

**RETAIL FOOD ESTABLISHMENT
SANITATION REQUIREMENTS**

TITLE 410 IAC 7-24

Effective November 13, 2004

**Indiana State Department of Health
2 North Meridian Street
Indianapolis, IN 46204**

Sec. 112. (a) Food equipment that is certified or classified for sanitation by an American National Standards Institute accredited certification program will be deemed to comply with sections 161, 205 through 213, 215 through 217, 219 through 226, 229 through 232, 253 through 256, 261 through 266, 271, 277 through 282, 288, 305 through 306, and 333 of this rule.

For purposes of this section, a violation of subsection (a) is a noncritical item.

MOBILE RETAIL FOOD ESTABLISHMENT

Section 113

10 IAC 7-24-113 Mobile Retail Food Establishment

Sec. 113. (a) A mobile retail food establishment must be physically transported to a commissary or servicing area, or both, at least once daily for all:

- (1) supplies;
- (2) cleaning; and
- (3) servicing operations.

(b) A mobile retail food establishment shall comply with this rule except as otherwise provided in this section.

(c) A mobile retail food establishment serving only food prepared, packaged in individual servings, transported, and stored under conditions meeting the requirements of this rule, or beverages that are not potentially hazardous and are dispensed from covered urns or other protected equipment, need not comply with this rule pertaining to the following:

(1) The necessity of water and sewage systems.

(2) The cleaning and sanitizing of equipment and utensils if the required equipment for cleaning and sanitizing exists at the commissary; however, frankfurters may be prepared and served from these units without the required cleaning and sanitizing equipment only.

(d) A mobile retail food establishment shall provide only single-service articles for use by the consumer.

(e) A mobile retail food establishment requiring a water system shall have a potable water system under pressure. The system shall be of sufficient capacity to furnish enough hot and cold water for food preparation, utensil cleaning and sanitizing, and hand washing, in accordance with this rule.

(f) If liquid waste results from the operation of a mobile retail food establishment, the waste shall be stored in a permanently installed retention tank that is of at least fifteen percent (15%) larger capacity than the water supply tank as specified in section 372 of this rule. Liquid waste shall not be discharged from the retention tank when the mobile retail food establishment is being moved.

(g) For purposes of this section, a violation of subsection (a), (c), (e), or (f) is a critical item.

(h) For purposes of this section, a violation of subsection (b) or (d) is a noncritical item.

VARIANCE

Section 114

10 IAC 7-24-114 Variance

Sec. 114. (a) An owner or operator of a retail food establishment may request a variance from one (1) or more of the sections in this rule as specified in IC 16-19-3-4.3 and IC 16-42-5-5.2.

(b) An owner or operator of a retail food establishment that requests a variance from one (1) or more requirements of this rule must complete a variance application provided by the department. The application information must adequately and completely address all areas of concern described in the department's "Policy for Processing Variance Requests".

(c) The department will process the variance request in accordance with the published and posted policy referenced in subsection (b).

(d) From the effective date of this rule, an owner or operator of a retail food establishment shall not commence implementation of a modification to this rule without first obtaining approval from the department.

on the determination of whether or not the violation significantly contributes to food contamination, an illness, or an environmental health hazard.

HACCP PLAN

Section 115

410 IAC 7-24-115 Contents of a HACCP plan

Sec. 115. (a) For a retail food establishment that is required under sections 114 and 195 of this rule to have a HACCP plan, the plan and specifications shall indicate the following:

(1) A categorization of the types of potentially hazardous foods that are specified in the menu, such as soups, sauces, salads, and bulk, solid foods, such as meat roasts, or other foods that are specified by the regulatory authority.

(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.

(B) Formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved.

(3) A 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 the following:

(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 points.

(E) Actions to be taken by the person-in-charge if the critical limits for each critical control point are not met.

(F) Records to be maintained by the person-in-charge to demonstrate that the HACCP plan is properly operated and managed.

(G) Additional scientific data or other information, as required by the regulatory authority, supporting the determination that food safety is not compromised by the proposal.

(b) For purposes of this section, a violation of subsection (a) is a noncritical item.

410 IAC 7-24-116 Preventing health hazards; provisions for conditions not addressed

Sec. 116. (a) If necessary to protect against public health hazards or nuisances, the regulatory authority may temporarily impose specific requirements in addition to the requirements contained in this rule that are authorized by law.

(b) The regulatory authority shall document the conditions that necessitate the imposition of additional requirements and the underlying public health rationale. The documentation shall be provided to the retail food establishment, and a copy shall be maintained in the regulatory authority's file for the retail food establishment.

(c) For purposes of this section, a violation of subsection (a) or (b) is a noncritical item.

SUPERVISION AND RESPONSIBILITY

Sections 117 through 119

410 IAC 7-24-117 Assignment of supervision responsibility

Sec. 117. (a) The owner or operator of a retail food establishment shall have a person-in-charge present at the retail food establishment during all hours of operation.

(b) For purposes of this section, a violation of subsection (a) is a critical item.

Sec. 179. (a) Except for nuts in the shell and whole, raw fruits and vegetables that are intended for hulling, peeling, or washing by the consumer before consumption, food on display shall be protected from contamination by the use of:

- (1) packaging;
- (2) counter, service line, or salad bar food guards;
- (3) display cases; or
- (4) other effective means.

(b) For purposes of this section, a violation of subsection (a) is a noncritical item.

10 IAC 7-24-180 Condiments; protection

Sec. 180. (a) Condiments shall be protected from contamination by being kept in:

- (1) dispensers that are designed to provide protection;
- (2) protected food displays provided with the proper utensils;
- (3) original containers designed for dispensing; or
- (4) individual packages or portions.

(b) Condiments at a vending machine location shall be in individual packages or provided in dispensers that are filled at an approved location, such as the following:

- (1) The retail food establishment that provides food to the vending machine location.
- (2) A food processing plant that is regulated by the agency that has jurisdiction over the operation.
- (3) A properly equipped facility that is located on the site of the vending machine location.

(c) For purposes of this section, a violation of subsection (a) or (b) is a noncritical item.

10 IAC 7-24-181 Consumer self-service operations

Sec. 181. (a) Raw, unpackaged animal food, such as beef, lamb, pork, poultry, and fish, may not be offered in consumer self-service. This section does not apply to:

- (1) consumer self-service of ready-to-eat foods at buffets or salad bars that serve foods, such as sushi or raw shellfish; or
- (2) ready-to-cook individual portions for immediate cooking and consumption on the premises, such as:
 - (A) consumer-cooked meats or consumer-selected ingredients for Mongolian barbecue; or
 - (B) raw, frozen, shell-on shrimp or lobster.

(b) Consumer self-service operations for ready-to-eat foods shall be provided with suitable utensils or effective dispensing methods that protect the food from contamination.

(c) Consumer self-service operations, such as buffets and salad bars, shall be monitored by food employees trained in safe operating procedures.

(d) For purposes of this section, a violation of subsection (a) is a critical item.

(e) For purposes of this section, a violation of subsection (b) or (c) is a noncritical item.

COOKING FOOD

Sections 182 through 185

10 IAC 7-24-182 Cooking of raw animal foods

Sec. 182. (a) Except as specified under subsections (b) through (d), raw animal foods, such as eggs, fish, meat, poultry, and foods containing these raw animal foods, shall be cooked to heat all parts of the food to a temperature and for a time that complies with one (1) of the following methods based on the food that is being cooked:

- (1) One hundred forty-five (145) degrees Fahrenheit or above for fifteen (15) seconds for the following:
 - (A) Raw shell eggs that are broken and prepared in response to a consumer's order and for immediate service.
 - (B) Except as specified under subdivisions (2) and (3) and subsection (b), fish, meat, and game animal.
- (2) One hundred fifty-five (155) degrees Fahrenheit for fifteen (15) seconds or the temperature specified in the chart in subsection (b) that corresponds to the holding time for the following:

- (B) Raw eggs, such as eggs that are pooled, that are not prepared as specified under subdivision (1).
- (C) Comminuted meat, fish, or game animal.
- (3) One hundred sixty-five (165) degrees Fahrenheit or above for fifteen (15) seconds for the following:
 - (A) Poultry.
 - (B) Game animals.
 - (C) Stuffed:
 - (i) fish;
 - (ii) meat;
 - (iii) pasta; or
 - (iv) poultry.
 - (D) Stuffing containing fish, meat, or poultry.

(b) Whole beef roasts, corned beef roasts, pork roasts, and cured pork roasts, such as ham, shall be cooked as follows:

- (1) In an oven that is preheated to the temperature specified for the roast's weight in the chart in subdivision (3) and that is held at that temperature.
- (2) As specified in the chart in subdivision (3), to heat all parts of the food to a temperature and for the holding time that corresponds to that temperature.
- (3) The minimum cooking temperatures and holding times at a specified temperature are as follows:

MINIMUM COOKING TEMPERATURES AND HOLDING TIMES AT SPECIFIED TEMPERATURE			
165°F for 15 seconds	Poultry and foods containing poultry; stuffed meat, fish, or pasta; and stuffing containing fish or meat; foods containing game animals.		
165°F for 2 minutes	Microwave cooking for raw animal foods; covered, rotated, or stirred throughout or midway through the cooking process and held for 2 minutes covered.		
158°F for 1 second 155°F for 15 seconds 150°F for 1 minute or 145°F for 3 minutes	Injected meats; comminuted raw meat, fish, or game animal; and raw shell eggs that are not prepared for immediate service (pooled or hot held).		
145°F for 15 seconds	Raw shell eggs prepared for immediate service; meat, fish, and game animal not otherwise specified in this chart.		
158°F for 0 seconds 157°F for 14 seconds 155°F for 22 seconds 151°F for 34 seconds 151°F for 54 seconds 149°F for 85 seconds 147°F for 134 seconds 145°F for 4 minutes 144°F for 5 minutes 142°F for 8 minutes 140°F for 12 minutes 138°F for 18 minutes 136°F for 28 minutes 135°F for 36 minutes 133°F for 56 minutes 131°F for 89 minutes or 130°F for 112 minutes	Roasts of beef, corned beef, pork, and cured pork: Note – holding time may include post-cooking heat rise.		
	<u>Oven Type</u>	<u>Roast Weight Less than 10 lbs.</u>	<u>Roast Weight More than 10 lbs.</u>
	Still Dry	Oven temperature ≥ 350°F	Oven temperature ≥ 250°F
	Convection	Oven temperature ≥ 325°F	Oven temperature ≥ 250°F
	High Humidity ⁽¹⁾	Oven temperature ≤ 250°F	Oven temperature ≤ 250°F
135°F	Potentially hazardous food cooked for hot holding; fruits, vegetables, and potentially hazardous foods not otherwise listed that will be hot held.		

⁽¹⁾ Relative humidity greater than ninety (90) percent for at least 1 hour as measured in the cooking chamber or exit of the oven or in a moisture-impermeable bag that provides one hundred (100) percent humidity.

(c) A raw or undercooked whole-muscle, intact beef steak may be served or offered for sale in a ready-to-eat form if the:

- (1) food establishment serves a population that is not a highly susceptible population;
- (2) steak is labeled to indicate that it meets the definition of whole-muscle, intact beef as specified under

(3) steak is cooked on both the top and bottom to a surface temperature of one hundred forty-five (145) degrees Fahrenheit or above and a cooked color change is achieved on all external surfaces.

(d) A raw animal food, such as:

- (1) raw egg;
- (2) raw fish;
- (3) raw-marinated fish;
- (4) raw molluscan shellfish; or
- (5) steak tartare;

or a partially cooked food, such as lightly cooked fish, soft cooked eggs, or rare meat other than whole-muscle, intact beef steaks as specified in subsection (c), may be served or offered for sale in a ready-to-eat form if the retail food establishment serves a population that is not a highly susceptible population and the consumer is informed as specified under section 196 of this rule that to ensure its safety, the food should be cooked as specified under subsection (a) or (b).

(e) For purposes of this section, a violation of subsection (a), (b), (c), or (d) is a critical item.

10 IAC 7-24-183 Microwave cooking

Sec. 183. (a) Raw animal foods cooked in a microwave oven shall be:

- (1) rotated or stirred throughout or midway during cooking to compensate for uneven distribution of heat;
 - (2) covered to retain surface moisture;
 - (3) heated to a temperature of at least one hundred sixty-five (165) degrees Fahrenheit in all parts of the food; and
 - (4) allowed to stand covered for two (2) minutes after cooking to obtain temperature equilibrium.
- (b) For purposes of this section, a violation of subsection (a) is a critical item.

10 IAC 7-24-184 Microwave ovens

Sec. 184. (a) Microwave ovens shall meet the safety standards specified in 21 CFR 1030.10.

(b) For purposes of this section, a violation of subsection (a) is a noncritical item.

10 IAC 7-24-185 Preparation for immediate service

Sec. 185. (a) Cooked and refrigerated food that is prepared for immediate service in response to an individual consumer order, such as a roast beef sandwich au jus, may be served at any temperature.

(b) For purposes of this section, a violation of subsection (a) is a noncritical item.

HOLDING TEMPERATURES

Sections 186 through 187

10 IAC 7-24-186 Cooking for hot holding

Sec. 186. (a) Fruits, vegetables, and any potentially hazardous foods not covered under sections 182 and 183 of this rule that are cooked for hot holding shall be cooked to an internal temperature of one hundred thirty-five (135) degrees Fahrenheit.

(b) For purposes of this section, a violation of subsection (a) is a noncritical item.

10 IAC 7-24-187 Potentially hazardous food; hot and cold holding

Sec. 187. (a) Except during preparation, cooking, or cooling, or when time is used as the public health control as specified under section 193 of this rule, potentially hazardous food shall be maintained as follows:

- (1) At one hundred thirty-five (135) degrees Fahrenheit or above, except that roasts cooked to a temperature and for a time specified under section 182(b) of this rule or reheated as specified in section 182(c) of this rule may be held at a temperature of one hundred thirty (130) degrees Fahrenheit.

(A) At forty-one (41) degrees Fahrenheit or less.

(B) At forty-five (45) degrees Fahrenheit or between forty-five (45) degrees Fahrenheit and forty-one (41) degrees Fahrenheit in existing refrigeration equipment that is not capable of maintaining the food at forty-one (41) degrees Fahrenheit or less if:

(i) the equipment is in place and in use in the retail food establishment; and

(ii) by April 29, 2010, the equipment is upgraded or replaced to maintain food at a temperature of forty-one (41) degrees Fahrenheit or less.

) For purposes of this section, a violation of subsection (a) is a critical item.

REHEATING OF FOOD

Section 188

10 IAC 7-24-188 Reheating for hot holding

Sec. 188. (a) Except as specified under subsections (b), (c), and (e), potentially hazardous food that is cooked, cooled, and reheated for hot holding shall be reheated so that all parts of the food reach a temperature of at least one hundred sixty-five (165) degrees Fahrenheit for fifteen (15) seconds.

(b) Except as specified under subsection (c), potentially hazardous food reheated in a microwave oven for hot holding shall be reheated so that all parts of the food reach a temperature of at least one hundred sixty-five (165) degrees Fahrenheit and the food is rotated or stirred, covered, and allowed to stand covered for two (2) minutes after reheating.

(c) Ready-to-eat food taken from:

(1) a commercially processed, hermetically sealed container; or

(2) an intact package from a food processing plant that is inspected by the food regulatory authority that has jurisdiction over the plant;

shall be heated to a temperature of at least one hundred thirty-five (135) degrees Fahrenheit for hot holding.

(d) Reheating for hot holding shall be done rapidly, and the time the food is between the temperature specified under section 187(a)(2) of this rule and one hundred sixty-five (165) degrees Fahrenheit may not exceed two (2) hours.

(e) Remaining unsliced portions of roasts of beef that are cooked as specified under section 182(b) of this rule may be reheated for hot holding using the oven parameters and minimum time and temperature conditions specified under section 182(b) of this rule.

(f) For purposes of this section, a violation of subsection (a), (b), (c), (d), or (e) is a critical item.

COOLING FOOD

Sections 189 through 190

10 IAC 7-24-189 Potentially hazardous food; cooling

Sec. 189. (a) Cooked potentially hazardous food shall be cooled as follows:

(1) Within two (2) hours, from one hundred thirty-five (135) degrees Fahrenheit to seventy (70) degrees Fahrenheit.

(2) Within four (4) hours, from seventy (70) degrees Fahrenheit to forty-one (41) degrees Fahrenheit or less, or to forty-five (45) degrees Fahrenheit as specified under section 187(a)(2) of this rule.

(3) The entire cooling process must be completed within six (6) continuous hours.

(b) Potentially hazardous food shall be cooled within four (4) hours to forty-one (41) degrees Fahrenheit or less, or to forty-five (45) degrees Fahrenheit as specified under section 187(a)(2) of this rule if prepared from ingredients at ambient temperature, such as reconstituted foods and canned tuna.

(c) Except as specified in subsection (d), a potentially hazardous food received in compliance with laws allowing a temperature above forty-one (41) degrees Fahrenheit during shipment from the supplier as specified in section 166(b) of this rule, shall be cooled within four (4) hours to forty-one (41) degrees Fahrenheit or less, or forty-five (45) degrees Fahrenheit or less as specified under section 187(a)(2) of this rule.

(d) Shell eggs need not comply with subsection (c) if the eggs are placed immediately upon their receipt in refrigerated equipment that is capable of maintaining food at forty-one (41) degrees Fahrenheit or less, or forty-five (45) degrees Fahrenheit or less as specified under section 187(a)(2) of this rule.

10 IAC 7-24-195 Reduced oxygen packaging; criteria

Sec. 195. (a) Except for a food establishment that obtains a variance as specified under section 114 of this rule, a retail food establishment that packages food using a reduced oxygen packaging method and *Clostridium botulinum* is identified as a microbiological hazard in the final packaged form shall ensure that there are at least two (2) barriers in place to control the growth and toxin formation of *Clostridium botulinum*.

(b) A food establishment that packages food using a reduced oxygen packaging method and *Clostridium botulinum* is identified as a microbiological hazard in the final packaged form shall have a HACCP plan that contains the information specified under section 115(a)(4) of this rule and that does the following:

- (1) Identifies the food to be packaged.
 - (2) Limits the food packaged to a food that does not support the growth of *Clostridium botulinum* because it complies with one (1) or more of the following:
 - (A) Has an a_w of 0.91 or less.
 - (B) Has a pH of 4.6 or less.
 - (C) Is a meat or poultry product cured at a food processing plant regulated by the United States Department of Agriculture using substances specified in 9 CFR 424.21 and is received in an intact package.
 - (D) Is a food with a high level of competing organisms such as raw meat or raw poultry.
 - (3) Specifies methods for maintaining food at forty-one (41) degrees Fahrenheit or below.
 - (4) Describes how the packages shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background with instructions to:
 - (A) maintain the food at forty-one (41) degrees Fahrenheit or below; and
 - (B) discard the food if within fourteen (14) calendar days of its packaging, it is not served for on-premises consumption, consumed if served, or sold for off-premises consumption.
 - (5) Limits the refrigerated shelf life to not more than fourteen (14) calendar days from packaging to consumption, except the time the product is maintained frozen, or the original manufacturer's "sell by" or "use by" date, whichever occurs first.
 - (6) Includes operational procedures that:
 - (A) prohibit contacting food with bare hands;
 - (B) identify a designated area and the method by which:
 - (i) physical barriers or methods of separation of raw foods and ready-to-eat foods minimize cross-contamination; and
 - (ii) access to the processing equipment is limited to responsible, trained personnel familiar with the potential hazards of the operation; and
 - (C) delineate cleaning and sanitization procedures for food-contact surfaces.
 - (7) Describes the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the following:
 - (A) Concepts required for a safe operation.
 - (B) Equipment and facilities.
 - (C) Procedures specified under subdivision (6) and section 115(a)(4) of this rule.
- (c) Except for fish that is frozen before, during, and after packaging, a food establishment may not package fish using a reduced oxygen packaging method.
- (d) For purposes of this section, a violation of subsection (a), (b), or (c) is a critical item.

10 IAC 7-24-196 Consumption of raw or undercooked foods of animal origin

Sec. 196. (a) Except as specified in sections 182(c), 182(d)(3), and 153 of this rule, if an animal food such as:

- (1) beef;
- (2) eggs;
- (3) fish;

Food Code

2005 Recommendations of the
United States Public Health Service
Food and Drug Administration



The Food Code is a model for safeguarding public health and ensuring food is unadulterated and honestly presented when offered to the consumer. It represents FDA's best advice for a uniform system of provisions that address the safety and protection of food offered at retail and in food service.

This model is offered for adoption by local, state, and federal governmental jurisdictions for administration by the various departments, agencies, bureaus, divisions, and other units within each jurisdiction that have been delegated compliance responsibilities for food service, retail food stores, or food vending operations. Alternatives that offer an equivalent level of public health protection to ensure that food at retail and foodservice is safe are recognized in this model.

This guidance represents FDA's current thinking on safeguarding public health and ensuring food is unadulterated and honestly presented when offered to the consumer. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. This guidance is being issued in accordance with FDA's Good Guidance Practices regulation (21 CFR 10.115; 65 FR 56468; September 19, 2000).

3-5 LIMITATION OF GROWTH OF ORGANISMS OF POTENTIAL PUBLIC HEALTH CONCERN

Subparts

3-501 Temperature and Time Control
3-502 Specialized Processing Methods

Temperature and Time Control

3-501.11 Frozen Food.

Stored frozen FOODS shall be maintained frozen.

3-501.12 Potentially Hazardous Food (Time/Temperature Control for Safety Food), Slacking.

FROZEN POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) that is slacked to moderate the temperature shall be held:

(A) Under refrigeration that maintains the FOOD temperature 5°C (41°F), or less, or at 7°C (45°F) or less as specified under Subparagraph 3-501.16(A)(2); or

(B) At any temperature if the FOOD remains frozen.

3-501.13 Thawing.

Except as specified in ¶ (D) of this section, POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) shall be thawed:

(A) Under refrigeration that maintains the FOOD temperature 5°C (41°F) or less, or at 7°C (45°F) or less as specified under Subparagraph 3-501.16(A)(2); or

(B) Completely submerged under running water.

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

(2) With sufficient water velocity to agitate and float off loose particles in an overflow, and

(3) For a period of time that does not allow thawed portions of READY-TO-EAT FOOD to rise above 5°C (41°F) or 7°C (45°F) as specified under Subparagraph 3-501.16(A)(2), or

(4) For a period of time that does not allow thawed portions of a raw animal FOOD requiring cooking as specified under ¶ 3-401.11(A) or (B) to be above 5°C (41°F), or 7°C (45°F) as specified under Subparagraph 3-501.16(A)(2), for more than 4 hours including:

(a) The time the FOOD is exposed to the running water and the time needed for preparation for cooking, or

(b) The time it takes under refrigeration to lower the FOOD temperature to 5°C (41°F), or 7°C (45°F) as specified under Subparagraph 3-501.16(A)(2);

(C) As part of a cooking process if the FOOD that is frozen is:

(1) Cooked as specified under ¶ 3-401.11(A) or (B) or § 3-401.12, or

(2) Thawed in a microwave oven and immediately transferred to conventional cooking EQUIPMENT, with no interruption in the process; or

(D) Using any procedure if a portion of frozen READY-TO-EAT FOOD is thawed and prepared for immediate service in response to an individual CONSUMER'S order.

3-501.14 Cooling.*

(A) COOKED POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) shall be cooled:

(1) Within 2 hours from: 57°C (135°F) to 21°C (70°F); and

(2) Within a total of 6 hours from 57°C (135°F) to 5°C (41°F) or less, or to 7°C (45°F) or less as specified under Subparagraph 3-501.16(A)(2)(b).

(B) POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) shall be cooled within 4 hours to 5°C (41°F) or

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less, or to 7°C (45°F) as specified under Subparagraph 3-501.16(A)(2)(b) if prepared from ingredients at ambient temperature, such as reconstituted FOODS such as canned tuna.

(C) Except as specified under ¶ (D) of this section, a POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) received in compliance with LAWS allowing a temperature above 5°C (41°F) during shipment from the supplier as specified in ¶ 3-202.11(B), shall be cooled within 4 hours to 5°C (41°F) or less, or 7°C (45°F) or less as specified under Subparagraph 3-501.16(A)(2)(b).

(D) Raw EGGS shall be received as specified under ¶ 3-202.11(C) and immediately placed in refrigerated EQUIPMENT that maintains an ambient air temperature of 7°C (45°F) or less.

3-501.15 Cooling Methods.

(A) Cooling shall be accomplished in accordance with the time and temperature criteria specified under § 3-501.14 by using one or more of the following methods based on the type of FOOD being cooled:

(1) Placing the FOOD in shallow pans;

(2) Separating the FOOD into smaller or thinner portions;

(3) Using rapid cooling EQUIPMENT;

(4) Stirring the FOOD in a container placed in an ice water bath

(5) Using containers that facilitate heat transfer;

(6) Adding ice as an ingredient or

(7) Other effective methods.

(B) When placed in cooling or cold holding EQUIPMENT, FOOD containers in which FOOD is being cooled shall be:

(1) Arranged in the EQUIPMENT to provide maximum heat transfer through the container walls; and

(2) Loosely covered, or uncovered if protected from overheating contamination as specified under Subparagraph

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3-501.17 Ready-to-Eat, Potentially Hazardous Food (Time/Temperature Control for Safety Food), Date Marking.

on-premises preparation
• prepare and hold cold

3-501.16 Potentially Hazardous Food (Time/Temperature Control for Safety Food), Hot and Cold Holding.

(A) Except during preparation, cooking, or cooling, or when time is used as the public health control as specified under § 3-507.19, and except as specified under ¶ (B) of this section, POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) shall be maintained:

(1) At 57°C (135°F) or above, except that roasts cooked to a temperature and for a time specified in ¶ 3-401.11(B) or reheated as specified in ¶ 3-403.11(E) may be held at a temperature of 54°C (130°F) or above; or

(2) At a temperature specified in the following:

(a) 5°C (41°F) or less; or

(b) 7°C (45°F) or between 5°C (41°F) and 7°C (45°F) in existing refrigeration equipment that is not capable of maintaining the food at 5°C (41°F) or less if:

(i) The EQUIPMENT is in place and in use in the FOOD ESTABLISHMENT, and

(ii) Within 5 years of the REGULATORY AUTHORITY'S adoption of this Code, the EQUIPMENT is upgraded or replaced to maintain FOOD at a temperature of 5°C (41°F) or less.

(B) EGGS that have not been treated to destroy all viable Salmonellae shall be stored in refrigerated EQUIPMENT that maintains an ambient air temperature of 7°C (45°F) or less.

3-501.17

(A) Except when PACKAGING FOOD using a REDUCED OXYGEN PACKAGING method as specified under § 3-502.12, and except as specified in ¶ (D) and (E) of this section, refrigerated, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) prepared and held in a FOOD ESTABLISHMENT for more than 24 hours shall be clearly marked to indicate the date day by which the FOOD shall be consumed on the PREMISES, sold or discarded, based on the temperature and time combinations specified below. The day of preparation shall be counted as Day 1.

(1) 5°C (41°F) or less for a maximum of 7 days; or

(2) 7°C (45°F) or between 5°C (41°F) and 7°C (45°F) for a maximum of 4 days in existing refrigeration EQUIPMENT that is not capable of maintaining the FOOD at 5°C (41°F) or less if:

(a) The EQUIPMENT is in place and in use in the FOOD ESTABLISHMENT, and

(b) Within 5 years of the REGULATORY AUTHORITY'S adoption of this Code, the EQUIPMENT is upgraded or replaced to maintain FOOD at a temperature of 5°C (41°F) or less.

commercially processed food
• open and hold cold

(B) Except as specified in ¶ (D) - (F) of this section, refrigerated READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) prepared and packaged by a FOOD PROCESSING PLANT shall be clearly marked, at the time the original container is opened in a FOOD ESTABLISHMENT and if the FOOD is held for more than 24 hours, to indicate the date or day by which the FOOD shall be consumed on the PREMISES, sold, or discarded based on the temperature and time combinations specified in ¶ (A) of this section and:

(1) The day the original container is opened in the FOOD ESTABLISHMENT shall be counted as Day 1; and

(2) The day or date marked by the FOOD ESTABLISHMENT may not exceed a manufacturer's use-by date if the manufacturer determined the use-by date based on FOOD safety.

(TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) ingredient portion of a refrigerated, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) that is subsequently combined with additional ingredients or portions of FOOD shall retain the date marking of the earliest-prepared or first-prepared ingredient.

(D) A date marking system that meets the criteria stated in ¶¶ (A) and (B) of this section may include:

(1) Using a method APPROVED by the REGULATORY AUTHORITY for refrigerated, READY-TO-EAT POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) that is frequently rewrapped, such as luncheon meat or a roast, or for which date marking is impractical, such as soft serve mix or milk in a dispensing machine;

(2) Marking the date or day of preparation, with a procedure to discard the FOOD or on before the last date or day by which the FOOD must be consumed on the premises, sold, or discarded as specified under ¶ (A) of this section;

(3) Marking the date or day the original container is opened in a FOOD ESTABLISHMENT, with a procedure to discard the FOOD on or before the last date or day by which the FOOD must be consumed on the premises, sold, or discarded as specified under ¶ (B) of this section; or

(4) Using calendar dates, days of the week, color-coded marks, or other effective marking methods, provided that the marking system is disclosed to the REGULATORY AUTHORITY upon request.

(E) Paragraphs (A) and (B) of this section do not apply to individual meal portions served or REPACKAGED for sale from a bulk container upon a consumer's request.

(F) Paragraph (B) of this section does not apply to the following FOODS prepared and PACKAGED by a FOOD PROCESSING PLANT inspected by a REGULATORY AUTHORITY:

salad, egg salad, pasta salad, potato salad, and macaroni salad, manufactured in accordance with CFR 110 Current good manufacturing practice in manufacturing, packing, or holding human food;

(2) Hard cheeses containing not more than 39% moisture as defined in 21 CFR 133 Cheeses and related cheese products such as cheddar, gruyere, parmesan and reggiano, and romano;

(3) Semi-soft cheeses containing more than 39% moisture, but not more than 50% moisture, as defined in 21 CFR 133 Cheeses and related cheese products, such as blue, edam, gorgonzola, gouda, and monterey jack;

(4) Cultured dairy products as defined in 21 CFR 131 Milk and cream, such as yogurt, sour cream, and buttermilk;

(5) Preserved FISH products, such as pickled herring and die or salted cod, and other acidified FISH products defined in 21 CFR 114 Acidified foods;

(6) Shelf stable, dry fermented sausages, such as pepperoni and Genoa salami that are not labeled "Keep Refrigerated" as specified in 9 CFR 317 Labeling, marking devices, and containers, and which retain the original CASING on the product; and

(7) Shelf stable salt-cured products such as prosciutto and Parma (ham) that are not labeled "Keep Refrigerated" as specified in 9 CFR 317 Labeling, marking devices, and containers.

3-501.18 Ready-to-Eat, Potentially Hazardous Food (Time/Temperature Control for Safety Food), Disposition.*

(A) A FOOD specified in ¶ 3-501.17(A) or (B) shall be discarded if it:

(1) Exceeds either of the temperature and time combinations specified in ¶ 3-501.17(A), except time that the product is frozen;

botulinum and Listeria monocytogenes Controls

(D) A FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION may not use time as specified under ¶¶ (A), (B) or (C) of this section as the public health control for raw EGGS.

Specialized Processing Methods

3-502.11 Variance Requirement.*

A FOOD ESTABLISHMENT shall obtain a VARIANCE from the REGULATORY AUTHORITY as specified in § 8-103.10 and under § 8-103.11 before:

- (A) Smoking FOOD as a method of FOOD preservation rather than as a method of flavor enhancement;
- (B) Curing FOOD;
- (C) Using FOOD ADDITIVES or adding components such as vinegar;
 - (1) As a method of FOOD preservation rather than as a method of flavor enhancement; or
 - (2) To render a FOOD so that it is not POTENTIALLY HAZARDOUS (TIME/TEMPERATURE CONTROL OF SAFETY FOOD);
- (D) Packaging FOOD using a REDUCED OXYGEN PACKAGING method except as specified under § 3-502.12 where a barrier to *Clostridium botulinum* in addition to refrigeration exists;
- (E) Operating a MOLLUSCAN SHELLFISH life-support system display tank used to store and display shellfish that are offered for human consumption;
- (F) Custom processing animals that are for personal use as FOOD and not for sale or service in a FOOD ESTABLISHMENT;
- (G) Preparing FOOD by another method that is determined by the REGULATORY AUTHORITY to require a VARIANCE; or
- (H) Sprouting seeds or beans.

(A) Except for a FOOD ESTABLISHMENT that obtains a VARIANCE as specified under § 3-502.11 and except as specified under ¶¶ (C) and (E) and as specified in ¶ (D) of this section, a FOOD ESTABLISHMENT that PACKAGES POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) using a REDUCED OXYGEN PACKAGING method shall ensure that there are at least barriers in place to control the growth and toxin formation of *Clostridium botulinum* and the growth of *Listeria monocytogenes*.

(B) A FOOD ESTABLISHMENT that PACKAGES POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) using a REDUCED OXYGEN PACKAGING method shall have a HACCP PLAN that contains the information specified under § 8-201.14(D) and that:

- (1) Identifies the FOOD to be PACKAGED;
- (2) Except as specified under ¶¶ (C) and (E) and as specified in ¶ (D) of this section, requires that the PACKAGED FOOD shall be maintained at 5°C (41°F) or less and meat at least one of the following criteria:
 - (a) Has an A_w of 0.91 or less;
 - (b) Has a PH of 4.6 or less;
 - (c) Is a MEAT or POULTRY product cured at a FOOD PROCESSING PLANT regulated by the USDA using substances specified in 9 CFR 424.21, Use of food ingredients and sources of radiation, and is received in an intact PACKAGE, or
 - (d) Is a FOOD with a high level of competing organisms such as raw MEAT or raw POULTRY;
- (3) Describes how the PACKAGE shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to:
 - (a) Maintain the FOOD at 5°C (41°F) or below; and
 - (b) Discard the FOOD if within 14 calendar days of its PACKAGING it is not served for on-PREMISES consumption;

(2) is in a container or package that does not bear a date or day; or

(3) is appropriately marked with a date or day that exceeds a temperature and time combination as specified in § 3-501.17(A).

(B) Refrigerated, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) prepared in a FOOD ESTABLISHMENT and dispensed through a VENDING MACHINE with an automatic shutoff control shall be discarded if it exceeds a temperature and time combination as specified in § 3-501.17(A).

3-501.18 Time as a Public Health Control.*

(A) Except as specified under ¶ (D) of this section, if time only is used as the public health control for a working supply of POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) before cooking, or for READY-TO-EAT POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) that is displayed or held for service for immediate consumption:

(1) Written procedures shall be prepared in advance, maintained in the FOOD ESTABLISHMENT and made available to the REGULATORY AUTHORITY upon request that specify:

(a) Methods of compliance with Subparagraphs (B)(1)-(3) or (C)(1)-(5) of this section; and

(b) Methods of compliance with § 3-501.14 for FOOD that is prepared, cooked, and refrigerated before time is used as a public health control.

(B) If time only, rather than time in conjunction with temperature control, up to a maximum of 4 hours, is used as the public health control:

(1) The FOOD shall have an initial temperature of 5°C (41°F) or less if removed from cold holding temperature control, or 57°C (135°F) or greater if removed from hot holding temperature control;

(2) The FOOD shall be marked or otherwise identified to indicate the time that is 4 hours past the point in time when the FOOD is removed from temperature control;

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(3) The FOOD shall be cooked and served if READY-TO-EAT, or discarded, within 4 hours from the point in time when the FOOD is removed from temperature control; and

(4) The FOOD in unmarked containers or PACKAGES, or marked to exceed a 4-hour limit shall be discarded.

(C) If time only, rather than time in conjunction with temperature control, up to a maximum of 6 hours, is used as the public health control:

Time -
maximum up to
6 hours

(1) The FOOD shall have an initial temperature of 5°C (41°F) or less when removed from temperature control and the FOOD temperature may not exceed 21°C (70°F) within a maximum time period of 6 hours;

(2) The FOOD shall be monitored to ensure the warmest portion of the FOOD does not exceed 21°C (70°F) during the 6-hour period, unless an ambient air temperature is maintained that ensures the FOOD does not exceed 21°C (70°F) during the 6-hour holding period;

(3) The FOOD shall be marked or otherwise identified to indicate:

(a) The time when the FOOD is removed from 5°C (41°F) or less cold holding temperature control; and

(b) The time that is 6 hours past the point in time when the FOOD is removed from cold holding temperature control;

(4) The FOOD shall be:

(a) Discarded if the temperature of the FOOD exceeds 21°C (70°F); or

(b) Cooked and served, served if READY-TO-EAT, or discarded within a maximum of 6 hours from the point in time when the FOOD is removed from 5°C (41°F) or less cold holding temperature control; and

(5) The FOOD in unmarked containers or PACKAGES, or marked with a time that exceeds the 6-hour limit shall be discarded.

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of consumed if served or sold for off-premise consumption.

(4) Limits the refrigerated shelf life to no more than 14 calendar days from PACKAGING to consumption, except the time the product is maintained frozen, or the original manufacturer's "sell by" or "use by" date, whichever occurs first;

(5) Includes operational procedures that:

(a) Prohibit contacting FOOD with bare hands,

(b) Identify a designated work area and the method by which:

(i) Physical barriers or methods of separation of raw FOODS and READY-TO-EAT FOODS minimize cross contamination, and

(ii) Access to the processing EQUIPMENT is limited to responsible trained personnel familiar with the potential HAZARDS of the operation, and

(c) Delineate cleaning and SANITIZATION procedures for FOOD-CONTACT SURFACES; and

(6) Describes the training program that ensures that the individual responsible for the REDUCED OXYGEN PACKAGING operation understands the:

(a) Concepts required for a safe operation,

(b) EQUIPMENT and facilities, and

(c) Procedures specified under Subparagraph (B)(5) of this section and ¶ 8-201.14(D).

Fish

(C) Except for FISH that is frozen before, during, and after PACKAGING, a FOOD ESTABLISHMENT may not PACKAGE FISH using a REDUCED OXYGEN PACKAGING method.

(D) Except as specified under ¶ (C) of this section, a FOOD ESTABLISHMENT may package FOOD using a cook-chill or sous vide process without obtaining a VARIANCE if:

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(1) The FOOD ESTABLISHMENT implement ACCP PLAN that contains the information as specified in § 8-201.14(D);

(2) The FOOD is:

(a) Prepared and consumed on the PREMISES, or prepared and consumed off the PREMISES but within the same business entity with no distribution or sale of the bagged product to another business entity or the CONSUMER;

(b) Cooked to heat all parts of the FOOD to a temperature and for a time as specified under § 3-401.11,

(c) Protected from contamination after cooking as specified under Part 3-3,

(d) Placed in a package or bag with an oxygen barrier before cooking, or placed in a PACKAGE or bag immediately after cooking and before reaching a temperature below 57°C (135°F),

(e) Except for frozen FOOD that is not shelf life restricted, cooled to 5°C (41°F) in the PACKAGE or bag as specified under § 3-501.14 and then cooked to 1°C (34°F) or less within 48 hours of reaching 5°C (41°F), and:

(i) Held at 1°C (34°F) and consumed or discarded within 30 days after the date of preparation, or

(ii) If removed from a storage unit that maintains a 1°C (34°F) FOOD temperature, held at 5°C (41°F) or less for no more than 72 hours before consumption.

(f) Held in a refrigeration unit that is equipped with an electronic system that continuously monitors time and temperature and is visually examined for proper operation twice daily.

(g) If transported off-site to a satellite location of the same business entity, equipped with verifiable electronic monitoring devices to ensure that times and temperatures are monitored during transportation, and

(h) Labeled with the product name and the date PACKAGE and

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holding refrigeration time/temperature parameters required as part of the HACCP PLAN, are main. J and are:

(a) Made available to the REGULATORY AUTHORITY upon request, and

(b) Held for 6 months; and

(4) Written operational procedures as specified under Subparagraph (B)(5) of this section and a training program as specified under Subparagraph (B)(6) of this section are implemented.

Cheese

(E) A FOOD ESTABLISHMENT may PACKAGE cheese using a REDUCED OXYGEN PACKAGING method without obtaining a VARIANCE if it:

(1) Limits the cheeses PACKAGED to those that are commercially manufactured in a FOOD PROCESSING PLANT with no ingredients added in the FOOD ESTABLISHMENT and that meet the Standards of Identity as specified in 21 CFR 133.150 Hard cheeses, 21 CFR 133.169 Pasteurized process cheese or 21 CFR 133.187 Semisoft cheeses;

(2) Has a HACCP PLAN that contains the information specified under ¶ 8-201.14(D);

(3) Except as specified under Subparagraphs (B)(2), (B)(3)(b), and (B)(4), complies with ¶ (B) of this section;

(4) Labels the PACKAGE on the principal display panel with a "use by" date that does not exceed 30 days or the original manufacturer's "sell by" or "use by" date, whichever occurs first; and

(5) Discards the REDUCED OXYGEN PACKAGED cheese if it is not sold for off-PREMISES consumption or consumed within 30 calendar days of its PACKAGING.

FDA Recommended Pasteurization Time/Temperatures

For apple juice at pH values of 4.0 or less, FDA recommends the following thermal processes to achieve a 5-log reduction for oocysts of *Cryptosporidium parvum*. Because this parasite is believed to be more heat resistant than *E. coli* O157:H7, these parameters will also control bacterial pathogens.

160 degrees F for at least 6 seconds
165 degrees F for at least 2.8 seconds,
170 degrees F for at least 1.3 seconds,
175 degrees F for at least 0.6 seconds, or
180 degrees F for at least 0.3 seconds

71.7 degrees C (161 degrees F) for 15 seconds (milk pasteurization) is also considered adequate.

Remember to set your Operational Limit higher to assure you meet your Critical Limit!

The complete section on validation of pasteurization treatments for juice is excerpted below from the Juice Hazards Guide <http://www.cfsan.fda.gov/%7Edms/juicgu10.html>

5.2 Validated Pasteurization Treatments for Juice

At this time there are some published studies on pasteurization processes for controlling pathogens in juice that we can comment on to assist you in developing your HACCP plan.

Study #1 Summary: A study done by the NFPA(7) has resulted in a recommended general thermal process of 3 seconds at 71.1 degrees C (160 degrees F), for achieving a 5-log reduction for *E. coli* O157:H7, *Salmonella*, and *Listeria monocytogenes* in fruit juices. The efficacy of this process was measured using single strength apple, orange, and white grape juices adjusted to a pH of 3.9. The authors noted that a pH in the range of 3.6 to 4.0 has been reported as a non-significant variable in the heat resistance of *E. coli* O157:H7. The authors also noted that the heat resistance of these vegetative bacterial pathogens might be considerably greater at pH values of 4.0 and higher. This process assumes that the pathogens will have increased thermal resistance due to their being acid-adapted.

Study #2 Summary: A study done at the University of Wisconsin(8) has shown that treatments of 68.1 degrees C (155 degrees F) for 14 seconds (recommended treatment conditions in Wisconsin) and 71.1 degrees C (160 degrees F) for 6 seconds (recommended treatment conditions in New York) are capable of achieving a 5-log reduction of acid adapted *E. coli* O157:H7 in apple cider (pH values of 3.3 and 4.1). The Wisconsin study also confirmed the adequacy of the treatment conditions of the NFPA study (71.1 degrees C (160 degrees F) for 3 seconds) for achieving a 5-log reduction for *E. coli* O157:H7 in apple cider.

FDA Comments/Recommendations: We believe that the process recommended in the NFPA study is adequate to ensure a 5-log reduction of the three stated vegetative bacterial pathogens, (*E. coli* O157:H7,

Salmonella and Listeria monocytogenes) at juice pH values comparable to those in the study. However, other validation studies may be needed for juices that have pH values greater than 4.0. We also believe that either of the processes evaluated in the University of Wisconsin study is adequate to ensure a 5-log reduction of the three stated bacterial pathogens, (E. coli O157:H7, Salmonella, and Listeria monocytogenes) (at juice pH values comparable to those in the study) if any of these pathogens are the pertinent microorganism in your juice.

Neither of these two studies evaluated thermal processes for achieving a 5-log reduction for oocysts of the protozoan parasite Cryptosporidium parvum that has been a cause of illness outbreaks associated with the consumption of apple juice. In fact, the thermal destruction of Cryptosporidium parvum oocysts has not been as widely studied in the published literature as it has for the vegetative bacterial pathogens; however, the available scientific literature suggests that Cryptosporidium parvum(9) oocysts may be more resistant to thermal processing than the three vegetative bacterial pathogens. Therefore, we recommend that you consider Cryptosporidium parvum to be the pertinent microorganism when you are establishing a HACCP plan for apple juice.

For apple juice at pH values of 4.0 or less, we are recommending the following thermal processes to achieve a 5-log reduction for oocysts of Cryptosporidium parvum (in addition to the three aforementioned vegetative bacterial pathogens) based upon a conservative evaluation of the available scientific data;

160 degrees F for 6 seconds (recommended treatment conditions in New York),
165 degrees F for 2.8 seconds,
170 degrees F for 1.3 seconds,
175 degrees F for 0.6 seconds, or
180 degrees F for 0.3 seconds

Also, while it appears that Cryptosporidium parvum may be more resistant to thermal processing than the vegetative bacterial pathogens noted, in view of the limited data on the thermal destruction of Cryptosporidium parvum, processors may designate both E. coli O157:H7 and Cryptosporidium parvum as the pertinent microorganism in their HACCP plans for apple juice, and use one of the recommended thermal processes given above for the a 5-log reduction of Cryptosporidium parvum oocysts, until more definitive data become available on the relative resistance to thermal processing of these two pathogens.

We also believe that the process that is typically carried out for milk pasteurization, 71.7 degrees C (161 degrees F) for 15 seconds, is adequate to achieve a 5-log reduction of oocysts of Cryptosporidium parvum and the aforementioned three vegetative bacterial pathogens when this process is used for apple juice (at juice pH values of 4.0 or less).