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Exempt Action Final Regulation Agency Background Document

Agency name	Commissioner of Agriculture and Consumer Services
Virginia Administrative Code (VAC) citation(s)	2 VAC 5-600
Regulation title(s)	Regulations Pertaining to Food for Human Consumption
Action title	Adopt by reference revised and new documents from the Code of Federal Regulations
Final agency action date	November 22, 2019
Date this document prepared	November 22, 2019

While a regulatory action may be exempt from executive branch review pursuant to § 2.2-4002 or § 2.2-4006 of the *Code of Virginia*, the agency is still encouraged to provide information to the public on the Regulatory Town Hall using this form. However, the agency may still be required to comply with the Virginia Register Act, Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations*.

Brief Summary

Please 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.

This regulations adopts by reference specific Parts in Title 21 of the Code of Federal Regulations and in Title 40 of the Code of Federal Regulations that were adopted by the U.S. Food and Drug Administration (FDA) and effective as of April 1, 2010. The amendments to this regulation will adopt by reference specific Parts in Title 21 of the Code of Federal Regulations and in Title 40 of the Code of Federal Regulations that were adopted by FDA and effective as of April 1, 2019.

These parts are being incorporated by reference to reflect the updated food safety standards adopted by FDA. Part 117 of Title 21 of the Code of Federal Regulations (CFR) (hereinafter “Part 117”), which replaces and incorporates 21 CFR Part 110 (hereinafter “Part 110”), is being adopted by reference to ensure Virginia’s food safety standards for manufacturers meet federal minimums. The existing standards for good manufacturing practices were established in Part 110, which will sunset in spring of 2020. The standards established in Part 110 have been incorporated into Part 117 with certain enhancements that will ultimately ensure a safer food supply for the citizens of the Commonwealth. Failure to adopt Part 117 in Virginia’s Regulations Pertaining to Food for Human Consumption will result in the agency losing FDA authorization to inspect certain food manufacturers after the sunset of Part 110.

Adoption and readoption of all of these parts will allow for appropriate regulatory oversight of food establishments and will allow the agency to properly address the risks and hazards associated with food products and food establishments thus enhancing the safety of the food supply in the Commonwealth.

Mandate and Impetus

Please identify the mandate for this regulatory change, and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, internal staff review, petition for rulemaking, periodic review, board decision, etc.). “Mandate” is defined as “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.”

Section 3.2-109 of the Code of Virginia (Code) establishes the Board of Agriculture and Consumer Services (Board) as a policy board and authorizes the Board to adopt regulations in accordance with the provisions of Title 3.2 of the Code. The Commissioner of Agriculture and Consumer Services (Commissioner) is authorized by § 3.2-5121 of the Code to adopt any regulation under the federal Food, Drug, and Cosmetic Act without public hearing. Such regulation shall be effective upon filing with the Registrar of Regulations. The Board, at its next regular meeting, shall adopt the regulation after notice but without public hearing unless a petition is filed.

This regulatory change was initiated in response to the upcoming sunset of 21 CFR Part 110. When Part 110 sunsets in 2020, Virginia will lose FDA authorization to regulate food manufacturers in accordance with federally-established Good Manufacturing Practices if it does not adopt 21 CFR Part 117, which will replace 21 CFR Part 110.

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 November 22, 2019, the Commissioner of Agriculture and Consumer Services adopted as final amendments to 2 VAC 5-600, Regulations Pertaining to Food for Human Consumption.

Periodic Review 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 is being conducted as part of this regulatory action, and was announced during the proposed stage, please

indicate whether the regulatory change meets the criteria set out in Executive Order 14 (as amended, July 16, 2018), e.g., is necessary for the protection of public health, safety, and welfare; minimizes the economic impact on small businesses consistent with the stated objectives of applicable law; and is clearly written and easily understandable.

In addition, as required by § 2.2-4007.1 E and F of the Code of Virginia, 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.

This form is not being used to report the result of a periodic or small business impact review.

Section 2.2-4007.1 E and F of the Code of Virginia:

1. There is a continued need for these regulations in order to ensure that Virginia food manufacturers comply with current federal Good Manufacturing Practices. Consistency between the related state and federal regulations is required in order for the Virginia Department of Agriculture and Consumer Services (VDACS) to continue to inspect food manufacturers on behalf of the FDA.
2. No public comment period is required for this amendment. The industry has not expressed concern regarding this regulation to VDACS at any point or expressed concerns about the recent updates to Title 21, Chapter 1 of the CFR.
3. This regulation is not complex, as it simply adopts by reference the CFR. The text of Title 21, Chapter 1 of the CFR is written in plain language and is accepted nationally.
4. This regulation enables VDACS to inspect and enforce food safety requirements in accordance with portions of Title 21, Chapter 1 of the CFR. It references, but does not duplicate, the CFR. With the proposed amendments, These regulations will not overlap, duplicate, or conflict with federal or state law or regulation.
5. The regulations were last amended in 2011. Since 2011, technological and economic developments have not altered the basic nature of the food industry. However, Title 21, Chapter 1 of the CFR has been updated annually, and this amendment will allow align Virginia's regulation with federal regulations.