Sample Fiscal Note

Also known as an economic impact statement

This document was drafted by the Food Protection & Facilities Branch of the Environmental Health Section of the Department of Health and Human Services in North Carolina Commission for Public Health to support the adoption of the 2017 Food Code. **This is a sample document; exact requirements for fiscal notes and economic impact statements may vary by jurisdiction.**

Fiscal Note for Permanent Amendment of 15A NCAC 18A .2650-.2676

Agency:	North Carolina Commission for Public Health Department of Health and Human Services Environmental Health Section Food Protection & Facilities Branch
Rule Citations:	15A NCAC 18A .2650 General-Adoption by Reference (readoption) 15A NCAC 18A .2651 Definitions (amendment) 15A NCAC 18A .2652 Management and Personnel (amendment) 15A NCAC 18A .2653 Food (amendment) 15A NCAC 18A .2654 Equipment, Utensils, and Linens (amendment) 15A NCAC 18A .2655 Water, Plumbing, and Waste (amendment) 15A NCAC 18A .2661 Inspections and Re-inspections (amendment) 15A NCAC 18A .2670 General Requirements for Pushcarts and Mobile Food Units (readoption) 15A NCAC 18A .2674 Limited Food Establishments (readoption)
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Rulemaking Authority:	S.L. 2019-129 G.S. 130A-248
Impact Summary:	State Government: Yes Local Government: Yes Private Sector: Yes Substantial Impact: Yes

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Introduction and Purpose

The Food Protection and Facilities Branch (FPFB), a branch of the Environmental Health Section within the North Carolina Division of Public Health, oversees the rules and regulations governing the protection of food and enforcement of sanitation requirements within food establishments, including restaurants, food stands, mobile food units and pushcarts, meat markets, school cafeterias, and food service facilities in hospitals, nursing homes, and child care centers. Currently, food service establishments in North Carolina are regulated under Section .2600 of 15A NCAC 18A titled "Rules Governing the Food Protection and Sanitation of Food Establishments" and the 2009 United States Food and Drug Administration (FDA) Food Code, which was adopted by North Carolina through incorporation by reference in Rule 15A NCAC 18A .2650 in 2012.

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The FDA Food Code is the national standard for state, local, and tribal food protection programs and has been adopted by 49 out of 50 states. It offers practical, science-based guidance that addresses the FDA risk factors known to cause foodborne illness outbreaks in retail food service settings. In addition, the FDA Food Code is uniquely qualified to address the food safety challenges of the twenty-first century, including an increasingly globalized food supply chain, the aging population, increased number of immune-compromised consumers, and the growing trend of consuming food prepared outside the home.

The FDA Food Code is updated and published every four years and amended every two years via the Conference for Food Protection, a national conference of food safety regulators, food scientists, industry representatives, and members of academia. In 2011, the North Carolina General Assembly determined that North Carolina should adopt the 2009 FDA Food Code, which led to the passage of S.L. 2011-394. In accordance with the language of S.L. 2011-394, the Section .2600 rules were amended to adopt the 2009 FDA Food Code by reference; however, pursuant to the session law, subsequent amendments or editions of the 2009 Food Code issued by the FDA could not be adopted by North Carolina and incorporated into the Administrative Code without prior legislative approval. Since 2011, the FDA has released new editions of the FDA Food Code, one in 2013 and one in 2017. Both editions had supplements added by the Conference for Food Protection. The most current edition is the 2017 FDA Food Code, with supplements added in 2019.

In 2019, the North Carolina General Assembly once again recognized the need to adopt the most current edition of the FDA Food Code and passed S.L. 2019-129. As a result, and in accordance with session law, the FPFB proposes to adopt and implement the most current version of the 2017 FDA Food Code to provide the food service industry, regulators, academia, consumer groups, and other stakeholders with the most current food safety standards available. Stakeholders will have access to new technologies and processes in food preparation, along with the most updated policies and procedures relating to food protection and employee health. Based on this, the adoption of the 2017 FDA Food Code will further the mission of protecting the public's health in North Carolina.

In addition to adopting the most recent edition of the FDA Food Code, three of the rules discussed in this fiscal note- .2650, .2670, and .2674- are proposed for readoption in accordance with G.S. 150B-21.3A.

Description of Proposed Rules:

As referenced earlier, the regulation of food service establishments in North Carolina is governed under 15A NCAC 18A .2600 rules, which incorporates by reference the 2009 Food Code. S.L. 2019-129 gives authority to the Commission of Public Health to update the .2600 rules to the most current edition of the FDA Food Code, which is the 2017 Food Code and Supplement. A workgroup comprised of State and local regulators as well as industry partnered to review and propose updates to the .2600 rules with the new language from the 2017 Food Code and Supplement. In some places in the current rules as well as the proposed updated rules covered in this fiscal note, the rule requirements vary from the Food Code to ensure alignment with North Carolina state law and practice.

For that reason, the 2017 Food Code and its Supplement are not simply incorporated by reference; instead, the rules described in this fiscal note are also being amended as necessary to ensure that the rules, in adopting of the 2017 Food Code and its Supplement, establish a comprehensive regulatory framework that is consistent with other areas of State law. The following narrative describes the proposed changes as well as adoption of the 2017 Food Code into the existing rules. The proposed rule language can also be found in Appendix 1 to this fiscal note.

15A NCAC 18A .2650 will be changed from incorporating the 2009 Food Code by reference to

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incorporating the 2017 Food Code and Supplement by reference, which is the basis of 15A NCAC 18A .2651-.2655 in this Section. Changes to 15A NCAC 18A .2661, .2670, and .2674 do not correspond to Chapters in the Food Code and will be updated to reflect needed changes to the administrative code.

15A NCAC 18A .2651," **Definitions,**" which reflects Chapter 1 in the Food Code, includes any changes in definitions in the 2017 Food Code as well as further amendments, additions, and deletions to those definitions as made by the FPFB.

Changes Not Resulting in an Economic Impact
In the definition in congregate nutrition sites in 1-201.10 (B), potentially hazardous food is changed to time/temperature control for safety food for consistency with language used throughout the Food Code. Also, in 1-102.10 under subsection (b), a definition of equipment has been amended to remove inclusion of the term "vending machine" because the FPFB and the Commission for Public Health do not have statutory authority to regulate vending machines.

The definition of Food Stand in 1-1201.10 (B) will be amended to reflect recent changes in N.C.G.S. 130A-248(a6), which now allows for limited seating at food stands. Imminent health hazard has been added back into the definition in 1-102.10 (B) to align with the language at N.C.G.S. 130A-2(3). A new definition for "intact meat" has been added in the 2017 Supplement which will be incorporated into the definition section and which was not present in the 2009 NC Food Code. Under the definition for "Limited Food Establishment" the word "Services" has been added to make .2674 be consistent with General Statute language. A new definition has been added for "Mechanically tenderized meat" from the 2017 Supplement.

The definition of "Mobile Food Unit" has been amended to include clarifying language to be consistent with guidance from the Attorney General's Office, which explains that mobile food units must not connect to permanent utilities nor provide seats. A definition has been updated for "shiga-toxin-producing Escherichia coli" to reflect current language in the 2017 Food Code in 1-102.10 (B). "Temporary Food Establishment (TFE)" and "Temporary Food Establishment Commissary" have been revised to reflect changes made pursuant to a legislative amendment of NC G.S. 130A-247. Farmer's markets will be removed from a list of ineligible businesses for TFE permits due to this statutory change,

The majority of the amendments to this Rule are technical in nature and align with existing North Carolina law and the 2017 Food Code. Therefore, no economic impact is expected as a result of these changes in the definitions and therefore is not explained further in the Impact Analysis section below.

15A NCAC 18A .2652, which reflects Chapter 2 in the Food Code, will include changes that amend the 2017 Food Code.

Changes Not Resulting in an Economic Impact
Beginning with 2-101.11 (A) of the Food Code, the reference to paragraph (C) of 2-101.11 will be removed from the rule language, as these rules do not regulate vending machines.

Additionally, the rule will add the word "or" to 2-102.11 of the Food Code to clarify that there are three separate options for industry to comply with demonstration of knowledge. This change was requested by industry in North Carolina to bring further clarity to this part of the Food Code. The references in the rule to paragraphs (A) and (C), which relate to 2-102.12 of the Food Code, have been deleted from the rule language because the topics addressed by the rule in those references to paragraphs (A) and (C) are now addressed in the Food Code.

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In 2-102.20 of the Food Code, a previous deletion of 2-102.11 (B) of the Food Code will be rescinded and section 2-102.11 (B) will now be included in the rule language as written in the 2017 Food Code. Duties have also been added to the Person in Charge requirements under 2-103.11 of the Food Code, which include monitoring after hours deliveries, employee monitoring of hot and cold temperatures, and maintenance of written documentation that is required by the 2017 Food Code.

The aforementioned changes are not expected to result in an economic impact and are therefore not discussed further in the Impact Analysis section below.

Changes Expected to Result in an Economic Impact

There are a few changes to this Rule that are expected to result in an economic impact. In the 2017 Food Code, 2-201.11, 2-201.12, and 2-201.13 add nontyphoidal *Salmonella* (NTS) as one of the reportable illnesses for action by the Person in Charge. Added 2017 Food Code language addresses employee health controls for the exclusion and restriction of nontyphoidal *Salmonella*. The 2017 Food Code also includes updated language in 2-301.14 (H) to clarify that the requirement to wash hands before donning gloves is specific to the beginning of a task involving working with food and not during the task.

Section 2-301.16 (A) (2) of the 2017 Food Code adds language to clarify which types of hand antiseptic are acceptable. Previous requirements for bandages, finger cots, or finger stalls that were listed under 2-201.13 will now be added by the addition of section 2-401.13. Section 2-501.11 will be added to require procedures for responding to contamination events involving vomit and/or diarrhea. This cohort of new requirements will be explained further below in the Impact Analysis section.

15A NCAC 18A .2653, which reflects Chapter 3 in the Food Code, will include changes that amend the 2017 Food Code.

Changes Not Resulting in an Economic Impact

The proposed rule language includes a new reference that will be added to 3-201.11 (A) of the Food Code that will clarify the permitting requirements set forth G.S. 130A-248(b). Changes to 3-201.16 of the Food Code were made to recognize a regulatory authority's ability to approve the sale of wild mushrooms within a food establishment in accordance with existing reporting policies. A change to 3-301.11 (D) of the Food Code will reduce the final cook temperature requirement from 165°F to 145°F when a ready-to-eat food has been touched with bare hands is added as an ingredient to another food that does not contain a raw animal food. In 3-302.11, additional language will be added to clarify that raw animal foods should be stored below or separate from washed or unwashed raw fruits and vegetables.

Provisions under 3-304.11 and 3-304.14 will be expanded to allow linens to be utilized as a food contact surface in 2017 Food Code. Under 3-304.17, language has been added to expand the use of returnable containers by the consumer to establishments that may now include refilling with time/temperature control for safety foods. These provisions may result in minor cost savings to industry; however, because we do not know the financial difference for establishments in using linens as a contact surface or refilling returnable containers with time/temperature control for safety foods, and because we cannot predict how many establishments will shift their practices in response to these provisions, the potential cost savings are challenging to quantify.

3-401.11 will now be revised to include the term “intact meat” which is defined in Chapter 1 and will also reflect new cooking time and temperature parameters for various raw animal products. Plant Foods will now replace “fruits and vegetables” in 3-401.13. Time/temperature changes will be updated in 3-401.11 as referenced in 3-401.14 to clarify specifications for “non-continuous cooking.”

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Text was italicized in 3-402.11 (B) (5) to indicate an exception to the code regarding parasite destruction. Paragraph 3-402.12 (C) will be amended to correctly cross reference methods of fish aquaculture found in 3-402.11 (B) (4). Hazard Analysis Critical Control Points (HACCP) plans for treating juice under 3-404.11 will now be required to include general information such as name of the permit holder, establishment address and contact information as well as any other information required by the regulatory authority. Under 3-501.13, the assigned risk designation will change from a core item to a priority foundation item which will require immediate correction or correction within 10 days. The ramifications of this re-designation will be explained further in the Impact Analysis.

Additional exclusions from date marking, which now includes shellfish, will be added to extend the shelf life of some foods under 3-501.17. An amendment will also be made to clarify that the exemption for date marking for shelf stable dried fermented sausages produced in United States Department of Agriculture regulated facilities is not dependent on the product retaining the original casing. This change could lead to a possible cost savings for industry, but due to limited data available on the offering of these menu items at establishments across the state, the exact cost savings are challenging to estimate. Wording in 3-501.18 has been amended to appropriately indicate foods that must be disposed of in accordance with date marking requirements. A missing cross reference will be added to 3-501.19 (A) (1) (a) which will now include subparagraphs 3-501.19 (B) (4). New subparagraphs will be added under 3-501.19 (B) (2) to address ready-to-eat produce or hermetically sealed food that is rendered time/temperature control for safety (TCS) upon cutting, chopping or opening.

Paragraph 3-502.12 (B) and subparagraphs (B) (6) (C), (D) (1), and (E) (2) were amended to replace cross reference to paragraphs 8-201.14 (B) and (D) with a cross reference to paragraphs 8-201.14 (C) and (D) due to rearranging of paragraphs in Chapter 8. Requirements for HACCP plans for unpackaged juice in a highly susceptible population in 3-801.11 (A) (3) will be amended from 8-201.14 (B)-(E) to 8-201.14 (C)-(E). This change reduces the amount of information required for a HACCP plan for unpackaged juice in a highly susceptible population setting.

The aforementioned changes are not expected to result in an economic impact and are therefore not discussed further in the Impact Analysis section below.

Changes Expected to Result in an Economic Impact

A labeling requirement will be added to 3-502.12 (C) to indicate that fish in reduced oxygen packaging (ROP) is to be kept frozen until time of use. In paragraph 3-502.12 (D) (2) (e) (ii) food in ROP for sous vide will have a refrigerated storage time extended to seven days. This extension will be a cost savings to industry and will be further explained in the Impact Analysis. Clarifying language will be put in place where labeling is required in 3-602.11 (B) (2) by including sub-ingredients for all foods made from multiple ingredients. This change will be explained further in the Impact Analysis.

15A NCAC 18A .2654, which reflects Chapter 4 of the Food Code, will include changes that amend the 2017 Food Code.

Changes Not Resulting in an Economic Impact

A new subpart 4-303 and section 4-303.11 are added in the 2017 Food Code to clarify the requirement that equipment and utensil cleaning agents and sanitizers be provided and readily accessible for use. No anticipated economic impact is expected and is therefore not discussed further in the Impact Analysis section below. An additional paragraph (F) will be added to 4-501.114 to provide requirements for establishments that produce their own sanitizer through an onsite device. No impact is expected with this new option as well.

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Additional language will be added to section 4-502.12 through this rule to reflect a change due to S.L. 2019-141, which allows the reuse of oyster shells. An amendment in 4-602.11(B) changes the cleaning and sanitizing frequency for food contact surfaces or utensils that are in contact with a raw animal food that is a major food allergen such as fish, followed by other types of raw animal foods. With this change, the exception to existing subparagraph (A)(1) found in paragraph (B) now applies only to raw meat and poultry. This will not result in an economic impact for industry. 4-603.17 is deleted and its requirements relocated to 3-304.17. An amendment in 4-802.11(C) was made to clarify that napkins in this section refers to cloth napkins and they are, by definition, considered linens as mentioned in 3-304.11(C) and 3-304.13. These changes are not expected to result in an economic impact and are therefore not discussed further in the Impact Analysis section below.

Changes Expected to Result in an Economic Impact
Section 4-302.13 of the Food Code now requires the availability of irreversible registering temperature indicators. This change will be discussed further in the Impact Analysis.

15A NCAC 18A .2655, which reflects Chapter 5 in the Food Code, will include changes that amend the 2017 Food Code.

Changes Expected to Result in an Economic Impact
The risk designation of 5-202.12(A) will be changed from priority foundation to core to be consistent with current science. This savings will be discussed further in the Impact Analysis.

15A NCAC 18A .2661 describes the grading of food service establishments, the inspection form, and how points are assessed for violation of the rules.

Changes Not Resulting in an Economic Impact
The rule will be updated to reflect changes stemming from adoption of the 2017 Food Code. These changes to the grading and point value assessments are not expected to result in an economic impact. Additionally, this rule includes a change to Chapter 8 of the Food Code. Specifically, Paragraph (K) in 8-304.11 is a new requirement of the 2017 Food Code. This requirement did not appear in the 2009 Food Code and is being deleted from applying under the updated rules, following discussions with industry. Members of the public can still readily access copies of inspection reports, which are public records, through the county or state.

15A NCAC 18A .2670 describes general requirements for mobile food units and push carts.

Changes Not Resulting in an Economic Impact
Paragraphs (e) through (l) have been struck from this rule. The requirements established in these paragraphs are now included in the 2017 Food Code and we have struck them from this rule to avoid duplicative language. These changes to the text of rule .2670 are not expected to result in an economic impact.

15A NCAC 18A .2674 describes requirements for Limited Food Services Establishments.

Changes Not Resulting in an Economic Impact
Paragraph (1) will be amended to change the expiration of permits from December 31 of each year to one year from the date of issuance. This change is necessary to coincide with other comparable permit renewals within the Section. Based on stakeholder request, paragraphs (5) and (6) will be amended to show an exception for Limited Food Service Establishments located in lodging facilities. The changes are not expected to result in an economic impact and are therefore not discussed further in the Impact Analysis section below.

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Impact Analysis:

State Government Impact

The impact on state government expected from the adoption of these rule amendments/readoptions and implementation of the 2017 FDA Food Code consists largely of training costs.. The FPFB offers training to local health department registered environmental health specialists (REHS) as part of its agency mission. State regional staff will develop training for the updated rules and provide updates to county REHS. The average salary for the program staff involved in this work is $56,452.[1] Using this figure, as well as an estimate of the value of fringe benefits, we have calculated the hourly rate of a State REHS staff member at $37.50. The time spent by State-level REHS staff will be an opportunity cost, as we do not intend to hire any additional staff to help do this work.

Table 1: Average Hourly Pay Rate for State REHS

Salary and Fringe Benefits[2]		
Salary/Benefit	% of Salary	Total Value
Salary	100	$56,452
FICA	7.65	$4,318.58
Retirement, Death, and Disability Benefit	19.70	$11,121.04
Health Insurance	10.81	$6,104
Hourly Rate Calculation		
Total Salary + Fringe	Hours Worked / Year	Hourly REHS Rate
$77,995.62	2080	$37.50

State-level REHS staff will be responsible for developing training for the new rules and hosting virtual and/or in-person meetings to provide that training to county REHS staff and industry partners. State-level REHS staff can present these materials at regional or district education meetings. State-level REHS staff already host these meetings to provide updates and training to each of the territories, so travel to these meetings does not represent a new expense for state government. Based on our familiarity with the subject matter and past experiences, state-level REHS staff members will spend approximately 20 hours total (a one-time effort) developing training materials for the newly adopted rules and code. Additionally, we anticipate that each local REHS will require five hours of training to become proficient in administration of the new rules and code.

The State will not take in any new fees as part of the newly adopted rules or Food Code.

Table 2: Impact on State Government (Opportunity Costs)

[1] This value was provided by the Division of Public Health, Environmental Health Section and was calculated using information available as of April 2, 2020.

[2] The benefits listed were identified using the North Carolina Office of State Human Resources "Total Compensation Calculator," which is available at https://oshr.nc.gov/state-employee-resources/classification-compensation/total-compensation-calculator.

REHS Staff Training Development (one time)		
Number of Hours to Complete	REHS Hourly Rate	Cost to State Government
20	$37.50	$750.00
REHS Staff Instructional Time		
Number of Hours to Complete	REHS Hourly Rate	Cost to State Government
20 hr. (5 hrs. x 4 meetings x 4 staff members)	$37.50	$3,000.00

TOTAL STATE GOVERNMENT IMPACT……$3,750.00

Local Government Impact

Local and district health departments will be responsible for ensuring that their staff receive training on the amended rules and the 2017 Food Code following its adoption.

The average salary for an REHS employed by a local or district health department in North Carolina is $48,057.[3] Using this figure, as well as an estimate of the value of fringe benefits, we have calculated the hourly rate of an REHS at $31.81. Although we cannot know for certain, we expect that the time spent by REHS staff will likely be an opportunity cost, as we do not expect that local and district health departments will hire additional staff to help do this work.

Table 3: Average Hourly Pay Rate for Local REHS

Salary and Fringe Benefits[4]		
Salary/Benefit	% of Salary	Total Value
Salary	100	$48,057.00
All Benefits	37.7	$18,117.49
Hourly Rate Calculation		
Total Salary + Fringe	Hours Worked / Year	Hourly REHS Rate
$66,174.49	2080	$31.81

Based on our experience working with local and district health departments, we believe that a single REHS will need five hours of training to implement the new rules and the 2017 Food Code and Supplement. Trainings will be provided by state-level staff at the Division of Public Health and will be held virtually.

[3] The average REHS salary was estimated from the UNC School of Government's 2019 County Salary Survey, which is available at: https://www.sog.unc.edu/publications/reports/county-salaries-north-carolina-2019.

[4] The value of benefits was identified using the U.S. Bureau of Labor Statistics' latest available figures from December 2019 on employer costs for employee compensation for state and local government workers, which is available at: https://www.bls.gov/news.release/ecec.t03.htm.

Local REHS staff will receive continuing education credits toward their yearly requirement for credentialing. The North Carolina Board of Registered Environmental Health Specialists requires local health department environmental health staff members to maintain a minimum number of continuing education training hours per year to maintain their registration as Environmental Health Specialists. The training is expected to be approved training per the Board and will count toward local REHS staffs' educational requirements. Mileage is not included as a cost because travel is expected to be unnecessary since the trainings will be held virtually. Similarly, costs for printed materials are not included because the new rules and the Food Code will be made available online at no cost. There are approximately 800 REHS staff employed at 85 local and district health departments across North Carolina who would each need to receive these five hours of training.

Additionally, after the 2017 Food Code is adopted, local REHS staff will incorporate a brief training on the new Food Code into their inspections of establishments. These inspections are already required and regularly scheduled. This additional time for training that will be tacked onto normal regulatory visits is estimated to add 30 minutes of time to the visit. The total number of permitted food establishments in 2019 was 39,914.

As demonstrated by our calculations in Table 4 below, the total cost for this one-time training to county staff and the half-hour training that will be provided to each establishment will amount to a total cost of $762,272.00 to local government. We expect that these costs will be opportunity costs, as participating in training and providing training to the industry is a regular part of REHS staff responsibilities and it is unlikely that local and district health departments will hire additional staff to do this work. It is challenging to know how this total cost to local government will translate to costs for each of the 85 local and district health departments, which employ different numbers of REHS staff and have different numbers of establishments under their jurisdiction to which they will need to provide training.

Table 4: Impact on Local Government (Opportunity Costs)

Training for Local REHS			
Number of Hours to Complete Training	REHS Hourly Rate	Number of REHS to Receive Training	Cost to Local Government
5	$31.81	800	$127,240.00
Time Spent on Training for One (1) Establishment	REHS Hourly Rate	Number of Permitted Establishments in North Carolina	Cost to Local Government
0.5	$31.81	39,914	$635,032.00
TOTAL LOCAL GOVERNMENT IMPACT …… $762,272.00			

Private Sector Impact

The first year of Food Code implementation will be a "transition period" in which local REHS staff will provide an in-service training to industry managers/supervisors during each establishment's initial routine inspection. During the inspection, local REHS staff will review the changes in compliance expectations and the inspection process based on the adoption of the 2017 Food Code and its supplement. The FPPB estimates that this type of "one-on-one training" will take approximately a half an hour to conduct and will be added on to the regular visit.

According to the U.S. Department of Labor, Bureau of Labor and Statistics, the average wage of a first line supervisor in a full-service restaurant is $16.49. Based on our experience and expertise, we estimate that, on average, most establishments will need to receive approximately 30 minutes of training once the 2017 Food Code is adopted. Based on our own 2018-2019 data, there are approximately 39,914 establishments in North Carolina. We have calculated the total cost to the private sector in Table 3 below to be $329,290.05. We expect these training-related costs to be one-time opportunity costs to the private sector, as this type of training is part of establishment employees' regular work and individual establishments are unlikely to hire additional staff to carry out this work.

Table 5: Impact to Private Sector

Cost per Establishment		
Number of Hours to Complete Training	Industry First Line Supervisor Hourly Rate	Cost to Industry per Establishment
0.5	$16.49	$ 8.25
Cost to Industry as a Whole		
Total Number of Permitted Establishments	Industry First Line Supervisor Training Rate	Total Cost to Industry for All Establishments Statewide
39,914	$ 8.25	$329,290.50
TOTAL COST TO PRIVATE SECTOR …… $329,290.50		

The changes in 2-201.11, 2-201.12, and 2-201.13 update the list illnesses that must be reported by establishments to local and district health departments when a staff person at the establishment falls ill. Specifically, these changes replace the term "Salmonella" in the Food Code with "Typhoid fever" (which is caused by Salmonella typhi) and add "Salmonella (non-typhoidal)." Salmonella (non-typhoidal) was already a reportable illness under existing North Carolina law and an average of 2,415 cases were reported per year between 2014 and 2018. In practice, the effect of this change to the list of reportable illnesses will be that employees who are sick with Typhoid fever will be required to be excluded from work to prevent further transmission of the illness to coworkers and customers. Although local and district health departments often already advise the exclusion of employees who have Typhoid fever, this change will now make exclusion of these employees mandatory.

Establishments will need to update their own health policies to reflect this requirement. We do not know how many cases of Typhoid fever per year involve individuals employed at establishments, making it a challenge to estimate the economic impact caused by the exclusion of these employees when they are diagnosed and management is required to exclude them from work. However, reporting of Typhoid fever and mandatory exclusion of sick employees from the workplace may reduce the risk of further transmission of the disease, thereby having a significant potential public health impact.

Looking to the next series of changes, the language that is amended in 2-301.14 (H) clarifies hand washing during glove use in processes that do not contaminate hands. This change will save facilities money on soap, water, and time spent by employee who to stop a task and wash hands; however, the total potential cost savings associated with these changes are challenging to pin down. Additionally, per changes to 2-501.11 in the Food Code, procedures will now be required to be kept on site for the cleanup of a vomit or diarrheal event. This will include a kit to be kept onsite with average cost ranging from

$12.00-$23.00. This figure was reported by industry partners who were part of the rule rewrite committee and who already had this protocol in their establishments. Based on feedback from our industry partners, we believe that most establishments already satisfy this requirement and have a vomit or diarrheal kit on-site; however, the benefit of codifying this requirement is that the risk of food borne illnesses such as Norovirus will be reduced because establishments will have to have a verified plan and kit in place for clean-up of contamination events.

Provisions under 3-304.11 and 3-304.14 will be expanded to allow linens to be utilized as a food contact surface in 2017 Food Code. Under 3-304.17, language has been added to expand the use of returnable containers by the consumer to establishments that may now include refilling with time/temperature control for safety foods. These provisions may result in minor cost savings to industry; however, because we do not know the financial difference for establishments in using linens as a contact surface or refilling returnable containers with time/temperature control for safety foods, and because we cannot predict how many establishments will shift their practices in response to these provisions, the potential cost savings are challenging to quantify.

The rule change in 3-304.17 provides allowances for more use of returnable containers by consumers, which could lead to a reduction in the use of single service items by industry. The actual cost savings associated with increased use of returnable containers by customers is challenging to quantify, as we do not know how many restaurants, or their customers, would take advantage of this new option following the adoption of the 2017 Food Code. In addition to cost savings, there could also be positive environmental impact associated with increased use of returnable containers and decreased use of single service items, which are often plastic, paper, aluminum foil, or Styrofoam. For the same reasons noted above, the likely environmental impact is difficult to determine because we cannot easily predict how the adoption of the 2017 Food Code will translate to changes in customer and establishment practices in this area.

The amendment in 3-501.13 that re-designates thawing frozen TCS products from a core item to a priority foundation item will have an impact in multiple areas. The first change under this amendment will require violations to be immediately corrected. In 2019, this item was marked 3,305 times in approximately 100,000 inspections. Under the 2009 Food Code, core items would not require immediate correction; this change will have a positive impact on public health by faster remediation of a potential foodborne illness risk. The extension of shelf life that results from the exclusion of products in 3-501.17 could result in cost savings to industry, as establishments may be able to avoid throwing away partially used ingredients and may be able to keep some ingredients in the kitchen longer. The types of items that are affected by this change will not be used in all establishments, however, and it is therefore difficult to determine the overall economic impact caused by this change in the 2017 Food Code.

In 3-502.12, the impact of the extension of ROP products from 72 hours to 7 days will be challenging to quantify savings to industry who utilize this method of food storage and product preservation. The requiring of sub-ingredients in 3-602.11 may result in some food service establishments having to make changes to existing labels. Although this was not a pre-existing rule under the 2009 Food Code, previous guidance from the FDA regarding label and allergen concerns has been shared with industry since the release of the 2013 Food Code. This new requirement will allow individuals to make more informed decisions when purchasing food and may impact consumer behavior; however, the economic impact of these changes, which is so dependent on consumer action, is challenging to predict and estimate.

The new requirement in 4-302.13 necessitates that establishments have an irreversible registering temperature indicator if they utilize hot water mechanical ware washing equipment. There are two options available to establishments that need to fulfill this requirement: the use of T-strips (25 strips/pack at $9.95/pack) or a thermometer-plate style device, which costs between at $48.50 and $65.00 and can be

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used repeatedly. We do not know the number of establishments that currently use hot water mechanical ware washing equipment and that would therefore be impacted by this change, making the economic impact challenging to quantify.

A change in the risk designation from priority foundation to core in 5-202.12 (A) will result in a savings to industry by making the repair costs associated with temperature adjustments unnecessary for hand washing facilities. The new allowance for facilities to operate under water or electrical emergencies as outlined in 8-404.11 (C) will be a savings to industry because it will no longer require a variance. This savings is difficult to assess because not all establishments will take advantage of this option. In 8-405.11, the change of priority violations to be corrected in 72 hours could result in rare additional emergency repair cost depending on nature of the violation, repair contract details, and day/time of inspection. Most priority violations can be corrected during the inspection. This change in the Food Code will be a benefit to North Carolina consumers because violations directly associated with increased risk of food borne illness will be corrected in a timelier manner, thereby reducing the risk of ongoing violations that could pose safety and health risks to consumers.

Summary

The proposed adoption of the 2017 FDA Food Code and Supplement and subsequent changes in the 15A NCAC 18A .2600 rules will help prevent food borne illness in North Carolina communities, expand options for industry partners engaging in specialized processes, and allow North Carolina to implement the most current Food Code, which is based on current science. According to FDA, 29 states have adopted a more current version of the FDA Food Code than the 2009 version that North Carolina utilizes presently. By updating to the newest version of the Food Code, North Carolina will remain a leader in protecting the residents of our state and continue to improve public health outcomes.

As noted throughout this fiscal note, the adoption of the 2017 Food Code and its Supplement will result in many changes that are challenging to quantify in dollars but that will overwhelmingly result in greater safety and better protection of the public's health. These changes include:

- Addition of non-Typhoidal Salmonella (NTS) as a reportable illness
- Clarification of handwashing requirements before donning gloves by food service workers
- Clarification of acceptable hand antiseptics
- Requirements for responding to contamination events involving vomit and/or diarrhea
- Labeling requirements for fish in reduce oxygen packaging (ROP)
- Shelf life extension of certain ROP foods
- Labeling requirement to include sub-ingredients
- Requirement to have an irreversible temperature indicator for hot temperature dish machines
- Change in risk designation of hand wash water temperature requirement
- Criteria for continuing operations during a water emergency or electrical outage
- Requirements to verify corrected Priority Foundation items within 72 hours
- Allowance of linens to be used as a food contact surface
- Expansion of the use or returnable containers by the consumer
- Redesignation of thawing TCS products from a core item to a Priority Foundation

For those changes for which the impact can be quantified, the total cost to state government, local government, and the private sector that will result from the adoption of the 2017 Food Code and its Supplement is summarized in Table 6 below.

Table 6: Summary of Total Costs

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State Government
$3,750.00
Local Government
$762,272.00
Private Sector
$329,292.50

NET TOTAL COST ……..…….. $1,095,314.50

Substantial Economic Impact: Alternatives

Pursuant to GS 150B-21.4(b2)(5), when an agency concludes its analysis and determines that the proposed rules will have a substantial economic impact[5], the agency shall include in its fiscal note a description of at least two alternatives to the proposed rules that were considered by the agency and rejected.

S.L. 2019-129 permits, but does not require, the adoption of the 2017 Food Code. Therefore, one alternative approach would involve not adopting the 2017 Food Code and continuing to implement the 2009 version of the Food Code. In this case, North Carolina would be one of fewer than a dozen states that is still implementing the 2009 Food Code and would not be able to take action on the most up to date science and information that facilitates better protection of the public's health through food safety measures. For this reason, this alternative approach was not pursued.

A second alternative approach could have involved not providing training to local health department staff on the changes that would take effect upon adoption of these rules. As explained in this impact analysis, the costs of providing this training constitute that majority of the expenses that state and local government will incur as a result of these rules. If training were not provided, then local health department staff would have to read through the 2017 Food Code and the rules on their own to determine how to implement the new requirements. Having the state provide training to our partners in the local health departments, however, is important to ensuring consistency in how the new requirements are implemented statewide and also provides an important opportunity for local health department staff to ask questions. Given the length of the 2017 Food Code document, it would likely not save local health department staff time if they had to read through the entire Food Code on their own to determine how to implement its changes. For these reasons, this alternative was not pursued.

[5] "Substantial economic impact" is defined at GS 150B-21.4(b1) as "an aggregate financial impact on all persons affected of at least one million dollars ($1,000,000) in a 12-month period."

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Appendix 1

15A NCAC 18A .2650 is proposed for readoption with substantive changes as follows:

15A NCAC 18A .2650 GENERAL – ADOPTION BY REFERENCE

The ~~2009~~ 2017 Food ~~Code,~~ Code and the accompanying 2017 Food Code Supplement, not including subsequent amendments and editions, established by the U.S. Department of Health and Human Services, Food and Drug Administration (hereinafter referred to as the "Food Code") ~~is~~ are hereby incorporated by reference. ~~The~~ A copy of the Food Code is available online and free of charge at: www.fda.gov/food/fda-food-code/food-code-2017. ~~may be accessed from the internet at www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/default.htm, or a copy can be obtained by contacting the U.S. Department of Commerce, National Technical Information Service, at (703) 605-6040, and is also available for inspection at the Division of Public Health, N.C. Department of Health and Human Services.~~

History Note: *Authority G.S. 130A-248; S.L. ~~2011-394, Section 15(a);~~ 2019-129;*
Eff. September 1, 2012.

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15A NCAC 18A .2651 is proposed for amendment as follows:

15A NCAC 18A .2651 DEFINITIONS

The provisions of this Rule make amendments, additions, and deletions to the Food Code incorporated by reference in Rule .2650 of this Section. In Chapter 1, the following apply:

(1) In Paragraph 1-201.10(B), add: "'Commissary' means a food establishment that services a mobile food unit or a pushcart."

(2) In Paragraph 1-201.10(B), add: "'Congregate nutrition sites' means food establishments where food preparation is limited to same day service, reheating of ~~potentially hazardous food (time/temperature control for safety food),~~ time/temperature control for safety food, and operated under the rules of the Division of Aging and Adult Services, N.C. Department of Health and Human Services."

(3) In Paragraph 1-201.10(B), add: "'Department' means the N.C. Department of Health and Human Services."

(4) In Paragraph 1-201.10(B), "Equipment (1)" to read: "means an article that is used in the operation of a food establishment such as a freezer, grinder, hood, ice maker, meat block, mixer, oven, reach-in refrigerator, scale, sink, slicer, stove, table, temperature measuring device for ambient air, or warewashing machine."

~~(4)~~(5) In Paragraph 1-201.10(B), amend "Food establishment (2)(b)" to read: "An operation that is conducted in a mobile, stationary, temporary, or permanent facility or location and where consumption is on or off the premises."

~~(5)~~(6) In Paragraph 1-201.10(B), amend "Food establishment (3)" to read: "'Food establishment' does not include entities exempted as described in G.S. 130A-250 or establishments that only serve such items as dip ice cream, popcorn, candied apples, or cotton candy."

~~(6)~~(7) In Paragraph 1-201.10(B), add: "'Food stand' means a food establishment that prepares or serves food and that ~~does not~~ only ~~provide~~ provides seating facilities ~~for customers to use while eating or drinking."~~ as set forth in G.S. 130A-248(a6)."

~~(7)~~(8) In Paragraph 1-201.10(B), add: "'Good repair' means equipment and utensils shall be maintained in a state of repair and condition that meets the requirements specified under Parts 4-1 and 4-2 of the Food Code as amended by Rule .2654."

~~(8)~~(9) In Paragraph 1-201.10(B), amend "Imminent health hazard" ~~to:~~ to read: "'Imminent health hazard' means an imminent hazard as defined in G.S. 130A-2(3)."

~~(9)~~(10) In Paragraph 1-201.10(B), add: "'Limited food services establishment' means a food establishment as defined in G.S. 130A-247(7)."

~~(10)~~(11) In Paragraph 1-201.10(B), add: "'Local health director' means a local health director as defined in G.S. 130A-2(6)."

~~(11)~~(12) In Paragraph 1-201.10(B), amend "Meat" to read: "'Meat' means the flesh of animals used as food including the dressed flesh of cattle, swine, sheep, or goat, other edible animals, and as defined in

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G.S. 106-549.15(14), except fish, poultry, and wild game animals as specified under Subparagraphs 3-201.17(A)(3) and (4)."

~~(12)~~(13) In Paragraph 1-201.10(B), add: "'Mobile food unit' means a food establishment ~~or pushcart~~ with no permanent utility connections, except for an onsite electrical connection, that is designed to be readily moved and vend ~~food."~~ food and that does not provide seating facilities for customers to use while eating or drinking."

~~(13)~~(14) In Paragraph 1-201.10(B), amend "Person" ~~to:~~ to read: "'Person' means person as defined in G.S. 130A-2(7)."

~~(14)~~(15) In Paragraph 1-201.10(B), amend "Poultry (1)" to read: "Any domesticated bird (chickens, turkeys, ducks, geese, guineas, ratites, or squabs), whether live or dead, as defined in 9 CFR 381.1 Poultry Products Inspection Regulations Definitions, Poultry, and G.S. 106-549.51(26); and"

~~(15)~~(16) In Paragraph 1-201.10(B), add: "'Pushcart' means a mobile piece of equipment or vehicle used to vend food."

~~(16)~~(17) In Paragraph 1-201.10(B), add: "'Registered Environmental Health Specialist' means a Registered Environmental Health Specialist as defined in G.S. 90A-51(2b) and 90A-51(4) and authorized agent of the Department."

~~(17)~~(18) In Paragraph 1-201.10(B), ~~add:~~ amend "Regulatory Authority" to read: "'Regulatory Authority' means the Department or authorized agent of the Department."

~~(18)~~(19) In Paragraph 1-201.10(B), add: "'Restaurant' means a food establishment that prepares or serves food and provides seating."

~~(19)~~(20) In Paragraph 1-201.10(B), add: "'Supplemental cooking room' means a separate attached or detached structure in that food is cooked on grills, pits, or fireplaces and no other processing occurs."

~~(20)~~(21) In Paragraph 1-201.10(B), amend "Temporary food establishment" ~~to:~~ to read: "(1) ~~"Temporary~~ 'Temporary food establishment' means a food establishment ~~that operates for a period of time not to exceed 21 days in one location, affiliated with and endorsed by a transitory fair, carnival, circus, festival, or public exhibition. Food establishments that operate in the same event location for more than 21 days per calendar year are not eligible for a temporary food establishment permit. Domestic yard sales and businesses such as auctions, flea markets, or farmers' markets are not eligible for a temporary food establishment permit."~~ as defined in G.S. 130A-247(8).

(2) 'Temporary food establishment' does not include domestic yard sales and businesses such as auctions and flea markets."

~~(21)~~(22) In Paragraph 1-201.10(B), add: "'Temporary food establishment commissary' means a food establishment affiliated with a temporary food establishment that prepares food in advance of or ~~off-site.~~ off-site from the event. The temporary food establishment commissary permit shall be valid for no more than ~~21 consecutive days~~ the time period described in G.S. 130A-247(8) and shall be permitted no more than 7 days prior to commencement of the event. Food establishments that operate in the same location for more than ~~21 days~~ the time period described in G.S. 130A-247(8)

SAMPLE

per calendar year are not eligible for a temporary food establishment commissary permit. Food shall not be sold directly from the temporary food establishment commissary. The temporary food establishment commissary shall comply with all temporary food establishment requirements."

~~(22)~~(23) In Paragraph 1-201.10(B), add: "'Transitional Permit' means ~~a permit issued by the regulatory authority upon the transfer of ownership or lease of an existing food establishment to allow the correction of construction and equipment problems that do not represent an immediate threat to public health.~~ as defined at G.S. 130A-248(c). The transitional permit shall expire 180 days after the date of issuance."

~~(23)~~(24) In Paragraph 1-201.10(B), delete the definition of "Vending machine."

~~(24)~~(25) In Paragraph 1-201.10(B), delete the definition of "Vending machine location."

History Note: *Authority G.S. 130A-248; S.L. ~~2011-394, Section 15(a);~~ 2019-129;*
Eff. September 1, 2012;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 20, 2019.

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15A NCAC 18A .2652 is proposed for amendment as follows:

15A NCAC 18A .2652 MANAGEMENT AND PERSONNEL

The provisions of this Rule make amendments, additions, and deletions to the Food Code incorporated by reference in Rule .2650 of this Section. In Chapter 2, the following apply:

(1) In Paragraph 2-101.11(B), amend to read: "In a food establishment with two or more separately permitted departments that are the legal responsibility of the same permit holder and that are located on the same premises, the permit holder may designate a single person in charge who is present on the premises during all hours of operation, and who is responsible for each separately permitted food establishment on the premises."

(2) In ~~Section~~ Paragraph ~~2-102.11,~~ 2-102.11(A), amend ~~the last sentence in the first paragraph to:~~ to read: ~~"The person in charge shall demonstrate this knowledge by being a certified food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program. The person in charge is not required to be a certified food protection manager when the food establishment is not operating and food is not being prepared, packaged, or served for immediate consumption."~~ "Complying with this code by having no violations of priority items during the current inspection; or"

~~(3) In Section 2-102.11, delete (A), (B), and (C).~~

~~(4) In Subpart 2-102, add Section 2-102.12, Certified Food Protection Manager, to read:~~

~~"2-102.12 Certified Food Protection Manager.~~

~~(A) At least one employee who has supervisory and management responsibility and the authority to direct and control food preparation and service shall be a certified food protection manager who has shown proficiency of required information through passing a test that is part of an American National Standards Institute (ANSI) accredited program.~~

~~(B) This section does not apply to congregate nutrition sites and Risk Category I food establishments as defined in 10A NCAC 46 .0213."~~

~~(C) The requirements of this section are effective on January 1, 2014.~~

~~(5)~~(3) ~~In Section 2-102.20, replace "Paragraph 2-102.11(B)" with "Section 2-102.11."~~ In Paragraph 2-102.12(B), amend to read: "This section does not apply to congregate nutrition sites and Risk Category I food establishments as defined in 10A NCAC 46 .0213."

History Note: *Authority G.S. 130A-248; S.L. ~~2011-394, Section 15(a);~~ 2019-129;*
Eff. September 1, 2012;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 20, 2019.

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15A NCAC 18A .2653 is proposed for amendment as follows:

15A NCAC 18A .2653 FOOD

The provisions of this Rule make amendments, additions, and deletions to the Food Code incorporated by reference in Rule .2650 of this Section. In Chapter 3, the following apply:

(1) In Paragraph 3-201.11(A), add at the end: "Food from food establishments in states adjacent to North Carolina may be sold within North Carolina if the food establishments are under jurisdiction of the local or state enforcement body in that originating state and approved by the regulatory authority in North ~~Carolina.~~ Carolina in accordance with G.S. 130A-248(b). To determine the extent of compliance with this Code, the regulatory authority shall obtain reports regarding compliance and compliance history from responsible authorities in other jurisdictions where the food establishments are located."

~~(2) In Paragraph 3-301.11(B), amend to read: "Except when washing fruits and vegetables as specified under Section 3-302.15 or as specified in Paragraphs (D) and (E) of this section, food employees may not contact exposed ready-to-eat food with their bare hands and shall use suitable utensils such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment."~~

~~(3) In Paragraph 3-301.11(D), amend to read:~~

~~"Paragraph (B) of this section does not apply to a food employee who contacts exposed, ready-to-eat food with bare hands at the time the ready-to-eat food is being added as an ingredient to a food that is to be cooked in the food establishment to heat all parts of the food to a temperature of at least 74°C (165°F)."~~

~~(4) In Section 3-301.11, redesignate existing Paragraph (D) as new Paragraph (E).~~

~~(5) In Subparagraph 3-301.11(D)(7), replace "(D)(1)-(6)" with "(E)(1)-(6)."~~

~~(6)~~(2) Delete Section 3-305.13.

~~(7)~~(3) In Section 3-306.12, delete (B).

~~(8) In Paragraph 3-403.11(D), amend to read: "Reheating for hot holding as specified under Paragraphs (A) through (C) of this section shall be completed within 2 hours and the time the food is between 5°C (41°F) or 7°C (45°F) and the temperatures specified under Paragraphs (A) through (C) of this section may not exceed 2 hours."~~

~~(9) In Paragraph 3-501.12(A), amend to read: "Under refrigeration that maintains the food temperature at 5°C (41°F) or less, or at 7°C (45°F) or less as specified under Subparagraph 3-501.16(A)(2)(b)."~~

~~(10) In Paragraph 3-501.13(A), amend to read: "Under refrigeration that maintains the food temperature at 5°C (41°F) or less, or at 7°C (45°F) or less as specified under Subparagraph 3-501.16(A)(2)(b)."~~

~~(11) In Paragraph 3-501.13(B), amend to read:~~

~~"Completely submerged under running water:~~

~~(1) At a water temperature of 21°C (70°F) or below,~~

~~(2) With sufficient water velocity to agitate and float off loose particles in an overflow,~~

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(3) Such that for ready-to-eat food, the temperature of thawed portions do not rise above 5°C (41°F), or 7°C (45°F) as specified under Subparagraph 3-501.16(A)(2)(b), and

(4) Such that for raw animal food requiring cooking as specified under Paragraph 3-401.11(A) or (B), thawed portions are not above 5°C (41°F), or 7°C (45°F) as specified under Subparagraph 3-501.16(A)(2)(b), for more than 4 hours including:

(a) The time the food is exposed to the running water and the time needed for preparation for cooking, or

(b) The time it takes under refrigeration to lower the food temperature to 5°C (41°F), or 7°C (45°F) as specified under Subparagraph 3-501.16(A)(2)(b);"

(12) In Subparagraph 3-501.14(A)(2), amend to read: "Within a total of 6 hours from 57°C (135°F) to 5°C (41°F) or less, or to 7°C (45°F) or less as specified under Subparagraph 3-501.16(A)(2)(b)."

(13) In Paragraph 3-501.14(B), amend to read: "Potentially hazardous food (time/temperature control for safety food) shall be cooled within 4 hours to 5°C (41°F) or less, or to 7°C (45°F) or less as specified under Subparagraph 3-501.16(A)(2)(b) if prepared from ingredients at ambient temperature such as reconstituted foods and canned tuna."

(14) In Subparagraph 3-501.16(A)(2), amend to read:

"At a temperature specified in the following:

(a) 5°C (41°F) or less; or

(b) 7°C (45°F) or between 5°C (41°F) and 7°C (45°F) in existing refrigeration equipment that is not capable of maintaining the food at 5°C (41°F) or less if:

(i) The equipment is in place and in use in the food establishment; and

(ii) On or before, January 1, 2019, the equipment is upgraded or replaced to maintain food at a temperature of 5°C (41°F) or less."

(15) In Paragraph 3-501.17(A), amend to read:

"(A) Except when packaging food using a reduced oxygen packaging method as specified under Section 3-502.12, and except as specified in Paragraphs (D) and (E) of this section, refrigerated, ready-to-eat, potentially hazardous food (time/temperature control for safety food) prepared and held in a food establishment for more than 24 hours shall be marked to indicate the date or day by which the food shall be consumed on the premises, sold, or discarded, based on the temperature and time combinations specified below. The day of preparation shall be counted as Day 1.

(1) 5°C (41°F) or less for a maximum of 7 days; or

(2) 7°C (45°F) or between 5°C (41°F) and 7°C (45°F) for a maximum of 4 days in existing refrigeration equipment that is not capable of maintaining the food at 5°C (41°F) or less if:

(a) The equipment is in place and in use in the food establishment, and

(b) On or before, January 1, 2019, the equipment is upgraded or replaced to maintain food at a temperature of 5°C (41°F) or less."

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~~(16) In Paragraph 3-501.19(B), amend to read: "If time without temperature control is used as the public health control up to a maximum of 4 hours:"~~

~~(17) In Subparagraph 3-501.19(B)(1), amend to read: "The food shall have an initial temperature of 5°C (41°F) or less, or 7°C (45°F) or less when removed from cold holding temperature control, or 57°C (135°F) or greater when removed from hot holding temperature control;"~~

~~(18) In Paragraph 3-801.11(D), amend to read: "Food employees may not contact ready-to-eat food as specified under Paragraphs 3-301.11(B) and (E)."~~

History Note: *Authority G.S. 130A-248; S.L. ~~2011-394, Section 15(a);~~ 2019-129;*
Eff. September 1, 2012;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 20, 2019.

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15A NCAC 18A .2654 is proposed for amendment as follows:

15A NCAC 18A .2654 EQUIPMENT, UTENSILS, AND LINENS

The provisions of this Rule make amendments, additions, and deletions to the Food Code incorporated by reference in Rule .2650 of this Section. In Chapter 4, the following apply:

(1) Delete Sections 4-204.14, 4-204.19, 4-204.111, 4-204.121, and 4-204.123.

(2) In Section 4-205.10, amend to read: "Except for toasters, mixers, microwave ovens, water heaters, and hoods, food equipment shall be used in accordance with the manufacturer's intended use and certified or classified for sanitation by an American National Standards Institute (ANSI)-accredited certification program. If the equipment is not certified or classified for sanitation, the equipment shall ~~meet~~ comply with Parts 4-1 and 4-2 of the Food Code as amended by this Rule. Nonabsorbent wooden shelves that are in good repair may be used in dry storage areas."

(3) In Section 4-301.14, amend to read: "Ventilation hood systems and devices shall prevent grease or condensation from collecting on equipment, walls, and ceilings."

(4) In Section 4-502.14, amend to read: “Except as permitted under G.S. 130A-248(c3), mollusk and crustacea shells shall not be used more than once as serving containers.”

History Note: *Authority G.S. 130A-248; S.L. ~~2011-394, Section 15(a);~~ 2019-129;*
Eff. September 1, 2012;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 20, 2019.

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15A NCAC 18A .2655 is proposed for amendment as follows:

15A NCAC 18A .2655 WATER, PLUMBING, AND WASTE

The provisions of this Rule make amendments, additions, and deletions to the Food Code incorporated by reference in Rule .2650 of this Section. In Chapter 5, the following applies: ~~Delete Paragraph 5-203.11(C) and Section 5-501.14.~~

(1) In Paragraph 5-202.12(A), change the risk designation from "priority foundation item" to "core item."

(2) Delete Section 5-501.14.

History Note: *Authority G.S. 130A-248; S.L. ~~2011-394, Section 15(a);~~ 2019-129;*
Eff. September 1, 2012;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 20, 2019.

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15A NCAC 18A .2661 is proposed for amendment as follows:

15A NCAC 18A .2661 INSPECTIONS AND REINSPECTIONS

(a) Upon entry into a food establishment, the regulatory authority shall provide identification and the purpose in visiting that establishment. The regulatory authority shall inquire as to the identity of the person in charge and invite the person in charge to accompany the regulatory authority during the inspection. If no employee is identified as the person in charge, the regulatory authority shall invite an employee to accompany the regulatory authority on the inspection. Following the inspection, the regulatory authority shall offer to review the results of the inspection with the person in charge or employee, as applicable.

(b) The grading of food establishments shall be conducted using an inspection form furnished by the regulatory authority. The form shall provide for the following information:

(1) ~~The~~ the name and mailing address of the food establishment;

(2) ~~The~~ the name of the permit holder;

(3) ~~The~~ the permit status and score given;

(4) ~~Standards~~ standards of construction and operation as listed in .2651 through .2677 of this Section;

(5) ~~An~~ an explanation for all points deducted;

(6) ~~The~~ the signature of the regulatory authority; and

(7) ~~The~~ the date.

(c) The grading of food establishments shall be based on the standards of operation and construction as set forth in Rules .2650 through .2676 of this Section.

(d) The Food Establishment Inspection form shall be used to document points assessed for violation of the rules of this Section as follows:

(1) Violation of Chapter 2 of the Food Code as amended by Rule .2652 of this Section related to person in charge present, demonstration of knowledge, ~~certification by accredited program~~ or performs duties shall equal no more than ~~2 points.~~ 1 point.

(2) Violation of Chapter 2 of the Food Code as amended by Rule .2652 of this Section related to the person in charge being a certified food protection manager by having certification from an accredited program shall equal no more than 1 point.

~~(2)~~(3) Violation of Chapter 2 of the Food Code as amended by Rule .2652 of this Section related to management awareness, policy present, and allergy awareness shall equal no more than 3 points.

~~(3)~~(4) Violation of Chapter 2 of the Food Code as amended by Rule .2652 of this Section related to proper use of reporting, restriction, and exclusion shall equal no more than 3 points.

(5) Violation of Chapter 2 of the Food Code as amended by Rule .2652 of this Section related to procedures responding to vomiting and diarrheal events shall equal no more than 1 point.

~~(4)~~(6) Violation of Chapters 2 and 3 of the Food Code as amended by Rules .2652 and .2653 of this Section related to proper eating, tasting, drinking, or tobacco use shall equal no more than ~~2 points.~~ 1 point.

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~~(5)~~(7) Violation of Chapter 2 of the Food Code as amended by Rule .2652 of this Section related to no discharge from eyes, nose, and mouth shall equal no more than 1 point.

~~(6)~~(8) Violation of Chapter 2 of the Food Code as amended by Rule .2652 of this Section related to hands clean and properly washed shall equal no more than 4 points.

~~(7)~~(9) Violation of Chapter 3 of the Food Code as amended by Rule .2653 of this Section related to no bare hand contact with ready-to-eat food or approved alternate method properly followed shall equal no more than ~~3~~ 4 points.

~~(8)~~(10) Violation of Chapters 5 and 6 of the Food Code as amended by Rules .2655 and .2656 of this Section related to handwashing facilities supplied and accessible shall equal no more than 2 points.

~~(9)~~(11) Violation of Chapters 3 and 5 of the Food Code as amended by Rules .2653 and .2655 of this Section related to food obtained from an approved source shall equal no more than 2 points.

~~(10)~~(12) Violation of Chapter 3 of the Food Code as amended by Rule .2653 of this Section related to food received at proper temperature shall equal no more than 2 points.

~~(11)~~(13) Violation of Chapter 3 of the Food Code as amended by Rule .2653 of this Section related to food in good condition, safe, and unadulterated shall equal no more than 2 points.

~~(12)~~(14) Violation of Chapter 3 of the Food Code as amended by Rule .2653 of this Section related to required records available, shellstock tags, and parasite destruction shall equal no more than 2 points.

~~(13)~~(15) Violation of Chapter 3 of the Food Code as amended by Rule .2653 of this Section related to food separated and protected shall equal no more than 3 points.

~~(14)~~(16) Violation of Chapter 4 of the Food Code as amended by Rule .2654 of this Section related to food-contact surfaces cleaned and sanitized shall equal no more than 3 points.

~~(15)~~(17) Violation of Chapter 3 of the Food Code as amended by Rule .2653 of this Section related to disposition of returned, previously served, reconditioned, and unsafe food shall equal no more than 2 points.

~~(16)~~(18) Violation of Chapter 3 of the Food Code as amended by Rule .2653 of this Section related to cooking time and temperatures shall equal no more than 3 points.

~~(17)~~(19) Violation of Chapter 3 of the Food Code as amended by Rule .2653 of this Section related to reheating for hot holding shall equal no more than 3 points.

~~(18)~~(20) Violation of Chapter 3 of the Food Code as amended by Rule .2653 of this Section related to cooling time and temperatures shall equal no more than 3 points.

~~(19)~~(21) Violation of Chapter 3 of the Food Code as amended by Rule .2653 of this Section related to hot holding temperatures shall equal no more than 3 points.

~~(20)~~(22) Violation of Chapter 3 of the Food Code as amended by Rule .2653 of this Section related to cold holding temperatures shall equal no more than 3 points.

~~(21)~~(23) Violation of Chapter 3 of the Food Code as amended by Rule .2653 of this Section related to date marking and disposition shall equal no more than 3 points.

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~~(22)~~(24) Violation of Chapter 3 of the Food Code as amended by Rule .2653 of this Section related to time as a public health control procedures and records shall equal no more than ~~2~~ 3 points.

~~(23)~~(25) Violation of Chapter 3 of the Food Code as amended by Rule .2653 of this Section related to consumer advisory provided for raw or undercooked foods shall equal no more than 1 point.

~~(24)~~(26) Violation of Chapter 3 of the Food Code as amended by Rule .2653 of this Section related to pasteurized foods used and prohibited foods not offered shall equal no more than 3 points.

~~(25)~~(27) Violation of Chapter 3 of the Food Code as amended by Rule .2653 of this Section related to food additives approved and properly used shall equal no more than 1 point.

~~(26)~~(28) Violation of Chapter 7 of the Food Code as amended by Rule .2657 of this Section related to toxic substances properly identified, stored, and used shall equal no more than 2 points.

~~(27)~~(29) Violation of Chapters 3, 4 and 8 of the Food Code as amended by Rules .2653, .2654, and .2658 of this Section related to compliance with variance, specialized process, and HACCP plan shall equal no more than 2 points.

~~(28)~~(30) Violation of Chapter 3 of the Food Code as amended by Rule .2653 of this Section related to pasteurized eggs used where required shall equal no more than 1 point.

~~(29)~~(31) Violation of Chapters 3 and 5 of the Food Code as amended by Rules .2653 and .2655 of this Section related to water from an approved source shall equal no more than 2 points.

~~(30)~~(32) Violation of Chapter 8 of the Food Code as amended by Rule .2658 of this Section related to variance obtained for specialized processing methods shall equal no more than ~~1point.~~ 2 points.

~~(31)~~(33) Violation of Chapters 3 and 4 of the Food Code as amended by Rules .2653 and .2654 of this Section related to proper cooling methods used or adequate equipment for temperature control shall equal no more than 1 point.

~~(32)~~(34) Violation of Chapter 3 of the Food Code as amended by Rule .2653 of this Section related to plant food properly cooked for hot holding shall equal no more than 1 point.

~~(33)~~(35) Violation of Chapter 3 of the Food Code as amended by Rule .2653 of this Section related to approved thawing methods used shall equal no more than 1 point.

~~(34)~~(36) Violation of Chapter 4 of the Food Code as amended by Rule .2654 of this Section related to thermometers provided and accurate shall equal no more than 1 point.

~~(35)~~(37) Violation of Chapter 3 of the Food Code as amended by Rule .2653 of this Section related to food properly labeled or original container shall equal no more than 2 points.

~~(36)~~(38) Violation of Chapters 2 and 6 of the Food Code as amended by Rules .2652 and .2656 of this Section related to insects and rodents not present or no unauthorized animals or persons shall equal no more than 2 points.

~~(37)~~(39) Violation of Chapters 3 and 6 of the Food Code as amended by Rules .2653 and .2656 of this Section related to contamination prevented during food preparation, storage, and display shall equal no more than 2 points.

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~~(38)~~(40) Violation of Chapter 2 of the Food Code as amended by Rule .2652 of this Section related to personal cleanliness shall equal no more than 1 point.

~~(39)~~(41) Violation of Chapters 3 and 4 of the Food Code as amended by Rules .2653 and .2654 of this Section related to wiping cloths properly used and stored shall equal no more than 1 point.

~~(40)~~(42) Violation of Chapters 3 and 7 of the Food Code as amended by Rules .2653 and .2657 of this Section related to washing fruits and vegetables shall equal no more than 1 point.

~~(41)~~(43) Violation of Chapter 3 of the Food Code as amended by Rule .2653 of this Section related to in-use utensils properly stored shall equal no more than 1 point.

~~(42)~~(44) Violation of Chapter 4 of the Food Code as amended by Rule .2654 of this Section related to utensils, equipment, and linens properly stored, dried and handled shall equal no more than 1 point.

~~(43)~~(45) Violation of Chapter 4 of the Food Code as amended by Rule .2654 of this Section related to single-use and single-service articles properly stored and used shall equal no more than 1 point.

~~(44)~~(46) Violation of Chapter 3 of the Food Code as amended by Rule .2653 of this Section related to gloves used properly shall equal no more than 1 point.

~~(45)~~(47) Violation of Chapters 3 and 4 of the Food Code as amended by Rules .2653 and .2654 of this Section related to equipment, food and non-food contact surfaces approved, cleanable, properly designed, constructed and used shall equal no more than ~~2 points.~~ 1 point.

~~(46)~~(48) Violation of Chapter 4 of the Food Code as amended by Rule .2654 of this Section related to warewashing facilities installed, maintained, used, and test strips shall equal no more than 1 point.

~~(47)~~(49) Violation of Chapter 4 of the Food Code as amended by Rule.2654 of this Section related to non-food contact surfaces clean shall equal no more than 1 point.

~~(48)~~(50) Violation of Chapter 5 of the Food Code as amended by Rule .2655 of this Section related to hot and cold water available and adequate pressure shall equal no more than ~~2 points.~~ 1 point.

~~(49)~~(51) Violation of Chapter 5 of the Food Code as amended by Rule .2655 of this Section related to plumbing installed and proper backflow devices shall equal no more than 2 points.

~~(50)~~(52) Violation of Chapter 5 of the Food Code as amended by Rule .2655 of this Section related to sewage and wastewater properly disposed shall equal no more than 2 points.

~~(51)~~(53) Violation of Chapters 5 and 6 of the Food Code as amended by Rules .2655 and .2656 of this Section related to toilet facilities properly constructed, supplied, and cleaned shall equal no more than 1 point.

~~(52)~~(54) Violation of Chapters 5 and 6 of the Food Code as amended by Rules .2655 and .2656 of this Section related to garbage and refuse properly disposed and facilities maintained shall equal no more than 1 point.

~~(53)~~(55) Violation of Chapters 4 and 6 of the Food Code as amended by Rules .2654 and .2656 of this Section related to physical facilities installed, maintained, and clean shall equal no more than 1 point.

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~~(54)~~(56) Violation of Chapters 4 and 6 of the Food Code as amended by Rules .2654 and .2656 of this Section related to meets ventilation and lighting requirements and designated areas used shall equal no more than 1 point.

(e) In filling out the inspection form, points may be deducted only once for a single occurrence or condition existing within or outside of the food establishment. Deductions shall be based on actual violations of the rules of this Section observed during the inspection. The regulatory authority shall take zero, one-half, or a full deduction of points depending upon the severity or the recurring nature of the core item violations. Priority items or priority foundation items may be corrected during the inspection and no more than one-half of the total point value shall be deducted when the violation meets the following criteria:

(1) ~~The~~ the priority item or priority foundation item violation was not documented on the previous inspection; and

(2) ~~Correction~~ correction of the item is documented on the inspection form.

(f) At the time of inspection, if a priority item or priority foundation item violation is observed and not corrected, the regulatory authority shall take one-half or a full deduction of points depending upon the severity or the recurring nature of the violation. ~~The regulatory authority shall specify a time frame of no more than 10 calendar days to correct the priority items or priority foundation items.~~

(g) In determining whether items or areas of a food establishment are clean for purposes of enforcing the rules set forth in this Section and grading a food establishment, the regulatory authority shall consider, among other things:

(1) ~~The~~ the age of the accumulated material;

~~(2) The relative percentage of items which are clean and not clean;~~

~~(3)~~(2) ~~The~~ the cleaning practices of the food establishment; and

~~(4)~~(3) ~~The~~ the health risk posed by the circumstances.

(h) Upon request of the permit holder or his or her representative a reinspection shall be made. In the case of a food establishment that requests an inspection for the purpose of raising the alphabetical grade, and that holds an unrevoked permit, the regulatory authority shall make an unannounced inspection within 15 calendar days from the date of the request.

(i) In the case of food establishments that have been closed for failure to comply with the rules of this Section, a reinspection to consider the issuance or reissuance of a permit shall be scheduled by ~~made at the earliest convenience of~~ the regulatory authority.

(j) In Section 8-304.11 of the Food Code delete (K).

History Note: *Authority G.S. 130A-248; S.L. ~~2011-394, Section 15(a);~~ 2019-129;*
Eff. September 1, 2012;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 20, 2019.

SAMPLE

15A NCAC 18A .2670 is proposed for readoption with substantive changes as follows:

15A NCAC 18A .2670 GENERAL REQUIREMENTS FOR PUSHCARTS AND MOBILE FOOD UNITS

Notwithstanding the provisions set forth in Rules .2671 and .2672, pushcarts and mobile food units shall comply with all requirements in this Section with the following exceptions:

~~(a)~~(1) A permit shall be issued by the regulatory authority that inspects the commissary from which a pushcart or mobile food unit is to operate~~,~~ if the regulatory authority determines that the pushcart or mobile food unit complies with the rules of this Section. The permit shall be maintained on the pushcart or mobile food unit and made available to the regulatory authority upon request.

~~(b)~~(2) The regulatory authority that issues the permit shall be provided by the permit holder a list of counties and locations where each pushcart or mobile food unit will operate.

~~(c)~~(3) Prior to initiating food service operations in a particular county, the pushcart or mobile food unit permit holder shall provide the regulatory authority in each county in which food service operations are proposed a list of locations where they will operate. Such lists must be kept current.

~~(d)~~(4) Pushcarts or mobile food units shall operate in conjunction with a permitted commissary and shall report at least daily to the commissary for supplies, cleaning, and servicing. Facilities, in compliance with this Section, shall be provided at the commissary for storage of all supplies. The pushcart shall also be stored in an area that protects it from dirt, debris, vermin, and other contamination. Water faucets used to supply water for pushcarts or mobile food units shall be protected to prevent contact with chemicals, splash, and other sources of contamination. Solid waste storage and liquid waste disposal facilities must also be provided on the commissary premises.

~~(e) All food shall be obtained from sources that comply with Chapter 3 of the Food Code as amended by Rule .2653 of this Section.~~

~~(f) All potentially hazardous food (time/temperature control for safety food) shall be maintained at temperatures as required in Chapter 3 of the Food Code as amended by Rule .2653 of this Section. A metal stem-type thermometer accurate to 1°C (2°F) shall be available to check food temperatures.~~

~~(g)~~(5) Single service articles shall be used for serving customers. ~~Single-service articles shall be purchased in sanitary containers, shall be stored therein in a clean, dry place until used, and shall be handled in a manner to prevent contamination.~~

~~(h) All garbage and other solid waste shall be stored and disposed in an approved manner.~~

~~(i) Employees shall wear effective hair restraints, clean outer clothing, and maintain good hygienic practices as specified in Part 2-4 of the Food Code as amended by Rule .2652 of this Section.~~

~~(j) Employees shall comply with the requirements in Subpart 2-201 of the Food Code as amended by Rule 2652. of this Section~~

~~(k) Equipment and utensils shall meet the requirements in Parts 4-1 and 4-2 of the Food Code as amended by Rule .2654 of this Section.~~

~~(l) The pushcart or mobile food unit shall be kept clean and free of flies, roaches, rodents, and other vermin.~~

SAMPLE

History Note: *Authority G.S. 130A-248; S.L. ~~2011-394, Section 15(a);~~ 2019-129;*
Eff. September 1, 2012.

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15A NCAC 18A .2674 is proposed for readoption with substantive changes as follows:

15A NCAC 18A .2674 LIMITED FOOD SERVICES ESTABLISHMENTS

Limited food services establishments shall comply with all the requirements in Rules .2650 through .2662 of this Section, except as follows: ~~that the following provisions apply in lieu of Rules .2654(2) and .2659(a) and (b), Section 5-204.11(b) of the Food Code as amended by Rule .2655 of this Section, and Sections 8-201.11 and 8-201.12 of the Food Code as amended by Rule .2658 of this Section:~~

(1) The permit for a limited food services establishment shall be posted in a conspicuous place where it can be readily seen by the public at all times. Permits for limited food services establishments shall expire ~~on December 31 of each year.~~ one (1) year from the date of issuance. A new permit from the regulatory authority shall be obtained before the limited food services establishment shall be allowed to operate each year. Transitional permits shall not be issued.

(2) The permit application shall be submitted to the local health department at least 30 days prior to construction or commencing operation. The permit application shall include a proposal for review and approval by the local health department that includes a menu, plans, and specifications for the proposed limited food services establishment, and ~~location~~ location, hours, and dates of operation.

(3) Limited food services establishments shall not prepare any ~~potentially hazardous food (time/temperature control for safety food)~~ time/temperature control for safety food prior to the day of sale.

(4) ~~Potentially hazardous food (time/temperature control for safety food)~~ Time/temperature control for safety food that has been heated at the limited food services establishment and remains at the end of the day shall not be served or placed in refrigeration to be used another day.

(5) ~~All~~ Except as set forth in Paragraph (6) of this Rule, all meats, poultry, and fish shall be purchased in a pre-portioned and ready-to-cook form.

(6) Equipment in the limited food services establishment that is not certified or classified for sanitation by an ANSI-accredited certificate program ~~that is in good repair and operating properly~~ may be used. At least a two-compartment sink shall be provided. The sink shall be of sufficient size to submerge, wash, rinse, and sanitize utensils and shall have splashback protection. At least one drainboard, table, or counter space shall be provided for air-drying.

(7) Only single-service articles shall be ~~used.~~ used as tableware as defined in Chapter 1 of the Food Code.

(8) Limited food services establishments may ~~prepare~~ reheat pre-cooked and cook food in accordance with the overhead protection requirements set forth in Rule .2669(b) of this Section.

(9) Floors, walls, and ceilings of limited food services establishments shall meet the requirements of this Section, except those limited food services establishments preparing food in accordance with Rule .2669(b) of this Section. ~~Limited food establishments shall use dustless methods of floor~~

SAMPLE

~~cleaning and all, except emergency floor cleaning, shall be done during those periods when the least amount of food and drink is exposed, such as after closing, or between meals.~~

(10) All areas in which food is handled, prepared, or in which utensils are washed, shall be provided with artificial lighting that complies with Section 6-202.11 of the Food Code as amended by Rule .2656 of this Section.

(11) A handwashing sink shall be provided in food service areas for use by employees only.

(12) Toilet facilities shall be provided for use by employees. Public toilet facilities provided on the grounds of the facility where the ~~associated amateur athletic~~ event is taking place are acceptable. Toilet facilities for the public are not required.

History Note: *Authority G.S. 130A-248; S.L. ~~2011-394, Section 15(a);~~ 2019-129;*
Eff. September 1, 2012.

SAMPLE