

SUBCHAPTER 09C - CURRENT GOOD MANUFACTURING PRACTICES FOR SPECIFIC FOOD INDUSTRIES

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History Note: Authority G.S. 106-122; 106-128; 106-139; 106-140;
Eff. February 1, 1976;
Amended Eff. May 1, 1983;
Repealed Eff. June 1, 1984.

SECTION .0200 - RETAIL AND WHOLESALE BAKERIES

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History Note: Authority G.S. 106-122; 106-128; 106-139; 106-140;
Eff. February 1, 1976;
Amended Eff. May 1, 1983; April 22, 1981;
Repealed Eff. June 1, 1984.

SECTION .0300 - FOOD BANKS

02 NCAC 09C .0301 SANITARY OPERATION OF FOOD BANKS

The sanitary requirements shall be in addition to those set out in Title 21, Code of Federal Regulations, Part 110.

History Note: Authority G.S. 106-141.1;
Eff. December 9, 1980;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 22, 2015.

02 NCAC 09C .0302 DEFINITIONS

The following definitions shall apply in this Section:

- (1) "Food Bank" means a nonprofit organization or nonprofit corporation engaged only in the practice of collecting donated food for distribution.
- (2) "Swells" means a condition of canned foods whereby internal pressure from gas production becomes sufficient to distort both ends of the container.
- (3) "Springers" means swollen cans characterized by one bulging end which, when pressed inward, causes the other end to bulge.
- (4) "Flippers" means normal appearing cans which when struck on one end (or side) will cause the other end to spring outward. The bulged end can be pushed back in with light pressure.
- (5) "Low-acid Foods" means any foods other than alcoholic beverages with a finished equilibrium pH value greater than 4.6 and a water activity greater than 0.85.
- (6) "Brights" means foods packaged in metal cans to which labels have not been attached.
- (7) "Department" means North Carolina Department of Agriculture.
- (8) "High Risk Foods" means foods which provide optimum conditions for microbial growth with special reference to pathogenic (disease causing) organisms.

*History Note: Authority G.S. 106-141.1;
Eff. December 9, 1980;
Amended Eff. October 1, 1987;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 22, 2015.*

02 NCAC 09C .0303 RECONDITIONING AREA

Areas used for reconditioning of food items for distribution shall be properly lighted and equipped with hot and cold water, facilities for sanitizing where required, adequate plumbing and waste disposal.

*History Note: Authority G.S. 106-141.1;
Eff. December 9, 1980;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 22, 2015.*

02 NCAC 09C .0304 RECONDITIONING AND LABELING

- (a) All metal cans of food offered for distribution shall be free from rust and rim and/or seam dents which would compromise the integrity of the can. Springers, flippers and swells shall be deemed to be unfit for distribution.
- (b) Fresh fruits and vegetables, especially those donated because of age or ripeness, must be culled to remove those which would be unfit for human consumption.
- (c) Meats offered for distribution must have originated from an inspected source, be free of microbiological spoilage and kept stored under adequate refrigeration temperature.
- (d) All packaged merchandise, including brights, shall be labeled with at minimum, the name of the food and the manufacturer or distributor.

*History Note: Authority G.S. 106-141.1;
Eff. December 9, 1980;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 22, 2015.*

02 NCAC 09C .0305 UNSUITABLE FOOD

The following foods have been deemed high risk and not suitable for distribution:

- (1) Home-canned low-acid foods including but not limited to asparagus, beans, beets, broccoli, carrots, corn (any style), dates, figs, hominy, peas, pimentos, potatoes, spinach, squash, sweet potatoes, turnip greens, and mixed vegetables;
- (2) Baked goods posing a potential health risk including but not limited to cream pies, egg custards, "eclairs," cream-filled products, coconut pies and coconut cakes.

History Note: Authority G.S. 106-141.1;

Eff. December 9, 1980;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 22, 2015.

02 NCAC 09C .0306 RECORDS

Records of all incoming donations shall be kept to include the following information:

- (1) product;
- (2) lot size;
- (3) lot code;
- (4) manufacturer;
- (5) donor; and
- (6) date of receipt.

History Note: Authority G.S. 106-141.1;
Eff. December 9, 1980;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 22, 2015.

02 NCAC 09C .0307 REGISTRATION

Each food bank shall register with the department prior to the commencing of distributing food.

History Note: Authority G.S. 106-141.1;
Eff. December 9, 1980;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 22, 2015.

02 NCAC 09C .0308 RESTRICTIONS

Food which has been received for distribution may not reenter commercial channels.

History Note: Authority G.S. 106-141.1;
Eff. December 9, 1980;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 22, 2015.

SECTION .0400 - HOME PROCESSORS OF ACIDIFIED FOODS

- 02 NCAC 09C .0401 GENERAL: GOOD MANUFACTURING PRACTICES**
- 02 NCAC 09C .0402 DEFINITIONS**
- 02 NCAC 09C .0403 INGREDIENTS IN PROCESSING**
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History Note: Authority G.S. 106-122; 106-128; 106-130; 106-139; 106-139.1; 106-140;
Eff. April 22, 1981;
Repealed Eff. June 1, 1984.

SECTION .0500 - SMOKED AND SMOKE-FLAVORED FISH

02 NCAC 09C .0501 GENERAL: CURRENT GOOD MANUFACTURING PRACTICES AND FISH AND FISHERY PRODUCTS

(a) The criteria in 21 CFR Part 110 shall apply in determining whether the facilities, methods, practices, and controls used for the manufacture, processing, packing, or holding of fish and seafood products comply with and are operated or administered in conformity with good manufacturing practices to produce, under sanitary conditions, food for human consumption.

(b) The criteria in 21 CFR Part 123 – Fish and Fishery Products, as adopted by reference in 02 NCAC 09B .0116(o)(56), shall apply to facilities subject to Part 123 process fish and fishery products.

*History Note: Authority G.S. 106-139;
Eff. January 1, 1985;
Readopted Eff. March 1, 2017.*

02 NCAC 09C .0502 DEFINITIONS

The following definitions shall apply to this Section:

- (1) Smoked or smoke-flavored fishery products means the finished food prepared by:
 - (a) Treating fish with salt (sodium chloride), and
 - (b) Subjecting it to the direct action of smoke from burning wood, sawdust, or similar material or imparting to it the flavor of smoke by a means other than the direct action of smoke such as immersing it in a solution of wood smoke. This definition shall not alter the labeling requirements.
 - (c) This Paragraph does not alter the labeling requirements.
- (2) "Hot process smoked or hot-process smoke-flavored fish" means the finished food prepared by subjecting forms of smoked fish to heat.

*History Note: Authority G.S. 106-139;
Eff. January 1, 1985;
Readopted Eff. March 1, 2017.*

02 NCAC 09C .0503 PLANTS AND GROUNDS

(a) Unloading platforms shall be:

- (1) maintained free of refuse; and
- (2) equipped with drainage facilities adequate to accommodate all seepage and wash water.

(b) The following processes shall be carried out in separate rooms or facilities, and the interior walls separating these processes shall extend from floor to ceiling and contain only necessary openings (such as for conveyors and doorways):

- (1) receiving or shipping;
- (2) storage of raw fish;
- (3) presmoking operations (thawing, dressing, brining, etc.);
- (4) drying and smoking;
- (5) cooling and packing; and
- (6) storage of final product.

(c) The product shall be so processed as to prevent contamination by exposure to areas, utensils, equipment involved in earlier processing steps, or refuse.

*History Note: Authority G.S. 106-139;
Eff. January 1, 1985;
Readopted Eff. March 1, 2017.*

02 NCAC 09C .0504 SANITARY FACILITIES

(a) Hand-washing and sanitizing facilities shall be located in all processing rooms or in one area easily accessible from the processing rooms.

(b) Readily understandable signs directing employees to wash and sanitize their hands after each absence from post of duty shall be posted in all processing rooms and elsewhere in the plant as appropriate, such as bathrooms or break areas.

(c) Offal shall be placed in covered containers for removal at least once a day, or more frequently if necessary, or shall be removed by conveyors or chutes.

*History Note: Authority G.S. 106-139;
Eff. January 1, 1985;
Readopted Eff. March 1, 2017.*

02 NCAC 09C .0505 SANITARY OPERATIONS

- (a) Before beginning the day's operation, all utensils and product-contact surfaces of equipment to be used for the day's operation shall be rinsed and sanitized.
- (b) Containers used to convey or store fish shall not be nested while they contain fish or otherwise handled during processing or storage in a manner conducive to direct or indirect contamination of their contents.
- (c) Cleaning and sanitizing of utensils and portable equipment shall be conducted in an area set aside for these purposes and shall be carried out in such a manner as to prevent contamination of fish or fish products.

*History Note: Authority G.S. 106-139;
 Eff. January 1, 1985;
 Readopted Eff. March 1, 2017.*

02 NCAC 09C .0506 EQUIPMENT AND PROCEDURES

- (a) All food-contact surfaces such as tanks, belts, tables, and utensils shall be so designed and of such material and workmanship as to be cleanable.
- (b) Metal seams shall be smoothly soldered, welded, or bonded.
- (c) Each freezer and cold storage compartment used for fish or fish products shall be fitted with the following:
 - (1) an automatic control for regulating temperature;
 - (2) an indicating thermometer so installed as to show accurately the temperature within the compartment; and
 - (3) a temperature recording device so installed as to indicate accurately at all times the temperature within the compartment.
- (d) Thermometers or other temperature-measuring devices shall have an accuracy of ± 2 degrees Fahrenheit.

*History Note: Authority G.S. 106-139;
 Eff. January 1, 1985;
 Readopted Eff. March 1, 2017.*

02 NCAC 09C .0507 PROCESSES AND CONTROLS

- (a) Raw materials
 - (1) Upon receipt, fresh fish shall be inspected and washed before processing. Only fish free from adulteration and organoleptically detectable spoilage shall be processed.
 - (2) Upon receipt, every lot of fish that has been partially processed in another plant, including frozen fish, shall be inspected, and only fish free from adulteration and organoleptically detectable spoilage shall be processed.
 - (3) Fresh or partially processed fish, except those to be immediately processed, shall be iced or otherwise refrigerated to an internal temperature of 38 degrees fahrenheit or below upon receipt and shall be maintained at 38 degrees fahrenheit until the fish are to be processed.
 - (4) All fish received in a frozen state shall be either thawed promptly and processed, or stored at a temperature that will maintain it in a frozen state.
- (b) Defrosting of frozen fish
 - (1) Defrosting shall be carried out in a sanitary manner and by such methods that the wholesomeness of the fish is not adversely affected. Frozen fish shall be defrosted:
 - (A) in air at 45 degrees fahrenheit or below until other than hard frozen; or
 - (B) in air so that the temperature in any part of the fish does not exceed 45 degrees fahrenheit; or
 - (C) in a continuous water-overflow thaw tank or spray system in such a manner that the temperature in any part of the fish does not exceed 45 degrees fahrenheit.
 - (2) When a thaw tank is used, fish shall not remain in the tank longer than one-half hour after they are completely defrosted.
 - (3) Fish entering the thaw tanks shall be free of exterior packaging material and free of liner material.
 - (4) After thawing, fish shall be washed with a water spray or a continuous waterflow system.
- (c) Presmoking operation
 - (1) Evisceration of fish shall be performed with minimum disturbance of intestinal tract contents.
 - (2) After evisceration, the fish (including the body cavity) shall be washed with a water spray or a continuous waterflow system.

- (3) All fish shall be dry-salted at a temperature not to exceed 38 degrees fahrenheit throughout the fish, or shall be brined in such a manner that the temperature of the fish and the brine:
 - (A) does not exceed 60 degrees fahrenheit at the start of brining;
 - (B) if between 38 degrees fahrenheit and 50 degrees fahrenheit at the start of brining, is continuously lowered to 38 degrees fahrenheit or below within 12 hours;
 - (C) if between 50 degrees fahrenheit and 60 degrees fahrenheit at the start of brining, is continuously lowered to 50 degrees fahrenheit or below within 2 hours and to 38 degrees fahrenheit or below within the following 10 hours; and
 - (D) does not rise above 38 degrees fahrenheit after reaching that temperature or below either prior to or during the brining operation.
- (4) Fish shall be rinsed with fresh water after brining.
- (d) Heating, cooking, smoking operation
 - (1) A point-sensitive, continuous temperature-recording device shall be used to monitor both the internal temperature of the fish and the ambient temperature within the oven. Each recording-device record shall be identified as to the specific oven load and date processed.
 - (2) Hot-process smoked or hot-process smoke-flavored fish shall be heated by a controlled heat process that provides a monitoring system positioned in as many locations in the oven as necessary to assure a continuous temperature throughout each fish.
 - (3) The process selected by the processor shall be at least equivalent to a process established by a competent processing authority to achieve a safe product.
- (e) Packing
 - (1) The finished product shall be handled only with clean, sanitized hands, gloves, or utensils.
 - (2) Manual manipulation of the finished product shall be kept to a minimum.
 - (3) The finished product shall be cooled to a temperature of 50 degrees fahrenheit or below within three hours after cooking and further cooled to a temperature of 38 degrees fahrenheit or below within 12 hours after cooking, and 38 degrees fahrenheit shall be maintained during all subsequent storage and distribution.
 - (4) The shipping containers, retail packages, and shipping records shall indicate by appropriate labeling the perishable nature of the product and shall specify that the product shall be shipped, stored, and held for sale at 38 degrees fahrenheit or below until consumed.
 - (5) Permanently legible code marks shall be placed on the outer layer of every finished product package and master carton. Such marks shall identify the plant where packed, the date of packing, and the oven load. Records shall be so maintained as to provide positive identification;
 - (A) of the process procedures used for the manufacture of hot-process smoked or hot-process smoke-flavored fish; and
 - (B) of the distribution of the finished product.
- (f) Testing. Microbiological and chemical examination of in-line and finished product samples shall be conducted with sufficient frequency to assure that processing steps and sanitary procedures are adequate.

*History Note: Authority G.S. 106-139;
Eff. January 1, 1985;
Readopted Eff. May 1, 2017.*

SECTION .0600 - PROCESSING OF EGGS

02 NCAC 09C .0601 COMMINGLING OF SHELL AND EGG PROHIBITED

Eggs for human food shall be processed in a manner which:

- (1) allows examination of the content of individual eggs being processed; and
- (2) does not allow egg content to commingle with the egg shell or shell membrane during processing.

*History Note: Authority G.S. 106-131; 106-139;
Eff. April 1, 1987;
Readopted Eff. March 1, 2017.*

SECTION .0700 - BOTTLED WATER

02 NCAC 09C .0701 SCOPE

The source approval requirements of this Section apply to bottled water sources located within this State. Bottled water from sources located outside this State must comply with the source approval requirements of Title 21, Code of Federal Regulations, Part 129, which is adopted by reference in 02 NCAC 09B .0116(o)(57).

*History Note: Authority G.S. 106-139;
Eff. April 1, 1992;
Temporary Amendment Eff. May 13, 1996;
Amended Eff. April 1, 2003; April 1, 1997;
Readopted Eff. March 1, 2017.*

02 NCAC 09C .0702 DEFINITIONS

For the purposes of this Section:

- (1) "Approved source" when used in reference to a plant's product or operations water, means a source of water and the water therefrom, whether it be from a spring, well, municipal water supply, or any other source that has been approved by the Department of Agriculture and Consumer Services' designated representative, the Department of Environmental Quality, Division of Water Resources in accordance with this Section;
- (2) "Spring" means a natural orifice in the earth's surface from which water freely flows without the aid of mechanical means;
- (3) "Well" means a hole that is cored, bored, drilled, jetted, dug, or otherwise constructed so as to tap an aquifer from which water is withdrawn by mechanical means.

*History Note: Authority G.S. 106-139;
Eff. April 1, 1992;
Temporary Amendment Eff. May 13, 1996;
Amended Eff. April 1, 1997;
Readopted Eff. March 1, 2017.*

02 NCAC 09C .0703 SOURCE APPROVAL

(a) If the proposed source is from an existing approved public water supply system, the provisions of Paragraphs (b), (c), and (d) of this Rule shall not apply.

(b) If the proposed source is a well, the provisions of 15A NCAC 18C, Rules Governing Public Water Supplies, shall apply. Copies are available upon request from the Public Water Supply Section.

(c) If the proposed source is a spring, source approval is reviewed in a two step process. The first step is approval of the spring site. A representative of the Department of Environmental Quality shall conduct an initial site investigation. Consideration shall be given to spring location, potential for surface water influence, hydrological and geological features, proximity of potential sources of pollution, and site ownership and control.

- (1) If the investigation reveals influence by surface water or other factors which render the site unsuitable for development as a safe water source, the investigation shall be terminated.
- (2) If the investigation does not reveal influence by surface waters, and all other factors as set forth in this Rule are considered satisfactory for site development, the provisions of Paragraph (d) of this Rule shall apply.
- (3) If the investigation reveals factors set forth in this Rule which warrant further investigation, the Department of Environmental Quality may require, as a condition for continued investigation, evaluation of the site or specific factors influencing the site by a geologist or engineer licensed to practice in North Carolina. If the Department of Environmental Quality determines that the investigation and report illustrate that the questionable factors do not hinder the suitability of the site to produce a safe water source, the provisions of Paragraph (d) of this Rule shall apply.

(d) In the second step of the spring investigation, spring water shall be sampled and data collected to determine the capability of source water to meet current North Carolina drinking water quality standards under the most severe anticipated environmental conditions. The following requirements shall apply to the water sampling and data collection process:

- (1) Sampling and data collection shall be conducted by the spring owner or his representative for the following parameters:
 - (A) Flow in gallons per minute (on-site measurement);

- (B) Precipitation in inches (on-site measurement);
 - (C) Temperature (on-site measurement);
 - (D) pH;
 - (E) Conductivity;
 - (F) Turbidity;
 - (G) Coliform bacteria; and
 - (H) Microscopic analysis for organic debris, larvae, animal or insect parts, algae, diatoms, rotifers, coccidia and giardia cysts.
- (2) The minimum sampling and data collection period shall be six consecutive months. The period shall also include a minimum of two storm events (two or more inches of rainfall in a 24-hour period). It is the owner's responsibility to monitor rainfall in the vicinity of the spring site.
 - (3) Water samples for parameters (1)(A) through (1)(F) of this Paragraph shall be collected and analyzed at least weekly on the same day of the week before a storm event occurs. After a storm event occurs, water samples for parameters (1)(A) through (1)(F) of this Paragraph shall be collected and analyzed within 24 hours and then twice a week for two weeks. Water samples for parameter (1)(G) of this Paragraph shall be collected and analyzed at least monthly and an additional sample shall be collected and analyzed within 24 hours after each storm event. Water samples for parameter (1)(H) of this Paragraph shall be measured at least two times during the sampling period. The first analysis of water samples for parameter (1)(H) of this Paragraph shall be conducted during the first month of the sampling period, and at least one of the samples shall be collected within 24 hours of a storm event.
 - (4) The owner may develop or begin to develop a spring before beginning the process of sample collection and analysis. Unfavorable sample results shall not be discounted on the basis of inadequate spring development at the time of sample collection. If the owner intends to develop the spring in its final form before monitoring, he shall complete the requirements of Paragraph (e) of this Rule prior to construction.
 - (5) Water sample collection and analysis shall be conducted in accordance with the recommendations of the current edition of "Standard Methods for the Examination of Water and Wastewater" which is adopted by reference at 02 NCAC 09B .0116(n), including subsequent amendments and editions. Water sample analyses for parameters (1)(D) through (1)(H) of this paragraph shall be conducted by a laboratory certified by the State of North Carolina. . All measurements and sample results (with attached laboratory analysis reports) shall be kept in a tabular form and submitted to the Department of Environmental Quality at the end of the monitoring period. Upon review of the data, sample results and sample analysis, the Department of Environmental Quality shall determine the capability of the source to meet current North Carolina drinking water quality standards. If the water source is determined to be unsatisfactory, the investigation shall be terminated. If the source is determined to be satisfactory, the provisions of Paragraph (e) of this Rule shall apply.

(e) Plans and specifications for construction of the source, protective covering, piping, and storage facilities shall be submitted to the Department of Environmental Quality by an engineer licensed to practice in the State of North Carolina for review and approval prior to beginning construction or letting a contract for construction. For spring sources, the plans and specifications may be presented by the licensed engineer at any point during the process outlined in Paragraph (d) of this Rule. Springs shall not be developed in their final form until plans and specifications for the spring have been approved.

(f) Neither the bottling of water nor the selling of water for bottling shall begin until compliance with this Section has been completed and the Department of Environmental Quality receives certification from an engineer licensed to practice in North Carolina that the project has been constructed in accordance with the approved plans and specifications.

*History Note: Authority G.S. 106-139;
Eff. April 1, 1992;
Readopted Eff. May 1, 2017.*

02 NCAC 09C .0704 LABELING

History Note: Authority G.S. 106-139;

Eff. April 1, 1992;
Temporary Repeal Eff. May 13, 1996;
Repealed Eff. April 1, 1997.