

**SUBCHAPTER 9C - CURRENT GOOD MANUFACTURING PRACTICES FOR SPECIFIC FOOD  
INDUSTRIES**

**SECTION .0100 - SOFT DRINK PLANTS**

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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Repealed Eff.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**

<b>02 NCAC 09C .0201</b>	<b>SANITARY OPERATION OF RETAIL AND WHOLESALE BAKERIES</b>
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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Repealed Eff.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.*

### 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.*

### 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.*

### 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.*

**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.*

**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.*

**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.*

**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.*

**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**
- 02 NCAC 09C .0404      SCHEDULED PROCESS REQUIRED**
- 02 NCAC 09C .0405      LABELING**

**02 NCAC 09C .0406      DAILY PROCESS RECORDS**

*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**

(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 are in conformance 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 these Rules set forth additional requirements for the hot process smoked or hot-process smoke-flavored fish industry.

*History Note:*      *Authority G.S. 106-139; 106-267; 106-267.2;*  
*Eff. January 1, 1985.*

**02 NCAC 09C .0502      DEFINITIONS**

The following definitions apply;

- (1) "Smoked fish" means any fish that is prepared by treating it with salt (sodium chloride) and then subjecting it to the direct action of smoke from burning wood, sawdust, or similar material.
- (2) "Smoke-flavored fish" means any fish that is prepared by treating it with salt (sodium chloride) and then imparting to it the flavor of smoke by other than the direct action of smoke. This Paragraph does not alter the labeling requirements.
- (3) "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; 106-267; 106-267.2;*  
*Eff. January 1, 1985.*

**02 NCAC 09C .0503      PLANTS AND GROUNDS**

(a) Unloading platforms shall be:

- (1) made of readily cleanable material; and
- (2) equipped with drainage facilities adequate to accommodate all seepage and wash water.

(b) The following processes should be carried out in separate rooms or facilities, and the interior walls separating these processes should 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.

(c) The following processes shall be carried out in separate room 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) Cooling and packing;
- (2) Storage of final product.

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

*History Note:* Authority G.S. 106-139; 106-267; 106-267.2;  
Eff. January 1, 1985.

#### **02 NCAC 09C .0504 SANITARY FACILITIES**

(a) Adequate hand-washing and sanitizing facilities shall be located in the processing room(s) or in one area easily accessible from the processing room(s).

(b) Readily understandable signs directing employees to wash and sanitize their hands after each absence from post of duty shall be conspicuously posted in the processing room(s) and elsewhere in the plant as conditions require.

(c) Offal shall be placed in suitable covered containers for removal at least once a day, or more frequently if necessary, or shall be removed by conveyors or chutes. Offal, debris, or refuse from any source whatever shall not be allowed to accumulate in or about the plant.

*History Note:* Authority G.S. 106-139; 106-267; 106-267.2;  
Eff. January 1, 1985.

#### **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 should be conducted in an area set aside for these purposes and shall be carried out in such a manner as to prevent contamination of the fish or fish products.

*History Note:* Authority G.S. 106-139; 106-267; 106-267.2;  
Eff. January 1, 1985.

#### **02 NCAC 09C .0506 EQUIPMENT AND PROCEDURES**

(a) All food-contact surfaces (tanks, belts, tables, utensils, and other equipment) shall be made of readily cleanable materials.

(b) Metal seams shall be smoothly soldered, welded, or bonded.

(c) Each freezer and cold storage compartment used for the product shall be fitted with at least the following:

(1) An automatic control for regulating temperature;

(2) An indicating thermometer so installed as to show accurately the temperature within the compartment;

(3) A recording thermometer 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; 106-267; 106-267.2;  
Eff. January 1, 1985.

#### **02 NCAC 09C .0507 PROCESSES AND CONTROLS**

(a) Raw materials

(1) Fresh fish received shall be inspected and adequately washed before processing. Only sound, wholesome fish free from adulteration and organoleptically detectable spoilage shall be processed.

- (2) Every lot of fish that has been partially processed in another plant, including frozen fish, shall be adequately inspected, and only clean, wholesome fish 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 that temperature 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 should 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 substantially free of liner material.
  - (4) After thawing, fish shall be washed thoroughly with a vigorous water spray or a continuous waterflow system.
- (c) Presmoking operation
- (1) Evisceration of fish shall be performed with minimum disturbance of intestinal tract contents. Removal of viscera shall be complete.
  - (2) After the evisceration process, the fish (including the body cavity) shall be thoroughly washed with a vigorous 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; and
    - (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; and
    - (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 strategic locations in the oven as necessary to assure a continuous temperature throughout each fish.
  - (3) The process selected by the processor as adequate under the conditions of manufacturer 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 this temperature 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/or 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 at least 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 should be conducted with sufficient frequency to assure that processing steps and sanitary procedures are adequate.

*History Note:* Authority G.S. 106-139; 106-267; 106-267.2;  
Eff. January 1, 1985.

## SECTION .0600 - PROCESSING OF EGGS

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

No person shall process any eggs for human food in any manner which:

- (1) does not allow examination of the content of individual eggs being processed; and
- (2) allows 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.

## SECTION .0700 - BOTTLED WATER

### 02 NCAC 09C .0701 SCOPE

The source approval requirements of this Section apply to bottled water sources located within the state. Bottled water from sources located outside the state must comply with the source approval requirements of Title 21, Code of Federal Regulations, Part 29, which is adopted by reference in 02 NCAC 09B .0116(p)(16).

*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.

### 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's designated representative, the Department of Environment, Health, and Natural Resources, Environmental Health Division, Public Water Supply Section in accordance with this Section;
- (2) "Spring" means a natural orifice in the earth's surface through 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 through which water is derived 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.*

**02 NCAC 09C .0703 SOURCE APPROVAL**

(a) If the proposed source is from an existing approved public water supply system, proceed to Paragraph (e) of this Rule.  
(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, approval requires a two step process. The first step is approval of the spring site. A representative of the Department of Environment, Health, and Natural Resources 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, proceed to Paragraph (d) of this Rule;
- (3) If the investigation reveals factors which warrant further investigation, the Department of Environment, Health, and Natural Resources 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 Environment, Health, and Natural Resources 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, proceed to Paragraph (d) of this Rule.

(d) The second step of the spring investigation requires water sampling and data collection 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 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;
  - (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) Parameters listed as (1)(A) through (1)(F) of this Paragraph shall be monitored at least weekly on the same day of the week before a storm event occurs. After a storm event occurs, parameters (1)(A) through (1)(F) of this Paragraph shall be monitored within 24 hours and then twice a week for two weeks. Parameter (1)(G) of this Paragraph shall be monitored at least monthly plus one sample within 24 hours after each storm event. Parameter (1)(H) of this Paragraph shall be measured at least two times during the sampling period. The first analysis shall be conducted during the first month of the sampling period. At least one of the samples shall be collected within 24 hours of a storm event;
- (4) The extent to which the spring is developed before beginning the monitoring process is at the discretion of the owner. This may have a bearing on the analysis results, and some spring site improvement may be advisable. Unfavorable sample results will not be discounted on the basis of inadequate spring development at the time of sample collection. The owner may wish to obtain the advice of an engineer or other consultant. 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) These measurements and analyses 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 2 NCAC 9B .0016(11) and at a laboratory certified by the State of North Carolina for parameters (1)(D) through (1)(H) of this Paragraph. All measurements and sample results (with attached laboratory analysis reports) shall be kept in a neat tabular form and submitted to the Department of Environment, Health, and Natural Resources at the end of the monitoring period. The spring owner may consult with the Department of Environment, Health, and Natural Resources at any point during the monitoring period. Upon review of the data and sample results, the Department of Environment, Health, and Natural Resources 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, proceed to Paragraph (e) of this Rule.

(e) Plans and specifications for construction of the source, protective covering, piping, and storage facilities shall be submitted to the Department of Environment, Health, and Natural Resources 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 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 constructed to the final intended form until plans and specifications for the spring have been approved.

(f) The bottling of water or the selling of water for bottling shall not begin until compliance with this Section has been completed and the Department of Environment, Health, and Natural Resources 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.

## **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.