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Fast-Track Regulation Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC5-421
VAC Chapter title(s)	Food Regulations
Action title	Amend Chapter 421 to Adopt 2022 FDA Food Code
Date this document prepared	October 24, 2023

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

The Food Regulations (12VAC5-421 et seq.) establish minimum sanitary standards for the operation of the Commonwealth's food establishments, which include traditional restaurants, mobile food units, temporary food vendors, hospital and nursing facility food service, and school food service. Those standards include: (1) the safe and sanitary maintenance, storage, operation, and use of equipment; (2) the safe preparation, handling, protection, and preservation of food, including necessary refrigeration and heating methods; (3) procedures for vector and pest control; (4) requirements for toilet and cleansing facilities for employees and customers; (5) requirements for appropriate lighting and ventilation not otherwise provided for in the Uniform Statewide Building Code; (6) requirements for an approved water supply and sewage disposal system; (7) personal hygiene standards for employees, particularly those engaged in food handling; and (8) the appropriate use of precautions to prevent the transmission of communicable diseases.

The proposed regulatory action would amend the existing Food Regulations to incorporate, in part, 2022 amendments to the Food and Drug Administration (FDA) Food Code. Proposed edits include the addition and revision of definitions, updates to cross references, and changes to standards related to temperatures, food donation, and risk categorization. The FDA Food Code serves as a model document to assist state and local agencies with regulatory authority over food safety by creating a regulatory scheme that reflects the most current science available to reduce the risk of food borne illnesses associated with food establishments. Additional amendments are intended to ensure clarity and uniform application.

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the “Definitions” section of the regulation.

No acronyms or technical terms were identified that were not included in the “Definitions” section of the Food Regulations.

Statement of Final Agency Action

Provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

The State Board of Health approved these Fast Track amendments to the Food Regulations (12VAC5-421) on December 15, 2023.

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, “mandate” has the same meaning as defined in the ORM procedures, “a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part.”

Consistent with Virginia Code § 2.2-4012.1, also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track rulemaking process.

The Virginia Department of Health (VDH) is initiating this regulatory action to amend its regulations to: (1) align the Food Regulations with the 2022 FDA Food Code, and (2) to ensure clarity and ensure uniform application of the regulations. The FDA Food Code, revised by the FDA approximately every four years, serves as a model document to assist state and local agencies with regulatory authority over food safety by creating a regulatory scheme that reflects the most current science available to reduce the risk of food borne illnesses associated with food establishments. VDH has used the FDA Food Code as a foundation of its regulations governing food safety in food establishments since before the year 2000.

This regulatory action is best suited for the fast-track process as it is non-controversial and follows the requirements outlined in § 35.1-14 C & E of the Code of Virginia. The proposed changes will ensure the Food Regulations reflect changes made to the 2022 FDA Food Code,

compliment current Virginia law, and provide minimal burdens on regulants while protecting public health.

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia and Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

The promulgating agency is the State Board of Health.

Section 35.1-11 of the Code of Virginia states,

“The Board shall make, adopt, promulgate, and enforce regulations necessary to carry out the provisions of this title and to protect the public health and safety. In promulgating regulations, the Board shall consider the accepted standards of health including the use of precautions to prevent the transmission of communicable diseases, hygiene, sanitation, safety, and physical plant management.”

Section 35.1-14 of the Code of Virginia states in part,

“A. Regulations of the Board governing restaurants shall include but not be limited to the following subjects: (i) a procedure for obtaining a license; (ii) the safe and sanitary maintenance, storage, operation, and use of equipment; (iii) the sanitary maintenance and use of a restaurant's physical plant; (iv) the safe preparation, handling, protection, and preservation of food, including necessary refrigeration or heating methods; (v) procedures for vector and pest control; (vi) requirements for toilet and cleansing facilities for employees and customers; (vii) requirements for appropriate lighting and ventilation not otherwise provided for in the Uniform Statewide Building Code; (viii) requirements for an approved water supply and sewage disposal system; (ix) personal hygiene standards for employees, particularly those engaged in food handling; (x) the appropriate use of precautions to prevent the transmission of communicable diseases; and (xi) training standards that address food safety and food allergy awareness and safety.”

B. In its regulations, the Board may classify restaurants by type and specify different requirements for each classification.

C. The Board may adopt any edition of the Food and Drug Administration's Food Code, or supplement thereto, or any portion thereof, as regulations, with any amendments as it deems appropriate. In addition, the Board may repeal or amend any regulation adopted pursuant to this subsection. No regulations adopted or amended by the Board pursuant to this subsection, however, shall establish requirements for any license, permit, or inspection unless such license, permit, or inspection is otherwise provided for in this title. The provisions of the Food and Drug Administration's Food Code shall not apply to farmers selling their own farm-produced products directly to consumers for their personal use, whether such sales occur on such farmer's farm or at a farmers' market, unless

such provisions are adopted in accordance with the Administrative Process Act (§ 2.2-4000 et seq.).”

Purpose

Explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it is intended to solve.

The U.S. Centers for Disease Control and Prevention estimate that foodborne diseases cause approximately 48 million people to become ill, 128,000 hospitalizations, and 3,000 deaths in the United States each year.¹ This translates into 1 in 6 Virginians who may become ill each year. The United States Department of Agriculture estimates that foodborne illnesses cost the United States more than \$15.6 billion a year.²

The purpose of these regulations is to prevent foodborne illness by ensuring that foods prepared and served at food establishments in Virginia are safe, unadulterated, and prepared under sanitary conditions. This is accomplished by ensuring regulations reflect current science and technology regarding minimum sanitary standards for food establishments to protect the dining public. These standards include approved sources for foods used in food establishments, specifications for safe handling, storage, preparation and serving of food, personal hygiene of employees, precautions to prevent the transmission of diseases communicable through food, and the general sanitation of the facility. When followed, these minimum standards will protect the public's health, safety, and welfare. In addition, amending the Food Regulations to conform to the 2022 FDA Food Code will ensure the regulation promotes uniformity in administration of the food safety program.

VDH's goals of the regulatory change is to ensure the Food Regulations represent the best practices related to food safety in food establishments, strengthen consumer confidence in the safety of the food served in the Commonwealth, and to ensure administration of the Food Regulations is carried out in the most cost-effective manner.

The benefits of adopting and implementing uniform standards have shown to lead to higher compliance, consistent training of public health staff, and an increased shared responsibility of the food industry and the government in ensuring food provided to the consumer is safe and does not become a vehicle for a disease outbreak or for the transmission of communicable disease.

¹ Center for Disease Control and Prevention (2023, August 9). *Foodborne Germs and Illness*.

<https://www.cdc.gov/foodsafety/foodborne-germs.html#:~:text=CDC%20estimates%20that%20each%20year,are%20hospitalized%2C%20and%203%2C000%20die.>

² Center for Disease Control and Prevention (2023, March 13). *CDC and Food Safety*.

<https://www.cdc.gov/foodsafety/pdfs/cdc-and-food-safety.pdf>

Substance

Briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of Changes" section below.

Substantive changes to the Food Regulations are as follows:

- A. Definitions
 - a. Add and amend definitions to conform with the 2022 FDA Food Code
- B. Management and Personnel
 - a. Amend the regulations to allow flexibility for food establishments that pose a minimal risk, expand the role of responsible management in the food establishment, and clarify conditions in which food employees shall be excluded or restricted from work duties due to illness.
- C. Food
 - a. Amend regulations with updated terminology, cross-references, and clarification of handling and tagging of shellfish products.
- D. Equipment, Utensils, and Linens
 - a. Amend regulations to conform with the 2022 FDA Food Code related to risk categorization.
- E. Water, Plumbing, Waste, Physical Facilities
 - a. Amend regulations to include new definitions and cross references.
- F. Poisonous or Toxic Materials
 - a. Amend regulations to conform with 2022 FDA Food Code related to poisonous material storage.
- G. Compliance and Enforcement
 - a. Amend regulations to conform with 2022 FDA Food Code related to enforcement, variances, and food donation.

Issues

Identify the issues associated with the regulatory change, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, include a specific statement to that effect.

The primary advantage of the proposed regulations for the public is the reduction of the risk of foodborne illnesses within food establishments, thus protecting consumers and industry from potentially devastating health consequences and financial losses. The revisions will also make the regulations more understandable and align them with best practices.

The primary advantage to the agency is the regulations will be based on current food science and clarify ambiguous areas relating to enforcement and inspection standards. Staff will have a better understanding of the improved regulatory scheme of food safety thus providing enhanced communication to the public and regulant community on how to prevent foodborne illness. The primary advantage to the regulated community, particularly chains and franchises that operate in other states as well as in multiple jurisdictions across the

Commonwealth that have adopted the current version of the FDA Food Code, will be more consistent regulatory application.

There are no known disadvantages to the public or the Commonwealth with the adoption of the proposed regulations.

Requirements More Restrictive than Federal

Identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements, or no requirements that exceed applicable federal requirements, include a specific statement to that effect.

There are no requirements in this change that would be more restrictive than those currently required in federal law.

Agencies, Localities, and Other Entities Particularly Affected

Consistent with § 2.2-4007.04 of the Code of Virginia, identify any other state agencies, localities, or other entities particularly affected by the regulatory change. Other entities could include local partners such as tribal governments, school boards, community services boards, and similar regional organizations. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected

No state agencies will bear any identified disproportionate material impact not experienced by other agencies, localities, or entities.

Localities Particularly Affected

No localities will bear any identified disproportionate material impact not experienced by other agencies, localities, or entities.

Other Entities Particularly Affected

No localities will bear any identified disproportionate material impact not experienced by other agencies, localities, or entities.

Economic Impact

Consistent with § 2.2-4007.04 of the Code of Virginia, identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Keep in mind that this is the proposed change versus the status quo.

Impact on State Agencies

<p><i>For your agency:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources</p>	<p>The Board does not expect any changes to costs, savings, fees or revenues as a result of the proposed regulatory change.</p>
<p><i>For other state agencies:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.</p>	<p>The Board does not expect any cost savings by other state agencies as a result of the regulatory change to chapter 421. In addition, the Board does not expect any changes to costs, fees or revenues for other state agencies as a result of the regulatory change to chapter 421.</p>
<p><i>For all agencies:</i> Benefits the regulatory change is designed to produce.</p>	<p>Benefits include alignment with the 2022 FDA Food Code, which promotes uniformity of food safety standards, reflects the most current science and knowledge regarding food safety, and improvement of agency understanding of food safety expectations.</p>

Impact on Localities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a or 2) on which it was reported. Information provided on that form need not be repeated here.

<p>Projected costs, savings, fees or revenues resulting from the regulatory change.</p>	<p>Analysis of the proposed regulations on localities has been reported on the ORM Economic Impact form under Table 2.</p>
<p>Benefits the regulatory change is designed to produce.</p>	<p>Analysis of the proposed regulations on localities has been reported on the ORM Economic Impact form under Table 2.</p>

Impact on Other Entities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a, 3, or 4) on which it was reported. Information provided on that form need not be repeated here.

<p>Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.</p>	<p>Analysis of the proposed regulations on other entities has been reported on the ORM Economic Impact form under Table 2,3, and 4.</p>
<p>Agency’s best estimate of the number of such entities that will be affected. Include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and;</p>	<p>Analysis of the proposed regulations on other entities has been reported on the ORM Economic Impact form under Table 2,3, and 4.</p>

<p>b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	
<p>All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.</p>	<p>Analysis of the proposed regulations on other entities has been reported on the ORM Economic Impact form under Table 2,3, and 4.</p>
<p>Benefits the regulatory change is designed to produce.</p>	<p>Analysis of the proposed regulations on other entities has been reported on the ORM Economic Impact form under Table 2,3, and 4.</p>

Alternatives to Regulation

Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulatory change.

Analysis of alternatives to the regulation has been reported on the ORM Economic Impact form under Table 1c.

Regulatory Flexibility Analysis

Consistent with § 2.2-4007.1 B of the Code of Virginia, describe the agency’s analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the regulatory change.

Section 35.1-11 of the Code of Virginia requires the Board to make, adopt, promulgate, and enforce regulations necessary to carry out the provisions of Title 35.1 (Hotels, Restaurants, Summer Camps and Campgrounds). No alternative methods are available, as the proposed regulations are necessary and do not impose unreasonably stringent compliance or reporting requirements. The amendments represent the simplest and most effective standards related to compliance and reporting requirements, and they contain exemptions from certain regulatory

requirements to allow flexibility for small businesses as to their operation while protecting public health.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below.

Consistent with § 2.2-4011 of the Code of Virginia, if an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

If you are objecting to the use of the fast-track process as the means of promulgating this regulation, please clearly indicate your objection in your comment. Please also indicate the nature of, and reason for, your objection to using this process.

The Virginia Department of Health is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal and any alternative approaches, (ii) the potential impacts of the regulation, and (iii) the agency's regulatory flexibility analysis stated in this background document.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: <https://townhall.virginia.gov>. Comments may also be submitted by mail, email or fax to: Olivia McCormick, Director of Food and General Environmental Health Services, 109 Governor St, 5th Floor, Richmond, VA 23219, (804)864-7474 (office) (804) 864-7475 (fax) Olivia.Mccormick@vdh.virginia.gov. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
12VAC5-421-10		Section Title: "Definitions" (Amendments) Section provides definitions to terms used throughout the regulations.	Change: Amend the definitions of: "Certification Number" "Commingle" "Intact Meat" "Major Food Allergen" "Mechanically Tenderized"

			<p>“Molluscan Shellfish” “Poisonous or Toxic Material” “Ready-to-eat” “Reduced oxygen-packaging” “Shellstock” “Shucked Shellfish”</p> <p>Add new definitions for the following terms: “In-Shell Product” “Tobacco Product”</p> <p>Intent: Ensure all technical terms are defined with the most appropriate definitions.</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code and update terminology utilized in the food safety industry.</p> <p>Impact: Improved understanding and application of the regulations.</p>
<p>12VAC5-421-50</p>		<p>Section Title: “Assignment of responsibility” This section assigns responsibility to a member of staff to ensure the continuous presence of someone who is responsible for monitoring and managing all food establishment operations.</p>	<p>Change/Intent: Add new subsection, subsection C, to establish an exception where the person-in-charge is not required to be present at all times of the establishment’s operation, if the establishment poses a minimal risk to causing or contributing to food borne illness.</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code and allows staff to establish criteria for what types of permitted establishments could be exempt from designating a person in charge present at all times during operation.</p> <p>Impact: Improved understanding and application of the regulations; reduction of unnecessary regulatory oversight. Food establishments may save money on staff costs.</p>
<p>12VAC5-421-65</p>		<p>Section Title: “Food protection manager certification” This section outlines the training standards for a certified food protection manager.</p>	<p>Change/Intent: To amend section A and B to correct the title of the Conference for Food Protection Standard to remove the “s” at end of the word ‘Standards’, and to remove a date, as this is a list that is constantly maintained by the Conference</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code and to accurately reflect the name of the</p>

			<p>standardizing organization. Keeping the dated version of the list would restrict industry and provide fewer options.</p> <p>Impact: Improved understanding and application of the regulations.</p>
12VAC5-421-70		<p>Section Title: “Duties of a person in charge”</p> <p>This section outlines the duties of the Person in Charge.</p>	<p>Change/Intent: Add subsection J. The new subsection includes a duty requirement for the Person in Charge to ensure food employees properly maintain the temperatures of time/temperature control for safety foods; amends former subsection ‘14’ (now ‘15’) to indicate what food allergy awareness includes.</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code and to ensure the Person in Charge maintains the food operations in a manner to protect the public from food borne illness.</p> <p>Impact: Improved understanding and application of the regulations; improved safety and prevention of food borne illness.</p>
12VAC5-421-80		<p>Section Title: “Responsibility of permit holder, person in charge, and conditional employees”</p> <p>This section outlines when food employees and conditional employees shall report certain information regarding their health as it relates to diseases transmissible through food.</p>	<p>Change/Intent: Correct a cross reference to when an employee should be excluded from working in the food establishment vs. restricted from performing specific types of tasks.(See definitions for “exclude” and “restrict” in 12VAC5-421-10.)</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code.</p> <p>Impact: Improved understanding and application of the regulations; improved safety and prevention of food borne illness.</p>
12VAC5-421-160		<p>Section Title: “When to wash”</p> <p>This section outlines when food employees shall clean their hands and exposed portion of their arms prior to food preparation.</p>	<p>Change/Intent: Require food employees to wash their hands after using tobacco products (see section 220).</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code and avoid contamination of food with tobacco products.</p> <p>Impact: Improved understanding and application of the regulations; improved safety, prevention of food borne illness and contamination of food.</p>

<p>12VAC5-421-220</p>		<p>Section Title: “Eating, drinking or using tobacco”</p> <p>This section outlines the areas in which an employee must eat, drink, or may use tobacco products.</p>	<p>Change/Intent: To amend the title and content of section 220: ‘tobacco’ is now ‘tobacco product’.</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code and to add the term ‘tobacco product’ to the list of actions that require usage in designated areas.</p> <p>Impact: Improved understanding and application of the regulations; improved safety, prevention of food borne illness and contamination of food.</p>
<p>12VAC5-421-250</p>		<p>Section Title: “Handling of animals prohibited”</p> <p>This section restricts food employees from handling animals.</p>	<p>Change/Intent: To amend the title of section 250, to add a cross reference which would restrict food employees from handling dogs that are allowed in an outdoor dining area of the food establishment.</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code and to restrict handling of dogs in a food establishment.</p> <p>Impact: Improved understanding and application of the regulations; improved safety, prevention of food borne illness and contamination of food from handling of animals.</p>
<p>12VAC5-421-270</p>		<p>Section Title: “Compliance with food law”</p> <p>This section requires food meet certain standards such being from an approved source, standards for package labeling, and proper food handling.</p>	<p>Change/Intent: To correct superscript, change ‘priority (P)’ to ‘priority foundation (Pf)’, lessening the severity of this violation, remove cross reference to 12VAC5-421-400; amend section to clarify types of meat obtained from a food processing plant that does not require a consumer advisory; under (E)1 strikes ‘labeled by’ and replaces it with ‘received from’; strikes subsection (E)3.c.</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code and to provide clarity to food establishments receiving whole-muscle meats and the appropriate use of consumer advisors.</p> <p>Impact: Improved understanding and application of the regulations; improved safety, prevention of food borne illness.</p>
<p>12VAC5-421-400</p>		<p>Section Title: “Molluscan shellfish, packaging, and identification</p>	<p>Change/Intent: To amend the title of section 400 from “shucked shellfish” to “molluscan shellfish”. In addition, the proposed language adds the option to</p>

		<p>This section requires packages or containers for molluscan shellfish to bear a tag or label that contains certain identifying information.</p>	<p>use terminology of “tags” in addition to “labels”, and clarifies what information is required on tags and labels.</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code and to ensure tags and labels contain accurate source identification of the harvesting area, harvester, and dealers so that if a shellfish-borne disease outbreak occurs, the information is available to expedite an epidemiological investigation and any necessary regulatory action.</p> <p>Impact: Improved understanding and application of the regulations; improved safety, prevention, and investigation of food borne illness.</p>
<p>12VAC5-421-420</p>		<p>Section Title: Shellstock, condition.</p> <p>This section requires a food establishment to ensure shellstock is free of mud and in good condition. Any dead or damaged shellstock shall be discarded.</p>	<p>Change/Intent: Replace each instance of the word “shellfish” to “shellstock.”</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code and to ensure food establishments dispose of dirty, damaged, or dead shellstock which can contaminate and degrade live and healthy shellstock and lead to foodborne illness.</p> <p>Impact: Improved understanding and application of the regulations; improved safety, prevention, and investigate of food borne illness.</p>
<p>12VAC5-421-430</p>		<p>Section Title: Molluscan shellfish, original container.</p>	<p>Change/Intent: To amend text to prohibit the commingling of molluscan shellfish from a different container with different certification dates, different harvest dates and areas. In addition, the proposed text reflects the addition of the terminology “in-shell product” to the regulations.</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code and to ensure lot separation of molluscan shellfish. Proper identification is vital for tracing the origin of shellfish in the event of a foodborne outbreak and is helpful when identifying products that require recall or growing waters that may need to be closed to harvesting.</p> <p>Impact: Improved understanding and application of the regulations; improved</p>

			safety, prevention, and investigation of food borne illness.
12VAC5-421-440		<p>Section Title: “Molluscan Shellfish, Maintain Identification”</p> <p>This section outlines the standards for identification of molluscan shellfish and recordkeeping of tags, labels, and invoices.</p>	<p>Change/Intent: Add the following terms: “molluscan shellfish”, “invoices”, “shucked shellfish” and “in-shell product.”</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code and to ensure accurate records are maintained in such a manner that allows them to trace molluscan shellfish to its original source. If an outbreak occurs, accurate records are vital to take appropriate actions to prevent further illnesses.</p> <p>Impact: Improved understanding and application of the regulations; improved safety, prevention of food borne illness.</p>
	12VAC5-421-445	<p>Section Title: “Food Donation”</p> <p>This section requires food offered for donation comply with law and the Food Regulations.</p>	<p>Change/Intent: Provide standards for donated food regarding storage, preparation, packaging, display, and labeling.</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code and to provide clarity to food establishments that it is permissible to donate food that complies with the Code of Virginia and the Food Regulations.</p> <p>Impact: Improved understanding and application of the regulations; to reduce food loss and waste; to reduce food insecurity; improved safety, prevention of food borne illness.</p>
12VAC5-421-470		<p>Section Title: “Packaged and unpackaged food - separation, packaging, and segregation”</p> <p>This section outlines standards for the separation of foods in a ready-to-eat form from raw animal foods.</p>	<p>Change/Intent: To amend section to include an additional exception as to when raw animal food does not need separation from ready-to-eat food.</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code and to provide clarity to food establishments when certain foods do not require separation from raw animal foods.</p> <p>Impact: Improved understanding and application of the regulations.</p>
12VAC5-421-510		<p>Section Title: “Washing fruits and vegetables”</p> <p>This section outlines when certain fruits and vegetables</p>	<p>Change/Intent: To amend section to allow the optional use of a test kit or device to measure wash solution concentration when chemical wash is used.</p>

		shall be washed prior to consumption.	<p>Rationale: Conformance to the 2022 Edition of the FDA Food Code.</p> <p>Impact: Improved understanding and application of the regulations; improved safety, prevention of food borne illness.</p>
12VAC5-421-620		<p>Section Title: “Food storage; prohibited areas”</p> <p>This section outlines the areas in which it is prohibited to store food.</p>	<p>Change/Intent: To amend section to change storing food in a toilet room from a core violation (to be corrected within 90 days of observation) to a priority foundation violation (corrected within 10 calendar days of observation).</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code. In addition, the amendment highlights the increased potential hazard of storing food in a toilet room as trace amounts of refuse or wastes in such areas could contaminate food.</p> <p>Impact: Improved understanding and application of the regulations; improved safety, prevention of food borne illness.</p>
12VAC5-421-700		<p>Section Title: “Raw animal foods”</p> <p>This section outlines the minimal cooking temperatures based on cooking methods for raw animal foods.</p>	<p>Change/Intent: To amend section to delete ‘mechanically tenderized and ‘injected’ and insert ‘nonintact meat’ and align terminology regarding mechanically tenderized beef products with the Food Code.</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code. In addition, the amendments ensure meats, under various types of processing, are cooked at appropriate temperatures to effectively eliminate pathogens.</p> <p>Impact: Improved understanding and application of the regulations; improved safety, prevention of food borne illness.</p>
	12VAC5-421-726	<p>Section Title: “Manufacturer Cooking Instructions”</p> <p>This section outlines cooking instructions for commercially packaged food.</p>	<p>Change/Intent: Add new section, which requires food establishments to cook commercially packaged foods according to manufacturer’s instructions or according to a time and temperature appropriate for the food.</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code. A food manufacturer may produce and provide food that has a known or reasonably foreseeable hazard (such as Salmonella) without first processing the food(cooking) to control that hazard so</p>

			<p>long as the manufacturer provides a disclosure. This section requires food establishments to cook such foods to control any foodborne illness hazards prior to making the food available for human consumption.</p> <p>Impact: Improved understanding and application of the regulations; improved safety, prevention of food borne illness.</p>
12VAC5-421-790		<p>Section Title: “Thawing”</p> <p>This section outlines the process to properly thaw time /temperature for safety food.</p>	<p>Change/Intent: Add cross references to a new section, “Manufacturer Cooking Instructions”, and amend certain subsections from core violations (to be corrected within 90 days of observation) to priority foundation violations (corrected within 10 calendar days of observation).</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code. In addition, amendment highlights the increased potential hazard of improper thawing of time/temperature for safety foods.</p> <p>Impact: Improved understanding and application of the regulations; improved safety, prevention of food borne illness.</p>
12VAC5-421-830		<p>Section Title: “Ready-to-eat, time/temperature control for safety food; date marking”</p> <p>This section outlines the process for date marking certain foods.</p>	<p>Change/Intent: Correct a citation to the Code of Federal Regulations.</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code; to correctly reflect citations to federal regulations.</p> <p>Impact: Improved understanding and application of the regulations; improved safety, prevention of food borne illness.</p>
12VAC5-421-850		<p>Section Title: “Time as a public health control”</p> <p>This section outlines food handling when time and not temperature is used as a public health control.</p>	<p>Change/Intent: Add a new subsection to address temperatures, within a four-hour window, for ready-to-eat produce or hermetically sealed food that is rendered time/temperature control for safety food.</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code; to recognize new technology that continuously monitors temperature control to prevent the growth of C. botulinum and L. monocytogenes, to add additional controlling factors to prevent pathogen growth.</p>

			<p>Impact: Improved understanding and application of the regulations; improved safety, prevention of food borne illness.</p>
12VAC5-421-870		<p>Section Title: “Reduced oxygen packaging without a variance, criteria”</p> <p>This section outlines the standards, such as a HACCP plan, for reduced oxygen packaging without a variance.</p>	<p>Change/Intent: Add a new subsection to include an additional option to package and seal food products by a cooling or sous-vide process so long as the food meets certain refrigeration standards. Correct cross-references to Section -3630 based on the addition of a new subdivision 4 in that section.</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code; to ensure ready-eat-foods are properly handled and disposed of when time and not temperature is used as a public health control prior to pathogen growth and possible toxin production.</p> <p>Impact: Improved understanding and application of the regulations; improved safety, prevention of food borne illness.</p>
12VAC5-421-900		<p>Section Title: “Food labels”</p> <p>This section outlines what is required on label information for food packaged at a food establishment.</p>	<p>Change/Intent: To amend subsection C2 to add a cross reference that would require a food establishment to add a notification regarding potential allergens in bulk food that is available for consumer self-dispensing.</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code; to reduce unintended food allergen exposures to consumers with food allergies.</p> <p>Impact: Improved understanding and application of the regulations; improved safety, prevention of food borne illness, reduction in serious illness such as anaphylaxis due to contact with an undisclosed food allergen.</p>
12VAC5-421-910		<p>Section Title: “Other forms of information”</p> <p>This section outlines requirements for miscellaneous notifications to the consumer.</p>	<p>Change/Intent: To add a new subsection that requires the food establishment to notify consumers in writing about major food allergens.</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code; to reduce unintended food allergen exposures to consumers with food allergies.</p>

			<p>Impact: Improved understanding and application of the regulations; improved safety, prevention of food borne illness, reduction in serious illness such as anaphylaxis due to contact with an undisclosed food allergen.</p>
12VAC5-421-950		<p>Section Title: “Pasteurized foods, prohibited reservice, and prohibited food.”</p> <p>This section sets forth the standards for the service of food to highly susceptible populations.</p>	<p>Change/Intent: To add subdivision 3(d), a cross reference to manufactured packaged food. Packaged food, as specified in the cross reference, in a ready-to-eat form is prohibited from service to highly susceptible populations. Correct cross-references to Section -3630 based on the addition of a new subdivision 4 in that section.</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code; to include additional safeguards to protect those who are particularly vulnerable to foodborne illness.</p> <p>Impact: Improved understanding and application of the regulations; improved safety, prevention of food borne illness.</p>
12VAC5-421-1435		<p>Section Title: “Food equipment, certification and classification”</p> <p>This section states food equipment meeting certain standards are deemed safe for use in food establishments.</p>	<p>Change/Intent: To amend section to clarify that the American National Standards Institute’s role is not as an accreditation organization.</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code; improved clarity of regulatory requirements.</p> <p>Impact: Improved understanding and application of the regulations.</p>
12VAC5-421-1535		<p>Section Title: “Cleaning Agents and sanitizers, availability”</p> <p>This section requires cleaning agents be available in the food establishment during hours of operation.</p>	<p>Change/Intent: To amend section to add a risk based categorization of “priority foundation” and to remove unnecessary styling.</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code; per the FDA this designation was inadvertently ‘left off’ the 2017 FDA Food Code.</p> <p>Impact: Improved understanding and application of the regulations.</p>
12VAC5-421-1540		<p>Section Title: “Equipment, clothes washers and dryers, and storage cabinets, contamination prevention”</p>	<p>Change/Intent: To amend section to change placing cabinets or equipment used to store food in a toilet room or vestibule from a core violation (to be corrected within 90 days of</p>

		<p>This section restricts the location of cabinets and equipment used to store food.</p>	<p>observation) to a priority foundation violation (corrected within 10 calendar days of observation).</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code. In addition, the amendment highlights the increased potential hazard of allowing food storage equipment in a toilet room or its vestibule as trace amounts of refuse or wastes in such areas could contaminate food.</p> <p>Impact: Improved understanding and application of the regulations; improved safety, prevention of food borne illness.</p>
<p>12VAC5-421-2010</p>		<p>Section Title: “Prohibitions”</p> <p>This section restricts the location of where cleaned and sanitized equipment, utensils, and other items are stored.</p>	<p>Change/Intent: To change placing cleaned and sanitized equipment, utensils, and other items in a toilet room or vestibule from a core violation (to be corrected within 90 days of observation) to a priority foundation violation (corrected within 10 calendar days of observation).</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code. In addition, the amendment highlights the increased potential hazard of storing cleaned and sanitized equipment, utensils, and other items in a toilet room or its vestibule as trace amounts of refuse or wastes in such areas could contaminate food.</p> <p>Impact: Improved understanding and application of the regulations; improved safety, prevention of food borne illness.</p>
<p>12VAC5-421-2190</p>		<p>Section Title: “Handwashing sinks, water temperature, and flow”</p> <p>This section outlines standards for the installation of handwashing sinks used in a food establishment that includes the temperature of the water delivered at the sink.</p>	<p>Change/Intent: To amend section to reduce the minimum hot water temperature at a handwashing sink from 100°F to 85°F.</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code and the International Plumbing Code which defines “tempered water” as having a temperature range between 29.4°C (85°F) and 43°C (110°F).</p> <p>Impact: Improved understanding and application of the regulations; alignment of regulatory requirements to industry standard, and reduction of unnecessary regulatory burden.</p>

<p>12VAC5-421-3140</p>		<p>Section Title: “Employee accommodations, designated areas”</p> <p>This section requires designated areas for employees to eat, drink, and use tobacco products.</p>	<p>Change/Intent: To include the term ‘tobacco product.’</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code.</p> <p>Impact: Improved understanding and application of the regulations; improved safety, prevention of food borne illness, and contamination of food.</p>
<p>12VAC5-421-3360</p>		<p>Section Title: “Conditions of Use”</p> <p>This section outlines the proper use and application of poisonous or toxic materials in a food establishment.</p>	<p>Change/Intent: To strike reference to “restricted use pesticide.”</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code; the definition of Poisonous or Toxic Materials with the Code of Federal Regulations was revised.</p> <p>Impact: Improved understanding and application of the regulations; improved safety, conformance to changes in federal definitions.</p>
<p>12VAC5-421-3370</p>		<p>Section Title: “Poisonous or toxic material containers.”</p> <p>This section prohibits the use of poisonous or toxic material containers to store, transport, or dispense food.</p>	<p>Change/Intent: To prohibit the storage of linens, single-service, or single-use articles in in containers that previously stored poisonous or toxic materials.</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code and to reduce the risk of potential contamination of food or food contact surfaces with poisonous or toxic material.</p> <p>Impact: Improved understanding and application of the regulations; improved safety, prevention of food contamination.</p>
<p>12VAC5-421-3510</p>		<p>Section Title: “Poisonous or toxic material containers.”</p> <p>This section prohibits the use of poisonous or toxic material containers to store, transport, or dispense food.</p>	<p>Change/Intent: To require the department to apply the regulations to donated food.</p> <p>Rationale: Conformance to the 2022 Edition of the FDA Food Code and to ensure donated food products are served, stored, and prepared safely.</p> <p>Impact: Improved understanding and application of the regulations; improved safety, and prevention of food borne illness.</p>
<p>12VAC5-421-3595</p>		<p>Section Title: “Conformance with approved procedures.”</p>	<p>Change/Intent: To require the permit holder to maintain any approved variance at the food establishment. Correct cross-reference to Section -</p>

		This section outlines the requirements of the permit holder when a variance is granted, or a HACCP plan is required.	3630 based on the addition of a new subdivision 4 in that section. Rationale: Conformance to the 2022 Edition of the FDA Food Code and to ensure a copy of an approved variance is on the premise of the food establishment available for inspection. Impact: Improved understanding and application of the regulations; improved safety, and improved compliance with approved variances.
12VAC5-421-3630		Section Title: "Contents of a HACCP Plan." This section outlines the information permit holders or applicants shall submit to the department when seeking the approval of a HACCP plan.	Change/Intent: To clarify and merge text to highlight items required for submission to the department. Rationale: Conformance to the 2022 Edition of the FDA Food Code. Impact: Improved understanding and application of the regulations; improved safety, and to improve the approval process of HACCP plans.
12VAC5-421-3700		Section title: "Contents of the application." This section outlines the requirements for a permit application.	Change/Intent: To correct a cross-reference to Section -3630. Rationale: A new subdivision 4 was added to section -3630 in this action.. Impact: Correct cross-references ensure proper interpretation and enforcement of the chapter.
12VAC5-421-3860		Section title: "Documenting information and observations." This section outlines the department's responsibilities during inspections.	Change/Intent: To correct a cross-reference to Section -3630. Rationale: New subdivisions 4 and 5 b are added to section -3630 in this action. Impact: Correct cross-references ensure proper interpretation and enforcement of the chapter.
Throughout			Change/Intent: Non-substantive edits were made throughout, such as correcting use of "must," "shall," and "may;" changing passive constructions to active voice; adding or clarifying definite/indefinite articles; correcting use of singular vs. plural; "if" vs. "when"; and other minor updates for readability. The intent is to conform to the Registrar of Regulations' <i>Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code</i> .

			<p>Rationale: The rationale is that proper style and format, grammatical correctness, and consistency of language are required to conform to the journalistic style of the Virginia Register of Regulations.</p> <p>Likely Impact: The likely impact is that the chapter will be more readable.</p>
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