, or cubed form and in single use safe plastic or wet strength paper bags~~
19 ~~filled and sealed at the point of manufacture.~~

20 ONLY ICE WHICH HAS BEEN MANUFACTURED FROM DRINKING WATER AND HANDLED IN
21 A SANITARY MANNER SHALL BE USED OR OFFERED FOR SALE. ICE USED AS A COOLING
22 MEDIUM FOR FOOD STORAGE, BEVERAGE CONTAINERS, FOOD CONTAINERS OR FOOD
23 UTENSILS SHALL NOT BE USED OR SOLD FOR HUMAN CONSUMPTION.

24 ~~**10-104 Equipment**~~

- 25 ~~A. Equipment shall be located and installed to prevent food contamination and to~~
26 ~~facilitate cleaning the establishment.~~
- 27 ~~B. Food contact surfaces of equipment shall be protected from contamination by~~
28 ~~consumers and other contaminating agents. Effective shields for such equipment~~
29 ~~shall be provided as necessary to prevent contamination.~~

30 **10- Single-Service Articles**

31 All temporary retail food establishments, ~~which do not have approved facilities for~~
32 ~~cleaning and sanitizing tableware,~~ shall provide only single-service articles for use by
33 the consumer.

34 ***10- Water**

35 A sufficient quantity of ~~potable~~ DRINKING water shall be available for food preparation,
36 WIPING CLOTH SOLUTIONS, and sanitization of food-contact surfaces. The water supply
37 system hoses, piping, and ~~appurtenances~~ FIXTURES SHALL ~~must~~ be FABRICATED of
38 approved food-contact materials. The water supply system must be installed to preclude
39 the backflow of contaminants into the ~~potable~~ DRINKING water supply.

1 **10- Wet Storage**

2 Packaged food may be stored in direct contact with ~~potable~~ DRINKING ice or ~~potable~~
3 DRINKING water if the packaging, wrapping, or container is not subject to entry of
4 water. THE STORAGE OF FOOD AND/OR BEVERAGE, IN UNDRAINED ICE IS PROHIBITED.

5 ***10- Waste**

6 All sewage, including liquid waste, shall be disposed of according to law. WASTE
7 WATER SHALL NOT BE DISCHARGED ONTO GROUND OR INTO STORM DRAINAGE SYSTEM.
8 Drainage from clean ~~potable~~ DRINKING ice ~~can~~ MAY be discharged onto the surface of
9 the ground provided it does not create a nuisance.

10 ***10- Handwashing**

11 ~~A conveniently located handwashing facility shall be available for employee~~
12 ~~handwashing. This facility must be capable of providing a hands free, continuous flow~~
13 ~~of warm water. The handwashing facility must be of adequate pressure and size to~~
14 ~~facilitate proper handwashing. Soap and individual paper towels must also be provided.~~

15 A. A MINIMUM OF FIVE (5) GALLONS OF DRINKING WATER SHALL BE PROVIDED FOR
16 HAND WASHING. THE REQUIRED VOLUME OF WATER WILL BE BASED UPON
17 MENU, EQUIPMENT, AND HOURS OF OPERATION. PUSH BUTTON SPIGOTS ON
18 THE WATER SUPPLY CONTAINERS ARE NOT PERMITTED.

19 B. SOAP AND DISPENSED PAPER TOWELS SHALL BE PROVIDED AT EACH HAND
20 WASHING STATION.

21 C. A HAND WASHING STATION THAT IS CAPABLE OF PROVIDING HANDS-FREE
22 CONTINUOUS FLOWING WARM WATER OF ADEQUATE PRESSURE SHALL BE
23 PROVIDED

24 D. A BASIN THAT IS CAPABLE OF CAPTURING HAND WASHING WASTE WATER AND
25 CONVEYING IT INTO A CLOSED WASTE WATER CONTAINER SHALL BE PROVIDED.

26 **10-111 SCREENING AND ENCLOSURES**

27 SCREENING OR OTHER PROVISIONS MAY BE REQUIRED TO PREVENT THE ENTRANCE OF
28 PESTS AND DEBRIS.

29 **10-112 GROUNDS**

30 AREAS WITHIN THE TEMPORARY RETAIL FOOD ESTABLISHMENT SHALL BE FREE FROM
31 STANDING WATER, MUD, DUST AND FECAL MATERIAL. ADDITIONAL GROUND COVERING
32 MATERIAL MAY BE REQUIRED SUCH AS REMOVABLE PLATFORMS, DUCKBOARDS, WOOD
33 CHIPS OR OTHER SUITABLE MATERIAL.

34 **10-113 OVERHEAD PROTECTION**

35 OVERHEAD PROTECTION SHALL BE PROVIDED AND BE MADE OF WOOD, CANVAS, OR
36 OTHER MATERIALS THAT PROTECT THE INTERIOR OF THE ESTABLISHMENT FROM
37 WEATHER, OR OTHER CONTAMINATION. ANY GREASE PRODUCING EQUIPMENT OR
38 EQUIPMENT WITH OPEN FLAMES SHALL NOT BE LOCATED UNDER OVERHEAD
39 PROTECTION.

1 ~~10-110 Floors~~

2 ~~Floors shall be constructed of concrete, asphalt, tight wood, or other similar material~~
3 ~~kept in good repair. Dirt or gravel, when graded to drain, may be used as sub flooring~~
4 ~~when covered with clean, removable platforms or duckboards, or covered with wood~~
5 ~~chips, shavings, grass or other suitable materials to control dust.~~

6 ~~10-111 Walls and Ceilings~~

7 ~~A. Ceilings shall be made of wood, canvas, or other materials that protect the~~
8 ~~interior of the establishment from the weather. Walls and ceilings shall be~~
9 ~~constructed in a way that prevents the entrance of insects. Doors to food~~
10 ~~preparation areas shall be solid or screened and shall be self closing. Screening~~
11 ~~material used for walls, doors, or windows shall be at least 16 mesh to the inch~~
12 ~~(16 mesh to 25.4 mm).~~

13 ~~B. Counter service openings shall not be larger than necessary for the particular~~
14 ~~operation conducted. These openings shall be provided with tight fitting, solid or~~
15 ~~screened doors or windows, or shall be provided with fans installed and operated~~
16 ~~to restrict the entrance of flying insects. Counter service openings shall be kept~~
17 ~~closed, except when in actual use. Screening of walls, doors and outer openings~~
18 ~~do not apply if flying insects and other pests are absent due to the location of the~~
19 ~~establishment, the weather, or other limiting condition.~~

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CHAPTER 11

COMPLIANCE PROCEDURES

11-1 COMPLIANCE

11-101 General.

A person shall have a valid retail food establishment license, certificate of license, as defined in section 25-4-1602, C.R.S. AND, ~~or~~ administration and inspection fees pursuant to sections 25-4-1607, C.R.S., to operate a retail food establishment. A person operating a retail food establishment without a valid license, certificate of license or appropriate administration and inspection fees may be prosecuted under sections 16-13-305, ~~and~~ 25-4-1609, 25-14-1610, 25-4-1611 C.R.S. Only a person who complies with the requirements of these rules and regulations shall be entitled to receive or retain such a license or certificate. Licenses, certificates, or administration and inspection fees are not transferable. When issued, a valid license or certificate shall be posted in every retail food establishment.

11-102 Issuance of License or Certificate of License.

- A. Any person desiring to operate a retail food establishment shall make written application for a license or certificate of license or pay administration and inspections fees using forms provided by the Department. Each application form shall include the name and address of each applicant, the location and type of the proposed retail food establishment, and the signature of each applicant.
- B. Prior to approval of an application for a license or certificate of license, the Department ~~shall~~ MAY inspect the proposed retail food establishment to determine compliance with the rules and regulations.
- C. The Department shall approve a license or certificate of license for the applicant if its inspection reveals that the proposed retail food establishment complies with the requirements of these rules and regulations.
- D. AN EXISTING RETAIL FOOD ESTABLISHMENT SHALL BE REQUIRED TO OBTAIN A NEW RETAIL FOOD ESTABLISHMENT LICENSE WHEN THERE IS A CHANGE OF OWNERSHIP THAT REQUIRES A NEW COLORADO DEPARTMENT OF REVENUE SALES TAX ACCOUNT NUMBER, OR IF THE PHYSICAL LOCATION OF THE ESTABLISHMENT CHANGES.

11-103 License Renewal.

The Department may refuse to renew a retail food establishment license or certificate of license for any violation of sections 25-4-1601 et seq., C.R.S., of these rules and regulations, or as otherwise provided by law. This notification shall be presented to license or certificate holders during the last quarter of each calendar year. Denial of a license renewal shall be treated in all respects as a revocation and, hence, procedures for revocation shall be followed. In a case in which the license or certificate holder has made timely and sufficient application for renewal of license, the existing license shall not expire until such application has been finally acted upon by the Department.

1 **11-104 Judicial Review.**

2 A license or certificate holder adversely affected or aggrieved by a Departmental action
3 may appeal the final action of the Department as provided in section 24-4-106, C.R.S.
4 Suspension or revocation of a license may be reviewed, upon application for an order in
5 the nature of mandamus or otherwise, by any court of general jurisdiction as provided in
6 section 25-4-1609, C.R.S.

7 **11-105 Closure Without Suspension.**

8 Acting under sections 25-1.5-101(1)(a) and 25-1.5-102(1)(a) & (d), C.R.S., the
9 Department, or its authorized representative, shall have the power and duty to close
10 retail food establishments and forbid the gathering of people therein to protect the public
11 health from the cause of epidemic and communicable diseases. Immediate closure shall
12 be used only when the situation imperatively requires emergency action or the operator
13 has been guilty of deliberate and willful violation THAT IS INJURIOUS OR CREATES AN
14 IMMINENT PUBLIC HEALTH HAZARD AS DEFINED IN SECTION 1-201(A)(56).

15 **11-106 Injunctive Relief.**

16 When serious or repeated violations of these rules and regulations have been found, the
17 Department or its authorized agents may abate the nuisance by seeking injunctive relief
18 through judicial means, as provided under section 16-13-308 and 309, C.R.S.

19 **11-2 INSPECTIONS**

20 **11-201 Inspection Frequency.**

- 21 A. An inspection of a retail food establishment shall be performed at least twice
22 every calendar or fiscal year; ~~a seasonal food service establishment shall be~~
23 ~~inspected once before it opens and at least once while it is in operation; and retail~~
24 ~~food establishments that operate as grocery stores without a restaurant or deli~~
25 ~~shall be inspected once every calendar or fiscal year.~~ OR
- 26 B. *The Colorado Retail Food Establishment Risk-Based Inspectional Frequency*
27 *Methodology Guidance Document* may be used as a model for an alternative
28 method for determining inspectional frequency. If this model is modified by an
29 agency, the agency must be able to defend the modifications utilizing the public
30 health risk factors contained in the model. The public health risk factors include:
31 1) food served, 2) operations, 3) weekly meal volume, and 4) inspectional history
32 including critical and non-critical violations. THE MINIMUM INSPECTION
33 FREQUENCY FOR AN ESTABLISHMENT FALLING IN THE LOW RISK CATEGORY IS
34 ONCE EVERY TWO YEARS.
- 35 C. Additional inspections ~~are to~~ MAY be performed based upon additional
36 assessments of potential risks of foodborne illness including a history of NON-
37 COMPLIANCE ~~critical violations and numerous or repeat noncritical violations of~~
38 WITH these rules and regulations; the hazards associated with the particular foods
39 being prepared, stored or served; the method and extent of food storage,
40 preparation and service; and the number and demographic characteristics of the
41 consumers.

1 **11-202 Access.**

2 Agents of the Department, after proper identification, shall be permitted to enter any
3 retail food establishment during business hours and at other times during which activity
4 is evident IN ACCORDANCE WITH 25-4-1604(1)(E) to determine compliance with these
5 rules and regulations. The agents shall be permitted to examine documents or true
6 copies of documents, excluding prices, that pertain directly to food and supplies
7 purchased, received or used, information pertinent to their HACCP plan, or to persons
8 employed in food and beverage operations when such examination is expected to
9 produce information necessary to protect the public health, enforce these rules and
10 regulations or investigate suspected incidents of foodborne illnesses.

11 **11-203 Report of Inspections.**

12 Whenever an inspection of a retail food establishment or commissary is made, the
13 findings shall be recorded on an inspection report form. The inspection report form
14 shall summarize the requirements of these rules and regulations. THE DEPARTMENT
15 SHALL DOCUMENT, ON THE INSPECTION REPORT FORM, SPECIFIC FACTUAL
16 OBSERVATIONS OF VIOLATIVE CONDITIONS OR OTHER DEVIATIONS FROM THESE RULES
17 AND REGULATIONS. ~~Inspectional remarks shall describe the violation that exists.~~ ONCE
18 THE INSPECTION HAS BEEN COMPLETED AND THE INSPECTION REPORT FORM IS
19 FINALIZED, ~~A~~ a copy of the completed inspection report form shall be furnished ~~by the~~
20 ~~end of the next workday, following conclusion of the inspection,~~ to the person in charge
21 of the establishment. The completed inspection report form is a public document that
22 shall be made available for public disclosure to any person who requests it according to
23 law.

24 **11-204 Correction of Violations.**

25 A. The inspection report form shall specify a reasonable period of time for the
26 correction of the violations found and correction of the violations shall be
27 accomplished within the period specified, in accordance with the following
28 provisions:

- 29 1. If an imminent health hazard exists, such as, but not limited to, ~~complete~~
30 ~~lack~~ ABSENCE OF ADEQUATE ~~of~~ refrigeration, NO WATER SUPPLY, NON
31 FUNCTIONAL WATER HEATING SYSTEM, SEVERE AND ACTIVE PEST
32 INFESTATION, or sewage backup into the establishment, the
33 establishment shall immediately cease food operations. Operations shall
34 not be resumed until authorized by the Department.
- 35 2. All critical violations are to be corrected as soon as possible, but in any
36 event, by the date and time specified by the ~~regulatory authority~~
37 DEPARTMENT, ~~but in no case to exceed (10) days.~~
- 38 3. All non-critical violations shall be corrected by the date and time agreed
39 to or specified by the ~~regulatory authority~~ DEPARTMENT based upon the
40 severity of potential health hazards, which could result from the non-
41 critical violation. The ~~regulatory authority~~ DEPARTMENT is not required
42 to conduct follow-up activities on non-critical violations.

43 B. The inspection report shall state that failure to comply with any time limits may
44 result in the initiation of administrative or legal regulatory action. An
45 opportunity for appeal of the inspection findings and time limitation will be
46 provided if a written request for an administrative hearing is filed with the

- 1 Department within five (5) days following the date of receipt of inspection. If
2 the request for a hearing is received, a hearing shall be held no sooner than
3 twenty (20) days after the operator is notified of the hearing.
- 4 C. Whenever a retail food establishment is required under the provisions of these
5 rules and regulations to cease operations, it shall not resume operations until a
6 re-inspection determines that conditions responsible for the requirement to cease
7 operations no longer exists. Opportunity for re-inspection shall be offered within
8 a reasonable time.
- 9

1 **11-205 Inspection Report.**

2 The format of an inspection form shall be based upon critical and non-critical categories.
 3 The following items must be included:

4
 5

Item	Category
FOOD SOURCE DATE MARKING AND CONSUMER ADVISORY a. Approved source b. Wholesome, free of spoilage c. Cross-contamination d. HACCP plan E. CONSUMER ADVISORY F. DATE MARKING	CRITICAL
PERSONNEL Employee Health a. Personnel with infections restricted b. Wounds properly covered Hygienic Practices c. Hands washed as needed d. Hygienic practices e. Smoking, eating, drinking Demonstration of knowledge f. Training needed G. PREVENTING FOOD CONTAMINATION FROM BARE HANDS	CRITICAL
FOOD TEMPERATURE CONTROL Temperature Control Procedures a. Rapidly cool foods to F or less b. Rapidly reheat to F or greater c. Hot hold at F or greater d. Required cook temperature e. Cold hold at F or less Temperature Control Equipment f. Use of Food thermometer (probe-type) g. Adequate equipment to maintain food temperatures	CRITICAL
SANITIZATION RINSE a. Clean b. Temperature c. Concentration d. Exposure	CRITICAL

Item	Category
WATER, SEWAGE, PLUMBING SYSTEMS a. Safe water source b. Hot and cold water under pressure c. Backflow, backsiphonage d. Sewage disposal	CRITICAL
HANDWASHING FACILITIES a. Adequate number, location b. Accessible c. Soap and drying devices available	CRITICAL
PEST CONTROL a. Evidence of insects or rodents b. Pesticide application c. Animals prohibited	CRITICAL
POISONOUS OR TOXIC ITEMS a. Properly stored b. Properly labeled c. Properly used	CRITICAL
FOOD LABELING , FOOD PROTECTION a. Original container, properly labeled b. Food protected from contamination	NON-CRITICAL
EQUIPMENT DESIGN CONSTRUCTION a. Food-contact surfaces b. Nonfood-contact surfaces c. Dishwashing facilities	NON-CRITICAL
TESTING DEVICES a. Refrigeration units provided with accurate, conspicuous thermometers b. Dishmachines provided with accurate thermometer and gauge cock c. Chemical test kits provided, accessible	NON-CRITICAL
CLEANING OF EQUIPMENT AND UTENSILS a. Food-contact surfaces b. Nonfood-contact surfaces c. Dishwashing operations d. Wiping cloths	NON-CRITICAL

Item	Category
UTENSILS, SINGLE SERVICE ARTICLES	NON-CRITICAL
<ul style="list-style-type: none"> a. Utensils provided, used, stored b. Single-service articles stored, dispensed, used c. No reuse of single-service articles 	
PHYSICAL FACILITIES	NON-CRITICAL
<ul style="list-style-type: none"> a. Plumbing: installed, maintained b. Garbage and refuse c. Floors, walls, ceiling d. Lighting e. Ventilation f. Locker rooms g. Premises maintained h. Separation of living, laundry i. Restroom facilities 	
OTHER OPERATIONS	NON-CRITICAL
<ul style="list-style-type: none"> a. Personnel: clean clothes, hair restraints, authorized b. Linen properly stored 	

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3 **11-3 ~~EMBARGO AND CONDEMNATION~~ AND EMBARGO OF FOOD**

4 **11-301 General.**

5 The power and duty to ~~embargo and~~ condemn AND EMBARGO food that the Department
6 finds probable cause to believe is in violation of section 3-101 of these rules and
7 regulations has been given to the Department under the statutory authority of sections
8 25-1.5-104(a) and 25-5-406 et. seg., C.R.S.

9 **11-302 Voluntary Condemnation.**

10 When the Department finds food that it has probable cause to believe is in violation of
11 section 3-101 of these rules and regulations, the Department shall bring the fact to the
12 attention of the person in charge and request that the food be voluntarily destroyed. If
13 the person in charge agrees to destroy the suspect food, a voluntary condemnation
14 agreement shall be completed and signed. The person in charge shall denature the food
15 under the supervision of the Department. A copy of the voluntary condemnation
16 agreement shall be left with the person in charge.

17 **11-303 Embargo Placement.**

18 When the Department finds food that it has probable cause to believe is in violation of
19 section 3-101 of these rules and regulations, the Department shall bring the fact to the
20 attention of the person in charge and request that the food be voluntarily destroyed.
21 Should the person in charge refuse to voluntarily destroy the food, the Department shall

1 embargo the remainder of the food. An embargo notice shall be completed and signed.
2 A copy of the embargo notice shall be left with the person in charge. The remainder of
3 the food product shall be set aside for storage in a container sealed with sampling tape to
4 prevent usage. No person shall remove or dispose of such embargoed article by sale or
5 otherwise.

6 **11-304 Embargo Release.**

- 7 A. The Department shall complete and sign an embargo release which dictates the
8 subsequent disposition of the product by:
- 9 1. Use of the product in the establishment where it was found if
10 demonstrated to be in compliance with section 3-101 of these rules and
11 regulations; or
 - 12 2. Use of the product by other approved means; or
 - 13 3. Destruction of the product.
- 14 B. A copy of this release shall be given to the person in charge.
- 15 C. Neither the Department nor the State shall be held liable for damages because of
16 such embargo.

17 **11-305 Condemnation of Product**

18 Should the food be found to be not sound or contaminated with filth and a voluntary
19 destruction cannot be obtained, the Department shall petition the court of jurisdiction for
20 seizure and disposition of the food.

21 **11-4 REVIEW OF PLANS**

22 **11-401 Submission of Plans**

23 It shall be necessary to submit to the Department detailed plans and specifications of a
24 proposed newly constructed retail food establishment and or the affected areas of any
25 proposed extensively remodeled retail food establishment. Each retail food operator, or
26 person intending to become a retail food operator, shall be responsible for submitting all
27 plans and specifications. Those assisting an operator may submit plans and
28 specifications on the operator's authority. The Department shall be consulted before
29 preparation of plans and specifications. Approval of both plans and specifications is
30 necessary before construction begins. A minimum of two (2) weeks shall be necessary
31 for the Department to review the plans. Any revision of plans shall be submitted to the
32 Department for review and modification or approval.

33 **11-402 Contents of Plans and Specifications**

34 Contents of the plans and specifications shall show evidence that the facility complies
35 with applicable portions of these rules and regulations. A plan-view scale drawing of the
36 establishment shall be provided. The plans shall include the location of all retail food
37 equipment, plumbing fixtures and connections, ventilation systems, menu and other
38 pertinent information. A dimensional sketch of the entrance, exits, streets, roadways and
39 alleys shall also be included. Specifications shall be provided on a form supplied by the
40 Department.

41 **11-403 CONTENTS OF A HACCP PLAN**

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- A. FOR A FOOD ESTABLISHMENT THAT IS REQUIRED IN SECTION 3-506 TO HAVE A HACCP PLAN, THE PLAN AND SPECIFICATIONS SHALL INDICATE:
 - 1. A CATEGORIZATION OF THE TYPES OF POTENTIALLY HAZARDOUS FOODS (TIME/TEMPERATURE CONTROL FOR SAFETY FOODS) THAT ARE SPECIFIED IN THE MENU SUCH AS SOUPS AND SAUCES, SALADS, AND BULK, SOLID FOOD SUCH AS MEAT ROASTS, OR OF OTHER FOODS THAT ARE SPECIFIED BY THE DEPARTMENT;
 - 2. A FLOW DIAGRAM BY SPECIFIC FOOD OR CATEGORY TYPE IDENTIFYING CRITICAL CONTROL POINTS AND PROVIDING INFORMATION ON THE FOLLOWING:
 - A. INGREDIENTS, MATERIALS, AND EQUIPMENT USED IN THE PREPARATION OF THAT FOOD; AND
 - B. FORMULATIONS OR RECIPES THAT DELINEATE METHODS AND PROCEDURAL CONTROL MEASURES THAT ADDRESS THE FOOD SAFETY CONCERNS INVOLVED;
 - 3. FOOD EMPLOYEE AND SUPERVISORY TRAINING PLAN THAT ADDRESSES THE FOOD SAFETY ISSUES OF CONCERN;
 - 4. A STATEMENT OF STANDARD OPERATING PROCEDURES FOR THE PLAN UNDER CONSIDERATION INCLUDING CLEARLY IDENTIFYING:
 - A. EACH CRITICAL CONTROL POINT;
 - B. THE CRITICAL LIMITS FOR EACH CRITICAL CONTROL POINT;
 - C. THE METHOD AND FREQUENCY FOR MONITORING AND CONTROLLING EACH CRITICAL CONTROL POINT BY THE FOOD EMPLOYEE DESIGNATED BY THE PERSON IN CHARGE;
 - D. THE METHOD AND FREQUENCY FOR THE PERSON IN CHARGE TO ROUTINELY VERIFY THAT THE FOOD EMPLOYEE IS FOLLOWING STANDARD OPERATING PROCEDURES AND MONITORING CRITICAL CONTROL POINT;
 - E. ACTION TO BE TAKEN BY THE PERSON IN CHARGE IF THE CRITICAL LIMITS FOR EACH CRITICAL CONTROL POINT ARE NOT MET; AND
 - F. RECORDS TO BE MAINTAINED BY THE PERSON IN CHARGE TO DEMONSTRATE THAT THE HACCP PLAN IS PROPERLY OPERATED AND MANAGED; AND
 - 5. ADDITIONAL SCIENTIFIC DATA OR OTHER INFORMATION, AS REQUIRED BY THE DEPARTMENT, SUPPORTING THE DETERMINATION THAT FOOD SAFETY IS NOT COMPROMISED BY THE PROPOSAL.

39 **11-403 Pre-Operational Inspection**

40 Whenever plans and specifications are required by section 11-401 of these rules and
41 regulations to be submitted to the Department, the Department shall inspect the retail
42 food establishment prior to its beginning operation to determine compliance with the
43 approved plans and specifications and with the requirements of these rules and

1 regulations. It shall be necessary to arrange for a pre-opening inspection fourteen (14)
2 days in advance of the date of the intended inspection. For areas of the state without a
3 Local Health Department, it shall be necessary to arrange for a pre-opening inspection
4 twenty-one (21) days in advance of the date of the intended inspection.

5 **11-5 PROCEDURE WHEN INFECTION IS SUSPECTED**

6 **11-501 General**

7 When the Department has reasonable cause to suspect the possibility of disease
8 transmission from any retail food establishment employee, it may secure a morbidity
9 history of the suspected employee or make any other investigation as necessary and shall
10 take appropriate action. The Department may require any or all of the following
11 measures:

- 12 A. The immediate exclusion of the employee from all retail food establishments IN
13 ACCORDANCE WITH 2-202;
- 14 B. The immediate closing of the retail food establishment concerned until, in the
15 opinion of the Department, no further danger of disease outbreak exists;
- 16 C. Restriction of the employee's services to some area of the establishment where
17 there would be no danger of disease transmission IN ACCORDANCE WITH 2-203;
- 18 D. Adequate medical and laboratory examination of the employee and other
19 employees IN ACCORDANCE WITH 2-203.

20 **11-6 VARIANCE PROCEDURE**

21 **11-601 Variance Procedure**

- 22 A. Any retail food establishment may request a variance from any requirement of
23 these rules and regulations when such an establishment believes that the
24 requirement results in an undue economic hardship or when it is believed a
25 standard may not apply to the specific situation.
- 26 B. Requests shall be submitted in writing to the Colorado Department of Public
27 Health and Environment and shall include the name and location of the
28 business, the name of the licensee or prospective licensee when applicable, and
29 the section for which a variance is being requested. This request must be
30 accompanied with a recommendation for approval or denial from the health
31 agency of jurisdiction. Evidence of undue economic hardship should include
32 estimates and costs for compliance. If it is believed that a standard may not
33 apply to the specific situation, an explanation shall be included.
- 34 C. Any person who requests a variance for the provisions of these regulations shall
35 have the burden of supplying the Department with information that
36 demonstrates the conditions exist which warrant the granting of a variance. All
37 doubts shall be resolved in favor of denial.
- 38 D. The Colorado Department of Public Health and Environment may grant a
39 variance if:
 - 40 1. Such variance is consistent with the purpose and intent of the act and
41 these regulations; and

- 1 2. It is consistent with the protection of the public health; and
- 2 3. The circumstances of the retail food establishment are unique; and
- 3 4. The cost of compliance is so great that it would threaten economic
- 4 viability of the retail food establishment or the retail food establishment
- 5 would be in grave jeopardy if compliance were enforced; and
- 6 5. The damage to the retail food establishment's economic viability is in
- 7 fact caused by compliance.
- 8 E. A variance shall expire upon a change of circumstances from those supporting
- 9 the variance or upon a change of ownership of the retail food establishment. THE
- 10 APPROVED VARIANCE AND ALL ASSOCIATED DOCUMENTATION SHALL BE
- 11 LOCATED AT THE ESTABLISHMENT AND MADE AVAILABLE TO THE DEPARTMENT
- 12 WHEN REQUESTED.
- 13 F. After review and in circumstances where the Department intends to deny a
- 14 variance, the Department shall refer the request to an advisory panel of three
- 15 persons, two persons who represent the retail food industry and a representative
- 16 from a local health department, to make recommendations to the Department.
- 17 G. Any retail food establishment for which a variance has been denied may appeal
- 18 such denial by requesting a hearing which will be held in accordance with section
- 19 24-4-105 (15), C.R.S.

20 **11-7 REFERENCE CITATIONS**

21 **11-701 General**

22 These regulations incorporated by reference (as indicated within) materials originally
23 published elsewhere. Such incorporation does not include later amendments to or
24 editions of the referenced material. The Department maintains certified copies of the
25 complete text of any material incorporated by reference for public inspection during
26 regular business hours and shall provide certified copies of the incorporated material at
27 cost upon request. Information regarding how to obtain or examine the incorporated
28 material is available from the Division Director, ~~Consumer Protection Division,~~
29 DIVISION OF ENVIRONMENTAL HEALTH AND SUSTAINABILITY, Colorado Department of
30 Public Health and Environment, 4300 Cherry Creek Drive South, Denver, CO 80246-
31 1530.

32 Copies of the incorporated materials have been provided to the State Publications
33 Depository and Distribution Center, and are available for interlibrary loan. Any
34 incorporated material may be examined at any State Publications Depository Library.

35 **11-702 Safe Materials**

36 The Colorado Pure Food and Drug Law, the Federal Food, Drug and Cosmetic Act and
37 applicable regulations of the U.S. Food and Drug Administration used for the
38 determination of material safety in section 1-202() of these rules and regulations may be
39 obtained from the DIVISION Director, ~~of the Consumer Protection Division~~ DIVISION OF
40 ENVIRONMENTAL HEALTH AND SUSTAINABILITY, ~~of the~~ Colorado Department of Public
41 Health and Environment, 4300 CHERRY CREEK DRIVE SOUTH, DENVER, CO 80246-
42 1530 and/or the U.S. Federal Food and Drug Administration.

1 **11-703 Food Protection Act**

2 Copies of section 25-4-1601 et seq., C.R.S may be obtained from the Director of the
3 ~~Consumer Protection Division~~ DIVISION OF ENVIRONMENTAL HEALTH AND
4 SUSTAINABILITY of the Colorado Department of Public Health and Environment

5 **11-704 Milk Standards**

6 Copies of the Grade A Standards referenced in section 3-305 of these regulations may be
7 obtained from the Director of the ~~Consumer Protection Division~~ DIVISION OF
8 ENVIRONMENTAL HEALTH AND SUSTAINABILITY of the Colorado Department of Public
9 Health and Environment.

10 **11-705 Ventilation Requirements**

11 Copies of the ~~(2000) Uniform Mechanical~~ 2006 INTERNATIONAL MECHANICAL CODE
12 or Local Ventilation Codes referenced in section 4-212 of these rules and regulations
13 may be obtained from the International Conference of Building Officials, 503 Alhambra
14 Avenue, Los Angeles, California 90032-3490 or the Local Building Department of
15 jurisdiction, respectively.

16 **11-706 Code of Federal Regulations**

17 Copies of the () Code of Federal Regulations referenced in sections ~~3-211, 4-202, 4-207,~~
18 ~~4-403, 5-103, 5-108, 7-107, and 7-108~~ 3-101, 3-312, 3-408, 3-607, 3-702, 4-202, 4-207,
19 4-403, 4-404, 5-103, 5-108, 7-105, 7-107, 7-108 may be obtained from the Director,
20 Office of the Federal Register, National Archives and Records Administration,
21 Washington DC 20408.

22 **11-707 Plumbing Requirements**

23 Copies of the ~~(2000) Uniform Plumbing~~ 2009 INTERNATIONAL PLUMBING CODE or
24 Local Plumbing Codes referenced in sections 5-201, 5-206, 5-208, and 5-209 may be
25 obtained from the International Association of Plumbing and Mechanical Officials,
26 20001 Walnut Drive South, Walnut, California 91789-2825 and/or the Local Building
27 Department of jurisdiction, respectively.

28 **11-708 Administrative Statutes**

29 Copies of sections 16-13-305, 306 and 308, C.R.S.; 24-4-106, C.R.S.; 25-1.5-101(1)(a),
30 C.R.S.; 25-1-108 (1)(k), C.R.S.; 25-1-506 (1)(d), C.R.S.; 25-4-401 et seq., C.R.S.;
31 25-4-1301 et seq., C.R.S.; 25-4-105, C.R.S.; 25-4-1608, C.R.S.; and 25-5-406 (1) and
32 (4) C.R.S., referenced in sections ~~3-312, 3-601,~~ 1-202, 3-305, 3-401, 3-409, 3-410, 3-
33 701, 5-101, 9-104, 11-101, 11-103, 11-104, 11-105, 11-106, 11-301 and 11-601 of these
34 rules and regulations may be obtained from the Director of the ~~Consumer Protection~~
35 ~~Division~~ DIVISION OF ENVIRONMENTAL HEALTH AND SUSTAINABILITY of the Colorado
36 Department of Public Health and Environment.

37 **11-709 American National Standards Institute (ANSI)**

38 Copies of the National Sanitation Foundation Standards for food equipment that are
39 classified for sanitation by an American National Standards Institute (ANSI) accredited
40 certification program referenced in section 4-101 of these rules and regulations may be
41 obtained from the Director of the ~~Consumer Protection Division~~ DIVISION OF

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1 ENVIRONMENTAL HEALTH AND SUSTAINABILITY of the Colorado Department of Public
2 Health and Environment

APPENDIX A ~~Potentially Hazardous (Time/Temperature Control for Safety Food)~~

~~"Potentially Hazardous Food" means any food or food ingredient, natural or synthetic, in a form capable of supporting the rapid and progressive growth of infectious or toxigenic microorganisms or the slower growth of *C. botulinum*.~~

~~A food is potentially hazardous: a) if it is of animal origin such as meat, milk, fish, shellfish, edible crustacea, or poultry; or b) if it is of plant origin and has been heat treated; or c) if it is raw seed sprouts.~~

~~The following is a limited list of specific food products that have been classified to be potentially hazardous.~~

- ~~1. Bacon If it has not been fully cooked.~~
- ~~2. Balutes Fertile eggs, generally chicken or duck eggs, which are incubated for a period of time shorter than is necessary for hatching. The developing embryo is incubated generally 14 to 18 days and is considered a delicacy by various ethnic populations when eaten raw or cooked.~~
- ~~3. Beans All types of cooked beans.~~
- ~~4. Whipped Butter Hazardous because of the apparent reduced microbiological safety factor created by whipping.~~
- ~~5. Cheese Soft unripened cheese. Ripened, low moisture hard cheese such as wheels, flats, blocks or longhorns of cheddar cheese produced from pasteurized milk, when waxed or packaged in "shrink" wrapping with the wax or packaging intact, can be safely shipped or stored for a short period of time without refrigeration but it is not recommended. If wheels, flats, blocks, longhorns, or any other forms of cheese have been damaged, cut and repackaged for display and/or sale, thereby exposing interior surfaces to possible contamination, the cut portions as well as the remaining cheese shall be held under refrigeration.~~
- ~~6. Coffee Creaming Agents All non dairy coffee creaming agents in liquid form, except aseptically processed ultra high temperature (UHT) liquid coffee creaming agents.~~
- ~~7. Eggs Cooked, cracked, fresh with outer shell removed, peeled hard boiled eggs, and hard boiled eggs with intact shells which have been hard boiled and then cooled in liquid. Refrigeration of raw whole eggs in the shell is required.~~
- ~~8. Garlic Garlic in oil products.~~
- ~~9. Mayonnaise or Other Acidified Salad Dressings If the pH is above 4.6 and/or combined with other food products.~~
- ~~1. Onions Cooked and dehydrated that have been reconstituted.~~
- ~~11. Pasta All types that have been cooked.~~
- ~~12. Pastries Meat, cheese and cream filled.~~

13. — ~~Pies — Meat, fish, poultry, natural cream, synthetic cream, custard, pumpkin and pies that are covered with toppings which will support microbial growth.~~
14. — ~~Potatoes — Baked, boiled or fried.~~
15. — ~~Rice — Boiled, steamed, fried, Spanish and cooked rice used in sushi.~~
16. — ~~Sauces — Hollandaise and other sauces, containing potentially hazardous ingredients. If these are held in the temperature range of $^{\circ}$ ($^{\circ}$) to 135°F ($^{\circ}$), they must be discarded within four hours of preparation.~~
17. — ~~Sour Cream — If the pH is above 4.6 and/or combined with other food products.~~
18. — ~~Soy Protein — Tofu and other moist soy protein products.~~
19. — ~~Seed Sprouts — All types.~~

~~Foods Which Are Not Potentially Hazardous Are:~~

1. — ~~Hard Boiled eggs with shells intact which have been air dried;~~
2. — ~~Foods with a water activity (α) value of 0.85 or less;~~
3. — ~~Foods with a measurement of acidity (pH) of 4.6 or below;~~
4. — ~~Foods which have been adequately commercially processed and remain in their unopened hermetically sealed container; and~~
5. — ~~Food for which laboratory evidence (acceptable to the regulatory authority) demonstrates that rapid progressive growth of infectious and toxigenic microorganisms or the slower growth of C. botulinum cannot occur.~~

APPENDIX A - POTENTIALLY HAZARDOUS FOODS

POTENTIALLY HAZARDOUS FOOD (PHF/TCS FOOD) IS DEFINED IN TERMS OF WHETHER OR NOT IT REQUIRES TIME/TEMPERATURE CONTROL FOR SAFETY TO LIMIT PATHOGEN GROWTH OR TOXIN FORMATION. THE TERM DOES NOT INCLUDE FOODS THAT DO NOT SUPPORT GROWTH BUT MAY CONTAIN A PATHOGENIC MICROORGANISM OR CHEMICAL OR PHYSICAL FOOD SAFETY HAZARD AT A LEVEL SUFFICIENT TO CAUSE FOODBORNE ILLNESS OR INJURY. THE PROGRESSIVE GROWTH OF ALL FOODBORNE PATHOGENS IS CONSIDERED WHETHER SLOW OR RAPID.

THE DEFINITION OF PHF/TCS FOOD TAKES INTO CONSIDERATION pH, a_w , pH AND INTERACTION, HEAT TREATMENT, AND PACKAGING FOR A RELATIVELY SIMPLE DETERMINATION OF WHETHER THE FOOD REQUIRES TIME/TEMPERATURE CONTROL FOR SAFETY. IF THE FOOD IS HEAT-TREATED TO ELIMINATE VEGETATIVE CELLS, IT NEEDS TO BE ADDRESSED DIFFERENTLY THAN A RAW PRODUCT WITH NO, OR INADEQUATE, HEAT TREATMENT. IN ADDITION, IF THE FOOD IS PACKAGED AFTER HEAT TREATMENT TO DESTROY VEGETATIVE CELLS AND SUBSEQUENTLY PACKAGED TO PREVENT RE-CONTAMINATION, HIGHER RANGES OF pH AND/OR a_w CAN BE TOLERATED BECAUSE REMAINING SPORE-FORMING BACTERIA ARE THE ONLY MICROBIAL HAZARDS OF CONCERN. WHILE FOODS WILL NEED TO BE COOLED SLIGHTLY TO PREVENT CONDENSATION INSIDE THE PACKAGE, THEY MUST BE PROTECTED FROM CONTAMINATION IN AN AREA WITH LIMITED ACCESS AND PACKAGED BEFORE TEMPERATURES DROP BELOW 135°F (57°C). IN SOME FOODS, IT IS POSSIBLE THAT NEITHER THE pH VALUE NOR THE a_w VALUE IS LOW ENOUGH BY ITSELF TO CONTROL OR ELIMINATE PATHOGEN GROWTH; HOWEVER, THE INTERACTION OF pH AND a_w MAY BE ABLE TO ACCOMPLISH IT. THIS IS AN EXAMPLE OF A HURDLE TECHNOLOGY. HURDLE TECHNOLOGY INVOLVES SEVERAL INHIBITORY FACTORS BEING USED TOGETHER TO CONTROL OR ELIMINATE PATHOGEN GROWTH, WHEN THEY WOULD OTHERWISE BE INEFFECTIVE IF USED ALONE. WHEN NO OTHER INHIBITORY FACTORS ARE PRESENT AND THE pH AND/OR a_w VALUES ARE UNABLE TO CONTROL OR ELIMINATE BACTERIAL PATHOGENS WHICH MAY BE PRESENT, GROWTH MAY OCCUR AND FOODBORNE OUTBREAKS RESULT. CUT MELONS, CUT TOMATOES, AND CUT LEAFY GREENS ARE EXAMPLES WHERE INTRINSIC FACTORS ARE UNABLE TO CONTROL BACTERIAL GROWTH ONCE PATHOGENS ARE EXPOSED TO THE CELLULAR FLUIDS AND NUTRIENTS AFTER CUTTING.

IN DETERMINING IF TIME/TEMPERATURE CONTROL IS REQUIRED, COMBINATION PRODUCTS PRESENT THEIR OWN CHALLENGE. A COMBINATION PRODUCT IS ONE IN WHICH THERE ARE TWO OR MORE DISTINCT FOOD COMPONENTS AND AN INTERFACE BETWEEN THE TWO COMPONENTS MAY HAVE A DIFFERENT PROPERTY THAN EITHER OF THE INDIVIDUAL COMPONENTS. A DETERMINATION MUST BE MADE ABOUT WHETHER THE FOOD HAS DISTINCT COMPONENTS SUCH AS PIE WITH MERINGUE TOPPING, FOCACCIA BREAD, MEAT SALADS, OR FETTUCCHINE ALFREDO WITH CHICKEN OR WHETHER IT HAS A UNIFORM CONSISTENCY SUCH AS GRAVIES, PUDDINGS, OR SAUCES. IN THESE PRODUCTS, THE pH AT THE INTERFACE IS IMPORTANT IN DETERMINING IF THE ITEM IS A PHF/TCS FOOD.

A WELL DESIGNED INOCULATION STUDY OR OTHER PUBLISHED SCIENTIFIC RESEARCH SHOULD BE USED TO DETERMINE WHETHER A FOOD CAN BE HELD WITHOUT TIME/TEMPERATURE CONTROL WHEN:

- PROCESS TECHNOLOGIES OTHER THAN HEAT ARE APPLIED TO DESTROY FOODBORNE PATHOGENS (E.G., IRRADIATION, HIGH PRESSURE PROCESSING, PULSED LIGHT, OZONATION);
- COMBINATION PRODUCTS ARE PREPARED; OR
- OTHER EXTRINSIC FACTORS (E.G., PACKAGING/ATMOSPHERES) OR INTRINSIC FACTORS (E.G., REDOX POTENTIAL, SALT CONTENT, AND ANTIMICROBIALS) ARE USED TO CONTROL OR ELIMINATE PATHOGEN GROWTH.

BEFORE USING TABLES A AND B LISTED IN THE DEFINITION SECTION UNDER ITEM 79 FOR "POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD)" IN DETERMINING WHETHER A FOOD REQUIRES TIME/TEMPERATURE CONTROL FOR SAFETY (TCS), ANSWERS TO THE FOLLOWING QUESTIONS SHOULD BE CONSIDERED:

- IS THE INTENT TO HOLD THE FOOD WITHOUT USING TIME OR TEMPERATURE CONTROL?
 - IF THE ANSWER IS NO, NO FURTHER ACTION IS REQUIRED. THE DECISION TREE LATER IN THIS APPENDIX IS NOT NEEDED TO DETERMINE IF THE ITEM IS A PHF/TCS FOOD.
- IS THE FOOD RAW, OR IS THE FOOD HEAT-TREATED?
- DOES THE FOOD ALREADY REQUIRE TIME/TEMPERATURE CONTROL FOR SAFETY UTILIZING THE DEFINITION OF "POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD)"?
- DOES A PRODUCT HISTORY WITH SOUND SCIENTIFIC RATIONALE EXIST INDICATING A SAFE HISTORY OF USE?
- IS THE FOOD PROCESSED AND PACKAGED SO THAT IT NO LONGER REQUIRES TCS SUCH AS ULTRA HIGH TEMPERATURE (UHT) CREAMERS OR SHELF-STABLE CANNED GOODS?
- WHAT IS THE pH AND a_w OF THE FOOD IN QUESTION USING AN INDEPENDENT LABORATORY AND ASSOCIATION OF OFFICIAL ANALYTICAL CHEMISTS (AOAC) METHODS OF ANALYSIS?

A FOOD DESIGNATED AS PRODUCT ASSESSMENT REQUIRED (PA), IN EITHER TABLE SHOULD BE CONSIDERED PHF/TCS FOOD UNTIL FURTHER STUDY PROVES OTHERWISE. THE PA MEANS THAT BASED ON THE FOOD'S pH AND a_w AND WHETHER IT WAS RAW OR HEAT-TREATED OR PACKAGED, IT HAS TO BE CONSIDERED PHF/TCS UNTIL INOCULATION STUDIES OR SOME OTHER ACCEPTABLE EVIDENCE SHOWS THAT THE FOOD IS A PHF/TCS FOOD OR NOT. THE RULES AND REGULATIONS REQUIRE A VARIANCE REQUEST TO THE REGULATORY AUTHORITY WITH THE EVIDENCE THAT THE FOOD DOES NOT REQUIRE TIME/TEMPERATURE CONTROL FOR SAFETY.

THE RULES AND REGULATIONS DEFINITION DESIGNATES CERTAIN RAW PLANT FOODS AS PHF/TCS FOOD BECAUSE THEY HAVE BEEN SHOWN TO SUPPORT THE GROWTH OF FOODBORNE PATHOGENS IN THE ABSENCE OF TEMPERATURE CONTROL AND TO LACK INTRINSIC FACTORS THAT WOULD INHIBIT PATHOGEN GROWTH. UNLESS PRODUCT ASSESSMENT SHOWS OTHERWISE, THESE DESIGNATIONS ARE SUPPORTED BY TABLES A AND B. FOR EXAMPLE:

FOR CUT CANTALOUPE (pH 6.2-7.1, $\text{a}_w > 0.99$, NOT HEAT-TREATED), FRESH SPROUTS (pH > 6.5 , $\text{a}_w > 0.99$, NOT HEAT-TREATED), AND CUT TOMATOES (pH 4.23 - 5.04, $\text{a}_w > 0.99$, NOT HEAT-TREATED), TABLE B INDICATES THAT THEY ARE CONSIDERED PHF/TCS FOODS UNLESS A PRODUCT ASSESSMENT SHOWS OTHERWISE. MAINTAINING THESE PRODUCTS UNDER THE TEMPERATURE CONTROL REQUIREMENTS PRESCRIBED IN THIS CODE FOR PHF/TCS FOOD WILL LIMIT THE GROWTH OF PATHOGENS THAT MAY BE PRESENT IN OR ON THE FOOD AND MAY HELP PREVENT FOODBORNE ILLNESS.

IF A FACILITY ADJUSTS THE pH OF A FOOD USING VINEGAR, LEMON JUICE, OR CITRIC ACID FOR PURPOSES OTHER THAN FLAVOR ENHANCEMENT, A HACCP PLAN AND APPROVAL FROM THE DEPARTMENT IS REQUIRED UNDER 3-606. A HACCP PLAN IS REQUIRED WHETHER THE FOOD IS A PHF/TCS FOOD AS IN SECTION 3-606 (A)(3)(A) OF THESE RULES AND REGULATIONS OR NOT A PHF/TCS FOOD, AS IN SECTION 3-606(A)(3)(B) OF THESE RULES AND REGULATIONS. A STANDARDIZED RECIPE VALIDATED BY LAB TESTING FOR pH AND a_w WOULD BE AN APPROPRIATE PART OF THE APPROVAL PROCESS WITH ANNUAL (OR OTHER FREQUENCY AS SPECIFIED BY THE REGULATORY AUTHORITY) SAMPLES TESTED TO VERIFY COMPLIANCE WITH THE CONDITIONS OF THE VARIANCE.

INSTRUCTIONS FOR USING THE FOLLOWING DECISION TREE AND TABLE A AND TABLE B:

1. DOES THE OPERATOR WANT TO HOLD THE FOOD WITHOUT USING TIME OR TEMPERATURE CONTROL?
 - a. No - CONTINUE HOLDING THE FOOD AT $\leq 41^\circ\text{F}$ (5°C) OR $\geq 135^\circ\text{F}$ (57°C) FOR SAFETY AND/OR QUALITY.

- b. YES - CONTINUE USING THE DECISION TREE TO IDENTIFY WHICH TABLE TO USE TO DETERMINE WHETHER TIME/TEMPERATURE CONTROL FOR SAFETY (TCS) IS REQUIRED.
2. IS THE FOOD HEAT-TREATED?
 - a. NO - THE FOOD IS EITHER RAW, PARTIALLY COOKED (NOT COOKED TO THE TEMPERATURE SPECIFIED IN SECTION 3-502 OF THE RULES AND REGULATIONS) OR TREATED WITH SOME OTHER METHOD OTHER THAN HEAT. PROCEED TO STEP #3.
 - b. YES - IF THE FOOD IS HEAT-TREATED TO THE REQUIRED TEMPERATURE FOR THAT FOOD AS SPECIFIED UNDER SECTION 3-502 OF THE RULES AND REGULATIONS, VEGETATIVE CELLS WILL BE DESTROYED ALTHOUGH SPORES WILL SURVIVE. PROCEED TO STEP #4.
 3. IS THE FOOD TREATED USING SOME OTHER METHOD?
 - a. NO - THE FOOD IS RAW OR HAS ONLY RECEIVED A PARTIAL COOK ALLOWING VEGETATIVE CELLS AND SPORES TO SURVIVE. PROCEED TO STEP #6.
 - b. YES - IF A METHOD OTHER THAN HEAT IS USED TO DESTROY PATHOGENS SUCH AS IRRADIATION, HIGH PRESSURE PROCESSING, PULSED LIGHT, ULTRASOUND, INDUCTIVE HEATING, OR OZONATION, THE EFFECTIVENESS OF THE PROCESS NEEDS TO BE VALIDATED BY INOCULATION STUDIES OR OTHER MEANS. PROCEED TO STEP #5.
 4. IS IT PACKAGED TO PREVENT RE-CONTAMINATION?
 - a. NO - RE-CONTAMINATION OF THE PRODUCT CAN OCCUR AFTER HEAT TREATMENT BECAUSE IT IS NOT PACKAGED. PROCEED TO STEP #6.
 - b. YES - IF THE FOOD IS PACKAGED IMMEDIATELY AFTER HEAT TREATMENT TO PREVENT RE-CONTAMINATION, HIGHER RANGES OF pH AND/OR CAN BE TOLERATED BECAUSE SPORE-FORMING BACTERIA ARE THE ONLY MICROBIAL HAZARD. PROCEED TO STEP #7.
 5. FURTHER PRODUCT ASSESSMENT OR VENDOR DOCUMENTATION REQUIRED.
 - a. THE VENDOR OF THIS PRODUCT MAY BE ABLE TO SUPPLY DOCUMENTATION THAT INOCULATION STUDIES INDICATE THE FOOD CAN BE SAFELY HELD WITHOUT TIME/TEMPERATURE CONTROL FOR SAFETY.
 - b. FOOD PREPARED OR PROCESSED USING NEW TECHNOLOGIES MAY BE HELD WITHOUT TIME/TEMPERATURE CONTROL PROVIDED THE EFFECTIVENESS OF THE USE OF SUCH TECHNOLOGIES IS BASED ON A VALIDATED INOCULATION STUDY.
 6. USING THE FOOD'S KNOWN pH AND/OR VALUES, POSITION THE FOOD IN THE APPROPRIATE TABLE.
 - a. CHOOSE THE COLUMN UNDER "pH VALUES" THAT CONTAINS THE pH VALUE OF THE FOOD IN QUESTION.
 - b. CHOOSE THE ROW UNDER " VALUES" THAT CONTAINS THE VALUE OF THE FOOD IN QUESTION.
 - c. NOTE WHERE THE ROW AND COLUMN INTERSECT TO IDENTIFY WHETHER THE FOOD IS "NON-PHF/NON-TCS FOOD" AND THEREFORE DOES NOT REQUIRE TIME/TEMPERATURE CONTROL, OR WHETHER FURTHER PRODUCT ASSESSMENT (PA) IS REQUIRED. OTHER FACTORS SUCH AS REDOX POTENTIAL, COMPETITIVE MICROORGANISMS, SALT CONTENT, OR PROCESSING METHODS MAY ALLOW THE PRODUCT TO BE HELD WITHOUT TIME/TEMPERATURE CONTROL BUT AN INOCULATION STUDY IS REQUIRED.
 7. USE **TABLE A** FOR FOODS THAT ARE HEAT-TREATED AND PACKAGED **OR** USE **TABLE B** FOR FOODS THAT ARE NOT HEAT-TREATED OR HEAT-TREATED BUT NOT PACKAGED.
 8. DETERMINE IF THE ITEM IS NON-PHF/NON-TCS OR NEEDS FURTHER PRODUCT ASSESSMENT (PA).

DECISION TREE #1 - USING pH, a_w , OR THE INTERACTION OF pH AND a_w TO DETERMINE IF A FOOD REQUIRES TIME/TEMPERATURE CONTROL FOR SAFETY

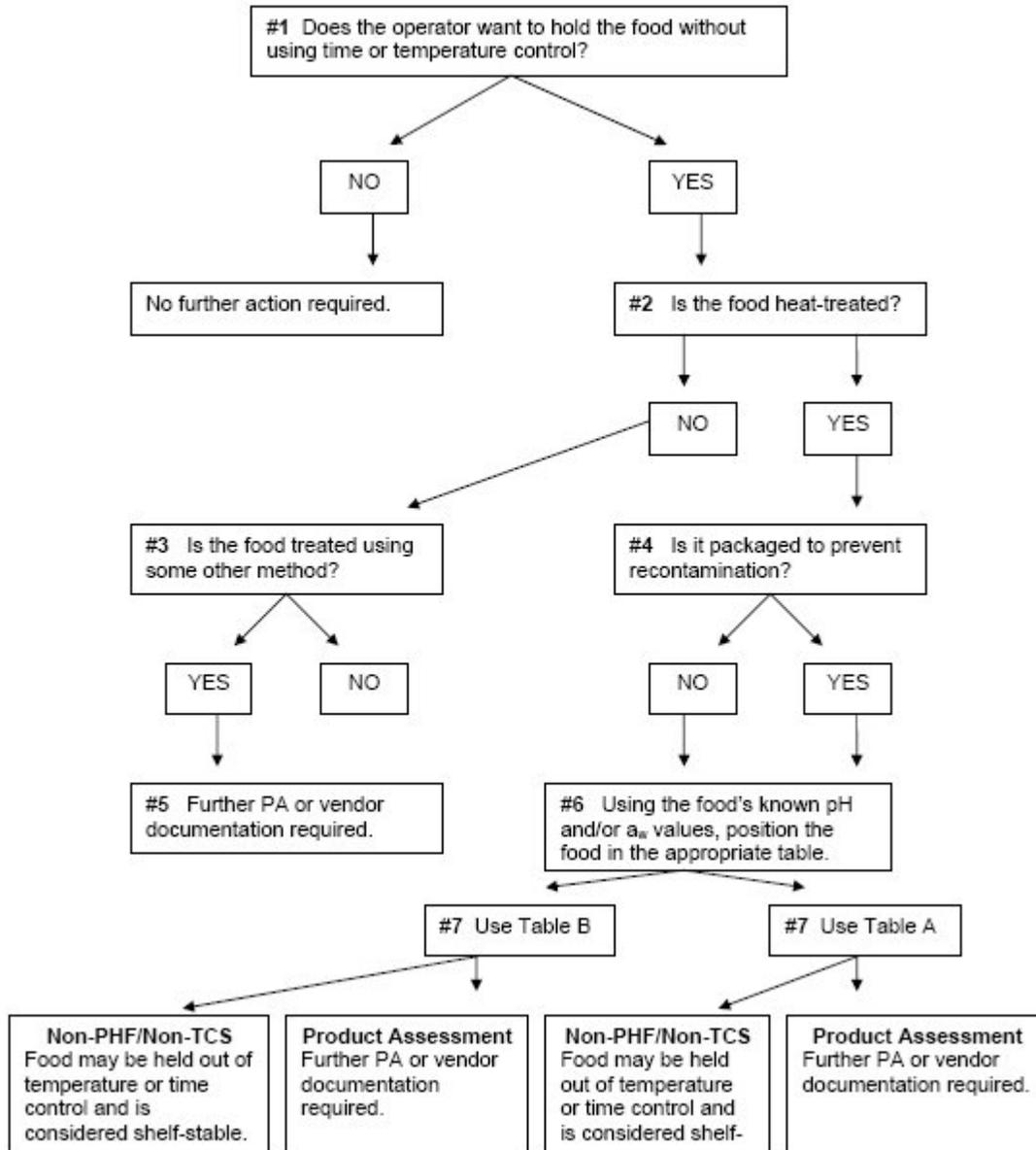


TABLE A AND TABLE B

TABLE A. INTERACTION OF PH AND FOR CONTROL OF SPORES IN FOOD HEAT-TREATED TO DESTROY VEGETATIVE CELLS AND SUBSEQUENTLY PACKAGED			
VALUES	<u>PH VALUES</u>		
	4.6 OR LESS	> 4.6 - 5.6	> 5.6
≤ 0.92	NON-PHF*/NON-TCS FOOD**	NON-PHF/NON-TCS FOOD	NON-PHF/NON-TCS FOOD
> 0.92 - .95	NON-PHF/NON-TCS FOOD	NON-PHF/NON-TCS FOOD	PA***
> 0.95	NON-PHF/NON-TCS FOOD	PA	PA

* PHF MEANS POTENTIALLY HAZARDOUS FOOD

** TCS FOOD MEANS TIME/TEMPERATURE CONTROL FOR SAFETY FOOD

*** PA MEANS PRODUCT ASSESSMENT REQUIRED

TABLE B. INTERACTION OF PH AND FOR CONTROL OF VEGETATIVE CELLS AND SPORES IN FOOD NOT HEAT-TREATED OR HEAT-TREATED BUT NOT PACKAGED

VALUES	<u>PH VALUES</u>			
	< 4.2	4.2 - 4.6	> 4.6 - 5.0	> 5.0
< 0.88	NON-PHF*/ NON-TCS FOOD**	NON-PHF/ NON-TCS FOOD	NON-PHF/ NON-TCS FOOD	NON-PHF/ NON-TCS FOOD
0.88 - 0.90	NON-PHF/ NON-TCS FOOD	NON-PHF/ NON-TCS FOOD	NON-PHF/ NON-TCS FOOD	PA***
> 0.90 - 0.92	NON-PHF/ NON-TCS FOOD	NON-PHF/ NON-TCS FOOD	PA	PA
> 0.92	NON-PHF/ NON-TCS FOOD	PA	PA	PA

* PHF MEANS POTENTIALLY HAZARDOUS FOOD

** TCS FOOD MEANS TIME/TEMPERATURE CONTROL FOR SAFETY FOOD

*** PA MEANS PRODUCT ASSESSMENT REQUIRED

THE FOLLOWING IS A LIMITED LIST OF SPECIFIC FOOD PRODUCTS THAT HAVE BEEN CLASSIFIED TO BE POTENTIALLY HAZARDOUS.

1. BACON - IF IT HAS NOT BEEN FULLY COOKED.
2. BALUTES - FERTILE EGGS, GENERALLY CHICKEN OR DUCK EGGS, WHICH ARE INCUBATED FOR A PERIOD OF TIME SHORTER THAN IS NECESSARY FOR HATCHING. THE DEVELOPING EMBRYO IS INCUBATED GENERALLY 14 TO 18 DAYS AND IS CONSIDERED A DELICACY BY VARIOUS ETHNIC POPULATIONS WHEN EATEN RAW OR COOKED.
3. BEANS - ALL TYPES OF COOKED BEANS.
4. WHIPPED BUTTER - HAZARDOUS BECAUSE OF THE APPARENT REDUCED MICROBIOLOGICAL SAFETY FACTOR CREATED BY WHIPPING.
5. CHEESE - SOFT UNRIPENED CHEESE. RIPENED, LOW MOISTURE HARD CHEESE SUCH AS WHEELS, FLATS, BLOCKS OR LONGHORNS OF CHEDDAR CHEESE PRODUCED FROM PASTEURIZED MILK, WHEN WAXED OR PACKAGED IN "SHRINK" WRAPPING WITH THE WAX OR PACKAGING INTACT, CAN BE SAFELY SHIPPED OR STORED FOR A SHORT PERIOD OF TIME WITHOUT REFRIGERATION BUT IT IS NOT

- RECOMMENDED. IF WHEELS, FLATS, BLOCKS, LONGHORNS, OR ANY OTHER FORMS OF CHEESE HAVE BEEN DAMAGED, CUT AND REPACKAGED FOR DISPLAY AND/OR SALE, THEREBY EXPOSING INTERIOR SURFACES TO POSSIBLE CONTAMINATION, THE CUT PORTIONS AS WELL AS THE REMAINING CHEESE SHALL BE HELD UNDER REFRIGERATION.
6. COFFEE CREAMING AGENTS - ALL NON-DAIRY COFFEE CREAMING AGENTS IN LIQUID FORM, EXCEPT ASEPTICALLY PROCESSED ULTRA HIGH TEMPERATURE (UHT) LIQUID COFFEE CREAMING AGENTS.
 7. CUT LEAFY GREENS- FOLLOWING 24 MULTI-STATE OUTBREAKS BETWEEN 1998 AND 2008, CUT LEAFY GREENS WAS ADDED TO THE DEFINITION OF POTENTIALLY HAZARDOUS FOOD REQUIRING TIME-TEMPERATURE CONTROL FOR SAFETY (TCS). THE TERM USED IN THE DEFINITION INCLUDES A VARIETY OF CUT LETTUCES AND LEAFY GREENS. RAW AGRICULTURAL COMMODITIES (RACs) THAT ARE NOT PROCESSED OR CUT ON-SITE ARE EXCLUDED FROM THE DEFINITION OF CUT LEAFY GREENS. HERBS SUCH AS CILANTRO OR PARSLEY ARE ALSO NOT CONSIDERED CUT LEAFY GREENS. THE pH, WATER ACTIVITY, AVAILABLE MOISTURE AND NUTRIENTS OF CUT LEAFY GREENS SUPPORTS THE GROWTH OF FOODBORNE PATHOGENS AND REFRIGERATION AT 41°F (5°C) OR LESS INHIBITS GROWTH AND PROMOTES GENERAL DIE OFF IN SOME PATHOGENS SUCH AS *E. COLI* O157:H7, *SALMONELLA*, *E. COLI* O157:H7 AND *LISTERIA MONOCYTOGENES*, ONCE ATTACHED TO THE SURFACE OR INTERNALIZED INTO CUT SURFACES OF LEAFY GREENS, ARE ONLY marginally affected BY CHEMICAL SANITIZERS.
 8. CUT TOMATOES- HISTORICALLY, UNCOOKED FRUITS AND VEGETABLES, SUCH AS CUT TOMATOES, HAVE BEEN CONSIDERED NON-PHF UNLESS THEY WERE EPIDEMIOLOGICALLY IMPLICATED IN FOODBORNE ILLNESS OUTBREAKS AND ARE CAPABLE OF SUPPORTING THE GROWTH OF PATHOGENIC BACTERIA IN THE ABSENCE OF TEMPERATURE CONTROL. THE US FOOD AND DRUG ADMINISTRATION (FDA) HAS REPORTED THAT SINCE 1990, AT LEAST 12 MULTI-STATE FOODBORNE ILLNESS OUTBREAKS HAVE BEEN ASSOCIATED WITH DIFFERENT VARIETIES OF TOMATOES AND ADDITIONALLY, FROM 1998-2006, OUTBREAKS ASSOCIATED WITH TOMATOES MADE UP 17% OF THE PRODUCE RELATED OUTBREAKS REPORTED TO FDA NATIONWIDE. *SALMONELLA* HAS BEEN THE PATHOGEN OF CONCERN MOST OFTEN ASSOCIATED WITH TOMATO OUTBREAKS.
 9. EGGS - COOKED, CRACKED, FRESH WITH OUTER SHELL REMOVED, PEELED HARD-BOILED EGGS, AND HARD-BOILED EGGS WITH INTACT SHELLS WHICH HAVE BEEN HARD-BOILED AND THEN COOLED IN LIQUID. REFRIGERATION OF RAW WHOLE EGGS IN THE SHELL IS REQUIRED.
 10. GARLIC - GARLIC IN OIL PRODUCTS.
 11. MAYONNAISE OR OTHER ACIDIFIED SALAD DRESSINGS - IF THE pH IS ABOVE 4.6 AND/OR COMBINED WITH OTHER FOOD PRODUCTS.
 12. ONIONS- COOKED AND DEHYDRATED THAT HAVE BEEN RECONSTITUTED.
 13. PASTA - ALL TYPES THAT HAVE BEEN COOKED.
 14. PASTRIES - MEAT, CHEESE AND CREAM FILLED.
 15. PIES - MEAT, FISH, POULTRY, NATURAL CREAM, SYNTHETIC CREAM, CUSTARD, PUMPKIN AND PIES THAT ARE COVERED WITH TOPPING WHICH WILL SUPPORT MICROBIAL GROWTH.
 16. POTATOES - BAKED, BOILED OR FRIED.
 17. RICE - BOILED, STEAMED, FRIED, SPANISH AND COOKED RICE USED IN SUSHI.
 18. SOUR CREAM - IF THE pH IS ABOVE 4.6 AND/OR COMBINED WITH OTHER FOOD PRODUCTS.
 19. SOY PROTEIN - TOFU AND OTHER MOIST SOY PROTEIN PRODUCTS.
 20. SEED SPROUTS - ALL TYPES.

FOODS WHICH ARE NOT POTENTIALLY HAZARDOUS ARE:

1. HARD-BOILED EGGS WITH SHELLS INTACT WHICH HAVE BEEN AIR-DRIED; AND
2. FOODS WHICH HAVE BEEN ADEQUATELY COMMERCIALY PROCESSED AND REMAIN IN THEIR UNOPENED HERMETICALLY SEALED CONTAINER.

APPENDIX B - Safe Materials Colorado Pure Food and Drug Law

Sections 25-5-402 (3) and (12), C.R.S.

- (3) a. ~~"Color additive" means a material which:~~
1. ~~Is a dye, pigment, or other substance made by a process of synthesis or similar artifice or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source; and~~
 2. ~~When added or applied to a food, drug, or cosmetic or to the human body or any part thereof; is capable (alone or through reaction with other substance) of imparting color thereto; except that such term does not include any material which is exempted under the federal act.~~
- b. ~~Nothing in this subsection (3) shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological process or produce of the soil and thereby affecting its color, whether before or after harvest.~~
- (12) ~~"Food additive" means any substance, the intended use of which results or may be reasonably expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding such substance is not generally recognized among experts qualified by scientific training and experience to evaluate its safety as having been adequately shown through scientific procedures or, in the case of a substance used in a food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use. The term does not include:~~
- a. ~~A pesticide chemical in or on a raw agricultural commodity;~~
 - b. ~~A pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity;~~
 - c. ~~A color additive; or~~
 - d. ~~Any substance used in accordance with a sanction or approval granted prior to the enactment of the amendment to the federal act known as the "Food Additives Amendment of 1958," the Poultry Products Inspectional Act" (21 U.S.C. 451-470), or the "Meat Inspection Act of March 4, 1907," as amended and extended (21 U.S.C. 71-91).~~

APPENDIX B - SAFE MATERIALS COLORADO PURE FOOD AND DRUG LAW

SECTIONS 25-5-402 (3) AND (12), C.R.S.

- (3) A. "COLOR ADDITIVE" MEANS A MATERIAL WHICH:
- (I.) IS A DYE, PIGMENT, OR OTHER SUBSTANCE MADE BY A PROCESS OF SYNTHESIS OR SIMILAR ARTIFICE OR EXTRACTED, ISOLATED, OR OTHERWISE DERIVED, WITH OR WITHOUT INTERMEDIATE OR FINAL CHANGE OF IDENTITY, FROM A VEGETABLE, ANIMAL, MINERAL, OR OTHER SOURCE; AND
 - (II.) WHEN ADDED OR APPLIED TO A FOOD, DRUG, OR COSMETIC OR TO THE HUMAN BODY OR ANY PART THEREOF; IS CAPABLE (ALONE OR THROUGH REACTION WITH OTHER SUBSTANCE) OF IMPARTING COLOR THERETO; EXCEPT THAT SUCH TERM DOES NOT INCLUDE ANY MATERIAL WHICH IS EXEMPTED UNDER THE FEDERAL ACT.
- B. NOTHING IN THIS SUBSECTION (3) SHALL BE CONSTRUED TO APPLY TO ANY PESTICIDE CHEMICAL, SOIL OR PLANT NUTRIENT, OR OTHER AGRICULTURAL CHEMICAL SOLELY BECAUSE OF ITS EFFECT IN AIDING, RETARDING, OR OTHERWISE AFFECTING, DIRECTLY OR INDIRECTLY, THE GROWTH OR OTHER NATURAL PHYSIOLOGICAL PROCESS OR PRODUCE OF THE SOIL AND THEREBY AFFECTING ITS COLOR, WHETHER BEFORE OR AFTER HARVEST.
- (12) "FOOD ADDITIVE" MEANS ANY SUBSTANCE, THE INTENDED USE OF WHICH RESULTS OR MAY BE REASONABLY EXPECTED TO RESULT, DIRECTLY OR INDIRECTLY, IN ITS BECOMING A COMPONENT OR OTHERWISE AFFECTING THE CHARACTERISTICS OF ANY FOOD (INCLUDING ANY SUBSTANCE INTENDED FOR USE IN PRODUCING, MANUFACTURING, PACKING, PROCESSING, PREPARING, TREATING, PACKAGING, TRANSPORTING, OR HOLDING SUCH SUBSTANCE IS NOT GENERALLY RECOGNIZED AMONG EXPERTS QUALIFIED BY SCIENTIFIC TRAINING AND EXPERIENCE TO EVALUATE ITS SAFETY AS HAVING BEEN ADEQUATELY SHOWN THROUGH SCIENTIFIC PROCEDURES OR, IN THE CASE OF A SUBSTANCE USED IN A FOOD PRIOR TO JANUARY 1, 1958, THROUGH EITHER SCIENTIFIC PROCEDURES OR EXPERIENCE BASED ON COMMON USE IN FOOD) TO BE SAFE UNDER THE CONDITIONS OF ITS INTENDED USE. THE TERM DOES NOT INCLUDE:
- A. A PESTICIDE CHEMICAL IN OR ON A RAW AGRICULTURAL COMMODITY;
 - B. A PESTICIDE CHEMICAL TO THE EXTENT THAT IT IS INTENDED FOR USE OR IS USED IN THE PRODUCTION, STORAGE, OR TRANSPORTATION OF ANY RAW AGRICULTURAL COMMODITY;
 - C. A COLOR ADDITIVE; OR
 - D. ANY SUBSTANCE USED IN ACCORDANCE WITH A SANCTION OR APPROVAL GRANTED PRIOR TO THE ENACTMENT OF THE AMENDMENT TO THE FEDERAL ACT KNOWN AS THE "FOOD ADDITIVES AMENDMENT OF 1958," THE POULTRY PRODUCTS INSPECTIONAL ACT" (21 U.S.C. 451-470), OR THE "MEAT INSPECTION ACT OF MARCH 4, 1907," AS AMENDED AND EXTENDED (21 U.S.C. 71-91)

APPENDIX C - Plan Review

_____ Date: _____

Name of Establishment: _____ Phone: _____
_____ Fax: _____

Address of Establishment: _____ Phone: _____
_____ Fax: _____

Name of Operator (owner): _____ Phone: _____
_____ FAX: _____

Address of Operator (owner): _____ Phone: _____
_____ FAX: _____

Name of Local Contact: _____ Phone: _____
_____ FAX: _____

Name of Contractor: _____ Phone: _____
_____ FAX: _____

Address of Architect: _____ Phone: _____
_____ FAX: _____

Name of Architect: _____ Phone: _____
_____ FAX: _____

Date Construction will begin: _____ Date of Planned Opening: _____

New Establishment: _____ Remodel: _____

Type of Establishment (check all that apply):

- | | |
|--|---|
| <input type="checkbox"/> Full Service | <input type="checkbox"/> Coffee Shop |
| <input type="checkbox"/> Bar | <input type="checkbox"/> Market (Grocery) |
| <input type="checkbox"/> Convenience Store | <input type="checkbox"/> Fish Market |
| <input type="checkbox"/> Deli | <input type="checkbox"/> Meat Market |
| <input type="checkbox"/> Caterer | <input type="checkbox"/> Concession |
| <input type="checkbox"/> School | <input type="checkbox"/> Specialty Shop |
| <input type="checkbox"/> Fast Food | <input type="checkbox"/> Mobile Unit |
| <input type="checkbox"/> Other (please specify): _____ | |

Seating Capacity (indoor and outdoor): _____

Total Square Feet of the Establishment: _____

Total Square Feet of the Kitchen Area: _____

Have these plans been submitted or do you intend to submit these plans to other counties in the State of Colorado? Yes No If yes, which county(s): _____

If Operation is Seasonal, List the Months of Operation: _____

Day(s) and Hours of Operation: _____
_____ day(s) _____ hours

Projected Daily Maximum Number of Meals to be Served: _____ Breakfast
_____ Lunch
_____ Dinner

Number of Staff (maximum per shift): _____

~~THE FOLLOWING DOCUMENTS ARE NECESSARY AND MUST BE INCLUDED IN ORDER TO COMPLETE THE PLAN REVIEW. LACK OF COMPLETE INFORMATION MAY DELAY REVIEW AND PLAN APPROVAL.~~

1. ~~Proposed menu, including a list of foods which will require cooling after cooking and the method that will be used to cool these foods.~~
2. ~~Facility floor plan. Drawn to scale.~~
3. ~~Specification sheets of all equipment, including make and model numbers.~~
4. ~~Shop drawings of all custom fabricated equipment and cabinetry. Drawn to scale.~~
5. ~~Site plan showing the location of the business in the building, location of the building on site including alleys, streets and the location of any outside facility (dumpsters, walk-in units, grease interceptors etc.).~~
6. ~~A complete interior finish schedule.~~
7. ~~Mechanical, plumbing and electrical schedules. Drawn to scale.~~
8. ~~Water heater specifications, including make and model number.~~
9. ~~Location of chemical and personal belongings storage.~~
10. ~~Water supply and wastewater systems.~~

I. Menu And Food Handling Procedures:

- A. Submit Menu
- B. Is there a Hazard Analysis Critical Control Point (HACCP) Plan/Food Handling Procedure Manual that describes preparation, cooling, reheating, cooking of foods and the handling of leftovers? Yes No If yes, please submit with plans.
- C. List the foods that will be prepared more than 12 hours in advance of service.
- D. List the foods and describe the methods of how hot foods will be cooled to $(\)$ or below.
- E. List the foods and describe the methods of how foods will be rapidly reheated to $(\)$ or above.
- F. List the foods and indicate how hot foods will be held at $(\)$ or above.
- G. How will frozen foods be thawed?
- H. Will raw meats, poultry, and seafood be stored/displayed in the same refrigerator(s) and freezer(s) with cooked, ready to eat foods? Yes No
- I. Indicate the total number of refrigeration and freezer units:
- J. Will catering be conducted? Yes No
- K. Will food be transported or delivered to another location? Yes No
If yes, what equipment will be provided to maintain food at proper temperatures during transport?
- L. Will the produce used be washed in the establishment, or will all produce be received pre-washed:
- M. Will vacuum packaging be conducted in the establishment? Yes No
If yes, please provide the required HACCP Plan for each category of food to be vacuum packaged.

~~II. Facility Floor Plan:~~

~~A. Submit Floor Plan Drawn To Scale.~~

~~B. Floor Plan Must Include Location and Identification of All Equipment and Areas Including:~~

- ~~1. Sinks~~
 - ~~a) Handsink(s)~~
 - ~~b) Vegetable/Food Preparation Sink(s)~~
 - ~~c) Utility/Mop Sink(s)~~
 - ~~d) Dump Sink(s)~~
 - ~~e) Warewashing Sink(s)~~
 - ~~f) Other~~
- ~~2. Wait Station(s)~~
- ~~3. Toilet Facilities~~
- ~~4. Dry/Food Storage Area(s)~~
- ~~5. Employee Break/Locker Area(s)~~
- ~~6. Chemical Storage Area(s)~~
- ~~7. Water Heater Location~~
- ~~8. Bar Service Area(s)~~
- ~~9. Indoor/Outdoor Seating~~
- ~~10. Outdoor Cooking/Bar Area(s)~~
- ~~11. Location Of Laundry Facility~~
- ~~12. Recycle/Damaged/Returned Goods Location~~
- ~~13. Location Of All Floor Sinks and Floor Drains~~
- ~~14. Grease Interceptor/Grease Trap~~
- ~~15. Ice Bins/Ice Machines~~
- ~~16. Dipper Wells~~
- ~~17. Chemical Dispensing Units~~

III.— Equipment Specifications:

~~A.— Submit equipment specification sheets, including make and model numbers of the equipment. If the specification sheet lists more than one piece of equipment, identify the specific equipment to be used. If there is no specification sheet available, the equipment will only be accepted upon a field inspection to determine if it meets commercial design criteria.~~

~~B.— Submit shop drawings of all ventilation hoods. Drawn to scale.~~

~~C.— Submit shop drawings of all custom fabricated equipment and cabinetry. Drawn to scale.~~

~~D.— Submit the following water heater information: (See Appendix D for criteria on calculating adequate amounts of hot water)~~

~~1. Make: _____ Model Number: _____~~

~~2. BTU/Kilowatt Rating: _____~~

~~3. Recovery Rate, rise, at sea level: _____~~

F. Submit the following warewashing information:

1. ~~MANUAL~~ Include the following for all warewashing sinks: (Kitchen, Dishroom, Bar, etc.)

a) Size of each sink compartment:

Length: _____ Width: _____ Depth: _____

Length: _____ Width: _____ Depth: _____

Length: _____ Width: _____ Depth: _____

b) Size of all soiled and clean drain board(s)/drying racks:

Length: _____ Width: _____ Depth: _____

Length: _____ Width: _____ Depth: _____

Length: _____ Width: _____ Depth: _____

c) Pre Rinse / Spray Hose Provided: _____ yes _____ no

2. MECHANICAL:

a) Make and model numbers of warewashing machine(s): _____

b) Heat or chemical sanitization: _____

c) Booster Heater:

1. Make and Model Number: _____

2. Recovery Rate, Rise, at sea level: _____

3. Distance from the Warewashing Machine: _____

d) Manufacturer's hot water requirement (gallons per hour): _____

e) Size of all drain boards/drying racks (length and width): _____

f) Pre Rinse / Spray Hose Provided: _____ Yes _____ No

g) Soak Sink Provided: Yes No

G. Garbage Disposals: Yes No If yes, Indicate Location(s) _____

H. Refrigeration/Freezer Capacities Complete the following table:

TYPE OF UNIT	# OF UNITS PROVIDED	TOTAL CUBIC FEET
Walk in Refrigeration		
Reach in Refrigeration		
Walk in Freezer		
Reach in Freezer		
Blast Chiller		
Retail Display		

I. Displayed Food Items:

1. Bulk Food Items: Yes No If yes, submit equipment specifications for food bins. Include vendor provided equipment.
2. Food Shields Submit the type and location (If custom design, please submit shop drawings): _____

IV. PREMISES:

A. Submit site plan which includes the following: Refuse Enclosures, Compactors, Outside Walk in Cooler(s)/Freezer(s), Location of Water Supply, Sewage Disposal System, Grease Interceptor, Alleys, Streets, Parking and Outside Storage Areas.

B. Water Supply and Wastewater Systems:

1. Water Supply:

a) Community/Public:

Name of District: _____

b) Non-Community/Private: _____ PWSID #: _____

c) Well: _____ Spring: _____

If it is a well, indicate the depth: _____

Method of Disinfection: _____

2. Sewage Disposal:

a) Municipal/Public: _____

Name of District: _____

b) Individual Sewage Disposal System (ISDS): _____

V. Interior Finishes:

Use the following chart to indicate all interior finishes:

ROOM FINISH SCHEDULE:

Room Name and Mark	Floors			Walls (Material and Finish)				Ceilings	
	material	finish	base	North	South	East	West	material	finish
example: Kitchen 101	quarry tile	smooth, sealed	6" quarry tile	FRP smooth	FRP smooth	painted smooth	painted smooth	Vinyl acoustical tile	smooth

VI. — Mechanical, Plumbing, and Electrical Schedules:

A. — Plumbing:

1. — Submit the location of all floor sinks and floor drains.
2. — List all the equipment that will be installed with an indirect waste pipe.
3. — Submit the location of all hose bibbs.
4. — Submit the number and location of all toilet fixtures (Including handsinks, urinals, and water closets).
5. — Submit the location of the grease trap or interceptor.
6. — Submit the make, model and location of all chemical dispensing unit(s).
7. — Use the following chart to list the location of all backflow prevention devices, including all vendor supplied items:

EQUIPMENT	INTERNAL PROTECTION	EXTERNAL PROTECTION
Warewashing Machines		
Water Wash Hoods		
Chemical Injection Towers		
Soda Stations		
Coffee Urns		
Ice Makers		
Dipper Wells		
Commercial Disposal with Pre-rinse		
Tea Dispenser		
Mop Sink		
Hose Bibb(s)		
Reel Lines		
Steam Kettle Faucets		

B. — Mechanical:

1. Submit a complete ventilation schedule including exhaust capacities (cubic feet per minute ratings) for all hoods and the location and capacity of all make-up air diffusers.
2. If the ventilation hoods are UL listed for lower air flows, submit the information located on the manufacturer's UL listing card.
3. Include ventilation systems in restrooms.

C. Electrical:

1. Submit the location and type of light fixtures throughout the facility, including the fixtures in walk-in refrigeration/freezer units.
2. Submit the type of bulbs and/or shielding for each type of light fixture, where required.
3. Indicate the location of transformers and electrical panels if located in the food preparation/ food storage areas.

APPENDIX C - WORKSHEETS FOR CALCULATING MINIMUM HOT WATER REQUIREMENTS

THE FOLLOWING WORKSHEET IS PROVIDED TO ASSIST OPERATORS IN CALCULATING HOT WATER USAGE AND SIZING OF THE WATER HEATER SYSTEM REQUIRED FOR THE OPERATION.

WHAT IS THE DISTANCE BETWEEN THE WATER HEATING SYSTEM(S) AND THE FIXTURE THAT IS FARTHEST FROM THE HEATING SYSTEM?

FIXTURE: _____ FEET FROM WATER HEATING SYSTEM: _____

STANDARD TANK TYPE SYSTEMS:

I. CALCULATE TOTAL WATER REQUIRED BY ALL FIXTURES:

A. THREE COMPARTMENT SINK CALCULATION OF WATER USAGE:

1. MEASURE DIMENSIONS, IN INCHES, OF EACH COMPARTMENT, IF COMPARTMENTS ARE NOT THE SAME DIMENSIONS SEE NOTE BELOW.

LENGTH = _____ WIDTH = _____ DEPTH = _____

2. INSERT MEASUREMENTS INTO EQUATION:

(_____ X _____ X _____ X 3 X 0.375) ÷ 231 = _____ GPH
LENGTH WIDTH DEPTH WATER USAGE

NOTE: IF ALL THE COMPARTMENT SIZES OF THE SINK ARE NOT THE SAME, THEN 3 IS TAKEN OUT OF THE EQUATION, AND THE ABOVE CALCULATION IS DONE FOR EACH COMPARTMENT. THE VOLUMES ARE ADDED TO OBTAIN THE TOTAL GALLONS PER HOUR OF HOT WATER USED IN THE SINK.

ENTER NUMBER INTO THE ATTACHED "TABLE TO CALCULATE TOTAL WATER REQUIRED BY ALL FIXTURES," FOUND ON PAGE C-4 .

B. UTENSIL SOAK SINK

1. MEASURE DIMENSIONS, IN INCHES, OF THE SINK

LENGTH = _____ WIDTH = _____ DEPTH = _____ GPH

2. INSERT MEASUREMENTS INTO EQUATION:

$$\left(\frac{\text{LENGTH}}{\text{LENGTH}} \times \frac{\text{WIDTH}}{\text{WIDTH}} \times \frac{\text{DEPTH}}{\text{DEPTH}} \times .375 \right) \div 231 = \frac{\text{WATER USAGE}}{\text{WATER USAGE}}$$

ENTER NUMBER INTO THE ATTACHED "TABLE TO CALCULATE TOTAL WATER REQUIRED BY ALL FIXTURES," FOUND ON PAGE C-4.

C. DISHMACHINE AND CONVEYOR PRE-RINSE WATER USAGE:

1. USE MANUFACTURER'S RATING IN GALLONS PER HOUR. ENTER NUMBER INTO ATTACHED "TABLE TO CALCULATE TOTAL WATER REQUIRED BY ALL FIXTURES," FOUND ON PAGE C-4.
2. CLOTHES WASHER WATER USAGE.
 - USE MANUFACTURER'S RATING: _____, OR
 - 32 GPH FOR 9-12 POUND WASHER, OR
 - 42 GPH FOR 16 POUND WASHER.

ENTER NUMBER INTO THE ATTACHED "TABLE TO CALCULATE TOTAL WATER REQUIRED BY ALL FIXTURES," FOUND ON PAGE C-4 .

D. "CALCULATE TOTAL WATER REQUIRED BY ALL FIXTURES" AND THE NUMBER OF FIXTURES IN THE OPERATION TO DETERMINE MAXIMUM HOURLY USAGE FOR EACH TYPE OF FIXTURE IN THE OPERATION.

TOTAL WATER (GPH) REQUIRED BY ALL FIXTURES: _____ GPH.

II. CALCULATE MAXIMUM HOURLY HOT WATER USAGE

IF GAS WATER HEATER IS USED GO TO STEP A; IF ELECTRIC, STEP B.

- A. GAS WATER HEATER: IF A GAS WATER HEATER IS TO BE USED, CALCULATE THE MAXIMUM HOURLY HOT WATER USAGE FOR THE FACILITY BY ADJUSTING THE TOTAL WATER REQUIRED BY ALL FIXTURES FOR ALTITUDE. THE ALTITUDE ADJUSTMENT IS 4% PER 1000 FEET OF ELEVATION, OR 20% AT 5000 FEET.

USE THE FOLLOWING EQUATIONS TO DETERMINE THE MAXIMUM HOURLY HOT WATER USAGE WHEN A GAS POWERED WATER HEATER IS TO BE USED:

$$(0.04 \times \frac{\text{ELEVATION OF FACILITY}}{\text{ELEVATION OF FACILITY}} \div 1000) + 1 = \frac{\text{ADJUSTMENT FACTOR}}{\text{ADJUSTMENT FACTOR}}$$

$$\frac{\text{ADJUSTMENT FACTOR}}{\text{ADJUSTMENT FACTOR}} \times \frac{\text{TOTAL WATER REQUIRED BY ALL FIXTURES}}{\text{TOTAL WATER REQUIRED BY ALL FIXTURES}} = \frac{\text{MAXIMUM HOURLY HOT WATER USAGE}}{\text{MAXIMUM HOURLY HOT WATER USAGE}} \text{ GPH}$$

EXAMPLE, IF THE TOTAL GALLON PER HOUR USAGE FOR AN ESTABLISHMENT AT AN ELEVATION OF 5000 FEET IS 100 GPH, THE ADJUSTMENT FACTOR IS 1.2. THEREFORE, A WATER HEATER WITH 120 GPH RECOVERY RATE WOULD BE REQUIRED.

USE THIS VALUE IN THE EQUATION TO CALCULATE THE MINIMUM BTU RATING OF THE WATER HEATER.

- B. ELECTRIC WATER HEATER: IF AN ELECTRIC WATER HEATER IS TO BE USED, THE MAXIMUM HOURLY USAGE FOR THE OPERATION IS THE SAME AS THE TOTAL WATER REQUIRED BY ALL FIXTURES. USE THIS VALUE IN THE EQUATION TO CALCULATE THE MINIMUM KILOWATT (KW) RATING OF THE WATER HEATER.
- C. THE VALUE DETERMINED IN STEP A OR B THE MINIMUM RECOVERY RATE OF THE WATER HEATER WHICH SHOULD BE PROVIDED FOR THE FACILITY.

III. CALCULATE THE MINIMUM BTU OR KILOWATT RATING OF WATER HEATER:

- A. FOR GAS WATER HEATER, CALCULATE THE MINIMUM BTU RATING:

$(\text{MAX HOURLY USAGE AS CALCULATED ABOVE}) \times (100^{\circ}\text{F}^*) \times (8.33) = \text{MINIMUM BTU RATING}$
.80 OR USE MANUFACTURER'S THERMAL EFFICIENCY

- B. FOR ELECTRIC WATER HEATER, CALCULATE THE MINIMUM KILOWATT RATING :

$(\text{MAX HOURLY USAGE AS CALCULATED ABOVE}) \times (100^{\circ}\text{F}^*) \times (8.33) = \text{MINIMUM KW RATING}$
3412

*IF THERE IS NO HIGH TEMPERATURE DISHWASHING MACHINE OR OTHER FIXTURES REQUIRING INPUT WATER TEMPERATURE OF 140°F (100°F RISE) OR MORE, THEN 80°F RISE CAN BE USED.

- C. SELECT WATER HEATER BASED UPON BTU OR KILOWATT RATING.

MAKE: _____ ; MODEL #: _____

BTU OR KILOWATT RATING: _____

RECOVERY RATE: _____ GALLONS PER HOUR AT 100°F RISE AT SEA LEVEL.

D. HEAT RECLAIM SYSTEMS:

MAKE: _____ ; MODEL #: _____

BTU RATING: _____

RECOVERY RATE: _____ GALLONS PER HOUR AT 100°F RISE AT SEA LEVEL.

TABLE TO CALCULATE TOTAL WATER REQUIRED FOR ALL FIXTURES.

PLUMBING FIXTURE	WATER USAGE (GALLONS PER HOUR)	NUMBER OF FIXTURES	MAXIMUM HOURLY WATER USAGE PER TYPE OF FIXTURE (GALLON PER HOUR)
<i>EXAMPLE: DISHWASHING MACHINE</i>	<i>50</i>	<i>1</i>	<i>50</i>
<i>EXAMPLE: HANDSINK(S)</i>	<i>5</i>	<i>4</i>	<i>(5 x 4 =) 20</i>
3-COMPARTMENT SINK			
3-COMPARTMENT SINK (BAR)			
UTENSIL SOAK SINK			
DISHMACHINE			
DISHWASHING MACHINE CONVEYOR PRE-RINSE			
CLOTHES WASHER			
HAND OPERATED PRE- RINSE SPRAYER*	32		
HAND WASHING SINKS (INCLUDING RESTROOMS)*	5		
MOP/UTILITY SINKS	7		
GARBAGE CAN WASHER	35		

SHOWERS*	14		
HOSE BIB USED FOR CLEANING	35		
TOTAL WATER (GPH) REQUIRED BY ALL FIXTURES:			

*A HOT WATER USE REDUCTION CAN BE CALCULATED FOR WATER SAVING DEVICES USED ON HAND OPERATED PRE-RINSE SPRAYERS, HAND WASHING SINKS AND SHOWERS BY DOING THE FOLLOWING CALCULATIONS.

A. WATER SAVINGS DEVICE. OBTAIN MANUFACTURER'S FLOW RATE FOR EACH DEVICE. THE MANUFACTURE'S FLOW RATE MUST BE LESS THAN WHAT IS LISTED BELOW TO BE CONSIDERED:

- HAND OPERATED PRE-RINSE SPRAYERS WITH FLOW RATE LESS THAN 3.5 GPM STANDARD FLOW RATE.

MAKE: _____ ; MODEL #: _____

MANUFACTURER'S FLOW RATING: _____ GPM

- HAND WASHING SINK FAUCET OR AERATOR WITH FLOW RATE LESS THAN 2.2 GPM STANDARD FLOW RATE.

MAKE: _____ ; MODEL #: _____

MANUFACTURER'S FLOW RATING: _____ GPM

- SHOWER HEAD WITH FLOW RATE LESS THAN 2.5 GPM STANDARD FLOW RATE.

MAKE: _____ ; MODEL #: _____

MANUFACTURER'S FLOW RATING: _____ GPM

B. USE THE FOLLOWING EQUATION TO DETERMINE THE REDUCED HOURLY HOT WATER USAGE FOR EACH OF THE THREE TYPES OF FIXTURES:

$$\left(\frac{\text{MANUFACTURER'S FLOW USE VALUE RATE}}{\text{WATER USE VALUE FROM TABLE TO CALCULATE TOTAL WATER REQUIRED FOR ALL FIXTURES ON PAGE C-4}} \times \frac{\text{GPM STANDARD FLOW RATE}}{\text{NEW WATER TO BE ENTERED INTO TABLE TO CALCULATE TOTAL WATER REQUIRED FOR ALL FIXTURES ON PAGE C-4}} \right) \div \text{GPM STANDARD FLOW RATE} = \text{NEW WATER TO BE ENTERED INTO TABLE TO CALCULATE TOTAL WATER REQUIRED FOR ALL FIXTURES ON PAGE C-4}$$

MANUFACTURER'S FLOW USE VALUE RATE

WATER USE VALUE FROM TABLE TO CALCULATE TOTAL WATER REQUIRED FOR ALL FIXTURES ON PAGE C-4

GPM STANDARD FLOW RATE

NEW WATER TO BE ENTERED INTO TABLE TO CALCULATE TOTAL WATER REQUIRED FOR ALL FIXTURES ON PAGE C-4)

EXAMPLE CALCULATION FOR A HAND WASHING SINK THAT HAS AN AERATOR WITH A MANUFACTURER'S FLOW RATE OF 0.5 GPM:

$$\left(\frac{0.5 \text{ GPM}}{\text{MANUFACTURER'S FLOW USE VALUE RATE}} \times \frac{5 \text{ GPH}}{\text{WATER USE VALUE FROM TABLE TO CALCULATE TOTAL WATER REQUIRED FOR ALL FIXTURES ON PAGE C-4}} \right) \div \frac{2.2 \text{ GPM}}{\text{GPM STANDARD FLOW RATE}} = \frac{1.14 \text{ GPH}}{\text{NEW WATER TO BE ENTERED INTO TABLE TO CALCULATE TOTAL WATER REQUIRED FOR ALL FIXTURES ON PAGE C-4}}$$

1.14 GPH WOULD BE ENTERED INTO THE "TABLE TO CALCULATE TOTAL WATER REQUIRED FOR ALL FIXTURES," FOUND ON PAGE APPENDIX C-4 IN PLACE OF THE 5 GPH FOR HAND WASHING SINKS.

REQUIREMENTS FOR DISHWASHING MACHINE BOOSTER HEATERS:

I. DISHWASHING MACHINE

MANUFACTURER: _____

MODEL NUMBER: _____

FINAL SANITIZING RINSE CYCLE GALLONS PER HOUR WATER CONSUMPTION: _____ GPH

II. CALCULATE THE MINIMUM BTU OR KILOWATT RATING OF THE BOOSTER HEATER:

A. FOR GAS BOOSTER HEATER, CALCULATE THE MINIMUM BTU RATING:

$$\frac{(\text{GALLONS PER HOUR WATER CONSUMPTION}) \times (40^\circ\text{F}) \times (8.33)}{.80 \text{ OR USE MANUFACTURER'S THERMAL EFFICIENCY}} = \text{MINIMUM BTU RATING}$$

B. FOR ELECTRIC WATER HEATER, CALCULATE THE MINIMUM KILOWATT RATING :

$$\frac{(\text{GALLONS PER HOUR WATER CONSUMPTION}) \times (40^\circ\text{F}) \times (8.33)}{3412} = \text{MINIMUM KW RATING}$$

C. SELECT BOOSTER HEATER BASED UPON BTU OR KILOWATT RATING. THE BOOSTER HEATER MUST HAVE RECOVERY RATE GREATER THAN THE DISHWASHING MACHINE'S FINAL RINSE WATER CONSUMPTION.

MAKE: _____ ; MODEL #: _____

BTU OR KILOWATT RATING: _____

RECOVERY RATE: _____ GALLONS PER HOUR AT 40°F RISE AT SEA LEVEL.

TANKLESS OR INSTANTANEOUS SYSTEMS

I. HEATER SPECIFICATIONS:

MANUFACTURER*: _____

MODEL NUMBER: _____

FLOW RATE IN GALLONS PER MINUTE (GPM) AT 100°F RISE** : _____ GPM

BTU RATING: _____ BTU***

*UNITS MUST BE DESIGNED FOR COMMERCIAL USE.

** IF THERE ARE NO HIGH TEMPERATURE DISHWASHING MACHINE OR OTHER FIXTURES REQUIRING INPUT WATER TEMPERATURE OF 140°F (100°F RISE) OR MORE, THEN 80°F RISE CAN BE USED.

***ELECTRIC UNITS WILL ONLY BE APPROVED AS A DEDICATED HOT WATER SUPPLY TO HAND WASHING SINKS.

III. CALCULATE THE TOTAL HOT WATER DEMAND FLOW RATE IN GALLONS PER MINUTE (GPM) USING THIS TABLE.

PLUMBING FIXTURE	WATER USAGE (GALLONS PER MINUTE)	NUMBER OF FIXTURES	WATER DEMAND FLOW RATE IN GALLONS PER MINUTE
<i>EXAMPLE: DISHWASHING MACHINE † HOBART AM 14</i>	<i>8.0</i>	<i>1</i>	<i>(8.0 × 1) = 8.0</i>
<i>EXAMPLE: HANDSINK(S)</i>	<i>0.5</i>	<i>4</i>	<i>(0.5 × 4) = 2.0</i>
3-COMPARTMENT SINK*	2.0 FOR EACH FAUCET		
3-COMPARTMENT SINK (BAR)*	2.0 FOR EACH FAUCET		
UTENSIL SOAK SINK	1.0		

DISHWASHING MACHINE†			
DISHWASHING MACHINE CONVEYOR PRE-RINSE†			
CLOTHES WASHER	2.0		
HAND OPERATED PRE-RINSE SPRAYER†	2.0		
FOOD PREPARATION SINK(S)	1.0		
HAND WASHING SINKS (INCLUDING RESTROOMS) *	0.5		
MOP/UTILITY SINKS	2.0		
GARBAGE CAN WASHER	1.0		
SHOWERS†	1.0		
HOSE BIB USED FOR CLEANING	5.0		
TOTAL WATER DEMAND (GPM) REQUIRED:			

*A FLOW RATE REDUCTION CAN BE USED FOR LOW FLOW WATER FAUCETS INSTALLED ON 3-COMPARTMENT SINKS, HAND OPERATED PRE-RINSE SPRAYERS, FOOD PREPARATION SINKS, HAND WASHING SINKS AND SHOWERS BY ENTERING THE MANUFACTURER'S FLOW RATE LISTED FOR THE FAUCET OR FAUCET'S AERATOR.

†USE MANUFACTURER'S FLOW RATE IN GPM FOR SPECIFIC MAKE AND MODEL OF DISHWASHING MACHINE OR SHOWER HEAD.

IV. CALCULATE THE MAXIMUM FLOW RATE FOR THE ESTABLISHMENT. THE THERMAL EFFICIENCY OF THE WATER HEATING UNITS MUST BE ADJUSTED FOR ALTITUDE. THE ALTITUDE ADJUSTMENT IS 4% PER 1000 FEET OF ELEVATION, OR 20% AT 5000 FEET.

USE THE FOLLOWING EQUATIONS TO DETERMINE THE ESTABLISHMENT'S MAXIMUM FLOW RATE IN GPM:

$$(0.04 \times \frac{\text{ELEVATION OF FACILITY}}{1000}) + 1 = \text{ADJUSTMENT FACTOR}$$

$$\frac{\text{ADJUSTMENT FACTOR}}{\text{ADJUSTMENT FACTOR}} \times \frac{\text{TOTAL WATER DEMAND FOR ALL FIXTURES CALCULATED IN III}}{\text{TOTAL WATER DEMAND FOR ALL FIXTURES CALCULATED IN III}} = \frac{\text{MAXIMUM GPM HOT WATER USAGE}}{\text{MAXIMUM GPM HOT WATER USAGE}}$$

USE CALCULATED MAXIMUM GPM HOT WATER USAGE VALUE IN THIS EQUATION TO DETERMINE THE MINIMUM NUMBER OF HEATING UNITS THAT WILL BE REQUIRED IN IV BELOW.

- V. DETERMINE THE NUMBER OF HEATING UNITS THAT WILL BE NEEDED TO MEET THE REQUIRED FLOW RATE.

$$\frac{\text{MAXIMUM DEMAND (GPM) CALCULATED IN PART III}}{\text{MAXIMUM DEMAND (GPM) CALCULATED IN PART III}} \div \frac{\text{MANUFACTURER'S FLOW RATE IN GPM @ 100°F}}{\text{MANUFACTURER'S FLOW RATE IN GPM @ 100°F}} = \frac{\text{NUMBER OF HEATING UNITS REQUIRED*}}{\text{NUMBER OF HEATING UNITS REQUIRED*}}$$

*MULTIPLE UNITS MUST BE INSTALLED AND PLUMBED TO OPERATE IN A PARALLEL CONFIGURATION.

VI. STORAGE TANK SIZING:

IF A DISHWASHING MACHINE(S) IS TO BE INSTALLED THE INSTANTANEOUS WATER HEATING SYSTEM MUST INCLUDE A STORAGE TANK. THE STORAGE TANK MUST BE AT LEAST 25 GALLONS OR AT LEAST 25% OF THE GALLONS PER HOUR (GPH) DEMAND OF THE DISHWASHING MACHINE(S). THE LARGER VALUE OF THE TWO IS THE REQUIRED STORAGE TANK SIZE.

DISHWASHING MACHINE*

MANUFACTURER: _____

MODEL NUMBER: _____

GALLONS PER HOUR WATER CONSUMPTION: _____ X 0.25 = _____

STORAGE TANK CAPACITY
IN GALLONS

CALCULATED STORAGE TANK CAPACITY: _____ VS. 25 GALLONS STORAGE TANK

ENTER THE LARGER OF THE TWO: _____ REQUIRED STORAGE TANK CAPACITY**

*HIGH TEMPERATURE, HEAT SANITIZING DISHWASHING MACHINES MUST BE PROVIDED WITH A SEPARATE BOOSTER HEATER. USE OF AN INSTANTANEOUS UNIT IS NOT ALLOWED FOR USE AS A BOOSTER HEATER.

**THE STORAGE TANK MUST BE INSTALLED IN THE HOT WATER SUPPLY LINE LOCATED BETWEEN THE HEATER UNIT(S) AND THE HOT WATER DISTRIBUTION LINE. A RECIRCULATION LINE, EQUIPPED

WITH A RECIRCULATION PUMP AND AQUASTAT, (WATER THERMOSTAT) MUST BE INSTALLED AT THE STORAGE TANK TO ASSURE THE WATER IN THE TANK REMAINS AT THE APPROPRIATE TEMPERATURE (120-140°F). THE RECIRCULATION LINE MUST BE CONNECTED BETWEEN THE STORAGE TANK AND THE COLD WATER SUPPLY LINE AT THE HEATER UNIT(S).

APPENDIX D – Worksheet for Calculating Minimum Hot Water Requirements

The following worksheet is provided to assist operators in calculating hot water usage and sizing of the water heater required for the operation.

I. Calculate Total Water Required By All Fixtures:

A. Three compartment sink calculation of water usage:

1. Measure dimensions, in inches, of each compartment, if compartments are not the same dimensions see note below.

Length = _____ Width = _____ Depth = _____

2. Insert measurements into equation

(_____ x _____ x _____ x 3 x .375) : 231 = _____
Length Width Depth Water Usage

Note: If all the compartment sizes of the sink are not the same, then 3 is taken out of the equation, and the above calculation is done for each compartment. The volumes are added to obtain the total gallons per hour of hot water used in the sink.

Enter number into the attached “Table to Calculate Total Water Required By All Fixtures,” found on page Appendix D-4.

B. Utensil soak sink

1. Measure dimensions, in inches, of the sink

Length = _____ Width = _____ Depth = _____

2. Insert measurements into equation

(_____ x _____ x _____ x .375) : 231 = _____
Length Width Depth Water Usage

Enter number into the attached “Table to Calculate Total Water Required By All Fixtures,” found on page Appendix D-4.

C. Dishmachine and conveyor pre-rinse water usage:

Use manufacturer's rating in gallons per hour

Enter number into attached "Table to Calculate Total Water Required By All Fixtures."

Clothes washer water usage:

Use manufacturer's rating, or 32 GPH for 9-12 pound washer, or 42 GPH for 16 pound washer.

Enter number into the attached "Table to Calculate Total Water Required By All Fixtures," found on page Appendix D-4.

D. Use the gallon per hour rating for each type of fixture found in the "Table to Calculate Total Water Required By All Fixtures" and the number of fixtures in the operation to determine maximum hourly usage for each type of fixture in the operation.

Total water (gph) required by all fixtures: _____

II. Calculate Maximum Hourly Hot Water Usage

If gas water heater is used go to Step A; if electric, Step B.

A. Gas Water Heater: If a gas water heater is to be used, calculate the maximum hourly hot water usage for the facility by adjusting the total water required by all fixtures for altitude. The altitude adjustment is 4% per 1000 feet of elevation, or 20% at 5000 feet.

Use the following equations to determine the maximum hourly hot water usage when a gas powered water heater is to be used:

$$\left(.04 \times \frac{\text{elevation of facility}}{1000} + 1 \right) = \text{adjustment factor}$$

$$\frac{\text{adjustment factor}}{\text{adjustment factor}} \times \frac{\text{total water required by all fixtures}}{\text{total water required by all fixtures}} = \frac{\text{maximum hourly hot water usage}}{\text{maximum hourly hot water usage}}$$

For example, if the total gallon per hour usage for an establishment at an elevation of 5000 feet is 100 GPH, the adjustment factor is 1.2. Therefore, a water heater with 120 GPH recovery rate would be required.

Use this value in the equation to calculate the minimum BTU rating of the water heater.

B. Electric Water Heater: If an electric water heater is to be used, the maximum hourly usage for the operation is the same as the total water required by all fixtures. Use this value in the equation to calculate the minimum Kilowatt rating of the water heater.

C. ~~Insert the value determined in step A or B above in III D (3), Appendix C, Plan Review Form, Page Appendix C-6. This value is the minimum recovery rate of the water heater which should be provided for the facility.~~

III. ~~Calculate the minimum BTU or Kilowatt rating of water heater:~~

~~A. For gas water heater, calculate the minimum BTU rating:~~

~~$(\text{Max hourly usage as calculated above}) \times (100) \times (8.33) = \text{minimum BTU rating}$
_____ .75 or use manufacturer's thermal efficiency~~

~~B. For electric water heater, calculate the minimum Kilowatt rating :~~

~~$(\text{Max hourly usage as calculated above}) \times (100) \times (8.33) = \text{minimum Kilowatt rating}$
_____ 3412~~

~~C. Select water heater based upon BTU or Kilowatt rating.~~

~~Make: _____ ; Model #: _____~~

~~BTU or Kilowatt Rating: _____~~

~~Recovery rate: _____ gallons per hour at 100°F rise at sea level.~~

Table to Calculate Total Water Required By All Fixtures.

Plumbing Fixture	Water Usage (gallons per hour)	Number of fixtures	Maximum hourly water usage per type of fixture (gallons per hour)
example: warewashing ——— machine	50	1	50
example: handsink(s)	5	4	(5 x 4 =) 20
3-compartment sink			
3-compartment sink (bar)			
utensils soak sink			
warewashing machine			
warewashing machine conveyor pre-rinse			
clothes washer			
hand-operated pre-rinse sprayer	32		
handsink(s), include rest rooms	5		
mop-sink	7		
garbage can washer	35		
showers	14		
hose bibb used for cleaning	35		
Total water (gph) required by all fixtures			

APPENDIX D – SPECIFIC USAGE ADDITIVES

173.310 BOILER WATER ADDITIVES.

BOILER WATER ADDITIVES MAY BE SAFELY USED IN THE PREPARATION OF STEAM THAT WILL CONTACT FOOD, UNDER THE FOLLOWING CONDITIONS:

- A. THE AMOUNT OF ADDITIVE IS NOT IN EXCESS OF THAT REQUIRED FOR ITS FUNCTIONAL PURPOSE, AND THE AMOUNT OF STEAM IN CONTACT WITH FOOD DOES NOT EXCEED THAT REQUIRED TO PRODUCE THE INTENDED EFFECT IN OR ON THE FOOD.
- B. THE COMPOUNDS ARE PREPARED FROM SUBSTANCES IDENTIFIED IN PARAGRAPHS (C) AND (D) OF THIS SECTION, AND ARE SUBJECT TO THE LIMITATIONS, IF ANY, PRESCRIBED:
- C. LIST OF SUBSTANCES:

SUBSTANCES	LIMITATIONS
<p>ACRYLAMIDE-SODIUM ACRYLATE RESIN.....</p> <p>ACRYLIC ACID/2-ACRYLAMIDO-2-METHYL PROPANE SULFONIC ACID COPOLYMER HAVING A MINIMUM WEIGHT AVERAGE MOLECULAR WEIGHT OF 9,900 AND A MINIMUM NUMBER AVERAGE MOLECULAR WEIGHT OF 5,700 AS DETERMINED BY A METHOD ENTITLED “DETERMINATION OF WEIGHT AVERAGE AND NUMBER AVERAGE MOLECULAR WEIGHT OF 60/40 AA/AMPS” (OCTOBER 23, 1987), WHICH IS INCORPORATED BY REFERENCE IN ACCORDANCE WITH 5 U.S.C. 552(A). COPIES MAY BE OBTAINED FROM THE CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (HFS-200), FOOD AND DRUG ADMINISTRATION, 200 C ST. SW., WASHINGTON, DC 20204, OR MAY BE EXAMINED AT THE OFFICE OF THE FEDERAL REGISTER, 800 NORTH CAPITOL STREET, NW., SUITE 700, WASHINGTON, DC.</p> <p>AMMONIUM ALGinate.</p> <p>COBALT SULFATE (AS CATALYST).</p> <p>1-HYDROXYETHYLIDENE-1, 1-DIPHOSPHONIC ACID (CAS REG. NO. 2809-21-4) AND ITS SODIUM AND POTASSIUM SALTS.</p> <p>LIGNOSULFONIC ACID.</p>	<p>CONTAINS NOT MORE THAN 0.05 PERCENT BY WEIGHT OF ACRYLAMIDE MONOMER.</p> <p>TOTAL NOT TO EXCEED 20 PARTS PER MILLION (ACTIVE) IN BOILER FEEDWATER.</p>
<p>MONOBUTYL ETHERS OF POLYETHYLENE-POLYPROPYLENE GLYCOL PRODUCED BY RANDOM CONDENSATION OF A 1:1 MIXTURE BY WEIGHT OF ETHYLENE OXIDE AND PROPYLENE OXIDE WITH BUTANOL.</p>	<p>MINIMUM MOL. WT. 1,500.</p>
<p>POLY(ACRYLIC ACID-CO-HYPOPHOSPHITE), SODIUM SALT (CAS REG. NO. 71050-62-9), PRODUCED FROM A 4:1 TO A 16:1 MIXTURE BY WEIGHT OF ACRYLIC ACID AND SODIUM HYPOPHOSPHITE.</p>	<p>TOTAL NOT TO EXCEED 1.5 PARTS PER MILLION IN BOILER FEED WATER. COPOLYMER CONTAINS NOT MORE THAN 0.5 PERCENT BY WEIGHT OF ACRYLIC ACID MONOMER (DRY WEIGHT BASIS).</p>

SUBSTANCES	LIMITATIONS
POLYETHYLENE GLYCOL..... POLYMALEIC ACID [CAS REG. No. 26099-09-2], AND/OR ITS SODIUM SALT. [CAS REG. No. 30915- 61-8 OR CAS REG. No. 70247-90-4]. POLYOXYPROPYLENE GLYCOL..... POTASSIUM CARBONATE. POTASSIUM TRIPOLYPHOSPHATE. SODIUM ACETATE. SODIUM ALGINATE. SODIUM ALUMINATE. SODIUM CARBONATE.	AS DEFINED IN 172.820 OF THIS CHAPTER. TOTAL NOT TO EXCEED 1 PART PER MILLION IN BOILER FEED WATER (CALCULATED AS THE ACID). MINIMUM MOL WT. 1,000.
SODIUM CARBOXY-METHYLCELLULOSE	CONTAINS NOT LESS THAN 95 PERCENT SODIUM CARBOXYMETHYLCELLULOSE ON A DRY-WEIGHT BASIS, WITH MAXIMUM SUBSTITUTION OF 0.9 CARBOXYMETHYLCELLULOSE GROUPS PER ANHYDROGLUCOSE UNIT, AND WITH A MINIMUM VISCOSITY OF 15 CENTIPOISES FOR 2 PERCENT BY WEIGHT AQUEOUS SOLUTION AT 25°C; BY METHOD PRESCRIBED IN THE "FOOD CHEMICALS CODEX," 3D ED. (1981), PP. 280-282, WHICH IS INCORPORATED BY REFERENCE. COPIES MAY BE OBTAINED FROM THE NATIONAL ACADEMY PRESS, 2101 CONSTITUTION AVE. NW., WASHINGTON, DC 20418, OR MAY BE EXAMINED AT THE OFFICE OF THE FEDERAL REGISTER, 800 NORTH CAPITOL STREET, NW., SUITE 700, WASHINGTON, DC 20408
SODIUM GLUCOHEPTONATE SODIUM HEXAMETAPHOSPHATE. SODIUM HUMATE. SODIUM HYDROXIDE. SODIUM LIGNOSULFONATE. SODIUM METABISULFITE. SODIUM METASILICATE. SODIUM NITRATE. SODIUM PHOSPHATE (MONO-, DI-, TRI-). SODIUM POLYACRYLATE. SODIUM POLYMETHACRYLATE. SODIUM SILICATE. SODIUM SULFATE. SODIUM SULFITE (NEUTRAL OR ALKALINE). SODIUM TRIPOLYPHOSPHATE. TANNIN (INCLUDING QUEBRACHO EXTRACT). TETRASODIUM EDTA. TETRASODIUM PYROPHOSPHATE.	LESS THAN 1 PART PER MILLION CYANIDE IN THE SODIUM GLUCOHEPTONATE.

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D. SUBSTANCES USED ALONE OR IN COMBINATION WITH SUBSTANCES IN PARAGRAPH (C) OF THIS SECTION:

SUBSTANCES	LIMITATIONS
CYCLOHEXYLAMINE	NOT TO EXCEED 10 PARTS PER MILLION IN STEAM, AND EXCLUDING USE OF SUCH STEAM IN CONTACT WITH MILK AND MILK PRODUCTS.
DIETHYLAMINOETHANOL	NOT TO EXCEED 15 PARTS PER MILLION IN STEAM, AND EXCLUDING USE OF SUCH STEAM IN CONTACT WITH MILK AND MILK PRODUCTS.
HYDRAZINE	ZERO IN STEAM.
MORPHOLINE	NOT TO EXCEED 10 PARTS PER MILLION IN STEAM, AND EXCLUDING USE OF SUCH STEAM IN CONTACT WITH MILK AND MILK PRODUCTS.
OCTADECYLAMINE	NOT TO EXCEED 3 PARTS PER MILLION IN STEAM, AND EXCLUDING USE OF SUCH STEAM IN CONTACT WITH MILK AND MILK PRODUCTS
TRISODIUM NITRILOTRIACETATE	NOT TO EXCEED 5 PARTS PER MILLION IN BOILER FEEDWATER; NOT TO BE USED WHERE STEAM WILL BE IN CONTACT WITH MILK AND MILK PRODUCTS.

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E. TO ASSURE SAFE USE OF THE ADDITIVE, IN ADDITION TO THE OTHER INFORMATION REQUIRED BY THE ACT, THE LABEL OR LABELING SHALL BEAR:

1. THE COMMON OR CHEMICAL NAME OR NAMES OF THE ADDITIVE OR ADDITIVES.
2. ADEQUATE DIRECTIONS FOR USE TO ASSURE COMPLIANCE WITH ALL THE PROVISIONS OF THIS SECTION.

APPENDIX E — Specific Usage Additives

173.310 — Boiler water additives.

Boiler water additives may be safely used in the preparation of steam that will contact food, under the following conditions:

- ~~A. The amount of additive is not in excess of that required for its functional purpose, and the amount of steam in contact with food does not exceed that required to produce the intended effect in or on the food.~~
- ~~B. The compounds are prepared from substances identified in paragraphs (c) and (d) of this section, and are subject to the limitations, if any, prescribed:~~

C. — List of substances:

Substances	Limitations
<p>Acrylamide-sodium acrylate resin.....</p> <p>Acrylic acid/2-acrylamido-2-methyl-propane sulfonic acid copolymer having a minimum weight average molecular weight of 9,900 and a minimum number average molecular weight of 5,700 as determined by a method entitled "Determination of Weight Average and Number Average Molecular Weight of 60/40 AA/AMPS" (October 23, 1987), which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies may be obtained from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.</p> <p>Ammonium alginate.</p> <p>Cobalt sulfate (as catalyst).</p> <p>1-hydroxyethylidene-1,1-diphosphonic acid (CAS Reg. No. 2809-21-4) and its sodium and potassium salts.</p> <p>Lignosulfonic acid.</p> <p>Monobutyl ethers of polyethylene-polypropylene glycol produced by random condensation of a 1:1 mixture by weight of ethylene oxide and propylene oxide with butanol.</p> <p>Poly(acrylic acid-co-hypophosphite), sodium salt (CAS Reg. No. 71050-62-9), produced from a 4:1 to a 16:1 mixture by weight of acrylic acid and sodium hypophosphite.</p> <p>Polyethylene glycol.....</p> <p>Polymaleic acid [CAS Reg. No. 26099-09-2], and/or its sodium salt. [.. CAS Reg. No. 30915-61-8 or CAS Reg. No. 70247-90-4].</p> <p>Polyoxypropylene glycol.....</p> <p>Potassium carbonate.</p> <p>Potassium tripolyphosphate.</p> <p>Sodium acetate.</p> <p>Sodium alginate.</p> <p>Sodium aluminate.</p> <p>Sodium carbonate.</p>	<p>Contains not more than 0.05 percent by weight of acrylamide monomer.</p> <p>Total not to exceed 20 parts per million (active) in boiler feedwater.</p> <p>Minimum mol. Wt. 1,500.</p> <p>Total not to exceed 1.5 parts per million in boiler feed water. Copolymer contains not more than 0.5 percent by weight of acrylic acid monomer (dry weight basis).</p> <p>As defined in 172.820 of this chapter.</p> <p>Total not to exceed 1 part per million in boiler feed water (calculated as the acid).</p> <p>Minimum mol wt. 1,000.</p>

Substances	Limitations
Sodium carboxy methylcellulose	Contains not less than 95 percent sodium carboxymethylcellulose on a dry weight basis, with maximum substitution of 0.9 carboxymethylcellulose groups per anhydroglucose unit, and with a minimum viscosity of 15 centipoises for 2 percent by weight aqueous solution at 25°C; by method prescribed in the "Food Chemicals Codex," 3d Ed. (1981), pp. 280-282, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408
Sodium glucoheptonate	Less than 1 part per million cyanide in the sodium glucoheptonate.
Sodium hexametaphosphate.	
Sodium humate.	
Sodium hydroxide.	
Sodium lignosulfonate.	
Sodium metabisulfite.	
Sodium metasilicate.	
Sodium nitrate.	
Sodium phosphate (mono-, di-, tri-).	
Sodium polyacrylate.	
Sodium polymethacrylate.	
Sodium silicate.	
Sodium sulfate.	
Sodium sulfite (neutral or alkaline).	
Sodium tripolyphosphate.	
Tannin (including quebracho extract).	
Tetrasodium EDTA.	
Tetrasodium pyrophosphate.	

D. ~~Substances used alone or in combination with substances in paragraph (c) of this section:~~

Substances	Limitations
Cyclohexylamine	Not to exceed 10 parts per million in steam, and excluding use of such steam in contact with milk and milk products.
Diethylaminoethanol	Not to exceed 15 parts per million in steam, and excluding use of such steam in contact with milk and milk products.
Hydrazine	Zero in steam.
Morpholine	Not to exceed 10 parts per million in steam, and excluding use of such steam in contact with milk and milk products.
Octadecylamine	Not to exceed 3 parts per million in steam, and excluding use of such steam in contact with milk and milk products.
Trisodium nitrilotriacetate	Not to exceed 5 parts per million in boiler feedwater; not to be used where steam will be in contact with milk and milk products.

~~E. To assure safe use of the additive, in addition to the other information required by the Act, the label or labeling shall bear:~~

- ~~1. The common or chemical name or names of the additive or additives.~~
- ~~2. Adequate directions for use to assure compliance with all the provisions of this section.~~

APPENDIX E –LUBRICANTS

21 CFR SECTION 178.3570 (2009) LUBRICANTS WITH INCIDENTAL FOOD CONTACT

LUBRICANTS WITH INCIDENTAL FOOD CONTACT MAY BE SAFELY USED ON MACHINERY USED FOR PRODUCING, MANUFACTURING, PACKING, PROCESSING, PREPARING, TREATING, PACKAGING, TRANSPORTING, OR HOLDING FOOD, SUBJECT TO THE PROVISIONS OF THIS SECTION.

- A. THE LUBRICANTS ARE PREPARED FROM ONE OR MORE OF THE FOLLOWING SUBSTANCES.
1. SUBSTANCES GENERALLY RECOGNIZED AS SAFE FOR USE IN FOOD.
 2. SUBSTANCES USED IN ACCORDANCE WITH THE PROVISIONS OF A PRIOR SANCTION OR APPROVAL.
 3. SUBSTANCES IDENTIFIED IN THIS PARAGRAPH (A)(3).

SUBSTANCES	LIMITATIONS
ALUMINUM STEAROYL BENZOYL HYDROXIDE	FOR USE ONLY AS A THICKENING AGENT IN MINERAL OIL LUBRICANTS AT A LEVEL NOT TO EXCEED 10 PCT BY WEIGHT OF THE MINERAL OIL.
BHA.	
BHT.	
α -BUTYL-OMEGA-HYDROXYPOLY(OXYETHYLENE) POLY(OXYPROPYLENE) PRODUCED BY RANDOM CONDENSATION OF A 1:1 MIXTURE BY WEIGHT OF ETHYLENE OXIDE AND PROPYLENE OXIDE WITH BUTANOL; MINIMUM MOLECULAR WEIGHT 1,500; CHEMICAL ABSTRACTS SERVICE REGISTRY No. 9038-95-3.	ADDITION TO FOOD NOT TO EXCEED 10 PARTS PER MILLION.
α -BUTYL-OMEGA-HYDROXYPOLY(OXYPROPYLENE); MINIMUM MOLECULAR WEIGHT 1,500; CHEMICAL ABSTRACTS SERVICE REGISTRY No. 9003-13-8.	Do.
CASTOR OIL	Do.
CASTOR OIL, DEHYDRATED	Do.
CASTOR OIL, PARTIALLY DEHYDRATED	Do.
DIALKYLDIMETHYLAMMONIUM ALUMINUM SILICATE (CAS REG. NO. 68953-58-2), WHICH MAY CONTAIN UP TO 7 PERCENT BY WEIGHT 1,6-HEXANEDIOL (CAS REG. NO. 629-11-8), WHERE THE ALKYL GROUPS ARE DERIVED FROM HYDROGENATED TALLOW FATTY ACIDS (-) AND WHERE THE ALUMINUM SILICATE IS DERIVED FROM BENTONITE.	FOR USE ONLY AS A WETTING AGENT IN MINERAL OIL LUBRICANTS AT A LEVEL NOT TO EXCEED 15 PERCENT BY WEIGHT OF THE MINERAL OIL.

SUBSTANCES	LIMITATIONS
DIMETHYLPOLYSILOXANE (VISCOSITY GREATER THAN 300 CENTISTOKES).	ADDITION TO FOOD NOT TO EXCEED 1 PART PER MILLION.
DISODIUM DECANEDIOATE (CAS REG. No. 17265-14-4).	FOR USE AS A CORROSION INHIBITOR OR RUST PREVENTATIVE IN MINERAL OIL-BENTONITE LUBRICANTS AT A LEVEL NOT TO EXCEED 2 PERCENT BY WEIGHT OF THE GREASE.
DISODIUM EDTA (CAS REG. No. 139-33-3)	FOR USE ONLY AS A CHELATING AGENT AND SEQUESTRANT AT A LEVEL NOT TO EXCEED 0.06 PERCENT BY WEIGHT OF LUBRICANT AT FINAL USE DILUTION.
<p>ETHOXYLATED RESIN PHOSPHATE ESTER MIXTURE CONSISTING OF THE FOLLOWING COMPOUNDS:</p> <ol style="list-style-type: none"> 1. POLY(METHYLENE-P-TERT-BUTYL-PHENOXY) POLY(OXYETHYLENE) MIXTURE OF DIHYDROGEN PHOSPHATE AND MONOHYDROGEN PHOSPHATE ESTERS (0-40 PERCENT OF THE MIXTURE). THE RESIN IS FORMED BY CONDENSATION OF 1 MOLE OF P-TERT-BUTYLPHENOL WITH 2 TO 4 MOLES OF FORMALDEHYDE AND SUBSEQUENT ETHOXYLATION WITH 4 TO 12 MOLES OF ETHYLENE OXIDE;. 2. POLY(METHYLENE-P-NONYLPHENOXY) POLY(OXYETHYLENE) MIXTURE OF DIHYDROGEN PHOSPHATE AND MONOHYDROGEN PHOSPHATE ESTERS (0-40 PERCENT OF THE MIXTURE). THE RESIN IS FORMED BY CONDENSATION OF 1 MOLE OF P-NONYLPHENOL WITH 2 TO 4 MOLES OF FORMALDEHYDE AND SUBSEQUENT ETHOXYLATION WITH 4 TO 12 MOLES OF ETHYLENE OXIDE; AND. 3. N-TRIDECYL ALCOHOL MIXTURE OF DIHYDROGEN PHOSPHATE AND MONOHYDROGEN PHOSPHATE ESTERS (40 TO 80 PERCENT OF THE MIXTURE; CAS REG. No. 56831-62-0). 	FOR USE ONLY AS A SURFACTANT TO IMPROVE LUBRICITY IN LUBRICATING FLUIDS COMPLYING WITH THIS SECTION AT A LEVEL NOT TO EXCEED 5 PERCENT BY WEIGHT OF THE LUBRICATING FLUID.
FATTY ACIDS DERIVED FROM ANIMAL OR VEGETABLE SOURCES, AND THE HYDROGENATED FORMS OF SUCH FATTY ACIDS.	
2-(8-HEPTADECENYL)-4,5-DIHYDRO-1 H-IMIDAZOLE-1-ETHANOL(CAS REG. No. 95-38-5).	FOR USE AT LEVELS NOT TO EXCEED 0.5 PERCENT BY WEIGHT OF THE LUBRICANT.
HEXAMETHYLENEBIS(3,5-DI-TERT-BUTYL-4-HYDROXYHYDROCINNAMATE) (CAS REG. No. 35074-77-2).	FOR USE AS AN ANTIOXIDANT AT LEVELS NOT TO EXCEED 0.5 PERCENT BY WEIGHT OF THE LUBRICANT.

SUBSTANCES	LIMITATIONS
<p>A-HYDRO-OMEGA-HYDROXYPOLY (OXYETHYLENE) POLY(OXYPROPYLENE) PRODUCED BY RANDOM CONDENSATION OF MIXTURES OF ETHYLENE OXIDE AND PROPYLENE OXIDE CONTAINING 25 TO 75 PERCENT BY WEIGHT OF ETHYLENE OXIDE; MINIMUM MOLECULAR WEIGHT 1,500; CHEMICAL ABSTRACTS SERVICE REGISTRY NO. 9003-11-6.</p> <p>12-HYDROXYSTEARIC ACID.</p>	<p>ADDITION TO FOOD NOT TO EXCEED 10 PARTS PER MILLION.</p>
<p>ISOPROPYL OLEATE</p>	<p>FOR USE ONLY AS AN ADJUVANT (TO IMPROVE LUBRICITY) IN MINERAL OIL LUBRICANTS.</p>
<p>MAGNESIUM RICINOLEATE</p>	<p>FOR USE ONLY AS AN ADJUVANT IN MINERAL OIL LUBRICANTS AT A LEVEL NOT TO EXCEED 10 PERCENT BY WEIGHT OF THE MINERAL OIL.</p>
<p>MINERAL OIL</p>	<p>ADDITION TO FOOD NOT TO EXCEED 10 PARTS PER MILLION.</p>
<p>N-METHYL-N-(1-OXO-9-OCTADECENYL)GLYCINE (CAS REG. NO. 110-25-8).</p>	<p>FOR USE AS A CORROSION INHIBITOR AT LEVELS NOT TO EXCEED 0.5 PERCENT BY WEIGHT OF THE LUBRICANT.</p>
<p>N-PHENYLBENZENAMINE, REACTION PRODUCTS WITH 2,4,4-TRIMETHYLPENTENE (CAS REG. NO. 68411-46-1).</p>	<p>FOR USE ONLY AS AN ANTIOXIDANT AT LEVELS NOT TO EXCEED 0.5 PERCENT BY WEIGHT OF THE LUBRICANT.</p>
<p>PETROLATUM</p>	<p>COMPLYING WITH 178.3700. ADDITION TO FOOD NOT TO EXCEED 10 PARTS PER MILLION.</p>
<p>PHENYL-α-AND/OR PHENYL-β-NAPHTHYLAMINE</p>	<p>FOR USE ONLY, SINGLY OR IN COMBINATION, AS ANTIOXIDANT IN MINERAL OIL LUBRICANTS AT A LEVEL NOT TO EXCEED A TOTAL OF 1 PERCENT BY WEIGHT OF THE MINERAL OIL.</p>
<p>PHOSPHORIC ACID, MONO- AND DIHEXYL ESTERS, COMPOUNDS WITH TETRAMETHYLNONYLAMINES AND -14 ALKYLAMINES.</p>	<p>FOR USE ONLY AS AN ADJUVANT AT LEVELS NOT TO EXCEED 0.5 PERCENT BY WEIGHT OF THE LUBRICANT.</p>
<p>PHOSPHORIC ACID, MONO- AND DIISOCTYL ESTERS, REACTED WITH TERTALKYL AND (-) PRIMARY AMINES (CAS REG. NO. 68187-67-7).</p>	<p>FOR USE ONLY AS A CORROSION INHIBITOR OR RUST PREVENTATIVE IN LUBRICANTS AT A LEVEL NOT TO EXCEED 0.5 PERCENT BY WEIGHT OF THE LUBRICANT.</p>
<p>POLYUREA, HAVING A NITROGEN CONTENT OF 9-14 PERCENT BASED ON THE DRY POLYUREA WEIGHT, PRODUCED BY REACTING TOLYLENE DIISOCYANATE WITH TALL OIL FATTY ACID (AND) AMINE AND ETHYLENE DIAMINE IN A 2:2:1 MOLAR RATIO.</p>	<p>FOR USE ONLY AS AN ADJUVANT IN MINERAL OIL LUBRICANTS AT A LEVEL NOT TO EXCEED 10 PERCENT BY WEIGHT OF THE MINERAL OIL.</p>
<p>POLYBUTENE (MINIMUM AVERAGE MOLECULAR WEIGHT 80,000)</p>	<p>ADDITION TO FOOD NOT TO EXCEED 10 PARTS PER MILLION</p>

SUBSTANCES	LIMITATIONS
POLYBUTENE, HYDROGENATED; COMPLYING WITH THE IDENTITY PRESCRIBED UNDER 178.3740. POLYETHYLENE POLYISOBUTYLENE (AVERAGE MOLECULAR WEIGHT 35,000-140,000 (FLORY)). SODIUM NITRITE TETRAKIS{ METHYLENE(3,5-DI-TERT-BUTYL-4-HYDROXYHYDRO-CINNAMATE) }METHANE (CAS REG, No. 6683-19-8). THIODIETHYLENEBIS (3,5-DI-TERT-BUTYL-4-HYDROXYHYDROCINNAMATE) (CAS REG. No. 41484-35-9).	Do. Do. FOR USE ONLY AS A THICKENING AGENT IN MINERAL OIL LUBRICANTS. FOR USE ONLY AS A RUST PREVENTIVE IN MINERAL OIL LUBRICANTS AT A LEVEL NOT TO EXCEED 3 PERCENT BY WEIGHT OF THE MINERAL OIL. FOR USE ONLY AS AN ANTIOXIDANT AT LEVELS NOT TO EXCEED 0.5 PERCENT BY WEIGHT OF THE LUBRICANT. FOR USE AS AN ANTIOXIDANT AT LEVELS NOT TO EXCEED 0.5 PERCENT BY WEIGHT OF THE LUBRICANT.
TRIPHENYL PHOSPHOROTHIONATE (CAS REG. No. 597-82-0)	FOR USE AS AN ADJUVANT IN LUBRICANTS HEREIN LISTED AT A LEVEL NOT TO EXCEED 0.5 PERCENT BY WEIGHT OF THE LUBRICANT.
TRIS(2,4-DI-TERT-BUTYLPHENYL)PHOSPHITE (CAS REG No. 31570-04-4). THIODIETHYLENEBIS(3,5-DI-TERT-BUTYL-4-HYDROXY-HYDRO-CINNAMATE)(CAS REG. No. 41484-35-9). ZINC SULFIDE	FOR USE ONLY AS A STABILIZER AT LEVELS NOT TO EXCEED 0.5 PERCENT BY WEIGHT OF THE LUBRICANT. FOR USE AS AN ANTIOXIDANT AT LEVELS NOT TO EXCEED 0.5 PERCENT BY WEIGHT OF THE LUBRICANT. FOR USE AT LEVELS NOT TO EXCEED 10 PERCENT BY WEIGHT OF THE LUBRICANT.

B. THE LUBRICANTS ARE USED ON FOOD PROCESSING EQUIPMENT AS A PROTECTIVE ANTIRUST FILM, AS A RELEASE AGENT ON GASKETS OR SEALS OF TANK CLOSURES, AND AS A LUBRICANT FOR MACHINE PARTS AND EQUIPMENT IN LOCATIONS IN WHICH THERE IS EXPOSURE OF THE LUBRICATED PART TO FOOD. THE AMOUNT USED IS THE MINIMUM REQUIRED TO ACCOMPLISH THE DESIRED TECHNICAL EFFECT ON THE EQUIPMENT, AND THE ADDITION TO FOOD OF ANY CONSTITUENT IDENTIFIED IN THIS SECTION DOES NOT EXCEED THE LIMITATIONS PRESCRIBED.

C. ANY SUBSTANCE EMPLOYED IN THE PRODUCTION OF THE LUBRICANTS DESCRIBED IN THIS SECTION THAT IS THE SUBJECT OF A REGULATION IN PARTS 174, 175, 176, 177, 178 AND 179.45 OF THIS CHAPTER CONFORMS WITH ANY SPECIFICATION IN SUCH REGULATION.

APPENDIX F -- Lubricants

178.3570 ~~Lubricants With Incidental Food Contact~~

~~Lubricants with incidental food contact may be safely used on machinery used for producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.~~

- A. ~~The lubricants are prepared from one or more of the following substances:~~
- ~~1. Substances generally recognized as safe for use in food.~~
 - ~~2. Substances used in accordance with the provisions of a prior sanction or approval.~~
 - ~~3. Substances identified in this paragraph (a)(3).~~

Substances	Limitations
Aluminum stearoyl benzoyl hydroxide	For use only as a thickening agent in mineral oil lubricants at a level not to exceed 10 pct by weight of the mineral oil.
BHA.	
BHT.	
α Butyl omega hydroxypoly(oxyethylene) poly(oxypropylene) produced by random condensation of a 1:1 mixture by weight of ethylene oxide and propylene oxide with butanol; minimum molecular weight 1,500; Chemical Abstracts Service Registry No. 9038-95-3.	Addition to food not to exceed 10 parts per million.
α Butyl omega hydroxypoly(oxypropylene); minimum molecular weight 1,500; Chemical Abstracts Service Registry No. 9003-13-8.	Do.
Castor oil	Do.
Castor oil, dehydrated	Do.
Castor oil, partially dehydrated	Do.
Dialkyldimethylammonium aluminum silicate (CAS Reg. No. 68953-58-2), which may contain up to 7 percent by weight 1,6-hexanediol (CAS Reg. No. 629-11-8), where the alkyl groups are derived from hydrogenated tallow fatty acids (-) and where the aluminum silicate is derived from bentonite.	For use only as a wetting agent in mineral oil lubricants at a level not to exceed 15 percent by weight of the mineral oil.
Dimethylpolysiloxane (viscosity greater than 300 centistokes).	Addition to food not to exceed 1 part per million.

Substances	Limitations
Disodium decanedioate (CAS Reg. No. 17265-14-4).	For use as a corrosion inhibitor or rust preventative in mineral oil-bentonite lubricants at a level not to exceed 2 percent by weight of the grease.
Disodium EDTA (CAS Reg. No. 139-33-3)	For use only as a chelating agent and sequestrant at a level not to exceed 0.06 percent by weight of lubricant at final use dilution.
<p>Ethoxylated resin-phosphate ester mixture consisting of the following compounds:</p> <ol style="list-style-type: none"> 1. Poly(methylene-p-tert-butylphenoxy) poly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters (0-40 percent of the mixture). The resin is formed by condensation of 1 mole of p-tert-butylphenol with 2 to 4 moles of formaldehyde and subsequent ethoxylation with 4 to 12 moles of ethylene oxide; 2. Poly(methylene-p-nonylphenoxy) poly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters (0-40 percent of the mixture). The resin is formed by condensation of 1 mole of p-nonylphenol with 2 to 4 moles of formaldehyde and subsequent ethoxylation with 4 to 12 moles of ethylene oxide; and. 3. N-Tridecyl alcohol mixture of dihydrogen phosphate and monohydrogen phosphate esters (40 to 80 percent of the mixture; CAS Reg. No. 56831-62-0). 	For use only as a surfactant to improve lubricity in lubricating fluids complying with this section at a level not to exceed 5 percent by weight of the lubricating fluid.
Fatty acids derived from animal or vegetable sources, and the hydrogenated forms of such fatty acids.	
2-(8-Heptadecenyl)-4,5-dihydro-1H-imidazole-1-ethanol (CAS Reg. No. 95-38-5).	For use at levels not to exceed 0.5 percent by weight of the lubricant.
Hexamethylenebis(3,5-di-tert-butyl-4-hydroxyhydrocinnamate) (CAS Reg. No. 35074-77-2).	For use as an antioxidant at levels not to exceed 0.5 percent by weight of the lubricant.
α -Hydro- ω -hydroxypoly(oxyethylene) poly(oxypropylene) produced by random condensation of mixtures of ethylene oxide and propylene oxide containing 25 to 75 percent by weight of ethylene oxide; minimum molecular weight 1,500; Chemical Abstracts Service Registry No. 9003-11-6.	Addition to food not to exceed 10 parts per million.
12-Hydroxystearic acid.	
Isopropyl oleate	For use only as an adjuvant (to improve lubricity) in mineral oil lubricants.

Substances	Limitations
Magnesium ricinoleate	For use only as an adjuvant in mineral oil lubricants at a level not to exceed 10 percent by weight of the mineral oil.
Mineral oil	Addition to food not to exceed 10 parts per million.
N Methyl N (1-oxo-9-octadecenyl)glycine (CAS Reg. No. 110-25-8).	For use as a corrosion inhibitor at levels not to exceed 0.5 percent by weight of the lubricant.
N-phenylbenzenamine, reaction products with 2,4,4-trimethylpentene (CAS Reg. No. 68411-46-1).	For use only as an antioxidant at levels not to exceed 0.5 percent by weight of the lubricant.
Petrolatum	Complying with 178.3700. Addition to food not to exceed 10 parts per million.
Phenyl- α and/or phenyl- β naphthylamine	For use only, singly or in combination, as antioxidant in mineral oil lubricants at a level not to exceed a total of 1 percent by weight of the mineral oil.
Phosphoric acid, mono- and dihexyl esters, compounds with tetramethylnonylamines and alkylamines.	For use only as an adjuvant at levels not to exceed 0.5 percent by weight of the lubricant.
Phosphoric acid, mono- and diisooctyl esters, reacted with tertalkyl and (-) primary amines (CAS Reg. No. 68187-67-7).	For use only as a corrosion inhibitor or rust preventative in lubricants at a level not to exceed 0.5 percent by weight of the lubricant.
Polyurea, having a nitrogen content of 9-14 percent based on the dry polyurea weight, produced by reacting tolylene diisocyanate with tall oil fatty acid (- and -) amine and ethylene diamine in a 2:2:1 molar ratio.	For use only as an adjuvant in mineral oil lubricants at a level not to exceed 10 percent by weight of the mineral oil.
Polybutene (minimum average molecular weight 80,000)	Addition to food not to exceed 10 parts per million
Polybutene, hydrogenated; complying with the identity prescribed under 178.3740.	Do:
Polyethylene	Do:
Polyisobutylene (average molecular weight 35,000-140,000 (Flory)).	For use only as a thickening agent in mineral oil lubricants.
Sodium nitrite	For use only as a rust preventive in mineral oil lubricants at a level not to exceed 3 percent by weight of the mineral oil.
Tetrakis[methylene(3,5-di-tert-butyl-4-hydroxyhydrocinnamate)]methane (CAS Reg. No. 6683-19-8).	For use only as an antioxidant at levels not to exceed 0.5 percent by weight of the lubricant.
Thiodiethylenebis(3,5-di-tert-butyl-4-hydroxyhydrocinnamate) (CAS Reg. No. 41484-35-9).	For use as an antioxidant at levels not to exceed 0.5 percent by weight of the lubricant.
Triphenyl phosphorothionate (CAS Reg. No. 597-82-0)	For use as an adjuvant in lubricants herein listed at a level not to exceed 0.5 percent by weight of the lubricant.

Substances	Limitations
Tris(2,4 di tert butylphenyl)phosphite (CAS Reg No. 31570-04-4).	For use only as a stabilizer at levels not to exceed 0.5 percent by weight of the lubricant.
Thiodiethylenebis(3,5 di tert butyl 4 hydroxy hydro cinnamate)(CAS Reg. No. 41484-35-9).	For use as an antioxidant at levels not to exceed 0.5 percent by weight of the lubricant.
Zinc sulfide	For use at levels not to exceed 10 percent by weight of the lubricant.

B. ~~The lubricants are used on food processing equipment as a protective antirust film, as a release agent on gaskets or seals of tank closures, and as a lubricant for machine parts and equipment in locations in which there is exposure of the lubricated part to food. The amount used is the minimum required to accomplish the desired technical effect on the equipment, and the addition to food of any constituent identified in this section does not exceed the limitations prescribed.~~

C. ~~Any substance employed in the production of the lubricants described in this section that is the subject of a regulation in parts 174, 175, 176, 177, 178 and 179.45 of this chapter conforms with any specification in such regulation.~~

APPENDIX F - SANITIZERS

REFER TO 40 CFR §180.940, (2010) SANITIZING SOLUTIONS

APPENDIX G - SANITIZERS

~~*Refer to 21 CFR § 178.101, (2003) Sanitizing solutions*~~

APPENDIX G - HACCP GUIDELINES

1. INTRODUCTION TO HACCP

A. WHAT IS HACCP AND HOW CAN IT BE USED BY OPERATORS AND REGULATORS OF RETAIL FOOD AND FOOD SERVICE ESTABLISHMENTS?

HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) IS A SYSTEMATIC APPROACH TO IDENTIFYING, EVALUATING, AND CONTROLLING FOOD SAFETY HAZARDS. FOOD SAFETY HAZARDS ARE BIOLOGICAL, CHEMICAL, OR PHYSICAL AGENTS THAT ARE REASONABLY LIKELY TO CAUSE ILLNESS OR INJURY IN THE ABSENCE OF THEIR CONTROL. BECAUSE A HACCP PROGRAM IS DESIGNED TO ENSURE THAT HAZARDS ARE PREVENTED, ELIMINATED, OR REDUCED TO AN ACCEPTABLE LEVEL BEFORE A FOOD REACHES THE CONSUMER, IT EMBODIES THE PREVENTIVE NATURE OF "ACTIVE MANAGERIAL CONTROL."

ACTIVE MANAGERIAL CONTROL THROUGH THE USE OF HACCP PRINCIPLES IS ACHIEVED BY IDENTIFYING THE FOOD SAFETY HAZARDS ATTRIBUTED TO PRODUCTS, DETERMINING THE NECESSARY STEPS THAT WILL CONTROL THE IDENTIFIED HAZARDS, AND IMPLEMENTING ON-GOING PRACTICES OR PROCEDURES THAT WILL ENSURE SAFE FOOD.

LIKE MANY OTHER QUALITY ASSURANCE PROGRAMS, HACCP PROVIDES A COMMON-SENSE APPROACH TO IDENTIFYING AND CONTROLLING PROBLEMS THAT ARE LIKELY TO EXIST IN AN OPERATION. CONSEQUENTLY, MANY FOOD SAFETY MANAGEMENT SYSTEMS AT THE RETAIL LEVEL ALREADY INCORPORATE SOME, IF NOT ALL, OF THE PRINCIPLES OF HACCP. COMBINED WITH GOOD BASIC SANITATION, A SOLID EMPLOYEE TRAINING PROGRAM, AND OTHER PREREQUISITE PROGRAMS, A FOOD SAFETY MANAGEMENT SYSTEM BASED ON HACCP PRINCIPLES WILL PREVENT, ELIMINATE, OR REDUCE THE OCCURRENCE OF FOODBORNE ILLNESS RISK FACTORS THAT LEAD TO OUT-OF-CONTROL HAZARDS.

HACCP REPRESENTS AN IMPORTANT TOOL IN FOOD PROTECTION THAT SMALL INDEPENDENT BUSINESSES AS WELL AS NATIONAL COMPANIES CAN USE TO ACHIEVE ACTIVE MANAGERIAL CONTROL OF RISK FACTORS. THE FOOD CODE REQUIRES A COMPREHENSIVE HACCP PLAN WHEN CONDUCTING CERTAIN SPECIALIZED PROCESSES AT RETAIL SUCH AS WHEN A VARIANCE IS GRANTED OR WHEN A REDUCED OXYGEN PACKAGING METHOD IS USED. HOWEVER, IN GENERAL, THE IMPLEMENTATION OF HACCP AT THE RETAIL LEVEL IS VOLUNTARY. FDA ENDORSES THE VOLUNTARY IMPLEMENTATION OF FOOD SAFETY MANAGEMENT SYSTEMS BASED ON HACCP PRINCIPLES AS AN EFFECTIVE MEANS FOR CONTROLLING THE OCCURRENCE OF FOODBORNE ILLNESS RISK FACTORS THAT RESULT IN OUT-OF-CONTROL HAZARDS.

WHILE THE OPERATOR IS RESPONSIBLE FOR DEVELOPING AND IMPLEMENTING A SYSTEM OF CONTROLS TO PREVENT FOODBORNE ILLNESS RISK FACTORS, THE ROLE OF THE REGULATOR IS TO ASSESS WHETHER THE SYSTEM THE OPERATOR HAS IN PLACE IS ACHIEVING CONTROL OF FOODBORNE ILLNESS RISK FACTORS. USING HACCP PRINCIPLES DURING INSPECTIONS WILL ENHANCE THE EFFECTIVENESS OF ROUTINE INSPECTIONS BY INCORPORATING A RISK-BASED APPROACH. THIS HELPS INSPECTORS FOCUS THEIR

INSPECTION ON EVALUATING THE EFFECTIVENESS OF FOOD SAFETY MANAGEMENT SYSTEMS IMPLEMENTED BY INDUSTRY TO CONTROL FOODBORNE ILLNESS RISK FACTORS.

FOR REGULATORY PROGRAM MANAGERS, THE USE OF RISK-BASED INSPECTION METHODOLOGY BASED ON HACCP PRINCIPLES IS A VIABLE AND PRACTICAL OPTION FOR EVALUATING THE DEGREE OF ACTIVE MANAGERIAL CONTROL OPERATORS HAVE OVER THE FOODBORNE ILLNESS RISK FACTORS.

B. WHAT ARE THE SEVEN HACCP PRINCIPLES?

IN NOVEMBER 1992, THE NATIONAL ADVISORY COMMITTEE ON MICROBIOLOGICAL CRITERIA FOR FOODS (NACMCF) DEFINED SEVEN WIDELY ACCEPTED HACCP PRINCIPLES THAT EXPLAINED THE HACCP PROCESS IN GREAT DETAIL. IN 1997, NACMCF RECONVENED TO REVIEW THE 1992 DOCUMENT AND COMPARE IT TO CURRENT HACCP GUIDANCE PREPARED BY THE CODEX COMMITTEE ON FOOD HYGIENE. BASED ON THIS REVIEW, NACMCF AGAIN ENDORSED HACCP AND DEFINED HACCP AS A SYSTEMATIC APPROACH TO THE IDENTIFICATION, EVALUATION, AND CONTROL OF FOOD SAFETY. BASED ON A SOLID FOUNDATION OF PREREQUISITE PROGRAMS TO CONTROL BASIC OPERATIONAL AND SANITATION CONDITIONS, THE FOLLOWING SEVEN BASIC PRINCIPLES ARE USED TO ACCOMPLISH THIS OBJECTIVE:

1. PRINCIPLE 1: CONDUCT A HAZARD ANALYSIS
2. PRINCIPLE 2: DETERMINE THE CRITICAL CONTROL POINTS (CCPs)
3. PRINCIPLE 3: ESTABLISH CRITICAL LIMITS
4. PRINCIPLE 4: ESTABLISH MONITORING PROCEDURES
5. PRINCIPLE 5: ESTABLISH CORRECTIVE ACTIONS
6. PRINCIPLE 6: ESTABLISH VERIFICATION PROCEDURES
7. PRINCIPLE 7: ESTABLISH RECORD-KEEPING AND DOCUMENTATION PROCEDURES.

THIS APPENDIX WILL PROVIDE A BRIEF OVERVIEW OF EACH OF THE SEVEN PRINCIPLES OF HACCP. A MORE COMPREHENSIVE DISCUSSION OF THESE PRINCIPLES IS AVAILABLE FROM FDA BY ACCESSING THE [NACMCF GUIDANCE](#) . FOLLOWING THE OVERVIEW, A PRACTICAL SCHEME FOR APPLYING AND IMPLEMENTING THE HACCP PRINCIPLES IN RETAIL AND FOOD SERVICE ESTABLISHMENTS IS PRESENTED.

C. WHAT ARE PREREQUISITE PROGRAMS?

IN ORDER FOR A HACCP SYSTEM TO BE EFFECTIVE, A STRONG FOUNDATION OF PROCEDURES THAT ADDRESS THE BASIC OPERATIONAL AND SANITATION CONDITIONS WITHIN AN OPERATION MUST FIRST BE DEVELOPED AND IMPLEMENTED. THESE PROCEDURES ARE COLLECTIVELY TERMED "PREREQUISITE PROGRAMS." WHEN PREREQUISITE PROGRAMS ARE IN PLACE, MORE ATTENTION CAN BE GIVEN TO CONTROLLING HAZARDS ASSOCIATED WITH THE FOOD AND ITS PREPARATION. PREREQUISITE PROGRAMS MAY INCLUDE SUCH THINGS AS:

- VENDOR CERTIFICATION PROGRAMS
- TRAINING PROGRAMS
- ALLERGEN MANAGEMENT
- BUYER SPECIFICATIONS
- RECIPE/PROCESS INSTRUCTIONS

- FIRST-IN-FIRST-OUT (FIFO) PROCEDURES
- OTHER STANDARD OPERATING PROCEDURES (SOPs).

BASIC PREREQUISITE PROGRAMS SHOULD BE IN PLACE TO:

- PROTECT PRODUCTS FROM CONTAMINATION BY BIOLOGICAL, CHEMICAL, AND PHYSICAL FOOD SAFETY HAZARDS
- CONTROL BACTERIAL GROWTH THAT CAN RESULT FROM TEMPERATURE ABUSE
- MAINTAIN EQUIPMENT.

ADDITIONAL INFORMATION ABOUT PREREQUISITE PROGRAMS AND THE TYPES OF ACTIVITIES USUALLY INCLUDED IN THEM CAN BE FOUND IN THE FDA'S RETAIL HACCP MANUALS DISCUSSED LATER IN THIS APPENDIX OR BY ACCESSING THE NACMCF GUIDANCE DOCUMENT ON THE FDA WEB PAGE.

2. THE HACCP PRINCIPLES

A. PRINCIPLE #1: CONDUCT A HAZARD ANALYSIS

1. WHAT IS A FOOD SAFETY HAZARD?

A HAZARD IS A BIOLOGICAL, CHEMICAL, OR PHYSICAL PROPERTY THAT MAY CAUSE A FOOD TO BE UNSAFE FOR HUMAN CONSUMPTION.

2. WHAT ARE BIOLOGICAL HAZARDS?

BIOLOGICAL HAZARDS INCLUDE BACTERIAL, VIRAL, AND PARASITIC MICROORGANISMS. SEE TABLE 1 IN THIS APPENDIX FOR A LISTING OF SELECTED BIOLOGICAL HAZARDS. BACTERIAL PATHOGENS COMPRISE THE MAJORITY OF CONFIRMED FOODBORNE DISEASE OUTBREAKS AND CASES. ALTHOUGH COOKING DESTROYS THE VEGETATIVE CELLS OF FOODBORNE BACTERIA TO ACCEPTABLE LEVELS, SPORES OF SPORE-FORMING BACTERIA SUCH AS *BACILLUS CEREUS*, *CLOSTRIDIUM BOTULINUM*, AND *CLOSTRIDIUM PERFRINGENS* SURVIVE COOKING AND MAY GERMINATE AND GROW IF FOOD IS NOT PROPERLY COOLED OR HELD AFTER COOKING. THE TOXINS PRODUCED BY THE VEGETATIVE CELLS OF *BACILLUS CEREUS*, *CLOSTRIDIUM BOTULINUM*, AND *STAPHYLOCOCCUS AUREUS* MAY NOT BE DESTROYED TO SAFE LEVELS BY REHEATING. POST-COOK RECONTAMINATION WITH VEGETATIVE CELLS OF BACTERIA SUCH AS *SALMONELLAE* AND *CAMPYLOBACTER JEJUNI* IS ALSO A MAJOR CONCERN FOR OPERATORS OF RETAIL AND FOOD SERVICE ESTABLISHMENTS.

VIRUSES SUCH AS NOROVIRUS, HEPATITIS A, AND ROTAVIRUS ARE DIRECTLY RELATED TO CONTAMINATION FROM HUMAN FECES. RECENT OUTBREAKS HAVE ALSO SHOWN THAT THESE VIRUSES MAY BE TRANSMITTED VIA DROPLETS IN THE AIR. IN LIMITED CASES, FOODBORNE VIRUSES MAY OCCUR IN RAW COMMODITIES CONTAMINATED BY HUMAN FECES (E.G., SHELLFISH HARVESTED FROM UNAPPROVED, POLLUTED WATERS). IN MOST CASES, HOWEVER, CONTAMINATION OF FOOD BY VIRUSES IS THE RESULT OF CROSS-CONTAMINATION BY ILL FOOD EMPLOYEES OR UNCLEAN EQUIPMENT AND UTENSILS. UNLIKE BACTERIA, A VIRUS CANNOT MULTIPLY OUTSIDE OF A LIVING CELL. COOKING AS A CONTROL FOR VIRUSES MAY BE INEFFECTIVE BECAUSE MANY FOODBORNE VIRUSES SEEM

TO EXHIBIT HEAT RESISTANCE EXCEEDING COOKING TEMPERATURE REQUIREMENTS, UNDER LABORATORY CONDITIONS. OBTAINING FOOD FROM APPROVED SOURCES, PRACTICING NO BARE HAND CONTACT WITH READY-TO-EAT FOOD AS WELL AS PROPER HANDWASHING, AND IMPLEMENTING AN EMPLOYEE HEALTH POLICY TO RESTRICT OR EXCLUDE ILL EMPLOYEES ARE IMPORTANT CONTROL MEASURES FOR VIRUSES.

PARASITES ARE MOST OFTEN ANIMAL HOST-SPECIFIC, BUT CAN INCLUDE HUMANS IN THEIR LIFE CYCLES. PARASITIC INFECTIONS ARE COMMONLY ASSOCIATED WITH UNDERCOOKING MEAT PRODUCTS OR CROSS-CONTAMINATION OF READY-TO-EAT FOOD WITH RAW ANIMAL FOODS, UNTREATED WATER, OR CONTAMINATED EQUIPMENT OR UTENSILS. LIKE VIRUSES, PARASITES DO NOT GROW IN FOOD, SO CONTROL IS FOCUSED ON DESTROYING THE PARASITES AND/OR PREVENTING THEIR INTRODUCTION. ADEQUATE COOKING DESTROYS PARASITES. IN ADDITION, PARASITES IN FISH TO BE CONSUMED RAW OR UNDERCOOKED CAN ALSO BE DESTROYED BY EFFECTIVE FREEZING TECHNIQUES. PARASITIC CONTAMINATION BY ILL EMPLOYEES CAN BE PREVENTED BY PROPER HANDWASHING, NO BARE HAND CONTACT WITH READY-TO-EAT FOOD, AND IMPLEMENTATION OF AN EMPLOYEE HEALTH POLICY TO RESTRICT OR EXCLUDE ILL EMPLOYEES.

APPENDIX G, TABLE 1. SELECTED BIOLOGICAL HAZARDS FOUND AT RETAIL, ASSOCIATED FOODS, AND CONTROL MEASURES

APPENDIX G, TABLE 1. SELECTED BIOLOGICAL HAZARDS FOUND AT RETAIL, ASSOCIATED FOODS, AND CONTROL MEASURES		
HAZARD	ASSOCIATED FOODS	CONTROL MEASURES
BACTERIA	BACILLUS CEREUS(INTOXICATION CAUSED BY HEAT STABLE, PREFORMED EMETIC TOXIN AND INFECTION BY HEAT LABILE, DIARRHEAL TOXIN)	MEAT, POULTRY, STARCHY FOODS (RICE, POTATOES), PUDDINGS, SOUPS, COOKED VEGETABLES
	CAMPYLOBACTER JEJUNI	POULTRY, RAW MILK
	CLOSTRIDIUM BOTULINUM	VACUUM-PACKED FOODS, REDUCED OXYGEN PACKAGED FOODS, UNDER-PROCESSED CANNED FOODS, GARLIC-IN-OIL MIXTURES, TIME/TEMPERATURE ABUSED BAKED POTATOES/SAUTÉED
		COOKING, COOLING, COLD HOLDING, HOT HOLDING
		COOKING, HANDWASHING, PREVENTION OF CROSS-CONTAMINATION
		THERMAL PROCESSING (TIME + PRESSURE), COOLING, COLD HOLDING, HOT HOLDING, ACIDIFICATION AND DRYING, ETC.

		ONIONS	
	CLOSTRIDIUM PERFRINGENS	COOKED MEAT AND POULTRY, COOKED MEAT AND POULTRY PRODUCTS INCLUDING CASSEROLES, GRAVIES	COOLING, COLD HOLDING, REHEATING, HOT HOLDING
	E. COLI O157:H7 (OTHER SHIGA TOXIN-PRODUCING E. COLI)	RAW GROUND BEEF, RAW SEED SPROUTS, RAW MILK, UNPASTEURIZED JUICE, FOODS CONTAMINATED BY INFECTED FOOD WORKERS VIA FECAL-ORAL ROUTE	COOKING, NO BARE HAND CONTACT WITH RTE FOODS, EMPLOYEE HEALTH POLICY, HANDWASHING, PREVENTION OF CROSS-CONTAMINATION, PASTEURIZATION OR TREATMENT OF JUICE
	LISTERIA MONOCYTOGENES	RAW MEAT AND POULTRY, FRESH SOFT CHEESE, PATÉ, SMOKED SEAFOOD, DELI MEATS, DELI SALADS	COOKING, DATE MARKING, COLD HOLDING, HANDWASHING, PREVENTION OF CROSS-CONTAMINATION
	SALMONELLA SPP.	MEAT AND POULTRY, SEAFOOD, EGGS, RAW SEED SPROUTS, RAW VEGETABLES, RAW MILK, UNPASTEURIZED JUICE	COOKING, USE OF PASTEURIZED EGGS, EMPLOYEE HEALTH POLICY, NO BARE HAND CONTACT WITH RTE FOODS, HANDWASHING, PASTEURIZATION OR TREATMENT OF JUICE
	SHIGELLA SPP.	RAW VEGETABLES AND HERBS, OTHER FOODS CONTAMINATED BY INFECTED WORKERS VIA FECAL-ORAL ROUTE	COOKING, NO BARE HAND CONTACT WITH RTE FOODS, EMPLOYEE HEALTH POLICY, HANDWASHING
	STAPHYLOCOCCUS AUREUS(PREFORMED HEAT STABLE TOXIN)	RTE PHF FOODS TOUCHED BY BARE HANDS AFTER COOKING AND FURTHER TIME/TEMPERATURE ABUSED	COOLING, COLD HOLDING, HOT HOLDING, NO BARE HAND CONTACT WITH RTE FOOD, HANDWASHING
	VIBRIO SPP.	SEAFOOD, SHELLFISH	COOKING, APPROVED SOURCE, PREVENTION OF CROSS-CONTAMINATION, COLD

			HOLDING
PARASITES	ANISAKIS SIMPLEX	VARIOUS FISH (COD, HADDOCK, FLUKE, PACIFIC SALMON, HERRING, FLOUNDER, MONKFISH)	COOKING, FREEZING
	TAENIA SPP.	BEEF AND PORK	COOKING
	TRICHINELLA SPIRALIS	PORK, BEAR, AND SEAL MEAT	COOKING
VIRUSES	HEPATITIS A AND E	SHELLFISH, ANY FOOD CONTAMINATED BY INFECTED WORKER VIA FECAL-ORAL ROUTE	APPROVED SOURCE, NO BARE HAND CONTACT WITH RTE FOOD, MINIMIZING BARE HAND CONTACT WITH FOODS NOT RTE, EMPLOYEE HEALTH POLICY, HANDWASHING
	OTHER VIRUSES (ROTAVIRUS, NOROVIRUS, REOVIRUS)	ANY FOOD CONTAMINATED BY INFECTED WORKER VIA FECAL-ORAL ROUTE	NO BARE HAND CONTACT WITH RTE FOOD, MINIMIZING BARE HAND CONTACT WITH FOODS NOT RTE, EMPLOYEE HEALTH POLICY, HANDWASHING

RTE = READY-TO-EAT

PHF = POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD)

3. WHAT ARE CHEMICAL HAZARDS?

CHEMICAL HAZARDS MAY BE NATURALLY OCCURRING OR MAY BE ADDED DURING THE PROCESSING OF FOOD. HIGH LEVELS OF TOXIC CHEMICALS MAY CAUSE ACUTE CASES OF FOODBORNE ILLNESS, WHILE CHRONIC ILLNESS MAY RESULT FROM LOW LEVELS.

THE CODE OF FEDERAL , TITLE 21 FOOD AND DRUGS, PROVIDES GUIDANCE ON NATURALLY OCCURRING POISONOUS OR DELETERIOUS SUBSTANCES, E.G., 21 CFR PARTS 109 UNAVOIDABLE CONTAMINANTS IN FOOD FOR HUMAN CONSUMPTION AND FOOD PACKAGING MATERIAL, AND 184 DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE. THE CFR ALSO PROVIDE ALLOWABLE LIMITS FOR MANY OF THE CHEMICALS ADDED DURING PROCESSING, E.G., 21 CFR PART 172 FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION.

FDA'S COMPLIANCE POLICY GUIDELINES ALSO PROVIDE INFORMATION ON NATURALLY OCCURRING CHEMICALS. SEE CHAPTER 5 - FOODS, COLORS AND . EXAMPLES INCLUDE SECTIONS:

- 540.600 FISH, SHELLFISH, CRUSTACEANS, AND OTHER AQUATIC ANIMALS - FRESH, FROZEN OR PROCESSED – METHYL MERCURY,
- 555.400 FOODS - ADULTERATION WITH AFLATOXIN, AND
- 570.200 AFLATOXIN IN BRAZIL NUTS, .375 PEANUTS AND PEANUT PRODUCTS, AND .500 PISTACHIO NUTS.

TABLE 2 OF THIS APPENDIX PROVIDES ADDITIONAL EXAMPLES OF CHEMICAL HAZARDS, BOTH NATURALLY OCCURRING AND ADDED.

4. **FOOD ALLERGENS AS FOOD SAFETY HAZARDS**

RECENT STUDIES INDICATE THAT OVER 11 MILLION AMERICANS SUFFER FROM ONE OR MORE FOOD ALLERGIES. A FOOD ALLERGY IS CAUSED BY A NATURALLY-OCCURRING PROTEIN IN A FOOD OR A FOOD INGREDIENT, WHICH IS REFERRED TO AS AN "ALLERGEN." FOR UNKNOWN REASONS, CERTAIN INDIVIDUALS PRODUCE IMMUNOGLOBULIN E (IGE) ANTIBODIES SPECIFICALLY DIRECTED TO FOOD ALLERGENS. WHEN THESE SENSITIVE INDIVIDUALS INGEST SUFFICIENT CONCENTRATIONS OF FOODS CONTAINING THESE ALLERGENS, THE ALLERGENIC PROTEINS INTERACT WITH IGE ANTIBODIES AND ELICIT AN ABNORMAL IMMUNE RESPONSE. A FOOD ALLERGIC RESPONSE IS COMMONLY CHARACTERIZED BY HIVES OR OTHER ITCHY RASHES, NAUSEA, ABDOMINAL PAIN, VOMITING AND/OR DIARRHEA, WHEEZING, SHORTNESS OF BREATH, AND SWELLING OF VARIOUS PARTS OF THE BODY. IN SEVERE CASES, ANAPHYLACTIC SHOCK AND DEATH MAY RESULT.

MANY FOODS, WITH OR WITHOUT IDENTIFIABLE ALLERGENS, HAVE BEEN REPORTED TO CAUSE FOOD ALLERGIES. HOWEVER, FDA BELIEVES THERE IS SCIENTIFIC CONSENSUS THAT THE FOLLOWING FOODS CAN CAUSE A SERIOUS ALLERGIC REACTION IN SENSITIVE INDIVIDUALS; THESE FOODS ACCOUNT FOR 90% OR MORE OF ALL FOOD ALLERGIES:

- MILK
- EGG
- FISH (SUCH AS BASS, FLOUNDER, OR COD)
- CRUSTACEAN SHELLFISH (SUCH AS CRAB, LOBSTER, OR SHRIMP)
- TREE NUTS (SUCH AS ALMONDS, PECANS, OR WALNUTS)
- WHEAT
- PEANUTS
- SOYBEANS.

CONSUMERS WITH FOOD ALLERGIES RELY HEAVILY ON INFORMATION CONTAINED ON FOOD LABELS TO AVOID FOOD ALLERGENS. EACH YEAR, FDA RECEIVES REPORTS FROM CONSUMERS WHO HAVE EXPERIENCED AN ADVERSE REACTION FOLLOWING EXPOSURE TO A FOOD ALLERGEN. FREQUENTLY, THESE REACTIONS OCCUR EITHER BECAUSE PRODUCT LABELING DOES NOT INFORM THE CONSUMER OF THE PRESENCE OF THE ALLERGENIC INGREDIENT IN THE FOOD OR BECAUSE OF THE CROSS-CONTACT OF A FOOD WITH AN ALLERGENIC SUBSTANCE NOT INTENDED AS AN INGREDIENT OF THE FOOD DURING PROCESSING AND PREPARATION.

IN AUGUST 2004, THE FOOD ALLERGEN LABELING AND CONSUMER PROTECTION ACT (PUBLIC LAW 108-282, TITLE II) WAS ENACTED, WHICH DEFINES THE TERM "MAJOR FOOD ALLERGEN." THE DEFINITION OF "MAJOR FOOD ALLERGEN" ADOPTED FOR USE IN THE FOOD CODE (SEE PARAGRAPH 1-201.10(B)) IS CONSISTENT WITH THE DEFINITION IN THE NEW LAW. THE FOLLOWING REQUIREMENTS ARE INCLUDED IN THE NEW LAW:

- FOR FOODS LABELED ON OR AFTER JANUARY 1, 2006, FOOD MANUFACTURERS MUST IDENTIFY IN PLAIN LANGUAGE ON THE LABEL OF THE FOOD ANY MAJOR FOOD ALLERGEN USED AS AN INGREDIENT IN THE FOOD, INCLUDING A COLORING, FLAVORING, OR INCIDENTAL ADDITIVE.
- FDA IS TO CONDUCT INSPECTIONS TO ENSURE THAT FOOD FACILITIES COMPLY WITH PRACTICES TO REDUCE OR ELIMINATE CROSS-CONTACT OF A FOOD WITH ANY MAJOR FOOD ALLERGENS THAT ARE NOT INTENTIONAL INGREDIENTS OF THE FOOD.
- WITHIN 18 MONTHS OF THE DATE OF ENACTMENT OF THE NEW LAW (I.E., BY FEBRUARY 2, 2006), FDA MUST SUBMIT A REPORT TO CONGRESS THAT ANALYZES THE RESULTS OF ITS FOOD INSPECTION FINDINGS AND ADDRESSES A NUMBER OF SPECIFIC ISSUES RELATED TO THE PRODUCTION, LABELING, AND RECALL OF FOODS THAT CONTAIN AN UNDECLARED MAJOR FOOD ALLERGEN.
- WITHIN 2 YEARS OF THE DATE OF ENACTMENT OF THE NEW LAW (I.E., BY AUGUST 2, 2006), FDA MUST ISSUE A PROPOSED RULE, AND WITHIN 4 YEARS OF THE DATE OF ENACTMENT OF THE NEW LAW (I.E., BY AUGUST 2, 2008), FDA MUST ISSUE A FINAL RULE TO DEFINE AND PERMIT THE USE OF THE TERM "GLUTEN-FREE" ON FOOD LABELING.
- FDA IS TO WORK IN COOPERATION WITH THE CONFERENCE FOR FOOD PROTECTION (CFP) TO PURSUE REVISION OF THE FOOD CODE TO PROVIDE GUIDELINES FOR PREPARING ALLERGEN-FREE FOODS IN FOOD ESTABLISHMENTS.

APPENDIX G, TABLE 2. COMMON CHEMICAL HAZARDS AT RETAIL, ALONG WITH THEIR ASSOCIATED FOODS AND CONTROL MEASURES

CHEMICAL HAZARDS		ASSOCIATED FOODS	CONTROL MEASURES
NATURALLY OCCURRING:	SCOMBROTOXIN	PRIMARILY ASSOCIATED WITH TUNA FISH, MAHI-MAHI, BLUE FISH, ANCHOVIES BONITO, MACKEREL; ALSO FOUND IN CHEESE	CHECK TEMPERATURES AT RECEIVING; STORE AT PROPER COLD HOLDING TEMPERATURES; BUYER SPECIFICATIONS: OBTAIN VERIFICATION FROM SUPPLIER THAT PRODUCT

			HAS NOT BEEN TEMPERATURE ABUSED PRIOR TO ARRIVAL IN FACILITY.
	CIGUATOXIN	REEF FIN FISH FROM EXTREME SE US, HAWAII, AND TROPICAL AREAS; BARRACUDA, JACKS, KING MACKEREL, LARGE GROUPERS, AND SNAPPERS	ENSURE FIN FISH HAVE NOT BEEN CAUGHT: PURCHASE FISH FROM APPROVED SOURCES. FISH SHOULD NOT BE HARVESTED FROM AN AREA THAT IS SUBJECT TO AN ADVERSE ADVISORY.
	TETRODOXIN	PUFFER FISH (FUGU; BLOWFISH)	DO NOT CONSUME THESE FISH.
	MYCOTOXINS	AFLATOXIN	CORN AND CORN PRODUCTS, PEANUTS AND PEANUT PRODUCTS, COTTONSEED, MILK, AND TREE NUTS SUCH AS BRAZIL NUTS, PECANS, PISTACHIO NUTS, AND WALNUTS. OTHER GRAINS AND NUTS ARE SUSCEPTIBLE BUT LESS PRONE TO CONTAMINATION.
		PATULIN	APPLE JUICE PRODUCTS
			CHECK CONDITION AT RECEIVING; DO NOT USE MOLDY OR DECOMPOSED FOOD.
			BUYER SPECIFICATION: OBTAIN VERIFICATION FROM SUPPLIER OR AVOID THE USE OF ROTTEN APPLES IN JUICE MANUFACTURING.
	TOXIC MUSHROOM SPECIES	NUMEROUS VARIETIES OF WILD MUSHROOMS	DO NOT EAT UNKNOWN VARIETIES OR MUSHROOMS FROM UNAPPROVED

			SOURCE.
SHELLFISH TOXINS	PARALYTIC SHELLFISH POISONING (PSP)	MOLLUSCAN SHELLFISH FROM NE AND NW COASTAL REGIONS; MACKEREL, VISCERA OF LOBSTERS AND DUNGENESS, TANNER, AND RED ROCK CRABS	ENSURE MOLLUSCAN SHELLFISH ARE: FROM AN APPROVED SOURCE; AND PROPERLY TAGGED AND LABELED.
	DIARRHETIC SHELLFISH POISONING (DSP)	MOLLUSCAN SHELLFISH IN JAPAN, WESTERN EUROPE, CHILE, NZ, EASTERN CANADA	
	NEUROTOXIN SHELLFISH POISONING (NSP)	MOLLUSCAN SHELLFISH FROM GULF OF MEXICO	
	AMNESIC SHELLFISH POISONING (ASP)	MOLLUSCAN SHELLFISH FROM NE AND NW COASTS OF NA; VISCERA OF DUNGENESS, TANNER, RED ROCK CRABS AND ANCHOVIES.	
	PYRROLIZIDINE ALKALOIDS	PLANTS FOOD CONTAINING THESE ALKALOIDS. MOST COMMONLY FOUND IN MEMBERS OF THE BORGINACEAE, COMPOSITAE, AND LEGUMINOSAE FAMILIES.	DO NOT CONSUME OF FOOD OR MEDICINALS CONTAMINATED WITH THESE ALKALOIDS.
	PHTYOHAEMMAGGLUTININ	RAW RED KIDNEY BEANS (UNDERCOOKED BEANS MAY BE MORE TOXIC THAN RAW BEANS)	SOAK IN WATER FOR AT LEAST 5 HOURS. POUR AWAY THE WATER. BOIL BRISKLY IN FRESH WATER, WITH OCCASIONAL STIRRING, FOR AT LEAST 10 MINUTES.
ADDED CHEMICALS:	ENVIRONMENTAL CONTAMINANTS: PESTICIDES, FUNGICIDES, FERTILIZERS, INSECTICIDES, ANTIBIOTICS,	ANY FOOD MAY BECOME CONTAMINATED.	FOLLOW LABEL INSTRUCTIONS FOR USE OF ENVIRONMENTAL CHEMICALS. SOIL

	GROWTH HORMONES		OR WATER ANALYSIS MAY BE USED TO VERIFY SAFETY.
	PCBS	FISH	COMPLY WITH FISH ADVISORIES.
	PROHIBITED SUBSTANCES (21 CFR 189)	NUMEROUS SUBSTANCES ARE PROHIBITED FROM USE IN HUMAN FOOD; NO SUBSTANCE MAY BE USED IN HUMAN FOOD UNLESS IT MEETS ALL APPLICABLE REQUIREMENTS OF THE FD&C ACT.	DO NOT USE CHEMICAL SUBSTANCES THAT ARE NOT APPROVED FOR USE IN HUMAN FOOD.
	TOXIC ELEMENTS/COMPOUNDS MERCURY	FISH EXPOSED TO ORGANIC MERCURY: SHARK, TILEFISH, KING MACKEREL AND SWORDFISH. GRAINS TREATED WITH MERCURY BASED FUNGICIDES	PREGNANT WOMEN/WOMEN OF CHILDBEARING AGE/NURSING MOTHERS, AND YOUNG CHILDREN SHOULD NOT EAT SHARK, SWORDFISH, KING MACKEREL OR TILEFISH BECAUSE THEY CONTAIN HIGH LEVELS OF MERCURY. DO NOT USE MERCURY CONTAINING FUNGICIDES ON GRAINS OR ANIMALS.
	COPPER	HIGH ACID FOODS AND BEVERAGES	DO NOT STORE HIGH ACID FOODS IN COPPER UTENSILS; USE BACKFLOW PREVENTION DEVICE ON BEVERAGE VENDING MACHINES.

LEAD	HIGH ACID FOOD AND BEVERAGES	DO NOT USE VESSELS CONTAINING LEAD.
PRESERVATIVES AND FOOD ADDITIVES: SULFITING AGENTS (SULFUR DIOXIDE, SODIUM AND POTASSIUM BISULFITE, SODIUM AND POTASSIUM METABISULFITE)	FRESH FRUITS AND VEGETABLES SHRIMP LOBSTER WINE	SULFITING AGENTS ADDED TO A PRODUCT IN A PROCESSING PLANT MUST BE DECLARED ON LABELING. DO NOT USE ON RAW PRODUCE IN FOOD ESTABLISHMENTS.
NITRITES/NITRATES NIACIN	CURED MEATS, FISH, ANY FOOD EXPOSED TO ACCIDENTAL CONTAMINATION, SPINACH MEAT AND OTHER FOODS TO WHICH SODIUM NICOTINATE IS ADDED	DO NOT USE MORE THAN THE PRESCRIBED AMOUNT OF CURING COMPOUND ACCORDING TO LABELING INSTRUCTIONS. SODIUM NICOTINATE (NIACIN) IS NOT CURRENTLY APPROVED FOR USE IN MEAT OR POULTRY WITH OR WITHOUT NITRATES OR NITRATES.
FLAVOR ENHANCERS MONOSODIUM GLUTAMATE (MSG)	ASIAN OR LATIN AMERICAN FOOD	AVOID USING EXCESSIVE AMOUNTS
CHEMICALS USED IN RETAIL ESTABLISHMENTS (E.G., LUBRICANTS, CLEANERS, SANITIZERS, CLEANING COMPOUNDS, AND PAINTS)	ANY FOOD COULD BECOME CONTAMINATED	ADDRESS THROUGH SOPs FOR PROPER LABELING, STORAGE, HANDLING, AND USE OF CHEMICALS; RETAIN MATERIAL SAFETY DATA

			SHEETS FOR ALL CHEMICALS.
	ALLERGENS	FOODS CONTAINING OR CONTACTED BY: <ul style="list-style-type: none"> ▪ MILK ▪ EGG ▪ FISH ▪ CRUSTACEAN SHELLFISH ▪ TREE NUTS ▪ WHEAT ▪ PEANUTS ▪ SOYBEANS 	USE A RIGOROUS SANITATION REGIME TO PREVENT CROSS CONTACT BETWEEN ALLERGENIC AND NON-ALLERGENIC INGREDIENTS.

5. WHAT ARE PHYSICAL HAZARDS?

ILLNESS AND INJURY CAN RESULT FROM FOREIGN OBJECTS IN FOOD. THESE PHYSICAL HAZARDS CAN RESULT FROM CONTAMINATION OR POOR PROCEDURES AT MANY POINTS IN THE FOOD CHAIN FROM HARVEST TO CONSUMER, INCLUDING THOSE WITHIN THE FOOD ESTABLISHMENT. AS ESTABLISHMENTS DEVELOP THEIR FOOD SAFETY MANAGEMENT SYSTEMS, APPENDIX G, TABLE 3 CAN BE USED TO AID IN THE IDENTIFICATION OF SOURCES OF POTENTIAL PHYSICAL HAZARDS TO THE FOOD BEING PREPARED, SERVED, OR SOLD. APPENDIX G, TABLE 3 PROVIDES SOME EXAMPLES OF COMMON PHYSICAL HAZARDS.

APPENDIX G, TABLE 3. MAIN MATERIALS OF CONCERN AS PHYSICAL HAZARDS AND COMMON^B		
MATERIAL	INJURY POTENTIAL	SOURCES
GLASS FIXTURES	CUTS, BLEEDING; MAY REQUIRE SURGERY TO FIND OR REMOVE	BOTTLES, JARS, LIGHTS, UTENSILS, GAUGE COVERS
WOOD	CUTS, INFECTION, CHOKING; MAY REQUIRE SURGERY TO REMOVE	FIELDS, PALLETS, BOXES, BUILDINGS
STONES, METAL FRAGMENTS	CHOKING, BROKEN TEETH CUTS, INFECTION; MAY REQUIRE SURGERY TO REMOVE	FIELDS, BUILDINGS, MACHINERY, WIRE, EMPLOYEES
INSULATION	CHOKING; LONG-TERM IF ASBESTOS	BUILDING MATERIALS
BONE	CHOKING, TRAUMA	FIELDS, IMPROPER PLANT PROCESSING

PLASTIC	CHOKING, CUTS, INFECTION; MAY REQUIRE SURGERY TO REMOVE	FIELDS, PLANT PACKAGING MATERIALS, PALLETS, EMPLOYEES
PERSONAL EFFECTS	CHOKING, CUTS, BROKEN TEETH; MAY REQUIRE SURGERY TO REMOVE	EMPLOYEES

^A ADAPTED FROM CORLETT (1991).

^B USED WITH PERMISSION, "HACCP PRINCIPLES AND APPLICATIONS", PIERSON AND CORLETT, EDS. 1992. CHAPMAN & HALL, NEW YORK, NY.

6. WHAT IS THE PURPOSE OF THE HAZARD ANALYSIS PRINCIPLE?

THE PURPOSE OF HAZARD ANALYSIS IS TO DEVELOP A LIST OF FOOD SAFETY HAZARDS THAT ARE REASONABLY LIKELY TO CAUSE ILLNESS OR INJURY IF NOT EFFECTIVELY CONTROLLED.

7. HOW IS THE HAZARD ANALYSIS CONDUCTED?

THE PROCESS OF CONDUCTING A HAZARD ANALYSIS INVOLVES TWO STAGES:

- HAZARD IDENTIFICATION
- HAZARD EVALUATION

HAZARD IDENTIFICATION CAN BE THOUGHT OF AS A BRAIN STORMING SESSION. THIS STAGE FOCUSES ON IDENTIFYING THE FOOD SAFETY HAZARDS THAT MIGHT BE PRESENT IN THE FOOD GIVEN THE FOOD PREPARATION PROCESS USED, THE HANDLING OF THE FOOD, THE FACILITY, AND GENERAL CHARACTERISTICS OF THE FOOD ITSELF. DURING THIS STAGE, A REVIEW IS MADE OF THE INGREDIENTS USED IN THE PRODUCT, THE ACTIVITIES CONDUCTED AT EACH STEP IN THE PROCESS, THE EQUIPMENT USED, THE FINAL PRODUCT, AND ITS METHOD OF STORAGE AND DISTRIBUTION, AS WELL AS THE INTENDED USE AND CONSUMERS OF THE PRODUCT. BASED ON THIS REVIEW, A LIST OF POTENTIAL BIOLOGICAL, CHEMICAL, OR PHYSICAL HAZARDS IS MADE AT EACH STAGE IN THE FOOD PREPARATION PROCESS.

IN STAGE TWO, THE HAZARD EVALUATION, EACH POTENTIAL HAZARD IS EVALUATED BASED ON THE SEVERITY OF THE POTENTIAL HAZARD AND ITS LIKELY OCCURRENCE. THE PURPOSE OF THIS STAGE IS TO DETERMINE WHICH OF THE POTENTIAL HAZARDS LISTED IN STAGE ONE OF THE HAZARD ANALYSIS WARRANT CONTROL IN THE HACCP PLAN. SEVERITY IS THE SERIOUSNESS OF THE CONSEQUENCES OF EXPOSURE TO THE HAZARD. CONSIDERATIONS MADE WHEN DETERMINING THE SEVERITY OF A HAZARD INCLUDE UNDERSTANDING THE IMPACT OF THE MEDICAL CONDITION CAUSED BY THE ILLNESS, AS WELL AS THE MAGNITUDE AND DURATION OF THE ILLNESS OR INJURY. CONSIDERATION OF THE LIKELY OCCURRENCE IS USUALLY BASED UPON A COMBINATION OF EXPERIENCE, EPIDEMIOLOGICAL DATA, AND INFORMATION IN THE TECHNICAL LITERATURE. HAZARDS THAT ARE NOT REASONABLY LIKELY TO OCCUR ARE NOT

CONSIDERED IN A HACCP PLAN. DURING THE EVALUATION OF EACH POTENTIAL HAZARD, THE FOOD, ITS METHOD OF PREPARATION, TRANSPORTATION, STORAGE, AND PERSONS LIKELY TO CONSUME THE PRODUCT SHOULD BE CONSIDERED TO DETERMINE HOW EACH OF THESE FACTORS MAY INFLUENCE THE LIKELY OCCURRENCE AND SEVERITY OF THE HAZARD BEING CONTROLLED.

UPON COMPLETION OF THE HAZARD ANALYSIS, A LIST OF SIGNIFICANT HAZARDS THAT MUST BE CONSIDERED IN THE HACCP PLAN IS MADE, ALONG WITH ANY MEASURE(S) THAT CAN BE USED TO CONTROL THE HAZARDS. THESE MEASURES, CALLED CONTROL MEASURES, ARE ACTIONS OR ACTIVITIES THAT CAN BE USED TO PREVENT, ELIMINATE, OR REDUCE A HAZARD. SOME CONTROL MEASURES ARE NOT ESSENTIAL TO FOOD SAFETY, WHILE OTHERS ARE. CONTROL MEASURES ESSENTIAL TO FOOD SAFETY LIKE PROPER COOKING, COOLING, AND REFRIGERATION OF READY-TO-EAT, POTENTIALLY HAZARDOUS FOODS (TIME/TEMPERATURE CONTROL FOR SAFETY FOODS) ARE USUALLY APPLIED AT CRITICAL CONTROL POINTS (CCPs) IN THE HACCP PLAN (DISCUSSED LATER). THE TERM CONTROL MEASURE IS USED BECAUSE NOT ALL HAZARDS CAN BE PREVENTED, BUT VIRTUALLY ALL CAN BE CONTROLLED. MORE THAN ONE CONTROL MEASURE MAY BE REQUIRED FOR A SPECIFIC HAZARD. LIKEWISE, MORE THAN ONE HAZARD MAY BE ADDRESSED BY A SPECIFIC CONTROL MEASURE (E.G., PROPER COOKING).

B. PRINCIPLE #2: DETERMINE CRITICAL CONTROL POINTS (CCPs)

1. WHAT IS THE CRITICAL CONTROL POINT (CCP)?

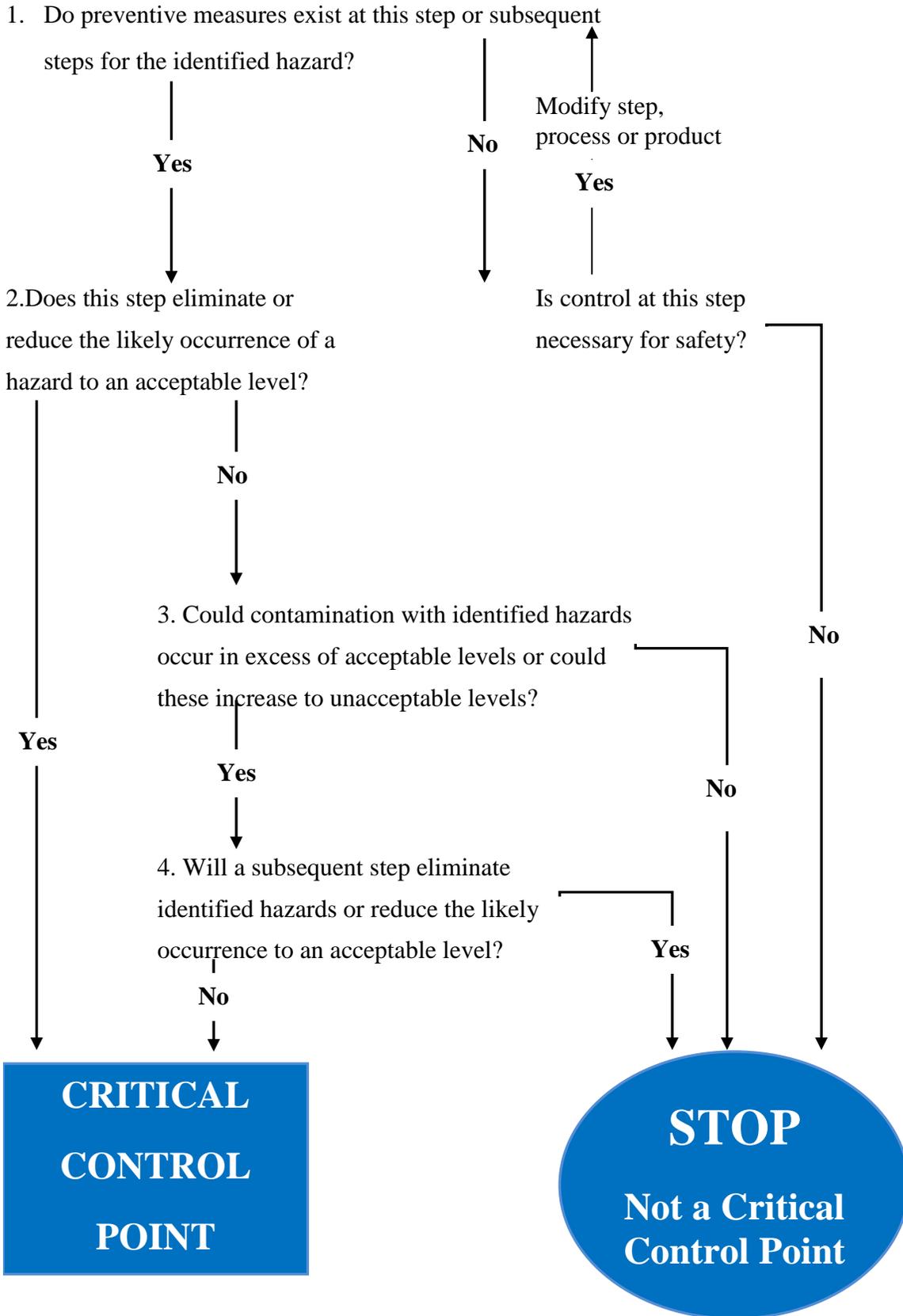
A CRITICAL CONTROL POINT (CCP) MEANS A POINT OR PROCEDURE IN A SPECIFIC FOOD SYSTEM WHERE LOSS OF CONTROL MAY RESULT IN AN UNACCEPTABLE HEALTH RISK. CONTROL CAN BE APPLIED AT THIS POINT AND IS ESSENTIAL TO PREVENT OR ELIMINATE A FOOD SAFETY HAZARD OR REDUCE IT TO AN ACCEPTABLE LEVEL. EACH CCP WILL HAVE ONE OR MORE CONTROL MEASURES TO ASSURE THAT THE IDENTIFIED HAZARDS ARE PREVENTED, ELIMINATED, OR REDUCED TO ACCEPTABLE LEVELS. COMMON EXAMPLES OF CCPs INCLUDE COOKING, COOLING, HOT HOLDING, AND COLD HOLDING OF READY-TO-EAT POTENTIALLY HAZARDOUS FOODS (TIME/TEMPERATURE CONTROL FOR SAFETY FOODS). DUE TO VEGETATIVE AND SPORE- AND TOXIN-FORMING BACTERIA THAT ARE ASSOCIATED WITH RAW ANIMAL FOODS, IT IS APPARENT THAT THE PROPER EXECUTION OF CONTROL MEASURES AT EACH OF THESE OPERATIONAL STEPS IS ESSENTIAL TO PREVENT OR ELIMINATE FOOD SAFETY HAZARDS OR REDUCE THEM TO ACCEPTABLE LEVELS.

2. ARE QUALITY ISSUES CONSIDERED WHEN DETERMINING CCPs?

CCPs ARE ONLY USED TO ADDRESS ISSUES WITH PRODUCT SAFETY. ACTIONS TAKEN ON THE PART OF THE ESTABLISHMENT SUCH AS FIRST-IN FIRST-OUT (FIFO) OR REFRIGERATING NONPOTENTIALLY HAZARDOUS FOODS (TIME/TEMPERATURE CONTROL FOR SAFETY FOODS) ARE TO ENSURE FOOD QUALITY RATHER THAN FOOD SAFETY AND THEREFORE SHOULD NOT BE CONSIDERED AS CCPs UNLESS THEY SERVE A DUAL-PURPOSE OF ENSURING FOOD SAFETY.

3. ARE THE CCPs THE SAME FOR EVERYONE?

DIFFERENT FACILITIES PREPARING SIMILAR FOOD ITEMS MAY IDENTIFY DIFFERENT HAZARDS AND THE CCPs. THIS CAN BE DUE TO DIFFERENCES IN EACH FACILITY'S LAYOUT, EQUIPMENT, SELECTION OF INGREDIENTS, AND PROCESSES EMPLOYED. IN MANDATORY HACCP SYSTEMS, THERE MAY BE RIGID REGULATORY REQUIREMENTS REGARDING WHAT MUST BE DESIGNATED A CCP. IN VOLUNTARY HACCP SYSTEMS, HAZARD CONTROL MAY BE ACCOMPLISHED AT CCPs OR THROUGH PREREQUISITE PROGRAMS. FOR INSTANCE, ONE FACILITY MAY DECIDE THAT IT CAN BEST MANAGE THE HAZARDS ASSOCIATED WITH COOLING THROUGH A STANDARDIZED PROCEDURE IN ITS PREREQUISITE PROGRAMS RATHER THAN AT A CCP IN ITS HACCP PLAN. ONE TOOL THAT CAN BE USED TO ASSIST EACH FACILITY IN THE IDENTIFICATION OF CCPs UNIQUE TO ITS OPERATION IS A CCP DECISION TREE.



C. PRINCIPLE #3: ESTABLISH CRITICAL LIMITS

1. WHAT IS A CRITICAL LIMIT AND WHAT IS ITS PURPOSE?

A CRITICAL LIMIT IS A PRESCRIBED PARAMETER (E.G., MINIMUM AND/OR MAXIMUM VALUE) THAT MUST BE MET TO ENSURE THAT FOOD SAFETY HAZARDS ARE CONTROLLED AT EACH CCP. A CRITICAL LIMIT IS USED TO DISTINGUISH BETWEEN SAFE AND UNSAFE OPERATING CONDITIONS AT A CCP. EACH CONTROL MEASURE AT A CCP HAS ONE OR MORE ASSOCIATED CRITICAL LIMITS. CRITICAL LIMITS MAY BE BASED UPON FACTORS LIKE TEMPERATURE, TIME, MOISTURE LEVEL, WATER ACTIVITY (), OR PH. THEY MUST BE SCIENTIFICALLY-BASED AND MEASURABLE.

2. WHAT ARE EXAMPLES OF CRITICAL LIMITS?

EXAMPLES OF CRITICAL LIMITS ARE THE TIME/TEMPERATURE PARAMETERS FOR COOKING CHICKEN (165°F FOR 15 SECONDS). IN THIS CASE, THE CRITICAL LIMIT DESIGNATES THE MINIMUM CRITERIA REQUIRED TO ELIMINATE FOOD SAFETY HAZARDS OR REDUCE THEM TO AN ACCEPTABLE LEVEL. THE CRITICAL LIMIT FOR THE ACIDIFICATION OF SUSHI RICE, A PH OF ≤ 4.6 , SETS THE MAXIMUM LIMIT FOR PH NECESSARY TO CONTROL THE GROWTH OF SPORE- AND TOXIN-FORMING BACTERIA. CRITICAL LIMITS MAY BE DERIVED FROM REGULATORY STANDARDS SUCH AS THE RULES AND REGULATIONS, OTHER APPLICABLE GUIDELINES, PERFORMANCE STANDARDS, OR EXPERIMENTAL RESULTS.

D. PRINCIPLE #4: ESTABLISH MONITORING PROCEDURES

1. WHAT IS THE PURPOSE OF MONITORING?

MONITORING IS THE ACT OF OBSERVING AND MAKING MEASUREMENTS TO HELP DETERMINE IF CRITICAL LIMITS ARE BEING MET AND MAINTAINED. IT IS USED TO DETERMINE WHETHER THE CRITICAL LIMITS THAT HAVE BEEN ESTABLISHED FOR EACH CCP ARE BEING MET.

2. WHAT ARE EXAMPLES OF MONITORING ACTIVITIES?

EXAMPLES OF MONITORING ACTIVITIES INCLUDE VISUAL OBSERVATIONS AND MEASUREMENTS OF TIME, TEMPERATURE, PH, AND WATER ACTIVITY. IF COOKING CHICKEN IS DETERMINED TO BE A CCP IN AN OPERATION, THEN MONITORING THE INTERNAL TEMPERATURE OF A SELECT NUMBER OF CHICKEN PIECES IMMEDIATELY FOLLOWING THE COOK STEP WOULD BE AN EXAMPLE OF A MONITORING ACTIVITY. ALTERNATIVELY, THE TEMPERATURE OF AN OVEN OR FRYER AND THE TIME REQUIRED TO REACH AN INTERNAL TEMPERATURE OF 165°F COULD ALSO BE MONITORED.

3. HOW IS MONITORING CONDUCTED?

TYPICALLY, MONITORING ACTIVITIES FALL UNDER TWO BROAD CATEGORIES:

- MEASUREMENTS
- OBSERVATIONS

MEASUREMENTS USUALLY INVOLVE TIME AND TEMPERATURE BUT ALSO INCLUDE OTHER PARAMETERS SUCH AS PH. IF AN OPERATION IDENTIFIES THE ACIDIFICATION OF SUSHI RICE AS A CCP AND THE CRITICAL LIMIT AS THE FINAL

PH OF THE PRODUCT BEING ≤ 4.6 , THEN THE PH OF THE PRODUCT WOULD BE MEASURED TO ENSURE THAT THE CRITICAL LIMIT IS MET.

OBSERVATIONS INVOLVE VISUAL INSPECTIONS TO MONITOR THE PRESENCE OR ABSENCE OF A FOOD SAFETY ACTIVITY. IF DATE MARKING IS IDENTIFIED AS A CCP IN A DELI OPERATION FOR CONTROLLING LISTERIA MONOCYTOGENES IN READY-TO-EAT DELI MEATS, THEN THE MONITORING ACTIVITY COULD INVOLVE MAKING VISUAL INSPECTIONS OF THE DATE MARKING SYSTEM TO MONITOR THE SELL, CONSUME, OR DISCARD DATES.

4. HOW OFTEN IS MONITORING CONDUCTED?

MONITORING CAN BE PERFORMED ON A CONTINUOUS OR INTERMITTENT BASIS. CONTINUOUS MONITORING IS ALWAYS PREFERRED WHEN FEASIBLE AS IT PROVIDES THE MOST COMPLETE INFORMATION REGARDING THE HISTORY OF A PRODUCT AT A CCP. FOR EXAMPLE, THE TEMPERATURE AND TIME FOR AN INSTITUTIONAL COOK-CHILL OPERATION CAN BE RECORDED CONTINUOUSLY ON TEMPERATURE RECORDING CHARTS.

IF INTERMITTENT MONITORING IS USED, THE FREQUENCY OF MONITORING SHOULD BE CONDUCTED OFTEN ENOUGH TO MAKE SURE THAT THE CRITICAL LIMITS ARE BEING MET.

5. WHO CONDUCTS MONITORING?

INDIVIDUALS DIRECTLY ASSOCIATED WITH THE OPERATION (E.G., THE PERSON IN CHARGE OF THE ESTABLISHMENT, CHEFS, AND DEPARTMENTAL SUPERVISORS) ARE OFTEN SELECTED TO MONITOR CCPs. THEY ARE USUALLY IN THE BEST POSITION TO DETECT DEVIATIONS AND TAKE CORRECTIVE ACTIONS WHEN NECESSARY. THESE EMPLOYEES SHOULD BE PROPERLY TRAINED IN THE SPECIFIC MONITORING TECHNIQUES AND PROCEDURES USED.

E. PRINCIPLE #5: ESTABLISH CORRECTIVE ACTIONS

1. WHAT ARE CORRECTIVE ACTIONS?

CORRECTIVE ACTIONS ARE ACTIVITIES THAT ARE TAKEN BY A PERSON WHENEVER A CRITICAL LIMIT IS NOT MET. DISCARDING FOOD THAT MAY POSE AN UNACCEPTABLE FOOD SAFETY RISK TO CONSUMERS IS A CORRECTIVE ACTION. HOWEVER, OTHER CORRECTIVE ACTIONS SUCH AS FURTHER COOKING OR REHEATING A PRODUCT CAN BE USED PROVIDED FOOD SAFETY IS NOT COMPROMISED. FOR EXAMPLE, A RESTAURANT MAY BE ABLE TO CONTINUE COOKING HAMBURGERS THAT HAVE NOT REACHED AN INTERNAL TEMPERATURE OF 155°F FOR 15 SECONDS UNTIL THE PROPER TEMPERATURE IS MET. CLEAR INSTRUCTIONS SHOULD BE DEVELOPED DETAILING WHO IS RESPONSIBLE FOR PERFORMING THE CORRECTIVE ACTIONS, THE PROCEDURES TO BE FOLLOWED, AND WHEN.

F. PRINCIPLE #6: ESTABLISH VERIFICATION PROCEDURES

1. WHAT IS VERIFICATION?

VERIFICATION INCLUDES THOSE ACTIVITIES, OTHER THAN MONITORING, THAT DETERMINE THE VALIDITY OF THE HACCP PLAN AND SHOW THAT THE SYSTEM IS OPERATING ACCORDING TO THE PLAN. VALIDATION IS A COMPONENT OF VERIFICATION WHICH FOCUSES ON COLLECTING AND EVALUATING SCIENTIFIC AND TECHNICAL INFORMATION TO DETERMINE IF THE HACCP SYSTEM, WHEN PROPERLY IMPLEMENTED, WILL EFFECTIVELY CONTROL THE HAZARDS. CLEAR INSTRUCTIONS SHOULD BE DEVELOPED DETAILING WHO IS RESPONSIBLE FOR CONDUCTING VERIFICATION, THE FREQUENCY OF VERIFICATION, AND THE PROCEDURES USED.

2. WHAT IS THE FREQUENCY OF VERIFICATION ACTIVITIES? WHAT ARE SOME EXAMPLES OF VERIFICATION ACTIVITIES?

VERIFICATION ACTIVITIES ARE CONDUCTED FREQUENTLY, SUCH AS DAILY, WEEKLY, MONTHLY, AND INCLUDE THE FOLLOWING:

- OBSERVING THE PERSON DOING THE MONITORING AND DETERMINING WHETHER MONITORING IS BEING DONE AS PLANNED
- REVIEWING THE MONITORING RECORDS TO DETERMINE IF THEY ARE COMPLETED ACCURATELY AND CONSISTENTLY
- DETERMINING WHETHER THE RECORDS SHOW THAT THE FREQUENCY OF MONITORING STATED IN THE PLAN IS BEING FOLLOWED
- ENSURING THAT CORRECTIVE ACTION WAS TAKEN WHEN THE PERSON MONITORING FOUND AND RECORDED THAT THE CRITICAL LIMIT WAS NOT MET
- VALIDATING THAT THE CRITICAL LIMITS ARE ACHIEVING THE DESIRED RESULTS OF CONTROLLING THE IDENTIFIED HAZARD
- CONFIRMING THAT ALL EQUIPMENT, INCLUDING EQUIPMENT USED FOR MONITORING, IS OPERATED, MAINTAINED, AND CALIBRATED PROPERLY.

G. PRINCIPLE #7: ESTABLISH RECORD KEEPING PROCEDURES

1. WHY ARE RECORDS IMPORTANT?

MAINTAINING DOCUMENTATION OF THE ACTIVITIES IN A FOOD SAFETY MANAGEMENT SYSTEM CAN BE VITAL TO ITS SUCCESS. RECORDS PROVIDE DOCUMENTATION THAT APPROPRIATE CORRECTIVE ACTIONS WERE TAKEN WHEN CRITICAL LIMITS WERE NOT MET. IN THE EVENT THAT AN ESTABLISHMENT IS IMPLICATED IN A FOODBORNE ILLNESS, DOCUMENTATION OF ACTIVITIES RELATED TO MONITORING AND CORRECTIVE ACTIONS CAN PROVIDE PROOF THAT REASONABLE CARE WAS EXERCISED IN THE OPERATION OF THE ESTABLISHMENT. DOCUMENTING ACTIVITIES PROVIDES A MECHANISM FOR VERIFYING THAT THE ACTIVITIES IN THE HACCP PLAN WERE PROPERLY COMPLETED. IN MANY CASES, RECORDS CAN SERVE A DUAL PURPOSE OF ENSURING QUALITY AND FOOD SAFETY.

2. WHAT TYPES OF RECORDS ARE MAINTAINED AS PART OF A FOOD SAFETY MANAGEMENT SYSTEM?

THERE ARE AT LEAST 5 TYPES OF RECORDS THAT COULD BE MAINTAINED TO SUPPORT A FOOD SAFETY MANAGEMENT SYSTEM:

- RECORDS DOCUMENTING THE ACTIVITIES RELATED TO THE PREREQUISITE PROGRAMS
- MONITORING RECORDS
- CORRECTIVE ACTION RECORDS
- VERIFICATION AND VALIDATION RECORDS
- CALIBRATION RECORDS.

3. THE PROCESS APPROACH - A PRACTICAL APPLICATION OF HACCP AT RETAIL TO ACHIEVE ACTIVE MANAGERIAL CONTROL

A. WHY FOCUS ON HACCP PRINCIPLES AT RETAIL AND FOOD SERVICE?

FDA RECOGNIZES THAT THERE ARE IMPORTANT DIFFERENCES BETWEEN USING HACCP PRINCIPLES IN A FOOD SAFETY MANAGEMENT SYSTEM DEVELOPED FOR FOOD MANUFACTURING PLANTS AND APPLYING THESE SAME PRINCIPLES IN FOOD SAFETY MANAGEMENT SYSTEM DEVELOPED FOR USE IN RETAIL AND FOOD SERVICE ESTABLISHMENTS.

SINCE THE 1980'S, OPERATORS AND REGULATORS HAVE BEEN EXPLORING THE USE OF THE HACCP PRINCIPLES IN RESTAURANTS, GROCERY STORES, INSTITUTIONAL CARE FACILITIES, AND OTHER RETAIL FOOD ESTABLISHMENTS. DURING THIS TIME, MUCH HAS BEEN LEARNED ABOUT HOW THESE PRINCIPLES CAN BE USED IN THESE VARIED OPERATIONS, COLLECTIVELY REFERRED TO AS RETAIL FOOD ESTABLISHMENTS. MOST OF THIS EXPLORATION HAS CENTERED AROUND THE FOCAL QUESTION OF HOW TO STAY TRUE TO THE NACMCF DEFINITIONS OF HACCP AND STILL MAKE THE PRINCIPLES USEFUL TO AN INDUSTRY THAT ENCOMPASSES THE BROADEST RANGE OF CONDITIONS.

UNLIKE INDUSTRIES SUCH AS CANNING, OTHER FOOD PROCESSING, AND DAIRY PLANTS, THE RETAIL INDUSTRY IS NOT EASILY DEFINED BY SPECIFIC COMMODITIES OR CONDITIONS. CONSIDER THE FOLLOWING CHARACTERISTICS THAT RETAIL FOOD ESTABLISHMENTS SHARE THAT SET THEM APART FROM MOST FOOD PROCESSORS:

1. EMPLOYEE AND MANAGEMENT TURNOVER IS EXCEPTIONALLY HIGH IN FOOD ESTABLISHMENTS, ESPECIALLY FOR ENTRY LEVEL POSITIONS. THIS MEANS THE MANY EMPLOYEES OR MANAGERS HAVE LITTLE EXPERIENCE AND FOOD SAFETY TRAINING MUST BE CONTINUOUSLY PROVIDED.
2. MANY ESTABLISHMENTS ARE START-UP BUSINESSES OPERATING WITHOUT BENEFIT OF A LARGE CORPORATE SUPPORT STRUCTURE AND HAVING A RELATIVELY LOW PROFIT MARGIN AND PERHAPS LESS CAPITAL TO WORK WITH THAN OTHER SEGMENTS OF THE FOOD INDUSTRY.
3. THERE IS AN ALMOST ENDLESS NUMBER OF PRODUCTION TECHNIQUES, PRODUCTS, MENU ITEMS, AND INGREDIENTS USED WHICH ARE NOT EASILY

ADAPTED TO A SIMPLE, STANDARDIZED APPROACH. CHANGES OCCUR FREQUENTLY AND LITTLE PREPARATION TIME IS AVAILABLE.

FDA FULLY RECOGNIZES THE DIVERSITY OF RETAIL AND FOOD SERVICE ESTABLISHMENTS AND THEIR VARYING IN-HOUSE RESOURCES TO IMPLEMENT HACCP. THAT RECOGNITION IS COMBINED WITH AN UNDERSTANDING THAT THE SUCCESS OF SUCH IMPLEMENTATION IS DEPENDENT UPON ESTABLISHING REALISTIC AND USEFUL FOOD SAFETY STRATEGIES THAT ARE CUSTOMIZED TO THE OPERATION.

B. WHAT IS THE PROCESS APPROACH?

WHEN CONDUCTING THE HAZARD ANALYSIS, FOOD MANUFACTURERS USUALLY USE FOOD COMMODITIES AS AN ORGANIZATIONAL TOOL AND FOLLOW THE FLOW OF EACH PRODUCT. THIS IS A VERY USEFUL APPROACH FOR PRODUCERS OR PROCESSORS SINCE THEY ARE USUALLY HANDLING ONE PRODUCT AT A TIME. BY CONTRAST, IN RETAIL AND FOOD SERVICE OPERATIONS, FOODS OF ALL TYPES ARE WORKED TOGETHER TO PRODUCE THE FINAL PRODUCT. THIS MAKES A DIFFERENT APPROACH TO THE HAZARD ANALYSIS NECESSARY. CONDUCTING THE HAZARD ANALYSIS BY USING THE FOOD PREPARATION PROCESSES COMMON TO A SPECIFIC OPERATION IS OFTEN MORE EFFICIENT AND USEFUL FOR RETAIL AND FOOD SERVICE OPERATORS. THIS IS CALLED THE "PROCESS APPROACH" TO HACCP.

THE PROCESS APPROACH CAN BEST BE DESCRIBED AS DIVIDING THE MANY FOOD FLOWS IN AN ESTABLISHMENT INTO BROAD CATEGORIES BASED ON ACTIVITIES OR STAGES IN THE PREPARATION OF THE FOOD, THEN ANALYZING THE HAZARDS, AND PLACING MANAGERIAL CONTROLS ON EACH GROUPING.

C. WHAT ARE THE THREE FOOD PREPARATION PROCESSES MOST OFTEN USED IN RETAIL AND FOOD SERVICE ESTABLISHMENTS AND HOW ARE THEY DETERMINED?

THE FLOW OF FOOD IN A RETAIL OR FOOD SERVICE ESTABLISHMENT IS THE PATH THAT FOOD FOLLOWS FROM RECEIVING THROUGH SERVICE OR SALE TO THE CONSUMER. SEVERAL ACTIVITIES OR STAGES MAKE UP THE FLOW OF FOOD AND ARE CALLED OPERATIONAL STEPS. EXAMPLES OF OPERATIONAL STEPS INCLUDE RECEIVING, STORING, PREPARING, COOKING, COOLING, REHEATING, HOLDING, ASSEMBLING, PACKAGING, SERVING, AND SELLING. THE TERMINOLOGY USED FOR OPERATIONAL STEPS MAY DIFFER BETWEEN FOOD SERVICE AND RETAIL FOOD STORE OPERATIONS.

MOST FOOD ITEMS PRODUCED IN A RETAIL OR FOOD SERVICE ESTABLISHMENT CAN BE CATEGORIZED INTO ONE OF THREE PREPARATION PROCESSES BASED ON THE NUMBER OF TIMES THE FOOD PASSES THROUGH THE TEMPERATURE DANGER ZONE BETWEEN 41°F AND 135°F:

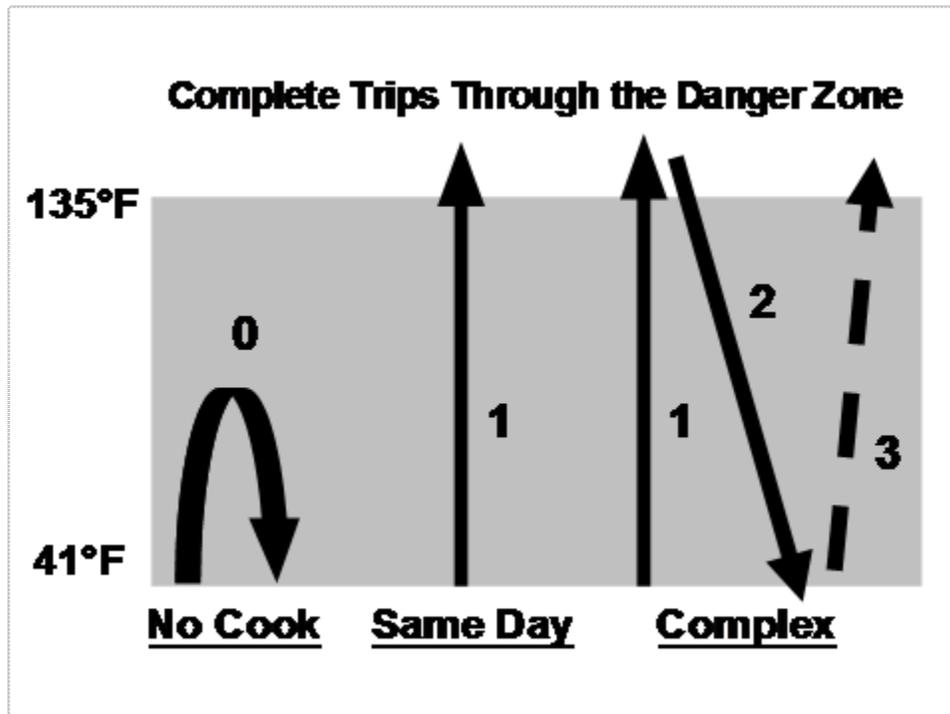
- **PROCESS 1: FOOD PREPARATION WITH NO COOK STEP**
EXAMPLE FLOW: RECEIVE - STORE - PREPARE - HOLD - SERVE
(OTHER FOOD FLOWS ARE INCLUDED IN THIS PROCESS, BUT THERE IS NO COOK STEP TO DESTROY PATHOGENS)
- **PROCESS 2: PREPARATION FOR SAME DAY SERVICE**
EXAMPLE FLOW: RECEIVE - STORE – PREPARE - COOK – HOLD - SERVE
(OTHER FOOD FLOWS ARE INCLUDED IN THIS PROCESS, BUT THERE IS ONLY ONE TRIP THROUGH THE TEMPERATURE DANGER ZONE)

○ **PROCESS 3: COMPLEX FOOD PREPARATION**

EXAMPLE FLOW: RECEIVE - STORE - PREPARE - COOK – COOL – REHEAT – HOT HOLD – SERVE

(OTHER FOOD FLOWS ARE INCLUDED IN THIS PROCESS, BUT THERE ARE ALWAYS TWO OR MORE COMPLETE TRIPS THROUGH THE TEMPERATURE DANGER ZONE)

A SUMMARY OF THE THREE FOOD PREPARATION PROCESSES IN TERMS OF NUMBER OF TIMES THROUGH THE TEMPERATURE DANGER ZONE CAN BE DEPICTED IN A DANGER ZONE DIAGRAM. ALTHOUGH FOODS PRODUCED USING PROCESS 1 MAY ENTER THE DANGER ZONE, THEY DO NOT PASS ALL THE WAY THROUGH IT. FOODS THAT GO THROUGH THE DANGER ZONE ONLY ONCE ARE CLASSIFIED AS SAME DAY SERVICE, WHILE FOODS THAT GO THROUGH MORE THAN ONCE ARE CLASSIFIED AS COMPLEX FOOD PREPARATION.



THE THREE FOOD PREPARATION PROCESSES CONDUCTED IN RETAIL AND FOOD SERVICE ESTABLISHMENTS ARE NOT INTENDED TO BE ALL-INCLUSIVE. FOR INSTANCE, QUICK SERVICE FACILITIES MAY HAVE "COOK AND SERVE" PROCESSES SPECIFIC TO THEIR OPERATION. THESE PROCESSES ARE LIKELY TO BE DIFFERENT FROM THE "SAME DAY SERVICE" PREPARATION PROCESSES IN FULL SERVICE RESTAURANTS SINCE MANY OF THEIR FOODS ARE GENERALLY COOKED AND HOT HELD BEFORE SERVICE. IN ADDITION, IN RETAIL FOOD STORES, OPERATIONAL STEPS SUCH AS PACKAGING AND ASSEMBLY MAY BE INCLUDED IN ALL OF THE FOOD PREPARATION PROCESSES BEFORE THE PRODUCT IS SOLD TO THE CONSUMER. IT IS ALSO VERY COMMON FOR A RETAIL OR FOOD SERVICE OPERATOR TO USE MULTIPLE FOOD PREPARATION PROCESSES TO CREATE A SINGLE MENU ITEM.

D. HOW IS A HAZARD ANALYSIS CONDUCTED IN PROCESS HACCP?

IN THE PROCESS APPROACH TO HACCP, CONDUCTING A HAZARD ANALYSIS ON INDIVIDUAL FOOD ITEMS IS TIME AND LABOR INTENSIVE AND IS GENERALLY UNNECESSARY. IDENTIFYING AND CONTROLLING THE HAZARDS IN EACH FOOD PREPARATION PROCESS ACHIEVES THE SAME CONTROL OF RISK FACTORS AS PREPARING A HACCP PLAN FOR EACH INDIVIDUAL PRODUCT.

EXAMPLE: AN ESTABLISHMENT HAS DOZENS OF FOOD ITEMS (INCLUDING BAKED CHICKEN AND BAKED MEATLOAF) IN THE "PREPARATION FOR SAME DAY SERVICE" CATEGORY. EACH OF THE FOOD ITEMS MAY HAVE UNIQUE HAZARDS, BUT REGARDLESS OF THE INDIVIDUAL HAZARDS, CONTROL VIA PROPER COOKING AND HOLDING WILL GENERALLY ENSURE THE SAFETY OF ALL OF THE FOODS IN THIS CATEGORY. AN ILLUSTRATION OF THIS CONCEPT FOLLOWS:

1. EVEN THOUGH THEY HAVE UNIQUE HAZARDS, BAKED CHICKEN AND MEATLOAF ARE ITEMS FREQUENTLY GROUPED IN THE "SAME DAY SERVICE" CATEGORY (PROCESS 2).
2. SALMONELLA SPP. AND CAMPYLOBACTER, AS WELL AS SPORE-FORMERS, SUCH AS BACILLUS CEREUS AND CLOSTRIDIUM PERFRINGENS, ARE SIGNIFICANT BIOLOGICAL HAZARDS IN CHICKEN.
3. SIGNIFICANT BIOLOGICAL HAZARDS IN MEATLOAF INCLUDE SALMONELLA SPP., E. COLI O157:H7, BACILLUS CEREUS, AND CLOSTRIDIUM PERFRINGENS.
4. DESPITE THEIR DIFFERENT HAZARDS, THE CONTROL MEASURE USED TO KILL PATHOGENS IN BOTH THESE PRODUCTS IS COOKING TO THE PROPER TEMPERATURE.
5. ADDITIONALLY, IF THE PRODUCTS ARE HELD AFTER COOKING, THEN PROPER HOT HOLDING OR TIME CONTROL IS ALSO REQUIRED TO PREVENT THE OUTGROWTH OF SPORE-FORMERS THAT ARE NOT DESTROYED BY COOKING.

AS WITH PRODUCT-SPECIFIC HACCP, CRITICAL LIMITS FOR COOKING REMAIN SPECIFIC TO EACH FOOD ITEM IN THE PROCESS. IN THE SCENARIO DESCRIBED ABOVE, THE COOKING STEP FOR CHICKEN REQUIRES A FINAL INTERNAL TEMPERATURE OF 165°F FOR 15 SECONDS TO CONTROL THE PATHOGEN LOAD FOR SALMONELLA SPP. MEATLOAF, ON THE OTHER HAND, IS A GROUND BEEF PRODUCT AND REQUIRES A FINAL INTERNAL TEMPERATURE OF 155°F FOR 15 SECONDS TO CONTROL THE PATHOGEN LOAD FOR BOTH SALMONELLA SPP. AND E. COLI O157:H7. SOME OPERATIONAL STEPS SUCH AS REFRIGERATED STORAGE OR HOT HOLDING HAVE CRITICAL LIMITS THAT APPLY TO ALL FOODS.

APPENDIX G, TABLE 4 FURTHER ILLUSTRATES THIS CONCEPT. NOTE THAT THE ONLY UNIQUE CONTROL MEASURE APPLIES TO THE CRITICAL LIMIT OF THE COOKING STEP FOR EACH OF THE PRODUCTS. OTHER FOOD SAFETY HAZARDS AND CONTROL MEASURES MAY EXIST THAT ARE NOT DEPICTED HERE:

APPENDIX G, TABLE 4: EXAMPLES OF HAZARDS AND CONTROL MEASURES FOR SAME DAY SERVICE ITEMS

PROCESS 2: PREPARATION FOR SAME DAY SERVICE
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EXAMPLE PRODUCTS	BAKED MEATLOAF	BAKED CHICKEN
EXAMPLE BIOLOGICAL HAZARDS	SALMONELLA SPP.	SALMONELLA SPP.
	E. COLI O157:H7	CAMPYLOBACTER
	CLOSTRIDIUM PERFRINGENS	CLOSTRIDIUM PERFRINGENS
	BACILLUS CEREUS	BACILLUS CEREUS
	VARIOUS FECAL-ORAL ROUTE PATHOGENS	VARIOUS FECAL-ORAL ROUTE PATHOGENS
EXAMPLE CONTROL MEASURES	REFRIGERATION AT 41°F OR BELOW	REFRIGERATION AT 41°F OR BELOW
	COOKING AT 155°F FOR 15 SECONDS	COOKING AT 165°F FOR 15 SECONDS
	HOT HOLDING AT 135°F OR ABOVE OR TIME CONTROL	HOT HOLDING AT 135°F OR ABOVE OR TIME CONTROL
	GOOD PERSONAL HYGIENE (NO BARE HAND CONTACT WITH RTE* FOOD, PROPER HANDWASHING, EXCLUSION/RESTRICTION OF ILL EMPLOYEES)	GOOD PERSONAL HYGIENE (NO BARE HAND CONTACT WITH RTE* FOOD, PROPER HANDWASHING, EXCLUSION/RESTRICTION OF ILL EMPLOYEES)

*RTE = READY-TO-EAT FOOD

E. HOW IS THE PROCESS APPROACH HELPFUL TO INDUSTRY IN DETERMINING THE MEASURES THAT MUST BE IMPLEMENTED TO ACTIVELY MANAGE THE FOODBORNE ILLNESS RISK FACTORS THAT RESULT IN OUT-OF-CONTROL HAZARDS?

EVEN THOUGH VARIATIONS IN FOODS AND IN THE THREE FOOD PREPARATION PROCESS FLOWS USED TO PREPARE THEM ARE COMMON, THE CONTROL MEASURES WILL GENERALLY BE THE SAME BASED ON THE NUMBER OF TIMES THE FOOD GOES THROUGH THE TEMPERATURE DANGER ZONE. SEVERAL OF THE MOST COMMON CONTROL MEASURES ASSOCIATED WITH EACH FOOD PREPARATION PROCESS ARE DISCUSSED IN THIS APPENDIX. RETAIL OR FOOD SERVICE ESTABLISHMENTS SHOULD USE THESE SIMPLE CONTROL MEASURES AS THE CORE OF THEIR FOOD SAFETY MANAGEMENT SYSTEMS; HOWEVER, THERE MAY BE OTHER RISK FACTORS UNIQUE TO AN OPERATION OR PROCESS THAT ARE NOT LISTED HERE. EACH OPERATION SHOULD BE EVALUATED INDEPENDENTLY.

IN DEVELOPING A VOLUNTARY FOOD SAFETY MANAGEMENT SYSTEM, ACTIVE MANAGERIAL CONTROL OF RISK FACTORS COMMON TO EACH PROCESS CAN BE ACHIEVED BY IMPLEMENTING CONTROL MEASURES AT CERTAIN OPERATIONAL STEPS DESIGNATED AS CRITICAL CONTROL POINTS (CCPs) OR BY IMPLEMENTING PREREQUISITE PROGRAMS. THIS IS EXPLAINED IN MORE DETAIL IN THE OPERATOR'S MANUAL DISCUSSED IN PART 5 OF THIS APPENDIX.

F. FACILITY-WIDE CONSIDERATIONS

IN ORDER TO HAVE ACTIVE MANAGERIAL CONTROL OVER PERSONAL HYGIENE AND CROSS-CONTAMINATION, CERTAIN CONTROL MEASURES MUST BE IMPLEMENTED IN ALL PHASES OF THE OPERATION. ALL OF THE FOLLOWING CONTROL MEASURES SHOULD BE IMPLEMENTED REGARDLESS OF THE FOOD PREPARATION PROCESS USED:

- **NO BARE HAND CONTACT WITH READY-TO-EAT FOODS (OR USE OF A PRE-APPROVED, ALTERNATIVE PROCEDURE)** TO HELP PREVENT THE TRANSFER OF VIRUSES, BACTERIA, OR PARASITES FROM HANDS TO FOOD
- **PROPER HANDWASHING** TO HELP PREVENT THE TRANSFER OF VIRUSES, BACTERIA, OR PARASITES FROM HANDS TO FOOD
- **RESTRICTION OR EXCLUSION OF ILL EMPLOYEES** TO HELP PREVENT THE TRANSFER OF VIRUSES, BACTERIA, OR PARASITES FROM HANDS TO FOOD
- **PREVENTION OF CROSS-CONTAMINATION** OF READY-TO-EAT FOOD OR CLEAN AND SANITIZED FOOD-CONTACT SURFACES WITH SOILED CUTTING BOARDS, UTENSILS, APRONS, ETC., OR RAW ANIMAL FOODS.

G. FOOD PREPARATION PROCESS 1 – FOOD PREPARATION WITH NO COOK STEP

EXAMPLE FLOW: RECEIVE → STORE → PREPARE → HOLD → SERVE

SEVERAL FOOD FLOWS ARE REPRESENTED BY THIS PARTICULAR PROCESS. MANY OF THESE FOOD FLOWS ARE COMMON TO BOTH RETAIL FOOD STORES AND FOOD SERVICE FACILITIES, WHILE OTHERS ONLY APPLY TO RETAIL OPERATIONS. RAW, READY-TO-EAT FOOD LIKE SASHIMI, RAW OYSTERS, AND SALADS ARE GROUPED IN THIS CATEGORY. COMPONENTS OF THESE FOODS ARE RECEIVED RAW AND WILL NOT BE COOKED BEFORE CONSUMPTION.

FOODS COOKED AT THE PROCESSING LEVEL BUT THAT UNDERGO NO FURTHER COOKING AT THE RETAIL LEVEL BEFORE BEING CONSUMED ARE ALSO REPRESENTED IN THIS CATEGORY. EXAMPLES OF THESE KINDS OF FOODS ARE DELI MEATS, CHEESES, AND OTHER PASTEURIZED DAIRY PRODUCTS (SUCH AS YOGURT). IN ADDITION, FOODS THAT ARE RECEIVED AND SOLD RAW BUT ARE TO BE COOKED BY THE CONSUMER AFTER PURCHASE, E.G., HAMBURGER MEAT, CHICKEN, AND STEAKS, ARE ALSO INCLUDED IN THIS CATEGORY.

ALL THE FOODS IN THIS CATEGORY LACK A COOK STEP WHILE AT THE RETAIL OR FOOD SERVICE FACILITY; THUS, THERE ARE NO COMPLETE TRIPS THROUGH THE DANGER ZONE. PURCHASE SPECIFICATIONS CAN BE REQUIRED BY THE RETAIL OR FOOD SERVICE ESTABLISHMENT TO ENSURE THAT FOODS ARE RECEIVED AS SAFE AS POSSIBLE. WITHOUT A KILL STEP TO DESTROY PATHOGENS, PREVENTING FURTHER CONTAMINATION BY ENSURING THAT EMPLOYEES FOLLOW GOOD HYGIENIC PRACTICES IS AN IMPORTANT CONTROL MEASURE.

CROSS-CONTAMINATION MUST BE PREVENTED BY PROPERLY STORING READY-TO-EAT FOOD AWAY FROM RAW ANIMAL FOODS AND SOILED EQUIPMENT AND UTENSILS. FOODBORNE ILLNESS MAY RESULT FROM READY-TO-EAT FOOD BEING HELD AT UNSAFE TEMPERATURES FOR LONG PERIODS OF TIME DUE TO THE OUTGROWTH OF BACTERIA.

IN ADDITION TO THE FACILITY-WIDE CONSIDERATIONS, A FOOD SAFETY MANAGEMENT SYSTEM INVOLVING THIS FOOD PREPARATION PROCESS SHOULD FOCUS ON ENSURING ACTIVE MANAGERIAL CONTROL OVER THE FOLLOWING:

- **COLD HOLDING OR USING TIME ALONE** TO CONTROL BACTERIAL GROWTH AND TOXIN PRODUCTION
- **FOOD SOURCE** (E.G., SHELLFISH DUE TO CONCERNS WITH VIRUSES, NATURAL TOXINS, AND VIBRIO AND FOR CERTAIN MARINE FINFISH INTENDED FOR RAW CONSUMPTION DUE TO CONCERNS WITH CIGUATERA TOXIN)
- **RECEIVING TEMPERATURES** (E.G., CERTAIN SPECIES OF MARINE FINFISH DUE TO CONCERNS WITH SCOMBROTOXIN)
- **DATE MARKING** OF READY-TO-EAT PHF (TCS FOOD) HELD FOR MORE THAN 24 HOURS TO CONTROL THE GROWTH OF PSYCHROPHILES SUCH AS LISTERIA MONOCYTOGENES
- **FREEZING** CERTAIN SPECIES OF FISH INTENDED FOR RAW CONSUMPTION DUE TO PARASITE CONCERNS
- **COOLING** FROM AMBIENT TEMPERATURE TO PREVENT THE OUTGROWTH OF SPORE-FORMING OR TOXIN-FORMING BACTERIA.

H. FOOD PREPARATION PROCESS 2 - PREPARATION FOR SAME DAY SERVICE

EXAMPLE FLOW: RECEIVE → STORE → PREPARE → COOK → HOLD → SERVE

IN THIS FOOD PREPARATION PROCESS, FOOD PASSES THROUGH THE DANGER ZONE ONLY ONCE IN THE RETAIL OR FOOD SERVICE FACILITY BEFORE IT IS SERVED OR SOLD TO THE CONSUMER. FOOD IS USUALLY COOKED AND HELD HOT UNTIL SERVED, E.G., FRIED CHICKEN, BUT CAN ALSO BE COOKED AND SERVED IMMEDIATELY. IN ADDITION TO THE FACILITY-WIDE CONSIDERATIONS, A FOOD SAFETY MANAGEMENT SYSTEM INVOLVING THIS FOOD PREPARATION PROCESS SHOULD FOCUS ON ENSURING ACTIVE MANAGERIAL CONTROL OVER THE FOLLOWING:

- **COOKING** TO DESTROY BACTERIA AND PARASITES
- **HOT HOLDING OR USING TIME ALONE** TO PREVENT THE OUTGROWTH OF SPORE-FORMING BACTERIA.

APPROVED FOOD SOURCE, PROPER RECEIVING TEMPERATURES, AND PROPER COLD HOLDING BEFORE COOKING WOULD ALSO BE IMPORTANT IF DEALING WITH CERTAIN MARINE FINFISH DUE TO CONCERNS WITH CIGUATERA TOXIN AND SCOMBROTOXIN.

I. FOOD PREPARATION PROCESS 3 – COMPLEX FOOD PREPARATION

EXAMPLE FLOW: RECEIVE → STORE → PREPARE → COOK → COOL → REHEAT
HOT HOLD → SERVE

FOODS PREPARED IN LARGE VOLUMES OR IN ADVANCE FOR NEXT DAY SERVICE USUALLY FOLLOW AN EXTENDED PROCESS FLOW. THESE FOODS PASS THROUGH THE TEMPERATURE DANGER ZONE MORE THAN ONE TIME; THUS, THE POTENTIAL FOR THE GROWTH OF SPORE-FORMING OR TOXIGENIC BACTERIA IS GREATER IN THIS PROCESS. FAILURE TO

ADEQUATELY CONTROL FOOD PRODUCT TEMPERATURES IS ONE OF THE MOST FREQUENTLY ENCOUNTERED RISK FACTORS CONTRIBUTING TO FOODBORNE ILLNESS. FOOD HANDLERS SHOULD MINIMIZE THE TIME FOODS ARE AT UNSAFE TEMPERATURES.

IN ADDITION TO THE FACILITY-WIDE CONSIDERATIONS, A FOOD SAFETY MANAGEMENT SYSTEM INVOLVING THIS FOOD PREPARATION PROCESS SHOULD FOCUS ON ENSURING ACTIVE MANAGERIAL CONTROL OVER THE FOLLOWING:

- **COOKING** TO DESTROY BACTERIA AND PARASITES
- **COOLING** TO PREVENT THE OUTGROWTH OF SPORE-FORMING OR TOXIN-FORMING BACTERIA
- **HOT AND COLD HOLDING OR USING TIME ALONE** TO CONTROL BACTERIAL GROWTH AND TOXIN FORMATION
- **DATE MARKING** OF READY-TO-EAT PHF (TCS FOOD) HELD FOR MORE THAN 24 HOURS TO CONTROL THE GROWTH OF PSYCHROPHILES SUCH AS LISTERIA MONOCYTOGENES
- **REHEATING** FOR HOT HOLDING, IF APPLICABLE.

APPROVED FOOD SOURCE, PROPER RECEIVING TEMPERATURES, AND PROPER COLD HOLDING BEFORE COOKING WOULD ALSO BE IMPORTANT IF DEALING WITH CERTAIN MARINE FINFISH DUE TO CONCERNS WITH CIGUATERA TOXIN AND SCOMBROTOXIN.

4. FDA RETAIL HACCP MANUALS

A. WHAT GUIDANCE HAS BEEN DEVELOPED BY FDA TO ASSIST OPERATORS OF RETAIL AND FOOD SERVICE ESTABLISHMENTS IN ACHIEVING ACTIVE MANAGERIAL CONTROL OF FOODBORNE ILLNESS RISK FACTORS?

FDA, IN PARTNERSHIP WITH FEDERAL, STATE, AND LOCAL REGULATORS, INDUSTRY, ACADEMIA, AND CONSUMERS, HAS WRITTEN A GUIDANCE DOCUMENT ENTITLED, "MANAGING FOOD SAFETY: A MANUAL FOR THE VOLUNTARY USE OF HACCP PRINCIPLES FOR OPERATORS OF FOOD SERVICE AND RETAIL ." COMMONLY REFERRED TO AS THE "OPERATOR'S MANUAL," THIS DOCUMENT IS DESIGNED TO ASSIST OPERATORS WITH DEVELOPING OR ENHANCING FOOD SAFETY MANAGEMENT SYSTEMS BASED ON THE PROCESS APPROACH TO HACCP. THE MANUAL PRESENTS A STEP-BY-STEP PROCEDURE FOR WRITING AND VOLUNTARILY IMPLEMENTING A FOOD SAFETY MANAGEMENT SYSTEM BASED ON THE PRINCIPLES OF HACCP. THE DESIRED OUTCOME IS AN OPERATOR WHO EMPLOYS A PREVENTIVE RATHER THAN A REACTIVE STRATEGY TO FOOD SAFETY.

THE OPERATOR'S MANUAL EMBODIES FDA'S CURRENT THINKING ON THE APPLICATION OF HACCP PRINCIPLES AT RETAIL. IT ADVOCATES THE VOLUNTARY USE OF HACCP PRINCIPLES USING THE PROCESS APPROACH AS A PRACTICAL AND EFFECTIVE MEANS OF REDUCING THE OCCURRENCE OF FOODBORNE ILLNESS RISK FACTORS LEADING TO OUT-OF-CONTROL HAZARDS. THE OPERATOR'S MANUAL IS STRICTLY FOR THE VOLUNTARY IMPLEMENTATION OF HACCP PRINCIPLES AT RETAIL AND SHOULD NOT BE USED TO DEVELOP HACCP PLANS THAT ARE REQUIRED THROUGH FEDERAL, STATE, OR LOCAL REGULATIONS, ORDINANCES, OR LAWS.

B. WHAT GUIDANCE HAS BEEN DEVELOPED BY FDA TO ASSIST REGULATORS OF RETAIL AND FOOD SERVICE ESTABLISHMENTS IN ASSESSING INDUSTRY'S ACTIVE MANAGERIAL CONTROL OF FOODBORNE ILLNESS RISK FACTORS?

FDA HAS WRITTEN A DOCUMENT FOR REGULATORS OF RETAIL AND FOOD SERVICE ESTABLISHMENTS ENTITLED, "MANAGING FOOD SAFETY: A REGULATOR'S MANUAL FOR APPLYING HACCP PRINCIPLES TO RISK-BASED RETAIL AND FOOD SERVICE INSPECTIONS AND EVALUATING VOLUNTARY FOOD SAFETY MANAGEMENT ." COMMONLY REFERRED TO AS THE "REGULATOR'S MANUAL," THIS DOCUMENT WAS WRITTEN TO PROVIDE A RISK-BASED INSPECTIONAL "ROADMAP" FOR EVALUATING THE DEGREE OF ACTIVE MANAGERIAL CONTROL AN OPERATOR HAS OVER FOODBORNE ILLNESS RISK FACTORS.

IN ADDITION, THE MANUAL ADVOCATES THE USE OF VOLUNTARY INTERVENTION STRATEGIES, INCLUDING THE DEVELOPMENT OF FOOD SAFETY MANAGEMENT SYSTEMS OR RISK CONTROL PLANS TO BRING ABOUT A LONG-TERM BEHAVIOR CHANGE THAT WILL RESULT IN A REDUCTION IN THE OCCURRENCE OF RISK FACTORS. IN CASES WHERE AN OPERATOR MAY WANT THEIR INSPECTOR TO PROVIDE THEM WITH FEEDBACK ON THEIR VOLUNTARILY-IMPLEMENTED FOOD SAFETY MANAGEMENT SYSTEM, THE MANUAL PROVIDES REGULATORS WITH INFORMATION ON HOW TO VALIDATE AND VERIFY AN EXISTING SYSTEM.

ANNEX 5 OF THE FOOD CODE OUTLINES THE BASIS FOR CONDUCTING SUCCESSFUL RISK-BASED INSPECTIONS AND IS PROVIDED TO ASSIST INDUSTRY IN ACHIEVING ACTIVE MANAGERIAL CONTROL OF FOODBORNE ILLNESS RISK FACTORS AS OUTLINED IN THE DRAFT RECOMMENDED NATIONAL RETAIL FOOD REGULATORY PROGRAM STANDARDS AND THE REGULATOR'S MANUAL.

5. ADVANTAGES OF THE HACCP PRINCIPLES

A. WHAT ADVANTAGES DOES USING HACCP PRINCIPLES OFFER OPERATORS OF RETAIL AND FOOD SERVICE ESTABLISHMENTS?

RATHER THAN RELYING SOLELY ON PERIODIC FEEDBACK FROM INSPECTIONS BY REGULATORY AGENCIES, AN ESTABLISHMENT OPERATOR WHO IMPLEMENTS A FOOD SAFETY MANAGEMENT SYSTEM BASED ON HACCP PRINCIPLES EMPHASIZES CONTINUOUS PROBLEM SOLVING AND PREVENTION. ADDITIONALLY, HACCP ENHANCES AND ENCOURAGES COMMUNICATION BETWEEN INDUSTRY AND REGULATORS.

A FOOD SAFETY MANAGEMENT SYSTEM BASED ON HACCP PRINCIPLES OFFERS MANY OTHER ADVANTAGES TO INDUSTRY. ONE ADVANTAGE IS THAT SUCH A SYSTEM MAY PROVIDE A METHOD FOR ACHIEVING ACTIVE MANAGERIAL CONTROL OF MULTIPLE RISK FACTORS ASSOCIATED WITH AN ENTIRE OPERATION. OTHER ADVANTAGES INCLUDE:

- REDUCTION IN PRODUCT LOSS
- INCREASE IN PRODUCT QUALITY
- BETTER INVENTORY CONTROL
- CONSISTENCY IN PRODUCT PREPARATION
- INCREASE IN PROFIT

- INCREASED EMPLOYEE AWARENESS AND PARTICIPATION IN FOOD SAFETY.

B. WHAT ADVANTAGES DOES USING HACCP PRINCIPLES OFFER REGULATORS OF RETAIL AND FOOD SERVICE ESTABLISHMENTS?

TRADITIONAL INSPECTIONS ARE RELATIVELY RESOURCE-INTENSIVE, INEFFICIENT, AND REACTIVE RATHER THAN PREVENTIVE IN NATURE. USING TRADITIONAL INSPECTION TECHNIQUES ALLOWS FOR A SATISFACTORY "SNAPSHOT" ASSESSMENT OF THE REQUIREMENTS OF THE CODE AT THE TIME OF THE INSPECTION. UNFORTUNATELY, UNLESS AN INSPECTOR ASKS QUESTIONS AND INQUIRES ABOUT THE ACTIVITIES AND PROCEDURES BEING UTILIZED BY THE ESTABLISHMENT EVEN AT TIMES WHEN THE INSPECTOR IS NOT THERE, THERE IS NO WAY TO KNOW IF AN OPERATOR IS ACHIEVING ACTIVE

WITH THE LIMITED TIME OFTEN AVAILABLE FOR CONDUCTING INSPECTIONS, REGULATORS MUST FOCUS THEIR ATTENTION ON THOSE AREAS THAT CLEARLY HAVE THE GREATEST IMPACT ON FOOD SAFETY – FOODBORNE ILLNESS RISK FACTORS. BY KNOWING THAT THERE ARE ONLY A FEW CONTROL MEASURES THAT ARE ESSENTIAL TO FOOD SAFETY AND FOCUSING ON THESE DURING THE INSPECTION, AN INSPECTOR CAN ASSESS THE OPERATOR'S ACTIVE MANAGERIAL CONTROL OF THE FOODBORNE ILLNESS RISK FACTORS.

REGULATORS CAN PROVIDE INVALUABLE FEEDBACK TO AN OPERATOR THROUGH THEIR ROUTINE INSPECTIONS. THIS IS ESPECIALLY USEFUL WHEN UTILIZING A RISK-BASED APPROACH. BY INCORPORATING HACCP PRINCIPLES INTO ROUTINE INSPECTIONS, AN INSPECTOR CAN PROVIDE AN OPERATOR WITH THE CONSTRUCTIVE INPUT NEEDED TO ESTABLISH THE CONTROL SYSTEM NECESSARY TO BRING THE FOODBORNE ILLNESS RISK FACTORS BACK UNDER CONTINUOUS CONTROL.

6. SUMMARY

IN ORDER TO MAKE A POSITIVE IMPACT ON FOODBORNE ILLNESS, RETAIL AND FOOD SERVICE OPERATORS MUST ACHIEVE ACTIVE MANAGERIAL CONTROL OF THE RISK FACTORS CONTRIBUTING TO FOODBORNE ILLNESS. COMBINED WITH BASIC SANITATION, EMPLOYEE TRAINING, AND OTHER PREREQUISITE PROGRAMS, THE PRINCIPLES OF HACCP PROVIDE AN EFFECTIVE SYSTEM FOR ACHIEVING THIS OBJECTIVE.

THE GOAL IN APPLYING HACCP PRINCIPLES IN RETAIL AND FOOD SERVICE IS TO HAVE THE OPERATOR TAKE PURPOSEFUL ACTIONS TO ENSURE SAFE FOOD. THE PROCESS APPROACH SIMPLIFIES HACCP PRINCIPLES FOR USE IN RETAIL AND FOOD SERVICE. THIS PRACTICAL AND EFFECTIVE METHOD OF HAZARD CONTROL EMBODIES THE CONCEPT OF ACTIVE MANAGERIAL CONTROL BY PROVIDING AN ON-GOING SYSTEM OF SIMPLE CONTROL MEASURES THAT WILL REDUCE THE OCCURRENCE OF RISK FACTORS THAT LEAD TO OUT-OF-CONTROL HAZARDS.

THE ROLE OF RETAIL AND FOOD SERVICE REGULATORY PROFESSIONALS IS TO CONDUCT RISK-BASED INSPECTIONS USING HACCP PRINCIPLES TO ASSESS THE DEGREE OF CONTROL INDUSTRY HAS OVER THE FOODBORNE ILLNESS RISK FACTORS. REGULATORS CAN ASSIST INDUSTRY IN ACHIEVING ACTIVE MANAGERIAL CONTROL OF RISK FACTORS BY USING A RISK-BASED INSPECTION APPROACH TO IDENTIFY STRENGTHS AND WEAKNESSES AND SUGGESTING POSSIBLE SOLUTIONS AND IMPROVEMENTS.

7. ACKNOWLEDGEMENTS

MUCH OF THIS APPENDIX IS ADAPTED FROM THE NATIONAL ADVISORY COMMITTEE ON MICROBIOLOGICAL CRITERIA FOR FOODS, HAZARD ANALYSIS AND CRITICAL CONTROL POINT PRINCIPLES AND GUIDELINES, ADOPTED AUGUST 14, 1997.

THE PHYSICAL HAZARDS TABLE (TABLE 3) WAS PROVIDED COURTESY OF "OVERVIEW OF BIOLOGICAL, CHEMICAL, AND PHYSICAL HAZARDS" IN "HACCP PRINCIPLES AND APPLICATIONS," MERLE PIERSON AND DONALD A. CORLETT, JR. (EDS.), 1992. P. 8-28. CHAPMAN AND HALL, NEW YORK.

BASED ON A RECOMMENDATION FROM THE RETAIL HACCP COMMITTEE OF THE CONFERENCE FOR FOOD PROTECTION, THE TWO HACCP MANUALS HAVE BEEN ENDORSED BY THE CONFERENCE.

8. RESOURCES AND REFERENCES

A. ARTICLES

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703-487-4650.

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U.S. FOOD AND DRUG ADMINISTRATION
OFFICE OF SEAFOOD
5100 PAINT BRANCH PARKWAY
COLLEGE PARK , MD 20740-3835

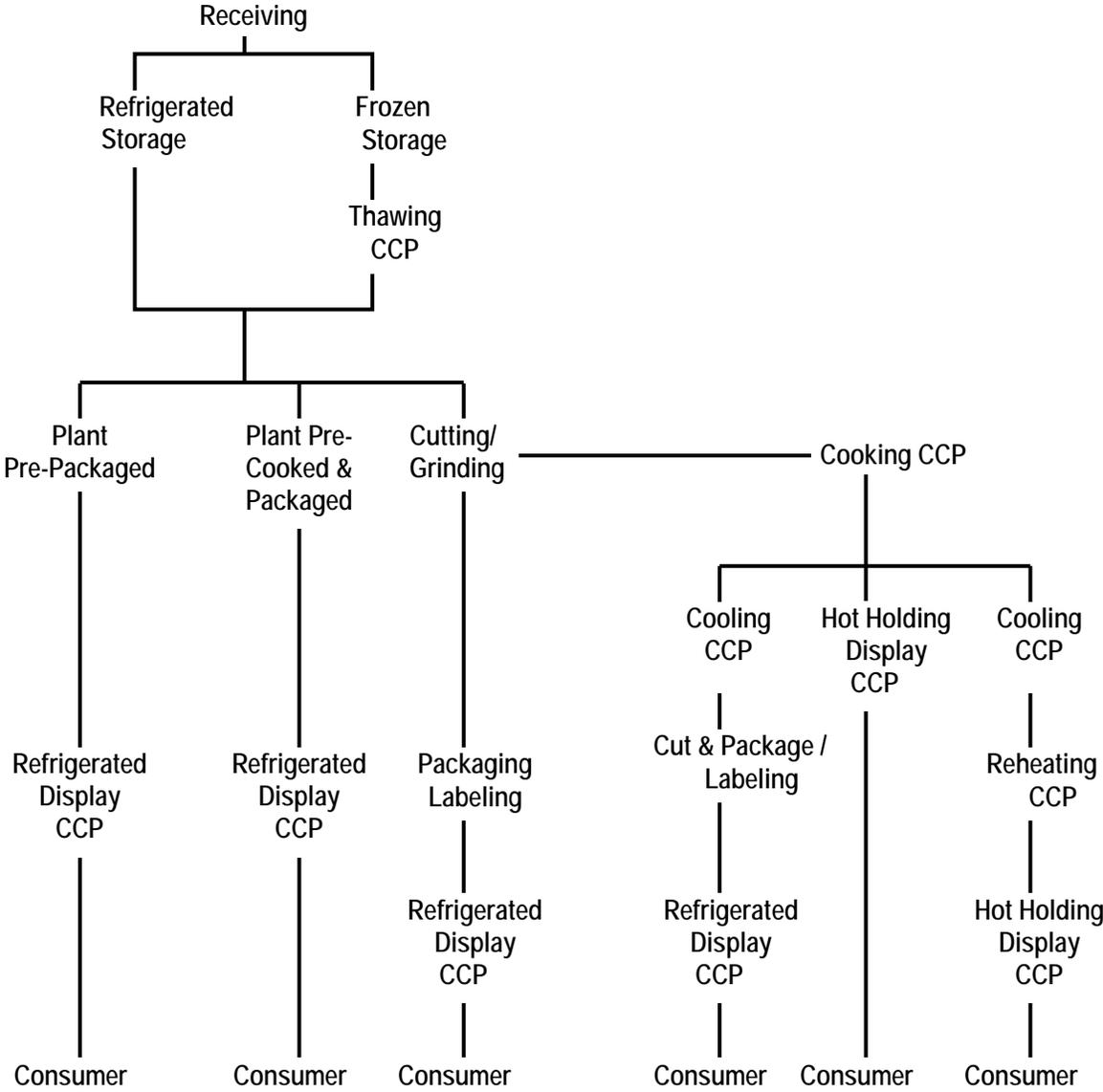
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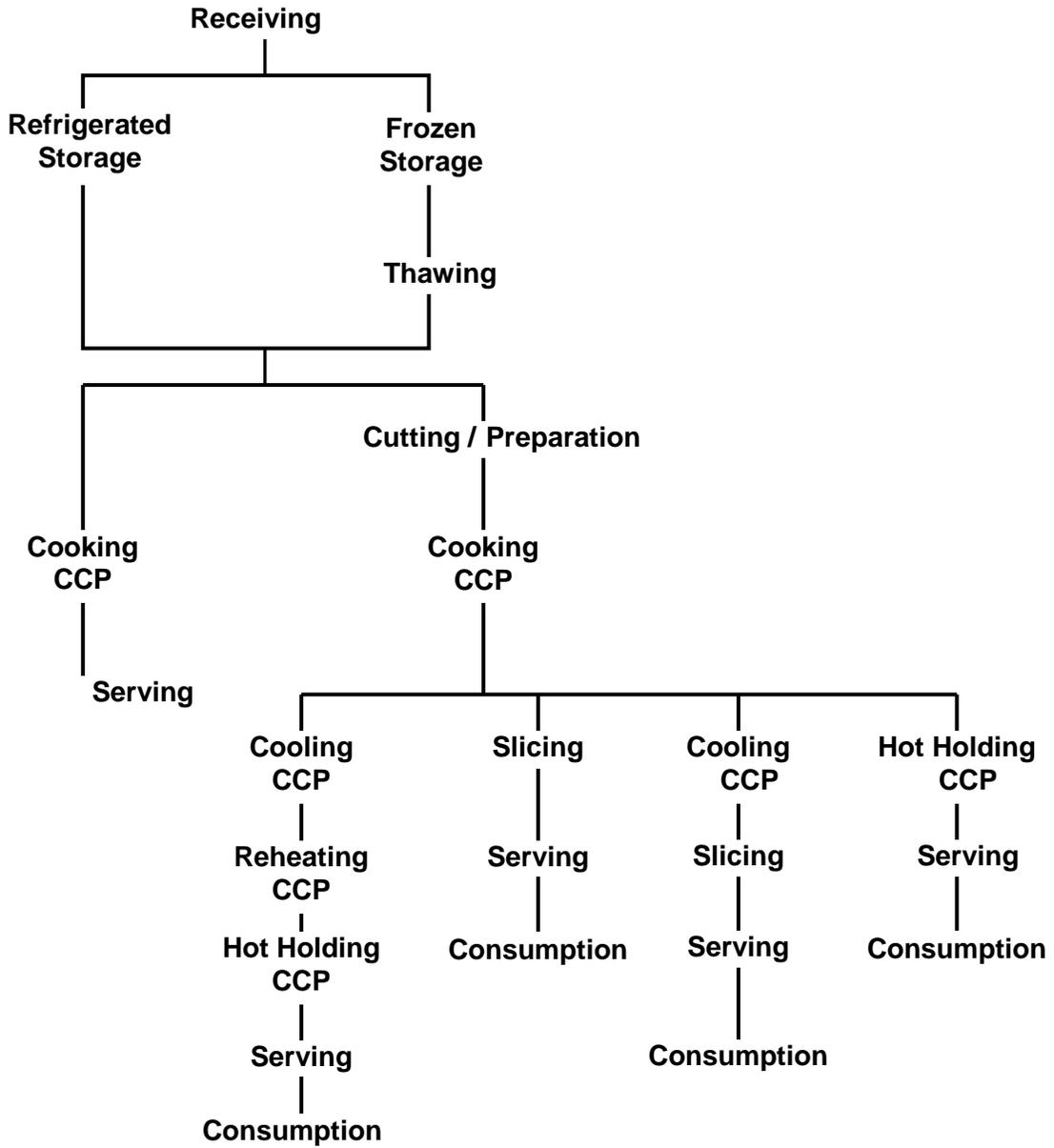
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Two Typical Flow Diagrams

Flow Chart 1



Flow Chart 2



APPENDIX H – HACCP Guidelines

- 1) — **Introduction**
- 2) — **HACCP Principles**
- 3) — **Summary**
- 4) — **Acknowledgments**
- 5) — **Bibliography**
- 6) — **Other Sources of HACCP Information**

1) — **Introduction**

The acronym HACCP stands for Hazard Analysis and Critical Control Point, which is a prevention-based food safety system. HACCP systems are designed to prevent the occurrence of potential food safety problems. This is achieved by assessing the inherent risks attributable to a product of a process and then determining the necessary steps that will control the identified risks.

Essentially, HACCP is a system that identifies and monitors specific foodborne hazards—biological, chemical, or physical properties—that can adversely affect the safety of the food product. This hazard analysis serves as the basis for establishing critical control points (CCPs). CCPs identify those points in the process that must be controlled to assure the safety of the food. Further, critical limits are established that document the appropriate parameters that must be met at each CCP. Monitoring and verification steps are included in the system, again, to assure that potential risks are controlled. The hazard analysis, critical control points, critical limits, and monitoring and verification steps are documented in a HACCP plan. Seven principles have been developed which provide guidance on the development of an effective HACCP plan.

HACCP represents an important food protection tool. HACCP is not something limited to food franchises or chains. The concept can be applied by small independents as well as national or regional companies and can be integrated into the recipes and standard operating procedures of any size establishment. Employee training is key to successful implementation. Employees must learn which control points are critical in an operation and what the critical limits are at these points, for each preparation step they perform.

Establishment management must also follow through by routinely monitoring the food operation to verify that employees are keeping the process under control by complying with the critical limits.

As is the case with industry, mastering and applying regulatory aspects of HACCP is not limited to large state programs. Local jurisdictions can effectively promote HACCP and apply the concept during inspections. The implementation of HACCP continues to evolve and to be further refined as new products and procedures are developed and as hazards and their control measures are more clearly defined. To meet the challenges presented by advances in food research, product development, and their impact at retail, regulatory personnel must keep themselves informed. Food protection publications issued by the food industry, professional organizations, and other groups and continuing education programs can be particularly helpful in

providing an understanding of food operations and how the application of HACCP can bring a focus to food safety that traditional inspection methods have lacked.

A) — Definitions

Many terms are used in discussion of HACCP that must be clearly understood to effectively develop and implement a plan. The following definitions are provided for clarity:

- 1) — **Acceptable level** means the presence of a hazard which does not pose the likelihood of causing an unacceptable health risk.
- 2) — **Control point** means any point in a specific food system at which loss of control does not lead to an unacceptable health risk.
- 3) — **Critical control point**, as defined in the Food Code, means a point at which loss of control may result in an unacceptable health risk.
- 4) — **Critical limit**, as defined in the Food Code, means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to minimize the risk that the identified food safety hazard may occur.
- 5) — **Deviation** means failure to meet a required critical limit for a critical control point.
- 6) — **HACCP plan**, as defined in the Food Code, means a written document that delineates the formal procedures for following the HACCP principles developed by The National Advisory Committee on Microbiological Criteria for Foods.
- 7) — **Hazard**, as defined in the Food Code, means a biological, chemical, or physical property that may cause an unacceptable consumer health risk.
- 8) — **Monitoring** means a planned sequence of observations or measurements of critical limits designed to produce an accurate record and intended to ensure that the critical limit maintains product safety. Continuous monitoring means an uninterrupted record of data.
- 9) — **Preventive measure** means an action to exclude, destroy, eliminate, or reduce a hazard and prevent recontamination through effective means.
- 10) — **Risk** means an estimate of the likely occurrence of a hazard.
- 11) — **Sensitive ingredient** means any ingredient historically associated with a known microbiological hazard that causes or contributes to production of a potentially hazardous food as defined in the Food Code.
- 12) — **Verification** means methods, procedures, and tests used to determine if the HACCP system in use is in compliance with the HACCP plan.

B) — History

The application of HACCP to food production was pioneered by the Pillsbury Company with the cooperation and participation of the National Aeronautic and Space Administration (NASA), Natick Laboratories of the U.S. Army, and the U.S. Air Force Space Laboratory Project Group. Application of the system in the early 1960s created food for the United State's space program that approached 100% assurance against contamination by bacterial and viral pathogen, toxins, and chemical or physical hazards that could cause illness or injury to astronauts. HACCP

replaced end product testing to provide food safety assurance and provided a preventive system for producing safe food that had universal application.

In the succeeding years, the HACCP system has been recognized worldwide as an effective system of controls. The system has undergone considerable analysis, refinement, and testing and is widely accepted in the United States and internationally.

C) — Advantages of HACCP

FDA is recommending the implementation of HACCP in food establishments because it is a system of preventive controls that is the most effective and efficient way to assure that food products are safe. A HACCP system will emphasize the industry's role in continuous problem solving and prevention rather than relying solely on periodic facility inspections by regulatory agencies.

HACCP offers two additional benefits over conventional inspection techniques. First, it clearly identifies the food establishment as the final party responsible for assuring the safety of the food it produces. HACCP requires the food establishment to analyze its preparation methods in a rational, scientific manner in order to identify critical control points and to establish critical limits and monitoring procedures. A vital aspect of the establishment's responsibility is to establish and maintain records that document adherence to the critical limits that relate to the identified critical control points, thus resulting in continuous self-inspection. Secondly, a HACCP system allows the regulatory agency to more comprehensively determine an establishment's level of compliance. A food establishment's use of HACCP requires development of a plan to prepare safe food. This plan must be shared with the regulatory agency because it must have access to CCP monitoring records and other data necessary to verify that the HACCP plan is working. Using conventional inspection techniques, an agency can only determine conditions during the time of inspection which provide a "snapshot" of conditions at the moment of the inspection. However, by adopting a HACCP approach, both current and past conditions can be determined. When regulatory agencies review HACCP records, they have, in effect, a look back through time. Therefore, the regulatory agency can better assure that processes are under control.

Traditional inspection is relatively resource intensive and inefficient and is reactive rather than preventive compared to the HACCP approach for assuring food safety. Regulatory agencies are challenged to find new approaches to food safety that enable them to become more focused and efficient and to minimize costs wherever possible. Thus, the advantages of HACCP based inspections are becoming increasingly acknowledged by the regulatory community.

Examples of the successful implementation of HACCP by food establishments may be found throughout the food industry. During the past several years, FDA and a number of state and local jurisdictions have worked with two national voluntary pilot projects for retail food stores and restaurants. These projects involved more than 20 food establishments and demonstrated that HACCP concepts have matured to the point at which they can be formally implemented for all food products on an industry wide basis.

2. — HACCP Principles

A) — Background

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF), which developed HACCP principles, was established in 1988 and has as members, officials from several federal agencies which include the Food and Drug Administration, the Centers for Disease Control and Prevention, the Food Safety Inspection Service, the Agricultural Research Service,

~~the National Marine Fisheries Service, and the U.S. Army. The NACMCF also has national experts from academia, state government, consumer groups, and the food industry.~~

~~B) — Principles~~

~~The NACMCF has developed seven widely accepted HACCP principles that explain this process in great detail. To prepare an effective HACCP plan these principles must be followed. Further, a comprehensive review of a HACCP plan must include consideration of these principles. These HACCP principles are discussed below.~~

~~1) — Principle #1: Hazard Analysis~~

~~a) — Purposes~~

~~The hazard analysis process accomplishes three purposes:~~

- ~~i) — Hazards of significance are identified;~~
- ~~ii) — The hazard analysis provides a risk basis for selecting likely hazards;~~
- ~~iii) — Identified hazards can be used to develop preventive measures for a process or product to assure or improve food safety.~~

~~Before beginning to develop a HACCP plan, a team should be assembled that is familiar with the overall food operation and the specific production processes to be included in the plan. The team's goal and each member's responsibilities in reaching the goal must be clearly defined.~~

~~The first step in the development of a HACCP plan for a food operation is identification of hazards associated with the product. A hazard may be a biological, chemical, or physical property that can cause a food to be unsafe.~~

~~Hazard analysis should include risk assessment of both the likelihood that these hazards will occur and their severity if they do occur. Hazard analysis also involves establishment of preventive measures for control. Hazards that involved low risk and that are not likely to occur need not be considered for the purposes of HACCP.~~

~~To be effectively addressed, hazards must be such that their prevention, elimination, or reduction to acceptable levels is attained.~~

~~Numerous issues have to be considered during hazard analysis. These relate to factors such as ingredients, processing, distribution, and the intended use of the product. These issues include whether a food contains sensitive ingredients that can create microbiological, chemical, or physical hazards; or whether sanitation practices that are used can introduce these hazards to the food that is being prepared or processed. An example is whether the finished food will be heated by the consumer, if it is consumed off the premises. Even factors beyond the immediate control of the food establishment, such as how the food will be treated if taken out by the consumer and how it will be consumed, must be considered because these factors could influence how food should be prepared or processed in the establishment.~~

~~b) — Flow Diagram~~

Consequently, a flow diagram that delineates the steps in the process from receipt to sale or service forms the foundation for applying the seven principles. The significant hazards associated with each step in the flow diagram should be listed along with preventive measures proposed to control the hazards. This tabulation will be used under Principle 2 to determine the CCPs. The flow diagram should be constructed by a HACCP team that has knowledge and expertise on the product, process, and the likely hazards. Each step in a process should be identified and observed to accurately construct the flow diagram. Some examples of flow diagrams are found at the end of this Appendix.

e) ——— Biological Hazards

Foodborne biological hazards include bacterial, viral, and parasitic organisms. These organisms are commonly associated with humans and with raw products entering the food establishment.

Many of these pathogens occur naturally in the environment where foods are grown. Most are killed or inactivated by adequate cooking and numbers are kept to a minimum by adequate cooling during distribution and storage.

Bacterial pathogens comprise the majority of reported foodborne disease outbreaks and cases. A certain level of the pathogens can be expected with some raw foods. Temperature abuse, such as improper hot or cold holding temperatures, can significantly magnify this number. Cooked food which has been subject to cross contamination with pathogens often provides a fertile medium for their rapid and progressive growth.

Enteric viruses can be foodborne, waterborne, or transmitted from a person or from animals. Unlike bacteria, a virus cannot multiply outside of a living cell. Hepatitis A and Noroviruses are examples of viral hazards associated with ready to eat foods.

Parasites are most often animal host specific and can include humans in their life cycles. Parasitic infections are commonly associated with undercooking meat products or cross contamination of ready to eat food. Fishborne parasites in products that are intended to be eaten raw, marinated, or partially cooked can be killed by effective freezing techniques.

The following table provides an assessment of severity of the biological hazards which may be associated with food being prepared, served, or sold in food establishments.

Table 1.—Hazardous Microorganisms and Parasites Grouped on the Basis of Risk

Severe Hazards

Clostridium botulinum types A, B, E, and F
Shigella dysenteriae
Salmonella typhi; *paratyphi* A, B
Hepatitis A and *E*
Brucella abortis; *B. suis*
Vibrio cholerae 01
Vibrio vulnificus
Taenia solium
Trichinella spiralis

Moderate Hazards: Potentially Extensive

Listeria monocytogenes
Salmonella spp.
Enterovirulent Escherichia coli (EEC)
Streptococcus pyogenes
Rotavirus
Norovirus group
Entamoeba histolytica
Diphyllobothrium latum
Ascaris lumbricoides
Cryptosporidium parvum

Moderate Hazards: Limited Spread

Bacillus cereus
Campylobacter jejuni
Clostridium perfringens
Staphylococcus aureus
Vibrio cholerae, non-01
Vibrio parahaemolyticus
Yersinia enterocolitica
Giardia lamblia
Taenia saginata

—from International Commission on Microbiological Specifications for Food (ICMSF) (1986).
Used with permission, “HACCP Principles and Applications,” Pierson and Corlett, Eds. 1992.
Chapman & Hall, New York, NY.

—classified as moderate hazards, complications and sequelae may be severe in certain
susceptible populations.

d) — Chemical Hazards

Chemical hazards in foods should be considered during a hazard analysis. Chemical contaminants may be naturally occurring or may be added during the processing of food. Harmful chemicals at very high levels have been associated with acute cases of foodborne illnesses and can be responsible for chronic illness at lower levels.

The following table provides some examples of chemical hazards found within the naturally occurring and added chemical categories. The Code of Federal Regulations, Title 21, provides guidance on naturally occurring toxic substances and allowable limits for many of the chemicals added during processing (food additives). The FDA Compliance Policy Guidelines also provide information on other naturally occurring chemicals.

Table 2. Types of Chemical Hazards and

Naturally Occurring Chemicals

- Mycotoxins (e.g., aflatoxin) from mold
- Seombrotoxin (histamine) from protein decomposition
- Ciguatoxin from marine dinoflagellates
- Toxic mushroom species
- Shellfish toxins (from marine dinoflagellates)
 - Paralytic shellfish poisoning (P.P.)
 - Diarrhetic shellfish poisoning (DSP)
 - Neurotoxic shellfish poisoning (NSP)
 - Amnesic shellfish poisoning (ASP)
- Plant toxins
 - Pyrrolizidine alkaloids
 - Phytohemagglutinin

Added Chemicals

- Agricultural chemicals: Pesticides, fungicides, fertilizers, insecticides, antibiotics and growth hormones
- Polychlorinated biphenyls (PCBs)
- Industrial chemicals
 - Prohibited substances (21 CFR §189)
 - Direct
 - Indirect
 - Toxic elements and compounds: Lead, zinc, arsenic, mercury, and cyanide
- Food additives:
 - Direct: allowable limits under GMPs
 - Preservatives (nitrite and sulfiting agents)
 - Flavor enhancers (monosodium glutamate)
 - Nutritional additives (niacin)
 - Color additives
 - Secondary direct and indirect
 - Chemicals used in establishments (e.g., lubricants, cleaners, sanitizers, cleaning compounds, coatings, and paints)

Poisonous or toxic chemicals intentionally added (sabotage)

with permission, "HACCP Principles and Applications," Pierson and Corlett, Eds. 1992. Chapman & Hall, New York, NY and adapted.

e) Physical Hazards

Illness and injury can result from hard foreign objects in food. These physical hazards can result from contamination and/or poor procedures at many points in the food chain from harvest to consumer, including those within the food establishment.

As establishments develop their HACCP programs, the following table can be used to further identify sources of potential physical risks to the food being prepared, served, or sold.

Table 3. Main Materials of Concern as Physical Hazards and Common ^{3b}

Material	Injury Potential	Sources
Glass fixtures	Cuts, bleeding; may require surgery to find or remove	Bottles, jars, light, utensils, gauge covers
Wood	Cuts, infection, choking; may require surgery to remove	Fields, pallets, boxes, buildings
Stones, metal fragments	Choking, broken teeth Cuts, infection; may require surgery to remove	Fields, buildings, machinery, wire, employees
Insulation	Choking; long term if asbestos	Building materials
Bone	Choking, trauma	Fields, improper plant processing
Plastic	Choking, cuts, infection; may require surgery to remove	Fields, plant packaging materials, pallets, employees
Personal effects	Choking, cuts, broken teeth; may require surgery to remove	Employees

from Corlett (1991).

with permission, "HACCP Principles and Applications," Pierson and Corlett, Eds. 1992. Chapman & Hall, New York, NY.

f) ——— Determining Level of Risk

The potential significance or risk of each hazard should be assessed by considering its likelihood of occurrence and severity. The estimate of risk for a hazard occurring is based upon a combination of experience, epidemiological data, and information in the technical literature. Severity is the degree of seriousness of the consequences of a hazard if it were to become an actuality.

Hazard identification in conjunction with risk estimation provides a rational basis for determining which hazards are significant and must be addressed in the HACCP plan. To determine risk during the hazard analysis, safety concerns must be differentiated from quality concerns. A food safety hazard is a biological, chemical, or physical property that may cause a food to be unsafe. There may be differences of opinion, even among experts, as to the risk of a hazard. The food establishment must rely upon the expert opinion published in peer reviewed literature or experts who actively assist in the development of the HACCP plan. The hazards must at least include those that are commonly associated with a specific product. If a hazard that is commonly associated is dismissed from the plan, the basis for rejecting it must be clearly stated in the hazard analysis so that it is understood and agreed to by the regulatory authority reviewing the HACCP plan.

g) ——— Hazard Analysis Process

This point in hazard analysis consists of asking a series of questions which are appropriate to each step in the flow diagram. The hazard analysis should question the effect of a variety of factors upon the safety of the food.

————— i) ——— Ingredients

- Does the food contain any sensitive ingredients that are likely to present microbiological hazards (e.g., Salmonella, Staphylococcus aureus), chemical hazards (e.g., aflatoxin, antibiotic, or pesticide residues) or physical hazards (stones, glass, bone, metal)?

ii) ——— Intrinsic Factors of Food

- Physical characteristics and composition (e.g., pH, type of acids, fermentable carbohydrate, water activity, preservatives) of the food during and after preparation can cause or prevent a hazard.
- Which intrinsic factors of the food must be controlled in order to assure food safety?
- Does the food permit survival or multiplication of pathogens and/or toxin formation in the food before or during preparation?
- Will the food permit survival or multiplication of pathogens and/or toxin formation during subsequent steps of preparation, storage, or consumer possession?
- Are there other similar products in the market place? What has been the safety record for these products?

iii) — Procedures Used for Preparation/ Processing

- Does the preparation procedure or process include a controllable step that destroys pathogens or their toxins? Consider both vegetative cells and spores.
- Is the product subject to recontamination between the preparation step (e.g., cooking) and packaging?

iv) — Microbial Content of the Food

- Is the food commercially sterile (i.e., low acid canned food)?
- Is it likely that the food will contain viable sporeforming or nonsporeforming pathogens?
- What is the normal microbial content of the food stored under proper conditions?
- Does the microbial population change during the time the food is stored before consumption?
- Does that change in microbial population alter the safety of the food?

v) — Facility Design

- Does the layout of the facility provide an adequate separation of raw materials from ready to eat foods?
- Is positive air pressure maintained in product packaging areas? Is this essential for product safety?
- Is the traffic pattern for people and moving equipment a potentially significant source of contamination?

vi) — Equipment Design

- Will the equipment provide the time/temperature control that is necessary for safe food?
- Is the equipment properly sized for the volume of food that will be prepared?
- Can the equipment be sufficiently controlled so that the variation in performance will be within the tolerance required to produce a safe food?
- Is the equipment reliable or is it prone to frequent breakdowns?
- Is the equipment designed so that it can be cleaned and sanitized?
- Is there a chance for product contamination with hazardous substances, e.g., glass?
- What product safety devices such as time/temperature integrators are used to enhance consumer safety?

vii) — Packaging

- Does the method of packaging affect the multiplication of microbial pathogens and/or the formation of toxins?
- Is the packaging material resistant to damage, thereby preventing the entrance of microbial contamination?
- Is the package clearly labeled “Keep Refrigerated” if this is required for safety?
- Does the package include instructions for the safe handling and preparation of the food by the consumer?
- Are tamper-evident packaging features used?
- Is each package legibly and accurately coded to indicate production lot?
- Does each package contain the proper label?

viii) — Sanitation

- Can the sanitation practices that are employed impact upon the safety of the food that is being prepared?
- Can the facility be cleaned and sanitized to permit the safe handling of food?
- Is it possible to provide sanitary conditions consistently and adequately to assure safe foods?

ix) — Employee health, hygiene, and education

- Can employee health or personal hygiene practices impact the safety of the food being prepared?
- Do the employees understand the food preparation process and the factors they must control to assure safe foods?
- Will the employees inform management of a problem which could impact food safety?

x) — Conditions of storage between packaging and the consumer

- What is the likelihood that the food will be improperly stored at the wrong temperature?
- Would storage at improper temperatures lead to a microbiologically unsafe food?

xi) — Intended use

- Will the food be heated by the consumer?
- Will there likely be leftovers?

xii) — Intended consumer

- Is the food intended for the general public, i.e., a population that does not have an increased risk of becoming ill.
- Is the food intended for consumption by a population with increased susceptibility to illness (e.g., infants, the elderly, the infirm, and immunocompromised individuals)?

h) — Developing Preventive Measures

The preventive measures procedure identifies the steps in the process at which hazards can be controlled.

After identifying the hazards the food establishment must then consider what preventive measures, if any, can be applied for each hazard. Preventive measures are physical, chemical, or other factors that can be used to control an identified health hazard. More than one preventive measure may be required to control a specific hazard and more than one hazard may be controlled by a specified preventive measure.

For example, if a HACCP team were to conduct a hazard analysis for the preparation of hamburgers from frozen beef patties, enteric pathogens on the incoming raw meat would be identified as a potential hazard. Cooking is a preventive measure which can be used to eliminate this hazard. Thus, cooking, the preventive measure, would be listed along with the hazard (i.e., enteric pathogens) as follows:

Step	Identified Hazard	Preventive Measures
Cooking	Enteric pathogens	Cooking sufficiently to kill enteric pathogens

2) — Principle #2: Identify the Critical Control Points (CCP) in Food Preparation

A CCP is a point, step, or procedure at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to acceptable levels. Points in food preparation that may be CCPs include cooking, chilling, specific sanitation procedures, product formulation control, prevention of cross contamination, and certain aspects of employee and environmental hygiene. For example, cooking that must occur at a specific temperature and for a specified time in order to destroy microbiological pathogens is a critical control point. Likewise, refrigeration or the adjustment of a food's pH to a level required to prevent hazardous microorganisms from multiplying or toxins from forming are also CCPs.

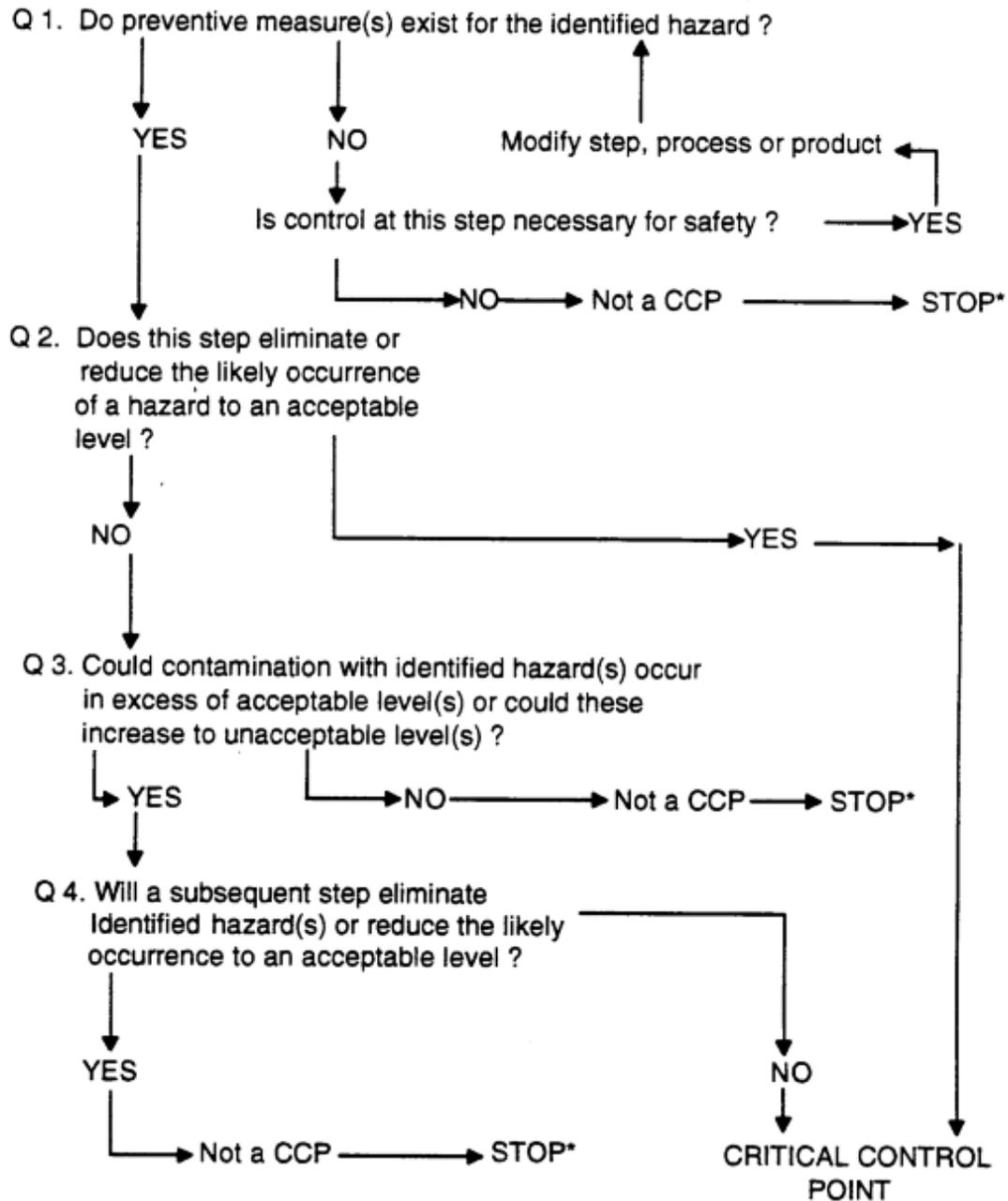
Many points in food preparation may be considered control points, but very few are actually critical control points. A control point is any point, step, or procedure at which biological, physical, or chemical factors can be controlled. Concerns that do not impact food safety may be addressed at control points; however, since these control points do not relate to food safety, they are not included in the HACCP plan.

Different facilities preparing the same food can differ in the risk of hazards and the points, steps, or procedures which are CCPs. This can be due to differences in each facility such as layout, equipment, selection of ingredients, or the process that is used. Generic HACCP plans can serve as useful guides; however, it is essential that the unique conditions within each facility be considered during the development of a HACCP plan.

CCPs must be carefully developed and documented. In addition, they must be used only for purposes of product safety. The following decision tree is helpful in verifying which of the food preparation steps should be designated as CCPs.

Critical Control Point Decision Tree

(Apply at each step in food preparation that has an identified hazard)



* PROCEED TO NEXT STEP IN THE DESCRIBED PROCESS

3) — Principle #3: Establish Critical Limits for Preventive Measures Associated with Each Identified Critical Control Point

This step involves establishing a criterion that must be met for each preventive measure associated with a CCP. Critical limits can be thought of as boundaries of safety for each CCP and may be set for preventive measures such as temperature, time, physical dimensions, pH, and available chlorine. Critical limits may be derived from sources such as regulatory standards and guidelines, scientific literature, experimental studies, and consultation with experts.

Criteria Most Frequently Used for Critical Limits

Time
Temperature
Humidity
pH
Titratable acidity
Preservatives
Salt concentration
Available chlorine
Viscosity

a) — Critical Limit

A critical limit is defined as a criterion that must be met for each preventive measure associated with a CCP. Each CCP will have one or more preventive measures that must be properly controlled to assure prevention, elimination, or reduction of hazards to acceptable levels. The food establishment is responsible for using competent authorities to validate that the critical limits chosen will control the identified hazard.

b) — Target Level

In some cases, variables involved in food preparation may require certain target levels to assure that critical limits are not exceeded. For example, a preventive measure and critical limit may be an internal product temperature of 71°C (160°F) during one stage of a process. The oven temperature, however, may be 71±3°C (160±5°F); thus an oven target temperature would have to be greater than 74°C (165°F) so that no product receives a cook of less than 71°C (160°F).

c) — Application Example

An example for Principle #3 is the cooking of beef patties. The process should be designed to eliminate the most heat resistant vegetative pathogen which could reasonably be expected to be in the product. Criteria may be required for factors such as temperature, time, and meat patty thickness. Technical development of the appropriate critical limits requires accurate information on the probable maximum numbers of these microorganisms in the meat and their heat resistance.

The relationship between the CCP and its critical limits for the meat patty example is shown below:

Process Step	CCP	Critical Limits
Cooking	YES	Minimum internal temperature of patty: 68°C/155°F Broiler temperature: _____ °C/ _____ °F Time; rate of heating/cooling (e.g., conveyer belt speed in): cm/min: _____ ft/min _____ Patty thickness: _____ cm/ _____ in Patty composition: e.g., % Fat, % Filler Oven humidity: _____ %RH

4) Principle #4: Establish Procedures to Monitor CCPs

a) Observations and Measurements

Monitoring is a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for use in future verification procedures. There are three main purposes for monitoring:

- i) It tracks the system's operation so that a trend toward a loss of control can be recognized and corrective action can be taken to bring the process back into control before a deviation occurs;
- ii) It indicates when loss of control and a deviation have actually occurred, and corrective action must be taken; and
- iii) It provides written documentation for use in verification of the HACCP plan.

Examples of Measurements for Monitoring

Visual observations
 Temperature
 Time
 pH

b) Continuous Monitoring

An unsafe food may result if a process is not properly controlled and a deviation occurs. Because of the potentially serious consequences of a critical defect, monitoring procedures must be effective.

Continuous monitoring is always preferred when feasible and continuous monitoring is possible with many types of physical and chemical methods. For

example, the temperature and time for an institutional cook-chill operation can be recorded continuously on temperature recording charts. If the temperature falls below the scheduled temperature or the time is insufficient, as recorded on the chart, the batch must be recorded as a process deviation and reprocessed or discarded.

Instrumentation used by the food establishment for measuring critical limits must be carefully calibrated for accuracy. Records of calibrations must be maintained as a part of the HACCP plan documentation.

e) — Monitoring Procedures

When it is not possible to monitor a critical limit on a continuous basis, it is necessary to establish that the monitoring interval will be reliable enough to indicate that the hazard is under control. Statistically designed data collection or sampling systems lend themselves to this purpose. When statistical process control is used, it is important to recognize that violations of critical limits must not occur. For example, when a temperature of 68°C (155°F) or higher is required for product safety, the minimum temperature of the product may be set at a target that is above this temperature to compensate for variation.

Most monitoring procedures for CCPs will need to be done rapidly because the time frame between food preparation and consumption does not allow for lengthy analytical testing. Microbiological testing is seldom effective for monitoring CCPs because of its time-consuming nature. Therefore, physical and chemical measurements are preferred because they may be done rapidly and can indicate whether microbiological control is occurring.

Assignment of responsibility for monitoring is an important consideration for each CCP within the operation. Specific assignments will depend on the number of CCPs, preventive measures, and the complexity of monitoring. The most appropriate employees for such assignments are often directly associated with the operation, such as the person in charge of the food establishment, chefs, and the departmental supervisors.

Individuals monitoring CCPs must be trained in the monitoring technique, completely understand the purpose and importance of monitoring, and be unbiased in monitoring and reporting so that monitoring is accurately recorded. The designated individuals must have ready access to the CCP being monitored and to the calibrated instrumentation designated in the HACCP plan.

The person responsible for monitoring must also record a food operation or product that does not meet critical limits and assure that immediate corrective action can be taken. All records and documents associated with CCP monitoring must be signed or initialed by the person doing the monitoring.

Random checks may be useful in supplementing the monitoring of certain CCPs. They may be used to check incoming ingredients, serve as a check for compliance where ingredients are recertified as meeting certain standards, and assess factors such as equipment. Random checks are also advisable for monitoring environmental factors such as airborne contamination, and cleaning and sanitizing gloves.

With some foods containing microbiologically sensitive ingredients, there may not be an alternative to microbiological testing. However, it is important to recognize that a sampling frequency which is adequate for reliable detection of low levels of pathogens is seldom possible because of the large number of samples needed. For this reason, microbiological testing has limitations in a HACCP system, but is valuable as a means of establishing and verifying the effectiveness of control at CCPs (such as through challenge tests, random testing, or testing the focuses on isolating the source of a problem).

5) Principle #5: Establish the Corrective Action to be Taken When Monitoring Shows That a Critical Limit Had Been Exceeded

a) Purpose of Corrective Action Plan

Although the HACCP system is intended to prevent deviations from occurring, perfection is rarely, if ever, achievable. Thus, there must be a corrective action plan in place to:

- i) Determine the disposition of any food that was produced when a deviation was occurring;
- ii) Correct the cause of the deviation and assure that the critical control point is under control; and
- iii) Maintain records of corrective actions.

b) Aspects of Corrective Action Plan

Because of the variations in CCPs for different food operations and the diversity of possible deviations, specific corrective action plans must be developed for each CCP. The actions must demonstrate that the CCP has been brought under control. Individuals who have a thorough understanding of the operation, product, and HACCP plan must be assigned responsibility for taking corrective action. Corrective action procedures must be documented in the HACCP plan.

Food establishments covered by the Food Code will usually be concerned with food which has a limited shelf life and distribution. Primary focus for the application of this HACCP principle will be on the correction of the procedure or condition which led to the noncompliance. More frequent monitoring may be temporarily required to assure that the deviation from the established critical limit is not continuing when the operation is resumed.

If a deviation should occur in food operations that are traditionally considered food processing operations, such as cook-chill, curing and smoking, or reduced oxygen packaging, the food establishment must place the product on hold pending completion of appropriate corrective actions and analyses. As appropriate, scientific experts and regulatory agencies must be consulted regarding additional testing or disposition of the product. Identification of deviant lots and corrective actions taken to assure safety of these lots must be noted in the HACCP record. This record must remain on file for a reasonable period after the expiration date of expected shelf life of the product.

6) Principle #6: Establish Effective Record Keeping Systems That Document the HACCP System

a) Written HACCP Plan

This principle requires the preparation and maintenance of a written HACCP plan by the food establishment. The plan must detail the hazards of each individual or categorical product covered by the plan. It must clearly identify the CCPs and critical limits for each CCP. CCP monitoring and record keeping procedures must be shown in the establishment's HACCP plan. HACCP plan implementation strategy should be provided as a part of the food establishment's documentation.

b) Record Keeping

The principle requires the maintenance of records generated during the operation of the plan. The record keeping associated with HACCP procedures ultimately makes the system work.

One conclusion of a study of HACCP performed by the U.S. Department of Commerce is that correcting problems without record keeping almost guarantees that problems will recur. The requirement to record events at CCPs on a regular basis assures that preventive monitoring is occurring in a systematic way. Unusual occurrences that are discovered as CCPs are monitored or that otherwise come to light must be corrected and recorded immediately with notation of the corrective action taken.

The level of sophistication of the record keeping necessary for the food establishment is dependent on the complexity of the food preparation operation. A sous vidé process or cook-chill operation for a large institution would require more record keeping than a limited menu cook-serve operation. The simplest effective record keeping system that lends itself well to integration within the existing operation is best.

c) Contents of the Plan and Records

The approved HACCP plan and associated records must be on file at the food establishment. Generally, the following are examples of documents that can be included in the total HACCP system:

- i) Listing of the HACCP team and assigned responsibilities;
- ii) Description of the product and its intended use;
- iii) Flow diagram food preparation indicating CCPs;
- iv) Hazards associated with each CCP and preventive measures;
- v) Critical limits;
- vi) Monitoring system;
- vii) Corrective action plans for deviations from critical limits;
- viii) Record keeping procedures; and
- ix) Procedures for verification of HACCP system.

d) Format for HACCP information

In addition to listing the HACCP team, product description and uses, and providing a flow diagram, other information in the HACCP plan can be tabulated as follows:

Process Step	CCP	Chemical Physical Biological Hazards	Critical Limit	Monitoring Procedures Frequency Person(s) Responsible	Corrective Action(s) Person(s) Responsible	HACCP Records	Verification Procedures/ Person(s) Responsible
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The following chart is an example of a HACCP plan documentation for a product cooling step in a retail level food establishment.

Process Step	Cooling
CCP	Critical Control Point #8
Criteria or Critical Limit	Cool Foods Rapidly in Small Quantities to 5°C (41°F)
Establish Monitoring	Department Personnel Break Down Food into Small Quantities and Monitor the Cooling Process
Corrective/Preventive Action	Modify Cooling Procedures/Discard
HACCP Records	Deli Cooking/Cooling Log
HACCP System Verification	Deli Safety Audit by Store Manager

e) ——— Examples of Records Obtained During the Operation of the Plan:

i) ——— Ingredients

- Supplier certification documenting compliance with establishment's specifications.
- Establishment audit records verifying supplier compliance.
- Storage temperature record for temperature sensitive ingredients.
- Storage time records of limited shelf life ingredients.

ii) ——— Preparation

Records from all monitored CCPs.

- Records verifying the continued adequacy of the food preparation procedures.

iii) — Packaging

- Records indicating compliance with specifications of packaging materials.
- Records indicating compliance with sealing specifications.

iv) — Finished product

- Sufficient data and records to establish the efficacy of barriers in maintaining product safety.
- Sufficient data and records establishing the safe shelf life of the product; if age of product can affect safety.
- Documentation of the adequacy of the HACCP procedures from an authority knowledgeable of the hazards involved and necessary controls.

v) — Storage and distribution

- Temperature records.
- Records showing no product shipped after shelf life date on temperature sensitive products.

vi) — Deviation and corrective action

- Validation records and modification to the HACCP plan indicating approved revisions and changes in ingredients, formulations, preparation, packaging, and distribution control, as needed.

vii) — Employee training

- Records indicating that food employees responsible for implementation of the HACCP plan understand the hazards, controls, and procedures. Refer to the discussion regarding Training and Knowledge under Principle #7.

7) — Principle #7: Establish Procedures to Verify that the HACCP System is Working

a) — Establishing Verification Procedures

- i) — The first phase of the process is the scientific or technical verification that critical limits at CCPs are satisfactory. This can be complex and may require intensive involvement of highly skilled professionals from a variety of disciplines capable of doing focused studies and analyses. A review of the critical limits is necessary to verify that the limits are adequate to control the hazards that are likely to occur.
- ii) — The second phase of verification assures that the facility's HACCP plan is functioning effectively. A functioning HACCP system requires little end product sampling, since appropriate safeguards are built in early in the food preparation. Therefore, rather than relying on end product sampling, food establishments

must rely on frequent reviews of their HACCP plan, verification that the HACCP plan is being correctly followed, review of CCP records, and determinations that appropriate risk management decisions and product dispositions are made when preparation deviations occur.

- iii) ~~The third phase consists of documented periodic revalidations, independent of audits or other verification procedures, that must be performed to assure the accuracy of the HACCP plan. Revalidations are performed to assure the accuracy of the HACCP plan. Revalidations are performed by a HACCP team on a regular basis and/or whenever significant product, preparation, or packaging changes require modification of the HACCP plan. The revalidation includes a documented on-site review and verification of all flow diagrams and CCPs in the HACCP plan. The HACCP team modifies the HACCP plan as necessary.~~
- iv) ~~The fourth phase of verification deals with the regulatory agency's responsibility and actions to assure that the establishment's HACCP system is functioning satisfactorily.~~
- b) ~~The following are some examples of HACCP plan verification activities which should be used as a part of a HACCP program:~~
 - i) ~~Verification procedures may include:~~
 - ~~Establishment of appropriate verification inspection schedules;~~
 - ~~Review of the HACCP plan;~~
 - ~~Review of CCP records;~~
 - ~~Review of deviations and their resolution, including the disposition of food;~~
 - ~~Visual inspections of operations to observe if CCPs are under control;~~
 - ~~Random sample collection and analysis;~~
 - ~~Review of critical limits to verify that they are adequate to control hazards;~~
 - ~~Review of written record of verification inspections which certifies compliance with the HACCP plan or deviations from the plan and the corrective actions taken;~~
 - ~~Validation of HACCP plan, including on-site review and verification of flow diagrams and CCP; and~~
 - ~~Review of modifications of the HACCP plan.~~
 - ii) ~~Verification inspections should be conducted:~~
 - ~~Routinely or on an unannounced basis, to assure that selected CCPs are under control;~~

- When it is determined that intensive coverage of a specific food is needed because of new information concerning food safety;
- When foods prepared at the establishment have been implicated as a vehicle of foodborne disease;
- When requested on a consultative basis and resources allow accommodating the request;
- When established criteria have not been met; and
- To verify that changes have been implemented correctly after a HACCP plan has been modified.

iii) — Verification reports should include information about:

- Existence of a HACCP plan and the person(s) responsible for administering and updating the HACCP plan;
- The status of records associated with CCP monitoring;
- Direct monitoring data of the CCP while in operation; Certification that monitoring equipment is properly calibrated and in working order;
- Deviations and corrective actions;
- Any samples analyzed to verify that CCPs are under control. Analyses may involve physical, chemical, microbiological, or organoleptic methods;
- Modifications to the HACCP plan; and
- Training and knowledge of individuals responsible for monitoring CCPs.

e) — Training and Knowledge

i) — Focus and Objective

Training and knowledge are very important in making HACCP successful in any food establishment. HACCP works best when it is integrated into each employee's normal duties rather than added as something extra.

The depth and breadth of training will depend on the particular employee's responsibilities within the establishment. Management or supervisory individuals will need a deeper understanding of the HACCP process because they are responsible for proper plan implementation and routine monitoring of CCPs such as product cooking temperatures and cooling times. The training plan should be specific to the establishment's operation rather than attempt to develop HACCP expertise for broad application.

The food employee's training should provide an overview of HACCP's prevention philosophy while focusing on the specifics of the employee's normal functions. The CCPs such as proper handwashing and use of utensils or gloves for working with ready-to-eat food should be stressed.

The use of recipes of Standard Operating Procedures (SOPs) which include the critical limits of cooking times and temperatures, with a final cooking time and temperature measurement step, should be included.

For all employees, the fundamental training goal should be to make them proficient in the specific tasks which the HACCP plan requires them to perform. This includes the development of a level of competency in their decision making about the implementation of proper corrective actions when monitoring reveals violation of the critical limit. The training should also include the proper completion and maintenance of any records specified in the establishment's plan.

ii) — Reinforcement

Training reinforcement is also needed for continued motivation of the food establishment employees. Some examples might include:

- A HACCP video training program such as the Pennsylvania Department of Environmental Regulation's Foodborne Illness: It's Your Business;
- Changing reminders about HACCP critical limits such as "HANDWASHING PAYS BIG DIVIDENDS" printed on employee's time cards or checks; and
- Work station reminders such as pictorials on how and when to take food temperatures.

Every time there is a change in a product or food operation within the establishment, the HACCP training needs should be evaluated. For example, when a food establishment substitutes a frozen seafood product for a fresh one, proper thawing critical limits should be taught and then monitored for implementation. The employees should be made sensitive to how the changes will affect food safety.

The HACCP plan should include a feedback loop for employees to suggest what additional training is needed. All employees should be made a part of the continuous food safety improvement cycle because the old statement is very true, "The customer's health is in their hands". This helps maintain their active awareness and involvement in the importance of each job to the safety of the food provided by their establishment.

3. — Summary

HACCP is a systematic approach to food safety which will dramatically improve the level of food safety. The NACMCF has developed the seven HACCP principles discussed within this Appendix. The FDA recommends the implementation of a HACCP system throughout the food industry using these NACMCF recommendations.

An effective national food safety program from food production to consumer is enhanced by the implementation of HACCP. The statistics from foodborne surveillance reveal that retail level food establishments can have a significant impact on the health of consumers.

Implementation of HACCP programs by the establishments will profoundly enhance their role in the protection of public health beyond the traditional emphasis on facility and equipment design and maintenance and adherence to the principles of sanitation, good manufacturing, and food

preparation practices. The education and training of all personnel are critical to the success and effectiveness of any HACCP program. The Food Code stresses the application to HACCP principles and the knowledge and responsibilities of establishment management and employees.

Specific HACCP plans for the products prepared and sold by the retail food establishment should be developed and implemented for optimal food safety management. HACCP systems are recommended for optimal food safety management. HACCP systems are recommended for use as a tool for regulatory inspections. The regulatory official should incorporate procedures in the inspection process that assure record reviews and active monitoring.

Because the retail food establishment industry is composed of large, small, chain, and independent establishments, the level of food safety expertise varies widely and is not necessarily linked to size or affiliation. Regardless of the size and sophistication of the establishment, a HACCP plan for safe food preparation and sales needs to be designed, implemented, and verified.

Studies have shown that a significant level of illness and mortality from foodborne disease in institutional feeding operations such as hospitals, nursing homes, and prisons is related to preventable causes. For populations that may be more vulnerable to foodborne disease, FDA and the NACMCF recommend that HACCP systems be immediately implemented by establishments and institutions preparing foods for these susceptible individuals.

Food processing operations at retail food establishments such as reduced oxygen packaging and curing and smoking under the Food Code are required to develop and implement a HACCP plan for that part of the operation. Additionally, any establishment seeking a variance from the requirements of the Code must submit a HACCP plan. The HACCP Appendix can serve to guide these establishments in this process.

Food establishments have the primary responsibility for food safety. The development and implementation of HACCP programs is a reliable and responsible step to help assure the safety of food offered for consumption.

4.—Acknowledgments

Much of this HACCP Appendix material is adapted from National Advisory Committee on Microbiological Criteria for Foods, Hazard Analysis and Critical Control Point System, adopted March 20, 1992.

Some of the charts were provided courtesy of “Overview of Biological, Chemical, and Physical Hazards” in “HACCP Principles and Applications”, Merle Pierson and Donald A. Corlett, Jr. (Eds.), 1992 p 8-28. Chapman and Hall, New York.

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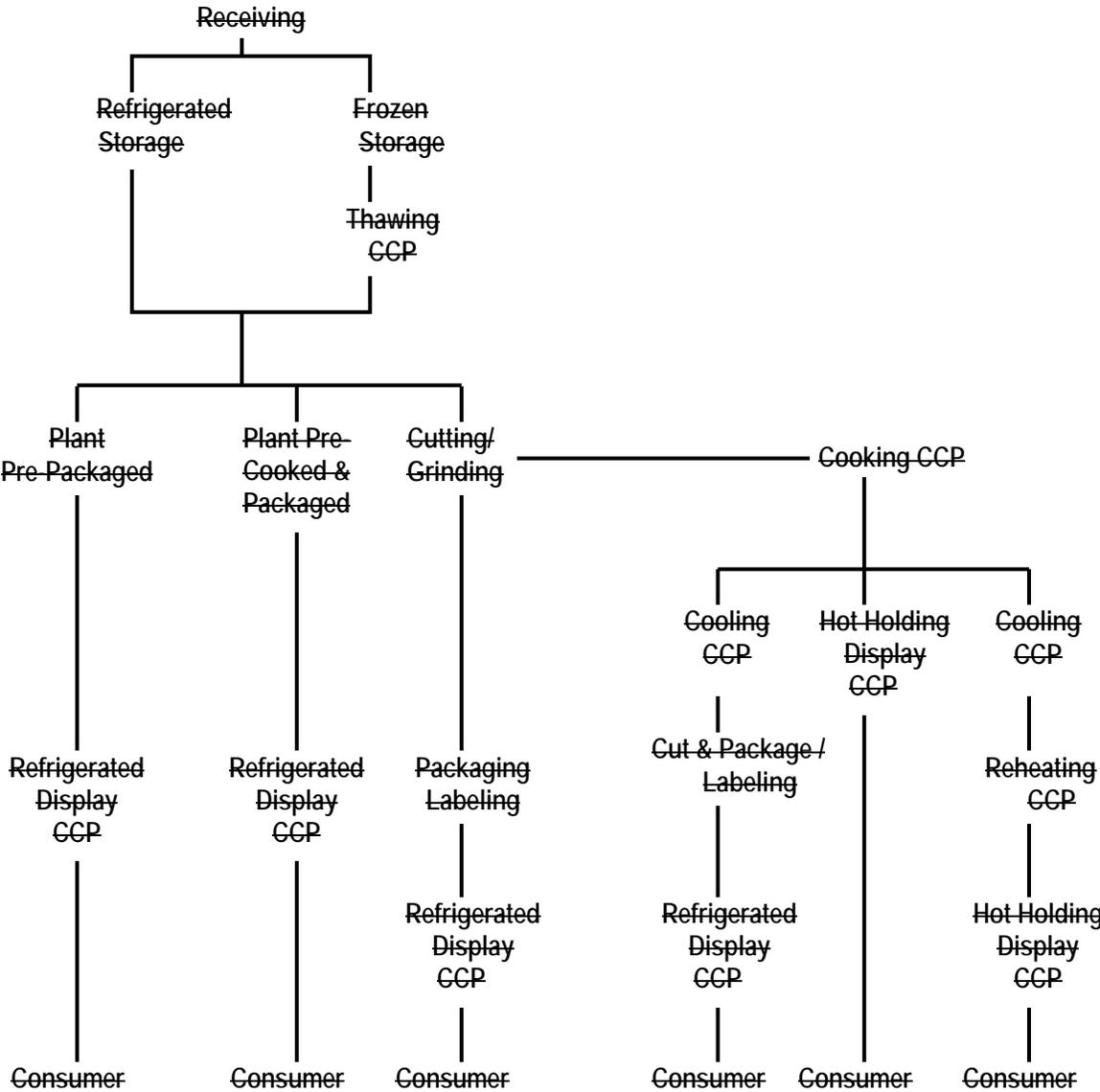
6. — Other Sources of HACCP Information

FDA Prime Connection. A Free On-Line HACCP Technical Database. For registration information, contact FDA PRIME CONNECTION, 200 C Street SW HFS-625, Washington, D.C. 20204-0001 or call (202) 205-8140.

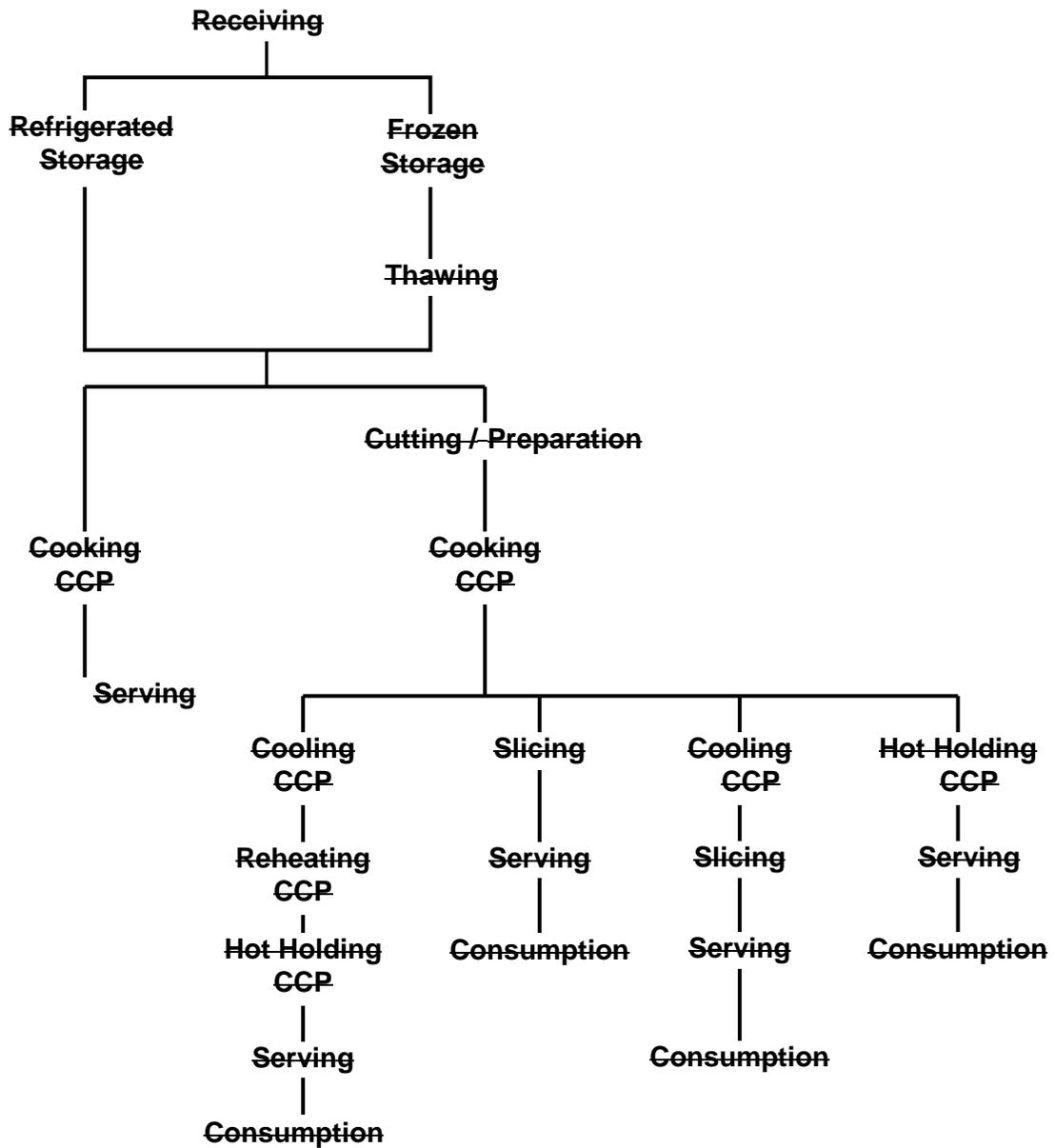
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Two Typical Flow Diagrams

Flow Chart 1



Flow Chart 2



APPENDIX H - RETAIL FOOD STORE SANITATION ACT

25-4-1301. LEGISLATIVE DECLARATION. THE GENERAL ASSEMBLY HEREBY DECLARES THAT THE SANITARY PROTECTION OF BULK FOODS AND THE SANITARY MAINTENANCE OF EQUIPMENT USED TO DISPLAY AND DISPENSE BULK FOODS ARE MATTERS OF STATEWIDE CONCERN AND ARE AFFECTED WITH A PUBLIC INTEREST AND THAT THE PROVISIONS OF THIS PART 13 ARE ENACTED IN THE EXERCISE OF THE POLICE POWERS OF THIS STATE FOR THE PURPOSE OF PROTECTING THE HEALTH, PEACE, SAFETY, AND GENERAL WELFARE OF THE PEOPLE OF THIS STATE.

25-4-1302. DEFINITIONS. AS USED IN THIS PART 13, UNLESS THE CONTEXT OTHERWISE REQUIRES:

(1) “BULK FOODS” MEANS UNPACKAGED OR UNWRAPPED FOODS, EITHER PROCESSED OR UNPROCESSED, IN AGGREGATE CONTAINERS FROM WHICH QUANTITIES DESIRED BY THE CONSUMER ARE WITHDRAWN. “BULK FOODS” DOES NOT INCLUDE FRESH FRUITS, FRESH VEGETABLES, NUTS IN THE SHELL, SALAD BAR, BULK PET FOODS, POTENTIALLY HAZARDOUS FOODS, AND BULK NONFOOD ITEMS.

(2) “DEPARTMENT” MEANS THE DEPARTMENT OF HEALTH.

(3) “DISPLAY AREA” MEANS A LOCATION INCLUDING PHYSICAL FACILITIES AND EQUIPMENT, WHERE BULK FOODS ARE OFFERED FOR CUSTOMER SELF-SERVICE.

(4) “POTENTIALLY HAZARDOUS FOODS” INCLUDES ANY FOOD THAT CONSISTS IN WHOLE OR IN PART, OF MILK OR MILK PRODUCTS, EGGS, MEAT, POULTRY, FISH, SHELLFISH, EDIBLE CRUSTACEA, OR OTHER FOOD PRODUCTS OR INGREDIENTS, INCLUDING SYNTHETIC INGREDIENTS, IN A FORM CAPABLE OF SUPPORTING RAPID AND PROGRESSIVE GROWTH OF INFECTIOUS OR TOXIGENIC MICROORGANISMS. THIS TERM DOES NOT INCLUDE REFRIGERATED, CLEAN, WHOLE, UNCRACKED, ODOR-FREE SHELL EGGS.

(5) “PRODUCT MODULE” MEANS A FOOD-CONTACT CONTAINER (MULTIUSE OR SINGLE-SERVICE) DESIGNED FOR CUSTOMER SELF-SERVICE OF BULK FOODS BY EITHER DIRECT OR INDIRECT MEANS.

(6) “SERVICING AREA” MEANS A DESIGNATED LOCATION EQUIPPED FOR CLEANING, SANITIZING DRYING, OR REFILLING PRODUCT MODULES OR FOR PREPARING BULK FOODS.

25-4-1303. LABELING - PRODUCT MODULES - TAKE-HOME CONTAINERS. (1) PRODUCT MODULES SHALL BE LABELED WITH EITHER:

(A) THE MANUFACTURER'S OR PROCESSOR'S BULK FOOD CONTAINER LABELING PLAINLY IN VIEW; OR

(B) A COUNTER CARD, A COUNTER SIGN, OR ANY OTHER APPROPRIATE DEVICE BEARING PROMINENTLY AND CONSPICUOUSLY THE COMMON NAME OF THE PRODUCT, A LIST OF INGREDIENTS IN THEIR PROPER ORDER OF PREDOMINANCE, AND A DECLARATION OF ARTIFICIAL COLOR OR FLAVOR AND CHEMICAL PRESERVATIVES IF CONTAINED IN THE PRODUCT.

(2) ANY UNPACKAGED BULK FOOD NEED NOT COMPLY WITH THE LABELING REQUIREMENTS OF THIS SECTION IF THE UNPACKAGED BULK FOOD IS MANUFACTURED ON THE PREMISES OF A STORE OR MANUFACTURED BY THE SAME STORE AT THE DIFFERENT LOCATION AND IF THE MANUFACTURED BULK FOOD IS OFFERED FOR RETAIL SALE ON THE STORE'S PREMISES AND IF THERE ARE NO STATE REQUIREMENTS.

(3) LABELS OR MARKING PENS SHALL BE AVAILABLE TO CUSTOMERS TO IDENTIFY THEIR TAKE-HOME CONTAINERS WITH THE COMMON NAME OF THE PRODUCT UNLESS THE PRODUCT IS READILY IDENTIFIABLE ON SIGHT.

25-4-1304. BULK FOOD PROTECTION. (1) BULK FOODS AND PRODUCT MODULES SHALL BE PROTECTED FROM CONTAMINATION DURING , DISPLAY, CUSTOMER SELF-SERVICE, REFILLING, AND STORAGE.

(2) CONTAINERS OF BULK PET FOODS AND BULK NONFOOD ITEMS SHALL BE SEPARATED FROM PRODUCT MODULES BY A BARRIER OR OPEN SPACE.

(3) BULK FOODS RETURNED TO STORES BY CUSTOMERS SHALL NOT BE OFFERED FOR RESALE.

(4) ONLY CONTAINERS PROVIDED BY STORES IN THEIR DISPLAY AREAS SHALL BE FILLED WITH BULK FOODS; EXCEPT THAT ANY CUSTOMER MAY FILL OR REFILL HIS OWN CONTAINERS WITH VENDED OR DISPENSED WATER; HOWEVER, THE RISK THAT THE CUSTOMER'S OWN CONTAINER IS UNSAFE, UNPURE, CONTAMINATED, OR IN A NON STERILE CONDITION WHEN IT IS FILLED OR REFILLED BY THE CUSTOMER, SHALL BE BORNE SOLELY BY THE CUSTOMER, AND, EXCEPT FOR WARRANTIES, NO LIABILITY SHALL ATTACH THERETO TO THE MANUFACTURER, SELLER, OR DISPENSER OF SUCH CONTAINER.

25-4-1305. BULK FOOD DISPLAY. (1) BULK FOODS SHALL BE DISPENSED ONLY FROM PRODUCT MODULES WHICH ARE PROTECTED BY CLOSE-FITTING, INDIVIDUAL COVERS. IF ANY PRODUCT MODULE IS TO BE OPENED BY CUSTOMERS, THE COVER SHALL BE SELF-CLOSING AND SHALL REMAIN CLOSE WHEN NOT IN USE.

(2) CUSTOMER ACCESS TO BULK FOODS IN PRODUCT MODULES SHALL BE LIMITED AND CONTROLLED TO AVOID THE INTRODUCTION OF CONTAMINANTS. ALL PRODUCT MODULES SHALL HAVE AN ACCESS HEIGHT OF THIRTY INCHES OR MORE ABOVE THE FLOOR AND A DEPTH OF EIGHTEEN INCHES OR LESS.

(3) POTENTIALLY HAZARDOUS FOODS SHALL NOT BE MADE AVAILABLE FOR CUSTOMER SELF-SERVICE.

25-4-1306. DISPENSING UTENSILS. (1) MANUAL HANDLING OF BULK FOODS BY CUSTOMERS DURING DISPENSING SHALL BY DISCOURAGED. MECHANICAL DISPENSING DEVICES SHALL BE USED, INCLUDING GRAVITY DISPENSERS, PUMPS, EXTRUDERS, AND AUGERS. MANUAL DISPENSING UTENSILS SHALL ALSO BE USED, INCLUDING TONGS, SCOOPS, LADLES, AND SPATULAS.

(2) IF THE DISPENSING DEVICES AND UTENSILS LISTED IN SUBSECTION (1) OF THIS SECTION DO NOT DISCOURAGE MANUAL CUSTOMER HANDLING OF BULK FOODS, SUCH BULK FOODS MUST BE WRAPPED OR SACKED PRIOR TO DISPLAY.

(3) MANUAL DISPENSING UTENSILS SHALL BE PROTECTED AGAINST BECOMING CONTAMINATED AND SERVING AS VEHICLES FOR INTRODUCING CONTAMINATION INTO BULK FOODS. A TETHER OF EASILY CLEANABLE MATERIAL SHALL BE ATTACHED TO SUCH A UTENSIL AND SHALL BE OF SUCH LENGTH THAT THE UTENSIL CANNOT CONTACT THE FLOOR. A SLEEVE OR PROTECTIVE HOUSING ATTACHED OR ADJACENT TO THE DISPLAY UNIT SHALL BE AVAILABLE FOR STORING A UTENSIL WHEN NOT IN USE.

(4) LADLES AND SPATULAS SHALL BE STORED IN BULK FOODS WITH HANDLES EXTENDING TO THE OUTSIDE OF PRODUCT MODULES. HANDLES SHALL NOT PREVENT LIDS FROM BEING SELF-CLOSING.

25-4-1307. MATERIALS. PRODUCT MODULES AND UTENSILS SHALL BE CONSTRUCTED OF SAFE MATERIALS AND SHALL BE CORROSION RESISTANT, NONABSORBENT, SMOOTH, EASILY CLEANABLE, AND DURABLE UNDER CONDITIONS OF NORMAL USE. WOOD SHALL NOT BE USED AS A FOOD-CONTACT SURFACE.

25-4-1308. FOOD-CONTACT SURFACES. PRODUCT MODULES, LIDS, DISPENSING UNITS, AND UTENSILS SHALL BE DESIGNED AND FABRICATED TO MEET THE REQUIREMENTS FOR FOOD-CONTACT SURFACES, AS PROVIDED IN SECTION 25-4-1307.

25-4-1309. NON-FOOD-CONTACT SURFACES. SURFACES OF PRODUCT MODULE DISPLAY UNITS, TETHERS, AND DISPLAY EQUIPMENT WHICH ARE NOT INTENDED FOR FOOD CONTACT BUT WHICH ARE EXPOSED TO SPLASH, FOOD DEBRIS, OR OTHER SOILING SHALL BE DESIGNED AND FABRICATED TO BE SMOOTH, CLEANABLE, DURABLE UNDER CONDITIONS OF NORMAL USE, AND FREE OF UNNECESSARY LEDGES, PROJECTIONS, AND CREVICES. THE MATERIALS FOR NON-FOOD-CONTACT SURFACES SHALL BE NONABSORBENT OR MADE NONABSORBENT BY BEING FINISHED AND SEALED WITH A CLEANABLE COATING.

25-4-1310. ACCESSIBILITY. INDIVIDUAL PRODUCT MODULES SHALL BE DESIGNED TO BE EASILY REMOVABLE FROM A DISPLAY UNIT FOR SERVICING UNLESS THE PRODUCT MODULES ARE SO DESIGNED AND FABRICATED THAT THEY CAN BE EFFECTIVELY CLEANED AND SANITIZED WHEN NECESSARY THROUGH A MANUAL IN-PLACE CLEANING PROCEDURE THAT WILL NOT CONTAMINATE OR OTHERWISE ADVERSELY AFFECT BULK FOODS OR EQUIPMENT IN ANY ADJOINING DISPLAY AREAS.

25-4-1311. EQUIPMENT SANITIZATION. (1) TONGS, SCOOPS, LADLES, SPATULAS, AND OTHER APPROPRIATE UTENSILS AND TETHERS USED BY CUSTOMERS SHALL BE CLEANED AND SANITIZED AT LEAST DAILY OR AT MORE FREQUENT INTERVALS BASED ON THE TYPE OF BULK FOOD AND THE AMOUNT OF FOOD PARTICLE ACCUMULATION OF SOILING.

(2) WHEN SOILED, PRODUCT MODULES, LIDS, AND OTHER EQUIPMENT SHALL BE CLEANED AND SANITIZED PRIOR TO RESTOCKING OR AT INTERVALS OF A SCHEDULE BASED ON THE TYPE OF BULK FOOD AND THE AMOUNT OF FOOD PARTICLE ACCUMULATION.

(3) FOOD-CONTACT SURFACES SHALL BE CLEANED AND SANITIZED IMMEDIATELY IF CONTAMINATION IS OBSERVED OR SUSPECTED.

(4) FACILITIES AND EQUIPMENT SHALL BE AVAILABLE, EITHER IN A SERVICING AREA OR IN PLACE, TO PROVIDE FOR THE PROPER CLEANING AND SANITIZING OF ALL FOOD-CONTACT SURFACES, INCLUDING PRODUCT MODULES, LIDS, AND DISPENSING UTENSILS.

(5) TAKE-HOME CONTAINERS, INCLUDING BUT NOT LIMITED TO BAGS, CUPS, AND LIDS, WHICH ARE PROVIDED IN A DISPLAY AREA FOR CUSTOMER USE SHALL BE STORED AND DISPENSED IN A SANITARY MANNER.

25-4-1312. VIOLATION - PENALTY. ANY RETAIL FOOD STORE OWNER VIOLATING ANY OF THE PROVISIONS OF THIS PART 13 IS GUILTY OF A MISDEMEANOR AND, UPON CONVICTION THEREOF, SHALL BE PUNISHED BY A FINE OF NOT MORE THAN FIVE HUNDRED DOLLARS, OR BY IMPRISONMENT IN THE COUNTY JAIL FOR NOT MORE THAN NINETY DAYS, OR BY BOTH SUCH FINE AND IMPRISONMENT. IT IS THE DUTY OF THE DISTRICT ATTORNEYS OF THE SEVERAL DISTRICTS OF THIS STATE TO PROSECUTE FOR VIOLATIONS OF THIS PART 13 AS FOR OTHER CRIMES AND MISDEMEANORS.

25-4-1313. RULES AND REGULATIONS. THE DEPARTMENT HAS THE POWER TO PROMULGATE RULES AND REGULATIONS FOR THE IMPLEMENTATION OF THIS PART 13.

25-4-1314. LIMITATION. THE PROVISIONS OF THIS PART 13 SHALL BE EXPRESSLY LIMITED TO RETAIL FOOD STORE OUTLETS.

Appendix I - RETAIL FOOD STORE SANITATION ACT

~~25-4-1301. Legislative declaration. The general assembly hereby declares that the sanitary protection of bulk foods and the sanitary maintenance of equipment used to display and dispense bulk foods are matters of statewide concern and are affected with a public interest and that the provisions of this part 13 are enacted in the exercise of the police powers of this state for the purpose of protecting the health, peace, safety, and general welfare of the people of this state.~~

~~25-4-1302. Definitions. As used in this part 13, unless the context otherwise requires:~~

~~(1) "Bulk foods" means unpackaged or unwrapped foods, either processed or unprocessed, in aggregate containers from which quantities desired by the consumer are withdrawn. "Bulk foods" does not include fresh fruits, fresh vegetables, nuts in the shell, salad bar, bulk pet foods, potentially hazardous foods, and bulk nonfood items.~~

~~(2) "Department" means the department of health.~~

~~(3) "Display area" means a location including physical facilities and equipment, where bulk foods are offered for customer self-service.~~

~~(4) "Potentially hazardous foods" includes any food that consists in whole or in part, of milk or milk products, eggs, meat, poultry, fish, shellfish, edible crustacea, or other food products or ingredients, including synthetic ingredients, in a form capable of supporting rapid and progressive growth of infectious or toxigenic microorganisms. This term does not include refrigerated, clean, whole, uncracked, odor-free shell eggs.~~

~~(5) "Product module" means a food-contact container (multiuse or single-service) designed for customer self-service of bulk foods by either direct or indirect means.~~

~~(6) "Servicing area" means a designated location equipped for cleaning, sanitizing drying, or refilling product modules or for preparing bulk foods.~~

~~25-4-1303. Labeling - product modules - take-home containers. (1) product modules shall be labeled with either:~~

~~(a) The manufacturer's or processor's bulk food container labeling plainly in view; or~~

~~(b) A counter card, a counter sign, or any other appropriate device bearing prominently and conspicuously the common name of the product, a list of ingredients in their proper order of predominance, and a declaration of artificial color or flavor and chemical preservatives if contained in the product.~~

~~(2) any unpack aged bulk food need not comply with the labeling requirements of this section if the unpackaged bulk food is manufactured on the premises of a store or manufactured by the same store at the different location and if the manufactured bulk food is offered for retail sale on the store's premises and if there are no state requirements.~~

~~(3) Labels or marking pens shall be available to customers to identify their take-home containers with the common name of the product unless the product is readily identifiable on sight.~~

~~25-4-1304. Bulk food protection. (1) Bulk foods and product modules shall be protected from contamination during , display, customer self service, refilling, and storage.~~

~~(2) Containers of bulk pet foods and bulk nonfood items shall be separated from product modules by a barrier or open space.~~

~~(3) Bulk foods returned to stores by customers shall not be offered for resale.~~

~~(4) Only containers provided by stores in their display areas shall be filled with bulk foods; except that any customer may fill or refill his own containers with vended or dispensed water; however, the risk that the customer's own container is unsafe, unpure, contaminated, or in a non-sterile condition when it is filled or refilled by the customer, shall be borne solely by the customer, and, except for warranties, no liability shall attach thereto to the manufacturer, seller, or dispenser of such container.~~

~~25-4-1305. Bulk food display. (1) Bulk foods shall be dispensed only from product modules which are protected by close fitting, individual covers. If any product module is to be opened by customers, the cover shall be self-closing and shall remain close when not in use.~~

~~(2) Customer access to bulk foods in product modules shall be limited and controlled to avoid the introduction of contaminants. All product modules shall have an access height of thirty inches or more above the floor and a depth of eighteen inches or less.~~

~~(3) Potentially hazardous foods shall not be made available for customer self-service.~~

~~25-4-1306. Dispensing utensils. (1) Manual handling of bulk foods by customers during dispensing shall be discouraged. Mechanical dispensing devices shall be used, including gravity dispensers, pumps, extruders, and augers. Manual dispensing utensils shall also be used, including tongs, scoops, ladles, and spatulas.~~

~~(2) If the dispensing devices and utensils listed in subsection (1) of this section do not discourage manual customer handling of bulk foods, such bulk foods must be wrapped or sacked prior to display.~~

~~(3) Manual dispensing utensils shall be protected against becoming contaminated and serving as vehicles for introducing contamination into bulk foods. A tether of easily cleanable material shall be attached to such a utensil and shall be of such length that the utensil cannot contact the floor. A sleeve or protective housing attached or adjacent to the display unit shall be available for storing a utensil when not in use.~~

~~(4) Ladles and spatulas shall be stored in bulk foods with handles extending to the outside of product modules. Handles shall not prevent lids from being self-closing.~~

~~25-4-1307. Materials. Product modules and utensils shall be constructed of safe materials and shall be corrosion resistant, nonabsorbent, smooth, easily cleanable, and durable under conditions of normal use. Wood shall not be used as a food contact surface.~~

~~25-4-1308. Food contact surfaces. Product modules, lids, dispensing units, and utensils shall be designed and fabricated to meet the requirements for food contact surfaces, as provided in section 25-4-1307.~~

~~25-4-1309. Non food contact surfaces. Surfaces of product module display units, tethers, and display equipment which are not intended for food contact but which are exposed to splash, food debris, or other soiling shall be designed and fabricated to be smooth, cleanable, durable under conditions of normal use, and free of unnecessary ledges, projections, and crevices. The materials for non food contact surfaces shall be nonabsorbent or made nonabsorbent by being finished and sealed with a cleanable coating.~~

~~25-4-1310. Accessibility. Individual product modules shall be designed to be easily removable from a display unit for servicing unless the product modules are so designed and fabricated that they can be effectively cleaned and sanitized when necessary through a manual in place cleaning procedure that will not contaminate or otherwise adversely affect bulk foods or equipment in any adjoining display areas.~~

~~25-4-1311. Equipment sanitization. (1) Tongs, scoops, ladles, spatulas, and other appropriate utensils and tethers used by customers shall be cleaned and sanitized at least daily or at more frequent intervals based on the type of bulk food and the amount of food particle accumulation of soiling.~~

~~(2) When soiled, product modules, lids, and other equipment shall be cleaned and sanitized prior to restocking or at intervals of a schedule based on the type of bulk food and the amount of food particle accumulation.~~

~~(3) Food contact surfaces shall be cleaned and sanitized immediately if contamination is observed or suspected.~~

~~(4) Facilities and equipment shall be available, either in a servicing area or in place, to provide for the proper cleaning and sanitizing of all food contact surfaces, including product modules, lids, and dispensing utensils.~~

~~(5) Take-home containers, including but not limited to bags, cups, and lids, which are provided in a display area for customer use shall be stored and dispensed in a sanitary manner.~~

~~25-4-1312. Violation Penalty. Any retail food store owner violating any of the provisions of this part 13 is guilty of a misdemeanor and, upon conviction thereof, shall be punished by a fine of not more than five hundred dollars, or by imprisonment in the county jail for not more than ninety days, or by both such fine and imprisonment. It is the duty of the district attorneys of the several districts of this state to prosecute for violations of this part 13 as for other crimes and misdemeanors.~~

~~25-4-1313. Rules and regulations. The department has the power to promulgate rules and regulations for the implementation of this part 13.~~

~~25-4-1314. Limitation. The provisions of this part 13 shall be expressly limited to retail food store outlets.~~

APPENDIX I - EQUIPMENT INVESTIGATION REPORT

SECTION 4-101 OF THE COLORADO RETAIL FOOD ESTABLISHMENT RULES AND REGULATION SPECIFY ALL EQUIPMENT, UTENSILS AND SINGLE-SERVICE ARTICLES SHALL BE FABRICATED WITH SAFE MATERIALS; BE OF COMMERCIAL DESIGN, THAT IS CERTIFIED OR CLASSIFIED BY AN AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI) ACCREDITED CERTIFICATION PROGRAM, SUCH AS THE NATIONAL SANITATION FOUNDATION (NSF), UNDERWRITERS LABORATORIES (UL) SANITATION STANDARDS, ENVIRONMENTAL TESTING LABORATORIES, INC. (ETL) SANITATION STANDARDS, BAKING INDUSTRY SANITATION STANDARDS COMMITTEE (BISSC), OR OTHER COMPARABLE DESIGN CRITERIA AS APPROVED BY THE DEPARTMENT DURING A STANDARDIZED EQUIPMENT REVIEW.

IF A RETAIL FOOD ESTABLISHMENT INTENDS TO HAVE ANY EQUIPMENT, UTENSILS AND SINGLE-SERVICE ARTICLES APPROVED BY THE DEPARTMENT, THE APPROVAL WILL BE BASED UPON SUBMISSION OF THE FOLLOWING INFORMATION TO BE PROVIDED TO THE LOCAL HEALTH AGENCY AND/OR THE COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT FOR EVALUATION.

16. RESULTS OF INVESTIGATION

17. ACTION TAKEN

18. COMMENTS

~~APPENDIX J – Equipment Investigation Report~~

~~Section 4-101 of the Colorado Retail Food Establishment Rules and Regulation specify all equipment, utensils and single service articles shall be fabricated with safe materials; be of commercial design, that is certified or classified for sanitation by an American National Standards Institute (ANSI) accredited certification program or a design approved by the Department.~~

~~If a retail food establishment intends to have any equipment, utensils and single service articles approved by the Department, the approval will be based upon submission of the following information to be provided to the local health agency and/or the Colorado Department of Public Health and Environment for evaluation.~~

**COLORADO DEPARTMENT OF PUBLIC HEALTH & ENVIRONMENT
4300 CHERRY CREEK DRIVE SOUTH
DENVER, CO 80246-1530**

EQUIPMENT INVESTIGATION REPORT	
1. LOCATION (STATE AND COUNTY)	
2. TYPE OF PROGRAM (CHECK ONE)	3. RECOMMENDATION
<input type="checkbox"/> FOOD SERVICE ESTABLISHMENT <input type="checkbox"/> FOOD WAREHOUSE AND MANUFACTURER <input type="checkbox"/> RETAIL MARKET	<input type="checkbox"/> ACCEPT <input type="checkbox"/> REJECT
4. PREPARED BY	
NAME _____	
TITLE _____	
AGENCY _____	
SIGNATURE _____	DATE _____
5. NAME / TITLE / ORGANIZATION REQUESTING INVESTIGATION	6. DATE OF REQUEST
7. NAME AND ADDRESS OF MANUFACTURER	8. DATE OF INVESTIGATION
9. NAME AND TITLE OF CONTACT	
EQUIPMENT INFORMATION	
10. TRADE NAME	11. MODEL NUMBER
12. DESCRIPTION OF EQUIPMENT (CHECK APPROPRIATE LINE AND DESCRIBE)	
<input type="checkbox"/> PROTOTYPE <input type="checkbox"/> PRODUCTION <input type="checkbox"/> IN USE <input type="checkbox"/> OTHER	
13. SPECIFIC USE OF EQUIPMENT	
14. FOOD-CONTACT SURFACE MATERIAL TYPE (CHECK APPROPRIATE LINE AND DESCRIBE)	
<input type="checkbox"/> METAL _____ <input type="checkbox"/> RUBBER _____	<input type="checkbox"/> PAINT _____ <input type="checkbox"/> PLASTIC _____
15. PLEASE ATTACH A SPECIFICATION SHEET OR A BLUE PRINT DRAWING OF EQUIPMENT	

16. RESULTS OF INVESTIGATION

17. ACTION TAKEN

18. COMMENTS