Fiscal Impact of 2009 FDA Food Code Adoption

(15A NCAC 18A .2651-.2677 Proposed for Adoption)

Name of Commission: Commission for Public Health

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Impact Summary:

State government:	Yes
Local government:	Yes
Private industry:	Yes
Substantial impact:	Yes

Authority: G.S. 130A-248; S.L. 2011-394, Section 15(a)

Necessity: The adoption of the 2009 Food Code is necessary to ensure current science-based standards are maintained to protect the public from contracting foodborne diseases and to provide an efficient and timely process to update North Carolina's food protection rules to be consistent with national standards.

This adoption is not required by federal law. The NC General Assembly passed a law in 2011 providing the Department the authority to adopt the 2009 Food Code.

Summary:
A number of requirements proposed for adoption from the 2009 Food Code will be different from North Carolina's current food protection rules (15A NCAC 18A .2601-.2645). See Appendix 1 for the text of the proposed rule changes (15A NCAC 18A .2651-.2678).

The rule text has been modified as a result of the public hearing process. See Appendix 3 for a description of the changes and their impact on the costs and benefits estimated below.

The following is a synopsis of the impact of implementing the Food Code:

Training related impact:

- The state Food Protection Program will provide training on the implementation of the Food Code to the food service industry, to food service establishments operated by local government, and to local health department environmental health staff.
  Total cost to industry: $471,400
  Total cost to state government: $400
  Total cost to local government: $860,500

Rule specific implementation costs:

- The definition of "potentially hazardous food" will change significantly, affecting the types of food that will be subject to regulation. The new definition will take into account the different properties of individual food items

allowing more foods to be exempt from time/temperatures controls and less foods to be discarded without affecting public health.
Total cost to industry: No cost
Total cost to state government: No cost
Total cost to local government: No cost
Benefits: Unquantifiable cost savings for industry by allowing certain foods to be exempt from time/temperature requirements

- Each food establishment will be required to have a person in charge demonstrate food safety knowledge by being a certified food protection manager (passing an American National Standards Institute (ANSI)-accredited exam).
  Total cost to industry: $4,496,000 ($181/person);
  Total cost to state government: No cost
  Total cost to local government: $391,000 ($181/person)
  Benefits: to industry of $182,200/year and to local government of $15,800/year.
  Unquantifiable benefits result from increased compliance with proper food safety practices that result in the prevention of foodborne illnesses.

- Each food establishment will be required to develop and adhere to an Employee Health Policy.
  Total cost to industry: $550,000 ($32.98 per policy) one-time cost
  Total cost to state government: No cost
  Total cost to local government: $47,800 ($32.98 per policy) one-time cost
  Benefits: See following bullet point which presents estimated savings from prevented foodborne illnesses

- Food establishments will be required to refrain from handling exposed, ready-to-eat foods with bare hands.
  Total cost to industry: Unquantifiable cost to industry or state/local government
  Total cost to state government: Unquantified cost, likely to be small
  Total cost to local government: No cost
  Benefits: $882,300 per year in estimated savings from prevented foodborne illnesses (includes savings from having an Employee Health Policy)

- Food establishments that serve raw-marinated, or marinated and partially cooked fish must ensure destruction of naturally-occurring parasites prior to serving.
  Total cost to industry: Little to no cost
  Total cost to state government: No cost
  Total cost to local government: No cost
  Benefits: Unquantifiable savings from prevented foodborne illnesses

- Food establishments will be required to decrease the refrigerated cold-holding temperature for potentially hazardous foods from 45˚ to 41˚ Fahrenheit and date-mark opened, ready-to-eat food for a maximum shelf life up to 7 days.
  Total cost to industry: $855,600 (one-time cost for refrigeration unit replacement)
  Total cost to state government: No cost
  Total cost to local government: $74,400 (one-time cost for refrigeration unit replacement)
  Benefits: $696,600 per year in savings from prevented foodborne illnesses

- Retail food establishments that wish to package juice must treat the juice under a HACCP plan that reduces pathogenic bacteria by 99.999% or label the package as unpasteurized.
  Total cost to industry: Unquantifiable cost
  Total cost to state government: Unquantifiable cost

Total cost to local government: Unquantifiable cost
Benefits: Unquantifiable savings from prevented foodborne illnesses

- Food establishments that wish to perform specialized food processes (specific high-risk practices) will be allowed to seek a variance from the rules. The use of reduced oxygen packaging will not require a variance if the criteria specified in the rules are utilized.
  Total cost to industry: Unquantifiable cost
  Total cost to state government: Unquantifiable cost
  Total cost to local government: Unquantifiable cost
  Benefits: Unquantifiable savings from prevented foodborne illnesses

- Food establishments that wish to serve raw or undercooked foods of animal origin per customer order will be required to advise consumers of the increased risk of foodborne illness.
  Total cost to industry: Unquantifiable cost
  Total cost to state government: Unquantifiable cost
  Total cost to local government: Unquantifiable cost
  Benefits: Unquantifiable savings from prevented foodborne illnesses

- Food establishments will be required to maintain a minimum water temperature of 110°F, as opposed to 130°F, in warewashing sinks while in use or use a detergent specially formulated for water temperatures below 110°F.
  Total cost to industry: Unquantifiable cost
  Total cost to state government: Unquantifiable cost
  Total cost to local government: Unquantifiable cost
  Benefits: 7.7%/day energy reduction for the water heater

Table 1. Summary of Costs and Benefits from the Proposed Rule Changes

Costs	Year 1	Year 2	Year 3	Year 4
Industry	$5,517,400			$855,600
State Government	$400			
Local Government	$1,299,300			$74,400
Unquantifiable Costs	Yes	Yes	Yes	Yes
Total Costs	**$6,817,100**	**$0**	**$0**	**$930,000**
4-year NPV of Costs	**$7,080,614**			
Benefits				
Industry	$182,200	$182,200	$182,200	$182,200
State Government	-	-	-	-
Local Government	$15,800	$15,800	$15,800	$15,800
Public	$1,578,900	$1,578,900	$1,578,900	$1,578,900
Unquantifiable Benefits	Yes	Yes	Yes	Yes
Total Benefits	**$1,776,900**	**$1,776,900**	**$1,776,900**	**$1,776,900**
4-year NPV of Benefits	**$6,018,736**			

*Net Present Value (NPV) is computed using a 7% discount rate.

Note:
Several rules currently in 15A NCAC 18A .2600 will be updated and included with adoption of the 2009 Food Code to ensure the language is consistent with the Code. These rules do not represent a significant change in intent or pose any additional fiscal impact on industry or state and local governments. These rules include:

- *15A NCAC 18A .2666 Temporary Food Establishment and Temporary Food Establishment Commissary Permit Requirements*
- *15A NCAC 18A .2667 Temporary Food Establishment Foodhandling Requirements*
- *15A NCAC 18A .2668 Temporary Food Establishment Employee Requirements*

- *15A NCAC 18A .2669 Temporary Food Establishment Equipment and Utensil Requirements*
- *15A NCAC 18A .2670 Temporary Food Establishment Physical Requirements*
- *15A NCAC 18A .2671 General Requirements for Pushcarts and Mobile Food Units*
- *15A NCAC 18A .2672 Specific Requirements for Pushcarts*
- *15A NCAC 18A .2673 Specific Requirements for Mobile Food Units*
- *15A NCAC 18A .2674 Congregate Nutrition Sites*
- *15A NCAC 18A .2675 Limited Food Establishments*

Although these rules are proposed as *new* rules, they are, in effect, replacing rules that will be repealed. Rules 15A NCAC 18A .2601 through .2645 will be repealed concurrent with the proposed Food Code adoption rules.

Introduction

Background

The Food Protection Program (FPP) of the Environmental Health Section, DPH/NCDHHS, oversees the food protection rules governing 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. The current rules, 15A NCAC 18A .2600, were adopted in 1976 and have been periodically amended to address specific needs. However, changes in consumer consumption patterns, recent emphasis on increased government efficiency, as well as shifts in the national food safety focus necessitate a more fundamental change to North Carolina's retail food protection rules. As a result, the FPP proposes to adopt the U.S. Food and Drug Administration's 2009 Food Code.

The Food Code is the national standard for state, local, and tribal food protection programs and has been adopted by 49 out of 50 states. The Food Code offers practical, science-based guidance that addresses the risk factors known to cause foodborne illness outbreaks in retail food service settings. It 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. Thus, the 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 toward consuming food prepared outside the home.

Purpose

The purpose of adopting the Food Code is to replace what has proven to be a labor-intensive and ineffective process of updating North Carolina's food protection rules with a more efficient and effective method. The legislature recognized that need and passed a law (S.L. 2011-394, Section 15(a)) in 2011 that provides the Department with the authority to adopt the 2009 Food Code by reference. As opposed to proposing new rules (and/or amendments to existing rules) each year, the FPP will have the option of adopting the latest version or adopting new provisions of the Food Code once every four years. Thus, the rulemaking process will be greatly shortened and unnecessary expenditures of staff resources will be prevented. Most importantly, North Carolina's food protection rules will remain consistent with the national standard.

The FPP's adoption of the Food Code has a variety of advantages and has gained support from all stakeholders within the food safety spectrum: industry, consumer groups, academia, regulators, and local, state, and federal agencies. For members of the food service industry, many of which are associated with national chains, the Food Code brings needed uniformity and consistency with the food safety rules of other states. The Food Code also provides effective means of reducing the risks of foodborne illnesses within food service facilities, thus protecting consumers and industry from potentially devastating health consequences and financial losses. In addition, the Food Code offers proven scientific reasons behind each rule and actively seeks input from the scientific and academic community as their understanding of foodborne pathogens increases. Local, state, and federal agencies and regulators support the adoption of the Food Code because it provides a comprehensive approach to food safety management, superior supporting documents and training, and is consistent with the national integrated food safety management system.

Methodology

To ensure that the adoption of the 2009 FDA Food Code received an accurate and thorough vetting process, several methods of review and input were utilized.

- ***Comparison***

  The existing food safety rules (15A NCAC 18A .2600) were carefully compared to criteria within the 2009 Food Code. Differences in the rules were listed and subsequently examined for possible financial impacts on the food service industry, as well as state and local governments.

  For comparisons requiring calculations, the following types and amounts of establishments (from FY 2010-2011) were used:

Table 2. Food establishments in FY 2010-2011

Establishment Type	Total Number of Establishments	Type of Impact
Restaurants	20,714	Industry
Food Stands	5196	Industry
Private School Lunchrooms	200	Industry
Educational Food Service	148	Local Government
Public School Lunchrooms	2306	Local Government
Commissaries for Push Carts and Mobile Units	28	Industry
Institutional Food Service	988	Industry
Meat Markets	1460	Industry
Total Number of Establishments	**31,040**	**28,586 Industry + 2,454 Local Government**

Private industry will be impacted via costs associated with all restaurants, food stands, private school lunchrooms, commissaries, institutional food service facilities (per contracted services), and meat markets. Educational food service establishments and public school lunchrooms are operated by local government and thus will be reflected in local government impacts (both costs and benefits). No establishment type affected by the adoption of the 2009 Food Code is operated by the State of North Carolina and thus no impact will be sustained by state government.

The following is a comparison of the total number of food service establishments during the past five years:

Table 3. Trend in Number of Food Establishments

Fiscal Year	Total Number of Food Service Establishments	Change in Number of Establishments
2006-2007	29,607	
2007-2008	32,103	8%
2008-2009	30,726	-4%
2009-2010	31,074	1%
2010-2011	31,040	-0.1%

Overall, there was an average variation of 3.3% in the total number of active establishments in the past five fiscal years. Therefore, the total number of establishments affected by the proposed rules may vary from year to year depending upon the number of permits issued to new establishments and the number of establishments that discontinue operation.

- ***Stakeholder Input***
  Multiple sources of stakeholder input were utilized. Specific trade associations were incorporated early into the planning process. The North Carolina Restaurant and Lodging Association and the North Carolina Retail Merchants Association, the two largest trade associations representing food service establishments, were instrumental in helping craft a practical model for Food Code adoption in North Carolina.

  Transition teams were also developed using stakeholders from industry, local health departments, state agencies, and federal agencies to examine the various aspects of Food Code adoption in North Carolina. During this period, stakeholders were asked to not only contribute to specific tasks involving transition issues but to also contribute their professional and organizational concerns with the potential effects that the adoption may have on their particular market or professional niche.

- ***Industry Survey***
  An industry survey was developed as a means to assess the current state of practice of food establishments with respect to additional requirements that adoption of the 2009 Food Code entails. Several potential areas of change for operators were identified and addressed in the survey, including employee health, manager food safety training, no bare-hand contact of food items, specialized food processes, lower cold-holding temperature requirements, date-marking of food items, and the serving of raw and undercooked food items.

  Participants in the survey (restaurants and food stands) were identified by means of email addresses within the North Carolina establishment database maintained by the Inspections, Statistics, and Fees section of the Environmental Health Services Branch. Email requests were sent to a total of 1,624 operators asking them to visit a web link where the survey questions were maintained on a SurveyMonkey® website. The survey remained open for approximately five weeks during which 391 surveys were initiated and 277 of those surveys were completed before the survey portal was closed and data collected. See Appendix 2 for survey results. Overall, the percent of completed surveys represent 0.9% of the total number of food service establishments within North Carolina. Therefore, the costs and benefits assigned to the results of the survey may not be indicative of all establishments.

- **Commission of Public Health Input**
  In May 2011, three members from the Commission for Public Health (Dr. Theodore Mayer, Dr. Claudia Berryhill, and Mr. Ted Rhodes) volunteered to serve on a subcommittee to meet with the Department and follow the progress of Food Code adoption. The subcommittee met with the Department and members of the Transition Team on August 17, 2011. An overview of the process and plans for Food Code adoption were discussed during the meeting and received a favorable response from the subcommittee members. The subcommittee recommended that an overview of the rules, manual, fiscal note, and related plans be provided during the February 15, 2012, CPH meeting. A meeting has been planned with the subcommittee on February 13, 2012, to discuss strategy for the CPH meeting.

Findings

Conclusions regarding the fiscal impact on industry and state/local governments were drawn using the information gathered by the methods described above supplemented with specific research on costs and benefits.

Training Costs

Industry Impact

The first year of Food Code implementation will be a “transition period” in which local authorized health department environmental health staff will provide an in-service training to industry managers/supervisors during each establishment’s initial routine inspection. During the inspection, staff will review the changes in compliance expectations and the inspection process and supply the establishment with educational materials. In addition, points may not be

taken for non-compliant practices associated with the new Food Code requirements; rather, training will be given on the proper methods of compliance.

The FPP estimates that this type of "one-on-one training" will take approximately one hour longer per establishment than a regular inspection under the current rules. 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.

The total cost for industry training is:

Estimated hours needed for training per establishment:	1 hour
Total number of industry establishments:	28,586
Total hours needed for Food Code implementation training:	28,586 hours
Average cost per hour:	$16.49
Total industry impact for Food Code training (approx.):	**$471,400**

State Government Impact

The impact on state and local governments for the implementation of the 2009 FDA Food Code consists largely of the costs of training. The FPP offers training to local health department environmental health personnel as part of its agency mission. In preparing for the adoption of the Food Code, the FPP will prioritize its allotted training time primarily on the implementation of the Food Code. Thus, the costs associated with training are in the form of opportunity costs of government employees' time since training session would have still taken place, but focused on a different topic if it were not for the new rules. The Division estimates that about 20 hours will be spent training local health department personnel, which translates to more than $400 of opportunity costs (assuming a state employee hourly wage of $21.12). This estimate does not take into account the amount of time that state employees would need to prepare for the training. The FPP will provide the training cost-free to local health department staff. The FPP considers no new state budgetary costs to be associated with its reallocation of resources.

Local Government Impact

Establishments Operated by Local Governments

Establishments operated by local government (i.e. educational food service establishments and public school lunchrooms) will receive the same in-service training as industry from local authorized health department environmental health staff. Thus, the training time is the same (1 hour). For the purpose of this analysis, the same average wage of a first line supervisor in a full-service restaurant will also be used ($16.49).

The local government impact for establishments receiving Food Code training will be:

Estimated hours needed for training per establishment:	1 hour
Total number of local government establishments:	2,454
Total hours needed for Food Code implementation training:	2,454 hours
Average cost per hour:	$16.49
Total training impact for establishments operated by local government (approx.):	**$40,500**

Local Government Staff

Local health department environmental health staff authorized to enforce the Food Code will be required to attend the training. Thus, there may be some opportunity costs associated with attending the training. The FPP will train local health department personnel on the specific changes the adoption will bring, proper inspection methods, rule interpretations, and inspection marking instructions. 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 Food Code training will be approved training per the Board and will count toward their educational requirements. Based on 2012 local government salary information for Environmental Health Specialists, the hourly wage rate is on average $20.48.

The cost for local government officials receiving training from state government on the Food Code is:

Estimated hours needed for training per authorized agent:	20 hours
Total number of authorized agents in NC (excluding state staff):	450 agents (per EHS Education & Training Program)
Total hours needed for Food Code implementation training:	9,000 hours
Average cost per hour:	$20.48
Total local government impact for *receiving* Food Code training:	**$184,300 (onetime cost)**

Local authorized health department environmental health staff will be responsible for providing an in-service training to industry managers/supervisors during each establishment's routine inspection (see industry impact above). During the inspection, staff will review the changes in compliance expectations and the inspection process and supply the establishment with educational materials. In addition, points may not be taken for non-compliant practices associated with the new Food Code requirements; rather, training will be given on the proper methods of compliance.

The FPP estimates that this type of "one-on-one training" will take approximately one hour per establishment.

The total cost for industry training is:

Estimated hours needed for training per establishment:	1 hour
Total number of industry & local government establishments:	31,040
Total hours needed for Food Code implementation training:	31,040 hours
Average cost per hour:	$20.48
Total local government impact for *giving* Food Code training:	**$635,700**

The total impact for local government associated with Food Code training is: **$860,500**
(includes training for establishments operated by local government, training for local environmental health staff, and training given by local environmental health staff)

Implementation Costs by Rule
The following information is a summary, by chapter, of the differences between the 2009 Food Code and 15A NCAC 18A .2600 with the anticipated fiscal impact. Overall, non-compliance with these new requirements would result in a pre-determined point deduction (per requirement) from the environmental health score of the establishment. In extreme cases, the cumulative amount of point deductions may result in a drop in the letter grade (e.g. from an "A" to a "B"). Though some establishment owners may equate a drop in establishment letter grade to undesirable public perception that leads to a reduction in business, there is no evidence to support this claim.

<u>Chapter 1: Purpose and Definitions</u>

- ***1-201.10 (b)-Potentially Hazardous Food***

  Description: The definition of "potentially hazardous food" will change significantly, affecting the types of food that will be subject to regulation. The change is seen as beneficial to industry by allowing more foods to be exempt from time/temperatures controls.

  Conclusion: No cost to industry; training costs for state/local government (see training costs)
  Benefits: Unquantifiable cost savings for industry and local governments by allowing certain foods to be exempt from time/temperature requirements

Within North Carolina's current food protection rules, 15A NCAC 18A .2601 (22) provides a very general definition for a "potentially hazardous food" or PHF. The definition is very restrictive in identifying those food items which may support the growth of microorganisms or the formation of toxins. As the current rule reads, any food item which falls outside of the pH or water activity (Aw) restrictions (pH>4.6 and/or Aw>0.85) must be handled using time and temperature control to minimize microorganism growth or toxin formation. Operators must monitor these food items closely for internal temperature and/or time being displayed or held for service to the customer. Potentially hazardous foods which fall outside of these required holding parameters must be discarded and cannot be served to customers. This is an ongoing expense for industry where food items are held hot, cold, or for display before being served to customers, and this narrow definition may cause operators to unnecessarily discard food which is actually safe to serve the consumer.

The definition for a PHF within the 2009 FDA Food Code (1-201.10 (b)) is very specific as it relates to Time and/or Temperature Control for Safety (or TCS). Under the Food Code definition, a TCS food item is not broadly categorized as any food item which has pH and water activity outside of the limits described in the current NC rule, but instead, TCS foods are divided into a hierarchy of both packaged and unpackaged foods, as well as pH and Aw levels. Additionally, the new definition takes into account the "hurdle" effect – the ability for several inhibitory factors to work together to control or eliminate pathogen growth, when they would otherwise be ineffective if used alone. For instance, a food product that may be considered potentially hazardous by the current definition due to its pH level could now be considered non-potentially hazardous if the water activity value is such that it creates a "hurdle" too large for pathogenic growth to take place when combined with the pH value. Thus, the new definition allows for more foods to be classified as "non-potentially hazardous" and therefore be exempt from time/temperature controls.

Food service establishments will also have a new option available for foods that meet the definition of potentially hazardous food: a product assessment. *Product Assessment Required*, or PA designation, allows individual food items which fall into the PHF category under the current NC rules to be evaluated, at the request and the expense of the food service operators, for the ability to support the growth of pathogenic organisms and toxin formation. This ability alone is a significant advantage for industry as it allows food service operators more latitude by which they can address the safety of certain foods.

The definition within the Food Code also specifies criteria for the handling of eggs, hermetically packaged and sealed foods, and special food preparation processes such as Reduced Oxygen Packaging (ROP). Addressing these additional food-handling categories in the definition will also allow food service operators to store and display these items outside of the strict time/temperature control which is required under the current NC rules. Additional cost savings will result from fewer foods being discarded as well as realized savings from equipment operation of both hot and cold holding of foods. This new definition is a benefit to industry with respect to both costs and operations. The Division does not have enough information to be able to estimate this benefit.

Note: Training costs associated with Food Code implementation is reflected in the "Training Costs" section.

Uncertainties: The process required for product assessment may vary in costs. An establishment that wishes to prove that a particular food item does not meet the definition of a potentially hazardous food must hire a certified laboratory (e.g. Silliker Laboratories) to conduct routine challenge studies to determine the pH and/or water activity of the food in question. The cost associated with the studies may vary according to the type of product. However, an establishment is not *required* to conduct the studies. Acceptance of the PHF designation and adherence to the time/temperature requirements will meet the requirements of the rules. In addition, there is no aspect of the new definition for potentially hazardous food that is more restrictive than the definition in the current rules.

Chapter 2: Management and Personnel

- ***2-102.11: Demonstration of Knowledge***

Description: Each food establishment will be required to demonstrate knowledge of food protection by passing an American National Standards Institute (ANSI)-accredited exam.

Conclusion: Total cost to industry: $4,496,000; Total Cost to local government: $391,000; training costs for state/local government (see training costs)

Benefits: Unquantifiable benefits result from increased compliance with proper food safety practices that result in the prevention of foodborne illnesses.

The Food Code requires the person in charge (i.e., the owner, operator, or manager at the time of inspection) to demonstrate knowledge of foodborne disease prevention, Hazard Analysis Critical Control Point (HACCP) principles, and the requirements of the Code. The rule language proposed by the FPP will require knowledge to be demonstrated by being a certified food protection manager who has shown proficiency of the required information through passing a test that is part of an accredited program. If knowledge cannot be demonstrated during the inspection, a violation is noted and points are deducted from the establishment's final environmental health score.

This requirement differs from the criteria within the current rules. Rule 15A NCAC 18A .2606(b) allows a two-point *credit* on the establishment's environmental health score if a manager or other employee responsible for operation of that establishment (and who is employed full time in that particular establishment) has successfully completed in the past three years a food service sanitation program approved by the Department. Therefore, demonstration of knowledge is not required; it is *voluntary*. However, food service sanitation programs approved by the Department must meet strict requirements, such as 12 hour minimum classroom contact time with detailed subject matter criteria. Classes are typically offered via local health departments and/or local cooperative extension programs over the course of 4-6 different days. No on-line classes or other distance education allowances are made, often making it difficult for food service owners and operators to leave their businesses long enough to attend the classes. There is typically a registration fee per person ($125 average), which covers the cost of educational materials and testing supplies provided for the class. The registrant must attend all sessions in order to complete the course.

Although a demonstration of knowledge will be required in the proposed rules (as opposed to voluntary) and a 2-point deduction will be taken from the environmental health score (as opposed to added), the ability to obtain food safety training will be markedly easier. The requirement in the proposed rules allows knowledge to be demonstrated by simply passing an exam that is part of an ANSI-accredited program. A minimum number of classroom training hours will not be required. Online training will be allowed. Simply by passing an accredited exam, the establishment can demonstrate knowledge and meet the requirements and no points will be deducted from the establishment's final score. In this manner, both industry and consumers will benefit. Industry will have a variety of options available in which to gain food safety knowledge and consumers will benefit by increased proficiency in food safety knowledge being practiced within all complying food establishments.

Currently, there are three programs and associated exams that meet ANSI accreditation standards:

- ServSafe (National Restaurant Association)
- Thomson Prometric
- National Registry of Food Safety Professionals

Each of these programs offers food safety certification programs in a variety of ways, including classroom training and online training. The exams may also be purchased without participating in the training. Listed below are cost examples of exams (per student) supplied by each program's website:

- ServSafe (National Restaurant Association)
  - Certification On-Line Exam Voucher: $36
- Thomson Prometric:
  - Exam: $28
- National Registry of Food Safety Professionals
  - Food Safety Certification Exam Voucher: $60
    (exam voucher is for online training and exam)

The average cost of the three exams is:

($36 + $28 + $60 = $124)/3 = **$41.33 (rounded to $41)**

To derive the average cost associated with this requirement, training costs have been included with the cost of the exam. Although training is not required by the proposed rules, we understand the necessity to have training in order for a food establishment to successfully pass the exam. Therefore, we sought input from industry regarding average anticipated training costs associated with this proposed rule and also utilized average training rates charged by local health departments.

Two of our industry partners-Food Lion/Delhaize and Harris Teeter-offered the following estimations of their training costs. Each of these establishments provide food safety education to their employees via in-service training.

Harris Teeter
Wages: $17 average hourly rate x 8 hrs = $136
Travel: Avg 1 hr drive time x $17 hourly rate = $17
60 miles x 0.55 = $33
Training materials: $32 each book
No Lodging/Meals
No cost for meeting room
Total estimated cost = $218/person

Food Lion
$12/hr. avg. wage per employee
X 10 hours of Training
Total estimated cost = $120/person

Local health departments, often in conjunction with local cooperative extension programs, currently offer ServSafe training as part of its educational offerings to industry. The average cost to industry is $125 per person, which includes the cost of the manual and exam. Instruction time and staffing costs are offered free of charge. This training is not a new cost and is not reflected in the local government impact.

Local Health Department Training
$125 (avg. cost statewide) adjusted for cost of exam included with this fee:
$125 - $41 (avg. cost of exam)

Total estimated cost less exam fee= $84/person

Based on the data collected, the average training cost (excluding the cost of the actual exam) is about:

($218 + $120 + $84) /3= **$140/person**

Considering the information above, the costs associated with the new Demonstration of Knowledge requirement is as follows:

Total Cost per Person
$140 (avg. training cost) + $41 (avg. cost for exam) = **$181.00/person**

As mentioned above, the current rule 15A NCAC 18A .2606(b) allows a two-point credit on the establishment's environmental health score if a manager or other employee responsible for operation of that establishment (and who is employed full time in that particular establishment) has voluntarily completed a food service sanitation program approved by the Department in the past three years.

According to Inspections, Statistics, and Fees data, 21,908 out of 31,040 food service facilities (70.6%) eligible to receive the two-point bonus (including restaurants, food stands, private school cafeterias, educational food service, public school cafeterias, commissaries, institutional food service, and meat markets) have completed the food safety certification training and have received the two-point bonus. Therefore, only the remaining facilities that have **not** elected to receive the training would find the new Demonstration of Knowledge requirement to be a *new* cost.

The Food Code requires a person in charge during all hours of operation (except when food is not being prepared and served) to be certified; therefore, assuming each establishment must have 3 persons in charge (morning and evening shift plus one back-up) and about 9,000 facilities must have certified food protection managers, then a total of 27,000 persons would need to meet this requirement.

Therefore, a cost subtotal is:

Number of Persons to be certified:	27,000
Average cost of exam and training:	x $181.00
Total cost for 5 year period:	**$4,887,000**

The total costs to meet the requirement can be further divided by establishment type, and thus by industry and local government impact:

$4,496,000	Industry Cost (restaurants, food stands, private school lunchrooms, commissaries, meat markets, and institutional kitchens)
+ $391,000	Local Government Cost (educational food service facilities and public school lunchrooms)
$4,887,000	**Total Cost**

The current rules allow the 2-point bonus for a 3-year period from the certification date. The proposed standards will allow the food safety certification to remain valid for five years per the ANSI standard. Therefore, some cost savings will occur by adding two years to the certification length. For instance, in a 15-year period, an establishment would need to renew a certification 5 times within the criteria of the current rules while only 3 times within the criteria of the proposed rules. Thus, a savings is achieved every 15 years. Assuming that under the current rules about 21,900 establishments would have gotten training and assuming all 31,040 would obtain

a certificate under the new rules, that savings over 15-years would be almost $3 million, which would be about $198,000 in annualized savings.

Noncompliance with this proposed rule will only result in a two-point deduction from the establishment's Environmental Health score. Some establishments may choose not to comply with the Demonstration of Knowledge requirement and instead elect to accept the two-point deduction.

There are obvious benefits that cannot be accurately calculated. Pilling et al. (2008) conducted a study that revealed food safety training increased employees' compliance with important food safety behaviors, including handwashing, use of thermometers, and proper handling of food and work surfaces. In another study, Kneller and Bierma (1990) found statistically significant improvements in total inspection scores.

Certification also reduced the number of critical violations. The FDA recently released results of a 10-year study of retail food risk factors which noted that the presence of a certified food protection manager on-site correlates with significantly higher compliance levels with food safety practices. Full-service restaurants with certified food protection managers had a 70% compliance rate with food safety practices, compared with a 58% compliance rate at restaurants without one. This would also result in decreased costs to local health departments who would not have as many follow-up visits to ensure critical violations have been corrected.

Uncertainties
Several factors could cause the cost of the new Demonstration of Knowledge requirement to vary. Fluctuations in the number of establishments or in the costs associated with travel, salaries, and materials could affect the training costs. Fluctuations in the exam fee could affect the overall costs. An establishment's training policies could also require more than the minimum number of employees as required in the rules to be certified food safety managers. Also, the estimates in this section are based on the assumption of 100% compliance, and they could overestimate the impact since establishments could choose not to comply and risk incurring the 2 point sanitation score deduction. Assuming only 75% compliance, the cost estimate could be about a million less and the annualized savings about 50,000 less than estimated (all other things equal).

- ***2-201.11 Responsibility of Permit Holder, Person in Charge, and Conditional Employees***
  2-201.12 Exclusions and Restrictions
  2-201.13 Removal, Adjustment, or Retention of Exclusions and Restrictions

Description: Each food establishment will be required to develop and adhere to an Employee Health Policy.

Conclusion: Total cost to industry: $550,000; Total Cost to local government: $47,800; training costs for state/local government (see training costs)

Benefits: $478,160 per year in savings from prevented foodborne illnesses

Chapter 2, subpart 201 of the 2009 Food Code requires permit holders to develop an Employee Health Policy that addresses employee health and diseases transmissible by food for the purpose of preventing foodborne illnesses. Within the Employee Health Policy, criteria must be specified that requires employees and conditional employees to report any diagnosis or exposure to norovirus, Hepatitis A virus, *Shigella* spp., Enterohemorrehagic or Shiga-toxin producing Escherichia coli, or *Salmonella* Typhi as well as certain symptoms, including vomiting, diarrhea, jaundice, sore throat with fever, and lesions containing pus on parts of the body that can come in contact with food. Based upon the exposure risk, the person in charge must either exclude the employee from the establishment or restrict the employee from working with food. The level of exclusion and restriction is based upon a tiered structure specified within the Code.

A study released by the Pew Charitable Trusts on March 3, 2010, estimates the costs of foodborne illnesses in the United States to be $152 billion per year. This study based the estimate on the costs of acute foodborne illnesses and a few long-term health-related costs. However, other factors, including economic losses to the food service industry due to tarnished reputations after foodborne illness outbreaks, were not included in the study (Scharff, 2010). Unfortunately, these factors can ruin a business. In fact, the National Restaurant Association has estimated that the average cost of a foodborne outbreak to an establishment is about $75,000 (Fraser, 2006).

An Employee Health Policy protects the food service industry by establishing procedures that prevent the risk of foodborne illness outbreaks. It ensures that the manager/operator can recognize the symptoms of specific foodborne illnesses and takes appropriate measures to prevent ill employees from handling food by either restricting them to non-food tasks within the establishment or excluding them from the establishment altogether, based upon the severity of their illness. It also establishes criteria by which the employee can re-enter the workplace after the illness subsides.

According to the industry survey, 92% of respondents currently monitor employees for illnesses and 61% of respondents currently have a policy in place detailing specific actions to enact based upon symptoms. Data gathered from the Inspections, Statistics, and Fees program within the Environmental Health Section/DPH/NCDHHS estimates a minimum of 12,914 chain establishments within North Carolina that also have establishments in states where the Food Code is the food safety standard. This is significant because these chains have already developed an Employee Health Policy in order to meet the requirements within those states. The Employee Health Policy is part of the chain's standard operating procedures and can also be used to meet the requirement in North Carolina.

There is minimal cost to industry or state/local government associated with developing an Employee Health Policy or enacting the requirements contained within. The Food Code has detailed information on the criteria and the supporting public health reasons. Additionally, FDA has provided the Employee Health and Personal Hygiene Handbook (found at http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm113827.htm) that can be used by the food service industry to address employee health issues. The Handbook provides templates that can be used for guidance in developing an Employee Health Policy. Local health Departments, the FPP, and FDA consultants are also available to assist industry for no additional cost. Further, the Employee Health Policy can be written or oral.

The FPP estimates that the development of a policy will require (at most) two hours of preparation time per policy. The FPP assumes that the establishment manager or supervisor will prepare the employee health policy. According to the U.S. Department of Labor, Bureau of Labor and Statistics, the average hourly wage of a first line supervisor in a full-service restaurant is $16.49. The total cost per employee health policy is:

$16.49/hour X 2 hours = $32.98 per employee health policy
31,040 establishments – 12,914 number of chain establishments =
18,126 number of establishments that must develop an Employee Health Policy

18,126 X $32.98 = about **$597,800 total estimated one-time cost**

The total costs to meet the requirement can be further divided by establishment type, and thus by industry and local government impact:

$550,000	Industry Cost (restaurants, food stands, private school lunchrooms, commissaries, meat markets, and institutional kitchens)
+ $47,800	Local Government Cost (educational food service facilities and public school lunchrooms)
$597,800	**Total Cost**

Note: Training costs associated with Food Code implementation is reflected in the "Training Costs" section.
Benefits
By requiring each food establishment to have an Employee Health policy, the FPP seeks to reduce the likelihood that certain viral and bacterial agents will be transmitted from infected food workers into food. Although a minimal amount of time and training may be necessary to ensure managers and food workers are aware of the requirements, the potential benefits attributed to the prevention of foodborne illness outbreaks far outweigh any negligible costs.

While there is data on the cost savings of preventing foodborne illnesses (see section on Preventing Contamination from Hands), there is no data estimating the percentage of cases that originate due to unsanitary practices in food service establishments, although it is generally assumed that it plays a significant role. It is difficult for the Division to estimate how many cases can actually be prevented from having an Employee Health Policy since there is no way to guarantee that the policy is followed at all times. The Division attempts to estimate the potential benefits of both having an Employee Health Policy and preventing contamination from hands in the following section. Given the size of potential heath cost savings, the benefits are expected to surpass the cost necessary to develop the policy.

Uncertainties
Several factors may affect the total cost of developing an employee health policy. One assumption made in the total cost calculation is that every establishment will need to produce a new policy. However, that is not the case. Chain establishments with locations in states using Food Code criteria will already have an employee health policy. The same policy can be used in North Carolina to meet the criteria of the rules. Also, there are a number of other establishments that already have a written or oral policy in place, so the costs presented above might be overestimated. Another factor that could affect the cost is the time estimated to develop a policy. The materials and resources available through the FPP and USFDA may reduce the time used in the cost estimation. Two important costs that are not presented above because of lack of data are the lost wages sick employees might experience as a result of the policy or the loss in revenue if the establishment loses business due to being short-staffed when an employee is sick. These costs can be significant when aggregated for all establishments.

- ***3-301.11 Preventing Contamination from Hands***

Description: *Food establishments will be required to refrain from handling exposed, ready-to-eat foods with bare hands.*

Conclusion: Unquantifiable cost to industry; training costs for state/local government (see Training Costs section)

Benefits: $882,300 per year in savings from prevented foodborne illnesses

Although handwashing is a cornerstone of proper employee hygiene, it is not enough to prevent the transmission of pathogens that cause foodborne illnesses. Employees infected with fecal-oral pathogens can shed viral and protozoan particles in their feces at levels up to 10^8 viral particles or oocysts per gram of feces (in the case of norovirus and hepatitis A). Because these pathogens have a low infectious dose (i.e. 10 or fewer viral particles or oocysts for norovirus and hepatitis A respectively), handwashing alone will not reduce the bacterial load to safe levels.

In 1999, the National Advisory Committee on Microbiological Criteria for Foods concluded that three factors must work together to effectively prevent the transmission of foodborne illnesses transmitted via the fecal-oral route: handwashing, an Employee Health Policy that prohibits ill employees from handling food, and no bare

hand contact with ready-to-eat foods. These three factors must work in unison to break the path of transmission as none of these three factors will prevent fecal-oral transmission alone.

North Carolina's current food safety rules (15A NCAC 18A .2600) requires all employees of food establishments to wash their hands thoroughly prior to working with food. Together with the Employee Health Policy requirement proposed within 2-201, the criteria within *3-301.11 Preventing Contamination from Hands* will effectively establish the three factors needed to prevent the transmission of fecal-oral pathogens to consumers of food establishments.

In 3-301.11, the Food Code prohibits food employees from contacting exposed, ready-to-eat food with their bare hands, except when washing fruits and vegetables. Foodborne illnesses can be prevented by simply using alternate means, such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment. The cost of gloves may be the sole cost associated with 3-301.11, although gloves are not required. Some establishments may wish to use gloves due to the nature of their business, as evidenced by many establishments already using gloves in their routine operations.

The FPP does not anticipate that the criteria within 3-301.11 will pose any fiscal impact on industry. According to the industry survey, 78% of respondents currently do not allow employees to use bare hand contact on exposed, ready-to-eat food items. For the remaining 22%, implements available within the establishment could easily meet the requirements (e.g. deli paper, sanitized utensils) for a small cost per establishment.

Note: training costs associated with Food Code implementation is reflected in the "Training Costs" section.

Benefits

As with the employee health policy requirement, the benefit of restricting bare hand contact with ready-to-eat foods is the prevention of foodborne illnesses. Scharff (2012) provides data detailing the cost per case of foodborne illness by pathogen, including the total costs associated with medical care, productivity loss of the caregiver and ill person, effect on quality of life, and death. To accurately calculate the cost for North Carolina, the average number of cases reported annually from 2008-2011 for the top foodborne fecal-oral pathogens were obtained from the Division of Public Health's database of reportable diseases.

Table 5. Costs Related to Foodborne Illnesses in NC

Pathogen	Number of Cases in NC (avg. 2008-2011)	Cost per Case*	Cost per Year Sub-Total	Additional Cost per Death	Sub-Total Cost for Death Cases**	Total Cost in NC per Year
Hepatitis A virus	187	$5,187	$969,969	$32,814	$65,628	$1,035,597
***Shigella* spp.**	307	$9,548	2,931,236	$558	$1,674	$2,932,910
Shiga-toxin producing Escerichia coli (STEC) 0157:H7	145	$2,349	$340,605	$8,097	$8,097	$348,702
***Salmonella* Typhi**	2286	12,421	$28,394,406	$2,697	$62,031	$28,456,437
Norovirus	19,000***	$595	$11,305,000	$200	$38,000	$11,343,000
Total						**$44,116,646**

* Cost per case includes cost of medical care, loss of productivity of the ill person and caregiver, and quality of life loss

** Cost per death assumes 1% of cases in NC result in death

*** The Division of Public health estimates 1,900,000 cases of norovirus per year. If 1% is attributed to food service establishment transmission, then the total number of cases in NC is 19,000.

As stated in the section above, there is no data available that states how many foodborne illness cases can be traced to not having or following an Employee Health Policy and not observing procedures for preventing contamination from hands. If the assumption is made, however, that the implementation of a policy and of a no

bare hand contact with ready-to-eat foods reduces the number of cases by about 2%, then the total cost savings from the two new requirements would be **(approx.): $882,300 per year**

Uncertainties
A number of factors could affect the costs of implementing a no bare hand contact with ready-to-eat foods requirement. Although no-cost alternatives are available, some establishments may wish to purchase gloves and/or deli paper to avoid handling food with bare hands and this could create of cost of a couple hundred dollars per establishment per year. Also, given the lack of data to more accurately estimate the percent of foodborne illness cases that could be prevented by better employee hygiene, the cost savings can vary greatly from tens of thousands to millions.

- ***3-402.11 Parasite Destruction***

Description: Food establishments that serve raw-marinated, or marinated and partially cooked fish must ensure destruction of naturally-occurring parasites prior to serving.

Conclusion: No cost to industry; training costs for state/local government (see Training Costs section)

Fish eaten raw, undercooked, raw-marinated, or marinated and partially cooked may present a threat for foodborne illnesses associated with naturally-occurring parasites that would normally be eliminated through proper cooking. For this reason, 3-402.11 of the Food Code requires the fish to be frozen prior to service to ensure it is parasite-free. The exception is molluscan shellfish, certain species of tuna that are naturally parasite-free, fish eggs, and fish raised in specific aquaculture environments.

Food establishments that serve raw, undercooked, raw-marinated, or marinated and partially cooked fish can ensure parasite destruction in one of two ways: freeze the fish themselves according to the parameters listed within 3-402.11 or receive certified parasite-free fish from their supplier.

To freeze the fish themselves, the establishment must provide a dedicated freezer capable of sustaining the fish:

- Frozen and stored at a temperature of -20^0 C (-4^0 F) or below for a minimum of 168 hours (7 days) in a freezer;
- Frozen at -35°C (-31°F) or below until solid and stored at -35°C (-31°F) or below for a minimum of 15 hours; or
- Frozen at -35°C (-31°F) or below until solid and stored at -20°C (-4°F) or below for a minimum of 24 hours.

The freezer must also have a thermometer capable of recording the temperature of the freezer as a means of ensuring the time and temperature parameters have been met. Typically, the costs associated with maintaining a freezer strictly for the destruction of parasites is prohibitive for most establishments.

The alternative is to receive fish intended to be served raw, undercooked, raw-marinated, or marinated and partially cooked from the supplier already parasite-free. A certification or, *Letter of Guarantee*, routinely accompanies fish intended for these purposes and will serve to meet the requirements of 3-402.11. According to the industry survey, 100% of establishments that serve raw seafood ensure parasite destruction by obtaining certification from the supplier. Thus, no cost is estimated to be incurred by the establishment to ensure that the fish are parasite-free since certificate can be provided by suppliers at no cost.

Note: Training costs associated with Food Code implementation is reflected in the “Training Costs” section.

Benefits: Unquantifiable savings from prevented foodborne illnesses

- ***3-501.16 Potentially Hazardous Food (Time/Temperature Control for Safety Food), Hot and Cold Holding***
  3-501.17 Ready-to-Eat, Potentially Hazardous Food (Time/Temperature for Safety Food), Date Marking

  Description: Food establishments will be required to decrease the refrigerated cold-holding temperature for potentially hazardous foods from 45˚ to 41˚ Fahrenheit and date-mark opened, ready-to-eat food for a maximum shelf life up to 7 days.

  Conclusion: The adoption of the 2009 Food Code will allow a three-year phase-in period after which all refrigeration units must meet the new cold-holding standard of 41°F. Since all refrigeration units manufactured after 1999 will meet the new cold-holding temperature requirement (per NSF/ANSI standards), and the life expectancy of reach-in units is 10-12 years, all establishments are expected to be in compliance by attrition. The use of 41°F for cold-holding food will also extend the safe shelf life of ready-to-eat foods and greatly reduce health costs associated with Listeriosis illnesses.

  Total cost to industry: Total cost to industry: $855,600; Total cost to local government: $74,400; training costs for state/local government (see Training Costs section)

  Benefits: $932,067 per year in savings from prevented foodborne illnesses

  41°F Cold-Holding Temperature
  The 2009 Food Code requires the cold-holding temperature for food that is time/temperature controlled for safety to be 41˚F or less. This differs from 15A NCAC 18A .2600 in that the current cold-holding requirement is 45˚F or less. By lowering the requirement by 4˚F, the occurrence of foodborne illnesses originating from *Listeria monocytogenes* can be greatly reduced.

  Originally, the 4˚F reduction in the cold-holding temperature requirement was thought to possibly produce an economic burden on the food service industry due to the inability of older refrigeration units to meet the reduction threshold, thus requiring the purchase of new equipment. However, research has proven that the need for new refrigeration equipment may be necessary in only rare circumstances.

  As the national food safety standard, the Food Code lowered the cold-holding temperature from 45°F to 41°F in 1993. To allay concerns that many existing refrigerators in food establishments would not be capable of maintaining food at that temperature, the 1997 Food Code allowed a 5-year phase-in period for the 41°F requirement to allow upgrading of existing equipment. During this period, establishments that could not meet the 41°F requirement were allowed to use a 45°F cold-holding temperature in conjunction with a shortened shelf life (4 days).

  According to the National Sanitation Foundation (NSF), most refrigerated storage units have been designed to achieve a 40°F holding temperature since 1966. In response to the 1993 USFDA Food Code standard, NSF/ANSI revised Standard 7 of their equipment manufacturing standards in 1997 and again in 1999 to ensure that all equipment conforming to the Standard, including open-top display cases, could achieve the desired performance. Since the majority of states use the Food Code as their food safety standard and use NSF/ANSI as their equipment standards, the refrigeration manufacturing industry changed their design standards to ensure that refrigeration units could meet the 41°F standard. Thus, any refrigeration equipment replaced since 1999 is designed to meet the 41°F standard.

  However, to ensure that establishments with older units will have adequate time to replace under-performing units, the proposed rule will allow a similar phase-in period of 3 years for equipment upgrades in North Carolina.

The FPP does not expect many establishments in North Carolina to need the phase-in period. The industry survey results show that, only 6.5% of respondents stated that their refrigeration units were older than 15 years.

A survey of local refrigeration companies revealed an average life expectancy of reach-in units of approximately 10-12 years. Thus, any unit purchased since 1999 would meet the 41°F standard and should not require replacement based solely on the new requirements. Walk-in coolers have a longer life expectancy.

Some establishments would experience higher energy bill costs related to decreasing the cold-holding temperature to 41°F. It is difficult to estimate the additional costs given that they will depend on the type and size of refrigerator. Data collected during the industry survey revealed that 76.2% of current refrigeration units were already holding food at 41°F or less.

Uncertainties
Due to the limitations of the industry survey, an accurate number of establishments with refrigeration units incapable of achieving the 41°F standard cannot be calculated. However, if an assumption is made that 1% of establishments will be required to replace 1 unit after the 3-year phase-in period, then the following costs can be expected:

> 310 units X $,3000 avg. price/unit = **$930,000** (One-time cost for refrigeration unit replacement, assumed to be incurred in year 4.)

The total costs to meet the requirement can be further divided by establishment type, and thus by industry and local government impact:

$855,600	Industry Cost (restaurants, food stands, private school lunchrooms, commissaries, meat markets, and institutional kitchens)
+ $74,400	Local Government Cost (educational food service facilities and public school lunchrooms)
$930,000	**Total Cost**

Date-Marking
Section 3-501.17 will require establishments to mark prepared ready-to-eat foods and opened, ready-to-eat packaged foods with a date that reflects a maximum of 7 days from the date prepared or opened, respectfully. After the 7 days are up, any remaining food must be discarded due to concerns with *Listeria monocytogenes* growth. According to the industry survey, 80.9% of the respondents already use a date-marking system. Only 1.4% of those that currently use date-marking hold their ready-to-eat foods more than the maximum amount of time that 3-501.17 will allow (7 days).

An establishment may use any number of means to mark the food as long as the system employed meets the criteria within 3-501.17, including calendar dates, days of the week, color-coded marks, or other effective marking methods, provided that the marking system is disclosed to the regulatory authority upon request. Therefore, the costs associated with marking are expected to be minimal.

Some establishments that do not use date-marking (could be as many as 6,000 establishments, based on the survey results) and establishment that do use it but do not discard items after 7 days (could be about 350 establishments) might experience costs related to discarding food sooner than they would otherwise. Given the unknowns, it is impossible for the Division to estimate the value of those discarded food items.

Note: Training costs associated with Food Code implementation is reflected in the “Training Costs” section.

Economic Benefits

Reduced Food Costs
The safe shelf life of ready-to-eat foods is extended from 4 days to 7 days when held at 41°F or less. These three extra days can benefit industry economically by allowing opened packages of deli meats, sauces, soups, and other ready-to-eat foods to continue to be used and by reducing the frequency of deliveries needed to maintain fresh food stocks.

Health Cost Savings
Listeria monocytogenes (Lm), is the causative agent for Listeriosis, a virulent foodborne pathogen that leads to death in 20-30% of clinical infections. As such, it is the leading cause of death among foodborne bacterial pathogens. The disease primarily affects older adults, pregnant women, newborns, and adults with weakened immune systems. However, rarely, persons without these risk factors can also be affected. Infections during pregnancy can lead to miscarriage, stillbirth, premature delivery, or life-threatening infection of the newborn. The risk may be reduced by recommendations for safe food preparation, consumption, and storage. Therefore, the control of Lm in retail food establishments is crucial for the protection of public health and the food service industry.

The growth of Lm is affected by the interplay of both time and temperature. When ready-to-eat foods are stored at higher temperature, the shelf life is reduced. Likewise, when the storage temperature is lowered, the shelf life is lengthened. For example, ready-to-eat foods stored at 45°F can be safely consumed for up to 4 days. However, ready-to eat foods stored at 41°F can be safely consumed for up to 7 days. By strict adherence to the requirements for time/temperature control and date marking, as detailed within 3-501.16 and 3-501.17 respectively, food establishments can safely serve ready-to-eat foods within the growth parameters of Lm.

Scharff (2012) provides data detailing the cost per case of foodborne illness by pathogen, including the total costs associated with medical care, productivity loss of the caregiver and ill person, effect on quality of life, and death. To accurately calculate the cost for North Carolina, the average number of cases reported annually from 2008-2011 for the top foodborne fecal-oral pathogens were obtained from the Division of Public Health's database of reportable diseases.

Table 6. Costs Related to Listeriosis in NC

Pathogen	Number of Cases in NC/year (avg. 2008-2011)	Cost per Case*	Cost per Year Sub-Total	Additional Cost per Death Case	Sub-total Cost for Death Cases**	Total Cost in NC per year
Listeriosis	23	$109,260	$2,512,980	$1,174,628	$3,523,884	**$6,036,864**

* Cost per case includes cost of medical care, loss of productivity of the ill person and caregiver, and quality of life loss
** Cost per death assumes 15% of cases in NC result in death, based on data from the US Center for Disease Control .

Based on the above data, a cost-benefit analysis can be performed. If the assumption is made that the implementation of new cold-holding and date-marking requirements reduces the number of cases by only 1 case, then the total cost savings could be between $109,000 and $1.28 million: **$696,600 on average per year**.

- ***3-404.11 Treating Juice***
  Description: Retail food establishments that wish to package juice must treat the juice under a HACCP plan that reduces pathogenic bacteria by 99.999% or label the package as unpasteurized.

  Conclusion: Unquantifiable cost to industry; training costs for state/local government (see Training Costs section)

  Benefits: Unquantifiable savings from prevented foodborne illnesses

Packaging juice within a retail food establishment is *voluntary*. Typically, the cost associated with pasteurizing juice on-site is prohibitive for most establishments. Pre-packaged, pasteurized juices can readily be obtained from food suppliers and retail food markets. To date, no retail food establishment within North Carolina is performing this process and the FPP is not aware of any establishment that wishes to do so in the future.

As a safeguard for highly susceptible populations from the risk of contracting foodborne illness from juice, prepackaged juice is required to be obtained pasteurized or in a commercially sterile, shelf-stable form in a hermetically sealed container. There are documented cases of foodborne illness throughout the United States that were associated with the consumption of various juice products contaminated with microorganisms such as Cryptosporidium*,* Shiga toxin-producing Escherichia coli*,* Salmonella *spp.,* and Vibrio cholera*.*

Uncertainties
Some establishments may wish to treat juice. If so, then the costs of developing a HACCP plan will be incurred. For the purpose of this analysis, authorities on HACCP within the Food Science Department of North Carolina State University were consulted. The following estimates of HACCP costs were obtained:

$500/day avg. cost for HACCP plan development
X 3 days avg. time required
$1,500 estimated cost per HACCP plan

Note: Training costs associated with Food Code implementation is reflected in the "Training Costs" section.

Benefits: Unquantifiable savings from prevented foodborne illnesses

- ***3-502.11 Variance Requirement***
  3-502.12 Reduced Oxygen Packaging Without a Variance, Criteria

Description: Food establishments that wish to perform specialized food processes (specific high-risk practices) will be allowed to seek a variance from the rules. The use of reduced oxygen packaging will not require a variance if the criteria specified in the rules are utilized.

Conclusion: Unquantifiable cost to industry; training costs for state/local government (see Training Costs section)

Benefits: Unquantifiable savings from prevented foodborne illnesses

Specialized food processes (the use of reduced oxygen packaging, curing, smoking, the addition of vinegar or other food additives for the purpose of lowering the pH of the food to the point that temperature control is unnecessary, and packaging juice) are not typically performed within retail food establishments. Therefore, the use of specialized food processes is a *voluntary* choice of the establishment for economic and/or quality control purposes.

Specialized food processes often require retail food establishments to utilize specialized equipment and demonstrate specific competencies. Because of the specialized requirements, the risk is greater and there is a higher incidence of foodborne illness occurrence. The 2009 Food Code requires retail food establishments who wish to perform specialized food processes to seek a variance from the rules. Currently, most specialized food processes are outside of the parameters of 15A NCAC 18A .2600, and the establishment must suffer the loss of points from their sanitation score and possibly be subject to enforcement action. A variance will allow a viable option for establishments who wish to utilize these practices.

If a variance is requested, a Hazard Analysis Critical Control Points (HACCP) plan must be submitted to the FPP for review and approval prior to engaging in specialized food processes. If the establishment lacks the expertise to write the plan themselves, then it may be necessary to employ a food scientist, process authority, or other qualified individual to complete the plan. Once the plan is accepted by the Department, additional employee training will be necessary to ensure that all aspects of the plan will be implemented correctly.

The costs establishments would incur in obtaining the variance and training employees would be outweighed by the benefits from having the variance. Given the lack of historical and other data, it is difficult to estimate what the net impact to establishments might be. If any variances are granted as a result of this rule change, the Department would incur some costs in terms of staff time to review the plans and local health inspectors might need to spend additional time when inspecting establishments with variances.

Note: Training costs associated with Food Code implementation is reflected in the "Training Costs" section.

Uncertainties
Some establishments may wish to utilize specialized processes for various reasons, such as to meet the market demand, gain a competitive advantage, or better control the quality of foods. If specialized processes are used, then the costs of developing a HACCP plan will be incurred. For the purpose of this analysis, authorities on HACCP within the Food Science Department of North Carolina State University were consulted. The following estimates of HACCP costs were obtained:

$500/day avg. cost for HACCP plan development
X 3 days avg. time required
$1,500 estimated cost per HACCP plan

Benefits
Unquantifiable savings from prevented foodborne illnesses

- ***3-603.11 Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens (Consumer Advisory)***

Description: Food establishments that wish to serve raw or undercooked foods of animal origin per customer order will be required to advise consumers of the increased risk of foodborne illness.

Conclusion: Unquantifiable cost to industry; training costs for state/local government (see Training Costs section)

Benefits: Unquantifiable savings from prevented foodborne illnesses

The 2009 Food Code requires retail food establishments to disclose animal foods (e.g. beef, eggs, fish, chicken, pork, lamb) on their menus that may be served raw or undercooked (as ordered by the consumer). Along with the disclosure, a reminder of the increased risk of foodborne illnesses associated with these foods must also be stated. This requirement allows establishments to offer a wider variety of options to consumers than offered by 15A NCAC 18A .2600.

Currently, establishments must comply with strict minimum cooking temperatures; no options for raw or undercooked animal foods are given. Thus, this requirement will allow establishments to meet customer demand for rare hamburgers, over-easy eggs, and other animal foods cooked to customer taste. The only exception is animal foods offered on children's menus; all animal foods intended for children will be required to meet the minimum cooking temperature requirements.

This requirement will also address new industry trends in manufacturing and marketing that may introduce new risks to the consumer. For instance, meat processing plants that routinely tenderize beef through injection methods are increasing the risks of pathogenic bacteria within the interior of the muscle, and thereby necessitating a higher cooking temperature for safe pathogen reduction. Also, the increased introduction of less traditional foods within North Carolina has led to a diversity of menu offerings, thus demonstrating the need to ensure that consumers are informed of risks associated with unfamiliar foods.

The Consumer Advisory (consisting of the disclosure and reminder) is not expected to be a significant fiscal impact for establishments within North Carolina. The information contained in both the disclosure and reminder should be publicly available and readable so that consumers have benefit of the total message before making their order selections. Specific language, as stated within the Food Code, must be used. However, the information could appear in a variety of formats, such as a menu, a placarded listing of available choices, or a table tent.

Many franchise establishments that also operate in states using the Food Code may already have the consumer advisory printed on their menus. Some establishments may have policies to serve all potentially hazardous animal products fully cooked.

Serving raw or undercooked foods of animal origin is voluntary; establishments may simply comply with the minimum final cooking temperature criteria in the current rules at no additional costs. However, if establishments wish to cook foods of animal origin per consumer order, they have options for providing the Consumer Advisory at little to no cost. Adding the disclosure and reminder to menus, posting a sign, or providing table tents can satisfy the requirement. The Consumer Advisory can be handwritten, printed on a personal computer, or printed at a copy service.

Note: Training costs associated with Food Code implementation is reflected in the "Training Costs" section.

Uncertainties
Variations in the cost of materials used for the Consumer Advisory may affect the total cost of the requirement. Establishments may wish to use more cost extensive means to provide the information to public according to their personal preferences.

Benefits
Unquantifiable savings from prevented foodborne illnesses

<u>Chapter 4 - Equipment, Utensils, and Linens</u>

- ***4-501.19 Manual Warewashing Equipment, Wash Solution Temperature.***

Description: Food establishments will be required to maintain a minimum water temperature of 110°F in warewashing sinks while in use or use a detergent specially formulated for water temperatures below 110°F.

Conclusion: Unquantifiable cost to industry; training costs for state/local government (see Training Costs section)

Benefits: 7.7%/day energy reduction for the water heater

The 2009 Food Code requires that the temperature of the wash solution in manual warewashing sinks be maintained at a minimum temperature of 110°F while in use. An exception is made for detergents that specially formulated for temperatures below 110°F. This requirement is different than the current rule that requires a minimum of 130°F water from the tap at all times and no minimum wash water temperature. The proposed

standard within 4-501.19 does not specify a minimum temperature from the tap other than what is required by the North Carolina plumbing code (110°F).

The 110°F wash solution temperature is essential for removing organic matter. Unless a detergent specially formulated for use in water temperatures below 110°F is used, the performance of the detergent may be adversely affected, allowing animal fats that may be present on the dirty dishes to remain intact. The proposed standard will be an improvement to the current criteria by encouraging batch washing of soiled utensils using wash water meeting the minimum effective temperature.

Economic Benefits

Hot Water Use

The change in standard will allow a decrease in the minimum temperature in the hot water tank. Since a minimum of 110°F is required in the warewashing sink, the FPP assumes that water within the hot water tank should be at least 120°F to maintain the minimum temperature long enough for batch washing. Therefore, an energy reduction savings due to a 10°F temperature decrease should be experienced.

Division staff engineers estimate that reducing temperature in water tank from 130°F to 120°F would lead to: 7.7%/day energy reduction for the water heater. This estimate is based on information received from a brief survey of area chain establishments and the following assumptions:

- 250 gallons/day usage,
- 40 gallons/day increase in water usage based upon two additional batch washings per day at 20 gallons per vat = 16% increase
- Incoming water temperature of 50°F:

The savings to establishments

Note: Training costs associated with Food Code implementation is reflected in the "Training Costs" section.

Uncertainties

Some establishments may wish to use detergents specially formulated for use in water below 110°F, therefore incurring potential a cost, depending on the cost of these detergents versus the regular ones. However, these costs would be likely offset by the energy bill savings. The actual savings could not be calculated for this fiscal note because data related to food establishment energy use is not available. Also it is unclear how many establishments would choose to decrease their water heater temperature. However, if at least 10% of establishments choose to lower the temperature, and assuming a monthly electricity bill of at least $1,000, the annual savings for establishments could be of the order of millions of dollars.

Alternatives to 2009 USFDA Food Code Adoption

Alternative #1: Maintain the Current Food Safety Rules

The current food safety rules, 15A NCAC 18A .2601-.2645) have been amended over time by pursuing rule additions and amendments in subsequent legislative sessions. All rule additions and amendments have been based upon the criteria within the USFDA Food Code, the national food safety standard. The complexity of the rules, changes in science and national interpretations, and changes in the food industry and market demand have required the FPP to continually reassess the current rules for their effectiveness and amend/update as needed. This piecemeal approach has proven to be costly to the FPP over the years in support costs for rule-making. In addition, the current rules have been incapable of addressing the food safety concerns of a changing marketplace and food industry in timely manner.

Alternative #2: Adoption with subsequent amendments

During the 2011 long session in the NC General Assembly, the legislature provided the Department with specific authority to adopt the 2009 FDA Food Code. However, they chose not to provide language including "subsequent amendments and editions" of the Code. They explained that adopting the Food Code is a new approach to food protection rules in North Carolina and thought it would be prudent to adopt the current Food Code, implement it, and then come back to the legislature to report how it is working. At that time, a request to include "subsequent amendments and editions" of the Code would be considered. The next Food Code will not be released until 2013, so they felt there was sufficient time for us to do this without delaying adoption of the next edition of the Code. The Department intends to follow through with their request and seek legislation allowing subsequent amendments and editions of the Food Code during the next long session (2013). Allowing subsequent amendments might mean that there could be new requirements in the future that would add to the costs. Because benefits, however, are incurred on an annual basis, as opposed to costs which are one-time mostly, the present value of benefits would definitely be greater.

Resources

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APPENDIX 1

Proposed Rule Text

15A NCAC 18A .2601-.2645 are proposed for repeal and 15A NCAC 18A .2651-.2678 are being proposed for adoption as follows:

SECTION .2650 – FOOD PROTECTION AND SANITATION OF FOOD ESTABLISHMENTS

15A NCAC 18A .2651 GENERAL – ADOPTION BY REFERENCE

The 2009 Food Code, 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 incorporated by reference. The Food Code 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);
Eff. XXXX 1, 2012.

15A NCAC 18A .2652 DEFINITIONS

The provisions of this Rule make amendments, additions, and deletions to the Food Code incorporated by reference in Rule .2651 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 a food establishment where food preparation is limited to same day service, reheating of potentially hazardous food (time/temperature control for safety food), and operated under the rules of the Division of Aging, 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), 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) 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."

(6) In Paragraph 1-201.10(B), add: "'Food stand' means a food establishment which prepares or serves food and which does not provide seating facilities for customers to use while eating or drinking."

(7) 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 .2655."

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

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

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

(11) 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 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) In Paragraph 1-201.10(B), add: "'Mobile food unit' means a food establishment or pushcart designed to be readily moved and vend food."

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

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

(16) 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) In Paragraph 1-201.10(B), add: "'Regulatory Authority' means the Department or authorized agent of the Department."

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

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

(20) In Paragraph 1-201.10(B), amend "Temporary food establishment" to: "'Temporary food establishment' means a food establishment which 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."

(21) In Paragraph 1-201.10(B), add: "'Temporary food establishment commissary' means a food establishment affiliated with a temporary food establishment which prepares food in advance or off-site. The temporary food establishment commissary permit shall be valid for no more than 21 consecutive days 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 per calendar year are not eligible for a temporary food establishment commissary permit. Food shall not be sold from the temporary food establishment commissary. The temporary food establishment commissary shall comply with all temporary food establishment requirements."

(22) 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. The transitional permit shall expire 180 days after the date of issuance."

(23) In Paragraph 1-201.10(B), delete "Vending machine."

(24) In Paragraph 1-201.10(B), delete "Vending machine location."

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

15A NCAC 18A .2653 MANAGEMENT AND PERSONNEL

The provisions of this Rule make amendments, additions, and deletions to the Food Code incorporated by reference in Rule .2651 of this Section. In Chapter 2, the following apply:

336 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."

337 In Section 2-102.11, amend the last sentence in the first paragraph to: "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."

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

339 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 that 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 accredited program.

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

340 In Section 2-102.20, replace "Paragraph 2-102.11(B)" with "Section 2-102.11."

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

15A NCAC 18A .2654 FOOD

The provisions of this Rule make amendments, additions, and deletions to the Food Code incorporated by reference in Rule .2651 of this Section. In Chapter 3, the following apply:

- 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 state and approved by the regulatory authority in North Carolina. To determine the extent of compliance with this Code, the regulatory authority may accept reports regarding compliance and compliance history from responsible authorities in other jurisdictions where the food establishments are located."
- 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."

- 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 74ºC (165ºF)."

- In Section 3-301.11, redesignate existing Paragraph (D) as new Paragraph (E).
- In Subparagraph 3-301.11(D)(7), replace "(D)(1)-(6)" with "(E)(1)-(6)."
- Delete Section 3-305.13.
- In Section 3-306.12, delete (B).
- 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 5ºC (41ºF) or 7ºC (45ºF) and the temperatures specified under Paragraphs (A) through (C) of this section may not exceed 2 hours."
- In Paragraph 3-501.12(A), amend to read: "Under refrigeration that maintains the food temperature at 5ºC (41ºF) or less, or at 7ºC (45ºF) or less as specified under Subparagraph 3-501.16(A)(2)(b); or"
- 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); or"
- 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, and

  (3) For a period of time that does not allow thawed portions of ready-to-eat food to rise above 5°C (41°F), or 7°C (45°F) as specified under Subparagraph 3-501.16(A)(2)(b), or

  (4) For a period of time that does not allow thawed portions of a raw animal food requiring cooking as specified under Paragraph 3-401.11(A) or (B) to be 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);"

- In Subparagraph 3-501.14(A)(2), amend to read: "Within a total of 6 hours from 57ºC (135ºF) to 5ºC (41ºF) or less, or to 7ºC (45ºF) or less as specified under Subparagraph 3-501.16(A)(2)(b)."
- 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 7ºC (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."
- In Subparagraph 3-501-16(A)(2), amend to read:

"At a temperature specified in the following:

(a) 5ºC (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, 2016, the equipment is upgraded or replaced to maintain food at a temperature of 5°C (41°F) or less."

- 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 clearly 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, 2016, the equipment is upgraded or replaced to maintain food at a temperature of 5°C (41°F) or less."

- 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:"
- In Subparagraph 3-501.19(B)(1), amend to read: "The food shall have an initial temperature of 5ºC (41ºF) or less, or 7ºC (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;"
- 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);*
Eff. XXX 1, 2012.

15A NCAC 18A .2655 EQUIPMENT, UTENSILS, AND LINENS

The provisions of this Rule make amendments, additions, and deletions to the Food Code incorporated by reference in Rule .2651 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 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 Parts 4-1 and 4-2 of the Food Code as amended by Rule 2655. Nonabsorbent wooden shelves which 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."

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

15A NCAC 18A .2656 WATER, PLUMBING, AND WASTE

The provisions of this Rule make amendments, additions, and deletions to the Food Code incorporated by reference in Rule .2651 of this Section. In Chapter 5, the following apply:

(1) Delete Paragraph 5-203.11(C) and Section 5-501.14.

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

15A NCAC 18A .2657 PHYSICAL FACILITIES

The provisions of this Rule make amendments, additions, and deletions to the Food Code incorporated by reference in Rule .2651 of this Section. In Chapter 6, the following apply:

(1) Delete Section 6-202.17.

(2) Delete Section 6-202.18.

(3) In Paragraph 6-501.115(B), amend to read:

"Live animals are allowed in the following situations if the owner or operator does not permit animals to physically contact food, serving dishes, utensils, tableware, linens, unwrapped single-service and single-use articles or other food service items that may result in contamination of food or food-contact surfaces and does not permit animals to physically contact employees engaged in the preparation or handling of food:

(1) Fish or crustacea in aquariums or display tanks;

(2) Patrol dogs accompanying police or security officers in offices and dining, sales, and storage areas; and sentry dogs in outside fenced areas;

(3) Service animals accompanying persons with disabilities in areas that are not used for food preparation; and

(4) Dogs *(Canis lupus familiaris)* and cats *(Felis catus)* in outdoor dining areas; provided that dogs and cats are physically restrained, and do not pass through any indoor areas of the food establishment. Except for service animals described in Subparagraph (3) of this Paragraph, nothing in this Rule prohibits a food establishment from prohibiting dogs and cats in outdoor dining areas.

(5) In areas that are not used for food preparation, storage, sales, display, or dining, in which there are caged animals or animals that are similarly confined, such as in a variety store that sells pets or a tourist park that displays animals."

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

15A NCAC 18A .2658 POISONOUS OR TOXIC MATERIALS

The provisions of this Rule make amendments, additions, and deletions to the Food Code incorporated by reference in Rule .2651 of this Section. In Chapter 7, the following apply:

- In Section 7-101.11, add at the end: "Only those pesticides which have been registered with the EPA and with the N.C. Department of Agriculture and Consumer Services shall be used. If the manufacturer's label is missing from a pesticide container, the container shall be identified with the manufacturer's product brand name, percentage of each active ingredient, and EPA registration number."
- In Section 7-203.11, add at the end: "Sanitizing solutions shall not be stored in or dispensed from containers previously containing other poisonous or toxic materials."

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

15A NCAC 18A .2659 COMPLIANCE AND ENFORCEMENT

The provisions of this Rule make amendments, additions, and deletions to the Food Code incorporated by reference in Rule .2651 of this Section. In Chapter 8, the following apply:

(1) In Section 8-103.10, add the following to the end: "Variance requests shall be submitted to a committee including a food scientist and representatives from industry and state and local public health agencies, appointed by the Department."

(2) In Section 8-201.11, add the following to the beginning: "Plans drawn to scale for franchised or chain food establishments shall be submitted for review and approval to the Environmental Health Services Branch, N.C. Division of Public Health. Plans drawn to scale for independent food establishments shall be submitted for review and approval to the local health department."

(3) In Paragraph 8-201.12(A), amend to read: "Intended menu and plan review application;"

(4) In Paragraph 8-302.14(G), amend to read: "A statement signed by the applicant that attests to the accuracy of the information provided in the application."

(5) In Paragraph 8-302.14(G), delete (1) and (2).

(6) In Section 8-303.20, delete "Permit Renewal" from the heading.

(7) In Section 8-303.20, amend to read: "As applicable, the regulatory authority may issue a permit in accordance with 15A NCAC 18A .2660, to a new owner of an existing food establishment after a properly completed application is submitted, reviewed, and approved, and an inspection shows that the establishment is in compliance with this Code.

If the establishment is not in compliance with the Code, a transitional permit may be issued in accordance with G.S. 130A-248 (b) and (c) and Rule .2660(b)."

(8) Delete Section 8-304.10.

(9) Delete Paragraph 8-304.11(A).

(10) Delete Section 8-304.20.

(11) In Section 8-401.10, delete (A) and replace with: "The regulatory authority shall inspect a food establishment in accordance with 10A NCAC 46 .0213."

(12) In Section 8-401.10, delete (B) and (C).

(13) Delete Section 8-401.20.

(14) Delete Section 8-402.10.

(15) In Subparagraph 8-402.20(A)(1), amend to read: "The permit holder shall allow access to the regulatory authority as specified under Section 8-402.11 of the Code and G.S. 130A-17 and 130A-249."

(16) In Subparagraph 8-402.20(A)(3), amend to read: "If access is denied, an administrative warrant may be obtained according to G.S. 15-27.2; and"

(17) In Section 8-402.40, amend heading to read: "Administrative Warrant to Gain Access."

(18) In Section 8-402.40, amend to read: "If denied access to a food establishment for an authorized purpose and after complying with Section 8-402.20 of the Food Code as amended by Rule .2659, the regulatory authority may issue, or apply for the issuance of, an administrative warrant to gain access as provided by G.S. 15-27.2."

(19) In Section 8-403.20, delete the reference to Section 8-406.11.

(20) Delete Section 8-406.11.

(21) Delete Subpart 8-501.

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

15A NCAC 18A .2660 PERMITS

(a) No permit to operate shall be issued to a person until an evaluation by the regulatory authority shows that the establishment complies with this Section. However, the regulatory authority shall allow a period of 210 days after the date of issuance to comply with the certified food protection manager requirements in Sections 2-102.11 and 2-102.12 of the Food Code as amended by Rule .2653.

(b) Upon transfer of ownership of an existing food establishment, the regulatory authority shall complete an evaluation. If the establishment satisfies all the requirements of the rules, a permit shall be issued. If the establishment does not satisfy all the requirements of the rules, a permit shall not be issued. A transitional permit may be issued if the regulatory authority determines that the noncompliant items are construction or equipment problems that do not represent a threat to public health, or no certified food protection manager is on the premises. The transitional permit shall expire 180 days after the date of issuance, unless suspended or revoked before that date, and shall not be renewed. Upon expiration of the transitional permit, the permit holder shall have corrected the noncompliant items and obtained a permit, or the food establishment shall not continue to operate.

(c) The regulatory authority may impose conditions on the issuance of a permit or transitional permit. Conditions shall be specified for one or more of the following areas:

(1) The number of seats or consumers served.

(2) The categories of food served.

(3) Time schedules in completing minor construction items.

(4) Modification or maintenance of water supplies.

(5) Use of facilities for more than one purpose.

(6) Continuation of contractual arrangements upon which basis the permit was issued.

(7) Submission and approval of plans for renovation.

(8) Any other conditions necessary for a food establishment to remain in compliance with this Section.

(d) If a permit or transitional permit has been suspended, the suspension shall be lifted if the regulatory authority has evaluated the food establishment and found that the violations causing the suspension have been corrected. If a permit or transitional permit has been revoked, a new permit shall be issued only after the regulatory authority has evaluated the food establishment and found it to comply with all applicable rules. The evaluations shall be conducted within 15 days after the request is made by the permit holder.

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

15A NCAC 18A .2661 PUBLIC DISPLAY OF GRADE CARDS

(a) Upon initial inspection of a food establishment or if a renovation or other change in the establishment makes the grade card inconspicuous, the regulatory authority shall designate the location for posting the grade card. The grade card shall be located in a conspicuous place where it may be readily observed by the public upon entering the food establishment. If the person in charge of the food establishment objects to the location designated by the regulatory authority then the person in charge may suggest an alternative location which meets the criteria of this Rule.

(b) When an inspection of a food establishment is made, the regulatory authority shall remove the existing grade card, issue a new grade card, and post the new grade card in the same location where the grade card was previously posted as long as that location remains conspicuous. The person in charge of the food establishment shall keep the grade card posted at the designated location at all times. The grade card may be posted in another location which meets the criteria of this Rule if agreed upon by the person in charge and the regulatory authority.

(c) On a mobile food unit and pushcart, the grade card shall be located where it is visible to the public when purchasing food. The grade card shall be maintained on the mobile food unit and pushcart and may be removed during transport to operating locations and the person in charge shall repost the grade card in the original location prior to commencing operation.

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

15A NCAC 18A .2662 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 them 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 name and mailing address of the food establishment;

(2) The name of the permit holder;

(3) The permit status and score given;

(4) Standards of construction and operation as listed in .2651 through .2678 of this Section;

(5) An explanation for all points deducted;

(6) The signature of the regulatory authority; and

(7) The date.

(c) The grading of food establishments shall be based on the standards of operation and construction as set forth in Rules .2651 through .2678 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 .2653 of this Section related to person in charge present, certification by accredited program or performs duties shall equal no more than 2 points.

(2) Violation of Chapter 2 of the Food Code as amended by Rule .2653 of this Section related to management awareness, policy present, and allergy awareness shall equal no more than 3 points.

(3) Violation of Chapter 2 of the Food Code as amended by Rule .2653 of this Section related to proper use of reporting, restriction, and exclusion shall equal no more than 3 points.

(4) Violation of Chapters 2 and 3 of the Food Code as amended by Rules .2653 and .2654 of this Section related to proper eating, tasting, drinking, or tobacco use shall equal no more than 2 points.

(5) Violation of Chapter 2 of the Food Code as amended by Rule .2653 of this Section related to no discharge from eyes, nose, and mouth shall equal no more than 1 point.

(6) Violation of Chapter 2 of the Food Code as amended by Rule .2653 of this Section related to hands clean and properly washed shall equal no more than 4 points.

(7) Violation of Chapter 3 of the Food Code as amended by Rule .2654 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 points.

(8) Violation of Chapters 5 and 6 of the Food Code as amended by Rules .2656 and .2657 of this Section related to handwashing facilities supplied and accessible shall equal no more than 2 points.

(9) Violation of Chapters 3 and 5 of the Food Code as amended by Rules .2654 and .2656 of this Section related to food obtained from an approved source shall equal no more than 2 points.

(10) Violation of Chapter 3 of the Food Code as amended by Rule .2654 of this Section related to food received at proper temperature shall equal no more than 2 points.

(11) Violation of Chapter 3 of the Food Code as amended by Rule .2654 of this Section related to food in good condition, safe, and unadulterated shall equal no more than 2 points.

(12) Violation of Chapter 3 of the Food Code as amended by Rule .2654 of this Section related to required records available, shellstock tags, and parasite destruction shall equal no more than 2 points.

(13) Violation of Chapter 3 of the Food Code as amended by Rule .2654 of this Section related to food separated and protected shall equal no more than 3 points.
(14) Violation of Chapter 4 of the Food Code as amended by Rule .2655 of this Section related to food-contact surfaces cleaned and sanitized shall equal no more than 3 points.
(15) Violation of Chapter 3 of the Food Code as amended by Rule .2654 of this Section related to disposition of returned, previously served, reconditioned, and unsafe food shall equal no more than 2 points.
(16) Violation of Chapter 3 of the Food Code as amended by Rule .2654 of this Section related to cooking time and temperatures shall equal no more than 3 points.
(17) Violation of Chapter 3 of the Food Code as amended by Rule .2654 of this Section related to reheating for hot holding shall equal no more than 3 points.
(18) Violation of Chapter 3 of the Food Code as amended by Rule .2654 of this Section related to cooling time and temperatures shall equal no more than 3 points.
(19) Violation of Chapter 3 of the Food Code as amended by Rule .2654 of this Section related to hot holding temperatures shall equal no more than 3 points.
(20) Violation of Chapter 3 of the Food Code as amended by Rule .2654 of this Section related to cold holding temperatures shall equal no more than 3 points.
(21) Violation of Chapter 3 of the Food Code as amended by Rule .2654 of this Section related to date marking and disposition shall equal no more than 3 points.
(22) Violation of Chapter 3 of the Food Code as amended by Rule .2654 of this Section related to time as a public health control procedures and records shall equal no more than 2 points.
(23) Violation of Chapter 3 of the Food Code as amended by Rule .2654 of this Section related to consumer advisory provided for raw or undercooked foods shall equal no more than 1 point.
(24) Violation of Chapter 3 of the Food Code as amended by Rule .2654 of this Section related to pasteurized foods used and prohibited foods not offered shall equal no more than 3 points.
(25) Violation of Chapter 3 of the Food Code as amended by Rule .2654 of this Section related to food additives approved and properly used shall equal no more than 1 point.
(26) Violation of Chapter 7 of the Food Code as amended by Rule .2658 of this Section related to toxic substances properly identified, stored, and used shall equal no more than 2 points.
(27) Violation of Chapters 3, 4 and 8 of the Food Code as amended by Rules .2654, .2655, and .2659 of this Section related to compliance with variance, specialized process, and HACCP plan shall equal no more than 2 points.
(28) Violation of Chapter 3 of the Food Code as amended by Rule .2654 of this Section related to pasteurized eggs used where required shall equal no more than 1 point.
(29) Violation of Chapters 3 and 5 of the Food Code as amended by Rules .2654 and .2656 of this Section related to water from an approved source shall equal no more than 2 points.
(30) Violation of Chapter 8 of the Food Code as amended by Rule .2659 of this Section related to variance obtained for specialized processing methods shall equal no more than 1 point.
(31) Violation of Chapters 3 and 4 of the Food Code as amended by Rules .2654 and .2655 of this Section related to proper cooling methods used or adequate equipment for temperature control shall equal no more than 1 point.

(32) Violation of Chapter 3 of the Food Code as amended by Rule .2654 of this Section related to plant food properly cooked for hot holding shall equal no more than 1 point.
(33) Violation of Chapter 3 of the Food Code as amended by Rule .2654 of this Section related to approved thawing methods used shall equal no more than 1 point.
(34) Violation of Chapter 4 of the Food Code as amended by Rule .2655 of this Section related to thermometers provided and accurate shall equal no more than 1 point.
(35) Violation of Chapter 3 of the Food Code as amended by Rule .2654 of this Section related to food properly labeled or original container shall equal no more than 2 points.
(36) Violation of Chapters 2 and 6 of the Food Code as amended by Rules .2653 and .2657 of this Section related to insects and rodents not present or no unauthorized animals or persons shall equal no more than 2 points.
(37) Violation of Chapters 3 and 6 of the Food Code as amended by Rules .2654 and .2657 of this Section related to contamination prevented during food preparation, storage, and display shall equal no more than 2 points.
(38) Violation of Chapter 2 of the Food Code as amended by Rule .2653 of this Section related to personal cleanliness shall equal no more than 1 point.
(39) Violation of Chapters 3 and 4 of the Food Code as amended by Rules .2654 and .2655 of this Section related to wiping cloths properly used and stored shall equal no more than 1 point.
(40) Violation of Chapters 3 and 7 of the Food Code as amended by Rules .2654 and .2658 of this Section related to washing fruits and vegetables shall equal no more than 1 point.
(41) Violation of Chapter 3 of the Food Code as amended by Rule .2654 of this Section related to in-use utensils properly stored shall equal no more than 1 point.
(42) Violation of Chapter 4 of the Food Code as amended by Rule .2655 of this Section related to utensils, equipment, and linens properly stored, dried and handled shall equal no more than 1 point.
(43) Violation of Chapter 4 of the Food Code as amended by Rule .2655 of this Section related to single-use and single-service articles properly stored and used shall equal no more than 1 point.
(44) Violation of Chapter 3 of the Food Code as amended by Rule .2654 of this Section related to gloves used properly shall equal no more than 1 point.
(45) Violation of Chapters 3 and 4 of the Food Code as amended by Rules .2654 and .2655 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.
(46) Violation of Chapter 4 of the Food Code as amended by Rule .2655 of this Section related to warewashing facilities installed, maintained, used, and test strips shall equal no more than 1 point.
(47) Violation of Chapter 4 of the Food Code as amended by Rule.2655 of this Section related to non-food contact surfaces clean shall equal no more than 1 point.
(48) Violation of Chapter 5 of the Food Code as amended by Rule .2656 of this Section related to hot and cold water available and adequate pressure shall equal no more than 2 points.
(49) Violation of Chapter 5 of the Food Code as amended by Rule .2656 of this Section related to plumbing installed and proper backflow devices shall equal no more than 2 points.
(50) Violation of Chapter 5 of the Food Code as amended by Rule .2656 of this Section related to sewage and wastewater properly disposed shall equal no more than 2 points.

(51) Violation of Chapters 5 and 6 of the Food Code as amended by Rules .2656 and .2657 of this Section related to toilet facilities properly constructed, supplied, and cleaned shall equal no more than 1 point.

(52) Violation of Chapters 5 and 6 of the Food Code as amended by Rules .2656 and .2657 of this Section related to garbage and refuse properly disposed and facilities maintained shall equal no more than 1 point.

(53) Violation of Chapters 4 and 6 of the Food Code as amended by Rules .2655 and .2657 of this Section related to physical facilities installed, maintained, and clean shall equal no more than 1 point.

(54) Violation of Chapters 4 and 6 of the Food Code as amended by Rules .2655 and .2657 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 priority item or priority foundation item violation was not documented on the previous inspection; and

(2) 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 age of the accumulated material;

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

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

(4) 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 which requests an inspection for the purpose of raising the alphabetical grade, and which holds an unrevoked permit, the regulatory authority shall make an unannounced inspection within 15 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 made at the earliest convenience of the regulatory authority.

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

15A NCAC 18A .2663 GRADING

(a) The grading of food establishments is based on a system of scoring. A food establishment that earns a score of at least:

(1) 90 percent shall receive a grade A;

(2) 80 percent and less than 90 percent shall receive a grade B;

(3) 70 percent and less than 80 percent shall receive a grade C.

Permits shall be immediately revoked in accordance with G.S. 130A-23(d) for food establishments receiving a score of less than 70 percent.

(b) The posted grade card shall be black on a white background. All graphics, letters, and numbers for the grade card shall be approved by the State. The alphabetical and numerical rating shall be 1.5 inches in height. No other public displays representing sanitation level of the establishment may be posted by the regulatory authority, except for sanitation awards issued by the local health department. Sanitation awards shall be in a different color and size from the grade card and must be labeled as an award.

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

15A NCAC 18A .2664 OUTDOOR DINING AND BEVERAGE FACILITIES

(a) A Food establishment may provide outdoor dining and beverage service.

(b) Beverages may be prepared outdoors if all equipment and utensils are provided with overhead protection.

(c) Portable cooking, food, and beverage serving facilities shall be allowed for food service provided to a club, organization, or private individual as a planned event and from which the public is excluded. All open food and utensils shall be provided with overhead protection or otherwise equipped with individual covers such as domes, chafing lids, or cookers with hinged lids.

(d) Food and beverage equipment and supplies shall be located in enclosed areas and protected from environmental contamination when not in operation.

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

15A NCAC 18A .2665 SUPPLEMENTAL COOKING ROOMS

The following construction standards apply to food establishments cooking on grills, pits, or fireplaces in supplemental cooking rooms:

(1) Grills, pits, and fireplaces shall be kept clean, maintained in good repair, and located in an enclosed room as specified in Sections 6-202.15 and 6-202.16 of the Food Code as amended by Rule .2657 and shall comply with Parts 4-1 and 4-2 of the Food Code as amended by Rule .2655.

(2) Walls and ceilings shall be kept clean and in good repair.

(3) Floors shall be constructed of easily cleanable concrete or equal and graded to drain.

(4) Water under pressure shall be provided for floor cleaning.

(5) Ventilation systems and devices shall prevent grease or condensation from collecting on walls and ceilings.

(6) A handwashing sink shall be provided as specified in Section 5-202.12 of the Food Code as amended by Rule .2656.

(7) Lighting shall comply with Sections 6-202.11 and 6-303.11 of the Food Code as amended by Rule .2657.

(8) All food shall be processed in an area meeting the requirements for operation and construction as set forth in Rules .2651 through .2658.

History Note: *Authority G.S. 130A-248; S.L. 2011-394, Section 15(a);*

Eff. XXX 1, 2012.

15A NCAC 18A .2666 TEMPORARY FOOD ESTABLISHMENT AND TEMPORARY FOOD ESTABLISHMENT COMMISSARY PERMIT REQUIREMENTS

(a) A permit shall be issued by the regulatory authority to each temporary food establishment and temporary food establishment commissary that complies with Rules .2666 through .2670 of this Section. Temporary food establishments and temporary food establishment commissaries are not eligible for transitional permits. A single permit shall be issued for a temporary food establishment that does not operate consecutive days as long as the total number of days does not exceed 21. The permit shall be posted in a conspicuous place designated by the regulatory authority. The permit shall include:

(1) Name and location of the temporary food establishment and temporary food establishment commissary;

(2) Permit holder ;

(3) Name and location of the event;

(4) Dates of operation; and

(5) Any other conditions necessary to remain in compliance with this Section.

(b) No food preparation shall occur prior to a permit being issued by the Regulatory Authority.

(c) When affiliated with a temporary food establishment for an event where the food will be served, a temporary food establishment commissary permit for prior food preparation may be issued for advance or off-site preparation. A temporary food establishment commissary may commence operation no more than 7 days prior to the event and operate for the length of the event up to a time period not to exceed 21 consecutive days.

(d) Temporary food establishments and temporary food establishment commissaries shall make application to the Regulatory Authority no less than 15 calendar days prior to commencing operation. This 15-day requirement does not prohibit the submission of applications for substitute vendors provided that these applications are submitted no less than 3 business days prior to the event. Applications shall be submitted to the regulatory authority and shall include the following:

(1) Name, mailing address, and telephone number of the permit holder of the temporary food establishment or temporary food establishment commissary;

(2) Name and location of the event at which the temporary food establishment operated immediately prior to the current event for which applying, if applicable;

(3) Name, mailing address, and telephone number of the event organizer;

(4) Event name, location, dates, and hours of operation;

(5) Proposed menu, food handling procedures, including anticipated food volume and sources;

(6) Food equipment list;

(7) Proposed water supply;

(8) Provisions for sewage and other waste disposal; and

(9) Any information necessary to ensure compliance.

(e) The regulatory authority shall require documentation to verify any provision of Rules .2666 through .2670 of this Section.

(f) The regulatory authority may condition the permit to ensure compliance with Rules .2666 through .2670 of this Section.

(g) Evaluations of temporary food establishments and temporary food establishment commissaries shall be made as often as necessary to ensure compliance. The regulatory authority shall immediately suspend the permit for repeated violations of priority items or priority foundation items.

(h) The permit shall be suspended or revoked immediately pursuant to G.S. 130A-23(d).

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

15A NCAC 18A .2667 TEMPORARY FOOD ESTABLISHMENT FOOD HANDLING REQUIREMENTS

(a) All sources of food shall comply with Chapter 3 of the Food Code as amended by Rule .2654.

(b) Raw meat, poultry, and fish shall be purchased in ready-to-cook portions, except that cutting and skewering shall be allowed where evaluation by the regulatory authority determines sufficient preparation areas and food equipment are provided.

(c) Salads containing ingredients that are cooked and cooled shall not be prepared in the temporary food establishment or temporary food establishment commissary, but may be served.

(d) Shellstock and shucked shellfish shall comply with Chapter 3 of the Food Code as amended by Rule .2654.

(e) All food shall be protected in accordance with Chapter 3 of the Food Code as amended by Rule .2654 and the following also apply:

(1) The regulatory authority may approve food preparation and storage for a temporary food establishment at a permitted temporary food establishment commissary or other permitted food establishment;

(2) Temporary food establishment or temporary food establishment commissary operations shall not be conducted in any room or area used for purposes not related to the temporary food establishment or other permitted food establishment;

(3) Food shall be secured in a manner to prevent tampering and contamination at all times;

(4) Ready-to-eat food shall not be stored in direct contact with ice; non-mechanical coolers must be provided with a drainage port;

(5) All food shall be stored above the ground or floor and arranged to prevent contamination of foods;

(6) Potentially hazardous food (time/temperature control for safety food) that has been heated at the temporary food establishment or temporary food establishment commissary shall not be sold or held for use on subsequent days. Approval may be granted to allow cooling and reheating of potentially hazardous food (time/temperature control for safety food) if the food can be handled in accordance with the rules of this Section; and

(7) The regulatory authority shall further limit the food to be prepared or served, based on methods of preparation and the adequacy of facilities, equipment, utensils, and available utilities.

(f) Food prepared at a previous event or potentially hazardous food (time/temperature control for safety food) removed from original packaging shall not be served at a subsequent event.

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

15A NCAC 18A .2668 TEMPORARY FOOD ESTABLISHMENT EMPLOYEE REQUIREMENTS

(a) Food 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 .2653.

(b) Employees shall wash their hands in a handwashing sink before starting work, after each visit to the toilet, and as often as necessary to remove soil and contamination.

(c) Employees shall not use tobacco in any form or consume food in food preparation, storage or serving areas, utensil washing, or utensil storage areas.
(d) Employees may consume beverages in the food establishment only if covered and consumed in a manner to prevent contamination of food and food-contact surfaces.
(e) Employees shall comply with the requirements in Subpart 2-201 of the Food Code as amended by Rule .2653.

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

15A NCAC 18A .2669 TEMPORARY FOOD ESTABLISHMENT EQUIPMENT AND UTENSIL REQUIREMENTS

(a) Equipment and utensils shall be kept clean and maintained in good repair. Those surfaces which come in contact with food, drink, or utensils shall comply with Parts 4-1 and 4-2 of the Food Code as amended by Rule .2655.
(b) Equipment and utensils shall be cleaned, sanitized, stored, and handled in accordance with Parts 4-6 and 4-7 of the Food Code as amended by Rule .2655.
(c) When multi-use utensils other than eating and drinking utensils are used, 3 basins of sufficient size to submerge, wash, rinse, and sanitize utensils shall be provided. Other equivalent products and procedures may be used in accordance with Part 4-7 of the Food Code as amended by Rule .2655. At least 1 drainboard, table, or counter space shall be provided for air-drying.
(d) When multi-use eating and drinking utensils are used, a 3-compartment sink of sufficient size to submerge, wash, rinse, and sanitize utensils must be provided. Drainboards shall be provided as specified in Section 4-301.13 of the Food Code as amended by Rule .2655.
(e) Wash, rinse, and sanitizing solutions shall be maintained as specified in Section 4-501.18 of the Food Code as amended by Rule .2655.
(f) A food preparation sink must be provided for washing produce.
(g) Food shields or other effective barriers shall be installed in a manner to protect food and food contact surfaces from contamination.

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

15A NCAC 18A .2670 TEMPORARY FOOD ESTABLISHMENT PHYSICAL REQUIREMENTS

(a) The temporary food establishment shall be located in an area kept in a clean and sanitary condition. The arrangement of temporary food establishments shall restrict public access to all areas of the food establishment, except dining areas.
(b) Overhead protection shall be provided such that all food, utensils, and equipment are protected. When bulk foods such as roasts, shoulders, and briskets are cooked, cooking equipment with attached lids, such as smokers, roasters, and other cooking devices, provide sufficient cover for the food being cooked. Food in individual servings such as hot dogs, hamburgers, and meat kabobs shall have additional overhead cover.
(c) Effective measures such as fans, screens, walls, or a combination thereof, shall be provided to keep dust, insects, rodents, animals, and other sources of potential contamination out of the food establishment and shall comply with Paragraph 6-501.15(B) of the Food Code as amended by Rule .2657 regarding live animals.

(d) Indoor/outdoor carpeting, matting, tarps, or similar nonabsorbent material is required as ground covering in the absence of asphalt, concrete, grass, or other surfaces that control dust or mud.

(e) The temporary food establishment and temporary food establishment commissary shall be equipped with a handwashing sink used only for employee handwashing. This facility shall consist of at least a 2 gallon container with an unassisted free flowing faucet such as a stopcock or turn spout, soap, single-use towels, and a wastewater receptacle. Warm water shall be used for handwashing.

(f) Water under pressure shall be provided as follows:

(1) The water supply used shall be in accordance with 15A NCAC 18A .1700, 15A NCAC 18C, or 02 NCAC 09C .0703;

(2) All potable water holding tanks, containers, and hoses used to transport or store water at the temporary food establishment shall be drained, washed, rinsed, and sanitized;

(3) Containers and hoses used to store, haul, or convey potable water shall be approved for potable water use, shall not be used for any other purpose, and shall be protected from contamination. Potable water hoses and containers shall be labeled; and

(4) Warm water shall be available and used for cleaning.

(g) Wastewater shall be disposed in accordance with 15A NCAC 18A .1900 or 15A NCAC 02H .0200. Portable wastewater containers may be used when the volume of potable water can be determined by the dimensions of sinks, basins, and interim storage containers and the portable wastewater containers are sized to contain the wastewater volume generated. Wastewater containers and hoses shall be labeled and not used for any other purpose. Wastewater containers shall not be emptied into waterways, storm drains, or on the ground.

(h) Employees must have access to toilet facilities that are kept clean and in good repair.

(i) Garbage and refuse shall be collected and stored in garbage containers with properly fitted lids. Nothing in this Rule shall prohibit uncovered garbage containers in the food establishment during periods of operation. Garbage and refuse shall be removed as needed and disposed in a manner to prevent vermin breeding and harborage. The premises shall be kept clean.

(j) Lighting shall comply with Section 6-202.11 of the Food Code as amended by Rule .2657. Lighting is required for nighttime operations.

(k) Temporary food establishments and temporary food establishment commissaries shall remain connected to necessary utilities at all times food is prepared, served, or stored in the food establishment.

(l) Toxic materials shall be labeled, used, and stored to prevent the contamination of food, equipment, utensils, linens, and single-service articles and meet the provisions of Sections 7-101.11 and 7-203.11 of the Food Code as amended by Rule .2658.

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

15A NCAC 18A .2671 GENERAL REQUIREMENTS FOR PUSHCARTS AND MOBILE FOOD UNITS

(a) A permit shall be issued by the regulatory authority which inspects the commissary from which the 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) The regulatory authority which 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) 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) Prior to initiating food service operations in a particular county, the operator of the pushcart or mobile food unit shall submit to that particular county such carts or units for inspection or reinspection to determine compliance with this Section.
(e) 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.
(f) All food shall be obtained from sources that comply with Chapter 3 of the Food Code as amended by Rule .2654.
(g) 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 .2654. A metal stem-type thermometer accurate to 1°C (2°F) shall be available to check food temperatures.
(h) Only single-service articles shall be used for serving customers. Single-service articles shall be purchased only in sanitary containers, shall be stored therein in a clean, dry place until used, and shall be handled in a manner to prevent contamination.
(i) All garbage and other solid waste shall be stored and disposed in an approved manner.
(j) 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 .2653.
(k) Employees shall comply with the requirements in Subpart 2-201 of the Food Code as amended by Rule .2653.
(l) Equipment and utensils shall meet the requirements in Parts 4-1 and 4-2 of the Food Code as amended by Rule .2655.
(m) The pushcart or mobile food unit shall be kept clean and free of flies, roaches, rodents, and other vermin.

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

15A NCAC 18A .2672 SPECIFIC REQUIREMENTS FOR PUSHCARTS

(a) Only hot dogs shall be prepared, handled, or served from a pushcart; however, food which has been prepared, pre-portioned, and individually pre-wrapped at a food establishment or commissary may be served from a pushcart.
(b) Food and utensils on the pushcart exposed to the public or to dust or insects shall be protected by glass, or otherwise, on the front, top, and ends, and exposed only as much as may be necessary to permit the handling and serving of food.
(c) Toilet facilities, handwashing sinks, and running water are not required. Single-service towels are required.
(d) All pre-wrapped 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 .2654 or as labeled on the food item. Each pre-wrapped food item shall contain the name of the food establishment at which it was prepared, the name of the food item, and the time and date of expiration. The wrapper shall enclose the food at all times but sealing is not required.
(e) Pre-portioned, individually pre-wrapped food that remains after the specified time period has elapsed shall not be sold for human consumption.
(f) Pushcarts shall not be provided with seating facilities.

(g) Pushcarts shall not be used for consumer self-service.

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

15A NCAC 18A .2673 SPECIFIC REQUIREMENTS FOR MOBILE FOOD UNITS

(a) A mobile food unit shall be constructed and arranged so that food, drink, utensils, and equipment will not be exposed to insects, dust, and other contamination. Protection against flies and other insects shall be provided by screening or by effective use of fans. Where food or griddles are exposed to the public or to dust or insects, they shall be protected by glass, or otherwise, on the front, top, and ends, and exposed only as much as may be necessary to permit the handling and serving of food.

(b) A mobile food unit shall have a potable water system under pressure. The system shall furnish hot and cold water for all food preparation, utensil cleaning, and handwashing. The water inlet shall be located so that it will not be contaminated by waste discharge, road dust, oil, or grease and it shall be kept capped unless being filled.

(c) Water heating facilities shall be provided.

(d) A handwashing sink with hot and cold water, combination supply faucet, soap, and single-service towels shall be provided.

(e) At least a 1-compartment sink shall be provided. The sink shall be of sufficient size to submerge, wash, rinse, and sanitize utensils and shall have splashback protection. Drainboards shall be provided as specified in Section 4-301.13 of the Food Code as amended by Rule .2655 to accommodate the drying of washed utensils. However, in cases where no food is prepared on the mobile food unit and all utensils are effectively cleaned at the commissary, the equipment sink is not required.

(f) Sewage disposal must be provided either by means of an approved sewage disposal system or approved sewage storage tanks. Sewage storage tanks must be maintained in a manner so as not to create a health hazard or nuisance and to prevent contamination of food or water supply. Toilets are not required on the unit. Liquid waste that results from the operation of a mobile food unit shall be disposed in an approved sewage disposal system or stored in a permanently installed sewage storage tank that is of at least 15 percent larger capacity than the water supply tank. Liquid waste shall not be discharged from the sewage storage tank when the mobile food unit is in motion. All connections on the vehicle for servicing mobile food unit waste disposal facilities shall be of a different size or type than those used for supplying potable water to the mobile food unit. The waste connection shall be located lower than the water inlet connection to preclude contamination of the potable water system.

(g) A servicing area shall be established at a commissary for the mobile food unit. Potable water servicing equipment shall be installed, stored, and handled to protect the water and equipment from contamination. The mobile food unit's sewage storage tank shall be flushed and drained during servicing operation. All sewage shall be discharged to an approved sewage disposal system in accordance with 15A NCAC 18A .1900 or 15A NCAC 02H .0200.

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

15A NCAC 18A .2674 CONGREGATE NUTRITION SITES

Congregate nutrition sites shall comply with all requirements in Rules .2651-.2663 of this Section with the following exceptions:

(1) Food preparation in a congregate nutrition site shall be limited to reheating food prepared in a food establishment or in a food processing plant or preparation of food that does not require cooking.

(2) Congregate nutrition sites shall not prepare any potentially hazardous food (time/temperature control for safety food) prior to the day of service.

(3) Potentially hazardous food (time/temperature control for safety food) which has been heated or reheated at the congregate nutrition site and remains at the end of the day shall not be served or placed in refrigeration to be used another day.

(4) Food prepared in a private home may not be used or offered for human consumption in a congregate nutrition site.

(5) All food prepared or served in a congregate nutrition site shall be consumed only on the premises.

(6) Only single-service articles shall be used.

(7) Consumer self-service is prohibited except for condiments in individual packages or in pour-type or squeeze-type containers.

(8) Equipment in the congregate nutrition site which is not certified or classified for sanitation by an ANSI-accredited certification program which is in good repair and operating properly may be used. At least a 2-compartment sink shall be provided. The sink shall be of sufficient size to submerge, wash, rinse, and sanitize utensils. At least 1 drainboard, table, or counter space shall be provided for air-drying.

(9) Garbage can liners are required for all garbage receptacles unless the site has receptacle cleaning facilities as specified in Section 5-501.18 of the Food Code as amended by Rule .2656.

(10) Water used for mop or receptacle cleaning shall not be disposed in the utensil sink. Wastewater from mopping, receptacle cleaning, and other cleaning operations shall be disposed in a service sink or another approved manner in accordance with 15A NCAC 18A .1900 or 15A NCAC 02H .0200.

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

15A NCAC 18A .2675 LIMITED FOOD ESTABLISHMENTS

Limited food establishments shall comply with all the requirements in Rules .2651-.2663 of this Section, except that the following provisions apply in lieu of Rule .2660 and Sections 8-201.11 and 8-201.12 of the Food Code as amended by Rule .2659:

(1) The permit for a limited food establishment shall be posted in a conspicuous place where it can be readily seen by the public at all times. Permits for limited food establishments shall expire on December 31 of each year. A new permit from the regulatory authority shall be obtained before the limited food 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 which includes a menu, plans, and specifications for the proposed limited food establishment, and location and dates of operation.

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

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

(5) Food prepared in a private home may not be used or offered for human consumption in a limited food establishment.

(6) All meats, poultry, and fish shall be purchased in a pre-portioned and ready-to-cook form.

(7) Equipment in the limited food establishment which is not certified or classified for sanitation by an ANSI-accredited certificate program which is in good repair and operating properly may be used. At least a 2-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 1 drainboard, table, or counter space shall be provided for air-drying.

(8) Only single-service articles shall be used.

(9) Consumer self-service is prohibited except for condiments in individual packages or in pour-type or squeeze-type containers.

(10) Floors, walls, and ceilings of limited food establishments shall meet the requirements of this Section. limited food establishments shall use dustless methods of floor 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.

(11) 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 .2657.

(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);
Eff. XXX 1, 2012.

15A NCAC 18A .2676 PROCEDURE WHEN INFECTION SUSPECTED

When the regulatory authority has reason to suspect the possibility of exposure to, or transmission of, infection within a food establishment from any person or from any food or drink, the local health director shall act in accordance with the Communicable Disease Laws and Rules (G.S. 130A-134 through 148, 15A NCAC 19A).

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

15A NCAC 18A .2678 INFORMAL REVIEW PROCESS AND APPEALS PROCEDURE

(a) If a permit holder disagrees with a decision of the local health department on the interpretation, application, or enforcement of the rules of this Section the permit holder may:

(1) Request an informal review pursuant to Paragraphs (d) and (e) of this Rule; or

(2) Initiate an appeal in accordance with G.S. 150B.

(b) The permit holder is not required to complete the alternative dispute resolution prior to initiating an appeal in accordance with G.S. 150B.

(c) When a petition for a contested case is filed, the informal review process shall terminate.

(d) If the permit holder requests an informal review, the request shall be in writing and shall be postmarked or hand-delivered to the local health department within 7 days of notice of the decision giving rise to the review. The request shall state the issues in dispute. If the inspection giving rise to the informal review was conducted by the Environmental Health Supervisor in the county or area where the food establishment is located, or when the county or area has only one registered environmental health specialist assigned to

inspect food establishments, the Environmental Health Regional Specialist assigned to that county or area shall conduct the local informal review. As soon as possible, but at least within 30 days of receipt of the request, the person conducting the review shall contact the permit holder, provide that permit holder an opportunity to be heard on the issues in dispute and issue a written decision addressing the issues raised in the appeal. Copies of the decision shall be mailed to the permit holder and to the State Health Director. That decision shall be binding for the purposes of future inspections of the establishment in question unless modified pursuant to Paragraph (e) of this Rule or by the State Health Director.

(e) Following receipt of the written decision of the Environmental Health Supervisor or his or her representative issued pursuant to Paragraph (d) of this Rule, the permit holder who initiated the informal review may appeal the resulting decision to an Informal Review Officer designated by the Department to be responsible for final decisions on appeals from throughout the state. Notice of such appeal shall be in writing, shall include a copy of the Environmental Health Supervisor's or his or her representative's decision, and shall be postmarked or hand-delivered to the local health department and to the Department within 7 days of receipt of the written decision issued pursuant to Paragraph (a) of this Rule. Within 35 days of receipt of this appeal, the designated Informal Review Officer shall hold a conference in Wake County. Notice of the time and place of this conference shall be provided to the permit holder and the Environmental Health Supervisor for the county or area where the issue arose. Within 10 days following the date of the conference, the Informal Review Officer shall issue a written decision addressing the issues raised in the appeal and that decision shall be binding for purposes of future inspections of the establishment in question unless modified pursuant to Paragraph (g) of this Rule or by the State Health Director.

(f) If the decision on appeal at the local or state level results in a change in the score resulting from an inspection of an establishment, the regulatory authority shall post a new grade card reflecting that new score.

(g) Appeals of the decision of the designated Informal Review Officer shall be in accordance with G.S. 150B.

(h) Nothing in this Rule shall impact the right of a permit holder to a reinspection pursuant to Rule .2662 of this Section.

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

APPENDIX 2

2010-2011 NC Food Code Transition Team – Fiscal Analysis Workgroup
Industry Survey On FDA Model Food Code Adoption by North Carolina: Effects of New 2009 Food Code Requirements on Current and Future Operations

Introduction:

The industry survey was proposed and developed as a means to assess the current state of practice of facilities' procedures in various areas of food protection with respect to the additional requirements that the adoption of the 2009 Food Code will bring to North Carolina. The Fiscal Analysis Workgroup met in October 2010 and identified several potential areas of change for operators when the new requirements under the Food Code are enforced at the local level during sanitation inspections. Employee illness, manager food safety training, bare-hand contact of food items, specialized food processes, lower cold holding temperature requirements, date marking of food items and serving of raw and undercooked food items were all addressed in the survey.

Members of the workgroup identified all restaurants and food stands in North Carolina whose email address was made available in the establishment database of inspections maintained by the Inspections, Statistics, and Fees section in the Environmental Health Services Branch. Email invitations were sent to a total of 1,624 operators to visit a web link where the survey questions were maintained on a SurveyMonkey® web site. The survey remained open for approximately five weeks where 391 surveys were initiated and 277 of those surveys were completed before the survey portal was closed and all data collected. Several surveys were completed from the same user IP Address (unique location identifier of individual internet connection from where survey was completed). For the purposes of reviewing the data, the workgroup members assumed these surveys were completed by the same or different individuals where each survey represented a unique food service operation (e.g., a regional manager completed the survey for his or her multiple retail locations).

Highlights of the results were as follows:

92% of respondents currently monitor employees for illnesses;
61% of respondents currently have a policy in place detailing specific actions taken regarding employee duties based on symptoms;
56% of respondents stated that the individual in charge is required to pass an accredited food safety examination;
78% of respondents currently do not allow employees to use bare hand contact on ready-to-eat (RTE) food items;
76% of respondents currently hold all cold food items at 41°F or less using existing equipment;
81% of respondents currently use date-marking for the purpose of disposing of RTE foods held for longer than one day;
21% of respondents currently offer raw or undercooked food items (hamburgers, steaks, oysters, eggs cooked over-easy); Of those, 75% warn the consumer of the health risks associated with consuming raw or undercooked food. Detail results are listed below.

In all cases, greater than half of the respondents already meet the proposed 2009 Food Code requirements. More than half of respondents indicate that the facility is already practicing the proposed new Food Code requirement for managers to be certified in food protection, and three-fourths enforce a no bare hand contact policy. Additionally, three-fourths of respondents currently warn consumers about consuming raw or undercooked food, possess equipment which meets or exceeds the proposed new cold-holding temperature requirements and use date marking as a means to manage unused food disposition requirements. Employee illness is currently monitored by nearly all respondents. These results indicate that there will not be a significant burden placed on operators to purchase new equipment and institute new policies in order to meet the new minimum requirements of the 2009 Food Code. The detailed results of the survey (below) show in more detail the practices and processes which are in current use.

Food Code Transition - Fiscal Analysis Industry Survey

SurveyMonkey

1. Do you monitor your employees for illnesses?

	Response Percent	Response Count
yes	**92.4%**	**256**
no	7.6%	21
	answered question	**277**
	skipped question	**0**

2. If yes, please indicate for which symptoms you monitor:

	Response Percent	Response Count
nausea	75.6%	192
vomiting	**89.0%**	**226**
diarrhea	71.3%	181
runny nose	78.3%	199
headache	33.5%	85
sore throat with fever	**89.0%**	**226**
jaundice	49.2%	125
lesions containing puss (such as an infected wound)	80.3%	204
Other (please specify)	12.2%	31
	answered question	**254**
	skipped question	**23**

3. Do you ask employees to tell you when they are ill?

	Response Percent	Response Count
yes	97.3%	250
no	2.7%	7
answered question		257
skipped question		20

4. Do you ask your employees to tell you their symptoms or diagnosed illness?

	Response Percent	Response Count
yes	92.5%	235
no	7.5%	19
answered question		254
skipped question		23

5. Do you a have a policy that provides the management with specific guidance for employee duties based upon their reported symptoms or diagnoses?

	Response Percent	Response Count
yes	61.0%	155
no	39.0%	99
answered question		254
skipped question		23

6. Is the person in charge (at the time of inspection) required to pass an accredited food safety exam?

	Response Percent	Response Count
yes	**55.6%**	**154**
no	44.4%	123
	answered question	**277**
	skipped question	**0**

7. Do you allow food workers to touch ready-to-eat food (ready to be served to customer) with their bare hands?

	Response Percent	Response Count
yes	22.0%	61
no	**78.0%**	**216**
	answered question	**277**
	skipped question	**0**

8. Do you use any of the following in lieu of bare hands?

	Response Percent	Response Count
Single-use Gloves	89.2%	247
Tongs or other utensils	**89.5%**	**248**
Deli paper	56.0%	155
Other (please specify)	4.0%	11
	answered question	**277**
	skipped question	**0**

9. What temperature are your refrigeration units currently holding your food?

	Response Percent	Response Count
45°F - 49°F	1.4%	4
41°F - 45°F	22.4%	62
Below 41°F	**76.2%**	**211**
	answered question	**277**
	skipped question	**0**

10. What is the age of your oldest refrigeration unit?

	Response Percent	Response Count
Less than 5 years	38.6%	107
5-10 years	**39.0%**	**108**
10-15 years	11.9%	33
15-20 years	6.5%	18
20 years or older	4.0%	11
	answered question	**277**
	skipped question	**0**

11. Do you use date-marking (identifying or marking the food with a disposal date) for holding ready-to-eat foods?

	Response Percent	Response Count
yes	**80.9%**	**224**
no	19.1%	53
	answered question	**277**
	skipped question	**0**

12. If yes, how many days do you hold the food before discarding?

	Response Percent	Response Count
1 day	8.8%	19
2 days	22.2%	48
3 days	**35.2%**	**76**
4 days	13.4%	29
5 days	7.4%	16
6 days	3.2%	7
7 days	8.3%	18
More than 7 days	1.4%	3
	answered question	**216**
	skipped question	**61**

13. Do you offer raw or undercooked foods (e.g. hamburgers, steaks, Caesar salad, over-easy eggs, or oysters)?

	Response Percent	Response Count
yes	20.9%	58
no	79.1%	219
answered question		277
skipped question		0

14. If yes, do you disclose to the consumer the types of foods offered raw or undercooked?

	Response Percent	Response Count
yes	74.6%	44
no	25.4%	15
answered question		59
skipped question		218

15. If yes, do you remind the consumer of the health risks associated with consuming raw or undercooked foods?

	Response Percent	Response Count
yes	75.0%	42
no	25.0%	14
answered question		56
skipped question		221

16. Do you prepare sushi within your establishment?

	Response Percent	Response Count
yes	3.2%	9
no	**96.8%**	**268**
	answered question	**277**
	skipped question	**0**

17. If yes, do you use raw seafood?

	Response Percent	Response Count
yes	**77.8%**	**7**
no	22.2%	2
	answered question	**9**
	skipped question	**268**

18. If yes, how do you guarantee that the seafood is parasite free? (You may choose multiple answers)

	Response Percent	Response Count
Obtain certification from supplier	**100.0%**	**7**
freeze seafood for parasite destruction on site	57.1%	4
use tuna species that is parasite free	42.9%	3
	answered question	**7**
	skipped question	**270**

Page 2, Q1. If yes, please indicate for which symptoms you monitor:		
1	alcohol	Mar 28, 2011 6:14 PM
2	mental	Mar 24, 2011 5:11 AM
3	If I feel or they tell me that they are sick, I send them go home	Mar 23, 2011 3:52 PM
4	pimpils	Mar 21, 2011 3:09 PM
5	coughing	Mar 19, 2011 8:52 AM
6	mental health	Mar 17, 2011 8:55 PM
7	general health, I make sure that employees are able to safely handle food	Mar 17, 2011 3:38 PM
8	general sickness	Mar 17, 2011 1:10 PM
9	coughing	Mar 16, 2011 10:02 PM
10	The employee must inform us of most of these.	Mar 16, 2011 10:54 AM
11	All	Mar 16, 2011 9:24 AM
12	Employees are advised NOT to come in EVEN IF they just "feel bad" and/or have "cold/allergy" symptons	Mar 16, 2011 1:03 AM
13	coughing/sneezing	Mar 16, 2011 12:00 AM
14	coughing	Mar 15, 2011 9:26 PM
15	coughing	Mar 15, 2011 6:08 PM

Page 2, Q1. If yes, please indicate for which symptoms you monitor:		
16	communication asking how they are or feel	Mar 15, 2011 5:47 PM
17	employee complaints	Mar 15, 2011 5:31 PM
18	Persistent Cough	Mar 15, 2011 5:18 PM
19	fever,cough,chills	Mar 15, 2011 5:02 PM
20	fatigue	Dec 30, 2010 4:21 PM
21	My policy is that IF EMPLOYEE feels or HAS the SLIGHTEST of ANY illness, STAY HOME!	Dec 20, 2010 2:00 PM
22	fever	Dec 14, 2010 8:49 PM
23	cough	Dec 13, 2010 3:32 PM
24	ask employee to disclose form of illness when present	Dec 13, 2010 1:30 PM
25	all the above and more !!!	Dec 11, 2010 6:57 PM
26	These are when we see them	Dec 10, 2010 5:48 PM
27	Any eye infections	Dec 10, 2010 4:38 PM
28	severe coughing	Dec 10, 2010 4:01 PM
29	cut or burn very bad	Dec 10, 2010 2:36 PM
30	open wounds, cough,skin rashes	Dec 10, 2010 2:09 PM
31	it's only me, unless I get a big job. But no one would work for me if they were even thinking they were getting sick.	Dec 10, 2010 12:37 PM

Page 4, Q2. Do you use any of the following in lieu of bare hands?		
1	quick sacks (portion bags)	Mar 25, 2011 5:32 PM
2	towels	Mar 21, 2011 3:11 PM
3	ladles	Mar 16, 2011 12:35 PM
4	Non powder vinyl gloves	Mar 16, 2011 11:36 AM
5	Spatulas	Mar 15, 2011 9:51 PM
6	gloves cause more bactirai when used wrong than bare hands, we are very responsible and use gloves and tongs at times bare hands mostly	Mar 15, 2011 5:13 PM
7	hands must be washed and sanitized before touching food	Mar 15, 2011 5:13 PM
8	portion bags	Dec 28, 2010 4:58 PM

Page 4, Q2. Do you use any of the following in lieu of bare hands?		
9	Corrugated food trays are used for shaking any excess oil; then placed directly onto plate without handling	Dec 20, 2010 2:02 PM
10	wash hands with anti bacterial soap before work in kitchen and after restroom	Dec 10, 2010 3:29 PM
11	Vinyl Gloves for food prep that are changed when contaminated	Dec 10, 2010 1:47 PM

APPENDIX 3

ADDENDUM: Fiscal Impact of 2009 FDA Food Code Adoption

The following is an addendum to the fiscal impact of the 2009 FDA Food Code adoption published in March 2012. Since the publication date, technical changes have been made and substantive changes have also been adopted because of comments. Please note that the rules as presented in the fiscal note approved by OSBM on 02/13/2012 have been renumbered because of changes made during the public comment period. The rules approved by the CPH may be accessed at the following link:
http://cph.publichealth.nc.gov/Rules/EnvHealth/15A_NCAC_18A_.2650-2676_Food_Protection_and_Sanitation_of_Food_Establishment.htm

Summary of Changes (and adjusted impact if applicable)

15A NCAC 18A .2651(5)

- Addition of language to clarify exemptions from the rules. This language is consistent with the language in the current definition of a food establishment.
- No Impact

15A NCAC 18A .2652(2)

- Clarifies that the person in charge is not required to be a certified food protection manager when the establishment is not operating and food is not being prepared, packaged, or served for immediate consumption.
- Changed because of Public Comment
- No Impact

15A NCAC 18A .2652(4)(B)

- Added congregate nutrition sites to the exemption from the certification requirement. These sites do not prepare potentially hazardous foods in advance, so it is consistent with the exemption for Category I facilities that are exempt.
- Changed because of Public Comment
- No Impact - The congregate nutrition sites were not included in the cost estimate presented in the fiscal note as the original intent was to exempt them since the food is only catered and they do not prepare potentially hazardous food in advance.

15A NCAC 18A .2652(4)(C)

- Delays implementation of the certified food protection manager requirement until January 1, 2014 (approximately 15 months)
- Changed because of Public Comment
- **Impact—This effectively delays $4,496,000 Industry Cost and $391,000 Local Government Cost to Year two.**

15A NCAC 18A .2653(14)

- Delays implementation of the 41°F cold holding requirement an additional three years, to January 1, 2019.
- Changed because of public comment
- **Impact—This removes the $855,600 Industry Cost and Local Government Cost of $74,400 in year four.** In effect there will be no cost as a result of this rule. Rationale—The Division's research shows that the average life span of refrigeration equipment is 10-12 years. However, the NC Retail Merchants Association polled their members and determined that 20 years was the expected life of refrigeration equipment. The average life span from these two surveys is 16 years. Refrigeration equipment replaced since 1999 is designed to meet the 41°F standard. Therefore, equipment purchased on or before 1999 will be replaced by 2015 because of the equipment life span.

15A NCAC 18A .2653(15)(A)(2)(b)

- Changed to be consistent with the delay to 41°F as previously described.
- Changed because of Public Comment
- No Change in Impact—Date marking still occurs at either 41°F or 45°F; this just allows the use of 45°F and four-day date marking to control *Listeria monocytogenes* for an additional three-year period.

15A NCAC 18A .2654(2)

- Clarifies the type of equipment that can be used in food establishments; rules reference was corrected.
- Change based on Staff Comment; Technical Change
- No Impact

15A NCAC 18A .2663

- Corrected a typo
- Technical Change
- No Impact

15A NCAC .2665(g) and (h)

- Deleted language that is unnecessary
- Changed as a result of a recommendation from DPH attorneys/affirmed by the Commission for Public Health (CPH)
- No Impact

15A NCAC 18A .2668(a)

- Corrected a citation
- Technical Change
- No Impact

15A NCAC 18A .2668(e)

- Added an additional reference to clarify how wash, rinse, and sanitizing solutions must be maintained.
- Changed based on Public Comment
- No Impact

15A NCAC 18A .2669(c)

- Corrected a citation
- Technical Change
- No Impact

15A NCAC 18A .2669(e)

- Terminology correction.
- Technical Change based on Public Comment
- No Impact

15A NCAC 18A .2670 (c) and (d)

- Paragraphs (c) and (d) were combined to simplify the language.
- Technical change based on Staff Comment
- No Impact

15A NCAC 18A .2673(2)

- Deleted due to a conflict with the definition
- Change based on Staff Comment/affirmed by the CPH
- No Impact

15A NCAC 18A .2673 (4), (5), and (7)

- Language unnecessary and already covered in references to .2650-.2662 in opening paragraph of .2673.
- Change based on Public Comment
- No Impact

15A NCAC 18A .2674 (5) and 9)

- Language unnecessary and already covered in references to .2650-.2662 in opening paragraph of .2674.
- Change based on Public Comment
- No Impact

15A NCAC 18A .2675

- Citation corrected
- Technical change
- No Impact

Based on the changes describe above, Table 1 from the fiscal note approved by OSBM on 02/13/2012 is revised below:

Table A1.Revised Summary of Costs and Benefits from the Proposed Rule Changes

Costs	Year 1 (2013)	Year 2 (2014)	Year 3 (2015)	Year 4 (2016)	Year 5 (2017)	Year 6 (2018)	Year 7 (2019)
Industry[1]	$1,021,400	$4,496,000					$5,351,600
State Government[1]	$400						
Local Government	$908,300	$391,000					$465,400
Unquantifiable Costs	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Total Costs	**$1,930,100**	**$4,887,000**	**$0**	**$0**	**$0**	**$0**	**$5,817,000**
4-year NPV of Costs[2]	**$ 9,694,862**						
Benefits							
Industry	$182,200	$182,200	$182,200	$182,200	$182,200	$182,200	$182,200
State Government	-	-	-	-	-	-	-
Local Government	$15,800	$15,800	$15,800	$15,800	$15,800	$15,800	$15,800
Public	$1,578,900	$1,578,900	$1,578,900	$1,578,900	$1,578,900	$1,578,900	$1,578,900
Unquantifiable Benefits	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Total Benefits	**$1,776,900**	**$1,776,900**	**$1,776,900**	**$1,776,900**	**$1,776,900**	**$1,776,900**	**$1,776,900**
4-year NPV of Benefits[2]	**$ 9,576,228**						

[1] The industry and local governments would incur in 2019 costs of $855,600 and $74,400, respectively, related to the replacement of old refrigerators that cannot maintain a temperature of 41°F. Also, in 2019 establishments would have to renew their food protection manager certification.

[2] Net Present Value (NPV) is computed using a 7% discount rate.