

APA-1  
11/96

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control 420 Department or Agency Alabama Department of Public Health

Rule Number 420-3-20-.01

Rule Title General Provisions

       New XXXX Amend        Repeal        Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare or safety? Yes

Is there a reasonable relationship between the state's police power and the protection of the public health, safety or welfare? Yes

Is there another, less restrictive method of regulation available that could adequately protect the public? No

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree? No

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule? n/a

Are all facts of the rulemaking process designed solely for the purpose of and so they have as their primary effect, the protection of the public? Yes

Does the proposed rule have an economic impact? No

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of §41-22-23, Code of Alabama, 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama, 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Reference Service.

Signature of Certifying Officer Fabricio Bine Date 9/18/2014

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FORM APA2  
11/96

**STATE BOARD OF HEALTH  
NOTICE OF INTENDED ACTION**

AGENCY NAME: Alabama Department of Public Health

RULE NUMBER AND TITLE: 420-3-20-.01, General Provisions.  
423-3-20-.02, Adoption by Reference.  
420-3-20-.03, Special Provisions.  
420-3-20-.04, Permits.  
420-3-20-.05, Inspections.  
420-3-20-.06, Examination and Condemnation of Food.  
420-3-20, Appendix A.

INTENDED ACTION: Amend Chapters 420-3-20-.01, 420-3-20-.02, 420-3-20-.03, 420-3-20-.04, 420-3-20-.05, 420-3-20-.06, 420-3-20 Appendix A.

SUBSTANCE OF PROPOSED ACTION: Update Code of Federal Regulations adopted by reference from 2009 version to 2013 version; specify priority levels for inspection and reinspection frequencies.

TIME, PLACE, AND MANNER OF PRESENTING VIEWS: A public hearing will be held at 10:00 a.m. October 28, 2014, at the Alabama Department of Public Health, RSA Tower, Suite 1540, 201 Monroe Street, Montgomery, AL 36104.

FINAL DATE FOR COMMENTS AND COMPLETION OF NOTICE: Written or oral comments will be received until the close of the record at 5:00 p.m. on November 4, 2014. All comments and requests for copies of the proposed amendments should be addressed to the contact person listed below.

CONTACT PERSON AT AGENCY: Ronald Dawsey, Division of Food, Milk, and Lodging, Bureau of Environmental Services, Department of Public Health, 201 Monroe Street, Suite 1250, Montgomery, Alabama 36104. Telephone number (334) 206-5375.

  
Pat Ivie, Agency Secretary

**RULES  
OF  
ALABAMA STATE BOARD OF HEALTH  
BUREAU OF ENVIRONMENTAL SERVICES  
CHAPTER 420-3-20  
FOOD PROCESSING ESTABLISHMENT SANITATION  
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**420-3-20-.01 General Provisions.**

**(1) Purpose.** The criteria in these rules shall apply in determining whether the facilities, methods, practices, and controls used in the manufacture, processing, packing, or holding of food are in conformance with, or are operated or administered in conformity with, good manufacturing practices to assure that food for human consumption is safe and has been prepared, packed, and held under sanitary conditions.

**(2) Statutory Authority.** The State Board of Health is authorized to adopt and promulgate these rules under and by virtue of the authority of Code of Ala. 1975, §§ 22-2-2(6), 22-2-5, and 22-20-5.

**(3) Definitions.** For the purposes of these rules:

(a) **Adulterated Food** means any food that bears or contains any poisonous or deleterious substance which may render it injurious to health; or if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or if it is otherwise defined as adulterated under § 402(A) of the Food, Drug, and Cosmetic Act (21 USC § 342).

(b) **Board** means the Board of Health of the State of Alabama as defined by Code of Ala. 1975, § 22-2-1, or the State Health Officer or his or her designee,

when acting for the Board, or for the purposes of these rules, the Alabama Department of Public Health's Bureau of Environmental Services.

(c) **CFR** means Code of Federal Regulations. Citations in this rule to the CFR refer sequentially to the Title, Part, and Section numbers, such as 21 CFR 110.80 refers to Title 21, Part 110, Section 80.

~~(c) **Critical-Item** means a provision of these rules pertaining to food operations that, if in non-compliance, is more likely than other items to contribute to food contamination or illness. Critical item provisions are listed in Appendix A.~~

(d) **Department** means the Alabama Department of Public Health.

(e) **Employee** means the permit holder, individuals having supervisory or management duties, and any other person working in a food processing establishment.

(f) **Food** means any raw, cooked, or processed edible substance, ice, beverage, or ingredient used or intended for use or for sale, in whole or in part, for human consumption, or chewing gum.

(g) **Food Processing Establishment** means a commercial food processing establishment, plant, or operation that manufactures, packages, labels, or stores food for human consumption and does not provide food directly to a consumer. *The term does not include a food service establishment or a retail food store in which such foods are processed if:*

*i. The food items are sold to, or sold from, no more than two other retail food establishments during the annual period coinciding with the food permit issuance and expiration date, and*

*ii The total value of food sales to other retail establishments during the annual period coinciding with the food permit issuance and expiration date is less than \$25,000.00.*

The term includes stand-alone ice manufacturing facilities- that require servicing by entering (walking inside) the ice manufacturing facility.

(h) **Health Officer** means the Health Officer, or his or her designee, of the county or district in which the food processing establishment in question is located as provided in Code of Ala. 1975, § 22-3-2.

(i) **Label** means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement of these rules that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such article, or is easily legible through the outside container or wrapper.

(i) **Labeling** means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article.

~~(j)~~ (k) **Law** includes federal, state and local statutes, ordinances and rules.

~~(j)~~ (l) **Permit** means the document issued by the Health Officer which authorizes a person to operate a food processing establishment.

~~(k)~~ (m) **Person** includes any individual, partnership, corporation, association, or other legal entity.

~~(l)~~ (n) **Person in Charge** means the individual present in a food processing establishment who is the apparent supervisor of the food processing establishment at the time of inspection. If no individual is the apparent supervisor, then any employee present is the person in charge.

~~(m)~~ (o) **Potentially Hazardous Food** means a food that requires temperature control to limit pathogenic microorganism growth or toxin formation and includes an animal food that is raw or heat-treated; a plant food that is heat-treated or consists of raw seed sprouts, cut melons, or garlic-in-oil mixtures that are not modified in a way that result in mixtures that do not support pathogenic microorganism growth or toxin formation. The term does not include a food that, due to any combination of intrinsic and extrinsic factors, does not support the growth or toxin formation of pathogenic microorganisms.

(p) **Priority Category 1 Food Processing Establishment** means any food processing establishment producing foods that, in final packaged form, do not require refrigeration to prevent growth of pathogenic microorganisms or do not require a specialized process under 21 CFR 113, 114, 120, or 123 for food manufacturing.

(q) **Priority Category 2 Food Processing Establishment** means an establishment which manufactures a food product that:

1. In final packaged form is a potentially hazardous food requiring refrigeration to prevent growth of pathogenic microorganisms, or

2. Includes a specialized process for food manufacturing or production required in 21 CFR Part 113 (thermally processed low acid foods), 21 CFR Part 114 (acidified foods), 21 CFR Part 120 (Hazard Analysis Critical Control Point [HACCP] plan required), or 21 CFR Part 123 (seafood HACCP plan required).

(r) **Priority Item** means a provision of these rules that, if in non-compliance, is likely to be a direct cause of food adulteration, contamination, or illness. Priority item provisions are listed in Appendix A.

~~(n)~~ (s) **Raw Agricultural Commodity** means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing. Fish and fishery products are not to be considered as raw agricultural commodities.

**(4) Exclusions.** Establishments engaged solely in the harvesting, storage, or distribution of one or more raw agricultural commodities, as defined in Rule 420-3-20-.01(03)~~(s)~~ ~~(n)~~, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the public for consumption, are not covered by the provisions of these rules.

**Author:** Ronald Dawsey

**Statutory Authority:** Code of Ala. 1975, §§ 22-2-2(6), 22-20-5.

**History:** Filed March 23, 1984. Repeal and replace filed November 19, 2010; effective date December 24, 2010.