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Exempt Action: Proposed Regulation Agency Background Document

Agency name	Board of Agriculture and Consumer Services
Virginia Administrative Code (VAC) Chapter citation(s)	2 VAC 5-595
VAC Chapter title(s)	Regulations Governing the Manufacturing and Sale of Products that Contain Industrial Hemp Extracts Intended for Human Consumption
Action title	Amendments to update the regulation, including those to reflect the 2023 legislation pertaining to edible hemp products
Date this document prepared	May 27, 2025

This information is required for executive branch review pursuant to 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. In addition, this information is required by the Virginia Registrar of Regulations pursuant to the Virginia Register Act (§ 2.2-4100 et seq. of the Code of Virginia). Regulations must conform to 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.

Article 5 of Chapter 51 of Title 3.2 of the Code of Virginia (Va. Code § 3.2-5145.1 et seq.), which pertains to the manufacture and sale of industrial hemp extracts intended for human consumption, authorizes the Board of Agriculture and Consumer Services (Board) to adopt regulations for the efficient enforcement of the article. The Department of Agriculture and Consumer Services administers the provisions established in this article and the regulations adopted pursuant thereto.

Pursuant to Section 3.2-5145.5 of the Code of Virginia, the Board adopted 2 VAC 5-595, Regulations Governing the Manufacturing and Sale of Products that Contain Industrial Hemp Extracts Intended for Human Consumption (Regulations), which became effective on August 15, 2022. The Regulations establish contaminant levels and production and labeling requirements for industrial hemp extracts intended for human consumption. The Regulations provide a regulatory framework that allows for essential clarity and understanding regarding industrial hemp extracts for both the industry and regulatory personnel.

The Board now proposes to amend the Regulations to update the title, definitions, and labeling and testing requirements for edible hemp products. The updates include the addition of the terms “edible hemp product,” “dietary supplement,” and “statement of identity.” Existing definitions have been revised to align with current practices. The Board also proposes amendments to address regulatory gaps, including establishing requirements to ensure the accessibility and reliability of certificates of analysis and related documentation and prohibiting variability in the cannabinoid content of edible hemp products. Additionally, the Board proposes amendments to reflect the statutory requirement that a person who manufactures, packages, holds, or sells a food in Virginia must obtain a food safety permit.

Section 50 of the Regulations references 18 VAC 110-60, Regulations Governing Pharmaceutical Processors, which the Virginia Board of Pharmacy repealed after its authority to regulate Virginia’s medical cannabis program was reassigned to the Virginia Cannabis Control Authority. These references in Section 50 incorporated certain contaminant standards established in the pharmaceutical processor regulation. The Board proposes to amend Section 50 of the Regulations to replace references to 18 VAC 110-60 with the specific contaminant criteria that was previously established in 18 VAC 110-60 for mycotoxins, heavy metals, and pesticides. The Board proposes to amend Section 50 of the Regulations to replace the reference to the microbiological content criteria established in 11 VAC 110-60, which references Section 1111 of the United States Pharmacopeia, with microbiological content criteria based on food safety standards. Section 1111 of the United States Pharmacopeia establishes stringent standards for nonsterile drug products. The Board proposes to amend the Regulation to establish microbiological criteria for edible hemp products based on food safety standards that are consistent with U.S. Food and Drug Administration regulations for ready-to-eat food. The proposed amendments to the microbiological content criteria establish appropriate microbiological limits based on risk, intended use, and the composition of edible hemp products.

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, internal staff review, 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.”

Chapters 744 and 794 of the 2023 Acts of Assembly amended Article 5 of Chapter 51 of Title 3.2 of the Code of Virginia to establish that an industrial hemp extract, when offered for retail

sale, must contain a total THC concentration no greater than 0.3 percent and must contain either no more than two milligrams of total THC per package or a cannabidiol (CBD) to THC ratio that is no less than 25 parts CBD to one part THC. Chapters 744 and 794 also established additional requirements for edible hemp products that are offered for retail sale, including child-resistant packaging for products that contain THC and labeling that states all ingredients contained in the product. These statutory requirements are reflected in the amendments to the Regulations proposed by the Board.

Chapter 204 of the 2022 Acts of Assembly amended the Food and Drink Law to require a food manufacturer, food storage warehouse, or retail food establishment to obtain a permit from the Commissioner of Agriculture and Consumer Services to operate. This statutory requirement is reflected in the amendments to the Regulations proposed by the Board.