



## Virginia Department of Planning and Budget **Economic Impact Analysis**

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**12 VAC 5-421 Food Regulations**  
**Virginia Department of Health**  
**Town Hall Action/Stage: 5460 / 8866**  
March 16, 2020

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### **Summary of the Proposed Amendments to Regulation**

The State Board of Health proposes numerous amendments to 12 VAC 5-421 *Food Regulations*, many of which conform to the latest U.S. Food and Drug Administration (FDA) model regulations.

### **Background**

The FDA describes its Food Code as “a model for safeguarding public health and ensuring food is unadulterated and honestly presented when offered to the consumer. It represents FDA's best advice for a uniform system of provisions that address the safety and protection of food offered at retail and in food service.”<sup>1</sup> The FDA encourages states to adopt the latest version of the FDA Food Code,<sup>2</sup> but it is not federal law.

### **Conforming to 2017 FDA Food Code**

The following proposed amendments to the regulation conform to requirements in the 2017 FDA Food Code:

- Require that there be a certified food protection manager (CFPM) on the premises of the food establishment<sup>3</sup> at all times of operation.

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<sup>1</sup> See <https://www.fda.gov/food/fda-food-code/food-code-2017>

<sup>2</sup> Ibid

<sup>3</sup> “Food establishment” is defined as “an operation that (i) stores, prepares, packages, serves, or vends food directly to the consumer, or otherwise provides food to the public for human consumption, such as a 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, market, vending location, conveyance used to transport people, institution, or food bank, and (ii) relinquishes possession of 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.”

- Require that if used, an impermeable cover such as a bandage, finger cot, or finger stall located on the wrist, hand or finger of the food employee working with exposed food shall be covered with a single-use glove.
- Require that food establishments have written procedures for employees to follow when responding to vomiting or diarrheal events that involve the discharge of vomitus or fecal matter onto surfaces in the food establishment. The procedures must address the specific actions employees must take to minimize the spread of contamination and the exposure of employees, consumers, food, and surfaces to vomitus or fecal matter.
- Require the protection of prewashed fruits and vegetables from cross contamination by separating them from raw animal foods during storage, preparation holding and display.
- Increase the minimum required cooking time from 15 to 17 seconds (at 155°F) for certain raw animal foods.<sup>4</sup>
- Reduce the minimum required cooking time from 15 seconds to less than one second (165°F or above) for certain raw animal foods.<sup>5</sup>
- Include timelines for required reporting of nitrate and E. coli positive lab results to the Virginia Department of Health (VDH).
- Require that food establishments notify customers that a copy of the most recent establishment inspection report is available upon request by either: a) posting a sign or placard in a location in the food establishment that is conspicuous to customers, or b) by another method acceptable to the department.

When inspectors find violations of any of the regulation's requirements, the food establishment must correct the deficiencies within specified time periods. All requirements are delineated as priority, priority foundation, or core. Priority items must be remedied within 72 hours, priority foundation items within 10 calendar days, and core items within 90 days. In order to conform to the 2017 FDA Food Code, the Board proposes to change times in which violations of requirements must be corrected as follows:

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<sup>4</sup> See 12VAC5-421-700.A.2 for affected raw animal foods.  
<https://townhall.virginia.gov/l/viewXML.cfm?textid=14169&replace=yes>

<sup>5</sup> See 12VAC5-421-700.A.3 for affected raw animal foods.  
<https://townhall.virginia.gov/l/viewXML.cfm?textid=14169&replace=yes>

Core to Priority (90 calendar days to 72 hours):

- When a food employee is excluded from the food establishment as required due to being diagnosed with an infection from Salmonella (nontyphoidal), the exclusion for the food employee who is symptomatic should be retained until either of the following are met: a) the excluded food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of a Salmonella (nontyphoidal) infection based on test results showing two consecutive negative stool specimen cultures that are taken, or b) the food employee was restricted after symptoms of vomiting or diarrhea are resolved, and more than 30 days have passed since the food employee became asymptomatic.
- In a food establishment that serves a highly susceptible population,<sup>6</sup> unpackaged juice that is prepared on the premises for service or sale in a ready-to-eat form must be processed under a Hazard Analysis and Critical Control Point (HACCP) plan<sup>7</sup> and as specified in 21 CFR 120.24.

Priority Foundation to Priority (10 calendar days to 72 hours):

- Food must be safe, unadulterated, and honestly presented.<sup>8</sup>
- Whole-muscle, intact beef steaks that are intended for consumption in an undercooked form without a consumer advisory must, if individually cut in a food establishment, be cut from whole-muscle intact beef that is labeled by a food processing plant.

Core to Priority Foundation (90 calendar days to 10 calendar days):

- In manual warewashing<sup>9</sup> operations, a temperature measuring device must be provided and readily accessible for frequently measuring the washing and sanitizing temperatures.

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<sup>6</sup> "Highly susceptible population" is defined as "persons who are more likely than other people in the general population to experience foodborne disease because they are: 1. immunocompromised, preschool age children, or older adults; and 2. obtaining food at a facility that provides services such as custodial care, health care, or assisted living, such as a child or adult day care center, kidney dialysis center, hospital or nursing home, or nutritional or socialization services such as a senior center."

<sup>7</sup> "Hazard Analysis and Critical Control Point plan" is defined as "a written document that delineates the formal procedures for following the Hazard Analysis and Critical Control Point principles developed by The National Advisory Committee on Microbiological Criteria for Foods."

<sup>8</sup> Pursuant to 12VAC5-421-890, honestly presented is: a) food shall be offered for human consumption in a way that does not mislead or misinform the consumer, and b) food or color additives, colored overwraps, or lights shall not be used to misrepresent the true appearance, color, or quality of a food.

<sup>9</sup> "Warewashing" is defined as "the cleaning and sanitizing of utensils and food-contact surfaces of equipment."

- In hot water mechanical warewashing operations, an irreversible registering temperature indicator must be provided and readily accessible for measuring the utensil surface temperature.
- Water from a private well must be sampled and tested at least annually for nitrate and total coliform.
- For a food establishment that is required to have a HACCP plan, the HACCP plan must include general information such as the name of the permit applicant or permit holder, the food establishment address, and contact information.

Priority to Priority Foundation (72 hours to 10 calendar days):

- If time without temperature control is used as the public health control up to a maximum of four hours, the food must be marked or otherwise identified to indicate the time that is four hours past the point in time when the food is removed from temperature control;
- If time without temperature control is used as the public health control up to a maximum of six hours, the food shall be monitored to ensure the warmest portion of the food does not exceed 70°F (21°C) during the six-hour period, unless an ambient air temperature is maintained that ensures the food does not exceed 70°F (21°C) during the six-hour holding period.

### **Other Proposed Changes**

The following proposed amendments to the regulation are not related to the 2017 FDA Food Code:

- Specify that shucked shellfish from one tagged or labeled container are not commingled with shellstock<sup>10</sup> or shucked shellfish from another container with different certification numbers, different harvest dates, or different growing areas as identified on the tag or label before being ordered by the consumer.
- Specify that records demonstrating inspection and service of water treatment devices and backflow preventers be maintained by the person in charge for a minimum of five years.

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<sup>10</sup> “Shellstock” is defined as “raw, in-shell molluscan shellfish.”

- Require that any food establishment permit applicant who fails to complete the application process within 12 months of receipt of the application by the local health department's office may be required to submit a new application and plan.
- Require that existing food establishments notify VDH in writing of a change of legal ownership or when business operations have terminated. Such notice must be submitted, in writing, to VDH at least 30 days prior to the legal ownership transfer or termination of business operation.
- Eliminate the option for Bed & Breakfast operations to have a food establishment permit.

## **Estimated Benefits and Costs**

### **Conforming to 2017 FDA Food Code**

The current regulation requires food establishments to employ a CFPM; however, they are not required to be onsite at all times of operation. The proposed regulation expands this, and requires that a CFPM be onsite at all times of operation. More specifically, the person in charge of the open food establishment would have to be a CFPM. The regulation defines “person in charge” as “the individual present at a food establishment who is responsible for the operation at the time of inspection.” Since most food establishments do not have one person who works 100 percent of open hours, most would need to get one or more additional employees certified.

Under both the existing and proposed regulations, proficiency as a certified food protection manager is established through passing a test, not completing a program. According to VDH, certification costs (for the test) range from \$28 to \$100 per individual and requires renewal every five years. Tests are available via six accredited programs and take approximately two hours. Those persons who elect to take training (not required) may sign up for a training course via an accredited provider where the training time varies from self-pace to approximately sixteen hours. Training and tests are available both online and in person.<sup>11</sup> The total cost of requiring that a CFPM be onsite at all times of operation would be: a) the test fees for each additional needed CFPM, b) fees for training if needed to pass the test, and c) the value of the staff time spent preparing for and taking the test. If say a CFPM candidate spends eight hours preparing for the test and two hours taking the test, there is the cost of ten hours of staff time that has to be covered by another employee. Having a CFPM always present in the open

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<sup>11</sup> Data and other information source: VDH

operation who is knowledgeable on food protection as guaranteed through certification, would likely reduce the probability of unsafe food practices occurring.

The current regulation only requires the use of a single-use glove when “a lesion containing pus such as a boil or infected wound that is open or draining and is on the hands or wrists ...” The proposed regulation requires that “If used, an impermeable cover such as a bandage, finger cot, or finger stall located on the wrist, hand or finger of the food employee working with exposed food shall be covered with a single-use glove.” This would include band aids for simple uninfected cuts. Thus, single use gloves would need to be purchased and used more often under the proposed regulation. Single-use gloves are available for about five cents a glove when purchasing in bulk (100 gloves).<sup>12</sup>

The current regulation requires that food establishments have procedures for employees to follow when responding to vomiting or diarrheal events that involve the discharge of vomitus or fecal matter onto surfaces in the food establishment. The procedures must address the specific actions employees must take to minimize the spread of contamination and the exposure of employees, consumers, food, and surfaces to vomitus or fecal matter. The Board proposes to specify that those procedures are written. This would help ensure that those procedures are consistent, regardless of whoever is in charge at a given time. VDH has a template that it can make available to food establishments to use for their written procedures. Thus, it should not be costly for the businesses to produce written procedures that satisfy the department.

The FDA believes that: a) requiring the protection of prewashed fruits and vegetables from cross contamination by separating them from raw animal foods during storage, preparation holding and display and b) increasing the minimum required cooking time from 15 to 17 seconds (at 155 °F) for certain raw animal foods,<sup>13</sup> would increase food safety. For any food establishments that do not already separate prewashed fruits and vegetables from raw animal foods during storage, preparation holding and display, there may be some cost in finding additional space to keep these items separated. For establishments that already keep such separation, neither of these two proposals appear to be particularly costly.

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<sup>12</sup> Source: Amazon.com accessed on March 13, 2020.

<sup>13</sup> See 12VAC5-421-700.A.2 for affected raw animal foods.

<https://townhall.virginia.gov/l/viewXML.cfm?textid=14169&replace=yes>

For other raw animal foods,<sup>14</sup> which must be cooked at 165°F or above, the FDA believes that it is safe to reduce the minimum required cooking time from 15 seconds to less than one second (instantaneous). The Board's proposal to make this amendment would cumulatively moderately reduce the time necessary to prepare such food without apparently increasing health risks.

The current regulation requires that water from a private well be sampled and tested at least annually for nitrate and total coliform. If nitrate exceeds 10 milligrams per liter, the owner must notify VDH. If a sample is total coliform positive, the positive culture medium must be further analyzed to determine if *E. coli* is present. The owner must notify VDH within two days from when the owner is notified of the coliform positive test result. If *E. coli* is present, the owner must notify VDH. The current regulation does not specify deadlines for notification for positive results of either nitrate exceeding 10 mg/L or the presence of *E. coli*. The Board proposes to specify that notification must be within 24 hours. This would be beneficial in that it would enable VDH to take faster action regarding a potential health threat.

The Board proposes to require that food establishments notify customers that a copy of the most recent establishment inspection report is available upon request by either: a) posting a sign or placard in a location in the food establishment that is conspicuous to customers, or b) by another method acceptable to department. According to VDH, the food establishment would not need to have the report on hand. The customers could be referred to VDH's online portal that publicly displays the reports, as well as the local health department. Thus, there would only be the minimal cost of posting the sign or placard.

### **Other Proposed Changes**

The current regulation specifies that shellstock from one tagged or labeled container are not to be commingled with shellstock from another container with different certification numbers, different harvest dates, or different growing areas as identified on the tag or label before being ordered by the consumer. "Shellstock" is defined as "raw, in-shell molluscan shellfish," and thus does not include shucked shellfish. The Board proposes to mandate that shucked shellfish from one tagged or labeled container are not commingled with shellstock or

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<sup>14</sup> See 12VAC5-421-700.A.3 for affected raw animal foods.  
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shucked shellfish from another container with different certification numbers, different harvest dates, or different growing areas as identified on the tag or label before being ordered by the consumer. To the extent that this is not already done by food establishments with shucked shellfish, this proposal would be beneficial in that it would likely reduce the probability that spoiled shellfish is mistakenly served to patrons.

The current regulation states that records demonstrating inspection and service of water treatment devices and backflow preventers be maintained by the person in charge. The Board proposes to specify that the records be maintained for a minimum of five years. Since the current language implies that the records must be kept indefinitely, the proposal for a five-year minimum reduces the burden in that the records could be disposed of after five years.

The Board proposes to state that any food establishment permit applicant who fails to complete the application process within 12 months of receipt of the application by the local health department's office may be required to submit a new application and plan. This is valuable for the department in that relevant information that was already submitted might have changed such that the application would no longer be appropriate for approval. The applicant would have to pay an additional \$40 application fee, and if a new plan review is deemed necessary, an additional \$40 plan review fee. The applicant would also incur the time needed to produce the new application and plan.

The current regulation does not specify that existing food establishments notify VDH in writing of a change of legal ownership or when business operations have terminated. The Board proposes to specify that such notice be submitted, in writing, to VDH at least 30 days prior to the legal ownership transfer or termination of business operation. To the extent that it is followed, this proposal would help the department maintain contact with those actually serving food to the public and help ensure food safety.

Bed & Breakfasts are not required to have a food establishment permit. Under the current regulation these businesses may optionally apply for such a permit, which does not provide them with any privileges that they would not possess without the permit. It is likely that the permit is used for marketing purposes.<sup>15</sup> The Board proposes to eliminate the option for Bed & Breakfasts

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<sup>15</sup> VDH does not have data on the number of Bed & Breakfasts with permits.



to have a food establishment permit. This would not prevent any Bed & Breakfast from operating, but to the extent that the permit helped garner demand for some, it may reduce revenue. According to VDH, allowing voluntary permitting has created issues for its staff when these facilities are found in violation and then elect to “deregulate” to avoid corrections.

### **Businesses and Other Entities Affected**

The proposed amendments affect the approximate 38,000 food establishments in the Commonwealth, the six accredited CFPM programs, and Bed & Breakfast<sup>16</sup>s that have or might wish to have a food establishment permit. As described in the Estimated Benefits and Costs section, the proposal to require that there be a CFPM on the premises of the food establishment at all times of operation would increase costs for most food establishments. The proposal to mandate that single-use gloves be worn whenever there is an impermeable cover such as a bandage, finger cot, or finger stall located on the wrist, hand or finger of the food employee would also increase costs for most food establishments. The proposal to state that any food establishment permit applicant who fails to complete the application process within 12 months of receipt of the application by the local health department's office may be required to submit a new application and plan would increase cost for applicants in such a situation. The proposal to eliminate the option for Bed & Breakfasts to have a food establishment permit may reduce revenue for those Bed & Breakfasts that have had a permit.

Adverse impact is indicated if there is any increase in net cost or reduction in net revenue for any entity, even if the benefits exceed the costs for all entities combined. While the benefits to public health may be large, there would likely be some increases in net costs for some of the affected entities as described in the Estimated Benefits and Costs section.

### **Small Businesses<sup>17</sup> Affected:**

#### Types and Estimated Number of Small Businesses Affected

VDH estimates that 95% to 100% of the approximate 38,000 food establishments in the Commonwealth are small businesses. The sizes of the six accredited CFPM programs are unknown.

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<sup>16</sup> Ibid

<sup>17</sup> 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.”

### Costs and Other Effects

Costs for small food establishments are affected by the proposed amendments as described in the Estimated Benefits and Costs section. The proposal to require that there be a CFPM on the premises of the food establishment at all times of operation would very likely increase revenue for at least some of the six accredited CFPM programs

### Alternative Method that Minimizes Adverse Impact

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

### **Localities<sup>18</sup> Affected<sup>19</sup>**

The proposed amendments affect food establishments in all localities, not disproportionately affecting any particularly. The proposed amendments do not appear to introduce additional costs for local governments.

### **Projected Impact on Employment**

The proposal to require that there be a CFPM on the premises of the food establishment at all times of operation would very likely increase demand for the services of the six accredited CFPM programs, which may moderately increase their employment.

### **Effects on the Use and Value of Private Property**

The proposals to require that there be a CFPM on the premises of the food establishment at all times of operation and that single-use gloves be worn whenever there is an impermeable cover on the wrist, hand or finger of the food employee would increase costs for most food establishments. The proposal to state that any food establishment permit applicant who fails to complete the application process within 12 months of receipt of the application by the local health department's office may be required to submit a new application and plan would increase cost for applicants in such a situation. The proposal to eliminate the option for Bed & Breakfasts to have a food establishment permit may reduce revenue for those Bed & Breakfasts that have had a permit. These cost increases and potential revenue reduction would likely moderately reduce the value of affected firms commensurately.

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<sup>18</sup> "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.

<sup>19</sup> § 2.2-4007.04 defines "particularly affected" as bearing disproportionate material impact.

The proposal to specify that records demonstrating inspection and service of water treatment devices and backflow preventers must only be maintained for five years would moderately reduce recordkeeping costs, producing a potential small commensurate increase in firm value. The proposal to require that there be a CFPM on the premises of the food establishment at all times of operation would very likely increase demand for the services of the six accredited CFPM programs, which may moderately increase their value.

The proposed amendments do not appear to affect real estate development costs.

## Legal Mandates

**General:** The Department of Planning and Budget 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 14 (as amended, July 16, 2018). Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the report 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.

**Adverse impacts:** 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 within the 45-day period.

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.