

APA-1
4/18

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control 420 Alabama Department of Public Health

Rule Number 420-3-22.01
Rule Title General Provisions

New 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? No

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 action relate to or affect in any manner any litigation which the agency is a party to concerning the subject matter of the proposed rule? No

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 proposed 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 Services Agency.

Signature of Certifying Officer F. John Hale Date 9/15/2021

REC'D & FILED
SEP 15 2021
LEGISLATIVE SVC AGENCY

**FORM APA2
10/17**

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

AGENCY NAME: Alabama Department of Public Health

RULE NUMBER AND TITLE: 420-3-22.01, General Provisions

INTENDED ACTION: To amend the food establishment sanitation rules.

SUBSTANCE OF PROPOSED ACTION: This amendment will allow the Department to revise cottage food production operations pursuant to Act 2021-461.

TIME, PLACE, AND MANNER OF PRESENTING VIEWS: A public hearing will be held on October 27, 2021, at 9:00 a.m., at the 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, 2021. All comments and requests for copies of the proposed amendments should be addressed to the contact person listed below.

CONTACT PERSON AT AGENCY: Mark Sestak, Division of Food, Milk, and Lodging, Department of Public Health, P.O. Box 303017, Montgomery, Alabama 36130-3017, Telephone number: (334) 206-5375.



P. Brian Hale, Agency Secretary

420-3-22-.01 General provisions.

(1) **Purpose** - The purpose of these rules is to safeguard public health and provide to consumers food that is safe, unadulterated, and honestly presented.

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

(3) **Adoption by reference** - Chapters 1 through 8 of the document entitled 2013 edition of the United States Department of Health and Human Services Food Code (“Food Code”) is hereby incorporated by reference and, except as provided for in Rules 420-3-22-.01 through 420-3-22-.08, made a part of these rules as if set out in full and all provisions thereof are adopted as a rule of the State Board of Health. Said document is available at <http://www.alabamapublichealth.gov/>.

(4) **Definitions** –

(a) In addition to definitions in the document entitled 2013 edition of the Food Code, for the purpose of these rules:

1. “Bed and breakfast” means a private owner-occupied residence providing accommodations for a charge to the public with no more than ten (10) guest rooms for rent. Breakfast only may be provided to the guests. Bed and Breakfast establishments are exempt from the Rules for Construction, Maintenance, and Operation of Hotels, (420-3-11) and the Rules for Food Service Sanitation, (420-3-22).

2. “Board” means the Board of Health of the State of Alabama as defined by Section 22- 2-1, Code of Alabama, 1975, or the State Health Officer or his designee, when acting for the Board, for the purposes of these rules, the Bureau of Environmental Services.

3. “Caterer” means a person operating from a permitted food service establishment who contracts with one individual or firm to provide a predetermined menu and quantity of food at a specific site, off the premises of the food establishment, which is generally different for each event; the site or event not being open to the general public.

4. “Catfish” means any species of fish classified within the family Ictaluridae.

5. “Catfish product” means, as used in Code of Alabama, 1975, Sections 22-20A-30, et seq., any catfish product capable of use as human food which is made wholly or in part from any catfish or portion thereof, except products which contain catfish only in small portions and which are exempt from this definition by rules of the State Board of Health.

6. "Child day care center" means any child care facility receiving more than 12 children for daytime or nighttime care for all or part of a day. The term "child day care center" includes but is not limited to facilities commonly called "day care centers," "day nurseries," "nursery schools," "kindergarten," "play groups," and "nighttime centers" with or without stated educational purposes. Such term further includes, but is not limited to, kindergarten or nursery schools or other programs operated as part of a private school and receiving more than 12 children younger than lawful school age for daytime care for more than 4 hours a day with or without stated educational purposes.

7. "Commissary" means a permitted food establishment to which a mobile food establishment or transportation vehicle returns daily for such things as discharging liquid or solid wastes, refilling water tanks and ice bins, and boarding food.

8. "Cottage Food" means a non-potentially hazardous food that has been prepared in a person's home that does not require time or temperature control for safety to limit pathogenic microorganism growth or toxin formation and that does not include meat, poultry, or fish, including the following:

a. Cakes, breads, Danish pastries, donuts, pastries, and pies.

b. Jam, jellies, and fruit preserves.

c. Candy.

d. Dried and dehydrated herbs, herb mixes, vegetables, or fruits.

e. Roasted coffee.

f. Dried baking mixes.

g. Fermented or preserved vegetables or fruit that do not result in the production of alcohol and that have an acidity level allowed by the department as defined in Chapter 1 of the Food Code under time/temperature control for safety food.

89. "Date limit" means all terms reasonably construed to mean food is not intended to be used or sold after the date limit, or that food quality is best before the date limit, and includes but is not limited to the terms "Sell By;" "Freeze By;" "Sell or Freeze By;" "Not to be Sold After;" "Best if Used By;" "Best if Purchased By;" "Expiration;" or other similar designations.

910. "Department" means the Alabama Department of Public Health.

~~10~~11. "Domestic" means, as used in Code of Alabama, 1975, Sections 22-20A-1, et seq., any farm-raised fish or wild fish hatched, raised, harvested, or processed within the United States or a territory of the United States.

~~11~~12. "Farm-raised fish" means, as used in Code of Alabama, 1975, Sections 22-20A-1, et seq., farm-raised shellfish and fillets, steaks, nuggets, and any other flesh from a farm-raised fish or shellfish and includes any product of which farm-raised fish is an ingredient.

~~12~~13. "Food establishment" means both food service establishments and retail food stores, along with the lower risk priority categories in either designation. The term does not include:

(i) A kitchen in a private home if only food that is not time/temperature control for safety food is prepared for sale or service at a function such as a charitable, religious, civic, or not-for-profit organization's food sale, or at a state sanctioned farmer's market, and if the consumer is informed by a clearly visible label, tag, or placard at the sales or service location that the food is prepared in a kitchen that is not inspected by a regulatory agency. This exclusion shall not be construed as allowing the sale of low acid foods in a hermetically sealed container (i.e. such as home-canned vegetables) when such food is not prepared in a permitted establishment; and

(ii) Private gatherings with a limited and identifiable membership where no sale of food takes place. A sale of food shall be any situation in which there is a charge for profit for the food, or a membership fee is required for entry or participation.

(iii) A Cottage Food Production Operation. A person operating out of his or her home who meets ~~all~~ the following requirements:

- ~~a. Produces a non-time/temperature control for safety baked good, a canned jam, jelly, or a dried herb or herb mix, or a candy~~ cottage food for sale at the person's home;
- ~~b. Has an annual gross income of twenty thousand dollars (\$20,000) or less from the sale of food from the cottage food operation;~~
- ~~a:~~ b. Sells the foods produced in a cottage food operation only directly to consumers, whether in-person, by phone, or online in the state;
- ~~b:~~ c. Delivers the foods directly to consumers in the state;
- ~~e. Sells the foods produced in a cottage food operation only directly to consumers, excluding internet sales;~~

d. A cottage food production operator shall complete a food safety course approved by the department and label all cottage foods that the operation sells. The label shall include in at least size 10-point font:

~~d. Has maintained certification by having attended and passed a food safety course approved by the health department; and~~

~~e. Labels all goods produced with:~~

~~1. The name and address of the cottage food production operation. A statement that the food is not inspected by the health department.~~

1. The common or usual name of the food.

2. The name, home or P.O. Box address of the cottage food production operation.

3. A statement that the food is not inspected by the department or local health department.

4. A list of the ingredients in the food in descending order of predominance and shall include a disclaimer that the food may contain allergens.

1314. "Food processing plant" means a commercial food processing establishment 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.

1415. "Food service establishment" means any place, vehicle, or vessel where food for individual portion service is prepared, stored, held, transported, served, or dispensed and includes any such place regardless of whether consumption is on or off the premises. The term also includes delicatessen type operations that prepare food intended for individual portion service; and also includes all schools and child day care centers.

~~15~~16. "Health Officer" means the Health Officer of the county or district in which the food establishment in question is located as provided in Section 22-3-2 Code of Alabama, 1975; or the authorized representative of the Health Officer.

~~16~~17. "Imported" means, as used in Code of Alabama, 1975, Sections 22-20A-1, et seq., any farm-raised fish or wild fish that was hatched, raised, harvested, or processed outside the United States or a territory of the United States.

~~17~~18. "Label" means, as used in and for the purpose of enforcement of Code of Alabama, 1975, Sections 22-20A-30, et seq. a legible display of written, printed, or graphic information on a placard, menu, sign, or other material that represents the product to the consumer.

~~18~~19. "May not" means a mandatory prohibition.

~~19~~20. "Mobile food establishment" means, except for pushcarts, a unit mounted on or pulled by a self-propelled vehicle; is self-contained with its own drinking water tank and waste water tank unless handling only prepackaged foods; is designed to be readily movable; and is moved daily to return to its commissary. A pushcart is a category of mobile food establishment.

~~20~~21. "Priority category" means, for purposes of permitting and inspection scheduling, a tiered structuring of food establishments based on the public health risk for foodborne illness inherent in the establishment due to its' menu, operations, or consumers.

~~21~~22. "Priority Category 4 establishment" means a food establishment meeting the definition of a Category 2 or Category 3 and in addition performs an operation requiring a variance as per 420-3-22.01(4)(a)31 or a HACCP plan.

~~22~~23. "Priority Category 3 establishment" means:

(i) a food establishment where unpackaged raw food from an animal source is handled, prepared, or used; or

(ii) time/temperature control for safety food that is not ready-to-eat is cooked or further prepared to eliminate or reduce pathogens; or

(iii) customer contact utensils are reused, or food is cooled, or food previously cooled in the establishment is reheated.

~~23~~24. "Priority Category 2 establishment" means a food establishment which, by the nature of its' operation and menu, does not use raw foods of animal origin, does not cool foods

that have been heated, and does not reuse tableware. This type of food establishment may dispense or sell on-premises, only in single-service articles, unpackaged:

(i) foods that are not time/temperature control for safety, or

(ii) raw foods of plant origin that would otherwise be considered a time/temperature control for safety food; or

(iii) time/temperature control for safety foods that are received from an approved processing establishment as ready-to-eat; provided, such foods may be removed from the original package and heated one time for quality reasons (not heated as a required step to destroy microorganisms of public health concern), or

(iv) any combination of these.

(v) The foods allowed include, but are not limited to, hard cheese such as cheddar; dip ice cream; fully cooked luncheon meat including wieners, or any other fully cooked meat received from a processing establishment approved by the USDA or a state Department of Agriculture; or the produce area of a retail food store if issued a separate permit. This type establishment may also be called a "Limited Food Service Establishment."

2425. "Priority Category 1 establishment" means those food establishments that sell or market only prepackaged time/temperature control for safety food items. The term does not include establishments that handle only prepackage foods that are not time/temperature control for safety, roadside markets that offer only fresh fruits and vegetables for sale, food service establishments, or food and beverage vending machines. This type establishment may also be called a "Limited Retail Food Store Establishment."

2526. "Pushcart" means a non-self propelled mobile food unit that is lightweight enough, designed, and intended to be moved by one person. A pushcart can be used to prepare and serve only:

(i) foods that are not time/temperature control for safety such as popcorn, lemonade, or flavored ice; or

(ii) foods pre-wrapped at the commissary and maintained at the required temperatures; or

(iii) foods that meet the definition of "Priority Category 2."

2627. "Regulatory authority" means the Health Officer of the county or district in which the food establishment in question is located as provided in Section 22-3-2 Code of Alabama,

1975; or the authorized representative of the Health Officer; except for the purpose of issuing a variance from these rules, for which action the Regulatory Authority is only the State Health Officer.

~~27~~28. "Retail food store" means any establishment or section of an establishment where food and food products are offered to the consumer and intended for off premise consumption. The term includes delicatessens that offer prepared food in bulk quantities only. The term does not include establishments that handle only prepackaged, food that is not time/temperature control for safety; roadside markets that offer only fresh fruits and fresh vegetables for sale; food service establishments; or food and beverage vending machines.

~~28~~29. "Shall" means a mandatory requirement.

~~29~~30. "Shellfish" means, as used in Code of Alabama, 1975, Sections 22-20A-1, et seq., crab, lobster, oyster, shrimp, crayfish, clam, and scallops in the wild and farm-raised shellfish and includes any product of which shellfish is an ingredient.

~~30~~31. "Temporary event" means a special occurrence or celebration that is community wide, such as a fair, carnival, public exhibition, festival, or similar occasion that lasts no more than 14 days. A temporary event does not include ongoing commercial activities, such as a sale at a retail store.

~~31~~32. "Variance" means, as used in the Food Code, review by the Bureau of Environmental Services and is not equivalent to the definition used in the Rules of the State Board of Health Chapter 420-1-2.

~~32~~33. "Waiver relating to pet dogs" means a written request from a food service establishment to permit pet dogs in a designated outdoor dining area of a food service establishment under certain conditions.

~~33~~34. "Wild fish" means, as used in Code of Alabama, 1975, Sections 22-20A-1, et seq., naturally born or hatchery raised fish and shellfish harvested in the wild. The term includes a fillet, steak, nugget, and any other flesh from wild fish or shellfish and also includes any product of which wild fish is an ingredient. Net pen aquaculture or other farm-raised fish are excluded from the definition.

~~34~~35. "Wild harvested mushroom" means a fresh mushroom that has been picked in the wild and has not been processed (e.g., dried). A wild harvested mushroom does not include mushrooms that have been packaged in an approved food processing plant or cultivated mushrooms.

3436. "Wild harvested mushroom identification expert" means an individual who has successfully completed and passed a comprehensive wild harvested mushroom certification course that includes, but is not limited to the following critical learning objectives as recommended in the Conference for Food Protection Guidance Document for a Model Wild-harvested Mushroom Program:

- (i) Illness information;
- (ii) Identification;
- (iii) Harvesting;
- (iv) Best handling practices; and
- (v) Regulatory requirements.

(5) **Control** – Where there is consistency between Chapter 420-3-22 and the Food Code, these rules control. Where these rules are silent, the Food Code controls.

AUTHORS: Ronald Dawsey, Mark Sestak, Phyllis Fenn, Lauren Gambill **STATUTORY AUTHORITY:** Sections 22-2-2(6) and 22-20-5, Code of Alabama, 1975. **HISTORY:** New rule: filed November 20, 1996, effective December 25, 1996. Repealed and Replaced: Filed July 20, 2005, effective August 24, 2005. Amended: Filed October 20, 2010; effective date November 24, 2010. Amended: Filed July 16, 2014; effective date August 21, 2014. Amended: Filed August 19, 2016; effective date October 3, 2016. Amended: Filed November 21, 2019; effective date January 13, 2020. Amended: Filed XX-XX-XXXX.