### NOTICE OF PROPOSED EXPEDITED RULEMAKING TITLE 9. HEALTH SERVICES

### CHAPTER 8. DEPARTMENT OF HEALTH SERVICES - FOOD, RECREATIONAL, AND INSTITUTIONAL SANITATION

#### **PREAMBLE**

### 1. Permission to proceed with this proposed expedited rulemaking was granted under A.R.S. § 41-1039(A) by the governor on:

April 17, 2024

#### 2. Article, Part, or Section Affected (as applicable) Rulemaking Action

R9-8-101 Amend

R9-8-101.01 Renumber

R9-8-101.01 Amend

R9-8-101.02 New Section R9-8-118 Renumber

# 3. <u>Citations to the agency's statutory rulemaking authority to include the authorizing statute</u> (general) and the implementing statute (specific):

Authorizing statutes: A.R.S. §§ 36-132(A)(1) and (7), 36-136(G)

Implementing statutes: A.R.S. § 36-136(I)(4), 36-931, 36-932, and 36-933

# 4. <u>Citations to all related notices published in the Register as specified in R1-1-409(A) that</u> pertain to the current record of the proposed expedited rule:

Notice of Rulemaking Docket Opening: 30 A.A.R. 933, Issue Date: May 10, 2024, Issue

Number: 19, File number: R24-77

#### 5. The agency's contact person who can answer questions about the rulemaking:

Name: Myrna Motta

Title: Office Chief, Food Safety and Environmental Services

Bureau of Resiliency and the Environment

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AZ 85007

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or

Name: Stacie Gravito

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Division: Policy and Intergovernmental Affairs

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rules/rules/index.php

# 6. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

Arizona Revised Statutes §§ 36-136 (A)(4) and (I)(4) require the Arizona Department of Health Services (Department) to make rules to ensure that food and drink are fit for human consumption. The Department has adopted rules to implement the statute requirements in 9 A.A.C. 8, Article 1. Exemptions to the requirements in 9 A.A.C. 8, Article 1, have been adopted in A.A.C. R9-8-118. On March 29, 2024, Governor Hobbs signed HB2042 creating new statutes pertaining to cottage foods. With this rulemaking, the Department plans to amend and create rules in 9 A.A.C. 8, Article 1, to align the rules with the new and amended statutory requirements.

A reference to any study relevant to the rule that the agency reviewed and proposes either to rely on or not to rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The Department did not review or rely on any study for this rulemaking.

8. A showing a good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. A statement that the agency is exempt from the requirements under A.R.S. § 41-1055(G) to obtain and file a preliminary summary of the economic, small business, and consumer impact under A.R.S. § 41-1055(D)(2):

Under A.R.S. 41-1055(D)(2), the Department is not required to provide an economic, small business, and consumer impact statement.

10. Where, when, and how a person may provide written comments on the proposed expedited rule:

Close of record: December 20, 2024

A person may submit written comments on the proposed expedited rules no later than the close of record to either of the individuals listed in item 5.

11. All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

There are no other matters prescribed by statute applicable specifically to the Department or this specific rulemaking.

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:

Not applicable. The rules in this Article and the proposed amendments pertaining to cottage foods require an individual, who intends to prepare and sell a cottage food product, to register with the Department. According to A.R.S. § 36-931, the cottage food product must be prepared in the home kitchen of the registrant. A general permit is not used.

Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:

Not applicable

Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:

No business competitiveness analysis was received by the Department of Health Services.

12. List all incorporated by reference material as specified in A.R.S. § 41-1028 and include a citation where the material is located:

Not applicable

13. The full text of the rules follows:

#### TITLE 9. HEALTH SERVICES

# CHAPTER 8. DEPARTMENT OF HEALTH SERVICES - FOOD, RECREATIONAL, AND INSTITUTIONAL SANITATION ARTICLE 1. FOOD ESTABLISHMENTS

#### Section

R9-8-101. Purpose and Definitions

R9-8-118.R9-8-101.01. Exempt Exemptions from Requirements and Inspections

R9-8-101.02. Cottage Food

R9-8-118. Renumbered

#### ARTICLE 1. FOOD ESTABLISHMENTS

#### **R9-8-101.** Purpose and Definitions

- **A.** The Department:
  - <u>1.</u> incorporates Incorporates by reference the United States Food and Drug Administration publication, Food Code: 2017 Recommendations of the United States Public Health Service, Food and Drug Administration, and shall comply with the 2017 Food Code (FC) as specified in this Article. This incorporation which is incorporated by reference, contains no future editions or amendments, is on file with the Department, and The incorporated material is on file with the Department and is available for order at: https://www.fda.gov/Food/ResourcesForYou/Consumers/ucm239035.htm, refer to publication number IFS17;
  - 2. Shall comply with the 2017 Food Code (FC) as specified in this Article; and
  - Designates in all capital letters the terms used in this Article that are defined in FC Part 1 Section 1-201.10(B).
- **B.** No change
  - 1. No change
  - 2. No change
- **C.** No change
  - 1. No change
  - 2. No change
  - 3. No change
    - a. No change
      - i. No change
      - ii. No change
    - b. No change
    - c. No change
    - d. No change
    - e. No change
      - i. No change
      - ii. No change
      - iii. No change
      - iv. No change
      - v. No change

- vi. No change
- f. No change
- g. No change
- h. No change
- **D.** No change
  - 1. No change
  - 2. No change
  - 3. No change
  - 4. No change
  - 5. No change
  - 6. No change
  - 7. No change
  - 8. No change
  - 9. No change
  - 10. No change
  - 11. No change
  - 12. No change
  - 13. No change
  - 14. No change
  - 15. No change
  - 16. No change

#### R9-8-118. R9-8-101.01. Exempt Exemptions from Requirements and Inspections

- A. No change
- **B.** This Article does not apply to the following, which are not subject to routine inspection or other regulatory activities by a REGULATORY AUTHORITY:
  - 1. No change
  - 2. No change
  - 3. No change
  - 4. Residential group care facilities, as defined in A.A.C. R6-5-7401 21 A.A.C. 7 that have 20 or fewer clients;
  - 5. No change
  - 6. No change
  - 7. No change

- 8. No change
- 9. No change
- 10. No change
- 11. No change
- 12. FOOD that is:
  - a. No change
  - b. No change
    - i. No change
    - ii. No change
    - iii. No change
    - iv. No change
  - c. No change
  - d. No change
  - e. A <u>Prepared as part of a demonstration of FOOD preparation or a cooking class offered by:</u>
    - A culinary school or educational institution and all FOOD prepared is consumed by attending students;
    - ii. A school or business and samples are not offered for human consumption; and or
    - iii. A business where an individual provides, prepares, cooks, and consumes their own FOOD;
  - f. Offered at a child care facility and limited to:
    - i. commercially Commercially pre-packaged FOOD that is not
       TIME/TEMPERATURE CONTROL FOR SAFETY FOOD, and or
    - <u>ii.</u> <u>whole Whole</u> fruits and vegetables that are washed and cut onsite for immediate consumption; or
  - g. Offered at locations that sell only commercially pre-packaged FOOD that is not time/temperature control for safety food;
- 13. A cottage FOOD product, as defined in A.R.S. § 36-136(Q), prepared for commercial purposes that: A.R.S. § 36-931, that is in compliance with R9-8-101.02;
  - a. Is not time/temperature control for safety food as defined in A.R.S. § 36-136(I)(4)(g); or
  - b. Is not a FOOD that requires time and temperature control for safety to limit pathogenic microorganism growth or toxin formation; and

- e. Is prepared in the kitchen of a home by a food preparer or under the supervision of an individual who:
  - Has a certificate of completion from completing a food handler training course from an accredited program;
  - ii. Maintains an active certification of completion; and
  - iii. If a food preparer, is registered with the Department, as required in A.R.S. § 36-136(I)(4)(g) and specified in subsection (D); and
- d. Is PACKAGED at the home with an attached label that includes:
  - i. The name, and registration number of the food preparer registered with the Department as specified in subsection (D);
  - ii. A list of the ingredients in the cottage FOOD;
  - iii. The date the cottage FOOD was prepared; and
  - iv. The statement: This product was produced in a home kitchen that may process common FOOD allergens and is not subject to public health inspection; and
  - v. If applicable, a statement that the cottage FOOD was prepared in the home kitchen of a facility for individuals with developmental disabilities.
- 14. No change
- 15. No change
- 16. No change
- C. A food preparer who meets the requirements in subsection (B)(13) is authorized to prepare cottage FOOD for commercial purpose.
- **D.** To be exempt from the requirements in this Article, a food preparer identified in subsection (C) shall:
  - 1. Complete a food handler training course from an accredited program;
  - 2. Register with the Department by submitting:
    - a. An application in a Department-provided format that includes:
      - i. The food preparer's name, address, telephone number, and e-mail address:
      - ii. If the food preparer is supervised, the supervisor's name, address, telephone number, and e-mail address;
      - iii. The address, including the county, of the home where the cottage FOOD is prepared;
      - iv. Whether the home where the cottage FOOD is prepared is a facility for

- developmentally disabled individuals; and
- v. A description of each cottage FOOD prepared for commercial purposes;
- b. A copy of the food preparer's certificate of completion for the completed food handler training course;
- e. If the food preparer is supervised, the supervisor's certificate of completion for the completed food handler training course; and
- d. An attestation in a Department-provided format that the food preparer:
  - Has reviewed Department provided information on FOOD safety and safe FOOD handling practices;
  - ii. Based on the Department-provided information, believes that the cottage FOOD prepared for commercial purposes is not time/temperature control for safety food or is not a FOOD that requires time or temperature control for safety to limit pathogenic microorganism growth or toxin formation; and
  - iii. Includes the food preparer's printed name and date.
- Maintain an active certification of completion for the completed food handler training course;
- 4. Renew the registration in subsection (D)(2) every three years;
- 5. Submit any change to the information or documents provided according to subsection (D)(2)(a) through (c) to the Department within 30 calendar days after the change; and
- 6. Display the food preparer's certificate of registration when operating as a temporary FOOD ESTABLISHMENT and selling cottage FOOD.
- **E.** Food establishments shall have until January 31, 2022 to comply with the certified food protection manager requirement specified in this Article.

#### **R9-8-101.02.** Cottage Food

- An individual wanting to prepare a cottage FOOD product, as defined in A.R.S. § 36-931, for commercial purposes and to be exempt from the requirements in all other Sections of this Article shall:
  - Complete a food handler training course from an accredited program that has been evaluated and listed by an accrediting agency as conforming to national standards for organizations that certify individuals;
  - 2. Submit an application for registration to the Department that includes:
    - <u>a.</u> The following information in a Department-provided format:
      - i. The individual's name, address, telephone number, and e-mail address;

- ii. The street address, city, county, and state of the home where the cottage FOOD is prepared;
- <u>iii.</u> Whether the home where the cottage FOOD is prepared is a facility for developmentally disabled individuals; and
- iv. A description of each cottage FOOD prepared for commercial purposes;
- b. A copy of the individual's active certificate of completion for the food handler training course from the accredited program in subsection (A)(1); and
- <u>c.</u> A signed attestation, in a Department-provided format, that the individual:
  - <u>i.</u> <u>Has reviewed Department-provided information on FOOD safety and</u> safe FOOD handling practices;
  - Will prepare and sell or offer for sale cottage FOOD to the public only if the cottage FOOD meets the requirements of A.R.S. Title 36, Chapter 8, Article 2, and this Section;
  - While preparing cottage FOOD for commercial purposes, will follow the safety guidance from the food handler's training course required according to subsection (A)(1), as well as the Department provided information on FOOD safety and safe FOOD handling practices, including the requirements for the safe handling, processing, and storage of FOOD that is a TIME/TEMPERATURE CONTROL FOR SAFETY FOOD;
  - iv. Will prepare the cottage FOOD in the home kitchen at the address provided in subsection (A)(2)(a)(ii), as defined in A.R.S. § 36-931(3);
  - v. Will make, package, and attach a legible label according to A.R.S. § 36-932;
  - vi. Will dispose of FOOD waste and kitchen waste in a safe and sanitary manner;
  - wii. Will directly supervise and be responsible for the tasks undertaken by another individual who is not registered with the Department and assisting in preparing cottage FOODS for commercial purposes, in accordance with A.R.S. § 36-932(C);
  - viii. If selling cottage FOOD products online, will advertise the sale in accordance with A.R.S. § 36-932(B);
  - ix. Will sell, transport, and deliver cottage FOOD products according to A.R.S. § 36-932(E);

- <u>x.</u> Except as otherwise permitted by A.R.S. § 36-931(1)(b), will not make cottage FOODS that are or that contain alcoholic beverages, unpasteurized milk products, fish, shellfish products, meat, meat byproducts, poultry, or poultry by-products;
- <u>xi.</u> Will not sell a cottage FOOD product with the intent for the cottage

  FOOD product to be used as an ingredient to make other products sold at
  a retail establishment, as specified in A.R.S. § 36-932(F)(1);
- <u>wii.</u> Will not prepare products containing marijuana or marijuana products, as specified in A.R.S. § 36-932(F)(2);
- <u>xiii.</u> Will only use an ingredient if the ingredient is from an approved source and allowed by law, as specified in A.R.S. § 36-932(G):
- <u>xiv.</u> Will not use the home kitchen, as defined in A.R.S. § 36-931(3), as a commissary for a mobile food unit, as specified in A.R.S. § 36-932(H);
- <u>wv.</u> Will not store cottage FOOD products or FOOD preparation equipment outside of the individual's home, in accordance with A.R.S. § 36-932(D)(2);
- <u>will not prepare cottage FOODS for commercial purposes if the individual's certification according to subsection (A)(3) and registration with the Department, according to subsection (A)(4) have expired;</u>
- <u>vvii.</u> Understands and acknowledges that the individual's registration as a cottage FOOD preparer with the Department does not exempt the individual or the FOOD or drink products that the individual prepares and sells or offers for sale from the requirements for brand inspections, animal health inspections, or any FOOD inspections required by state or federal law or the requirements for the sale of milk, milk products, raw milk, and raw milk products under A.R.S. § 3-606 and that the individual may be subject to disciplinary action by the agencies charged with enforcing those requirements should those requirements be violated; and
- <u>vviii.</u> Understands that noncompliance with the requirements in A.R.S. §§ 36-931 through 36-933 and this Section may result in suspension or revocation of registration, according to A.R.S. § 36-933(C), or to civil or criminal penalties;
- 3. Not prepare a cottage FOOD product for sale to a consumer, if the individual does not have a current registration with the Department;

- 4. Maintain an active certification from a food handler training course from an accredited program that has been evaluated and listed by an accrediting agency as conforming to national standards for organizations that certify individual;
- 5. Renew the registration in subsection (A)(3) every three years;
- 6. Submit any change to the information or documents provided according to subsection (A)(2) to the Department within 30 calendar days after the change; and
- 7. Display the cottage food preparer's certificate of registration when selling cottage FOOD at a location other than from the home kitchen.
- An individual is not exempt from all other requirements in this Article if the individual does not maintain both an active food handler's certification, according to subsection (A)(4), and a current registration as a cottage food preparer with the Department, according to subsection (A)(5).
- <u>C.</u> The registered cottage food preparer shall:
  - 1. Prepare FOOD in the home kitchen of the registered cottage food preparer;
  - Only use ingredients from an approved source and allowed by law, as specified in A.R.S.§ 36-932(G);
  - Package the food at the home with an attached label that meets the requirements in
     A.R.S. § 36-932, including:
    - a. The name and registration number of the cottage food preparer registered with the Department;
    - b. A list of all ingredients in the cottage FOOD;
    - <u>c.</u> The date the cottage FOOD was prepared;
    - d. The statement required by A.R.S. § 36-932(A)(3): This product was produced in a home kitchen that may come in contact with common FOOD allergens and pet allergens and is not subject to public health inspection;
    - e. The statement required by A.R.S. § 36-932(A)(5): To obtain additional information about cottage foods or to report a foodborne illness, go to azdhs.gov/Cottagefood; and
    - <u>f.</u> <u>If applicable, a statement that the cottage FOOD was prepared in the home</u> <u>kitchen of a facility for individuals with developmental disabilities; and</u>
  - 4. Ensure that the packaging:
    - a. <u>Is clean and sanitary, and secure; is appropriate for the consistency and temperature of the food; and totally encloses the food; and</u>
    - b. Contains a tamper-evident seal, which could be the label.
- **D.** The registered cottage food preparer selling the cottage food:

- 1. Shall only offer cottage FOODS for sale and delivery in Arizona;
- <u>For cottage food products that are not Time/Temperature Control for Safety FOODS,</u> may:
  - <u>a.</u> <u>Sell and deliver directly to a consumer, or</u>
  - b. Use a third-party food delivery platform for delivery to a consumer;
- 3. <u>If using a third-party delivery platform, shall utilize a third-party delivery platform that</u> agrees to comply with A.R.S. § 36-932 (E)(2);
- 4. For cottage food products that are Time/Temperature Control for Safety FOODS or contain meat or poultry products, shall ensure that the food:
  - <u>a.</u> <u>Is delivered in person directly to the consumer;</u>
  - <u>b.</u> <u>Is not delivered by a third-party food delivery platform;</u>
  - c. <u>Is maintained at the appropriate temperature during delivery and until provided to the consumer;</u>
  - <u>d.</u> <u>Is transported to no more than one destination and for no longer than two hours</u>
     <u>in duration, including any time spent delayed in traffic; and</u>
  - e. Is not sold to the public except at the initial destination; and
- 5. <u>If selling a cottage food product through a third-party vendor, such as inside a store or kiosk, shall ensure that:</u>
  - a. The cottage food product is sold in a separate section of the store or on a display case separate from non-homemade food items, and
  - b. The third-party vendor displays a sign that indicates that the cottage food product is homemade and exempt from state licensing and inspection.
- <u>E.</u> <u>If a cottage food product is offered for sale online, the registered cottage food preparer shall provide a prominent notification that includes all of the labeling information required in subsections (C)(3)(a) through (f).</u>
- **F.** The Department shall:
  - 1. Process an application in subsection (A)(2) according to A.R.S. § 41-1073;
  - 2. <u>Issue a certificate of registration if the application is in compliance with the requirements of this Section;</u>
  - 3. Notify the applicant in writing if additional information is required;
  - 4. Consider the application withdrawn if the Department does not receive a response to the notification in subsection (F)(3) within 30 days after the notification; and
  - 5. Deny an application that is not in compliance with this Section.

#### G. The Department:

- 1. Shall notify the registered cottage food preparer in writing of:
  - <u>a.</u> Suspected noncompliance with A.R.S. Title 36, Chapter 8, Article 1, or this Section; or
  - b. Receipt of a food safety complaint; and
- 2. May suspend or revoke the cottage food preparer's registration for:
  - <u>a.</u> Noncompliance with A.R.S. Title 36, Chapter 8, Article 1, or this Section;
  - <u>b.</u> Receipt of a verified food safety complaint;
  - <u>c.</u> <u>Impeding the investigation, according to 9 A.A.C. 6, Article 2 or 3, of a reported foodborne illness; or </u>
  - d. A violation under A.R.S. § 36-601.
- <u>H.</u> A registered cottage food preparer may appeal a suspension or revocation according to A.R.S. Title 41, Chapter 6, Article 10.