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Exempt Action: Final 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	Promulgate regulation regarding industrial hemp extracts intended for human consumption as required by Ch. 659 and 660 of the 2020 Acts of Assembly
Final agency action date	July 19, 2022
Date this document prepared	July 22, 2022

Although 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 (1VAC7-10), 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.

This regulation is designed to ensure the efficient and effective enforcement of Article 5 of Chapter 51 of Title 3.2 of the Code of Virginia (Va. Code § 3.2-5145.1 et seq.), which addresses the manufacture, distribution, and sale of industrial hemp extracts intended for human consumption and was enacted by the 2020 Session of the General Assembly. Chapters 659 and 660 of the 2020 Acts of Assembly, which became effective on April 6, 2020, define "industrial hemp extract" as an extract (i) of a *Cannabis sativa* plant that has a concentration of tetrahydrocannabinol that is no greater than that allowed for hemp by federal law and (ii) that is intended for human consumption. The legislation requires that industrial hemp extracts comply with regulations adopted by the Board of Agriculture and Consumer Services (Board) pursuant to Va. Code § 3.2-5145.5.

The proposed regulation provides essential standards that must be adhered to in order for an industrial hemp manufacturer to remain in compliance with the proposed regulation as well as the industrial hemp extract article (Article 5) of the Virginia Food and Drink Law. The regulation provides a regulatory framework that allows for essential clarity and understanding regarding industrial hemp extracts for both the industry as well as regulatory personnel. The regulation identifies specific contaminants that may be present in an industrial hemp extract or a food containing an industrial hemp extract and establishes tolerances for these contaminants. The regulation establishes labeling requirements for an industrial hemp extract or a food containing an industrial hemp extract. The regulation also establishes testing requirements for industrial hemp extracts and criteria for independent testing laboratories that conduct required batch testing of industrial hemp extracts.

The Board amended the proposed regulation in response to comments received during the required public comment period and language included in the 2022 Appropriation Act. The proposed regulation underwent a 60-day public comment period from November 8, 2021, through January 7, 2022, during which the agency received approximately 10 comments, with the primary concerns being the definition of “cannabinoid” and the regulation of delta-8 tetrahydrocannabinol (THC) products. Item 4-14 #5c of the 2022 Appropriation Act mandates that this regulation address additional labeling requirements, and the progression of this regulatory action was such that the timing of the Board’s final adoption of the regulation allowed the Board to concurrently respond to the requirement in the 2022 Appropriation Act.

The definition of “cannabinoid” was amended to ensure that the definition is straightforward and less confusing. The term “commissioner” was replaced with “department.” The Board replaced language specifying contaminant limits for microbiological, mycotoxins, and heavy metals and pesticide chemical residue tolerances with references to identical limits for these contaminants established in the Board of Pharmacy’s regulation that pertains to cannabis products produced by permitted pharmaceutical processors. The Board adopted requirements for the package label of an industrial hemp extract that contains THC or food containing an industrial hemp extract that contains THC to reflect the mandatory labeling requirements established by the language in Item 4-14 #5c of the 2022 Appropriation Act.

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). “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.”

Chapters 659 and 660 of the 2020 Acts of Assembly, which became effective on April 6, 2020, amended the Virginia Food and Drink Law to create a new article that establishes requirements for the production, distribution, and sale of industrial hemp extracts intended for human consumption. This article also requires the Board to promulgate regulations designed to provide specific requirements and standards for these manufacturers and provides for a regulatory framework that allows for the efficient and effective enforcement of the article. Additionally, Item 4-14 #5c of the 2022 Appropriation Act mandates that this regulation address specific labeling requirements.

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.

On July 19, 2022, the Board of Agriculture and Consumer Services adopted as final 2 VAC 5-595, Regulations Governing the Manufacturing and Sale of Products that Contain Industrial Hemp Extracts

Intended for Human Consumption, and authorized staff to take any and all steps necessary to have this regulation become a final regulation of the Board through an exempt regulatory action as authorized by Section 3.2-5145.5 of the Virginia Food and Drink Law.