

Virginia Department of Planning and Budget Economic Impact Analysis

12 VAC 5-421 Food Regulations Virginia Department of Health Town Hall Action/Stage: 6418 / 10257 March 21, 2024

The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Code of Virginia (Code) and Executive Order 19. The analysis presented below represents DPB's best estimate of the potential economic impacts as of the date of this analysis.¹

Summary of the Proposed Amendments to Regulation

The State Board of Health (Board) proposes to amend the existing *Food Regulations* to incorporate, in part, 2022 amendments to the Food and Drug Administration (FDA) Food Code.

Background

The *Food Regulations* establish minimum sanitary standards for the operation of the Commonwealth's food establishments,² which include traditional restaurants, mobile food units, temporary food vendors, hospital and nursing facility food service, and school food service. Those standards include: (1) the safe and sanitary maintenance, storage, operation, and use of equipment; (2) the safe preparation, handling, protection, and preservation of food, including necessary refrigeration and heating methods; (3) procedures for vector and pest control; (4)

¹ Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the analysis should include but not be limited to: (1) the projected number of businesses or other entities to whom the proposed regulatory action would apply, (2) the identity of any localities and types of businesses or other entities particularly affected, (3) the projected number of persons and employment positions to be affected, (4) the projected costs to affected businesses or entities to implement or comply with the regulation, and (5) the impact on the use and value of private property.

² The regulation defines food establishment as "an operation that (i) stores, prepares, packages, serves, vends food directly to the consumer, or otherwise provides food for human consumption such as a market, restaurant, satellite or catered feeding location, catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people, vending location, conveyance used to transport people, institution, or food bank and (ii) relinquishes possession of a food to a consumer directly, or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers."

requirements for toilet and cleansing facilities for employees and customers; (5) requirements for appropriate lighting and ventilation not otherwise provided for in the Uniform Statewide Building Code; (6) requirements for an approved water supply and sewage disposal system; (7) personal hygiene standards for employees, particularly those engaged in food handling; and (8) the appropriate use of precautions to prevent the transmission of communicable diseases.

Standards in the regulation are labelled as either priority, priority foundation, or core. The current and proposed regulation state that "... a permit holder shall at the time of inspection correct a priority item or priority foundation item in this chapter and implement corrective actions for a HACCP [Hazard Analysis and Critical Control Point] plan provision that is not in compliance with its critical limit." Further,

Considering the nature of the potential hazard involved and the complexity of the corrective action needed, the department may agree to or specify a longer timeframe, not to exceed:

1. 72 hours after the inspection for the permit holder to correct priority items; or

2. 10 calendar days after the inspection for the permit holder to correct priority foundation items or HACCP plan deviations.

For core items, the current and proposed regulation state that "... the permit holder shall correct core items by a date and time agreed to or specified by the department but no later than 90 calendar days after the inspection."³

Proposed amendments with potential impact include the following, by section:

Section 10 Definitions

There are several amendments to this section. Adding "sesame' to the definition of "Major food allergen" may have impact as described below in the Estimated Benefits and Costs section.

Section 50 Assignment of responsibility

The current and proposed regulation both state that "... the permit holder shall be the person in charge or shall designate a person in charge and shall ensure that a person in charge is

³ The regulation also states that "The department may approve a compliance schedule that extends beyond the time limits specified under subsection A of this section if a written schedule of compliance is submitted by the permit holder and no health hazard exists or will result from allowing an extended schedule for compliance."

present at the food establishment during all hours of operation." The Board proposes to add that "This section shall not apply to certain types of food establishments deemed by the department to pose minimal risk of causing, or contributing to, foodborne illness based on the nature of the operation and extent of the food preparation."

Section 70 Duties of person in charge

The Board proposes to add the following to the list of items for which the person in charge is responsible to ensure: "Food employees are properly maintaining the temperature of time/temperature control for safety foods during thawing through daily oversight of the food employees' routine monitoring of food temperatures."

Section 80 Responsibility of permit holder, person in charge, and conditional employees

Under the current regulation, food employees who are diagnosed with an infection from Salmonella (nontyphoidal) and are asymptomatic, are to be prevented from working as an employee in the food establishment or entering the food establishment as an employee. The Board proposes to amend the text to indicate that such individuals are to be restricted rather than be excluded from working. The current and proposed regulation define "restrict" as "to limit the activities of a food employee so that there is no risk of transmitting a disease that is transmissible through food and the food employee does not work with exposed food, clean equipment, utensils, linens, or unwrapped single-service or single-use articles."

Section 250 Handling of animals prohibited

The Board proposes to add text which would restrict food employees from handling dogs that are allowed in an outdoor dining area of the food establishment.

Section 270 Compliance with food law

The requirement that "Food prepared in a private home shall not be used or offered for human consumption in a food establishment unless the home kitchen is inspected and regulated by the Virginia Department of Agriculture and Consumer Services" is currently a priority standard. The Board proposes to make it priority foundation.

Section 430 Molluscan shellfish; original container

The Board proposes to add that "Molluscan shellfish from one tagged or labeled container may not be commingled with molluscan shellfish from another container with different certification numbers, different harvest dates, or different harvest areas identified on the tag or label before being ordered by the consumer."

Section 440 Molluscan shellfish; maintain identification

The current regulation requires specified recordkeeping information on the tag or label. The proposed regulation adds a third option, the invoice.

Section 620 Food storage; prohibited areas

Currently, the prohibition on storing food in toilet rooms or their vestibules is a core standard. The Board proposes to make it priority foundation.

Section 726 Manufacturer cooking instructions

This section is new under the proposed regulation. In its entirety, it states that:

A. Commercially packaged food that bears a manufacturer's cooking instructions shall be cooked according to those instructions before use in ready-to-eat foods or offered in unpackaged form for human consumption, unless the manufacturer's instructions specify that the food may be consumed without cooking. ^P

B. Food for which the manufacturer has provided information that it has not been processed to control pathogens, when used in ready-to-eat foods or offered for human consumption, shall be cooked according to a time and temperature appropriate for the food. ^P

The "P" superscripts indicate that the proposed new standards are priority items.

Section 790 Thawing

The Board proposes to convert several thawing standards from core to priority foundation.

Section 850 Time as a public health control

The current regulation states that:

B. If time without temperature control is used as the public health control up to a maximum of four hours:

1. The food shall have an initial temperature of $41^{\circ}F$ (5°C) or less when removed from cold holding temperature control or $135^{\circ}F$ (57°C) or greater when removed from hot holding temperature control. ...

The Board proposes to add the following exception:

2. The food may have an initial temperature of 70°F (21°C) of less if:

a. It is a ready-to-eat fruit or vegetable that upon cutting is rendered a time/temperature control for safety food; or

b. It is a ready-to-eat hermetically sealed food that upon opening is rendered a time/temperature control for safety food;

c. The food temperature does not exceed 70°F (21°C) within a maximum time period of 4 hours from the time it was rendered a time/temperature control for safety food; and

d. The food is marked or otherwise identified to indicate the time that is 4 hours after the food is rendered a time/temperature control for safety food as specified in subdivisions B 2 a and B 2 b of this section.

Section 870 Reduced oxygen packaging without a variance, criteria

The Board proposes to include an additional option to package and seal food products by a cooling or sous-vide process so long as the food meets certain refrigeration requirements.

Section 900 Food labels

The Board proposes to require food establishments to notify (through card, sign, or other method) patrons regarding potential allergens in bulk food that is available for consumer self-dispensing.

Section 910 Other forms of information

The Board proposes to require food establishment permit holders to notify consumers in writing of the presence of major food allergens as an ingredient in unpackaged food items that are served or sold to the consumer.

Section 1535 Cleaning agents and sanitizers, availability

This section in its entirety states that:

A. Cleaning agents that are used to clean equipment and utensils as specified under Article 6 (12VAC5-421-1770 et seq.) of this part shall be provided and available for use during all hours of operation.

B. Except for chemical sanitizers that are generated on site at the time of use, chemical sanitizers that are used to sanitize equipment and utensils as specified under Article 7 shall be provided and available for use during all hours of operation.

In addition to stylistic changes, the Board proposes to convert these two standards from core to priority foundation.

Section 1540 Equipment, clothes washers and dryers, and storage cabinets, contamination prevention

Currently, the prohibition on locating equipment, cabinets used for the storage of food, or cabinets used to store cleaned and sanitized equipment, utensils, laundered linens, and singleservice and single-use article in toilet rooms or their vestibules is a core standard. The Board proposes to make it priority foundation.

Section 2010 Prohibitions

Currently, the prohibition on storing cleaned and sanitized equipment, utensils, laundered linens, and single-service and single-use articles in toilet rooms or their vestibules is a core standard. The Board proposes to make it priority foundation.

Section 2190 Handwashing sinks, water temperature, and flow

The Board proposes to reduce the minimum hot water temperature at a handwashing sink from 100°F to 85°F.

Section 3370 Poisonous or toxic material containers

The current section in its entirety is the following sentence: "A container previously used to store poisonous or toxic materials shall not be used to store, transport, or dispense food.^P" Ther Board proposes to add ", equipment, utensils, linens, single-service, or single-use articles" after "food" and before the period.

Section 3510 Public health protection

The Board proposes to amend this section to indicate that the Virginia Department of Health (VDH) shall apply this regulation to donated food.

Estimated Benefits and Costs

Alignment of the Virginia *Food Regulations* to the 2022 FDA Food Code may benefit chain food 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.⁴ By adopting current changes to the FDA Food Code, there is also consistency with the Virginia Department of Agriculture and Consumer Services Retail Food Establishment Regulations.⁵

Section 10 Definitions

The current regulation (Section 900) requires that labels on food packaged in a food establishment include "The name of the food source for each major food allergen contained in the food unless the food source is already part of the common or usual name of the respective ingredient." In the proposed regulation (Section 900), bulk food that is available for consumer self-dispensing must also be prominently labeled with each major food allergen contained in the food unless the food source is already part of the common or usual name of the respective ingredient. The Board also proposes to state (Section 910) that "The permit holder shall notify consumers by written notification of the presence of major food allergens as an ingredient in unpackaged food items that are served or sold to the consumer."

Given the current and proposed notification requirements (see above paragraph), adding sesame to the definition of "major food allergen" would make it substantively more likely that individuals allergic to sesame would be aware that food that they may have eaten at or from a food establishment contains sesame. According to the U.S. Department of Health and Human Services, National Institutes of Health, the sesame allergy is one of the ten most common

 ⁴ Source: VDH (see page three of Office of Regulatory Management Economic Review Form: <u>https://townhall.virginia.gov/L/GetFile.cfm?File=58\6418\10257\ORM_EconomicImpact_VDH_10257_v1.pdf</u>)
⁵ See https://law.lis.virginia.gov/admincode/title2/agency5/chapter585/

childhood food allergies, and reactions can be severe.⁶ Sesame allergies can cause anaphylaxis, a serious and potentially life-threatening reaction.⁷ Thus, adding sesame to the definition of "major food allergen" would likely be substantively beneficial for public health.

The cost to the food establishment permit holder of providing this information on menus, packages, bulk food containers, etc., would likely be small, particularly compared to the potential benefit. The National Restaurant Association has indicated that they believe the costs would be minor.⁸

Section 50 Assignment of responsibility

Exempting food establishments deemed by VDH to pose minimal risk of causing, or contributing to, foodborne illness from the requirement that a person in charge is present at the food establishment during all hours of operation would reduce labor costs for such food establishments. According to the agency, this would primarily apply to vending machine operations.

Section 70 Duties of person in charge

As mentioned above, the Board proposes to add the following to the list of items for which the person in charge is responsible to ensure: "Food employees are properly maintaining the temperature of time/temperature control for safety foods during thawing through daily oversight of the food employees' routine monitoring of food temperatures." The regulation already contains specific time/temperature control requirements for thawing. Adding this to the list of items for which the person in charge is responsible to ensure would put a greater emphasis on the importance of following safe thawing methods, but it would not likely produce a large change on what occurs in practice. The person in charge may remind the employees more often on what the safe thawing methods are.

Section 80 Responsibility of permit holder, person in charge, and conditional employees

⁶ See <u>https://www.nih.gov/news-events/nih-research-matters/sesame-allergy-common-among-children-food-allergies</u>

⁷ See <u>https://www.healthline.com/health/allergies/understanding-sesame-allergies</u>

⁸ Source: VDH (see page one of Office of Regulatory Management Economic Review Form: <u>https://townhall.virginia.gov/L/GetFile.cfm?File=58\6418\10257\ORM_EconomicImpact_VDH_10257_v1.pdf</u>)

As described above, under the current regulation food employees who are diagnosed with an infection from Salmonella (nontyphoidal) and are asymptomatic, are to be prevented from working as an employee in the food establishment. The Board proposes to amend the text to allow such individuals to work in a capacity where their activities are limited to where there is no risk of transmitting the disease and the food employee does not work with exposed food, clean equipment, utensils, linens, or unwrapped single-service or single-use articles. This proposed amendment would be beneficial for both employees with such infections in that they can earn income, and for the food establishment in staffing.

Section 250 Handling of animals prohibited

The Board proposes to add text which would restrict food employees from handling dogs that are allowed in an outdoor dining area of the food establishment. The current text already requires hand washing. To the extent that hand washing is not sufficient from preventing contamination of food from handling dogs, this proposed amendment may improve public health.

Section 270 Compliance with food law

The requirement that "Food prepared in a private home shall not be used or offered for human consumption in a food establishment unless the home kitchen is inspected and regulated by the Virginia Department of Agriculture and Consumer Services" is currently a priority standard. The Board proposes to make it priority foundation instead. As described above, this could allow the food establishment more time to correct the violation (up to ten calendar days rather than 72 hours).

Section 430 Molluscan shellfish; original container

The Board proposes to add that "Molluscan shellfish from one tagged or labeled container may not be commingled with molluscan shellfish from another container with different certification numbers, different harvest dates, or different harvest areas identified on the tag or label before being ordered by the consumer." Proper identification is vital for tracing the origin of shellfish in the event of a foodborne outbreak. Prohibiting the comingling may make it more likely that tracing the origin of shellfish in the event of a foodborne outbreak can be done accurately. This is beneficial in that it may reduce the likelihood that people consume unsafe molluscan shellfish. It could also potentially be beneficial for the food establishment and providers of the molluscan shellfish in that recalls of the product could be narrower and the area of growing waters closed to harvesting could be smaller when identification is more precise.

Section 440 Molluscan shellfish; maintain identification

Adding a third option (invoices) for recordkeeping could be beneficial for food establishments that would prefer that option over the existing two (tag or label).

Section 620 Food storage; prohibited areas

Currently, the prohibition on storing food in toilet rooms or their vestibules is a core standard. The Board proposes to make it priority foundation. This would reduce the maximum number of days that the food establishment could be given to correct this violation from 90 to ten.

Section 726 Manufacturer cooking instructions

This section is new under the proposed regulation. In its entirety, it states that:

A. Commercially packaged food that bears a manufacturer's cooking instructions shall be cooked according to those instructions before use in ready-to-eat foods or offered in unpackaged form for human consumption, unless the manufacturer's instructions specify that the food may be consumed without cooking. ^P

B. Food for which the manufacturer has provided information that it has not been processed to control pathogens, when used in ready-to-eat foods or offered for human consumption, shall be cooked according to a time and temperature appropriate for the food. ^P

The "P" superscripts indicate that the proposed new standards are priority items.

The proposed new standards may be beneficial for food safety, but may also limit a chef's creativity if she or he wishes to cook the commercially packaged food in a different way than is described in the manufacturer's instructions.

Section 790 Thawing

The Board proposes to convert several thawing standards from core to priority foundation. This would reduce the maximum number of days that the food establishment could be given to correct this violation from 90 to ten. Section 850 Time as a public health control

The current regulation states that:

B. If time without temperature control is used as the public health control up to a maximum of four hours:

1. The food shall have an initial temperature of 41°F (5°C) or less when removed from cold holding temperature control or 135°F (57°C) or greater when removed from hot holding temperature control. ...

The Board proposes to add the following exception to this requirement, which provides that:

2. The food may have an initial temperature of 70°F (21°C) of less if:

a. It is a ready-to-eat fruit or vegetable that upon cutting is rendered a time/temperature control for safety food; or

b. It is a ready-to-eat hermetically sealed food that upon opening is rendered a time/temperature control for safety food;

c. The food temperature does not exceed 70°F (21°C) within a maximum time period of 4 hours from the time it was rendered a time/temperature control for safety food; and

d. The food is marked or otherwise identified to indicate the time that is 4 hours after the food is rendered a time/temperature control for safety food as specified in subdivisions B 2 a and B 2 b of this section.

This could be beneficial for food establishments in that it gives them greater flexibility. Also, by increasing the maximum initial temperature (from 41°F to 70°F) for certain circumstances, this could result in energy costs savings (reduced need for refrigeration).

Section 870 Reduced oxygen packaging without a variance, criteria

The Board proposes to include an additional option to package and seal food products by a cooling or sous-vide process so long as the food meets certain refrigeration requirements. The additional option could be beneficial for food establishments that wish to use it.

Section 900 Food labels

The Board proposes to require food establishments to notify patrons (through a card, sign, or other method) regarding potential allergens in bulk food that is available for consumer selfdispensing. This would make it substantively more likely that individuals with food allergies would be aware that the bulk food contains the food for which they are allergic. As described above, food allergies can potentially be life threatening. Thus, this proposal would likely be substantively beneficial for public health. As mentioned above, the National Restaurant Association has indicated that they believe the costs would be minor.⁹

Section 910 Other forms of information

The Board proposes to require food establishment permit holders to notify consumers in writing of the presence of major food allergens as an ingredient in unpackaged food items that are served or sold to the consumer. This would make it substantively more likely that individuals with food allergies would be aware that the unpackaged food, including meals at restaurants, contains the food for which they are allergic. As described above, food allergies can potentially be life threatening. Thus, this proposal would likely be substantively beneficial for public health. As mentioned above, the National Restaurant Association has indicated that they believe the costs would be minor.¹⁰

Section 1535 Cleaning agents and sanitizers, availability

This section in its entirety states that:

A. Cleaning agents that are used to clean equipment and utensils as specified under Article 6 (12VAC5-421-1770 et seq.) of this part shall be provided and available for use during all hours of operation.

B. Except for chemical sanitizers that are generated on site at the time of use, chemical sanitizers that are used to sanitize equipment and utensils as specified under Article 7 shall be provided and available for use during all hours of operation.

In addition to stylistic changes, the Board proposes to convert these two standards from core to priority foundation. This would reduce the maximum number of days that the food establishment could be given to correct this violation from 90 to ten.

Section 1540 Equipment, clothes washers and dryers, and storage cabinets, contamination prevention

Currently, the prohibition on locating equipment, cabinets used for the storage of food, or cabinets used to store cleaned and sanitized equipment, utensils, laundered linens, and single-

⁹ Ibid

¹⁰ Ibid

service and single-use article in toilet rooms or their vestibules is a core standard. The Board proposes to make it priority foundation. This would reduce the maximum number of days that the food establishment could be given to correct this violation from 90 to ten.

Section 2010 Prohibitions

Currently, the prohibition on storing cleaned and sanitized equipment, utensils, laundered linens, and single-service and single-use articles in toilet rooms or their vestibules is a core standard. The Board proposes to make it priority foundation. This would reduce the maximum number of days that the food establishment could be given to correct this violation from 90 to ten.

Section 2190 Handwashing sinks, water temperature, and flow

The Board proposes to reduce the minimum hot water temperature at a handwashing sink from 100°F to 85°F. This could result in energy cost savings for food establishments.

Section 3370 Poisonous or toxic material containers

The current section in its entirety is the following sentence: "A container previously used to store poisonous or toxic materials shall not be used to store, transport, or dispense food.^P" The Board proposes to add ", equipment, utensils, linens, single-service, or single-use articles" at the end of the sentence, after "food." To the extent that containers previously used to store poisonous or toxic materials are actually used to store, transport, or dispense equipment, utensils, linens, single-service, or single-use articles, and the poisonous or toxic materials are not consistently 100 percent removed from the containers, this proposed amendment could improve public health. It seems unlikely that finding containers that were not previously used to store poisonous or toxic materials would be costly.

Section 3510 Public health protection

The Board proposes to amend this section to indicate that VDH shall apply this regulation to donated food. According to the agency, this would not increase staff workload more than negligibly. By ensuring that donated food at food establishments also meets the regulation's standards, public health may be improved.

Businesses and Other Entities Affected

The proposed amendments affect the approximate 31,000 permitted food establishments in the Commonwealth.¹¹

The Code of Virginia requires DPB to assess whether an adverse impact may result from the proposed regulation.¹² An adverse impact is indicated if there is any increase in net cost or reduction in net benefit for any entity, even if the benefits exceed the costs for all entities combined.¹³ Some of the proposed amendments likely produce a net benefit for society overall, but still do increase costs for some individual entities. For example, though the proposed required notifications for the presence of allergens potentially have large benefits for people with food allergies, they do (moderately) increase costs for food establishments. Thus, an adverse impact is indicated for food establishments.

Small Businesses¹⁴ Affected:¹⁵

Types and Estimated Number of Small Businesses Affected

VDH believes that the vast majority of the approximate 31,000 permitted food establishments would qualify as small businesses, with exceptions for large chains that do not operate as franchises and large medical care corporations that have food service.

¹¹ Data source: VDH

¹² Pursuant to Code § 2.2-4007.04(D): In the event this economic impact analysis reveals that the proposed regulation would have an adverse economic impact on businesses or would impose a significant adverse economic impact on a locality, business, or entity particularly affected, the Department of Planning and Budget shall advise the Joint Commission on Administrative Rules, the House Committee on Appropriations, and the Senate Committee on Finance.

¹³ Statute does not define "adverse impact," state whether only Virginia entities should be considered, nor indicate whether an adverse impact results from regulatory requirements mandated by legislation. As a result, DPB has adopted a definition of adverse impact that assesses changes in net costs and benefits for each affected Virginia entity that directly results from discretionary changes to the regulation.

¹⁴ Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as "a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million."

 $^{^{15}}$ If the proposed regulatory action may have an adverse effect on small businesses, Code § 2.2-4007.04 requires that such economic impact analyses include: (1) an identification and estimate of the number of small businesses subject to the proposed regulation, (2) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the proposed regulation, including the type of professional skills necessary for preparing required reports and other documents, (3) a statement of the probable effect of the proposed regulation on affected small businesses, and (4) a description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation. Additionally, pursuant to Code § 2.2-4007.1, if there is a finding that a proposed regulation may have an adverse impact on small business, the Joint Commission on Administrative Rules shall be notified.

Costs and Other Effects

The proposed required notifications for the presence of allergens moderately increase costs for small food establishments.

Alternative Method that Minimizes Adverse Impact

There are no clear alternative methods that both reduce adverse impact and meet the intended policy goals.

Localities¹⁶ Affected¹⁷

The proposed amendments neither disproportionally affect any particular localities, nor directly affect costs for local governments.

Projected Impact on Employment

The proposed amendments are not likely to have a large impact on total employment.

Effects on the Use and Value of Private Property

As described above, the proposals to reduce the minimum hot water temperature at a handwashing sink from 100°F to 85°F and to increase the maximum initial temperature from 41°F to 70°F for certain circumstances when time without temperature control is used as the public health control, may result in reduced energy costs for some food establishments. These reduced costs could increase the value of these businesses. The proposed exemption from the requirement that a person in charge is present at the food establishment during all hours of operation for food establishments deemed by VDH to pose minimal risk of causing, or contributing to, foodborne illness would reduce labor costs for such businesses, resulting in increase dvalue. The proposed required notifications for the presence of allergens moderately increase costs for food establishments, potentially moderately reducing value. The proposed amendments do not affect real estate development costs.

¹⁶ "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulatory change are most likely to occur.

¹⁷ § 2.2-4007.04 defines "particularly affected" as bearing disproportionate material impact.