



## Proposed Regulation Agency Background Document

<b>Agency name</b>	Virginia Department of Health (State Board of Health)
<b>Virginia Administrative Code (VAC) citation</b>	12 VAC 5 -421
<b>Regulation title</b>	Food Regulations
<b>Action title</b>	Amend to conform with 2007 FDA Food Code Supplement
<b>Date this document prepared</b>	June 25, 2009

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### Brief summary

*In a short paragraph, please summarize all substantive provisions of new regulations or changes to existing regulations that are being proposed in this regulatory action.*

The Food Regulations establish minimum sanitary standards for operating restaurants. 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 or 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 restaurant owners or operators how to obtain a permit to operate a restaurant from the Department. The regulations are being amended to be consistent with the current 2007 supplement to the 2005 Food and Drug Administration's (FDA) Food Code. The current Food Regulations are based on the 2003 Supplement to the 2001 FDA Food Code. These changes are also being proposed concurrently with the Virginia Department of Agriculture and Consumer Services (VDACS) adoption of the 2007 Supplement to the 2005 FDA Food Code. Pursuant to § 35.1-14 C and E of the *Code of Virginia*, this action is exempt from portions of the Administrative Process Act (APA), provided VDACS adopts the same version and both agency's regulations have the same effective date. Both agencies are working toward that end. Both VDH and VDACS previously adopted the 2003 supplement to the 2001 FDA Food Code with an effective date of October 16, 2007.

## 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.*

FDA – U.S. Food and Drug Administration  
 VDH – Virginia Department of Health  
 VDACS – Virginia Department of Agriculture and Consumer Services  
 PPM – parts per million

### Definitions:

Antiseptic – a substance which prevents infection by inhibiting the growth of microorganisms  
 Cook-Chill – a method of preparing food by cooking followed by fast chilling and then storage  
 CFR – Code of Federal Regulations  
 Hepatitis A virus – a disease causing microorganism (virus)  
 Norovirus – a disease causing microorganism (virus)  
 Jaundice – a yellow discoloration of the skin, whites of the eyes, etc., due to an increase of bile pigments in the blood  
 Pasteurize - to expose a food product to an elevated temperature for a period of time sufficient to destroy certain microorganisms  
 Salmonella enteritidis - a disease causing microorganism (bacteria)  
 Salmonella typhi – a disease causing microorganism (bacteria)  
 Shigella spp – a disease causing microorganism (bacteria)  
 Streptococcus pyogenes - a disease causing microorganism (bacteria)  
 Sous-vide – a method of cooking food in a vacuum-sealed plastic pouch  
 Sulfiting agent – a compound used in food products as a preservative

## Legal basis

*Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.*

The amendment to these regulations is exempt from the requirements of the APA pursuant to § 35.1-14.E of the *Code of Virginia*. The Board still has to comply with subsections §§ 2.2-4007.03 through 2.2-4007-05 of the *Code of Virginia*. This form is being used to satisfy those requirements. The regulations are authorized and mandated by § 35.1-11 and § 35.1-14 of the *Code of Virginia*. The code requires the regulations to provide minimum standards for the following: (i) procedure for obtaining a license; (ii) the safe and sanitary maintenance, storage, operation, and use of equipment; (iii) the sanitary maintenance and use of a restaurant's physical plant; (iv) the safe preparation, handling, protection, and preservation of food, including necessary refrigeration and heating methods; (v) procedures for vector and pest control; (vi) requirements for toilet and cleansing facilities for employees and customers; (vii) requirements for appropriate lighting and ventilation not otherwise specified for in the Uniform Statewide Building Code; (viii) requirements for an approved water supply and sewage disposal system; (ix) personal hygiene standards for employees, particularly those engaged in food handling; and (x) the appropriate use of precautions to prevent the transmission of communicable diseases.

## Purpose

*Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.*

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The purpose of these regulations is to prevent foodborne illness by ensuring that foods prepared and served by food establishments in Virginia are safe, unadulterated, and prepared under sanitary conditions. This is accomplished by providing minimum sanitary standards for restaurants to protect the dining public. These standards include approved sources for foods used in restaurants, 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.

### Substance

*Please briefly identify and explain new substantive provisions (for new regulations), substantive changes to existing sections or both where appropriate. (More detail about all provisions or changes is requested in the "Detail of changes" section.)*

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The proposed regulations will amend the current Food Regulations so that they will be consistent with latest food safety information and guidance provided in the FDA's 2007 supplement to the 2005 FDA Food Code. The FDA Food Code is reviewed biennially at the Conference for Food Protection. The conference is attended by regulators from all states, territories, and the District of Columbia, academia from across the nation, food processors, food distributors, food scientists, food service establishments, professional associations, and consumer groups. Recommendations resulting from the conference are forwarded to FDA for incorporation into the next version of the Food Code, which is modified every four years with a supplement, if necessary, issued two years after the Food Code's issuance. The FDA Food Code represents the current standards based on current food science and technology. Most of the changes being proposed in this amendment process are to increase clarity of the regulations but there will be some changes in the current standards that will reflect current food science and safety knowledge. VDH's current Food Regulations were amended effective October 16, 2007 to update the previous edition of the Food Regulations based on the 1999 FDA Food Code to the current Food Regulations based on the 2003 Supplement to the 2001 FDA Food Code. The current regulations were reviewed and compared to the 2003 Supplement to the 2001 FDA Food Code by a committee comprised of VDH staff, VDACS, and members of the Virginia Hospitality and Travel Association (the parent association over the Virginia Restaurant Association). The committee was in agreement the regulations should be updated to the 2007 supplement. There are four major changes to the regulations including; (1) adding awareness of the eight major food allergens to the food safety knowledge base of a person-in-charge of a food establishment; (2) adding Norovirus and its symptoms to the list of reportable diseases reflecting that it now accounts for more than half of the foodborne illnesses in Virginia; (3) extending the time a food can be left out of temperature control from 4 to 6 hours when it has an initial temperature of 41°F; and ( 4) exempting certain foods from date marking requirements.

### 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 the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.*

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The primary advantage of the regulations to the public is that they establish modern science-based standards that have broad supporting the food service and food regulatory communities. The revisions will also make the regulations more understandable. The primary advantage to the agency is that the regulations will be based on current food science. The primary advantage to the regulated community, particularly chains that operate in other states, will be better consistency between states as more adopt the FDA Food Code. 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 are 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.*

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There are no requirements more stringent than 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.*

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All localities will be equally affected.

**Public participation**

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

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In addition to any other comments, the board/agency 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 may do so via the Regulatory Townhall website, [www.townhall.virginia.gov](http://www.townhall.virginia.gov), or by mail, email or fax to Gary Hagy, 109 Governor Street, Fifth Floor, Richmond, Virginia, 23219, Phone: 804-864-7455, FAX 804-864-7475, [gary.hagy@vdh.virginia.gov](mailto:gary.hagy@vdh.virginia.gov). Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last date of the public comment period.

A public hearing will be held and notice of the public hearing may appear on the Virginia Regulatory Town Hall website ([www.townhall.virginia.gov](http://www.townhall.virginia.gov)) and the Commonwealth Calendar. Both oral and written comments may be submitted at that time.

**Economic impact**

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

<b>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source, and (b) a delineation of one-time versus on-going expenditures.</b>	Little or no additional cost to implement. Restaurants are already under inspection by VDH. The proposed changes do not include any change in the inspection process.
<b>Projected cost of the <i>new regulations or changes to existing regulations</i> on localities.</b>	None, for the same reasons as above.
<b>Description of the individuals, businesses or other entities likely to be affected by the <i>new regulations or changes to existing regulations</i>.</b>	Restaurants operating in the Commonwealth of Virginia.
<b>Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected.</b> Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.	Currently there are approximately 27,000 restaurants in the Commonwealth. Based on employing 500 or fewer employees, estimated 95 to 100% of the total number of restaurants will fall into the small business category.
<b>All projected costs of the <i>new regulations or changes to existing regulations</i> for affected individuals, businesses, or other entities. Please be specific and do include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.</b>	The regulations will not place any additional reporting or recordkeeping requirements upon the restaurants beyond what they already have.
<b>Beneficial impact the regulation is designed to produce.</b>	The regulations will be based on the most current food science. Benefits will be better protection of public health with no cost in the program. In some cases, the amendments lessens standards without negatively impacting public health which will result in savings to the restaurant operator or owner.

**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.*

No alternatives were identified in the preliminary review process. Permitting and inspecting restaurants is mandated by the *Code of Virginia*.

**Regulatory flexibility analysis**

*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.*

This amended regulation is intended to provide safer food by addressing areas involving food handling and service while applying current science to existing and emerging food service practices. An alternative considered was to leave the current regulations in place without modifications. However, the amended regulation essentially provides no more reporting requirements than the current regulation. Furthermore, the amended regulation provides more options and a greater degree of flexibility to both large and small businesses. Additionally, the reporting requirements for both large and small businesses in both the current and amended regulations are minimal and consist primarily of recordkeeping costs associated with the few establishments that are required to provide an initial variance request (12 VAC 5-421-860) and/or HACCP plan (12 VAC 5-421-3620).

The proposed amended regulation will provide the food service segment of Virginia’s food industry the alternative and the opportunity to incorporate performance standards into their processes. Such performance standards in effect define public food safety expectations for food products, usually in terms of lethality to a pathogenic microorganism of particular concern. The use of performance standards as a measure of regulatory compliance means that food establishments are free to use innovative approaches in producing safe products, in lieu of adherence to traditional processing approaches.

Exemption of small businesses from this regulation (or portions thereof) and/or the establishment of less stringent reporting requirements for other establishments would seriously compromise the safety of the food prepared and served in those establishments.

**Public comment**

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

Commenter	Comment	Agency response

A NOIRA is not required. This action is exempt the NOIRA requirement pursuant to § 2.2-4002 A 23.

**Family impact**

*Please assess the impact of the proposed 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.*

These regulations should not have any impact on the institution of family and family stability.

**Detail of changes**

*Please detail all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact if implemented in each section. Please detail the difference between the requirements of the new provisions and the current practice or if applicable, the requirements of other existing regulations in place.*

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all provisions of the new regulation or changes to existing regulations between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.*

For changes to existing regulations, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, rationale, and consequences

## Description of Changes to the Food Regulations

<b>Section</b>	<b>Discussion</b>
12 VAC 5-421-10	Added some new definitions that reflect changes in the regulations. The predominant change is to provide restaurant operators and staff a standard guide to determine if a food is potentially hazardous requiring temperature control for safety or not.
12 VAC 5-421-50	Changed the number of people in charge of separately permitted departments in a food establishment to only one during periods when food is not being prepared.

12 VAC 5-421-60	Added another means to demonstrate knowledge by having no critical violations during an inspection. Also requires person in charge to be able to describe major food allergens and symptoms.
12 VAC 5-421-70	Added duty of person in charge to assure employees are informed of their responsibility to report health status as it relates to diseases transmissible through food.
12 VAC 5-421-80	Updated list of reportable diseases and symptoms to include Norovirus.
12 VAC 5-421-90	Updated exclusions and restrictions to include those for Norovirus.
12 VAC 5-421-100	Updated removal and adjustments of exclusions and restrictions to include Norovirus.
12 VAC 5-421-110	Repealed this section since it is now addressed in 12 VAC 5-421-80.
12 VAC 5-421-120	Repealed this section since it is now addressed in 12 VAC 5-421-80.
12 VAC 5-421-140	Changed wording to stress importance of removing debris from underneath fingernails during handwashing.
12 VAC 5-421-150	Repealed a section that is reserved.
12 VAC 5-421-180	Changed term from hand sanitizer to hand antiseptic to be consistent with FDA monograph language.
12 VAC 5-421-360	Updated specifications for receipt of eggs.
12 VAC 5-421-370	Changed language that milk products not only be pasteurized but meet Grade A standards as well.
12 VAC 5-421-400	Updated options for labeling containers of shellfish to include 'best if used by' dates.
12 VAC 5-421-410	Updated reference for source of information regarding Shellstock Identification labels.
12 VAC 5-421-430	Updated options for operators to remove shellfish from the original container as long as identification tag is preserved.
12 VAC 5-421-440	Clarifies language relating to maintaining Shellstock Identification labels.

12 VAC 5-421-450	Clarifies how a local health department may approve bare-hand contact with ready-to-eat foods in certain instances.
12 VAC 5-421-490	Added 'meringue' to list of foods requiring substitution of raw shell eggs for pasteurized eggs.
12 VAC 5-421-500	Clarified language for protection from unapproved additives
12 VAC 5-421-540	Clarifies language for approved food contact surfaces
12 VAC 5-421-570	Updated storage of wet-wiping cloths to include new EPA guidelines
12 VAC 5-421-680	Added new definition for PHF (time/temperature control for safety food)
12 VAC 5-421-700	Updated definitions to reflect cook temperature references
12 VAC 5-421-730	Added three more options for parasite destruction of raw fish for sushi or sashimi
12 VAC 5-421-740	Added one more option for record verification of parasite destruction
12 VAC 5-421-750	Repealed section since it is a reference, not a debitable violation
12 VAC 5-421-760	Added new definition for PHF (time/temperature control for safety food)
12 VAC 5-421-780	Added new definition for PHF (time/temperature control for safety food)
12 VAC 5-421-790	Added new definition for PHF (time/temperature control for safety food)
12 VAC 5-421-800	Added new definition for PHF (time/temperature control for safety food)
12 VAC 5-421-820	Added new definition for PHF (time/temperature control for safety food)
12 VAC 5-421-830	Added new definition for PHF (time/temperature control for safety food). Exempts deli salads, certain cheeses, cultured dairy products, preserved fish, shelf-stable dry fermented sausages and salt-cured products from date marking.

12 VAC 5-421-850	Added another time interval for time as a public health control
12 VAC 5-421-860	Added sprouting beans or seeds to list of processes needing a variance
12 VAC 5-421-870	Added cook-chill and sous-vide reduced oxygen packaging standards
12 VAC 5-421-900	Added allergen labeling to food label information
12 VAC 5-421-950	Added prohibition of re-service of food to individuals in isolation or quarantine
12 VAC 5-421-980	Clarified standards for allowable lead levels in food contact equipment
12 VAC 5-421-1020	Repealed section since it is now addressed in 12 VAC 5-421-980
12 VAC 5-421-1030	Repealed section since it is now addressed in 12 VAC 5-421-1030
12 VAC 5-421-1200	Clarified language for pressure measuring devices
12 VAC 5-421-1230	Added language for new types of food equipment storage
12 VAC 5-421-1260	Clarified language for beverage tubing separation
12 VAC 5-421-1310	Added new definition for PHF (time/temperature control for safety food)
12 VAC 5-421-1420	Added new definition for apparatus
12 VAC 5-421-1440	Repealed section since it is a reference, not a debitable violation
12 VAC 5-421-1550	Updated definition of table-mounted equipment
12 VAC 5-421-1560	Updated definition of table-mounted equipment
12 VAC 5-421-1690	Added allowable range of sanitization pressures for mechanical warewashing machines
12 VAC 5-421-1880	Repealed section since it is a reference, not a debitable violation
12 VAC 5-421-1890	Added article heading to section number
12 VAC 5-421-1980	Specified reference for approved food contact lubricants

12 VAC 5-421-2040	Specified proper storage of pre-set tableware
12 VAC 5-421-2190	Added new language for handsink
12 VAC 5-421-2230	Added new language for handsink
12 VAC 5-421-2280	Added new language for handsink
12 VAC 5-421-2310	Added new language for handsink
12 VAC 5-421-2510	Repealed section since it is a reference, not a debitable violation
12 VAC 5-421-2520	Clarifies when drain to sewage direct connections are permitted
12 VAC 5-421-2590	Repealed section since it is a reference, not a debitable violation
12 VAC 5-421-2600	Added article heading to section number
12 VAC 5-421-2630	Clarified refuse collection location in vending machines
12 VAC 5-421-2790	Deleted ambiguous language
12 VAC 5-421-2810	Clarified language for cleanability for floors, walls, ceilings
12 VAC 5-421-2920	Clarified when restrooms need to be enclosed
12 VAC 5-421-2950	Specifies when vending machines require overhead protection
12 VAC 5-421-2960	Specifies when service areas require overhead protection
12 VAC 5-421-3010	Repealed section since it is a reference, not a debitable violation
12 VAC 5-421-3020	Added article heading to section number. Added new language for handsink.
12 VAC 5-421-3030	Added new language for handsink
12 VAC 5-421-3040	Added new language for handsink
12 VAC 5-421-3045	Added new language for handsink
12 VAC 5-421-3050	Repealed section since it is a reference, not a debitable violation
12 VAC 5-421-3060	Repealed section since it is a reference, not a debitable violation
12 VAC 5-421-3080	Clarified ranges of allowable levels of ambient light

- 12 VAC 5-421-3110 Repealed section since it is a reference, not a debitable violation
- 12 VAC 5-421-3120 Repealed section since it is a reference, not a debitable violation
- 12 VAC 5-421-3130 Added article heading to section number.
- 12 VAC 5-421-3160 Repealed section since it is a reference, not a debitable violation
- 12 VAC 5-421-3180 Clarifies when facility shall be cleaned
- 12 VAC 5-421-3240 Clarified language for cleaning of plumbing fixtures
- 12 VAC 5-421-3460 Specified where medicines may be stored
- 12 VAC 5-421-3750 Updated references for responsibilities of permit holder
- 12 VAC 5-421-3860 Updated references for documenting information and observations
- 12 VAC 5-421-4040 Clarifies when information shall be obtained during a foodborne outbreak
- 12 VAC 5-421-4050 Added definition of conditional employee to restriction or exclusion requirements.
- 12 VAC 5-421-4070 Added definition of conditional employee to release of restriction or exclusion requirements.

For new chapters, use this chart:

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements