Ministry for Primary Industries
Manatū Ahu Matua

Guidance Document

Further Processing: Commercial Sterilisation

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Title

Guidance Document: GD Further Processing: Commercial Sterilisation

About this document

This Part applies to the commercial sterilisation of low acid non-dairy animal products, and more specifically, processors of meat (including poultry), and seafood products. It provides guidance to assist operators to comply with the Animal Products Act 1999 (APA), as they develop and validate their RMPs for commercial sterilisation, and for routine processing.

Related Requirements

- Animal Products Regulations 2000 [AP Regs]
- Animal Products (Risk Management Programme Specifications) Notice 2008 [RMP Spec]
- Animal Products (Requirements for Risk Management Programme Outlines) 2008
- Animal Products Notice: Specifications for Products Intended for Human Consumption [HC Spec]

Document history

Version	Version Date	Section Changed	Change(s) Description
1	July 2009		
2	May 2018	Entire Part	Content updated, reformatted and rebranded

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1 Purpose

Commercial sterilisation is the process of heating products to achieve long term shelf stability. This Part explains the requirements for operators carrying out commercial sterilisation of low acid canned foods (i.e. retorted products with a pH of 4.6 or higher or a water activity of greater than 0.85). It applies to processors of non-dairy animal products such as red meat, poultry and seafood. The term 'canned' includes rigid, semi-rigid and flexible packaging options such as cans, glass jars, trays and pouches.

There are detailed requirements to be met by those operating commercial sterilisation processes, contained in the Codes listed in HC Spec clause 14.10 (see section 4.1). Operators must select one of the Codes to follow and ensure that their operation complies.

This Part provides guidance on aspects of the Codes, and other legal requirements under the APA (e.g. competency and calibration). If there is a contradiction in this Part with a Code, the Code takes precedence. As the focus of the Codes is on the control of biological hazards the operator must ensure that their RMP also addresses any chemical and physical hazards, and wholesomeness risk factors.

This Part does not apply to ultra-high temperature processing and aseptic packaging (i.e. UHT processing).

1.1 Layout of part

The layout of this Part aligns with the activities carried out as an operator develops, validates and operates a commercial sterilisation process. Some or all of the sections may be relevant, depending on the process and equipment involved.

This Part contains:

- references to the following regulatory requirements with citations given in square brackets:
  - Animal Products Regulations 2000 [Ap Reg];
  - Animal Products Notice: Specifications for Products Intended for Human Consumption [HC Spec];
  - Animal Products (Risk Management Programme Specifications) Notice 2008 [RMP Spec]; and
  - Australia New Zealand Food Standards Code [FSC].
- procedures to assist with compliance; and
- additional information (shown in boxes).

Operators must comply with regulatory requirements and should follow the procedures for compliance unless alternative practices have been included in their registered RMP. The additional information in boxes is to assist with understanding.

2 Definitions

canned product means food that:

a) is processed and packed in accordance with good manufacturing practice; and
b) is packed in clean or sterilised containers that are hermetically sealed; and
c) is processed by heat to ensure preservation, whether before or after being sealed in a container. [HC Spec]

come up time means the time between the introduction of heat to the retort and when the retort reaches the specified processing temperature

commercial sterilisation means the condition achieved by application of heat, alone or in combination with other treatments to eliminate microorganisms capable of growing under normal non-refrigerated conditions at which the product is likely to be held during distribution and storage

critical failure, in relation to container closures, means anything that would affect the integrity of the container

F0 means a measure of the amount of lethal heat which results from a specified thermal process (usually measured at the point of lowest lethality in the container). The F0 number is the lethal effect equivalent to the number of minutes at 121.1°C when assuming instantaneous heating and cooling and a **z value** of 10°C

flexible container means a container whose shape is affected by the enclosed product (e.g. retort pouches) (Codex)

headspace means the volume in a container not occupied by the product

heat penetration tests means experiments conducted to determine heating and cooling behaviour of a product/package combination, processed in a specific retort system, to establish safe thermal (scheduled) processes that will result in commercially sterile product or to evaluate process deviations

heat processing time means the time that the containers are held at the specified processing temperature

heat transfer distribution study means a study used to determine the ability of the retort to uniformly mix and distribute the heat transfer medium

hermetically sealed means air tight, completely sealed and impermeable to gas

initial temperature (IT) means the average temperature of the contents of the coldest container to be retorted when heat processing begins, (i.e. at the start of the come-up time), and is usually the first container to be prepared for processing

leaker means a sealed and heat processed container which has a defect that allows the passage of water, gas or microbes into the container

lethality means the effect of exposure to time and temperature transformed mathematically to give a measure of the sterilisation achieved (summed values usually being expressed as F or F0)

low-acid product means:

a) any animal product, other than an alcoholic beverage, where any component has a pH value greater than 4.6 after heat processing, and a water activity (aw) greater than 0.85; but
b) does not include animal product in a hermetically sealed container that is required to be stored under refrigeration [HC Spec]

minimum initial temperature means the lowest initial product temperature in a container (specified in the scheduled process) that the process has been developed for

over pressure means pressure in excess of that corresponding to the saturated steam pressure at a given temperature and corrected for altitude

operator means the owner or other person in control of the business

qualified canner means a person who meets the competency specification set out in clause 5.2 of the HC Spec

retort means a pressure vessel, designed for heat processing product packed in hermetically sealed containers

rigid container is a container whose shape is not affected by the enclosed product or deformed by an external mechanical pressure of up to 0.7kg/cm2 (10psig) (e.g. cans, glass jars) (Codex)

saturated steam means pure steam in equilibrium with water at the same temperature. Under these conditions, the temperature of the steam is entirely dependent on its pressure

scheduled process means the thermal process alone or in combination with critical factors for a given product formulation, container type and size and thermal processing system that will achieve commercial sterility of the product

semi-rigid container means a container whose shape is not affected by the enclosed product under normal atmospheric temperature and pressure but can be deformed by an external mechanical pressure of less than 0.7kg/cm2 (10 psig) (e.g. tetra-bricks, pottles) (Codex)

suitably skilled person means a person who, in the opinion of the operator, is skilled in a particular activity or task through training, experience or qualifications

temperature distribution study means a study carried out using distributed measuring devices to establish venting schedules, and temperature stability and uniformity throughout the retort system

vacuum means the negative internal pressure in the container produced during the seaming process

venting means flushing air out of steam retorts at the beginning of a heat process. It is done by allowing large volumes of steam to flow through the retort to drive and carry air out through open vents in the retort

z value means a measure of the temperature resistance of the target microorganism, i.e. the temperature change required to effect a tenfold change in the rate of microbial destruction

3 Regulatory Requirements

Refer to Chapter 1 for the specific legal requirements that apply to commercial sterilisation.

4 Commercial Sterilisation Procedures

4.1 General requirements

(1) The operator must document procedures for the commercial sterilisation of low acid canned products that comply with the principles detailed in one of the following codes:

a) the Code of Hygiene Practice for Low Acid and Acidified Low-Acid Canned Foods, as published by the Codex Alimentarius Commission: (CAC/RCP 23-1979); or

b) the United States Food and Drug Administration requirements for Thermally Processed Low-acid Foods Packaged in Hermetically Sealed Containers, as contained in 21 CFR Part 113; and Acidified Foods as contained in 21 CFR Part 114. [HC Spec 14.10].

(2) The operator must document and meet any regulatory limits applicable to the product [RMP Spec 7 & 11].

Additional Information – Regulatory limits

There are currently no regulatory limits for commercially sterilised products.

(3) The operator must establish, document and meet operator-defined limits that are appropriate for the product and have evidence to justify their selection. [RMP Spec 7 & 11].

Additional Information – Operator-defined limits

Operator-defined limits are measurable limits that are established by the operator and are not defined in legislation. Operator-defined limits may be expressed as:

- a product requirement (e.g. a microbiological limit);
- a process parameter (e.g. a minimum time and temperature combination);
- a performance criteria (e.g. a 12 $\log_{10}$ reduction in the concentration of a pathogen, i.e. 12D reduction).

(4) Calibrated equipment must be used to take critical measurements during validation work and routine processing, and records kept [HC Spec Part 6].

4.2 Outcome of commercial sterilisation

(1) The operator should ensure that an F0 of 3 or greater is achieved in the product, unless scientific justification for a lower F0 has been validated in the RMP.

(2) The operator must ensure that any spoilage organisms capable of growing under normal non-refrigerated conditions (at which the product is likely to be exposed to) are eliminated or reduced to acceptable levels by the process.

4.3 Competency requirements

(1) Personnel who supervise low acid canned food operations must meet the competency requirements for "Supervisors of thermal processing of low acid canned products" in clause 5.2(1)(b) of the HC Spec:

Additional Information

Personnel who are carrying out the following activities must be supervised:

- operators of heat processing systems (retort operators);
- those involved with product preparation;
- those performing container closure inspections.

At least one qualified supervisor with the specified competency should be on-site when processing. The operator should ensure that there are sufficient trained staff available to cover for illnesses, holidays and resignations etc.

(2) Personnel carrying out container closure evaluations must be suitably skilled [HC Spec 14.10].

(3) Personnel carrying out or supervising the development of scheduled processes (including equipment commissioning) must meet the competency requirements for "Qualified persons" in clause 5.2(2) of the HC Spec.

(4) Personnel responsible for checking and signing off scheduled processes prior to release for commercial production must:

a) be independent of the development process; and
b) meet the competency requirements of clause 5.2(2) of the HC Spec.

Additional Information

These people are often referred to as "qualified canners" or "approved persons".

(5) Personnel carrying out any other key tasks must be identified in the RMP and any required competencies specified [RMP Spec 15].

(6) Training records must be kept [HC Spec 5.3 and RMP Spec 15].

4.4 Equipment

Additional Information

Detailed equipment requirements are specified in the two Codes listed in 4.1 General Requirements. The following information highlights the key equipment requirements only.

(1) Retorts must be equipped with:

a) a pressure gauge;
b) an independent temperature measuring device (e.g. resistance-temperature device (RTD)) that:

i) is calibrated in accordance with HC Spec 6.2;
ii) if defective or cannot be adjusted to the accurate calibrated reference device, is repaired before further use, or replaced.

c) an automatic temperature recording device adjusted to read no higher than the known accurate independent temperature measuring device to provide a permanent record of the process;
d) an accurate temperature controller;
e) for automated systems, a programmable logic controller (PLC) or computer to run the system, that is protected from unauthorised access. [HC Spec 14.9]

(2) An accurate, readable timing device must be readily visible to personnel in the retorting room.

4.5 Raw materials

(1) Raw materials must comply with the requirements of the Food Standards Code.

(2) Raw materials must be protected from contamination, handled hygienically and stored in a manner that will minimise deterioration [AP Reg 9].

(3) When developing new products or modifying existing formulations, ingredient microbiological loading must be considered.

(4) The operator must have procedures to ensure that raw materials are not changed in a formulation (including supplier, type or addition rate) without input from a qualified canner.

Additional Information – Microbiological loading

In general, the higher the initial microbiological loading of raw materials, the more severe the thermal process will need to be. The microbiological criteria for raw materials should not exceed the ability of the process to reduce the loadings to acceptable levels.

Raw materials must be handled and GOP maintained to minimise contamination and growth prior to thermal processing.

4.6 Packaging

(1) All packaging must:

a) comply with clause 7.2(1) of the HC Spec and the operator must have documented evidence of compliance, by stating the full reference to the regulation, part, section or standard with which the packaging complies; and
b) be used in accordance with the manufacturer's specifications; and
c) be appropriate to the intended use, and filling and sealing equipment used [HC Spec 7.2(2)];
d) be clean and sound before filling.

Additional Information – Package sealing and cleaning

Sealing
Packaging should be obtained from reputable suppliers who can provide competent technical support. Written specifications for can or other packaging sealing parameters should be obtained from the supplier.

Cleaning
Rigid containers may be cleaned by:

- inverting the containers to dump out dust and foreign matter, where appropriate; and
- blasting their interior surfaces with water (including steam), air, or vacuum to loosen and remove dust and foreign matter.

Semi-rigid containers should not be washed prior to use (unless effective drying is possible) as water in the sealing area may reduce the seal reliability. Flexible containers (pouches) usually don't require cleaning before use.

(2) Packaging must be stored in a way that prevents contamination [AP Reg 16].

4.7 Thermal process development

(1) A qualified canner must carry out or supervise the development and validation of each scheduled process [HC Spec 5.2(2)].

(2) A qualified canner who is independent of the development process in (1) must check and sign off the scheduled process [HC Spec 5.2(2)].

(3) A report of the validation work must be documented by the qualified canner [RMP Spec 18].

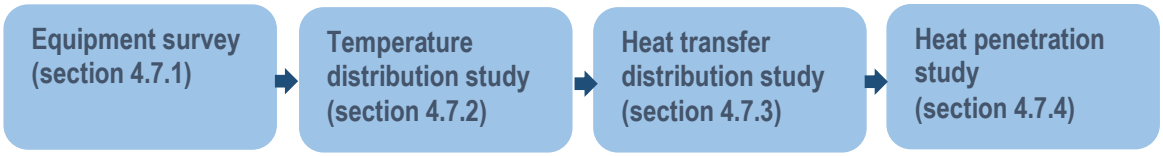
(4) The validation report and associated records must be kept by the operator [RMP Spec 18 and 19, HC Spec 9.2].

Additional Information
Qualified canners should use their knowledge and experience, gained through training and other means when developing and validating scheduled processes. The following documents may provide useful guidance:

- The Institute for Thermal Processing Specialists provides Guidelines for conducting thermal processing studies
- The Canadian Food Inspection Agency provides guidance on Process Determinations for Thermal Processes

The operator must have evidence that the RMP is effective. Part of this evidence are the reports produced by qualified canners. The reports must be retained for the life of the process (unless they are superseded, in which case the obsolete documents must be stored for an additional 4 years). If production of a particular product ceases, the validation reports should be kept for another 4 years (or for the shelf life of the product, if that is longer than 4 years).

Developing a scheduled process is likely to involve some, or all, of the following activities:



These activities are discussed in succeeding sections.

4.7.1 Processing equipment survey

(1) A survey of all retort installations should be carried out to ensure that they are properly installed.

Additional Information

Further detail about equipment surveys is given in the IFTPS Guidelines for conducting thermal processing studies.

4.7.2 Temperature distribution studies

Additional Information

When validating a scheduled process it is important to know that the each retort will deliver the required thermal process to all product. Before a retort is brought into service and any heat penetration work undertaken, temperature distribution studies should be carried out. If only one retort from a range is to be tested rather than each individual retort, the reason for selecting the retort should be documented.

Temperature distribution studies may not be necessary for continuous retorts, at the discretion of the qualified canner.

(1) Temperature distribution studies must be carried out to:

a) determine temperature uniformity and stability throughout the loaded retort; and
b) identify the point that is slowest to reach the scheduled processing temperature; and
c) where required, establish an adequate venting schedule for each container size and loading configuration, or the venting schedule for the most difficult container size and loading configuration to vent that can then be used as the standard.

(2) The decision to carry out temperature distribution studies rests with the qualified canner. If the trials are not carried out, justification for this should be documented in the RMP.

(3) The qualified canner must identify all factors critical to temperature distribution within the retort.

(4) Temperature distribution studies should be carried out under worst case conditions for temperature uniformity, that are likely to be encountered during commercial operations, for example:

a) operating at full design capacity and under partial loading;
b) using each container size or loading density, or using the container size and loading density that would be most difficult to achieve uniform temperatures;
c) using retort separator or divider sheets that have the smallest percentage of open areas;
d) operating at full capacity of the essential services;
e) operating at the highest retort temperature to be used during commercial production.

(5) Temperature distribution studies should be conducted:

a) when a retort is commissioned;
b) when there are changes to a critical factor such as a retort component, plumbing, container arrangement, introduction of dividers, retort relocation or any other change that could negatively impact on heat transfer;
c) as a minimum, every 2-3 years.

(6) The retort installation and process lines should be assessed at least annually by the qualified canner to check for any unplanned variation or modification that has been made to the design, installation or operation of equipment, process lines or essential services that would impact on food safety.

(7) The frequency of assessment in (6) should be documented in the RMP.

Additional Information – Records

Records may include diagrams of the retort and temperature probe placements, photos, calibration records, descriptions of the test conditions, retort programme, readings and records taken during the trials, trial data, results and analysis.

4.7.3 Heat transfer distribution studies

Additional Information – Heat transfer distribution studies

In addition to temperature distribution studies, heat transfer distribution studies may be needed (e.g. if using steam and air overpressure systems) to ensure adequate heat transfer into packages throughout the retort.

See the IFTPS Guidelines for conducting thermal processing studies for further guidance on when heat transfer distribution studies maybe needed and how to carry them out.

4.7.4 Development of a scheduled process and heat penetration tests

Additional Information - Heat penetration tests

Heat penetration tests are used to collect the time-temperature history of a product in a specific retort system, measured at the slowest heating point in the container, to establish the scheduled process. The results are used to calculate the lethal effect of the process, usually expressed as an F0 value.

The tests are carried out at locations in the retort that will achieve the lowest lethality. All critical factors associated with the product, package, retort loading and process which may affect heating rate are investigated. The tests are carried out using the product formulation, package, loading and retort process that will be used for commercial production.

(1) The maximum time from the containers being filled to being processed should be specified as part of the scheduled process, taking into consideration;

a) conditions which may permit microbial growth;
b) the production of heat stable toxins; and
c) the impact on heat transfer characteristics of the product.

(2) The time referred to in (1) should not exceed 2 hours unless the operator has evidence to support an acceptable alternative.

Additional Information – Longer holding times

Evidence for longer holding times may be gained using computer modelling programmes, literature or trials and experiments, considering the factors listed in (1).

(3) The operator should have evidence to support the location selected to be the slowest heating point (i.e. cold spot) of the product inside the container.

(4) The operator should have confidence that the temperature measuring devices and/or data loggers (e.g. thermocouples, wireless data loggers) used to collect data, provide accurate readings under the conditions of use.

(5) Qualified canners must use their experience to ensure that all relevant factors are addressed when developing and validating the scheduled process. Factors that should be addressed are listed as follows (note, this list is not exhaustive):

a) date of development of the scheduled process;
b) name of the qualified canner that developed the scheduled process;
c) name of the qualified canner who independently checked the scheduled process;
d) product name, code, type and formulation reference;

e) preparation, filling and closure of product (e.g. hot fill, cold fill, product arrangement, headspace, pre-cook);
f) detailed formulation (including maximum particle size, fat content, % composition, % solids, pH, net weight, consistency or viscosity (particularly for rotary processes);
g) weight, size, type and manufacturer of the containers;
h) minimum initial product temperature;
i) all other critical factors in the product that must be controlled and the associated parameters (e.g. maximum product thickness for flexible containers);
j) pre-process hold time (minimum and maximum);
k) retort(s) the process applies to;
l) container/tray loading, nesting, orientation;
m) the line speeds for continuous operations, and rotation speed where appropriate;
n) venting schedule where appropriate;
o) come up time and temperature parameters;
p) sterilisation time and temperature parameters;
q) over-pressure schedule where appropriate;
r) cooling procedure, including cooling water temperature;
s) testing carried out to validate the scheduled process, including information about the equipment used to collect the data, results of temperature distribution studies, cold spot location within the container, heat penetration tests etc.;
t) F0 achieved by the process;
u) any other information that is relevant to a particular product and process.

(6) The scheduled process should be based on the worst case scenario likely to be encountered during commercial production, for the given product specifications and equipment capabilities.

(7) Heat penetration tests must be validated in the production retort under commercial operating conditions to confirm the adequacy of the process parameters. This includes provisional schedules that are derived from F0 calculations using data from similar processes or from reference material.

(8) Temperature measuring devices should be inserted into at least 10 containers for each heat penetration test. Where this is not possible, more replicate test runs should be carried out (IFTPS, 2014).

(9) At least 2 confirmatory runs should be carried out to confirm the scheduled process (IFTPS, 2014). This may need to be increased in situations where there is unacceptable variation within and between runs as determined by the qualified canner.

(10) Any changes that are made to a critical process or product factor, including the product formulation, container size or retorting must be assessed and where necessary the process revalidated by a qualified canner.

(11) If a process is revalidated, it must be independently checked and signed off by a qualified canner, prior to implementation.

(12) If an automatic control system is used to control the process, the system must be validated by the qualified canner.

4.8 Container washing

(1) When required, to remove organic material, containers should be washed after closure using water sprays or a continuous flow water bath, at a temperature that is adequate to ensure the removal of any product scraps.

(2) The wash water may contain an approved maintenance compound.

Additional Information

In the case of cans, extraneous material should not remain on the surface as this will induce corrosion and rusting.

Sealed containers that are dirty should be rinsed to remove protein residues and then washed with hot water and detergent. Washing containers in hot water without pre-rinsing may coagulate soluble proteins making them difficult to remove.

4.9 Retort loading

(1) To ensure that all containers undergo a thermal process, all retort baskets, trolleys or containers must be marked with temperature change indicators (e.g. cards, strips) which change colour permanently if they are heated to a specific temperature, or other effective means to visually indicate whether or not the product has been retorted.

(2) Retort racks must be capable of holding flexible containers (pouches) so that they do not move during the retort process.

Additional information

Loose edges of the pouches may overlap but the product inside the pouch must not overlap.

(3) Any flexible containers (pouches) that have overlapped or are found to be out of position after the process must be discarded or, if appropriate, reprocessed.

4.10 Container closure and handling

(1) All containers must be hermetically sealed.

(2) During closure every container must be marked with the date of packing (e.g. at the time of closure or immediately after).

Additional information – Coding

When coding product, it is desirable to state the retort load and/or production time period. A company may date a day's production, instead of the individual retort load or time period, on the understanding that the whole day's production is involved if a non-compliance occurs.

(3) Procedures must be developed to manage dropped or damaged packaged product that has not been commercially sterilised, to ensure that it is not mistaken for fully processed product.

(4) If processing with glass:

a) line design and operation should be managed to minimise the impact of any breakages; and
b) a procedure must be developed to deal with glass breakages.

4.11 Container closure evaluation

(1) Container closure evaluation must be conducted at sufficient frequency to ensure the adequacy of the hermetic seal. The intervals must be appropriate to the equipment, line speed and container type. [HC Spec 14.10]

(2) The operator should determine the appropriate sample numbers for each sample period.

(3) Containers must be assessed during production and corrective actions taken immediately if there are any critical failures. Corrective actions are likely to include stopping container closure on the affected equipment until control is restored.

(4) In the event of a critical closure failure, all products produced since the last in-specification check must be isolated and assessed by suitably skilled staff and appropriate disposition made (e.g. to release with or without restriction, rework or disposal).

(5) Closure evaluation records must be kept [HC Spec 9.2].

4.11.1 Can closure evaluation

(1) Table 1 describes the checks to be carried out and frequencies for can closures from each head of each filling machine.

Table 1: Can closure evaluation.

Evaluation/Check	Frequency	Method
Gross container defects	Regularly	Visual observation
Visual examination	At least every 30 minutes	
Tear-down or optical seam cross section analysis	Intervals not exceeding 4 hours	Micrometer method or analysis using seam scope or projector

(2) Evaluations should also be carried out:

a) at start-up;
b) after work has been done on the seamer;
c) after a prolonged shutdown;
d) after a seamer jam-up; and
e) after changing container size or body and end material.

4.11.2 Glass jar closure evaluation

(1) Table 2 describes the checks to be carried out and frequencies for jar closures from each head of each filling machine.

Table 2: Glass jar closure evaluation.

Evaluation/Check	Frequency	Method
Gross container defects	Regularly	Visual observation
Visual examination	At least every 30 minutes	
Physical (destructive testing)	Intervals not exceeding 4 hours of continuous operation	As appropriate to the type of closure

(2) Evaluations should also be carried out:

a) at start-up;
b) after a container jam;
c) after machine adjustments;
d) after a prolonged shutdown; and
e) after changing jars or caps.

If using glass containers with vacuum closures, capper efficiency must be checked by measuring the cold water vacuum before filling operations commence.

Additional Information – Glass jar closures

There are many different designs for glass jar closures. The manufacturers recommendations should be followed as well as the guidelines for closure evaluation contained in "Principles of Thermal Process Control, Acidification and Container Closure Evaluation".

4.11.3 Semi-rigid and flexible container closure evaluation

Additional Information – Semi-rigid and flexible container closures

The evaluation of seal quality may differ between package designs, construction and sealing methods. This requires thorough research. The following documents may provide useful guidance.

- Canned Foods. Guidelines for closure evaluation are contained in Principles of Thermal Process Control, Acidification and Container Closure Evaluation.
- CFIA. 2002. Flexible Retort Pouch Defects Identification and Classification Manual;
- FDA, Bacteriological Analytical Manual (BAM), Chapter 22C.

(1) Operators should determine the seal tests to be carried out and their frequency by consulting their packaging and sealing equipment suppliers.

(2) Visual and physical tests must be carried out.

(3) Closures must be examined from each sealing or closing head at least every 30 minutes [21 CFR 113].

Additional Information – Semi-rigid and flexible container closures

When evaluating closures of semi-rigid and flexible containers, the evaluation should assess the entire container not just the seal produced by the processor.

Semi-rigid containers

As a guide, the seals of semi-rigid containers from each head of each filling machine should be evaluated as a minimum at the following frequencies:

- visual examination for defects at least every 15 or 30 minutes; and
- other tests every four hours of continuous production.

Evaluations should also be carried out:

- at start-up;
- after work has been done on the sealer;
- after a prolonged shutdown;
- after a sealer jam-up; and
- after a splice or lot change of the body or lid material.

Table 3: Examples of seal tests for selected packaging types

Test Method	Packaging type		
	Plastic with double seamed metal end	Semi-rigid sealed lid	Paperboard
Burst test	X		
Compression, squeeze test			X
Dye penetration test		X	X
Electrolytic		X	X
Proximity tester			X
Seam scope projection			X

Sound	X	X	X
Tensile (peel) test		X	
Vacuum testing		X	

Source: Canned Foods. Principles of Thermal Process Control, Acidification and Container Closure Evaluation

Flexible containers

As a guide, pouch seals formed by the processor from each fill tube or sealing lane should be evaluated as a minimum at the following frequencies:

- if possible, 100% inspection of seals;
- visual examination of seals for completeness and a squeeze test at least every 30 minutes; and
- other tests every four hours of continuous production e.g. burst test, tensile (peel) test, drop test, dye penetration test.

Evaluations should also to be carried out:

- at start-up;
- after work has been done on the sealer;
- after a prolonged shutdown;
- after a sealer jam-up;
- for web-fed systems, after every splice; and
- after changes to the sealing temperature, pressure or dwell time.

4.12 Processing

(1) The process must be operated in accordance with the scheduled process documented in the RMP [RMP Spec 11].

(2) The scheduled process, including all parameters critical to the retort operation for the product being retorted must be prominently displayed or obviously readily available to the retort operator(s).

(3) Retort operators must know the corrective actions to take in the event of a process deviation.

Additional Information – Corrective actions

Retort operators be informed about the actions to be taken through training and written procedures that are readily available.

(4) In accordance with the scheduled process, containers must be filled:

a) with correctly formulated and prepared product, that is maintained at or above the minimum initial temperature;
b) with the correct weight of product;
c) to the correct level (i.e. sufficient headspace (as applicable) and sufficient vacuum);
d) ensuring that the maximum residual air is not exceeded for flexible and some semi-rigid packaging.

(5) The initial temperature (IT) of the coldest container(s) in a retort load must be checked and recorded, ensuring that the contents are thoroughly mixed before measuring the temperature. The temperature is measured:

a) For still and discontinuous agitating retorts by:

i) selecting the container that would have been loaded first, or the coldest container from those being loaded into the retort; and
ii) after the steam is turned on, measuring the IT in the selected container.

b) For continuous agitating retorts and hydrostatic retorts, periodically selecting containers just before it would enter the retort and measuring the IT.

(6) The IT must never be lower than the minimum IT specified in the scheduled process. If the` IT is below that specified in the scheduled process and heat processing has started, the process time may be recalculated based on the new IT and the time of retorting extended as calculated. The procedures in 4.18 Deviation from the Scheduled Process apply.

(7) If pre-programmed controls are used to operate and/or control a process, unauthorised access to the programmed parameters must be prevented [HC Spec 14.9].

4.13 Cooling

(1) Cooling must take place in accordance with the scheduled process.

(2) Cooling water must:

a) not be a source of contamination to the product [AP reg 6];
b) be potable, or of an alternative standard as determined from an analysis of hazards and other risk factors [HC Spec 2.5];

Additional Information

Cooling water should be of consistently low microbial content, e.g. with an aerobic mesophile count of less than 100 cfu/ml at the end of cooling. (Codex).

It is generally recommended that aerobic mesophile count of cooling water is checked at least weekly and coliforms tested for monthly. Any significant variation from the established limits should be investigated and the level of sampling increased. The presence of coliforms in any sample indicates the need for immediate investigation.

(3) Chlorinated cooling water must contain a detectable amount of free residual chlorine (usually 0.5 to 2 ppm). The chlorine level must be measured:

a) After each processing batch, or hourly for continuous operations; and
b) At the point after the water has been used for cooling; and
c) If there is no amount of free residual chlorine, the product produced since last compliant result must be reprocessed or disposed of.

(4) Chlorine must have a water contact time of at least 20 minutes at a suitable pH and temperature (Codex).

(5) Retorts that operate using a closed system of re-circulating the same water for both heating and cooling (e.g. "Steriflow", where the water is sterilised as part of the process) do not need chlorinated water for cooling, provided the operator has evidence that the water used is acceptable for cooling.

(6) Alternative methods of water treatment may be used, provided there is evidence that the water is of an acceptable standard for cooling.

(7) Cooling water may be re-used for further cooling purposes provided the water is treated to meet the full physicochemical and microbiological standards for potable water and is re-chlorinated or otherwise treated to meet the requirements above.

4.14 Post–heat treatment handling

(1) Post-heat treatment handling must be carried out in a manner that prevents recontamination of the product [AP Reg 9].

(2) Containers must be rapidly cooled to a temperature of 40°C or less after sterilisation and dried quickly before handling (Codex).

(3) Containers may be removed from a retort at temperatures warmer than 40°C, provided:

a) there are appropriate procedures in place to ensure the hygienic cooling and drying of containers; and
b) the hygiene of the container handling and storage environment will not result in contamination or the growth of bacteria in the container.

Additional Information – Container cooling

There is an optimum temperature range for the removal of cooled containers. Thermophiles can grow in the range of 35°C-50°C, but excess cooling may mean that containers don't dry. In cans, this may lead to rust formation and can degradation.

If cooling failure occurs and containers are removed for cooling at high temperatures, incubation and/or microbiological assessment should be undertaken to determine product disposition.

(4) Containers must not be removed from a retort at a temperature that is likely to result in container distortion as a result of any physical stress.

(5) Containers must be handled in a manner that will prevent damage to the seal area and potential microbial contamination.

(6) Handling of hot and wet containers after retorting must be minimised.

Additional Information

Manually unloading wet containers can present a risk of contamination from pathogens transferred from the worker's hands into the container via micro-leaks.

Flexible pouches are more susceptible to damage than metal cans and need to be handled carefully to avoid damage.

(7) All conveyors, tracks, belts and bars that the containers may come in contact with must be thoroughly cleaned and sanitised to minimise build-up of microorganisms.

(8) Cans must not be washed after retort cooling.

(9) Only single-use sterile wipes may be used for wiping containers.

(10) Personnel access to container cooling areas must be controlled and minimised.

(11) The container cooling environment must be protected from sources of contamination (Codex)

Additional Information – Potential contamination sources

Air flow, presence of water (including condensation) and personnel should be considered when investigating potential contamination sources. Personnel working in areas used for container cooling should be trained in the importance of maintaining good personal hygiene and behaviours appropriate to the area. Access should be limited to people who need to be present to complete the required tasks.

(12) The operator must have a system to monitor the integrity of processed containers (e.g. dud detection equipment, visual inspection programme, teardowns).

(13) Defective containers must be rejected.

4.15 Labelling and storage

(1) Adhesives and labels that do not attract water should be used if the containers could corrode.

(2) Stored product should be kept dry and not subjected to extremes of temperature and humidity.

4.16 Incubation

Additional Information - Incubation

Preferably two containers from each retort load should be incubated for 10 days at 37°C. For continuous retorts (chain, carrier, rotational mechanism), incubate at least one container for each processing cycle. The retort load or lot from which the container was taken should be held in storage until satisfactory incubation tests have been completed. Product may be released prior to completion of the incubation tests if all other records indicate that the product is within specification and it remains under the control of the operator, (i.e. is prevented from entering retail sale) and can be withdrawn efficiently and effectively in the event of an unsatisfactory incubation test results.

The temperature of the incubator should be recorded periodically using a calibrated independent thermometer.

(1) If an incubation test is unsatisfactory, the retort load or lot from which the container(s) came must be disposed of and the controls reviewed.

Additional Information

"Unsatisfactory" includes any deviation from the product specification such as gas formation, vacuum change, can leakages or pH changes at levels which are considered unacceptable for that product as defined by the qualified canner.

4.17 Records

Additional Information - Records

The critical factors to be checked and recorded will depend on the sterilising system used. Types of sterilising systems and their operation are detailed in "Canned Foods: Principles of Thermal Process Control, Acidification and Container Close Evaluation". Also detailed in the publication are the requirements for the records to demonstrate control of the process.

(1) Permanent records must be kept for each retort load/operation and all test results must be recorded.

(2) Records must be kept for 4 years or the shelf life of the product – whichever is longer. [HC Spec 14.10, RMP Spec 20].

(3) The information to be recorded at the time of processing (as appropriate to the nature of the process and equipment), includes:

a) business identifier;
b) date;
c) retort identification;
d) product name, product code and/or other identification;
e) container size;
f) approximate number of containers per retort load/operation;
g) product initial temperature (IT);
h) time that steam was turned on for a batch process;
i) time that vents were closed, where appropriate;

j) temperature in the retort when the vents were closed, where appropriate;
k) time that process was started and in the case of a continuous process, the time the first container enters the retort;
l) processing temperature;
m) processing time;
n) water level and water flow rate (if processing in water);
o) temperature reading from the independent temperature measuring device and from the temperature recorder/controller taken at the same time at least once during the process, and in the case of a continuous operation, at least every hour;
p) pressure (if appropriate);
q) speed (chain, carrier, rotational) checked and recorded at the start of operations, and:

i) at least once per load; or
ii) at least once every 4 hours during continuous operations; or
iii) if the speed is changed; or
iv) continuously recorded;

r) time steam was turned off and in the case of a continuous process, the time the last container leaves the retort;
s) water cooling time;
t) chlorine (or other sanitiser) levels;
u) seam check results;
v) cross reference to the automatic temperature record for the cook (record identifies retort number, date, product, batch or lot, retort operator's name and reviewer's name);
w) all other critical factors specified in the scheduled process, at a frequency sufficient to ensure that they remain within the specified limits;
x) retort operator's signature or other means of providing sign off.

(4) Processing records, including product specification and container closure evaluations must be verified within 24 hours (1 working day) by a suitably skilled person.

(5) Records must allow traceability of raw materials and final products from the supplier to the next person in the supply chain.

Additional Information

The time within which processing records are verified may be extended to 36 hours if an event occurs which is unforeseen and the required personnel are unavailable. All product must remain under the control of the operator.

4.18 Deviation from the scheduled process

(1) Deviations from a scheduled process that may result in under-processed product must be:

a) addressed during processing by adjusting the time and/or temperature of the heat process during the process to ensure the product is made commercially sterile and as agreed to by a qualified canner; or
b) assessed by a qualified canner after processing if the process is completed without alteration, and either the product is:

i) immediately reprocessed using the scheduled process; or
ii) reprocessed using a valid scheduled process, designed for product that has previously been processed;
iii) appropriately disposed of.

Additional Information

If reprocessing is to occur, the thermal process may need to vary from the standard scheduled process. This may be necessary if the original process significantly altered the heat transfer characteristics and/or IT of the product. When determining appropriate reprocessing parameters, the potential for spoilage and growth of pathogens during the product cooling and storage (prior to reprocessing) also needs to be considered.

(2) Any product lot(s) affected by a deviation that may result in under processed product must be identified, segregated, and detained pending the outcome of an assessment by a qualified canner.

(3) Assessments of all deviations must be based on detailed information of the conditions during the non-scheduled process and on the heat transfer characteristics of the product, in accordance with procedures adequate to detect any potential hazard to public health.

(4) The impact on public health must be the primary consideration of the qualified canner in any decision taken.

(5) A full report of the assessment and corrective actions taken must be prepared by the qualified canner, including:

a) date and time of deviation;
b) retort identification;
c) description of the nature and scope of the deviation, including processing records;
d) description of affected product, including any identifiers and quantities involved;
e) corrective action taken, including restoration of control, product disposition and prevention of recurrence;
f) records of the tests undertaken and any reprocessing records;
g) the name and signature of the qualified canner who conducted the assessment.

Additional Information

If the decision is taken to release product affected by a deviation, consideration should be given to having the assessment reviewed by a qualified canner who was independent of the original assessment.

Product may be disposed of by:

- reprocessing (subject to any processing constraints) and release for trade;
- released for trade if the applied process was determined by the qualified canner to be sufficient to render the product lot(s) commercially sterile; or
- condemned and appropriately disposed of.

5 References

Canadian Food Inspection Agency. (2002). Flexible Retort Pouch Defects Identification and Classification Manual. http://www.inspection.gc.ca/food/fish-and-seafood/manuals/flexible-retort-pouch/eng/1350916942104/1350932698250

Canadian Food Inspection Agency. (2012). Metal Can Defects Manual - Identification and Classification. http://www.inspection.gc.ca/food/fish-and-seafood/manuals/metal-can-defects/eng/1348848316976/1348849127902

Canadian Food Inspection Agency. (2015). Facilities Inspection Manual, Chapter 13. Process Determinations for Thermal Processes http://www.inspection.gc.ca/food/fish-and-seafood/manuals/facilities-inspection-manual/eng/1354209008142/1354209083903

CODEX. (1933). Recommended International Code of Hygienic Practice for Low Acid and Acidified canned foods CAC/RCP 23-1979, Rev 2.

GMA Science and Education Foundation. (2015). Canned Foods: Principles of Thermal Process Control, Acidification and Container Closure Evaluation. National Food Processors Association. The Food Processors Institute, Washington D.C.

Institute for Thermal Processing Specialists. (2014) Guidelines for Conducting Thermal Processing Studies. http://www.iftps.org/pdf/guidelines/Retort_Processing_Guidelines_02_13_14.pdf