

MARYLAND REGISTER

Proposed Action on Regulations

Comparison to Federal Standards Submission and Response

Name: Michele Phinney
Agency: Department of Health and Mental Hygiene
Address: 201 W. Preston Street
State: MD
Zip: 21201
Phone: 410-767-5623
Email: michele.phinney@maryland.gov

In accordance with Executive Order 01.01.1996.03 and memo dated July 26, 1996, the attached document is submitted to the Department of Business and Economic Development for review.

The Proposed Action is not more restrictive or stringent than corresponding federal standards.

COMAR Codification: 10.07.04.11

COMAR Codification: 10.15.01.02, .05-10

COMAR Codification: 10.15.02.11 and .15

COMAR Codification: 10.15.03.02, .04, .10, .11, .27 and .32

COMAR Codification: 10.15.04.02, .03, .09, .13-.16, .18 and .28

Corresponding Federal Standard:

The corresponding federal standards are: (1) 21 CFR 113 Thermally Processed Low Acid Foods Packaged in Hermetically Sealed Containers; and (2) 21 CFR 114 Acidified Foods.

Discussion/Justification:

The proposed changes simply update the regulations and would still be governed by 21 CFR 113 and 21 CFR 114 at the federal level. There is no need or requirement for Maryland to promulgate regulations more stringent than these federal standards.

TO BE COMPLETED BY DBED

Agree

Disagree

Comments:

Commerce believes DHMH has appropriate subject matter expertise and trusts their assertion that the regulation is not more stringent or restrictive than corresponding federal standards.

Name: Sandy Popp

Date: 10/13/2015

Submit to Governor's Office

Governor's Office Response

Comments:

Transmittal Sheet PROPOSED OR REPROPOSED Actions on Regulations	Date Filed with AELR Committee	TO BE COMPLETED BY DSD
	10/13/2015	Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

1. Desired date of publication in Maryland Register: 11/30/2015

2. COMAR Codification

Title	Subtitle	Chapter	Regulation
10	07	04	11
10	15	01	02, .05-10
10	15	02	11 and .15
10	15	03	02, .04, .10, .11, .27 and .32
10	15	04	02, .03, .09, .13-.16, .18 and .28

3. Name of Promulgating Authority

Department of Health and Mental Hygiene

4. Name of Regulations Coordinator **Telephone Number**
Michele Phinney 410-767-5623

Mailing Address

201 W. Preston Street

City **State** **Zip Code**
Baltimore MD 21201

Email
michele.phinney@maryland.gov

Secretary

410-767-6500

Date

October 13, 2015

Title 10
DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 07 HOSPITALS

10.07.04 Related Institutions — Residential Treatment Centers for Emotionally Disturbed Children and Adolescents

Subtitle 15 FOOD

10.15.01 [Canning] Low Acid and Acidified Food [Manufacturing] Canning

Subtitle 15 FOOD

10.15.02 Crab Meat

Subtitle 15 FOOD

10.15.03 Food Service Facilities

Subtitle 15 FOOD

10.15.04 Food and Drink Processing and Transportation

Authority: See proposal.

Notice of Proposed Action

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The Secretary of Health and Mental Hygiene proposes to :

(1) Amend Regulation .11 under COMAR 10.07.04 Related Institutions — Residential Treatment Centers for Emotionally Disturbed Children and Adolescents;

(2) Amend Regulations .00, .02, .05—.10 and repeal Regulation .08 under COMAR 10.15.01 Low Acid and Acidified Food Canning;

(3) Amend Regulations .11 and .15 under COMAR 10.15.02 Crab Meat;

(4) Amend Regulations .02, .04, .10—.11, .27, and .32 under COMAR 10.15.03 Food Service Facilities; and

(5) Amend Regulations .02, .03, .09, .13—.16, .18, and .28 under COMAR 10.15.04 Food and Drink Processing and Transportation.

Statement of Purpose

The purpose of this action is to :

- (1) Under COMAR 10.07.04 – update reference to COMAR 10.15.03;
- (2) Under COMAR 10.15.01 – rename the regulation, clarify which canning operations must comply with this chapter, provide additional guidance on canning processing, and repeal Regulation .08 because acid foods do not require scheduled processes;
- (3) Under COMAR 10.15.02 – amend to be consistent with current crabmeat sampling practices;
- (4) Under COMAR 10.15.03 – update certain definitions, amend information recorded on certain shellfish tags, update information on preparation for cooking and the cooling and reheating of potentially hazardous foods, clarify language about the processing and packaging of cottage food businesses products, and amend the list of required postings in food service facilities;
- (5) Update COMAR 10.15.04 – exclude warehouses that store only bottled water or packaged ice from the definition of a food processing plant, specify which firms are considered to be food transfer stations, clarify the requirement for continuous recording thermometers, remove the freezer temperature requirement to be consistent with COMAR 10.15.03 and federal regulations, and clarify that acidified foods are allowed to be processed in an on-farm home kitchen; and
- (6) Revise certain stylistic errors.

Comparison to Federal Standards

There is a corresponding federal standard to this proposed action, but the proposed action is not more restrictive or stringent.

Estimate of Economic Impact

The proposed action has no economic impact.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499; TTY:800-735-2258, or email to dhmh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through December 30, 2015. A public hearing has not been scheduled.

Economic Impact Statement Part C

A. Fiscal Year in which regulations will become effective: FY 2016

B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?

C. If 'yes', state whether general, special (exact name), or federal funds will be used:

D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:

E. If these regulations have no economic impact under Part A, indicate reason briefly:

The proposed action will have no economic impact because the proposed changes update the regulations to align with current practice. The regulated industry has already implemented the changes included in this proposal.

F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.

The proposed changes are clarifying in nature and align regulations with current practice. Therefore, this proposal will not result in an economic impact on food processing plants that are small businesses.

G. Small Business Worksheet:

Attached Document:

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 07 HOSPITALS

10.07.04 Related Institutions — Residential Treatment Centers for Emotionally Disturbed Children and Adolescents

Authority: Health-General Article, §19-308, Annotated Code of Maryland

10.07.04.11 (downloaded 5/28/15)

.11 Food Services.

A. (text unchanged)

B. Sanitation and Personal Hygiene. All applicable requirements of COMAR 10.15.03 ["Regulations Governing Eating and Drinking Establishments,"] shall be observed.

Subtitle 15 FOOD

10.15.01 [Canning] *Low Acid and Acidified Food* [Manufacturing] *Canning*

Authority: Health-General Article, §§18-102, 21-211, 21-234, 21-304, 21-321, 21-340, and 21-350, Annotated Code of Maryland

10.15.01.02 (downloaded 6/24/14)

.02 Definitions.

- A. (text unchanged)
- B. Terms Defined.
 - (1) (text unchanged)
 - (2) Acidified Foods.
 - (a) "Acidified foods" means low-acid foods to which acid or acids or acid food or acid foods are added and that have a:
 - (i) Water activity (aw) greater than 0.85[.]; and
 - (ii) Finished equilibrium pH of 4.6 or below[.].
 - (b) "Acidified foods" includes, but is not limited to:
 - (i) Beans, cucumbers, cabbage, artichokes, cauliflower, puddings, peppers, tropical fruits, and fish, singly or in combination[.]; and
 - (ii) Foods that are called, or may purport to be, "pickles" or "pickled"[.].
 - (c) "Acidified foods" does not include:
 - (i) Carbonated beverages, jams, jellies, or preserves[.];
 - (ii) Acid foods that contain small amounts of low-acid food or foods and have a resultant finished equilibrium pH that does not significantly differ from that of the predominate acid or acid food, including such foods as standardized and nonstandardized food dressings and condiment sauces[.]; and
 - (iii) (text unchanged)
 - (3) (text unchanged)
 - (4) "Commercially sterile" means the condition achieved by the:
 - (a) Application of heat that renders the food free of:
 - (i) Microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution[.]; and
 - (ii) (text unchanged)
 - (b) (text unchanged)
 - (5)—(10) (text unchanged)
 - (11) "Scheduled process" means the process selected by the processor as adequate under the conditions of manufacture that:
 - (a) (text unchanged)
 - (b) For thermally processed low-acid foods packaged in hermetically sealed containers:
 - (i) Achieves a commercially sterile product[.]; and
 - (ii) (text unchanged)
 - (c) For acidified foods:
 - (i) Achieves and maintains a food that will not permit the growth of microorganisms that cause disease[.]; and
 - (ii) (text unchanged)
 - (d) For thermally processed acid foods packaged in hermetically sealed containers:
 - (i) Achieves a commercially sterile product[.]; or
 - (ii) (text unchanged)
 - (12)—(13) (text unchanged)

.05 Plant Facilities and Operations.

- A. (text unchanged)
- B. The person-in-charge shall ensure that:
 - (1)—(3) (text unchanged)
 - (4) Food contact surfaces are effectively cleaned and sanitized:
 - (a) (text unchanged)
 - (b) At a minimum:
 - (i) Following processing[.];
 - (ii) Between an interruption in processing of greater than 2 hours[.]; and
 - (iii) (text unchanged)
 - (5) (text unchanged)
 - (6) Non-food contact surfaces that:
 - (a) Receive splash or waste are cleaned and sanitized:

- (i) As necessary to maintain a sanitary condition[.]; and
- (ii) (text unchanged)
- (b) (text unchanged)
- (7)—(9) (text unchanged)

.06 Equipment.

The person-in-charge shall ensure that:

- A. Processing equipment used to heat or cool food in hermetically sealed containers is:
 - (1) Designed to provide even and adequate processing[.];
 - (2) Provided adequate instrumentation and recording devices to allow process control, monitoring, and verification[.];
 - (3) Durable and impervious to water[.];
 - (4) Maintained in a sanitary and working condition[.];
 - (5) Monitored to verify that process requirements are met[.]; and
 - (6) (text unchanged)
- B. Food equipment other than that used for heating and cooling food in hermetically sealed containers is:
 - (1) Non-toxic and does not impart any toxic or deleterious matter to the food[.];
 - (2) Corrosion resistant[.];
 - (3) Durable[.];
 - (4) Impervious[.]; and
 - (5) (text unchanged)
- C.—D. (text unchanged)

.07 Manufacturing Practices for Low-Acid Food [Canning] and Acidified Food [Processing] Canning.

The person-in-charge shall ensure that:

- A. Low-acid foods are processed and labeled in accordance with 21 CFR 113; [and]
- B. Acidified foods are processed and labeled in accordance with 21 CFR 114[.];
- C. *When canning is taking place, a scheduled process is used that takes into account the critical factors and limits that are likely to influence the food's safety, stability, or shelf life, such as:*
 - (1) *Food characteristics;*
 - (2) *Spoilage organisms;*
 - (3) *Time and temperature of thermal process;*
 - (4) *Cooling parameters;*
 - (5) *Acidification;*
 - (6) *Storage conditions;*
 - (7) *Design and performance of the processing equipment; and*
 - (8) *Batch size and configuration;*
- D. *Before a food processing plant processes food in a closed vessel, such as a retort or steam cabinet, a process authority performs a thermal process validation study that includes:*
 - (1) *Heat penetration tests;*
 - (2) *Heat distribution tests;*
 - (3) *Cooling parameters; and*
 - (4) *Any other measurements, observations, or calculations needed to ensure that the process is effective and reliable;*
- E. *The scheduled thermal process and validation study are re-established each time there is a change in the processing system; and*
- F. *All thermal processes and validation studies being used are available for inspection by the Department.*

.08 Manufacturing Practices for Acid Food Canning.

The person-in-charge shall ensure that:

- A.—B. (text unchanged)
- C. The scheduled process takes into account the critical factors and limits that are likely to influence the food's safety, stability, or shelf life, such as:
 - (1) Food characteristics[.];
 - (2) Spoilage organisms[.];
 - (3) Time and temperature of thermal process[.];
 - (4) Cooling parameters[.];
 - (5) Acidification[.];
 - (6) Storage conditions[.];
 - (7) Design and performance of the processing equipment[.];
 - (8) Initial food temperature[.];
 - (9) Food temperature at filling[.]; and
 - (10) (text unchanged)

- D. (text unchanged)
- E. A thermal process validation study includes:
 - (1) Heat penetration tests[.];
 - (2) Heat distribution tests[.];
 - (3) Cooling parameters[.]; and
 - (4) (text unchanged)
- F.—H. (text unchanged)

.09 Process Controls in *Low Acid and Acidified Food Canning.*

- The person-in-charge shall ensure that:
- A. (text unchanged)
 - B. The cook time, cook temperatures, and pH of each batch of canned [acid] food are measured and recorded;
 - C. Through strict processing criteria, monitoring, record keeping, and corrective action, a container of food processed as an [acid] *acidified* food is not distributed if the final pH measurement of the food is greater than 4.6 (4.7 for tomatoes and tomato products) when the food's water activity is greater than 0.85;
 - D. (text unchanged)
 - E. When a deviation from the scheduled process occurs:
 - (1) The food manufactured during the deviation is:
 - (a) Held for evaluation by a process authority[.]; and
 - (b) (text unchanged)
 - (2) (text unchanged)
 - F.—G. (text unchanged)

.10 Labeling and Marking of Containers.

- The person-in-charge shall ensure that:
- A.—B. (text unchanged)
 - C. A container of canned [food] *low acid* or acidified food is marked with a permanently visible identifying code that is:
 - (1)—(2) (text unchanged)
 - D. The identifying code required in §C of this regulation:
 - (1) Specifies the following:
 - (a) The establishment where the product was packed[.];
 - (b) The product contained in the container[.]; and
 - (c) (text unchanged)
 - (2) Is changed:
 - (a) Every 4 to 5 hours[.];
 - (b) With a personnel shift change[.];
 - (c) With each batch, as long as the containers that constitute a batch do not extend over a period of more than one personnel shift[.]; or
 - (d) (text unchanged)
 - [E. A container of canned acid food that has not been processed for commercial sterility is prominently and conspicuously marked with a use-by date established by a shelf life study;
 - [F.] E.—[G.] F. (text unchanged)

10.15.02 Crab Meat

Authority: Health-General Article, §§18-102, 21-211, 21-234, 21-304, 21-321, 21-339, 21-340, and 21-350, Annotated Code of Maryland

10.15.02.11 (downloaded 6/24/14)

.11 Unit Processing Operations — Repacking.

- The person-in-charge shall ensure that:
- A. (text unchanged)
 - B. Repacking does not occur except when written approval for the repacking is given by the Department, based on a review of a written proposal plan to repack that complies with this chapter, and includes the:
 - (1) Information in Regulation .10G of this chapter; [and]
 - (2)—(3) (text unchanged)
 - C.—K. (text unchanged)

.15 Bacteriological Standards.

- A.—B. (text unchanged)
- C. (text unchanged)
 - (1) Generic *Escherichia coli* may not exceed a Most Probable Number of [36 per 100 grams] *0.36 per gram* of fresh crabmeat;

(2)—(3) (text unchanged)

D. (text unchanged)

[E. The Department shall construe numbers of bacteria in excess of the standards set forth in this regulation as rendering the product adulterated, pursuant to Health-General Article, §21-207, Annotated Code of Maryland, and unfit for human consumption.]

10.15.03 Food Service Facilities

Authority: Health-General Article, §§21-101, 21-102, 21-211, 21-234, 21-301, 21-304, 21-309.2, and 21-330.1 Annotated Code of Maryland

10.15.03.02 (downloaded 6/24/14)

.02 Definitions.

A. (text unchanged)

B. Terms Defined.

(1)—(17) (text unchanged)

(17-1) "Cottage food business" means a business that:

(a) Produces or packages cottage food products in a residential kitchen *in Maryland*; and

(b) (text unchanged)

(17-2) "Cottage food product" means [a]:

(a) A non-potentially hazardous food as specified in Regulation .27 of this chapter that is offered for sale only at a farmer's market or public event; *and*

(b) A food that is not offered for sale through internet sales or interstate commerce.

(18)—(86) (text unchanged)

.04 Food Supplies and Sources: General.

The person-in-charge shall ensure that:

A.—D. (text unchanged)

E. Shellfish:

(1) (text unchanged)

(2) [When received through interstate commerce, are] *Are* from a firm listed in the "Interstate Certified Shellfish Shippers List";

(3)—(4) (text unchanged)

(5) Tags are maintained on the premises for 90 *calendar* days after a container of [unshucked] shellfish is emptied to identify readily the source of the shellfish, *by*:

(a) *Recording the date on the tag or label when the last shellfish from the container is sold or served;*

(b) *Using an approved record keeping system that:*

(i) *Keeps the tags or labels in chronological order; and*

(ii) *Preserves source identification if tags or labels are removed from the container; and*

(c) *Ensuring that shellfish from one tagged or labeled container is not mixed with shellfish from another container if the tags or labels are removed from the container.*

F.—I. (text unchanged)

.10 Food Preparation — Cooking.

A. Except as provided in §§B—D of this regulation, the person-in-charge shall ensure that potentially hazardous food is cooked to the minimum internal temperature and for the specified holding time as follows:

(1) Chart 1. Summary of Minimum Cooking and Reheating Food Temperatures and Holding Times.

Food	Minimum Internal Temperature		Holding Time at Specified Temperature
	°F	°C	
Shell eggs — Raw foods	(text unchanged)		
Fruits and vegetables [and ready-to-eat commercially processed foods] cooked for hot holding.	135	57	None
Ready-to-eat commercially processed foods for immediate service.	(text unchanged)		

(2)—(6) (text unchanged)

(7) A minimum internal temperature of 135°F for fruits and vegetables [and ready-to-eat commercially processed foods] cooked for hot holding.

B.—F. text unchanged

.11 Food Preparation — Cooling and Reheating of Potentially Hazardous Foods.

The person-in-charge shall ensure that:

A.—B. (text unchanged)

- C. Potentially hazardous food is reheated:
 - (1) (text unchanged)
 - (2) [To] *Within 2 hours* to a minimum internal temperature of 135°F [for 15 seconds] for ready-to-eat food taken from a commercially processed, hermetically sealed container or from an intact package from a food processing plant that is inspected by a food regulatory authority for hot holding;
 - (3)—(4) (text unchanged)

.27 Farmer's Market, Bake Sales, and Cottage Food Business.

- A.—B. (text unchanged)
- C. Cottage Food Business.
 - (1) The approving authority shall allow the owner of a cottage food business to sell only cottage food products *processed and packaged in Maryland* that are:
 - (a)—(c) (text unchanged)
 - (2)—(4) (text unchanged)
 - D. (text unchanged)

.32 [Choking Posters] Required Postings.

- The person-in-charge shall ensure that a food service facility [that]:
- A. *That* prepares food and provides seating for patrons posts a diagram on the use of manual maneuvers to prevent asphyxiation due to choking, in accordance with Health-General Article, §21-326, Annotated Code of Maryland; and
 - B. *Displays prominently in the staff area of the food establishment a poster related to food allergy awareness that includes information regarding the risk of an allergic reaction, in accordance with Health-General Article, §21-330.2(a), Annotated Code of Maryland.*

10.15.04 Food and Drink Processing and Transportation

Authority: Health-General Article, §§18-102, 21-101, 21-102, 21-211, 21-234, 21-301, 21-304, 21-308, 21-309.1, 21-309.2, and 21-336; Agriculture Article, §4-311; Annotated Code of Maryland

10.15.04.02 (downloaded 6/24/14)

.02 Definitions.

- A. (text unchanged)
- B. Terms Defined.
 - (1)—(13) (text unchanged)
 - (14) Food Processing Plant.
 - (a)—(b) (text unchanged)
 - (c) "Food processing plant" does not include a warehouse or distribution center that:
 - (i) (text unchanged)
 - (ii) Stores only sealed containers of *water, ice, whole bean, ground or instant coffee, leaf or instant teas, nondairy dehydrated whiteners, sugar, or sugar-free sweeteners.*
 - (15) "Food transfer station" means a food processing plant where:
 - (a) (text unchanged)
 - (b) [The food transfer is not direct but rather involves food sorting or storage] *There is an area maintained for food storage.*
 - (16) (text unchanged)
 - (17) "HACCP plan" means a Hazard Analysis Critical Control Point (HACCP) as specified by:
 - (a)—(c) (text unchanged)
 - [(c)] (d) The National Advisory Committee on the Microbiological Criteria for Food.
 - (18)—(34) (text unchanged)

.03 Incorporation by Reference.

- A. (text unchanged)
- B. Documents Incorporated.
 - (1)—(2) (text unchanged)
 - (3) 21 U.S.C. §343, as amended;
 - (4)—(5) (text unchanged)

.09 Plant and Facilities — Design and Construction.

- A.—C. (text unchanged)
- D. The person-in-charge shall ensure that, except as provided for in Regulation [.18C(1)] *I&B(I)* of this chapter and §§L and N of this regulation, a room or area in which food is processed or stored or in which utensils or equipment are cleaned, sanitized, or kept:
 - (1)—(8) (text unchanged)
- E.—N. (text unchanged)

.13 Unit Processing Operations — Storage and Transportation.

- A. The person-in-charge shall ensure that:
- (1)—(6) (text unchanged)
 - (7) A [refrigerated room and a refrigerated area of a vehicle] *refrigerator or freezer unit* used to store or transport food is:
 - (a)—(f) (text unchanged)
 - (g) Except as provided in §B of this regulation, when monitoring and verifying temperature at a critical control point, provided one or more recording thermometers that:
 - (i)—(iii) (text unchanged)
 - (iv) Are calibrated in accordance with Regulation [15P] .14Q of this chapter;
 - [(8) When a freezer used to store or transport frozen food:
 - (a) Provided a recording thermometer, datalogger, or similar device in accordance with §A(7)(g) of this regulation; and
 - (b) Maintained at an air temperature of 0°F or below except during cycles for defrosting;]
 - [(9)] (8)—[(13)] (12) (text unchanged)
- B. (text unchanged)

.14 Unit Processing Operations — Processing Food for Safety and Shelf Life.

- The person-in-charge shall ensure that:
- A. (text unchanged)
 - B. The thermal processing of food:
 - (1)—(2) (text unchanged)
 - (3) For a commercially sterile product, produces the condition set forth in Regulation [.02B (4)] .02B(5) of this chapter;
 - C.—Q. (text unchanged)

.15 Unit Processing Operations — Packaging Food.

- The person-in-charge shall ensure that:
- A. Food packaging is:
 - (1)—(3) (text unchanged)
 - (4) *Stored so that it is protected from contamination; and*
 - (5) *Not reused if intended for single-service;*
 - B.—C. (text unchanged)
 - D. Food packaging allows the labeling of the food with the information set forth in Regulation [.17] .16 of this chapter; and
 - E. (text unchanged)

.16 Unit Processing Operations — Food Labeling.

- A. The person-in-charge shall ensure that:
- (1) Except as provided in §B of this regulation, or as otherwise stipulated in COMAR 10.15.01, 10.15.02, 10.15.04, 10.15.07, or [10.1510]10.15.10 food labeling is accomplished by:
 - (a)—(b) (text unchanged)
 - (2) Except as provided in §B of this regulation, the following information is provided on a label of food in packaged form:
 - (a)—(b) (text unchanged)
 - (c) Name and address of the manufacturer or distributor with:
 - (i) The full street address including the zip code if the manufacturer or distributor is not listed [in] on a *website*, current city directory or telephone directory; or
 - (ii) A minimum of the town and zip code if the manufacturer or distributor is listed [in] on a *website*, current city directory or telephone directory;
 - (d)—(j) (text unchanged)
 - (k) A "sell by" date if the package contains a potentially hazardous food that is:
 - (i) (text unchanged)
 - (ii) A bakery product manufactured, packaged, and labeled as set forth in Regulation [.14O] .14P of this chapter;
 - (l)—(q) (text unchanged)
 - (3)—(8) (text unchanged)
- B.—C. (text unchanged)

.18 On-Farm Home Processing.

- A. (text unchanged)

[B. In addition to the training required in Regulation .06H of this chapter, before an individual may be licensed as set forth in §A of this regulation, the individual shall complete a course given or approved by the Department that provides a minimum of 8 hours of training in:

- (1) Sanitation;
- (2) Cross-contamination controls; and
- (3) Food security.

C. While operating with a license issued in accordance with §A of this regulation, the person-in-charge:

- (1) Shall comply with this chapter except for:
 - (a) Regulation .09D(2)(b), (4), and (5) of this chapter;
 - (b) Regulation .09K of this chapter; and
 - (c) Regulation .11B(1), (3), and (4) of this chapter;]

B. While operating with a license issued in accordance with §A of this regulation, the person-in-charge shall:

- (1) Comply with this chapter except for:
 - (a) Regulation .09D(2)(b),(4), and (5) of this chapter;
 - (b) Regulation .09E, F, G, I(1)-(2), and K of this chapter; and
 - (c) Regulation .11B(1),(3), and (4) of this chapter;

(2) Limit processed food production to:

(a) An amount of food that can safely be produced in the domestic kitchen as evidenced by sanitation, process, and cross-contamination control; and

(b) \$40,000 of sales;

(3) Process commercially only during times when the kitchen is not being used for domestic purposes;

(4) Clean and sanitize all food contact surfaces, equipment, and utensils, immediately before and after processing commercially;

(5) While processing commercially:

(a) Use only building areas, equipment, and utensils that the Department has reviewed or inspected and approved; and

(b) Remove all animals and individuals not involved in food processing from the kitchen; and

(6) Store ingredients for commercial manufacturing and finished manufactured food in a separate area from foods used domestically.

[(2)] C. Except as provided in [§D(1) and (2)] §E and F of this regulation, shall manufacture and process only [non-potentially hazardous foods such as]:

[(a)] (1)—[(d)] (4) (text unchanged)

[(e)] (5) Honey and herb mixtures; [and]

[(f)] (6) Dried fruit and vegetables; and

(7) Acidified foods;

[(3)] D. [May] An individual licensed in accordance with this regulation may not process:

[(a)] (1)—[(b)] (2) (text unchanged)

[(c)] (3) Except as provided in [§D(2)] E(4) of this regulation, seafood;

[(d)] (4)—[(e)] (5) (text unchanged)

[(f)] (6) A frozen dessert as defined in Health-General Article, §21-801(b), Annotated Code of Maryland [;].

[(4)] Shall process food in accordance with manufacturing procedures and standard processes as set forth in Regulation .07 of this chapter;

(5) Shall limit processed food production to:

(a) An amount of food that can safely be produced in the domestic kitchen as evidenced by sanitation and process and cross-contamination control; and

(b) \$40,000 of sales;

(6) Shall process commercially only during times when the kitchen is not being used for domestic purposes;

(7) Immediately before and after processing commercially, shall clean and sanitize all food contact surfaces, equipment, and utensils;

(8) While processing commercially, shall:

(a) Use only building areas, equipment, and utensils that the Department has reviewed or inspected and approved; and

(b) Exclude pets and other animals and individuals not involved in the manufacturing from the kitchen; and

(9) Shall store ingredients for commercial manufacturing and finished manufactured food in a separate area from foods used domestically.]

[D.] E.—[H.] I. (text unchanged)

.28 Federal Compliance.

In addition to the other requirements set forth in this chapter, the person in charge shall ensure that the food processing plant meets all of the requirements applicable to food sources, storage, and preparation that are set forth at:

A.—B. (text unchanged)

C. 21 U.S.C. §343, as amended;

D.—E. (text unchanged)

VAN T.MITCHELL

Secretary of Health and Mental Hygiene