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## Proposed Regulation Agency Background Document

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| <b>Agency name</b>                                    | Virginia Department of Health  |
| <b>Virginia Administrative Code (VAC) citation(s)</b> | 12 VAC 5-421   |
| <b>Regulation title(s)</b>                            | Food Regulations   |
| <b>Action title</b>                                   | Amend the regulations to be consistent with the 2013 U.S. Food and Drug Administration Food Code and the Supplement to the Code. |
| <b>Date this document prepared</b>                    | 12/01/2015   |

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 (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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 Food and Drug Administration's (FDA) 2005 Food Code and the 2005 Food Code Supplement. The existing regulation is being amended to be consistent with the current 2013 FDA Food Code. Many of the changes simply refine and provide further clarity to our 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. 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.

Additional changes include changes in the requirements for water supplies and changes regarding the presence of dogs in food establishments under certain conditions.

## 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.

## 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.

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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.*

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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 modifications is to maintain a scientifically-sound basis for regulation of the food industry. The modifications 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. A more detailed discussion is provided in the "Detail of changes" section below.*

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Substantive changes are as follows:

### Part I

- Added "Catering" definition and included exclusions from the term "Caterer"
- Added "Core Item" definition
- Added "Cut leafy greens" definition (used in TCS food definition)
- Amended "Drinking Water" to comply with Office of Drinking Water definitions
- Deleted "Enterohemorrhagic *Escherichia coli* (EHEC)" definition
- Included further explanation of "Food Establishment" and amended the bed and breakfast operations exemption to reflect 12VAC5-431 (Hotel Regulations) definition.
- Added "Continental Breakfast" definition
- Added "Mechanically Tenderized" definition as it relates to meat products
- Added "Non-Continuous Cooking" definition
- Deleted the term "Potentially Hazardous Food (Time/Temperature Control for Safety Food)" and made a universal change throughout the regulation to replace it with the term "Time/Temperature Control for Safety Food" (TCS)
- Added "Potable Water" definition
- Added "Priority Item" definition
- Added "Priority Foundation Item" definition
- Added "Private Well" definition
- Amended "Sewage" definition to reflect 12VAC5-610 definition
- Added "Temporary Food Event" definition
- Added "Waterworks" definition to comply with Office of Drinking Water standards

### Part II

- Sections have been added that require at least one employee who supervises or has authority over food establishment operations to be a Certified Food Protection Manager (CFPM). Food establishments that pose minimal risk to contributing to foodborne illness may be exempt from the requirement to have a CFPM. Specifically exempt from the CFPM requirement are food establishments that only serve non-TCS foods and whose extent of food handling does not exceed reheating, cold holding, and hot holding of commercially prepared ready-to-eat foods.
- The revisions specify that CFPM certification must be obtained through one of the following programs approved by the Conference for Food Protection:
  - o National Restaurant Association Solutions
  - o National Registry of Food Safety Professionals
  - o Prometric
  - o 360 Training
- Employee training must now include food allergy awareness, in addition to food safety.

- Amended to add Salmonella (nontyphoidal) as one of the reportable illnesses for action by the person in charge. Added language to address employee health controls for the exclusion and restriction of Salmonella (nontyphoidal), as well as the removal of exclusion and restriction from Salmonella (nontyphoidal) once clearance has been received.
- Language has been added that requires food establishments be able to verify that all food employees have been informed of their responsibility to report certain information about their health status as it relates to diseases that are transmitted by food. The person in charge must be able to provide the regulatory authority access to the documentation.
- Language has been added to include the washing of prosthetic hand devices for the cleaning procedures of hands and arms
- A new section was added that requires a food establishment to have procedures in place for employees to follow when responding to vomitus or fecal matter discharge on surfaces in the establishment.

### Part III

- Removed existing language that requires a mushroom identification expert to identify all wild mushrooms sold in retail establishments. New language was added that recognized a regulatory authority's ability to approve the sale of wild mushrooms within a food establishment.
- Updated 12VAC5-421-330 addressing game animals to require either voluntary inspection by the state regulatory agency that has animal health jurisdiction or voluntary inspection by USDA.
- Removed existing language that allows for exceptions to shellfish tags and identification in food establishments.
- Amended regulation to allow bare hand contact with ready-to-eat food if the ingredient is added to a food that will be cooked to temperatures that comply with 12VAC5-421-700 A through B or 12VAC5-421-710 or is cooked to a minimum temperature of 145°F.
- Added "mechanically tenderized" meats to the list of foods that should be cooked to heat all parts of the food to 155°F (68°C) for 15 seconds.
- Amended 12VAC5-421-700 to add a new subdivision D 2 to not allow the sale of undercooked, comminuted meat from a children's menu.
- Added new section, 12VAC5-421-725, entitled "Noncontinuous cooking of raw animal foods". This section allows food establishments to partially cook raw animal foods with prior approval from the regulatory authority. Written procedures must be maintained at the food establishment.

### Part IV

- Amended 12VAC5-421-1520 to add new subsection B that requires food establishments with a mechanical warewasher that sanitizes with hot water to provide an irreversible registering temperature indicator.
- Added language to include specifications on the use of chemical sanitizer devices generated on-site.

## Part V

- Amended the reporting procedures for private wells.
- Amended to allow 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.
  - 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.
  - A sign, clearly observable to the public and within the outdoor dining area, states the requirements as specified in d, e, and f of this section.

## 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.
- Added requirement for applicants seeking to operate a temporary food establishment to submit an application for a permit at least 10 days before the date planned for opening the temporary food establishment.
- Added language that will require the correction of a Priority Item within 72 hours and a Priority Foundation Item or HACCP Plan deviation within 10 days.
- Amended all terms referencing "hearing" as "informal fact finding conference" in accordance with § 2.2-4019 of the Code of Virginia.
- Removed language pursuant on the appeals process to align procedure with the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).

The following items have been added to the regulation in relevant areas to designate the criticality of certain regulatory requirements:

- The term "Critical item" has been changed to "Priority item". "Priority item" means a provision whose application contributes directly to the elimination, prevention, or reduction to an acceptable level, hazards associated with foodborne illness or injury and, for which, there is no other provision that more directly controls the hazard. "Priority item" includes items with a quantifiable measure to show control of hazards such as cooking, reheating, cooling, handwashing; and is denoted using a superscript P<sup>P</sup>.
- "Priority foundation item" has been added. "Priority foundation item" means a provision

whose application supports, facilitates, or enables one or more priority items. "Priority foundation item" includes an item that requires the purposeful incorporation of specific actions, equipment, or procedures by industry management to attain control of risk factors that contribute to foodborne illness or injury such as personnel training, infrastructure or necessary equipment, HACCP plans, documentation or record keeping, and labeling; and is denoted in this chapter with a superscript Pf <sup>(Pf)</sup>.

- The term "Core Item" has been added. "Core item" means a provision that is not designated as a "priority item" or a "priority foundation item". "Core item" includes an item that usually relates to general sanitation, operational controls, sanitation standard operating procedures, facilities or structures, equipment design, or general maintenance. Any item that is not designated as a "priority" or "priority foundation" item is a "core item".

**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 revisions 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 applicable federal 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.



## Public participation

*Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.*

In addition to any other comments, the Virginia Department of Health is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments for the public comment file may do so by mail, email or fax to Julie Henderson, 109 Governor Street, 5<sup>th</sup> Floor, Richmond, Virginia, 23233, (804) 864-7455, (804) 864-7475 and [Julie.Henderson@vdh.virginia.gov](mailto:Julie.Henderson@vdh.virginia.gov). Comments may also be submitted through the Public Forum feature of the Virginia Regulatory Town Hall web site at: <http://www.townhall.virginia.gov>. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will be held following the publication of this stage and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (<http://www.townhall.virginia.gov>) and on the Commonwealth Calendar website (<https://www.virginia.gov/connect/commonwealth-calendar>). Both oral and written comments may be submitted at that time.

## Economic impact

*Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.*

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| <p><b>Projected cost to the state to implement and enforce the proposed regulation, including:</b><br/> <b>a) fund source / fund detail; and</b><br/> <b>b) a delineation of one-time versus on-going expenditures</b></p>  | <p>Little or no additional cost to implement. Food service establishments are already regulated and inspected by VDH. The proposed changes do not include any change in the inspection process.</p>   |
| <p><b>Projected cost of the new regulations or changes to existing regulations on localities.</b></p>   | <p>None, for the same reasons as above.</p>   |
| <p><b>Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.</b></p>  | <p>Food service establishments operating in the Commonwealth of Virginia.<br/> ANSI-Certified Food Manager Training providers.<br/> Food Allergen Training providers.<br/> Food service equipment suppliers.</p>                                |
| <p><b>Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected.</b> Small business means a business entity, including its affiliates, that:<br/> a) is independently owned and operated and;<br/> b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p> | <p>Currently there are approximately 36,000 food establishments in the Commonwealth. Based on employing 500 or fewer employees, estimated 95 to 100% of the total number of food establishments will fall into the small business category.</p> |



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| <p><b>All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including:</b></p> <p><b>a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and</b></p> <p><b>b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.</b></p> | <p>a) There may be additional reporting or recordkeeping costs associated with the proposed requirements for food establishments that choose to supply a written form of verification for employee health and allergen awareness training. Costs for implementation could vary widely depending on the choice of training delivery methods. Nationally recognized allergen awareness courses currently cost anywhere from \$19 to \$70 per person. Allergen awareness educational materials cost an estimated amount of \$2 -\$4 per document. For food establishments that choose to train food handler staff in house, the cost could be minimal. Costs of staff time for employees to attend training depend on length of time for training. Since there is currently no standard requirement for the training. VDH staff estimate that of the 36,000 permitted food establishments in the Commonwealth, there are currently a minimum of 12,000 establishments that operate under local ordinance requirement to have a certified food manager. Of the remaining 24,000 establishments, a large majority are national or regional restaurant chains or franchises that have certified food managers on staff. Certification costs range from \$100 to \$200 per individual every five years. For restaurants that choose to allow for dogs on the premises there may be construction costs associated with meeting the conditions; however, this is a discretionary requirement and is difficult to estimate the costs. Food establishments with limited food storage capacity may incur additional costs to store cut leafy greens under adequate refrigeration. The majority of establishments who already store leafy greens under refrigeration will now be required to store at less than 41°F, which potentially would require equipment adjustments and/or increase in capacity, but VDH staff estimate that additional cost to be negligible. Food establishments that use hot water-sanitizing dish machines will need to provide an irreversible temperature measuring indicators. VDH staff estimate cost of doing so for each permitted food establishment to be minimal. Indicator temperature strips can be purchased for as little as 50 cents. Food establishments that currently offer undercooked comminuted meat on the children’s menu are estimated to be low. Those establishments will need to change their menus to remove the consumer advisory from the children’s menu from any menu items on a children’s menu that contain comminuted meat. National or regional restaurant chains or franchises have already addressed this concern since the</p> |
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|  | <p>requirement was implemented in a previous version of the U. S. Food and Drug Administration’s Food Code.</p> <p>b) The agency is not aware of any identified costs related to the development of real estate for commercial or residential purposes.</p>   |
| <p><b>Beneficial impact the regulation is designed to produce.</b></p> | <p>The regulations will be based on the most current food science. Benefits will be better protection of public health. In some cases, the amendments reduce regulatory requirements without negatively impacting public health which will result in savings to the restaurant operator or owner.</p> |

## Alternatives

*Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. 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 regulation.*

Alternatives to the proposed amendments to this regulation would be to leave the regulation in place without any revision. However, this will result in a regulation that does not incorporate the latest science-based principles and U. S. Food and Drug Administration recommended requirements to address the evolving food industry. The result will be a food supply that is not optimally safe and a lower level of public health protection for the residents of and visitors to the Commonwealth. Other than the requirement to have a Certified Food Protection Manager at certain permitted food establishments to ensure that proper and appropriate food safety principles are adhered to, the amendments proposed will not be a financial burden to the industry. Although this requirement could be eliminated from the proposed amendments, the result would be less food safety protection for Virginia’s residents. The current regulation along with the proposed amendments allow the food establishment operator additional flexibility with respect to sanitation and product processing.

Congress has mandated, through the 2011 Food Safety Modernization Act, the establishment of a national food safety system that integrates federal, state, and local food protection agencies. One component of this integration process is the establishment of uniform regulations at all levels. Currently, most states and localities have adopted FDA’s Food Code and continue to update their regulations as new versions of the Food Code are released by FDA. This ensures that states are enforcing the same science-based regulations that are focused on public health protection and is a significant step in the integration of all states into one singular national food safety system. Failure to incorporate the proposed amendments to this regulation will result in VDH enforcing regulations that are out of step with the rest of the nation and with those of multiple jurisdictions in the Commonwealth. Additionally, it will result in the enforcement of regulations that are not uniform with VDACS. If both VDACS and VDH are inspecting a retail food establishment (i.e. many retail food stores have restaurants) this could subject the food industry to two different sets of regulations. This situation would be both costly and confusing to retail food establishments.

## Regulatory flexibility analysis

*Pursuant to § 2.2-4007.1B of the Code of Virginia, please 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) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of 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 proposed regulation.*

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1. There are only minimal reporting requirements relative to the subject regulations or the amendments proposed. Food establishments should provide documentation to the VDH Environmental Health Specialist verifying that they have a Certified Food Protection Manager at the establishment. However, this is necessary in order to ensure that an individual is in place at the establishment who fully understands food safety risk factors, practices, and principles. A 2014 CDC study suggests that the presence of a Certified Food Protection Manager reduces the risk for a foodborne disease outbreak and was a distinguishing factor between food establishments that had been associated with a foodborne illness outbreak and those that had not. An incidence of foodborne illness linked to a food establishment has the potential to have a significant negative impact on the economic stability of that industry. The requirement to document the safety of alternate processes and to verify to the regulatory authority that necessary and critical information regarding public health has been disseminated to employees will require minimal cost and time and is necessary to ensure the safety of the food supply.

2. Compliance requirement time frames for violations noted as “Priority item” and “Priority foundation item” could be extended. However, “Priority Item” and “Priority foundation item” are those violations or deficiencies that could contribute directly or indirectly to a foodborne illness. Extending the time for compliance regarding these violations or deficiencies is not advisable. Inspectional frequency is already minimal and to inspect less frequently than is currently being done would put the public at unnecessary risk.

3. As noted above, there are only minimal reporting requirements. Compliance requirements are already streamlined and cannot be further simplified. Compliance violations are provided to food establishments by VDH Environmental Health Specialists who inspect the establishments.

4. This regulation as well as the proposed amendments, are consistent with and, where appropriate, incorporate federal performance standards for the same products and processes. This regulation allows food establishments the flexibility to establish performance standards and use innovative techniques in the production of safe foods. Food establishments may apply to the regulatory authority for a variance to use a specific food safety performance standard for a product or a process in lieu of compliance with otherwise applicable specifications in this regulation, as long as the establishment can show that the controls are in place to ensure that the standard is being met.

5. Small businesses can readily comply with the requirements of this regulation and the proposed amendments. Elimination of the requirements of this regulation for small businesses will compromise the safety of the food produced or sold by these businesses and may lead to an increase in foodborne illnesses. Foodborne illnesses associated with these small businesses will have a significant negative economic effect on said businesses.

### **Periodic review and small business impact review report of findings**

*If you are using this form to report the result of a periodic review/small business impact review that was announced during the NOIRA stage, please indicate whether the regulation meets the criteria set out in Executive Order 17 (2014), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable. In addition, as required by 2.2-4007.1 E and F, please include a discussion of the agency’s consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity*

of the regulation; (4) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

The periodic review for the *Food Regulations* is required and was completed on February 12, 2014 with a decision to amend the regulations. This action is exempt from the NOIRA stage

### Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

Not Applicable

### 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.

### Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please list separately: (1) all differences between the pre-emergency regulation and this proposed regulation; and 2) only changes made since the publication of the emergency 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, intent, rationale, and likely impact of proposed requirements   |
|------------------------|--|--|--|
| 12VAC5-421-10          | None                                       | 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. |
| 12VAC5-421-50          | None                                       | Requires assignment of responsibility to a person in charge during all hours of operation of a food establishment. | Added a new section that allows for separately-inspected departments to have one person in charge of the operation. Allows industry flexibility without compromising food safety or public health.   |
| None                   | 12VAC5-421-55                              | None   | Requires at least one employee to be a certified food protection manager.  |

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|                |               |   | 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  | None          | 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 the demonstration of knowledge. 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  | None          | 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  | None          | 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  | None          | 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 | None          | Identifies when exclusions or restrictions of food employees diagnosed with certain   | S Typhoid fever and Salmonella (nontyphoidal) added to list of diagnosed illnesses. Necessary for the control of   |

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|                |                | diseases can be removed by the person in charge.   | foodborne disease and assurance of food safety.  |
| 12VAC5-421-140 | None           | 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 | None           | 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 | None           | 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 | None           | 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 | None           | 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 | None           | 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 | None   | 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 | None           | 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 | None           | 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 | 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.  |



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|                |      | disease.   |  |
| 12VAC5-310     | None | 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 | None | 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 | None | 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 | None | Grading requirements for eggs.   | Adds the exemption for eggs sold pursuant to §3.2-5305   |
| 12VAC5-421-400 | None | Requires that raw, shucked shellfish bear a label that states the sell by date and has the name, address, and certification number of the shucker, packer, or repacker.                                  | 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.  |
| 12VAC5-421-410 | None | 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 | None | 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 | None | 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 | None | 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 | None | 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 | 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  |

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|                |                | population, and a consumer advisory is issued warning consumers about the dangers of consuming raw or undercooked animal foods.   |   |
| 12VAC5-421-510 | None           | 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.   |
| 12VAC5-421-700 | None           | 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 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 | None  | 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     | None           | 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 | None           | 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 | None           | 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 | None           | 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 hrs to 7 days for cook-chill or sous-vide packaged TCS foods. |

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|                 |                 |  | 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. Added subsection about when a HACCP plan is not required. Necessary for the control of foodborne disease and assurance of food safety and allows industry flexibility without compromising food safety or public health industry flexibility without compromising food safety or public health. |
| 12VAC5-421-1300 | None            | Requires a variance and a HACCP plan for food establishments to use molluscan shellfish life support system display tanks. | Added requirement that display tanks be conspicuously marked so consumers know they are display only. Necessary for the control of foodborne disease associated with shellfish and assurance of food safety.  |
| None            | 12VAC5-421-1435 | None   | Food equipment that is certified or classified for sanitation by an American National Standards Institute (ANSI)-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 | None            | 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 | None   | Added requirement for cleaning agents and sanitizers to be available during all hours of operation.   |
| 12VAC5-421-1700 | None            | 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 | None            | 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-         | None            | Specifies the time/temperature   | Exposure time changed to contact time.  |

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| 421-1900         |                 | requirements for sanitizing equipment, food-contact surfaces and utensils.                      | 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  | None            | 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 | None  | 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  | None            | 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  | None            | 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  | None            | 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  | None            | 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 | None            | 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  | None            | 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  | None            | 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  | None            | 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.   |

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| 12VAC5-421-2190 | None | 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 | None | 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 | None | 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 | None | 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 | None | 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 | None | 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 | None | 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 | None | 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 | None | 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 | None | 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 | None | 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  |

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|                 |      |   | sanitizers. Necessary for the control of foodborne disease and assurance of food safety.  |
| 12VAC5-421-3390 | None | 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 | None | 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 | None | 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 | None | 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 | None | 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 | None | 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 | None | 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 | None | 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 | None | Requires timely correction of critical violations.  | Changed "critical" to "priority items or priority foundation items". Changed the 10 calendar day time frame for correction  |

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|                 |      |  | 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 | None | 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 | None | Requires correction of noncritical violations within 90 days or in accordance with a compliance schedule approved by the Department.                               | Changed "noncritical" to "core items". Necessary to ensure compliance with the provisions of the regulation.   |
| 12VAC5-421-3960 | None | 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 | None | 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 | None | 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 | None | 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     | None | 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                                  |