

Office of Regulatory Management
Economic Review Form

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
Regulatory Stage (including Issuance of Guidance Documents)	Exempt, Proposed

Cost Benefit Analysis

Complete Tables 1a and 1b for all regulatory actions. You do not need to complete Table 1c if the regulatory action is required by state statute or federal statute or regulation and leaves no discretion in its implementation.

Table 1a should provide analysis for the regulatory approach you are taking. Table 1b should provide analysis for the approach of leaving the current regulations intact (i.e., no further change is implemented). Table 1c should provide analysis for at least one alternative approach. You should not limit yourself to one alternative, however, and can add additional charts as needed.

Report both direct and indirect costs and benefits that can be monetized in Boxes 1 and 2. Report direct and indirect costs and benefits that cannot be monetized in Box 4. See the ORM Regulatory Economic Analysis Manual for additional guidance.

Table 1a: Costs and Benefits of the Proposed Changes (Primary Option)

<p>(1) Direct & Indirect Costs & Benefits (Monetized)</p>	<p>There are no monetizable, direct benefits or monetizable, direct or indirect costs associated with the proposed amendments to the Regulations Governing the Manufacturing and Sale of Products that Contain Industrial Hemp Extracts Intended for Human Consumption.</p> <p>There may be monetizable, indirect benefits associated with the proposed amendment to Section 50 that will replace the reference to the microbiological content criteria established in 11 VAC 110-60, which references Section 1111 of the United States Pharmacopeia (USP), with microbiological content criteria based on food safety standards. Section 1111 of the USP 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. Adopting microbiological content criteria based on food safety standards rather than Section 1111 of the USP may reduce compliance costs related to producing an edible hemp product that complies with the more stringent microbiological content criteria (e.g., high-cost sterilization steps, advanced microbial remediation, repeated microbial testing, more complex and costly laboratory testing) or costs related to a product exceeding the more stringent microbiological content criteria (e.g., product loss or reprocessing). Due to the number of variables that may influence the indirect benefit manufacturers may experience as a result of this proposed amendment, the agency does not have data on which it can base an estimate of this potential indirect benefit.</p>	
<p>(2) Present Monetized Values</p>	<p>Direct & Indirect Costs</p>	<p>Direct & Indirect Benefits</p>
	<p>(a) 0</p>	<p>(b) unknown</p>
<p>(3) Net Monetized Benefit</p>	<p>0</p>	
<p>(4) Other Costs & Benefits (Non-Monetized)</p>	<p>The entities subject to the requirements set forth in the Industrial Hemp Extract Intended for Human Consumption Article of the Food and Drink Law (Va. Code § 3.2-5145.1 et seq.) will benefit from the clarity provided by the proposed amendments. The amendments to the regulations outline requirements more precisely.</p>	

(5) Information Sources	N/A
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Table 1b: Costs and Benefits under the Status Quo (No change to the regulation)

(1) Direct & Indirect Costs & Benefits (Monetized)	There are no monetizable, direct or indirect costs or benefits associated with not amending this regulation.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) 0	(b) 0
(3) Net Monetized Benefit	N/A	
(4) Other Costs & Benefits (Non-Monetized)	Without the proposed amendments to the regulations, the regulation will not reflect current law, which will create confusion for regulated entities.	
(5) Information Sources	N/A	

Table 1c: Costs and Benefits under Alternative Approach(es)

(1) Direct & Indirect Costs & Benefits (Monetized)	The proposed amendments are necessary to align the regulation with current statutory requirements. The agency has not identified an alternative approach that accomplishes the goal of aligning the regulation with current statutory requirements.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) N/A	(b) N/A
(3) Net Monetized Benefit	N/A	
(4) Other Costs & Benefits (Non-Monetized)	N/A	
(5) Information Sources	N/A	

Impact on Local Partners

Use this chart to describe impacts on local partners. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

Table 2: Impact on Local Partners

(1) Direct & Indirect Costs & Benefits (Monetized)	The proposed amendments to the regulations will have no impact on local partners.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) 0	(b) 0
(3) Other Costs & Benefits (Non-Monetized)	The proposed amendments to the hemp product regulations will have no impact on local partners.	
(4) Assistance	N/A	
(5) Information Sources	N/A	

Impacts on Families

Use this chart to describe impacts on families. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

Table 3: Impact on Families

(1) Direct & Indirect Costs & Benefits (Monetized)	The proposed amendments to the regulations will have no impact on families.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) 0	(b) 0
(3) Other Costs & Benefits (Non-Monetized)	The proposed amendments to the regulations will have no impact on families.	

(4) Information Sources	N/A
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Impacts on Small Businesses

Use this chart to describe impacts on small businesses. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

Table 4: Impact on Small Businesses

(1) Direct & Indirect Costs & Benefits (Monetized)	There are no monetizable, direct benefits or direct or indirect costs associated with the proposed amendments. See Table 1A for potential, monetizable, indirect benefits associated with the proposed amendments.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) 0	(b) unknown
(3) Other Costs & Benefits (Non-Monetized)	There are not any reasonable alternatives that would make the regulatory burden on small businesses more equitable compared to larger businesses.	
(4) Alternatives	N/A	
(5) Information Sources	N/A	

Changes to Number of Regulatory Requirements

Table 5: Regulatory Reduction

For each individual action, please fill out the appropriate chart to reflect any change in regulatory requirements, costs, regulatory stringency, or the overall length of any guidance documents.

Change in Regulatory Requirements

VAC Section(s) Involved*	Authority of Change	Initial Count	Additions	Subtractions	Total Net Change in Requirements
595-10	(M/A):	0	0	0	0
	(D/A):	0	0	0	0
	(M/R):	0	0	0	0
	(D/R):	0	0	0	0
595-20	(M/A):	0	0	0	0
	(D/A):	0	0	0	0
	(M/R):	0	0	0	0
	(D/R):	0	0	0	0
595-30	(M/A):	0	0	0	0
	(D/A):	0	0	0	0
	(M/R):	0	1	0	+1
	(D/R):	3	0	3	-3
595-40	(M/A):	0	0	0	0
	(D/A):	0	0	0	0
	(M/R):	1	3	0	+3
	(D/R):	2	4	0	+4
595-50	(M/A):	0	0	0	0
	(D/A):	0	0	0	0
	(M/R):	2	2	1	+1
	(D/R):	48	30	4	+26
595-60	(M/A):	0	0	0	0
	(D/A):	0	0	0	0
	(M/R):	6	2	0	+2
	(D/R):	5	9	1	+8
Grand Total of Changes in Requirements:					(M/A): 0
					(D/A): 0
					(M/R): +7

(D/R): +35

Key:

Please use the following coding if change is mandatory or discretionary and whether it affects externally regulated parties or only the agency itself:

(M/A): Mandatory requirements mandated by federal and/or state statute affecting the agency itself

(D/A): Discretionary requirements affecting agency itself

(M/R): Mandatory requirements mandated by federal and/or state statute affecting external parties, including other agencies

(D/R): Discretionary requirements affecting external parties, including other agencies

Cost Reductions or Increases (if applicable)

VAC Section(s) Involved*	Description of Regulatory Requirement	Initial Cost	New Cost	Overall Cost Savings/Increases
2 VAC 5-595-50	A proposed amendment will 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.	unknown	unknown	Adopting microbiological content criteria based on food safety standards rather than Section 1111 of the USP may reduce compliance costs related to producing an edible hemp product that complies with the more stringent microbiological content criteria (e.g., high-cost sterilization steps, advanced microbial remediation, repeated microbial testing, more complex and costly laboratory testing) or costs related to a product exceeding the more stringent microbiological content criteria (e.g., product loss or

				reprocessing). Due to the number of variables that may influence the indirect benefit manufacturers may experience as a result of this proposed amendment, the agency does not have data on which it can base an estimate of this potential indirect benefit.

Other Decreases or Increases in Regulatory Stringency (if applicable)

VAC Section(s) Involved*	Description of Regulatory Change	Overview of How It Reduces or Increases Regulatory Burden
2 VAC 5-595-50	A proposed amendment will 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 content 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.

Length of Guidance Documents (only applicable if guidance document is being revised)

Title of Guidance Document	Original Word Count	New Word Count	Net Change in Word Count
N/A			

*If the agency is modifying a guidance document that has regulatory requirements, it should report any change in requirements in the appropriate chart(s).