Legend: (Proposed Amendments)
Single Underline = Proposed new language
[Bold, Print, and Brackets] = Current language proposed for deletion
Regular Print = Current language
(No change.) = No changes are being considered for the designated subdivision

§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 at the individual's home, subject to Section 437.0196:

(i) a baked good that is not a potentially hazardous food, as defined by Section 437.0196;
(ii) candy;
(iii) coated and uncoated nuts;
(iv) unroasted nut butters;
(v) fruit butters;
(vi) a canned jam or jelly;
(vii) a fruit pie;
(viii) dehydrated fruit or vegetables, including dried beans;
(ix) popcorn and popcorn snacks;
(x) cereal, including granola;
(xi) dry mix;
(xii) vinegar;
(xiii) pickles;
(xiv) mustard;
(xv) roasted coffee or dry tea; or
(xvi) a dried herb or dried 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 at the individual's home, a farmers' market, a farm stand, or a municipal, county, or nonprofit fair, festival, or event; and

(D) delivers products to the consumer at the point of sale or another location designated by the consumer..

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

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

(5) Farm stand – a premises owned and operated by a producer of agricultural food products at which the producer or other persons may offer for sale produce or foods described by in 229.661(b)(2).

(6) Farmers' market – a designated location used primarily for the distribution and sale directly to consumers of food by farmers or other producers.

[(5)] (7) 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; 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)] (8) 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)] (9) Home--A primary residence that contains a kitchen and appliances designed for common residential usage.

[(8)] (10) Pickle -- a cucumber preserved in vinegar, brine, or a similar solution. Only pickled cucumbers are allowed under the Cottage Food Law. All other pickled vegetables are prohibited. Federal requirements have been established for production of acidified foods such as pickles. If foods are sold across state lines, then the federal requirements would definitely apply. Under the FDA's interpretation of "interstate commerce," the federal requirements might also apply to cottage food producers who purchase supplies from out-of-state. As a precautionary measure, you may wish to take the federal course if you intend to sell pickles under the cottage foods law.

(11) Potentially hazardous food (PHF) -- a food that requires time and temperature control for safety to limit pathogen growth or toxin production. The term includes a food that must be held under proper temperature controls, such as refrigeration, to prevent the growth of bacteria that may cause human illness. A potentially hazardous food may include a food that contains protein and moisture and is neutral or slightly acidic, such as meat, poultry, fish, and shellfish products, pasteurized and unpasteurized milk and dairy products, raw seed sprouts, baked goods that require refrigeration, including cream or custard pies or cakes, and ice

products. The term does not include a food that uses potentially hazardous food as ingredients if the final food product does not require time or temperature control for safety to limit pathogen growth or toxin production. **[(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) Packaging and labeling**[Labeling]** requirements for cottage food production operations. All foods prepared by a cottage food production operation must be packaged and labeled in a manner that prevents product contamination, except that a food item is not required to be packaged if it is too large or bulky for conventional packaging.

(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;

(C) if a food is made with a major food allergen, such as eggs, nuts, soy, peanuts, milk or wheat that ingredient must be listed on the label; and

(D) the following statement: "This food is made in a home kitchen and is not inspected by the Department of State Health Services or a local health department."

(2) Labels must be legible.

(e) Certain sales **[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, by mail order or wholesale. No health claims may be made on any of the advertising medium of the finished products because they are conventional foods.

(f) A cottage food production operation is not exempt from meeting the application of Health and Safety Code Sections 431.045, 431.0495, and 431.247. The department or local health authority may act to prevent an immediate and serious threat to human life or health.

(g) Prohibition for Cottage Food Production Operations. A cottage food production operation may not sell potentially hazardous foods to customers.

(h) Production of Cottage Food Products – Basic Food Safety Education or Training Requirements.

(1) An individual who operates a cottage food production operation must have successfully completed a basic food safety education or training program for food handlers accredited under Subchapter D, Chapter 438, Health and Safety Code.

(2)An individual may not process, prepare, package, or handle cottage food products unless the individual:

(A) meets the requirements of Subsection (h)(1);

(B) is directly supervised by an individual described by Subsection (h)(1); or

(C) is a member of the household in which the cottage food products are produced.

[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			
a_w values	**pH values**		
	4.6 or less	**> 4.6 - 5.6**	**> 5.6**
≤0.92	**non-PHF*/non-TCS food****	**non-PHF/non-TCS food**	**non-PHF/non-TCS food**
>0.92 - .95	**non-PHF/non-TCS food**	**non-PHF/non-TCS food**	**PA*****
>0.95	**non-PHF/non-TCS food**	**PA**	**PA**
*** PHF means Potentially Hazardous Food ** TCS food means Time/Temperature Control for Safety Food *** PA means Product Assessment required]**			

[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				
a_w values	**pH values**			
	<4.2	**4.2 - 4.6**	**>4.6 - 5.0**	**>5.0**
<0.88	**non-PHF*/non-TCS food****	**non-PHF/non-TCS food**	**non-PHF/non-TCS food**	**non-PHF/non-TCS food**
0.88 - 0.90	**non-PHF/non-TCS food**	**non-PHF/non-TCS food**	**non-PHF/non-TCS food**	**PA*****
>0.90 - 0.92	**non-PHF/non-TCS food**	**non-PHF/non-TCS food**	**PA**	**PA**
>0.92	**non-PHF/non-TCS food**	**PA**	**PA**	**PA**
*** PHF means Potentially Hazardous Food ** TCS food means Time/Temperature Control for Safety Food *** PA means Product Assessment required]**				