

Legend: (Proposed New Rule)  
Regular Print = Proposed new language

## 229.661. Cottage Food Production Operations.

(a) Purpose. The purpose of this section is to implement Health and Safety Code, Chapter 437, related to cottage food production operations, which requires the department to adopt rules for labeling of foods produced by cottage food production operations.

(b) Definitions. The following words and terms when used in this subchapter shall have the following meanings unless the context clearly indicates otherwise.

(1) Baked good--A food item prepared by baking the item in an oven, which includes cookies, cakes, breads, Danishes, donuts, pastries, pies, and other items that are prepared by baking. A baked good does not include a potentially hazardous food (time/temperature control for safety foods).

(2) Cottage food production operation--An individual, operating out of the individual's home, who:

(A) produces a baked good, a canned jam or jelly, or a dried herb or herb mix for sale at the person's home;

(B) has an annual gross income of \$50,000 or less from the sale of this food described by subparagraph (A) of this paragraph; and

(C) sells foods produced under subparagraph (A) of this paragraph only directly to consumers.

(3) Department--The Department of State Health Services.

(4) Executive Commissioner--The Executive Commissioner of the Health and Human Services Commission.

(5) Food establishment--

(A) Food establishment means an operation that stores, prepares, packages, serves, vends, or otherwise provides food for human consumption:

(i) such as a restaurant; retail food store; satellite or catered feeding location; catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people; market; farmers market; vending location; conveyance used to transport people; institution; or food bank; and

(ii) that relinquishes possession of food to a consumer directly, or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

(B) Food establishment includes:

(i) an element of the operation such as a transportation vehicle or a central preparation facility that supplies a vending location or satellite feeding location unless the vending or feeding location is permitted by the regulatory authority; and

(ii) an operation that is conducted in a mobile, stationary, temporary, or permanent facility or location; where consumption is on or off the premises; and regardless of whether there is a charge for the food.

(C) Food establishment does not include:

(i) an establishment that offers only prepackaged foods that are not potentially hazardous (time/temperature control for safety) foods;

(ii) a produce stand that only offers whole, uncut fresh fruits and vegetables;

(iii) a food processing plant including those that are located on the premises of a food establishment;

(iv) a kitchen in a private home if only food that is not potentially hazardous (time/temperature control for safety) food is prepared for sale or service at a function such as a religious or charitable organization's bake sale if allowed by law;

(v) an area where food that is prepared as specified in clause (iv) of this subparagraph is sold or offered for human consumption;

(vi) a Bed and Breakfast Limited establishment as defined in §229.162 of this title (relating to Definitions) concerning food establishments;

(vii) a private home that receives catered or home-delivered food;

or

(viii) a cottage food production operation.

(6) Herbs--Herbs are from the leafy green parts of a plant (either fresh or dried) used for culinary purposes and not for medicinal uses.

(7) Home--A primary residence that contains a kitchen and appliances designed for common residential usage.

(8) Potentially hazardous food (PHF) (time/temperature control for safety food (TCS))--

(A) Potentially hazardous food (time/temperature control for safety food) means a food that requires time/temperature control for safety to limit pathogenic microorganism growth or toxin formation.

(B) Potentially hazardous food (time/temperature control for safety food) includes:

(i) an animal food that is raw or heat-treated; a plant food that is heat-treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation; and

(ii) except as specified in subparagraph (C)(iv) of this paragraph, a food that because of the interaction of its  $a_w$  and pH values is designated as Product Assessment required (PA) in Table A or B of this clause.

(I) Table A. Interaction of pH and  $a_w$  for control of spores in food heat-treated to destroy vegetative cells and subsequently packaged.

Figure: 25 TAC §229.661(b)(8)(B)(ii)(I)

(II) 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.

Figure: 25 TAC §229.661(b)(8)(B)(ii)(II)

(C) Potentially hazardous food (time/temperature control for safety food) does not include:

(i) an air-cooled hard-boiled egg with shell intact, or an egg with shell intact that is not hard-boiled, but has been pasteurized to destroy all viable salmonellae;

(ii) a food in an unopened hermetically sealed container that is commercially processed to achieve and maintain commercial sterility under conditions of non-refrigerated storage and distribution;

(iii) a food that because of its pH or  $a_w$  value, or interaction of  $a_w$  and pH values, is designated as a non-PHF/non-TCS food in Table A or B in subparagraph (B)(ii)(I) and (II) of this paragraph;

(iv) a food that is designated as PA in Table A or B in subparagraph (B)(ii)(I) and (II) of this paragraph and has undergone a Product Assessment showing that the growth or toxin formation of pathogenic microorganisms that are reasonably likely to occur in that food is precluded due to:

(I) intrinsic factors including added or natural characteristics of the food such as preservatives, antimicrobials, humectants, acidulants, or nutrients;

(II) extrinsic factors including environmental or operational factors that affect the food such as packaging, modified atmosphere such as reduced oxygen packaging, shelf life and use, or temperature range of storage and use; or

(III) a combination of intrinsic and extrinsic factors; or

(v) a food that does not support the growth or toxin formation of pathogenic microorganisms in accordance with one of the clauses (i) - (iv) of this subparagraph even though the food may contain a pathogenic microorganism or chemical or physical contaminant at a level sufficient to cause illness or injury.

(c) Complaints. The department shall maintain a record of a complaint made by a person against a cottage food production operation.

(d) Labeling requirements for cottage food production operations. All foods prepared by a cottage food production operation must be labeled.

(1) The label information shall include:

(A) the name and physical address of the cottage food production operation;

(B) the common or usual name of the product and an adequately descriptive statement of identity;

(C) if made from two or more ingredients, a list of ingredients in descending order of predominance by net weight, including a declaration of artificial color or flavor and chemical preservatives, if contained in the food;

(D) an accurate declaration of the net quantity of contents including metric measurements;

(E) allergen labeling in compliance with the Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-282, Title II, 118. Stat. 905; and

(F) the following statement: "Made in home kitchen, food is not inspected by the Department of State Health Services or a local health department" in at least the equivalent of 11-point font and in a color that provides a clear contrast to the background.

(2) Labels must be clearly legible and printed with durable, permanent ink.

(A) Ingredient statements shall be at 1/16 of an inch or larger.

(B) Ingredients shall include components of the ingredients.

(C) Net quantity of contents shall be separated from other text on the label and must be located in the bottom third of the label.

(e) Sales by cottage food production operations through Internet prohibited. A cottage food production operation may not sell any of the foods described in these rules through the Internet. No health claims may be made on any of the advertising medium of the finished products because they are conventional foods.

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Figure: 25 TAC §229.661(b)(8)(B)(ii)(I)

**Table A. Interaction of pH and  $a_w$  for control of spores in food heat-treated to destroy vegetative cells and subsequently packaged**

<b><math>a_w</math> values</b>	<b>pH values</b>		
	<b>4.6 or less</b>	<b>&gt; 4.6 - 5.6</b>	<b>&gt; 5.6</b>
<b>≤0.92</b>	non-PHF*/non-TCS food**	non-PHF/non-TCS food	non-PHF/non-TCS food
<b>&gt;0.92 - .95</b>	non-PHF/non-TCS food	non-PHF/non-TCS food	PA***
<b>&gt;0.95</b>	non-PHF/non-TCS food	PA	PA

\* PHF means Potentially Hazardous Food  
 \*\* TCS food means Time/Temperature Control for Safety Food  
 \*\*\* PA means Product Assessment required

Figure: 25 TAC §229.661(b)(8)(B)(ii)(II)

**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**

<b><math>a_w</math> values</b>	<b>pH values</b>			
	<b>&lt;4.2</b>	<b>4.2 - 4.6</b>	<b>&gt;4.6 - 5.0</b>	<b>&gt;5.0</b>
<b>&lt;0.88</b>	non-PHF*/non-TCS food**	non-PHF/non-TCS food	non-PHF/non-TCS food	non-PHF/non-TCS food
<b>0.88 - 0.90</b>	non-PHF/non-TCS food	non-PHF/non-TCS food	non-PHF/non-TCS food	PA***
<b>&gt;0.90 - 0.92</b>	non-PHF/non-TCS food	non-PHF/non-TCS food	PA	PA
<b>&gt;0.92</b>	non-PHF/non-TCS food	PA	PA	PA

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