

3717-1-03.4 **Food: limitation of growth of organisms of public health concern.**

[Comment: For publication dates of the C.F.R. referenced in this rule, see paragraph (B) (15)(b) of rule 3717-1-01 of the Administrative Code.]

(A) Frozen food - temperature and time control.

Stored frozen foods shall be maintained frozen.

(B) Time/temperature controlled for safety food - slacking.

Frozen time/temperature controlled for safety food that is slacked to moderate the temperature shall be held:

- (1) Under refrigeration that maintains the food temperature at forty-one degrees Fahrenheit (five degrees Celsius) or less; or
- (2) At any temperature if the food remains frozen.

(C) Thawing - temperature and time control.

Except as specified in paragraph (C)(4) of this rule, time/temperature controlled for safety food shall be thawed:

- (1) Under refrigeration that maintains the food temperature at forty-one degrees Fahrenheit (five degrees Celsius) or less; or
- (2) Completely submerged under running water:
 - (a) At a water temperature of seventy degrees Fahrenheit (twenty-one degrees Celsius) or below;
 - (b) With sufficient water velocity to agitate and float off loose particles in an overflow; and
 - (c) For a period of time that does not allow thawed portions of ready-to-eat food to rise above forty-one degrees Fahrenheit (five degrees Celsius); or
 - (d) For a period of time that does not allow thawed portions of a raw animal food requiring cooking as specified under paragraph (A)(1) or (A)(4) of rule 3717-1-03.3 of the Administrative Code to be above forty-one degrees Fahrenheit (five degrees Celsius), for more than four hours including:

- (i) The time the food is exposed to the running water and the time needed for preparation for cooking; or
 - (ii) The time it takes under refrigeration to lower the food temperature to forty-one degrees Fahrenheit (five degrees Celsius).
 - (3) As part of a cooking process if the food that is frozen is:
 - (a) Cooked as specified under paragraph (A)(1) or (A)(4) of rule 3717-1-03.3 of the Administrative Code or paragraph (B) of rule 3717-1-03.3 of the Administrative Code; or
 - (b) Thawed in a microwave oven and immediately transferred to conventional cooking equipment, with no interruption in the process; or
 - (4) 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.
 - (5) Reduced oxygen packaged fish that bears a label indicating that it is to be kept frozen until time of use shall be removed from the reduced oxygen environment:
 - (a) Prior to its thawing under refrigeration as specified in paragraph (C)(1) of this rule; or
 - (b) Prior to, or immediately upon completion of its thawing, using procedures specified in paragraph (C)(2) of this rule.
- (D) Cooling - temperature and time control.
- (1) Cooked time/temperature controlled for safety food shall be cooled:
 - (a) Within two hours from one hundred thirty-five degrees Fahrenheit (fifty-seven degrees Celsius) to seventy degrees Fahrenheit (twenty-one degrees Celsius); and
 - (b) Within a total of six hours from one hundred thirty-five degrees Fahrenheit (fifty-seven degrees Celsius) to forty-one degrees Fahrenheit (five degrees Celsius) or less.
 - (2) Time/temperature controlled for safety food shall be cooled within four hours to forty-one degrees Fahrenheit (five degrees Celsius) or less if prepared from ingredients at ambient temperature, such as reconstituted foods and canned tuna.

- (3) Except as specified under paragraph (D)(4) of this rule, a time/temperature controlled for safety food received in compliance with laws allowing a temperature above forty-one degrees Fahrenheit (five degrees Celsius) during shipment from the supplier as specified in paragraph (H)(1) of rule 3717-1-03.1 of the Administrative Code, shall be cooled within four hours to forty-one degrees Fahrenheit (five degrees Celsius) or less.
- (4) Raw eggs shall be received as specified under paragraph (H)(1) of rule 3717-1-03.1 of the Administrative Code and immediately placed in refrigerated equipment that maintains an ambient air temperature of forty-five degrees Fahrenheit (seven degrees Celsius) or less.

(E) Cooling methods - temperature and time control.

- (1) Cooling shall be accomplished in accordance with the time and temperature criteria specified under paragraph (D) of this rule by using one or more of the following methods based on the type of food being cooled:
 - (a) Placing the food in shallow pans;
 - (b) Separating the food into smaller or thinner portions;
 - (c) Using rapid cooling equipment;
 - (d) Stirring the food in a container placed in an ice water bath;
 - (e) Using containers that facilitate heat transfer;
 - (f) Adding ice as an ingredient; or
 - (g) Other effective methods.
- (2) When placed in cooling or cold holding equipment, food containers in which food is being cooled shall be:
 - (a) Arranged in the equipment to provide maximum heat transfer through the container walls; and
 - (b) Loosely covered, or uncovered if protected from overhead contamination as specified under paragraph (Q)(2) of rule 3717-1-03.2 of the Administrative Code, during the cooling period to facilitate heat transfer from the surface of the food.

(F) Time/temperature controlled for safety food - hot and cold holding.

- (1) Except during preparation, cooking, or cooling, or when time is used as the public health control as specified under paragraph (I) of this rule, and except as specified under paragraph (F)(2) and in paragraph (F)(3) of this rule, time/temperature controlled for safety food shall be maintained at a temperature specified as follows:
 - (a) At one hundred thirty-five degrees Fahrenheit (fifty-seven degrees Celsius) or above, except that roasts cooked to a temperature and for a time specified in paragraph (A)(4) of rule 3717-1-03.3 of the Administrative Code or reheated as specified in paragraph (H)(1) of rule 3717-1-03.3 of the Administrative Code may be held at a temperature of one hundred thirty degrees Fahrenheit (fifty-four degrees Celsius) or above; or
 - (b) At forty-one degrees Fahrenheit (five degrees Celsius) or less.
 - (2) Eggs that have not been treated to destroy all viable *Salmonellae* shall be stored in refrigerated equipment that maintains an ambient air temperature of forty-five degrees Fahrenheit (seven degrees Celsius) or less.
 - (3) Time/temperature controlled for safety food in a homogenous liquid form may be maintained outside of the temperature control requirements, as specified under paragraph (F)(1) of this rule, while contained within specially designed equipment that complies with the design and construction requirements as specified under paragraph (P)(5) of rule 3717-1-04.1 of the Administrative Code.
- (G) Ready-to-eat, time/temperature controlled for safety food - date marking.
- (1) Except when packaging food using a reduced oxygen packaging method as specified under paragraph (K) of this rule, and except as specified in paragraphs (G)(5) and (G)(6) of this rule, refrigerated, ready-to-eat, time/temperature controlled for safety food prepared and held in a food service operation or in a retail food establishment for more than twenty-four hours; shall be clearly marked to indicate the date or day by which the food shall be consumed on the premises, sold, or discarded when held at a temperature of forty-one degrees Fahrenheit (five degrees Celsius) or less for a maximum of seven days. The day of preparation shall be counted as day one.
 - (2) Except as specified in paragraphs (G)(5) to (G)(7) of this rule; refrigerated, ready-to-eat time/temperature controlled 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 service operation or retail food establishment and if the food is held for more than twenty-four 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 combination specified in paragraph (G)(1) of this rule and:

- (a) The day the original container is opened in the food service operation or retail food establishment shall be counted as day one; and
 - (b) The day or date marked by the food service operation or retail food establishment may not exceed a manufacturer's use-by date if the manufacturer determined the use-by date based on food safety.
- (3) A refrigerated, ready-to-eat, time/temperature controlled for safety food ingredient or a portion of a refrigerated, ready-to-eat, time/temperature controlled 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.
- (4) A date marking system that meets the criteria stated in paragraphs (G)(1) and (G)(2) of this rule may include:
- (a) Using a method approved by the licenser for refrigerated, ready-to-eat time/temperature controlled for safety food that is frequently rewrapped, such as lunchmeat or a roast, or for which date marking is impractical, such as soft serve mix or milk in a dispensing machine;
 - (b) Marking the date or day of preparation, 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 paragraph (G)(1) of this rule;
 - (c) Marking the date or day the original container is opened in a food service operation or retail 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 paragraph (G)(2) of this rule; or
 - (d) Using calendar dates, days of the week, color-coded marks, or other effective marking methods, provided that the marking system is disclosed to the licenser upon request.
- (5) Paragraphs (G)(1) and (G)(2) of this rule do not apply to individual meal portions served or repackaged for sale from a bulk container upon a consumer's request.
- (6) Paragraphs (G)(1) and (G)(2) of this rule do not apply to shellstock.

(7) Paragraph (G)(2) of this rule does not apply to the following foods prepared and packaged by a food processing plant under inspection:

- (a) Deli salads manufactured in accordance with 21 C.F.R. 110, such as ham salad, seafood salad, chicken salad, egg salad, pasta salad, potato salad, and macaroni salad;
- (b) Hard cheeses containing not more than thirty-nine per cent moisture as defined in 21 C.F.R. 133, such as cheddar, gruyere, parmesan and reggiano, and romano;
- (c) Semi-soft cheeses containing more than thirty-nine per cent moisture, but not more than fifty per cent moisture, as defined in 21 C.F.R. 133, such as blue, edam, gorgonzola, gouda, and monterey jack;
- (d) Cultured dairy products as defined in 21 C.F.R. 131, such as yogurt, sour cream, and buttermilk;
- (e) Preserved fish products, such as pickled herring and dried or salted cod, and other acidified fish products defined in 21 C.F.R. 114;
- (f) Shelf stable, dry fermented sausages, such as pepperoni and Genoa; and
- (g) Shelf stable salt-cured products such as prosciutto and Parma (ham).

(H) Ready-to-eat, time/temperature controlled for safety food - disposition.

- (1) A food specified under paragraph (G)(1) or (G)(2) of this rule shall be discarded if it:
 - (a) Exceeds the temperature or time specified in paragraph (G)(1) of this rule, except time that the product is frozen;
 - (b) Is in a container or package that does not bear a date or day; or
 - (c) Is appropriately marked with a date or day that exceeds the temperature and time combination as specified in paragraph (G)(1) of this rule.
- (2) Refrigerated, ready-to-eat, time/temperature controlled for safety food, dispensed through a vending machine with an automatic shut-off control, shall be discarded if the automatic shut-off control is activated as specified in paragraph (X)(2) of rule 3717-1-04.1 of the Administrative Code.

- (3) Refrigerated, ready-to-eat, time/temperature controlled for safety food, displayed at a micro market, shall be discarded if the automatic shutoff control is activated as specified in paragraph (LL)(1) of rule 3717-1-04.1 of the Administrative Code.

(I) Time as a public health control.

- (1) If time without temperature control is used as the public health control for a working supply of time/temperature controlled for safety food before cooking, or for ready-to-eat time/temperature controlled for safety food that is displayed or held for sale or service, written procedures shall be prepared in advance, maintained in the food service operation or retail food establishment and made available to the licensor upon request that specify:
 - (a) Methods of compliance with paragraphs (I)(2)(a) to (I)(2)(c), or paragraphs (I)(3)(a) to (I)(3)(e) of this rule; and
 - (b) Methods of compliance with paragraph (D) of this rule for food that is prepared, cooked, and refrigerated before time is used as a public health control.
- (2) If time without temperature control is used as the public health control up to a maximum of four hours:
 - (a) The food shall have an initial temperature of forty-one degrees Fahrenheit (five degrees Celsius) or less when removed from cold holding temperature control, or one hundred thirty-five degrees Fahrenheit (fifty-seven degrees Celsius) or greater when removed from hot holding temperature control;
 - (b) The food shall be marked or otherwise identified to indicate the time that is four hours past the point in time when the food is removed from temperature control;
 - (c) The food shall be cooked and served, served at any temperature if ready-to-eat, or discarded, within four hours from the point in time when the food is removed from temperature control; and
 - (d) The food in unmarked containers or packages, or marked to exceed a four-hour limit shall be discarded.
- (3) If time without temperature control is used as the public health control up to a maximum of six hours:

- (a) The food shall have an initial temperature of forty-one degrees Fahrenheit (five degrees Celsius) or less when removed from temperature control and the food temperature may not exceed seventy degrees Fahrenheit (twenty-one degrees Celsius) within a maximum time period of six hours;
 - (b) The food shall be monitored to ensure the warmest portion of the food does not exceed seventy degrees Fahrenheit (twenty-one degrees Celsius) during the six-hour period, unless an ambient air temperature is maintained that ensures the food does not exceed seventy degrees Fahrenheit (twenty-one degrees Celsius) during the six-hour holding period;
 - (c) The food shall be marked or otherwise identified to indicate:
 - (i) The time when the food is removed from forty-one degrees Fahrenheit (five degrees Celsius) or less cold holding temperature control; and
 - (ii) The time that is six hours past the point in time when the food is removed from cold holding temperature control.
 - (d) The food shall be:
 - (i) Discarded if the temperature of the food exceeds seventy degrees Fahrenheit (twenty-one degrees Celsius); or
 - (ii) Cooked and served, served at any temperature if ready-to-eat, or discarded within a maximum of six hours from the point in time when the food is removed from forty-one degrees Fahrenheit (five degrees Celsius) or less cold holding temperature control; and
 - (e) The food in unmarked containers or packages, or marked with a time that exceeds the six-hour limit shall be discarded.
- (4) A food service operation or a retail food establishment that serves a highly susceptible population, may not use time as specified under paragraph (I)(1), (I)(2) or (I)(3) of this rule as the public health control for raw eggs that are for service to a highly susceptible population.

(J) Variance requirement.

The license holder shall obtain a variance from the Ohio department of health if an operation is a food service operation, or from the Ohio department of agriculture if an operation is a retail food establishment before:

- (1) Smoking food as a method of food preservation rather than as a method of flavor enhancement;
 - (2) Curing food;
 - (3) Except as provided in rule 3717-1-08.4 of the Administrative Code, using food additives or adding components such as vinegar as a method of food preservation rather than as a method of flavor enhancement, or to render a food so that it is not a time/temperature controlled for safety food;
 - (4) Packaging time/temperature controlled for safety food using a reduced oxygen packaging method except where the growth of and toxin formation by *Clostridium botulinum* and the growth of *Listeria monocytogenes* are controlled as specified under paragraph (K) of this rule;
 - (5) Operating a molluscan shellfish life-support system display tank used to store or display shellfish that are offered for human consumption;
 - (6) Custom processing of animals that are for personal use as food and not for sale or service in a food service operation or retail food establishment if the processing is not done in compliance with rule 3717-1-08.2 of the Administrative Code;
 - (7) Pressing or bottling juice unless the processing is done in compliance with rule 3717-1-08 of the Administrative Code;
 - (8) Use of a heat treatment dispensing freezer in a manner other than as specified in rule 3717-1-08.1 of the Administrative Code;
 - (9) Preparing food by another method that is determined by the Ohio department of health or Ohio department of agriculture to require a variance; or
 - (10) Sprouting seeds or beans.
- (K) Reduced oxygen packaging without a variance, criteria.
- (1) Except for a food service operation or retail food establishment that obtains a variance as specified under paragraph (J) of this rule, a food service operation or retail food establishment that packages time/temperature controlled for safety food using a reduced oxygen packaging method shall control the growth and toxin formation of *Clostridium botulinum* and the growth of *Listeria monocytogenes*.
 - (2) Except as specified under paragraph (K)(6) of this rule a food service operation or retail food establishment that packages time/temperature controlled for safety

food using a reduced oxygen packaging method shall have a HACCP plan that contains the information specified under paragraph (L) of this rule and that:

- (a) Identifies the food to be packaged;
- (b) Except as specified under paragraphs (K)(3) to (K)(5) of this rule, requires that the packaged food shall be maintained at forty-one degrees Fahrenheit (five degrees Celsius) or less and meet at least one of the following criteria:
 - (i) Has an a_w of 0.91 or less;
 - (ii) Has a pH of 4.6 or less;
 - (iii) Is a meat or poultry product cured at a food processing plant regulated by the Ohio department of agriculture under Chapter 918. of the Revised Code or USDA using substances specified in 9 C.F.R. 424.21, and is received in an intact package; or
 - (iv) Is a food with a high level of competing organisms such as raw meat, raw poultry, or raw vegetables.
- (c) 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:
 - (i) Maintain the food at forty-one degrees Fahrenheit (five degrees Celsius) or below; and
 - (ii) Discard the food if within thirty calendar days of its packaging it is not served for on-premises consumption, or consumed if served or sold for off-premises consumption.
- (d) Limits the refrigerated shelf life to no more than thirty 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;
- (e) Includes operational procedures that:
 - (i) Prohibit contacting ready-to-eat food with bare hands as specified under paragraph (A)(2) of rule 3717-1-03.2 of the Administrative Code;

- (ii) Identify a designated work area and the method by which:
 - (a) Physical barriers or methods of separation of raw foods and ready-to-eat foods minimize cross contamination; and
 - (b) Access to the processing equipment is limited to responsible trained personnel familiar with the potential hazards of the operation; and
 - (iii) Delineate cleaning and sanitization procedures for food-contact surfaces; and
- (f) Describes the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the:
- (i) Concepts required for a safe operation;
 - (ii) Equipment and facilities; and
 - (iii) Procedures specified under paragraph (K)(2)(e) of this rule and the HACCP plan for the operation.
- (g) Regulatory authority is notified prior to implementation.
- (3) Except for fish that is frozen before, during, and after packaging, a food service operation or retail food establishment may not package fish using a reduced oxygen packaging method.
- (4) Except as specified under paragraphs (K)(3) and (K)(6) of this rule, a food service operation or retail food establishment that packages time/temperature controlled for safety food using a cook-chill or sous vide process shall:
- (a) Notify the regulatory authority prior to implementation and execute a HACCP plan that contains the information as specified under paragraph (L) of this rule;
 - (b) Ensure the food is:
 - (i) Prepared and consumed on the premises with no distribution or sale of the packaged product to another business location or the consumer;
 - (ii) Cooked to heat all parts of the food to a temperature and for a time as specified under paragraphs (A)(1), (A)(2) and (A)(4) of rule 3717-1-03.3 of the Administrative Code;

- (iii) Protected from contamination before and after cooking as specified under rule 3717-1-03.2 of the Administrative Code and under rule 3717-1-03.3 of the Administrative Code;
 - (iv) Placed in a package with an oxygen barrier and sealed before cooking, or placed in a package and sealed immediately after cooking and before reaching a temperature below one hundred thirty-five degrees Fahrenheit (fifty-seven degrees Celsius);
 - (v) Cooled to forty-one degrees Fahrenheit (five degrees Celsius) in the sealed package or bag as specified under paragraph (D) of this rule, and:
 - (a) Cooled to thirty-four degrees Fahrenheit (one degree Celsius) within forty-eight hours of reaching forty-one degrees Fahrenheit (five degrees Celsius) and held at that temperature until consumed or discarded within thirty days after the date of packaging;
 - (b) Held at forty-one degrees Fahrenheit (five degrees Celsius) or less for no more than seven days, at which time the food must be consumed or discarded; or
 - (c) Held frozen with no shelf life restriction while frozen until consumed or used.
 - (vi) 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; and
 - (vii) Labeled with the product name and the date packaged; and
- (c) Maintain the records required, to confirm that cooling and cold holding refrigeration time/temperature parameters are monitored as part of the HACCP plan, and:
- (i) Make such records available to the regulatory authority upon request; and
 - (ii) Hold such records for at least six months; and
- (d) Implement written operational procedures as specified under paragraph (K)(2)(e) of this rule and a training program as specified under paragraph (K)(2)(f) of this rule.

- (5) Except as specified under paragraph (K)(6) of this rule, a food service operation or retail food establishment that packages cheese using a reduced oxygen packaging method shall:
- (a) Limit the cheeses packaged to those that are commercially manufactured in a food processing plant with no ingredients added in the food service operation or retail food establishment and that meet the standards of identity as specified in 21 C.F.R. 133.150, 21 C.F.R. 133.169 or 21 C.F.R. 133.187;
 - (b) Have a HACCP plan that contains the information specified under paragraph (L) of this rule and as specified under paragraphs (K)(2)(a), (K)(2)(c)(i), (K)(2)(e) and (K)(2)(f) of this rule;
 - (c) Labels the package on the principal display panel with a "use by" date that does not exceed thirty days from its packaging or the original manufacturer's "sell by" or "use by" date, whichever occurs first; and
 - (d) Discards the reduced oxygen packaged cheese if it is not sold for off-premises consumption or consumed within thirty calendar days of its packaging.
- (6) A HACCP plan is not required for a specific food when a food service operation or retail food establishment uses a reduced oxygen packaging method to package that specific time/temperature controlled for safety food that is always:
- (a) Labeled with the production time and date;
 - (b) Held at forty-one degrees Fahrenheit (five degrees Celsius) or less during refrigerated storage; and
 - (c) Removed from its package in the food service operation or retail food establishment within forty-eight hours after packaging.

(L) Contents of a HACCP plan.

For a food service operation or retail food establishment that is required to have a HACCP plan, the plan and specifications shall include:

- (1) 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.
- (2) A description of the training program that ensures individuals responsible for implementing the HACCP plan understand the:
- (a) Application of HACCP principles;
 - (b) Procedures identified in the HACCP plan;
 - (c) Maintenance of records and verification of procedures identified in the HACCP plan; and
 - (d) Maintenance of equipment and facilities.
- ~~(2)~~(3) 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 points;
 - (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
- ~~(3)~~(4) Additional scientific data or other information, as required by the regulatory authority, supporting the determination that food safety is not compromised by the proposal.

Effective:

Five Year Review (FYR) Dates: 11/13/2018

Certification

Date

Promulgated Under: 119.03
Statutory Authority: 3717.04, 3717.05
Rule Amplifies: 3717.04, 3717.05
Prior Effective Dates: 03/01/2001, 03/01/2005, 03/01/2009, 01/01/2013,
06/01/2016