

December 15, 2017

TO: Industry and Regulatory Food Safety Professionals and Food Business Owners

FROM: Division of Food and Lodging, ND Department of Health

SUBJECT: The Adoption of the 2013 FDA Model Food Code – Effective January 1, 2018

The North Dakota Department of Health, Division of Food and Lodging, recognizes the U.S. Food and Drug Administration (FDA) Model Food Code as the most practical, science-based guidance for ensuring that food offered at retail and in food service is safe, unadulterated and honestly presented. The current ND Food Code, NDAC 33-33-04, will be repealed and replaced, effective January 1, 2018, with NDAC 33-33-04.1, which adopts the 2013 FDA Model Food Code and its supplement by reference with modifications available online at www.ndhealth.gov/FoodLodging/.

To download a copy of the 2013 FDA Model Food Code, visit the U.S Food and Drug Administration's (FDA) website at:

www.fda.gov/food/guidanceregulation/retailfoodprotection/foodcode/ucm374275.htm. Click the link "Download Food Code 2013" and the link "Download Food Code 2013 Supplement" for a complete copy of the FDA 2013 Model Food Code.

The enclosed summary provides a synopsis of the major changes from the 2012 North Dakota Food Code (based on the 2009 FDA Food Code) to the newly adopted 2013 FDA Food Code. Please note, the requirement that at least one certified food protection manager is employed at the food establishment (paragraph 2-102.12) has been excluded from the ND Food Code, NDAC 33-33-04.1. For food establishments serving an extensive menu including complex food processes and for those serving a highly susceptible population (for example, infants, toddlers, the elderly, or the immunocompromised), the presence and supervision of a certified food manager is recommended by the Department as a best practice, but is not required unless otherwise specified under local ordinance.

Consultation with inspection staff is available regarding the new food code requirements to licensed food establishments during onsite inspections. Also, food establishments may contact their local health unit or the Food and Lodging Division to address questions about food code changes. Food businesses will be provided with a reasonable time (up to 6 months from the effective date of the rules) to come into compliance with the new requirements.

For questions about the provisions of the 2013 FDA Food Code, please call the Food and Lodging Division at 701.328.1291 or email foodandlodging@nd.gov, or contact your local health unit.

Summary of ND Food Code Changes North Dakota Administrative Code 33-33-04.1: Adoption of the 2013 FDA Model Food Code

The North Dakota Department of Health, Division of Food and Lodging, recognizes the U.S. Food and Drug Administration (FDA) model Food Code as the most practical, science-based guidance for ensuring that food offered at retail and in food service is safe, unadulterated and honestly presented. Starting January 1, 2018, the current ND Food Code, North Dakota Administrative Code (NDAC) 33-33-04, is replaced with NDAC 33-33-04.1 which adopts the 2013 FDA Model Food Code and its supplement by reference with modifications.

This summary provides a list of changes from the 2012 North Dakota Food Code (repeal effective on December 31, 2017) to the 2013 FDA Food Code adoption by reference (effective on January 1, 2018). The primary intent of this document is to provide a synopsis of the major changes to the Food Code and should not be relied upon as an absolute comparison that identifies each and every change.

To download the complete 2013 FDA Food Code, visit www.ndhealth.gov/foodlodging or the FDA's website at http://www.fda.gov/food/quidanceregulation/retailfoodprotection/foodcode/ucm374275.htm.

For questions about the provisions of the 2013 FDA Food Code, please call 701.328.1292, or contact your location health department.

Chapter 1 Purpose and Definitions

Added "Core Item", "Priority Item", and "Priority Foundation Item" in place of "Core Item" and "Critical Item."

Amended "Packaged" in (1) to delete the term "securely" to avoid undue emphasis on nature of the package; Amended "Packaged" in (2) to remove the phrase "or other nondurable container" to clarify when foods packaged at retail need to be labeled so that it reads: "Packaged" does not include wrapped or placed in a carry-out container to protect the food during service or delivery to the consumer, by a food employee, upon consumer request.

Deleted "Enterohemorrhagic Escherichia coli" (EHEC) as use of EHEC terminology is outdated.

Deleted the term Potentially Hazardous Food (Time/Temperature Control for Safety Food)" (PHF/TCS) and made a universal change throughout the Code to replace it with the term "Time/Temperature Control for Safety Food" (TCS). The definition remains the same.

Revised "Reduced Oxygen Packaging" subparagraph (2)(e), to delete the phrase "placed in a hermetically sealed, impermeable bag" and replace it with "vacuum packaged in an impermeable bag" so it clearly defines the sous vide process as outlined in Annex 6(2)(B)(4)(b). It now reads: "Sous vide packaging, in which raw or partially cooked food is vacuum packaged in an impermeable bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychotropic pathogens."

Revised "Shiga toxin-producing Escherichia coli" (STEC) to reflect current nomenclature.

Chapter 2 Management and Personnel

2-102.11(A)

Amended to replace "Critical Items" with "Priority Items".

Add the risk designations (Priority ^(P), Priority Foundation ^(Pf) and Core ^(C)) to each applicable code section for reference when recording observations in the inspection report.

2-102.12 (Excluded from ND Food Code NDAC 33-33-04.1)

Requirement of at least one certified food protection manager employed at the food establishment, when applicable.

2-103.11(L)

Added "food allergy awareness" as a part of the food safety training of employees by the Person in Charge

2-201.11, 2-201.12, 2-201.13

Amended to add nontyphoidal *Salmonella* (NTS) as one of the reportable illnesses for action by the Person in Charge; Added Code language to address employee health controls for the exclusion and restriction of nontyphoidal *Salmonella*, and removal of exclusion and restriction from NTS.

2-301.14(H)

Amended to clarify that the requirement to wash hands before donning gloves is specific to the beginning of a task involving working with food and not during the task.

Chapter 3 Food

3-201.16(A)

Amended to remove existing 2009 paragraph (A) language in reserve; Added new paragraph (A) to recognize a regulatory authority's ability to approve the sale of wild mushrooms within a food establishment and regulate wild mushrooms according to their LAW.

3-301.11(D)

Amended to revise subparagraph (D)(2) to clarify that paragraph (B) does not apply where a ready-to-eat food is added as an ingredient to another food that does not contain a raw animal food and the combined product will be heated to at least 63°C (145°F).

3-302.11(A)(1)

Amended language to exempt frozen, commercially processed and packaged raw animal foods from separate storage or display from RTE foods; Added new subparagraph (c) that allows this exemption.

3-304.11

Amended to add a new (C) to clarify that food may contact surfaces of linens and napkins as specified in Paragraph 3-304.13 and added term "Linens" to the tag line.

3-304.13

Amended to clarify that napkins in this section refers to cloth napkins and they are by definition considered linens.

3-401.11(D)

Amended to add new subparagraph (D) (2) to not allow the sale of undercooked, comminuted meat from a children's menu.

3-401.14

Added a new section on Non-continuous cooking of raw animal foods that specifies the criteria for using a non-continuous cooking process.

3-401.14(D)

Amended to revise paragraph (D) to clarify that prior to sale or service, raw animal foods cooked using a non-continuous cooking process shall be cooked to a temperature and for a time as specified under paragraph 3-401.11 (A)-(C).

3-402.11

Amended paragraph 3-402.11(B) to add a new paragraph (2) to clarify that scallop products consisting solely of the shucked adductor muscle are excluded from the requirements for parasite destruction and redesignated existing paragraph (2)-(4) to be new paragraph (3)-(5).

3-403.11

Amended paragraph 3-403.11(C) to clarify that this provision applies to all commercially processed TCS foods that are ready-to-eat. Previous text suggested that it applied only immediately upon removal of the food from a sealed container.

3-501.13

Amended to add new paragraph (E) specifying frozen fish packaged using a ROP method be removed from the ROP environment either prior to initiating thawing procedures under refrigeration as specified in paragraph (A) or prior to, or immediately upon completion of, its thawing using procedures specified in paragraph (B) of this section.

3-501.17

Amended to add new paragraph (F) that exempts raw, live in-shell molluscan shellfish from date marking and re-designated former paragraph (F) as new paragraph (G).

Amended existing subparagraph 3-501.17 (F)(6) to clarify that the exemption from date marking for shelf stable dry fermented sausages produced in USDA-regulated facilities is not dependent on the product retaining the original casing; Renumbered existing paragraph (F)(6) as new paragraph (G)(6) as a result of the addition of new paragraph (F).

3-502.11

Amended to revise paragraph (D) to make clear that only TCS foods prepared under ROP methods that do not control for growth of and toxin formation by *Clostridium botulinum* and the growth of *Listeria monocytogenes* require a variance.

3-502.12

Amended subparagraphs 3-502.12(B)(3)(b) and (B)(4) to delete 14 days and add 30 days.

Amended Paragraph 3-502.12(B) to add new subparagraph 7 specifying that a HACCP plan be provided to the regulatory authority prior to implementation.

Amended Paragraph 3-502.12(D) lead in paragraph to delete the word "FOOD" and replace it with the term "Time/Temperature control for safety food" to clarify that this section applies to TCS food.

Amended subparagraph 3-502.12(D)(2)(b) to specify only the cooking parameters in paragraph 3-401.11(A), (B) and (C) apply.

Amended subparagraph 3-502.12(D)(2)(e)(ii) to allow for cold holding at 41°F for 7 days after cooling to 41°F.

Amended to add new paragraph (F) to identify the conditions under which a HACCP Plan is not required for ROP TCS foods.

3-602.11

Amended paragraph 3-602.11(B)(2),(3),(5), and (7) to clarify the information that a label should include.

Amended subparagraph 3-602.11(B)(2) to clarify what information must be included in the statement of ingredients. The term "sub ingredients" was added to this subparagraph to clarify that individual component ingredients of a main ingredient must be disclosed in the statement of ingredients. This clarification helps to

make clear that all individual ingredients in a packaged food will be disclosed in the statement of ingredients.

Chapter 4 Equipment, Utensils, and Linens

4-302.13

Amended the tag line to add "mechanical warewashing"

Amended to redesignate the existing section into paragraph (A) and new paragraph (B) to require the availability of irreversible registering temperature indicators.

4-501.114(C)(3)

Amended to change "manufacturer's label" to "EPA-registered label use instructions" to harmonize with EPA terminology (CFP 2008-III-010).

4-602.11

Amended paragraph 4-602.11(B) to change the cleaning and sanitizing frequency for food contact surfaces or utensils that are in contact with a raw animal food that is a major food allergen such as fish, followed by other types of raw animal foods. With this change, the exception to existing subparagraph (A)(1) found in paragraph (B) now applies only to raw meat and poultry.

4-802.11

Amended paragraph 4-802.11(C) to clarify that napkins in this section refers to cloth napkins and they are by definition considered linens as mentioned in paragraph 3-304.11(C) and paragraph 3-304.13.

Chapter 5 Water, Plumbing, and Waste - No Changes

Chapter 6 Physical Facilities

6-301.12

Added new Paragraph (D) to allow the use of a high velocity blade of non-heated, pressurized air for hand drying.

Chapter 7 Poisonous or Toxic Materials

7-204.12

Amended paragraph 7-204.12(A) to redesignate paragraph (A) into a lead-in paragraph with four new subparagraphs: Added 21 CFR 173 Secondary Direct Food Additives Permitted in Food for Human Consumption as new subparagraph (A)(1); Added GRAS ingredients as new subparagraph (A)(2); Added effective food contact notifications as new subparagraph (A)(3); Added 40 CFR 156 Labeling Requirements for Pesticides and Devices as new subparagraph (A)(4) to allow the use of other antimicrobial agents allowed under the food contact notification program for washing fruits and vegetables as well as GRAS ingredients permitted as antimicrobials or for general food use.

Chapter 8 Compliance and Enforcement

8-201.13

Amended paragraph 8-201.13(B) to add new language to have the food establishment notify the Regulatory Authority through submission of a HACCP plan that they will be conducting ROP operations that conform with procedures in paragraph 3-502.12.

8-304.11

Amended to add new paragraph (K) to include a requirement for the permit holder to post a sign or placard notifying the public that inspectional information is available for review.