

 This content was archived on June 24, 2013.

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Low Acid and Acidified Low Acid Foods  
In  
Hermetically Sealed Containers

**VISUAL INSPECTION PROTOCOL**

This protocol was developed co-operatively by Health Canada and the Canadian Food Inspection Agency and is intended to be used by government inspectors to inspect low acid and acidified low acid foods in hermetically sealed containers.

NOTE

Canadian Food Inspection Agency has specific legislation concerning the inspection of products packaged in hermetically sealed containers. When the requirements under this protocol differ from the regulations, the regulations will prevail.

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## **1.0 INTRODUCTION**

It is the responsibility of companies that manufacture or import food for sale or distribution in Canada to ensure that these products meet the health and safety requirements of all applicable Acts and Regulations. The Canadian regulatory agencies are responsible for monitoring the food offered for sale or distribution in Canada to assess compliance to Canadian requirements.

The presence of serious container defects in lots of low acid and acidified low acid foods in hermetically sealed containers in excess of Canadian requirements renders the lot of food unacceptable for sale or distribution in Canada. The presence of serious defects results in either a loss of container integrity or microbial contamination; or the increased risk of loss of container integrity or microbial contamination.

## 2.0 DEFINITIONS

For the purpose of this document the following definitions apply.

### Canned Food:

means a commercially sterile low acid or acidified low acid food packed in hermetically sealed containers.

### Commercially Sterile:

means the condition obtained in a food 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 food at temperatures at which the food is designed normally to be held during distribution and storage.

### Container:

means the individual can or package containing the food product.

### Cull:

means the removal of containers with serious defects from a lot of low acid or acidified low acid foods.

### Cull Report:

means the report detailing:

- a) the procedures used to cull the inspection lot;
- b) the number of affected containers that were removed from the lot; and
- c) the number and types of defects found.

This report must be submitted by the legal agent to the Regulatory agency having jurisdiction.

### Good Order:

means acceptable to the inspector to that point in the protocol.

### Hermetically Sealed Container:

means a container designed and intended to be secure against the entry of micro-organisms including spores.

Inspection:

means the physical examination of a lot of low acid or acidified low acid canned foods for the presence of serious defects.

Lot: (see NOTE on page 2)

means a number of containers limited to one container type and size, one product type and style, originating from one processing establishment.

Note: with respect to fish the lot must be comprised of the same species and bear the same label.

Inspector:

means a person with adequate training who is charged with the responsibility of inspecting a lot of low acid or acidified low acid foods in hermetically sealed containers for the presence of serious defects.

Laboratory:

means a laboratory acceptable to the regulatory agency having jurisdiction.

Legal Agent:

means the person or company by whom or for whom the food was produced for sale or distribution.

Overview inspection:

means a visual examination of the cases of the lot to determine their condition.

Reinspection:

means the examination of a previously inspected lot for the presence of serious defects.

Compliance Sampling and Sample Size:

The sampling plan is based on a two class attribute acceptance plan.

Inspection: sample size (n) is 200 containers and the acceptance number (c) is zero(0) serious defects.



Reinspection: sample size (n) is 1250 containers and the acceptance number (c) is zero(0) serious defects.

Serious defect:

means any container;

- a) which is swollen;
- b) which shows evidence that the hermetic seal is lost or seriously compromised; or
- c) which is unsuitable for distribution and sale as stipulated in the Food and Drug Act section 4 and/or section 27.003 and 27.005 of the Food and Drug Regulations.

These defects are described in the Metal Can Defects Manual.

Sort:

means the segregation and control of cases that have been damaged during storage or transportation.

Suspect Codes :

means those codes that may contain defective containers.

### **3.0 INSPECTION EQUIPMENT**

It is recommended that inspectors be equipped with the following items during each inspection, however additional items may be required:

- Magnifying glass, at least 5x magnification
- Light meter
- Auxiliary light source \*
- Seam micrometer
- Center depth gauge
- Indelible marking pen
- Tags, labels, and sample bags, for sample identification
- Sturdy durable container to transport samples
- Metal Can Defect Manual
- Visual inspection report form
- Detention or seizure forms
- Flash light
- Probe

\* Lighting

For the detailed inspection of the selected containers, and any re-inspection, the light used must be a minimum of 100 foot candles or 1000 lux. If the inspector feels the lighting does not meet this requirement, a light meter should be used to evaluate the lighting.

#### **4.0 INSPECTION**

Inspections shall be carried out under the authority of the regulatory agency having jurisdiction.

##### **4.1 IDENTIFY AND LOCATE LOT**

Prior to inspecting a lot, the inspector should obtain the following information:

- location of the lot;
- name and address of the legal agent ;
- lot size (number of cases, containers per case);
- lot codes and their interpretation;
- brand name;
- product type and style of pack;
- container type and size;
- processing establishment;
- country of origin;
- other pertinent information.

##### **4.2 ENSURE LOT ACCESSIBILITY**

The inspector must have adequate access to the inspection lot. If, in the inspector's opinion, the inspection lot is inaccessible due to the presence of other lots or the manner in which it is stored, and the inspector deems access is required, then the inspection lot must be moved to an area which allows the inspector to adequately examine the cases.

##### **4.3 OVERVIEW INSPECTION**

The presence of damaged cases must be assessed. The inspector will determine if any damaged cases have been sorted out from the lot and verify that any sorting has been properly performed.

If the results of this inspection show:

- A) No wet, stained or damaged cases, then commence inspection. See section 4.4.
- B) The presence of wet, stained or damaged cases. **Detain the whole inspection lot.** Proceed to section 5.0 - Wet, Stained or Damaged Cases.

#### **4.4 COMPLIANCE SAMPLE**

The compliance sample consists of 200 containers taken from throughout the inspection lot.

##### **4.4.1 SELECTION OF CONTAINERS**

Determine the number of containers in each case.

<b>Number of Containers Per Case</b>	<b>Number of Cases to be Opened for Inspection</b>	<b>Number of Containers to Pick From Cases</b>
5 or less	40	all
6-12	34	6
13-60	17	12
61-250	13	16
251 or more	9	24

In accordance with the above table, identify the number of containers in a case, select the number of cases to be opened for inspection, and examine the required number of containers from each of the opened cases.

Example: If each case contains 24 containers, open 17 cases for inspection and examine 12 containers from 16 cases and 8 containers from the 17<sup>th</sup>. case. A total of 200 containers will be examined.

For inspection lots having less than two hundred containers, the entire inspection lot must be examined and the total number of containers must be recorded on the report form.

All two hundred containers shall be examined by the inspector and the result of the examination recorded and maintained on file.

##### **4.4.2 LABEL REMOVAL (see NOTE on page 2)**

1. The labels will be removed from all containers in the compliance sample by the inspector in order to permit a thorough examination of the containers.
2. When a defect and the relationship to the label are important, mark the label so that it can be placed in the same position on the container prior to its removal.
3. Examine the inside surface of the label for stains.

#### **4.5 DECISION - COMPLIANCE SAMPLE**

If the results of the visual examination\* show:

- A) No serious defects, permit distribution of lot.
- B) One or more serious Defects, detain the inspection lot and proceed to Section 4.6 - Serious Defects.

Where an inspector needs to further assess a defect, the inspector may consult with other people, knowledgeable in the area of container integrity defects, or submit the containers in question to the laboratory for further analysis. The lot must be detained pending a final decision.

\* A visual inspection may also include results obtained through destructive examination (teardown and sectioning) of sample units.

#### **4.6 SERIOUS DEFECTS**

All containers with serious defects shall be retained by the inspector and the defects identified. No sale or distribution of the inspection lot is permitted.

Control of all defective containers must be maintained until a final decision is reached as to the disposition of the inspection lot.

The Office of Food Safety and Recall, CFIA, must be notified when a lot containing serious container integrity defect(s) has been distributed.

The regulatory authority shall maintain documentation to demonstrate control or disposition of rejected lots with serious container integrity defects.

Note: If at any time during an inspection a swollen or leaking container is found, the inspection or re-inspection shall be discontinued until such time that the lot has been evaluated to determine the cause. Proceed to section 7.0, Swollen or Leaking Containers.

#### **4.7 DISPOSITION OF THE LOT**

Lots, which do not meet Canadian requirements upon initial inspection are not permitted for sale or distribution in Canada.

The legal agent may:

- A) Remove the imported lot from Canada with the approval of the government agency having jurisdiction.
- B) Destroy the lot under the supervision of the government agency having jurisdiction.
- C) Request permission to cull the lot.

If the Legal Agent requests permission to cull the lot, proceed to section 6.0, Lot Culling.

## **5.0 WET, STAINED OR DAMAGED CASES**

### **5.1 INVESTIGATION**

The inspector will examine the wet, stained or damaged cases and their containers in order to determine the reason the cases are wet, stained or damaged. Cases in close proximity to the wet, stained or damaged cases should also be closely examined to determine if they may be the source of the problem.

If the problem is due to:

A) swollen or leaking containers:

The inspection or re-inspection shall be discontinued until such time that the lot has been evaluated to determine the cause. Proceed to section 7.0, Swollen or Leaking Containers.

B) physical damage to cases and/or containers (e.g. forklift), or other damage (e.g. water damage, leakage from another lot)::

Suspend the inspection until the wet, stained or damaged cases are segregated from the lot by the legal agent.

If wet or stained cases are due to leaking containers from other lots of foods in close proximity to the lot, the lot which is the source of the problem must be identified and detained for further examination.

### **5.2 SORTING OF WET, STAINED OR DAMAGED CASES**

If the legal agent chooses to sort the lot, they must ensure that the wet, stained or damaged cases are segregated from the rest of the lot. Proceed to section 5.3

If the legal agent does not sort the lot, the lot remains under detention and is not permitted for sale or distribution. The legal agent has two options:

A) Remove the imported lot from Canada with the approval of the government agency having jurisdiction.

B) Destroy the lot under the supervision of the government agency having jurisdiction.

### **5.3 IDENTIFICATION**

The number and location of wet, stained or damaged cases segregated from the lot must be

recorded. The legal agent must maintain control of these cases until a final decision on the lot has been taken by the regulatory agency having jurisdiction.

#### **5.4 INSPECTION OF CONTAINERS FROM WET, STAINED OR DAMAGED CASES**

The legal agent is responsible for examining the containers from the wet, stained or damaged cases. All containers showing evidence of stains or damage must be removed from the cases by the legal agent. The government agency having jurisdiction will examine all the segregated containers and if any serious defects, other than serious defects caused by physical damage, are noted, they shall be part of the official sample taken for inspection.

The good order containers from the wet, stained or damaged cases may be returned to the lot.

The affected containers from the wet stained or damaged cases must be kept under detention and disposed of under the supervision of the regulatory agency having jurisdiction.

**Note:** If the inspector confirms that the defect is due to physical damage and if the legal agent chooses not to remove the affected containers in the wet, stained or damaged cases, those cases shall be destroyed under the supervision of the regulatory agency having jurisdiction.

#### **5.5 GOOD ORDER CASES**

Proceed to section 4.4 to carry out an inspection on the containers in the good order cases.

### **6.0 LOT CULLING**

#### **6.1 AUTHORIZATION**

The legal agent shall request, in writing, authorization from the regulatory agency having jurisdiction prior to culling a lot and must provide the Agency with a written procedure outlining the culling operation.

Permission to cull will be assessed based on an evaluation of the nature and number of defects observed during the inspection, results of the visual inspection, teardown and sectioning, and the written procedure for culling that has been submitted by the legal agent. The regulatory agency having jurisdiction shall advise the legal agent in writing of the decision.

#### **6.2 DECISION**

##### **6.2.1 CULL PERMITTED**

The legal agent is responsible to ensure that the cull is carried out according to the written procedure submitted to and accepted by the regulatory agency having jurisdiction.

After the completion of the cull, the lot shall be re-inspected by the regulatory agency having jurisdiction. Proceed to section 8.0 - Reinspection

**Note:** All defective containers that are culled from the lot, must be segregated by the legal agent and kept for inspection by the regulatory agency having jurisdiction. A cull report, detailing the number and types of defects, must be submitted to the agency at the completion of the cull.

## **6.2.2 CULL NOT PERMITTED**

Culling shall not be permitted if the nature and quantity of the serious defect indicate that culling would not be effective in removing these defects from the lot.

Culling shall not be permitted when a serious defect cannot be visually detected.

Culling of swollen or leaking containers shall not be permitted:

1. when the presence of swollen or leaking containers is related to underprocessing; or
2. when there is no evidence of visible serious container integrity defect; or
3. when swollen containers cannot be related to an overfill.

See Section 7.0

The legal agent, normally has two options:

- A) Remove the imported lot from Canada with the approval of the government agency having jurisdiction.
- B) Destroy the lot under the supervision of the government agency having jurisdiction.

## **7.0 SWOLLEN OR LEAKING CONTAINERS**

Lots with swollen containers may be in violation of Section B.27.003 of the Food and Drug Regulations.

### **7.1 LABORATORY ANALYSIS**

The samples submitted to the laboratory will be tested using microbiological methods according to the Health Canada Compendium of Analytical Methods.

### **7.2 LOT EVALUATION**

#### **7.2.1 UNDERPROCESSING**

If the reason for the swollen or leaking containers is due to **Underprocessing**, the lot is

unacceptable for sale and must be destroyed.:

The Office of Food Safety and Recall, CFIA, must be notified immediately for direction relating to product in distribution.

### **7.2.2 POST PROCESS CONTAMINATION**

If the reason for the swollen or leaking containers is due to the presence of a **Container Integrity Defect**, the lot cannot be sold.

The legal agent may:

- A) Remove the imported lot from Canada with the approval of the government agency having jurisdiction;
- B) Destroy the lot under the supervision of the government agency having jurisdiction;
- C) Request permission to cull the lot. See Section 6.0, Lot Culling.

### **7.2.3 OVERFILLS**

If the reason for the swollen or leaking containers is due to an **overflow**:

All overfills are to be investigated to determine whether the overflow has compromised the safety of the product, whether a process deviation has occurred.

Some products may appear slightly swollen due to by design or due to gas packing. If this is verified by the inspector, these containers are not considered to be swollen as per Metal Can Defect Manual.

## **8.0 REINSPECTION**

Reinspection shall be carried out under the authority of the regulatory agency having jurisdiction.

Prior to the reinspection, the owner or legal agent may do any or all of the following, provided the details of the intended work are outlined in the request for reinspection and are approved by the regulatory agent having jurisdiction:

- a) cull the lot;
- b) remove the suspect codes from a mixed code lot;
- c) request that the lot be reinspected on a code by code basis or a lot basis.

Culled defective containers will be examined in conjunction with the cull report. Evaluate the report to determine if a Health Risk Assessment is required.



## 8.1 COMPLIANCE SAMPLING

The compliance sample consists of 1250 containers taken from throughout the lot.

### 8.1.1 SELECTION OF CONTAINERS

Determine the number of containers in each case.

# of containers per case	# of cases to sample	# containers to pick from case
5 or less	250	all
6 - 12	209	6
13 - 60	105	12
61 - 250	79	16
251 or more	55	24

In accordance with the above table, identify the number of containers in a case, select the required number of cases to be opened for inspection, and examine the required number of containers from each to be opened.

For lots having less than 1250 containers, the entire lot must be examined and the total number of containers must be recorded on the report form.

All 1250 containers shall be examined by the inspector and the result of the examination recorded and maintained on file.

### 8.1.2 LABEL REMOVAL (see NOTE on page 2)

1. The labels will be removed from all containers in the compliance sample by the inspector in order to permit a thorough examination of the containers.
2. When a defect and the relationship to the label are important, mark the label so that it can be placed in the same position on the container prior to its removal.
3. Examine the inside surface of the label for stains.

## **8.2     DECISION - COMPLIANCE SAMPLE**

If the results of the visual examination\* show:

- A) No serious defects, permit distribution of lot.
- B) One or more serious defects - The lot may not be offered for sale or distribution.

\* A visual inspection may also include results obtained through destructive examination (teardown and sectioning) of sample units.

Where an inspector needs to further assess a defect, the inspector may consult with other people, knowledgeable in the area of container integrity defects, or submit the containers in question to the laboratory for further analysis. The lot must be detained pending a final decision.

## **8.3     DISPOSITION OF THE LOT**

Lots which do not meet Canadian requirements are not permitted for sale or distribution in Canada.

The legal agent may:

- A) Remove the imported lot from Canada with the approval of the government agency having jurisdiction.
- B) Destroy the lot under the supervision of the government agency having jurisdiction.

## **9.     MECHANICAL SCREENING.**

Mechanical screening of canned product has been recognized as an alternative to compliance sampling under the Visual Inspection Protocol for canned salmon

The Fish Inspection Act and Regulations provide the authority to license mechanical screening operators.

The mechanical screening of canned product, by double dud detector and check-weigher, is recognized as an alternative to compliance sampling under the Visual Inspection Protocol, if it is performed in accordance with the procedures as outlined in the Fish Inspection Program Facilities Inspection Manual, Chapter 5, Subject 3, *Compliance Guidelines for Mechanical Can Screening Operations Using Double Dud Detector and Check-Weigher.*(To be issued at a later date.)

Note: Chapter 5, Subject 3 of the Facilities Inspection Manual, *Compliance Guidelines for Mechanical Can Screening Operations Using Double Dud Detector and Check-Weigher*, outlines the regulations, policies and operating procedures a licensed can-screening establishment, using double dud detector and check-weigher, will follow in order to comply with the export licensing requirements for a can-screening establishment.

## **REFERENCES**

Metal Can Defects Identification and Classification Manual, Canadian Food Inspection Agency

Compendium of Analytical Methods. Evaluation Division, Bureau of Microbiological Hazards, Food Directorate, Health Products and Food Branch, Health Canada.