

**Maryland General Assembly
Department of Legislative Services**

**Proposed Regulations
Department of Health and Mental Hygiene
(DLS Control No. 15-298)**

Overview and Legal and Fiscal Impact

The regulations update food safety standards related to low acid and acidified food canning, crab meat, food service facilities, and food and drink processing and transportation.

The regulations present no legal issues of concern.

There is no fiscal impact on State or local agencies.

Regulations of COMAR Affected

Department of Health and Mental Hygiene:

Hospitals: Related Institutions – Residential Treatment Centers for Emotionally Disturbed

Children and Adolescents: COMAR 10.07.04.11

Food: Low Acid and Acidified Food Canning: COMAR 10.15.01.02 and .05-.10

Crab Meat: COMAR 10.15.02.11 and .15

Food Service Facilities: COMAR 10.15.03.02, .04, .10, .11, .27, and .32

Food and Drink Processing and Transportation:

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

Legal Analysis

Background

The regulations are a result of a review of food regulations by the Department of Health and Mental Hygiene’s Office of Food Protection. The office regularly reviews food regulations to stay current with food safety standards.

Summary of Regulations

The regulations change the title of COMAR 10.15.01 from “Canning and Acidified Food Manufacturing” to “Low Acid and Acidified Food Canning” and make similar conforming changes throughout the chapter. The regulations require the person in charge of manufacturing practices for low-acid food and acidified food canning to ensure that (1) when canning is taking place, a scheduled process is used that takes into account specified critical factors and limits that are likely to influence the food’s safety, stability, or shelf life; (2) before a food processing plant processes food in a closed vessel, a process authority performs a specified thermal process

validation study; (3) the scheduled thermal process and validation study are re-established each time there is a change in the processing system; and (4) all thermal processes and validation studies being used are available to the department. The regulations repeal the chapter on manufacturing processes for acid food canning.

The regulations update COMAR 10.15.02 governing crab meat by repealing the requirement that the department construe numbers of bacteria in excess of the standards set forth in regulations as rendering the product adulterated and unfit for human consumption.

The regulations update COMAR 10.15.03 relating to food service facilities. The regulations alter the definition of “cottage food product” to require that the food is not offered for sale through internet sales or interstate commerce. The regulations require the person-in-charge of a food service facility to maintain tags for shellfish on the premises for 90 calendar days after a container of shellfish is emptied to identify readily the source of the shellfish by (1) recording the date on the tag when the last shellfish from the container is sold or served; (2) using a specified approved record keeping system; and (3) ensuring that shellfish from one tagged container is not mixed with shellfish from another container if the tags are removed from the container. In addition, the regulations repeal the requirement that the person-in-charge ensure that ready-to-eat commercially processed foods are cooked at a minimum internal temperature of 135 degrees Fahrenheit. A person-in-charge is also required to ensure that potentially hazardous food is reheated within two hours to a minimum internal temperature of 135 degrees Fahrenheit for ready-to-eat food taken from certain containers or packaging. The regulations provide that cottage food products sold by a cottage food business must be processed and packaged in Maryland. Finally, the regulations require each food service facility to display prominently in the staff area of the food establishment a specified poster related to food allergy awareness.

COMAR 10.15.04 relates to food and drink processing and transportation. The regulations exclude from the definition of “food processing plant” a warehouse or distribution center that stores only sealed containers of water or ice. The regulations also add to the definition of “food transfer station” a food processing plant where there is an area maintained for food storage. The regulations repeal freezer temperature requirements. In addition, the regulations require food packaging to be stored so that it is protected from contamination and not reused if intended for single-service. The regulations repeal the requirement that an individual complete a specified course given or approved by the department before receiving a food processing plant license. The regulations authorize an individual with a food processing plant license to manufacture and process acidified foods.

Legal Issues

The regulations present no legal issues of concern.

Statutory Authority and Legislative Intent

The department cites § 4-311 of the Agriculture Article and §§ 18-102, 19-308, 21-101, 21-102, 21-211, 21-234, 21-301, 21-304, 21-308, 21-309.1, 21-309.2, 21-321, 21-330.1, 21-336, 21-339, 21-340, and 21-350 of the Health – General Article as statutory authority for the

regulations. More specifically, the regulations are authorized by §§ 18-102, 19-308, 21-211, 21-234, 21-304, 21-308, 21-330.1, 21-340, and 21-350 of the Health – General Article. Section 18-102 authorizes the Secretary of Health and Mental Hygiene to adopt regulations necessary to prevent the spread of an infectious or contagious disease that endangers public health in the State. Section 19-308 requires the Secretary to adopt reasonable regulations that set standards of services for related institutions, including dietary matters. Section 21-211 requires the Secretary to adopt regulations that provide for the issuance of permits to food manufacturers, processors, or packers in any locality if, on investigation, the Secretary makes certain findings. Section 21-234 authorizes the Secretary to adopt regulations to carry out the provisions of the Maryland Food, Drug, and Cosmetic Act. Section 21-304 authorizes the department to adopt regulations necessary to carry out the provisions of the subtitle related to food establishments, while § 21-308 provides that an on-farm home processing facility that obtains an on-farm home processing plant license may manufacture or process only foods provided for in regulations of the department. Section 21-330.1 requires the department to adopt regulations to carry out the section of law related to cottage food businesses. Section 21-340 requires all crab meat sold in the State to comply with standards set by regulations adopted under Title 21, Subtitle 3 of the Health - General Article. Section 21-350 provides that any vehicle that is used to transport, store, or sell shellfish or processed crabs for commercial purposes shall be capable of maintaining the shellfish or processed crabs at a temperature established by the department. The remaining cited authority is not relevant to these regulations.

The relevant cited authority is correct and complete. The regulations comply with the legislative intent of the law.

Technical Corrections and Special Notes

The department has resubmitted the regulations to clarify that COMAR 10.15.01.08 is being repealed. The department made the change after being notified of the omission by legislative counsel.

Fiscal Analysis

There is no fiscal impact on State or local agencies.

Agency Estimate of Projected Fiscal Impact

The department advises that the regulations have no impact on State or local government because the regulations merely clarify and update regulations to reflect current practice. The Department of Legislative Services concurs.

Impact on Budget

There is no impact on the State operating or capital budget.

Agency Estimate of Projected Small Business Impact

The department advises that the regulations have minimal or no economic impact on small businesses in the State. The Department of Legislative Services concurs.

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