DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH

Statutory Authority: 16 Delaware Code, Section 122(3)u.1 (16 **Del.C.** §122(3)u.1) 16 **DE Admin. Code** 4458

PROPOSED

PUBLIC NOTICE

4458 State of Delaware Food Code Regulations

Pursuant to 16 **Del.C.** §122(3)u.1, The Department of Health and Social Services, Division of Public Health, Health Systems Protection Section, is proposing revisions to the regulations governing the State of Delaware Food Code (16 **DE Admin. Code** 4458).

The proposed amendments will introduce several important changes to better serve and protect Delawareans. Changes include, but are not limited to, the adoption of the United States Public Health Service 2022 Food Code and additional technical changes to bring the regulation into compliance with the *Delaware Administrative Code Style Manual*.

Copies of the proposed regulation are available for review in the June 1, 2025 issue of the *Delaware Register of Regulations*, accessible online at: http://regulations.delaware.gov or by calling the Division of Public Health at 302-744-4951.

Public comments will be accepted until 4:30 PM on July 1, 2025. Comments will be accepted in written form via email to DHSS_DPH_regulations@delaware.gov, or by U.S. mail to the following address:

Vicki Schultes, Hearing Officer Division of Public Health 417 Federal Street Dover, DE 19901

4458 State of Delaware Food Code Regulations

1.0 State of Delaware Food Code

- 1.1 Name. These Regulations Name. This regulation shall hereby be known as the "State of Delaware Food Code".
- <u>1.2</u> <u>Effective Date</u> <u>Effective Date</u>. The State of Delaware Food Code shall be effective <u>August 11, 2020 10 days</u> after publication of the final regulation.
- <u>1.3</u> **Prior Regulations Repealed** Prior Regulations Repealed. All current or previous regulations or parts of regulations in conflict with this State of Delaware Food Code are hereby repealed.
- 1.4 Location Location. A copy of the proposed State of Delaware Food Code is available for public view at the following location: Office of Food Protection, Jesse Cooper Building, 417 Federal Street Edgehill Shopping Center, 43 South Dupont Highway, Suite C, Dover, DE 19901. The 2017 2022 US FDA Food Code is available at: https://www.fda.gov/food/fda-food-code/food-code-2017 https://www.fda.gov/food/fda-food-code/food-code-2022.
- <u>Severability</u> Severability. Should any part, sub-part, section, paragraph, sentence sentence, or phrase of this State of Delaware Food Code be declared unconstitutional or invalid by any competent authority, the remainder of this Code regulation shall not be affected in any way.

2.0 Adoption of United States Public Health Service 2017 2022 Food Code

- 2.1 The State of Delaware Food Code adopts, as if fully set forth herein in this regulation, the United States Public Health Service 2017 2022 Food Code, available at https://www.fda.gov/media/110822/download https://www.fda.gov/media/164194/download?attachment, as amended herein in this regulation:
 - 2.1.1 Amend **Subpart 1-101.10** by inserting the words "State of Delaware" before the words "Food Code" and after the words "as the".
 - 2.1.2 Amend **Subpart 1-102.10** by deleting the subpart in its entirety and by inserting in lieu thereof the following: "The purpose of this Code is to safeguard public health, reduce the risk of foodborne illness and

provide to consumers food that is safe, unadulterated unadulterated, and honestly presented. The purpose is also to regulate, within the State of Delaware, the production, transportation, storage, processing, handling, preparation preparation, and consumer service of human food; the inspections of food establishments; the issuing and revocation of permits to food establishments; and the application of compliance and enforcement procedures."

- 2.1.3 Amend Subpart 1-201.10(B) Terms Defined
 - 2.1.3.1 Amend Subpart **1-201.10(B)** by adding thereto-new defined terms:
 - "Alternative Food Establishment food establishment" means food establishments inclusive of alternative facilities to prepare food for public consumption. Specified under §8-305.
 - "Approval to Construct" or "ATC" means the record produced by the regulatory authority approving the construction of a food establishment in accordance with applicable laws and regulations.
 - "Caterer without a Premise premise" or "CWOP" means an alternative to traditional brick and mortar food establishments that results in a food establishment permit. This alternative operation is one whereby the permit holder conducts food establishment activities within another permit holder's permitted food establishment and the foods are relinquished directly to the consumer. The utilities, physical facilities, food equipment, capacity and access must meet the needs of the CWOP operation and comply with the Food Code.
 - "Commissary" See "Servicing Area area".
 - "Confirmed foodborne disease outbreak" means confirmed foodborne disease outbreak is defined as an incident in which two or more persons from separate households experience a similar illness after ingestion of a common food or meal and epidemiologic evaluation implicates the meal or food as the source of illness. Confirmed outbreaks may or may not be laboratoryconfirmed.
 - "Conveniently located" means the ability to access the equipment and/or and location without (A) risk of contamination; and (B) obstructions.
 - "Food Preparation" means a broad topic, involving all of the steps that occur between obtaining raw ingredients and consuming them as food.
 - "High Risk risk" means a food establishment that prepares food with multiple (3 or more) risk steps: handling, (combining mixing combining/mixing), of raw ingredients; cooking; cooling; reheating; hot and cold holding for service; freezing and thawing; and time as public health control and control, including:
 - (1) Non-compliance on the same non-critical items on multiple inspections (3 or more) without correction, or
 - (2) Non-compliance with the same CDC <u>Centers for Disease Control and Prevention</u> risk factors in two consecutive inspections no corrections; or
 - (3) Serves a highly susceptible population.
 - "Limited Frozen Dessert Stand frozen dessert stand" or "LFDS" means an alternative food establishment that dispenses Italian water ice, snow cones, bulk hard-pack ice cream or frozen yogurt; yogurt, and other similar products. It does not include the sites at which these products are processed; facilities which mechanically dispense (soft-serve style machines) these products; nor, nor facilities which add toppings.
 - "Low Risk risk" means a food establishment that:
 - Prepares TCS Temperature Control for Safety (TCS) Foods with only one or two of the following steps: cooking; cooling; reheating; hot and cold holding for service; low volume of foods; or
 - (2) Is Medium Risk with Hazard Analysis Critical Control Point (HACCP) plan, or substantial compliance.
 - "Medium Risk risk" means a food establishment that:
 - (1) Prepares TCS Foods with multiple (3 or more) risk steps: handling (combining-mixing combining/mixing) of raw ingredients; cooking; cooling; reheating; hot and cold holding for service; freezing and Thawing; Time as Public Health control; or
 - (2) Is High Risk with HACCP plan or substantial compliance; or
 - (3) Is Low Risk with non-compliance on multiple inspections (3 or more)
 - "Mobile Food Establishment food establishment" or "MFE" means a mobile food establishment is a vehicle mounted alternative food establishment that is readily moveable. MFEs require an

- agreement with a servicing area/commissary to ensure that the MFE in conjunction with the servicing area/ commissary area meets the Food Code.
- "Outdoor Spaces" means a porch, patio, deck deck, or other structure with less than two contiguous walls that does not require travel through any indoor areas, including for entrance and exit.
- "Peak hot water demand" is the quantity of hot water that the food establishment must have to meet all hot water needs in the food establishment.
- "Peak Water Demand water demand" is the quantity of water that the food establishment must have in order to meet all water needs in the food establishment.
- "Peak Hot Water Demand" is the quantity of hot water that the food establishment must have in order to meet all hot water needs in the food establishment.
- "**Private**" means a use or function that is intended for a particular individual or group, such as a celebration of a birthday, wedding, anniversary anniversary, or funeral, and that is not intended for consumers as members of the general public.
- "Probable foodborne disease outbreak" means a probable foodborne disease outbreak is defined as an incident in which two or more persons from separate households experience a similar illness after ingestion of a common food or meal, and a specific food or meal is suspected, but person-to-person transmission or other exposures cannot be ruled out.
- "Request for Information" or "RFI" means a record produced by the regulatory authority requesting information related to the application for a permit to operate a food establishment in accordance with applicable laws and regulations.
- "Very Low Risk low risk" means a food establishment that:
 - (1) Serves food to the public on 52 occasions or less per year and does not serve a highly susceptible population; or
 - (2) Serves no Time/Temperature Control for Safety (TCS) foods and does not serve a highly susceptible population.
- 2.1.3.2 Amend **Subpart 1-201.10(B)** by amending defined terms:
 - Amend "Food Establishment establishment" by adding thereto after (1)(b) the following: "(c) meets the physical facilities requirements of this Code regulation."
 - Amend "Food Establishment establishment" by deleting the words "that are not TIME/TEMPERATURE CONTROL FOR SAFETY FOODS".
 - Amend "Food Establishment establishment" by adding thereto after (3)(g) the following: "(h) A private catered event." and "(i) A Cottage Food Establishment."
 - Amend "Food Processing Plant processing plant" by deleting the existing text after (1) "Food processing plant" and by inserting in lieu thereof the following: "means a type of food service establishment that is a commercial operation that processes food for human consumption, consumption and provides processed food for sale and distribution to other business entities such as other food establishments."
 - Amend "**Person in Charge**" by deleting the existing definition and replacing it to read as follows: "means the individual present at a food establishment who is responsible for the operation during all hours of food operations."
 - Amend "Public Water System water system" to read as follows: "has the meaning stated in 40 CFR 141 National Primary Drinking Water Regulations and is also applicable to those private wells designated by the Division of Public Health as a Miscellaneous Public Well miscellaneous public well."
 - Amend "**Regulatory authority**" by deleting the existing definition and replacing it to read as follows: "means the Secretary, Delaware Department of Health and Social Services, or his/her their authorized representative."
 - Amend "Service Animal animal" by deleting the existing definition and replacing it to read as follows: "as defined under 28 CFR §35.136 and by the Americans with Disabilities Act."
 - Amend "Servicing Area area" by adding the following after the last sentence: "The servicing area must be within our the servicing area's jurisdiction and reviewed during risk-based inspections. The servicing area must complement any caterer or mobile food establishment to allow the establishment to meet the physical facilities requirements of this Code regulation."
 - Amend "Temporary Food Establishment food establishment" by deleting the existing definition and replacing it to read as follows: "or "TFE" means an alternative food establishment that

results in a TFE permit and prepares food for the public, free or for a cost. Events sanctioned to operate by a local or state jurisdiction may operate for up to fourteen (14) 14 consecutive days in conjunction with that single event or celebration. All other non-sanctioned vendors may operate, with each day counting as one event. Vendors are limited to fourteen (14) 14 event permits per calendar year."

2.2 Amend Part 2-103 by adding thereto a new Subpart 2-103.11(Q) to read as follows:

<u>"2-103.11</u> Person in Charge.

- (R) Food Establishments must restrict use of plastic and polystyrene products as required by 84 Del. Laws, c. 177, § 2.
- (S) Food Establishments that offer children's meals for sale that include a beverage must follow all requirements mandated in 16 **Del.C.** §140B."
- 2.2 2.3 Amend **Subpart 2-201.13** to revise paragraph (A)(1)(a) by deleting the phrase "24 hours" and replacing it with the words "48 hours".
- 2.3 2.4 Amend **Subpart 2-401.11(A)** by adding thereto after the words "any form of tobacco" the following: "and/or or devices that people use to inhale an aerosol".
- 2.4 2.5 Amend **Subpart 3-305.12(I)** by deleting the existing text and by inserting in lieu thereof the following: "Under or in contact with sources of contamination."
- 2.5 2.6 Amend Part 3-305 by adding thereto a new subpart 3-305.15 to read as follows:

"3-305.15 Food Preparation Sink.

- (A) A dedicated food preparation sink shall be installed in the food establishment.
- (B) This section does not apply to certain types of food establishments deemed by the regulatory authority to pose minimal risk in the absence of a dedicated food preparation sink, such as establishments with non-TCS foods or those with commissaries that provide prewashed and prepared foods."
- 2.6 2.7 Amend **Subpart 3-602.11(B)(4)** by deleting the phrase "manufacturer, packer, or distributor" and replacing it with the words "location of food preparation and packaging".
- 2.7 2.8 Amend **Subpart 4-205.10** by deleting the existing text and by inserting in lieu thereof the following:
 - (A) Food equipment that is certified or classified for sanitation by an American National Standards Institute (ANSI)-accredited certification program is deemed to comply with Parts 4-1 and 4-2 of this chapter; and
 - (B) Manufacturer's specifications are required as documentation to support compliance with Parts 4-1 and 4-2 of this chapter.
- 2.8 2.9 Amend **Subpart 4-501.16(B)** by deleting the existing text and by inserting in lieu thereof the following: "If a WAREWASHING sink is used to wash wiping cloths the sink shall be cleaned as specified under §4-501.14 before and after each time it is used to wash wiping cloths."
- 2.9 2.10 Amend **Subpart 5-104.12(E)** by adding thereto before the words "Piping, tubing, or hoses connected to an adjacent APPROVED source." the following: "Safely connected and protected".
- 2.10 2.11 Amend **Subpart 5-202.12(A)** by adding thereto before the words "A HANDWASHING SINK" the following: "With the exception of facilities at a TEMPORARY FOOD ESTABLISHMENT,".
- 2.11 2.12 Amend **Subpart 5-203.11** by adding paragraph (D) to read as follows: "If approved, an ALTERNATIVE FOOD ESTABLISHMENT may use alternative handwashing equipment:
 - (1) Provided with clean, running running, and warm water; and
 - (2) Provided with a safe means to collect gray water."
- 2.12 2.13 Amend **Subpart 6-101.11(B)** by deleting the phrase "covered with mats, removable platforms, duckboards, or other APPROVED materials that are" in subparagraph (1) and by deleting the existing text in subparagraph (2) and inserting in lieu thereof the following: "Protection from weather and windblown dust and debris shall be provided."
- 2.13 2.14 Amend **Subpart 6-202.13(B)(1)** by adding thereto after the words "a food preparation" the following: "warewashing or food dispensing".
- 2.14 2.15 Amend **Subpart 6-301.12** by deleting subparagraph (B) in its entirety.
- 2.15 2.16 Amend **Subpart 6-501.115(B)** by adding subparagraph (6) to read as follows: "Dogs <u>are permitted</u> in designated OUTDOOR SPACES that are not used for food storage or preparation, when a person controls the animal and if a health or safety hazard will not result from the presence or activities."
- 2.16 2.17 Amend **Subpart 8-201.11(A)** by adding thereto after the words "FOOD ESTABLISHMENT" the following: "or ALTERNATIVE FOOD ESTABLISHMENT".
- 2.17 2.18 Amend **Subpart 8-201.11(C)** by adding thereto after the words "remodeling of a FOOD ESTABLISHMENT," the following: "change of ownership".

- 2.18 2.19 Amend **Subpart 8-302.11** by deleting the existing text and by inserting in lieu thereof the following: "An applicant shall submit an application apply sufficiently in advance of date of planned opening to allow for review and approval. The REGULATORY AUTHORITY regulatory authority will communicate with the applicant with REQUEST FOR INFORMATION and APPROVAL TO CONSTRUCT Request for Information and Approval to Construct records."
- 2.19 2.20 Amend **Subpart 8-302.14(A)** by adding thereto before the words "telephone number," the following: "email address,"; and by adding thereto before the word "signature" the following: "electronic or print".
- 2.20 2.21 Amend **Subpart 8-302.14(D)** by adding thereto after the word "title," the following: "mailing"; and by adding thereto before the words "and telephone number" the following: "email address,".
- 2.21 2.22 Amend **Subpart 8-302.14** by deleting subparagraph (E) in its entirety.
- 2.22 2.23 Amend 8-304.10(A) by deleting the phrase "a copy of" and replacing it with the words "access to".

3.0 Miscellaneous Provisions for the Delaware Division of Public Health

3.1 Amend Chapter 8 by adding thereto a new subpart 8-305.10 to read as follows:

"8-305.10 Alternative Food Establishments

The regulatory authority may authorize alternative food establishments to operate, following plan review and given that specific requirements are met for each type.

- (A) Requires a signed Servicing Area Agreement:
 - (1) Caterer without A Premise Premises;
 - (2) Limited Frozen Dessert Stand; and
 - (3) Mobile Food Establishment.
- (B) May require a signed Servicing Area Agreement:
 - (1) Temporary Food Establishment."
- 3.2 Amend Chapter 8 by adding thereto a new subpart 8-305.11 to read as follows:

"8-305.11 Alternative Food Establishment Closed or Suspended Permit

Alternative Food Establishments that require a servicing area must cease operations if the servicing area's permit is suspended or closed."

- 3.3 Amend **Subpart 8-401.10(B)(2)** by deleting the existing text and by inserting in lieu thereof the following: "The food establishment is assigned a less frequent inspection schedule that is being uniformly applied throughout the jurisdiction. The REGULATORY AUTHORITY regulatory authority will assign a risk category that correlates with inspection frequency. The categories are: VERY LOW RISK, LOW RISK, MEDIUM RISK and HIGH RISK very low risk, low risk, medium risk, and high risk."
- Amend **Subpart 8-404.11(A)** by deleting the words "an apparent foodborne illness outbreak" and by inserting in lieu thereof the following: "a PROBABLE or CONFIRMED FOODBORNE DISEASE OUTBREAK probable or confirmed foodborne disease outbreak".
- 3.5 Amend Chapter 8 by adding thereto a new Part 8-6 to read as follows:

"8-6 Enforcement Procedures

8-601 Re-inspection Fee

8-601.10 Fee Assessment and Failure to Pay

- (A) A re-inspection fee shall be assessed when an inspection is required beyond the routine schedule set for the risk category of the food establishment.
- (B) The re-inspection fee, required by Chapter 1, Section 134 of Title 16 of the Delaware Code, 16

 Del.C. §134 shall be paid upon or prior to inspection, in the following manner:
 - (1) The sum of \$50 shall be required for a second inspection,
 - (2) The sum of \$100 shall be required for a third inspection,
 - (3) The sum of \$150 shall be required for each subsequent inspection.
- (C) Failure to pay the re-inspection fee, as specified, shall result in the automatic suspension of the permit to operate a food establishment. The permit shall remain suspended until the Regulatory Authority regulatory authority receives full payment of all fees.

8-602 Administrative Action

8-602.10 General

If the Regulatory Authority regulatory authority determines that a food establishment is operating without a valid permit; that ene 1 or more conditions exist which represent an Imminent Health Hazard; or that serious violations, repeat violations, or general unsanitary

conditions are found to exist, administrative action may occur. Administrative action will be conducted in accordance with the law.

(A) Operation without a Permit

- (1) Immediate Closure Order. If a food establishment is found operating without a valid permit as required by subpart 8-301.11 of this Code regulation, the Regulatory Authority regulatory authority shall order the facility immediately closed.
- (2) Notice of Closure. The closure shall be effective upon receipt of a written notice by the person in charge of the food establishment or an employee of the food establishment. A closure notice statement recorded on the inspection report by the representative of the Regulatory Authority regulatory authority constitutes a written notice.
- (3) Duration of Closure. The food establishment shall remain closed until a permit application; applicable fees and any required plans have been received and approved by the Regulatory Authority regulatory authority.

(B) Imminent Health Hazard(s) Hazards

- (1) Permit Suspension without Hearing. If some condition is determined to exist in a food establishment, which presents an imminent health hazard to the public, the Regulatory Authority regulatory authority may suspend the operating permit of the food establishment without a prior hearing. The suspension shall be effective upon receipt of written notice by the person in charge of the food establishment or an employee of the food establishment. A suspension statement recorded on the inspection report by the Regulatory Authority regulatory authority constitutes a written notice.
- (2) A permit issued pursuant to subpart (1) shall not be suspended for a period longer than ten (10) 10 government business days without a hearing. Failure to hold a hearing within the ten (10) 10 government business day period shall automatically terminate the suspension.
- (3) Hearing Request. The permit holder of the food establishment may request, in writing, a hearing before the Regulatory Authority regulatory authority at any time during the period of suspension, for demonstrating that the imminent health hazard(s) hazards no longer exist. The request for hearing shall not stay the suspension.
- (4) Discontinued operation for the mitigation of an imminent health hazard requires a food establishment to remain closed for at least twenty-four (24) 24 hours.
- (C) Serious Violations, Repeat Violations and General Unsanitary Conditions. When conditions exist in a food establishment that represent serious violations, repeat violations or general unsanitary conditions, the Regulatory Authority regulatory authority may initiate a corrective action plan or schedule a hearing.

8-603 Agency Emergency Actions

8-603.10 Examination of Food.

Food may be examined or sampled by the Regulatory Authority regulatory authority as often as necessary for enforcement of this Code regulation.

8-603.20 Wholesome and Free from Spoilage.

All food shall be wholesome and free from spoilage. Food that is spoiled or unfit for human consumption shall not be kept on the premises. The established administrative procedures for the implementation and enforcement of the provisions of Chapter 33 of Title 16 of the Delaware Code, relating to the embargo of misbranded or adulterated food, and penalties shall be applicable to this subpart.

8-604 Penalties

8-604.10 Operation in Violation of Code.

Any person (or responsible officer of that person) who violates a provision of this Code, and any person (or responsible officer of that person) who is the holder of a permit or who otherwise operates a food establishment that does not comply with the requirements of this Code shall be subject to the provisions of Section 107 of Title 16 of the Delaware Code.

8-604.20 Refusal, Failure or Neglect to Comply with Order of the Regulatory Authority.

Any person (or responsible officer of that person) who violates a provision of this Code, and any person (or responsible officer of that person) who is the holder of a permit or who otherwise operates a food establishment that refuses, fails or neglects to comply with an order of the

Regulatory Authority shall be subject to an administrative penalty of not less than \$100 and not more than \$1,000, together with costs.

8-604.30 Injunction. The Regulatory Authority may seek to enjoin violations of this Code.

8-604.40 Public Notification. A placard, as provided by the Division of Public Health, shall be prominently displayed at all entrances of food establishments that have failed to obtain a valid permit or have a permit that is suspended, revoked, or expired. This placard shall only be removed by order of the Regulatory Authority."

14 DE Reg. 822 (02/01/11) 17 DE Reg. 1084 (05/01/14) 24 DE Reg. 158 (08/01/20) 28 DE Reg. 853 (06/01/25) (Prop.)