

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-.02

Rule Title Adoption by Reference

       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 Jamie Bue Date 9/18/2014

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**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

**420-3-20-.02 Adoption by Reference**

**(1) Adoption by reference of 21 CFR parts 1 through 100.** The following listed parts of Title 21 Code of Federal Regulations, Parts 1 through 100, ~~2009~~ 2013 Revision, promulgated by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, are hereby incorporated by reference and made a part of these rules as if set out in full and all provisions thereof are adopted as rules of the State Board of Health.

- (a) Parts 1.20 through 1.24 (accurate labeling).
- (b) Parts 7.1 through 7.13 (guaranty).
- (c) Parts ~~7.50~~ 7.40 through 7.59 (recalls).
- (d) Parts 70.20 through 70.25 (packaging and labeling requirements for colors).
- (e) Parts 73.1 through 73.615 (listing of color additives exempt from certification).
- (f) Parts 74.101 through 74.706 (listing of color additives subject to certification).
- (g) Part 81 (general specifications and restrictions for provisional color additives).
- (h) Parts 82.3 through 82.706 (listing of certified provisionally listed colors and specifications).
- (i) Part 100.155 (labeling of iodized salt).

**(2) Adoption by reference of 21 CFR Parts 101 through 190.** Except as excluded in Rule 420-3-20-.02(3), Title 21, Code of Federal Regulations, Parts 101 to 190, ~~2009~~ 2013 Revision, promulgated by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, is hereby incorporated by reference and made a part of these rules as if set out in full and all provisions thereof are adopted as rules of the State Board of Health.

**(3) Exclusion.** This adoption by reference of Title 21, Code of Federal Regulations, Chapter 1, Subchapter B, Parts 101 to 190, ~~2009~~ 2013 Revision, promulgated by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, specifically excludes these parts:

- (a) Part 101.69 (refers to application to FDA for nutrient labeling).
- (b) Part 101.108 (refers to FDA food labeling experiments).
- (c) Part 102.19 (refers to petitions to FDA for food names).
- (d) Part 106.120 (refers to infant formula quality procedures).
- (e) Part 107.200 (refers to FDA-mandated recall of infant formula).
- (f) Part 107.280 (refers to records retention of FDA-mandated recall of infant formula).
- (g) Part 108 except Parts 108.25 and 108.35 (refers to FDA emergency permit control).
- (h) Part 111 (refers to dietary supplements).
- (i) Part 118 (refers to shell egg producers).
- ~~(h)~~ (j) Part 130.5-6 (refers to FDA procedure for establishing a food standard).
- (i) (k) Part 130.17 (refers to FDA allowance for temporary food standards).
- (j) (l) Part 170.6 (refers to FDA opinion letters on food additives).

(k) (m) Parts 170.15 and 170.17 (refers to FDA commissioner).

**(4) Availability.** The above referenced Title 21, Code of Federal Regulations, is available at the office of Director, Division of Food, Milk, and Lodging, RSA Tower, Suite 1250, 201 Monroe Street, Montgomery, Alabama 36104.

**(5) Control.** Where there is inconsistency between Chapter 420-3-20 and parts incorporated by reference of Title 21 Code of Federal Regulations, Parts 1 to 190, ~~2009~~ 2013 Revision, these rules control. Where these rules are silent, those parts incorporated by reference of Title 21 Code of Federal Regulations, Parts 1 to 190, ~~2009~~ 2013 Revision, control.

**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.