

Office of Regulatory Management
Economic Review Form

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-421
VAC Chapter title(s)	Food Regulations
Action title	Amend Chapter 421 to Adopt 2022 FDA Food Code
Date this document prepared	November 1, 2023
Regulatory Stage (including Issuance of Guidance Documents)	Fast Track

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)

(1) Direct & Indirect Costs & Benefits (Monetized)	<p>Direct Costs: The majority of the changes in this regulatory action are to terminology and have no direct or indirect associated costs. Exceptions are listed below.</p> <p>Addition of sesame as a major allergen (section 10): This addition requires the permit holder to notify customers by written notification of the presence of major food allergens in unpackaged foods. Costs associated with this amendment are indeterminate but are expected to be minor based on feedback from the National Restaurant Association via Virginia Restaurant Lodging and Travel Association. Establishments that add sesame to foods will have one-time costs to provide written notification of any allergens present (section 910), which may vary depending on the type of menu offered. Establishments using QR Code</p>
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	<p>digital menus or that change a limited paper menu regularly may bear no costs.</p> <p>Addition of requirements to the duties of the Person In Charge (PIC) may require limited costs for initial training, but are unlikely to require staffing changes.</p> <p>Additional requirements for hazard control plans may result in very limited but indeterminate costs.</p> <p>Other amendments are not estimated to result in direct costs.</p> <p>Indirect Costs: Indeterminate. There are no monetizable indirect costs associated with this change unless food establishments choose to change existing recipes or food product sources to avoid sesame products. Other amendments are not estimated to result in indirect costs.</p> <p>Direct Benefits: Indeterminate. There may be direct monetizable benefits associated with amendments to sections 50, 80, and 2190: Section 50 allows certain low-risk food establishments to operate without a designated Person In Charge (PIC). While there is no direct cost associated with a PIC, these establishments may benefit monetarily from an increased flexibility in scheduling. Section 80 reclassifies certain ill employees that were previously required to be excluded from work as those who are allowed to work in a restricted capacity. These employees will benefit as they will not lose wages, and employers will benefit from a reduced impact on staffing. Section 2190 reduces the requirement for the temperature of hot water required in food establishments. This may reduce energy costs or costs borne in the maintenance or replacement of hot water heaters.</p> <p>Indirect Benefits: Indeterminate, however, indirect monetizable benefits to food establishments may occur due to reduction in foodborne illness and outbreak. One 2018 study estimated the cost of a single outbreak “ranged from \$3,968 to \$1.9 million for a fast-food restaurant, \$6,330 to \$2.1 million for a fast-casual restaurant, \$8,030 to \$2.2 million for a casual-dining restaurant, and \$8,273 to \$2.6 million for a fine-dining restaurant”.</p> <p>The indirect benefit to the individual may be significant as well. The Centers for Disease Control estimate that 48 million people get sick, 128,000 are hospitalized, and 3,000 die from foodborne diseases each year in the United States. A 2010 estimate placed the cost to an affected (ill) individual at \$1,850 on average nationwide.</p> <p>The United States Department of Agriculture estimates the negative impact of foodborne pathogens at 17.6 billion dollars in 2018.</p>
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(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
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	(a) Indeterminate	(b) Indeterminate
(3) Net Monetized Benefit	Indeterminate; however, given the potential costs for foodborne illness to industry and individuals, the agency estimates that the benefits of the action outweigh costs.	
(4) Other Costs & Benefits (Non-Monetized)	Alignment of the Virginia Food Regulations to the 2022 Food Code may benefit chain establishments that operate in other states and localities that also use the most up to date version of the Food Code. Many large chain operations use the most recent edition of the Food Code as an operational standard to ensure they reduce liability and operate consistently throughout their operational region. By adopting current changes to FDA Food Code, there is consistency with VDACS Retail Food Regulations.	
(5) Information Sources	<p>Bartsch SM, Asti L, Nyathi S, Spiker ML, Lee BY. Estimated Cost to a Restaurant of a Foodborne Illness Outbreak. Public Health Rep. 2018 May/Jun;133(3):274-286. doi: 10.1177/0033354917751129. Epub 2018 Apr 15. PMID: 29656701; PMCID: PMC5958383.</p> <p>https://www.cdc.gov/foodborneburden/estimates-overview.html</p> <p>https://www.pewtrusts.org/en/research-and-analysis/reports/0001/01/01/healthrelated-costs-from-foodborne-illness-in-the-united-states</p> <p>https://www.ers.usda.gov/amber-waves/2021/april/economic-cost-of-major-foodborne-illnesses-increased-2-billion-from-2013-to-2018/</p>	

Table 1b: Costs and Benefits under the Status Quo (No change to the regulation)

(1) Direct & Indirect Costs & Benefits (Monetized)	Direct Costs: There are no direct or indirect monetized costs or benefits associated with not updating the regulation to align to the 2022 FDA Food Code.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) None	(b) None
(3) Net Monetized Benefit	None	
(4) Other Costs & Benefits (Non-Monetized)	None	

(5) Information Sources	N/A
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Table 1c: Costs and Benefits under Alternative Approach(es)

(1) Direct & Indirect Costs & Benefits (Monetized)	<p>One alternative would be to amend the respective sections in the regulation in a way that is not to align with the 2022 FDA Food Code.</p> <p>The direct and indirect monetized costs associated with this alternative are that the Board of Health and the Board of Agriculture and Consumer Services would be inconsistent, and food establishments may have to navigate and comply with differing sets of requirements, potentially increasing the total number of requirements imposed on them and the associated cost of compliance.</p> <p>There are no direct or indirect costs or benefits associated with this alternative.</p>	
(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)	<p>The non-monetized costs associated with this alternative are the confusion and frustration for regulated entities, the public, and VDH and VDACS staff in reading, interpreting, enforcing, and complying with inconsistent regulations. It would jeopardize the success of the two agencies' joint oversight over food establishments.</p>	
(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)	There are no known direct or indirect, monetized costs or benefits that impact local partners.
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(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) None	(b) None
(3) Other Costs & Benefits (Non-Monetized)	None	
(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)	<p>Direct Costs: There are no direct costs to families that do not operate a food establishment (see Table 1a for impacts on those operating a food establishment).</p> <p>Indirect Costs: There are no indirect costs to families that do not operate a food establishment (see Table 1a for impacts on those operating a food establishment).</p> <p>Direct Benefits: Indeterminate. A reduced risk of foodborne illness may result in reduced healthcare costs and reduced loss of wages associated with foodborne illness. See Table 1a.</p> <p>Indirect Benefits: Indeterminate. It is possible that improvement in food safety as a result of the fast track amendments may lead to greater economic stability in the food service sector in the Commonwealth, as high profile outbreaks weaken consumer confidence in restaurants. A significant outbreak may have deleterious effects on the economic performance of the food service or tourism sectors, which may have trickle-down effects on the economy of the Commonwealth at large. These effects may impact the family economy, especially if the employment and wages of the family are dependent on the food service or tourism sectors.</p>
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(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) None	(b) Indeterminate
(3) Other Costs & Benefits (Non-Monetized)	Improvements in food safety associated with the amendments help ensure families avoid the pain, suffering, and potential death associated with foodborne illness.	
(4) Information Sources	N/A	

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)	Almost all the approximately 30,000 food establishments in the Commonwealth are estimated to be small businesses. None of the proposed changes are anticipated to have any particular or disproportionate impact on food establishments that are small businesses. See Table 1a for more information.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) See Table 1a	(b) See Table 1a
(3) Other Costs & Benefits (Non-Monetized)	None of the proposed changes are anticipated to have any particular or disproportionate impact on food establishments that are small businesses. See Table 1a for more information.	
(4) Alternatives	None of the proposed changes are anticipated to have any particular or disproportionate impact on food establishments that are small businesses. See Table 1a for more information. Thus, no alternatives to these changes is being considered.	
(5) Information Sources	See Table 1a	

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	Net Change
12VAC5-421-10	Statutory:	0	0	0	0
	Discretionary:	0	0	0	0
12VAC5-421-50	Statutory:	1	0	0	0
	Discretionary:	2	0	2	-2
12VAC5-421-65	Statutory:	0	0	0	0
	Discretionary:	2	0	0	0
12VAC5-421-70	Statutory:	0	0	0	0
	Discretionary:	74	3	0	3
12VAC5-421-80	Statutory:	0	0	0	0
	Discretionary:	183	0	1	-1
12VAC5-421-160	Statutory:	0	0	0	0
	Discretionary:	12	0	0	0
12VAC5-421-220	Statutory:	0	0	0	0
	Discretionary:	30	0	0	0
12VAC5-421-250	Statutory:	0	0	0	0
	Discretionary:	4	0	0	0
12VAC5-421-270	Statutory:	0	0	0	0
	Discretionary:	28	0	1	-1
12VAC5-421-400	Statutory:	0	0	0	0
	Discretionary:	7	0	0	0
12VAC5-421-420	Statutory:	0	0	0	0
	Discretionary:	4	0	0	0
12VAC5-421-430	Statutory:	0	0	0	0
	Discretionary:	15	3	0	3
12VAC5-421-440	Statutory:	0	0	0	0
	Discretionary:	9	0	1	-1
12VAC5-421-445	Statutory:	0	0	0	0
	Discretionary:	0	5	0	5
12VAC5-421-470	Statutory:	0	0	0	0
	Discretionary:	69	0	1	-1
12VAC5-421-510	Statutory:	0	0	0	0
	Discretionary:	9	0	0	0
12VAC5-421-620	Statutory:	0	0	0	0
	Discretionary:	12	0	0	0
12VAC5-421-700	Statutory:	0	0	0	0
	Discretionary:	68	0	0	0
12VAC5-421-720	Statutory:	0	0	0	0
	Discretionary:	1	0	0	0
12VAC5-421-726	Statutory:	0	0	0	0
	Discretionary:	0	3	0	3
	Statutory:	0	0	0	0

12VAC5-421-790	Discretionary:	20	0	1	-1
12VAC5-421-830	Statutory:	0	0	0	0
	Discretionary:	30	0	0	0
12VAC5-421-850	Statutory:	0	0	0	0
	Discretionary:	28	0	1	-1
12VAC5-421-870	Statutory:	0	0	0	0
	Discretionary:	111	0	1	-1
12VAC5-421-900	Statutory:	0	0	0	0
	Discretionary:	42	1	0	1
12VAC5-421-910	Statutory:	0	0	0	0
	Discretionary:	3	1	0	1
12VAC5-421-950	Statutory:	0	0	0	0
	Discretionary:	47	1	0	1
12VAC5-421-1435	Statutory:	0	0	0	0
	Discretionary:	1	0	0	0
12VAC5-421-1535	Statutory:	0	0	0	0
	Discretionary:	8	0	0	0
12VAC5-421-1540	Statutory:	0	0	0	0
	Discretionary:	63	0	0	0
12VAC5-421-2010	Statutory:	0	0	0	0
	Discretionary:	46	0	0	0
12VAC5-421-2190	Statutory:	0	0	0	0
	Discretionary:	4	0	1	-1
12VAC5-421-3140	Statutory:	0	0	0	0
	Discretionary:	22	0	0	0
12VAC5-421-3360	Statutory:	0	0	0	0
	Discretionary:	46	0	0	0
12VAC5-421-3370	Statutory:	0	0	0	0
	Discretionary:	3	5	0	5
12VAC5-421-3510	Statutory:	0	0	0	0
	Discretionary:	10	1	0	1
12VAC5-421-3595	Statutory:	0	0	0	0
	Discretionary:	7	1	0	1
12VAC5-421-3630	Statutory:	0	0	0	0
	Discretionary:	30	4	0	4
Total Net Change of Statutory Requirements:					0
Total Net Change of Discretionary Requirements:					18

Cost Reductions or Increases (if applicable)

VAC Section(s) Involved*	Description of Regulatory Requirement	Initial Cost	New Cost	Overall Cost Savings/Increases
12VAC5-421-10	Adds sesame to the list of what constitutes a major allergen	Indeterminate	Indeterminate (see Table 1a)	Indeterminate

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
12VAC5-421-50	Removes the requirement for a Person In Charge (PIC) at establishments deemed to be at low risk for causing illness.	Reduces cost burden on low risk food establishments.
12VAC5-421-80	Ill employees previously excluded from work may now work in a restricted capacity.	Positive effect on both employee income and food establishment staffing.
12VAC5-421-440	Adds 'invoice' as a recordkeeping option.	Allows greater flexibility while maintaining food safety rigor.
12VAC5-421-850	Establishes standards for an exemption for the initial temperature of received food product.	Allows greater flexibility while maintaining food safety rigor.
12VAC5-421-870	Creates additional option for the cold holding of food that requires refrigeration.	Allows additional options for food holding while maintaining rigor of food safety
12VAC5-421-2190	Reduction in the temperature required for hot water.	Indeterminate but positive effect on potential costs for hot water heater upkeep and power costs associated with hotter water use.