State Board of Health
Nominating Committee
Agenda
June 2, 2016 – 8:30 a.m.
Perimeter Center – Boardroom 1

Welcome and Introductions
Amy Vest, Chair

Discussion
Nominating Committee Members

Adjourn

State of Board of Health
Agenda
June 2, 2016 – 9:00 a.m.
Perimeter Center – Boardroom 2

Call to Order and Welcome
Bruce Edwards, Chair

Pledge of Allegiance
Megan Getter

Introductions
Mr. Edwards

Review of Agenda
Joseph Hilbert
Director of Governmental and Regulatory Affairs

Approval of March 17, 2016 Minutes
Mr. Edwards

Commissioner’s Report
Marissa Levine, MD, MPH, FAAFP
State Health Commissioner

Zika Virus Disease – Public Health Planning and Response
Laurie Forlano, DO, MPH, Director
Office of Epidemiology

Bob Mauskapf, Director
Office of Emergency Preparedness

Jennifer McDonald
Office of Family Health Services

Maribeth Brewster
Risk Communication Manager

Break

Abortion Facility Licensure Status Report
Erik Bodin, Director
Office of Licensure and Certification

Regulatory Action Update
Mr. Hilbert
Public Comment Period

Regulatory Action Items

Regulations for the Physician Assistant Scholarship Program
Adrienne McFadden, MD, JD, Director
Office of Minority Health and Health Equity
12VAC5-525
(Proposed Regulations)

Working Lunch
Lunch Speaker – Dr. Terry Dickinson, Executive Director, Virginia Dental Association
Virginia Dental Association’s Community Dental Health Coordinator Program

Food Regulations
Allen Knapp, Director
Office of Environmental Health Services
12VAC5-421
(Final Amendments)

Report of Nominating Committee
Ms. Vest

Election of Officers and Executive Committee Members
Mr. Edwards

Member Reports

Other Business

Adjourn
Enclosed for your review are the proposed permanent regulations to implement the Physician Assistant Scholarship Program (12VAC5-525). This regulatory action will implement a new regulatory chapter which creates a physician assistant scholarship program. The substantive elements of this program are modeled after similar regulatory programs administered by the Agency.

Chapter 806 of the 1997 Virginia Acts of Assembly amended and reenacted § 32.1-122.6:03 of the Code of Virginia to require the establishment of an annual physician assistant scholarship program for students who intend to enter an accredited physician assistant program. Section 32.1-122.6:03 of the Code further mandates the Board of Health to adopt regulations governing the implementation of such a scholarship program within 280 days of its enactment. There is no record within the Agency of any past regulatory action to implement the required regulations. Permanent regulations are necessary to support the implementation of § 32.1-122.6:03. The intent of this regulatory action is to implement the regulatory action required by § 32.1-122.6:03 and address the shortage of trained medical professionals in the Commonwealth.

The Virginia Department of Health has developed regulatory language to implement this program. Permanent regulations are necessary to support the implementation of the amendments to § 32.1-122.6:03 enacted by Chapter 806 (1997). The proposed regulations contain provisions pertaining to definitions, composition of Advisory Committee, eligibility for scholarships, conditions of scholarships, the process to apply, deadlines, selection criteria, contract requirements, practice site selection and repayment information.

The Board of Health is requested to approve the proposed regulations. Should the Board of Health approve the proposed regulations, they will be submitted to the Virginia Register of Regulations. The Virginia Department of Health will then conduct a 60 day public comment period. After the public comment period the proposed regulations and comments will be reviewed and final regulations will be submitted for approval by the Board of Health.
Proposed Regulation
Agency Background Document

<table>
<thead>
<tr>
<th>Agency name</th>
<th>Virginia Department of Health</th>
</tr>
</thead>
<tbody>
<tr>
<td>Virginia Administrative Code (VAC) citation(s)</td>
<td>12VAC5-525</td>
</tr>
<tr>
<td>Regulation title(s)</td>
<td>Regulations for Physician Assistant Scholarship Program</td>
</tr>
<tr>
<td>Action title</td>
<td>Implement Regulations for Physician Assistant Scholarships</td>
</tr>
<tr>
<td>Date this document prepared</td>
<td>March 15, 2016</td>
</tr>
</tbody>
</table>

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 proposed new regulations will bring the Board of Health into compliance with § 32.1-122.6:03 of the Code of Virginia, which requires the establishment of an annual physician assistant scholarship program for students who intend to enter an accredited physician assistant program. Currently no implementing regulations exist. The substantive elements are modeled after similar regulatory incentive programs administered by the Agency.

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.
No acronyms are used in this Agency Background Document. No technical terms are utilized in this document.

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.

The regulation is promulgated under the authority of § 32.1-122.6:03 of the Code of Virginia. Section 32.1-122.6:03 of the Code of Virginia requires the Board to establish an annual physician assistant scholarship program and mandates that the Board promulgate regulations in order to administer the program.

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.

Chapter 806 of the 1997 Virginia Acts of Assembly amended and reenacted § 32.1-122.6:03 of the Code of Virginia to require the establishment of an annual physician assistant scholarship program for students who intend to enter an accredited physician assistant program and mandated the Board of Health to adopt regulations governing the implementation of such a scholarship program within 280 days of its enactment. There is no record within the Agency of any past regulatory action to implement the required regulations. Permanent regulations are necessary to support the implementation of § 32.1-122.6:03. The intent of this regulatory action is to implement the regulatory action required by § 32.1-122.6:03 and address the shortage of trained medical professionals in the Commonwealth.

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.

This regulatory action will implement a new regulatory chapter which will create a physician assistant scholarship program. The substantive elements of this program will be modeled after similar regulatory programs administered by the Agency. Substantive elements that will be created include:

Definitions – Will provide clarification on key or frequently use terms in the regulatory text.

Advisory Committee – Will establish that an Advisory Committee as appointed by the Board of Health shall make all scholarship recommendations.
Eligibility for scholarships – Will provide eligibility requirements including acceptance in or enrollment in an approved education program, a 2.5 cumulative GPA if already enrolled in a program, application, financial need and no active military obligation.

Conditions of scholarships – Will provide guidance and provisions on the contract requirements, calculations of the service obligation, employment requirements, transfer of practice site, default, waiver, partial, hardship, and default payments.

Number of applications, Amounts of scholarships & How to apply - Will provide information and provisions regarding applicant renewals, minimum and maximum award amounts, location of application form and deadline dates for submission of applications.

Selection criteria – Will provide information regarding preferential consideration of applications, including Virginia residents, residents of medically underserved areas and minority students.

Scholarship contract – Will provide information regarding the required elements of the scholarship contract.

Practice site selection – Will provide information regarding where a participant in the program will be able to perform his service obligation.

Functional elements of the repayment program – Will provide program information regarding reporting requirements, breach of contract, and deferments and waivers.

**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 proposed regulatory action to the public will be an increase in the availability of primary care providers in medically underserved communities, should this program be funded by the Commonwealth. Additionally, these medically underserved communities will be better positioned to retain qualified primary care providers because of the obligation created by accepting the scholarship funds. The Virginia Department of Health sees no disadvantage to the public, the agency or the Commonwealth associated with the proposed regulatory action.

**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 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.

No locality will be particularly affected by the proposed regulation.

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 Board 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 Dr. Adrienne McFadden, 109 Governor Street, Richmond, VA, phone (804) 864-7435, fax (804) 864-7440, or email adrienne.mcfadden@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 not be held following the publication of this stage of this regulatory action.

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.

<table>
<thead>
<tr>
<th>Economic impact</th>
<th>Cost to the state to implement and enforce the proposed regulation, including: a) fund source / fund detail; and b) a delineation of one-time versus on-going expenditures</th>
<th>Projected cost to the state is negligible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Projected cost of the new regulations or changes to existing regulations on localities.</td>
<td>No foreseeable projected cost to implement and enforce this regulatory proposal</td>
<td></td>
</tr>
<tr>
<td>Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.</td>
<td>Physician assistant students desiring to work in medically underserved areas, patients and facilities within medically underserved areas within the commonwealth</td>
<td></td>
</tr>
<tr>
<td>Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses</td>
<td>According to the Health Resources and Services Administration there are currently 241 Health Professional Shortage Areas (HPSA) within the</td>
<td></td>
</tr>
</tbody>
</table>
affected. Small business means a business entity, including its affiliates, that:
a) is independently owned and operated and;
b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.

Commonwealth of Virginia. In counties where HPSA's are located, there are approximately 784 non-hospital facilities providing primary care services in Virginia’s primary care HPSAs, including 606 Physician Offices and 178 independent Outpatient Clinics. Of these, 647 physician office and outpatient clinics have fewer than 50 employees. There are 1,151,170 Virginia residents who live in primary care HPSAs. Currently, there are 4 fully accredited PA programs in Virginia with a class capacity ranging in size from 30 to 80 students. Additionally there are 2 provisionally accredited PA programs with a combined class capacity of 75 students.

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:
a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and
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.

Beneficial impact the regulation is designed to produce.

Fulfillment of statutory requirement to establish the Physician Assistant Scholarship Program in the Virginia Administrative Code.

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.

There are no other viable alternatives other than the intended regulatory action to carry out the board’s statutory mandate to establish a physician assistant scholarship program. The regulations are mandated by § 32.1-122.6:03 of the Code.

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.

The alternative regulatory methods are not applicable. The regulations are mandated by law and there is no other method than by the proposed amendments to carry out the board’s mandate to establish a physician assistant scholarship program. The regulatory chapter is not anticipated to be intrusive or bring a cost to small 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.

N/A

**Public comment**

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

<table>
<thead>
<tr>
<th>Commenter</th>
<th>Comment</th>
<th>Agency response</th>
</tr>
</thead>
<tbody>
<tr>
<td>David Falkenstein, PA-C, Virginia Academy of Physician Assistants</td>
<td>The Virginia Academy of Physician Assistants (VAPA) is supportive of implementation of permanent regulations as required by §32.1-122.6:03. for the Physician Assistant Scholarships as a means to address the shortage of trained medical professionals in the Commonwealth. In addition the VAPA encourages the Department of Health to introduce a budget amendment for funding of the scholarship at the 2016 legislature.</td>
<td>VDH acknowledges the support and will consider introduction of a budget amendment to fund this scholarship program.</td>
</tr>
</tbody>
</table>

**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 board has assessed the impact the proposed amendments will have on the institution of the family and family stability. The board anticipates no impact to the family or family stability.

**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.

If a new regulation is being promulgated, use this chart:

<table>
<thead>
<tr>
<th>Section number</th>
<th>Proposed requirements</th>
<th>Other regulations and law that apply</th>
<th>Intent and likely impact of proposed requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Definition of terms</td>
<td></td>
<td>Defines terms used in this regulatory chapter to assist readers in understanding regulations</td>
</tr>
<tr>
<td>20</td>
<td>Establishes the Physician Assistant Scholarship Committee</td>
<td>The 8 member scholarship committee will determine scholarship awards</td>
<td></td>
</tr>
<tr>
<td>30</td>
<td>Outlines eligibility criteria for scholarships</td>
<td>To assist readers in understanding how to qualify for the scholarship program</td>
<td></td>
</tr>
<tr>
<td>40</td>
<td>Outlines the conditions of receiving and participating in the scholarship program</td>
<td>Describes the conditions including requirement for a signed contract with commissioner, minimum requirements for service obligation and terms for failure of completing condition of scholarship.</td>
<td></td>
</tr>
<tr>
<td>50</td>
<td>Number of applications per student</td>
<td>Delineates maximum number of scholarship that each applicant is eligible to receive.</td>
<td></td>
</tr>
<tr>
<td>60</td>
<td>Establishes scholarship amount at $5000</td>
<td>Provides clarity to reader about the dollar amount of the scholarship awards</td>
<td></td>
</tr>
<tr>
<td>70</td>
<td>Establishes application process</td>
<td>Provides clarity on the process for applicants to apply for the scholarship</td>
<td></td>
</tr>
<tr>
<td>Page</td>
<td>Provides</td>
<td>Establishes</td>
<td></td>
</tr>
<tr>
<td>------</td>
<td>----------</td>
<td>-------------</td>
<td></td>
</tr>
<tr>
<td>80</td>
<td>selection criteria</td>
<td>selection standards which will serve as guidance to scholarship committee in selecting the scholarship recipients</td>
<td></td>
</tr>
<tr>
<td>90</td>
<td>content of the scholarship contracts</td>
<td>elements of the scholarship contract that is to be signed by recipient and commissioner.</td>
<td></td>
</tr>
<tr>
<td>100</td>
<td>standards to use for practice site selection</td>
<td>minimal criteria which the practice site must meet to serve as an eligible practice site to repay service obligation</td>
<td></td>
</tr>
<tr>
<td>105</td>
<td>process by which an applicant can change practice sites</td>
<td>direction to reader about how to change a practice site once a participant begins his service obligation</td>
<td></td>
</tr>
<tr>
<td>110</td>
<td>the reporting requirements that must be fulfilled by each recipient.</td>
<td>reporting requirements that each recipient must fulfill during their participation in the scholarship program</td>
<td></td>
</tr>
<tr>
<td>120</td>
<td>clarity on what constitutes a breach of contract</td>
<td>those conditions which constitute a breach of contract and provide for the terms of reimbursement of the Commonwealth by the recipient in the case of a breach of contract or default.</td>
<td></td>
</tr>
<tr>
<td>130</td>
<td>a deferment and waiver process</td>
<td>clarity to the reader about the process by which a deferment may be considered</td>
<td></td>
</tr>
<tr>
<td>140</td>
<td>a process for repayment if service obligation is fulfilled after default payments</td>
<td>a process by which a participant may be reimbursed by the Commonwealth upon fulfilling service obligation after repaying the Commonwealth for default.</td>
<td></td>
</tr>
</tbody>
</table>
CHAPTER 525
REGULATIONS FOR PHYSICIAN ASSISTANT SCHOLARSHIP PROGRAM

Part I
General Information

12VAC5-525-10. Definitions.

The following words and terms when used in this chapter shall have the following meanings:

"Approved physician assistant program" means a fully accredited physician assistant school in Virginia as approved by the Board.

"Board" or "Board of Health" means the State Board of Health.

"Commissioner" means the State Health Commissioner.

"Department" means Virginia Department of Health.

"Full-time" means at least 32 hours per week for 45 weeks per year.

"Health professional shortage area" or "HPSA" means an area in Virginia designated by the U.S. Secretary of Health and Human Services as having a shortage of health professionals in accordance with the procedures of the Public Health Service Act (42 USC §254e) and implementing regulations (42 CFR Part 5).

"Interest" means the legal rate of interest pursuant to § 6.2-302 of the Code of Virginia.

"Participant" or "recipient" means an eligible registered physician assistant student of an approved physician assistant program who enters into a contract with the commissioner and participates in the scholarship program.

"Penalty" means twice the amount of all monetary payments to the scholarship participant, less any service obligation completed.

"Physician assistant" or "PA" means an individual who has met the requirements of the Board of Medicine for licensure and who works under the supervision of a licensed doctor of medicine, osteopathy, or podiatry as defined in § 54.1-2900.

"Practice" means the practice of medicine by a recipient in one of the defined primary care specialties in a location within Virginia that is designated as a health professional shortage area or a Virginia medically underserved area to fulfill the recipient's service obligation.

"Primary care" means the specialties of family practice medicine, general internal medicine, pediatric medicine and obstetrics and gynecology.

"Virginia medically underserved area" or "VMUA" means an area in Virginia designated by the State Board of Health in accordance with the Rules and Regulations for the Identification of Medically Underserved Areas (12VAC 5-540) or § 32.1-122.5 of the Code of Virginia.

12VAC5-525-20. Physician Assistant Scholarship Committee.

All scholarship awards shall be made by a physician assistant scholarship committee appointed by the State Board of Health. The physician assistant scholarship committee shall consist of eight members: four deans or directors of physician assistant programs or their designees, two former scholarship recipients, and two members with experience in the administration of student financial aid programs. Committee appointments shall be for two-year terms and members shall not serve for more than two successive terms.

Part II
Administration of Physician Assistant Scholarship Program

12VAC5-525-30. Eligibility for scholarships.

In order to be considered for a scholarship, an applicant shall:

1. Be a United States citizen, national, or a qualified alien pursuant to 8 USC § 1621;
2. Be accepted for enrollment or enrolled in an approved PA program in the
Commonwealth of Virginia preparing him for examination for licensure as a PA in the
Commonwealth of Virginia;
3. If already enrolled in an approved PA program in the Commonwealth the student must
have a cumulative grade point average of 2.5;
4. Submit a completed application form and appropriate grade transcript prior to the
established deadline dates;
5. Demonstrate financial need which is verified by the school’s financial aid officer or
authorized person as part of the application process; and
6. Not have an active military obligation.

An applicant who fails to meet all of these requirements shall be ineligible for a scholarship.

12VAC5-525-40. Conditions of scholarships.
A. Prior to becoming a participant in the PA scholarship program, the applicant shall enter
into a contract with the commissioner agreeing to the terms and conditions upon which the
scholarship is granted.
B. For each $5000 of scholarship money received, the participant agrees to engage in the
equivalent of one year of full-time primary care medical practice in a HPSA or VMUA within the
Commonwealth. The recipient shall notify the department, within 180 days of being awarded a
PA degree, of the type of practice to be performed and give the name and address of the
employer for approval. Voluntary military service, even if stationed in Virginia, cannot be used to
repay the service obligation required when a scholarship is awarded.
C. If a participant fails to complete his studies, the full amount of the scholarship or
scholarships received, plus the applicable interest charge, shall be repaid.
D. If upon graduation a participant leaves the Commonwealth or fails to engage or ceases to
engage in primary care medical practice in Virginia before all employment conditions of the
scholarship award are fulfilled, the participant shall repay the award amount reduced by the
proportion of obligated years served plus the applicable interest and penalty.
E. If the participant is in default due to death or permanent disability so as not to be able to
engage in medical practice, the participant or his personal representative, upon repayment of
the total amount of scholarship funds received plus applicable interest, may be relieved of his
obligation under the contract to engage in medical practice. For participants completing part of
the PA obligation prior to becoming permanently disabled or in the event of death, the total
amount of scholarship funds owed shall be reduced by the proportion of obligated years served.
The obligation to make restitution may be waived by the board upon application of the
participant or the participant's personal representative to the board.
F. All default payments shall be made payable to the Commonwealth of Virginia.

12VAC5-525-50. Number of applications per student.
Scholarships are awarded for single academic years. However, the same student may, after
demonstrating satisfactory progress in his studies, which is demonstrated by a cumulative grade
point average of 2.5, apply for and receive scholarship awards for a succeeding academic year
or years. No student shall receive scholarships for more than a total of four years.

12VAC5-525-60. Amounts of scholarships.
The number of scholarships awarded shall be dependent upon the amount of money
appropriated by the General Assembly, the amount of funds available within the Physician
Assistant Scholarship Fund administered by the State Board of Health, and the number of
qualified applicants. Each participant shall receive an award of $5,000 per year.
12VAC5-525-70. How to apply.

Eligible applicants shall submit a complete application made available by the department on the department’s website. A complete application shall include documentation of all eligibility requirements. The deadline for submission of the application shall be announced by the department on the department’s website.

12VAC5-525-80. Selection criteria.

Applicants shall be competitively reviewed and selected for participation in the Physician Assistant Scholarship Program based upon the following criteria pursuant to § 32.1-122.6:03 of the Code of Virginia:

1. Qualifications. All of an individual's professional qualifications and competency to practice in an underserved area will be considered, including eligibility for Virginia licensure, professional achievements, and other indicators of competency received from supervisors, program directors, or other individuals who have previously entered into an employment contract with the individual.

2. Virginia residents. Preferential consideration shall be given to individuals who are or have been Virginia residents (verification will be obtained by the Virginia Physician Assistant Scholarship Program).

3. Resident of medically underserved areas. Preferential consideration shall be given to individuals who reside in rural, Virginia medically underserved areas, or Health Professional Shortage Areas (verification shall be obtained by the Virginia Physician Assistant Scholarship Program).

12VAC5-525-90. Scholarship contract.

Applicants selected to receive scholarship awards by the Advisory Committee shall sign and return a written contract to the department by the specified deadline date. Failure to return the contract by the specified deadline date may result in the award being rescinded. At minimum, the scholarship contract shall include the following elements:

1. The total amount of the award and the award period;

2. Agreement to pursue a degree at an accredited PA program in the Commonwealth of Virginia that is approved by the State Board of Health;

3. Agreement to begin continuous full-time employment within 180 days of the recipient's graduation;

4. Agreement to comply with all reporting requirements;

5. Agreement to the terms of service requiring continuous full-time primary care medical practice in the Commonwealth for a specified period of time and the terms and conditions associated with a breach of contract;

6. Signature of the applicant; and

7. Signature of the commissioner or his designee.

A recipient may terminate a contract while enrolled in school after notice to the board and upon repayment within 90 days of the entire amount of the scholarship plus interest.

12VAC5-525-100. Practice site selection.

Each recipient shall perform his service obligation at a practice site in either a health professional shortage area or a Virginia medically underserved area. The participant shall agree to provide health services without discrimination, regardless of a patient’s ability to pay. Maps of health professional shortage areas and Virginia medically underserved areas shall be available on the department’s website.
12VAC5-525-105. Change of practice site.

Should any participant find that he is unable to fulfill the service commitment at the practice site to which he has committed to practice, he may request approval of a change of practice site. Such requests shall be made in writing. The department in its discretion may approve such a request. All practice sites, including changes of practice sites, shall be selected with the approval of the commissioner.

In the event of a dispute between the participant and the practice site, every effort shall be made to resolve the dispute before reassignment will be permitted.

12VAC5-525-110. Reporting requirements.

A. Each participant shall provide information as required by the department to verify compliance with the practice requirements of the PA scholarship program (e.g., verification of employment in a primary care setting form once every six months).

B. Each participant shall promptly notify the department in writing within 30 days if any of the following events occur:

1. Participant changes name;
2. Participant changes address;
3. Participant changes practice site. Participant is required to request in writing and obtain prior approval of changes in practice site;
4. Participant no longer intends or is able to fulfill service obligation as a PA in the Commonwealth;
5. Participant ceases to practice as a PA; or
6. Participant ceases or no longer intends to complete his PA academic program.

12VAC5-525-120. Breach of contract.

The following shall constitute a breach of contract:

1. The recipient fails to complete his PA studies;
2. The recipient fails to begin or complete the term of obligated service under the terms and conditions of the scholarship contract;
3. The recipient falsifies or misrepresents information on the program application, the verification of employment forms, or other required documents; and
4. The recipient’s employment is terminated for good cause as determined by the employer and confirmed by the department. If employment is terminated for reasons beyond the participant’s control (e.g., closure of site), the participant shall transfer to another site approved by the board in the Commonwealth within six months of termination. Failure of participant to transfer to another site shall be deemed to be a breach of the contract.

In the event of a breach of contract and in accordance with the terms of the contract, the recipient shall make default payments as described in 12VAC5-525-40. In the event of a breach of contract where the recipient has partially fulfilled his obligation, the total amount of reimbursement shall be prorated by the proportion of obligation completed.

12VAC5-525-130. Deferment and waivers.

A. If the participant is in default due to death or permanent disability so as not to be able to engage in primary care practice in a region designated as a HPSA or VMUA in the Commonwealth, the participant or his personal representative may be relieved of his obligation under the contract to engage in practice, upon repayment of the total amount of scholarship received plus applicable interest. For participants completing part of the obligation prior to becoming permanently disabled or in the event of death, the total amount of scholarship funds
owed shall be reduced by the proportion of obligated years served. The obligation to make restitution may be waived by the board upon application of the participant or the participant's personal representative to the board.

B. Individual cases of undue hardship may be considered for a variance by the board of payment or service pursuant to § 32.1-12 of the Code of Virginia.

C. All requests for deferments, waivers or variances must be submitted in writing to the department for consideration and final disposition by the board.

12VAC5-525-140. Fulfillment after default payments.

In the event that a recipient, in accordance with the terms of the contract, fully repays the Commonwealth for part or all of any scholarship because of breach of contract and later fulfills the terms of the contract after repayment, the Commonwealth shall reimburse the award amount repaid by the recipient minus applicable interest and fees.
MEMORANDUM

DATE: April 27, 2016

TO: State Board of Health

FROM: Allen L. Knapp, Director, Office of Environmental Health Services
       Julie Henderson, Director, Division of Food and General Environmental Services

RE: Commonwealth of Virginia Board of Health Food Regulations (12VAC5-421)

The text of final amendments to the Commonwealth of Virginia Board of Health Food Regulations (Food Regulations) is attached. We are asking you to adopt the final amendments to the Food Regulations.

DISCUSSION:

The Board of Health (Board) adopted the current food regulations in 2010; that regulatory action incorporated the provisions of the 2005 FDA Food Code. The Food Regulations establish minimum sanitary standards for operating food establishments. The amendments to the Regulations include the 2009 and 2013 changes to the FDA Food Code. These changes are also being proposed by the Virginia Department of Agriculture and Consumer Services (VDACS) and simply refine and provide further clarity to the existing regulations. Additional changes include changes in the requirements for water supplies and changes regarding the presence of dogs in food establishments under certain conditions. Changes were also made as a result of legislation passed in 2015 to require allergen awareness for employees in restaurants.

Section 35.1-14.E of the Code of Virginia (Code) provides that the Administrative Process Act (§ 2.2-4000 et seq. of the Code) does not apply to the Board’s adoption of regulations based on the FDA Food Code as long as the Board of Agriculture and Consumer Services adopts the same edition or the same portions of the FDA Food Code and the regulations adopted by the Board and the Board of Agriculture and Consumer Services have the same effective date.

Although there is no requirement for a NOIRA, the exemption provided in Va. Code § 35.1-14.E preserves certain requirements of the APA which include publishing notice in the Virginia Register of Regulations (Register) of the proposed amendments for public comment, publishing
the final regulation, and addressing the requirements pertaining to economic impact analysis. In addition, Va. Code § 35.1-14.E requires the Board to hold at least one public hearing with proper notice during the 60-day public comment period.

VDH completed a periodic review of the Food Regulations on February 12, 2014, and concluded that the regulations needed to be amended. This regulatory action flows from that determination. VDH began regulatory action to adopt the 2013 FDA Food Code on December 17, 2015. The Office of the Attorney General (OAG) certified that action on December 23, 2015, and the Department of Planning and Budget (DPB) concluded its Economic Impact Analysis January, 27, 2016. VDH submitted the proposed amendments to the Register on February 10, 2016, and the mandatory public comment period closed on April 23, 2016. VDH received public comment on Town Hall in favor of the proposed amendments to the Food Regulations regarding bed and breakfasts. The proposed language amends the bed and breakfast operations exemption to be consistent with the Virginia Department of Health Hotel and Motel Regulations (12VAC5-431) definition of a bed and breakfast. VDH did not receive any public comment during the public hearing held on March 29, 2016.

A brief listing of the proposed changes follows:

Part I

- Added “Catering” definition and included exclusions from the term “Caterer”
- Added “Core Item” definition
- Added "Cut leafy greens" as a time/temperature control for safety food (added to 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 “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 “Pure Water” definition
- Added “Priority Item” definition
- Added “Priority Foundation Item” definition
- Added “Private Well” definition
- Amended “Sewage” definition to reflect 12VAC5-610 definition
- Added “Waterworks” definition to comply with Office of Drinking Water standards
Part II

- Sections have been added to the Food Code 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 are exempt from the requirement to have a CFPM.
- The revisions require that CFPM certification must be obtained through the specified programs approved by the Conference for Food Protection.
- 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 the regulatory authority to verify that food establishment employees have been informed of their responsibility to report information to the person in charge regarding their health and illnesses that can be transmitted through food.
- Language has been added that requires food establishments to mandate that all food employees sign a reporting agreement form and maintain the signed forms on-site. 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 has been 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.
MEMORANDUM
April 27, 2016
Page 4

- 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 specific conditions are met.

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 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).

Please note that for ease of reading, only the sections of the regulations that are proposed to be amended have been included in this packet. As mentioned above, the final amendments are necessary to provide consistency with the FDA Food Code and the Virginia Department of Agriculture and Consumer Services’ Retail Food Regulations. As such, VDH recommends that the Board act pursuant to its authority provided in § 32.1-12 of the Code of Virginia and adopt the final amendments to the Food Regulations.
Form: TH-03
11/14
townhall.virginia.gov

Final Regulation
Agency Background Document

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

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.
o Dogs are kept on a leash or within a pet carrier and under the control of an adult at all times.
o 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

<table>
<thead>
<tr>
<th>Section number</th>
<th>Requirement at proposed stage</th>
<th>What has changed</th>
<th>Rationale for change</th>
</tr>
</thead>
<tbody>
<tr>
<td>12VAC5-421-60</td>
<td>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.</td>
<td>Added “when not controlled” to critical control points requirement.</td>
<td>Inadvertently left out of proposed changes and is based on FDA Food Code changes.</td>
</tr>
<tr>
<td><strong>12VAC5-421-70</strong></td>
<td>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.</td>
<td>Add phrase “including Food allergy awareness”</td>
<td>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.</td>
</tr>
<tr>
<td><strong>12VAC5-421-220</strong></td>
<td>Food employees may drink from a closed beverage container but must use a straw.</td>
<td>Removed &quot;with a straw&quot;.</td>
<td>This change was made by FDA to allow for other types of containers that are closed and do not need a &quot;straw&quot; to drink from and still provide protection.</td>
</tr>
<tr>
<td><strong>12VAC5-421-270</strong></td>
<td>Foods prepared in a private home must be approved by the Virginia Department of Agriculture and Consumer Services.</td>
<td>Removed &quot;approved&quot; and added &quot;regulated&quot;.</td>
<td>Virginia Department of Agriculture and Consumer Services asked the agency to make this change since they do not approve foods to be sold but regulate the processor.</td>
</tr>
<tr>
<td><strong>12VAC5-421-490</strong></td>
<td>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.</td>
<td>Added &quot;eggnog and ice cream&quot;</td>
<td>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.</td>
</tr>
<tr>
<td><strong>12VAC5-421-560</strong></td>
<td>Linens may not be used in contact with food, except for lining containers for food service.</td>
<td>Added an example of a linen type.</td>
<td>Additional clarification on type of linen.</td>
</tr>
<tr>
<td><strong>12VAC5-421-600</strong></td>
<td>Provides requirements for refilling returnable containers.</td>
<td>Combined sections 600 and 1870 by deleting section 1870.</td>
<td>Sections were combined for ease of application.</td>
</tr>
<tr>
<td><em>12VAC5-421-755</em></td>
<td>This is a new section in the FDA Food Code.</td>
<td>Added language for cooked and refrigerated food prepared for immediate service.</td>
<td>To be consistent with FDA Food Code.</td>
</tr>
<tr>
<td><strong>12VAC5-421-820</strong></td>
<td>Provides specific requirements for time and temperature control for hot and cold holding of foods.</td>
<td>Added “except as specified under B and C of this section.”</td>
<td>Additional clarification to recognize that not all foods must be stored at specific temperatures during hot holding and cold holding.</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
<td>Changes</td>
<td>Agency response</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>12VAC5-421-900</td>
<td>States information required on food labels.</td>
<td>Added sub-ingredients and clarified artificial flavors. Added net to qualify quantity and added astaxanthin as an additional color additive in salmonid fish.</td>
<td>This change was made in the FDA Food Code to further clarify based on requirements in the Code of Federal Regulations.</td>
</tr>
<tr>
<td>12VAC5-421-990</td>
<td>Allowance for copper and copper alloys use in contact with apple butter and molasses.</td>
<td>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.</td>
<td>Further clarification was needed to define the preparation period and also recognized lab analysis as a prohibiting factor.</td>
</tr>
<tr>
<td>12VAC5-421-1100</td>
<td>Construction requirements for multi-use food contact surfaces.</td>
<td>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.</td>
<td>This change was made in the FDA Food Code based on relative risk.</td>
</tr>
<tr>
<td>12VAC5-421-1780</td>
<td>Provides requirements for cleaning food contact surfaces.</td>
<td>Removed “raw animal foods” and replaced with “different types of raw meat and poultry”.</td>
<td>This change was made in FDA Food Code to further clarify raw animal foods.</td>
</tr>
<tr>
<td>12VAC5-421-3310</td>
<td>Includes an additional allowance for dogs on the outside premises of food establishments under certain conditions.</td>
<td>The requirements of subdivision &quot;h&quot; were realigned to follow subdivision &quot;c&quot;.</td>
<td>This change was made in order to comply with the requirements in the Registrars Style Manual and to group requirements in logical order.</td>
</tr>
<tr>
<td>12VAC5-421-3620</td>
<td>HACCP plans were required but did not need to be expressly approved prior to implementation of reduced oxygen packaging.</td>
<td>Language was added to address reduced oxygen packaging HACCP plan submission requirements.</td>
<td>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.</td>
</tr>
</tbody>
</table>

**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.

<table>
<thead>
<tr>
<th>Commenter</th>
<th>Comment</th>
<th>Agency response</th>
</tr>
</thead>
<tbody>
<tr>
<td>John and Pat North, Mayhurst Inn via Town Hall.</td>
<td>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 definition of a “food establishment”. The proposed language amends the bed and breakfast operations.</td>
<td>Comment was in support of proposed amendment in the definition of a “food establishment”. The proposed language amends the bed and breakfast operations.</td>
</tr>
<tr>
<td>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 &amp; B’s are not restaurants and preparing and serving breakfast to no more than 12 guests should not require restaurant level equipment.</td>
<td>Exemption to reflect 12VAC5-431 (Hotel Regulations) definition. No amendments made to final text.</td>
<td></td>
</tr>
<tr>
<td>Jeanne Jeffers, Inn at Riverbend via Town Hall.</td>
<td>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.</td>
<td>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.</td>
</tr>
</tbody>
</table>

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:

The following sections have a superscript Pf added, which denotes a priority foundation item:

For changes to existing regulation(s), use this chart:
<table>
<thead>
<tr>
<th>Current section number</th>
<th>Proposed new section number, if applicable</th>
<th>Current requirement</th>
<th>Proposed change and rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>12VAC5-421-10</td>
<td>N/A</td>
<td>Definitions Section</td>
<td>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.</td>
</tr>
<tr>
<td>None</td>
<td>12VAC5-421-55</td>
<td>N/A</td>
<td>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.</td>
</tr>
<tr>
<td>12VAC5-421-60</td>
<td>N/A</td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>None</td>
<td>12VAC5-421-65</td>
<td>Food Protection Manager Certification</td>
<td>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.</td>
</tr>
<tr>
<td>Regulation</td>
<td>Code</td>
<td>Notes</td>
<td></td>
</tr>
<tr>
<td>------------</td>
<td>------</td>
<td>-------</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-70</td>
<td>N/A</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-80</td>
<td>N/A</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-90</td>
<td>N/A</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-100</td>
<td>N/A</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-140</td>
<td>N/A</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-160</td>
<td>N/A</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-170</td>
<td>N/A</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-180</td>
<td>N/A</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>Regulation</td>
<td>Action</td>
<td>Description</td>
<td></td>
</tr>
<tr>
<td>------------</td>
<td>--------</td>
<td>-------------</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-200</td>
<td>N/A</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-250</td>
<td>N/A</td>
<td>Prohibits food employees from handling animals. Support animals have been changed to service animals. Change made to comply with common terminology.</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>12VAC5-421-255</td>
<td>N/A</td>
<td>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.</td>
</tr>
<tr>
<td>12VAC5-421-270</td>
<td>N/A</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-295</td>
<td>N/A</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-310</td>
<td>N/A</td>
<td>Requires that molluscan shellfish be obtained from an approved source. Amended the NSSP Model Ordinance language to recognize the most current version.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-320</td>
<td>N/A</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-330</td>
<td>N/A</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-360</td>
<td>N/A</td>
<td>Grading requirements for eggs. Adds the exemption for eggs sold pursuant to §3.2-5305</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-400</td>
<td>N/A</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>Code</td>
<td>Type</td>
<td>Description</td>
<td>Details</td>
</tr>
<tr>
<td>----------------------</td>
<td>------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>12VAC5-421-410</td>
<td>N/A</td>
<td>Amends shellstock identification requirements to be consistent with the requirements of the National Shellfish Sanitation Program.</td>
<td>Updated the requirements for shellstock tags to meet industry standards. Necessary for the control of foodborne disease and assurance of food safety.</td>
</tr>
<tr>
<td>12VAC5-421-450</td>
<td>N/A</td>
<td>Food shall be prepared with a minimum of manual contact.</td>
<td>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.</td>
</tr>
<tr>
<td>12VAC5-421-470</td>
<td>N/A</td>
<td>Requirements for protecting food from cross-contamination during storage, preparation, holding, and display.</td>
<td>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.</td>
</tr>
<tr>
<td>12VAC5-421-480</td>
<td>N/A</td>
<td>Specifies requirements for identification of food storage containers.</td>
<td>Clarified requirements for identification of food storage containers. Necessary to prevent misidentification of ingredients that are added to food.</td>
</tr>
<tr>
<td>12VAC5-421-490</td>
<td>N/A</td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>12VAC5-421-510</td>
<td>N/A</td>
<td>Requires fruits and vegetables to be washed prior to human consumption. Also allows for the use of chemicals to clean the fruits and vegetables.</td>
<td>Allows for the on-site generation of chemicals used in washing fruit and vegetables. Allows industry flexibility without compromising food safety or public health.</td>
</tr>
<tr>
<td>12VAC5-421-560</td>
<td>N/A</td>
<td>Linens may not be used in contact with food, except for lining containers for food service.</td>
<td>Additional clarification on type of linen.</td>
</tr>
<tr>
<td>12VAC5-421-600</td>
<td>N/A</td>
<td>Provides requirements for returning refillable containers</td>
<td>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.</td>
</tr>
<tr>
<td>12VAC5-421-700</td>
<td>N/A</td>
<td>Specifies the required cooking temperature and length of time for raw animal food.</td>
<td>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 &quot;upon consumer request of selection&quot; to section which refers to raw/undercooked animal.</td>
</tr>
<tr>
<td>Town Hall Agency Background Document</td>
<td>Form: TH-03</td>
<td></td>
<td></td>
</tr>
<tr>
<td>------------------------------------</td>
<td>-------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-725</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Allows for noncontinuous cooking of raw animal foods but requires department approval and written procedures. This provides some additional flexibility to the industry.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12VAC5-730</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td>Added shucked scallops and fish eggs removed from skein to the exempt list. Allows industry flexibility without compromising food safety or public health.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-790</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specifies the procedures allowed for thawing food.</td>
<td>Added section with the requirements for thawing reduced oxygen packaged fish. Necessary for the control of foodborne disease and assurance of food safety.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-860</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td>Variance now requires control of Listeria monocytogenes. Necessary for the control of foodborne disease and assurance of food safety.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-870</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td>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 &quot;ready-to-eat&quot; 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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-1300</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Requires a variance and a HACCP plan for food establishments to use molluscan shellfish life support</td>
<td>Added requirement that display tanks be conspicuously marked so consumers know they are display only. Necessary for the control of foodborne disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>12VAC5-421-1435</td>
<td>N/A</td>
<td>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.</td>
</tr>
<tr>
<td>12VAC5-421-1520</td>
<td>N/A</td>
<td>Requires, in manual warewashing operations, a temperature measuring device be provided and readily accessible.</td>
<td>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.</td>
</tr>
<tr>
<td>None</td>
<td>12VAC5-421-1535</td>
<td>N/A</td>
<td>Added requirement for cleaning agents and sanitizers to be available during all hours of operation.</td>
</tr>
<tr>
<td>12VAC5-421-1700</td>
<td>N/A</td>
<td>Specifies temperature and concentration requirements for chemical sanitizing solutions.</td>
<td>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.</td>
</tr>
<tr>
<td>12VAC5-421-1870</td>
<td>N/A</td>
<td>Specifies requirements for cleaning of returnable containers for filling.</td>
<td>This section has been repealed. Its contents are covered under section 12VAC5-421-600. Change made without compromising food safety or public health.</td>
</tr>
<tr>
<td>12VAC5-421-1900</td>
<td>N/A</td>
<td>Specifies the time/temperature requirements for sanitizing equipment, food-contact surfaces and utensils.</td>
<td>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.</td>
</tr>
<tr>
<td>12VAC5-421-1920</td>
<td>N/A</td>
<td>Specifies the laundering of linens, cloth gloves, and wiping cloths.</td>
<td>Amended title of section to reflect section requirements. Necessary for the control of foodborne disease and assurance of food safety.</td>
</tr>
<tr>
<td>None</td>
<td>12VAC5-421-2045</td>
<td>N/A</td>
<td>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.</td>
</tr>
<tr>
<td>12VAC5-421-2050</td>
<td>N/A</td>
<td>Requires that drinking water be obtained from an approved source.</td>
<td>Amended language to be consistent with drinking water and private well regulations. Necessary for the control of</td>
</tr>
<tr>
<td>Code</td>
<td>Section</td>
<td>N/A</td>
<td>Description</td>
</tr>
<tr>
<td>------</td>
<td>---------</td>
<td>-------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>12VAC5-421-2060</td>
<td>N/A</td>
<td>Requirements for flushing and disinfecting an approved water system.</td>
<td>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.</td>
</tr>
<tr>
<td>12VAC5-421-2080</td>
<td>N/A</td>
<td>Requirements for water quality standards.</td>
<td>Amended language to be consistent with drinking water and private well regulations. Necessary for the control of foodborne disease and assurance of food safety.</td>
</tr>
<tr>
<td>12VAC5-421-2090</td>
<td>N/A</td>
<td>Requires that nondrinking water is only used if approved and only for non-culinary purposes.</td>
<td>Changes “nondrinking” to “nonpotable”. Necessary for consistency with definitions.</td>
</tr>
<tr>
<td>12-VAC5-421-2100</td>
<td>N/A</td>
<td>Specifies the sampling requirements in private wells.</td>
<td>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.</td>
</tr>
<tr>
<td>12VAC5-421-2110</td>
<td>N/A</td>
<td>Mandates how long the sample reports must be maintained.</td>
<td>Amended language to be consistent with drinking water and private well regulations. Necessary for the control of foodborne disease and assurance of food safety.</td>
</tr>
<tr>
<td>12VAC5-421-2120</td>
<td>N/A</td>
<td>Requires that the nonpublic water system sample report be maintained in the food establishment.</td>
<td>Requires food establishment to meet &quot;peak&quot; water demand. Necessary for the control of foodborne disease and assurance of food safety.</td>
</tr>
<tr>
<td>12VAC5-421-2150</td>
<td>N/A</td>
<td>Distribution, delivery and retention systems of water systems.</td>
<td>Repealed this section due to added language in §2050. Necessary for the control of foodborne disease and assurance of food safety.</td>
</tr>
<tr>
<td>12VAC5-421-2190</td>
<td>N/A</td>
<td>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.</td>
<td>Added subsection about automatic handwashing facility. Allows industry flexibility without compromising food safety or public health.</td>
</tr>
<tr>
<td>12VAC5-421-2250</td>
<td>N/A</td>
<td>Requires at least one service sink be provided.</td>
<td>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.</td>
</tr>
<tr>
<td>12VAC5-421-2270</td>
<td>N/A</td>
<td>Specifies circumstances for use of a backflow prevention device with a carbonator.</td>
<td>Requires a dual check valve attached to the carbonator. Necessary for the control of foodborne disease and assurance of food safety.</td>
</tr>
<tr>
<td>12VAC5-421-2280</td>
<td>N/A</td>
<td>Specifies that handwash sinks are readily accessible for employees in food preparation areas and in toilet rooms.</td>
<td>Changed wording from &quot;readily accessible&quot; to “allow convenient” with regard to the use of the handwash sink. Allows industry flexibility without</td>
</tr>
<tr>
<td>Regulation</td>
<td>Action</td>
<td>Description</td>
<td></td>
</tr>
<tr>
<td>---------------------</td>
<td>----------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-2310</td>
<td>Specified</td>
<td>Specifies the use of a handwash sink.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adds language to specify that an automatic handwash sink shall be used in accordance with manufacturer's instructions.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-2320</td>
<td>Prohibited</td>
<td>Prohibits cross connections between drinking water and nondrinking water systems. Further requires that nondrinking water system piping is identified.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Removed the fire fighting exemption in section. Necessary for the control of foodborne disease and assurance of food safety.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-2550</td>
<td>Required</td>
<td>Requires that sewage be removed from a mobile food establishment in a manner that doesn’t create a public health hazard or nuisance.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Clarifies section to state that the removal of sewage may not cause a public health hazard or nuisance. Necessary for the control of foodborne disease, and food safety provisions of the regulation.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-2570</td>
<td>Required</td>
<td>Requires sewage to be disposed through an approved facility that is either a public sewage treatment system or an individual sewage disposal system.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Clarifies that disposal must be in accordance with the Code of Virginia. Necessary for the control of foodborne disease and assurance of food safety.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-3030</td>
<td>Requires</td>
<td>Requires that handwashing sinks are equipped with paper towels, continuous towel system or heated-air hand drying device.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-3310</td>
<td>Prohibited</td>
<td>Prohibits animals on the premises of food establishments, with some exceptions.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Includes an additional allowance for dogs on the outside premises of food establishments under certain conditions.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-3380</td>
<td>Requires</td>
<td>Requires that chemical sanitizers meet 40 CFR 180.940 requirements</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-3390</td>
<td>Requires</td>
<td>Requires that chemicals used to wash vegetables meet 21CFR 173.315 requirements</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-3410</td>
<td>Specifies</td>
<td>Specifies the requirements that drying agents used in conjunction with sanitizers must meet.</td>
<td></td>
</tr>
<tr>
<td>Code</td>
<td>Action</td>
<td>Explanatory Note</td>
<td></td>
</tr>
<tr>
<td>------------------</td>
<td>-----------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-3630</td>
<td>N/A</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-3670</td>
<td>N/A</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-3800</td>
<td>N/A</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-3810</td>
<td>N/A</td>
<td>Outlines evaluation criteria for determining need of performance-based or risk based inspections by the Department. Changed &quot;critical&quot; to &quot;priority item&quot; or &quot;priority foundation item&quot;. Changed &quot;noncritical&quot; to &quot;core item&quot;. Necessary to ensure compliance with public health, foodborne disease and food safety provisions of the regulation.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-3815</td>
<td>N/A</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-3860</td>
<td>N/A</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-3930</td>
<td>N/A</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-3940</td>
<td>N/A</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-3950</td>
<td>N/A</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>Regulation Code</td>
<td>Amplification</td>
<td>Compliance Schedule/Action</td>
<td></td>
</tr>
<tr>
<td>-----------------</td>
<td>--------------</td>
<td>---------------------------</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-3960</td>
<td>N/A</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-3970</td>
<td>N/A</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-3980</td>
<td>N/A</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-421-3990</td>
<td>N/A</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>12VAC5-4000</td>
<td>N/A</td>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>
12VAC5-421-10. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise.

“Accredited program” means a food protection manager certification program that has been evaluated and listed by an accrediting agency as conforming to national standards that certify individuals. “Accredited program” refers to the certification process and is a designation based upon an independent evaluation of factors such as the sponsor’s mission; organizational structure; staff resources; revenue sources; policies; public information regarding program scope, eligibility requirements, recertification, discipline and grievance procedures; and test development and administration. “Accredited program” does not refer to training functions or educational programs.

“Additive” means either a (i) “food additive” having the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 201(s) and 21 CFR Part 170.3(e)(1) or (ii) “color additive” having the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 201(t) and 21 CFR Part 70.3(f).

“Adulterated” has the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 402.

“Agent” means a legally authorized representative of the owner.

“Agent of the commissioner” means the district or local health director, unless otherwise stipulated.

“Approved” means acceptable to the department based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.

“Approved water supply” system” means a permitted waterworks constructed, maintained, and operated pursuant to 12VAC5-590; or a private well constructed, maintained, and operated pursuant to 12VAC5-630, which has a valid waterworks operation permit from the department or a nonpublic water supply which is evaluated, tested and if found in reasonable compliance with the construction standards of the Private Well Regulations (12VAC5-630) and the bacteriological water quality standards of the Virginia Waterworks Regulations (12VAC5-590), accepted and approved by the director or the director’s designee.

“Asymptomatic” means without obvious symptoms; not showing or producing indication indications of a disease or other medical condition, such as an individual infected with a pathogen but not exhibiting or producing any signs or symptoms of vomiting, diarrhea, or jaundice. Asymptomatic includes not showing symptoms because symptoms have resolved or subsided, or because symptoms never manifested.

“a_w” means water activity which is a measure of the free moisture in a food, is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature, and is indicated by the symbol a_w.

“Balut” means an embryo inside a fertile egg that has been incubated for a period sufficient for the embryo to reach a specific stage of development after which it is removed from incubation before hatching.

“Bed and breakfast” means a tourist home that serves meals.
"Beverage" means a liquid for drinking, including water.
"Board" means the State Board of Health.
"Bottled drinking water" means water that is sealed in bottles, packages, or other containers and offered for sale for human consumption, including bottled mineral water.
"Building official" means a representative of the Department of Housing and Community Development.
"Casing" means a tubular container for sausage products made of either natural or artificial material.
"Catering operation" means a person who contracts with a client to prepare a specific menu and amount of food in an approved and permitted food establishment for service to the client's guests or customers at a service location different from the permitted food establishment. Catering may also include cooking or performing final preparation of food at the service location.
"Catering operation" does not include:
1. A private chef or cook who, as the employee of a consumer, prepares food solely in the consumer's home.
2. Delivery service of food by an approved and permitted food establishment to an end consumer.
"Certification number" means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish dealer according to the provisions of the National Shellfish Sanitation Program.
"CFR" means Code of Federal Regulations. Citations in this chapter to the CFR refer sequentially to the title, part, and section number, such as 40 CFR 180.194 refers to Title 40, Part 180, Section 194.
"CIP" means cleaned in place by the circulation or flowing by mechanical means through a piping system of a detergent solution, water rinse, and sanitizing solution onto or over equipment surfaces that require cleaning, such as the method used, in part, to clean and sanitize a frozen dessert machine. CIP does not include the cleaning of equipment such as band saws, slicers or mixers that are subjected to in-place manual cleaning without the use of a CIP system.
"CFR" means Code of Federal Regulations. Citations in these regulations to the CFR refer sequentially to the title, part, and section numbers, such as 21 CFR 178.1010 refers to Title 21, Part 178, Section 1010.
"Code of Federal Regulations" means the compilation of the general and permanent rules published in the Federal Register by the executive departments and agencies of the federal government which:
1. Is published annually by the U.S. Government Printing Office; and
"Comminuted" means:
1. To combine shellstock harvested on different days or from different growing areas as identified on the tag or label; or
2. To combine shucked shellfish from containers with different container codes or different shucking dates.
"Comminuted" means reduced in size by methods including chopping, flaking, grinding, or mincing. "Comminuted" includes (i) fish or meat products that are reduced in size and restructured or reformulated such as gefilte fish, gyros, ground beef, and sausage; and (ii) a
mixture of two or more types of meat that have been reduced in size and combined, such as sausages made from two or more meats.

"Commissary" means a catering establishment, restaurant food establishment, or any other place in which food, food containers, or supplies are kept, handled, prepared, packaged, or stored for distribution to satellite operations.

"Commissioner" means the State Health Commissioner, his duly designated officer, or his agent.

"Conditional employee" means a potential food employee to whom a job offer is made, with employment dependent upon responses to subsequent medical questions or examinations designed to identify potential food employees who may be suffering from a disease that can be transmitted through food and done in compliance with Title 1 of the Americans with Disabilities Act of 1990.

"Confirmed disease outbreak" means a foodborne disease outbreak in which laboratory analysis of appropriate specimens identifies a causative organism or chemical and epidemiological analysis implicates the food as the source of the illness.

"Consumer" means a person who is a member of the public, takes possession of food, is not functioning in the capacity of an operator of a food establishment or food processing plant, and does not offer the food for resale.

"Core item" means a provision in this chapter 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 (SSOPs), facilities or structures, equipment design, or general maintenance.

"Corrosion-resistant materials" means a material that maintains acceptable surface cleanability characteristics under prolonged influence of the food to be contacted, the normal use of cleaning compounds and sanitizing solutions, and other conditions of the use environment.

"Counter-mounted equipment" means equipment that is not easily movable and is designed to be mounted off the floor on a table, counter, or shelf.

"Critical control point" means a point or procedure in a specific food system where loss of control may result in an unacceptable health risk.

"Critical item" means a provision of these regulations that, if in noncompliance, is more likely than other violations to contribute to food contamination, illness, or environmental degradation.

"Critical limit" means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to minimize the risk that the identified food safety hazard may occur.

"Cut leafy greens" means fresh leafy greens whose leaves have been cut, shredded, sliced, chopped, or torn. The term "leafy greens" includes iceberg lettuce, romaine lettuce, leaf lettuce, butter lettuce, baby leaf lettuce (i.e., immature lettuce or leafy greens), escarole, endive, spring mix, spinach, cabbage, kale, arugula, and chard. The term "leafy greens" does not include herbs such as cilantro or parsley.

"Dealer" means a person who is authorized by a shellfish control authority for the activities of a shellstock shipper, shucker-packer, repacker, reshipper, or depuration processor of molluscan shellfish according to the provisions of the National Shellfish Sanitation Program and is listed in the U.S. Food and Drug Administration's Interstate Certified Shellfish Shippers List, updated monthly (U.S. Food and Drug Administration).

"Delicatessen" means a store where ready to eat products such as cooked meats, prepared salads, etc. are sold for off-premises consumption.
"Department" means the Virginia Department of Health.

"Director" means the district or local health director.

"Disclosure" means a written statement that clearly identifies the animal foods that are, or can be ordered, raw, undercooked, or without otherwise being processed to eliminate pathogens in their entirety, or items that contain an ingredient that is raw, undercooked, or without otherwise being processed to eliminate pathogens.

"Drinking water" means water that meets the water quality standards for bacteria of the Virginia Waterworks Regulations (12VAC5-590). Drinking water is traditionally known as "potable water." Drinking water includes the term water except where the term used connotes that the water is not potable, such as "boiler water," "mop water," "rainwater," "wastewater," and "nondrinking" water.

"Dry storage area" means a room or area designated for the storage of packaged or containerized bulk food that is not potentially hazardous time/temperature control for safety food and dry goods such as single-service items.

"Easily cleanable" means a characteristic of a surface that:

1. Allows effective removal of soil by normal cleaning methods;
2. Is dependent on the material, design, construction, and installation of the surface; and
3. Varies with the likelihood of the surface's role in introducing pathogenic or toxigenic agents or other contaminants into food based on the surface's approved placement, purpose, and use.

"Easily cleanable" includes a tiered application of the criteria that qualify the surface as easily cleanable as specified above to different situations in which varying degrees of cleanliness are required such as:

1. The appropriateness of stainless steel for a food preparation surface as opposed to the lack of need for stainless steel to be used for floors or for tables used for consumer dining; or
2. The need for a different degree of cleanability for a utilitarian attachment or accessory in the kitchen as opposed to a decorative attachment or accessory in the consumer dining area.

"Easily movable" means:

1. Portable (weighing 30 pounds or less); mounted on casters, gliders, or rollers; or provided with a mechanical means to safely tilt a unit of equipment for cleaning; and
2. Having no utility connection, a utility connection that disconnects quickly, or a flexible utility connection line of sufficient length to allow the equipment to be moved for cleaning of the equipment and adjacent area.

"Egg" means the shell egg of avian species such as chicken, duck, goose, guinea, quail, ratites, or turkey. Egg does not include a balut; egg of the reptile species such as alligator; or an egg product.

"Egg product" means all, or a portion of, the contents found inside eggs separated from the shell and pasteurized in a food processing plant, with or without added ingredients, intended for human consumption, such as dried, frozen, or liquid eggs. Egg product does not include food that contains eggs only in a relatively small proportion such as cake mixes.

"Employee" means the permit holder, person in charge, food employee, person having supervisory or management duties, person on the payroll, family member, volunteer, person performing work under contractual agreement, or other person working in a food establishment.
"Enterohemorrhagic Escherichia coli (EHEC)" means E.coli that cause hemorrhagic colitis, meaning bleeding enterically or bleeding from the intestine. The term is typically used in association with E.coli that have the capacity to produce Shiga toxins and to cause attaching and effacing lesion in the intestine. EHEC is a subset of STE C, whose members produce additional virulence factors. Infections with EHEC may be asymptomatic but are classically associated with bloody diarrhea (hemorrhagic colitis) and hemolytic uremic syndrome (HUS) or thrombotic thrombocytopenic purpura (TTP). Examples of serotypes of EHEC include: E.coli O157:H7; E.coli O157:NM; E.coli O26:H11; E.coli O145:NM; E.coli O103:H2; or E.coli O111:NM. Also see Shiga toxin-producing E.coli.

"EPA" means the U.S. Environmental Protection Agency.

"Equipment" means an article that is used in the operation of a food establishment. Equipment includes, but is not limited to, items such as a freezer, grinder, hood, ice maker, meat block, mixer, oven, reach-in refrigerator, scale, sink, slicer, stove, table, temperature measuring device for ambient air, vending machine, or warewashing machine. Equipment does not include apparatuses used for handling or storing large quantities of packaged foods that are received from a supplier in a cased or overwrapped lot, such as hand trucks, forklifts, dollies, pallets, racks, and skids.

"Exclude" means to prevent a person from working as a food employee in a food establishment or entering a food establishment as an employee.

"°F" means degrees Fahrenheit.

"FDA" means the U.S. Food and Drug Administration.

"Fish" means: fresh or saltwater finfish, crustaceans, and other forms of aquatic life (including alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals; and all mollusks, if such animal life is intended for human consumption; and includes any edible human food product derived in whole or in part from fish, including fish that has been processed in any manner.

"Food" means (i) a raw, cooked, or processed edible substance, ice, beverage, or ingredient used or intended for use or for sale in whole or in part for human consumption or (ii) chewing gum.

"Foodborne disease outbreak" means the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food.

"Food-contact surface" means a surface of equipment or a utensil with which food normally comes into contact, or a surface of equipment or a utensil from which food may drain, drip, or splash into a food, or onto a surface normally in contact with food.

"Food employee" means an individual working with unpackaged food, food equipment or utensils, or food-contact surfaces.

"Food establishment" means an operation that (i) stores, prepares, packages, serves, or vends food directly to the consumer or otherwise provides food to the public for human consumption (ii) such as a restaurant, satellite or catered feeding location, catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people, market, vending location, conveyance used to transport people, institution, or food bank, and (ii) that relinquishes possession of food to a consumer directly, or indirectly through a delivery service, such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

"Food establishment" includes (a) (i) an element of the operation such as a transportation vehicle or a central preparation facility that supplies a vending location or satellite feeding location; (b) (ii) an operation that is conducted in a mobile, stationary, temporary, or permanent facility or location, where consumption is on or off the premises; and regardless of whether there
is a charge for the food; and (c) (iii) a facility that does not meet the exemption criteria identified in subdivision 6 of this definition or a facility that meets the exemption requirements but chooses to be regulated under these regulations this chapter.

For the purpose of implementing this chapter, the following places are also included in the definition of a "food establishment" as defined in subdivision 9 of § 35.1-1 of the Code of Virginia:

1. Any place where food is prepared for service to the public on or off the premises, or any place where food is served. Examples of such places include but are not limited to lunchrooms, short order places, cafeterias, coffee shops, cafés, taverns, delicatessens, dining accommodations of public or private clubs, kitchen facilities of hospitals and nursing homes, dining accommodations of public and private schools and colleges, and kitchen areas of local correctional facilities subject to standards adopted under § 53.1-68 of the Code of Virginia.

2. Any place or operation that prepares or stores food for distribution to persons of the same business operation or of a related business operation for service to the public. Examples of such places or operations include but are not limited to operations preparing or storing food for catering services, push cart operations, hotdog stands, and other mobile points of service. Such mobile points of service are also deemed to be restaurants unless the point of service and of consumption is in a private residence.

"Food establishment" does not include:

1. An establishment that offers only prepackaged foods that are not potentially hazardous food that is not time/temperature control for safety food;

2. A produce stand that only offers whole, uncut fresh fruits and vegetables;

3. A food processing plant, including those that are located on the premises of a food establishment;

4. A kitchen in a private home if only food that is not potentially hazardous time/temperature control for safety food is prepared for sale or service at a function such as a religious or charitable organization's bake sale if allowed by law and if the consumer is informed by a clearly visible placard at the sales or service location that the food is prepared in a kitchen that is not subject to regulation and inspection by the regulatory authority;

5. An area where food that is prepared as specified in subdivision 4 above of this definition is sold or offered for human consumption;

6. A kitchen in a private home, such as, but not limited to, a family day-care provider or a home for adults, serving 12 or fewer recipients; or a bed-and-breakfast operation that prepares and offers food only to guests if the premises of the home is owner or owner-agent occupied, the number of available guest bedrooms does not exceed six, breakfast is the only meal offered, the number of guests served does not exceed 18, and the consumer is informed by statements contained in published advertisements, mailed brochures, and placards posted at the registration area that the food is prepared in a kitchen that is, by these regulations this chapter, exempt from this chapter; or

7. A private home that receives catered or home-delivered food; or

8. Places manufacturing packaged or canned foods that are distributed to grocery stores or other similar food retailers for sale to the public.

For the purpose of implementing this chapter, the following are also exempt from the definition of a "food establishment" in this chapter, as defined in §§ 35.1-25 and 35.1-26 of the Code of Virginia:
1. Boarding houses that do not accommodate transients;
2. Cafeterias operated by industrial plants for employees only;
3. Churches, fraternal, school and social organizations and volunteer fire departments
   and rescue squads that hold dinners and bazaars not more than one time per week and
   not in excess of two days duration at which food prepared in homes of members or in
   the kitchen of the church or organization and is offered for sale to the public;
4. Grocery stores, including the delicatessen that is a part of a grocery store, selling
   exclusively for off-premises consumption and places manufacturing or selling packaged
   or canned goods;
5. Churches that serve meals for their members as a regular part of their religious
   observance; and
6. Convenience stores or gas stations that are subject to the State Board of Agriculture
   and Consumer Services’ Retail Food Establishment Regulations (2VAC5-585) or any
   regulations subsequently adopted and that (i) have 15 or fewer seats at which food is
   served to the public on the premises of the convenience store or gas station and (ii) are
   not associated with a national or regional restaurant chain. Notwithstanding this
   exemption, such convenience stores or gas stations shall remain responsible for
   collecting any applicable local meals tax.

"Food processing plant" means a commercial operation that manufactures, packages,
labels, or stores food for human consumption and provides food for sale or distribution to other
business entities such as food processing plants or food establishments. Food processing plant
does not include a food establishment.

"Game animal" means an animal, the products of which are food, that is not classified as:
cattle, sheep, swine, goat, horse, mule, or other equine in 9 CFR Part 301 Definitions, as poultry
in 9 CFR Part 381 Poultry Products Inspection Regulations, or as Fish as defined in this
section (i) livestock, sheep, swine, goat, horse, mule, or other equine in 9 CFR 301.2; (ii) poultry;
or (iii) fish.

"Game animal" includes mammals such as reindeer, elk, deer, antelope, water buffalo,
bison, rabbit, squirrel, opossum, raccoon, nutria, or muskrat and nonaquatic reptiles such as
land snakes.

"Game animal" does not include ratites such as ostrich, emu, and rhea.

"General use pesticide" means a pesticide that is not classified by EPA for restricted use as
specified in 40 CFR 152.175.

"Grade A standards" means the requirements of the USPHS/FDA “Grade [A] Grade “A”
Pasteurized Milk Ordinance” and “Grade A Condensed and Dry Milk Ordinance”, 2013 Revision,
(U.S. Food and Drug Administration), with which certain fluid and dry milk and milk products
comply.

"HACCP Plan" means a written document that delineates the formal procedures for following
the Hazard Analysis Critical Control Point principles developed by The National Advisory
Committee on Microbiological Criteria for Foods.

"Handwashing sink" means a lavatory, a basin or vessel for washing, a wash basin, or a
plumbing fixture especially placed for use in personal hygiene and designed for the washing of
hands. Handwashing sink includes an automatic handwashing facility.

"Hazard" means a biological, chemical, or physical property that may cause an
unacceptable consumer health risk.

"Health practitioner" means a physician licensed to practice medicine, or if allowed by law, a
nurse practitioner, physician assistant, or similar medical profession [professional].
"Hermetically sealed container" means a container that is designed and intended to be secure against the entry of microorganisms and, in the case of low acid canned foods, to maintain the commercial sterility of its contents after processing.

"Highly susceptible population" means persons who are more likely than other people in the general population to experience foodborne disease because they are:

1. Immunocompromised, preschool age children, or older adults; and
2. Obtaining food at a facility that provides services such as custodial care, health care, or assisted living, such as a child or adult day care center, kidney dialysis center, hospital or nursing home, or nutritional or socialization services such as a senior center.

"Hot water" means water at a temperature of 100°F or higher unless otherwise stated.

"Imminent health hazard" means a significant threat or danger to health that is considered to exist when there is evidence sufficient to show that a product, practice, circumstance, or event creates a situation that requires immediate correction or cessation of operation to prevent injury based on the number of potential injuries, and the nature, severity, and duration of the anticipated injury.

"Injected" means tenderizing a meat with deep penetration or injecting the meat such as with juices which may be referred to as "injecting," "pinning," or "stitch pumping." During injection infectious or toxigenic microorganisms may be introduced from its surface to its interior. Manipulating meat to which a solution has been introduced into its interior by processes such as "injecting," "pump marinating," or "stitch pumping."

"Juice" means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purées of the edible portions of one or more fruits or vegetables, or any concentrate of such liquid or purée. Juice does not include, for purposes of HACCP, liquids, purées, or concentrates that are not used as beverages or ingredients of beverages.

"Kitchenware" means food preparation and storage utensils.

"Law" means applicable local, state, and federal statutes, regulations, and ordinances.

"Linens" means fabric items such as cloth hampers, cloth napkins, table cloths, wiping cloths, and work garments including cloth gloves.

"Major food allergen" means milk, egg, fish (such as bass, flounder, cod, and including crustacean shellfish such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or walnuts), wheat, peanuts, and soybeans; or a food ingredient that contains protein derived from one of these foods. Major food allergen does not include any highly refined oil derived from a major food allergen in this definition and any ingredient derived from such highly refined oil; or any ingredient that is exempt under the petition or notification process specified in the Food Allergen Labeling and Consumer Protection Act of 2004 (Pub. L. 108-282).

"Meat" means the flesh of animals used as food including the dressed flesh of cattle, swine, sheep, or goats and other edible animals, except fish, poultry, and wild game animals as specified under 12VAC5-421-330 A 3 and 4.

"Mechanically tenderized" means manipulating meat with deep penetration by processes which may be referred to as "blade tenderizing," "jaccarding," "pinning," "needling," or using blades, pins, needles, or any mechanical device. "Mechanically tenderized" does not include processes by which solutions are injected into meat.

"mg/L" means milligrams per liter, which is the metric equivalent of parts per million (ppm).

"Mobile food unit" means a food establishment that is mounted on wheels that is readily moveable from place to place at all times during operation and shall include, but not be limited to, pushcarts, trailers, trucks, or vans. There is no size limit to mobile food units but they must be mobile at all times during operation and must be on wheels.
Molluscan shellfish" means any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, except when the scallop product consists only of the shucked adductor muscle.

"Noncontinuous cooking" means the cooking of food in a food establishment using a process in which the initial heating of the food is intentionally halted so that it may be cooled and held for complete cooking at a later time prior to sale or service. "Noncontinuous cooking" does not include cooking procedures that only involve temporarily interrupting or slowing an otherwise continuous cooking process.

"Occasional" means not more than one time per week, and not in excess of two days duration.

"Organization" means any one of the following:

1. A volunteer fire department or rescue squad or auxiliary unit thereof which has been recognized in accordance with § 15.2-955 of the Code of Virginia by an ordinance or resolution of the political subdivision where the volunteer fire department or rescue squad is located as being a part of the safety program of such political subdivision;

2. An organization operated exclusively for religious, charitable, community or educational purposes;

3. An association of war veterans or auxiliary units thereof organized in the United States;

4. A fraternal association or corporation operating under the lodge system;

5. A local chamber of commerce; or

6. A nonprofit organization that raises funds by conducting raffles which generate annual gross receipts of less than $75,000, provided such gross receipts from the raffle, less expenses and prizes, are used exclusively for charitable, educational, religious or community purposes.

"Packaged" means bottled, canned, cartoned, securely bagged, or securely wrapped, whether packaged in a food establishment or a food processing plant. Packaged does not include wrapped or placed in a carry-out container to protect the food during service or delivery to the consumer, by a food employee, upon consumer request.

"Permit" means a license issued by the regulatory authority that authorizes a person to operate a food establishment.

"Permit holder" means the entity that is legally responsible for the operation of the food establishment such as the owner, the owner's agent, or other person, and possesses a valid permit to operate a food establishment.

"Person" means an association, a corporation, individual, partnership, other legal entity, government, or governmental subdivision or agency.

"Person in charge" means the individual present at a food establishment who is responsible for the operation at the time of inspection.

"Personal care items" means items or substances that may be poisonous, toxic, or a source of contamination and are used to maintain or enhance a person's health, hygiene, or appearance. Personal care items include items such as medicines; first aid supplies; and other items such as cosmetics, and toiletries such as toothpaste and mouthwash.

"pH" means the symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution. Values between 0 and 7.0

(excluding boats in the water) at all times. The unit, all operations, and all equipment must be integral to and be within or attached to the unit.
indicate acidity and values between 7.0 and 14 indicate alkalinity. The value for pure distilled water is 7.0, which is considered neutral.

"Physical facilities" means the structure and interior surfaces of a food establishment including accessories such as soap and towel dispensers and attachments such as light fixtures and heating or air conditioning system vents.

"Plumbing fixture" means a receptacle or device that is permanently or temporarily connected to the water distribution system of the premises and demands a supply of water from the system or discharges used water, waste materials, or sewage directly or indirectly to the drainage system of the premises.

"Plumbing system" means the water supply and distribution pipes; plumbing fixtures and traps; soil, waste, and vent pipes; sanitary and storm sewers and building drains, including their respective connections, devices, and appurtenances within the premises; and water-treating equipment.

"Poisonous or toxic materials" means substances that are not intended for ingestion and are included in four categories:

1. Cleaners and sanitizers, which include cleaning and sanitizing agents and agents such as caustics, acids, drying agents, polishes, and other chemicals;
2. Pesticides except sanitizers, that include substances such as insecticides and rodenticides;
3. Substances necessary for the operation and maintenance of the establishment such as nonfood grade lubricants, paints, and personal care items that may be deleterious to health; and
4. Substances that are not necessary for the operation and maintenance of the establishment and are on the premises for retail sale, such as petroleum products and paints.

"Potentially hazardous food (time/temperature control for safety food)" means a food that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation:

1. Potentially hazardous food (time/temperature control for safety food) includes an animal food that is raw or heat-treated; a plant food that is heat-treated or consists of raw seed sprouts, cut melons, cut tomatoes, or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way that results in mixtures that do not support pathogenic microorganism growth or toxin formation; and except as specified in subdivision 2 of this definition, a food that because of the interaction of its Aw and pH values is designated as Product Assessment Required (PA) in Table A or B of this definition.

Table A. Interaction of pH and Aw for control of spores in food heat-treated to destroy vegetative cells and subsequently packaged.

<table>
<thead>
<tr>
<th>Aw values</th>
<th>pH values</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4.6 or less</td>
</tr>
<tr>
<td>&lt;0.92</td>
<td>non-PHF/non-TCS food**</td>
</tr>
<tr>
<td>&gt;0.92-0.95</td>
<td>non-PHF/non-TCS food</td>
</tr>
</tbody>
</table>
2. Potentially hazardous food (time/temperature control for safety food) does not include:

   a. An air-cooled hard-boiled egg with shell intact, or an egg with shell intact that is not hard-boiled, but has been pasteurized to destroy all viable Salmonellae;

   b. A food in an unopened hermetically sealed container that is commercially processed to achieve and maintain commercial sterility under conditions of nonrefrigerated storage and distribution;

   c. A food that because of its pH or Aw value, or interaction of Aw and pH values, is designated as a non-PHF/non-TCS food in Table A or B of this definition;

   d. A food that is designated as Product Assessment required (PA) in Table A or B of this definition and has undergone a Product Assessment showing that the growth or toxin formation of pathogenic microorganisms that are reasonably likely to occur in that food is precluded due to:

      (1) Intrinsic factors including added or natural characteristics of the food such as preservatives, antimicrobials, humectants, acidulants, or nutrients;

      (2) Extrinsic factors including environmental or operational factors that affect the food such as packaging, modified atmosphere such as reduced oxygen packaging, shelf-life and use, or temperature range of storage and use, or

      (3) A combination of intrinsic and extrinsic factors; or

<table>
<thead>
<tr>
<th>Aw values</th>
<th>pH values</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt; 4.2</td>
</tr>
<tr>
<td>&lt;0.88</td>
<td>non-PHF/*non-TCS food</td>
</tr>
<tr>
<td>0.88-0.90</td>
<td>non-PHF/non-TCS food</td>
</tr>
<tr>
<td>&gt;0.90-0.92</td>
<td>non-PHF/non-TCS food</td>
</tr>
<tr>
<td>&gt;0.92</td>
<td>non-PHF/non-TCS food</td>
</tr>
</tbody>
</table>

*PHF means Potentially Hazardous Food
**TCS means Time/Temperature Control for Safety Food
***PA means Product Assessment required
e. A food that does not support the growth or toxin formation of pathogenic microorganisms in accordance with one of the subdivisions 2 a through 2 d of this definition even though the food may contain a pathogenic microorganism or chemical or physical contaminant at a level sufficient to cause illness or injury.

"Potable water" means water fit for human consumption that is obtained from an approved water supply and that is (i) sanitary and normally free of minerals, organic substances, and toxic agents in excess of reasonable amounts and (ii) adequate in quantity and quality for the minimum health requirements of the persons served (see Article 2 (§ 32.1-167 et seq.) of Chapter 6 of Title 32.1 of the Code of Virginia). Potable water is traditionally known as drinking water and excludes such nonpotable forms as "boiler water," "mop water," "rainwater," "wastewater," and "nondrinking" water.

"Poultry" means any domesticated bird (chickens, turkeys, ducks, geese, or guineas, guineas, ratites, or squabs), whether live or dead, as defined in 9 CFR Part 381, Poultry Products Inspection Regulations, and any migratory waterfowl, game bird, or squab such as pheasant, partridge, quail, grouse, guineas, or pigeon or squab whether live or dead, as defined in 9 CFR Part 362, Voluntary Poultry Inspection Regulations. "Poultry" does not include ratites.

"Premises" means the physical facility, its contents, and the contiguous land or property under the control of the permit holder; or the physical facility, its contents, and the land or property which are under the control of the permit holder and may impact food establishment personnel, facilities, or operations, if a food establishment is only one component of a larger operation such as a health care facility, hotel, motel, school, recreational camp, or prison.

"Primal cut" means a basic major cut into which carcasses and sides of meat are separated, such as a beef round, pork loin, lamb flank or veal breast.

"Priority foundation item" means a provision in this chapter 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 regulation with a superscript Pf.

"Priority item" means a provision in this chapter whose application contributes directly to the elimination, prevention or reduction to an acceptable level of hazards associated with foodborne illness or injury and 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, and handwashing and is denoted in this chapter with a superscript P.

"Private well" means any water well constructed for a person on land that is owned or leased by that person and is usually intended for household, groundwater source heat pump, agricultural use, industrial use, or other nonpublic water well.

"Public water system" has the meaning stated in 40 CFR Part 141, National Primary Drinking Water Regulations.

"Pure water" means potable water fit for human consumption that is (i) sanitary and normally free of minerals, organic substances, and toxic agents in excess of reasonable amounts and (ii) adequate in quantity and quality for the minimum health requirements of the persons served (see § 32.1-176.1 and 32.1-167 of the Code of Virginia and 12VAC5-590 and 12VAC5-630-370. Potable water is traditionally known as drinking water, and excludes such nonpotable forms as "boiler water," "mop water," "rainwater," "wastewater," and "nondrinking water."

"Pushcart" means any wheeled vehicle or device other than a motor vehicle or trailer that may be moved with or without the assistance of a motor and that does not require registration.
by the department of motor vehicles. A pushcart is limited to the sale and/or service of hot dogs and frankfurter-like foods.

"Ratite" means a flightless bird such as an emu, ostrich, or rhea.

"Ready-to-eat food" means food that:

1. Is in a form that is edible without additional preparation to achieve food safety, as specified under 12VAC5-421-700 A through B, and C, 12VAC5-421-710, or 12VAC5-421-730;
2. Is a raw or partially cooked animal food and the consumer is advised as specified under 12VAC5-421-700 D 1 and 2 3; or
3. Is prepared in accordance with a variance that is granted as specified under 12VAC5-421-700 D 4 and 2 4.

Ready-to-eat food may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes.

"Ready-to-eat food" includes:

1. Raw animal food that is cooked as specified under 12VAC5-421-700, or 12VAC5-421-710 or frozen as specified under 12VAC5-421-730;
2. Raw fruits and vegetables that are washed as specified under 12VAC5-421-510;
3. Fruits and vegetables that are cooked for hot holding as specified under 12VAC5-421-720;
4. All potentially hazardous food time/temperature control for safety food that is cooked to the temperature and time required for the specific food under 12VAC5-421-700 and cooled as specified in 12VAC5-421-800;
5. Plant food for which further washing, cooking, or other processing is not required for food safety, and from which rinds, peels, husks, or shells, if naturally present, are removed;
6. Substances derived from plants such as spices, seasonings, and sugar;
7. A bakery item such as bread, cakes, pies, fillings, or icing for which further cooking is not required for food safety;
8. The following products that are produced in accordance with USDA guidelines and that have received a lethality treatment for pathogen (pathogens) : dry, fermented sausages, such as dry salami or pepperoni; salt-cured meat and poultry products, such as prosciutto ham, country cured ham, and Parma ham; and dried meat and poultry products, such as jerky or beef sticks; and

"Reduced oxygen packaging" means the reduction of the amount of oxygen in a package by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the atmosphere (approximately 21% at sea level); and a process as specified in this definition that involves a food for which the hazards Clostridium botulinum or Listeria monocytogenes require control in the final packaged form. Reduced oxygen packaging includes:

1. Vacuum packaging, in which air is removed from a package of food and the package is hermetically sealed so that a vacuum remains inside the package;
2. Modified atmosphere packaging, in which the atmosphere of a package of food is modified so that its composition is different from air but the atmosphere may change over time due to the permeability of the packaging material or the respiration of the food.
Modified atmosphere packaging includes reduction in the proportion of oxygen, total replacement of oxygen, or an increase in the proportion of other gases such as carbon dioxide or nitrogen;

3. Controlled atmosphere packaging, in which the atmosphere of a package of food is modified so that until the package is opened, its composition is different from air, and continuous control of that atmosphere is maintained, such as by using oxygen scavengers or a combination of total replacement oxygen, nonrespiring food, and impermeable packaging material;

4. Cook chill packaging, in which cooked food is hot filled into impermeable bags that have the air expelled and are then sealed or crimped closed. The bagged food is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens; or

5. Sous vide packaging, in which raw or partially cooked food is placed in a hermetically sealed, [vacuum packaged in an] impermeable bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

"Refuse" means solid waste not carried by water through the sewage system.

"Regulatory authority" means the Virginia Department of Agriculture and Consumer Services, the Virginia Department of Health or their authorized representative having jurisdiction over the food establishment.

"Reminder" means a written statement concerning the health risk of consuming animal foods raw, undercooked, or without otherwise being processed to eliminate pathogens.

"Reservice" means the transfer of food that is unused and returned by a consumer after being served or sold and in the possession of the consumer, to another person.

"Restrict" means to limit the activities of a food employee so that there is no risk of transmitting a disease that is transmissible through food and the food employee does not work with exposed food, clean equipment, utensils, linens, and unwrapped single-service or single-use articles.

"Restricted egg" means any check, dirty egg, incubator reject, inedible, leaker, or loss as defined in 9 CFR Part 590.

"Restricted use pesticide" means a pesticide product that contains the active ingredients specified in 40 CFR 152.175 (pesticides classified for restricted use) and that is limited to use by or under the direct supervision of a certified applicator.

"Risk" means the likelihood that an adverse health effect will occur within a population as a result of a hazard in a food.

"Safe material" means an article manufactured from or composed of materials that shall not reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of any food; an additive that is used as specified in § 409 or 706 of the Federal Food, Drug, and Cosmetic Act (21 USC § 348); or other materials that are not additives and that are used in conformity with applicable regulations of the Food and Drug Administration.

"Sanitization" means the application of cumulative heat or chemicals on cleaned food contact food-contact surfaces that, when evaluated for efficacy, yield a reduction of five logs, which is equal to a 99.999% reduction, of representative disease microorganisms of public health importance.

"Sealed" means free of cracks or other openings that permit the entry or passage of moisture.
"Service animal" means an animal such as a guide dog, signal dog, or other animal individually trained to provide assistance to an individual with a disability.

"Servicing area" means an operating base location to which a mobile food establishment or transportation vehicle returns regularly for such things as vehicle and equipment cleaning, discharging liquid or solid wastes, refilling water tanks and ice bins, and boarding food.

"Sewage" means liquid waste containing animal or vegetable matter in suspension or solution and may include liquids containing chemicals in solution. Sewage includes water-carried and non-water-carried human excrement or kitchen, laundry, shower, bath, or lavatory waste separately or together with such underground surface, storm, or other water and liquid industrial wastes as may be present from residences, buildings, vehicles, industrial establishments, or other places.

"Shellfish control authority" means a state, federal, foreign, tribal or other government entity legally responsible for administering a program that includes certification of molluscan shellfish harvesters and dealers for interstate commerce such as the Virginia Department of Health Division of Shellfish Sanitation.

"Shellstock" means raw, in-shell molluscan shellfish.

"Shiga toxin-producing Escherichia coli" (STEC) or "STEC" means any E. coli capable of producing Shiga toxins (also called verocytotoxins or "Shiga-like" toxins) verocytotoxins. STEC infections can be asymptomatic or may result in a spectrum of illness ranging from mild nonbloody diarrhea, to hemorrhagic colitis (i.e., bloody diarrhea) to hemolytic uremic syndrome (HUS), which is a type of kidney failure. Examples of serotypes of STEC include both O157 and non-O157 E. coli. Also see Enterohemorrhagic Escherichia coli. E. coli O157:H7, E. coli O157:NM, E. coli O26:H11; E. coli O145NM, E. coli O103:H2, and E. coli O111:NM. STEC are sometimes referred to as VTEC (verocytotoxigenic E. coli) or as EHEC (Enterohemorrhagic E. coli). EHEC are a subset of STEC that can cause hemorrhagic colitis or HUS.

"Shucked shellfish" means molluscan shellfish that have one or both shells removed.

"Single-service articles" means tableware, carry-out utensils, and other items such as bags, containers, placemats, stirrers, straws, toothpicks, and wrappers that are designed and constructed for one time, one person use after which they are intended for discard.

"Single-use articles" means utensils and bulk food containers designed and constructed to be used once and discarded. Single-use articles includes items such as wax paper, butcher paper, plastic wrap, formed aluminum food containers, jars, plastic tubs or buckets, bread wrappers, pickle barrels, ketchup bottles, and number 10 cans which do not meet the materials, durability, strength and cleanability specifications contained in 12VAC5-421-960, 12VAC5-421-1080, and 12VAC5-421-1100 for multiuse utensils.

"Slacking" means the process of moderating the temperature of a food such as allowing a food to gradually increase from a temperature of -10°F (-23°C) to 25°F (-4°C) in preparation for deep-fat frying or to facilitate even heat penetration during the cooking of previously block-frozen food such as spinach shrimp.

"Smooth" means a food-contact surface having a surface free of pits and inclusions with a cleanability equal to or exceeding that of (100 grit) number three stainless steel; a nonfood-contact non-food-contact surface of equipment having a surface equal to that of commercial grade hot-rolled steel free of visible scale; and a floor, wall, or ceiling having an even or level surface with no roughness or projections that render it difficult to clean.

"Substantial compliance" shall mean that details of means equipment or structure design or construction and/or; food preparation, handling, storage, transportation and/or; cleaning procedures that will not substantially affect health consideration or performance of the facility or its the employees.
"Tableware" means eating, drinking, and serving utensils for table use such as flatware including forks, knives, and spoons; hollowware including bowls, cups, serving dishes, tumblers; and plates.

"Temperature measuring device" means a thermometer, thermocouple, thermistor, or other device that indicates the temperature of food, air, or water.

"Temporary food establishment" means a food establishment that operates for a period of no more than 14 consecutive days in conjunction with a single event or celebration.

"Time/temperature control for safety food" or "TCS food" means a food that requires time/temperature control for safety to limit pathogenic microorganism growth or toxin formation:

1. TCS food includes an animal food that is raw or heat treated; a plant food that is heat treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes, or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation; and except as specified in subdivision 2 d of this definition, a food that because of the interaction of its $A_w$ and pH values is designated as product assessment required (PA) in Table A or B of this definition:

<table>
<thead>
<tr>
<th>$A_w$ values</th>
<th>pH values</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 0.92</td>
<td>non-TCS food*</td>
</tr>
<tr>
<td>&gt; 0.92 - 0.95</td>
<td>non-TCS food</td>
</tr>
<tr>
<td>&gt; 0.95</td>
<td>non-TCS food</td>
</tr>
</tbody>
</table>

*TCS food means time/temperature control for safety food
**PA means product assessment required

Table A. Interaction of pH and $A_w$ for control of spores in food heat treated to destroy vegetative cells and subsequently packaged.

<table>
<thead>
<tr>
<th>$A_w$ values</th>
<th>pH values</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 4.2</td>
<td>4.2 - 4.6</td>
</tr>
<tr>
<td>&lt; 0.88</td>
<td>non-TCS food*</td>
</tr>
<tr>
<td>0.88-0.90</td>
<td>non-TCS food</td>
</tr>
<tr>
<td>&gt; 0.90-0.92</td>
<td>non-TCS food</td>
</tr>
<tr>
<td>&gt; 0.92</td>
<td>non-TCS food</td>
</tr>
</tbody>
</table>

*TCS food means time/temperature control for safety food
2. TCS food does not include:

   a. An air-cooled hard-boiled egg with shell intact, or an egg with shell intact that is not hard-boiled, but has been pasteurized to destroy all viable salmonellae;

   b. A food in an unopened hermetically sealed container that is commercially processed to achieve and maintain commercial sterility under conditions of nonrefrigerated storage and distribution;

   c. A food that because of its pH or Aw value, or interaction of Aw and pH values, is designated as a non-TCS food in Table A or B of this definition;

   d. A food that is designated as PA in Table A or B of this definition and has undergone a product assessment showing that the growth or toxin formation of pathogenic microorganisms that are reasonably likely to occur in that food is precluded due to:

      (1) Intrinsic factors including added or natural characteristics of the food such as preservatives, antimicrobials, humectants, acidulants, or nutrients;

      (2) Extrinsic factors including environmental or operational factors that affect the food such as packaging, modified atmosphere such as reduced oxygen packaging, shelf-life and use, or temperature range of storage and use; or

      (3) A combination of intrinsic and extrinsic factors; or

   e. A food that does not support the growth or toxin formation of pathogenic microorganisms in accordance with one of the subdivisions 2 a through 2 d of this definition even though the food may contain a pathogenic microorganism or chemical or physical contaminant at a level sufficient to cause illness or injury.

"USDA" means the U.S. Department of Agriculture.

"Utensil" means a food-contact implement or container used in the storage, preparation, transportation, dispensing, sale, or service of food, such as kitchenware or tableware that is multiuse, single service, or single use; gloves used in contact with food; temperature sensing probes of food temperature measuring devices and probe-type price or identification tags used in contact with food.

"Variance" means a written document issued by the regulatory authority that authorizes a modification or waiver of one or more requirements of this chapter if, in the opinion of the regulatory authority, a health hazard or nuisance will not result from the modification or waiver.

"Vending machine" means a self-service device that, upon insertion of a coin, paper currency, token, card, or key, or by optional manual operation, dispenses unit servings of food in bulk or in packages without the necessity of replenishing the device between each vending operation.

"Vending machine location" means the room, enclosure, space, or area where one or more vending machines are installed and operated and includes the storage and servicing areas on the premises that are used in conjunction with the vending machines, areas and areas on the premises that are used to service and maintain the vending machines.

"Warewashing" means the cleaning and sanitizing of utensils and food-contact surfaces of equipment and utensils.

"Waterworks" means a system that serves piped water for human consumption to at least 15 service connections or 25 or more individuals for at least 60 days out of the year. "Waterworks" includes all structures, equipment and appurtenances used in the storage, collection, purification, treatment, and distribution of potable water except the piping and fixtures inside the...
building where such water is delivered (see Article 2 (§ 32.1-167 et seq.) of Chapter 6 of Title 32.1 of the Code of Virginia).

"Whole-muscle, intact beef" means whole muscle beef that is not injected, mechanically tenderized, reconstructed, or scored and marinated, from which beef steaks may be cut.

**Part II**

**Management and Personnel**

**Article 1**

**Supervision**

**12VAC5-421-50. Assignment of responsibility.**

A. Except as specified in subsection B of this section, the permit holder shall be the person in charge or shall designate a person in charge and shall ensure that a person in charge is present at the food establishment during all hours of operation.

B. In a food establishment with two or more separately permitted departments that are the legal responsibility of the same permit holder and that are located on the same premises, the permit holder may, during specific time periods when food is not being prepared, packaged, or served, designate a single person in charge who is present on the premises during all hours of operation, and who is responsible for each separately permitted food establishment on the premises.

**12VAC5-421-55. Certified food protection manager.**

A. At least one employee with supervisory and management responsibility and the authority to direct and control food preparation and service shall be a certified food protection manager, demonstrating proficiency of required knowledge and information through passing a test that is part of an accredited program.

B. This section does not apply to food establishments that serve only non-temperature control for safety food and food establishments where food handling does not exceed reheating, cold holding, and hot holding of commercially processed and packaged ready-to-eat foods.

C. For purposes of enforcement, this section will take effect on July 1, 2018.

**12VAC5-421-60. Demonstration of knowledge.**

Based on the risks of foodborne illness inherent to the food operation, during inspections and upon request the person in charge shall demonstrate to the regulatory authority knowledge of foodborne disease prevention, and the requirements of these regulations this chapter. The person in charge shall demonstrate this knowledge by:

1. Complying with the Food Regulations this chapter by having no violations of critical priority items during the current inspection;
2. Being a certified food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program;
3. Responding correctly to the environmental health specialist's questions as they relate to the specific food operation. The areas of operation may include:
   a. Describing the relationship between the prevention of foodborne disease and the personal hygiene of a food employee;
   b. Explaining the responsibility of the person in charge for preventing the transmission of foodborne disease by a food employee who has a disease or medical condition that may cause foodborne disease;
   c. Describing the symptoms associated with the diseases that are transmissible through food;
d. Explaining the significance of the relationship between maintaining the time and temperature of potentially hazardous food (time/temperature control for safety food) time/temperature control for safety food and the prevention of foodborne illness;

e. Explaining the hazards involved in the consumption of raw or undercooked meat, poultry, eggs, and fish;

f. Stating the required food temperatures and times for safe cooking of potentially hazardous food (time/temperature control for safety food) time/temperature control for safety food;

g. Stating the required temperatures and times for the safe refrigerated storage, hot holding, cooling, and reheating of potentially hazardous food (time/temperature control for safety food) time/temperature control for safety food;

h. Describing the relationship between the prevention of foodborne illness and the management and control of the following:

(1) Cross contamination;

(2) Hand contact with ready-to-eat foods;

(3) Handwashing;

(4) Maintaining the food establishment in a clean condition and in good repair;

i. Describing the foods identified as major food allergens and the symptoms that a major food allergen could cause in a sensitive individual who has an allergic reaction;

j. Explaining the relationship between food safety and providing equipment that is:

(1) Sufficient in number and capacity;

(2) Properly designed, constructed, located, installed, operated, maintained, and cleaned;

k. Explaining correct procedures for cleaning and sanitizing utensils and food-contact surfaces of equipment;

l. Identifying the source of water used and measures taken to ensure that it remains protected from contamination such as providing protection from backflow and precluding the creation of cross connections;

m. Identifying poisonous or toxic materials in the food establishment and the procedures necessary to ensure that they are safely stored, dispensed, used, and disposed of according to law;

n. Identifying critical control points in the operation from purchasing through sale or service that may contribute to the transmission of foodborne illness and explaining steps taken to ensure that the points are controlled in accordance with the requirements of this chapter;

o. Explaining the details of how the person in charge and food employees comply with a HACCP plan if such a plan is required by the law, this chapter, or a voluntary agreement between the regulatory authority and the food establishment;

p. Explaining the responsibilities, rights, and authorities assigned by this chapter to the:

(1) Food employee;

(2) Conditional employee;

(3) Person in charge;

(4) Regulatory authority;
q. Explaining how the person in charge, food employees, and conditional employees comply with reporting responsibilities and the exclusion or restriction of food employees.

12VAC5-421-65. Food protection manager certification.

A. A person in charge who demonstrates knowledge by being a food protection manager who is certified by a food protection manager certification program that is evaluated by a Conference for Food Protection-recognized accrediting agency as conforming to the Conference for Food Protection Standards for Accreditation of Food Protection Manager Certification Programs, April 2012, (Conference for Food Protection) is deemed to comply with subdivision 2 of 12VAC5-421-60.

B. A food establishment that has an employee who is certified by a food protection certification program that is evaluated and listed by a Conference for Food Protection-recognized accrediting agency as conforming to the Conference for Food Protection Standards for Accreditation of Food Protection Manager Certification Programs, April 2012, (Conference for Food Protection) is deemed to comply with 12VAC5-421-55.

12VAC5-421-70. Duties of person in charge.

The person in charge shall ensure that:

1. Food establishment operations are not conducted in a private home or in a room used as living or sleeping quarters as specified under 12VAC5-421-2990;

2. Persons unnecessary to the food establishment operation are not allowed in the food preparation, food storage, or warewashing areas, except that brief visits and tours may be authorized by the person in charge if steps are taken to ensure that exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles are protected from contamination;

3. Employees and other persons such as delivery and maintenance persons and pesticide applicators entering the food preparation, food storage, and warewashing areas comply with these regulations this chapter;

4. Employees are effectively cleaning their hands, by routinely monitoring the employees' handwashing;

5. Employees are visibly observing foods as they are received to determine that they are from approved sources, delivered at the required temperatures, protected from contamination, unadulterated, and accurately presented, by routinely monitoring the employees' observations and periodically evaluating foods upon their receipt;

6. Employees are verifying that foods delivered to the food establishment during non-operating hours are from approved sources and are placed into appropriate storage locations such that they are maintained at the required temperatures, protected from contamination, unadulterated, and accurately presented.

6. 7. Employees are properly cooking potentially hazardous food [TCS time/temperature control for safety food] and being particularly careful in cooking those foods known to cause severe foodborne illness and death, such as eggs and comminuted meats, through daily oversight of the employees’ routine monitoring of the cooking temperatures using appropriate temperature measuring devices properly scaled and calibrated as specified under 12VAC5-421-1180 and 12VAC5-421-1730 B;

7. 8. Employees are using proper methods to rapidly cool potentially hazardous foods time/temperature control for safety food that are not held hot or are not for consumption within four hours, through daily oversight of the employees’ routine monitoring of food temperatures during cooling.
9. Employees are properly maintaining the temperatures of time/temperature control for safety food during hot and cold holding through daily oversight of the employees routine monitoring of food temperatures.  

8. Consumers who order raw or partially cooked ready-to-eat foods of animal origin are informed as specified under 12VAC5-421-930 that the food is not cooked sufficiently to ensure its safety.  

9. Employees are properly sanitizing cleaned multiuse equipment and utensils before they are reused, through routine monitoring of solution temperature and exposure time for hot water sanitizing, and chemical concentration, pH, temperature, and exposure time for chemical sanitizing.  

10. Consumers are notified that clean tableware is to be used when they return to self-service areas such as salad bars and buffets.  

11. Except when approval is obtained from the regulatory authority as specified in 12VAC5-421-450 B E, employees are preventing cross-contamination of ready-to-eat food with bare hands by properly using suitable utensils such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment.  

12. Employees are properly trained in food safety [including food allergy awareness,] as it relates to their assigned duties and  

13. Food employees and conditional employees are informed in a verifiable manner of their responsibility to report in accordance with law, to the person in charge, information about their health and activities as they relate to diseases that are transmissible through food, as specified under 12VAC5-421-80; and  

14. Written procedures and plans, where specified by this chapter and as developed by the food establishment, are maintained and implemented as required.

Article 2  
Employee Health  

12VAC5-421-80. Responsibility of permit holder, person in charge, and conditional employees.  

A. The permit holder shall require food employees and conditional employees to report to the person in charge information about their health and activities as they relate to diseases that are transmissible through food. A food employee or conditional employee shall report the information in a manner that allows the person in charge to reduce the risk of foodborne disease transmission, including providing necessary additional information, such as the date of onset of symptoms and an illness, or of a diagnosis without symptoms, if the food employee or conditional employee:  

1. Has any of the following symptoms:  
   a. Vomiting;  
   b. Diarrhea;  
   c. Jaundice;  
   d. Sore throat with fever; or  
   e. A lesion containing pus such as a boil or infected wound that is open or draining and is:  
      (1) On the hands or wrists, unless an impermeable cover such as a finger cot or stall protects the lesion and a single-use glove is worn over the impermeable cover; or  
      (2) On exposed portions of the arms, unless the lesion is protected by an impermeable cover; or
(3) On other parts of the body, unless the lesion is covered by a dry, durable, tight-fitting bandage;  

2. Has an illness diagnosed by a health practitioner due to:  
   a. Norovirus;  
   b. Hepatitis A virus;  
   c. Shigella spp.;  
   d. Enterohemorrhagic or Shiga-toxin-producing Shiga toxin-producing Escherichia coli;  
   e. Typhoid fever (caused by Salmonella Typhi); or  
   f. Salmonella (nontyphoidal).  

3. Had a previous illness Typhoid fever, diagnosed by a health practitioner, within the past three months due to Salmonella Typhi, without having received antibiotic therapy, as determined by a health practitioner;  

4. Has been exposed to, or is the suspected source of, a confirmed disease outbreak, because the food employee or conditional employee consumed or prepared food implicated in the outbreak, or consumed food at an event prepared by a person who is infected or ill with:  
   a. Norovirus within the past 48 hours of the last exposure;  
   b. Enterohemorrhagic or Shiga-toxin-producing Shiga toxin-producing Escherichia coli, or Shigella spp. within the past three days of the last exposure;  
   c. Typhoid fever (caused by Salmonella Typhi) within the past 14 days of the last exposure; or  
   d. Hepatitis A virus within the past 30 days of the last exposure;  

5. Has been exposed by attending or working in a setting where there is a confirmed disease outbreak, or living in the same household as, and has knowledge about an individual who works or attends a setting where there is a confirmed disease outbreak, or living in the same household as, and has knowledge about, and individual diagnosed with an illness caused by:  
   a. Norovirus within the past 48 hours of exposure;  
   b. Enterohemorrhagic or Shiga-toxin-producing Shiga toxin-producing Escherichia coli or Shigella spp. within the past three days of the last exposure;  
   c. Typhoid fever (caused by Salmonella Typhi) within the past 14 days of the last exposure; or  
   d. Hepatitis A virus within the past 30 days of the last exposure.  

B. The person in charge shall notify the regulatory authority when a food employee is:  
   1. Jaundiced; or  
   2. Diagnosed with an illness due to a pathogen as specified under subdivision A 2 a through e f of this section.  

C. The person in charge shall ensure that a conditional employee:  
   1. Who exhibits or reports a symptom, or who reports a diagnosed illness as specified under subdivision A 2 a through e subdivisions A 1, 2, and 3 of this section, is prohibited from becoming a food employee until the conditional employee meets the criteria for the specific symptoms or diagnosed illness as specified under 12VAC5-421-100; and  
   2. Who will work as a food employee in a food establishment that serves a highly susceptible population and reports a history of exposure as specified
under subdivision subdivisions A 4 through  and 5 of this section, is prohibited from
becoming a food employee until the conditional employee meets the criteria specified
under subdivision 9 10 of 12VAC5-421-100.2

D. The person in charge shall ensure that a food employee who exhibits or reports a
symptom, or who reports a diagnosed illness or history of exposure as specified
under subdivision subdivisions A 1 through 5 of this section is:

1. Excluded as specified under subdivisions 1 through, 2, and 3 of 12VAC5-421-90, and
subdivisions D 1, E 1, F 1, or G 1 4 a, 5 a, 6 a, 7, or 8 a of 12VAC5-421-90 and in
compliance with the provisions specified under subdivision subdivisions 1 through Z 8 of
12VAC5-421-100;2 or

2. Restricted as specified under subdivisions subdivision 4 b, 5 b, 6 b, or Z 8 b of
12VAC5-421-90, or subdivisions 8 or subdivision 9 or 10 of 12VAC5-421-90 and in
compliance with the provisions specified under subdivisions 4 through 9 10 of 12VAC5-
421-100.2

E. A food employee or conditional employee shall report to the person in charge the
information as specified under subsection A of this section.2

F. A food employee shall:

1. Comply with an exclusion as specified under subdivisions 1 through, 2, and 3 of
12VAC5-421-90 and subdivisions subdivision 4 a, 5 a, 6 a, or Z 8 a of 12VAC5-421-
90 and with the provisions specified under subdivisions 1 through Z 8 of 12VAC5-421-
100;2 or

2. Comply with a restriction as specified under subdivisions 4 b, 5 b, 6 b, or Z 8 b of
12VAC5-421-90, or subdivisions subdivision 8, 9, or 9 10 of 12VAC5-421-90 and comply
with the provisions specified under subdivisions 4 through 9 10 of 12VAC5-421-100.2

12VAC5-421-90. Exclusions and restrictions.

The person in charge shall exclude or restrict a food employee from a food establishment in
accordance with the following:

1. Except when the symptom is from a noninfectious condition, exclude a food employee
if the food employee is:

a. Symptomatic with vomiting or diarrhea;

b. Symptomatic with vomiting or diarrhea and diagnosed with an infection from
Norovirus, Shigella spp., Salmonella (nontyphoidal), or Enterohemorrhagic or Shiga-
toxin-producing Shiga toxin-producing Escherichia coli.

2. Exclude a food employee who is:

a. Jaundiced and the onset of jaundice occurred within the last seven calendar days,
unless the food employee provides to the person in charge written medical
documentation from a health practitioner specifying that the jaundice is not caused
by Hepatitis A virus or other fecal-orally transmitted infection;

b. Diagnosed with an infection from Hepatitis A virus within 14 calendar days from
the onset of any illness symptoms, or within seven calendar days of the onset of
jaundice;

   or

   c. Diagnosed with an infection from Hepatitis A virus without developing symptoms.

3. Exclude a food employee who is diagnosed with an infection from Salmonella
Typhi Typhoid fever, or reports a previous infection with Salmonella Typhi having had
Typhoid fever within the past three months as specified in 12VAC5-421-80 A 3.

4. If a food employee is diagnosed with an infection from Norovirus and is asymptomatic:
a. Exclude the food employee who works in a food establishment serving a highly susceptible population; or
b. Restrict the food employee who works in a food establishment not serving a highly susceptible population.

5. If a food employee is diagnosed with an infection from Shigella spp. and is asymptomatic:
a. Exclude the food employee who works in a food establishment serving a highly susceptible population; or
b. Restrict the food employee who works in a food establishment not serving a highly susceptible population.

6. If a food employee is diagnosed with an infection from Enterohemorrhagic or Shiga-toxin producing E.coli, Shiga toxin-producing Escherichia coli, and is asymptomatic:
a. Exclude the food employee who works in a food establishment serving a highly susceptible population; or
b. Restrict the food employee who works in a food establishment not serving a highly susceptible population.

7. If a food employee is diagnosed with an infection from Salmonella (nontyphoidal) and is asymptomatic, restrict the food employee who works in a food establishment:
a. Serving a highly susceptible population; or
b. Not serving a highly susceptible population.

7. If a food employee is ill with symptoms of acute onset of sore throat with fever:
a. Exclude the food employee who works in a food establishment serving a highly susceptible population; or
b. Restrict the food employee who works in a food establishment not serving a highly susceptible population.

8. If a food employee is infected with a skin lesion containing pus such as a boil or infected wound that is open or draining and not properly covered as specified under 12VAC5-421-80 A 1 e, restrict the food employee.

9. If a food employee is exposed to a foodborne pathogen as specified under 12VAC5-421-80 A 4 or 5, restrict the food employee who works in a food establishment serving a highly susceptible population.

12VAC5-421-100. Removal, adjustment, or retention of exclusions and restrictions.
The person in charge shall adhere to the following conditions when removing, adjusting, or retaining the exclusion or restriction of a food employee:

1. Except when a food employee is diagnosed with Typhoid fever or an infection from Hepatitis A virus or Salmonella Typhi:
a. Reinstate a food employee who was excluded as specified under subdivision 1 a of 12VAC5-421-90 if the food employee:
   (1) Is asymptomatic for at least 24 hours; or
   (2) Provides to the person in charge written medical documentation from a health practitioner that states the symptom is from a noninfectious condition.
b. If a food employee was diagnosed with an infection from Norovirus and excluded as specified under subdivision 1 b of 12VAC5-421-90:
   (1) Restrict the food employee, who is asymptomatic for at least 24 hours and works in a food establishment not serving a highly susceptible population until the
conditions for reinstatement as specified in subdivision 4 a or b of this section are met; or

(2) Retain the exclusion for the food employee, who is asymptomatic for at least 24 hours and works in a food establishment that serves a highly susceptible population, until the conditions for reinstatement as specified in subdivision 4 a or b of this section are met.  

c. If a food employee was diagnosed with an infection from Shigella spp. and excluded as specified under subdivision 1 b of 12VAC5-421-90:

(1) Restrict the food employee, who is asymptomatic, for at least 24 hours and works in a food establishment not serving a highly susceptible population, until the conditions for reinstatement as specified in subdivision 5 a or b of this section are met; or

(2) Retain the exclusion for the food employee, who is asymptomatic for at least 24 hours and works in a food establishment that serves a highly susceptible population, until the conditions for reinstatement as specified in subdivision 5 a or b of this section are met.  

d. If a food employee was diagnosed with an infection from \(E\). coli and excluded as specified under subdivision 1 b of 12VAC5-421-90:

(1) Restrict the food employee, who is asymptomatic for at least 24 hours and works in a food establishment not serving a highly susceptible population, until the conditions for reinstatement as specified in subdivision 6 a or b of this section are met; or

(2) Retain the exclusion for the food employee, who is asymptomatic for at least 24 hours and works in a food establishment that serves a highly susceptible population, until the conditions for reinstatement as specified in subdivision 6 a or b of this section are met.  

e. If a food employee was diagnosed with an infection from Salmonella (nontyphoidal) and excluded as specified under subdivision 1 b of 12VAC5-421-90:

(1) Restrict the food employee who is asymptomatic for at least 30 days until conditions for reinstatement as specified under subdivision 7 a or 7 b of this section are met; or

(2) Retain the exclusion for the food employee who is symptomatic, until conditions for reinstatement as specified under subdivision 7 a or 7 b of this section are met.

2. Reinstate a food employee who was excluded as specified under subdivision 2 of 12VAC5-421-90 if the person in charge obtains approval from the regulatory authority and one of the following conditions is met:

a. The food employee has been jaundiced for more than seven calendar days;

b. The anicteric food employee has been symptomatic with symptoms other than jaundice for more than 14 calendar days; or

c. The food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of a Hepatitis A virus infection.  

3. Reinstate a food employee who was excluded as specified under subdivision 3 of 12VAC5-421-90 if:

a. The person in charge obtains approval from the regulatory authority; and
b. The food employee provides to the person in charge written medical documentation from a health practitioner that states the employee is free from *S. Typhi* infection Typhoid fever.

4. Reinstate a food employee who was excluded as specified under subdivision 1 b or 4 a of 12VAC5-421-90, who was restricted under subdivision 4 b of 12VAC5-421-90 if the person in charge obtains approval from the regulatory authority and one of the following conditions is met:

a. The excluded or restricted food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of a Norovirus infection;

b. The food employee was excluded or restricted after symptoms of vomiting or diarrhea resolved, and more than 48 hours have passed since the food employee became symptomatic; or

c. The food employee was excluded or restricted and did not develop symptoms and more than 48 hours have passed since the food employee was diagnosed.

5. Reinstate a food employee who was excluded as specified under subdivision 1 b or 5 a of 12VAC5-421-90 or who was restricted under subdivision 5 b of 12VAC5-421-90 if the person in charge obtains approval from the regulatory authority and one of the following conditions is met:

a. The excluded or restricted food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of a *Shigella* spp. infection based on test results showing two consecutive negative stool specimen cultures that are taken:

(1) Not earlier than 48 hours after discontinuance of antibiotics; and

(2) At least 24 hours apart;

b. The food employee was excluded or restricted after symptoms of vomiting or diarrhea resolved, and more than seven calendar days have passed since the food employee became asymptomatic; or

c. The food employee was excluded or restricted and did not develop symptoms and more than seven calendar days have passed since the food employee was diagnosed.

6. Reinstate a food employee who was excluded or restricted as specified under subdivision 1 b or 6 a of 12VAC5-421-90 or who was restricted under subdivision 6 b of 12VAC5-421-90 if the person in charge obtains approval from the regulatory authority and one of the following conditions is met:

a. The excluded or restricted food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of an infection from *Enterohemorrhagic* or *Shiga toxin-producing* *Shiga toxin-producing* *Escherichia coli* based on test results that show two consecutive negative stool specimen cultures that are taken:

(1) Not earlier than 48 hours after the discontinuance of antibiotics; and

(2) At least 24 hours apart;

b. The food employee was excluded or restricted after symptoms of vomiting or diarrhea resolved and more than seven calendar days have passed since the employee became asymptomatic; or

c. The food employee was excluded or restricted and did not develop symptoms and more than seven days have passed since the employee was diagnosed.
7. Reinstate a food employee who was excluded as specified under subsection 1 a of 12VAC5-421-90 or who was restricted as specified under subsection 7 of 12VAC5-421-90 if the person in charge obtains approval from the regulatory authority and one of the following conditions is met:

   a. The excluded or restricted food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of a nontyphoidal Salmonella infection based on test results showing two consecutive negative stool specimen cultures that are taken:
      (1) Not earlier than 48 hours after discontinuance of antibiotics; or
      (2) At least 24 hours apart.

   b. The food employee was restricted after symptoms of vomiting or diarrhea resolved, and more than 30 days have passed since the food employee became asymptomatic.

   c. The food employee was excluded or restricted and did not develop symptoms and more than 30 days have passed since the food employee was diagnosed.

7. 8. Reinstate a food employee who was excluded or restricted as specified under subdivision 7 8 a or b of 12VAC5-421-90 if the food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee meets one of the following conditions:

   a. Has received antibiotic therapy for Streptococcus pyogenes infection for more than 24 hours.

   b. Has at least one negative throat specimen culture for Streptococcus pyogenes infection.

   c. Is otherwise determined by a health practitioner to be free of Streptococcus pyogenes infection.

8. 9. Reinstate a food employee who was restricted as specified under subdivision 8 9 of 12VAC5-421-90 if the skin, infected wound, cut, or pustular boil is properly covered with one of the following:

   a. An impermeable cover such as a finger cot or stall and a single-use glove over the impermeable cover if the infected wound or pustular boil is on the hand, finger, or wrist.

   b. An impermeable cover on the arm if the infected wound or pustular boil is on the arm.

   c. A dry, durable, tight-fitting bandage if the infected wound or pustular boil is on another part of the body.

9. 10. Reinstate a food employee who was restricted as specified under subdivision 9 10 of 12VAC5-421-90 and was exposed to one of the following pathogens as specified under 12VAC5-421-80 A 4 or 5:

   a. Norovirus and one of the following conditions is met:
      (1) More than 48 hours have passed since the last day the food employee was potentially exposed, or
      (2) More than 48 hours have passed since the food employee's household contact became asymptomatic.

   b. Shigella spp. or Enterohemorrhagic Shiga-toxin producing Escherichia coli and one of the following conditions is met:
(1) More than three calendar days have passed since the last day the food employee was potentially exposed; or
(2) More than three calendar days have passed since the food employee's household contact became asymptomatic.

c. **S. Typhi** Typhoid fever (caused by *Salmonella Typhi*) and one of the following conditions is met:
(1) More than 14 calendar days have passed since the last day the food employee was potentially exposed; or
(2) More than 14 calendar days have passed since the food employee's household contact became asymptomatic.

d. Hepatitis A virus and one of the following conditions is met:
(1) The food employee is immune to Hepatitis A virus infection because of prior illness from Hepatitis A;
(2) The food employee is immune to Hepatitis A virus infection because of vaccination against Hepatitis A;
(3) The food employee is immune to Hepatitis A virus infection because of IgG administration;
(4) More than 30 calendar days have passed since the last the food employee was potentially exposed; or
(5) More than 30 calendar days have passed since the food employee's household contact became jaundiced; or
(6) The food employee does not use an alternative procedure that allows bare hand contact with ready-to-eat food until at least 30 days after the potential exposure, as specified in subdivisions 9 and 10 d (4) and (5) of this section, and the food employee receives additional training about:
(a) Hepatitis A symptoms and preventing the transmission of infection;
(b) Proper handwashing procedures; and
(c) Protecting ready-to-eat food from contamination introduced by bare hand contact.

### Article 3

**Personal Cleanliness**

12VAC5-421-130. Clean condition of hands and arms.

Food employees shall keep their hands and exposed portions of their arms clean.

12VAC5-421-140. Cleaning procedure of hands and arms.

A. Except as specified in subsection D of this section, food employees shall clean their hands and exposed portions of their arms (or surrogate prosthetic devices for hands or arms) for at least 20 seconds or surrogate prosthetic devices for hands or arms for at least 20 seconds, using a cleaning compound in a lavatory that is equipped as specified under 12VAC5-421-2190 A.

B. Food employees shall use the following cleaning procedure in the order stated to clean their hands and exposed portions of their arms, including surrogate prosthetic devices for hands and arms:
1. Rinse under clean, running warm water;
2. Apply an amount of cleaning compound recommended by the cleaning compound manufacturer;
3. Rub together vigorously for at least 10 to 15 seconds while:
   a. Paying particular attention to removing soil from underneath the fingernails during the cleaning procedure; and
   b. Creating friction on the surfaces of the hands and arms or surrogate prosthetic devices for hands and arms, finger tips, and areas between the fingers;
4. Thoroughly rinsing under clean, running warm water; and
5. Immediately follow the cleaning procedure with thorough drying using a method as specified under 12VAC5-421-3030.

C. To avoid recontaminating their hands or surrogate prosthetic devices, food employees may use disposable paper towels or similar clean barriers when touching surfaces such as manually operated faucet handles on a handwashing sink or the handle of a restroom door.

D. If approved and capable of removing the types of soils encountered in the food operations involved, an automatic handwashing facility may be used by food employees to clean their hands or surrogate prosthetic devices.

12VAC5-421-160. When to wash.

Food employees shall clean their hands and exposed portions of their arms as specified under 12VAC5-421-140 immediately before engaging in food preparation including working with exposed food, clean equipment and utensils, and unwrapped single-service and single-use articles and:

1. After touching bare human body parts or hair other than clean hands and clean, exposed portions of arms;
2. After using the toilet room;
3. After caring for or handling support service animals or aquatic animals as allowed under 12VAC5-421-250 B;
4. Except as specified in 12VAC5-421-220 B, after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking;
5. After handling soiled equipment or utensils;
6. During food preparation, as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks;
7. When switching between working with raw foods and working with ready-to-eat foods;
8. Before donning gloves for [to initiate a task that involves] working with foods; and
9. After engaging in other activities that contaminate the hands.

12VAC5-421-170. Where to wash.

Food employees shall clean their hands in a handwashing lavatory sink or approved automatic handwashing facility and shall not clean their hands (i) in a sink used for food preparation or utensil washing or (ii) in a service sink or a curbed cleaning facility used for the disposal of mop water and similar liquid waste.

12VAC5-421-180. Hand antiseptics.

A. A hand antiseptic used as a topical application, a hand antiseptic solution used as a hand dip, or a hand antiseptic soap shall:

1. Comply with one of the following:
and Drug Administration) as an approved drug based on safety and effectiveness; or

b. Have active antimicrobial ingredients that are listed in the FDA monograph for OTC (over the counter) Health-Care Antiseptic Drug Products as an antiseptic handwash; and

2. [Comply Consist only of components which the intended use of each complies with one of the following:

a. [Have components that are exempted from the requirement of being listed in the federal Food Additive regulations as specified in 21 CFR 170.39 - Threshold of regulation for substances used in food-contact articles. A threshold of regulation exemption under 21 CFR 170.39 ]; or

b. [ Comply with and be listed in:

(i) 21 CFR Part 178 - Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers, as regulated for use as a food additive with conditions of safe use; or

(ii) 21 CFR Part 182 - Determination of generally recognized as safe (GRAS). Partial listings of substances with food uses that are GRAS may be found in 21 CFR 182—Substances Generally Recognized as Safe, 21 CFR 184—Direct Food Substances Affirmed as Generally Recognized as Safe, or 21 CFR Part 186 - Indirect Food Substances Affirmed as Generally Recognized as Safe for use in contact with food and in FDA’s Inventory of GRAS Notices; or

d. A prior sanction listed under 21 CFR 181; or

e. A Food Contact Notification that is effective;]

3. Be applied only to hands that are cleaned as specified under 12VAC5-421-140.

B. If a hand antiseptic or a hand antiseptic solution used as a hand dip does not meet the criteria specified in subdivision A 2 of this section, use shall be:

1. Followed by thorough hand rinsing in clean water before hand contact with food or by the use of gloves; or

2. Limited to situations that involve no direct contact with food by the bare hands.

C. A hand antiseptic solution used as a hand dip shall be maintained clean and at a strength equivalent to 100 ppm (mg/l) chlorine or above.

12VAC5-421-190. Maintenance of fingernails.

Food employees shall keep their fingernails trimmed, filed, and maintained so the edges and surfaces are cleanable and not rough. Unless wearing intact gloves in good repair, a food employee shall not wear fingernail polish or artificial nails when working with exposed food.


While preparing food, food employees shall not wear jewelry on their arms and hands. This section does not apply to a plain ring such as a wedding band. Except for a plain ring such as a wedding band, while preparing food, food employees shall not wear jewelry, including medical information jewelry on their arms and hands.

12VAC5-421-210. Clean condition of outer clothing.

Food employees shall wear clean outer clothing to prevent contamination of food equipment, utensils, linens, and single-service and single-use articles.
Article 4
Hygienic Practices

12VAC5-421-220. Eating, drinking, or using tobacco.
A. Except as specified in subsection B of this section, an employee shall eat, drink, or use any form of tobacco only in designated areas where the contamination of exposed food; clean equipment, utensils, and linens; unwrapped single-service and single-use articles; or other items needing protection cannot result.

B. A food employee may drink from a closed beverage container [with a straw] if the container is handled to prevent contamination of:
1. The employee's hands;
2. The container; and
3. Exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles.

12VAC5-421-250. Handling of animals prohibited.
A. Except as specified in subsection B of this section, food employees shall not care for or handle animals that may be present such as patrol dogs, support service animals, or pets that are allowed under 12VAC5-421-3310 B 2 through, 3, and 4.

B. Food employees with support service animals may handle or care for their support service animals and food employees may handle or care for fish in aquariums or molluscan shellfish or crustacea in display tanks if they wash their hands as specified under 12VAC5-421-140 and subdivision 3 of 12VAC5-421-160.

12VAC5-421-255. Clean-up of vomiting and diarrheal events.
A food establishment shall have procedures for employees to follow when responding to vomiting or diarrheal events that involve the discharge of vomitus or fecal matter onto surfaces in the food establishment. The procedures shall address the specific actions employees must take to minimize the spread of contamination and the exposure of employees, consumers, food, and surfaces to vomitus or fecal matter.

Part III
Food

Article 1
Characteristics

12VAC5-421-260. Safe and unadulterated.
Food shall be safe and unadulterated.

Article 2
Sources, Specifications, and Original Containers and Records

12VAC5-421-270. Compliance with food law.
A. Food shall be obtained from sources that comply with law.
B. Food prepared in a private home shall not be used or offered for human consumption in a food establishment unless the home kitchen is inspected and [approved regulated] by the Virginia Department of Agriculture and Consumer Services.
D. Fish, other than molluscan shellfish, that are intended for consumption in their raw form and allowed as specified under 12VAC5-421-700 D 1 may be offered for sale or service if they...
are obtained from a supplier that freezes the fish as specified under 12VAC5-421-730, or frozen on the premises as specified under 12VAC5-421-730, and records are retained as specified under 12VAC5-421-740.

D. Fish, other than those specified in 12VAC5-421-730 B, that are intended for consumption in raw or undercooked form and allowed as specified in 12VAC5-421-700 D, may be offered for sale or service if they are obtained from a supplier that freezes fish as specified under 12VAC5-421-730 A; or if they are frozen on premises as specified under 12VAC5-421-730 A and records are retained as specified under 12VAC5-421-740.

E. Whole-muscle, intact beef steaks that are intended for consumption in an undercooked form without a consumer advisory as specified in 12VAC5-421-700 C shall be:

1. Obtained from a food processing plant that, upon request by the purchaser, packages the steaks and labels them to indicate that they meet the definition of whole-muscle, intact beef; or

2. Deemed acceptable by the regulatory authority based on other evidence, such as written buyer specifications or invoices, that indicates that the steaks meet the definition of whole-muscle, intact beef; and

3. If individually cut in a food establishment:
   a. Cut from whole-muscle intact beef that is labeled by a food processing plant as specified in subdivision 1 of this subsection or identified as specified in subdivision 2 of this subsection; or
   b. Prepared so they remain intact; and
   c. If packaged for undercooking in a food establishment, labeled to indicate that they meet the definition of whole-muscle, intact beef, as specified in subdivision 1 of this subsection or identified as specified in subdivision 2 of this subsection.

F. Meat and poultry that are not a ready-to-eat food and are in a packaged form when offered for sale or otherwise offered for consumption shall be labeled to include safe handling instructions as specified in law, including 9 CFR 317.2(l) and 9 CFR 381.125(b).

G. Shell eggs that have not been specifically treated to destroy all viable Salmonellae shall be labeled to include safe handling instructions as specified in law, including 21 CFR 101.17(h).

12VAC5-421-280. Food in a hermetically sealed container.

Food in a hermetically sealed container shall be obtained from a food processing plant that is regulated by the food regulatory agency that has jurisdiction over the plant.

12VAC5-421-290. Fluid milk and milk products.

Fluid milk and milk products shall be obtained from sources that comply with Grade A standards as specified in law.

12VAC5-421-295. Juice treated.

Prepackaged juice shall:

1. Be obtained from a processor with a HACCP system as specified in 21 CFR Part 120; or
2. Be obtained pasteurized or otherwise treated to attain a five-log reduction of the most resistant microorganism of public health significance as specified in 21 CFR 120.24; or
3. Bear a warning label as specified in 12VAC5-421-765 and 21 CFR 101.17(g).

12VAC5-421-300. Fish.

A. Fish that are received for sale or service shall be:

1. Commercially and legally caught or harvested; or
12VAC5-421-310. Molluscan shellfish.

12VAC5-421-320. Wild mushrooms.
A. Except as specified in subsection B of this section, mushroom species picked in the wild shall be obtained from sources where each mushroom is individually inspected and found to be safe by an approved mushroom identification expert not be offered for sale or service by a food establishment unless the food establishment has been approved to do so.

12VAC5-421-330. Game animals.
A. If game animals are received for sale or service they shall be:
   1. Commercially raised for food and:
      a. Raised, slaughtered, and processed under a voluntary inspection program that is conducted by the state agency that has animal health jurisdiction; or
      b. Under a routine inspection program conducted by a regulatory agency other than the agency that has animal health jurisdiction; and
      c. Raised, slaughtered, and processed according to:
         (1) Laws governing meat and poultry as determined by the agency; and
         (2) Requirements that are developed by the agency that has animal health jurisdiction and the agency that conducts the inspection program with consideration of factors such as the need for antemortem and postmortem examination by an approved veterinarian or veterinarian's designee;
     2. Under a voluntary inspection program administered by the USDA for game animals such as exotic animals including animals (reindeer, elk, deer, antelope, water buffalo, or bison) that are "inspected and approved" in accordance with 9 CFR Part 352, Exotic Animals: Voluntary Inspection, or rabbits that are "inspected and certified" in accordance with 9 CFR Part 354, Voluntary Inspection of Rabbits and Edible Products Thereof;
     3. As allowed by law, wild game animals that are live-caught are:
a. Under a routine inspection program conducted by a regulatory agency such as the agency that has animal health jurisdiction;

b. Slaughtered and processed according to:

(1) Laws governing meat and poultry as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program; and

(2) Requirements that are developed by the agency that has animal health jurisdiction and the agency that conducts the inspection program with consideration of factors such as the need for antemortem and postmortem examination by an approved veterinarian or veterinarian's designee;

or

4. As allowed by law for field-dressed wild game animals under a routine inspection program that ensures the animals:

a. Receive a postmortem examination by an approved veterinarian or veterinarian's designee, or are

b. Field-dressed and transported according to requirements specified by the agency that has animal health jurisdiction and the agency that conducts the inspection program and

b. Are processed according to laws governing meat and poultry as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program.

B. A game animal shall not be received for sale or service if it is a species of wildlife that is listed in 50 CFR Part 17, Endangered and Threatened Wildlife and Plants.


A. Except as specified in subsection B of this section, refrigerated, potentially hazardous food time/temperature control for safety food shall be at a temperature of 41°F (5°C) or below when received.

B. If a temperature other than 41°F (5°C) for a potentially hazardous food time/temperature control for safety food is specified in law governing its distribution, such as laws governing milk, and molluscan shellfish, and shell eggs, the food may be received at the specified temperature.

C. Raw shell eggs shall be received in refrigerated equipment that maintains an ambient air temperature of 45°F (7°C) or less.

D. Potentially hazardous food time/temperature control for safety food that is cooked to a temperature and for a time specified under 12VAC5-421-700 through, 12VAC5-421-710, and 12VAC5-421-720 and received hot shall be at a temperature of 135°F (57°C) or above.

E. A food that is labeled frozen and shipped frozen by a food processing plant shall be received frozen.

F. Upon receipt, potentially hazardous food time/temperature control for safety food shall be free of evidence of previous temperature abuse.

12VAC5-421-350. Additives.

Food shall not contain unapproved food additives or additives that exceed amounts allowed in 21 CFR Parts 170-180 relating to food additives; generally recognized as safe (GRAS) or prior sanctioned substances that exceed amounts allowed in 21 CFR Parts 181-186; substances that exceed amounts specified in 9 CFR 424.21(b), Subpart C, Approval of Substances for Use in the Preparation of Products; or pesticide residues that exceed provisions specified in 40 CFR Part 180, Tolerances for Pesticides in Food, and exceptions.
12VAC5-421-360. Shell eggs.  
Shell eggs shall be received clean and sound and shall not exceed the restricted egg tolerances for U.S. Consumer Grade B as specified in United States Standards, Grades, and Weight Classes for Shell Eggs, AMS 56.200 et seq., administered by the Agricultural Marketing Service of USDA. Eggs sold pursuant to § 3.2-5305 of the Code of Virginia are exempt from the restricted egg tolerances for U.S. Consumer Grade B as specified in United States Standards, Grades, and Weight Classes for Shell Eggs, AMS 56, effective July 20, 2000, (Agricultural Marketing Service of USDA).

12VAC5-421-370. Eggs and milk products, pasteurized.  
A. Egg products shall be obtained pasteurized. 
B. Fluid and dry milk and milk products shall:
   1. Be obtained pasteurized; and  
   2. Comply with Grade A standards as specified in law.  
C. Frozen milk products, such as ice cream, shall be obtained pasteurized in accordance with 21 CFR Part 135, Frozen Desserts.  
D. Cheese shall be obtained pasteurized unless alternative procedures to pasteurization are provided for specified in the Code of Federal Regulations CFR, such as 21 CFR Part 133, Cheeses and Related Cheese Products, for curing certain cheese varieties.

12VAC5-421-380. Package integrity.  
Food packages shall be in good condition and protect the integrity of the contents so that the food is not exposed to adulteration or potential contaminants.

12VAC5-421-390. Ice.  
Ice for use as a food or a cooling medium shall be made from pure water.

12VAC5-421-400. Shucked shellfish, packaging, and identification.  
A. Raw shucked shellfish shall be obtained in nonreturnable packages that bear a legible label that identifies the:
   1. Name, address, and certification number of the shucker, packer, or repacker of the molluscan shellfish;  
   2. The "sell by" or "best if used by" date for packages with a capacity of less than one-half gallon (1.89 L) or the date shucked for packages with a capacity of one-half gallon (1.89 L) or more.  
B. A package of raw shucked shellfish that does not bear a label or which bears a label which does not contain all the information as specified under subsection A of this section shall be subject to a hold order, as allowed by law, or seizure and destruction in accordance with 21 CFR 1240.60(d), Subpart D, Specific Administrative Decisions Regarding Interstate Shipments.

A. Shellstock shall be obtained in containers bearing legible source identification tags or labels that are affixed by the harvester and each a dealer that depurates, ships, or reships the shellstock, as specified in the National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish, 2013 Revision, (U.S. Food and Drug Administration) and that list include the following information:
   1. Except as specified under subsection C of this section, on the harvester's tag or label, the following information in the following order:
      a. The harvester's identification number that is assigned by the shellfish control authority,  
      b. The date of harvesting.
c. The most precise identification of the harvest location or aquaculture site that is
practicable based on the system of harvest area designations that is in use by the
shellfish control authority and including the abbreviation of the name of the state or
country in which the shellfish are harvested,
d. The type and quantity of shellfish, and
e. The following statement in bold, capitalized type: "This tag is required to be
attached until container is empty or retagged and thereafter kept on file for 90 days";
and
2. Except as specified under subsection D of this section, on each dealer's tag or
label, the following information in the following order:

a. 1. The dealer's name and address, and the certification number assigned by the
shellfish control authority,
b. 2. The original shipper's certification number including the abbreviation of the name of
the state or country in which the shellfish are harvested, assigned by the shellfish control
authority,
c. The same information as specified for a harvester's tag under subdivisions 1 b through
d of this subsection, and 3. The harvest date, or if depurated, the date of depuration
processing, or if wet stored, the original harvest date and the final harvest date,
d. 7. The following statement in bold, capitalized type: "THIS TAG IS REQUIRED TO BE
ATTACHED UNTIL CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE FOR
90 DAYS."

e. 8. All shellstock intended for raw consumption shall include a consumer advisory using
the statement from 12VAC5-421-930 C, or an equivalent statement.

B. A container of shellstock that does not bear a tag or label or that bears a tag or label that
does not contain all the information as specified under subsection A of this section shall be
subject to a hold order, as allowed by law, or seizure and destruction in accordance with 21
CFR 1240.60(d), Subpart D, Specific Administrative Decisions Regarding Interstate Shipments.

C. If a place is provided on the harvester's tag or label for a dealer's name, address, and
certification number, the dealer's information shall be listed first.

D. If the harvester's tag or label is designed to accommodate each dealer's identification as
specified under subdivisions A 2 a and b of this section, individual dealer tags or labels need not
be provided.

12VAC5-421-430. Molluscan shellfish; original container.

A. Except as specified in subsections B and, C, and D of this section, molluscan shellfish
shall not be removed from the container in which they were received other than immediately
before sale or preparation for service.

B. For display purposes, shellstock may be removed from the container in which they are
received, displayed on drained ice, or held in a display container, and a quantity specified by a
consumer may be removed from the display or display container and provided to the consumer
if:

1. The source of the shellstock on display is identified as specified under 12VAC5-421-
410 and recorded as specified under 12VAC5-421-440; and
2. The shellstock are protected from contamination.

C. Shucked shellfish may be removed from the container in which they were received and held in a display container from which individual servings are dispensed upon a consumer's request if:

1. The labeling information for the shellfish on display as specified under 12VAC5-421-400 is retained and correlated to the date when, or dates during which, the shellfish are sold or served; and

2. The shellfish are protected from contamination.

D. Shucked shellfish may be removed from the container in which they were received and repacked in consumer self-service containers where allowed by law if:

1. The labeling information for the shellfish is on each consumer self-service container as specified under 12VAC5-421-400 and 12VAC5-421-900 A and B 1 through 5;

2. The labeling information as specified under 12VAC5-421-400 is retained and correlated with the date when, or dates during which, the shellfish are sold or served;

3. The labeling information and dates specified under subdivision D 2 of this section are maintained for 90 days; and

4. The shellfish are protected from contamination.

12VAC5-421-440. Shellstock; maintaining identification.

A. Except as specified under subdivision C 2 of this section, shellstock tags or labels shall remain attached to the container in which the shellstock are received until the container is empty.

B. The date when the last shellstock from the container is sold or served shall be recorded on the tag or label.

C. The identity of the source of shellfish shellstock that are sold or served shall be maintained by retaining shellstock tags or labels for 90 calendar days from the date that is recorded on the tag or label as specified in subsection B of this section, by:

1. Using an approved recordkeeping system that keeps the tags or labels in chronological order correlated to the date that is recorded on the tag or label, as specified under subsection B of this section; and

2. If shellstock are removed from its tagged or labeled container:

   a. Preserving source identification by using a recordkeeping system as specified under subdivision C 1 of this section; and

   b. Ensuring that shellstock from one tagged or labeled container are not commingled with shellstock from another container with different certification numbers, different harvest dates, or different growing areas as identified on the tag or label before being ordered by the consumer.

Article 3
Protection from Contamination after Receiving

12VAC5-421-450. Preventing contamination.

A. Food employees shall wash their hands as specified under 12VAC5-421-140.

B. Except when washing fruits and vegetables as specified under 12VAC5-421-510 or as specified in subsections D and E of this section, food employees shall not contact exposed, ready-to-eat food with their bare hands and shall use suitable utensils such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment.

C. Food employees shall minimize bare hand and arm contact with exposed food that is not in a ready-to-eat form.
D. Subsection B of this section does not apply to a food employee who contacts exposed, ready-to-eat food with bare hands at the time the ready-to-eat food is being added as an ingredient to food that:

1. Contains a raw animal food and is to be cooked in the food establishment to heat all parts of the food to the minimum temperatures specified in [subsections A or B in 12VAC5-421-700 or 12VAC5-421-710; or

2. Does not contain a raw animal food but is to be cooked in the food establishment to heat all parts of the food to a temperature of at least 145°F (63°C).

D. E. Food employees not serving a highly susceptible population may contact exposed, ready-to-eat food with their bare hands if:

1. The permit holder obtains prior approval from the regulatory authority;

2. Written procedures are maintained in the food establishment and made available to the regulatory authority upon request that include:

   a. For each bare hand contact procedure, a listing of the specific ready-to-eat foods that are touched by bare hands;

   b. Diagrams and other information showing that handwashing facilities, installed, located, equipped, and maintained as specified under 12VAC5-421-2230, 12VAC5-421-2280, 12VAC5-421-2310, 12VAC5-421-3020, 12VAC5-421-3030, and 12VAC5-421-3045 are in an easily accessible location and in close proximity to the work station where the bare hand contact procedure is conducted;

3. A written employee health policy that details how the food establishment complies with 12VAC5-421-80, 12VAC5-421-90, and 12VAC5-421-100 including:

   a. Documentation that the food employees and conditional employees acknowledge that they are informed to report information about their health and activities as they relate to gastrointestinal symptoms and diseases that are transmittable through food as specified under 12VAC5-421-80 A;

   b. Documentation that food employees and conditional employees acknowledge their responsibilities as specified under 12VAC5-421-80 E and F and

   c. Documentation that the person in charge acknowledges the responsibilities as specified under 12VAC5-421-80 B, C, and D, and 12VAC5-421-90 and 12VAC5-421-100;

4. Documentation that the food employees acknowledge that they have received training in:

   a. The risks of contacting the specific ready-to-eat foods with their bare hands;

   b. Proper handwashing as specified under 12VAC5-421-140;

   c. When to wash their hands as specified under 12VAC5-421-160;

   d. Where to wash their hands as specified under 12VAC5-421-170;

   e. Proper fingernail maintenance as specified under 12VAC5-421-190;

   f. Prohibition of jewelry as specified under 12VAC5-421-200 and

   g. Good hygienic practices as specified under 12VAC5-421-220 and 12VAC5-421-230;

5. Documentation that hands are washed before food preparation and as necessary to prevent cross-contamination by food employees as specified under 12VAC5-421-130, 12VAC5-421-140, 12VAC5-421-160, and through 12VAC5-421-170 during all hours of operation when the specific ready-to-eat foods are prepared;
6. Documentation that food employees contacting ready-to-eat food with bare hands use two or more of the following control measures to provide additional safeguards to hazards associated with bare hand contact:
   a. Double handwashing;
   b. Nail brushes;
   c. A hand antiseptic after handwashing as specified under 12VAC5-421-180;
   d. Incentive programs such as paid sick leave that assist or encourage food employees not to work when they are ill or
   e. Other control measures approved by the regulatory authority; and

7. Documentation that corrective action is taken when subdivision D subdivisions 1 through 6 of this section subsection are not followed.

12VAC5-421-460. Preventing contamination when tasting.

A food employee shall not use a utensil more than once to taste food that is to be sold or served.

12VAC5-421-470. Packaged and unpackaged food - separation, packaging, and segregation.

A. Food shall be protected from cross contamination by:

1. Separating Except as specified in subdivision 1 c of this subsection, separating raw animal foods during storage, preparation, holding, and display from:
   a. Raw ready-to-eat food including other raw animal food such as fish for sushi or molluscan shellfish, or other raw ready-to-eat food such as [fruits and] vegetables, and
   b. Cooked ready-to-eat food;
   c. Frozen, commercially processed, and packaged raw animal food may be stored or displayed with or above frozen, commercially processed and packaged, ready-to-eat food.

2. Except when combined as ingredients, separating types of raw animal foods from each other such as beef, fish, lamb, pork, and poultry during storage, preparation, holding, and display by:
   a. Using separate equipment for each type or arranging
   b. Arranging each type of food in equipment so that cross contamination of one type with another is prevented, and
   c. Preparing each type of food at different times or in separate areas;

3. Cleaning equipment and utensils as specified under 12VAC5-421-1780 A and sanitizing as specified under 12VAC5-421-1900;

4. Except as specified in subsection B of this section and 12VAC5-421-810 B 2, storing the food in packages, covered containers, or wrappings;

5. Cleaning hermetically sealed containers of food of visible soil before opening;

6. Protecting food containers that are received packaged together in a case or overwrap from cuts when the case or overwrap is opened;

7. Storing damaged, spoiled, or recalled food being held in the food establishment as specified under 12VAC5-421-3150; and

8. Separating fruits and vegetables, before they are washed as specified under 12VAC5-421-510 from ready-to-eat food.

B. Subdivision A 4 of this section does not apply to:
1. Whole, uncut, raw fruits and vegetables and nuts in the shell, that require peeling or hulling before consumption;
2. Primal cuts, quarters, or sides of raw meat or slab bacon that are hung on clean, sanitized hooks or placed on clean, sanitized racks;
3. Whole, uncut, processed meats such as country hams, and smoked or cured sausages that are placed on clean, sanitized racks;
4. Food being cooled as specified under 12VAC5-421-810 B 2; or
5. Shellstock.

12VAC5-421-480. Food storage containers; identified with common name of food.

Working containers holding food or food ingredients that are removed from their original packages for use in the food establishment, such as cooking oils, flour, herbs, potato flakes, salt, spices, and sugar, shall be identified with the common name of the food (in English and the common language of the food workers) except that containers holding food that can be readily and unmistakably recognized such as dry pasta need not be identified. Except for containers holding food that can be readily and unmistakably recognized such as dry pasta, working containers holding food or food ingredients that are removed from their original packages for use in the food establishment, such as cooking oils, flour, herbs, potato flakes, salt, spices, and sugar shall be identified with the common name of the food.

12VAC5-421-490. Pasteurized eggs; substitute for shell raw eggs for certain recipes and populations.

Pasteurized eggs or egg products shall be substituted for raw shell eggs in the preparation of foods such as Caesar salad, hollandaise or [béarnaise, béarnaise] sauce, mayonnaise, meringue, [eggnog, ice cream,] and egg-fortified beverages that are not:

1. Cooked as specified in 12VAC5-421-700 A 1 or 2; or
2. Included in 12VAC5-421-700 D.

12VAC5-421-500. Protection from unapproved additives.

A. Food, as specified in 12VAC5-421-350, shall be protected from contamination that may result from the addition of:

1. Unsafe or unapproved food or color additives; and
2. Unsafe or unapproved levels of approved food and color additives.

B. A food employee shall not:

1. Apply sulfiting agents to fresh fruits and vegetables intended for raw consumption or to a food considered to be a good source of vitamin B1; or
2. Except for grapes, serve or sell food specified under subdivision B 1 of this section that is treated with sulfiting agents before receipt by the food establishment.

12VAC5-421-510. Washing fruits and vegetables.

A. Raw fruits and vegetables shall be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in ready-to-eat form except as specified in subsection B of this section and except that whole, raw fruits and vegetables that are intended for washing by the consumer before consumption need not be washed before they are sold. Except as specified in subsection B of this section and except for whole, raw fruits and vegetables that are intended for washing by the consumer before consumption, raw fruits and vegetables shall be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in ready-to-eat form.
B. Fruits and vegetables may be washed by using chemicals as specified under 12VAC5-421-3390.

C. Devices used for onsite generation of chemicals meeting the requirements specified in 21 CFR 173.315 shall be used in accordance with the manufacturer's instructions.\(^1\)

12VAC5-421-520. Ice used as exterior coolant, prohibited as ingredient.

After use as a medium for cooling the exterior surfaces of food such as melons or fish, packaged foods such as canned beverages, or cooling coils and tubes of equipment, ice shall not be used as food.\(^2\)

12VAC5-421-540. Food contact with equipment and utensils.

Food shall only contact surfaces of:

1. Equipment and utensils that are cleaned as specified under 12VAC5-421-1770 through 12VAC5-421-1870, and sanitized as specified under 12VAC5-421-1880 through 12VAC5-421-1890 and 12VAC5-421-1900;\(^2\) or

2. Single-service and single-use articles;\(^2\) or

3. Linens, such as cloth napkins, as specified under 12VAC5-421-560 that are laundered as specified under 12VAC5-421-1920.\(^2\)

12VAC5-421-550. In-use utensils, between-use storage.

During pauses in food preparation or dispensing, food preparation and dispensing utensils shall be stored:

1. Except as specified under subdivision 2 of this section, in the food with their handles above the top of the food and the container;

2. In food that is not potentially hazardous time/temperature control for safety food with their handles above the top of the food within containers or equipment that can be closed, such as bins of sugar, flour, or cinnamon;

3. On a clean portion of the food preparation table or cooking equipment only if the in-use utensil and the food-contact surface of the food preparation table or cooking equipment are cleaned and sanitized at a frequency specified under 12VAC5-421-1780 and 12VAC5-421-1890;

4. In running water of sufficient velocity to flush particulates to the drain, if used with moist food such as ice cream or mashed potatoes;

5. In a clean, protected location if the utensils, such as ice scoops, are used only with a food that is not potentially hazardous time/temperature control for safety food; or

6. In a container of water if the water is maintained at a temperature of at least 135°F (57°C) and the container is cleaned at a frequency specified under 12VAC5-421-1780 D 7.

12VAC5-421-560. Linens and napkins, use limitation.

Linens \(\text{[and, such as cloth]}\) napkins, shall not be used in contact with food unless they are used to line a container for the service of foods and the linens and napkins are replaced each time the container is refilled for a new customer.

12VAC5-421-570. Wiping cloths; used for one purpose use limitation.

A. Cloths in-use for wiping food spills from tableware and carry-out containers that occur as food is being served shall be:

1. Maintained dry; and

2. Used for no other purpose.

B. Cloths in-use for wiping counters and other equipment surfaces shall be:
1. Held between uses in a chemical sanitizer solution at a concentration specified in 12VAC5-421-3380; and

2. Laundered daily as specified under 12VAC5-421-1920 D.

C. Cloths in-use for wiping surfaces in contact with raw animal foods shall be kept separate from other cloths used for other purposes.

D. Dry wiping cloths and the chemical sanitizing solutions specified in subdivision B 1 of this section in which wet wiping cloths are held between uses shall be free of food debris and visible soil.

E. Containers of chemical sanitizing solutions specified in subdivision B 1 of this section in which wet wiping cloths are held between uses shall be stored off the floor and used in a manner that prevents contamination of food, equipment, utensils, linens, single-service, or single-use articles.

F. Single-use disposable sanitizer wipes shall be used in accordance with EPA-approved manufacturer's label use instructions.

12VAC5-421-580. Gloves; use limitation.

A. If used, single-use gloves shall be used for only one task such as working with ready-to-eat food or with raw animal food, used for no other purpose, and discarded when damaged or soiled, or when interruptions occur in the operation.

B. Except as specified in subsection C of this section, slash-resistant gloves that are used to protect the hands during operations requiring cutting shall be used in direct contact only with food that is subsequently cooked as specified under 12VAC5-421-700 through 12VAC5-421-760 such as frozen food or a primal cut of meat.

C. Slash-resistant gloves may be used with ready-to-eat food that will not be subsequently cooked if the slash-resistant gloves have a smooth, durable, and nonabsorbent outer surface; or if the slash-resistant gloves are covered with a smooth, durable, nonabsorbent glove, or a single-use glove.

D. Cloth gloves shall not be used in direct contact with food unless the food is subsequently cooked as required under 12VAC5-421-700 through 12VAC5-421-760 such as frozen food or a primal cut of meat.

12VAC5-421-600. Refilling returnables.

A. Except as specified in subsections B through E of this section, empty containers returned to a food establishment for cleaning and refilling with food shall be cleaned and refilled in a regulated food processing plant.

B. A take-home food container returned to a food establishment shall not be refilled at a food establishment with potentially hazardous time/temperature control for safety if the food container is:

1. Designed and constructed for reuse and in accordance with the requirements specified in 12VAC5-421-960 through 12VAC5-421-1430;

2. One that was initially provided by the food establishment to the consumer, either empty or filled with food by the establishment, for the purpose of being returned for reuse;

3. Returned to the food establishment by the consumer after use;

4. Subject to the following steps before being refilled with food:

   a. Cleaned as specified in 12VAC5-421-1770 through 12VAC5-421-1860.

   b. Sanitized as specified in 12VAC5-421-1880 through 12VAC5-421-1900; and
C. A take-home food container returned to a food establishment may be refilled at a food establishment with beverage if:

1. The beverage is not a time/temperature control for safety food;
2. The design of the container and the rinsing equipment and the nature of the beverage, when considered together, allow effective cleaning at home or in the food establishment;
3. Facilities before rinsing or refilling returned containers with fresh, hot water that is under pressure and not recirculated are provided as part of the dispensing system;
4. The consumer-owned container returned to the food establishment for refilling is refilled for sale or service only to the same consumer; and
5. The container is refilled by:
   a. An employee of the food establishment, or
   b. The owner of the container if the beverage system includes a contamination-free transfer process as specified in subsections 1, 2, and 4 of 12VAC5-421-1230.

[B. Except as specified in subsection C of this section, a take-home food container refilled with food that is not potentially hazardous time/temperature control for safety food shall be cleaned as specified under 12VAC5-421-1870.]

[C-D. Consumer-owned, personal personal] take-out beverage containers, such as thermally insulated bottles, nonspill coffee cups and promotional beverage glasses, may be refilled by employees or the consumer if refilling is a contamination-free process as specified under subdivisions 1, 2, and 4 of 12VAC5-421-1230.

[E. Consumer-owned containers that are not food-specific may be filled at a water vending machine or system.]

12VAC5-421-630. Vended potentially hazardous time/temperature control for safety food; original container.

Potentially hazardous time/temperature control for safety food dispensed through a vending machine shall be in the package in which it was placed at the food establishment or food processing plant at which it was prepared.

12VAC5-421-650. Food display.

Except for nuts in the shell and whole, raw fruits and vegetables that are intended for hulling, peeling, or washing by the consumer before consumption, food on display shall be protected from contamination by the use of packaging; counter, service line, or salad bar food guards; display cases; or other effective means.


A. Raw, unpackaged animal food, such as beef, lamb, pork, poultry, and fish shall not be offered for consumer self-service. This subsection does not apply to:

1. Consumer self-service of ready-to-eat foods at buffets or salad bars that serve foods such as sushi or raw shellfish;
2. Ready-to-cook individual portions for immediate cooking and consumption on the premises such as consumer-cooked meats or consumer-selected ingredients for Mongolian barbecue; or
3. Raw, frozen, shell-on shrimp or lobster.

B. Consumer self-service operations for ready-to-eat foods shall be provided with suitable utensils or effective dispensing methods that protect the food from contamination.
Consumer self-service operations such as buffets and salad bars shall be monitored by food employees trained in safe operating procedures.

12VAC5-421-680. Returned food and reservice of food.

A. Except as specified under subsection B of this section, after being served or sold and in the possession of a consumer, food that is unused or returned by the consumer shall not be offered as food for human consumption.

B. Except as specified in subdivision 8 of 12VAC5-421-950, a container of food that is not potentially hazardous (time/temperature control for safety food) may be re-served from one consumer to another if:

1. The food is dispensed so that it is protected from contamination and the container is closed between uses such as a narrow-neck bottle containing catsup, steak sauce, or wine; or
2. The food, such as crackers, salt or pepper, is in an unopened original package and maintained in sound condition.

Article 4
Destruction of Organisms of Public Health Concern

12VAC5-421-700. Raw animal foods.

A. Except as specified in subsections B, C, and D of this section, raw animal foods such as eggs, fish, meat, poultry, and foods containing these raw animal foods shall be cooked to heat all parts of the food to a temperature and for a time that complies with one of the following methods based on the food that is being cooked:

1. 145°F (63°C) or above for 15 seconds for:
   a. Raw shell eggs that are broken and prepared in response to a consumer's order and for immediate service; and
   b. Except as specified under subdivisions A 2 and 3 and subsection subsections B and C of this section, fish and meat, including game animals commercially raised for food as specified under 12VAC5-421-330 A 1 and game animals under a voluntary inspection program as specified under 12VAC5-421-330 A 2 ;

2. 155°F (68°C) for 15 seconds or the temperature specified in the following chart that corresponds to the holding time for ratites and injected meats, mechanically tenderized meats, and injected meats; the following if they are comminuted: fish, meat, game animals commercially raised for food as specified under 12VAC5-421-330 A 1, and game animals under a voluntary inspection program as specified under 12VAC5-421-330 A 2 ; and raw eggs that are not prepared as specified under subdivision 1 a of this subsection:

<p>| Minimum |</p>
<table>
<thead>
<tr>
<th>Temperature °F (°C)</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>145 (63)</td>
<td>3 minutes</td>
</tr>
<tr>
<td>150 (66)</td>
<td>1 minute</td>
</tr>
<tr>
<td>158 (70)</td>
<td>&lt;1 second (instantaneous)</td>
</tr>
</tbody>
</table>

3. 165°F (74°C) or above for 15 seconds for poultry, [baluts] wild game animals as specified under 12VAC5-421-330 A 3, stuffed fish, stuffed meat, stuffed pasta, stuffed poultry, stuffed ratites, or stuffing containing fish, meat, or poultry, or ratites.
B. Whole meat roasts including beef, corned beef, lamb, pork, and cured pork roasts such as ham shall be cooked:

1. In an oven that is preheated to the temperature specified for the roast's weight in the following chart and that is held at that temperature; and

<table>
<thead>
<tr>
<th>Oven Type</th>
<th>Oven Temperature Based on Roast Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Less than 10 lbs (4.5 kg)</td>
</tr>
<tr>
<td></td>
<td>10 lbs (4.5 kg) or more</td>
</tr>
<tr>
<td>Still Dry</td>
<td>350°F (177°C) or more</td>
</tr>
<tr>
<td>Convection</td>
<td>325°F (163°C) or more</td>
</tr>
<tr>
<td>High Humidity¹</td>
<td>250°F (121°C) or less</td>
</tr>
</tbody>
</table>

¹Relative humidity greater than 90% for at least 4 one hour as measured in the cooking chamber or exit of the oven; or in a moisture-impermeable bag that provides 100% humidity.

2. As specified in the following chart, to heat all parts of the food to a temperature and for the holding time that corresponds to that temperature.

<table>
<thead>
<tr>
<th>Temperature °F (°C)</th>
<th>Time¹ in Minutes</th>
<th>Temperature °F (°C)</th>
<th>Time¹ in Seconds</th>
</tr>
</thead>
<tbody>
<tr>
<td>130 (54.4)</td>
<td>112</td>
<td>147 (63.9)</td>
<td>134</td>
</tr>
<tr>
<td>131 (55.0)</td>
<td>89</td>
<td>149 (65.0)</td>
<td>85</td>
</tr>
<tr>
<td>133 (56.1)</td>
<td>56</td>
<td>151 (66.1)</td>
<td>54</td>
</tr>
<tr>
<td>135 (57.2)</td>
<td>36</td>
<td>153 (67.2)</td>
<td>34</td>
</tr>
<tr>
<td>136 (57.8)</td>
<td>28</td>
<td>155 (68.3)</td>
<td>22</td>
</tr>
<tr>
<td>138 (58.9)</td>
<td>18</td>
<td>157 (69.4)</td>
<td>14</td>
</tr>
<tr>
<td>140 (60.0)</td>
<td>12</td>
<td>158 (70.0)</td>
<td>0</td>
</tr>
<tr>
<td>142 (61.1)</td>
<td>8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>144 (62.2)</td>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>145 (62.8)</td>
<td>4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

¹Holding time may include postoven heat rise.

C. A raw or undercooked whole-muscle, intact beef steak may be served or offered for sale in a ready-to-eat form if:

1. The food establishment serves a population that is not a highly susceptible population;
2. The steak is labeled, as specified under 12VAC5-421-270 E, to indicate that it meets the definition of "whole-muscle, intact beef"; and
3. The steak is cooked on both the top and bottom to a surface temperature of 145°F (63°C) or above and a cooked color change is achieved on all external surfaces.

D. A raw animal food such as raw egg, raw fish, raw-marinated fish, raw molluscan shellfish, or steak tartare, or a partially cooked food such as lightly cooked fish, soft cooked eggs, or rare meat other than whole-muscle, intact beef steaks as specified in subsection C of this section, may be served or offered for sale [upon request or consumer selection] in a ready-to-eat form if:
1. (i) As specified under subdivisions 3 a and b of 12VAC5-421-950 the food establishment serves a population that is not a highly susceptible population and (ii) the;

2. The food, if served or offered for service by consumer selection from a children's menu, does not contain comminuted meat; and

3. The consumer is informed as specified under 12VAC5-421-930 that to ensure its safety, the food should be cooked as specified under subsection A or B of this section; or

2. 4. The regulatory authority grants a variance from subsection A or B of this section as specified in 12VAC5-421-3570 based on a HACCP plan that:

   a. Is submitted by the permit holder and approved as specified under 12VAC5-421-3570;
   b. Documents scientific data or other information that shows that a lesser time and temperature regimen results in a safe food; and
   c. Verifies that equipment and procedures for food preparation and training of food employees at the food establishment meet the conditions [of the variance].

**12VAC5-421-710. Microwave cooking.**

Raw animal foods cooked in a microwave oven shall be:

1. Rotated or stirred throughout or midway during cooking to compensate for uneven distribution of heat;
2. Covered to retain surface moisture;
3. Heated to a temperature of at least 165°F (74°C) in all parts of the food; and
4. Allowed to stand covered for two minutes after cooking to obtain temperature equilibrium.

**12VAC5-421-720. Plant food cooking for hot holding.**

Fruits and vegetables that are cooked for hot holding shall be cooked to a temperature of 135°F (57°C).

**12VAC5-421-725. Noncontinuous cooking.**

Raw animal foods that are cooked using a noncontinuous cooking process shall be:

1. Subject to an initial heating process that is no longer than 60 minutes in duration;
2. Immediately after initial heating, cooled according to the time and temperature requirements specified for cooked time/temperature control for safety food under 12VAC5-421-800 A;
3. After cooling, held frozen or cold, as specified for time/temperature control for safety food under 12VAC5-421-820 A;
4. Prior to sale or service, cooked using a process that heats all parts of the food to a temperature [and for a time] as designated in 12VAC5-421-700 A, B, and C;
5. Cooled according to the time and temperature parameters specified for cooked time/temperature control for safety food under 12VAC5-421-800 A if not [either] hot held as specified under 12VAC5-421-820 A, served immediately, or held using time as a public health control as specified under 12VAC5-421-850 after complete [cookingcooling]; and
6. Prepared and stored according to written procedures that:
   a. Have obtained prior approval from the regulatory authority;
   b. Are maintained in the food establishment and are made available to the regulatory authority upon request.
c. Describe how the requirements specified under subdivisions 1 through 5 of this section are to be monitored and documented by the permit holder and the corrective actions to be taken if the requirements are not met.

d. Describe how the foods, after initial heating, but prior to complete cooking, are to be marked or otherwise identified as foods that must be cooked as specified under subdivision 4 of this section prior to being offered for sale or service; and

e. Describe how the foods, after initial heating but prior to cooking as specified in subdivision 4 of this section, are to be separated from ready-to-eat foods as specified under 12VAC5-421-470 A.

12VAC5-421-730. Parasite destruction.

A. Except as specified in subsection B of this section, before service or sale in ready-to-eat form, raw, raw-marinated, partially cooked or marinated-partially cooked fish shall be:

1. Frozen and stored at a temperature of -4°F (-20°C) or below for a minimum of 168 hours (seven days) in a freezer;

2. Frozen at -31°F (-35°C) or below until solid and stored at -31°F (-35°C) or below for a minimum of 15 hours; or

3. Frozen at -31°F (-35°C) or below until solid and stored at -4°F (-20°C) or below for a minimum of 24 hours.

B. Subsection A of this section does not apply to:

1. Molluscan shellfish, including the shucked adductor muscle of scallops;

2. Tuna of the species Thunnus alalunga, Thunnus albacares (Yellowfin tuna), Thunnus atlanticus, Thunnus maccopyii (Bluefin tuna, Southern), Thunnus obesus (Bigeye tuna), or Thunnus thynnus (Bluefin, Northern);

3. Aquacultured fish, such as salmon, that:
   a. If raised in open water, are raised in net-pens; or
   b. Are raised in land-based operations such as ponds or tanks; and
   c. Are fed formulated feed, such as pellets, that contains no live parasites infective to the aquacultured fish;

4. Fish eggs that have been removed from the skein and rinsed.

12VAC5-421-740. Records, creation and retention.

A. Except as specified in 12VAC5-421-730 B and subsection B of this section, if raw, marinated, raw-marinated, partially cooked, or marinated-partially cooked fish are served or sold in ready-to-eat form, the person in charge shall record the freezing temperature and time to which the fish are subjected and shall retain the records at the food establishment for 90 calendar days beyond the time of service or sale of the fish.

B. If the fish are frozen by a supplier, a written agreement or statement from the supplier stipulating that the fish supplied are frozen to a temperature and for a time specified under 12VAC5-421-730 may substitute for the records specified under subsection A of this section.

C. If raw, raw-marinated, partially cooked, or marinated-partially cooked fish are served or sold in ready-to-eat form, and the fish are raised and fed as specified in 12VAC5-421-730 B 3, a written agreement or statement from the supplier or aquaculturist stipulating that the fish were raised and fed as specified in 12VAC5-421-730 B 3 shall be obtained by the person in charge and retained in the records of the food establishment for 90 calendar days beyond the time of service or sale of the fish.
12VAC5-421-755. Preparation for immediate service.

Cooked and refrigerated food that is prepared for immediate service in response to an individual consumer order, such as a roast beef sandwich au jus, may be served at any temperature.

12VAC5-421-760. Reheating for hot holding.

A. Except as specified under subsections B, C, and E of this section, potentially hazardous food (time/temperature control for safety food) that is cooked, cooled, and reheated for hot holding shall be reheated so that all parts of the food reach at least 165°F (74°C) for 15 seconds.²

B. Except as specified under subsection C of this section, potentially hazardous food (time/temperature control for safety food) reheated in a microwave oven for hot holding shall be reheated so that all parts of the food reach a temperature of at least 165°F (74°C) and the food is rotated or stirred, covered, and allowed to stand covered two minutes after reheating.²

C. Ready-to-eat food (time/temperature control for safety food) taken from a food processing plant that is inspected by the regulatory authority that has jurisdiction over the plant, shall be heated to a temperature of at least 135°F (57°C) when being reheated for hot holding.²

D. Reheating for hot holding as specified under subsections A through, B, and C of this section shall be done rapidly and the time the food is between 41°F (5°C) and the temperatures specified under subsections A through, B, and C of this section may not exceed two hours.²

E. Remaining unsliced portions of meat roasts that are cooked as specified under 12VAC5-421-700 B may be reheated for hot holding using the oven parameters and minimum time and temperature conditions specified under 12VAC5-421-700 B.

Article 5

Limitation of Growth of Organisms of Public Health Concern

12VAC5-421-765. Treating juice.

Juice packaged in a food establishment shall be:

1. Treated under a HACCP plan as specified in subdivisions 2 through 5 of 12VAC5-421-3630 to attain a five-log reduction, which is equal to a 99.999% reduction, of the most resistant microorganism of public health significance;² or

2. Labeled, if not treated to yield a five-log reduction of the most resistant microorganism of public health significance;²

   a. As specified under 12VAC5-421-900;² and

   b. As specified in 21 CFR 101.17(g) with the following, "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems."²

12VAC5-421-780. Potentially hazardous Time/temperature control for safety food, slacking.

Frozen potentially hazardous food (time/temperature control for safety food) that is slacked to moderate the temperature shall be held:

1. Under refrigeration that maintains the food temperature at 41°F (5°C) or less; or

2. At any temperature if the food remains frozen.
12VAC5-421-790. Thawing.

A. Except as specified in subdivision 4 of this section, potentially hazardous food (time/temperature control for safety food) shall be thawed:

1. Under refrigeration that maintains the food temperature at 41°F (5°C) or less; or
2. Completely submerged under running water:
   a. At a water temperature of 70°F (21°C) or below;
   b. With sufficient water velocity to agitate and float off loose particles in an overflow; and
   c. For a period of time that does not allow thawed portions of ready-to-eat food to rise above 41°F (5°C); or
   d. For a period of time that does not allow thawed portions of a raw animal food requiring cooking as specified under 12VAC5-421-700 A or B to be above 41°F (5°C) for more than four hours including:
      (1) The time the food is exposed to the running water and the time needed for preparation for cooking; or
      (2) The time it takes under refrigeration to lower the food temperature to 41°F (5°C);
3. As part of a cooking process if the food that is frozen is:
   a. Cooked as specified under 12VAC5-421-700 A or B or 12VAC5-421-710; or
   b. Thawed in a microwave oven and immediately transferred to conventional cooking equipment, with no interruption in the process; or
4. Using any procedure if a portion of frozen ready-to-eat food is thawed and prepared for immediate service in response to an individual consumer's order.

B. Reduced oxygen packaged fish that bears a label indicating that it is to be kept frozen shall be removed from the reduced oxygen environment:

1. Prior to its thawing under refrigeration as specified in subdivision A 1 of this section.
2. Prior to, or immediately upon completion of, its thawing using procedures specified in subdivision A 2 of this section.

12VAC5-421-800. Cooling.

A. Cooked potentially hazardous food (time/temperature controlled for safety food) shall be cooled:

1. Within two hours, from 135°F (57°C) to 70°F (21°C); and
2. Within a total of six hours from 135°F (57°C) to 41°F (5°C) or less.

B. Potentially hazardous food (time/temperature control for safety food) shall be cooled within four hours to 41°F (5°C) or less if prepared from ingredients at ambient temperature, such as reconstituted foods and canned tuna.

C. Except as specified in subsection D of this section, a potentially hazardous food (time/temperature control for safety food) received in compliance with laws allowing a temperature above 41°F (5°C) during shipment from the supplier as specified in 12VAC5-421-340 B, shall be cooled within four hours to 41°F (5°C) or less.

D. Raw shell eggs shall be received as specified under 12VAC5-421-340 C and immediately placed in refrigerated equipment that maintains an ambient air temperature of 45°F (7°C) or less.
12VAC5-421-810. Cooling methods.

A. Cooling shall be accomplished in accordance with the time and temperature criteria specified under 12VAC5-421-800 by using one or more of the following methods based on the type of food being cooled:

1. Placing the food in shallow pans;
2. Separating the food into smaller or thinner portions;
3. Using rapid cooling equipment;
4. Stirring the food in a container placed in an ice water bath;
5. Using containers that facilitate heat transfer;
6. Adding ice as an ingredient; or
7. Other effective methods.

B. When placed in cooling or cold holding equipment, food containers in which food is being cooled shall be:

1. Arranged in the equipment to provide maximum heat transfer through the container walls; and
2. Loosely covered, or uncovered if protected from overhead contamination as specified under 12VAC5-421-610 A 2, during the cooling period to facilitate heat transfer from the surface of the food.

12VAC5-421-820. Potentially hazardous time/temperature control for safety food; hot and cold holding.

A. Except during preparation, cooking, or cooling, or when time is used as the public health control as specified under 12VAC5-421-850 [and except as specified under B and C of this section], potentially hazardous food (time/temperature control for safety food) shall be maintained:

1. At 135°F (57°C) or above, except that roasts cooked to a temperature and for a time specified under 12VAC5-421-700 B or reheated as specified in 12VAC5-421-760 E may be held at a temperature of 130°F (54°C) or above; or
2. At 41°F (5°C) or less.

B. Shell eggs that have not been treated to destroy all viable Salmonellae shall be stored in refrigerated equipment that maintains an ambient air temperature of 45°F (7°C) or less.

C. Potentially hazardous food (time/temperature control for safety food) in a homogenous liquid form may be maintained outside the temperature control requirements, as specified in subsection A of this section, while contained within specially designed equipment that complies with the design and construction requirements as specified under subdivision 5 of 12VAC5-421-1230.

12VAC5-421-830. Ready-to-eat, potentially hazardous food time/temperature control for safety food; date marking.

A. Except when packaging food using a reduced oxygen packaging method as specified under 12VAC5-421-870, and except as specified in subsections D and E of this section, refrigerated ready-to-eat potentially hazardous food (time/temperature control for safety food) prepared and held in a food establishment for more than 24 hours shall be clearly marked to indicate the date or day by which the food shall be consumed on the premises, sold, or discarded when held at a temperature of 41°F (5°C) or less for a maximum of seven days. The day of preparation shall be counted as day 1.
B. Except as specified in subsections D through E and F of this section, refrigerated ready-to-eat, potentially hazardous food (time/temperature control for safety food) time/temperature control for safety food prepared and packaged by a food processing plant shall be clearly marked at the time the original container is opened in a food establishment and if the food is held for more than 24 hours, to indicate the date or day by which the food shall be consumed on the premises, sold, or discarded, based on the temperature and time combinations specified in subsection A of this section and:

1. The day the original container is opened in the food establishment shall be counted as day 1; and

2. The day or date marked by the food establishment shall not exceed a manufacturer's use-by "use by" date if the manufacturer determined the use-by "use by" date based on food safety.

C. A refrigerated, ready-to-eat, potentially hazardous food (time/temperature control for safety food) time/temperature control for safety food ingredient or a portion of a refrigerated, ready-to-eat, potentially hazardous food (time/temperature control for safety food) that is subsequently combined with additional ingredients or portions of food shall retain the date marking of the earliest-prepared or first-prepared ingredient.

D. A date marking system that meets the criteria specified in subsections A and B of this section may include:

1. Using a method approved by the regulatory authority for refrigerated, ready-to-eat potentially hazardous food (time/temperature control for safety food) time/temperature control for safety food that is frequently rewrapped, such as lunchmeat or a roast, or for which date marking is impractical, such as soft-serve mix or milk in a dispensing machine;

2. Marking the date or day of preparation, with a procedure to discard the food on or before the last date or day by which the food must be consumed on the premises, sold, or discarded as specified in subsection A of this section;

3. Marking the date or day the original container is opened in a food establishment, with a procedure to discard the food on or before the last date of or day by which the food must be consumed on the premises, sold, or discarded as specified under subsection B of this section; or

4. Using calendar dates, days of the week, color-coded marks, or other effective marking methods, provided that the marking system is disclosed to the regulatory authority upon request.

E. Subsections A and B of this section do not apply to individual meal portions served or repackaged for sale from a bulk container upon a consumer's request.

F. Subsections A and B of this section do not apply to shellstock.

G. Subsection B of this section does not apply to the following foods prepared and packaged by a food processing plant inspected by a regulatory authority:

1. Deli salads, such as ham salad, seafood salad, chicken salad, egg salad, pasta salad, potato salad, and macaroni salad, manufactured in accordance with 21 CFR Part 110 Current good manufacturing practice in manufacturing, packing or holding food;

2. Hard cheeses containing not more than 39% moisture as defined in 21 CFR Part 133Cheeses and related cheese products, such as cheddar, gruyere, parmesan and reggiano, and romano;
3. Semi-soft cheese containing more than 39% moisture, but not more than 50% moisture, as defined in 21 CFR Part 133 Cheeses and cheese related products, such as blue, edam, gorgonzola, gouda, and monterey jack;

4. Cultured dairy products as defined in 21 CFR Part 131 Milk and cream, such as yogurt, sour cream, and buttermilk;

5. Preserved fish products, such as pickled herring and dried or salted cod, and other acidified fish products as defined in 21 CFR Part 114 Acidified foods;

6. Shelf stable, dry fermented sausages, such as pepperoni and Genoa salami that are not labeled "Keep Refrigerated" as specified in 9 CFR Part 317 Labeling, marking devices, and containers, and that retain the original casing on the product; and

7. Shelf stable salt-cured products such as prosciutto and Parma (ham) that are not labeled "Keep Refrigerated" as specified in 9 CFR Part 317 Labeling, marking devices, and containers.

12VAC5-421-840. Ready-to-eat, potentially hazardous time/temperature control for safety food; disposition.

A. A food specified under 12VAC5-421-830 A or B shall be discarded if it:

1. Exceeds either of the temperature and time combinations specified in 12VAC5-421-830 A, except time that the product is frozen;

2. Is in a container or package that does not bear a date or day; or

3. Is appropriately marked with a date or day that exceeds a temperature and time combination as specified in 12VAC5-421-830 A.

[B. Refrigerated, ready-to-eat, time/temperature control for safety food prepared in a food establishment and dispensed through a vending machine with an automatic shutoff control if it exceeds a temperature and time combination as specified in 12VAC5-421-830 A.]

12VAC5-421-850. Time as a public health control.

A. Except as specified under subsection D of this section, if time without temperature control is used as the public health control for a working supply of potentially hazardous food (time/temperature control for safety food) before cooking or for ready-to-eat potentially hazardous food (time/temperature control for safety food) that is displayed or held for sale or service, written procedures shall be prepared in advance, maintained in the food establishment, and made available to the regulatory authority upon request that specify:

1. Methods of compliance with subdivisions B 1 through, 2, and 3 or C 1 through 5 of this section; and

2. Methods of compliance with 12VAC5-421-800 for food that is prepared, cooked, and refrigerated before time is used as a public health control.

B. If time without temperature control is used as the public health control up to a maximum of four hours:

[1. The food shall have an initial temperature of 41°F (5°C) or less when removed from cold holding temperature control, or 135°F (57°C) or greater when removed from hot-holding temperature control;]

[4. The food shall be marked or otherwise identified to indicate the time that is four hours past the point in time when the food is removed from temperature control;]

[2. The food shall be cooked and served, served at any temperature if ready-to-eat, or discarded, within four hours from the point in time when the food is removed from temperature control; and]
The food in unmarked containers or packages, or marked to exceed a four-hour limit shall be discarded.  

C. If time without temperature control is used as the public health control up to a maximum of six hours:

1. The food shall have an initial temperature of 41ºF (5ºC) or less when removed from temperature control and the food temperature may not exceed 70ºF (21ºC) within a maximum time period of six hours;  

2. The food shall be monitored to ensure the warmest portion of the food does not exceed 70ºF (21ºC) during the six-hour period, unless an ambient air temperature is maintained that ensures the food does not exceed 70ºF (21ºC) during the six-hour holding period;  

3. The food shall be marked or otherwise identified to indicate:
   a. The time when the food is removed from 41ºF (5ºC) or less cold-holding temperature control,  
   b. The time that is six hours past the point in time when the food is removed from 41ºF (5ºC) or less cold-holding temperature control;  

4. The food shall be:
   a. Discarded if the temperature of the foods exceeds 70ºF (21ºC), or
   b. Cooked and served, served at any temperature if ready-to-eat, or discarded within a maximum of six hours from the point in time when the food is removed from 41ºF (5ºC) or less cold-holding temperature control;  

5. The food in unmarked containers or packages, or marked with a time that exceeds the six-hour limit shall be discarded.  

D. A food establishment that serves a highly susceptible population may not use time as specified under subsections A, B, or C of this section as the public health control for raw eggs.  

12VAC5-421-860. Variance requirement.  
A food establishment shall obtain a variance from the regulatory authority as specified in 12VAC5-421-3570 and 12VAC5-421-3580 before:

1. Smoking food as a method of food preservation rather than as a method of flavor enhancement;  
2. Curing food;  
3. Using food additives or adding components such as vinegar:
   a. As a method of food preservation rather than as a method of flavor enhancement;  
   b. To render a food so that it is not potentially hazardous a time/temperature control for safety food;  

4. Packaging time/temperature control for safety food using a reduced oxygen packaging method except as specified under 12VAC5-421-870 where a barrier to Clostridium botulinum in addition to refrigeration exists where the growth of and toxin formation by Clostridium botulinum and the growth of Listeria monocytogenes are controlled as specified under 12VAC5-421-870;  

5. Operating a molluscan shellfish life-support system display tank used to store or display shellfish that are offered for human consumption;  

6. Custom processing animals that are for personal use as food and not for sale or service in a food establishment;
7. Sprouting seeds or beans; or

8. Preparing food by another method that is determined by the regulatory authority to require a variance.

12VAC5-421-870. Reduced oxygen packaging without a variance; criteria.

A. Except for a food establishment that obtains a variance as specified under 12VAC5-421-860 and except as specified under subsections C and E of this section, a food establishment that packages potentially hazardous food (time/temperature control for safety food) shall ensure that there are at least two barriers in place to control the growth and toxin formation of Clostridium botulinum and the growth of Listeria monocytogenes.

B. A except as specified under subsection F of this section, a food establishment that packages potentially hazardous food (time/temperature control for safety food) using a reduced oxygen packaging method shall have a HACCP plan that contains the following information specified under subdivisions 3 and 4 of 12VAC5-421-3630 D:

1. Identifies food to be packaged;

2. Except as specified in subsections C and E and as specified in subsection D of this section, requires that the packaged food shall be maintained at 41°F (5°C) or less and meet at least one of the following criteria:
   a. Has an A_w of 0.91 or less,
   b. Has a pH of 4.6 or less,
   c. Is a meat or poultry product cured as at a food processing plant regulated by the USDA using substances specified in 9 CFR 424.21, Use of food ingredients and sources of radiation, and is received in an intact package, or
   d. Is a food with a high level of competing organisms such as raw meat, raw poultry, or raw vegetables.

3. Describes how the package shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to:
   a. Maintain food at 41°F (5°C) or below, and
   b. Discard the food if within 44 30 calendar days of its packaging if it is not served for on-premises consumption, or consumed if served or sold for off-premises consumption;

4. Limits the refrigerated shelf life to no more than 44 30 calendar days from packaging to consumption, except the time the product is maintained frozen, or the original manufacturer's "sell by" or "use by" date, whichever occurs first;

5. Includes operational procedures that:
   a. Prohibit contacting ready-to-eat food with bare hands [as specified in 12VAC5-421-450 B],
   b. Identify a designated work area and the method by which:
      (1) Physical barriers or methods of separation of raw foods and ready-to-eat foods minimize cross contamination, and
      (2) Access to the processing equipment is limited to responsible trained personnel familiar with the potential hazards of the operation, and
   c. Delineate cleaning and sanitization procedures for food contact surfaces; and

6. Describes the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the:
   a. Concepts required for safe operation;
b. Equipment and facilities, ² and

c. Procedures specified under subdivision B 5 of this section and subdivisions 3 and

4 of 12VAC5-421-3630 D.; and ²

7. Is provided to the regulatory authority prior to implementation as specified under

12VAC5-421-3620 [B].

C. Except for fish that is frozen before, during, and after packaging, a food establishment

may not package fish using a reduced oxygen packaging method. ²

D. Except as specified in subsection subsections C and F of this section, a food

establishment may package that packages time/temperature control for safety food using a

cook-chill or sous-vide process without obtaining a variance if shall:

1. The food establishment implements: Provide to the regulatory authority prior to

implementation a HACCP plan that contains the information as specified

under subdivisions 3 and 4 of 12VAC5-421-3630 D.; ²

2. The Ensure the food is:

a. Prepared and consumed on the premises, or prepared and consumed off the

premises but within the same business entity with no distribution or sale of the

bagged product to another business entity or the consumer ²

b. Cooked to heat all parts of the food to a temperature and for a time as specified

under subsections A, B, and C of 12VAC5-421-700, subsections A, B, and C of this

section ²

c. Protected from contamination before and after cooking as specified in 12VAC5-

421-450 through 12VAC5-421-[690,765],²

d. Placed in a package or bag with an oxygen barrier and sealed before cooking, or

placed in a package or bag and sealed immediately after cooking, and before

reaching a temperature below 135°F (57°C),…

e. Cooled to 41°F (5°C) in the sealed package or bag as specified under 12VAC5-

421-800, and subsequently: ²

(1) Cooled to 34°F (1°C) within 48 hours of reaching 41°F (5°C) and held at that

temperature until consumed or discarded within 30 days after the date

of preparation, packaging; ²

(2) Cooled to 34°F (1°C) within 48 hours of reaching 41°F (5°C), removed from

refrigeration equipment that maintains a 34°F (1°C) food temperature and then

held at 41°F (5°C) or less for no more than 72 hours seven days, at which time

the food must be consumed or discarded; or

(3) Cooled to 38°F (3°C) or less within 24 hours of reaching 41°F (5°C) and held

there for no more than 72 hours from packaging, at which time the food must be

consumed or discarded; or

(4) (3) Held frozen with no shelf-life restriction while frozen until consumed or used.
²

f. Held in a refrigeration unit that is equipped with an electronic system that

continuously monitors time and temperature and is visually examined for proper

operation twice daily ²

or

g. If transported off-site off site to a satellite location of the same business entity,

equipped with verifiable electronic monitoring devices to ensure that times and

temperatures are monitored during transportation ² and

h. Labeled with the product name and the date packed ² and
3. The records required to confirm that cooling and cold holding refrigeration time/temperature parameters are required as part of the HACCP plan, are maintained and are:
   a. Made available to the regulatory authority upon request, and
   b. Held for six months, and
4. Written Implement written operational procedures as specified under subdivision B 5 of this section and a training program as specified under subdivision B 6 of this section are implemented.

E. Except as specified under subsection F of this section, a food establishment may package that packages cheese using a reduced oxygen packaging method without obtaining a variance if it shall:
   1. Limits Limit the cheeses packaged to those that are commercially manufactured in a food processing plant with no ingredients added in the food establishment and that meet the Standards of Identity as specified in 21 CFR 133.150 Hard Cheeses, 21 CFR 133.169 Pasteurized process cheese, or 21 CFR 133.187 Semi-soft cheeses;
   2. Has Have a HACCP plan that contains the information specified in subdivisions 3 and 4 of 12VAC5-421-3630 and as specified under subdivisions B 1, B 3 a, B 5, and B 6 of this section;
   3. Except as specified under subdivision B 2, B 3 b, and B 4, complies with subsection B of this section;
   4. Labels Label the package on the principal display panel with a "use by" date that does not exceed 30 days from its packaging or the original manufacturer’s "sell by" or "use by" date, whichever comes first; and
   5. Discards Discard the reduced oxygen packaged cheese if it is not sold for off-premises consumption or consumed within 30 calendar days of its packaging.

F. A HACCP plan is not required when a food establishment uses a reduced oxygen packaging method to package food that is always:
   1. Labeled with the production time and date.
   2. Held at 41°F (5°C) or less during refrigerated storage; and
   3. Removed from its packaging in the food establishment within 48 hours after packaging.
2. If made from two or more ingredients, a list of ingredients and sub-ingredients in descending order of predominance by weight, including a declaration of artificial color(s) or artificial flavor(s) and chemical preservatives, if contained in the food;
3. An accurate declaration of the net quantity of contents;
4. The name and place of business of the manufacturer, packer, or distributor;
5. The name of the food source for each major food allergen contained in the food unless the food source is already part of the common or usual name of the respective ingredient;
7. For any salmonid fish containing canthaxanthin or astaxanthin as a color additive, the labeling of the bulk fish container, including a list of ingredients, displayed on the retail container or by other written means, such as a counter card, that discloses the use of canthaxanthin or astaxanthin.

C. Bulk food that is available for consumer self-dispensing shall be prominently labeled with the following information in plain view of the consumer:
1. The manufacturer's or processor's label that was provided with the food; or
2. A card, sign, or other method of notification that includes the information specified under subdivisions B 1, 2 and 5 of this section.

D. Bulk, unpackaged foods such as bakery products and unpackaged foods that are portioned to consumer specification need not be labeled if:
1. A health, nutrient content, or other claim is not made;
2. There are no state or local laws requiring labeling; and
3. The food is manufactured or prepared on the premises of the food establishment or at another food establishment or a food processing plant that is owned by the same person and is regulated by the food regulatory agency that has jurisdiction.

12VAC5-421-930. Consumer Advisory: Consumption of animal products foods that are raw, undercooked, or not otherwise processed to eliminate pathogens.

A. Except as specified in 12VAC5-421-700 C and D 4 and under 12VAC5-421-950 C, if an animal food such as beef, eggs, fish, lamb, pork, poultry, or shellfish is served or sold raw, undercooked, or without otherwise being processed to eliminate pathogens, either in ready-to-eat form or as an ingredient in another ready-to-eat food, the permit holder shall inform consumers of the significantly increased risk of consuming such foods by way of a disclosure and reminder, as specified in subsections B and C of this section, using brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means.

B. Disclosure shall include:
1. A description of the animal-derived foods, such as "oysters on the half shell (raw oysters)," "raw-egg Caesar salad," and "hamburgers (can be cooked to order)"; or
2. Identification of the animal-derived foods by asterisking them to a footnote that states that the items are served raw or undercooked, or contain (or may contain) raw or undercooked ingredients.

C. Reminder shall include asterisking the animal-derived foods requiring disclosure to a footnote that states:
1. "Regarding the safety of these items, written information is available upon request";
2. "Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness" or 
3. "Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions."

**Article 7**

**Contaminated Food**

**12VAC5-421-940. Discarding unsafe, adulterated, or contaminated food.**

A. A food that is unsafe, adulterated, or not from an approved source as specified under 12VAC5-421-270 through 12VAC5-421-330 shall be rendered unusable and discarded.

B. Ready-to-eat food that may have been contaminated by an employee who has been restricted or excluded as specified under 12VAC5-421-90 shall be rendered unusable and discarded.

C. Food that is contaminated by food employees, consumers, or other persons through contact with their hands, bodily discharges, such as nasal or oral discharges, or other means shall be rendered unusable and discarded.

**Article 8**

**Special Requirements for Highly Susceptible Populations**

**12VAC5-421-950. Pasteurized foods, prohibited reservice, and prohibited food.**

In a food establishment that serves a highly susceptible population:

1. The following criteria apply to juice:
   a. For the purposes of this paragraph only, children who are age nine or less and receive food in a school, day care setting, or similar facility that provides custodial care are included as highly susceptible populations;
   b. Prepackaged juice or a prepackaged beverage containing juice, that bears a warning label as specified in 21 CFR 101.17(g) Food Labeling, (Juices that have not been specifically processed to prevent, reduce or eliminate the presence of pathogens) or a packaged juice or beverage containing juice, that bears a warning label as specified under subdivision 2 of 12VAC5-421-765 shall may not be served or offered for sale; and
   c. Unpackaged juice that is prepared on the premises for service or sale in a ready-to-eat form shall be processed under a HACCP plan that contains the information specified in subdivisions 2 through 5 of 12VAC5-421-3630 and as specified under 21 CFR 120.24, Process controls.

2. Pasteurized shell eggs or egg products shall be substituted for raw shell eggs in the preparation of:
   a. Foods such as Caesar salad, hollandaise or Bearnaise sauce, mayonnaise, meringue, eggnog, ice cream, and egg-fortified beverages; and
   b. Except as specified in subdivision 6 of this section, recipes in which more than one egg is broken and the eggs are combined.

3. The following foods shall not be served or offered for sale in a ready-to-eat form:
   a. Raw animal foods such as raw fish, raw-marinated fish, raw molluscan shellfish, and steak tartare;
   b. A partially cooked animal food such as lightly cooked fish, rare meat, soft-cooked eggs that are made from raw shell eggs, and meringue; and
   c. Raw seed sprouts.
4. Food employees shall not contact ready-to-eat food as specified in 12VAC5-421-450 B and E.

5. Time only, as the public health control as specified under 12VAC5-421-850 D, may not be used for raw eggs.

6. Subdivision 2 b of this section does not apply if:

   a. The raw eggs are combined immediately before cooking for one consumer's serving at a single meal, cooked as specified under 12VAC5-421-700 A 1, and served immediately, such as an omelet, soufflé, or scrambled eggs;

   b. The raw eggs are combined as an ingredient immediately before baking and the eggs are thoroughly cooked to a ready-to-eat form, such as a cake, muffin, or bread;

   or

   c. The preparation of the food is conducted under a HACCP plan that:

      (1) Identifies the food to be prepared;

      (2) Prohibits contacting ready-to-eat food with bare hands;

      (3) Includes specifications and practices that ensure:

         (a) Salmonella Enteritidis growth is controlled before and after cooking; and

         (b) Salmonella Enteritidis is destroyed by cooking the eggs according to the temperature and time specified in 12VAC5-421-700 A 2;

      d. Contains the information specified under subdivision 4 of 12VAC5-421-3630 including procedures that:

         (1) Control cross contamination of ready-to-eat food with raw eggs; and

         (2) Delineate cleaning and sanitization procedures for food-contact surfaces; and

      e. Describes the training program that ensures that the food employee responsible for the preparation of the food understands the procedures to be used.

7. Except as specified in subdivision 8 of this section, food may be re-served as specified under 12VAC5-421-680 B 1 and 2.

8. Foods may not be re-served under the following conditions:

   1. Any food served to patients or clients who are under contact precautions in medical isolation or quarantine, or protective environment isolation may not be re-served to others outside.

   2. Packages of food from any patients, clients, or other consumers should not be re-served to persons in protective environment isolation

   Part IV

   Equipment, Utensils, and Linens

   Article 1

   Materials for Construction and Repair

12VAC5-421-960. Multiuse, characteristics.

Materials that are used in the construction of utensils and food-contact surfaces of equipment shall not allow the migration of deleterious substances or impart colors, odors, or tastes to food and under normal use conditions shall be:

1. Safe;

2. Durable, corrosion-resistant, and nonabsorbent;

3. Sufficient in weight and thickness to withstand repeated warewashing;

4. Finished to have a smooth, easily cleanable surface; and
5. Resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition.

12VAC5-421-980. Lead, use limitation.

A. Ceramic, china, crystal utensils, and decorative utensils such as hand-painted ceramic or china that are used in contact with food shall be lead-free or contain levels of lead not exceeding the limits of the following utensil categories:²

<table>
<thead>
<tr>
<th>Utensil Category</th>
<th>Ceramic Article Description</th>
<th>Maximum Lead mg/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beverage Mugs, Cups, Pitchers</td>
<td>Coffee Mugs</td>
<td>0.5</td>
</tr>
<tr>
<td>Large Hollowware (excluding pitchers)</td>
<td>Bowls &gt; 1.1 Liter (1.16 Quart)</td>
<td>1.0</td>
</tr>
<tr>
<td>Small Hollowware (excluding cups and mugs)</td>
<td>Bowls &lt;1.1 Liter (1.16 Quart)</td>
<td>2.0</td>
</tr>
<tr>
<td>Flat tableware</td>
<td>Plates, Saucers</td>
<td>3.0</td>
</tr>
</tbody>
</table>

B. Pewter alloys containing lead in excess of 0.05% may not be used as a food contact surface.²

C. Solder and flux containing lead in excess of 0.2% may not be used as a food contact surface.

12VAC5-421-990. Copper, use limitation.

A. Except as specified in subsections B and C of this section, copper and copper alloys such as brass shall not be used in contact with a food that has a pH below 6 such as vinegar, fruit juice, or wine or for a fitting or tubing installed between a backflow prevention device and a carbonator.²

B. Copper and copper alloys may be used in contact with beer brewing ingredients that have a pH below 6 in the prefermentation and fermentation steps of a beer brewing operation such as a brewpub or microbrewery.

C. Copper and copper alloys may be used in contact with apple butter and molasses ingredients that have a pH below 6 during the typical processing times (i.e. mixing, cooking, and cooling) for these products, as long as laboratory analysis does not reveal excessive levels of copper or other heavy metals in the finished product. Apple butter and molasses may not be held or stored in copper or copper alloys for time periods any longer than the typical processing times for these products.

12VAC5-421-1000. Galvanized metal, use limitation.

Galvanized metal shall not be used for utensils or food-contact surfaces of equipment that are used in contact with acidic food.²

12VAC5-421-1070. Single-service and single-use, characteristics.

A. Materials that are used to make single-service and single-use articles shall not:

1. Allow the migration of deleterious substances;² or

2. Impart colors, odors, or tastes to food.

B. Materials that are used to make single-service and single-use articles shall be safe and clean:

1. Safe² and
2. Clean.


Food temperature measuring devices shall not have sensors or stems constructed of glass, except that thermometers with glass sensors or stems that are encased in a shatterproof coating such as candy thermometers may be used.

12VAC5-421-1100. Food-contact surfaces; cleanability.

A. Multiuse food-contact surfaces shall be:

1. Smooth;
2. Free of breaks, open seams, cracks, chips, inclusions, pits, and similar imperfections;
3. Free of sharp internal angles, corners, and crevices;
4. Finished to have smooth welds and joints; and
5. Accessible. Except as specified in subsection B of this section, accessible for cleaning and inspection by one of the following methods:
   a. Without being disassembled;
   b. By disassembling without the use of tools or
c. By easy disassembling with the use of handheld tools commonly available to maintenance and cleaning personnel such as screwdrivers, pliers, open-end wrenches, and Allen wrenches.

B. Subdivision A. 5 of this section does not apply to cooking oil storage tanks, distribution lines for cooking oils, or beverage syrup lines or tubes.

12VAC5-421-1110. CIP equipment.

A. CIP equipment shall meet the characteristics specified under 12VAC5-421-1100 and shall be designed and constructed so that:

1. Cleaning and sanitizing solutions circulate throughout a fixed system and contact all interior food-contact surfaces, and
2. The system is self-draining or capable of being completely drained of cleaning and sanitizing solutions.

B. CIP equipment that is not designed to be disassembled for cleaning shall be designed with inspection access points to ensure that all interior food-contact surfaces throughout the fixed system are being effectively cleaned.

12VAC5-421-1180. Temperature measuring devices; food.

A. Food temperature measuring devices that are scaled only in Fahrenheit or dually scaled in Fahrenheit and Celsius shall be scaled in 2°F increments and accurate to ±2°F in the intended range of use.

B. Food temperature measuring devices that are scaled only in Celsius shall be scaled in 1°C increments and accurate to ±1°C in the intended range of use.

12VAC5-421-1190. Temperature measuring devices; ambient air and water.

A. Ambient air and water temperature measuring devices that are scaled in Fahrenheit or dually scaled in Fahrenheit and Celsius and shall be designed to be easily readable and scaled in 3°F increments and accurate to ±3°F in the intended range of use.

B. Ambient air and water temperature measuring devices that are scaled only in Celsius shall be scaled in 1.5°C increments and accurate to ±1.5°C in the intended range of use.

12VAC5-421-1230. Dispensing equipment, protection of equipment and food.

In equipment that dispenses or vends liquid food or ice in unpackaged form:
1. The delivery tube, chute, orifice, and splash surfaces directly above the container receiving the food shall be designed in a manner, such as with barriers, baffles, or drip aprons, so that drips from condensation and splash are diverted from the opening of the container receiving the food;

2. The delivery tube, chute, and orifice shall be protected from manual contact such as by being recessed;

3. The delivery tube or chute and orifice of equipment used to vend liquid food or ice in unpackaged form to self-service consumers shall be designed so that the delivery tube or chute and orifice are protected from dust, insects, rodents, and other contamination by a self-closing door if the equipment is:

   a. Located in an outside area that does not otherwise afford the protection of an enclosure against the rain, windblown debris, insects, rodents, and other contaminants that are present in the environment, or

   b. Available for self-service during hours when it is not under the full-time supervision of a food employee; and

4. The dispensing equipment actuating lever or mechanism and filling device of consumer self-service beverage dispensing equipment shall be designed to prevent contact with the lip-contact surface of glasses or cups that are refilled.

5. Dispensing equipment in which potentially hazardous food (time/temperature control for safety food) in homogenous liquid form is maintained outside of the temperature control requirements as specified in 12VAC5-421-820 C shall:

   a. Be specifically designed and equipped to maintain the commercial sterility of aseptically packaged food in a homogenous liquid form for a specified duration from the time of opening the packaging within the equipment; and


12VAC5-421-1240. Vending machine, vending stage closure.

The dispensing compartment of a vending machine including a machine that is designed to vend prepackaged snack food that is not potentially hazardous time/temperature control for safety food such as chips, party mixes, and pretzels shall be equipped with a self-closing door or cover if the machine is:

1. Located in an outside area that does not otherwise afford the protection of an enclosure against the rain, windblown debris, insects, rodents, and other contaminants that are present in the environment; or

2. Available for self-service during hours when it is not under the full-time supervision of a food employee.

12VAC5-421-1300. Molluscan shellfish tanks.

A. Except as specified under subsection B of this section, molluscan shellfish life support system display tanks shall not be used to display shellfish that are offered for human consumption and shall be conspicuously marked so that it is obvious to consumers that the shellfish are for display only.

B. Molluscan shellfish life-support system display tanks that are used to store and display shellfish that are offered for human consumption shall be operated and maintained in accordance with a variance granted by the regulatory authority as specified in 12VAC5-421-3570 and a HACCP plan that:
1. Is submitted by the permit holder and approved as specified under 12VAC5-421-3580; and
2. Ensures that:
   a. Water used with fish other than molluscan shellfish does not flow into the molluscan tank;
   b. The safety and quality of the shellfish as they were received are not compromised by the use of the tank; and
   c. The identity of the source of the shellstock is retained as specified under 12VAC5-421-440.

12VAC5-421-1310. Vending machines, automatic shutoff.

A. A machine vending potentially hazardous food (time/temperature control for safety food) shall have an automatic control that prevents the machine from vending food:
   1. If there is a power failure, mechanical failure, or other condition that results in an internal machine temperature that cannot maintain food temperatures as specified under Part III (12VAC5-421-260 et seq.) of this chapter; and
   2. If a condition specified under subdivision 1 of this subsection occurs, until the machine is serviced and restocked with food that has been maintained at temperatures specified under Part III.

B. When the automatic shutoff within a machine vending potentially hazardous food is activated:
   1. In a refrigerated vending machine, the ambient temperature shall not exceed 41°F (5°C) for more than 30 minutes immediately after the machine is filled, serviced, or restocked; or
   2. In a hot holding vending machine, the ambient temperature shall not be less than 135°F (57°C) for more than 120 minutes immediately after the machine is filled, serviced, or restocked.

12VAC5-421-1320. Temperature measuring devices.

A. In a mechanically refrigerated or hot food storage unit, the sensor of a temperature measuring device shall be located to measure the air temperature or a simulated product temperature in the warmest part of a mechanically refrigerated unit and in the coolest part of a hot food storage unit.

B. Except as specified in subsection C of this section, cold or hot holding equipment used for potentially hazardous food shall be designed to include and shall be equipped with at least one integral or affixed temperature measuring device that is located to allow easy viewing of the device's temperature display.

C. Subsection B of this section does not apply to equipment for which the placement of a temperature measuring device is not a practical means for measuring the ambient air surrounding the food because of the design, type, and use of the equipment, such as calrod units, heat lamps, cold plates, bainmaries, steam tables, insulated food transport containers, and salad bars.

D. Temperature measuring devices shall be designed to be easily readable.

E. Food temperature measuring devices and water temperature measuring devices on warewashing machines shall have a numerical scale, printed record, or digital readout in increments no greater than 2°F or 1°C in the intended range of use.
12VAC5-421-1350. Warewashing machines, temperature measuring devices.

A warewashing machine shall be equipped with a temperature measuring device that indicates the temperature of the water:

1. In each wash and rinse tank; and
2. As the water enters the hot water sanitizing final rinse manifold or in the chemical sanitizing solution tank.


If hot water is used for sanitization in manual warewashing operations, the sanitizing compartment of the sink shall be:

1. Designed with an integral heating device that is capable of maintaining water at a temperature not less than 171°F (77°C); and
2. Provided with a rack or basket to allow complete immersion of equipment and utensils into the hot water.

12VAC5-421-1370. Warewashing machines, sanitizer level indicator automatic dispensing of detergents and sanitizers.

A. A warewashing machine installed after March 1, 2002, shall be equipped to:

1. Automatically dispense detergents and sanitizers; and
2. Incorporate a visual means to verify that detergents and sanitizers are delivered or a visual or audible alarm to signal if the detergents and sanitizers are not delivered to the respective washing and sanitizing cycles.

B. Existing warewashing equipment shall be upgraded or replaced to meet the requirements of subsection A of this section.

12VAC5-421-1435. Food equipment, certification and classification.

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 of Articles 1 (12VAC5-421-960 et seq.) and 2 (12VAC5-421-1080 et seq.) of this part.

Article 3
Numbers and Capacities

12VAC5-421-1450. Cooling, heating, and holding capacities.

Equipment for cooling and heating food, and holding cold and hot food, shall be sufficient in number and capacity and capable of providing to provide food temperatures as specified under Part III (12VAC5-421-260 et seq.) of this chapter.

12VAC5-421-1460. Manual warewashing, sink compartment requirements.

A. Except as specified in subsection C of this section, a sink with at least three compartments shall be provided for manually washing, rinsing, and sanitizing equipment and utensils.

B. Sink compartments shall be large enough to accommodate immersion of the largest equipment and utensils. If equipment or utensils are too large for the warewashing sink, a warewashing machine or alternative equipment as specified in subsection C of this section shall be used.

C. Alternative manual warewashing equipment may be used when there are special cleaning needs or constraints and its use is approved. Alternative manual warewashing equipment may include:

1. High-pressure detergent sprayers;
2. Low-pressure or line-pressure spray detergent foamers;
3. Other task-specific cleaning equipment;
4. Brushes or other implements;
5. 2 Two-compartment sinks as specified under subsections D and E of this section; or
6. Receptacles that substitute for the compartments of a multicompartment sink.

D. Before a 2 two-compartment sink is used:
1. The permit holder shall have its use approved; and
2. The permit holder shall limit the number of kitchenware items cleaned and sanitized in the two-compartment sink and shall limit warewashing to batch operations for cleaning kitchenware such as between cutting one type of raw meat and another or cleanup at the end of a shift, and shall:
   a. (i) Make up the cleaning and sanitizing solutions immediately before use and drain them immediately after use, and (ii) use a detergent-sanitizer to sanitize and apply the detergent-sanitizer in accordance with the manufacturer’s label instructions and as specified under 12VAC5-421-1710; or
   b. A hot water sanitization immersion step shall be used as specified under subdivision 3 of 12VAC5-421-1860.

E. A 2 two-compartment sink shall not be used for warewashing operations where cleaning and sanitizing solutions are used for a continuous or intermittent flow of kitchenware or tableware in an ongoing warewashing process.

12VAC5-421-1500. Utensils, consumer self-service.
A food dispensing utensil shall be available for each container displayed at a consumer self-service unit such as a buffet or salad bar.

12VAC5-421-1510. Food temperature measuring devices.
A. Food temperature measuring devices shall be provided and readily accessible for use in ensuring attainment and maintenance of food temperatures as specified under Part III (12VAC5-421-260 et seq.) of this chapter.
B. A temperature measuring device with a suitable small-diameter probe that is designed to measure the temperature of thin masses shall be provided and readily accessible to accurately measure the temperature in thin foods such as meat patties and fish fillets.

12VAC5-421-1520. Temperature measuring devices, manual and mechanical warewashing.
A. In manual warewashing operations, a temperature measuring device shall be provided and readily accessible for frequently measuring the washing and sanitizing temperatures.
B. In hot water mechanical warewashing operations, an irreversible registering temperature indicator shall be provided and readily accessible for measuring the utensil surface temperature.

12VAC5-421-1530. Sanitizing solutions, testing devices.
A test kit or other device that accurately measures the concentration in mg/L (ppm) of sanitizing solutions shall be provided and readily accessible for use.

12VAC5-421-1535. Cleaning agents and sanitizers, availability.
A. Cleaning agents that are used to clean equipment and utensils as specified under Article 6 (12VAC5-421-1770 et seq.) of this part shall be provided and available for use during all hours of operation.
B. Except for chemical sanitizers that are generated on site at the time of use, chemical sanitizers that are used to sanitize equipment and utensils as specified under Article 6 shall be provided and available for use during all hours of operation.

12VAC5-421-1630. Warewashing equipment, cleaning agents.

When used for warewashing, the wash compartment of a sink, mechanical warewasher, or wash receptacle of alternative manual warewashing equipment as specified in 12VAC5-421-1460 C, shall contain a wash solution of soap, detergent, acid cleaner, alkaline cleaner, degreaser, abrasive cleaner, or other cleaning agent according to the cleaning agent manufacturer's label instructions.


The temperature of the wash solution in manual warewashing equipment shall be maintained at not less than 110°F (43°C) or the temperature specified on the cleaning agent manufacturer's label instructions.

12VAC5-421-1660. Mechanical warewashing equipment, wash solution temperature.

A. The temperature of the wash solution in spray type warewashers that use hot water to sanitize shall not be less than:

1. For a stationary rack, single temperature machine, 165°F (74°C);
2. For a stationary rack, dual temperature machine, 150°F (66°C);
3. For a single tank, conveyor, dual temperature machine, 160°F (71°C); or
4. For a multitank, conveyor, multitemperature machine, 150°F (66°C).

B. The temperature of the wash solution in spray-type warewashers that use chemicals to sanitize shall not be less than 120°F (49°C).


If immersion in hot water is used for sanitizing in a manual operation, the temperature of the water shall be maintained at 171°F (77°C) or above.

12VAC5-421-1680. Mechanical warewashing equipment, hot water sanitization temperatures.

A. Except as specified in subsection B of this section, in a mechanical operation, the temperature of the fresh hot water sanitizing rinse as it enters the manifold shall not be more than 194°F (90°C), or less than:

1. For a stationary rack, single temperature machine, 165°F (74°C); or
2. For all other machines, 180°F (82°C).

B. The maximum temperature specified under subsection A of this section does not apply to the high pressure and temperature systems with wand-type, hand-held, spraying devices used for the in-place cleaning and sanitizing of equipment such as meat saws.


A chemical sanitizer used in a sanitizing solution for a manual or mechanical operation at exposure contact times specified under subdivision 3 of 12VAC5-421-1900 A-3 shall be listed in 40 CFR 180.940 Sanitizing solutions, shall be used in accordance with the EPA-approved manufacturer's registered label use instructions, and shall be used as follows:

1. A chlorine solution shall have a minimum temperature based on the concentration and pH of the solution as listed in the following chart:

<table>
<thead>
<tr>
<th>Minimum Concentration</th>
<th>Minimum Temperature</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Minimum Concentration</th>
<th>Minimum Temperature</th>
</tr>
</thead>
</table>

66
mg/L (ppm) | pH 10 or less °F (°C) | pH 8 or less °F (°C) |
---|---|---|
25-49 | 120 (49) | 120 (49) |
50-99 | 100 (38) | 75 (24) |
100 | 55 (13) | 55 (13) |

2. An iodine solution shall have:
   a. Minimum temperature of 75°F (24°C) 68°F (20°C);\(^\text{P}\)
   b. pH of 5.0 or less or a pH no higher than the level for which the manufacturer specifies the solution is effective;\(^\text{P}\) and
   c. Concentration between 12.5 mg/L (ppm) and 25 mg/L (ppm);\(^\text{P}\)

3. A quaternary ammonium compound solution shall:
   a. Have a minimum temperature of 75°F (24°C);\(^\text{P}\)
   b. Have a concentration as specified under 40 CFR 180.940 and as indicated by the manufacturer's use directions included in the labeling;\(^\text{P}\) and
   c. Be used only in water with 500 mg/L hardness or less or in water having a hardness no greater than specified by the manufacturer's label;\(^\text{P}\)

4. If another solution of a chemical specified under subdivisions 1, 2 and 3 of this section is used, the permit holder shall demonstrate to the regulatory authority that the solution achieves sanitization and the use of the solution shall be approved;\(^\text{P}\) or

5. If a chemical sanitizer other than chlorine, iodine, or a quaternary ammonium compound is used, it shall be applied in accordance with the manufacturer's use directions included in the labeling EPA-registered label use instructions;\(^\text{P}\) and

6. If a chemical sanitizer is generated by a device located on site at the food establishment it shall be used as specified in subdivisions 1 through 4 of this section and shall be produced by a device that:
   a. Complies with regulation as specified in §§ 2(q)(1) and 12 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA);\(^\text{P}\)
   b. Complies with 40 CFR 152.500 and 40 CFR 156.10;\(^\text{P}\)
   c. Displays the EPA device manufacturing facility registration number on the device;\(^\text{P}\)
   and
   d. Is operated and maintained in accordance with manufacturer's instructions.\(^\text{P}\)

12VAC5-421-1720. Warewashing equipment, determining chemical sanitizer concentration.

Concentration of the sanitizing solution shall be accurately determined by using a test kit or other device.\(^\text{P}\)

12VAC5-421-1730. Good repair and calibration.

A. Utensils shall be maintained in a state of repair or condition that complies with the requirements specified under Articles 1 (12VAC5-421-960 et seq.) and 2 (12VAC5-421-1080 et seq.) of this part or shall be discarded.

B. Food temperature measuring devices shall be calibrated in accordance with manufacturer's specifications as necessary to ensure their accuracy.\(^\text{P}\)

C. Ambient air temperature, water pressure, and water temperature measuring devices shall be maintained in good repair and be accurate within the intended range of use.
12VAC5-421-1740. Single-service and single-use articles, required use.

A food establishment without facilities specified under Articles 6 (12VAC5-421-1770 et seq.) and 7 (12VAC5-421-1880 (12VAC5-421-1890 et seq.) of this part for cleaning and sanitizing kitchenware and tableware shall provide only single-use kitchenware, single-service articles, and single-use articles for use by food employees and single-service articles for use by consumers.\(^2\)

---

### Article 6

**Cleaning of Equipment and Utensils**

### 12VAC5-421-1770. Equipment, food-contact surfaces, nonfood-contact surfaces, and utensils.

A. Equipment food-contact surfaces and utensils shall be clean to sight and touch.\(^1\)

B. The food-contact surfaces of cooking equipment and pans shall be kept free of encrusted grease deposits and other soil accumulations.

C. Nonfood-contact surfaces of equipment shall be kept free of an accumulation of dust, dirt, food residue, and other debris.

### 12VAC5-421-1780. Equipment food-contact surfaces and utensils.

A. Equipment food-contact surfaces and utensils shall be cleaned:

1. Except as specified in subsection B of this section, before each use with a different type of raw animal food such as beef, fish, lamb, pork, or poultry;\(^6\)

2. Each time there is a change from working with raw foods to working with ready-to-eat foods;\(^6\)

3. Between uses with raw fruits and vegetables and with potentially hazardous food/temperature control for safety food;\(^2\)

4. Before using or storing a food temperature measuring device;\(^6\) and

5. At any time during the operation when contamination may have occurred.\(^6\)

B. Subdivision A 1 of this section does not apply if the food contact surface or utensil is in contact with a succession of different raw animal foods [different types of raw meat and poultry] each requiring a higher cooking temperature as specified under 12VAC5-421-700 than the previous food, such as preparing raw fish followed by cutting raw poultry on the same cutting board[type].

C. Except as specified in subsection D of this section, if used with potentially hazardous food/temperature control for safety food, equipment food-contact surfaces and utensils shall be cleaned throughout the day at least every four hours.\(^6\)

D. Surfaces of utensils and equipment contacting potentially hazardous food/temperature control for safety food may be cleaned less frequently than every four hours if:

1. In storage, containers of potentially hazardous food/temperature control for safety food and their contents are maintained at temperatures specified under Part III (12VAC5-421-260 et seq.) of this chapter and the containers are cleaned when they are empty;

2. Utensils and equipment are used to prepare food in a refrigerated room or area that is maintained at one of the temperatures in the following chart and (i) the utensils and equipment are cleaned at the frequency in the following chart that corresponds to the temperature; and (ii) the cleaning frequency based on the ambient temperature of the refrigerated room or area is documented in the food establishment:

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Cleaning Frequency</th>
</tr>
</thead>
</table>

---
<table>
<thead>
<tr>
<th>Temperature Range</th>
<th>Holding Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>41°F (5.0°C) or less</td>
<td>24 hours</td>
</tr>
<tr>
<td>&gt;41°F - 45°F (5.0°C - 7.2°C)</td>
<td>20 hours</td>
</tr>
<tr>
<td>&gt;45°F - 50°F (7.2°C - 10.0°C)</td>
<td>16 hours</td>
</tr>
<tr>
<td>&gt;50°F - 55°F (10.0°C - 12.8°C)</td>
<td>10 hours</td>
</tr>
</tbody>
</table>

3. Containers in serving situations such as salad bars, delis, and cafeteria lines hold ready-to-eat potentially hazardous food, time/temperature control for safety food that is maintained at the temperatures specified under Part III, are intermittently combined with additional supplies of the same food that is at the required temperature, and the containers are cleaned at least every 24 hours;

4. Temperature measuring devices are maintained in contact with food, such as when left in a container of deli food or in a roast, held at temperatures specified under Part III;

5. Equipment is used for storage of packaged or unpackaged food such as a reach-in refrigerator and the equipment is cleaned at a frequency necessary to preclude accumulation of soil residues;

6. The cleaning schedule is approved based on consideration of:
   a. Characteristics of the equipment and its use;
   b. The type of food involved;
   c. The amount of food residue accumulation; and
   d. The temperature at which the food is maintained during the operation and the potential for the rapid and progressive multiplication of pathogenic or toxigenic microorganisms that are capable of causing foodborne disease; or

7. In-use utensils are intermittently stored in a container of water in which the water is maintained at 135°F (57°C) or more and the utensils and container are cleaned at least every 24 hours or at a frequency necessary to preclude accumulation of soil residues.

E. Except when dry cleaning methods are used as specified under 12VAC5-421-1810, surfaces of utensils and equipment contacting food that is not potentially hazardous time/temperature control for safety food shall be cleaned:

1. At any time when contamination may have occurred;

2. At least every 24 hours for iced tea dispensers and consumer self-service utensils such as tongs, scoops, or ladles;

3. Before restocking consumer self-service equipment and utensils such as condiment dispensers and display containers;

4. (Equipment at a frequency specified by the manufacturer or absent manufacturer specifications, at a frequency necessary to preclude accumulation of soil or mold. To include equipment such as ice bins and beverage dispensing nozzles and enclosed components of equipment such as ice makers, cooking oil storage tanks and distribution lines, beverage [and syrup] dispensing lines or tubes, coffee bean grinders, and water vending equipment):
   a. At a frequency specified by the manufacturer; or
   b. Absent manufacturer specifications, at a frequency necessary to preclude accumulation of soil or mold.
12VAC5-421-1810. Dry cleaning.
   A. If used, dry cleaning methods such as brushing, scraping, and vacuuming shall contact only surfaces that are soiled with dry food residues that are not potentially hazardous time/temperature control for safety food.
   B. Cleaning equipment used in dry cleaning food-contact surfaces shall not be used for any other purpose.

12VAC5-421-1870. Returnables, cleaning for refilling. (Repealed.)
   A. Except as specified in subsections B and C of this section, returned empty containers intended for cleaning and refilling with food shall be cleaned and refilled in a regulated food processing plant.
   B. A food-specific container for beverages may be refilled at a food establishment if:
      1. Only a beverage that is not a potentially hazardous food is used as specified under 12VAC5-421-600.A;
      2. The design of the container and of the rinsing equipment and the nature of the beverage, when considered together, allow effective cleaning at home or in the food establishment;
      3. Facilities for rinsing before refilling returned containers with fresh, hot water that is under pressure and not recirculated are provided as part of the dispensing system;
      4. The consumer-owned container returned to the food establishment for refilling is refilled for sale or service only to the same consumer; and
      5. The container is refilled by an employee of the food establishment, or the owner of the container if the beverage system includes a contamination-free transfer process that can not be bypassed by the container owner.
   C. Consumer-owned containers that are not food-specific may be filled at a water vending machine or system.

Sanitation of Equipment and Utensils

12VAC5-421-1890. Before use after cleaning.
   Utensils and food-contact surfaces of equipment shall be sanitized before use after cleaning.

12VAC5-421-1900. Hot water and chemical.
   After being cleaned, equipment food-contact surfaces and utensils shall be sanitized in:
   1. Hot water manual operations by immersion for at least 30 seconds as specified under 12VAC5-421-1670;
   2. Hot water mechanical operations by being cycled through equipment that is set up as specified under 12VAC5-421-1610, 12VAC5-421-1680, and 12VAC5-421-1690 and achieving a utensil surface temperature of 160°F (71°C) as measured by an irreversible registering temperature indicator or
   3. Chemical manual or mechanical operations, including the application of sanitizing chemicals by immersion, manual swabbing, brushing, or pressure spraying methods, using a solution as specified under 12VAC5-421-1700. Contact times shall be consistent with those on EPA-registered label use instructions by providing:
      a. Except as specified under subdivision 3 b of this section, an exposure a contact time of at least 10 seconds for a chlorine solution specified under subdivision 1 of 12VAC5-421-1700 A.
b. An exposure contact time of at least 7 seconds for a chlorine solution of 50 mg/L that has a pH of 10 or less and a temperature of at least 100°F (38°C) or a pH of 8 or less and a temperature of at least 75°F (24°C); or

c. An exposure contact time of at least 30 seconds for other chemical sanitizing solutions; or

d. An exposure contact time used in relationship with a combination of temperature, concentration, and pH that, when evaluated for efficacy, yields sanitization as defined in 12VAC5-421-10.

12VAC5-421-1920. Specifications Laundering frequency for linens, cloth gloves, napkins, and wiping cloths.

A. Linens that do not come in direct contact with food shall be laundered between operations if they become wet, sticky, or visibly soiled.

B. Cloth gloves used as specified in 12VAC5-421-580 D shall be laundered before being used with a different type of raw animal food such as beef, lamb, pork, and fish.

C. Linens and napkins that are used as specified under 12VAC5-421-560 and cloth napkins shall be laundered between each use.

D. Wet wiping cloths shall be laundered daily.

E. Dry wiping cloths shall be laundered as necessary to prevent contamination of food and clean serving utensils.

12VAC5-421-2040. Preset tableware.

A. Tableware Except as specified in subsection B of this section, tableware that is preset shall be protected from contamination by being wrapped, covered, or inverted.

B. When Preset tableware is preset, may be exposed, unused settings shall be if:

1. Removed Unused settings are removed when a consumer is seated; or

2. Cleaned and sanitized before further use if the settings are Settings not removed when a consumer is seated are cleaned and sanitized before further use.

12VAC5-421-2045. Rinsing equipment and utensils after cleaning and sanitizing.

After being cleaned and sanitized, equipment and utensils shall not be rinsed before air drying or used unless:

1. The rinse is applied directly from a potable water supply by a warewashing machine that is maintained and operated as specified under Articles 2 (12VAC5-421-1080 et seq.) and 5 (12VAC5-421-1570) of this part; and

2. The rinse is applied only after the equipment and utensils have been sanitized by the application of hot water or by the application of a chemical sanitizer solution whose EPA-registered label use instructions call for rinsing off the sanitizer after it is applied in a commercial warewashing machine.

Part V
Water, Plumbing, and Waste

12VAC5-421-2050. Approved system.

Drinking Pure water shall be obtained from an approved source that is water system defined as:

1. A public water system waterworks constructed, maintained, and operated in compliance with 12VAC5-590; or
2. A nonpublic water system that is private well constructed, maintained, and operated according to law in compliance with 12VAC5-630.

12VAC5-421-2060. System flushing and disinfection.

A drinking water system shall be flushed and disinfected before being placed in service after construction, repair, or modification and after an emergency situation, such as a flood, that may introduce contaminants to the system. A sample shall be collected from the water system and the results of the analysis shall be total coliform negative prior to placing the water system into service.

12VAC5-421-2070. Bottled drinking water.

Bottled drinking water used or sold in a food establishment shall be obtained from approved sources in accordance with 21 CFR Part 129 -Processing and Bottling of Bottled drinking water.

12VAC5-421-2080. Quality Pure water standards.

Except as specified under 12VAC5-421-2090:

1. Water from a public water system waterworks shall meet the applicable water quality and quantity standards found in the Virginia Waterworks Regulations (12VAC5-590) accordance with 12VAC5-590 and

2. Water from a nonpublic water system private well shall meet the bacteriological water quality standards found in the Virginia Waterworks Regulations (12VAC5-590) accordance with 12VAC5-630-370 [and not exceed 10 mg/L of nitrate (as N)].


A. A nondrinking nonpotable water supply shall be used only if its use is approved by the regulatory authority.

B. Nondrinking Nonpotable water shall be used only for nonculinary purposes such as air conditioning, nonfood equipment cooling, fire protection, and irrigation.

12VAC5-421-2100. Sampling.

Except when used as specified under 12VAC5-421-2090, water from a nonpublic water system private well shall be sampled and tested at least annually and as required by state water quality regulations for nitrate and total coliform.

1. If nitrate [(as N), which is reports as "N" on the test results,] exceeds 10 mg/L, the owner shall notify the regulatory authority.

2. If a sample is total coliform positive, the positive culture medium shall be further analyzed to determine if E. coli is present. The owner shall notify the regulatory authority within two days from when the owner is notified of the coliform positive test result.

3. If E. coli is present, the owner shall notify the regulatory authority.

12VAC5-421-2110. Sample report.

The most recent All sample report reports for the nonpublic water system private well shall be retained on file in the food establishment or the report shall be maintained as specified by state water quality regulations for a minimum of five years and be made available to the regulatory authority upon request.

12VAC5-421-2120. Capacity.

A. The approved water source and system capacity shall be of sufficient capacity to meet the maximum daily water demands and the peak hourly water demands of the food establishment.

B. Hot water generation and distribution systems shall be sufficient to meet the peak hot water demands throughout the food establishment.
12VAC5-421-2130. Pressure.

Water under pressure shall be provided to all fixtures, equipment, and nonfood equipment that are required to use water except that water supplied as specified under subdivisions 1 and 2 of 12VAC5-421-2160 to a temporary food establishment or in response to a temporary interruption of a water supply need not be under pressure.\textsuperscript{pf}

12VAC5-421-2150. Distribution, delivery, and retention system. (Repealed.)

Water shall be received from the source through the use of:

1. An approved public water main; or
2. One or more of the following that shall be constructed, maintained, and operated according to law:
   a. Nonpublic water main, water pumps, pipes, hoses, connections, and other appurtenances,
   b. Water transport vehicles, and
   c. Water containers.

12VAC5-421-2160. Alternative water supply.

Water meeting the requirements specified under 12VAC5-421-2050 through 12VAC5-421-2130 shall be made available for a mobile facility, for a temporary food establishment without a permanent water supply, and for a food establishment with a temporary interruption of its water supply through:

1. A supply of containers of commercially bottled drinking water;\textsuperscript{pf}
2. One or more closed portable water containers;\textsuperscript{pf}
3. An enclosed vehicular water tank;\textsuperscript{pf}
4. An on-premises water storage tank;\textsuperscript{pf} or
5. Piping, tubing, or hoses connected to an adjacent approved source system in a manner approved by the department.\textsuperscript{pf}

Article 2

Plumbing System

12VAC5-421-2170. Approved materials.

A. A plumbing system and hoses conveying water shall be constructed and repaired with approved materials according to law.\textsuperscript{p}

B. A water filter shall be made of safe materials.\textsuperscript{p}

12VAC5-421-2180. Approved system and cleanable fixtures.

A. A plumbing system shall be designed, constructed, and installed according to law.\textsuperscript{p}

B. A plumbing fixture such as a handwashing lavatory, toilet, or urinal shall be easily cleanable.

12VAC5-421-2190. Handwashing sink, water temperature, and flow.

A. A handwashing sink shall be equipped to provide water at a temperature of at least 100°F (38°C) through a mixing valve or combination faucet.\textsuperscript{pf}

B. A steam mixing valve shall not be used at a handwashing sink.

C. A self-closing, slow-closing, or metering faucet shall provide a flow of water for at least 15 seconds without the need to reactivate the faucet.

D. An automatic handwashing facility shall be installed in accordance with manufacturer's instructions.
12VAC5-421-2200. Backflow prevention, air gap.

An air gap between the water supply inlet and the flood level rim of the plumbing fixture, equipment, or nonfood equipment shall be at least twice the diameter of the water supply inlet and shall not be less than 4 one inch (25 mm).\textsuperscript{b}

12VAC5-421-2210. Backflow prevention device, design standard.

A backflow or backsiphonage prevention device installed on a water supply system shall comply with the Virginia Statewide Uniform Building Code (13VAC5-63) for construction, installation, maintenance, inspection, and testing for that specific application and type of device.\textsuperscript{p}

12VAC5-421-2230. Handwashing sinks, numbers, and capacities.

A. Except as specified in subsection B and C of this section, at least one handwashing sink, or the number of handwashing sinks necessary for their convenient use by employees in areas specified under 12VAC5-421-2280, and not fewer than the number of handwashing sinks required by law shall be provided.\textsuperscript{b}

B. If approved and capable of removing the types of soils encountered in the food operations involved, automatic handwashing facilities may be substituted for handwashing sinks in a food establishment that has at least one handwashing sink.

B. C. If approved, when food exposure is limited and handwashing sinks are not conveniently available, such as in some mobile or temporary food establishments or at some vending machine locations, employees may use chemically treated towelettes for handwashing.

12VAC5-421-2250. Service sink.

A. At least one service sink or one curbed cleaning facility equipped with a floor drain shall be provided and conveniently located for the cleaning of mops or similar wet floor cleaning tools and for the disposal of mop water and similar liquid waste.

B. Toilets and urinals shall not be used as a service sink for the disposal of mop water and similar liquid waste.

12VAC5-421-2260. Backflow prevention device, when required.

A plumbing system shall be installed to preclude backflow of a solid, liquid, or gas contaminant into the water supply system at each point of use at the food establishment, including on a hose bibb (threaded faucet) if a hose is attached or on a hose bibb if a hose is not attached and backflow prevention is required by law by:

1. Providing an air gap as specified under 12VAC5-421-2200;\textsuperscript{b} or
2. Installing an approved backflow prevention device as specified under 12VAC5-421-2200.\textsuperscript{b}

12VAC5-421-2270. Backflow prevention device, carbonator.

A. If not provided with an air gap as specified under 12VAC5-421-2200, a double check valve with an intermediate vent preceded by a screen of not less than 100 mesh to 1 inch (100 mesh to 25.4mm) shall be installed upstream from a carbonating device and downstream from any copper in the water supply line.\textsuperscript{b}

B. A single or double dual check valve attached to the carbonator need not be of the vented type if an air gap or vented backflow prevention device has been otherwise provided approved as specified under subsection A of this section.

12VAC5-421-2280. Handwashing sinks, location.

A handwashing sink shall be located:

1. To be readily accessible for allow convenient use by employees in food preparation, food dispensing, and warewashing areas;\textsuperscript{b} and
2. In, or immediately adjacent to, toilet rooms.

**12VAC5-421-2310. Using a handwashing sink.**

A. A handwashing sink shall be maintained so that it is accessible at all times for employee use.

B. A handwashing sink shall not be used for purposes other than handwashing.

C. An automatic handwashing facility shall be used in accordance with manufacturer's instructions.

**12VAC5-421-2320. Prohibiting a cross connection.**

A. Except as specified in 9 CFR 308.3(d) for firefighting, a person shall not create a cross connection by connecting a pipe or conduit between the drinking water system and a nondrinking water system or a water system of unknown quality.

B. The piping of a nondrinking water system shall be durably identified so that it is readily distinguishable from piping that carries drinking water.

**12VAC5-421-2330. Scheduling inspection and service for a water system device.**

A device such as a water treatment device or backflow preventer shall be scheduled for inspection and service, in accordance with manufacturer's instructions and as necessary to prevent device failure based on local water conditions, and records demonstrating inspection and service shall be maintained by the person in charge.

**12VAC5-421-2340. Water reservoir of fogging devices, cleaning.**

A. A reservoir that is used to supply water to a device such as a produce fogger shall be:

1. Maintained in accordance with manufacturer's specifications; and
2. Cleaned in accordance with manufacturer's specifications or according to the procedures specified under subsection B of this section, whichever is more stringent.

B. Cleaning procedures shall include at least the following steps and shall be conducted at least once a week:

1. Draining and complete disassembly of the water and aerosol contact parts;
2. Brush-cleaning the reservoir, aerosol tubing, and discharge nozzles with a suitable detergent solution;
3. Flushing the complete system with water to remove the detergent solution and particulate accumulation; and
4. Rinsing by immersing, spraying, or swabbing the reservoir, aerosol tubing, and discharge nozzles with at least 50 mg/L (ppm) hypochlorite solution.

**12VAC5-421-2350. System maintained in good repair.**

A plumbing system shall be (i) repaired according to law and (ii) maintained in good repair.

**Article 3**

Mobile Water Tank and Mobile Food Establishment Water Tank

**12VAC5-421-2360. Approved Mobile water tank approved materials.**

Materials that are used in the construction of a mobile water tank, mobile food establishment water tank, and appurtenances shall be:

1. Safe;
2. Durable, corrosion resistant, and nonabsorbent; and
3. Finished to have a smooth, easily cleanable surface.

**12VAC5-421-2420. Hose, construction and identification.**

A hose used for conveying drinking potable water from a water tank shall be:
1. Safe;
2. Durable, corrosion resistant, and nonabsorbent;
3. Resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition;
4. Finished with a smooth interior surface; and
5. Clearly and durably identified as to its use if not permanently attached.

12VAC5-421-2430. Filter, compressed air.

A filter that does not pass oil or oil vapors shall be installed in the air supply line between the compressor and drinking potable water system when compressed air is used to pressurize the water tank system.²

12VAC5-421-2460. System flushing and disinfection.

A water tank, pump, and hoses shall be flushed and sanitized before being placed in service after construction, repair, modification, and periods of nonuse.²

12VAC5-421-2490. Tank, pump, and hoses, dedication.

A. Except as specified in subsection B of this section, a water tank, pump, and hoses used for conveying drinking water shall be used for no other purpose.²

B. Water tanks, pumps, and hoses approved for liquid foods may be used for conveying drinking water if they are cleaned and sanitized before they are used to convey water.


A. Except as specified in subsections B, C, and D of this section, a direct connection may not exist between the sewage system and a drain originating from equipment in which food, portable equipment, or utensils are placed.²

B. Subsection A of this section does not apply to floor drains that originate in refrigerated spaces that are constructed as an integral part of the building.

C. If allowed by law, a warewashing machine may have a direct connection between its waste outlet and a floor drain when the machine is located within five feet (1.5 meters) of a trapped floor drain and the machine outlet is connected to the inlet side of a properly vented floor drain trap.

D. If allowed by law, a warewashing or culinary sink may have a direct connection.

12VAC5-421-2540. Conveying sewage.

Sewage shall be conveyed to the point of disposal through an approved sanitary sewage system or other system, including use of sewage transport vehicles, waste retention tanks, pumps, pipes, hoses, and connections that are constructed, maintained, and operated according to law.²

12VAC5-421-2550. Removing mobile food establishment wastes.

Sewage No public health hazard or nuisance shall result when sewage and other liquid wastes shall be are removed from a mobile food establishment at an approved waste servicing area or by a permitted sewage transport vehicle in such a way that a public health hazard or nuisance is not created.²

12VAC5-421-2570. Approved sewage disposal system.

Sewage shall be disposed through an approved facility that is:

1. A public sewage treatment plant;² or
2. An individual sewage disposal system that is sized, constructed, maintained, and operated according to law the State Board of Health’s regulations promulgated pursuant
to Chapter 6 (§ 32.1-163 et seq.) of Title 32 of the Code of Virginia, including 12VAC5-610, 12VAC5-613, and 12VAC5-640.

12VAC5-421-2990. Private homes and living or sleeping quarters, use prohibition.

A private home, a room used as living or sleeping quarters, or an area directly opening into a room used as living or sleeping quarters shall not be used for conducting food establishment operations.

Article 3

Numbers and Capacities

12VAC5-421-3020. Handwashing cleanser, availability.

Each handwashing sink or group of two adjacent handwashing sinks shall be provided with a supply of hand cleaning liquid, powder, or bar soap.

12VAC5-421-3030. Hand drying provision.

Each handwashing sink or group of adjacent handwashing sinks shall be provided with:

1. Individual, disposable towels;
2. A continuous towel system that supplies the user with a clean towel; or
3. A heated-air hand drying device; or
4. A hand drying device that employs an air-knife system that delivers high-velocity, pressurized air at ambient temperatures.

12VAC5-421-3070. Toilet tissue, availability.

A supply of toilet tissue shall be available at each toilet.

12VAC5-421-3150. Distressed merchandise, segregation and location.

Products that are held by the permit holder for credit, redemption, or return to the distributor, such as damaged, spoiled, or recalled products, shall be segregated and held in designated areas that are separated from food, equipment, utensils, linens, and single-service and single-use articles.

12VAC5-421-3210. Cleaning maintenance tools, preventing contamination.

Food preparation sinks, handwashing lavatories, and warewashing equipment shall not be used for the cleaning of maintenance tools, the preparation or holding of maintenance materials, or the disposal of mop water and similar liquid wastes.

12VAC5-421-3270. Controlling pests.

The presence of insects, rodents, and other pests shall be controlled to minimize their presence on the premises by:

1. Routinely inspecting incoming shipments of food and supplies;
2. Routinely inspecting the premises for evidence of pests;
3. Using methods, if pests are found, such as trapping devices or other means of pest control as specified under 12VAC5-421-3360, 12VAC5-421-3440, and 12VAC5-421-3450; and
4. Eliminating harborage conditions.

12VAC5-421-3310. Prohibiting animals.

A. Except as specified in subsections B and C of this section, live animals shall not be allowed on the premises of a food establishment.

B. Live animals may be allowed in the following situations if the contamination of food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles cannot result:
1. Edible fish or decorative fish in aquariums, shellfish or crustacea on ice or under refrigeration, and shellfish and crustacea in display tank systems;

2. Patrol dogs accompanying police or security officers in offices and dining, sales, and storage areas, and sentry dogs running loose in outside fenced areas;

3. In areas that are not used for food preparation and that are usually open for customers, such as dining and sales areas, service animals that are controlled by the disabled employee or person, if a health or safety hazard will not result from the presence or activities of the service animal;

4. Pets in the common dining areas of institutional care facilities such as nursing homes, assisted living facilities, group homes, or residential care facilities, and food establishment bed and breakfast facilities at times other than during meals if:
   a. Effective partitioning and self-closing doors separate the common dining areas from food storage or food preparation areas;
   b. Condiments, equipment, and utensils are stored in enclosed cabinets or removed from the common dining areas when pets are present; and
   c. Dining areas including tables, countertops, and similar surfaces are effectively cleaned before the next meal service; and

5. In areas that are not used for food preparation, storage, sales, display, or dining, in which there are caged animals or animals that are similarly restricted, such as in a variety store that sells pets or a tourist park that displays animals.

6. Dogs in outdoor dining areas if:
   a. The outdoor dining area is not fully enclosed with floor to ceiling walls and is not considered a part of the interior physical facility.
   b. 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.
   c. 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.
   
   [d. A sign within the outdoor dining area stating the requirements as specified in subdivisions 6 e, f, and g of this subsection is provided in such a manner as to be clearly observable by the public.]

   [d-e.] 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.

   [e-f.] Dogs are not allowed on chairs, seats, benches, or tables.

   [f-g.] Dogs are kept on a leash or within a pet carrier and under the control of an adult at all times.

   [g-h.] Establishment provides effective means for cleaning up dog vomitus and fecal matter.

   [h. A sign within the outdoor dining area stating the requirements as specified in subdivisions 6 d, e, and f of this subsection is provided in such a manner as to be clearly observable by the public.]

   C. Live or dead fish bait may be stored if contamination of food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles can not result.
D. In bed and breakfast facilities serving 18 or fewer customers, live animals shall be
allowed in the facility but shall not be fed using the same equipment or utensils that are used to
feed humans.

Part VII
Poisonous or Toxic Materials

Article 1
Labeling and Identification

12VAC5-421-3320. Original containers - identifying information, prominence.
Containers of poisonous or toxic materials and personal care items shall bear a legible
manufacturer's label.\(^1\)

12VAC5-421-3330. Working containers - common name.
Working containers used for storing poisonous or toxic materials such as cleaners and
sanitizers taken from bulk supplies shall be clearly and individually identified with the common
name of the material.\(^1\)

Article 2
Operational Supplies and Applications

12VAC5-421-3340. Storage, separation.
Poisonous or toxic materials shall be stored so they cannot contaminate food,
equipment, utensils, linens, and single-service and single-use articles by:

1. Separating the poisonous or toxic materials by spacing or partitioning; \(^1\) and

2. Locating the poisonous or toxic materials in an area that is not above food,
equipment, utensils, linens, and single-service or single-use articles. This subsection
does not apply to equipment and utensil cleaners and sanitizers that are stored in
warewashing areas for availability and convenience if the materials are stored to prevent
contamination of food, equipment, utensils, linens, and single-service and single-use
articles; \(^1\) and\(^2\)

3. Detergents, sanitizers, related cleaning or drying agents and caustics, acids, polishes
and other chemicals shall be stored separately from insecticides and rodenticides.

12VAC5-421-3350. Presence and use restriction.
A. Only those poisonous or toxic materials that are required for the operation and
maintenance of a food establishment, such as for the cleaning and sanitizing of equipment and
utensils and the control of insects and rodents, shall be allowed in a food establishment.\(^1\)
B. Subsection A of this section does not apply to packaged poisonous or toxic materials that
are for retail sale.

12VAC5-421-3360. Conditions of use.
Poisonous or toxic materials shall be:

1. Used according to:
   a. Law and this chapter; \(^1\)
   b. Manufacturer's use directions included in labeling, and, for a pesticide,
manufaturer's label instructions that state that use is allowed in a food
establishment; \(^1\)
   c. The conditions of certification, if certification is required, for use of the pest control
materials; \(^1\) and
   d. Additional conditions that may be established by the regulatory authority; \(^1\)

2. Applied so that:
a. A hazard to employees or other persons is not constituted, and
b. Contamination including toxic residues due to drip, drain, fog, splash, or spray on food, equipment, utensils, linens, and single-service and single-use articles is prevented, and for a restricted-use pesticide, this is achieved by:
(1) Removing the items, covering the items with impermeable covers, or taking other appropriate preventive actions, and
(2) Cleaning and sanitizing equipment and utensils after the application.

3. A restricted use pesticide shall be applied only by an applicator certified as defined in 7 USC § 136(e) (Federal Insecticide, Fungicide and Rodenticide Act), or a person under the direct supervision of a certified applicator.

12VAC5-421-3370. Poisonous or toxic material containers.
A container previously used to store poisonous or toxic materials shall not be used to store, transport, or dispense food.

12VAC5-421-3380. Sanitizers, criteria.
Chemical sanitizers, including chemical sanitizing solutions generated on site, and other chemical antimicrobials applied to food-contact surfaces shall meet:
1. Meet the requirements specified in 40 CFR 180.940, or

12VAC5-421-3390. Chemicals for washing fruits and vegetables, criteria.
A. Chemicals, including those generated on site, used to wash or peel raw, whole fruits and vegetables shall meet the requirements specified in 21 CFR 173.315:
1. Be an approved food additive listed for this intended use in 21 CFR 173, or
2. Be generally recognized as safe (GRAS) for this intended use, or
3. Be the subject of an effective food contact notification for this intended use (only effective for the manufacturer or supplier identified in the notification), and
4. Meet the requirements in the 40 CFR Part 156.

B. Ozone as an antimicrobial agent used in the treatment, storage, and processing of fruits and vegetables in a food establishment shall meet the requirements specified in 21 CFR 173.368.

12VAC5-421-3400. Boiler water additives, criteria.
Chemicals used as boiler water additives shall meet the requirements specified in 21 CFR 173.310.

12VAC5-421-3410. Drying agents, criteria.
Drying agents used in conjunction with sanitization shall:
1. Contain only components that are listed as one of the following:
   a. Generally recognized as safe for use in food as specified in 21 CFR Part 182 - Substances Generally Recognized as Safe, or 21 CFR Part 184 - Direct Food Substances Affirmed as Generally Recognized as Safe,
   b. Generally recognized as safe for the intended use as specified in 21 CFR Part 186 - Indirect Food Substances Affirmed as Generally Recognized as Safe,
   c. Generally recognized as safe for the intended use as determined by experts qualified in scientific training and experience to evaluate the safety of substances added, directly or indirectly, to food as described in 21 CFR 170.30,
   d. Subject of an effective Food Contact Notification as described in the Federal Food Drug and Cosmetic Act (FFDCA) § 409(h).
Approved for use as a drying agent under a prior sanction specified in 21 CFR Part 181 - Prior-Sanctioned Food Ingredients, as specified in the Federal Food Drug and Cosmetic Act (FFDCA) § 201(s)(4).  

Specifically regulated as an indirect food additive for use as a drying agent as specified in 21 CFR Parts 175- through 178, or

Approved for use as a drying agent under the threshold of regulation process established by 21 CFR 170.39 - Threshold of Regulation for Substances Used in Food-contact Articles.  

2. When sanitization is with chemicals, the approval required under subdivisions subdivision 1 c e or e g of this section or the regulation as an indirect food additive required under subdivision 1 d f of this section, shall be specifically for use with chemical sanitizing solutions.

12VAC5-421-3420. Lubricants - incidental food contact, criteria.

Lubricants shall meet the requirements specified in 21 CFR 178.3570 if they are used on food-contact surfaces, on bearings and gears located on or within food-contact surfaces, or on bearings and gears that are located so that lubricants may leak, drip, or be forced into food or onto food-contact surfaces.

12VAC5-421-3430. Restricted use pesticides, criteria.

Restricted use pesticides specified under subdivision 3 of 12VAC5-421-3360 C shall meet the requirements specified in 40 CFR 152, Subpart I - Classification of Pesticides.

12VAC5-421-3440. Rodent bait stations.

Rodent bait shall be contained in a covered, tamper-resistant bait station.

12VAC5-421-3450. Tracking powders, pest control, and monitoring.

A. Except as specified in subsection B of this section, a tracking powder pesticide shall not be used in a food establishment.

B. If used, a nontoxic tracking powder such as talcum or flour shall not contaminate food, equipment, utensils, linens, and single-service and single-use articles.

12VAC5-421-3460. Medicines - restriction and storage.

A. Except for medicines that are stored or displayed for retail sale, only those medicines that are necessary for the health of employees shall be allowed in a food establishment.

B. Medicines that are in a food establishment for the employees' use shall be labeled as specified under 12VAC5-421-3320 and located to prevent the contamination of food, equipment, utensils, linens, and single-service and single-use articles.

12VAC5-421-3470. Refrigerated medicines, storage.

Medicines belonging to employees or to children in a day care center that require refrigeration and are stored in a food refrigerator shall be:

1. Stored in a package or container and kept inside a covered, leakproof container that is identified as a container for the storage of medicines, and

2. Located so they are inaccessible to children.

12VAC5-421-3480. First aid supplies, storage.

First aid supplies that are in a food establishment for the employees' use shall be:

1. Labeled as specified under 12VAC5-421-3320, and

2. Stored in a kit or a container that is located to prevent the contamination of food, equipment, utensils, and linens, and single-service and single-use articles.
12VAC5-421-3500. Storage and display, separation.

Poisonous or toxic materials shall be stored and displayed for retail sale so they cannot contaminate food, equipment, utensils, linens, and single-service and single-use articles by:

1. Separating the poisonous or toxic materials by spacing or partitioning; and
2. Locating the poisonous or toxic materials in an area that is not above food, equipment, utensils, linens, and single-service or single-use articles.

12VAC5-421-3590. Disposition of a variance request.

A. The commissioner may grant the variance request and if he proposes to deny the variance he shall provide the owner an opportunity to an informal hearing fact-finding conference as provided in § 2.2-4019 of the Code of Virginia. Following this opportunity for an informal hearing fact-finding conference the commissioner may reject any application for a variance by sending a rejection notice to the applicant. The rejection notice shall be in writing and shall state the reasons for the rejection. A rejection notice constitutes a case decision.

B. If the commissioner proposes to grant a variance request submitted pursuant to this part, the applicant shall be notified in writing of this decision. Such notice shall identify the variance, the food establishment involved, and shall specify the period of time for which the variance will be effective. Such notice shall provide that the variance will be terminated when the food establishment comes into compliance with the applicable regulation and may be terminated upon a finding by the commissioner that the food establishment has failed to comply with any requirements or schedules issued in conjunction with the variance. The effective date of the variance shall be as noted in the variance letter.

C. All variances granted to any food establishment may not be transferable unless otherwise stated. Each variance shall be attached to the permit to which it is granted. Each variance is revoked when the permit to which it is attached operate and posted prominently in a conspicuous place for public view.

D. No owner or permit holder may challenge the terms or conditions of a variance after 30 calendar days have elapsed from the receipt of the variance.

E. Each variance shall be posted prominently in a conspicuous place for public view and in close proximity to the permit to which it relates. Each variance is revoked when the permit to which it operate is attached is revoked, suspended, or if the permit is not revalidated or renewed expired.

12VAC5-421-3600. Facility and operating plans - when plans are required.

A permit applicant or permit holder shall submit to the regulatory authority properly prepared plans and specifications for review and approval before:

1. The construction of a food establishment;
2. The conversion of an existing structure for use as a food establishment; or
3. The remodeling of a food establishment or a change of type of food establishment or food operation as specified under 12VAC5-421-3710 C subsection 3 in 12VAC-421-3700 if the regulatory authority determines that plans and specifications are necessary to ensure compliance with this regulation this chapter.
When a HACCP plan is required.

A. Before engaging in an activity that requires a HACCP plan, a permit applicant or permit holder shall submit to the regulatory authority for approval a properly prepared HACCP plan as specified under 12VAC5-421-3630 and the relevant provisions of this chapter if:

1. Submission of a HACCP plan is required according to law;
2. A variance is required as specified under 12VAC5-421-860, 12VAC5-421-1300 B, or 12VAC5-421-700 D 2; or
3. The regulatory authority determines that a food preparation or processing method requires a variance based on a plan submittal specified under 12VAC5-421-3610, an inspectional finding, or a variance request.

B. A permit applicant or permit holder shall have a properly prepared HACCP plan before engaging in reduced oxygen packaging without a variance as specified under 12VAC5-421-870, a permit applicant or permit holder shall submit a properly prepared HACCP plan to the regulatory authority.

12VAC5-421-3630. Contents of a HACCP plan.

For a food establishment that is required under 12VAC5-421-3620 to have a HACCP plan, the plan and specifications shall indicate the permit applicant or permit holder shall submit to the regulatory authority a properly prepared HACCP plan that includes:

1. General information such as the name of the permit applicant or permit holder, the food establishment address, and contact information;
2. A categorization of the types of potentially hazardous foods time/temperature control for safety food that are specified in the menu such as soups and sauces, salads, and bulk, solid foods such as meat roasts, or of other foods that are specified by the regulatory authority is to be controlled under the HACCP plan;
3. A flow diagram by specific food or category type identifying critical control points and providing information on the following or chart for each specific food or category type that identifies:
   a. Each step in the process;
   b. The hazards and controls for each step in the flow diagram or chart;
   c. The steps that are critical control points;
   a. Ingredients;
   d. The ingredients, materials, and equipment used in the preparation of that food, and
   b. e. Formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved;
3. Food employee and supervisory training plan that addresses the food safety issues of concern.
4. A statement of standard operating procedures for the plan under consideration including clearly identifying A critical control point summary for each specific food or category type that clearly identifies:
   a. Each critical control point;
   b. The critical limits for each critical control point;
   c. The method and frequency for monitoring and controlling each critical control point by the food employee designated by the person in charge;
   d. The method and frequency for the person in charge to routinely verify that the food employee is following standard operating procedures and monitoring critical control points.
e. Action to be taken by the person in charge if the critical limits for each critical control point are not met; and

f. Records to be maintained by the person in charge to demonstrate that the HACCP plan is properly operated and managed; and

5. Supporting documents such as:
   a. Food employee and supervisory training plan addressing food safety issues; 
   b. Copies of blank records forms that are necessary to implement a HACCP plan; 
   c. Additional scientific data or other information, as required by the regulatory authority supporting the determination that food safety is not compromised by the proposal.

5. Additional scientific data or other information, as required by the regulatory authority, supporting the determination that food safety is not compromised by the proposal.

6. Any other information required by the regulatory authority.

12VAC5-421-3670. Application procedure, submission 30 calendar days before proposed opening.

An applicant seeking to operate a nontemporary food establishment shall submit an application for a permit at least 30 calendar days before the date planned for opening a food establishment or at least 30 calendar days before the expiration date of the current permit for an existing facility. An applicant seeking to operate a temporary food establishment shall submit an application for a permit at least 10 calendar days before the date planned for opening the temporary food establishment.

12VAC5-421-3700. Contents of the application.

The application shall include:

1. The name, mailing address, telephone number, and signature of the person applying for the permit and the name, mailing address, and location of the food establishment;

2. Information specifying whether the food establishment is owned by an association, corporation, individual, partnership, or other legal entity;

3. A statement specifying whether the food establishment:
   a. Is mobile or stationary and temporary or permanent; and
   b. Is an operation that includes one or more of the following:
      (1) Prepares, offers for sale, or serves potentially hazardous food time/temperature control for safety food:
         (a) Only to order upon a consumer's request;
         (b) In advance in quantities based on projected consumer demand and discards food that is not sold or served at an approved frequency; or
         (c) Using time as the public health control as specified under 12VAC5-421-850;
      (2) Prepares potentially hazardous food time/temperature control for safety food in advance using a food preparation method that involves two or more steps which may include combining potentially hazardous time/temperature control for safety food ingredients; cooking; cooling; reheating; hot or cold holding; freezing; or thawing;
      (3) Prepares food as specified under subdivision 3 b (2) of this section for delivery to and consumption at a location off the premises of the food establishment where it is prepared;
      (4) Prepares food as specified under subdivision 3 b (2) of this section for service to a highly susceptible population;
4. The name, title, address, and telephone number of the person directly responsible for the food establishment;

5. The name, title, address, and telephone number of the person who functions as the immediate supervisor of the person specified under subdivision 4 of this section such as the zone, district, or regional supervisor;

6. The names, titles, and addresses of:
   a. The persons comprising the legal ownership as specified under subdivision 2 of this section including the owners and officers; and
   b. The local resident agent if one is required based on the type of legal ownership;

7. A statement signed by the applicant that:
   a. Attests to the accuracy of the information provided in the application; and
   b. Affirms that the applicant will:
      (1) Comply with this chapter; and
      (2) Allow the regulatory authority access to the establishment as specified under 12VAC5-421-3820 and to the records specified under 12VAC5-421-440 and 12VAC5-421-2330 and subdivision 4 of 12VAC5-421-3630; and

8. Other information required by the regulatory authority.

12VAC5-421-3770. Suspension Summary suspension of a permit.

The director may summarily suspend without a hearing a permit to operate a restaurant if the director finds the continued operation constitutes a substantial and imminent threat to the public health, except the director may summarily suspend the permit of a temporary restaurant as addressed under 12VAC5-421-3870. Upon receipt of such notice that a permit is suspended, the permit holder shall cease food operations immediately and begin corrective action.

Whenever a permit is suspended, the holder of the permit or the person in charge shall be notified in writing by certified mail or by hand delivery. Upon service of notice that the permit is immediately suspended, the former permit holder shall be given an opportunity for an informal fact-finding conference in accordance with § 2.2-4019 of the Code of Virginia. The request for a hearing an informal fact-finding conference shall be in writing. The written request shall be filed with the local department by the former holder of the permit. If written request for a hearing an informal fact-finding conference is not filed within 10 working days, the suspension is sustained. Each holder of a suspended permit shall be afforded an opportunity for an informal fact-finding conference, within three working days of receipt of a request for the hearing informal fact-finding conference. The director may end the suspension at any time if the reasons for the suspension no longer exist.

12VAC5-421-3780. Revocation of a permit.

The director may, after providing an opportunity for a hearing an informal fact-finding conference in accordance with § 2.2-4019 of the Code of Virginia, revoke a permit for flagrant or continuing violation of any of the requirements of this part.

Prior to revocation, the director shall notify in writing the holder of the permit, or the person in charge, of the specific reason for which the permit is to be revoked. The permit shall be revoked at the end of the 15 days following service of such notice unless a written request for a hearing is filed before then with the director from which the permit was obtained. If no request for a hearing is filed within the 15 day period, the revocation of the permit shall be final.
Article 4
Inspection and Correction of Violations

12VAC5-421-3800. Periodic inspection.

Food establishments shall be inspected by the designee of the director. Inspections of the food establishments shall be performed as often as necessary for the enforcement of this part in accordance with the following:

1. Except as specified in subdivisions 2 and 3 of this section, the regulatory authority shall inspect a food establishment at least once every six months.

2. The regulatory authority may increase the interval between inspections beyond six months if:
   a. The food establishment is fully operating under an approved and validated HACCP plan as specified under 12VAC5-421-3630;
   b. The food establishment is assigned a less frequent inspection frequency based on a written risk-based inspection schedule that is being uniformly applied throughout the jurisdiction Commonwealth and at least once every six months the establishment is contacted by telephone or other means by the regulatory authority to ensure that the establishment manager and the nature of the food operation are not changed updated annually upon reissuance of the annual permit; or
   c. The establishment's operation involves only coffee service and other unpackaged or prepackaged food that is not potentially hazardous time/temperature control for safety food, such as carbonated beverages and snack food such as chips, nuts, popcorn, and pretzels.

3. The regulatory authority shall periodically inspect throughout its permit period a temporary food establishment that prepares, sells, or serves unpackaged potentially hazardous food and that during its permit period, unless the Virginia Department of Health develops a written risk-based plan for adjusting the frequency of inspections of temporary food establishments that is uniformly applied throughout the Commonwealth.
   a. Has improvised rather than permanent facilities or equipment for accomplishing functions such as handwashing, food preparation and protection, food temperature control, warewashing, providing drinking water, waste retention and disposal, and insect and rodent control; or
   b. Has inexperienced food employees.


Within the parameters specified in 12VAC5-421-3800, the regulatory authority shall prioritize, and conduct more frequent inspections based upon its assessment of a food establishment's history of compliance with this chapter and the establishment's potential as a vector of foodborne illness by evaluating:

1. Past performance for nonconformance with this chapter or HACCP plan requirements that are critical priority items or priority foundation items;
2. Past performance for numerous or repeat violations of this chapter or HACCP plan requirements that are noncritical core items;
3. Past performance for complaints investigated and found to be valid;
4. The hazards associated with the particular foods that are prepared, stored, or served;
5. The type of operation including the methods and extent of food storage, preparation, and service;
6. The number of people served; and
7. Whether the population served is a highly susceptible population.

12VAC5-421-3815. Competency of environmental health specialists.

A. An authorized representative of the commissioner who inspects a food establishment or conducts plan review for compliance with this chapter shall have the knowledge, skills, and ability to adequately perform the required duties. For the purposes of this section, competency shall be demonstrated when an environmental health specialist meets the training and standardization requirements specified in the Virginia Department of Health Procedures for Certification and Standardization of Retail Food Protection Staff, 2014, (VDH, Division of Food and Environmental Services).

B. The regulatory authority shall ensure that authorized representatives who inspect a food establishment or conduct plan review for compliance with this chapter have access to training and continuing education as needed to properly identify violations and apply this chapter.

12VAC5-421-3860. Documenting information and observations.

The regulatory authority shall document on an inspection report form:

1. Administrative information about the food establishment's legal identity, street and mailing addresses, type of establishment and operation as specified under 12VAC5-421-3700, inspection date, and other information such as type of water supply and sewage disposal, status of the permit, and personnel certificates that may be required; and

2. Specific factual observations of violative conditions or other deviations from this chapter that require correction by the permit holder including:

   a. Failure of the person in charge to demonstrate the knowledge of foodborne illness prevention, application of HACCP principles, and the requirements of this chapter specified under 12VAC5-421-60;

   b. Failure of food employees, conditional employees, and the person in charge to demonstrate their knowledge of their responsibility to report a disease or medical condition as specified under 12VAC5-421-80 B and D;

   c. Nonconformance with critical priority items or priority foundation items of this chapter;

   d. Failure of the appropriate food employees to demonstrate their knowledge of, and ability to perform in accordance with, the procedural, monitoring, verification, and corrective action practices required by the regulatory authority as specified under 12VAC5-421-60;

   e. Failure of the person in charge to provide records required by the regulatory authority for determining conformance with a HACCP plan as specified under subdivision 4 f of 12VAC5-421-3630; and

   f. Nonconformance with critical limits of a HACCP plan.

12VAC5-421-3910. Imminent health hazard, ceasing operations and reporting.

A. Except as specified in subsection B of this section, a permit holder shall immediately discontinue operations and notify the regulatory authority if an imminent health hazard may exist because of an emergency such as a fire, flood, extended interruption of electrical or water service, sewage backup, misuse of poisonous or toxic materials, onset of an apparent foodborne illness outbreak, gross insanitary occurrence or condition, or other circumstance that may endanger public health.

B. A permit holder need not discontinue operations in an area of an establishment that is unaffected by the imminent health hazard.
12VAC5-421-3930. Critical violation, timely correction.

A. Except as specified in subsection B of this section, a permit holder shall at the time of inspection correct a critical violation of priority item or priority foundation item in this chapter and implement corrective actions for a HACCP plan provision that is not in compliance with its critical limit.\(^\text{21}\)

B. Considering the nature of the potential hazard involved and the complexity of the corrective action needed, the regulatory authority may agree to or specify a longer timeframe, not to exceed 10 calendar days:

1. 72 hours after the inspection, for the permit holder to correct critical violations priority items; or
2. 10 calendar days after the inspection for the permit holder to correct priority foundation items or HACCP plan deviations.

12VAC5-421-3940. Verification and documentation of correction.

A. After observing at the time of inspection a correction of a critical violation or deviation priority item or priority foundation item, the regulatory authority shall enter the violation observation and information about the corrective action on the inspection report.

B. As specified under 12VAC5-421-3930 B, after receiving notification that the permit holder has corrected a critical violation priority item or priority foundation item or a HACCP plan deviation, or at the end of the specified period of time, the regulatory authority shall verify the correction of the violation, document the information on an inspection report, and enter the report in the regulatory authority's records.

12VAC5-421-3950. Noncritical violation Core item, timeframe for correction.

A. Except as specified in subsection B of this section, the permit holder shall correct noncritical violations core items by a date and time agreed to or specified by the regulatory authority but no later than 90 calendar days after the inspection.

B. The regulatory authority may approve a compliance schedule that extends beyond the time limits specified under subsection A of this section if a written schedule of compliance is submitted by the permit holder and no health hazard exists or will result from allowing an extended schedule for compliance.

12VAC5-421-3960. Examination for condemnation of food.

Food may be examined or sampled by the department as often as necessary for enforcement of this chapter. Also, the department may, upon written notice to the owner or permit holder or person in charge impound any food which it believes is in violation of Part III (12VAC5-421-260 et seq.) or any other section of this chapter. The department shall tag, label, or otherwise identify any food subject to impoundment. No food under conditions specified in the impoundment shall be used, served or moved from the establishment. The department shall permit storage of the food under conditions specified in the impoundment unless storage is not possible without risk to the public health in which case immediate destruction shall be ordered and accomplished by the owner or permit holder or person in charge. The impoundment shall state that a request for a hearing an informal fact-finding conference may be filed within 10 days and that if no hearing conference is requested, the food shall be destroyed by the owner or permit holder or person in charge. A hearing shall be held. The department shall hold an informal fact-finding conference if so requested, and on the basis of evidence produced at the hearing, the impoundment may be vacated, or the owner or permit holder or person in charge of the food may be directed by written order in writing by the director to denature or destroy such food or to bring it into compliance with the provisions of this chapter.
12VAC5-421-3970. Enforcement of regulation.

A. This chapter shall be enforced by the State Board of Health and the State Health Commissioner, as executive officer of the board.

B. The directors are appointed by the board and commissioner as duly designated officers and are responsible for the implementation and enforcement of this chapter.

C. All food establishments shall operate in compliance with the requirements set forth in this chapter and shall not operate without a valid permit.

D. The commissioner shall be vested with all the authority of the board when it is not in session, subject to such rules and regulations as may be prescribed by the board.

E. Pursuant to the authority granted in §§ 32.1-26 and 35.1-6 of the Code of Virginia, the commissioner may issue orders to require any owner or permit holder or other person to comply with the provisions of these regulations this chapter. The order may require the following:

1. The immediate cessation and correction of the violation;
2. Appropriate remedial action to ensure that the violation does not continue or recur;
3. The submission of a plan to prevent future violations;
4. The submission of an application for a variance; and
5. Any other corrective action deemed necessary for proper compliance with the regulations.

F. Before the issuance of an order, the commissioner must comply with the requirements of § 35.1-6 of the Code of Virginia.

G. All orders issued pursuant to 12VAC5-421-3970 C shall become effective not less than 15 days after mailing a copy thereof by certified mail to the last known address of the owner or permit holder or person violating these regulations. Violation of an order is a Class 3 misdemeanor. See § 35.1-7 of the Code of Virginia.

H. The commissioner may act as the agent of the board to enforce all effective orders and these regulations this chapter. Should any owner or permit holder fail to comply with any effective order or these regulations this chapter, the commissioner may:

1. Institute a proceeding to revoke the owner's or permit holder's permit in accordance with 12VAC5-421-3780;
2. Request the attorney for the Commonwealth to bring a criminal action;
3. Request the Attorney General to bring an action for civil penalty, injunction, or other appropriate remedy; or
4. Do any combination of the above.

I. Not exclusive means of enforcement. Nothing contained in 12VAC5-421-3970 this section shall be interpreted to require the commissioner to issue an order prior to seeking enforcement of any regulations or statute through an injunction, mandamus or criminal prosecution.

J. Hearings Proceedings before the commissioner or his designee shall include any of the following forms depending on the nature of the controversy and the interests of the parties involved.

1. Informal hearings fact-finding conferences. An informal hearing fact-finding conference is a meeting with a district or local health department with the district or local health director presiding and held in conformance with § 2.2-4019 of the Code of Virginia.
2. Adjudicatory hearing. The adjudicatory hearing is a formal, public adjudicatory proceeding before the commissioner, or his designated hearing officer.
as defined by § 2.2-4001 of the Code of Virginia, and held in conformance with § 2.2-4020 of the Code of Virginia.


A request for an informal hearing fact-finding conference shall be made by sending the request in writing to the district or local health department in the locality where the food establishment is located. Requests for hearings on informal fact-finding conference shall cite the reason(s) or reasons for the hearing request and shall cite the section(s) of these regulations involved and must be received within 30 days of the decision by the department that lead to the hearing request.

12VAC5-421-3990. Hearing as a matter of right. (Repealed.)

Any owner or permit holder or named party whose rights, duties, or privileges have been, or may be affected by any case decision of the board or its subordinates in the administration of these regulations, shall have a right to both informal and adjudicatory hearings. The commissioner may require participation in an informal hearing before granting the request for a full adjudicatory hearing. Exception: No person other than an owner shall have the right to an adjudicatory hearing to challenge the issuance of a permit to operate unless the person can demonstrate at an informal hearing that the minimum standards contained in these regulations have not been applied and that he will be injured in some manner by the issuance of the permit.

12VAC5-421-4000. Appeals.

A. Any appeal from a denial of a permit to operate a food establishment must be made in writing and received by the department within 30 days after service of the final order in the case decision denial. In the event that service of the case decision upon a party is accomplished by mail, three days shall be added to the 30-day period. Notice shall be consistent with Part 2A of the Rules of the Supreme Court of Virginia.

1. Any request for hearing on the denial of an application for a variance pursuant to 12VAC5-421-3590.A must be made in writing and received within sixty days of receipt of the denial notice.

2. Any request for a variance must be made in writing and received by the department prior to the denial of the food establishment permit, or within 60 days after such denial.

3. In the event a person applies for a variance within the 60-day period provided by subdivision 2 of this section, the date for appealing the denial of the permit, pursuant to subdivision 1 of this section, shall commence from the date on which the department acts on the request for a variance.

4. B. Pursuant to the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia) an aggrieved owner or permit holder may appeal a final case decision of the commissioner to an appropriate circuit court.

FORMS (12VAC5-421)

Foodservice Establishment Inspection Report, EHS-152 (rev. 9/95).


Food Establishment Inspection Report Form - Cover Page (eff. 2016)

Food Establishment Inspection Report Form - Narrative Page with Temperatures (eff. 2016)

Food Establishment Inspection Report Form - Narrative Page (eff. 2016)

DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-421)


Grade "A" Pasteurized Milk Ordinance, 2013 Revision, U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Milk Safety Branch (HFS-626), 5100 Paint Branch Parkway, College Park, MD 20740-3835

Interstate Certified Shellfish Shippers List (updated monthly), published by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Office of Seafood (HFS-417), 5100 Paint Branch Parkway, College Park, MD 20740-3835


National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish, 2013 Revision, U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Office of Seafood (HFS-417), 5100 Paint Branch Parkway, College Park, MD 20740-3835


Standards for Accreditation of Food Protection Manager Certification Programs, April 2012, Conference for Food Protection, 30 Elliott Court, Martinsville, IN 46151-1331

United States Standards, Grades, and Weight Classes for Shell Eggs, AMS-56, effective July 20, 2000, U.S. Department of Agriculture, Agricultural Marketing Service, Poultry Programs, STOP 0259, Room 3944-South, 1400 Independence Avenue, SW, Washington, DC 20250-0259

VDH Procedures for Certification and Standardization of Retail Food Protection Staff Workbook, 2014, Virginia Department of Health, Division of Food and Environmental Services, 109 Governor Street, 5th Floor, Richmond, VA 23219