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Fast-Track Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC 5- 421
VAC Chapter title(s)	Food Regulations
Action title	Fast Track Amendments to Update APA Language and Remove DIBR
Date this document prepared	February 27, 2024

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

The Food Regulations (12VAC5-421 et seq.) establish minimum sanitary standards for the operation of the Commonwealth's food establishments, which include traditional restaurants, mobile food units, temporary food vendors, hospital and nursing facility food service, and school food service. This amendment is limited to three items: the requirements for who can preside over an informal conference or proceeding, the allowance for the presiding officer to release impounded food after an informal conference, and the removal of a Document Included by Reference (DIBR) which has no corresponding reference in the text of the regulation.

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the "Definitions" section of the regulation.

DIBR means a Document Included by Reference

IFFC means an informal fact-finding conference, also referred to as an informal conference or informal proceeding.

Impounded Food means a food that has originated from an unapproved source; may be unsafe, adulterated, or not honestly presented; or is not otherwise in compliance with the regulations. The department may place these foods under a hold order and securely tagged or labeled in the food establishment. The food establishment may not use, sell, move, or destroy the foods. The food establishment may appeal the hold order and hold orders may be affirmed or released as a result of an informal conference or other appeal.

Statement of Final Agency Action

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.

The State Board of Health approved these Fast Track Amendments to the Food Regulations (§12VAC5-421) at the April 10th, 2024 Board of Health Meeting.

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, "mandate" has the same meaning as defined in the ORM procedures, "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

Consistent with Virginia Code § 2.2-4012.1, also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track rulemaking process.

There is no legal mandate for these changes.

Amending the language describing an informal conference allows the department greater flexibility in providing a presiding officer. In the current language, an informal conference must be presided over by the district health director. This often causes scheduling delays as Health Directors have many obligations. Health Directors may also have to recuse themselves from presiding over conferences when they have been significantly involved in decision making in a case prior to the informal conference. Allowing the presiding officer to release impounded food after an informal conference removes the restriction that the Health Director perform this action.

Removing the DIBR is a correction to a previous regulatory action (Action 5460 / Stage 8866) which removed the reference to this document from the text. At that time this DIBR should have been stricken.

These changes are not expected to be controversial.

Expanding the options for a presiding officer for informal conferences is expected to provide greater expediency for a regulant, and generally provides benefit to the public as Health Directors may be more involved in decisions in their district without concern for a potential need for future recusal.

Removing the DIBR is not controversial, as without reference to it in the regulation, it currently holds no force of administrative law, and is only potentially confusing to the public.

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia and Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

The promulgating agency is the Virginia Department of Health.

Section 35.1-11 of the Code of Virginia states,

“The Board shall make, adopt, promulgate, and enforce regulations necessary to carry out the provisions of this title and to protect the public health and safety. In promulgating regulations, the Board shall consider the accepted standards of health including the use of precautions to prevent the transmission of communicable diseases, hygiene, sanitation, safety, and physical plant management.”

Section 35.1-14 of the Code of Virginia states in part,

“A. Regulations of the Board governing restaurants shall include but not be limited to the following subjects: (i) a 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 or 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 provided 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; (x) the appropriate use of precautions to prevent the transmission of communicable diseases; and (xi) training standards that address food safety and food allergy awareness and safety.”

B. In its regulations, the Board may classify restaurants by type and specify different requirements for each classification.

C. The Board may adopt any edition of the Food and Drug Administration's Food Code, or supplement thereto, or any portion thereof, as regulations, with any amendments as it deems appropriate. In addition, the Board may repeal or amend any regulation adopted pursuant to this subsection. No regulations adopted or amended by the Board pursuant to this subsection, however, shall establish requirements for any license, permit, or inspection unless such license, permit, or inspection is otherwise provided for in this title. The provisions of the Food and Drug Administration's Food Code shall not apply to farmers selling their own farm-produced products directly to consumers for their personal use, whether such sales occur on such farmer's farm or at a farmers' market, unless such provisions are adopted in accordance with the Administrative Process Act (§ 2.2-4000 et seq.).”

Purpose

Explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it is intended to solve.

- 1) The proposed changes are intended to clear up a potential inaccuracy with a DIBR that does not have a reference in the regulatory text, and are designed to provide more options for regulatory enforcement informal conferences.
- 2) Administrative efficiency ensures fair and expedient application of the regulation, and regulations should not include incorrect documents as DIBRs, and
- 3) These minor changes are needed to improve administrative procedures and remove a DIBR that did not apply to the regulatory text.

Substance

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.

The presiding officer and impoundment release duties for administrative hearings will no longer be restricted to a local health department's director, and a DIBR with no reference in the text will be removed.

Issues

Identify the issues associated with the regulatory change, 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, include a specific statement to that effect.

Both changes provide advantages to the public and the agency. The presiding officer and impoundment release changes allow greater flexibility to both the agency and the public in scheduling informal conferences, potentially reducing the regulatory burden on citizens and businesses, and the DIBR removal eliminates confusion on the part of the public and agency staff as it is currently not in effect.

There are no disadvantages to the public or the Commonwealth.

Requirements More Restrictive than Federal

Identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and 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 specific statement to that effect.

There are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Consistent with § 2.2-4007.04 of the Code of Virginia, identify any other state agencies, localities, or other entities particularly affected by the regulatory change. Other entities could include local partners such as tribal governments, school boards, community services boards, and similar regional organizations. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected: There are no other state agencies particularly affected.

Localities Particularly Affected: There are no localities particularly affected.

Other Entities Particularly Affected: There are no other entities particularly affected.

Economic Impact

Consistent with § 2.2-4007.04 of the Code of Virginia, identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Keep in mind that this is the proposed change versus the status quo.

Impact on State Agencies

<i>For your agency:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	There are no projected costs or revenues associated with this change.
<i>For other state agencies:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	NA
<i>For all agencies:</i> Benefits the regulatory change is designed to produce.	There is no economic impact associated with this change.

Impact on Localities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a or 2) on which it was reported. Information provided on that form need not be repeated here.

Projected costs, savings, fees or revenues resulting from the regulatory change.	There are no projected costs or revenues associated with this change.
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Benefits the regulatory change is designed to produce.	There is no economic impact associated with this change.
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Impact on Other Entities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a, 3, or 4) on which it was reported. Information provided on that form need not be repeated here.

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	There are no external entities likely to be impacted by this change.
Agency's best estimate of the number of such entities that will be affected. Include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.	There are no external entities likely to be impacted by this change.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	There are no projected costs or revenues associated with this change
Benefits the regulatory change is designed to produce.	

Alternatives to Regulation

Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. 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 regulatory change.

The alternative to this regulatory amendment would be to leave the regulation as-is; this would result in less flexibility for regulants and the agency in scheduling informal conferences or releasing impounded foods, and an incorrectly listed DIBR in the regulation. The pursued change has virtually no cost or intrusive effect to any entity.

If this analysis has been reported on the ORM Economic Impact form, indicate the tables on which it was reported. Information provided on that form need not be repeated here.

Regulatory Flexibility Analysis

Consistent with § 2.2-4007.1 B of the Code of Virginia, 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) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing 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 regulatory change.

As this change has virtually no cost or intrusive effect to any entity, there is no ability to reduce stringency.

If this analysis has been reported on the ORM Economic Impact form, indicate the tables on which it was reported. Information provided on that form need not be repeated here.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below.

Consistent with § 2.2-4011 of the Code of Virginia, if an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

If you are objecting to the use of the fast-track process as the means of promulgating this regulation, please clearly indicate your objection in your comment. Please also indicate the nature of, and reason for, your objection to using this process.

The Virginia Department of Health is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal and any alternative approaches, (ii) the potential impacts of the regulation, and (iii) the agency's regulatory flexibility analysis stated in this background document.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: <https://townhall.virginia.gov>. Comments may also be submitted by mail, email or fax to Olivia McCormick, 109 Governor Street, Richmond Virginia, 23222; 804-864-8146, 804-864-7454 (fax); Olivia.McCormick@vdh.virginia.gov. To be considered, comments must be received by 11:59 pm on the last day of the public comment period.

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

If an existing VAC Chapter(s) is being amended or repealed, use Table 1 to describe the changes between existing VAC Chapter(s) and the proposed regulation. If existing VAC Chapter(s) or sections are being repealed and replaced, ensure Table 1 clearly shows both the current number and the new number for each repealed section and the replacement section.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
12VAC5-421-3966		Establishes procedures for addressing impounded food after an informal conference.	<p>Change: Removes specific reference to the local health director.</p> <p>Intent: Allows a presiding officer to release impounded food.</p> <p>Rationale: Local health directors may need to recuse themselves from presiding due to prior involvement in the case, and restricting the options of impoundment release to one individual increases the chances of delays in agency response.</p> <p>Impact: Improved flexibility and timeliness for the release of impounded foods.</p>
12VAC5-421-3970		Establishes requirements for the agency and regulant in the process of enforcement of the regulation. Specifically names the local health department director as the individual who must preside over an informal conference.	<p>Change: Removes specific reference to the local health director.</p> <p>Intent: Allows other representatives of the agency to act as presiding officers</p> <p>Rationale: Local health directors may need to recuse themselves from presiding due to prior involvement in the case, and restricting the options of a presiding officer to one individual increases the chances of delay in scheduling.</p> <p>Impact: Improved flexibility and timeliness for the scheduling of informal conferences.</p>
12VAC5-421 DIBR		Lists all DIBRs in the regulation. Includes a reference to an internal VDH training document.	<p>Change: Strikes the internal document describing staff training methods.</p> <p>Intent: Removes erroneous inclusion of this document; it should have been stricken in a prior regulatory action (action 5460/ stage 8866).</p> <p>Rationale: This DIBR is not referenced in the text and has no force of law. Its inclusion is erroneous and misleading.</p>

			Impact: Decreases potential for incorrect interpretation that this document has the force of administrative law.
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