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Final Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-421
Regulation title(s)	Food Regulations
Action title	Amend the regulations to be consistent with the 2013 U. S. Food and Drug Administration Food Code and the Supplement to the Code.
Date this document prepared	04/24/2016

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

The Food Regulations establish minimum sanitary standards for operating food establishments. Those standards include the safe and sanitary maintenance, storage, operation, and use of equipment, the safe preparation, handling, protection, and preservation of food, including necessary refrigeration and heating methods, procedures for vector and pest control, requirements for toilet and cleansing facilities for employees and customers, requirements for appropriate lighting and ventilation not otherwise provided for in the Uniform Statewide Building Code, requirements for an approved water supply and sewage disposal system, personal hygiene standards for employees, particularly those engaged in food handling, and the appropriate use of precautions to prevent the transmission of communicable diseases. The regulations also inform potential food establishment owners or operators how to obtain a permit to operate a food establishment from the Department of Health. The regulations are being amended to be consistent with the current 2013 Food and Drug Administration's (FDA) Food Code and the Supplement to the 2013 FDA Food Code. The current regulation is based on the FDA's 2005 Food Code and the 2005 Food Code Supplement. Many of the changes simply refine and provide further clarity to the existing

regulations. Significant changes include (i) the addition of cut leafy greens to the list of foods that food establishments need to refrigerate in order to ensure that the product is safe to consume; (ii) food establishments must have employees who are fully informed regarding food allergens and their dangers; (iii) food establishment employees must be aware of their responsibility to inform management of any health or illness issues that might affect the safety of food products; (iv) the establishment must have procedures in place for addressing vomitus or fecal matter discharge on surfaces in the food establishment; (v) wild mushrooms cannot be sold unless the establishment has been approved to do so by the regulatory authority; (vi) bare hand contact with ready-to-eat food ingredients is allowed in certain instances; (vii) game animals that are sold must be raised, slaughtered, and processed under a voluntary inspection program that is conducted by the United States Department of Agriculture or the state agency that has animal health jurisdiction; (viii) the food establishment must discontinue operations and notify the Virginia Department of Health (VDH) if an imminent health hazard exists at the establishment; (ix) the establishment must immediately contact the VDH to report a food employee illness due to nontyphoidal Salmonella if it is determined that the illness is of a nature that can be transmitted through food; (x) the establishment must correct all Priority Item violations within 72 hours and all Priority Foundation Item violations within 10 days; and (xi) the food establishment must have at least one supervisor who is a Certified Food Protection Manager, with some exceptions. Additional changes include changes in the requirements for water supplies and changes regarding the presence of dogs in food establishments under certain conditions. These changes are being proposed concurrently with the Virginia Department of Agriculture and Consumer Services' (VDACS) adoption of the current 2013 FDA Food Code and the Supplement. Pursuant to § 35.1-14 C and E of the Code of Virginia, this action is exempt from portions of the Administrative Process Act, provided VDACS adopts the same version and both agencies' regulations have the same effective date. Both agencies are working toward that end. Both VDH and VDACS previously adopted the 2005 FDA Code and the Supplement with an effective date of January 1, 2010.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

Acronyms:

"CFPM" means Certified Food Protection Manager.

"FDA" means the United States Food and Drug Administration.

"Food Code" means the food safety regulations developed by the FDA for adoption by states and localities.

"HACCP" means Hazard Analysis and Critical Control Points; a food production system that identifies control points that are critical to the safety of the food.

"Nontyphoidal Salmonella" means a microorganism that can cause food poisoning.

"TCS" means Time/Temperature Control for Safety Food.

"USDA" means the United States Department of Agriculture.

"VDH" means the Virginia Department of Health.

Statement of final agency action

Please 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.

On June 2, 2016, the Board of Health approved final amendments to the Food Regulations (12VAC5-421).

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

Sections 35.1-11 and 14 of the Code of Virginia (Code) authorize and require the Board of Health to promulgate and enforce regulations governing restaurants in accordance with the provisions of Title 35.1 of the Code.

Section 35.1-14.C of the Code provides the legal basis for the promulgation and modification of this regulation. Specifically, subsections C and E identify the authority and certain requirements for the expedited adoption of the FDA's Food Code. The authority to adopt the FDA Food Code is discretionary; the authority to regulate restaurants is not.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The purpose of these regulations is to prevent foodborne illness by ensuring that foods prepared and served by food establishments in Virginia are safe, unadulterated, and prepared under sanitary conditions. This is accomplished by providing 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. Additionally, 12VAC5-421-30 of the regulation states the following, "The chapter has been promulgated by the State Board of Health to specify the following requirements to protect public health."

The first goal of the regulation and the proposed amendments is to maintain a scientifically-sound basis for regulation of the food industry. The amendments proposed to the existing regulation are necessary to ensure appropriate measures are put in place that address emerging and ongoing food safety concerns that exist within an evolving food industry.

The second goal is to facilitate the shared responsibility of the food industry and the government in ensuring that food provided to the consumer is safe and does not become a vehicle for a disease outbreak or for the transmission of communicable disease. Foodborne disease in the United States is a major cause of personal distress, preventable death, and avoidable economic burden. 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. Epidemiological outbreak data repeatedly identify five major risk factors related to employee behaviors and preparation practices in retail and food service establishments as contributing to foodborne illness. Those risk factors include (i) improper holding temperatures; (ii) inadequate cooking, such as undercooking raw eggs; (iii) contaminated equipment; (iv) food from unsafe sources; and (v) poor personal hygiene. This regulation and the proposed modifications address controls for these risk factors.

The regulation also provides the necessary guidance to the food industry relative to controlling risk factors and implementing appropriate intervention strategies.

The third goal of the proposed regulation is to ensure a regulatory approach that is uniform throughout Virginia’s food industry by administering standards that are equivalent to those administered by VDACS in the retail food industry. This regulatory uniformity also extends throughout the nation as most states have adopted versions of these regulations.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both.

There were technical amendments made to the final regulation in order to comply with the requirements in the Registrar Style Manual. There were additional changes made to the final regulation that were not included in the proposed regulations but that were in the supplement to the FDA Food Code and those substantive changes are as follows:

Part II

- Employee training must include food allergy awareness, in addition to food safety.

Part III

- Added a new section that addresses cooked and refrigerated food prepared for immediate service. This language is intended to clarify that foods may be served for immediate service and do not need to be heated to a specific temperature.
- Added requirements for food labels to include sub-ingredients and astaxanthin as an additional color additive in salmonid fish.

Part IV

- Added clarifying language for the processing of apple butter and molasses in copper and copper alloy containers based on Virginia Department of Agriculture and Consumer Services processing requirements.

Part V

- Amended to the section allowing for dogs in outdoor dining areas of retail food establishments if certain conditions are met:
 - The outdoor dining area is not fully enclosed with floor to ceiling walls and is not considered a part of the interior physical facility.
 - The outdoor dining area is equipped with an entrance that is separate from the main entrance to the food establishment and the separate entrance serves as the sole means of entry for patrons accompanied by dogs.
 - A sign stating that dogs are allowed in the outdoor dining area is posted at each entrance to the outdoor dining area in such a manner as to be clearly observable by the public.
 - A sign, clearly observable to the public and within the outdoor dining area, states the following requirements as specified in d, e, and f of this section.
 - Food and water provided to dogs is served using equipment that is not used for service of food to persons or is served in single-use articles.
 - Dogs are not allowed on chairs, seats, benches or tables.

- Dogs are kept on a leash or within a pet carrier and under the control of an adult at all times.
- Establishments provide effective means for cleaning up dog vomitus and fecal matter.
- Added language to HACCP plan approval requirements for permit holders who are engaged in reduced oxygen packaging with two barriers. Prior to this amendment, permit holders had to have and implement a HACCP Plan, but they were not required to be submitted prior to implementation.

Part VII

- Amended language to add further clarification of chemicals allowed for use to wash or assist in the peeling process of fruits and vegetables if done so in accordance with 21 CFR 173 and within the manufacturer’s instructions.

Issues

Please identify the issues associated with the proposed regulatory action, 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, please indicate.

The primary advantage of the regulations to the public is that they establish modern science-based standards that support the prevention of foodborne illness risk factors and ensure the safety of food service within the Commonwealth. The amendments will also make the regulations more understandable. The primary advantage to the agency is that the regulations will be based on current food science. 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 better consistency in regulatory application. There will be no disadvantages to the public or the Commonwealth with the adoption of these regulations.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include 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 statement to that effect.

There are no known requirements that exceed applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There is no known impact to any locality particularly affected by the proposed regulation. All localities will be equally affected.

Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one’s spouse, and one’s children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The impact of the proposed regulatory action on the institution of the family and family stability is from the perspective of foodborne illness and the availability of safe food for the consumer. As previously stated, the proposal is based, in part, on providing practical, science-based guidance and manageable, enforceable provisions for mitigating risk factors known to cause foodborne illness. It is a goal of all government food safety agencies within the United States to reduce the incidence of foodborne illness and ensure that foods available to consumers are safe to consume. Ensuring the safety of the food supply and reducing the level of foodborne illness have a direct impact on the family and family stability by positively affecting a family’s disposable income; improving family health; reducing medical care costs; reducing absences from the work place; and reducing mental, physical, and emotional pain and suffering. Additional disposable income and improved family health should strengthen parents’ ability to provide education, nurturing, and supervision to their children and should contribute to economic self-sufficiency and the assumption of responsibility for and commitment to one’s immediate and extended family.

Changes made since the proposed stage

*Please list all changes that were made to the text of the proposed regulation and the rationale for the changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. *Please put an asterisk next to any substantive changes.*

The following sections include amendments to comply with technical requirements to Registrars Style Manual.

10, 70, 100, 180, 765, 790, 870, 930, 2080, 2230, 3310, 3340, 3450, 3600, 3810, 3860

Section number	Requirement at proposed stage	What has changed	Rationale for change
12VAC5-421-60	Requires that the person in charge demonstrate knowledge of foodborne disease prevention, application of Hazard Analysis Critical Control Point principles, and the other requirements of the regulation. This section provides for numerous options for the demonstration of this knowledge.	Added “when not controlled” to critical control points requirement.	Inadvertently left out of proposed changes and is based on FDA Food Code changes.

*12VAC5-421-70	Required that employees are notified in a verifiable manner of their responsibility to report illness. Also, included a section on written procedures needing to be maintained.	Add phrase "including Food allergy awareness"	Inadvertently omitted from proposal change. Employee training on allergy awareness is now required in §35.1 Necessary for the control of foodborne allergies and assurance of food safety.
12VAC5-421-220	Food employees may drink from a closed beverage container but must use a straw.	Removed "with a straw".	This change was made by FDA to allow for other types of containers that are closed and do not need a "straw" to drink from and still provide protection.
12VAC5-421-270	Foods prepared in a private home must be approved by the Virginia Department of Agriculture and Consumer Services.	Removed "approved" and added "regulated".	Virginia Department of Agriculture and Consumer Services asked the agency to make this change since they do not approved foods to be sold but regulate the processor.
12VAC5-421-490	Requires that pasteurized eggs or egg products shall be substituted for raw shell eggs in the preparation of foods that are not thoroughly cooked, unless the food is not served to a highly susceptible population, and a consumer advisory is issued warning consumers about the dangers of consuming raw or undercooked animal foods.	Added "eggnog and ice cream"	Eggnog and ice cream added to list of foods that will require pasteurized egg or egg product. Necessary for the control of foodborne disease and assurance of food safety. This change was not included in the proposed.
12VAC5-421-560	Linens may not be used in contact with food, except for lining containers for food service.	Added an example of a linen type.	Additional clarification on type of linen.
12VAC5-421-600	Provides requirements for refilling returnable containers.	Combined sections 600 and 1870 by deleting section 1870.	Sections were combined for ease of application.
*12VAC5-421-755	This is a new section in the FDA Food Code.	Added language for cooked and refrigerated food prepared for immediate service.	To be consistent with FDA Food Code.
12VAC5-421-820	Provides specific requirements for time and temperature control for hot and cold holding of foods.	Added "except as specified under B and C of this section.	Additional clarification to recognize that not all foods must be stored at specific temperatures during hot holding and cold holding.

*12VAC5-421-900	States information required on food labels.	Added sub-ingredients and clarified artificial flavors. Added net to qualify quantity and added astaxanthin as an additional color additive in salmonid fish.	This change was made in the FDA Food Code to further clarify based on requirements in the Code of Federal Regulations.
*12VAC5-421-990	Allowance for copper and copper alloys use in contact with apple butter and molasses.	Added language to clarify that apple butter and molasses may not be stored in cooper or copper alloys for time periods longer than the typical processing time.	Further clarification was needed to define the preparation period and also recognized lab analysis as a prohibiting factor.
12VAC5-421-1100	Construction requirements for multi-use food contact surfaces.	Added language to except cooking oil storage tanks, distribution lines for cooling oils, or beverage syrup lines or tubes from cleaning accessibility requirements. Additionally added "inclusions" to the list of prohibitions for food-contact surface characteristics.	This change was made in the FDA Food Code based on relative risk.
12VAC5-421-1780	Provides requirements for cleaning food contact surfaces.	Removed "raw animal foods" and replaced with "different types of raw meat and poultry".	This change was made in FDA Food Code to further clarify raw animal foods.
12VAC5-421-3310	Includes an additional allowance for dogs on the outside premises of food establishments under certain conditions.	The requirements of subdivision "h" were realigned to follow subdivision "c".	This change was made in order to comply with the requirements in the Registrars Style Manual and to group requirements in logical order.
*12VAC5-421-3620	HACCP plans were required but did not need to be expressly approved prior to implementation of reduced oxygen packaging.	Language was added to address reduced oxygen packaging HACCP plan submission requirements.	Prior to this change a permit holder engaged in reduced oxygen packaging (ROP) with two barriers had to have a HACCP plan but did not need to submit the plan to the agency prior to conducting ROP. The change now requires plan submission.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate. Please distinguish between comments received on Town Hall versus those made in a public hearing or submitted directly to the agency or board.

Commenter	Comment	Agency response
John and Pat North, Mayhurst Inn via Town Hall.	Mr. North is the owner of Mayhurst Inn located in Orange, Virginia. He stated that he was in support of the proposed amendment in the	Comment was in support of proposed amendment in the definition of a "food establishment". The proposed language amends the bed and breakfast operations

	definition section that strikes 6 rooms or less as meeting the exemption for a food establishment permit requirement. The exemption includes 12 persons served and breakfast as the only meal served. Mr. North stated that B & B's are not restaurants and preparing and serving breakfast to no more than 12 guests should not require restaurant level equipment.	exemption to reflect 12VAC5-431 (Hotel Regulations) definition. No amendments made to final text.
Jeanne Jeffers, Inn at Riverbend via Town Hall.	Ms. Jeffers, applied for and received a variance in 2015 to allow for a seven room bed and breakfast to operate under an existing bed and breakfast permit only. Ms. Jeffers comment was that it was a very painful experience to have to receive a variance to continue business as a bed and breakfast. She stated that striking the six room limit was a sensible change to the regulation.	Comment was in support of proposed amendment in the definition of a "food establishment". The proposed language amends the bed and breakfast operations exemption to reflect 12VAC5-431 (Hotel Regulations) definition. No amendments made to final text.

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections. Explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation

The following sections include amendments to replace "potentially hazardous food" with "time/temperature control for safety food":
 10, 60, 70, 340, 550, 600, 630, 680, 760, 780, 790, 800, 820, 830, 840, 850, 860, 870, 1230, 1240, 1310, 1320, 1780, and 1810.

The following sections have a superscript P added, which denotes a priority item:
 80, 90, 100, 130, 140, 160, 270, 280, 290, 295, 300, 310, 320, 330, 340, 350, 360, 370, 390, 450, 460, 470, 490, 500, 520, 540, 580, 650, 670, 680, 700, 710, 725, 730, 760, 765, 800, 820, 840, 850, 870, 940, 950, 960, 980, 990, 1000, 1070, 1090, 1230, 1300, 1310, 1670, 1700, 1740, 1780, 1890, 1900, 2050, 2060, 2070, 2080, 2090, 2170, 2180, 2200, 2210, 2260, 2270, 2320, 2340, 2350, 2360, 2420, 2460, 2430, 2460, 2490, 2520, 2540, 2570, 2990, 3340, 3360, 3370, 3380, 3390, 3400, 3410, 3420, 3430, 3440, 3450, 3460, 3470, 3480, 3500, and 3910.

The following sections have a superscript Pf added, which denotes a priority foundation item:
 50, 60, 70, 80, 170, 180, 190, 250, 255, 260, 270, 295, 340, 380, 400, 410, 440, 450, 510, 670, 700, 720, 725, 740, 765, 810, 830, 850, 860, 870, 900, 930, 1100, 1110, 1180, 1190, 1300, 1320, 1350, 1360, 1370, 1450, 1460, 1500, 1510, 1530, 1630, 1650, 1660, 1680, 1700, 1720, 1730, 1770, 2100, 2120, 2130, 2160, 2190, 2230, 2280, 2310, 2320, 2330, 2550, 3020, 3030, 3070, 3150, 3210, 3270, 3310, 3320, 3330, 3350, 3360, 3460, 3480, 3600, 3630, and 3930.

For changes to existing regulation(s), use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12VAC5-421-10	N/A	Definitions Section	Definitions for “Critical Item”, “Drinking Water”, “Enterohemorrhagic Escherichia coli”, “°F”, and “Potentially hazardous food” have been removed as they are no longer necessary. Added/updated definitions for “Approved water system”, “Catering Operation”, “CFR”, “Core Item”, “Cut-leafy greens”, “Equipment”, “Food”, “Food Establishment”, “Game Animal”, “Injected”, “Mechanically tenderized”, “Mobile Food Unit”, “Noncontinuous cooking”, “Packaged”, “pH”, “Poultry”, “Priority item”, “Priority foundation item”, “Pure Water”, “Shiga toxin-producing Escherichia coli”, “Time/temperature control for safety food”, and Waterworks”. The additional definitions, along with the updated and expanded definitions, will provide greater clarification and understanding to the users of this regulation.
None	12VAC5-421-55	N/A	Requires at least one employee to be a certified food protection manager. Requirement will not apply to minimal risk food establishments that serve only non-temperature control for safety foods and food establishments where food handling does not exceed reheating, cold holding, and hot holding of commercially packaged ready-to-eat foods. Goes into effect July 1, 2018. Necessary for the control of foodborne disease and assurance of food safety.
12VAC5-421-60	N/A	Requires that the person in charge demonstrate knowledge of foodborne disease prevention, application of Hazard Analysis Critical Control Point principles, and the other requirements of the regulation. This section provides for numerous options for the demonstration of this knowledge.	Added conditional employee to the list of rights and responsibilities assigned by the regulation for those to whom the explanation of responsibilities rights and authority component of demonstration of knowledge applies. Necessary for the control of foodborne disease and assurance of food safety.
None	12VAC5-421-65	Food Protection Manager Certification	States how and when owners/operators are determined to be in compliance with 12VAC5-421-60(B) and 12VAC5-421-55. Necessary to ensure compliance with public health, foodborne disease, and food safety provisions of the regulation.

12VAC5-421-70	N/A	Identifies the responsibilities of the person in charge.	Employee training on allergy awareness is now required. Requires that employees are notified in a verifiable manner of their responsibility to report illness. Also, now includes a section on written procedures needing to be maintained. Necessary for the control of foodborne disease and assurance of food safety.
12VAC5-421-80	N/A	Requires person in charge to require employees or applicants who have been offered employment to report to the person in charge their health and activities as they relate to diseases that are transmissible through food.	Typhoid fever and Salmonella (nontyphoidal) added to list of diagnosed illnesses. Necessary for the control of foodborne disease and assurance of food safety.
12VAC5-421-90	N/A	Provides appropriate exclusion and restriction requirements for food employees diagnosed with one of the listed pathogens.	Adds appropriate exclusions and restrictions for food employees diagnosed with Salmonella (nontyphoidal). Also added Typhoid fever and E. coli to address pathogen name change. Necessary for the control of foodborne disease and assurance of food safety.
12VAC5-421-100	N/A	Identifies when exclusions or restrictions of food employees diagnosed with certain diseases can be removed by the person in charge.	S Typhoid fever and Salmonella (nontyphoidal) added to list of diagnosed illnesses. Necessary for the control of foodborne disease and assurance of food safety.
12VAC5-421-140	N/A	Identifies specific cleaning procedures of hands and arms.	Clarifies that washing includes surrogate prosthetic devices. Necessary to prevent contamination of foods by hands or prosthetic devices.
12VAC5-421-160	N/A	Identifies when employees must wash their hands.	Support animals have been changed to service animals. Change made to comply with common terminology. Requires that hands must be washed after handling aquatic animals. Clarifies that washing hands before donning gloves is only required prior to initiating a task that involves food. Necessary to prevent contamination of foods by hands.
12VAC5-421-170	N/A	Provides requirement for where employees must wash their hands.	Language added specifying that employees may not wash their hands in a service sink or a curbed cleaning facility used for mop water. Necessary for the control of foodborne disease and assurance of food safety
12VAC5-421-180	N/A	Identifies acceptability for use of hand sanitizers and chemical hand sanitizing solutions.	Updated the requirements for complying with hand antiseptic components. Necessary to prevent contamination of food by hands.

12VAC5-421-200	N/A	Prohibits the wearing of jewelry while preparing food.	Adds language to not allow the wearing of medical information jewelry on the arms and hands of food employees. Necessary to prevent contamination of food by hands
12VAC5-421-250	N/A	Prohibits food employees from handling animals.	Support animals have been changed to service animals. Change made to comply with common terminology.
None	12VAC5-421-255	N/A	Requires the facility to have procedures for cleaning up vomiting or diarrheal events. Necessary to ensure compliance with public health, foodborne disease, and food safety provisions of the regulation.
12VAC5-421-270	N/A	Identifies conditions necessary for food products to comply with all applicable laws and regulations.	Updated section by removing molluscan shellfish and changing to species specified in 12VAC5-421-730B. Necessary for the control of foodborne disease and assurance of food safety.
12VAC5-421-295	N/A	Requires pre-packaged juice to be obtained from a processor with a HACCP system, pasteurized or otherwise treated to eliminate microorganisms of public health significance, or bear a warning statement that the juice may contain pathogens that may cause foodborne disease.	Removed warning label requirement. Warning Label is still required in section 12VAC5-421-795. Removes redundant requirement. Change made without compromising food safety or public health.
12VAC5-310	N/A	Requires that molluscan shellfish be obtained from an approved source.	Amended the NSSP Model Ordinance language to recognize the most current version.
12VAC5-421-320	N/A	Requires that wild mushrooms be obtained from sources where each mushroom is individually inspected and found to be safe by an approved mushroom identification expert	Removed mushroom expert requirement and now requires department approval prior to food establishment selling/using wild mushrooms. Necessary for the control of foodborne disease and assurance of food safety.
12VAC5-421-330	N/A	Requires appropriate handling and processing of game animals received for sale or service.	Updated section to require either voluntary inspection by the state regulatory agency that has animal health jurisdiction or voluntary inspection by USDA for game animals that are commercially raised for food and sold in retail establishments. Necessary for the control of foodborne disease and assurance of food safety.
12VAC5-421-360	N/A	Grading requirements for eggs.	Adds the exemption for eggs sold pursuant to §3.2-5305
12VAC5-421-400	N/A	Requires that raw, shucked shellfish bear a label that states the sell by date and has the name, address, and	Changed metric equivalent of one-half gallon from 1.87 L to 1.89 L. This was done to correct a mistake in the previous version of the regulation.

		certification number of the shucker, packer, or repacker.	
12VAC5-421-410	N/A	Amends shellstock identification requirements to be consistent with the requirements of the National Shellfish Sanitation Program.	Updated the requirements for shellstock tags to meet industry standards. Necessary for the control of foodborne disease and assurance of food safety.
12VAC5-421-450	N/A	Food shall be prepared with a minimum of manual contact.	Allows for bare hand contact with ready to eat food that will be properly cooked. Allows industry flexibility without compromising food safety or public health.
12VAC5-421-470	N/A	Requirements for protecting food from cross-contamination during storage, preparation, holding, and display.	Added section allowing for frozen, commercially packaged raw food to be stored above frozen, commercially packaged ready to eat food. Allows industry flexibility without compromising food safety or public health.
12VAC5-421-480	N/A	Specifies requirements for identification of food storage containers.	Clarified requirements for identification of food storage containers. Necessary to prevent misidentification of ingredients that are added to food.
12VAC5-421-490	N/A	Requires that pasteurized eggs or egg products shall be substituted for raw shell eggs in the preparation of foods that are not thoroughly cooked, unless the food is not served to a highly susceptible population, and a consumer advisory is issued warning consumers about the dangers of consuming raw or undercooked animal foods.	Eggnog and ice cream added to list of foods that will require pasteurized egg or egg product. Necessary for the control of foodborne disease and assurance of food safety.
12VAC5-421-510	N/A	Requires fruits and vegetables to be washed prior to human consumption. Also allows for the use of chemicals to clean the fruits and vegetables.	Allows for the on-site generation of chemicals used in washing fruit and vegetables. Allows industry flexibility without compromising food safety or public health.
12VAC5-421-560	N/A	Linens may not be used in contact with food, except for lining containers for food service.	Additional clarification on type of linen.
12VAC5-421-600	N/A	Provides requirements for returning refillable containers	Combined sections 600 and 1870 contents are covered under section 12VAC5- 421-600. Section 1870 was repealed. Change made without compromising food safety or public health.
12VAC5-421-700	N/A	Specifies the required cooking temperature and length of time for raw animal food.	Added mechanically tenderized meats to food that must be cooked to 155°F. Added balutes and ratites to food that must be cooked to 165°F. Added “upon consumer request of selection” to section which refers to raw/undercooked animal

			food. Added provision that prohibits undercooked comminuted meat from being offered for sale on a children’s menu. Necessary for the control of foodborne disease and assurance of food safety.
None	12VAC5-421-725	N/A	Allows for noncontinuous cooking of raw animal foods but requires department approval and written procedures. This provides some additional flexibility to the industry.
12VAC5-730	N/A	Requires appropriate freezing of fish before the sale or service of ready-to eat raw, raw-marinated, partially cooked, or marinated- partially cooked fish (sushi) to destroy parasites.	Added shucked scallops and fish eggs removed from skein to the exempt list. Allows industry flexibility without compromising food safety or public health.
12VAC5-421-790	N/A	Specifies the procedures allowed for thawing food.	Added section with the requirements for thawing reduced oxygen packaged fish. Necessary for the control of foodborne disease and assurance of food safety.
12VAC5-421-860	N/A	Requires a food establishment to obtain a variance from the Department if performing certain high-risk food operations that are traditionally not performed at the restaurant level.	Variance now requires control of Listeria monocytogenes. Necessary for the control of foodborne disease and assurance of food safety.
12VAC5-421-870	N/A	Outlines the requirements necessary to package foods using a reduced oxygen packaging method when Clostridium botulinum is identified as a microbiological hazard in the final packaged food.	Added raw vegetables to list of food with high level of competing organisms. Changed discard date from 14 days to 30 days for reduced oxygen package foods. Clarified that bare hand contact with “ready to-eat” food is prohibited. Added subdivision requiring submission of HACCP plan to the department prior to implementation. Changed discard date from 72 hours to 7 days for cook-chill or sous-vide packaged TCS foods. Removed 38°F holding option for cook-chill or sous-vide packaged TCS foods. Clarified the wording about maintaining records. Added subsection about when a HACCP plan is not required. Clarified the wording about maintaining records. Necessary for the control of foodborne disease and assurance of food safety and allows industry flexibility without compromising food safety or public health.
12VAC5-421-1300	N/A	Requires a variance and a HACCP plan for food establishments to use molluscan shellfish life support	Added requirement that display tanks be conspicuously marked so consumers know they are display only. Necessary for the control of foodborne disease

		system display tanks.	associated with shellfish and assurance of food safety.
None	12VAC5-421-1435	N/A	Food equipment that is certified or classified for sanitation by an American National Standards Institute- accredited certification program is deemed to comply with the requirements in the regulation. Necessary to ensure compliance with public health, foodborne disease and food safety provisions of the regulation.
12VAC5-421-1520	N/A	Requires, in manual warewashing operations, a temperature measuring device be provided and readily accessible.	Added requirement that hot water mechanical warewashing operations have an irreversible registering temperature indicator provided. Necessary for the control of foodborne disease and assurance of food safety.
None	12VAC5-421-1535	N/A	Added requirement for cleaning agents and sanitizers to be available during all hours of operation.
12VAC5-421-1700	N/A	Specifies temperature and concentration requirements for chemical sanitizing solutions.	Changed exposure time to contact time. Updated minimum concentration levels in chart 1. Updated minimum temperature requirements for iodine. Changed manufacturer's label to EPA-registered label use instructions throughout section. Added subsection about requirements for generating a chemical sanitizer on-site. Necessary for the control of foodborne disease and assurance of food safety.
12VAC5-421-1870	N/A	Specifies requirements for cleaning of returnable containers for filling.	This section has been repealed. Its contents are covered under section 12VAC5- 421-600. Change made without compromising food safety or public health.
12VAC5-421-1900	N/A	Specifies the time/temperature requirements for sanitizing equipment, food-contact surfaces and utensils.	Exposure time changed to contact time. Requires contact times to be consistent with EPA-registered label use instructions. Necessary for the control of foodborne disease and assurance of food safety.
12VAC5-421-1920	N/A	Specifies the laundering of linens, cloth gloves, and wiping cloths.	Amended title of section to reflect section requirements. Necessary for the control of foodborne disease and assurance of food safety.
None	12VAC5-421-2045	N/A	States criteria for when rinsing clean/sanitized dishes is allowed. Necessary for the control of foodborne disease and assurance of food safety. This provides some additional flexibility to the industry.
12VAC5-421-2050	N/A	Requires that drinking water be obtained from an approved source.	Amended language to be consistent with drinking water and private well regulations. Necessary for the control of

			foodborne disease and assurance of food safety.
12VAC5-421-2060	N/A	Requirements for flushing and disinfecting an approved water system.	Amended language to be consistent with the drinking water regulations and also added an additional requirement to sample after flushing and disinfection of the system. Necessary for the control of foodborne disease and assurance of food safety.
12VAC5-421-2080	N/A	Requirements for water quality standards.	Amended language to be consistent with drinking water and private well regulations. Necessary for the control of foodborne disease and assurance of food safety.
12VAC5-421-2090	N/A	Requires that nondrinking water is only used if approved and only for non-culinary purposes.	Changes “nondrinking” to “nonpotable”. Necessary for consistency with definitions.
12-VAC5-421-2100	N/A	Specifies the sampling requirements in private wells.	Amended language to be consistent with the drinking water and private well regulations. Added a nitrate and total coliform sampling requirement. Necessary for the control of foodborne disease and assurance of food safety.
12VAC5-421-2110	N/A	Mandates how long the sample reports must be maintained.	Amended language to be consistent with drinking water and private well regulations. Necessary for the control of foodborne disease and assurance of food safety.
12VAC5-421-2120	N/A	Requires that the nonpublic water system sample report be maintained in the food establishment.	Requires food establishment to meet “peak” water demand. Necessary for the control of foodborne disease and assurance of food safety.
12VAC5-421-2150	N/A	Distribution, delivery and retention systems of water systems.	Repealed this section due to added language in §2050. Necessary for the control of foodborne disease and assurance of food safety.
12VAC5-421-2190	N/A	Requires that water be delivered at a temperature of 100° F and that self-closing faucets flow for at least 15 seconds without the need to reactivate the faucet.	Added subsection about automatic handwashing facility. Allows industry flexibility without compromising food safety or public health.
12VAC5-421-2250	N/A	Requires at least one service sink be provided.	Added subsection prohibiting the use of toilets and urinals as a service sink. Necessary for the control of foodborne disease and assurance of food safety.
12VAC5-421-2270	N/A	Specifies circumstances for use of a backflow prevention device with a carbonator.	Requires a dual check valve attached to the carbonator. Necessary for the control of foodborne disease and assurance of food safety.
12VAC5-421-2280	N/A	Specifies that handwash sinks are readily accessible for employees in food preparation areas and in toilet rooms.	Changed wording from “readily accessible” to “allow convenient” with regard to the use of the handwash sink. Allows industry flexibility without

			compromising food safety or public health.
12VAC5-421-2310	N/A	Specifies the use of a handwash sink.	Adds language to specify that an automatic handwash sink shall be used in accordance with manufacturer's instructions.
12VAC5-421-2320	N/A	Prohibits cross connections between drinking water and nondrinking water systems. Further requires that nondrinking water system piping is identified.	Removed the fire fighting exemption in section. Necessary for the control of foodborne disease and assurance of food safety.
12VAC5-421-2550	N/A	Requires that sewage be removed from a mobile food establishment in a manner that doesn't create a public health hazard or nuisance.	Clarifies section to state that the removal of sewage may not cause a public health hazard or nuisance. Necessary to ensure compliance with public health, foodborne disease, and food safety provisions of the regulation.
12VAC5-421-2570	N/A	Requires sewage to be disposed through an approved facility that is either a public sewage treatment system or an individual sewage disposal system.	Clarifies that disposal must be in accordance with the Code of Virginia. Necessary for the control of foodborne disease and assurance of food safety.
12VAC5-421-3030	N/A	Requires that handwashing sinks are equipped with paper towels, continuous towel system or heated-air hand drying device.	Allows a hand-drying device that employs an air-knife system that delivers high velocity, pressurized air at ambient temperatures. Allows industry flexibility without compromising food safety or public health.
12VAC5-421-3310	N/A	Prohibits animals on the premises of food establishments, with some exceptions.	Includes an additional allowance for dogs on the outside premises of food establishments under certain conditions.
12VAC5-421-3380	N/A	Requires that chemical sanitizers meet 40 CFR 180.940 requirements	Includes chemical sanitizers generated on-site. Updated with new Code of Federal Regulations citations for sanitizers. Necessary for the control of foodborne disease and assurance of food safety.
12VAC5-421-3390	N/A	Requires that chemicals used to wash vegetables meet 21CFR 173.315 requirements	Now includes chemical sanitizers generated on-site. Updated with new Code of Federal Regulations citations and chemicals that are "Generally Recognized As Safe." Added subsection B, which allows for the use of ozone. Necessary for the control of foodborne disease and assurance of food safety.
12VAC5-421-3410	N/A	Specifies the requirements that drying agents used in conjunction with sanitizers must meet.	Updated section with the addition of specific references from the Code of Federal Regulations and the federal Food, Drug, and Cosmetic Act. Necessary for the control of foodborne disease and assurance of food safety.

12VAC5-421-3630	N/A	Specifies when a HACCP Plan is required.	Updated wording in section to clarify that it is referencing reduced oxygen packaging without a variance. Necessary for the control of foodborne disease, the assurance of food safety, and protection of public health.
12VAC5-421-3670	N/A	Specifies requirements for the submittal of plans.	Amended to allow for temporary food establishments to submit plans within 10 days. Necessary to ensure compliance with the provisions of the regulation.
12VAC5-421-3800	N/A	Places requirements on the regulatory authority regarding periodic inspections.	Updated to reflect the use of a risk based inspection plan and removed language requiring a phone call every six months if the facility is inspected less frequently.
12VAC5-421-3810	N/A	Outlines evaluation criteria for determining need of performance-based or risk based inspections by the Department.	Changed "critical" to "priority item" or "priority foundation item". Changed "noncritical" to "core item". Necessary to ensure compliance with public health, foodborne disease and food safety provisions of the regulation.
12VAC5-421-3815	N/A	Provides requirements to determine for the competency of environmental health specialists.	Ensures competency of environmental health specialists by meeting the requirements specified in the Virginia Department of Health Procedures for Certification and Standardization of Retail Food Protection Staff.
12VAC5-421-3860	N/A	Identifies information and observations to be provided on an inspection report form by the authorized representative of the Commissioner.	Added conditional employees to list of people required to report. Removed requirement of employees to "demonstrate their knowledge of their responsibility" to report a disease. Changed "critical" to "priority items or priority foundation items". Necessary to ensure compliance with the provisions of the regulation.
12VAC5-421-3930	N/A	Requires timely correction of critical violations.	Changed "critical" to "priority items or priority foundation items". Changed the 10 calendar day time frame for correction of all violations to 72 hours for a priority item and 10 calendar days for a priority foundation item or HACCP plan deviation. Necessary to ensure compliance with public health, foodborne disease, and food safety provisions of the regulation.
12VAC5-421-3940	N/A	Requires the authorized representative of the Commissioner to enter corrective action on the inspection report after observing correction of a critical violation.	Changed "critical" to "priority items or priority foundation items". Updated wording in section regarding documentation of correction. Necessary to ensure compliance with public health, foodborne disease, and food safety provisions of the regulation.
12VAC5-421-3950	N/A	Requires correction of noncritical violations within 90 days or in accordance with a	Changed "noncritical" to "core items". Necessary to ensure compliance with the provisions of the regulation.

		compliance schedule approved by the Department.	
12VAC5-421-3960	N/A	Allows for the examination and sampling of food by the Department.	Amended language pertaining to due process to meet the requirements in the Administrative Process Act. Necessary to ensure compliance with public health, foodborne disease, and food safety provisions of the regulation.
12VAC5-421-3970	N/A	Covers the enforcement of the regulation.	Amended language pertaining to due process to meet the requirements in the Administrative Process Act. Necessary to ensure compliance with public health, foodborne disease, and food safety provisions of the regulation
12VAC5-421-3980	N/A	Request for an informal hearing.	Amended language pertaining to due process to meet the requirements in the Administrative Process Act. Necessary to ensure compliance with public health, foodborne disease, and food safety provisions of the regulation
12VAC5-421-3990	N/A	Language stating that a hearing is a right.	Removed language pertaining to due process since it is already required in the APA. Necessary to ensure compliance with public health, foodborne disease, and food safety provisions of the regulation
12VAC5-4000	N/A	Language pertaining to appeals.	Amended language pertaining to due process to meet the requirements in the Administrative Process Act. Necessary to ensure compliance with public health, foodborne disease, and food safety provisions of the regulation