

511-6-1- .01 DEFINITIONS

The individual definitions in Rule -.01 are consistent with current conventions regarding the use of plain language in drafting rules, and with use in national and international standards and some Federal regulations. This facilitates making changes to the definitions as they become necessary in subsequent editions of the Chapter.

Accredited Program

"Accredited program" means a food protection manager certification program that has been evaluated and listed by an accrediting agency as conforming to national standards for organizations that certify individuals. It refers to the certification process and is a designation based upon an independent evaluation of factors such as the sponsor's mission; organizational structure; staff resources; revenue sources; policies; public information regarding program scope, eligibility requirements, re-certification, discipline and grievance procedures; test development and administration. Accredited programs does not refer to training functions or educational programs. Food protection manager certification occurs when individuals demonstrate through a certification program that they have met specified food safety knowledge standards. Food protection certification program accreditation occurs when certification organizations demonstrate through an accreditation program that they have met specified program standards. Accreditation is a conformity assessment process through which organizations that certify individuals may voluntarily seek independent evaluation and listing by an accrediting agency based upon the certifying organizations meeting program accreditation standards. Such accreditation standards typically relate to such factors as the certifying organization's structure, mission, policies, procedures, and the defensibility of its examination processes. These standards are intended to affirm or enhance the quality and credibility of the certification process, minimize the potential for conflicts of interest, ensure fairness to candidates for certification and others, and thereby increase public health protection. Program accreditation standards known to be relevant to food protection manager certification programs include those contained in the *Standards for Accreditation of Food Protection Manager Certification Programs* available from the Conference for Food Protection, 2792 Miramar Lane, Lincoln, CA 95648 and found at <http://www.foodprotect.org/>. Allowing food protection managers to demonstrate their required food safety knowledge "through passing a test that is part of an accredited program" is predicated on the fact that their credentials have been issued by certifying organizations that have demonstrated conformance with rigorous and nationally recognized program standards.

Adulterated

"Adulterated" means contaminated with extraneous ingredients not usually meant for the food product and is further defined as stated in the Federal Food, Drug, and Cosmetic Act, § 402. It can be found under Subpart IV – Food, Section 342 at the following link: <https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section342&num=0&edition=prelim>.

Color additive

"Color additive" means, (1) a material which:

(A) 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

(B) 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 the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

(2) The term "color" includes black, white, and intermediate grays.

(3) Nothing in subparagraph (1) of this paragraph 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 processes of produce of the soil and thereby affecting its color, whether before or after harvest. The definition can be found under Subpart II – Definitions, Section 321(t) at the following link: <https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section321&num=0&edition=prelim>.

Egg

The definition of egg includes avian species' shell eggs known to be commercially marketed in the United States. Also included are the eggs of quail and ratites such as ostrich. Baluts are not included in the definition of egg. Baluts are considered a delicacy among Philippine and Vietnamese populations. They are derived from fertile eggs, typically duck eggs, subjected to incubation temperatures for a period of time less than necessary for the embryo to hatch resulting in a partially formed embryo within the shell. Under the Egg Products Inspection Act (EPIA), an egg is typically considered adulterated if it has been subjected to incubation. However, in 9 CFR 590.5, baluts are specifically exempted from inspection as eggs under the EPIA. In producing baluts, fertile duck eggs are incubated for approximately 18 days at a temperature of 42.5°C (108.5°F) in incubators with a relatively high humidity (complete development and hatching would take place in 28 days). Under these conditions, the potential for growth of transovarian *Salmonella* organisms such as *S. Enteritidis* within the shell, and the potential for an increase in pathogenic microflora on the shell itself, are increased. Where chicken eggs are used in preparing baluts, the incubation period may only be 14 days at an incubation temperature of 37°C (99°F). A balut is a time/temperature control for safety food subject to time/temperature management including proper cooking and hot and cold holding. Baluts are typically boiled and packed in salt before sale or service.

Also, not included in this definition are the eggs of reptile species such as alligators and turtles. Alligator eggs are available for sale in some parts of the southern United States. In restaurants, the menu item "Alligator Eggs" is sometimes made of alligator egg, but other times is simply a fanciful

name for a menu item that may include seafood items such as shrimp, but contains no alligator egg.

Sea turtle eggs have been consumed in Asian and Latin American Countries. However, turtle eggs are not mentioned in the definitions section because sea turtles (Loggerhead, East Pacific Green, Leatherback, Hawksbill, Kemp's Ridley, and Olive Ridley) are protected by The Endangered Species Act of 1973 and therefore may not be sold or consumed. This Act, with respect to turtle eggs, is enforced by the United States Department of Interior, U.S. Fish and Wildlife Service, Washington, DC.

Employee

"Employee" means the permit holder, person in charge, food employee, person having supervisory or management duties, person on the payroll, family member, volunteer, person performing work under contractual agreement, or other person working in a food service establishment. An employee is an individual who is on the payroll of a food service establishment or an individual who performs work that is necessary for the food service establishment to function and to provide its services to the public. He or she can be an individual who may not be on the payroll of the food service establishment and who is performing work on behalf of the food service establishment that is necessary for it to provide its services to the public. He or she can be an individual who is employed by a company that is not on the food service establishment payroll, such as a pest exterminator, equipment servicing or repair provider or provision supplier, whose services are necessary for the operation of the establishment.

Food Additive

The term "food additive" means any substance the intended use of which results or may reasonably be 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 food; and including any source of radiation intended for any such use), if 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 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; except that such term does not include—

1. a pesticide chemical residue in or on a raw agricultural commodity or processed food; or
2. a pesticide chemical; or
3. a color additive; or
4. any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to this chapter, the Poultry Products Inspection Act [21 U.S.C. 451 et seq.] or the Meat Inspection Act of March 4, 1907, as amended and extended [21 U.S.C. 601 et seq.];
5. a new animal drug; or
6. an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.
7. The definition can be found under Subpart II – Definitions, Section 321(s) at the following link: <https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21->

section321&num=0&edition=prelim.

Food Establishment and Food Processing Plant

Some food businesses perform operations that provide food directly to consumers as a “Food Establishment,” and also supply food to other business entities as a “Food Processing Plant.” Within such a business, those operations that provide food directly to consumers only should be considered part of a “Food Service Establishment” for the purposes of applying the Chapter while those operations that supply food to other business entities may be subject to Georgia Department of Agriculture rules and regulations that apply to “Food Processing Plants”. It is essential that the permit holder and persons in charge be aware that regulatory requirements and the appropriate operational practices for “Food Service Establishments” may differ from those for “Food Processing Plants.”

Some facilities and functions may be subject to different regulatory requirements depending on whether that facility or function is regulated as a “Food Establishment” or as a “Food Processing Plant”, or both.

Food processing plant” means a commercial operation that manufactures, packages, labels, or stores food for human consumption, and provides food for sale or distribution to other business entities such as food processing plants or food service establishments.

"Food service establishment" means public or private establishments which prepare and serve meals, lunches, short orders, sandwiches, frozen desserts, or other edible products either for carry out or service within the establishment. The term includes restaurants; coffee shops; cafeterias; short order cafes; luncheonettes; taverns; lunchrooms; places which retail sandwiches or salads; soda fountains; food carts; itinerant restaurants; industrial cafeterias; catering establishments; and similar facilities by whatever name called. Within a food service establishment, there may be a food sales component, not separately operated. This food sales component shall be considered as part of the food service establishment. This term shall not include a “food sales establishment,” as defined in the Code Section 26-2-21, except as stated in this definition. The food service component of any food sales establishment defined in Code Section 26-2-21 shall not be included in this definition. This term shall not include the following:

- a. a “food sales establishment” as defined in the O.C.G.A. Section 26-2-21 and subject to regulation by the Georgia Commissioner of Agriculture, except as stated in this definition. The food service component of any food sales establishment defined in O.C.G.A. Section 26-2-21 shall not be included in this exception;
- b. any outdoor recreation activity sponsored by the state, a county, a municipality, or any department or entity thereof, any outdoor or indoor (other than school cafeteria food service) public school function, or any outdoor private school function;
- c. any organization which is operating on its own property or on the property of a party that has provided written consent for the use of such property for such purpose and which is exempt from taxes under O.C.G.A. Section 48-7-25(a)(1) or under Section 501(d) or paragraphs (1) through (8) or paragraph (10) of Section 501 (c) of the Internal Revenue Code for the purpose of operating a house or other residential structures where seriously ill or injured children and their families are provided temporary accommodations in proximity to their treatment

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- hospitals and where food is prepared, served, transported, or stored by volunteer personnel;
- d. establishments for the preparation and serving of meals, lunches, short orders, sandwiches, frozen desserts, or other edible products if such preparation or serving is an authorized part of and occurs upon the site of an event which:
 1. Is sponsored by a political subdivision of this state or by an organization exempt from taxes under of O.C.G.A. Section 48-7-25(a)(1) or under Section 501(d) or paragraphs (1) through (8) or paragraph (10) of section 501(c) of the Internal Revenue Code, as that code is defined in O.C.G.A. Section 48-1-2;
 2. Is held on the property of such sponsor or on the property of a party that has provided written consent for use of such property for such event;
 3. Lasts 120 hours or less; and
 4. When sponsored by such an organization, is authorized to be conducted pursuant to a permit issued by the municipality or county in which it is conducted.

Establishment Descriptions

1. Institutions (both public and private):

These would be organizations, societies, corporations, having a public character and function with a component of preparation and service of food to the public such as schools; churches; colleges; correction facilities; and caring facilities for the elderly and the disabled such as nursing homes, adult daycare, and congregate personal care homes with 25 or more beds.

An example of an institution that normally is not thought as having a food service component is a church. If a church has a dinner function for only its members and guests, it would not be considered a food service establishment. However, if it prepares food and serves it to the general public such as a soup kitchen or school, it would be considered a food service establishment.

2. Food Carts:

Examples of these can be found in Rule -.08 of Chapter 511-6-1 and include hot dog carts, popcorn carts, and snow cone carts. These type of establishments will have a limited menu and method of operation.

3. Short Order Cafes:

These are dine-in or carryout, quick-service, cooked-to-order establishments serving a limited menu. An example of this would be a traditional diner or lunch counter.

4. Luncheonettes:

These are establishments where light lunches are served such as in tearooms. Menus are usually limited to items such as soups, salads and sandwiches.

5. Taverns:

These are establishments where liquor, beer, and wine are sold to be consumed on the premises such as a saloon or bar. They may be equipped to serve food and in some cases, these type of establishments may be associated with a tourist accommodation component such as an inn.

6. Cafeterias:

These are restaurants equipped to display food for consumer self-service or displayed for immediate service upon order of the consumer. These establishments may be stand-alone facilities or found in such locations such as institutions, schools, office and industrial buildings.

7. Catering Establishments:

These are food service establishments that have entered into a contractual agreement with their consumers to prepare food in bulk quantities for delivery and/or service off the premises at a specific date, time, and location. For example, food is prepared and containerized at a permitted Base of Operation for a client who is planning a wedding. The catering establishment and the client enter into a contractual agreement, verbal or written – usually written, to provide food and services for the wedding reception. The client selects from the establishment's menu items for service for a fee and the event is scheduled. On the day of the wedding event, the caterer prepares the food and delivers it to the site for service. After the event concludes, the caterer removes his/her equipment and returns it to the base of operation for cleaning and sanitization.

Home delivery food service establishments, such as pizza or Chinese delivery, sometimes are loosely described as being a form of catering, but it is not. The customer will call the establishment and will make a verbal request of the establishment to deliver a food item from their menu. This type of food service is food delivery provided by the establishment to the customer within an approximate short distance from the establishment. There is no contractual agreement for food to be prepared and delivered off-site. Mobile food service operations are not catering operations by the characteristics of how they operate. Mobile food service units go from place to place vending food as an extension of their permitted base of operation and not to any specific event nor under any contractual request by its consumers. Moreover, mobile food service units must provide a listing of their vending locations to the health authority. However, mobile food service establishments may enter into a contractual agreement with a consumer to cater an event as long as the mobile food service operation has the space and capability to handle catered events. The mobile food unit permit holder would be required to keep a calendar of events catered for the last 6 months. (See *Mobile Food Service Units and Catering Operations* later in this document under Rule .08 Special Food Service Operations.)

8. Places that Retail Sandwiches or Salads:

These could be any food service establishment that prepares sandwiches or salads for sale to their patrons. However, they are not establishments that manufacture sandwiches and or salads for sale to other establishments (or wholesaling) who will in turn sell such products to their patrons. Such manufacturers are considered as sandwich and salad manufacturers and are permitted and regulated by the Georgia Department of Agriculture.

An example of this establishment would be deli shops. They usually bake their own bread and display various toppings for patrons to select to complete the sandwich. They may offer salads of which are usually made in-house and they may offer soups that are usually commercially prepared and packaged, reheated, and hot held prior to service.

9. Similar Facilities by Whatever Name Called:

This part of the definition of “Food Service Establishment” is added to the definition of food service establishment to include any establishment that prepares and serves food to the public no matter how it operates or what it is called. The exception would be if the Official Code of Georgia Annotated (O.C.G.A.) excludes activities with food from the definition or if the food service activity falls under the jurisdiction of the Federal Government. Currently, there are seven exclusions to the food service establishment definition. They are: (i) food sales establishment, (ii) sandwich manufacturers and food processors all permitted by the Georgia Department of Agriculture; (iii) non-profit temporary food service establishments; (iv) outdoor recreation activities with food concessions sponsored by the state, a county, a municipality, or any department or entity thereof, or public school function or any outdoor or indoor private school function (other than school cafeteria food service); (v) child care facility licensed by the Georgia Department of Early Care and Learning (DECaL); (vi) those food service establishments located on Federal Government property such as military bases; and (vii) non-profit organizations that operating a house or other residential structures where seriously ill or injured children and their families are provided temporary accommodations in proximity to their treatment hospitals to prepare, serve, transport, or store food by volunteer personnel on their own property or on the property of a party that has provided written consent for the use of the property for the aforementioned purpose. Head Start Children’s Programs, operating under funding provided by the United States Department of Agriculture (USDA) and the United States Health and Human Services (USHHS), are generally required to hold a food service permit from the local Health Authority.

Rationale for Determining What Falls within the Definition of “Food Service Establishment”

From time to time, questions do come up in various situations as to how to determine if a particular operation or an event falls within the definition of a food service establishment requiring the issuance of a food service permit. These food operations would be those that are not clearly listed as not being within the definition of a food service establishment as noted above within the section entitled, “Similar Facilities by whatever named called”. In order to make the determination, the Environmental Health Specialist (EHS) will need to ask the question, “Will this operation and or event prepare and serve food to the public or will the operation prepare food and serve itself (its members) and not the public?”

Examples are as follows:

1. A party is open only to an invited group of people in a rented facility where someone is hired to prepare food on the premises. All of the food will be provided by the party giver or attendees, and the person preparing the food does everything on site using that food and equipment provided by the party giver. This person would fall into the category of a Personal Chef.

Answer: No food permit is necessary. This is a private event open only to invited guests in a facility rented for private use.

Exception: If the rental facility has a service that routinely provides food service, then Yes, the facility must have a food service permit. Very often, however, the party giver will prepare his or her own food or friends will prepare it. This can be considered private, the same as if someone has a party in his/her home. However, if the person that is hired to prepare the food is contracted to supply the food along with any equipment needed for cooking, preparation or holding food under temperature control, then this person would be considered a caterer and be required to have a food service permit with a base of operation.

2. A political fundraising event in which people are invited to meet the political candidate and enjoy free food. Donations may or may not be accepted.

Answer: By definition, a political fund raising event would be a non-profit if a local government or political action group (most of which are non-profit) sponsors it. If the event does not meet the criteria of a non-profit temporary food service establishment as established within the Chapter, then the event would be considered as a for-profit temporary food service event and must be permitted as a temporary food service establishment under Chapter 511-6-1.

3. A party is open only to an invited group of people in a rented facility where someone is hired to prepare food off the premises and bring it to the site.

Answer: Food service permit is required at the preparation site (ex., at the caterer's kitchen or off-site kitchen).

Exception: No food service permit would be necessary if the party giver or friends participating in the party prepare the food.

4. A Boarding House is serving food only to the tenants (sometimes the tenants prepare their own meals).

Answer: No permit is necessary. This is to be considered the tenants private home.

5. A club such as a Country Club, Elks Lodge, or Moose Lodge is serving food only to its members that is prepared by members or catered-in for members.

Answer: Generally, no permit is necessary for such an operation.

Exception: If the club or lodge invites or solicits the public to come in to eat through any form of advertisement with the public such as word-of-mouth, the media, signage, etc., then yes it must hold a food service permit. In addition, a food service permit would be required should the facility provide a catering service.

6. Churches that serve food only to the church members and to guests invited by church

members.

Answer: A food service permit is not necessary as long as the food is prepared in the church kitchen and is only for church members and not for service to the public through invitation or solicitation through any form of advertisement such as word-of-mouth, the media, signage, etc.

Exception: A church will need a food service permit should it serve food off from the premises of the church, such as events organized by a for-profit organizer. In addition, a food service permit would be required should a church serve food to the public such as a soup kitchen for the homeless and or a private school.

The Environmental Health Specialist (EHS) must evaluate proposed methods of operation on a case-by-case basis to determine if food is being prepared and/or served to the public. The purpose of this case-by-case evaluation is to determine if an operation meets the term, “food service establishment”, as defined in the Chapter.

Packaged

The definition of “packaged” was revised to clarify when foods packaged at retail do not need to be labeled. The definition of packaged was amended to clarify the intent of what the term packaged includes and does not include. This definition was revised in response to requests for clarification on which types of foods packaged in a food service establishment are not required to be labeled. Rather than determine the need for labeling on the basis of the durability of the packaging material, the language clarifies that labeling need not be provided if the packaged food is provided by the employee to the consumer upon request. This has been our interpretation under the previous Chapter; however, now the definition is in line with the risk that it was intended to control. The specific changes to the definition of “Packaged” deleted the term “securely” to avoid undue emphasis on the nature of the package; and removed the phrase “or other nondurable container” to clarify when foods packaged at retail need to be labeled. For Example - If a restaurant places a food item such as cookies in a plastic bag and ties the bag off, and places them out on a shelf in the restaurant for consumers to purchase at the restaurant, then that would not be considered “packaged” – the consumer would be able to ask an employee at the restaurant what type of cookies they are or the specific ingredients in the cookies. However, food packaging and labeling is required by the Chapter for the grab-and-go method of food display for consumer self-service operations such as for food vending machines or third party sales. With the use of this method of consumer self-service, the consumer does not have the opportunity to inquire about specific ingredients in the food from an employee of the establishment in which the food was prepared since the food is not directly received from the establishment employee. Food and salad self-service bars are exempt from requirements for packaging and labeling by Federal Law, as referenced in Rule -.04 of the Chapter.

Permit

"Permit" means the document issued by the Health Authority that authorizes a person to operate a food service establishment and signifies satisfactory compliance with the Chapter.

In regards to food service establishment operations, DPH Rule 511-6-1-.02's provision for the

issuance of a permit is the legal means by which the Health Authority fulfills its mandated mission – to protect the public health from the impact of food-borne illness (FBI). The permit represents the Health Authority's permission given to a single applicant (or management) to operate a specific, single establishment that prepares and serves food to the public. It also signifies that a single establishment has satisfactorily demonstrated through the plans and specifications review and the initial inspection processes to have the necessary design, construction, and equipment installation for management to be successful in maintaining active managerial control over foodborne illness risk factors inherent to its method of operation (or business model).

As required by DPH Rule 511-6-1-.02(1)(c)2, permits cannot be issued by the Health Authority unless the permit applicant demonstrates satisfactory compliance with not only the provisions of the Chapter, but with all other applicable provisions of laws (i.e., federal, state, local) concerning the establishment's location, construction and maintenance, and the safety of persons therein. The person who is granted a permit must have the legal responsibility for the day-to-day management and operation of the establishment. This statement goes to DPH Rule 511-5-14-.03 "Management and Personnel" that requires active management control of risk factors that most often cause foodborne illness, as well as Good Retail Practices (GRPs) and the physical facilities that support the control of risk factors. As such, DPH Rule 511-5-14-.02(1)(a)3 requires that a food service permit be issued to the person who is legally responsible for the operation (i.e., control of food safety risk factors for foodborne illness) of a proposed food service establishment, at one location (i.e., Health Authority approved establishment built to Health Authority approved plans and specifications), and one method of operation (i.e., mobile food service, temporary food service, etc.).

Permit Holder

"Permit holder" means the person who possesses a valid permit to operate a food service establishment and is legally responsible for the operation of the food service establishment such as the owner, the owner's agent, or other person.

The permit holder can be different from the person that owns the equipment and physical facilities. For example, a public school system or hospital authority owns the food service facility and food service equipment and leases out the food service operation to a management firm. The management firm would be the permit holder and the public school system or hospital authority would be the landlord. As permit holder, the management firm would be legally responsible for the day-to-day operation of the food service establishment.

Time/Temperature Control for Safety Food

Time Temperature Control for Safety Food (TCS) 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 TCS food takes into consideration pH, a_w , pH and a_w 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 57°C (135°F). 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 fettuccine 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 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, antimicrobials) are used to control or eliminate pathogen growth.

Before using Tables A and B of the definition for “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 Manual is not needed to determine if the item is a TCS food.
- Is the food raw, or is the food heat-treated?
- Does the food already require time/temperature control for safety by definition of TCS 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 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 TCS until inoculation studies or some other acceptable evidence shows that the food is a TCS food or not. The Chapter requires a variance request to the regulatory authority with the evidence that the food does not require time/temperature control for safety. Oftentimes, the study will provide a length of time and temperature by which the food may be held without temperature control.

The Chapter definition designates certain raw plant foods as 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, $a_w > 0.99$, not heat-treated), fresh sprouts (pH > 6.5 , $a_w > 0.99$, not heat-treated), and cut tomatoes (pH 4.23 – 5.04, $a_w > 0.99$, not heat-treated), Table B indicates that they are considered TCS Foods unless a product assessment shows otherwise. Maintaining these products under the temperature control requirements prescribed in this code for 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 variance is required as specified in Rule -.04(6)(j)3. A standardized recipe validated by approved laboratory testing for pH and a_w would be an appropriate part of the variance request with annual samples tested to verify compliance with the conditions of the variance.

More information can be found in the Institute of Food Technologists (IFT) Report, "Evaluation and Definition of Potentially Hazardous Foods" at <https://www.fda.gov/files/food/published/Evaluation-and-Definition-of-Potentially-Hazardous-Foods.pdf> Hand in the NATIONAL ADVISORY COMMITTEE ON MICROBIOLOGICAL CRITERIA FOR FOODS, Parameters for Determining Inoculated Pack/Challenge Study Protocols at https://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/nacmcf/current-subcommittees/parameters-for-inoculated-pack-challenge-study-protocols/ct_index9.

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 $\leq 41^\circ\text{F}$ or $\geq 135^\circ\text{F}$ 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 Rule -.04(5)(a) of the Chapter) or treated with some other method other than heat. Proceed to step #3.

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- b. Yes – If the food is heat-treated to the required temperature for that food as specified in Rule -.04(5)(a) of the Chapter, 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 a_w 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 a_w 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 " a_w values" that contains the a_w value of the food in question.
 - c. Note where the row and column intersect to identify whether the food is "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-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

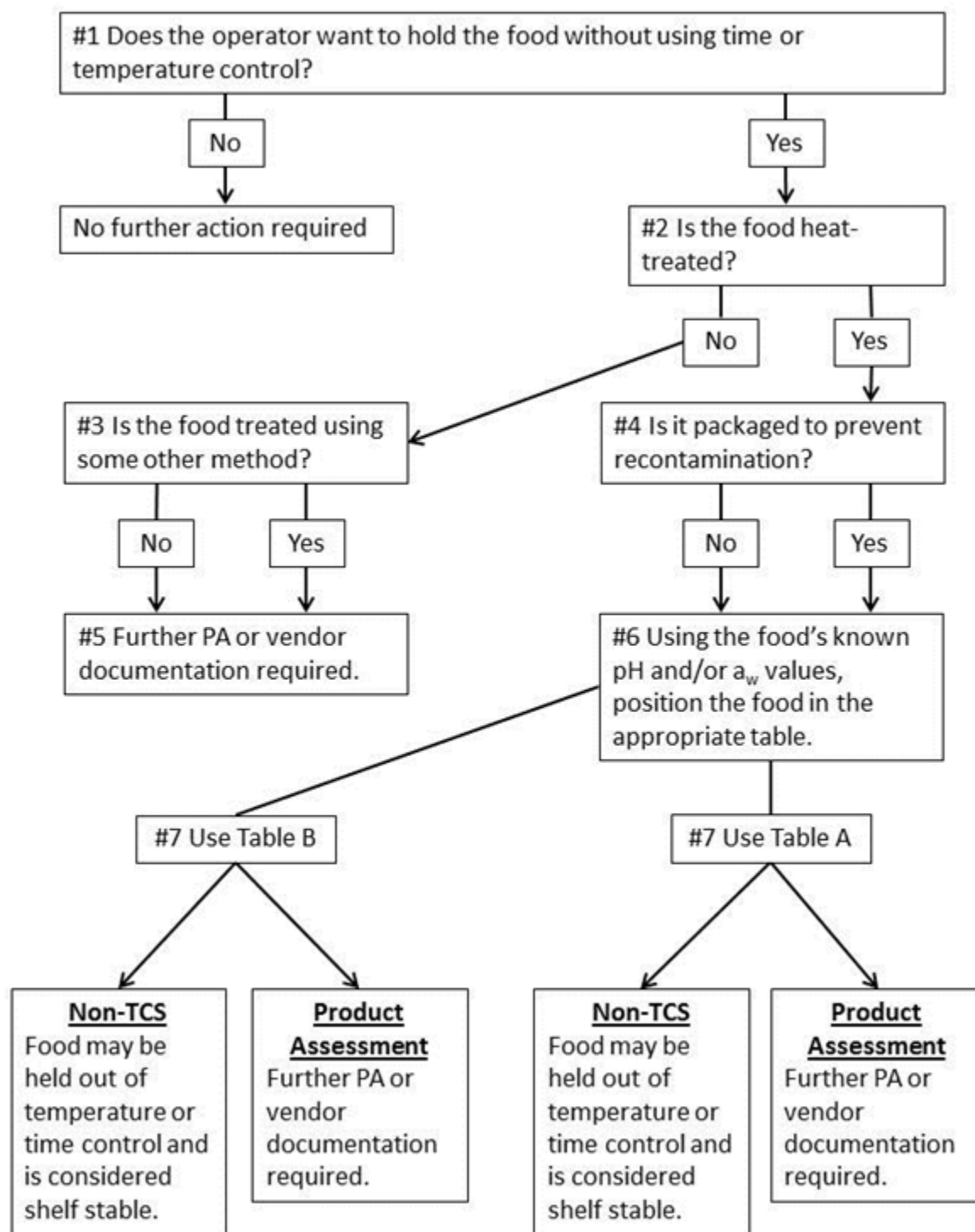


Table A. Interaction of PH and A_w for control of spores in FOOD heat-treated to destroy vegetative cells and subsequently PACKAGED

a_w values	pH: 4.6 or less	pH: > 4.6 - 5.6	pH: > 5.6
≤ 0.92	non-TCS FOOD*	non-TCS FOOD	non-TCS FOOD
> 0.92 - 0.95	non-TCS FOOD	non-TCS FOOD	PA**
> 0.95	non-TCS FOOD	PA	PA

* TCS food means Time/Temperature Control for Safety food

** PA means Product Assessment required

Table B. Interaction of PH and A_w for control of vegetative cells and spores in FOOD not heat-treated or heat-treated but not PACKAGED

A_w values	pH: < 4.2	pH: 4.2 - 4.6	pH: > 4.6 - 5.0	pH: > 5.0
< 0.88	non-TCS food*	non-TCS food	non-TCS food	non-TCS food
0.88 – 0.90	non-TCS food	non-TCS food	non-TCS food	PA**
> 0.90 – 0.92	non-TCS food	non-TCS food	PA	PA
> 0.92	non-TCS food	PA	PA	PA

* TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY FOOD

** PA means Product Assessment required

Vending Machine

"Vending machine" means a self-service device that, upon insertion of a coin, paper currency, token, card, or key, or by optional manual operation, dispenses unit servings of food in bulk or in packages without the necessity of replenishing the device between each vending operation.

The term vending machine in the Chapter refers only to vending machines owned by a food service establishment permit holder and operated on the premises of the permit holder's food service establishment. Such vending machines are considered to be food service equipment of the establishment