CHAPTER 13, SUBJECT 1

THERMAL PROCESS CONTROL POLICY FOR FEDERALLY REGISTERED CANNERIES

1. SCOPE

This document outlines the regulations, policies and procedures governing the control of thermal processes for the commercial sterilization of low-acid and acidified low acid canned foods. It explains thermal processing controls that are to be followed by registered canneries which are in addition to the general requirements for registration of establishments covered in Chapter 2, Subject 1; Chapter 5, Subject 2 and Chapter 6, Subject 2 of this manual.

2. AUTHORITIES

Fish Inspection Act, R.S.C., 1985, c F-12; Part I, Fish Inspection Regulations (FIR), C.R.C., 1978, c. 802

Section 34 (FIR)

Canned fish shall be sterilized by a method approved by the President of the Agency.

3. DEFINITIONS

Acidified Low-Acid Food: a low-acid food that has been treated in a manner, acid(s) or acid food(s) are added, so that all components have attained an equilibrium pH of 4.6 or below by the time the thermal process is completed.

Come-up Time: the time, including vent time, which elapses between the introduction of the heating medium into the closed retort and the time when the temperature in the retort reaches the required processing temperature.

Commercial Sterility of Canned Fish: the condition obtained in a canned fish product which has been processed by the application of heat, alone or in combination with other treatments, to render the food free from viable forms of microorganisms, including spores, capable of growing in the foods at temperatures at which the food is normally designed to be held during storage and distribution.

Such a process is designed to result in the reduction of

the reference organism, *Clostridium botulinum*, by 12 log (12D concept). This value may not ensure the destruction of all spoilage organisms. It is the processor's responsibility to determine which critical factors will be used to ensure destruction of the pathogen *C. botulinum* as well as spoilage organisms.

Can: means any hermetically sealed container.

Canned Fish: means any fish that is sealed in a can and is sterilized.

Control Measure: an action performed to eliminate a hazard or reduce it to an acceptable level.

Corrective Action: the procedure that is to be followed whenever a deviation from a critical limit in a HACCP plan occurs or whenever the results of monitoring procedures in respect of a prerequisite program plan or regulatory action point plan show that there is non-compliance with the Fish Inspection Regulations.

Critical Control Point: a point in a process operation at which control is to be applied in order to prevent or eliminate a hazard or reduce it to an acceptable level.

Critical Factor: physical and chemical factors that can influence the thermal response of a product to a thermal process, the variation of which may influence the scheduled process, including container, product, retort and processing conditions

Critical Limit: the maximum or minimum value to which a hazard must be controlled at a critical control point.

Deviation: failure to deliver the scheduled thermal process, meet critical factors related to the delivery of the thermal process, or critical limits relating to the process.

Deviation Procedure: documented set of corrective actions that are implemented when a process deviation occurs.

Documentation: the physical or electronic record of the procedures or activities that are to be followed as they relate to the thermal process. Documentation explains what controls are in place and how these controls are delivered. They include but are not limited to written formulae, procedures or specifications used by the processor or required by a manufacturer.

Equilibrium pH: the condition attained in an acidified low-acid food product in which there is no further change in the pH of any of the components.

Heat-Penetration Tests: scientific experiments conducted to determine heating and cooling behavior of a product/package combination, processed in a specific retort system, in order to establish safe thermal processes that will result in commercially sterile product or to evaluate process deviations. Chapter 13, Subject 3 contains a protocol for carrying out heat-penetration studies.

Hermetically Sealed Container: a container designed and intended to be secure against the entry of microorganisms, including spores.

Incubation: tests in which the thermally processed product is kept at a specific temperature for a specific period of time in order to determine if outgrowth of micro-organisms or other problems occur under tested conditions.

Initial Temperature: the product temperature of the coldest container to be processed at the time the sterilization cycle begins.

Inoculated Pack: a test pack used in scientific experiments wherein microorganisms to be targeted by the thermal process are added to a substrate (product) to confirm the adequacy of a theoretical process.

Lethality: F represents the time intercept from a thermal-death time curve (log t_{gm} vs T) at T = Tx. The F value is often referred to as the process lethality and it is the equivalent time in minutes, at a specific temperature, required to reduce the bacterial load of a target organism whose *z* value is known. The sterilizing value of a process is generally expressed as an F_0 value which is equivalent to the number of minutes required to destroy a specific number of organisms with a *z* value of 10 °C (18 °F), at 121.1 °C (250 °F).

Low-Acid Food: a food where any component of the product has a pH greater than 4.6 and a water activity greater than 0.85.

Minimum Initial Temperature: the lowest temperature in a container for which the thermal process was established.

Objective Evidence: information which can be proven true, based on facts obtained through observation, measurement,

test or other means.

Process Authority: means any person or organization that has been recognized by the Agency as being competent in developing and evaluating thermal processes.

This would include competency in the following areas:

- considerable knowledge concerning product characteristics, critical factors relating to the thermal process and the effect the commercial equipment and procedures will have on the heating and cooling characteristics of the product and the delivery of the thermal process;

- experience in conducting studies relating to thermal processing of food, such as heat-penetration and temperature-distribution studies, and thermal-death time and validation studies and the application of other scientific methods relating to thermal processing;

- the ability to evaluate data generated by scientific studies and tests in order to document: the effectiveness of the thermal process relating to the production of safe and commercially sterile product; and, that testing has been carried out to identify all possible factors which could affect the heating characteristics of the product and the safety of the final product.

Process Verification: written confirmation from a thermal process specialist or process authority that the calculated lethality from the use of a non-standardized process achieved commercial sterility or that the use of a standardized process resulted in commercial sterility.

Records: observations, measurements and other data written by the processor, or recorded by means of monitoring equipment to document the adherence to critical limits, critical factors, or other process requirements.

Retort: a pressure vessel designed for thermally processing food, packed in hermetically sealed containers, by an appropriate heating medium and where necessary with super-imposed pressure.

Scheduled Process: the thermal process alone or in combination with critical factors, and verified by the thermal process specialist or process authority, for a given product formulation, container type and size and thermal processing system to achieve commercial sterility

of the product.

Standardized process: a thermal process, that has been published and subject to peer review, based on generally accepted scientific principles, and designed to produce a commercially sterile product.

Temperature-Distribution Study: test(s) performed to determine the time, temperature or other parameters that must be met to ensure uniform temperature is established in the retort system.

Thermal Process: the thermal treatment required to achieve commercial sterility and is quantified in terms of time and temperature.

Thermal-Process Specialist: person(s) or organization having expert knowledge of thermal-processing requirements for foods in hermetically sealed containers, having access to facilities for making such determinations, and designated by the cannery to determine the scheduled thermal process(es) and vent schedule(s). The thermal-process specialist is responsible for:

- establishing the thermal process and identifying all critical factors;

- establishing the vent schedule;

- assuring the retort system is capable of delivering the thermal process; and

- analyzing process deviations and providing the processor with appropriate corrective actions.

Time Lapse: the time between sealing containers filled with product and retorting.

Underprocessed Product: product that has been thermally processed but not all of the requirements specified of the scheduled process have been met.

Unprocessed Product: product that has been sealed in containers but has not yet been subjected to a thermal process.

Venting: means the complete removal of air from steam retorts through the vents by the introduction of steam, or other appropriate methods, prior to the attainment of the sterilization temperature.

Vent Schedule: a schedule indicating a specific period of time and a specific temperature that must be achieved in order to effectively remove air from the retort, so that a uniform sterilizing temperature can be obtained throughout the retort. The vent schedule is determined by analyzing data generated during a temperature distribution study.

Verification: confirmation by examination and provision of objective evidence that specified requirements (standard) have been fulfilled.

Water Activity: the ratio of the water vapor pressure of a food to the vapor pressure of pure water at the same temperature and pressure.

4. POLICY

4.1 No thermal process shall be used to process canned fish in a federally registered establishment until a Quality Management Plan (QMP) has been developed and documented and the processor's system verification has been accepted by the Fish, Seafood and Production Division of the Canadian Food Inspection Agency (CFIA) for the specific canned fish product.

4.2.1 The following information must be in the processor's QMP and available for review by the CFIA:

a) management roles and responsibilities (recommended information);

b) product and process information;

c) the product description, which must identify those product attributes and characteristics as described in Section 2 of the Fish Inspection Regulations that are important in ensuring a safe and acceptable canned fish product;

d) the process flow diagram, which must outline all of the production steps and assist in identifying those steps that are important in processing a safe canned fish product meeting all regulatory requirements;

e) a Prerequisite Plan;

f) a Regulatory Action Point Plan; and

g) a Hazard Analysis Critical Control Point (HACCP) Plan.

4.2.2 The following is a list of the type of information that must be maintained in the QMP file:

a) name and address of the thermal-process specialist, or the process authority;

b) product preparation and formulation;

c) container type and size;

d) vent schedule (time and temperature) for the cannery's specific retort system;

e) the process time, process temperature, and cooling procedure for the specific canned fish product being processed;

f) heat-penetration data relating to the canned fish product, or a letter from the cannery's thermal-process specialist or process authority;

g) temperature-distribution study(s) for the retort system and a retort survey (a Cannery Retort Survey is included in Appendix A);

h) method of container loading of the retort;

i) written verification of the thermal process to be used by the processor, provided by the thermal-process specialist or process authority for standardized and non-standardized thermal processes;

j) non-standardized thermal process: written documentation expressing the minimum lethality being delivered by the thermal process in order to achieve commercial;

k) standardized thermal process: written verification provided by the thermal process specialist or process authority that the process produces a commercial sterile product;

l) all critical factors related to achieving commercial sterility must be identified to ensure the adequacy of the thermal process;

m) test conditions used to design the thermal process.

This list is not all inclusive as there may be other information which is relevant to a particular process and that must be recorded in the file.

4.3 The vent schedule shall be based on temperature-distribution studies performed under the supervision of a thermal-process specialist or process authority. The vent schedule shall identify the minimum time and temperature required for a specific retort installation to reach uniform temperature. The vent schedule shall specify the testing conditions and all critical factors that will impact on the retort system reaching uniform temperature. Consideration should be given to steam-header pressure, divider hole size/spacing, valve settings, container loading, maximum number of retorts being vented at one time, and other steam operations that may impact on venting.

4.4.1 The Fish, Seafood and Production Division recognizes Bulletin 26L (Thermal Processes for Low-Acid Foods in Metal Containers) published by the Grocery Manufacturers Association (GMA) as containing standardized processes. When using a standardized process from Bulletin 26L, the processor will not have to report the lethality (F_o) being delivered by the process.

However, the processor must have a thermal-process specialist or process authority verify in writing that the standardized process being used commercially by the processor satisfies all of the process design parameters and critical factors that have been identified with the product being thermally processed, and renders it commercially sterile. Commercial sterility is not defined in the regulations in terms of a sterilizing value (F_o) but it is internationally accepted that a minimum sterilizing value (F_0) of 3 minutes is required to render a low-acid food microbiologically safe. It is the processor's responsibility to determine which critical factors will be used to ensure destruction of the pathogen *C.botulinum* as well as spoilage organisms and based on such information, a sterilizing value (F_0) above 3 may be necessary. Written verification provided by the thermal-process specialist or process authority is to be placed in the processor's QMP file.

4.4.2 If an unstandardized process is used, the processor must have on file documentation supporting the design and development of the thermal process. The thermal-process specialist or process authority must verify in writing that the process being used commercially by the processor delivers a commercially sterile product and report the minimum process lethality (F_o), delivered by the process. Commercial sterility is not defined in the regulations in terms of a sterilizing value (F_o) but it is internationally

accepted that a minimum sterilizing value (F_0) of 3 minutes is required to render a low-acid food microbiologically safe. It is the processor's responsibility to determine which critical factors will be used to ensure destruction of the pathogen *C. botulinum* as well as spoilage organisms and based on such information, a sterilizing value (F_0) above 3 may be necessary to achieve commercial sterility.

4.4.3 All critical factors related to the product, as specified by the thermal-process specialist, must be monitored and controlled as part of the cannery's QMP. The processor must maintain records to demonstrate that these critical factors are being controlled.

4.5 A temperature-distribution test must be conducted to verify the effectiveness of the vent schedule when changes are made to the retort, steam supply piping or to ancillary equipment that may affect temperature distribution. The equipment must also be inspected by the thermal-process specialist, in accordance with the requirements of Chapters 5.2 and 6.2 of this Manual, before production commences. All relevant documentation verifying the vent schedule must be available for review.

Replacement of a steam spreader with an identical spreader would not require additional testing, but replacement of a pipe with a different diameter or a change in hole size or spacing would require a temperature distribution test to validate the change(s). New valves would be accepted providing the processor could demonstrate that the valves had the same flow coefficients (C_v value).

4.6 The CFIA shall audit all retort installations and scheduled thermal processes. The Canadian Food Inspection Agency shall also review the names and qualifications of the thermal-process specialist or process authority used by the processor. The results of the retort audit shall be recorded on the Cannery Retort Survey form (Appendix A) and this form will become part of the cannery QMP audit.

4.7 In the event of a process deviation, the processor shall be responsible under the QMP to have a procedure in place to effectively control the product; evaluate the deviation to ensure that potential health and safety hazards have been addressed and commercial sterility has been achieved; and to take product action as necessary. Product shall be held for evaluation and disposition by the thermal-process specialist or process authority when the critical factors of a scheduled process are not being met by the processor.

4.8 Heat-penetration and temperature-distribution studies being carried out in registered establishments, to develop scheduled processes or vent schedules, must be performed under the direction of a thermal-process specialist or process authority. All relevant data associated with these tests is to be documented in the QMP file.

5. FORMS/DOCUMENTS

The following documents are provided for optional use:

Appendix A - Cannery Retort Survey Reports

APPENDIX A

Cannery Retort Survey Report

PLANT NAME: _____ **LOCATION**:_____

PLANT ADDRESS: _____ **DATE**:_____

1. EQUIPMENT

RETORT SHELL

Diameter_____ Length_____

Single door _____ Double door _____

STEAM SUPPLY

1. Steam header pipe size _____(in.)
2. Pipe size to retort _____(in.)
3. Number of branch lines off main header _____
4. Size of regulating valve _____(in.)
5. Steam line pressure _____(p.s.i.) (regulated Pressure)
6. Steam spreader size _____(in.)
   number of holes _____
   size of holes _____(in.)
7. Boiler type _____
8. Capacity of boiler _____

INSTRUMENTS AND CONTROLS

1. Type of controller unit- _____
2. Controller probe wells bled - Yes_____ No_____
3. Thermometer - range _____
   - degrees per scale division _____
   - easily read from operating station _____
4. Thermometer wells bled _____
5. Pressure gauges - range _____
   - pounds per scale division _____
   - easily read _____
6. Date of last servicing _____

RETORT LOADING EQUIPMENT

Bussy cart _____ baskets _____

Jumble pack _____ divider plates _____ metal _____ plastic _____

divider plate holes- size_____ spacing_____

chimneys used _____

Note: **Attach a drawing of the retort piping and valve configuration to complete this section.**

2. OPERATION

Written instructions provided to retort operator for:

Venting procedure _____

Process time _____

Process temperature _____

Venting Schedule used:

Time_____(min), and

Temperature_____^{0}F minimum

Temperature distribution test conducted by: _____

Date of test: _____

Cooking Processes Used:

Product	**Can Size**	**Init. Temp.**	**Validated Scheduled Process**		
			deg. F	Time(min.)	Temp.(deg.C)
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____

Thermal-process specialist: _____

Can Cooling:

In retort _____ Out of retort _____
Water spray _____ In air _____
Water flood _____ Water channel _____
Air overpressure _____

Cooling Time_____(min.)

Cannery Retort Survey Report - Detailed

Plant Name:_____

Reg.No.:_____

Plant Address: _____ Date: _____

A. RETORT SHELL

Retort Number : _____

Horizontal: Diameter/Width _____ Length _____ No. Of Doors _____

Vertical: Diameter /Width _____ Height _____ No. Of Doors _____

Manufacturer/Date of Manufacture/Model (where available)_____

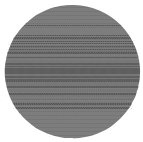
_____

B. STEAM SUPPLY:

1. No. of Boilers _____
2. Manufacturer/Model No./Capacity_____

   _____
3. Steam header pipe size _____ (in.)
4. Pipe size to retort _____ (in.)
5. Number branch lines off main header _____
6. Size of regulating valve _____ (in.)
7. Steam line pressure _____ (p.s.i., regulated pressure)
8. Steam spreader
   a. Location of spreader _____
   b. Configuration of spreader _____
   c. Pipe diameter _____ (in.)
   d. No. Of Holes _____
   e. Diameter of Holes _____ (in.)
   f. Location of holes on spreader pipe (sketch):

   Show placement of holes on spreader cross-section, indicate retort wall and direction to vent



C. VENT PIPING

1. Water-spreader used for venting? Yes _____ No _____
2. Location of vent (reference steam inlet) _____
3. Smallest restriction in vent outlet _____ (in.)
4. Valve type (if other than gate, describe in full) _____

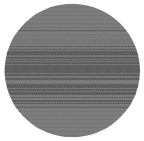
_____

5. Valve size _____ (in.)

D. WATER & AIR PIPING, BLEEDERS

1. Water Spreader
   a. Location of spreader _____
   b. Configuration of spreader _____
   c. Pipe diameter _____ (in.)
   d. No. Of Holes _____
   e. Diameter of Holes _____ (in.)
   f. Location of holes on spreader pipe (sketch):

Show placement of holes on spreader cross-section, indicate retort wall



2. Water/Air valves are positive-closing? Yes _____ No (describe) _____
3. Evidence of leaking water/air valves? No _____ Yes (describe)_____
4. Retort Bleeders
   i. Number _____
   ii. Bleeder opening diameter _____ (in)
   iii.Locations (on horizontal retorts reference distance from the retort ends, on all retorts reference steam inlet)_____

   _____
5. Condensate drain visible by operator? Yes _____ No (describe) _____

E. INSTRUMENTS AND CONTROLS

1. Controller Manufacturer & Model No. - _____
2. Controller probe wells bled? Yes____ No____
   a. Bleeder diameter _____ (in.) b. Smallest restriction to bleeder well _____ (in.)

3. Manufacturer's required/equivalent chart type(s):_____
4. Continous Time/Temperature Recorder
   a. Temperature range - _____
   b. No. of degrees per division - _____
   c. Time range - _____
   d. No. of minutes per division- _____
5. Temperature Measuring Device
   a. MIG thermometer ? Yes ____ Other (describe) _____
   b. Length of thermometer scale _____
   c. Temperature range - _____ No. of degrees per division - _____
   d. Easily readable by operator? Yes _____ No (describe) _____
   e. Last calibration date: _____
   f. Calibration records checked: Yes _____ No (describe) _____
   g. Evidence of break in mercury column No ___Yes Describe)_____
   h. MIG thermometer wells bled? Yes____ No____
      1) Bleeder diameter _____ (in.) 2) Smallest restriction to bleeder well _____ (in.)
6. Pressure gauges
   a. Locations: Retort: _____ Main steam supply to retort: _____
   b. Compound -type pressure gauge (on retort) Yes _____ No _____
   c. Gooseneck/Gauge siphon present (on retort) Yes _____ No _____
   d. Range of pressure gauges -_____
   e. Pounds per scale divsion - _____
   f. Easily readable by operator? Yes _____ No (describe) _____
   g. Last calibration dates: _____
   h. Calibration records checked: Yes _____ No (describe) _____
7. Wall clock
   a. No. of clocks: _____ b. Location _____
   c. Clock description (type/size/hh.mm.ss indicated) _____
   d. Easily readable by operator? Yes _____ No (explain) _____

F. RETORT LOADING EQUIPMENT

1. Container Loading Equipment

a. Retort baskets (4-walls & base) _____

i. Bottoms perforated Yes _____ No (describe) _____

ii. Hole diameter & spacing _____ (in.) on _____ (in.) centre, or describe,

_____

_____

b. Retort buggies (base, no walls) _____

i.Bottoms perforated Yes _____ No (describe) _____

ii. Hole diameter & spacing _____ (in.) on _____ (in.) centre, or describe,

_____

_____

c. Flexible container racking used _____

i. Maximum allowable pouch thickness(es) _____

ii. Racking design: Describe, _____

_____

_____

d. Container contact surfaces in good repair, no sharp edges ? Yes _____ No _____

e. Dividers used? Yes _____

i. Divider construction material _____

ii. Hole diameter & spacing _____ (in.) on _____ (in.) centre, or describe,

_____

_____

f. Are chimnies used? No _____ Yes _____

Comments:

**** Attach a drawing of the retort installation to complete this section.**

CANNERY RETORT OPERATION

A. RETORT OPERATION

1. Retort operation is

   a. Fully automated _____ , Describe _____

   b. Partially automated _____ , Describe _____

   _____

   c. Fully manual _____

2. Written instructions are provided to retort operator for:

   Venting procedure? _____

   Cooking time - temperature? _____

   Cooling procedure? _____

   Process Deviation? _____

3. Vent and Thermal Processes are Posted ? Yes _____ No (explain) _____

4. Can Cooling:

In retort?_____ Out of retort?_____

Water spray?_____ In air?_____

Water flood?_____ Water channel?_____

Air overpressure?_____

Where drains are large enough to allow passage of containers drains are screened?

Yes _____ No (describe) _____

Retort cooling water - _____ppm free residual chlorine at discharge from cooling cycle

Retort cooling water protected from contamination after treatment? _____

Cooling water temperature _____ (where critical)

Comments:

B. THERMAL PROCESSES IN USE (*Attach additional pages where required*):

Product Description	Vent	Thermal Process	Critical Factors