

**Department of State Health Services
Council Agenda Memo for State Health Services Council
November 20-21, 2013**

Agenda Item Title: Amendment to a rule concerning cottage food production operations

Agenda Number: 4.g

Recommended Council Action:

For Discussion Only

For Discussion and Action by the Council

Background:

The Public Sanitation and Retail Foods Safety Group in the Regulatory Services Division inspects retail food establishments, youth camps, and school cafeterias and conducts nuisance complaint investigations in Texas that are not inspected by local health jurisdictions. The program includes licensing, inspections, complaint investigations, enforcement, technical guidance, and emergency response for the retail sale of food and youth camp programs. The Group also provides accreditation for food handler education or training programs and conducts training for local inspectors.

The Group regulates approximately 11,000 retail food establishment licensees, and completes 1,148 school cafeteria inspections and 596 youth camp inspections. The Group is funded from dedicated fees charged for licenses issued to retail food establishments.

A cottage food production operation is an individual who operates out of the individual's home; produces at the individual's home certain non-potentially hazardous foods; has an annual gross income of \$50,000 or less from the sale of foods; sells the foods produced 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 delivers products to the consumer at the point of sale or another location designated by the consumer.

Summary:

The purpose of the amendment is to comply with House Bill 970, 83rd Legislature, Regular Session, 2013, which amends Health and Safety Code, Chapter 437, regarding cottage food production operations.

The proposed amendment:

- Revises definitions for baked good, cottage food production operation, and potentially hazardous food; and adds definitions for farm stand, farmers' market, and pickles.
- Revises labeling and adds packaging requirements in a manner that prevents product contamination, except for foods that are too large or bulky for conventional packaging and this requires the invoice or receipt to provide the labeling information.
- Allows delivery of products to the consumer at the point of sale or another location designated by the consumer.
- Prohibits sales by mail order or wholesale.
- Does not exempt a cottage food production operation from the Health and Safety Code regarding emergency order, recall orders, or delegation of powers or duties.

- Prohibits a cottage food production operation from selling potentially hazardous foods to consumers.
- Requires an individual who operates a cottage food production operation to successfully complete a basic food safety education or training program for food handlers accredited under the Health and Safety Code, Chapter 438, Subchapter D.

Key Health Measures:

The Group will collect and analyze data about the number of complaints received and process data from stakeholders related to cottage food production operations, as well as monitor and investigate food-borne illness outbreaks.

During fiscal years 2012 and 2013, the Group received a total of 25 complaints related to cottage food production operations. These complaints included allegations regarding individuals selling products via the Internet, foods purchased that were contaminated, selling potentially hazardous foods, and the delivery of food.

Summary of Input from Stakeholder Groups:

Stakeholder input has been solicited by posting the draft of the proposed rule on the program’s website at www.dshs.state.tx.us/foode establishments, making notification of its availability by using emails, and distributing the draft and the proposed rule to DSHS staff. No written comments have been received at this time; however, phone calls from industry and regulatory representatives have been received, mostly asking for clarification as to what types of products can be produced at cottage food production operations and locations where the foods produced are allowed to be sold.

Proposed Motion:

Motion to recommend HHSC approval for publication of rules contained in agenda item #4.g.

Approved by Assistant Commissioner/Director:	Kathryn C. Perkins, R.N., M.B.A.	Date:	10/31/2013
Presenter:	Cheryl Wilson	Program:	Public Sanitation & Retail Foods Safety Group
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Approved by CCEA:	Carolyn Bivens	Date:	10/31/2013

Title 25. Health Services
Part 1. Department of State Health Services
Chapter 229. Food and Drug
Subchapter EE. Cottage Food Production Operation
Amendments §229.661

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission on behalf of the Department of State Health Services (department), proposes an amendment to §229.661 concerning cottage food production operations.

BACKGROUND AND PURPOSE

The proposed amendment to §229.661 implements House Bill (HB) 970, 83rd Legislature, Regular Session, 2013. HB 970 amends Health and Safety Code, Chapter 437 relating to cottage food production operations. HB 970 added and revised definitions, expanded the types of foods that a cottage food production operation may produce, identified locations where cottage foods may be sold, clarified packaging and labeling requirements, prohibited sales by mail or at wholesale, and required a cottage food production operator to complete basic food safety training.

A cottage food production operation is an individual who operates out of the individual's home; produces at the individual's home certain non-potentially hazardous foods; has an annual gross income of \$50,000 or less from the sale of foods; sells the foods produced 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 delivers products to the consumer at the point of sale or another location designated by the consumer.

SECTION-BY-SECTION SUMMARY

Section 229.661(b)(1) revises the definition for baked good by deleting the statement, "A baked good does not include a potentially hazardous food item as defined by department rule."

Section 229.661(b)(2)(A) revises the definition for cottage food production operation by expanding the foods that may be produced to include candy; coated and uncoated nuts; unroasted nut butters; fruit butters, fruit pie, dehydrated fruit or vegetables, including dried beans; popcorn and popcorn snacks; cereal, including granola; dry mix; vinegar; pickles; mustard; roasted coffee or dry tea; and dried herbs or dried herb mix; and deletes the phrase "for sale at the person's home."

Section 229.661(b)(2)(C) allows cottage food to be sold from an individual's home; a farmers' market; a farm stand; a municipal fair, festival or event; a county fair, festival or event; or a nonprofit fair, festival or event.

Section 229.661(b)(2)(D) allows cottage foods to be delivered to the consumer at the point of sale or another location designated by the consumer.

Section 229.661(b)(5) adds a new definition for “farm stand.”

Section 229.661(b)(6) adds a new definition for “farmers’ market.”

Section 229.661(b)(10) adds a new definition for “pickles.”

Section 229.661(b)(11) revises the definition for potentially hazardous food with the definition in HB 970.

Section 229.661(d) adds packaging to the labeling requirements to require all cottage foods to be packaged and labeled in a manner that prevents product contamination, except when food is too large or bulky for conventional packaging.

Section 229.661(e) is amended to prohibit the sale of cottage foods by mail and wholesale.

The new §229.661(f) clarifies that a cottage food production operation is not exempt from meeting the application of Health and Safety Code, §431.045 - Emergency Order, §431.0495 - Recall Orders, and §431.247 - Delegation of Powers or Duties. The department or local health authority may act to prevent an immediate and serious threat to human life or health.

The new §229.661(g) prohibits a cottage food production operation from selling potentially hazardous foods.

The new §229.661(h) requires an individual who operates a cottage food production operation to complete a basic food safety education or training program for food handlers accredited under Health and Safety Code, Chapter 438, Subchapter D.

FISCAL NOTE

John Huss, Section Director, Environmental and Consumer Safety Section, has determined that for each year of the first five years that the section will be in effect, there will be no fiscal implications to state or local governments as a result of enforcing and administering the sections as proposed.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Mr. Huss has also determined that there will be no adverse economic impact on small businesses or micro-businesses required to comply with the section as proposed. This is determined by interpretation of the rule that small businesses and micro-businesses will not be required to alter their business practices in order to comply with the section.

ECONOMIC COSTS TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

There are no anticipated economic costs to persons who are required to comply with the section as proposed. There is no anticipated negative impact on local employment.

PUBLIC BENEFIT

In addition, Mr. Huss has also determined that for each year of the first five years the section is in effect, the public will benefit from adoption of the section. The public benefit anticipated as the result of administering these section is to ensure the public is aware that food produced by a cottage food production operation is not inspected by the department or a local health department. The public will also be aware that an individual who operates a cottage food production operation must have successfully completed a basic food safety education or training program.

REGULATORY ANALYSIS

The department has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state.

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposed amendment does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposed amendment may be submitted to Cheryl Wilson, Public Sanitation and Retail Food Safety Group, Policy, Standards and Quality Assurance Unit, Division of Regulatory Services, Environmental and Consumer Safety Section, Department of State Health Services, Mail Code 1987, P. O. Box 149347, Austin, Texas 78714-9347, (512) 834-6770, extension 2053, or by email to Cheryl.Wilson@dshs.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

PUBLIC HEARING

A public hearing to receive comments on the proposal will be scheduled after publication in the *Texas Register* and will be held at the Department of State Health Services, Exchange Building, 8407 Wall Street, Austin, Texas 78754. The meeting date will be posted on the Food Establishments Group website at www.dshs.state.tx.us/foodestablishments. Please contact Cheryl Wilson at (512) 834-6770, extension 2053, or Cheryl.Wilson@dshs.state.tx.us if you have questions.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the proposed rule has been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The amended rule is authorized under the Health and Safety Code, §437.0193, which provides the Executive Commissioner of the Health and Human Services Commission with authority to adopt rules and guidelines relating to labeling requirements for cottage food production operations; Health and Safety Code, §438.042, which requires the department to adopt standards for accreditation of education and training programs for persons employed in the food service industry; and Government Code, §531.0055(e), and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001.

The amendment affects Government Code, Chapter 531; and Health and Safety Code, Chapters 437, 438, and 1001.

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) (No change.)

(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:

(i) a baked good that is not a potentially hazardous food, as defined in paragraph (11) of this subsection: [;]

(ii) candy;

(iii) coated and uncoated nuts;

(iv) unroasted nut butters;

(v) fruit butters;

(vi) a canned jam or jelly; [, or]

(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, as defined in paragraph (10) of this subsection;

(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 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; a municipal, fair, festival, or event; a county fair, festival, or event; or a 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) - (4) (No change.)

(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 in paragraph (2) of this subsection.

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

(7) [(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; 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.

(8) [(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.

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

(10) Pickle--A cucumber preserved in vinegar, brine, or similar solution, and excluding all other pickled vegetables.

(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.

[(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) (No change.)

(d) Packaging and labeling [**Labeling**] requirements for cottage food production operations. All foods prepared by a cottage food production operation shall [**must**] be packaged and labeled in a manner that prevents product contamination.

(1) - (2) (No change.)

(3) A food item is not required to be packaged if it is too large or bulky for conventional packaging. For these food items, the information required under paragraph (1) of this subsection shall be provided to the consumer on an invoice or receipt.

(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 this section [**these rules**] through the Internet, by mail order, or at wholesale. No health claims may

be made on any of the advertising media [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, §431.045, Emergency Order; § 431.0495, Recall Orders; and §431.247, Delegation of Powers or Duties. 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 Health and Safety Code, Chapter 438, Subchapter D.

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

(A) meets the requirements of paragraph (1) of this subsection;

(B) is directly supervised by an individual described by paragraph (1) of this subsection; 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]