

EXHIBIT E

DEPARTMENT OF HEALTH

(3505)

SUBJECT: Food Service Establishments

DESCRIPTION: The purpose of this rule is to safeguard public health and provide to consumers food that is safe, unadulterated, and honestly presented. The goal is to provide safe food, prevent illness, and ensure honest presentation of food to the public.

This rule establishes definitions; sets standards for management and personnel, food operations, and equipment and facilities; and provides for food establishment plan review, permit issuance, inspection, and employee restriction.

PUBLIC COMMENT: A public hearing was held on November 16, 2018. The public comment period expired on November 16, 2018. The Department did not receive any public comments. The proposed effective date is pending legislative review and approval.

FINANCIAL IMPACT: The proposed rule requires a certified manager to be employed by the establishment. The agency reported that the food-certified-manager requirement adds minimal cost to the operation of a food service establishment. Several nationally recognized online and in-person trainings are available for less than \$200 for each certification. These certifications are renewable on a three-to-five year cycle.

LEGAL AUTHORIZATION: The State Board of Health is authorized to make all necessary and reasonable rules and regulations of a general nature for the protection of public health and safety and the general amelioration of the sanitary and hygienic conditions within the state. *See Ark. Code Ann. § 20-7-109(a)(1).* The Board is authorized to promulgate rules for the efficient enforcement of the Food, Drug, and Cosmetic Act. *See Ark. Code Ann. § 20-56-219.* Additionally, the Director of the Department of Health has the power and authority to prevent the proliferation of infections and contagious and communicable diseases resulting from unsanitary food-service operations. *See Ark. Code Ann. § 20-57-203.*

QUESTIONNAIRE FOR FILING PROPOSED RULES AND REGULATIONS
WITH THE ARKANSAS LEGISLATIVE COUNCIL

DEPARTMENT/AGENCY Arkansas Department of Health
DIVISION Center for Local Public Health/Environmental Health Protection
DIVISION DIRECTOR J. Don Adams
CONTACT PERSON J. Terry Paul
ADDRESS Slot 46, 4815 West Markham, Little Rock AR, 72205-3867
PHONE NO. 501-661-2171 FAX NO. 501-661-2572 E-MAIL jpaul@arkansas.gov
NAME OF PRESENTER AT COMMITTEE MEETING Laura Shue, Chief Counsel
PRESENTER E-MAIL Laura.Shue@arkansas.gov

INSTRUCTIONS

- A. Please make copies of this form for future use.
- B. Please answer each question completely using layman terms. You may use additional sheets, if necessary.
- C. If you have a method of indexing your rules, please give the proposed citation after "Short Title of this Rule" below.
- D. Submit two (2) copies of this questionnaire and financial impact statement attached to the front of two (2) copies of the proposed rule and required documents.

RECEIVED

Donna K. Davis
Administrative Rules Review Section
Arkansas Legislative Council
Bureau of Legislative Research
One Capitol Mall, 5th Floor
Little Rock, AR 72201

NOV 5 2018

**BUREAU OF
LEGISLATIVE RESEARCH**

- 1. What is the short title of this rule? R & R Pertaining to Food Service Establishments
- 2. What is the subject of the proposed rule? Food Preparation and Service to the Public
- 3. Is this rule required to comply with a federal statute, rule, or regulation? Yes No X
If yes, please provide the federal rule, regulation, and/or statute citation. _____
- 4. Was this rule filed under the emergency provisions of the Administrative Procedure Act?
Yes No X
If yes, what is the effective date of the emergency rule? _____

When does the emergency rule expire? _____

Will this emergency rule be promulgated under the permanent provisions of the Administrative Procedure Act?

Yes No

5. Is this a new rule? Yes No
If yes, please provide a brief summary explaining the regulation. _____

Does this repeal an existing rule? Yes No
If yes, a copy of the repealed rule is to be included with your completed questionnaire. If it is being replaced with a new rule, please provide a summary of the rule giving an explanation of what the rule does. _____

Is this an amendment to an existing rule? Yes No
If yes, please attach a mark-up showing the changes in the existing rule and a summary of the substantive changes. **Note: The summary should explain what the amendment does, and the mark-up copy should be clearly labeled "mark-up."**

6. Cite the state law that grants the authority for this proposed rule? If codified, please give the Arkansas Code citation. A.C.A. § 20-7-101 through 20-7-130, §§ 20-56-201 through 20-56-223, and §§ 20-57-201 through 20-57-208.

7. What is the purpose of this proposed rule? Why is it necessary? This proposal updates the Arkansas code to the 2013 FDA Food Code guidance.

8. Please provide the address where this rule is publicly accessible in electronic form via the Internet as required by Arkansas Code § 25-19-108(b). <https://www.healthy.arkansas.gov/proposed-amendment-to-existing-rules>

9. Will a public hearing be held on this proposed rule? Yes No
If yes, please complete the following:

Date: 11-16-2018
Time: 9:30 to 10:30 am
Room 2508, ADH 4815 West Markham,
Place: Little Rock, AR

10. When does the public comment period expire for permanent promulgation? (Must provide a date.)
11-16-2018

11. What is the proposed effective date of this proposed rule? (Must provide a date.)
April 2019

12. Please provide a copy of the notice required under Ark. Code Ann. § 25-15-204(a), and proof of the publication of said notice. _____

13. Please provide proof of filing the rule with the Secretary of State and the Arkansas State Library as required pursuant to Ark. Code Ann. § 25-15-204(e). _____

14. Please give the names of persons, groups, or organizations that you expect to comment on these rules? Please provide their position (for or against) if known. Restaurant owners, Arkansas Hospitality Association, and Oil Marketers Organization.

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Department of Health

DIVISION Center for Local Public Health

PERSON COMPLETING THIS STATEMENT J. Terry Paul

TELEPHONE 501-786-9144 **FAX** 501-661-2572 **EMAIL:** jpaul@arkansas.gov

To comply with Ark. Code Ann. § 25-15-204(e), please complete the following Financial Impact Statement and file two copies with the questionnaire and proposed rules.

SHORT TITLE OF THIS RULE R & R Pertaining to Food Service Establishments

- 1. Does this proposed, amended, or repealed rule have a financial impact? Yes X No
- 2. Is the rule based on the best reasonably obtainable scientific, technical, economic, or other evidence and information available concerning the need for, consequences of, and alternatives to the rule? Yes X No
- 3. In consideration of the alternatives to this rule, was this rule determined by the agency to be the least costly rule considered? Yes No X

If an agency is proposing a more costly rule, please state the following:

(a) How the additional benefits of the more costly rule justify its additional cost;
The Food Certified manager requirement adds minimal cost to the operation of a food service establishment.

(b) The reason for adoption of the more costly rule;
The proposal requires a certified manager to be employed by the establishment. Several nationally recognized online and inperson trainings are available for less than 200 dollars for each certification. These certifications are renewable on a three to five year cycle.

(c) Whether the more costly rule is based on the interests of public health, safety, or welfare, and if so, please explain; and;
Management knowledge of food safety rules, practice, and methods of proper sanitation is an added safeguard to public health.

(d) Whether the reason is within the scope of the agency's statutory authority; and if so, please explain.
It is the duty of the Department of Health to educate and regulate for the protection of Arkansans from food borne illness by means of adoption of the most current science and guidance.

4. If the purpose of this rule is to implement a federal rule or regulation, please state the following:

(a) What is the cost to implement the federal rule or regulation?

Current Fiscal Year

Next Fiscal Year

General Revenue _____
Federal Funds _____

General Revenue _____
Federal Funds _____

Cash Funds _____
 Special Revenue _____
 Other (Identify) _____
 Total na

Cash Funds _____
 Special Revenue _____
 Other (Identify) _____
 Total na

(b) What is the additional cost of the state rule?

Current Fiscal Year

Next Fiscal Year

General Revenue _____
 Federal Funds _____
 Cash Funds _____
 Special Revenue _____
 Other (Identify) _____
 Total _____

General Revenue _____
 Federal Funds _____
 Cash Funds _____
 Special Revenue _____
 Other (Identify) _____
 Total _____

5. What is the total estimated cost by fiscal year to any private individual, entity and business subject to the proposed, amended, or repealed rule? Identify the entity(ies) subject to the proposed rule and explain how they are affected.

Current Fiscal Year

Next Fiscal Year

\$ _____

\$ _____

6. What is the total estimated cost by fiscal year to state, county, and municipal government to implement this rule? Is this the cost of the program or grant? Please explain how the government is affected.

Current Fiscal Year

Next Fiscal Year

\$ _____

\$ _____

7. With respect to the agency's answers to Questions #5 and #6 above, is there a new or increased cost or obligation of at least one hundred thousand dollars (\$100,000) per year to a private individual, private entity, private business, state government, county government, municipal government, or to two (2) or more of those entities combined?

Yes No

If YES, the agency is required by Ark. Code Ann. § 25-15-204(c)(4) to file written findings at the time of filing the financial impact statement. The written findings shall be filed simultaneously with the financial impact statement and shall include, without limitation, the following:

- (1) a statement of the rule's basis and purpose;
- (2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute;
- (3) a description of the factual evidence that:
 - (a) justifies the agency's need for the proposed rule; and

- (b) describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs;
- (4) a list of less costly alternatives to the proposed rule and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;
- (5) a list of alternatives to the proposed rule that were suggested as a result of public comment and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;
- (6) a statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule and, if existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response; and
- (7) an agency plan for review of the rule no less than every ten (10) years to determine whether, based upon the evidence, there remains a need for the rule including, without limitation, whether:
 - (a) the rule is achieving the statutory objectives;
 - (b) the benefits of the rule continue to justify its costs; and
 - (c) the rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives.

This Summary provides a synopsis of the textual changes from the 2012 Rules and Regulations Pertaining to Retail Food Establishments to the proposed 2017 edition. The primary intent of this record is to capture the nature of the changes rather than to identify every word or editing change. ***This record should not be relied upon as an absolute comparison that identifies each and every change.***

General

- Numerous editing changes were made throughout the document for internal consistency, to correct some errors in the 2009 Code and for clarification.
- Section and paragraph numbers listed refer to the 2009 Regulation unless otherwise noted.

Chapter 1 Purpose and Definitions

Deleted "**Enterohemorrhagic *Escherichia coli***" (**EHEC**) as use of EHEC terminology is outdated.

Amended "**Packaged**" in (1) to delete the term "securely" to avoid undue emphasis on nature of the package; Amended "**Packaged**" in (2) to remove the phrase "or other nondurable container" to clarify when foods packaged at retail need to be labeled so that it reads: "**Packaged**" does not include wrapped or placed in a carry-out container to protect the food during service or delivery to the consumer, by a food employee, upon consumer request.

Deleted the term **Potentially Hazardous Food (Time/Temperature Control for Safety Food)** (**PHF/TCS**) and made a universal change throughout the Code to replace it with the term "**Time/Temperature Control for Safety Food**" (**TCS**). The definition remains the same.

Revised "**Reduced Oxygen Packaging**" subparagraph (2)(e), to delete the phrase "placed in a hermetically sealed, impermeable bag" and replace it with "vacuum packaged in an impermeable bag" so it clearly defines the sous vide process as outlined in Annex 6(2)(B)(4)(b). It now reads:

"Sous vide packaging, in which raw or partially cooked food is vacuum packaged in an impermeable bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens."

Revised "**Shiga toxin-producing *Escherichia coli***" (**STEC**) to reflect current nomenclature.

Revised "**Service Animal**" to clarify match definition to Americans With Disabilities Act definition of "service animal".

Chapter 2 Management and Personnel

2-102.12

Amended to add requirement for one employee with supervisory/management responsibility to be a certified food protection manager. Provides 1 year from effective date for compliance and exempts stores that retail commercially prepackaged foods and facilities providing low risk non time/temperature control for safety foods.

2-201.11, 2-201.12, 2-201.13

Amended to add nontyphoidal *Salmonella* (NTS) as one of the reportable illnesses for action by the Person in Charge; Added Code language to address employee health controls for the exclusion and restriction of nontyphoidal *Salmonella*, and removal of exclusion and restriction from NTS.

2-201.12 2-201.13

Revised to add restriction/exclusion times for food employees with foodborne illness.

2-201.13

Added to provide protocols for removing, adjusting, or retaining an exclusion or restriction of a food employee with a foodborne illness.

2-301.14(H)

Amended to clarify that the requirement to wash hands before donning gloves is specific to the beginning of a task involving working with food and not during the task.

2-301.16(A)(2)

Amended to remove (A)(2)(b)(i-ii) and add new subparagraphs (A)(2)(b-e) to clarify and align the codified text with applicable CFR's and the FD&C Act with regard to the use of hand antiseptics as a food additive.

Chapter 3 Food

3-301.11(D)

Amended to revise subparagraph (D)(2) to clarify that Paragraph (B) does not apply where a ready-to-eat food is added as an ingredient to another food that does not contain a raw animal food and the combined product will be heated to at least 63°C (145°F).

3-302.11

Amended to remove subparagraph (A)(3) and renumbered the remaining paragraphs as (4) – (8).

3-304.11

Amended to add a new ¶(C) to clarify that food may contact surfaces of linens and napkins as specified in §3-304.13 and added term "Linens" to the tag line.

3-304.13

Amended to clarify that napkins in this section refers to cloth napkins and they are by definition considered linens.

3-304.17

Amended to relocate the requirement regarding the cleaning of returnables into this section from §4- 603.17.

Amended ¶3-304.17(A) to clarify conditions under which the re-use of returnables are permitted.

Amended ¶3-304.17(B) to establish conditions under which refilling of returnable take-home containers is permitted.

Amended to relocate the exception for filling a food-specific container with a beverage from ¶4-603.17(B) to ¶3-304.17(C).

Amended to renumber ¶3-304.17(C) as a new ¶3-304.17(D).

Amended to relocate the exception for filling consumer-owned, personal take-out containers that are not food-specific from ¶4-603.17(C) to ¶3-304.17(E).

3-401.14

Amended to revise ¶(D) to clarify that prior to sale or service, raw animal foods cooked using a non-continuous cooking process shall be cooked to a temperature and for a time as specified under ¶¶3-401.11 (A)-(C).

3-402.11

Amended ¶3-402.11(B) to add a new ¶(2) to clarify that scallop products consisting solely of the shucked adductor muscle are excluded from the requirements for parasite destruction and re-designated existing ¶¶(2)-(4) to be new ¶¶ (3)-(5).

3-403.11

Amended ¶3-403.11(C) to clarify that this provision applies to all commercially processed TCS foods that are ready-to-eat. Previous text suggested that it applied only immediately upon removal of the food from a sealed container.

3-501.13

Amended to add new ¶(E) specifying frozen fish packaged using a ROP method be removed from the ROP environment either prior to initiating thawing procedures under refrigeration as specified in ¶ (A) or prior to, or immediately upon completion of, its thawing using procedures specified in ¶ (B) of this section.

3-501.17

Amended to add new ¶(F) that exempts raw, live in-shell molluscan shellfish from date marking and re-designated former ¶(F) as new ¶(G)

Amended existing subparagraph 3-501.17 (F)(6) to clarify that the exemption from date marking for shelf stable dry fermented sausages produced in USDA-regulated facilities is not dependent on the product retaining the original casing; Renumbered existing ¶(F)(6) as new ¶(G)(6) as a result of the addition of new ¶ (F).

3-502.11

Amended to revise ¶(D) to make clear that only TCS foods prepared under ROP methods that do not control for growth of and toxin formation by *Clostridium botulinum* and the growth of *Listeria monocytogenes* require a variance.

3-502.12

Amended ¶¶3-502.12(B), (D), and (E) lead-in paragraphs to reference new ¶ (F) of this section.

Amended ¶3-502.12(B) lead in paragraph and subparagraphs (B)(6)(c), (D)(1), and (E)(2) to reference ¶8-201.14(B) along with existing reference to ¶ (D).

Amended subparagraphs 3-502.12(B)(3)(b) and (B)(4) to delete 14 days and add 30 days.

Amended ¶ 3-502.12(B) to add new subparagraph 7 specifying that a HACCP plan be provided to the regulatory authority prior to implementation.

Amended ¶3-502.12(D) lead in paragraph to delete the word "FOOD" and replace it with the term "Time/Temperature control for safety food" to clarify that this section applies to TCS food.

Amended subparagraph 3-502.12(D)(2)(b) to specify only the cooking parameters in ¶¶ 3-401.11(A), (B) and (C) apply.

Amended subparagraph 3-502.12(D)(2)(e)(ii) to allow for cold holding at 41°F for 7 days after cooling to 41°F.

Amended to delete existing subparagraph 3-502.12(D)(2)(e)(iii) and amended subparagraph 3-502.12(D)(2)(e)(iv) to renumber it as the new subparagraph (D)(2)(e)(iii).

Amended to add new ¶(F) to identify the conditions under which a HACCP Plan is not required for ROP TCS foods.

3-602.11

Amended ¶3-602.11(B)(2),(3),(5), and (7) to clarify the information that a label should include.

Amended subparagraph 3-602.11(B)(2) to clarify what information must be included in the statement of ingredients. The term "sub ingredients" was added to this subparagraph to clarify that individual component ingredients of a main ingredient must be disclosed in the statement of ingredients. This clarification helps to make clear that all individual ingredients in a packaged food will be disclosed in the statement of ingredients.

Amended subparagraph 3-602.11(C)(2) to remove cross reference to subparagraph (B)(5) to correctly refer to what a labeling device such as a card, sign, or other method of notification needs to declare. This change corrects an inadvertent error that was created in the 2005 Food Code when a new subparagraph (B)(5) for food allergens was added and the subparagraph for nutritional labeling was renumbered to (B)(6), but the accompanying cross reference in (C)(2) was not changed to correctly cross reference (B)(1), (2), and (6), nutritional labeling.

Chapter 4 Equipment, Utensils, and Linens

4-302.13

Amended the tag line to add "mechanical warewashing"

Amended to redesignate the existing section into ¶(A) and new ¶(B) to require the availability of irreversible registering temperature indicators.

4-602.11

Amended ¶ 4-602.11(B) to change the cleaning and sanitizing frequency for food contact surfaces or utensils that are in contact with a raw animal food that is a major food allergen such as fish, followed by other types of raw animal foods. With this change, the exception to existing subparagraph (A)(1) found in ¶(B) now applies only to raw meat and poultry.

4-603.17

Amended to delete §4-603.17 and relocate its requirements into §3-304.17.

4-802.11

Amended ¶4-802.11(C) to clarify that napkins in this section refers to cloth napkins and they are by definition considered linens as mentioned in ¶3-304.11(C) and §3-304.13.

Chapter 5 Water, Plumbing, and Waste

5-203.11

Removed (C) due to a conflict with 2-301.12

Chapter 6 Physical Facilities

No Changes.

Chapter 7 Poisonous or Toxic Materials

7-204.12

Amended ¶7-204.12(A) to redesignate ¶(A) into a lead-in paragraph with four new subparagraphs: Added 21 CFR 173 Secondary Direct Food Additives Permitted in Food for Human Consumption as new subparagraph (A)(1); Added GRAS ingredients as new subparagraph (A)(2); Added effective food contact notifications as new subparagraph (A)(3); Added 40 CFR 156 Labeling Requirements for Pesticides and Devices as new subparagraph (A)(4) to allow the use of other antimicrobial agents allowed under the food contact notification program for washing fruits and vegetables as well as GRAS ingredients permitted as antimicrobials or for general food use.

Chapter 8 Compliance and Enforcement

8-201.13

Amended ¶8-201.13(B) to add new language to have the food establishment notify the Regulatory Authority through submission of a HACCP plan that they will be conducting ROP operations that conform with procedures in § 3-502.12.

8-304.11

Amended to add new ¶(K) to include a requirement for the permit holder to post a sign or placard notifying the public that inspectional information is available for review.