

**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 Mauskopf, 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
12VAC5-525
(Proposed Regulations)

Adrienne McFadden, MD, JD, Director
Office of Minority Health and Health Equity

Working Lunch

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

Food Regulations
12VAC5-421
(Final Amendments)

Allen Knapp, Director
Office of Environmental Health Services

Report of Nominating Committee

Ms. Vest

Election of Officers and Executive
Committee Members

Mr. Edwards

Member Reports

Other Business

Adjourn

MEMORANDUM

DATE: April 25, 2016

TO: Virginia State Board of Health

FROM: Adrienne McFadden, MD, JD, FACEP, FAAEM, FCLM
Director Office of Minority Health and Health Equity

SUBJECT: Regulations for Physician Assistant Scholarship Program (12VAC5-525).

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.



townhall.virginia.gov

Proposed Regulation Agency Background Document

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

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

Brief summary

Please provide a brief summary (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.

Projected 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	Projected cost to the state is negligible
Projected cost of the new regulations or changes to existing regulations on localities.	No foreseeable projected cost to implement and enforce this regulatory proposal
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	Physician assistant students desiring to work in medically underserved areas, patients and facilities within medically underserved areas within the commonwealth
Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses	According to the Health Resources and Services Administration there are currently 241 Health Professional Shortage Areas (HPSA) within the

<p>affected. Small business means a business entity, including its affiliates, that:</p> <p>a) is independently owned and operated and;</p> <p>b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>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.</p>
<p>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:</p> <p>a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and</p> <p>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.</p>	<p>None.</p>
<p>Beneficial impact the regulation is designed to produce.</p>	<p>Fulfillment of statutory requirement to establish the Physician Assistant Scholarship Program in the Virginia Administrative Code.</p>

Alternatives

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

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.

Commenter	Comment	Agency response
David Falkenstein, PA-C, Virginia Academy of Physician Assistants	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.	VDH acknowledges the support and will consider introduction of a budget amendment to fund this scholarship program.

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:

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
10	Definition of terms		Defines terms used in this regulatory chapter to assist readers in understanding regulations
20	Establishes the Physician Assistant Scholarship Committee		The 8 member scholarship committee will determine scholarship awards
30	Outlines eligibility criteria for scholarships		To assist readers in understanding how to qualify for the scholarship program
40	Outlines the conditions of receiving and participating in the scholarship program		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.
50	Number of applications per student		Delineates maximum number of scholarship that each applicant is eligible to receive.
60	Establishes scholarship amount at \$5000		Provides clarity to reader about the dollar amount of the scholarship awards
70	Establishes application process		Provides clarity on the process for applicants to apply for the scholarship

80	Provides selection criteria		Establishes selection standards which will serve as guidance to scholarship committee in selecting the scholarship recipients
90	Provides content of the scholarship contracts		Establishes elements of the scholarship contract that is to be signed by recipient and commissioner.
100	Provides standards to use for practice site selection		Establishes minimal criteria which the practice site must meet to serve as an eligible practice site to repay service obligation
105	Establishes process by which an applicant can change practice sites		Provides direction to reader about how to change a practice site once a participant begins his service obligation
110	Provides the reporting requirements that must be fulfilled by each recipient.		Establishes reporting requirements that each recipient must fulfill during their participation in the scholarship program
120	Provides clarity on what constitutes a breach of contract		Establishes 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.
130	Establishes a deferment and waiver process		Provides clarity to the reader about the process by which a deferment may be considered
140	Establishes a process for repayment if service obligation is fulfilled after default payments		Establishes a process by which a participant may be reimbursed by the Commonwealth upon fulfilling service obligation after repaying the Commonwealth for default.

1 CHAPTER 525
2 REGULATIONS FOR PHYSICIAN ASSISTANT SCHOLARSHIP PROGRAM

3 Part I
4 General Information

5 **12VAC5-525-10. Definitions.**

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

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

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

10 "Commissioner" means the State Health Commissioner.

11 "Department" means Virginia Department of Health.

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

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

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

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

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

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

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

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

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

34 **12VAC5-525-20. Physician Assistant Scholarship Committee.**

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

41 Part II

42 Administration of Physician Assistant Scholarship Program

43 **12VAC5-525-30. Eligibility for scholarships.**

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

- 45 1. Be a United States citizen, national, or a qualified alien pursuant to 8 USC § 1621;

- 46 2. Be accepted for enrollment or enrolled in an approved PA program in the
47 Commonwealth of Virginia preparing him for examination for licensure as a PA in the
48 Commonwealth of Virginia;
49 3. If already enrolled in an approved PA program in the Commonwealth the student must
50 have a cumulative grade point average of 2.5;
51 4. Submit a completed application form and appropriate grade transcript prior to the
52 established deadline dates;
53 5. Demonstrate financial need which is verified by the school's financial aid officer or
54 authorized person as part of the application process; and
55 6. Not have an active military obligation.

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

57 **12VAC5-525-40. Conditions of scholarships.**

58 A. Prior to becoming a participant in the PA scholarship program, the applicant shall enter
59 into a contract with the commissioner agreeing to the terms and conditions upon which the
60 scholarship is granted.

61 B. For each \$5000 of scholarship money received, the participant agrees to engage in the
62 equivalent of one year of full-time primary care medical practice in a HPSA or VMUA within the
63 Commonwealth. The recipient shall notify the department, within 180 days of being awarded a
64 PA degree, of the type of practice to be performed and give the name and address of the
65 employer for approval. Voluntary military service, even if stationed in Virginia, cannot be used to
66 repay the service obligation required when a scholarship is awarded.

67 C. If a participant fails to complete his studies, the full amount of the scholarship or
68 scholarships received, plus the applicable interest charge, shall be repaid.

69 D. If upon graduation a participant leaves the Commonwealth or fails to engage or ceases to
70 engage in primary care medical practice in Virginia before all employment conditions of the
71 scholarship award are fulfilled, the participant shall repay the award amount reduced by the
72 proportion of obligated years served plus the applicable interest and penalty.

73 E. If the participant is in default due to death or permanent disability so as not to be able to
74 engage in medical practice, the participant or his personal representative, upon repayment of
75 the total amount of scholarship funds received plus applicable interest, may be relieved of his
76 obligation under the contract to engage in medical practice. For participants completing part of
77 the PA obligation prior to becoming permanently disabled or in the event of death, the total
78 amount of scholarship funds owed shall be reduced by the proportion of obligated years served.
79 The obligation to make restitution may be waived by the board upon application of the
80 participant or the participant's personal representative to the board.

81 F. All default payments shall be made payable to the Commonwealth of Virginia.

82 **12VAC5-525-50. Number of applications per student.**

83 Scholarships are awarded for single academic years. However, the same student may, after
84 demonstrating satisfactory progress in his studies, which is demonstrated by a cumulative grade
85 point average of 2.5, apply for and receive scholarship awards for a succeeding academic year
86 or years. No student shall receive scholarships for more than a total of four years.

87 **12VAC5-525-60. Amounts of scholarships.**

88 The number of scholarships awarded shall be dependent upon the amount of money
89 appropriated by the General Assembly, the amount of funds available within the Physician
90 Assistant Scholarship Fund administered by the State Board of Health, and the number of
91 qualified applicants. Each participant shall receive an award of \$5,000 per year.

92 **12VAC5-525-70. How to apply.**

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

97 **12VAC5-525-80. Selection criteria.**

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

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

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

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

113 **12VAC5-525-90. Scholarship contract.**

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

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

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

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

123 4. Agreement to comply with all reporting requirements;

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

127 6. Signature of the applicant; and

128 7. Signature of the commissioner or his designee.

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

131 **12VAC5-525-100. Practice site selection.**

132 Each recipient shall perform his service obligation at a practice site in either a health
133 professional shortage area or a Virginia medically underserved area. The participant shall agree
134 to provide health services without discrimination, regardless of a patient's ability to pay. Maps
135 of health professional shortage areas and Virginia medically underserved areas shall be
136 available on the department's website.

137 **12VAC5-525-105. Change of practice site.**

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

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

145 **12VAC5-525-110. Reporting requirements.**

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

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

151 1. Participant changes name;

152 2. Participant changes address;

153 3. Participant changes practice site. Participant is required to request in writing and
154 obtain prior approval of changes in practice site;

155 4. Participant no longer intends or is able to fulfill service obligation as a PA in the
156 Commonwealth;

157 5. Participant ceases to practice as a PA; or

158 6. Participant ceases or no longer intends to complete his PA academic program.

159 **12VAC5-525-120. Breach of contract.**

160 The following shall constitute a breach of contract:

161 1. The recipient fails to complete his PA studies;

162 2. The recipient fails to begin or complete the term of obligated service under the terms
163 and conditions of the scholarship contract;

164 3. The recipient falsifies or misrepresents information on the program application, the
165 verification of employment forms, or other required documents; and

166 4. The recipient's employment is terminated for good cause as determined by the
167 employer and confirmed by the department. If employment is terminated for reasons
168 beyond the participant's control (e.g., closure of site), the participant shall transfer to
169 another site approved by the board in the Commonwealth within six months of
170 termination. Failure of participant to transfer to another site shall be deemed to be a
171 breach of the contract.

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

176 **12VAC5-525-130. Deferment and waivers.**

177 A. If the participant is in default due to death or permanent disability so as not to be able to
178 engage in primary care practice in a region designated as a HPSA or VMUA in the
179 Commonwealth, the participant or his personal representative may be relieved of his obligation
180 under the contract to engage in practice, upon repayment of the total amount of scholarship
181 received plus applicable interest. For participants completing part of the obligation prior to
182 becoming permanently disabled or in the event of death, the total amount of scholarship funds

183 owed shall be reduced by the proportion of obligated years served. The obligation to make
184 restitution may be waived by the board upon application of the participant or the participant's
185 personal representative to the board.

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

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

190 **12VAC5-525-140. Fulfillment after default payments.**

191 In the event that a recipient, in accordance with the terms of the contract, fully repays the
192 Commonwealth for part or all of any scholarship because of breach of contract and later fulfills
193 the terms of the contract after repayment, the Commonwealth shall reimburse the award
194 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

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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

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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.

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- 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.



townhall.virginia.gov

Final Regulation Agency Background Document

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

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

Brief summary

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

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

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

Acronyms and Definitions

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

Acronyms:

"CFPM" means Certified Food Protection Manager.

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

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

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

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

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

"USDA" means the United States Department of Agriculture.

"VDH" means the Virginia Department of Health.

Statement of final agency action

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

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

Legal basis

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

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

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

Purpose

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

The purpose of these regulations is to prevent foodborne illness by ensuring that foods prepared and served by food establishments in Virginia are safe, unadulterated, and prepared under sanitary conditions. This is accomplished by providing minimum sanitary standards for food establishments to protect the dining public. These standards include approved sources for foods used in food establishments, specifications for safe handling, storage, preparation and serving of food, personal hygiene of employees, precautions to prevent the transmission of diseases communicable through food, and the general sanitation of the facility. When followed, these minimum standards will protect the public's health, safety, and welfare. Additionally, 12VAC5-421-30 of the regulation states the following, "The chapter has been promulgated by the State Board of Health to specify the following requirements to protect public health."

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

The second goal is to facilitate the shared responsibility of the food industry and the government in ensuring that food provided to the consumer is safe and does not become a vehicle for a disease outbreak or for the transmission of communicable disease. Foodborne disease in the United States is a major cause of personal distress, preventable death, and avoidable economic burden. The U.S. Centers for Disease Control and Prevention estimate that foodborne diseases cause approximately 48 million people to become ill, 128,000 hospitalizations, and 3,000 deaths in the United States each year. Epidemiological outbreak data repeatedly identify five major risk factors related to employee behaviors and preparation practices in retail and food service establishments as contributing to foodborne illness. Those risk factors include (i) improper holding temperatures; (ii) inadequate cooking, such as undercooking raw eggs; (iii) contaminated equipment; (iv) food from unsafe sources; and (v) poor personal hygiene. This regulation and the proposed modifications address controls for these risk factors.

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

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

Substance

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

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

Part II

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

Part III

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

Part IV

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

Part V

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

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

Part VII

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

Issues

Please identify the issues associated with the proposed regulatory action, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.

The primary advantage of the regulations to the public is that they establish modern science-based standards that support the prevention of foodborne illness risk factors and ensure the safety of food service within the Commonwealth. The amendments will also make the regulations more understandable. The primary advantage to the agency is that the regulations will be based on current food science. The primary advantage to the regulated community, particularly chains and franchises that operate in other states as well as in multiple jurisdictions across the Commonwealth that have adopted the current version of the FDA Food Code, will be better consistency in regulatory application. There will be no disadvantages to the public or the Commonwealth with the adoption of these regulations.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no known requirements that exceed applicable federal requirements.

Localities particularly affected

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

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

Family impact

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

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

Changes made since the proposed stage

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

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

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

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

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

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

Public comment

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

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

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

All changes made in this regulatory action

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 **Project 2701 - Proposed**

2 **DEPARTMENT OF HEALTH**

3 **Amend Regulations to be consistent with the 2013 USFDA Food Code and the**
4 **Supplement to the Food Cod**

5
6 **Part I**

7 **Definitions, Purpose and Administration**

8 **12VAC5-421-10. Definitions.**

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

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

19 "Additive" means either a (i) "food additive" having the meaning stated in the Federal Food,
20 Drug, and Cosmetic Act, § 201(s) and 21 CFR ~~Part 170~~ 170.3(e)(1) or (ii) "color additive" having
21 the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 201(t) and 21 CFR ~~Part~~
22 ~~70~~ 70.3(f).

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

24 "Agent" means a legally authorized representative of the owner.

25 "Agent of the commissioner" means the district or local health director, unless otherwise
26 stipulated.

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

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

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

41 "a_w" means water activity ~~which~~ that is a measure of the free moisture in a food, is the
42 quotient of the water vapor pressure of the substance divided by the vapor pressure of pure
43 water at the same temperature, and is indicated by the symbol a_w.

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

47 "Bed and breakfast" means a tourist home that serves meals.

48 "Beverage" means a liquid for drinking, including water.

49 "Board" means the State Board of Health.

50 "Bottled drinking water" means water that is sealed in bottles, packages, or other containers
51 and offered for sale for human consumption [including bottled mineral water] .

52 "Building official" means a representative of the Department of Housing and Community
53 Development.

54 "Casing" means a tubular container for sausage products made of either natural or artificial
55 (synthetic) material.

56 "Catering operation" means a person who contracts with a client to prepare a specific menu
57 and amount of food in an approved and permitted food establishment for service to the client's
58 guests or customers at a service location different from the permitted food establishment.
59 Catering may also include cooking or performing final preparation of food at the service location.

60 "Catering operation" does not include:

61 1. A private chef or cook who, as the employee of a consumer, prepares food solely in
62 the consumer's home.

63 2. Delivery service of food by an approved and permitted food establishment to an end
64 consumer.

65 "Certification number" means a unique combination of letters and numbers assigned by a
66 shellfish control authority to a molluscan shellfish dealer according to the provisions of the
67 National Shellfish Sanitation Program.

68 "CFR" means Code of Federal Regulations. Citations in this chapter to the CFR refer
69 sequentially to the title, part, and section number, such as 40 CFR 180.194 refers to Title 40,
70 Part 180, Section 194.

71 "CIP" means cleaned in place by the circulation or flowing by mechanical means through a
72 piping system of a detergent solution, water rinse, and sanitizing solution onto or over
73 equipment surfaces that require cleaning, such as the method used, in part, to clean and
74 sanitize a frozen dessert machine. CIP does not include the cleaning of equipment such as
75 band saws, slicers or mixers that are subjected to in-place manual cleaning without the use of a
76 CIP system.

77 ~~"CFR" means Code of Federal Regulations. Citations in these regulations to the CFR refer
78 sequentially to the title, part, and section numbers, such as 21 CFR 178.1010 refers to Title 21,
79 Part 178, Section 1010.~~

80 ~~"Code of Federal Regulations" means the compilation of the general and permanent rules
81 published in the Federal Register by the executive departments and agencies of the federal
82 government which:~~

83 ~~1. Is published annually by the U.S. Government Printing Office; and~~

84 ~~2. Contains FDA rules in 21 CFR, USDA rules in 7 CFR and 9 CFR, EPA rules in 40
85 CFR, and Wildlife and Fisheries Rules in 50 CFR.~~

86 "Commingle" means:

87 1. To combine shellstock harvested on different days or from different growing areas as
88 identified on the tag or label; or

89 2. To combine shucked shellfish from containers with different container codes or
90 different shucking dates.

91 "Comminuted" means reduced in size by methods including chopping, flaking, grinding, or
92 mincing. "Comminuted" includes (i) fish or meat products that are reduced in size and
93 restructured or reformulated such as gefilte fish, gyros, ground beef, and sausage; and (ii) a

94 mixture of two or more types of meat that have been reduced in size and combined, such as
95 sausages made from two or more meats.

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

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

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

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

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

112 "Core item" means a provision in this chapter that is not designated as a priority item or a
113 priority foundation item. Core item includes an item that usually relates to general sanitation,
114 operational controls, sanitation standard operating procedures (SSOPs), facilities or structures,
115 equipment design, or general maintenance.

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

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

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

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

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

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

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

139 "Delicatessen" means a store where ready to eat products such as cooked meats, prepared
140 salads, etc. are sold for off-premises consumption.

141 "Department" means the ~~State Health~~ Virginia Department of Health.

142 "Director" means the district or local health director.

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

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

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

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

156 1. Allows effective removal of soil by normal cleaning methods;

157 2. Is dependent on the material, design, construction, and installation of the surface; and

158 3. Varies with the likelihood of the surface's role in introducing pathogenic or toxigenic
159 agents or other contaminants into food based on the surface's approved placement,
160 purpose, and use.

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

164 1. The appropriateness of stainless steel for a food preparation surface as opposed to
165 the lack of need for stainless steel to be used for floors or for tables used for consumer
166 dining; or

167 2. The need for a different degree of cleanability for a utilitarian attachment or accessory
168 in the kitchen as opposed to a decorative attachment or accessory in the consumer
169 dining area.

170 "Easily movable" means:

171 1. Portable (~~weighing 30 pounds or less~~); mounted on casters, gliders, or rollers; or
172 provided with a mechanical means to safely tilt a unit of equipment for cleaning; and

173 2. Having no utility connection, a utility connection that disconnects quickly, or a flexible
174 utility connection line of sufficient length to allow the equipment to be moved for cleaning
175 of the equipment and adjacent area.

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

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

183 "Employee" means the permit holder, person in charge, food employee, person having
184 supervisory or management duties, person on the payroll, family member, volunteer, person
185 performing work under contractual agreement, or other person working in a food establishment.

186 "~~Enterohemorrhagic *Escherichia coli* (EHEC)~~" means ~~*E. coli* that cause hemorrhagic colitis,~~
187 ~~meaning bleeding enterically or bleeding from the intestine. The term is typically used in~~
188 ~~association with *E. coli* that have the capacity to produce Shiga toxins and to cause attaching~~
189 ~~and effacing lesion in the intestine. EHEC is a subset of STEC, whose members produce~~
190 ~~additional virulence factors. Infections with EHEC may be asymptomatic but are classically~~
191 ~~associated with bloody diarrhea (hemorrhagic colitis) and hemolytic uremic syndrome (HUS) or~~
192 ~~thrombotic thrombocytopenic purpura (TTP). Examples of serotypes of EHEC include: *E. coli*~~
193 ~~O157:H7; *E. coli* O157:NM; *E. coli* O26:H11; *E. coli* O145:NM; *E. coli* O103:H2; or *E. coli*~~
194 ~~O111:NM. Also see Shiga toxin-producing *E. coli*.~~

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

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

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

205 "°F" means degrees Fahrenheit.

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

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

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

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

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

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

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

230 "Food establishment" includes ~~(a)~~ (i) an element of the operation such as a transportation
231 vehicle or a central preparation facility that supplies a vending location or satellite feeding
232 location; ~~(b)~~ (ii) an operation that is conducted in a mobile, stationary, temporary, or permanent
233 facility or location; where consumption is on or off the premises; and regardless of whether there

234 is a charge for the food; and ~~(e)~~ (iii) a facility that does not meet the exemption criteria identified
235 in subdivision 6 of this definition or a facility that meets the exemption requirements but chooses
236 to be regulated under ~~these regulations~~ this chapter.

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

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

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

253 "Food establishment" does not include:

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

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

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

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

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

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

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

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

278 For the purpose of implementing this chapter, the following are also exempt from the
279 definition of a "food establishment" in this chapter, as defined in §§ 35.1-25 and 35.1-26 of the
280 Code of Virginia:

- 281 1. Boarding houses that do not accommodate transients;
- 282 2. Cafeterias operated by industrial plants for employees only;
- 283 3. Churches, fraternal, school and social organizations and volunteer fire departments
- 284 and rescue squads that hold dinners and bazaars not more than one time per week and
- 285 not in excess of two days duration at which food prepared in homes of members or in
- 286 the kitchen of the church or organization and is offered for sale to the public;
- 287 4. Grocery stores, including the delicatessen that is a part of a grocery store, selling
- 288 exclusively for off-premises consumption and places manufacturing or selling packaged
- 289 or canned goods;
- 290 5. Churches that serve meals for their members as a regular part of their religious
- 291 observance; and
- 292 6. Convenience stores or gas stations that are subject to the State Board of Agriculture
- 293 and Consumer Services' Retail Food Establishment Regulations (2VAC5-585) or any
- 294 regulations subsequently adopted and that (i) have 15 or fewer seats at which food is
- 295 served to the public on the premises of the convenience store or gas station and (ii) are
- 296 not associated with a national or regional restaurant chain. Notwithstanding this
- 297 exemption, such convenience stores or gas stations shall remain responsible for
- 298 collecting any applicable local meals tax.
- 299 "Food processing plant" means a commercial operation that manufactures, packages,
- 300 labels, or stores food for human consumption and provides food for sale or distribution to other
- 301 business entities such as food processing plants or food establishments. Food processing plant
- 302 does not include a food establishment.
- 303 "Game animal" means an animal, the products of which are food, that is not classified as:
- 304 ~~cattle, sheep, swine, goat, horse, mule, or other equine in 9 CFR Part 301 Definitions, as poultry~~
- 305 ~~in 9 CFR Part 381 Poultry Products Inspection Regulations, or as Fish as defined in this~~
- 306 ~~section (i) livestock, sheep, swine, goat, horse, mule, or other equine in 9 CFR 301.2; (ii)~~
- 307 ~~poultry; or (iii) fish.~~
- 308 "Game animal" includes mammals such as reindeer, elk, deer, antelope, water buffalo,
- 309 bison, rabbit, squirrel, opossum, raccoon, nutria, or muskrat and nonaquatic reptiles such as
- 310 land snakes.
- 311 "Game animal" does not include ratites such as ostrich, emu, and rhea.
- 312 "General use pesticide" means a pesticide that is not classified by EPA for restricted use as
- 313 specified in 40 CFR 152.175.
- 314 "Grade A standards" means the requirements of the ~~USPHS/FDA "Grade [A] Grade "A"~~
- 315 ~~Pasteurized Milk Ordinance" and "Grade A Condensed and Dry Milk Ordinance", 2013 Revision,~~
- 316 ~~(U.S. Food and Drug Administration),~~ with which certain fluid and dry milk and milk products
- 317 comply.
- 318 "HACCP Plan" means a written document that delineates the formal procedures for following
- 319 the Hazard Analysis Critical Control Point principles developed by The National Advisory
- 320 Committee on Microbiological Criteria for Foods.
- 321 "Handwashing sink" means a lavatory, a basin or vessel for washing, a wash basin, or a
- 322 plumbing fixture especially placed for use in personal hygiene and designed for the washing of
- 323 hands. Handwashing sink includes an automatic handwashing facility.
- 324 "Hazard" means a biological, chemical, or physical property that may cause an
- 325 unacceptable consumer health risk.
- 326 "Health practitioner" means a physician licensed to practice medicine, or if allowed by law, a
- 327 nurse practitioner, physician assistant, or similar medical ~~profession~~ professional .

328 "Hermetically sealed container" means a container that is designed and intended to be
329 secure against the entry of microorganisms and, in the case of low acid canned foods, to
330 maintain the commercial sterility of its contents after processing.

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

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

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

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

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

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

352 "Kitchenware" means food preparation and storage utensils.

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

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

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

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

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

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

371 "Mobile food unit" means a food establishment ~~that is mounted on wheels that is~~ (excluding
372 boats in the water) readily moveable from place to place at all times during operation and shall
373 include, but not be limited to, pushcarts, trailers, trucks, or vans. ~~There is no size limit to mobile~~
374 ~~food units but they must be mobile at all times during operation and must be on wheels~~

375 ~~(excluding boats in the water) at all times.~~ The unit, all operations, and all equipment must be
376 integral to and be within or attached to the unit.

377 "Molluscan shellfish" means any edible species of fresh or frozen oysters, clams, mussels,
378 and scallops or edible portions thereof, except when the scallop product consists only of the
379 shucked adductor muscle.

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

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

387 "Organization" means any one of the following:

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

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

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

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

397 5. ~~A local chamber of commerce; or~~

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

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

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

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

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

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

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

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

421 indicate acidity and values between 7.0 and 14 indicate alkalinity. The value for pure distilled
 422 water is 7.0, which is considered neutral.

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

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

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

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

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

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

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

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

Aw values	pH values		
	4.6 or less	>4.6-5.6	>5.6
≤0.92	non-PHF*/non-TCS food**	non-PHF/non-TCS food	non-PHF/non-TCS food
>0.92-0.95	non-PHF/non-TCS food	non-PHF/non-TCS food	PA***

>0.95	non-PHF/non-TCS food	PA	PA
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*PHF means Potentially Hazardous Food

**TCS means Time/Temperature Control for Safety Food

***PA means Product Assessment required

458

Table B. Interaction of pH and Aw for control of vegetative cells and spores in food not heat-treated or heat treated but not packaged.

Aw values	pH values			
	<4.2	4.2-4.6	>4.6-5.0	>5.0
<0.88	non-PHF*/non-TCS food**	non-PHF/non-TCS food	non-PHF/non-TCS food	non-PHF/non-TCS food
0.88-0.90	non-PHF/non-TCS food	non-PHF/non-TCS food	non-PHF/non-TCS food	PA***
>0.90-0.92	non-PHF/non-TCS food	non-PHF/non-TCS food	PA	PA
>0.92	non-PHF/non-TCS food	PA	PA	PA

*PHF means Potentially Hazardous Food

**TCS means Time/Temperature Control for Safety Food

***PA means Product Assessment required

459

2. Potentially hazardous food (time/temperature control for safety food) does not include:

460

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*;

461

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;

462

463

464

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

465

466

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:

467

468

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470

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

471

472

(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

473

474

475

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

476

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

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

488 "Poultry" means any domesticated bird (chickens, turkeys, ducks, geese, or
489 guineas) guineas, ratites, or squabs), whether live or dead, as defined in 9 CFR Part 381 9 CFR
490 381.1, Poultry Products Inspection Regulations, and any migratory waterfowl, game bird, or
491 squab such as pheasant, partridge, quail, grouse, guineas, or pigeon or squab whether live or
492 dead, as defined in 9 CFR Part 362, Voluntary Poultry Inspection Regulations 9 CFR
493 362.1. "Poultry" does not include ratites.

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

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

501 "Priority foundation item" means a provision in this chapter whose application supports,
502 facilitates, or enables one or more priority items. "Priority foundation item" includes an item that
503 requires the purposeful incorporation of specific actions, equipment, or procedures by industry
504 management to attain control of risk factors that contribute to foodborne illness or injury such as
505 personnel training, infrastructure or necessary equipment, HACCP plans, documentation or
506 record keeping, and labeling and is denoted in this regulation with a superscript P^{PI}.

507 "Priority item" means a provision in this chapter whose application contributes directly to the
508 elimination, prevention or reduction to an acceptable level of hazards associated with foodborne
509 illness or injury and there is no other provision that more directly controls the hazard. "Priority
510 item" includes items with a quantifiable measure to show control of hazards such as cooking,
511 reheating, cooling, and handwashing and is denoted in this chapter with a superscript P^P.

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

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

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

523 "Pushcart" means any wheeled vehicle or device other than a motor vehicle or trailer that
524 may be moved with or without the assistance of a motor and that does not require registration

525 by the department of motor vehicles. ~~A pushcart is limited to the sale and/or service of hot dogs~~
526 ~~and frankfurter-like foods.~~

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

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

529 1. Is in a form that is edible without additional preparation to achieve food safety, as
530 specified under 12VAC5-421-700 A ~~through, B, and C~~, 12VAC5-421-710, or 12VAC5-
531 421-730;

532 2. Is a raw or partially cooked animal food and the consumer is advised as specified
533 under 12VAC5-421- 700 D 1 and ~~2~~ 3; or

534 3. Is prepared in accordance with a variance that is granted as specified under 12VAC5-
535 421-700 D ~~1 and 2~~ 4.

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

538 "Ready-to-eat food" includes:

539 1. Raw animal food that is cooked as specified under 12VAC5-421-700, or 12VAC5-421-
540 710 or frozen as specified under 12VAC5-421-730;

541 2. Raw fruits and vegetables that are washed as specified under 12VAC5-421-510;

542 3. Fruits and vegetables that are cooked for hot holding as specified under 12VAC5-421-
543 720;

544 4. All ~~potentially hazardous food~~ time/temperature control for safety food that is cooked
545 to the temperature and time required for the specific food under 12VAC5-421-700 and
546 cooled as specified in 12VAC5-421-800;

547 5. Plant food for which further washing, cooking, or other processing is not required for
548 food safety, and from which rinds, peels, husks, or shells, if naturally present, are
549 removed;

550 6. Substances derived from plants such as spices, seasonings, and sugar;

551 7. A bakery item such as bread, cakes, pies, fillings, or icing for which further cooking is
552 not required for food safety;

553 8. The following products that are produced in accordance with USDA guidelines and
554 that have received a lethality treatment for ~~pathogen~~ [pathogens] : dry, fermented
555 sausages, such as dry salami or pepperoni; salt-cured meat and poultry products, such
556 as prosciutto ham, country cured ham, and Parma ham; and dried meat and poultry
557 products, such as jerky or beef sticks; and

558 9. Food manufactured according to 21 CFR Part 113, ~~Thermally Processed Low-Acid~~
559 ~~Foods Packaged in Hermetically Sealed Containers.~~

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

566 1. Vacuum packaging, in which air is removed from a package of food and the package
567 is hermetically sealed so that a vacuum remains inside the package;

568 2. Modified atmosphere packaging, in which the atmosphere of a package of food is
569 modified so that its composition is different from air but the atmosphere may change
570 over time due to the permeability of the packaging material or the respiration of the food.

571 Modified atmosphere packaging includes reduction in the proportion of oxygen, total
572 replacement of oxygen, or an increase in the proportion of other gases such as carbon
573 dioxide or nitrogen;

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

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

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

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

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

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

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

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

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

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

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

605 "Safe material" means an article manufactured from or composed of materials that shall not
606 reasonably be expected to result, directly or indirectly, in their becoming a component or
607 otherwise affecting the characteristics of any food; an additive that is used as specified in §
608 409 ~~or 706~~ of the Federal Food, Drug, and Cosmetic Act (21 USC § 348); or other materials that
609 are not additives and that are used in conformity with applicable regulations of the Food and
610 Drug Administration.

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

615 "Sealed" means free of cracks or other openings that permit the entry or passage of
616 moisture.

617 "Service animal" means an animal such as a guide dog, signal dog, or other animal
618 individually trained to provide assistance to an individual with a disability.

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

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

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

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

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

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

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

646 "Single-use articles" means utensils and bulk food containers designed and constructed to
647 be used once and discarded. Single-use articles includes items such as wax paper, butcher
648 paper, plastic wrap, formed aluminum food containers, jars, plastic tubs or buckets, bread
649 wrappers, pickle barrels, ketchup bottles, and number 10 cans which do not meet the materials,
650 durability, strength and cleanability specifications contained in 12VAC5-421-960, 12VAC5-421-
651 1080, and 12VAC5-421-1100 for multiuse utensils.

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

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

661 "Substantial compliance" ~~shall mean that details of~~ means equipment or structure design or
662 construction ~~and/or~~; food preparation, handling, storage, transportation ~~and/or~~; or cleaning
663 procedures that will not substantially affect health consideration or performance of the facility
664 or its the employees.

665 "Tableware" means eating, drinking, and serving utensils for table use such as flatware
 666 including forks, knives, and spoons; hollowware including bowls, cups, serving dishes, tumblers;
 667 and plates.

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

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

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

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

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

<u>A_w values</u>	<u>pH values</u>		
	<u>4.6 or less</u>	<u>>4.6-5.6</u>	<u>>5.6</u>
<u>≤ 0.92</u>	<u>non-TCS food*</u>	<u>non-TCS food</u>	<u>non-TCS food</u>
<u>$> 0.92-$ <u>0.95</u></u>	<u>non-TCS food</u>	<u>non-TCS food</u>	<u>PA**</u>
<u>>0.95</u>	<u>non-TCS food</u>	<u>PA</u>	<u>PA</u>

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

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Table B. Interaction of pH and A_w for control of vegetative cells and spores in food not heat treated or heat treated but not packaged.

<u>A_w values</u>	<u>pH values</u>			
	<u>< 4.2</u>	<u>4.2 - 4.6</u>	<u>> 4.6 - 5.0</u>	<u>> 5.0</u>
<u><0.88</u>	<u>non-TCS food*</u>	<u>non-TCS food</u>	<u>non-TCS food</u>	<u>non-TCS food</u>
<u>0.88-0.90</u>	<u>non-TCS food</u>	<u>non-TCS food</u>	<u>non-TCS food</u>	<u>PA**</u>
<u>$>0.90-0.92$</u>	<u>non-TCS food</u>	<u>non-TCS food</u>	<u>PA</u>	<u>PA</u>
<u>>0.92</u>	<u>non-TCS food</u>	<u>PA</u>	<u>PA</u>	<u>PA</u>

*TCS food means time/temperature control for safety food

**PA means product assessment required

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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 A_w value, or interaction of A_w 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

728 building where such water is delivered (see Article 2 (§ 32.1-167 et seq.) of Chapter 6 of Title
729 32.1 of the Code of Virginia).

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

732 Part II
733 Management and Personnel
734 Article 1
735 Supervision

736 **12VAC5-421-50. Assignment of responsibility.**

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

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

746 **12VAC5-421-55. Certified food protection manager.**

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

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

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

755 **12VAC5-421-60. Demonstration of knowledge.**

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

- 760 1. Complying with ~~the Food Regulations this chapter~~ this chapter by having no violations
761 of ~~critical~~ critical priority items during the current inspection;^{Pf}
- 762 2. Being a certified food protection manager who has shown proficiency of required
763 information through passing a test that is part of an accredited program;^{Pf} or
- 764 3. Responding correctly to the environmental health specialist's questions as they relate
765 to the specific food operation. The areas of operation may include:
 - 766 a. Describing the relationship between the prevention of foodborne disease and the
767 personal hygiene of a food employee;^{Pf}
 - 768 b. Explaining the responsibility of the person in charge for preventing the
769 transmission of foodborne disease by a food employee who has a disease or
770 medical condition that may cause foodborne disease;^{Pf}
 - 771 c. Describing the symptoms associated with the diseases that are transmissible
772 through food;^{Pf}

- 773 d. Explaining the significance of the relationship between maintaining the time and
774 temperature of ~~potentially hazardous food (time/temperature control for safety~~
775 ~~food) time/temperature control for safety food~~ and the prevention of foodborne
776 illness;^{Pf}
- 777 e. Explaining the hazards involved in the consumption of raw or undercooked meat,
778 poultry, eggs, and fish;^{Pf}
- 779 f. Stating the required food temperatures and times for safe cooking of ~~potentially~~
780 ~~hazardous food (time/temperature control for safety food) time/temperature control~~
781 ~~for safety food~~ including meat, poultry, eggs, and fish;^{Pf}
- 782 g. Stating the required temperatures and times for the safe refrigerated storage, hot
783 holding, cooling, and reheating of ~~potentially hazardous food (time/temperature~~
784 ~~control for safety food) time/temperature control for safety food~~;^{Pf}
- 785 h. Describing the relationship between the prevention of foodborne illness and the
786 management and control of the following:
- 787 (1) Cross contamination;^{Pf}
- 788 (2) Hand contact with ready-to-eat foods;^{Pf}
- 789 (3) Handwashing;^{Pf} and
- 790 (4) Maintaining the food establishment in a clean condition and in good repair;^{Pf}
- 791 i. Describing the foods identified as major food allergens and the symptoms that a
792 major food allergen could cause in a sensitive individual who has an allergic
793 reaction;^{Pf}
- 794 j. Explaining the relationship between food safety and providing equipment that is:
- 795 (1) Sufficient in number and capacity;^{Pf} and
- 796 (2) Properly designed, constructed, located, installed, operated, maintained, and
797 cleaned;^{Pf}
- 798 k. Explaining correct procedures for cleaning and sanitizing utensils and food-contact
799 surfaces of equipment;^{Pf}
- 800 l. Identifying the source of water used and measures taken to ensure that ~~it~~ the water
801 supply remains protected from contamination such as providing protection from
802 backflow and precluding the creation of cross connections;^{Pf}
- 803 m. Identifying poisonous or toxic materials in the food establishment and the
804 procedures necessary to ensure that they are safely stored, dispensed, used, and
805 disposed of according to law;^{Pf}
- 806 n. Identifying critical control points in the operation from purchasing through sale or
807 service that [when not controlled] may contribute to the transmission of foodborne
808 illness and explaining steps taken to ensure that the points are controlled in
809 accordance with the requirements of this chapter;^{Pf}
- 810 o. Explaining the details of how the person in charge and food employees comply
811 with a HACCP plan if such a plan is required by the law, this chapter, or a voluntary
812 agreement between the regulatory authority and the food establishment; ~~and~~^{Pf}
- 813 p. Explaining the responsibilities, rights, and authorities assigned by this chapter to
814 the:
- 815 (1) Food employee;^{Pf}
- 816 (2) Conditional employee;^{Pf}
- 817 ~~(2)~~ (3) Person in charge;^{Pf} and
- 818 ~~(3)~~ (4) Regulatory authority;^{Pf} and

819 q. Explaining how the person in charge, food employees, and conditional employees
820 comply with reporting responsibilities and the exclusion or restriction of food
821 employees.^{Pf}

822 **12VAC5-421-65. Food protection manager certification.**

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

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

834 **12VAC5-421-70. Duties of person in charge.**

835 The person in charge shall ensure that:

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

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

843 3. Employees and other persons such as delivery and maintenance persons and
844 pesticide applicators entering the food preparation, food storage, and warewashing
845 areas comply with ~~these regulations~~ this chapter;^{Pf}

846 4. Employees are effectively cleaning their hands, by routinely monitoring the
847 employees' handwashing;^{Pf}

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

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

856 ~~6. 7.~~ 7. Employees are properly cooking potentially hazardous food [TC
857 time/temperature control for safety]food, being particularly careful in cooking those foods known to cause
858 severe foodborne illness and death, such as eggs and comminuted meats, through daily
859 oversight of the employees' routine monitoring of the cooking temperatures using
860 appropriate temperature measuring devices properly scaled and calibrated as specified
861 under 12VAC5-421-1180 and 12VAC5-421-1730 B;^{Pf}

862 ~~7. 8.~~ 8. Employees are using proper methods to rapidly cool potentially hazardous
863 foods time/temperature control for safety food that are is not held hot or are is not for
864 consumption within four hours, through daily oversight of the employees' routine
865 monitoring of food temperatures during cooling.^{Pf}

866 9. Employees are properly maintaining the temperatures of time/temperature control for
867 safety food during hot and cold holding through daily oversight of the employees routine
868 monitoring of food temperatures.^{Pf}

869 ~~8. 10.~~ Consumers who order raw or partially cooked ready-to-eat foods of animal origin
870 are informed as specified under 12VAC5-421-930 that the food is not cooked sufficiently
871 to ensure its safety;^{Pf}

872 ~~9. 11.~~ Employees are properly sanitizing cleaned multiuse equipment and utensils before
873 they are reused, through routine monitoring of solution temperature and exposure time
874 for hot water sanitizing, and chemical concentration, pH, temperature, and exposure
875 time for chemical sanitizing;^{Pf}

876 ~~10. 12.~~ Consumers are notified that clean tableware is to be used when they return to
877 self-service areas such as salad bars and buffets;^{Pf}

878 ~~11. 13.~~ Except when approval is obtained from the regulatory authority as specified in
879 12VAC5-421-450 B E, employees are preventing cross-contamination of ready-to-eat
880 food with bare hands by properly using suitable utensils such as deli tissue, spatulas,
881 tongs, single-use gloves, or dispensing equipment;^{Pf}

882 ~~12. 14.~~ Employees are properly trained in food safety [including food allergy
883 awareness.] as it relates to their assigned duties;^{Pf} ~~and~~

884 ~~13. 15.~~ Food employees and conditional employees are informed in a verifiable manner
885 of their responsibility to report in accordance with law, to the person in charge,
886 information about their health and activities as they relate to diseases that are
887 transmissible through food, as specified under 12VAC5-421-80-^{Pf}; and

888 16. Written procedures and plans, where specified by this chapter and as developed by
889 the food establishment, are maintained and implemented as required.^{Pf}

Article 2

Employee Health

892 **12VAC5-421-80. Responsibility of permit holder, person in charge, and conditional** 893 **employees.**

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

901 1. Has any of the following symptoms:

902 a. Vomiting;^P

903 b. Diarrhea;^P

904 c. Jaundice;^P

905 d. Sore throat with fever;^P or

906 e. A lesion containing pus such as a boil or infected wound that is open or draining
907 and is:

908 (1) On the hands or wrists, unless an impermeable cover such as a finger cot or stall
909 protects the lesion and a single-use glove is worn over the impermeable cover;^P

910 (2) On exposed portions of the arms, unless the lesion is protected by an
911 impermeable cover;^P or

- 912 (3) On other parts of the body, unless the lesion is covered by a dry, durable, tight-
 913 fitting bandage;^P
- 914 2. Has an illness diagnosed by a health practitioner due to:
- 915 a. Norovirus;^P
- 916 b. Hepatitis A virus;^P
- 917 c. Shigella spp.;^P
- 918 d. ~~Enterohemorrhagic or Shiga-toxin-producing~~ Shiga toxin-producing Escherichia
 919 coli; ~~or~~^P
- 920 e. Typhoid fever (caused by Salmonella Typhi);^P or
- 921 f. Salmonella (nontyphoidal).^P
- 922 3. Had ~~a previous illness~~ Typhoid fever, diagnosed by a health practitioner, within the
 923 past three months ~~due to Salmonella Typhi~~, without having received antibiotic therapy,
 924 as determined by a health practitioner;^P
- 925 4. Has been exposed to, or is the suspected source of, a confirmed disease outbreak,
 926 because the food employee or conditional employee consumed or prepared food
 927 implicated in the outbreak, or consumed food at an event prepared by a person who is
 928 infected or ill with:
- 929 a. Norovirus within the past 48 hours of the last exposure;^P
- 930 b. ~~Enterohemorrhagic or Shiga-toxin-producing~~ Shiga toxin-producing Escherichia
 931 coli, or Shigella spp. within the past three days of the last exposure;^P
- 932 c. Typhoid fever (caused by Salmonella Typhi) within the past 14 days of the last
 933 exposure;^P or
- 934 d. Hepatitis A virus within the past 30 days of the last exposure;^P or
- 935 5. Has been exposed by attending or working in a setting where there is a confirmed
 936 disease outbreak, or living in the same household as, and has knowledge about an
 937 individual who works or attends a setting where there is a confirmed disease outbreak,
 938 or living in the same household as, and has knowledge about, and individual diagnosed
 939 with an illness caused by:
- 940 a. Norovirus within the past 48 hours of exposure;^P
- 941 b. ~~Enterohemorrhagic or Shiga-toxin-producing~~ Shiga toxin-producing Escherichia coli
 942 or Shigella spp. within the past three days of the last exposure;^P
- 943 c. Typhoid fever (caused by Salmonella Typhi) within the past 14 days of the last
 944 exposure;^P or
- 945 d. Hepatitis A virus within the past 30 days of the last exposure.^P
- 946 B. The person in charge shall notify the regulatory authority when a food employee is:
- 947 1. Jaundiced;^{Pf} or
- 948 2. Diagnosed with an illness due to a pathogen as specified under subdivision A 2 a
 949 through e f of this section.^{Pf}
- 950 C. The person in charge shall ensure that a conditional employee:
- 951 1. Who exhibits or reports a symptom, or who reports a diagnosed illness as specified
 952 under ~~subdivision A 2 a through e~~ subdivisions A 1, 2, and 3 of this section, is prohibited
 953 from becoming a food employee until the conditional employee meets the criteria for the
 954 specific symptoms or diagnosed illness as specified under 12VAC5-421-100;^P and
- 955 2. Who will work as a food employee in a food establishment that serves a highly
 956 susceptible population and reports a history of exposure as specified

957 under ~~subdivision~~ subdivisions A 4 ~~through~~ and 5 of this section, is prohibited from
958 becoming a food employee until the conditional employee meets the criteria specified
959 under subdivision ~~9~~ 10 of 12VAC5-421-100.^P

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

963 1. Excluded as specified under subdivisions 1 ~~through, 2, and~~ 3 of 12VAC5-421-90, and
964 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
965 compliance with the provisions specified under ~~subdivision~~ subdivisions 1 through ~~7~~ 8 of
966 12VAC5-421-100;^P or

967 2. Restricted as specified under ~~subdivisions~~ subdivision 4 b, 5 b, 6 b, or ~~7~~ 8 b of
968 12VAC5-421-90, or ~~subdivisions 8 or~~ subdivision 9 or 10 of 12VAC5-421-90 and in
969 compliance with the provisions specified under subdivisions 4 through ~~9~~ 10 of 12VAC5-
970 421-100.^P

971 E. A food employee or conditional employee shall report to the person in charge the
972 information as specified under subsection A of this section.^{Pf}

973 F. A food employee shall:

974 1. Comply with an exclusion as specified under subdivisions 1 ~~through, 2, and~~ 3 of
975 12VAC5-421-90 and ~~subdivisions~~ subdivision 4 a, 5 a, 6 a, ~~or 7, or 8~~ a of 12VAC5-421-
976 90 and with the provisions specified under subdivisions 1 through ~~7~~ 8 of 12VAC5-421-
977 100;^P or

978 2. Comply with a restriction as specified under subdivisions 4 b, 5 b, 6 b, ~~or 7, or 8~~ b of
979 12VAC5-421-90, or ~~subdivisions~~ subdivision 8, 9, or 10 of 12VAC5-421-90 and comply
980 with the provisions specified under subdivisions 4 through ~~9~~ 10 of 12VAC5-421-100.^P

981 **12VAC5-421-90. Exclusions and restrictions.**

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

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

986 a. Symptomatic with vomiting or diarrhea;^P or

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

990 2. Exclude a food employee who is:

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

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

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

999 3. Exclude a food employee who is diagnosed with ~~an infection from Salmonella~~
1000 Typhi Typhoid fever, or reports a ~~previous infection with Salmonella Typhi~~ having had
1001 Typhoid fever within the past three months as specified in 12VAC5-421-80 A 3.^P

1002 4. If a food employee is diagnosed with an infection from Norovirus and is asymptomatic:

- 1003 a. Exclude the food employee who works in a food establishment serving a highly
 1004 susceptible population;^P or
 1005 b. Restrict the food employee who works in a food establishment not serving a highly
 1006 susceptible population.^P
- 1007 5. If a food employee is diagnosed with an infection from *Shigella* spp. and is
 1008 asymptomatic:
 1009 a. Exclude the food employee who works in a food establishment serving a highly
 1010 susceptible population;^P or
 1011 b. Restrict the food employee who works in a food establishment not serving a highly
 1012 susceptible population.^P
- 1013 6. If a food employee is diagnosed with an infection from ~~Enterohemorrhagic or Shiga-~~
 1014 ~~toxin-producing E.coli~~ Shiga toxin-producing Escherichia coli, and is asymptomatic:
 1015 a. Exclude the food employee who works in a food establishment serving a highly
 1016 susceptible population;^P or
 1017 b. Restrict the food employee who works in a food establishment not serving a highly
 1018 susceptible population.^P
- 1019 7. If a food employee is diagnosed with an infection from Salmonella (nontyphoidal) and
 1020 is asymptomatic, restrict the food employee who works in a food establishment:
 1021 a. Serving a highly susceptible population.^P or
 1022 b. Not serving a highly susceptible population.^P
- 1023 ~~7.~~ 8. If a food employee is ill with symptoms of acute onset of sore throat with fever:
 1024 a. Exclude the food employee who works in a food establishment serving a highly
 1025 susceptible population;^P or
 1026 b. Restrict the food employee who works in a food establishment not serving a highly
 1027 susceptible population.^P
- 1028 ~~8.~~ 9. If a food employee is infected with a skin lesion containing pus such as a boil or
 1029 infected wound that is open or draining and not properly covered as specified under
 1030 12VAC5-421-80 A 1 e, restrict the food employee.^P
- 1031 ~~9.~~ 10. If a food employee is exposed to a foodborne pathogen as specified under
 1032 12VAC5-421-80 A 4 or 5, restrict the food employee who works in a food establishment
 1033 serving a highly susceptible population.^P

1034 **12VAC5-421-100. Removal, adjustment, or retention of exclusions and restrictions.**

1035 The person in charge shall adhere to the following conditions when removing, adjusting, or
 1036 retaining the exclusion or restriction of a food employee:

- 1037 1. Except when a food employee is diagnosed with Typhoid fever or an infection from
 1038 Hepatitis A virus ~~or Salmonella Typhi~~:
- 1039 a. Reinstatement of a food employee who was excluded as specified under subdivision 1 a
 1040 of 12VAC5-421-90 if the food employee:
 1041 (1) Is asymptomatic for at least 24 hours;^P or
 1042 (2) Provides to the person in charge written medical documentation from a health
 1043 practitioner that states the symptom is from a noninfectious condition.^P
- 1044 b. If a food employee was diagnosed with an infection from Norovirus and excluded
 1045 as specified under subdivision 1 b of 12VAC5-421-90:
 1046 (1) Restrict the food employee, who is asymptomatic for at least 24 hours and works
 1047 in a food establishment not serving a highly susceptible population until the

- 1048 conditions for reinstatement as specified in subdivision 4 a or b of this section are
1049 met;^P or
- 1050 (2) Retain the exclusion for the food employee, who is asymptomatic for at least 24
1051 hours and works in a food establishment that serves a highly susceptible population,
1052 until the conditions for reinstatement as specified in subdivision 4 a or b of this
1053 section are met.^P
- 1054 c. If a food employee was diagnosed with an infection from *Shigella* spp. and
1055 excluded as specified under subdivision 1 b of 12VAC5-421-90:
- 1056 (1) Restrict the food employee, who is asymptomatic, for at least 24 hours and works
1057 in a food establishment not serving a highly susceptible population, until the
1058 conditions for reinstatement as specified in subdivision 5 a or b of this section are
1059 met;^P or
- 1060 (2) Retain the exclusion for the food employee, who is asymptomatic for at least 24
1061 hours and works in a food establishment that serves a highly susceptible population,
1062 until the conditions for reinstatement as specified in subdivision 5 a or b, or 5 a and 1
1063 c (1) of this section are met.^P
- 1064 d. If a food employee was diagnosed with an infection from ~~Enterohemorrhagic or~~
1065 ~~Shiga toxin-producing~~ Shiga toxin-producing *Escherichia coli* and excluded as
1066 specified under subdivision 1 b of 12VAC5-421-90:
- 1067 (1) Restrict the food employee, who is asymptomatic for at least 24 hours and works
1068 in a food establishment not serving a highly susceptible population, until the
1069 conditions for reinstatement as specified in subdivision 6 a or b of this section are
1070 met;^P or
- 1071 (2) Retain the exclusion for the food employee, who is asymptomatic for at least 24
1072 hours and works in a food establishment that serves a highly susceptible population,
1073 until the conditions for reinstatement as specified in subdivision 6 a or b are met.^P
- 1074 e. If a food employee was diagnosed with an infection from *Salmonella*
1075 (nontyphoidal) and excluded as specified under subdivision 1 b of 12VAC5-421-90:
- 1076 (1) Restrict the food employee who is asymptomatic for at least 30 days until
1077 conditions for reinstatement as specified under subdivision 7 a or 7 b of this section
1078 are met;^P or
- 1079 (2) Retain the exclusion for the food employee who is symptomatic, until conditions
1080 for reinstatement as specified under subdivision 7 a or 7 b of this section are met.
- 1081 2. Reinstatement a food employee who was excluded as specified under subdivision 2 of
1082 12VAC5-421-90 if the person in charge obtains approval from the regulatory authority
1083 and one of the following conditions is met:
- 1084 a. The food employee has been jaundiced for more than seven calendar days;^P
- 1085 b. The anicteric food employee has been symptomatic with symptoms other than
1086 jaundice for more than 14 calendar days;^P or
- 1087 c. The food employee provides to the person in charge written medical
1088 documentation from a health practitioner stating that the food employee is free of a
1089 Hepatitis A virus infection.^P
- 1090 3. Reinstatement a food employee who was excluded as specified under subdivision 3 of
1091 12VAC5-421-90 if:
- 1092 a. The person in charge obtains approval from the regulatory authority;^P and

- 1093 b. The food employee provides to the person in charge written medical
1094 documentation from a health practitioner that states the employee is free from ~~S.~~
1095 ~~Typhi infection~~ Typhoid fever.^P
- 1096 4. Reinstatement of a food employee who was excluded as specified under subdivision 1 b or 4
1097 a of 12VAC5-421-90, who was restricted under subdivision 4 b of 12VAC5-421-90 if the
1098 person in charge obtains approval from the regulatory authority and one of the following
1099 conditions is met:
- 1100 a. The excluded or restricted food employee provides to the person in charge written
1101 medical documentation from a health practitioner stating that the food employee is
1102 free of a Norovirus infection;^P
- 1103 b. The food employee was excluded or restricted after symptoms of vomiting or
1104 diarrhea resolved, and more than 48 hours have passed since the food employee
1105 became symptomatic;^P or
- 1106 c. The food employee was excluded or restricted and did not develop symptoms and
1107 more than 48 hours have passed since the food employee was diagnosed.^P
- 1108 5. Reinstatement of a food employee who was excluded as specified under subdivision 1 b or 5
1109 a of 12VAC5-421-90 or who was restricted under subdivision 5 b of 12VAC5-421-90 if
1110 the person in charge obtains approval from the regulatory authority and one of the
1111 following conditions is met:
- 1112 a. The excluded or restricted food employee provides to the person in charge written
1113 medical documentation from a health practitioner stating that the food employee is
1114 free of a Shigella spp. infection based on test results showing two consecutive
1115 negative stool specimen cultures that are taken:
- 1116 (1) Not earlier than 48 hours after discontinuance of antibiotics;^P and
1117 (2) At least 24 hours apart;^P
- 1118 b. The food employee was excluded or restricted after symptoms of vomiting or
1119 diarrhea resolved, and more than seven calendar days have passed since the food
1120 employee became asymptomatic;^P or
- 1121 c. The food employee was excluded or restricted and did not develop symptoms and
1122 more than seven calendar days have passed since the food employee was
1123 diagnosed.^P
- 1124 6. Reinstatement of a food employee who was excluded or restricted as specified under
1125 subdivision 1 b or 6 a of 12VAC5-421-90 or who was restricted under subdivision 6 b of
1126 12VAC5-421-90 if the person in charge obtains approval from the regulatory authority
1127 and one of the following conditions is met:
- 1128 a. The excluded or restricted food employee provides to the person in charge written
1129 medical documentation from a health practitioner stating that the food employee is
1130 free of an infection from ~~Enterohemorrhagic or Shiga toxin-producing~~ Shiga toxin-
1131 producing Escherichia coli based on test results that show two consecutive negative
1132 stool specimen cultures that are taken:
- 1133 (1) Not earlier than 48 hours after the discontinuance of antibiotics;^P and
1134 (2) At least 24 hours apart;^P
- 1135 b. The food employee was excluded or restricted after symptoms of vomiting or
1136 diarrhea resolved and more than seven calendar days have passed since the
1137 employee became asymptomatic;^P or
- 1138 c. The food employee was excluded or restricted and did not develop symptoms and
1139 more than seven days have passed since the employee was diagnosed.^P

- 1140 7. Reinstatement of a food employee who was excluded as specified under subsection 1 a of
 1141 12VAC5-421-90 or who was restricted as specified under subsection 7 of 12VAC5-421-
 1142 90 if the person in charge obtains approval from the regulatory authority^P and one of the
 1143 following conditions is met:
- 1144 a. The excluded or restricted food employee provides to the person in charge written
 1145 medical documentation from a health practitioner stating that the food employee is
 1146 free of a ~~nontyphoidal Salmonella~~ Salmonella (nontyphoidal) infection based on test
 1147 results showing two consecutive negative stool specimen cultures that are taken;
 1148 (1) Not earlier than 48 hours after discontinuance of antibiotics;^P and
 1149 (2) At least 24 hours apart;^P
- 1150 b. The food employee was restricted after symptoms of vomiting or diarrhea
 1151 resolved, and more than 30 days have passed since the food employee became
 1152 asymptomatic;^P or
- 1153 c. The food employee was excluded or restricted and did not develop symptoms and
 1154 more than 30 days have passed since the food employee was diagnosed.^P
- 1155 ~~7.~~ 8. Reinstatement of a food employee who was excluded or restricted as specified under
 1156 subdivision 7 8 a or b of 12VAC5-421-90 if the food employee provides to the person in
 1157 charge written medical documentation from a health practitioner stating that the food
 1158 employee meets one of the following conditions:
- 1159 a. Has received antibiotic therapy for Streptococcus pyogenes infection for more
 1160 than 24 hours;^P
- 1161 b. Has at least one negative throat specimen culture for Streptococcus pyogenes
 1162 infection;^P or
- 1163 c. Is otherwise determined by a health practitioner to be free of Streptococcus
 1164 pyogenes infection.^P
- 1165 ~~8.~~ 9. Reinstatement of a food employee who was restricted as specified under subdivision 8 9 of
 1166 12VAC5-421-90 if the skin, infected wound, cut, or pustular boil is properly covered with
 1167 one of the following:
- 1168 a. An impermeable cover such as a finger cot or stall and a single-use glove over the
 1169 impermeable cover if the infected wound or pustular boil is on the hand, finger, or
 1170 wrist;^P
- 1171 b. An impermeable cover on the arm if the infected wound or pustular boil is on the
 1172 arm;^P or
- 1173 c. A dry, durable, tight-fitting bandage if the infected wound or pustular boil is on
 1174 another part of the body.^P
- 1175 ~~9.~~ 10. Reinstatement of a food employee who was restricted as specified under subdivision 9 10
 1176 of 12VAC5-421-90 and was exposed to one of the following pathogens as specified
 1177 under 12VAC5-421-80 A 4 or 5:
- 1178 a. Norovirus and one of the following conditions is met:
 1179 (1) More than 48 hours have passed since the last day the food employee was
 1180 potentially exposed;^P or
 1181 (2) More than 48 hours have passed since the food employee's household contact
 1182 became asymptomatic.^P
- 1183 b. Shigella spp. or ~~Enterohemorrhagic~~ or ~~Shiga-toxin-producing~~ Shiga toxin-
 1184 producing Escherichia coli and one of the following conditions is met:

- 1185 (1) More than three calendar days have passed since the last day the food employee
 1186 was potentially exposed;^P or
- 1187 (2) More than three calendar days have passed since the food employee's
 1188 household contact became asymptomatic.^P
- 1189 c. ~~S. Typhi~~ Typhoid fever (caused by Salmonella Typhi) and one of the following
 1190 conditions is met:
- 1191 (1) More than 14 calendar days have passed since the last day the food employee
 1192 was potentially exposed;^P or
- 1193 (2) More than 14 calendar days have passed since the food employee's household
 1194 contact became asymptomatic.^P
- 1195 d. Hepatitis A virus and one of the following conditions is met:
- 1196 (1) The food employee is immune to Hepatitis A virus infection because of prior
 1197 illness from Hepatitis A;^P
- 1198 (2) The food employee is immune to Hepatitis A virus infection because of
 1199 vaccination against Hepatitis A;^P
- 1200 (3) The food employee is immune to Hepatitis A virus infection because of IgG
 1201 administration;^P
- 1202 (4) More than 30 calendar days have passed since the last the food employee was
 1203 potentially exposed;^P
- 1204 (5) More than 30 calendar days have passed since the food employee's household
 1205 contact became jaundiced;^P or
- 1206 (6) The food employee does not use an alternative procedure that allows bare hand
 1207 contact with ready-to-eat food until at least 30 days after the potential exposure, as
 1208 specified in subdivisions 9 10 d (4) and (5) of this section, and the food employee
 1209 receives additional training about:
- 1210 (a) Hepatitis A symptoms and preventing the transmission of infection;^P
- 1211 (b) Proper handwashing procedures;^P and
- 1212 (c) Protecting ready-to-eat food from contamination introduced by bare hand
 1213 contact.^P

Article 3

Personal Cleanliness

1216 **12VAC5-421-130. Clean condition of hands and arms.**

1217 Food employees shall keep their hands and exposed portions of their arms clean.^P

1218 **12VAC5-421-140. Cleaning procedure of hands and arms.**

1219 A. Except as specified in subsection D of this section, food employees shall clean their
 1220 hands and exposed portions of their arms ~~(or surrogate prosthetic devices for hands or arms)~~
 1221 ~~for at least 20 seconds~~ or surrogate prosthetic devices for hands or arms for at least 20
 1222 seconds, using a cleaning compound in a lavatory that is equipped as specified under 12VAC5-
 1223 421-2190 A.^P

1224 B. Food employees shall use the following cleaning procedure in the order stated to clean
 1225 their hands and exposed portions of their arms, including surrogate prosthetic devices for hands
 1226 and arms:

- 1227 1. Rinse under clean, running warm water;^P
- 1228 2. Apply an amount of cleaning compound recommended by the cleaning compound
 1229 manufacturer;^P

- 1230 3. Rub together vigorously for at least 10 to 15 seconds while:
- 1231 a. Paying particular attention to removing soil from underneath the fingernails during
- 1232 the cleaning procedure;^P and
- 1233 b. Creating friction on the surfaces of the hands and arms or surrogate prosthetic
- 1234 devices for hands and arms, finger tips, and areas between the fingers;^P
- 1235 4. Thoroughly rinsing under clean, running warm water;^P and
- 1236 5. Immediately follow the cleaning procedure with thorough drying using a method as
- 1237 specified under 12VAC5-421-3030.^P

1238 C. To avoid recontaminating their hands or surrogate prosthetic devices, food employees

1239 may use disposable paper towels or similar clean barriers when touching surfaces such as

1240 manually operated faucet handles on a handwashing sink or the handle of a restroom door.

1241 D. If approved and capable of removing the types of soils encountered in the food

1242 operations involved, an automatic handwashing facility may be used by food employees to

1243 clean their hands or surrogate prosthetic devices.

1244 **12VAC5-421-160. When to wash.**

1245 Food employees shall clean their hands and exposed portions of their arms as specified

1246 under 12VAC5-421-140 immediately before engaging in food preparation including working with

1247 exposed food, clean equipment and utensils, and unwrapped single-service and single-use

1248 articles^P and:

- 1249 1. After touching bare human body parts or hair other than clean hands and clean,
- 1250 exposed portions of arms;^P
- 1251 2. After using the toilet room;^P
- 1252 3. After caring for or handling ~~support~~ service animals or aquatic animals as allowed
- 1253 under 12VAC5-421-250 B;^P
- 1254 4. Except as specified in 12VAC5-421-220 B, after coughing, sneezing, using a
- 1255 handkerchief or disposable tissue, using tobacco, eating, or drinking;^P
- 1256 5. After handling soiled equipment or utensils;^P
- 1257 6. During food preparation, as often as necessary to remove soil and contamination and
- 1258 to prevent cross contamination when changing tasks;^P
- 1259 7. When switching between working with raw foods and working with ready-to-eat
- 1260 foods;^P
- 1261 8. Before donning gloves for ~~for~~ [to initiate a task that involves] working with foods;^P and
- 1262 9. After engaging in other activities that contaminate the hands.^P

1263 **12VAC5-421-170. Where to wash.**

1264 Food employees shall clean their hands in a handwashing lavatory sink or approved

1265 automatic handwashing facility and shall not clean their hands (i) in a sink used for food

1266 preparation or utensil washing or (ii) in a service sink or a curbed cleaning facility used for the

1267 disposal of mop water and similar liquid waste.^P

1268 **12VAC5-421-180. Hand antiseptics.**

1269 A. A hand antiseptic used as a topical application, a hand antiseptic solution used as a hand

1270 dip, or a hand antiseptic soap shall:

- 1271 1. Comply with one of the following:
- 1272 a. Be an approved drug that is listed in the FDA publication "Approved Drug
- 1273 Products with Therapeutic Equivalence Evaluations," 34th Edition, 2014, (U.S. Food

1274 and Drug Administration) as an approved drug based on safety and effectiveness;^{Pf}
1275 or
1276 b. Have active antimicrobial ingredients that are listed in the FDA monograph for
1277 OTC (over the counter) Health-Care Antiseptic Drug Products as an antiseptic
1278 handwash;^{Pf} and
1279 2. [Comply Consist only of components which the intended use of each complies]with
1280 one of the following:
1281 a. ~~[Have components that are exempted from the requirement of being listed in the~~
1282 ~~federal Food Additive regulations as specified in 21 CFR 170.39 – Threshold of~~
1283 ~~regulation for substances used in food-contact articles~~ A threshold of regulation
1284 exemption under 21 CFR 170.39];^{Pf} or
1285 b. ~~[Comply with and be listed in:~~
1286 ~~(i) 21 CFR Part 178 –Indirect Food Additives: Adjuvants, Production Aids, and~~
1287 ~~Sanitizers, as regulated for use as a food additive with conditions of safe use;~~^{Pf} or
1288 ~~(ii)c. 21 CFR Part 182 A determination of generally recognized as safe (GRAS).~~
1289 Partial listings of substances with food uses that are GRAS may be found in 21 CFR
1290 182–Substances Generally Recognized as Safe, 21 CFR 184 –Direct Food
1291 Substances Affirmed as Generally Recognized as Safe, or 21 CFR Part 186 -
1292 Indirect Food Substances Affirmed as Generally Recognized as Safe for use in
1293 contact with food and in FDA’s Inventory of GRAS Notices;^{Pf} and or
1294 d. A prior sanction listed under 21 CFR 181, ^{Pf}or
1295 e. A Food Contact Notification that is effective, ^{Pf}and]
1296 3. Be applied only to hands that are cleaned as specified under 12VAC5-421-140.^{Pf}
1297 B. If a hand antiseptic or a hand antiseptic solution used as a hand dip does not meet the
1298 criteria specified in subdivision A 2 of this section, use shall be:
1299 1. Followed by thorough hand rinsing in clean water before hand contact with food or by
1300 the use of gloves;^{Pf} or
1301 2. Limited to situations that involve no direct contact with food by the bare hands.^{Pf}
1302 C. A hand antiseptic solution used as a hand dip shall be maintained clean and at a strength
1303 equivalent to 100 ppm (mg/l) chlorine or above.^{Pf}
1304 **12VAC5-421-190. Maintenance of fingernails.**
1305 Food employees shall keep their fingernails trimmed, filed, and maintained so the edges and
1306 surfaces are cleanable and not rough.^{Pf} Unless wearing intact gloves in good repair, a food
1307 employee shall not wear fingernail polish or artificial nails when working with exposed food.^{Pf}
1308 **12VAC5-421-200. Prohibition of jewelry.**
1309 ~~While preparing food, food employees shall not wear jewelry on their arms and hands. This~~
1310 ~~section does not apply to a plain ring such as a wedding band. Except for a plain ring such as a~~
1311 ~~wedding band, while preparing food, food employees shall not wear jewelry, including medical~~
1312 ~~information jewelry on their arms and hands.~~
1313 **12VAC5-421-210. Clean condition of outer clothing.**
1314 Food employees shall wear clean outer clothing to prevent contamination of food,
1315 equipment, utensils, linens, and single-service and single-use articles.

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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.~~^{Pf}

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.^{Pf}

Part III
Food
Article 1
Characteristics

12VAC5-421-260. Safe and unadulterated.

Food shall be safe and unadulterated.^{Pf}

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.^P

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.^P

C. Packaged food shall be labeled as specified in law, including 21 CFR Part 101, ~~Food Labeling;~~ 9 CFR Part 317, ~~Labeling, Marking Devices, and Containers;~~ and Subpart N of 9 CFR Part 381, Subpart N Labeling and Containers; and as specified under 12VAC5-421-400 and 12VAC5-421-410.^{Pf}

~~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~~

1362 are obtained from a supplier that freezes the fish as specified under 12VAC5-421-730, or frozen
1363 on the premises as specified under 12VAC5-421-730, and records are retained as specified
1364 under 12VAC5-421-740.

1365 D. Fish, other than those specified in 12VAC5-421-730 B, that are intended for consumption
1366 in raw or undercooked form and allowed as specified in 12VAC5-421-700 D, may be offered for
1367 sale or service if they are obtained from a supplier that freezes fish as specified under 12VAC5-
1368 421-730 A; or if they are frozen on premises as specified under 12VAC5-421-730 A and records
1369 are retained as specified under 12VAC5-421-740.

1370 E. Whole-muscle, intact beef steaks that are intended for consumption in an undercooked
1371 form without a consumer advisory as specified in 12VAC5-421-700 C shall be:

1372 1. Obtained from a food processing plant that, upon request by the purchaser, packages
1373 the steaks and labels them to indicate that they meet the definition of whole-muscle,
1374 intact beef;^{Pf} or

1375 2. Deemed acceptable by the regulatory authority based on other evidence, such as
1376 written buyer specifications or invoices, that indicates that the steaks meet the definition
1377 of whole-muscle, intact beef;^{Pf} and

1378 3. If individually cut in a food establishment:

1379 a. Cut from whole-muscle intact beef that is labeled by a food processing plant as
1380 specified in subdivision 1 of this subsection or identified as specified in subdivision 2
1381 of this subsection;^{Pf}

1382 b. Prepared so they remain intact;^{Pf} and

1383 c. If packaged for undercooking in a food establishment, labeled to indicate that they
1384 meet the definition of whole-muscle, intact beef, as specified in subdivision 1 of this
1385 subsection or identified as specified in subdivision 2 of this subsection.^{Pf}

1386 F. Meat and poultry that are not a ready-to-eat food and are in a packaged form when
1387 offered for sale or otherwise offered for consumption shall be labeled to include safe handling
1388 instructions as specified in law, including 9 CFR 317.2(l) and 9 CFR 381.125(b).

1389 G. Shell eggs that have not been specifically treated to destroy all viable Salmonellae shall
1390 be labeled to include safe handling instructions as specified in law, including 21 CFR 101.17(h).

1391 **12VAC5-421-280. Food in a hermetically sealed container.**

1392 Food in a hermetically sealed container shall be obtained from a food processing plant that
1393 is regulated by the food regulatory agency that has jurisdiction over the plant.^P

1394 **12VAC5-421-290. Fluid milk and milk products.**

1395 Fluid milk and milk products shall be obtained from sources that comply with Grade A
1396 standards as specified in law.^P

1397 **12VAC5-421-295. Juice treated.**

1398 Prepackaged juice shall:

1399 1. Be obtained from a processor with a HACCP system as specified in 21 CFR Part
1400 120;^{Pf}

1401 2. Be obtained pasteurized or otherwise treated to attain a five-log reduction of the most
1402 resistant microorganism of public health significance as specified in 21 CFR 120.24; or;^P

1403 3. ~~Bear a warning label as specified in 12VAC5-421-765 and 21 CFR 101.17(g).~~

1404 **12VAC5-421-300. Fish.**

1405 A. Fish that are received for sale or service shall be:

1406 1. Commercially and legally caught or harvested;^P or

1407 2. Approved for sale or service by a regulatory authority agency of competent
1408 jurisdiction.^P

1409 B. Molluscan shellfish that are recreationally caught shall not be received for sale or
1410 service.^P

1411 **12VAC5-421-310. Molluscan shellfish.**

1412 A. Molluscan shellfish shall be obtained from sources according to law and the requirements
1413 specified in the U.S. Department of Health and Human Services, Public Health Service, Food
1414 and Drug Administration, National Shellfish Sanitation Program ~~Manual of Operations, Part II,~~
1415 ~~Sanitation of the Harvesting, Processing and Distribution of Shellfish, 1995 Revision (NSSP)~~
1416 Guide for the Control of Molluscan Shellfish, 2013 Revision, (U.S. Food and Drug
1417 Administration).^P

1418 B. Molluscan shellfish ~~received in interstate commerce~~ shall be from sources that are listed
1419 in the "Interstate Certified Shellfish Shippers List," updated monthly (U.S. Food and Drug
1420 Administration).^P

1421 **12VAC5-421-320. Wild mushrooms.**

1422 A. Except as specified in subsection B of this section, mushroom species picked in the wild
1423 shall be obtained from sources where each mushroom is individually inspected and found to be
1424 safe by an approved mushroom identification expert not be offered for sale or service by a food
1425 establishment unless the food establishment has been approved to do so.^P

1426 B. This section does not apply to:

1427 1. Cultivated wild mushroom species that are grown, harvested, and processed in an
1428 operation that is regulated by the food regulatory agency that has jurisdiction over the
1429 operation; or

1430 2. Wild mushroom species if they are in packaged form and are the product of a food
1431 processing plant that is regulated by the food regulatory agency that has jurisdiction over
1432 the plant.

1433 **12VAC5-421-330. Game animals.**

1434 A. If game animals are received for sale or service they shall be:

1435 1. Commercially raised for food and: ~~a. Raised~~ raised, slaughtered, and processed
1436 under a voluntary inspection program that is conducted by the state agency that has
1437 animal health jurisdiction; or

1438 ~~b. Under a routine inspection program conducted by a regulatory agency other than~~
1439 ~~the agency that has animal health jurisdiction; and~~

1440 ~~c. Raised, slaughtered, and processed according to:~~

1441 ~~(1) Laws governing meat and poultry as determined by the agency; and~~

1442 ~~(2) Requirements that are developed by the agency that has animal health~~
1443 ~~jurisdiction and the agency that conducts the inspection program with consideration~~
1444 ~~of factors such as the need for antemortem and postmortem examination by an~~
1445 ~~approved veterinarian or veterinarian's designee;~~

1446 2. ~~Under~~ under a voluntary inspection program administered by the USDA for game
1447 animals such as exotic animals ~~including animals~~ (reindeer, elk, deer, antelope, water
1448 buffalo, or bison) that are "inspected and approved" in accordance with 9 CFR Part 352,
1449 ~~Exotic Animals; Voluntary Inspection,~~ or rabbits that are "inspected and certified" in
1450 accordance with 9 CFR Part 354, ~~Voluntary Inspection of Rabbits and Edible Products~~
1451 ~~Thereof;~~

1452 3. ~~2.~~ As allowed by law, wild game animals that are live-caught are:

1453 a. Under a routine inspection program conducted by a regulatory agency such as the
1454 agency that has animal health jurisdiction;^P

1455 b. Slaughtered and processed according to:

1456 (1) Laws governing meat and poultry as determined by the agency that has animal
1457 health jurisdiction and the agency that conducts the inspection program;^P and

1458 (2) Requirements that are developed by the agency that has animal health
1459 jurisdiction and the agency that conducts the inspection program with consideration
1460 of factors such as the need for antemortem and postmortem examination by an
1461 approved veterinarian or veterinarian's designee;^P or

1462 4. ~~3.~~ As allowed by law for field-dressed wild game animals under a routine inspection
1463 program that ensures the animals:

1464 a. Receive a postmortem examination by an approved veterinarian or veterinarian's
1465 designee; or ~~are~~

1466 b. Are field-dressed and transported according to requirements specified by the
1467 agency that has animal health jurisdiction and the agency that conducts the
1468 inspection program^P and

1469 ~~b. c.~~ c. Are processed according to laws governing meat and poultry as determined by
1470 the agency that has animal health jurisdiction and the agency that conducts the
1471 inspection program.^P

1472 B. A game animal shall not be received for sale or service if it is a species of wildlife that is
1473 listed in 50 CFR Part 17, ~~Endangered and Threatened Wildlife and Plants.~~

1474 **12VAC5-421-340. Temperature.**

1475 A. Except as specified in subsection B of this section, refrigerated, ~~potentially hazardous~~
1476 ~~food~~ time/temperature control for safety food shall be at a temperature of 41°F (5°C) or below
1477 when received.^P

1478 B. If a temperature other than 41°F (5°C) for a ~~potentially hazardous food~~ time/temperature
1479 control for safety food is specified in law governing its distribution, such as laws governing
1480 milk, and molluscan shellfish, ~~and shell eggs~~, the food may be received at the specified
1481 temperature.

1482 C. Raw shell eggs shall be received in refrigerated equipment that maintains an ambient air
1483 temperature of 45°F (7°C) or less.^P

1484 D. ~~Potentially hazardous food~~ time/temperature control for safety food that is cooked to a
1485 temperature and for a time specified under 12VAC5-421-700 ~~through~~, 12VAC5-421-710, and
1486 12VAC5-421-720 and received hot shall be at a temperature of 135° (57°C) or above.^P

1487 E. A food that is labeled frozen and shipped frozen by a food processing plant shall be
1488 received frozen.^P

1489 F. Upon receipt, ~~potentially hazardous food~~ time/temperature control for safety food shall be
1490 free of evidence of previous temperature abuse.^P

1491 **12VAC5-421-350. Additives.**

1492 Food shall not contain unapproved food additives or additives that exceed amounts allowed
1493 in 21 CFR Parts 170-180 relating to food additives; generally recognized as safe (GRAS) or
1494 prior sanctioned substances that exceed amounts allowed in 21 CFR Parts 181-186;
1495 substances that exceed amounts specified in 9 CFR 424.21(b), Subpart C, ~~Approval of~~
1496 ~~Substances for Use in the Preparation of Products~~; or pesticide residues that exceed provisions
1497 specified in 40 CFR Part 185, ~~Tolerances for Pesticides in Food~~, and exceptions.^P

1498 **12VAC5-421-360. Shell eggs Eggs.**

1499 Shell eggs Eggs shall be received clean and sound and shall not exceed the restricted egg
1500 tolerances for U.S. Consumer Grade B as specified in United States Standards, Grades, and
1501 Weight Classes for Shell Eggs, AMS 56.200 et seq., administered by the Agricultural Marketing
1502 Service of USDA. Eggs sold pursuant to § 3.2-5305 of the Code of Virginia are exempt from the
1503 restricted egg tolerances for U.S. Consumer Grade B as specified in United States Standards,
1504 Grades, and Weight Classes for Shell Eggs, AMS 56, effective July 20, 2000, (Agricultural
1505 Marketing Service of USDA).^P

1506 **12VAC5-421-370. Eggs and milk products, pasteurized.**

1507 A. Egg products shall be obtained pasteurized.^P

1508 B. Fluid and dry milk and milk products shall:

1509 1. Be obtained pasteurized;^P and

1510 2. Comply with Grade A standards as specified in law.

1511 C. Frozen milk products, such as ice cream, shall be obtained pasteurized in accordance
1512 with 21 CFR Part 135, ~~Frozen Desserts.~~^P

1513 D. Cheese shall be obtained pasteurized unless alternative procedures to pasteurization
1514 are provided for specified in the ~~Code of Federal Regulations~~ CFR, such as 21 CFR Part 133,
1515 ~~Cheeses and Related Cheese Products, for curing certain cheese varieties.~~^P

1516 **12VAC5-421-380. Package integrity.**

1517 Food packages shall be in good condition and protect the integrity of the contents so that
1518 the food is not exposed to adulteration or potential contaminants.^{Pf}

1519 **12VAC5-421-390. Ice.**

1520 Ice for use as a food or a cooling medium shall be made from [~~drinking water~~pure water].^P

1521 **12VAC5-421-400. Shucked shellfish, packaging, and identification.**

1522 A. Raw shucked shellfish shall be obtained in nonreturnable packages that bear a legible
1523 label that identifies the:^{Pf}

1524 1. Name, address, and certification number of the shucker, packer, or repacker of the
1525 molluscan shellfish;^{Pf} and

1526 2. The "sell by" or "best if used by" date for packages with a capacity of less than one-
1527 half gallon (~~4.87~~) (1.89 L) or the date shucked for packages with a capacity of one-half
1528 gallon (~~4.87~~) (1.89 L) or more.^{Pf}

1529 B. A package of raw shucked shellfish that does not bear a label or ~~which~~ that bears a label
1530 which does not contain all the information as specified under subsection A of this section shall
1531 be subject to a hold order, as allowed by law, or seizure and destruction in accordance with 21
1532 CFR 1240.60(d), Subpart D, ~~Specific Administrative Decisions Regarding Interstate Shipments.~~

1533 **12VAC5-421-410. Shellstock identification.**

1534 A. Shellstock shall be obtained in containers bearing legible source identification tags or
1535 labels that are affixed by ~~the harvester and each~~ a dealer that depurates, ships, or reships the
1536 shellstock, as specified in the National Shellfish Sanitation Program (NSSP) Guide for the
1537 Control of Molluscan Shellfish, 2013 Revision, (U.S. Food and Drug Administration) and
1538 that list include the following information:^{Pf}

1539 1. ~~Except as specified under subsection C of this section, on the harvester's tag or label,~~
1540 ~~the following information in the following order:~~

1541 a. ~~The harvester's identification number that is assigned by the shellfish control~~
1542 ~~authority,~~

1543 b. ~~The date of harvesting,~~

1544 ~~c. The most precise identification of the harvest location or aquaculture site that is~~
1545 ~~practicable based on the system of harvest area designations that is in use by the~~
1546 ~~shellfish control authority and including the abbreviation of the name of the state or~~
1547 ~~country in which the shellfish are harvested,~~
1548 ~~d. The type and quantity of shellfish, and~~
1549 ~~e. The following statement in bold, capitalized type: "This tag is required to be~~
1550 ~~attached until container is empty or retagged and thereafter kept on file for 90 days";~~
1551 ~~and~~

1552 ~~2. Except as specified under subsection D of this section, on each dealer's tag or~~
1553 ~~label, the following information in the following order:~~

1554 ~~a. 1. The dealer's name and address, and the certification number assigned by the~~
1555 ~~shellfish control authority.^{Pf}~~

1556 ~~b. 2. The original shipper's certification number including the abbreviation of the name of~~
1557 ~~the state or country in which the shellfish are harvested, assigned by the shellfish control~~
1558 ~~authority.^{Pf}~~

1559 ~~c. The same information as specified for a harvester's tag under subdivisions 1 b through~~
1560 ~~d of this subsection, and 3. The harvest date, or if depurated, the date of depuration~~
1561 ~~processing, or if wet stored, the original harvest date and the final harvest date.^{Pf}~~

1562 ~~4. If wet stored or depurated, the wet storage or depuration cycle or lot number. The wet~~
1563 ~~storage lot number shall begin with the letter "w."^{Pf}~~

1564 ~~5. The harvest area, including the initials of the state of harvest.^{Pf}~~

1565 ~~6. The type and quantity of shellstock.^{Pf}~~

1566 ~~d. 7. The following statement in bold, capitalized type: "THIS TAG IS REQUIRED TO BE~~
1567 ~~ATTACHED UNTIL CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE FOR~~
1568 ~~90 DAYS."^{Pf}~~

1569 ~~8. All shellstock intended for raw consumption shall include a consumer advisory using~~
1570 ~~the statement from 12VAC5-421-930 C, or an equivalent statement.~~

1571 B. A container of shellstock that does not bear a tag or label or that bears a tag or label that
1572 does not contain all the information as specified under subsection A of this section shall be
1573 subject to a hold order, as allowed by law, or seizure and destruction in accordance with 21
1574 CFR 1240.60(d), Subpart D, ~~Specific Administrative Decisions Regarding Interstate Shipments.~~

1575 C. ~~If a place is provided on the harvester's tag or label for a dealer's name, address, and~~
1576 ~~certification number, the dealer's information shall be listed first.~~

1577 D. ~~If the harvester's tag or label is designed to accommodate each dealer's identification as~~
1578 ~~specified under subdivisions A 2 a and b of this section, individual dealer tags or labels need not~~
1579 ~~be provided.~~

1580 **12VAC5-421-430. Molluscan shellfish; original container.**

1581 A. Except as specified in subsections B ~~and~~, C, and D of this section, molluscan shellfish
1582 shall not be removed from the container in which they were received other than immediately
1583 before sale or preparation for service.

1584 B. For display purposes, shellstock may be removed from the container in which they are
1585 received, displayed on drained ice, or held in a display container, and a quantity specified by a
1586 consumer may be removed from the display or display container and provided to the consumer
1587 if:

1588 1. The source of the shellstock on display is identified as specified under 12VAC5-421-
1589 410 and recorded as specified under 12VAC5-421-440; and

- 1590 2. The shellstock are protected from contamination.
- 1591 C. Shucked shellfish may be removed from the container in which they were received and
 1592 held in a display container from which individual servings are dispensed upon a consumer's
 1593 request if:
- 1594 1. The labeling information for the shellfish on display as specified under 12VAC5-421-
 1595 400 is retained and correlated to the date when, or dates during which, the shellfish are
 1596 sold or served; and
- 1597 2. The shellfish are protected from contamination.
- 1598 D. Shucked shellfish may be removed from the container in which they were received and
 1599 repacked in consumer self-service containers where allowed by law if:
- 1600 1. The labeling information for the shellfish is on each consumer self-service container
 1601 as specified under 12VAC5-421-400 and 12VAC5-421-900 A and B 1 through 5;
- 1602 2. The labeling information as specified under 12VAC5-421-400 is retained and
 1603 correlated with the date when, or dates during which, the shellfish are sold or served;
- 1604 3. The labeling information and dates specified under subdivision D 2 of this section are
 1605 maintained for 90 days; and
- 1606 4. The shellfish are protected from contamination.
- 1607 **12VAC5-421-440. Shellstock; maintaining identification.**
- 1608 A. Except as specified under subdivision C 2 of this section, shellstock tags or labels shall
 1609 remain attached to the container in which the shellstock are received until the container is
 1610 empty.^{Pf}
- 1611 B. The date when the last shellstock from the container is sold or served shall be recorded
 1612 on the tag or label.^{Pf}
- 1613 C. The identity of the source of ~~shellfish~~ shellstock that are sold or served shall be
 1614 maintained by retaining shellstock tags or labels for 90 calendar days from the date that is
 1615 recorded on the tag or label as specified in subsection B of this section, by:^{Pf}
- 1616 1. Using an approved recordkeeping system that keeps the tags or labels in
 1617 chronological order correlated to the date that is recorded on the tag or label, as
 1618 specified under subsection B of this section;^{Pf} and
- 1619 2. If shellstock are removed from its tagged or labeled container:
- 1620 a. Preserving source identification by using a recordkeeping system as specified
 1621 under subdivision C 1 of this section,^{Pf} and
- 1622 b. Ensuring that shellstock from one tagged or labeled container are not commingled
 1623 with shellstock from another container with different certification numbers, different
 1624 harvest dates, or different growing areas as identified on the tag or label before being
 1625 ordered by the consumer.^{Pf}

Article 3

Protection from Contamination after Receiving

- 1628 **12VAC5-421-450. Preventing contamination.**
- 1629 A. Food employees shall wash their hands as specified under 12VAC5-421-140.
- 1630 B. Except when washing fruits and vegetables as specified under 12VAC5-421-510 or as
 1631 specified in ~~subsection~~ subsections D and E of this section, food employees shall not contact
 1632 exposed, ready-to-eat food with their bare hands and shall use suitable utensils such as deli
 1633 tissue, spatulas, tongs, single-use gloves, or dispensing equipment.^P
- 1634 C. Food employees shall minimize bare hand and arm contact with exposed food that is not
 1635 in a ready-to-eat form.^{Pf}

1636 D. Subsection B of this section does not apply to a food employee who contacts exposed,
1637 ready-to-eat food with bare hands at the time the ready-to-eat food is being added as an
1638 ingredient to food that:

1639 1. Contains a raw animal food and is to be cooked in the food establishment to heat all
1640 parts of the food to the minimum temperatures specified in [subsections A or B in]
1641 12VAC5-421-700 or 12VAC5-421-710; or

1642 2. Does not contain a raw animal food but is to be cooked in the food establishment to
1643 heat all parts of the food to a temperature of at least 145°F (63°C).

1644 D. E. Food employees not serving a highly susceptible population may contact exposed,
1645 ready-to-eat food with their bare hands if:

1646 1. The permit holder obtains prior approval from the regulatory authority;

1647 2. Written procedures are maintained in the food establishment and made available to
1648 the regulatory authority upon request that include:

1649 a. For each bare hand contact procedure, a listing of the specific ready-to-eat foods
1650 that are touched by bare hands;

1651 b. Diagrams and other information showing that handwashing facilities, installed,
1652 located, equipped, and maintained as specified under 12VAC5-421-2230, 12VAC5-
1653 421-2280, 12VAC5-421-2310, 12VAC5-421-3020, 12VAC5-421-3030, and 12VAC5-
1654 421-3045 are in an easily accessible location and in close proximity to the work
1655 station where the bare hand contact procedure is conducted;

1656 3. A written employee health policy that details how the food establishment complies
1657 with 12VAC5-421-80, 12VAC5-421-90, and 12VAC5-421-100 including:

1658 a. Documentation that the food employees and conditional employees acknowledge
1659 that they are informed to report information about their health and activities as they
1660 relate to gastrointestinal symptoms and diseases that are transmittable through food
1661 as specified under 12VAC5-421-80 A;

1662 b. Documentation that food employees and conditional employees acknowledge their
1663 responsibilities as specified under 12VAC5-421-80 E and F; and

1664 c. Documentation that the person in charge acknowledges the responsibilities as
1665 specified under 12VAC5-421-80 B, C, and D, and 12VAC5-421-90 and 12VAC5-421-
1666 100;

1667 4. Documentation that the food employees acknowledge that they have received training
1668 in:

1669 a. The risks of contacting the specific ready-to-eat foods with their bare hands;

1670 b. Proper handwashing as specified under 12VAC5-421-140;

1671 c. When to wash their hands as specified under 12VAC5-421-160;

1672 d. Where to wash their hands as specified under 12VAC5-421-170;

1673 e. Proper fingernail maintenance as specified under 12VAC5-421-190;

1674 f. Prohibition of jewelry as specified under 12VAC5-421-200; and

1675 g. Good hygienic practices as specified under 12VAC5-421-220 and 12VAC5-421-
1676 230;

1677 5. Documentation that hands are washed before food preparation and as necessary to
1678 prevent cross-contamination by food employees as specified under 12VAC5-421-130,
1679 ~~12VAC5-421-140, 12VAC5-421-160, and through~~ 12VAC5-421-170 during all hours of
1680 operation when the specific ready-to-eat foods are prepared;

- 1681 6. Documentation that food employees contacting ready-to-eat food with bare hands use
 1682 two or more of the following control measures to provide additional safeguards to
 1683 hazards associated with bare hand contact:
- 1684 a. Double handwashing;²
 - 1685 b. Nail brushes;²
 - 1686 c. A hand antiseptic after handwashing as specified under 12VAC5-421-180;²
 - 1687 d. Incentive programs such as paid sick leave that assist or encourage food
 1688 employees not to work when they are ill;² or
 - 1689 e. Other control measures approved by the regulatory authority; and
- 1690 7. Documentation that corrective action is taken when ~~subdivision D~~ subdivisions 1
 1691 ~~through 6 of this section~~ subsection are not followed.

1692 **12VAC5-421-460. Preventing contamination when tasting.**

1693 A food employee shall not use a utensil more than once to taste food that is to be sold or
 1694 served.²

1695 **12VAC5-421-470. Packaged and unpackaged food - separation, packaging, and**
 1696 **segregation.**

1697 A. Food shall be protected from cross contamination by:

- 1698 1. ~~Separating~~ Except as specified in subdivision 1 c of this subsection, separating raw
 1699 animal foods during storage, preparation, holding, and display from:
 - 1700 a. Raw ready-to-eat food including other raw animal food such as fish for sushi or
 1701 molluscan shellfish, or other raw ready-to-eat food such as [fruits
 1702 and]vegetables,² and
 - 1703 b. Cooked ready-to-eat food;²
 - 1704 c. Frozen, commercially processed, and packaged raw animal food may be stored or
 1705 displayed with or above frozen, commercially processed and packaged, ready-to-eat
 1706 food.
- 1707 2. Except when combined as ingredients, separating types of raw animal foods from
 1708 each other such as beef, fish, lamb, pork, and poultry during storage, preparation,
 1709 holding, and display by:
 - 1710 a. Using separate equipment for each type;² or ~~arranging~~
 - 1711 b. Arranging each type of food in equipment so that cross contamination of one type
 1712 with another is prevented,² and
 - 1713 ~~b. c.~~ c. Preparing each type of food at different times or in separate areas;²
- 1714 3. Cleaning equipment and utensils as specified under 12VAC5-421-1780 A and
 1715 sanitizing as specified under 12VAC5-421-1900;
- 1716 4. Except as specified in subsection B of this section and 12VAC5-421-810 B 2, storing
 1717 the food in packages, covered containers, or wrappings;
- 1718 5. Cleaning hermetically sealed containers of food of visible soil before opening;
- 1719 6. Protecting food containers that are received packaged together in a case or overwrap
 1720 from cuts when the case or overwrap is opened;
- 1721 7. Storing damaged, spoiled, or recalled food being held in the food establishment as
 1722 specified under 12VAC5-421-3150; and
- 1723 8. Separating fruits and vegetables, before they are washed as specified under 12VAC5-
 1724 421-510 from ready-to-eat food.

1725 B. Subdivision A 4 of this section does not apply to:

- 1726 1. Whole, uncut, raw fruits and vegetables and nuts in the shell; that require peeling or
 1727 hulling before consumption;
- 1728 2. Primal cuts, quarters, or sides of raw meat or slab bacon that are hung on clean,
 1729 sanitized hooks or placed on clean, sanitized racks;
- 1730 3. Whole, uncut, processed meats such as country hams, and smoked or cured
 1731 sausages that are placed on clean, sanitized racks;
- 1732 4. Food being cooled as specified under 12VAC5-421-810 B 2; or
- 1733 5. Shellstock.

1734 **12VAC5-421-480. Food storage containers; identified with common name of food.**

1735 ~~Working containers holding food or food ingredients that are removed from their original~~
 1736 ~~packages for use in the food establishment, such as cooking oils, flour, herbs, potato flakes,~~
 1737 ~~salt, spices, and sugar, shall be identified with the common name of the food (in English and the~~
 1738 ~~common language of the food workers) except that containers holding food that can be readily~~
 1739 ~~and unmistakably recognized such as dry pasta need not be identified. Except for containers~~
 1740 ~~holding food that can be readily and unmistakably recognized such as dry pasta, working~~
 1741 ~~containers holding food or food ingredients that are removed from their original packages for~~
 1742 ~~use in the food establishment, such as cooking oils, flour, herbs, potato flakes, salt, spices, and~~
 1743 ~~sugar shall be identified with the common name of the food.~~

1744 **12VAC5-421-490. Pasteurized eggs; substitute for shell raw eggs for certain recipes and**
 1745 **populations.**

1746 Pasteurized eggs or egg products shall be substituted for raw ~~shell~~ eggs in the preparation
 1747 of foods such as Caesar salad, hollandaise or [~~bearnaise~~béarnaise]sauce, mayonnaise,
 1748 meringue, [eggnog, ice cream,] and egg-fortified beverages that are not:^P

- 1749 1. Cooked as specified in 12VAC5-421-700 A 1 or 2;^P or
- 1750 2. Included in 12VAC5-421-700 D.^P

1751 **12VAC5-421-500. Protection from unapproved additives.**

1752 A. Food, as specified in 12VAC5-421-350, shall be protected from contamination that may
 1753 result from the addition of:

- 1754 1. Unsafe or unapproved food or color additives;^P and
- 1755 2. Unsafe or unapproved levels of approved food and color additives.^P

1756 B. A food employee shall not:

- 1757 1. Apply sulfiting agents to fresh fruits and vegetables intended for raw consumption or
 1758 to a food considered to be a good source of vitamin B₁;^P or
- 1759 2. Except for grapes, serve or sell food specified under subdivision B 1 of this section
 1760 that is treated with sulfiting agents before receipt by the food establishment.^P

1761 **12VAC5-421-510. Washing fruits and vegetables.**

1762 A. ~~Raw fruits and vegetables shall be thoroughly washed in water to remove soil and other~~
 1763 ~~contaminants before being cut, combined with other ingredients, cooked, served, or offered for~~
 1764 ~~human consumption in ready-to-eat form except as specified in subsection B of this section and~~
 1765 ~~except that whole, raw fruits and vegetables that are intended for washing by the consumer~~
 1766 ~~before consumption need not be washed before they are sold. Except as specified in subsection~~
 1767 ~~B of this section and except for whole, raw fruits and vegetables that are intended for washing~~
 1768 ~~by the consumer before consumption, raw fruits and vegetables shall be thoroughly washed in~~
 1769 ~~water to remove soil and other contaminants before being cut, combined with other ingredients,~~
 1770 ~~cooked, served, or offered for human consumption in ready-to-eat form.~~

1771 B. Fruits and vegetables may be washed by using chemicals as specified under 12VAC5-
1772 421-3390.

1773 C. Devices used for onsite generation of chemicals meeting the requirements specified in 21
1774 CFR 173.315 shall be used in accordance with the manufacturer's instructions.^{Pf}

1775 **12VAC5-421-520. Ice used as exterior coolant, prohibited as ingredient.**

1776 After use as a medium for cooling the exterior surfaces of food such as melons or fish,
1777 packaged foods such as canned beverages, or cooling coils and tubes of equipment, ice shall
1778 not be used as food.^P

1779 **12VAC5-421-540. Food contact with equipment and utensils.**

1780 Food shall only contact surfaces of:

1781 1. Equipment and utensils that are cleaned as specified under 12VAC5-421-1770
1782 through 12VAC5-421-1870, and sanitized as specified under ~~12VAC5-421-1880~~
1783 through 12VAC5-421-1890 and 12VAC5-421-1900;^P or

1784 2. Single-service and single-use articles;^P or

1785 3. Linens, such as cloth napkins, as specified under 12VAC5-421-560 that are laundered
1786 as specified under 12VAC5-421-1920 C.^P

1787 **12VAC5-421-550. In-use utensils, between-use storage.**

1788 During pauses in food preparation or dispensing, food preparation and dispensing utensils
1789 shall be stored:

1790 1. Except as specified under subdivision 2 of this section, in the food with their handles
1791 above the top of the food and the container;

1792 2. In food that is not ~~potentially hazardous~~ time/temperature control for safety food with
1793 their handles above the top of the food within containers or equipment that can be
1794 closed, such as bins of sugar, flour, or cinnamon;

1795 3. On a clean portion of the food preparation table or cooking equipment only if the in-
1796 use utensil and the food-contact surface of the food preparation table or cooking
1797 equipment are cleaned and sanitized at a frequency specified under 12VAC5-421-1780
1798 and 12VAC5-421-1890;

1799 4. In running water of sufficient velocity to flush particulates to the drain, if used with
1800 moist food such as ice cream or mashed potatoes;

1801 5. In a clean, protected location if the utensils, such as ice scoops, are used only with a
1802 food that is not ~~potentially hazardous~~ time/temperature control for safety food; or

1803 6. In a container of water if the water is maintained at a temperature of at least 135°F
1804 (57°C) and the container is cleaned at a frequency specified under 12VAC5-421-1780 D
1805 7.

1806 **12VAC5-421-560. Linens and napkins, use limitation.**

1807 Linens [~~and, such as cloth~~] napkins, shall not be used in contact with food unless they are
1808 used to line a container for the service of foods and the linens and napkins are replaced each
1809 time the container is refilled for a new customer.

1810 **12VAC5-421-570. Wiping cloths; ~~used for one purpose~~ use limitation.**

1811 A. Cloths in-use for wiping food spills from tableware and carry-out containers that occur as
1812 food is being served shall be:

1813 1. Maintained dry; and

1814 2. Used for no other purpose.

1815 B. Cloths in-use for wiping counters and other equipment surfaces shall be:

1816 1. Held between uses in a chemical sanitizer solution at a concentration specified in
1817 12VAC5-421-3380; and

1818 2. Laundered daily as specified under 12VAC5-421-1920 D.

1819 C. Cloths in-use for wiping surfaces in contact with raw animal foods shall be kept separate
1820 from other cloths used for other purposes.

1821 D. Dry wiping cloths and the chemical sanitizing solutions specified in subdivision B 1 of this
1822 section in which wet wiping cloths are held between uses shall be free of food debris and visible
1823 soil.

1824 E. Containers of chemical sanitizing solutions specified in subdivision B 1 of this section in
1825 which wet wiping cloths are held between uses shall be stored off the floor and used in a
1826 manner that prevents contamination of food, equipment, utensils, linens, single-service, or
1827 single-use articles.

1828 F. Single-use disposable sanitizer wipes shall be used in accordance with EPA-approved
1829 manufacturer's label use instructions.

1830 **12VAC5-421-580. Gloves; use limitation.**

1831 A. If used, single-use gloves shall be used for only one task such as working with ready-to-
1832 eat food or with raw animal food, used for no other purpose, and discarded when damaged or
1833 soiled, or when interruptions occur in the operation.^P

1834 B. Except as specified in subsection C of this section, slash-resistant gloves that are used to
1835 protect the hands during operations requiring cutting shall be used in direct contact only with
1836 food that is subsequently cooked as specified under 12VAC5-421-700 through 12VAC5-421-
1837 760 such as frozen food or a primal cut of meat.

1838 C. Slash-resistant gloves may be used with ready-to-eat food that will not be subsequently
1839 cooked if the slash-resistant gloves have a smooth, durable, and nonabsorbent outer surface; or
1840 if the slash-resistant gloves are covered with a smooth, durable, nonabsorbent glove, or a
1841 single-use glove.

1842 D. Cloth gloves shall not be used in direct contact with food unless the food is subsequently
1843 cooked as required under 12VAC5-421-700 through 12VAC5-421-760 such as frozen food or a
1844 primal cut of meat.

1845 **12VAC5-421-600. Refilling returnables.**

1846 [A. Except as specified in subsections B through E of this section, empty containers
1847 returned to a food establishment for cleaning and refilling with food shall be cleaned and refilled
1848 in a regulated food processing plant.^P]

1849 [A-B.] A take-home food container returned to a food establishment [shall not may] be
1850 refilled at a food establishment with a potentially hazardous time/temperature control for safety
1851 food [if the food container is-;

1852 1. Designed and constructed for reuse and in accordance with the requirements
1853 specified in 12VAC5-421-960 through 12VAC5-421-1430;^P

1854 2. One that was initially provided by the food establishment to the consumer, either
1855 empty or filled with food by the establishment, for the purpose of being returned for
1856 reuse;

1857 3. Returned to the food establishment by the consumer after use;

1858 4. Subject to the following steps before being refilled with food;

1859 a. Cleaned as specified in 12VAC5-421-1770 through 12VAC5-421-1860,
1860 b. Sanitized as specified in 12VAC5-421-1880 through 12VAC5-421-1900;^P and

1861 c. Visually inspected by a food employee to verify that the container, as returned,
1862 meets the requirements specified in 12VAC5-421-960 through 12VAC5-421-
1863 1430; ^Pand

1864 C. A take-home food container returned to a food establishment may be refilled at a food
1865 establishment with beverage if:

1866 1. The beverage is not a time/temperature control for safety food;

1867 2. The design of the container and the rinsing equipment and the nature of the beverage,
1868 when considered together, allow effective cleaning at home or in the food establishment;

1869 3. Facilities before rinsing or refilling returned containers with fresh, hot water that is
1870 under pressure and not recirculated are provided as part of the dispensing system;

1871 4. The consumer-owned container returned to the food establishment for refilling is
1872 refilled for sale or service only to the same consumer; and

1873 5. The container is refilled by:

1874 a. An employee of the food establishment, or

1875 b. The owner of the container if the beverage system includes a contamination-free
1876 transfer process as specified in subsections 1, 2, and 4 of 12VAC5-421-1230.]

1877 [~~B. Except as specified in subsection C of this section, a take-home food container refilled~~
1878 ~~with food that is not potentially hazardous time/temperature control for safety food shall be~~
1879 ~~cleaned as specified under 12VAC5-421-1870.]~~

1880 [~~C.D. Consumer-owned, Personal personal~~] take-out beverage containers, such as
1881 thermally insulated bottles, nonspill coffee cups and promotional beverage glasses, may be
1882 refilled by employees or the consumer if refilling is a contamination-free process as specified
1883 under subdivisions 1, 2, and 4 of 12VAC5-421-1230.

1884 [E. Consumer-owned containers that are not food-specific may be filled at a water vending
1885 machine or system.]

1886 **12VAC5-421-630. Vended ~~potentially hazardous~~ time/temperature control for safety food;**
1887 **original container.**

1888 ~~Potentially hazardous~~ Time/temperature control for safety food dispensed through a vending
1889 machine shall be in the package in which it was placed at the food establishment or food
1890 processing plant at which it was prepared.

1891 **12VAC5-421-650. Food display.**

1892 Except for nuts in the shell and whole, raw fruits and vegetables that are intended for
1893 hulling, peeling, or washing by the consumer before consumption, food on display shall be
1894 protected from contamination by the use of packaging; counter, service line, or salad bar food
1895 guards; display cases; or other effective means.^P

1896 **12VAC5-421-670. Consumer self-service operations.**

1897 A. Raw, unpackaged animal food, such as beef, lamb, pork, poultry, and fish shall not be
1898 offered for consumer self-service.^P This subsection does not apply to:

1899 1. Consumer self-service of ready-to-eat foods at buffets or salad bars that serve foods
1900 such as sushi or raw shellfish;

1901 2. Ready-to-cook individual portions for immediate cooking and consumption on the
1902 premises such as consumer-cooked meats or consumer-selected ingredients for
1903 Mongolian barbecue; or

1904 3. Raw, frozen, shell-on shrimp or lobster.

1905 B. Consumer self-service operations for ready-to-eat foods shall be provided with suitable
1906 utensils or effective dispensing methods that protect the food from contamination.^{Pf}

1907 C. Consumer self-service operations such as buffets and salad bars shall be monitored by
1908 food employees trained in safe operating procedures.^{Pf}

1909 **12VAC5-421-680. Returned food and reservice of food.**

1910 A. Except as specified under subsection B of this section, after being served or sold and in
1911 the possession of a consumer, food that is unused or returned by the consumer shall not be
1912 offered as food for human consumption.^P

1913 B. Except as specified in subdivision 8 of 12VAC5-421-950, a container of food that is
1914 not ~~potentially hazardous (time/temperature control for safety food)~~ time/temperature control for
1915 safety food may be re-served from one consumer to another if:

- 1916 1. The food is dispensed so that it is protected from contamination and the container is
1917 closed between uses such as a narrow-neck bottle containing catsup, steak sauce, or
1918 wine; or
1919 2. The food, such as crackers, salt, or pepper, is in an unopened original package and
1920 maintained in sound condition.

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1923 **12VAC5-421-700. Raw animal foods.**

1924 A. Except as specified in subsections B, C, and D of this section, raw animal foods such as
1925 eggs, fish, meat, poultry, and foods containing these raw animal foods shall be cooked to heat
1926 all parts of the food to a temperature and for a time that complies with one of the following
1927 methods based on the food that is being cooked:

- 1928 1. 145°F (63°C) or above for 15 seconds for:^P
1929 a. Raw ~~shell~~ eggs that are broken and prepared in response to a consumer's order
1930 and for immediate service;^P and
1931 b. Except as specified under subdivisions A 2 and 3 and ~~subsection~~ subsections B
1932 and C of this section, fish and meat, including game animals commercially raised for
1933 food ~~as specified under 12VAC5-421-330 A 1~~ and game animals under a voluntary
1934 inspection program as specified under 12VAC5-421-330 A 2 1;^P
1935 2. 155°F (68°C) for 15 seconds or the temperature specified in the following chart that
1936 corresponds to the holding time for ~~ratites and injected meats,~~ mechanically tenderized
1937 meats, and injected meats; the following if they are comminuted: fish, meat, game
1938 animals commercially raised for food ~~as specified under 12VAC5-421-330 A 1,~~ and
1939 game animals under a voluntary inspection program as specified under 12VAC5-421-
1940 330 A 2 1; and raw eggs that are not prepared as specified under subdivision 1 a of this
1941 subsection.^P

Minimum	
Temperature °F (°C)	Time
145 (63)	3 minutes
150 (66)	1 minute
158 (70)	<1 second (instantaneous)

- 1942 3. 165°F (74°C) or above for 15 seconds for poultry, [baluts,] wild game animals as
1943 specified under 12VAC5-421-330 A 3 2, stuffed fish, stuffed meat, stuffed pasta, stuffed
1944 poultry, stuffed ratites, or stuffing containing fish, meat, ~~or~~ poultry, or ratites.^P

1945 B. Whole meat roasts including beef, corned beef, lamb, pork, and cured pork roasts such
1946 as ham shall be cooked:

1947 1. In an oven that is preheated to the temperature specified for the roast's weight in the
1948 following chart and that is held at that temperature;^{P1} and

Oven Type	Oven Temperature Based on Roast Weight	
	Less than 10 lbs (4.5 kg)	10 lbs (4.5 kg) or more
Still Dry	350°F (177°C) or more	250°F (121°C) or more
Convection	325°F (163°C) or more	250°F (121°C) or more
High Humidity ¹	250°F (121°C) or less	250°F (121°C) or less
¹ Relative humidity greater than 90% for at least 4 <u>one</u> hour as measured in the cooking chamber or exit of the oven; or in a moisture-impermeable bag that provides 100% humidity.		

1949 2. As specified in the following chart, to heat all parts of the food to a temperature and
1950 for the holding time that corresponds to that temperature.^P

Temperature °F (°C)	Time ¹ in Minutes	Temperature °F (°C)	Time ¹ in Seconds
130 (54.4)	112	147 (63.9)	134
131 (55.0)	89	149 (65.0)	85
133 (56.1)	56	151 (66.1)	54
135 (57.2)	36	153 (67.2)	34
136 (57.8)	28	155 (68.3)	22
138 (58.9)	18	157 (69.4)	14
140 (60.0)	12	158 (70.0)	0
142 (61.1)	8		
144 (62.2)	5		
145 (62.8)	4		
¹ Holding time may include postoven heat rise.			

1951 C. A raw or undercooked whole-muscle, intact beef steak may be served or offered for sale
1952 in a ready-to-eat form if:

- 1953** 1. The food establishment serves a population that is not a highly susceptible population;
- 1954** 2. The steak is labeled, as specified under 12VAC5-421-270 E, to indicate that it meets
1955 the definition of "whole-muscle, intact beef"; and
- 1956** 3. The steak is cooked on both the top and bottom to a surface temperature of 145°F
1957 (63°C) or above and a cooked color change is achieved on all external surfaces.

1958 D. A raw animal food such as raw egg, raw fish, raw-marinated fish, raw molluscan shellfish,
1959 or steak tartare, or a partially cooked food such as lightly cooked fish, soft cooked eggs, or rare
1960 meat other than whole-muscle, intact beef steaks as specified in subsection C of this section,
1961 may be served or offered for sale [upon request or consumer selection] in a ready-to-eat form if:

1962 1. (i) As specified under subdivisions 3 a and b of 12VAC5-421-950 the food
1963 establishment serves a population that is not a highly susceptible population and (ii) the;
1964 2. The food, if served or offered for service by consumer selection from a children's
1965 menu, does not contain comminuted meat;^{Pf} and
1966 3. The consumer is informed as specified under 12VAC5-421-930 that to ensure its
1967 safety, the food should be cooked as specified under subsections subsection A or B of
1968 this section; or

1969 2. 4. The regulatory authority grants a variance from subsection A or B of this section as
1970 specified in 12VAC5-421-3570 based on a HACCP plan that:

1971 a. Is submitted by the permit holder and approved as specified under 12VAC5-421-
1972 3570;

1973 b. Documents scientific data or other information that shows that a lesser time and
1974 temperature regimen results in a safe food; and

1975 c. Verifies that equipment and procedures for food preparation and training of food
1976 employees at the food establishment meet the conditions [of the variance].

1977 **12VAC5-421-710. Microwave cooking.**

1978 Raw animal foods cooked in a microwave oven shall be:

1979 1. Rotated or stirred throughout or midway during cooking to compensate for uneven
1980 distribution of heat;

1981 2. Covered to retain surface moisture;

1982 3. Heated to a temperature of at least 165°F (74°C) in all parts of the food;^P and

1983 4. Allowed to stand covered for two minutes after cooking to obtain temperature
1984 equilibrium.

1985 **12VAC5-421-720. Plant food cooking for hot holding.**

1986 Fruits and vegetables that are cooked for hot holding shall be cooked to a temperature of
1987 135°F (57°C).^{Pf}

1988 **12VAC5-421-725. Noncontinuous cooking.**

1989 Raw animal foods that are cooked using a noncontinuous cooking process shall be:

1990 1. Subject to an initial heating process that is no longer than 60 minutes in duration;^P

1991 2. Immediately after initial heating, cooled according to the time and temperature
1992 requirements specified for cooked time/temperature control for safety food under
1993 12VAC5-421-800 A;^P

1994 3. After cooling, held frozen or cold, as specified for time/temperature control for safety
1995 food under 12VAC5-421-820 A 2;^P

1996 4. Prior to sale or service, cooked using a process that heats all parts of the food to a
1997 temperature [and for a time] as designated in 12VAC5-421-700 A, B, and C;^P

1998 5. Cooled according to the time and temperature parameters specified for cooked
1999 time/temperature control for safety food under 12VAC5-421-800 A if not [either] hot held
2000 as specified under 12VAC5-421-820 A 1, served immediately, or held using time as a
2001 public health control as specified under 12VAC5-421-850 after
2002 complete [cooling];^P and

2003 6. Prepared and stored according to written procedures that:

2004 a. Have obtained prior approval from the regulatory authority;^{Pf}

2005 b. Are maintained in the food establishment and are made available to the regulatory
2006 authority upon request;^{Pf}

2007 c. Describe how the requirements specified under subdivisions 1 through 5 of this
2008 section are to be monitored and documented by the permit holder and the corrective
2009 actions to be taken if the requirements are not met.^{Pf}

2010 d. Describe how the foods, after initial heating, but prior to complete cooking, are to
2011 be marked or otherwise identified as foods that must be cooked as specified under
2012 subdivision 4 of this section prior to being offered for sale or service;^{Pf} and

2013 e. Describe how the foods, after initial heating but prior to cooking as specified in
2014 subdivision 4 of this section, are to be separated from ready-to-eat foods as specified
2015 under 12VAC5-421-470 A.^{Pf}

2016 **12VAC5-421-730. Parasite destruction.**

2017 A. Except as specified in subsection B of this section, before service or sale in ready-to-eat
2018 form, raw, raw-marinated, partially cooked or marinated-partially cooked fish shall be:

2019 1. Frozen and stored at a temperature of -4°F (-20°C) or below for a minimum of 168
2020 hours (seven days) in a freezer;^P

2021 2. Frozen at -31°F (-35°C) or below until solid and stored at -31°F (-35°C) or below for a
2022 minimum of 15 hours;^P or

2023 3. Frozen at -31°F (-35°C) or below until solid and stored at -4°F (-20°C) or below for a
2024 minimum of 24 hours.^P

2025 B. Subsection A of this section does not apply to:

2026 1. Molluscan shellfish, including the shucked adductor muscle of scallops;

2027 2. Tuna of the species *Thunnus alalunga*, *Thunnus albacares* (Yellowfin tuna), *Thunnus*
2028 *atlanticus*, *Thunnus maccoyii* (Bluefin tuna, Southern), *Thunnus obesus* (Bigeye tuna),
2029 or *Thunnus thynnus* (Bluefin, Northern); or

2030 3. Aquacultured fish, such as salmon, that:

2031 a. If raised in open water, are raised in net-pens; or

2032 b. Are raised in land-based operations such as ponds or tanks; and

2033 c. Are fed formulated feed, such as pellets, that contains no live parasites infective to
2034 the aquacultured fish; or

2035 4. Fish eggs that have been removed from the skein and rinsed.

2036 **12VAC5-421-740. Records, creation and retention.**

2037 A. Except as specified in 12VAC5-421-730 B and subsection B of this section, if raw,
2038 marinated, raw-marinated, partially cooked, or marinated-partially cooked fish are served or sold
2039 in ready-to-eat form, the person in charge shall record the freezing temperature and time to
2040 which the fish are subjected and shall retain the records at the food establishment for 90
2041 calendar days beyond the time of service or sale of the fish.^{Pf}

2042 B. If the fish are frozen by a supplier, a written agreement or statement from the supplier
2043 stipulating that the fish supplied are frozen to a temperature and for a time specified under
2044 12VAC5-421-730 may substitute for the records specified under subsection A of this section.

2045 C. If raw, raw-marinated, partially cooked, or marinated-partially cooked fish are served or
2046 sold in ready-to-eat form, and the fish are raised and fed as specified in 12VAC5-421-730 B 3, a
2047 written agreement or statement from the supplier or aquaculturist stipulating that the fish were
2048 raised and fed as specified in 12VAC5-421-730 B 3 shall be obtained by the person in charge
2049 and retained in the records of the food establishment for 90 calendar days beyond the time of
2050 service or sale of the fish.^{Pf}

2051 **12VAC5-421-755. Preparation for immediate service.**

2052 Cooked and refrigerated food that is prepared for immediate service in response to an
2053 individual consumer order, such as a roast beef sandwich au jus, may be served at any
2054 temperature.]

2055 **12VAC5-421-760. Reheating for hot holding.**

2056 A. Except as specified under subsections B, C, and E of this section, ~~potentially hazardous~~
2057 ~~food (time/temperature control for safety food)~~ time/temperature control for safety food that is
2058 cooked, cooled, and reheated for hot holding shall be reheated so that all parts of the food
2059 reach at least 165°F (74°C) for 15 seconds.^P

2060 B. Except as specified under subsection C of this section, ~~potentially hazardous food~~
2061 ~~(time/temperature control for safety food)~~ time/temperature control for safety food reheated in a
2062 microwave oven for hot holding shall be reheated so that all parts of the food reach a
2063 temperature of at least 165°F (74°C) and the food is rotated or stirred, covered, and allowed to
2064 stand covered two minutes after reheating.^P

2065 C. Ready-to-eat ~~[time/temperature control for safety]~~ time/temperature control for safety food ~~[taken from a that has~~
2066 ~~been] commercially processed and packaged in, hermetically sealed container, or from an~~
2067 ~~intact package from]~~ a food processing plant that is inspected by the ~~[food]~~ regulatory authority
2068 that has jurisdiction over the plant, shall be heated to a temperature of at least 135°F (57°C)
2069 ~~[when being reheated]~~ for hot holding.^P

2070 D. Reheating for hot holding as specified under subsections A ~~through, B, and~~ C of this
2071 section shall be done rapidly and the time the food is between 41°F (5°C) and the temperatures
2072 specified under subsections A ~~through, B, and~~ C of this section may not exceed two hours.^P

2073 E. Remaining unsliced portions of meat roasts that are cooked as specified under 12VAC5-
2074 421-700 B may be reheated for hot holding using the oven parameters and minimum time and
2075 temperature conditions specified under 12VAC5-421-700 B.

2076 Article 5

2077 Limitation of Growth of Organisms of Public Health Concern

2078 **12VAC5-421-765. Treating juice.**

2079 Juice packaged in a food establishment shall be:

2080 1. Treated under a HACCP plan as specified in ~~subdivisions 2 through 5 of~~ 12VAC5-
2081 421-3630 to attain a five-log reduction, which is equal to a 99.999% reduction, of the
2082 most resistant microorganism of public health significance;^P or

2083 2. Labeled, if not treated to yield a five-log reduction of the most resistant microorganism
2084 of public health significance:^{Pf}

2085 a. As specified under 12VAC5-421-900;^{Pf} and

2086 b. As specified in 21 CFR 101.17(g) with the ~~[phrase following]~~, "WARNING: This
2087 product has not been pasteurized and, therefore, may contain harmful bacteria that
2088 can cause serious illness in children, the elderly, and persons with weakened
2089 immune systems."^{Pf}

2090 **12VAC5-421-780. ~~Potentially hazardous~~ Time/temperature control for safety food,**
2091 **slacking.**

2092 Frozen ~~potentially hazardous food (time/temperature control for safety~~
2093 ~~food)~~ time/temperature control for safety food that is slacked to moderate the temperature shall
2094 be held:

2095 1. Under refrigeration that maintains the food temperature at 41°F (5°C) or less; or

2096 2. At any temperature if the food remains frozen.

2097 **12VAC5-421-790. Thawing.**

2098 A. Except as specified in subdivision 4 of this section subsection, ~~potentially hazardous food~~
2099 (~~time/temperature control for safety food~~) time/temperature control for safety food shall be
2100 thawed:

- 2101 1. Under refrigeration that maintains the food temperature at 41°F (5°C) or less; or
- 2102 2. Completely submerged under running water:
- 2103 a. At a water temperature of 70°F (21°C) or below;
- 2104 b. With sufficient water velocity to agitate and float off loose particles in an overflow;
- 2105 and
- 2106 c. For a period of time that does not allow thawed portions of ready-to-eat food to
- 2107 rise above 41°F (5°C); or
- 2108 d. For a period of time that does not allow thawed portions of a raw animal food
- 2109 requiring cooking as specified under 12VAC5-421-700 A or B to be above 41°F (5°C)
- 2110 for more than four hours including:
- 2111 (1) The time the food is exposed to the running water and the time needed for
- 2112 preparation for cooking; or
- 2113 (2) The time it takes under refrigeration to lower the food temperature to 41°F (5°C);
- 2114 3. As part of a cooking process if the food that is frozen is:
- 2115 a. Cooked as specified under 12VAC5-421-700 A or B or 12VAC5-421-710; or
- 2116 b. Thawed in a microwave oven and immediately transferred to conventional cooking
- 2117 equipment, with no interruption in the process; or
- 2118 4. Using any procedure if a portion of frozen ready-to-eat food is thawed and prepared
- 2119 for immediate service in response to an individual consumer's order.

2120 B. Reduced oxygen packaged fish that bears a label indicating that it is to be kept frozen
2121 until time of use shall be removed from the reduced oxygen environment:

- 2122 1. Prior to its thawing under refrigeration as specified [~~under in~~] subdivision A 1 of this
2123 section.
- 2124 2. Prior to, or immediately upon completion of, its thawing using procedures specified in
2125 subdivision A 2 of this section.

2126 **12VAC5-421-800. Cooling.**

2127 A. ~~Cooked potentially hazardous food (time/temperature controlled for safety~~
2128 ~~food)~~ time/temperature control for safety food shall be cooled:

- 2129 1. Within two hours, from 135°F (57°C) to 70°F (21°C);^E and
- 2130 2. Within a total of six hours from 135°F (57°C) to 41°F (5°C) or less.^E

2131 B. ~~Potentially hazardous food (time/temperature control for safety food)~~ Time/temperature
2132 control for safety food shall be cooled within four hours to 41°F (5°C) or less if prepared from
2133 ingredients at ambient temperature, such as reconstituted foods and canned tuna.^E

2134 C. Except as specified in subsection D of this section, a ~~potentially hazardous food~~
2135 (~~time/temperature control for safety food~~) time/temperature control for safety food received in
2136 compliance with laws allowing a temperature above 41°F (5°C) during shipment from the
2137 supplier as specified in 12VAC5-421-340 B, shall be cooled within four hours to 41°F (5°C) or
2138 less.^E

2139 D. Raw ~~shell~~ eggs shall be received as specified under 12VAC5-421-340 C and immediately
2140 placed in refrigerated equipment that maintains an ambient air temperature of 45°F (7°C) or
2141 less.^E

2142 **12VAC5-421-810. Cooling methods.**

2143 A. Cooling shall be accomplished in accordance with the time and temperature criteria
2144 specified under 12VAC5-421-800 by using one or more of the following methods based on the
2145 type of food being cooled:

- 2146 1. Placing the food in shallow pans;^{Pf}
- 2147 2. Separating the food into smaller or thinner portions;^{Pf}
- 2148 3. Using rapid cooling equipment;^{Pf}
- 2149 4. Stirring the food in a container placed in an ice water bath;^{Pf}
- 2150 5. Using containers that facilitate heat transfer;^{Pf}
- 2151 6. Adding ice as an ingredient;^{Pf} or
- 2152 7. Other effective methods.^{Pf}

2153 B. When placed in cooling or cold holding equipment, food containers in which food is being
2154 cooled shall be:

- 2155 1. Arranged in the equipment to provide maximum heat transfer through the container
2156 walls; and
- 2157 2. Loosely covered, or uncovered if protected from overhead contamination as specified
2158 under 12VAC5-421-610 A 2, during the cooling period to facilitate heat transfer from the
2159 surface of the food.

2160 **12VAC5-421-820. ~~Potentially hazardous~~ Time/temperature control for safety food; hot and**
2161 **cold holding.**

2162 A. Except during preparation, cooking, or cooling, or when time is used as the public health
2163 control as specified under 12VAC5-421-850 [and except as specified under B and C of this
2164 section], ~~potentially hazardous food (time/temperature control for safety food)~~ time/temperature
2165 control for safety food shall be maintained:

- 2166 1. At 135°F (57°C) or above, except that roasts cooked to a temperature and for a time
2167 specified under 12VAC5-421-700 B or reheated as specified in 12VAC5-421-760 E may
2168 be held at a temperature of 130°F (54°C) or above;^E or
- 2169 2. At 41°F (5°C) or less.^P

2170 B. ~~Shell eggs~~ Eggs that have not been treated to destroy all viable Salmonellae shall be
2171 stored in refrigerated equipment that maintains an ambient air temperature of 45°F (7°C) or
2172 less.^P

2173 C. ~~Potentially hazardous food (time/temperature control for safety food)~~ Time/temperature
2174 control for safety food in a homogenous liquid form may be maintained outside the temperature
2175 control requirements, as specified in subsection A of this section, while contained within
2176 specially designed equipment that complies with the design and construction requirements as
2177 specified under subdivision 5 of 12VAC5-421-1230.^P

2178 **12VAC5-421-830. Ready-to-eat, ~~potentially hazardous food~~ time/temperature control for**
2179 **safety food; date marking.**

2180 A. Except when packaging food using a reduced oxygen packaging method as specified
2181 under 12VAC5-421-870, and except as specified in subsections D and E of this section,
2182 refrigerated ready-to-eat ~~potentially hazardous food (time/temperature control for safety~~
2183 ~~food)~~ time/temperature control for safety food prepared and held in a food establishment for
2184 more than 24 hours shall be clearly marked to indicate the date or day by which the food shall
2185 be consumed on the premises, sold, or discarded when held at a temperature of 41°F (5°C) or
2186 less for a maximum of seven days. The day of preparation shall be counted as day 1.^{Pf}

2187 B. Except as specified in subsections D ~~through, E, and F~~ of this section, refrigerated ready-
2188 to-eat, ~~potentially hazardous food (time/temperature control for safety food)~~ time/temperature
2189 control for safety food prepared and packaged by a food processing plant shall be clearly
2190 marked at the time the original container is opened in a food establishment and if the food is
2191 held for more than 24 hours, to indicate the date or day by which the food shall be consumed on
2192 the premises, sold, or discarded, based on the temperature and time combinations specified in
2193 subsection A of this section and:^{Pf}

2194 1. The day the original container is opened in the food establishment shall be counted as
2195 day 1;^{Pf} and

2196 2. The day or date marked by the food establishment shall not exceed a
2197 manufacturer's ~~use-by~~ "use by" date if the manufacturer determined the ~~use-by~~ "use by"
2198 date based on food safety.^{Pf}

2199 C. A refrigerated, ready-to-eat, ~~potentially hazardous food (time/temperature control for~~
2200 ~~safety food)~~ time/temperature control for safety food ingredient or a portion of a refrigerated,
2201 ready-to-eat, ~~potentially hazardous food (time/temperature control for safety~~
2202 ~~food)~~ time/temperature control for safety food that is subsequently combined with additional
2203 ingredients or portions of food shall retain the date marking of the earliest-prepared or first-
2204 prepared ingredient.^{Pf}

2205 D. A date marking system that meets the criteria specified in subsections A and B of this
2206 section may include:

2207 1. Using a method approved by the regulatory authority for refrigerated, ready-to-
2208 eat ~~potentially hazardous food (time/temperature control for safety~~
2209 ~~food)~~ time/temperature control for safety food that is frequently rewrapped, such as
2210 lunchmeat or a roast, or for which date marking is impractical, such as soft-serve mix or
2211 milk in a dispensing machine;

2212 2. Marking the date or day of preparation, with a procedure to discard the food on or
2213 before the last date or day by which the food must be consumed on the premises, sold,
2214 or discarded as specified in subsection A of this section;

2215 3. Marking the date or day the original container is opened in a food establishment, with
2216 a procedure to discard the food on or before the last date of or day by which the food
2217 must be consumed on the premises, sold, or discarded as specified under subsection B
2218 of this section; or

2219 4. Using calendar dates, days of the week, color-coded marks, or other effective marking
2220 methods, provided that the marking system is disclosed to the regulatory authority upon
2221 request.

2222 E. Subsections A and B of this section do not apply to individual meal portions served or
2223 repackaged for sale from a bulk container upon a consumer's request.

2224 F. Subsections A and B of this section do not apply to shellstock.

2225 F. G. Subsection B of this section does not apply to the following foods prepared and
2226 packaged by a food processing plant inspected by a regulatory authority:

2227 1. Deli salads, such as ham salad, seafood salad, chicken salad, egg salad, pasta salad,
2228 potato salad, and macaroni salad, manufactured in accordance with 21 CFR Part
2229 110 ~~Current good manufacturing practice in manufacturing, packing or holding food~~;

2230 2. Hard cheeses containing not more than 39% moisture as defined in 21 CFR Part
2231 133 ~~Cheeses and related cheese products~~, such as cheddar, gruyere, parmesan and
2232 reggiano, and romano;

- 2233 3. Semi-soft cheese containing more than 39% moisture, but not more than 50%
- 2234 moisture, as defined in 21 CFR Part 133 ~~Cheeses and cheese-related products~~, such as
- 2235 blue, edam, gorgonzola, gouda, and monterey jack;
- 2236 4. Cultured dairy products as defined in 21 CFR Part 131 ~~Milk and cream~~, such as
- 2237 yogurt, sour cream, and buttermilk;
- 2238 5. Preserved fish products, such as pickled herring and dried or salted cod, and other
- 2239 acidified fish products as defined in 21 CFR Part 114 ~~Acidified foods~~;
- 2240 6. Shelf stable, dry fermented sausages, such as pepperoni and Genoa salami ~~that are~~
- 2241 ~~not labeled "Keep Refrigerated" as specified in 9 CFR Part 317 Labeling, marking~~
- 2242 ~~devices, and containers, and that retain the original casing on the product; and~~
- 2243 7. Shelf stable salt-cured products such as prosciutto and Parma (ham) ~~that are not~~
- 2244 ~~labeled "Keep Refrigerated" as specified in 9 CFR Part 317 Labeling, marking devices,~~
- 2245 ~~and containers.~~

2246 **12VAC5-421-840. Ready-to-eat, potentially hazardous time/temperature control for safety**
 2247 **food; disposition.**

- 2248 A. A food specified under 12VAC5-421-830 A or B shall be discarded if it:
 - 2249 1. Exceeds either of the temperature and time combinations [combination]specified in
 - 2250 12VAC5-421-830 A, except time that the product is frozen;^P
 - 2251 2. Is in a container or package that does not bear a date or day;^P or
 - 2252 3. Is ~~appropriately~~ [inappropriately] marked with a date or day that exceeds a
 - 2253 temperature and time combination as specified in 12VAC5-421-830 A.^P

2254 [B. Refrigerated, ready-to-eat, time/temperature control for safety food prepared in a food
 2255 establishment and dispensed through a vending machine with an automatic shutoff control if it
 2256 exceeds a temperature and time combination as specified in 12VAC5-421-830 A. ^P]

2257 **12VAC5-421-850. Time as a public health control.**

2258 A. Except as specified under subsection D of this section, if time without temperature control
 2259 is used as the public health control for a working supply of ~~potentially hazardous food~~
 2260 ~~(time/temperature control for safety food)~~ time/temperature control for safety food before
 2261 cooking or for ready-to-eat ~~potentially hazardous food (time/temperature control for safety food)~~
 2262 time/temperature control for safety food that is displayed or held for sale or service, written
 2263 procedures shall be prepared in advance, maintained in the food establishment, and made
 2264 available to the regulatory authority upon request that specify:^{Pf}

- 2265 1. Methods of compliance with subdivisions B 1 ~~through, 2, and 3~~ or C 1 through 5 of this
- 2266 section;^{Pf} and
- 2267 2. Methods of compliance with 12VAC5-421-800 for food that is prepared, cooked, and
- 2268 refrigerated before time is used as a public health control.^{Pf}

2269 B. If time without temperature control is used as the public health control up to a maximum
 2270 of four hours:

2271 [1. The food shall have an initial temperature of 41°F (5°C) or less when removed from
 2272 cold holding temperature control, or 135°F (57°C) or greater when removed from hot-
 2273 holding temperature control; ^P]

2274 [4-2.]The food shall be marked or otherwise identified to indicate the time that is four
 2275 hours past the point in time when the food is removed from temperature control;^P

2276 [2-3.]The food shall be cooked and served, served at any temperature if ready-to-eat, or
 2277 discarded, within four hours from the point in time when the food is removed from
 2278 temperature control;^P and

2279 [3-4.] The food in unmarked containers or packages, or marked to exceed a four-hour
2280 limit shall be discarded.^{Pf}

2281 C. If time without temperature control is used as the public health control up to a maximum
2282 of six hours:

2283 1. The food shall have an initial temperature of 41°F (5°C) or less when removed from
2284 temperature control and the food temperature may not exceed 70°F (21°C) within a
2285 maximum time period of six hours;^{Pf}

2286 2. The food shall be monitored to ensure the warmest portion of the food does not
2287 exceed 70°F (21°C) during the six-hour period, unless an ambient air temperature is
2288 maintained that ensures the food does not exceed 70°F (21°C) during the six-hour
2289 holding period;^{Pf}

2290 3. The food shall be marked or otherwise identified to indicate:^{Pf}

2291 a. The time when the food is removed from 41°F (5°C) or less cold-holding
2292 temperature control;^{Pf} and

2293 b. The time that is six hours past the point in time when the food is removed from
2294 41°F (5°C) or less cold-holding temperature control;^{Pf}

2295 4. The food shall be:

2296 a. Discarded if the temperature of the foods exceeds 70°F (21°C);^{Pf} or

2297 b. Cooked and served, served at any temperature if ready-to-eat, or discarded within
2298 a maximum of six hours from the point in time when the food is removed from 41°F
2299 (5°C) or less cold-holding temperature control;^{Pf} and

2300 5. The food in unmarked containers or packages, or marked with a time that exceeds the
2301 six-hour limit shall be discarded.^{Pf}

2302 D. A food establishment that serves a highly susceptible population may not use time as
2303 specified under ~~subsections~~ subsection A, B, or C of this section as the public health control for
2304 raw eggs.

2305 **12VAC5-421-860. Variance requirement.**

2306 A food establishment shall obtain a variance from the regulatory authority as specified in
2307 12VAC5-421-3570 and 12VAC5-421-3580 before:^{Pf}

2308 1. Smoking food as a method of food preservation rather than as a method of flavor
2309 enhancement;^{Pf}

2310 2. Curing food;^{Pf}

2311 3. Using food additives or adding components such as vinegar:^{Pf}

2312 a. As a method of food preservation rather than as a method of flavor
2313 enhancement;^{Pf} or

2314 b. To render a food so that it is not ~~potentially hazardous~~ a time/temperature control
2315 for safety food; ^{Pf}

2316 4. Packaging time/temperature control for safety food using a reduced oxygen packaging
2317 method ~~except as specified under 12VAC5-421-870 where a barrier to Clostridium~~
2318 ~~botulinum in addition to refrigeration exists~~ where the growth of and toxin formation by
2319 Clostridium botulinum and the growth of Listeria monocytogenes are controlled as
2320 specified under 12VAC5-421-870; ^{Pf}

2321 5. Operating a molluscan shellfish life-support system display tank used to
2322 store ~~and~~ display shellfish that are offered for human consumption; ^{Pf}

2323 6. Custom processing animals that are for personal use as food and not for sale or
2324 service in a food establishment; ^{Pf}

- 2325 7. Sprouting seeds or beans;^{Pf} or
2326 8. Preparing food by another method that is determined by the regulatory authority to
2327 require a variance.^{Pf}

2328 **12VAC5-421-870. Reduced oxygen packaging without a variance; criteria.**

2329 A. Except for a food establishment that obtains a variance as specified under 12VAC5-421-
2330 860 and ~~except as specified under subsections C and E of this section~~, a food establishment
2331 that packages ~~potentially hazardous food (time/temperature control for safety~~
2332 ~~food)~~ time/temperature control for safety food using a reduced oxygen packaging method
2333 shall ~~ensure that there are at least two barriers in place~~ to control the growth and toxin formation
2334 of Clostridium botulinum and the growth of Listeria monocytogenes.^P

2335 B. A ~~Except as specified under subsection F of this section~~, a food establishment that
2336 packages ~~potentially hazardous food (time/temperature control for safety food)~~ time/temperature
2337 control for safety food using a reduced oxygen method shall have a HACCP plan that contains
2338 the following information specified under subdivisions 3 and 4 of 12VAC5-421-3630 D:^{Pf}

- 2339 1. Identifies food to be packaged;^{Pf}
2340 2. Except as specified in subsections C and E and as specified in subsection D of this
2341 section, requires that the packaged food shall be maintained at 41°F (5°C) or less and
2342 meet at least one of the following criteria:^{Pf}
2343 a. Has an A_w of 0.91 or less,^{Pf}
2344 b. Has a pH of 4.6 or less,^{Pf}
2345 c. Is a meat or poultry product cured ~~as at~~ a food processing plant regulated by the
2346 USDA using substances specified in 9 CFR 424.21, ~~Use of food ingredients and~~
2347 ~~sources of radiation~~, and is received in an intact package,^{Pf} or
2348 d. Is a food with a high level of competing organisms such as raw meat ~~or~~ raw
2349 poultry; or raw vegetables.^{Pf}
2350 3. Describes how the package shall be prominently and conspicuously labeled on the
2351 principal display panel in bold type on a contrasting background, with instructions to:^{Pf}
2352 a. Maintain food at 41°F (5°C) or below,^{Pf} and
2353 b. Discard the food if within 44 30 calendar days of its packaging if it [is] not served
2354 for on-premises consumption, or consumed if served or sold for off-premises
2355 consumption;^{Pf}
2356 4. Limits the refrigerated shelf life to no more than 44 30 calendar days from packaging
2357 to consumption, except the time the product is maintained frozen, or the original
2358 manufacturer's "sell by" or "use by" date, whichever occurs first;^P
2359 5. Includes operational procedures that:
2360 a. Prohibit contacting [ready-to-eat] food with bare hands [as specified in 12VAC5-
2361 421-450 B].^{Pf}
2362 b. Identify a designated work area and the method by which:^{Pf}
2363 (1) Physical barriers or methods of separation of raw foods and ready-to-eat foods
2364 minimize cross contamination,^{Pf} and
2365 (2) Access to the processing equipment is limited to responsible trained personnel
2366 familiar with the potential hazards of the operation,^{Pf} and
2367 c. Delineate cleaning and sanitization procedures for food contact surfaces; and^{Pf}
2368 6. Describes the training program that ensures that the individual responsible for the
2369 reduced oxygen packaging operation understands the:^{Pf}
2370 a. Concepts required for safe operation,^{Pf}

2371 b. Equipment and facilities,^{Pf} and
2372 c. Procedures specified under subdivision B 5 of this section and subdivisions 3 and
2373 4 of 12VAC5-421-3630 D; and^{Pf}
2374 7. Is provided to the regulatory authority prior to implementation as specified under
2375 12VAC5-421-3620 [B].

2376 C. Except for fish that is frozen before, during, and after packaging, a food establishment
2377 may not package fish using a reduced oxygen packaging method.^P

2378 D. Except as specified in subsection subsections C and F of this section, a food
2379 establishment ~~may package that packages time/temperature control for safety~~ food using a
2380 cook-chill or sous-vide process ~~without obtaining a variance if shall:~~

2381 1. ~~The food establishment implements~~ Provide to the regulatory authority prior to
2382 implementation a HACCP plan that contains the information as specified
2383 under subdivisions 3 and 4 of 12VAC5-421-3630 D;^{Pf}

2384 2. ~~The~~ Ensure the food is:

2385 a. Prepared and consumed on the premises, or prepared and consumed off the
2386 premises but within the same business entity with no distribution or sale of the
2387 bagged product to another business entity or the consumer;^{Pf}

2388 b. Cooked to heat all parts of the food to a temperature and for a time as specified
2389 under [subsections A, B, and C of 12VAC5-421-700, subsections A, B, and C of this
2390 section];^P

2391 c. Protected from contamination [before and]after cooking as specified in 12VAC5-
2392 421-450 through 12VAC5-421-~~[690,765];~~^P

2393 d. Placed in a package ~~or bag~~ with an oxygen barrier and sealed before cooking, or
2394 placed in a package ~~or bag~~ and sealed immediately after cooking, and before
2395 reaching a temperature below 135°F (57°C);^P

2396 e. Cooled to 41°F (5°C) in the sealed package ~~or bag~~ as specified under 12VAC5-
2397 421-800, and ~~subsequently;~~^P

2398 (1) Cooled to 34°F (1°C) within 48 hours of reaching 41°F (5°C) and held at that
2399 temperature until consumed or discarded within 30 days after the date
2400 of ~~preparation, packaging;~~^P

2401 (2) ~~Cooled to 34°F (1°C) within 48 hours of reaching 41°F (5°C), removed from~~
2402 ~~refrigeration equipment that maintains a 34°F (1°C) food temperature and then~~
2403 ~~held~~ Held at 41°F (5°C) or less for no more than ~~72 hours~~ seven days, at which time
2404 the food must be consumed or discarded;^P or

2405 (3) ~~Cooled to 38°F (3°C) or less within 24 hours of reaching 41°F (5°C) and held~~
2406 ~~there for no more than 72 hours from packaging, at which time the food must be~~
2407 ~~consumed or discarded;~~^P or

2408 (4) ~~(3)~~ Held frozen with no shelf-life restriction while frozen until consumed or used.^P

2409 f. Held in a refrigeration unit that is equipped with an electronic system that
2410 continuously monitors time and temperature and is visually examined for proper
2411 operation twice daily;^{Pf}

2412 g. If transported ~~off-site~~ off site to a satellite location of the same business entity,
2413 equipped with verifiable electronic monitoring devices to ensure that times and
2414 temperatures are monitored during transportation;^{Pf} and

2415 h. Labeled with the product name and the date packaged;^{Pf} and

2416 3. ~~The~~ Maintain the records required to confirm that cooling and cold holding
2417 refrigeration time/temperature parameters are required as part of the HACCP plan, are
2418 maintained and are:

2419 a. Made available to the regulatory authority upon request,^{Pf} and

2420 b. Held for six months;^{Pf} and

2421 4. ~~Written~~ Implement written operational procedures as specified under subdivision B 5
2422 of this section and a training program as specified under subdivision B 6 of this section
2423 are implemented.^{Pf}

2424 E. A Except as specified under subsection F of this section, a food establishment may
2425 package that packages cheese using a reduced oxygen packaging method ~~without obtaining a~~
2426 variance if it shall:

2427 1. Limits Limit the cheeses packaged to those that are commercially manufactured in a
2428 food processing plant with no ingredients added in the food establishment and that meet
2429 the Standards of Identity as specified in 21 CFR 133.150 ~~Hard Cheeses~~, 21 CFR
2430 133.169 ~~Pasteurized process cheese~~, or 21 CFR 133.187 ~~Semi-soft cheeses~~;^P

2431 2. Has Have a HACCP plan that contains the information specified in subdivisions 3 and
2432 4 of 12VAC5-421-3630 D and as specified under subdivisions B 1, B 3 a, B 5, and B 6 of
2433 this section.^{Pf}

2434 3. ~~Except as specified under subdivision B 2, B 3 b, and B 4, complies with subsection B~~
2435 ~~of this section;~~

2436 4. ~~Labels~~ 3. Label the package on the principal display panel with a "use by" date that
2437 does not exceed 30 days [from its packaging] or the original manufacturer's "sell by" or
2438 "use by" date, whichever ~~comes~~ [occurs] first;^{Pf} and

2439 5. ~~Discards~~ 4. Discard the reduced oxygen packaged cheese if it is not sold for off-
2440 premises consumption or consumed within 30 calendar days of its packaging.^{Pf}

2441 F. A HACCP plan is not required when a food establishment uses a reduced oxygen
2442 packaging method to package [TCStime/temperature control for safety] food that is always:

2443 1. Labeled with the production time and date.

2444 2. Held at 41°F (5°C) or less during refrigerated storage; and

2445 3. Removed from its packaging in the food establishment within 48 hours after
2446 packaging.

2447 Article 6

2448 Food Identity, Presentation, and On-Premises Labeling

2449 **12VAC5-421-880. Standards of identity.**

2450 Packaged food shall comply with standard of identity requirements in 21 CFR Parts 131-168
2451 and 9 CFR Part 319 ~~–Definitions and Standards of Identity or Composition~~, and the general
2452 requirements in 21 CFR Part 130 ~~–Food Standards: General~~ and 9 CFR Part 319, Subpart A -
2453 ~~General~~.

2454 **12VAC5-421-900. Food labels.**

2455 A. Food packaged in a food establishment, shall be labeled as specified in accordance with
2456 all applicable laws and regulations, including 21 CFR Part 101 ~~–Food Labeling~~, and 9 CFR Part
2457 317 ~~–Labeling, Marking Devices, and Containers~~.

2458 B. Label information shall include:

2459 1. The common name of the food, or absent a common name, an adequately descriptive
2460 identity statement;

- 2461 2. If made from two or more ingredients, a list of ingredients and sub-ingredients in
 2462 descending order of predominance by weight, including a declaration of
 2463 artificial ~~color~~colors, or artificial flavor flavors and chemical preservatives, if contained in
 2464 the food;
- 2465 3. An accurate declaration of the net quantity of contents;
- 2466 4. The name and place of business of the manufacturer, packer, or distributor;
- 2467 5. The name of the food source for each major food allergen contained in the food
 2468 unless the food source is already part of the common or usual name of the respective
 2469 ingredient;^{Pf}
- 2470 6. Except as exempted in the Federal Food, Drug, and Cosmetic Act § 403(Q)(3) -
 2471 through (5), nutrition labeling as specified in 21 CFR Part 101 ~~Food Labeling~~, and 9
 2472 CFR Part 317, Subpart B ~~Nutrition Labeling~~; and
- 2473 7. For any salmonid fish containing canthaxanthin or astaxanthin as a color additive, the
 2474 labeling of the bulk fish container, including a list of ingredients, displayed on the retail
 2475 container or by other written means, such as a counter card, that discloses the use of
 2476 canthaxanthin or astaxanthin.
- 2477 C. Bulk food that is available for consumer self-dispensing shall be prominently labeled with
 2478 the following information in plain view of the consumer:
- 2479 1. The manufacturer's or processor's label that was provided with the food; or
- 2480 2. A card, sign, or other method of notification that includes the information specified
 2481 under subdivisions B 1, 2 and 5 of this section.
- 2482 D. Bulk, unpackaged foods such as bakery products and unpackaged foods that are
 2483 portioned to consumer specification need not be labeled if:
- 2484 1. A health, nutrient content, or other claim is not made;
- 2485 2. There are no state or local laws requiring labeling; and
- 2486 3. The food is manufactured or prepared on the premises of the food establishment or at
 2487 another food establishment or a food processing plant that is owned by the same person
 2488 and is regulated by the food regulatory agency that has jurisdiction.
- 2489 **12VAC5-421-930. Consumer Advisory: Consumption of animal products foods that are**
 2490 **raw, undercooked, or not otherwise processed to eliminate pathogens.**
- 2491 A. Except as specified in 12VAC5-421-700 C and D 4 and under 12VAC5-421-950 C, if an
 2492 animal food such as beef, eggs, fish, lamb, pork, poultry, or shellfish is served or sold raw,
 2493 undercooked, or without otherwise being processed to eliminate pathogens, either in ready-to-
 2494 eat form or as an ingredient in another ready-to-eat food, the permit holder shall inform
 2495 consumers of the significantly increased risk of consuming such foods by way of a disclosure
 2496 and reminder, as specified in subsections B and C of this section, using brochures, deli case or
 2497 menu advisories, label statements, table tents, placards, or other effective written means.^{Pf}
- 2498 B. Disclosure shall include:
- 2499 1. A description of the animal-derived foods, such as "oysters on the half shell (raw
 2500 oysters)," "raw-egg Caesar salad," and "hamburgers (can be cooked to order)";^{Pf} or
- 2501 2. Identification of the animal-derived foods by asterisking them to a footnote that states
 2502 that the items are served raw or undercooked, or contain (or may contain) raw or
 2503 undercooked ingredients.^{Pf}
- 2504 C. Reminder shall include asterisking the animal-derived foods requiring disclosure to a
 2505 footnote that states:
- 2506 1. "Regarding the safety of these items, written information is available upon request";^{Pf}

- 2507 2. "Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may
2508 increase your risk of foodborne illness";^{Pf} or
2509 3. "Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may
2510 increase your risk of foodborne illness, especially if you have certain medical
2511 conditions."^{Pf}

2512 Article 7
2513 Contaminated Food

2514 **12VAC5-421-940. Discarding unsafe, adulterated, or contaminated food.**

2515 A. A food that is unsafe, adulterated, or not from an approved source as specified under
2516 12VAC5-421-270 through 12VAC5-421-330 shall be rendered unusable and discarded.^P

2517 B. Ready-to-eat food that may have been contaminated by an employee who has been
2518 restricted or excluded as specified under 12VAC5-421-90 shall be rendered unusable and
2519 discarded.^P

2520 C. Food that is contaminated by food employees, consumers, or other persons through
2521 contact with their hands, bodily discharges, such as nasal or oral discharges, or other means
2522 shall be rendered unusable and discarded.^P

2523 Article 8
2524 Special Requirements for Highly Susceptible Populations

2525 **12VAC5-421-950. Pasteurized foods, prohibited reservice, and prohibited food.**

2526 In a food establishment that serves a highly susceptible population:

2527 1. The following criteria apply to juice:

2528 a. For the purposes of this paragraph only, children who are age nine or less and
2529 receive food in a school, day care setting, or similar facility that provides custodial
2530 care are included as highly susceptible populations;

2531 b. Prepackaged juice or a prepackaged beverage containing juice, that bears a
2532 warning label as specified in 21 CFR 101.17(g) ~~Food Labeling~~, (Juices that have not
2533 been specifically processed to prevent, reduce or eliminate the presence of
2534 pathogens) or a packaged juice or beverage containing juice, that bears a warning
2535 label as specified under subdivision 2 of 12VAC5-421-765 shall may not be served
2536 or offered for sale;^P and

2537 c. Unpackaged juice that is prepared on the premises for service or sale in a ready-
2538 to-eat form shall be processed under a HACCP plan that contains the information
2539 specified in subdivisions 2 through 5 of 12VAC5-421-3630 and as specified ~~under~~ 21
2540 CFR 120.24, ~~Process controls~~.^P

2541 2. Pasteurized ~~shell~~ eggs or egg products shall be substituted for raw ~~shell~~ eggs in the
2542 preparation of:^P

2543 a. Foods such as Caesar salad, hollandaise or ~~biarnaise~~ Bearnaise sauce,
2544 mayonnaise, meringue, eggnog, ice cream, and egg-fortified beverages;^P and

2545 b. Except as specified in subdivision 6 of this section, recipes in which more than one
2546 egg is broken and the eggs are combined.^P

2547 3. The following foods shall not be served or offered for sale in a ready-to-eat form:

2548 a. Raw animal foods such as raw fish, raw-marinated fish, raw molluscan shellfish,
2549 and steak tartare;^P

2550 b. A partially cooked animal food such as lightly cooked fish, rare meat, soft-cooked
2551 eggs that are made from raw ~~shell~~ eggs, and meringue;^P and

2552 c. Raw seed sprouts.^P

- 2553 4. Food employees shall not contact ready-to-eat food as specified in 12VAC5-421-450
 2554 B and E.^P
- 2555 5. Time only, as the public health control as specified under 12VAC5-421-850 D, may
 2556 not be used for raw eggs.^P
- 2557 6. Subdivision 2 b of this section does not apply if:
- 2558 a. The raw eggs are combined immediately before cooking for one consumer's
 2559 serving at a single meal, cooked as specified under 12VAC5-421-700 A 1, and
 2560 served immediately, such as an omelet, soufflé, or scrambled eggs;
- 2561 b. The raw eggs are combined as an ingredient immediately before baking and the
 2562 eggs are thoroughly cooked to a ready-to-eat form, such as a cake, muffin, or bread;
 2563 or
- 2564 c. The preparation of the food is conducted under a HACCP plan that:
- 2565 (1) Identifies the food to be prepared;
- 2566 (2) Prohibits contacting ready-to-eat food with bare hands;
- 2567 (3) Includes specifications and practices that ensure:
- 2568 (a) Salmonella Enteritidis growth is controlled before and after cooking; and
- 2569 (b) Salmonella Enteritidis is destroyed by cooking the eggs according to the
 2570 temperature and time specified in 12VAC5-421-700 A 2;
- 2571 d. Contains the information specified under subdivision 4 of 12VAC5-421-3630
 2572 including procedures that:
- 2573 (1) Control cross contamination of ready-to-eat food with raw eggs; and
- 2574 (2) Delineate cleaning and sanitization procedures for food-contact surfaces; and
- 2575 e. Describes the training program that ensures that the food employee responsible
 2576 for the preparation of the food understands the procedures to be used.
- 2577 7. Except as specified in subdivision 8 of this section, food may be re-served as
 2578 specified under 12VAC5-421-680 B 1 and 2.
- 2579 8. Foods may not be re-served under the following conditions:
- 2580 1. Any food served to patients or clients who are under contact precautions in
 2581 medical isolation or quarantine, or protective environment isolation may not be re-
 2582 served to others outside.
- 2583 2. Packages of food from any patients, clients, or other consumers should not be re-
 2584 served to persons in protective environment isolation

2585 Part IV

2586 Equipment, Utensils, and Linens

2587 Article 1

2588 Materials for Construction and Repair

2589 **12VAC5-421-960. Multiuse, characteristics.**

2590 Materials that are used in the construction of utensils and food-contact surfaces of
 2591 equipment shall not allow the migration of deleterious substances or impart colors, odors, or
 2592 tastes to food and under normal use conditions shall be:^P

- 2593 1. Safe;^P
- 2594 2. Durable, corrosion-resistant, and nonabsorbent;
- 2595 3. Sufficient in weight and thickness to withstand repeated warewashing;
- 2596 4. Finished to have a smooth, easily cleanable surface; and

2597 5. Resistant to pitting, chipping, crazing, scratching, scoring, distortion, and
 2598 decomposition.

2599 **12VAC5-421-980. Lead, use limitation.**

2600 A. Ceramic, china, crystal utensils, and decorative utensils such as hand-painted ceramic or
 2601 china that are used in contact with food shall be lead-free or contain levels of lead not
 2602 exceeding the limits of the following utensil categories:^P

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

2603 B. Pewter alloys containing lead in excess of 0.05% may not be used as a food contact
 2604 surface.^P

2605 C. Solder and flux containing lead in excess of 0.2% may not be used as a food contact
 2606 surface.

2607 **12VAC5-421-990. Copper, use limitation.**

2608 A. Except as specified in subsections B and C of this section, copper and copper alloys such
 2609 as brass shall not be used in contact with a food that has a pH below 6 such as vinegar, fruit
 2610 juice, or wine or for a fitting or tubing installed between a backflow prevention device and a
 2611 carbonator.^P

2612 B. Copper and copper alloys may be used in contact with beer brewing ingredients that have
 2613 a pH below 6 in the prefermentation and fermentation steps of a beer brewing operation such as
 2614 a brewpub or microbrewery.

2615 C. Copper and copper alloys may be used in contact with apple butter and molasses
 2616 ~~[ingredients that have a pH below 6 in the preparation of these items provided the contact time~~
 2617 ~~is less than 24 hours.]~~ that have a pH below 6 during the typical processing times (i.e. mixing,
 2618 cooking, and cooling) for these products, as long as laboratory analysis does not reveal
 2619 excessive levels of copper or other heavy metals in the finished product. Apple butter and
 2620 molasses may not be held or stored in copper or copper alloys for time periods any longer than
 2621 the typical processing times for these products.]

2622 **12VAC5-421-1000. Galvanized metal, use limitation.**

2623 Galvanized metal shall not be used for utensils or food-contact surfaces of equipment that
 2624 are used in contact with acidic food.^P

2625 **12VAC5-421-1070. Single-service and single-use, characteristics.**

2626 A. Materials that are used to make single-service and single-use articles shall not:

- 2627 1. Allow the migration of deleterious substances;^P or
- 2628 2. Impart colors, odors, or tastes to food.

2629 B. Materials that are used to make single-service and single-use articles shall be ~~safe and~~
 2630 ~~clean.;~~

- 2631 1. Safe,^P and

- 2632 2. Clean.
- 2633 **12VAC5-421-1090. Food temperature measuring devices.**
- 2634 Food temperature measuring devices shall not have sensors or stems constructed of glass,
 2635 except that thermometers with glass sensors or stems that are encased in a shatterproof
 2636 coating such as candy thermometers may be used.^{Pf}
- 2637 **12VAC5-421-1100. Food-contact surfaces; cleanability.**
- 2638 A. Multiuse food-contact surfaces shall be:
- 2639 1. Smooth;^{Pf}
- 2640 2. Free of breaks, open seams, cracks, chips, inclusions, pits, and similar
 2641 imperfections;^{Pf}
- 2642 3. Free of sharp internal angles, corners, and crevices;^{Pf}
- 2643 4. Finished to have smooth welds and joints;^{Pf} and
- 2644 5. Accessible Except as specified in subsection B of this section, accessible for cleaning
 2645 and inspection by one of the following methods:
- 2646 a. Without being disassembled;^{Pf}
- 2647 b. By disassembling without the use of tools;^{Pf} or
- 2648 c. By easy disassembling with the use of handheld tools commonly available to
 2649 maintenance and cleaning personnel such as screwdrivers, pliers, open-end
 2650 wrenches, and Allen wrenches.^{Pf}
- 2651 B. Subdivision A. 5 of this section does not apply to cooking oil storage tanks, distribution
 2652 lines for cooking oils, or beverage syrup lines or tubes.
- 2653 **12VAC5-421-1110. CIP equipment.**
- 2654 A. CIP equipment shall meet the characteristics specified under 12VAC5-421-1100 and
 2655 shall be designed and constructed so that:
- 2656 1. Cleaning and sanitizing solutions circulate throughout a fixed system and contact all
 2657 interior food-contact surfaces,^{Pf} and
- 2658 2. The system is self-draining or capable of being completely drained of cleaning and
 2659 sanitizing solutions.
- 2660 B. CIP equipment that is not designed to be disassembled for cleaning shall be designed
 2661 with inspection access points to ensure that all interior food-contact surfaces throughout the
 2662 fixed system are being effectively cleaned.
- 2663 **12VAC5-421-1180. Temperature measuring devices; food.**
- 2664 A. Food temperature measuring devices that are scaled only in Fahrenheit or dually scaled
 2665 in Fahrenheit and Celsius shall be scaled in 2°F increments and accurate to ±2°F in the
 2666 intended range of use.^{Pf}
- 2667 B. Food temperature measuring devices that are scaled only in Celsius shall be scaled in
 2668 1°C increments accurate to ±1°C in the intended range of use.^{Pf}
- 2669 **12VAC5-421-1190. Temperature measuring devices; ambient air and water.**
- 2670 A. Ambient air and water temperature measuring devices that are scaled in Fahrenheit or
 2671 dually scaled in Fahrenheit and Celsius and shall be designed to be easily readable and scaled
 2672 in 3°F increments and accurate to ±3°F in the intended range of use.^{Pf}
- 2673 B. Ambient air and water temperature measuring devices that are scaled only in Celsius
 2674 shall be scaled in 1.5°C increments and accurate to ±1.5°C in the intended range of use.^{Pf}
- 2675 **12VAC5-421-1230. Dispensing equipment, protection of equipment and food.**
- 2676 In equipment that dispenses or vends liquid food or ice in unpackaged form:

- 2677 1. The delivery tube, chute, orifice, and splash surfaces directly above the container
 2678 receiving the food shall be designed in a manner, such as with barriers, baffles, or drip
 2679 aprons, so that drips from condensation and splash are diverted from the opening of the
 2680 container receiving the food;
- 2681 2. The delivery tube, chute, and orifice shall be protected from manual contact such as
 2682 by being recessed;
- 2683 3. The delivery tube or chute and orifice of equipment used to vend liquid food or ice in
 2684 unpackaged form to self-service consumers shall be designed so that the delivery tube
 2685 or chute and orifice are protected from dust, insects, rodents, and other contamination
 2686 by a self-closing door if the equipment is:
- 2687 a. Located in an outside area that does not otherwise afford the protection of an
 2688 enclosure against the rain, windblown debris, insects, rodents, and other
 2689 contaminants that are present in the environment, or
- 2690 b. Available for self-service during hours when it is not under the full-time supervision
 2691 of a food employee; and
- 2692 4. The dispensing equipment actuating lever or mechanism and filling device of
 2693 consumer self-service beverage dispensing equipment shall be designed to prevent
 2694 contact with the lip-contact surface of glasses or cups that are refilled.
- 2695 5. Dispensing equipment in which ~~potentially hazardous food (time/temperature control~~
 2696 ~~for safety food)~~ time/temperature control for safety food in homogenous liquid form is
 2697 maintained outside of the temperature control requirements as specified in 12VAC5-421-
 2698 820 C shall:
- 2699 a. Be specifically designed and equipped to maintain the commercial sterility of
 2700 aseptically packaged food in a homogenous liquid form for a specified duration from
 2701 the time of opening the packaging within the equipment;^P and
- 2702 b. Conform to the requirements for this equipment as specified in NSF/ANSI 18-2006
 2703 Manual Food and Beverage Dispensing Equipment, 2012, (NSF International).^P
- 2704 **12VAC5-421-1240. Vending machine, vending stage closure.**
- 2705 The dispensing compartment of a vending machine including a machine that is designed to
 2706 vend prepackaged snack food that is not ~~potentially hazardous~~ time/temperature control for
 2707 safety food such as chips, party mixes, and pretzels shall be equipped with a self-closing door
 2708 or cover if the machine is:
- 2709 1. Located in an outside area that does not otherwise afford the protection of an
 2710 enclosure against the rain, windblown debris, insects, rodents, and other contaminants
 2711 that are present in the environment; or
- 2712 2. Available for self-service during hours when it is not under the full-time supervision of
 2713 a food employee.
- 2714 **12VAC5-421-1300. Molluscan shellfish tanks.**
- 2715 A. Except as specified under subsection B of this section, molluscan shellfish life support
 2716 system display tanks shall not be used to display shellfish that are offered for human
 2717 consumption and shall be conspicuously marked so that it is obvious to consumers that the
 2718 shellfish are for display only.^P
- 2719 B. Molluscan shellfish life-support system display tanks that are used to store and display
 2720 shellfish that are offered for human consumption shall be operated and maintained in
 2721 accordance with a variance granted by the regulatory authority as specified in 12VAC5-421-
 2722 3570 and a HACCP plan that:^{Pf}

- 2723 1. Is submitted by the permit holder and approved as specified under 12VAC5-421-
 2724 3580;^{Pf} and
- 2725 2. Ensures that:
- 2726 a. Water used with fish other than molluscan shellfish does not flow into the
 2727 molluscan tank;^{Pf}
- 2728 b. The safety and quality of the shellfish as they were received are not compromised
 2729 by the use of the tank;^{Pf} and
- 2730 c. The identity of the source of the shellstock is retained as specified under 12VAC5-
 2731 421-440.^{Pf}

2732 **12VAC5-421-1310. Vending machines, automatic shutoff.**

2733 A. A machine vending ~~potentially hazardous food (time/temperature control for safety~~
 2734 ~~food) time/temperature control for safety food~~ shall have an automatic control that prevents the
 2735 machine from vending food:

- 2736 1. If there is a power failure, mechanical failure, or other condition that results in an
 2737 internal machine temperature that ~~can not~~ cannot maintain food temperatures as
 2738 specified under Part III (12VAC5-421-260 et seq.) of this chapter;^P and
- 2739 2. If a condition specified under subdivision 1 of this subsection occurs, until the machine
 2740 is serviced and restocked with food that has been maintained at temperatures specified
 2741 under Part III.^P

2742 B. When the automatic shutoff within a machine vending ~~potentially hazardous food~~
 2743 ~~(time/temperature control for safety food) time/temperature control for safety food~~ is activated:

- 2744 1. In a refrigerated vending machine, the ambient temperature shall not exceed 41°F
 2745 (5°C) for more than 30 minutes immediately after the machine is filled, serviced, or
 2746 restocked;^P or
- 2747 2. In a hot holding vending machine, the ambient temperature shall not be less than
 2748 135°F (57°C) for more than 120 minutes immediately after the machine is filled,
 2749 serviced, or restocked.^P

2750 **12VAC5-421-1320. Temperature measuring devices.**

2751 A. In a mechanically refrigerated or hot food storage unit, the sensor of a temperature
 2752 measuring device shall be located to measure the air temperature or a simulated product
 2753 temperature in the warmest part of a mechanically refrigerated unit and in the coolest part of a
 2754 hot food storage unit.

2755 B. Except as specified in subsection C of this section, cold or hot holding equipment used
 2756 for ~~potentially hazardous food~~ time/temperature control for safety food shall be designed to
 2757 include and shall be equipped with at least one integral or affixed temperature measuring device
 2758 that is located to allow easy viewing of the device's temperature display.

2759 C. Subsection B of this section does not apply to equipment for which the placement of a
 2760 temperature measuring device is not a practical means for measuring the ambient air
 2761 surrounding the food because of the design, type, and use of the equipment, such as calrod
 2762 units, heat lamps, cold plates, ~~bainmaries~~ bains-marie, steam tables, insulated food transport
 2763 containers, and salad bars.

2764 D. Temperature measuring devices shall be designed to be easily readable.

2765 E. Food temperature measuring devices and water temperature measuring devices on
 2766 warewashing machines shall have a numerical scale, printed record, or digital readout in
 2767 increments no greater than 2°F or 1°C in the intended range of use.^{Pf}

2768 **12VAC5-421-1350. Warewashing machines, temperature measuring devices.**

2769 A warewashing machine shall be equipped with a temperature measuring device that
2770 indicates the temperature of the water:

2771 1. In each wash and rinse tank;^{Pf} and

2772 2. As the water enters the hot water sanitizing final rinse manifold or in the chemical
2773 sanitizing solution tank.^{Pf}

2774 **12VAC5-421-1360. Manual warewashing equipment, heaters and baskets.**

2775 If hot water is used for sanitization in manual warewashing operations, the sanitizing
2776 compartment of the sink shall be:

2777 1. Designed with an integral heating device that is capable of maintaining water at a
2778 temperature not less than 171°F (77°C);^{Pf} and

2779 2. Provided with a rack or basket to allow complete immersion of equipment and utensils
2780 into the hot water.^{Pf}

2781 **12VAC5-421-1370. Warewashing machines, sanitizer level indicator automatic dispensing
2782 of detergents and sanitizers.**

2783 A. A warewashing machine installed after March 1, 2002, shall be equipped to:

2784 1. Automatically dispense detergents and sanitizers;^{Pf} and

2785 2. Incorporate a visual means to verify that detergents and sanitizers are delivered or a
2786 visual or audible alarm to signal if the detergents and sanitizers are not delivered to the
2787 respective washing and sanitizing cycles.^{Pf}

2788 B. Existing warewashing equipment shall be upgraded or replaced to meet the requirements
2789 of subsection A of this section.^{Pf}

2790 **12VAC5-421-1435. Food equipment, certification and classification.**

2791 Food equipment that is certified or classified for sanitation by an American National
2792 Standards Institute (ANSI)-accredited certification program is deemed to comply with the
2793 requirements of Articles 1 (12VAC5-421-960 et seq.) and 2 (12VAC5-421-1080 et seq.) of this
2794 part.

2795 Article 3

2796 Numbers and Capacities

2797 **12VAC5-421-1450. Cooling, heating, and holding capacities.**

2798 Equipment for cooling and heating food, and holding cold and hot food, shall be sufficient in
2799 number and capacity ~~and capable of providing to provide~~ food temperatures as specified under
2800 Part III (12VAC5-421-260 et seq.) of this chapter.^{Pf}

2801 **12VAC5-421-1460. Manual warewashing, sink compartment requirements.**

2802 A. Except as specified in subsection C of this section, a sink with at least three
2803 compartments shall be provided for manually washing, rinsing, and sanitizing equipment and
2804 utensils.^{Pf}

2805 B. Sink compartments shall be large enough to accommodate immersion of the largest
2806 equipment and utensils. If equipment or utensils are too large for the warewashing sink, a
2807 warewashing machine or alternative equipment as specified in subsection C of this section shall
2808 be used.^{Pf}

2809 C. Alternative manual warewashing equipment may be used when there are special
2810 cleaning needs or constraints and its use is approved. Alternative manual warewashing
2811 equipment may include:

2812 1. High-pressure detergent sprayers;

- 2813 2. Low-pressure or line-pressure spray detergent foamers;
- 2814 3. Other task-specific cleaning equipment;
- 2815 4. Brushes or other implements;
- 2816 5. 2 Two-compartment sinks as specified under subsections D and E of this section; or
- 2817 6. Receptacles that substitute for the compartments of a multicompartment sink.

2818 D. Before a 2 two-compartment sink is used:

- 2819 1. The permit holder shall have its use approved; and
- 2820 2. The permit holder shall limit the number of kitchenware items cleaned and sanitized in
- 2821 the two-compartment sink and shall limit warewashing to batch operations for cleaning
- 2822 kitchenware such as between cutting one type of raw meat and another or cleanup at
- 2823 the end of a shift, and shall:

2824 a. (i) Make up the cleaning and sanitizing solutions immediately before use and drain

2825 them immediately after use, and (ii) use a detergent-sanitizer to sanitize and apply

2826 the detergent-sanitizer in accordance with the manufacturer's label instructions and

2827 as specified under 12VAC5-421-1710; or

2828 b. A hot water sanitization immersion step shall be used as specified under

2829 subdivision 3 of 12VAC5-421-1860.

2830 E. A 2 two-compartment sink shall not be used for warewashing operations where cleaning

2831 and sanitizing solutions are used for a continuous or intermittent flow of kitchenware or

2832 tableware in an ongoing warewashing process.

2833 **12VAC5-421-1500. Utensils, consumer self-service.**

2834 A food dispensing utensil shall be available for each container displayed at a consumer self-

2835 service unit such as a buffet or salad bar.^{Pf}

2836 **12VAC5-421-1510. Food temperature measuring devices.**

2837 A. Food temperature measuring devices shall be provided and readily accessible for use in

2838 ensuring attainment and maintenance of food temperatures as specified under Part III (12VAC5-

2839 421-260 et seq.) of this chapter.^{Pf}

2840 B. A temperature measuring device with a suitable small-diameter probe that is designed to

2841 measure the temperature of thin masses shall be provided and readily accessible to accurately

2842 measure the temperature in thin foods such as meat patties and fish fillets.^{Pf}

2843 **12VAC5-421-1520. Temperature measuring devices, manual and mechanical**

2844 **warewashing.**

2845 A. In manual warewashing operations, a temperature measuring device shall be provided

2846 and readily accessible for frequently measuring the washing and sanitizing temperatures.

2847 B. In hot water mechanical warewashing operations, an irreversible registering temperature

2848 indicator shall be provided and readily accessible for measuring the utensil surface temperature.

2849 **12VAC5-421-1530. Sanitizing solutions, testing devices.**

2850 A test kit or other device that accurately measures the concentration in mg/L (ppm) of

2851 sanitizing solutions shall be provided and readily accessible for use.^{Pf}

2852 **12VAC5-421-1535. Cleaning agents and sanitizers, availability.**

2853 A. Cleaning agents that are used to clean equipment and utensils as specified under Article

2854 6 (12VAC5-421-1770 et seq.) of this part shall be provided and available for use during all hours

2855 of operation.

2856 B. Except for chemical sanitizers that are generated on site at the time of use, chemical
2857 sanitizers that are used to sanitize equipment and utensils as specified under Article 6 shall be
2858 provided and available for use during all hours of operation.

2859 **12VAC5-421-1630. Warewashing equipment, cleaning agents.**

2860 When used for warewashing, the wash compartment of a sink, mechanical warewasher, or
2861 wash receptacle of alternative manual warewashing equipment as specified in 12VAC5-421-
2862 1460 C, shall contain a wash solution of soap, detergent, acid cleaner, alkaline cleaner,
2863 degreaser, abrasive cleaner, or other cleaning agent according to the cleaning agent
2864 manufacturer's label instructions.^{Pf}

2865 **12VAC5-421-1650. Manual warewashing equipment, wash solution temperature.**

2866 The temperature of the wash solution in manual warewashing equipment shall be
2867 maintained at not less than 110°F (43°C) or the temperature specified on the cleaning agent
2868 manufacturer's label instructions.^{Pf}

2869 **12VAC5-421-1660. Mechanical warewashing equipment, wash solution temperature.**

2870 A. The temperature of the wash solution in spray type warewashers that use hot water to
2871 sanitize shall not be less than:

- 2872 1. For a stationary rack, single temperature machine, 165°F (74°C);^{Pf}
- 2873 2. For a stationary rack, dual temperature machine, 150°F (66°C);^{Pf}
- 2874 3. For a single tank, conveyor, dual temperature machine, 160°F (71°C);^{Pf} or
- 2875 4. For a multitank, conveyor, multitemperature machine, 150°F (66°C).^{Pf}

2876 B. The temperature of the wash solution in spray-type warewashers that use chemicals to
2877 sanitize shall not be less than 120°F (49°C).^{Pf}

2878 **12VAC5-421-1670. Manual warewashing equipment, hot water sanitization temperatures.**

2879 If immersion in hot water is used for sanitizing in a manual operation, the temperature of the
2880 water shall be maintained at 171°F (77°C) or above.^P

2881 **12VAC5-421-1680. Mechanical warewashing equipment, hot water sanitization**
2882 **temperatures.**

2883 A. Except as specified in subsection B of this section, in a mechanical operation, the
2884 temperature of the fresh hot water sanitizing rinse as it enters the manifold shall not be more
2885 than 194°F (90°C), or less than:^{Pf}

- 2886 1. For a stationary rack, single temperature machine, 165°F (74°C);^{Pf} or
- 2887 2. For all other machines, 180°F (82°C).^{Pf}

2888 B. The maximum temperature specified under subsection A of this section does not apply to
2889 the high pressure and temperature systems with wand-type, hand-held, spraying devices used
2890 for the in-place cleaning and sanitizing of equipment such as meat saws.

2891 **12VAC5-421-1700. Manual and mechanical warewashing equipment, chemical**
2892 **sanitization - temperature, pH, concentration, and hardness.**

2893 A chemical sanitizer used in a sanitizing solution for a manual or mechanical operation
2894 at exposure contact times specified under subdivision 3 of 12VAC5-421-1900 A-3 shall be listed
2895 in 40 CFR 180.940 Sanitizing solutions, shall be used in accordance with the EPA-approved
2896 manufacturer's registered label use instructions,^P and shall be used as follows:

- 2897 1. A chlorine solution shall have a minimum temperature based on the concentration and
2898 pH of the solution as listed in the following chart;^P

Minimum Concentration	Minimum Temperature
--------------------------	------------------------

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)

- 2899 2. An iodine solution shall have a:
- 2900 a. Minimum temperature of ~~75°F (24°C)~~ 68°F (20°C);^P
- 2901 b. pH of 5.0 or less or a pH no higher than the level for which the manufacturer
- 2902 specifies the solution is effective;^P and
- 2903 c. Concentration between 12.5 mg/L (ppm) and 25 mg/L (ppm);^P
- 2904 3. A quaternary ammonium compound solution shall:
- 2905 a. Have a minimum temperature of 75°F (24°C);^P
- 2906 b. Have a concentration as specified under 40 CFR 180.940 and as indicated by the
- 2907 manufacturer's use directions included in the labeling;^P and
- 2908 c. Be used only in water with 500 mg/L hardness or less or in water having a
- 2909 hardness no greater than specified by the manufacturer's label;^P
- 2910 4. If another solution of a chemical specified under subdivisions 1, 2 and 3 of this section
- 2911 is used, the permit holder shall demonstrate to the regulatory authority that the solution
- 2912 achieves sanitization and the use of the solution shall be approved;^P or
- 2913 5. If a chemical sanitizer other than chlorine, iodine, or a quaternary ammonium
- 2914 compound is used, it shall be applied in accordance with the ~~manufacturer's use~~
- 2915 ~~directions included in the labeling~~ EPA-registered label use instructions;^P and
- 2916 6. If a chemical sanitizer is generated by a device located on site at the food
- 2917 establishment it shall be used as specified in subdivisions 1 through 4 of this section and
- 2918 shall be produced by a device that:
- 2919 a. Complies with regulation as specified in §§ 2(q)(1) and 12 of the Federal
- 2920 Insecticide, Fungicide and Rodenticide Act (FIFRA).^P
- 2921 b. Complies with 40 CFR 152.500 and 40 CFR 156.10.^P
- 2922 c. Displays the EPA device manufacturing facility registration number on the device.^{Pf}
- 2923 and
- 2924 d. Is operated and maintained in accordance with manufacturer's instructions.^{Pf}
- 2925 **12VAC5-421-1720. Warewashing equipment, determining chemical sanitizer**
- 2926 **concentration.**
- 2927 Concentration of the sanitizing solution shall be accurately determined by using a test kit or
- 2928 other device.^{Pf}
- 2929 **12VAC5-421-1730. Good repair and calibration.**
- 2930 A. Utensils shall be maintained in a state of repair or condition that complies with the
- 2931 requirements specified under Articles 1 (12VAC5-421-960 et seq.) and 2 (12VAC5-421-1080 et
- 2932 seq.) of this part or shall be discarded.
- 2933 B. Food temperature measuring devices shall be calibrated in accordance with
- 2934 manufacturer's specifications as necessary to ensure their accuracy.^{Pf}
- 2935 C. Ambient air temperature, water pressure, and water temperature measuring devices shall
- 2936 be maintained in good repair and be accurate within the intended range of use.

2937 **12VAC5-421-1740. Single-service and single-use articles, required use.**

2938 A food establishment without facilities specified under Articles 6 (12VAC5-421-1770 et seq.)
2939 and 7 (~~12VAC5-421-1880~~ 12VAC5-421-1890 et seq.) of this part for cleaning and sanitizing
2940 kitchenware and tableware shall provide only single-use kitchenware, single-service articles,
2941 and single-use articles for use by food employees and single-service articles for use by
2942 consumers.^P

2943 Article 6
2944 Cleaning of Equipment and Utensils

2945 **12VAC5-421-1770. Equipment, food-contact surfaces, ~~nonfood-contact~~ non-food-contact**
2946 **surfaces, and utensils.**

- 2947 A. Equipment food-contact surfaces and utensils shall be clean to sight and touch.^{Pf}
2948 B. The food-contact surfaces of cooking equipment and pans shall be kept free of encrusted
2949 grease deposits and other soil accumulations.
2950 C. ~~Nonfood-contact~~ Non-food-contact surfaces of equipment shall be kept free of an
2951 accumulation of dust, dirt, food residue, and other debris.

2952 **12VAC5-421-1780. Equipment food-contact surfaces and utensils.**

- 2953 A. Equipment food-contact surfaces and utensils shall be cleaned:
2954 1. Except as specified in subsection B of this section, before each use with a different
2955 type of raw animal food such as beef, fish, lamb, pork, or poultry;^P
2956 2. Each time there is a change from working with raw foods to working with ready-to-eat
2957 foods;^P
2958 3. Between uses with raw fruits and vegetables and with ~~potentially hazardous~~
2959 ~~food~~ time/temperature control for safety food;^P
2960 4. Before using or storing a food temperature measuring device;^P and
2961 5. At any time during the operation when contamination may have occurred.^P

2962 B. Subdivision A 1 of this section does not apply if the food contact surface or utensil is in
2963 contact with a succession of different ~~raw animal foods~~ [different types of raw meat and
2964 poultry] each requiring a higher cooking temperature as specified under 12VAC5-421-700 than
2965 the previous food, ~~such as preparing raw fish followed by cutting raw poultry on the same~~
2966 ~~cutting board~~[type].

2967 C. Except as specified in subsection D of this section, if used with ~~potentially hazardous~~
2968 ~~food~~ time/temperature control for safety food, equipment food-contact surfaces and utensils
2969 shall be cleaned throughout the day at least every four hours.^P

2970 D. Surfaces of utensils and equipment contacting ~~potentially hazardous~~
2971 ~~food~~ time/temperature control for safety food may be cleaned less frequently than every four
2972 hours if:

- 2973 1. In storage, containers of ~~potentially hazardous food~~ time/temperature control for
2974 safety food and their contents are maintained at temperatures specified under Part III
2975 (12VAC5-421-260 et seq.) of this chapter and the containers are cleaned when they are
2976 empty;
2977 2. Utensils and equipment are used to prepare food in a refrigerated room or area that is
2978 maintained at one of the temperatures in the following chart and (i) the utensils and
2979 equipment are cleaned at the frequency in the following chart that corresponds to the
2980 temperature; and (ii) the cleaning frequency based on the ambient temperature of the
2981 refrigerated room or area is documented in the food establishment:

Temperature	Cleaning Frequency
-------------	--------------------

41°F (5.0°C) or less	24 hours
>41°F - 45°F (>5.0°C - 7.2°C)	20 hours
>45°F - 50°F (>7.2°C - 10.0°C)	16 hours
>50°F - 55°F (>10.0°C - 12.8°C)	10 hours

- 2982 3. Containers in serving situations such as salad bars, delis, and cafeteria lines hold
2983 ready-to-eat ~~potentially hazardous food~~ time/temperature control for safety food that is
2984 maintained at the temperatures specified under Part III, are intermittently combined with
2985 additional supplies of the same food that is at the required temperature, and the
2986 containers are cleaned at least every 24 hours;
- 2987 4. Temperature measuring devices are maintained in contact with food, such as when
2988 left in a container of deli food or in a roast, held at temperatures specified under Part III;
- 2989 5. Equipment is used for storage of packaged or unpackaged food such as a reach-in
2990 refrigerator and the equipment is cleaned at a frequency necessary to preclude
2991 accumulation of soil residues;
- 2992 6. The cleaning schedule is approved based on consideration of:
- 2993 a. Characteristics of the equipment and its use;
- 2994 b. The type of food involved;
- 2995 c. The amount of food residue accumulation; and
- 2996 d. The temperature at which the food is maintained during the operation and the
2997 potential for the rapid and progressive multiplication of pathogenic or toxigenic
2998 microorganisms that are capable of causing foodborne disease; or
- 2999 7. In-use utensils are intermittently stored in a container of water in which the water is
3000 maintained at 135°F (57°C) or more and the utensils and container are cleaned at least
3001 every 24 hours or at a frequency necessary to preclude accumulation of soil residues.
- 3002 E. Except when dry cleaning methods are used as specified under 12VAC5-421-1810,
3003 surfaces of utensils and equipment contacting food that is not ~~potentially~~
3004 ~~hazardous~~ time/temperature control for safety food shall be cleaned:
- 3005 1. At any time when contamination may have occurred;
- 3006 2. At least every 24 hours for iced tea dispensers and consumer self-service utensils
3007 such as tongs, scoops, or ladles;
- 3008 3. Before restocking consumer self-service equipment and utensils such as condiment
3009 dispensers and display containers;
- 3010 4. ~~[Equipment~~ At a frequency specified by the manufacturer or absent manufacturer
3011 specifications, at a frequency necessary to preclude accumulation of soil or mold. To
3012 include equipment]such as ice bins and beverage dispensing nozzles and enclosed
3013 components of equipment such as ice makers, [cooking oil storage tanks and distribution
3014 lines, beverage [and syrup] dispensing lines or tubes, coffee bean grinders, and water
3015 vending equipment[;:]
- 3016 a. ~~At a frequency specified by the manufacturer; or~~
- 3017 b. ~~Absent manufacturer specifications, at a frequency necessary to preclude~~
3018 ~~accumulation of soil or mold.~~

3019 **12VAC5-421-1810. Dry cleaning.**

3020 A. If used, dry cleaning methods such as brushing, scraping, and vacuuming shall contact
3021 only surfaces that are soiled with dry food residues that are not potentially
3022 hazardous time/temperature control for safety food.

3023 B. Cleaning equipment used in dry cleaning food-contact surfaces shall not be used for any
3024 other purpose.

3025 **12VAC5-421-1870. Returnables, cleaning for refilling. (Repealed.)**

3026 A. ~~Except as specified in subsections B and C of this section, returned empty containers~~
3027 ~~intended for cleaning and refilling with food shall be cleaned and refilled in a regulated food~~
3028 ~~processing plant.~~

3029 B. ~~A food-specific container for beverages may be refilled at a food establishment if:~~

3030 1. ~~Only a beverage that is not a potentially hazardous food is used as specified under~~
3031 ~~12VAC5-421-600 A;~~

3032 2. ~~The design of the container and of the rinsing equipment and the nature of the~~
3033 ~~beverage, when considered together, allow effective cleaning at home or in the food~~
3034 ~~establishment;~~

3035 3. ~~Facilities for rinsing before refilling returned containers with fresh, hot water that is~~
3036 ~~under pressure and not recirculated are provided as part of the dispensing system;~~

3037 4. ~~The consumer-owned container returned to the food establishment for refilling is~~
3038 ~~refilled for sale or service only to the same consumer; and~~

3039 5. ~~The container is refilled by: an employee of the food establishment, or the owner of~~
3040 ~~the container if the beverage system includes a contamination-free transfer process that~~
3041 ~~can not be bypassed by the container owner.~~

3042 C. ~~Consumer-owned containers that are not food-specific may be filled at a water vending~~
3043 ~~machine or system.~~

3044 **Article 7**
3045 **Sanitization of Equipment and Utensils**

3046 **12VAC5-421-1890. Before use after cleaning.**

3047 Utensils and food-contact surfaces of equipment shall be sanitized before use after
3048 cleaning.^P

3049 **12VAC5-421-1900. Hot water and chemical.**

3050 After being cleaned, equipment food-contact surfaces and utensils shall be sanitized in:

3051 1. Hot water manual operations by immersion for at least 30 seconds as specified under
3052 12VAC5-421-1670;^P

3053 2. Hot water mechanical operations by being cycled through equipment that is set up as
3054 specified under 12VAC5-421-1610, 12VAC5-421-1680, and 12VAC5-421-1690 and
3055 achieving a utensil surface temperature of 160°F (71°C) as measured by an irreversible
3056 registering temperature indicator;^P or

3057 3. Chemical manual or mechanical operations, including the application of sanitizing
3058 chemicals by immersion, manual swabbing, brushing, or pressure spraying methods,
3059 using a solution as specified under 12VAC5-421-1700. Contact times shall be consistent
3060 with those on EPA-registered label use instructions by providing:

3061 a. Except as specified under subdivision 3 b of this section, an exposure a
3062 contact time of at least 10 seconds for a chlorine solution specified under subdivision
3063 1 of 12VAC5-421-1700 A;^P

- 3064 ~~b. An exposure~~ A contact time of at least 7 seconds for a chlorine solution of 50 mg/L
 3065 that has a pH of 10 or less and a temperature of at least 100°F (38°C) or a pH of 8 or
 3066 less and a temperature of at least 75°F (24°C);^P
 3067 c. ~~An exposure~~ A contact time of at least 30 seconds for other chemical sanitizing
 3068 solutions;^P or
 3069 d. ~~An exposure~~ A contact time used in relationship with a combination of
 3070 temperature, concentration, and pH that, when evaluated for efficacy, yields
 3071 sanitization as defined in 12VAC5-421-10.^P

3072 **12VAC5-421-1920. Specifications Laundering frequency for linens, cloth gloves, napkins,**
 3073 **and wiping cloths.**

- 3074 A. Linens that do not come in direct contact with food shall be laundered between
 3075 operations if they become wet, sticky, or visibly soiled.
 3076 B. Cloth gloves used as specified in 12VAC5-421-580 D shall be laundered before being
 3077 used with a different type of raw animal food such as beef, lamb, pork, and fish.
 3078 C. Linens and napkins that are used as specified under 12VAC5-421-560 and cloth napkins
 3079 shall be laundered between each use.
 3080 D. Wet wiping cloths shall be laundered daily.
 3081 E. Dry wiping cloths shall be laundered as necessary to prevent contamination of food and
 3082 clean serving utensils.

3083 **12VAC5-421-2040. Preset tableware.**

- 3084 A. ~~Tableware~~ Except as specified in subsection B of this section, tableware that is preset
 3085 shall be protected from contamination by being wrapped, covered, or inverted.
 3086 B. ~~When Preset tableware is preset, may be exposed, unused settings shall be if:~~
 3087 1. ~~Removed~~ Unused settings are removed when a consumer is seated; or
 3088 2. ~~Cleaned and sanitized before further use if the settings are~~ Settings not removed
 3089 when a consumer is seated are cleaned and sanitized before further use.

3090 **12VAC5-421-2045. Rinsing equipment and utensils after cleaning and sanitizing.**

- 3091 After being cleaned and sanitized, equipment and utensils shall not be rinsed before air
 3092 drying or used unless:
 3093 1. The rinse is applied directly from a potable water supply by a warewashing machine
 3094 that is maintained and operated as specified under Articles 2 (12VAC5-421-1080 et
 3095 seq.) and 5 (12VAC5-421-1570) of this part; and
 3096 2. The rinse is applied only after the equipment and utensils have been sanitized by the
 3097 application of hot water or by the application of a chemical sanitizer solution whose EPA-
 3098 registered label use instructions call for rinsing off the sanitizer after it is applied in a
 3099 commercial warewashing machine.

3100 Part V
 3101 Water, Plumbing, and Waste

3102 Article 1
 3103 Water

3104 **12VAC5-421-2050. Approved system.**

- 3105 ~~Drinking Pure~~ water shall be obtained from an approved source ~~that is~~ water system defined
 3106 as:
 3107 1. ~~A public water system~~ waterworks constructed, maintained, and operated in
 3108 compliance with 12VAC5-590;^P or

3109 2. A ~~nonpublic water system that is~~ private well constructed, maintained, and
3110 operated ~~according to law in compliance with 12VAC5-630.~~^P

3111 **12VAC5-421-2060. System flushing and disinfection.**

3112 ~~A drinking~~ An approved water system shall be flushed and disinfected ~~before being placed~~
3113 ~~in service~~ after construction, repair, or modification and after an emergency situation, such as a
3114 flood, that may introduce contaminants to the system. A sample shall be collected from the
3115 water system and the results of the analysis shall be total coliform negative prior to placing the
3116 water system into service.^P

3117 **12VAC5-421-2070. Bottled drinking water.**

3118 Bottled drinking water used or sold in a food establishment shall be obtained from approved
3119 sources in accordance with 21 CFR Part 129 ~~Processing and Bottling of Bottled drinking~~
3120 ~~water.~~^P

3121 **12VAC5-421-2080. Quality Pure water standards.**

3122 Except as specified under 12VAC5-421-2090:

3123 1. Water from a ~~public water system~~ waterworks shall meet the ~~applicable water quality~~
3124 ~~and quantity standards found in the Virginia Waterworks Regulations (12VAC5-~~
3125 ~~590)~~ accordance with 12VAC5-590;^P and

3126 2. Water from a ~~nonpublic water system~~ private well shall meet the ~~bacteriological water~~
3127 ~~quality standards found in the Virginia Waterworks Regulations (12VAC5-~~
3128 ~~590)~~ accordance with 12VAC5-630-370 [and not exceed 10 mg/L of nitrate (as N)] .^P

3129 **12VAC5-421-2090. Nondrinking Nonpotable water.**

3130 A. ~~A nondrinking~~ nonpotable water supply shall be used only if its use is approved by the
3131 regulatory authority.^P

3132 B. ~~Nondrinking~~ Nonpotable water shall be used only for nonculinary purposes such as air
3133 conditioning, nonfood equipment cooling, fire protection, and irrigation.^P

3134 **12VAC5-421-2100. Sampling.**

3135 ~~Except when used as specified under 12VAC5-421-2090, water~~ Water from a ~~nonpublic~~
3136 ~~water system~~ private well shall be sampled and tested at least annually ~~and as required by state~~
3137 ~~water quality regulations~~ for nitrate and total coliform.

3138 1. If nitrate[(as N) , which is reports as "N" on the test results,]exceeds 10 mg/L, the
3139 owner shall notify the regulatory authority.^{Pf}

3140 2. If a sample is total coliform positive, the positive culture medium shall be further
3141 analyzed to determine if E. coli is present. The owner shall notify the regulatory authority
3142 within two days from when the owner is notified of the coliform positive test result.^{Pf}

3143 3. If E. coli is present, the owner shall notify the regulatory authority.^{Pf}

3144 **12VAC5-421-2110. Sample report.**

3145 ~~The most recent~~ All sample report reports for the ~~nonpublic water system~~ private well shall
3146 be retained on file in the food establishment ~~or the report shall be maintained as specified by~~
3147 ~~state water quality regulations~~ for a minimum of five years and be made available to the
3148 regulatory authority upon request.

3149 **12VAC5-421-2120. Capacity.**

3150 A. The approved water ~~source and~~ system capacity shall be of sufficient capacity to meet
3151 the maximum daily water demands and the peak hourly water demands of the food
3152 establishment.^{Pf}

3153 B. Hot water generation and distribution systems shall ~~be sufficient to~~ meet the peak hot
3154 water demands throughout the food establishment.^{Pf}

3155 **12VAC5-421-2130. Pressure.**

3156 Water under pressure shall be provided to all fixtures, equipment, and nonfood equipment
3157 that are required to use water except that water supplied as specified under subdivisions 1 and
3158 2 of 12VAC5-421-2160 to a temporary food establishment or in response to a temporary
3159 interruption of a water supply need not be under pressure.^{Pf}

3160 **~~12VAC5-421-2150. Distribution, delivery, and retention system. (Repealed.)~~**

3161 ~~Water shall be received from the source through the use of:~~

3162 ~~1. An approved public water main; or~~

3163 ~~2. One or more of the following that shall be constructed, maintained, and operated~~
3164 ~~according to law:~~

3165 ~~a. Nonpublic water main, water pumps, pipes, hoses, connections, and other~~
3166 ~~appurtenances;~~

3167 ~~b. Water transport vehicles, and~~

3168 ~~c. Water containers.~~

3169 **12VAC5-421-2160. Alternative water supply.**

3170 Water meeting the requirements specified under 12VAC5-421-2050 through 12VAC5-421-
3171 2130 shall be made available for a mobile facility, for a temporary food establishment without a
3172 permanent water supply, and for a food establishment with a temporary interruption of its water
3173 supply through:

3174 1. A supply of containers of commercially bottled drinking water;^{Pf}

3175 2. One or more closed portable water containers;^{Pf}

3176 3. An enclosed vehicular water tank;^{Pf}

3177 4. An on-premises water storage tank;^{Pf} or

3178 5. Piping, tubing, or hoses connected to an adjacent approved source system in a
3179 manner approved by the department.^{Pf}

3180 Article 2

3181 Plumbing System

3182 **12VAC5-421-2170. Approved materials.**

3183 A. A plumbing system and hoses conveying water shall be constructed and repaired with
3184 approved materials according to law.^P

3185 B. A water filter shall be made of safe materials.^P

3186 **12VAC5-421-2180. Approved system and cleanable fixtures.**

3187 A. A plumbing system shall be designed, constructed, and installed according to law.^P

3188 B. A plumbing fixture such as a handwashing lavatory, toilet, or urinal shall be easily
3189 cleanable.

3190 **12VAC5-421-2190. Handwashing sink, water temperature, and flow.**

3191 A. A handwashing sink shall be equipped to provide water at a temperature of at least 100°F
3192 (38°C) through a mixing valve or combination faucet.^{Pf}

3193 B. A steam mixing valve shall not be used at a handwashing sink.

3194 C. A self-closing, slow-closing, or metering faucet shall provide a flow of water for at least 15
3195 seconds without the need to reactivate the faucet.

3196 D. An automatic handwashing facility shall be installed in accordance with manufacturer's
3197 instructions.

- 3198 12VAC5-421-2200. Backflow prevention, air gap.**
- 3199** An air gap between the water supply inlet and the flood level rim of the plumbing fixture,
3200 equipment, or nonfood equipment shall be at least twice the diameter of the water supply inlet
3201 and shall not be less than one inch (25 mm).^P
- 3202 12VAC5-421-2210. Backflow prevention device, design standard.**
- 3203** A backflow or backsiphonage prevention device installed on a water supply system shall
3204 comply with the Virginia Statewide Uniform Building Code (13VAC5-63) for construction,
3205 installation, maintenance, inspection, and testing for that specific application and type of
3206 device.^P
- 3207 12VAC5-421-2230. Handwashing sinks, numbers, and capacities.**
- 3208** A. Except as specified in subsection B and C of this section, at least one handwashing sink,
3209 or the number of handwashing sinks necessary for their convenient use by employees in areas
3210 specified under 12VAC5-421-2280, and not fewer than the number of handwashing sinks
3211 required by law shall be provided.^{Pf}
- 3212** B. If approved and capable of removing the types of soils encountered in the food
3213 operations involved, automatic handwashing facilities may be substituted for handwashing sinks
3214 in a food establishment that has at least one handwashing sink.
- 3215** ~~B. C.~~ C. If approved, when food exposure is limited and handwashing sinks are not
3216 conveniently available, such as in some mobile or temporary food establishments or at some
3217 vending machine locations, employees may use chemically treated towelettes for handwashing.
- 3218 12VAC5-421-2250. Service sink.**
- 3219** A. At least one service sink or one curbed cleaning facility equipped with a floor drain shall
3220 be provided and conveniently located for the cleaning of mops or similar wet floor cleaning tools
3221 and for the disposal of mop water and similar liquid waste.
- 3222** B. Toilets and urinals shall not be used as a service sink for the disposal of mop water and
3223 similar liquid waste.
- 3224 12VAC5-421-2260. Backflow prevention device, when required.**
- 3225** A plumbing system shall be installed to preclude backflow of a solid, liquid, or gas
3226 contaminant into the water supply system at each point of use at the food establishment,
3227 including on a hose bibb (threaded faucet) if a hose is attached or on a hose bibb if a hose is
3228 not attached and backflow prevention is required by law by:
- 3229** 1. Providing an air gap as specified under 12VAC5-421-2200;^P or
- 3230** 2. Installing an approved backflow prevention device as specified under 12VAC5-421-
3231 2210.^P
- 3232 12VAC5-421-2270. Backflow prevention device, carbonator.**
- 3233** A. If not provided with an air gap as specified under 12VAC5-421-2200, a double check
3234 valve with an intermediate vent preceded by a screen of not less than 100 mesh to 1 inch (100
3235 mesh to 25.4mm) shall be installed upstream from a carbonating device and downstream from
3236 any copper in the water supply line.^P
- 3237** ~~B. A single or double dual~~ check valve attached to the carbonator need not be of the vented
3238 type if an air gap or vented backflow prevention device has been otherwise ~~provided~~ approved
3239 as specified under subsection A of this section.
- 3240 12VAC5-421-2280. Handwashing sinks, location.**
- 3241** A handwashing sink shall be located:
- 3242** 1. ~~To be readily accessible for~~ allow convenient use by employees in food preparation,
3243 food dispensing, and warewashing areas;^{Pf} and

- 3244 2. In, or immediately adjacent to, toilet rooms.^{Pf}
- 3245 **12VAC5-421-2310. Using a handwashing sink.**
- 3246 A. A handwashing sink shall be maintained so that it is accessible at all times for employee
3247 use.^{Pf}
- 3248 B. A handwashing sink shall not be used for purposes other than handwashing.^{Pf}
- 3249 C. An automatic handwashing facility shall be used in accordance with manufacturer's
3250 instructions.^{Pf}
- 3251 **12VAC5-421-2320. Prohibiting a cross connection.**
- 3252 A. ~~Except as specified in 9 CFR 308.3(d) for firefighting,~~ a A person shall not create a cross
3253 connection by connecting a pipe or conduit between the drinking water system and a
3254 nondrinking water system or a water system of unknown quality.^P
- 3255 B. The piping of a nondrinking water system shall be durably identified so that it is readily
3256 distinguishable from piping that carries drinking water.^{Pf}
- 3257 **12VAC5-421-2330. Scheduling inspection and service for a water system device.**
- 3258 A device such as a water treatment device or backflow preventer shall be scheduled for
3259 inspection and service, in accordance with manufacturer's instructions and as necessary to
3260 prevent device failure based on local water conditions, and records demonstrating inspection
3261 and service shall be maintained by the person in charge.^{Pf}
- 3262 **12VAC5-421-2340. Water reservoir of fogging devices, cleaning.**
- 3263 A. A reservoir that is used to supply water to a device such as a produce fogger shall be:
3264 1. Maintained in accordance with manufacturer's specifications;^P and
3265 2. Cleaned in accordance with manufacturer's specifications or according to the
3266 procedures specified under subsection B of this section, whichever is more stringent.^P
- 3267 B. Cleaning procedures shall include at least the following steps and shall be conducted at
3268 least once a week:
- 3269 1. Draining and complete disassembly of the water and aerosol contact parts;^P
3270 2. Brush-cleaning the reservoir, aerosol tubing, and discharge nozzles with a suitable
3271 detergent solution;^P
3272 3. Flushing the complete system with water to remove the detergent solution and
3273 particulate accumulation;^P and
3274 4. Rinsing by immersing, spraying, or swabbing the reservoir, aerosol tubing, and
3275 discharge nozzles with at least 50 mg/L (ppm) hypochlorite solution.^P
- 3276 **12VAC5-421-2350. System maintained in good repair.**
- 3277 A plumbing system shall be (i) repaired according to law^P and (ii) maintained in good repair.
- 3278 Article 3
- 3279 Mobile Water Tank and Mobile Food Establishment Water Tank
- 3280 **12VAC5-421-2360. ~~Approved~~ Mobile water tank approved materials.**
- 3281 Materials that are used in the construction of a mobile water tank, mobile food establishment
3282 water tank, and appurtenances shall be:
- 3283 1. Safe;^P
3284 2. Durable, corrosion resistant, and nonabsorbent; and
3285 3. Finished to have a smooth, easily cleanable surface.
- 3286 **12VAC5-421-2420. Hose, construction and identification.**
- 3287 A hose used for conveying drinking potable water from a water tank shall be:

- 3288 1. Safe;^P
- 3289 2. Durable, corrosion resistant, and nonabsorbent;
- 3290 3. Resistant to pitting, chipping, crazing, scratching, scoring, distortion, and
- 3291 decomposition;
- 3292 4. Finished with a smooth interior surface; and
- 3293 5. Clearly and durably identified as to its use if not permanently attached.
- 3294 **12VAC5-421-2430. Filter, compressed air.**
- 3295 A filter that does not pass oil or oil vapors shall be installed in the air supply line between the
- 3296 compressor and ~~drinking~~ potable water system when compressed air is used to pressurize the
- 3297 water tank system.^P
- 3298 **12VAC5-421-2460. System flushing and disinfection.**
- 3299 A water tank, pump, and hoses shall be flushed and sanitized before being placed in service
- 3300 after construction, repair, modification, and periods of nonuse.^P
- 3301 **12VAC5-421-2490. Tank, pump, and hoses, dedication.**
- 3302 A. Except as specified in subsection B of this section, a water tank, pump, and hoses used
- 3303 for conveying drinking water shall be used for no other purpose.^P
- 3304 B. Water tanks, pumps, and hoses approved for liquid foods may be used for conveying
- 3305 drinking water if they are cleaned and sanitized before they are used to convey water.
- 3306 **12VAC5-421-2520. Backflow prevention.**
- 3307 A. Except as specified in subsections B, C, and D of this section, a direct connection may
- 3308 not exist between the sewage system and a drain originating from equipment in which food,
- 3309 portable equipment, or utensils are placed.^P
- 3310 B. Subsection A of this section does not apply to floor drains that originate in refrigerated
- 3311 spaces that are constructed as an integral part of the building.
- 3312 C. If allowed by law, a warewashing machine may have a direct connection between its
- 3313 waste outlet and a floor drain when the machine is located within five feet (1.5 meters) of a
- 3314 trapped floor drain and the machine outlet is connected to the inlet side of a properly vented
- 3315 floor drain trap.
- 3316 D. If allowed by law, a warewashing or culinary sink may have a direct connection.
- 3317 **12VAC5-421-2540. Conveying sewage.**
- 3318 Sewage shall be conveyed to the point of disposal through an approved sanitary sewage
- 3319 system or other system, including use of sewage transport vehicles, waste retention tanks,
- 3320 pumps, pipes, hoses, and connections that are constructed, maintained, and operated
- 3321 according to law.^P
- 3322 **12VAC5-421-2550. Removing mobile food establishment wastes.**
- 3323 Sewage No public health hazard or nuisance shall result when sewage and other liquid
- 3324 wastes ~~shall be~~ are removed from a mobile food establishment at an approved waste servicing
- 3325 area or by a permitted sewage transport vehicle ~~in such a way that a public health hazard or~~
- 3326 ~~nuisance is not created.~~^{Pf}
- 3327 **12VAC5-421-2570. Approved sewage disposal system.**
- 3328 Sewage shall be disposed through an approved facility that is:
- 3329 1. A public sewage treatment plant;^P or
- 3330 2. An individual sewage disposal system that is sized, constructed, maintained, and
- 3331 operated according to ~~law~~ the State Board of Health's regulations promulgated pursuant

3332 to Chapter 6 (§ 32.1-163 et seq.) of Title 32 of the Code of Virginia, including 12VAC5-
3333 610, 12VAC5-613, and 12VAC5-640.^{Pf}

3334 **12VAC5-421-2990. Private homes and living or sleeping quarters, use prohibition.**

3335 A private home, a room used as living or sleeping quarters, or an area directly opening into
3336 a room used as living or sleeping quarters shall not be used for conducting food establishment
3337 operations.^{Pf}

3338 Article 3
3339 Numbers and Capacities

3340 **12VAC5-421-3020. Handwashing cleanser, availability.**

3341 Each handwashing sink or group of two adjacent handwashing sinks shall be provided with
3342 a supply of hand cleaning liquid, powder, or bar soap.^{Pf}

3343 **12VAC5-421-3030. Hand drying provision.**

3344 Each handwashing sink or group of adjacent handwashing sinks shall be provided with:

- 3345 1. Individual, disposable towels;^{Pf}
- 3346 2. A continuous towel system that supplies the user with a clean towel; ~~or~~^{Pf}
- 3347 3. A heated-air hand drying device;^{Pf} ~~or~~
- 3348 4. A hand drying device that employs an air-knife system that delivers high-velocity,
3349 pressurized air at ambient temperatures.^{Pf}

3350 **12VAC5-421-3070. Toilet tissue, availability.**

3351 A supply of toilet tissue shall be available at each toilet.^{Pf}

3352 **12VAC5-421-3150. Distressed merchandise, segregation and location.**

3353 Products that are held by the permit holder for credit, redemption, or return to the distributor,
3354 such as damaged, spoiled, or recalled products, shall be segregated and held in designated
3355 areas that are separated from food, equipment, utensils, linens, and single-service and single-
3356 use articles.^{Pf}

3357 **12VAC5-421-3210. Cleaning maintenance tools, preventing contamination.**

3358 Food preparation sinks, handwashing lavatories, and warewashing equipment shall not be
3359 used for the cleaning of maintenance tools, the preparation or holding of maintenance materials,
3360 or the disposal of mop water and similar liquid wastes.^{Pf}

3361 **12VAC5-421-3270. Controlling pests.**

3362 The presence of insects, rodents, and other pests shall be controlled to minimize their
3363 presence on the premises by:

- 3364 1. Routinely inspecting incoming shipments of food and supplies;
- 3365 2. Routinely inspecting the premises for evidence of pests;
- 3366 3. Using methods, if pests are found, such as trapping devices or other means of pest
3367 control as specified under 12VAC5-421-3360, 12VAC5-421-3440, and 12VAC5-421-
3368 3450;^{Pf} and
- 3369 4. Eliminating harborage conditions.

3370 **12VAC5-421-3310. Prohibiting animals.**

3371 A. Except as specified in subsections B and C of this section, live animals shall not be
3372 allowed on the premises of a food establishment.^{Pf}

3373 B. Live animals may be allowed in the following situations if the contamination of food; clean
3374 equipment, utensils, and linens; and unwrapped single-service and single-use articles cannot
3375 result:

- 3376 1. Edible fish or decorative fish in aquariums, shellfish or crustacea on ice or under
3377 refrigeration, and shellfish and crustacea in display tank systems;
- 3378 2. Patrol dogs accompanying police or security officers in offices and dining, sales, and
3379 storage areas, and sentry dogs running loose in outside fenced areas;
- 3380 3. In areas that are not used for food preparation and that are usually open for
3381 customers, such as dining and sales areas, service animals that are controlled by the
3382 disabled employee or person, if a health or safety hazard will not result from the
3383 presence or activities of the service animal;
- 3384 4. Pets in the common dining areas of institutional care facilities such as nursing homes,
3385 assisted living facilities, group homes, ~~or~~ residential care facilities, and food
3386 establishment bed and breakfast facilities at times other than during meals if:
- 3387 a. Effective partitioning and self-closing doors separate the common dining areas
3388 from food storage or food preparation areas;
- 3389 b. Condiments, equipment, and utensils are stored in enclosed cabinets or removed
3390 from the common dining areas when pets are present; and
- 3391 c. Dining areas including tables, countertops, and similar surfaces are effectively
3392 cleaned before the next meal service; and
- 3393 5. In areas that are not used for food preparation, storage, sales, display, or dining, in
3394 which there are caged animals or animals that are similarly restricted, such as in a
3395 variety store that sells pets or a tourist park that displays animals.
- 3396 6. Dogs in outdoor dining areas if:
- 3397 a. The outdoor dining area is not fully enclosed with floor to ceiling walls and is not
3398 considered a part of the interior physical facility.
- 3399 b. The outdoor dining area is equipped with an entrance that is separate from the
3400 main entrance to the food establishment and the separate entrance serves as the
3401 sole means of entry for patrons accompanied by dogs.
- 3402 c. A sign stating that dogs are allowed in the outdoor dining area is posted at each
3403 entrance to the outdoor dining area in such a manner as to be clearly observable by
3404 the public.
- 3405 [d. A sign within the outdoor dining area stating the requirements as specified in
3406 subdivisions 6 e, f, and g of this subsection is provided in such a manner as to be
3407 clearly observable by the public.]
- 3408 [d.e.] Food and water provided to dogs is served using equipment that is not used for
3409 service of food to persons or is served in single-use articles.
- 3410 [e.f.] Dogs are not allowed on chairs, seats, benches, or tables.
- 3411 [f.g.] Dogs are kept on a leash or within a pet carrier and under the control of an adult
3412 at all times.
- 3413 [g-h.] Establishment provides effective means for cleaning up dog vomitus and fecal
3414 matter.
- 3415 ~~[h. A sign within the outdoor dining area stating the requirements as specified in~~
3416 ~~subdivisions 6 d, e, and f of this subsection is provided in such a manner as to be~~
3417 ~~clearly observable by the public.]~~
- 3418 C. Live or dead fish bait may be stored if contamination of food; clean equipment, utensils,
3419 and linens; and unwrapped single-service and single-use articles ~~can not~~ cannot result.

3420 D. In bed and breakfast facilities serving 18 or fewer customers, live animals shall be
3421 allowed in the facility but shall not be fed using the same equipment or utensils that are used to
3422 feed humans.

3423 Part VII
3424 Poisonous or Toxic Materials
3425 Article 1
3426 Labeling and Identification

3427 **12VAC5-421-3320. Original containers - identifying information, prominence.**

3428 Containers of poisonous or toxic materials and personal care items shall bear a legible
3429 manufacturer's label.^{Pf}

3430 **12VAC5-421-3330. Working containers - common name.**

3431 Working containers used for storing poisonous or toxic materials such as cleaners and
3432 sanitizers taken from bulk supplies shall be clearly and individually identified with the common
3433 name of the material.^{Pf}

3434 Article 2
3435 Operational Supplies and Applications

3436 **12VAC5-421-3340. Storage, separation.**

3437 Poisonous or toxic materials shall be stored so they ~~can not~~ cannot contaminate food,
3438 equipment, utensils, linens, and single-service and single-use articles by:

- 3439 1. Separating the poisonous or toxic materials by spacing or partitioning; ^P and
3440 2. Locating the poisonous or toxic materials in an area that is not above food,
3441 equipment, utensils, linens, and single-service or single-use articles. This subsection
3442 does not apply to equipment and utensil cleaners and sanitizers that are stored in
3443 warewashing areas for availability and convenience if the materials are stored to prevent
3444 contamination of food, equipment, utensils, linens, and single-service and single-use
3445 articles; ~~and,~~ ^P
3446 ~~3. Detergents, sanitizers, related cleaning or drying agents and caustics, acids, polishes~~
3447 ~~and other chemicals shall be stored separately from insecticides and rodenticides.~~

3448 **12VAC5-421-3350. Presence and use restriction.**

3449 A. Only those poisonous or toxic materials that are required for the operation and
3450 maintenance of a food establishment, such as for the cleaning and sanitizing of equipment and
3451 utensils and the control of insects and rodents, shall be allowed in a food establishment.^{Pf}

3452 B. Subsection A of this section does not apply to packaged poisonous or toxic materials that
3453 are for retail sale.

3454 **12VAC5-421-3360. Conditions of use.**

3455 Poisonous or toxic materials shall be:

- 3456 1. Used according to:
3457 a. Law and this chapter;
3458 b. Manufacturer's use directions included in labeling, and, for a pesticide,
3459 manufacturer's label instructions that state that use is allowed in a food
3460 establishment;^P
3461 c. The conditions of certification, if certification is required, for use of the pest control
3462 materials;^P and
3463 d. Additional conditions that may be established by the regulatory authority; ~~and,~~ ^P
3464 2. Applied so that:

- 3465 a. A hazard to employees or other persons is not constituted;^P and
- 3466 b. Contamination including toxic residues due to drip, drain, fog, splash, or spray on
- 3467 food, equipment, utensils, linens, and single-service and single-use articles is
- 3468 prevented, and for a restricted-use pesticide, this is achieved by:^P
- 3469 (1) Removing the items, covering the items with impermeable covers, or taking other
- 3470 appropriate preventive actions;^P and
- 3471 (2) Cleaning and sanitizing equipment and utensils after the application.^P
- 3472 3. A restricted use pesticide shall be applied only by an applicator certified as defined in
- 3473 7 USC § 136(e) (Federal Insecticide, Fungicide and Rodenticide Act), or a person under
- 3474 the direct supervision of a certified applicator.^{Pf}
- 3475 **12VAC5-421-3370. Poisonous or toxic material containers.**
- 3476 A container previously used to store poisonous or toxic materials shall not be used to store,
- 3477 transport, or dispense food.^P
- 3478 **12VAC5-421-3380. Sanitizers, criteria.**
- 3479 Chemical sanitizers, including chemical sanitizing solutions generated on site, and other
- 3480 chemical antimicrobials applied to food-contact surfaces shall meet:
- 3481 1. Meet the requirements specified in 40 CFR 180.940,^P or
- 3482 2. Meet the requirements as specified in 40 CFR 180.2020.^P
- 3483 **12VAC5-421-3390. Chemicals for washing fruits and vegetables, criteria.**
- 3484 A. Chemicals, including those generated on site, used to wash or peel raw, whole fruits and
- 3485 vegetables shall ~~meet the requirements specified in 21 CFR 173.315;~~
- 3486 1. Be an approved food additive listed for this intended use in 21 CFR 173,^P or
- 3487 2. Be generally recognized as safe (GRAS) for this intended use,^P or
- 3488 3. Be the subject of an effective food contact notification for this intended use (only
- 3489 effective for the manufacturer or supplier identified in the notification),^P and
- 3490 4. Meet the requirements in the 40 CFR Part 156.^P
- 3491 B. Ozone as an antimicrobial agent used in the treatment, storage, and processing of fruits
- 3492 and vegetables in a food establishment shall meet the requirements specified in 21 CFR
- 3493 173.368.^P
- 3494 **12VAC5-421-3400. Boiler water additives, criteria.**
- 3495 Chemicals used as boiler water additives shall meet the requirements specified in 21 CFR
- 3496 173.310.^P
- 3497 **12VAC5-421-3410. Drying agents, criteria.**
- 3498 Drying agents used in conjunction with sanitization shall:
- 3499 1. Contain only components that are listed as one of the following:
- 3500 a. Generally recognized as safe for use in food as specified in 21 CFR Part 182 -
- 3501 Substances Generally Recognized as Safe, or 21 CFR Part 184 —Direct Food
- 3502 Substances Affirmed as Generally Recognized as Safe,^P
- 3503 b. Generally recognized as safe for the intended use as specified in 21 CFR Part
- 3504 186 —Indirect Food Substances Affirmed as Generally Recognized as Safe,^P
- 3505 c. Generally recognized as safe for the intended use as determined by experts
- 3506 qualified in scientific training and experience to evaluate the safety of substances
- 3507 added, directly or indirectly, to food as described in 21 CFR 170.30,^P
- 3508 d. Subject of an effective Food Contact Notification as described in the Federal Food
- 3509 Drug and Cosmetic Act (FFDCA) § 409(h).^P

3510 e. ~~e.~~ Approved for use as a drying agent under a prior sanction specified in 21 CFR
3511 Part 181 ~~—Prior-Sanctioned-Food-Ingredients,~~ as specified in the Federal Food Drug
3512 and Cosmetic Act (FFDCA) § 201(s)(4).^P

3513 ~~d.~~ f. Specifically regulated as an indirect food additive for use as a drying agent as
3514 specified in 21 CFR Parts 175- through178,^P or

3515 e. g. Approved for use as a drying agent under the threshold of regulation process
3516 established by 21 CFR 170.39 ~~—Threshold-of-Regulation-for-Substances-Used-in~~
3517 ~~Food-contact-Articles;~~^P and

3518 2. When sanitization is with chemicals, the approval required
3519 under ~~subdivisions~~ subdivision 1 e e or e g of this section or the regulation as an indirect
3520 food additive required under subdivision 1 ~~d~~ f of this section, shall be specifically for use
3521 with chemical sanitizing solutions.^P

3522 **12VAC5-421-3420. Lubricants - incidental food contact, criteria.**

3523 Lubricants shall meet the requirements specified in 21 CFR 178.3570 if they are used on
3524 food-contact surfaces, on bearings and gears located on or within food-contact surfaces, or on
3525 bearings and gears that are located so that lubricants may leak, drip, or be forced into food or
3526 onto food-contact surfaces.^P

3527 **12VAC5-421-3430. Restricted use pesticides, criteria.**

3528 Restricted use pesticides specified under subdivision 3 of 12VAC5-421-3360 ~~G~~ shall meet
3529 the requirements specified in 40 CFR 152, Subpart I ~~—Classification-of-Pesticides.~~^P

3530 **12VAC5-421-3440. Rodent bait stations.**

3531 Rodent bait shall be contained in a covered, tamper-resistant bait station.^P

3532 **12VAC5-421-3450. Tracking powders, pest control, and monitoring.**

3533 A. Except as specified in subsection B of this section, A a tracking powder pesticide shall
3534 not be used in a food establishment.^P

3535 B. If used, a nontoxic tracking powder such as talcum or flour shall not contaminate food,
3536 equipment, utensils, linens, and single-service and single-use articles.

3537 **12VAC5-421-3460. Medicines - restriction and storage.**

3538 A. Except for medicines that are stored or displayed for retail sale, only those medicines that
3539 are necessary for the health of employees shall be allowed in a food establishment.^{Pf}

3540 B. Medicines that are in a food establishment for the employees' use shall be labeled as
3541 specified under 12VAC5-421-3320 and located to prevent the contamination of food, equipment,
3542 utensils, linens, and single-service and single-use articles.^P

3543 **12VAC5-421-3470. Refrigerated medicines, storage.**

3544 Medicines belonging to employees or to children in a day care center that require
3545 refrigeration and are stored in a food refrigerator shall be:

3546 1. Stored in a package or container and kept inside a covered, leakproof container that is
3547 identified as a container for the storage of medicines;^P and

3548 2. Located so they are inaccessible to children.^P

3549 **12VAC5-421-3480. First aid supplies, storage.**

3550 First aid supplies that are in a food establishment for the employees' use shall be:

3551 1. Labeled as specified under 12VAC5-421-3320;^{Pf} and

3552 2. Stored in a kit or a container that is located to prevent the contamination of food,
3553 equipment, utensils, and linens, and single-service and single-use articles.^P

Article 3
Stock and Retail Sale

3554
3555
3556 **12VAC5-421-3500. Storage and display, separation.**

3557 Poisonous or toxic materials shall be stored and displayed for retail sale so they can
3558 not cannot contaminate food, equipment, utensils, linens, and single-service and single-use
3559 articles by:

- 3560 1. Separating the poisonous or toxic materials by spacing or partitioning;^P and
3561 2. Locating the poisonous or toxic materials in an area that is not above food,
3562 equipment, utensils, linens, and single-service or single-use articles.^P

3563 **12VAC5-421-3590. Disposition of a variance request.**

3564 A. ~~The commissioner may grant the variance request and if~~ If the commissioner proposes to
3565 deny the variance he shall provide the owner an opportunity to an informal hearing fact-finding
3566 conference as provided in § 2.2-4019 of the Code of Virginia. Following this opportunity for an
3567 informal hearing fact-finding conference the commissioner may reject any application for a
3568 variance by sending a rejection notice to the applicant. The rejection notice shall be in writing
3569 and shall state the reasons for the rejection. ~~A rejection notice constitutes a case decision.~~

3570 B. If the commissioner proposes to grant a variance request submitted pursuant to this part,
3571 the applicant shall be notified in writing of this decision. Such notice shall identify the variance,
3572 the food establishment involved, and shall specify the period of time for which the variance will
3573 be effective. Such notice shall provide that the variance will be terminated when the food
3574 establishment comes into compliance with the applicable regulation and may be terminated
3575 upon a finding by the commissioner that the food establishment has failed to comply with any
3576 requirements or schedules issued in conjunction with the variance. The effective date of the
3577 variance shall be as noted in the variance letter.

3578 C. All variances granted to any food establishment may not be transferable unless otherwise
3579 stated. Each variance shall be attached to the permit to which it is granted. ~~Each variance is~~
3580 ~~revoked when the permit to which it is attached is revoked~~ operate and posted prominently in a
3581 conspicuous place for public view.

3582 D. No owner or permit holder may challenge the terms or conditions of a variance after 30
3583 calendar days have elapsed from the receipt of the variance.

3584 E. ~~Each variance shall be posted prominently in a conspicuous place for public view and in~~
3585 ~~close proximity to the permit to which it relates.~~ Each variance is revoked when the permit
3586 to which it operate is attached is revoked, suspended, or if the permit is not revalidated or
3587 renewed expired.

Article 2
Plan Submission and Approval

3590 **12VAC5-421-3600. Facility and operating plans ~~–when plans are required.~~**

3591 A permit applicant or permit holder shall submit to the regulatory authority properly prepared
3592 plans and specifications for review and approval before:

- 3593 1. The construction of a food establishment;^{Pf}
3594 2. The conversion of an existing structure for use as a food establishment;^{Pf} or
3595 3. The remodeling of a food establishment or a change of type of food establishment or
3596 food operation as specified under ~~42VAC5-421-3740~~ subsection 3 in 12VAC-421-
3597 3700 if the regulatory authority determines that plans and specifications are necessary to
3598 ensure compliance with ~~this regulation~~ this chapter.^{Pf}

3599 **[12VAC5-421-3620. When a HACCP plan is required.**

3600 A. Before engaging in an activity that requires a HACCP plan, a permit applicant or permit
3601 holder shall submit to the regulatory authority for approval a properly prepared HACCP plan as
3602 specified under 12VAC5-421-3630 and the relevant provisions of this chapter if:

- 3603 1. Submission of a HACCP plan is required according to law;
- 3604 2. A variance is required as specified under 12VAC5-421-860, 12VAC5-421-1300 B, or
3605 12VAC5-421-700 D 2; or
- 3606 3. The regulatory authority determines that a food preparation or processing method
3607 requires a variance based on a plan submittal specified under 12VAC5-421-3610, an
3608 inspectional finding, or a variance request.

3609 B. A permit applicant or permit holder shall have a properly prepared HACCP plan before
3610 engaging in reduced oxygen packaging without a variance as specified under 12VAC5-421-870,
3611 a permit applicant or permit holder shall submit a properly prepared HACCP plan to the
3612 regulatory authority.]

3613 **12VAC5-421-3630. Contents of a HACCP plan.**

3614 For a food establishment that is required under 12VAC5-421-3620 to have a HACCP
3615 plan, the plan and specifications shall indicate the permit applicant or permit holder shall submit
3616 to the regulatory authority a properly prepared HACCP plan that includes:

3617 1. General information such as the name of the permit applicant or permit holder, the
3618 food establishment address, and contact information;^{Pf}

3619 ~~1. 2.~~ A categorization of the types of potentially hazardous foods time/temperature
3620 control for safety food that are specified in the menu such as soups and sauces, salads,
3621 and bulk, solid foods such as meat roasts, or of other foods that are specified by the
3622 regulatory authority is to be controlled under the HACCP plan;^{Pf}

3623 ~~2. 3.~~ A flow diagram by specific food or category type identifying critical control points
3624 and providing information on the following or chart for each specific food or category
3625 type that identifies;^{Pf}

3626 a. Each step in the process;^{Pf}

3627 b. The hazards and controls for each step in the flow diagram or chart;^{Pf}

3628 c. The steps that are critical control points;^{Pf}

3629 a. ~~Ingredients~~ The ingredients, materials, and equipment used in the preparation
3630 of that food;^{Pf} and

3631 ~~b. e.~~ Formulations or recipes that delineate methods and procedural control
3632 measures that address the food safety concerns involved;^{Pf}

3633 3. ~~Food employee and supervisory training plan that addresses the food safety issues of~~
3634 ~~concern.~~

3635 4. ~~A statement of standard operating procedures for the plan under consideration~~
3636 ~~including clearly identifying~~ A critical control point summary for each specific food or
3637 category type that clearly identifies:

3638 a. Each critical control point;^{Pf}

3639 b. The critical limits for each critical control point;^{Pf}

3640 c. The method and frequency for monitoring and controlling each critical control point
3641 by the food employee designated by the person in charge;^{Pf}

3642 d. The method and frequency for the person in charge to routinely verify that the food
3643 employee is following standard operating procedures and monitoring critical control
3644 points;^{Pf}

3645 e. Action to be taken by the person in charge if the critical limits for each critical
3646 control point are not met;^{Pf} and

3647 f. Records to be maintained by the person in charge to demonstrate that the HACCP
3648 plan is properly operated and managed;^{Pf} and

3649 5. Supporting documents such as;

3650 a. Food employee and supervisory training plan addressing food safety issues;^{Pf}

3651 b. Copies of blank records forms that are necessary to implement a HACCP plan;^{Pf}

3652 c. Additional scientific data or other information, as required by the regulatory
3653 authority supporting the determination that food safety is not compromised by the
3654 proposal.^{Pf}

3655 ~~5. Additional scientific data or other information, as required by the regulatory authority,~~
3656 ~~supporting the determination that food safety is not compromised by the proposal.~~

3657 6. Any other information required by the regulatory authority.

3658 **12VAC5-421-3670. Application procedure, submission ~~30 calendar days~~ before proposed**
3659 **opening.**

3660 An applicant seeking to operate a nontemporary food establishment shall submit an
3661 application for a permit at least 30 calendar days before the date planned for opening a food
3662 establishment or at least 30 calendar days before the expiration date of the current permit for an
3663 existing facility. An applicant seeking to operate a temporary food establishment shall submit an
3664 application for a permit at least 10 calendar days before the date planned for opening the
3665 temporary food establishment.

3666 **12VAC5-421-3700. Contents of the application.**

3667 The application shall include:

3668 1. The name, mailing address, telephone number, and signature of the person applying
3669 for the permit and the name, mailing address, and location of the food establishment;

3670 2. Information specifying whether the food establishment is owned by an association,
3671 corporation, individual, partnership, or other legal entity;

3672 3. A statement specifying whether the food establishment:

3673 a. Is mobile or stationary and temporary or permanent; and

3674 b. Is an operation that includes one or more of the following:

3675 (1) Prepares, offers for sale, or serves ~~potentially hazardous food~~ time/temperature
3676 control for safety food:

3677 (a) Only to order upon a consumer's request;

3678 (b) In advance in quantities based on projected consumer demand and discards food
3679 that is not sold or served at an approved frequency; or

3680 (c) Using time as the public health control as specified under 12VAC5-421-850;

3681 (2) Prepares ~~potentially hazardous food~~ time/temperature control for safety food in
3682 advance using a food preparation method that involves two or more steps which may
3683 include combining ~~potentially hazardous~~ time/temperature control for safety food
3684 ingredients; cooking; cooling; reheating; hot or cold holding; freezing; or thawing;

3685 (3) Prepares food as specified under subdivision 3 b (2) of this section for delivery to
3686 and consumption at a location off the premises of the food establishment where it is
3687 prepared;

3688 (4) Prepares food as specified under subdivision 3 b (2) of this section for service to
3689 a highly susceptible population;

- 3690 (5) Prepares only food that is not potentially hazardous; or
 3691 (6) Does not prepare, but offers for sale only prepackaged food that is not potentially
 3692 hazardous time/temperature control for safety food;
- 3693 4. The name, title, address, and telephone number of the person directly responsible for
 3694 the food establishment;
- 3695 5. The name, title, address, and telephone number of the person who functions as the
 3696 immediate supervisor of the person specified under subdivision 4 of this section such as
 3697 the zone, district, or regional supervisor;
- 3698 6. The names, titles, and addresses of:
- 3699 a. The persons comprising the legal ownership as specified under subdivision 2 of
 3700 this section including the owners and officers; and
- 3701 b. The local resident agent if one is required based on the type of legal ownership;
- 3702 7. A statement signed by the applicant that:
- 3703 a. Attests to the accuracy of the information provided in the application; and
 3704 b. Affirms that the applicant will:
- 3705 (1) Comply with this chapter; and
 3706 (2) Allow the regulatory authority access to the establishment as specified under
 3707 12VAC5-421-3820 and to the records specified under 12VAC5-421-440 and
 3708 12VAC5-421-2330 and subdivision 4 of 12VAC5-421-3630; and
- 3709 8. Other information required by the regulatory authority.

3710 **12VAC5-421-3770. Suspension Summary suspension of a permit.**

3711 The director may summarily suspend ~~without a hearing~~ a permit to operate a restaurant if
 3712 the director finds the continued operation constitutes a substantial and imminent threat to the
 3713 public health, except the director may summarily suspend the permit of a temporary restaurant
 3714 as addressed under 12VAC5-421-3870. Upon receipt of such notice that a permit is suspended,
 3715 the permit holder shall cease food operations immediately and begin corrective action.

3716 Whenever a permit is suspended, the holder of the permit or the person in charge shall be
 3717 notified in writing by certified mail or by hand delivery. Upon service of notice that the permit is
 3718 immediately suspended, the former permit holder shall be given an opportunity for ~~a hearing~~ an
 3719 informal fact-finding conference in accordance with § 2.2-4019 of the Code of Virginia. The
 3720 request for ~~a hearing~~ an informal fact-finding conference shall be in writing. The written request
 3721 shall be filed with the local department by the former holder of the permit. If written request for a
 3722 hearing an informal fact-finding conference is not filed within 10 working days, the suspension is
 3723 sustained. Each holder of a suspended permit shall be afforded an opportunity for an
 3724 informal hearing fact-finding conference, within three working days of receipt of a request for
 3725 the hearing informal fact-finding conference. The director may end the suspension at any time if
 3726 the reasons for the suspension no longer exist.

3727 **12VAC5-421-3780. Revocation of a permit.**

3728 The director may, after providing an opportunity for ~~a hearing~~ an informal fact-finding
 3729 conference in accordance with § 2.2-4019 of the Code of Virginia, revoke a permit for flagrant or
 3730 continuing violation of any of the requirements of this part.

3731 ~~Prior to revocation, the director shall notify in writing the holder of the permit, or the person~~
 3732 ~~in charge, of the specific reason for which the permit is to be revoked. The permit shall be~~
 3733 ~~revoked at the end of the 15 days following service of such notice unless a written request for a~~
 3734 ~~hearing is filed before then with the director from which the permit was obtained. If no request~~
 3735 ~~for a hearing is filed within the 15 day period, the revocation of the permit shall be final.~~

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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~~ an established 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.~~

12VAC5-421-3810. Performance- and priority risk-based inspections.

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;

- 3782 6. The number of people served; and
3783 7. Whether the population served is a highly susceptible population.

3784 **12VAC5-421-3815. Competency of environmental health specialists.**

3785 A. An authorized representative of the commissioner who inspects a food establishment or
3786 conducts plan review for compliance with this chapter shall have the knowledge, skills, and
3787 ability to adequately perform the required duties. For the purposes of this section, competency
3788 shall be demonstrated when an environmental health specialist meets the training and
3789 standardization requirements specified in the Virginia Department of Health Procedures for
3790 Certification and Standardization of Retail Food Protection Staff, 2014, (VDH, Division of Food
3791 and Environmental Services).

3792 B. The regulatory authority shall ensure that authorized representatives who inspect a food
3793 establishment or conduct plan review for compliance with this chapter have access to training
3794 and continuing education as needed to properly identify violations and apply this chapter.

3795 **12VAC5-421-3860. Documenting information and observations.**

3796 The regulatory authority shall document on an inspection report form:

- 3797 1. Administrative information about the food establishment's legal identity, street and
3798 mailing addresses, type of establishment and operation as specified under 12VAC5-421-
3799 3700, inspection date, and other information such as type of water supply and sewage
3800 disposal, status of the permit, and personnel certificates that may be required; and
3801 2. Specific factual observations of violative conditions or other deviations from this
3802 chapter that require correction by the permit holder including:
3803 a. Failure of the person in charge to demonstrate the knowledge of foodborne illness
3804 prevention, application of HACCP principles, and the requirements of this chapter
3805 specified under 12VAC5-421-60;
3806 b. Failure of food employees, conditional employees, and the person in charge to
3807 ~~demonstrate their knowledge of their responsibility~~ to report a disease or medical
3808 condition as specified under 12VAC5-421-80 B and D;
3809 c. Nonconformance with ~~critical~~ priority items or priority foundation items of this
3810 chapter;
3811 d. Failure of the appropriate food employees to demonstrate their knowledge of, and
3812 ability to perform in accordance with, the procedural, monitoring, verification, and
3813 corrective action practices required by the regulatory authority as specified under
3814 12VAC5-421-60;
3815 e. Failure of the person in charge to provide records required by the regulatory
3816 authority for determining conformance with a HACCP plan as specified under
3817 subdivision 4 f of 12VAC5-421-3630; and
3818 f. Nonconformance with critical limits of a HACCP plan.

3819 **12VAC5-421-3910. Imminent health hazard, ceasing operations and reporting.**

3820 A. Except as specified in subsection B of this section, a permit holder shall immediately
3821 discontinue operations and notify the regulatory authority if an imminent health hazard may exist
3822 because of an emergency such as a fire, flood, extended interruption of electrical or water
3823 service, sewage backup, misuse of poisonous or toxic materials, onset of an apparent
3824 foodborne illness outbreak, gross insanitary occurrence or condition, or other circumstance that
3825 may endanger public health.^f

3826 B. A permit holder need not discontinue operations in an area of an establishment that is
3827 unaffected by the imminent health hazard.

3828 **12VAC5-421-3930. ~~Critical violation, timely~~ Timely correction.**

3829 A. Except as specified in subsection B of this section, a permit holder shall at the time of
3830 inspection correct a ~~critical violation of~~ priority item or priority foundation item in this chapter and
3831 implement corrective actions for a HACCP plan provision that is not in compliance with its
3832 critical limit.^{Pf}

3833 B. Considering the nature of the potential hazard involved and the complexity of the
3834 corrective action needed, the regulatory authority may agree to or specify a longer ~~time~~
3835 frame timeframe, not to exceed ~~40 calendar days~~:

3836 1. 72 hours after the inspection; for the permit holder to correct ~~critical violations~~ priority
3837 items; or

3838 2. 10 calendar days after the inspection for the permit holder to correct priority
3839 foundation items or HACCP plan deviations.

3840 **12VAC5-421-3940. Verification and documentation of correction.**

3841 A. After observing at the time of inspection a correction of a ~~critical violation or~~
3842 deviation priority item or priority foundation item, the regulatory authority shall enter
3843 the ~~violation~~ observation and information about the corrective action on the inspection report.

3844 B. As specified under 12VAC5-421-3930 B, after receiving notification that the permit holder
3845 has corrected a ~~critical violation~~ priority item or priority foundation item or a HACCP plan
3846 deviation, or at the end of the specified period of time, the regulatory authority shall verify
3847 correction ~~of the violation~~, document the information on an inspection report, and enter the
3848 report in the regulatory authority's records.

3849 **12VAC5-421-3950. ~~Noncritical violation~~ Core item, time frame timeframe for correction.**

3850 A. Except as specified in subsection B of this section, the permit holder shall
3851 correct ~~noncritical violations~~ core items by a date and time agreed to or specified by the
3852 regulatory authority but no later than 90 calendar days after the inspection.

3853 B. The regulatory authority may approve a compliance schedule that extends beyond the
3854 time limits specified under subsection A of this section if a written schedule of compliance is
3855 submitted by the permit holder and no health hazard exists or will result from allowing an
3856 extended schedule for compliance.

3857 **12VAC5-421-3960. Examination for condemnation of food.**

3858 Food may be examined or sampled by the department as often as necessary for
3859 enforcement of this chapter. Also, the department may, upon written notice to the owner or
3860 permit holder or person in charge impound any food which it believes is in violation of Part
3861 III (12VAC5-421-260 et seq.) or any other section of this chapter. The department shall tag,
3862 label, or otherwise identify any food subject to impoundment. No food under conditions specified
3863 in the impoundment shall be used, served or moved from the establishment. The department
3864 shall permit storage of the food under conditions specified in the impoundment unless storage is
3865 not possible without risk to the public health in which case immediate destruction shall
3866 be ~~ordered and accomplished~~ by the owner or permit holder or person in charge. The
3867 impoundment shall state that a request for a hearing an informal fact-finding conference may be
3868 filed within 10 days and that if no hearing conference is requested, the food shall be
3869 destroyed by the owner or permit holder or person in charge. ~~A hearing shall be held~~ The
3870 department shall hold an informal fact-finding conference if so requested, and on the basis of
3871 evidence produced at the hearing, the impoundment may be vacated, or the owner or permit
3872 holder or person in charge of the food may be directed ~~by written order~~ in writing by the director
3873 to denature or destroy such food or to bring it into compliance with the provisions of this chapter.

3874 **12VAC5-421-3970. Enforcement of regulation.**

3875 A. This chapter shall be enforced by the State Board of Health and the State Health
3876 Commissioner, as executive officer of the board.

3877 B. The directors are appointed by the board and commissioner as duly designated officers
3878 and are responsible for the implementation and enforcement of this chapter.

3879 C. All food establishments shall operate in compliance with the requirements set forth in this
3880 chapter and shall not operate without a valid permit.

3881 D. The commissioner shall be vested with all the authority of the board when it is not in
3882 session, subject to such rules and regulations as may be prescribed by the board.

3883 E. Pursuant to the authority granted in §§ 32.1-26 and 35.1-6 of the Code of Virginia, the
3884 commissioner may issue orders to require any owner or permit holder or other person to comply
3885 with the provisions of ~~these regulations~~ this chapter. The order may require the following:

- 3886 1. The immediate cessation and correction of the violation;
- 3887 2. Appropriate remedial action to ensure that the violation does not continue or recur;
- 3888 3. The submission of a plan to prevent future violations;
- 3889 4. The submission of an application for a variance; and
- 3890 5. Any other corrective action deemed necessary for proper compliance with the
3891 regulations.

3892 ~~F. Before the issuance of an order, the commissioner must comply with the requirements of~~
3893 ~~§ 35.1-6 of the Code of Virginia.~~

3894 ~~G. All orders issued pursuant to 12VAC5-421-3970 C shall become effective not less than~~
3895 ~~15 days after mailing a copy thereof by certified mail to the last known address of the owner or~~
3896 ~~permit holder or person violating these regulations. Violation of an order is a Class 3~~
3897 ~~misdemeanor. See § 35.1-7 of the Code of Virginia.~~

3898 ~~H. E.~~ The commissioner may act as the agent of the board to enforce all effective orders
3899 and ~~these regulations~~ this chapter. Should any owner or permit holder fail to comply with any
3900 effective order or ~~these regulations~~ this chapter, the commissioner may:

- 3901 1. Institute a proceeding to revoke the owner's or permit holder's permit in accordance
3902 with 12VAC5-421-3780;
- 3903 2. Request the attorney for the Commonwealth to bring a criminal action;
- 3904 3. Request the Attorney General to bring an action for civil penalty, injunction, or other
3905 appropriate remedy; or
- 3906 4. Do any combination of the above.

3907 ~~I. G.~~ Not exclusive means of enforcement. Nothing contained in ~~12VAC5-421-3970~~ this
3908 section shall be interpreted to require the commissioner to issue an order prior to seeking
3909 enforcement of any regulations or statute through an injunction, mandamus or criminal
3910 prosecution.

3911 ~~J. H.~~ Hearings Proceedings before the commissioner or his designee shall include any of
3912 the following forms depending on the nature of the controversy and the interests of the parties
3913 involved.

3914 1. Informal hearings fact-finding conferences. An informal hearing fact-finding
3915 conference is a meeting with a district or local health department with the district or local
3916 health director presiding and held in conformance with § 2.2-4019 of the Code of
3917 Virginia.

3918 2. Adjudicatory hearing. The adjudicatory hearing is a formal, public adjudicatory
3919 proceeding before ~~the commissioner, or his designated hearing officer~~ a hearing officer

3920 as defined by § 2.2-4001 of the Code of Virginia, and held in conformance with § 2.2-
3921 4020 of the Code of Virginia.

3922 **12VAC5-421-3980. Request for hearing informal fact-finding conference.**

3923 A request for an informal hearing fact-finding conference shall be made by sending the
3924 request in writing to the district or local health department in the locality where the food
3925 establishment is located. Requests for hearings an informal fact-finding conference shall cite
3926 the reason(s) reason or reasons for the hearing request and shall cite the section(s) section or
3927 sections of these regulations this chapter involved and must be received within 30 days of the
3928 decision by the department that lead to the hearing request.

3929 **12VAC5-421-3990. Hearing as a matter of right. (Repealed.)**

3930 ~~Any owner or permit holder or named party whose rights, duties, or privileges have been, or~~
3931 ~~may be affected by any case decision of the board or its subordinates in the administration of~~
3932 ~~these regulations shall have a right to both informal and adjudicatory hearings. The~~
3933 ~~commissioner may require participation in an informal hearing before granting the request for a~~
3934 ~~full adjudicatory hearing. Exception: No person other than an owner shall have the right to an~~
3935 ~~adjudicatory hearing to challenge the issuance of a permit to operate unless the person can~~
3936 ~~demonstrate at an informal hearing that the minimum standards contained in these regulations~~
3937 ~~have not been applied and that he will be injured in some manner by the issuance of the permit.~~

3938 **12VAC5-421-4000. Appeals.**

3939 A. Any appeal from a denial of a permit to operate a food establishment must be made in
3940 writing and received by the department within 30 days after service of the final order in the case
3941 decision denial. In the event that service of a case decision upon a party is accomplished by
3942 mail, three days shall be added to the 30-day period. Notice shall be consistent with Part 2A of
3943 the Rules of the Supreme Court of Virginia.

3944 ~~1. Any request for hearing on the denial of an application for a variance pursuant to~~
3945 ~~12VAC5-421-3590 A must be made in writing and received within sixty days of receipt of~~
3946 ~~the denial notice.~~

3947 ~~2. Any request for a variance must be made in writing and received by the department~~
3948 ~~prior to the denial of the food establishment permit, or within 60 days after such denial.~~

3949 ~~3. In the event a person applies for a variance within the 60-day period provided by~~
3950 ~~subdivision 2 of this section, the date for appealing the denial of the permit, pursuant to~~
3951 ~~subdivision 1 of this section, shall commence from the date on which the department~~
3952 ~~acts on the request for a variance.~~

3953 4. B. Pursuant to the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia)
3954 an aggrieved owner or permit holder may appeal a final case decision of the commissioner to an
3955 appropriate circuit court.

3956 FORMS (12VAC5-421)

3957 ~~Foodservice Establishment Inspection Report, EHS-152 (rev. 9/95).~~

3958 ~~Foodservice Critical Procedures Report, EHS-153 (rev. 9/95).~~

3959 [Food Establishment Inspection Report Form - Cover Page \(eff. 2016\)](#)

3960 [Food Establishment Inspection Report Form - Narrative Page with Temperatures \(eff. 2016\)](#)

3961 [Food Establishment Inspection Report Form - Narrative Page \(eff. 2016\)](#)

3962 DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-421)

3963 [Approved Drug Products with Therapeutic Equivalence Evaluations, 34th Edition, 2014, U.S.](#)
3964 [Department of Health and Human Services, Food and Drug Administration, Center for Drug](#)

- 3965 [Evaluation and Research, Office of Pharmaceutical Science, Office of Generic Drugs at](http://www.fda.gov/cder/ob/default.htm)
3966 <http://www.fda.gov/cder/ob/default.htm>
- 3967 [Grade "A" Pasteurized Milk Ordinance, 2013 Revision, U.S. Department of Health and](#)
3968 [Human Services, Public Health Service, Food and Drug Administration, Milk Safety Branch](#)
3969 [\(HFS-626\), 5100 Paint Branch Parkway, College Park, MD 20740-3835](#)
- 3970 [Interstate Certified Shellfish Shippers List \(updated monthly\), published by the U.S.](#)
3971 [Department of Health and Human Services, Public Health Service, Food and Drug](#)
3972 [Administration, Office of Seafood \(HFS-417\), 5100 Paint Branch Parkway, College Park, MD](#)
3973 [20740-3835](#)
- 3974 ~~[National Shellfish Sanitation Program Manual of Operations, Part II, Sanitation of the](#)~~
3975 ~~[Harvesting, Processing and Distribution of Shellfish, 1995 Revision, U.S. Department of Health](#)~~
3976 ~~[and Human Services, Public Health Service, Food and Drug Administration](#)~~
- 3977 [National Shellfish Sanitation Program \(NSSP\) Guide for the Control of Molluscan Shellfish,](#)
3978 [2013 Revision, U.S. Department of Health and Human Services, Public Health Service, Food](#)
3979 [and Drug Administration, Office of Seafood \(HFS-417\), 5100 Paint Branch Parkway, College](#)
3980 [Park, MD 20740-3835](#)
- 3981 [NSF/ANSI 18-2012 Manual Food and Beverage Dispensing Equipment, 2012, NSF](#)
3982 [International, 789 North Dixboro Road, P.O. Box 130140, Ann Arbor, MI 48113-](#)
3983 [0140, www.nsf.org](#)
- 3984 [Standards for Accreditation of Food Protection Manager Certification Programs, April 2012,](#)
3985 [Conference for Food Protection, 30 Elliott Court, Martinsville, IN 46151-1331](#)
- 3986 [United States Standards, Grades, and Weight Classes for Shell Eggs, AMS-56, effective](#)
3987 [July 20, 2000, U.S. Department of Agriculture, Agricultural Marketing Service, Poultry Programs,](#)
3988 [STOP 0259, Room 3944-South, 1400 Independence Avenue, SW, Washington, DC 20250-](#)
3989 [0259](#)
- 3990 [VDH Procedures for Certification and Standardization of Retail Food Protection Staff](#)
3991 [Workbook, 2014, Virginia Department of Health, Division of Food and Environmental Services,](#)
3992 [109 Governor Street, 5th Floor, Richmond, VA 23219](#)