Minimizing the Presence of and Handling of Abnormal Containers of Commercially Sterile Foods

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Introduction

Today's marketplace for shelf stable foods offers consumers a variety of packaging options. The presence of traditional metal cans and glass containers has been augmented by the introduction of shelf stable commodities available in semi-rigid containers, flexible packages, and paperboard containers. Regardless of the container, the safety and quality of the contents need to be protected throughout the manufacturing process and the distribution chain, all the way to the customer's cupboard. Security of the container contents does not occur by chance. It is an active management process encompassing the establishment and implementation of a series of practices appropriate to specific processing systems and container designs. Product protection includes two strong elements: container integrity and process reliability.

Container integrity includes two important facets. The first of these occurs well before processing and involves the purchase, receipt, storage and handling of incoming containers, closures, pouch stock and paperboard stock. After securing a consistent and dependable supply of container and/or container stock and closures, processors should ensure that those packaging materials delivered to their facilities are of high quality, and will be stored and handled correctly. Proper sourcing, receipt, storage and handling will make certain that only containers and container stock of high quality will be delivered to processing and packaging systems.

The other end of the manufacturing chain is no less crucial. Once quality containers and closures have been assembled and processed into finished goods, processors and distributors should have programs, practices and procedures in place that protect container integrity throughout storage, labeling, packaging and distribution systems.

Bracketed between these two container quality bookends is the practice of process reliability. Using documented processes designed by recognized process authorities on well-maintained, dependable and properly functioning equipment is the foundation of process reliability.

Unfortunately, spoilage will happen. Processors need to be aware of the situations and circumstances that can compromise processed food and its containers and have practices in place that serve to minimize these occurrences. Microbial spoilage within the container may be caused by leakage, underprocessing, or elevated storage temperatures. Hydrogen swells and sulfide stains caused by chemical corrosion sometimes occur. In addition, prolonged storage of containers at elevated temperatures promotes corrosion and may result in perforation.

Scope

GMA's "Minimizing the Presence of and Handling Abnormal Containers of Commercially Sterile Foods" was developed for processors, transporters and warehouse

operators in the commercially sterile food industry. These practices can be applied universally, but the regulations cited herein are those that apply in the United States. Processors, transporters and warehouse operators may want to consider the food safety programs referenced in this document as the foundation for a successful system designed to minimize the potential for product spoilage from both underprocessing and container abuse.

Definitions:

Abnormal container: A container with any sign or evidence that the contents of the unopened container may be compromised, including those containers that have obvious seam/seal defects, or are swollen or leaking.

Acid food: Foods that have a natural pH of 4.6 or below.

Brights: Canned goods that are put into storage without labels and further packaged at a later date. Also called "shiners."

Compound: A resinous plastic-like material placed near the curl of the can lid that serves to fill in voids in the double seam of metal cans.

Disinfection: For the purpose of this document, disinfection is the treatment of container cooling water with chemicals, or other means, to minimize to the extent possible the number of microorganisms.

Finish: The very top part of a glass jar that contains threads or lugs that contact and hold the cap or closure.

Flexible package/container: A container, the shape or contour of which, when filled and sealed, is significantly affected by the enclosed product.

Headspace: The area between the top of the product and the bottom of the closure.

Hermetic seal: A seal designed to be secure against the entry of microorganisms.

Incubation: Placing shelf stable foods in a controlled environment to encourage the growth of microorganisms.

Low-acid food: Any foods, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity (a_w) greater than 0.85.

Oxidation reduction potential: The electrical current generated by the transfer of electrons during disinfection procedures using chemical oxidizers.

Plastisol: A dispersion of resin in a plasticizer, forming a liquid or paste that gels when heated, serving as a sealing compound on caps for glass containers used for shelf stable foods.

Process Authority: A person who has expert knowledge of thermal processing requirements for low-acid foods packaged in hermetically sealed containers, or has expert knowledge in the acidification and processing of acidified foods. Expert implies experience and knowledge achievement as well as recognition as an authority on the subject.

Process Deviation: Any process that fails to meet all necessary critical factors as defined in the scheduled process.

Semi-rigid container: A container, the shape and contour of which, when filled and sealed, is not significantly affected by the enclosed product under normal atmospheric temperature and pressure, but which can be deformed by external mechanical pressure of less than 10 pounds per square inch.

Scheduled Process: The process selected by the processor as adequate under the conditions of manufacture, for a given product to achieve commercial sterility.

Temperature distribution: The work performed to ensure that the retort instrumentation accurately reflects that adequate and consistent temperature delivery is achieved throughout the retort and throughout the sterilization cycle.

Vacuum: The absence of gas in a container to prevent deterioration of the contents. Vacuum exerts less pressure than the surrounding environment.

Acronyms

APC: Aerobic Plate Count

BAM: Bacteriological Analytical Manual

BOL: Bill of Lading

BT Act: Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (also known as “The Bioterrorism Act”)

CFR: Code of Federal Regulations

CFU: Colony forming unit

DSIMS: Digital Seam Image Measurement Software

FDA: Food and Drug Administration (United States)

FFDCA: Federal Food Drug and Cosmetic Act

FSIS: Food Safety and Inspection Service (an agency within USDA)

GMA: Grocery Manufacturers Association

GMP: Good Manufacturing Practices

IR: Infrared

IT: Initial Temperature

LACF: Low-acid Canned Foods

ORP: Oxidation Reduction Potential

PPM: Parts-per-million

RTD: Resistance Temperature Detector

USDA: United States Department of Agriculture

Sourcing Packaging Materials

Supplier pre-assessment and review

Today's global food marketplace must strategically place greater emphasis on preventive measures for food safety. Such measures can promote improved food protection capabilities throughout the food supply chain. Prevention requires that food safety be built in from the beginning. One such measure is via close interaction with all suppliers, including those for food contact packaging.

Customers should take appropriate steps to ensure that packaging manufacturers have adequate quality systems in place to be able to deliver a consistent supply of acceptable, clean containers or packaging materials. Prior to doing business with any supplier, it is often beneficial for companies to perform an initial supplier assessment. In conducting a pre-assessment, customers have a variety of methods at their disposal to use. Supplier inspection surveys, facility audits, materials testing, and evaluation and review of materials specification compliance are but a few of the approaches that could be employed. Whatever approach is utilized, the assessment should be designed to provide

a level of knowledge that programs are present, effective and operating at a level that will ensure food safety, regulatory compliance and other quality assurance attributes. For further information on supplier management activities see GMA's *Food Supply Chain Handbook* available at http://www.gmabrands.com/publications/GMA_SupplyChain2.pdf

Companies should consider developing written specifications for all food contact packaging materials. A written specification could include, where appropriate:

- General description of the packaging material (roll stock, flexible pouches, metal containers etc.)
- Description of the packaging composition (tin-free steel, polypropylene etc.)
- General requirements that the materials be produced under sanitary conditions and in compliance with all pertinent laws and regulations
- Specific dimensions and tolerances of the packaging material
- Requirements for sealing compounds and plastisols, where appropriate
- The form in which the materials will be delivered (palletized, cased, sleeved)
- Lot coding requirements so that materials can be traced (a requirement under U.S. Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (BT Act))
- Shipping requirements

Incoming Inspections and Material Evaluations

Incoming inspections of food contact packaging material

After qualified and dependable suppliers are sourced, materials will be ordered and delivered to the processing establishment. Upon arrival, customers should employ an incoming inspection to help ensure that packaging materials meet processing requirements. The inspection can fulfill two tasks when needed. First, it can be a tool to assure that food contact packaging has been transported in a clean and sanitary manner and that the physical integrity of the packaging has not been compromised during shipping. Attributes to examine during this evaluation could include:

- The cargo section of the truck is sealed or otherwise protected from potential tampering
- The seal number is noted on the Bill of Lading (BOL) or other shipping documents
- The lot codes of the packaging material are noted on the BOL or other shipping documents
- The cargo area is clean and free of any off odors
- There is no evidence of insect or rodent activity
- There is no evidence of physical damage to the material (e.g., crushed cases, scored roll stock)

Records should be kept of all incoming inspections.

The second activity that can be conducted during an incoming inspection is the taking of samples for further evaluation such as acceptance testing. Since roll stock for pouches and aseptic containers is often difficult to inspect, customers may wish to receive Certificates of Analysis, results of in-process testing when the packaging was being produced, or a combination of both. Potential evaluation for roll stock packaging will be discussed later in this document.

With respect to packaging lot codes and traceability, the BT Act mandates that all members of the food chain shall be able to trace goods, **including food contact packaging,** one step forward and one step backward, as well as know the shipper/transporter of the goods. Those who cannot perform these duties can be found in violation of the BT Act. Specifically, as outlined in the BT Act, when purchasing packaging through a broker, processors shall have programs to define the physical location from which their packaging was shipped as well as the shipper/transporter. Simply knowing the name and the P.O. Box address of the brokerage that provided the packaging, and that it was shipped "by truck," would not be sufficient.

Metal cans and lids

Note: It is a good practice to source cans and lids from the same supplier when possible. This will better ensure effective seams. It will also aid in troubleshooting should problems arise.

Incoming inspections for metal cans could include evaluation for various can quality attributes and the absence of defects such as:

- Visible double seam defects, including knocked down flanges, droops, incomplete seams (deadheads) etc.
- Bent or creased flanges, body dents and out-of round containers
- Defects determined by teardown such as loose seams or too little overlap.
- Incomplete application of enamel coating, if any
- Application of the wrong enamel (Often they are a different color than normal. The type of enamel is often coded into the manufacturer's item number that should be on the pallet ID tag too).

For further information regarding defects in metal cans see the attachment to "Guide to Inspections of Low-acid Canned Food Manufacturers" at (http://www.fda.gov/ora/inspect_ref/igs/lacfpt3/attachments.html) or "Metal Can Defects Manual - Identification and Classification" at (http://www.inspection.gc.ca/english/anima/fispoi/manman/canboi/toctdme.shtml)

Incoming inspections for metal lids could include evaluation for various lid quality attributes and the absence of defects such as:

- Incomplete application of sealing compound

- Incorrect compound (detected by differences in color). High fat items (e.g., chicken broth) require different compounds than foods containing little or no fat
- Incomplete application of enamel coatings, or scratches in the enamel.
- End curl defects that could affect double seam formation

Glass containers and caps

Incoming inspections for glass containers and their closures could include evaluation for various glass quality and vacuum closure quality attributes, and the absence of defects such as:

- Voids in the application of sealing compounds or plastisols
- Absence of sealing compounds or plastisols
- Application of the incorrect sealing compound
- Miscellaneous glass defects such as crooked or cracked finishes, cocked bases etc.

For more information on glass container and closure quality and defects see the attachments to "Guide to Inspections of Low-acid Canned Food Manufacturers" at http://www.fda.gov/ora/inspect_ref/igs/lacfpt3/attachments/21.html or http://www.fda.gov/ora/inspect_ref/igs/lacfpt3/attachments/19.html

Roll stock packaging

Inspection of roll stock packaging is often difficult due to the physical nature of the bulk package. As the name implies, this type of packaging material, which can be used for retortable pouches, top film for semi-rigid trays or bowls, and aseptic packaging systems, is delivered in large rolls. This makes uniform or representative sampling throughout the roll extremely difficult. The outside layer of the roll, which is the only section readily accessible to sampling, represents a mere fraction of the total stock available on a given roll. It is not uncommon for a roll of packaging material to contain several thousand impressions.

One way in which incoming roll stock can be evaluated is to perform an on-line acceptance test. To perform this test a processor interrupts the normal first-in-first-out rotation of packaging material to place one or more rolls of new, incoming material onto packaging machinery at the next roll change or later. The new material is then run during production and the performance of the new material is carefully monitored. Statistical sampling while the new material is running may also be utilized.

The advantage of the on-line acceptance test is that it gives the processor an opportunity to evaluate the performance of a given lot or shipment of new packaging without exposing their production to an entire truckload or lot of defective packaging. The ability to discover a potential defect while there is still plenty of acceptable packaging material in inventory can save considerable costs and downtime.

A typical process of producing roll stock may involve the production of several customer-sized rolls from a much larger master roll. Rolls of packaging material should be numbered or otherwise coded to indicate the order in which they were produced and their location in the original master roll. A master "reel map" or other documentation should be available to customers so they can effectively trace the location of film defects should they develop. For example, assume rolls 2 and 3 are found to have a defect that may be indicative of a uniform film supply problem such as delamination. It would be easy to assume that rolls 1 through 4 were produced in succession and may all contain the problem. What may not be obvious without a reel map is that rolls 2 and 19 may have been next to each other on the master roll before the material was cut down to customer size specifications. If roll 2 has delaminated film, it is possible that roll 19 could have this defect also. Without the master "reel map" or similar document, the customer would be unable to fully isolate this defect.

Customer specifications for roll stock packaging can ask that all rolls be marked to facilitate their tracing should problems develop. Also, rolls containing splices should be clearly marked so operators are aware of their presence. Splices must usually be cut away and not used for finished packaging. The same specification could also indicate that customers will be supplied the master reel-map, or similar document where applicable.

Defects that could be found in roll stock packaging include blisters, abrasions, flex cracks and delamination. For further information see FDA's *Bacteriological Analytical Manual*, (BAM) Chapter 22 available at: http://www.cfsan.fda.gov/~ebam/bam-22c.html.

Preformed pouches

Preformed pouches should be evaluated for material defects as well as seal defects. Seal strength can be evaluated using techniques such as tensile strength and burst testing. Visual defects in the seam area could include wrinkles, waffling and seal creep (NFPA, 1989). Material defects in preformed pouches could be the same as those for roll stock pouch material; blisters, abrasions, delamination and flex cracks. For further information see FDA's *Bacteriological Analytical Manual*, (BAM) Chapter 22 available at: http://www.cfsan.fda.gov/~ebam/bam-22c.html

Process Controls

As indicated above, abnormal containers may arise from underprocessing, leaker spoilage, or elevated storage temperatures among other factors. Processors should implement process control systems designed to minimize creation of abnormal containers and spoiled product. Process controls can be categorized into four segments:

- Use of recognized process authorities
- Maintenance and calibration of processing equipment
- Prevention of leaker spoilage, including
    - Disinfection of cooling water
    - Proper GMPs during air cooling
    - Container closure evaluations
- Design of container handling equipment and practices

Use of recognized process authorities

Processes for shelf stable foods must be established by competent processing authorities. This is a requirement of federal regulations 21 CFR 113 (Low-acid Canned Foods or LACF), 21 CFR 114 (Acidified Foods), 9 CFR 318, Subpart G, (beef canning regulations), and 9 CFR 381, Subpart X, (poultry canning regulations). As noted in these regulations, processors may only operate with approved processes and **any** deviation from these processes must be handled as a process deviation under specific portions of the same regulations. When a process cannot be met for whatever reason, the implicated product must be isolated. Procedures as designated in 21 CFR 113.89, "Deviations in processing, venting, or control of critical factors" and 9 CFR 318.308 and 9 CFR 381.308 "Deviations in processing" must be followed as applicable. Departures from scheduled processes for acidified foods are covered in 21 CFR 114.100 (c).

Maintenance and calibration of processing equipment

Prudent processors should have programs in place to ensure that sterilization systems will operate at optimum efficiency and consistently deliver processes equal to or exceeding scheduled processes. Programs to accomplish this could include calibration of processing equipment, initial temperature distribution and periodic re-evaluation of temperature distribution.

Upon installation, all hardware, instrumentation and controls, and auxiliary equipment should be checked for proper functioning and accuracy. Additionally at any time their functionality or accuracy is suspect they should be rechecked. Each thermal processing system should be routinely examined by an individual not directly involved in daily operations to ensure the proper functioning of the system. This, in fact, is a requirement in USDA facilities and must be conducted at least annually according to the regulations (9 CFR 318.305 (g) (2) and 9 CFR 381.305 (g) (2)). In addition, each thermal processing system should be examined before the resumption of operations following an extended shut down. This can be especially prudent for seasonal packers where the equipment may have been sitting idle for months. USDA also requires processors to keep records on all maintenance items that could affect the adequacy of the thermal process, including the

date and type of maintenance performed and the person conducting the maintenance (9 CFR 318.305 (g) (6) and 9 CFR 381.305 (g) (6)).

Periodic temperature distribution assessments can be a valuable tool for ensuring proper retort function. These studies are typically run when a new retort is installed. Repeating them on a periodic basis, such as every three years, can verify that the system is still functioning as designed.

Calibration programs should be implemented to further guarantee that processing systems are operating at their optimum. These programs should include, where appropriate, mercury-in-glass thermometers, recording devices, resistance temperature detectors (RTD), hand held thermometers used to measure initial temperatures (ITs), and other temperature indicating and recording devices. Since the IT is typically part of a scheduled process and these small hand held thermometers are usually very easy to calibrate, packers may find daily calibration a useful program to implement. In operations that do not run 24 hours/day, it could be practical to calibrate hand held thermometers at the beginning and end of every day to verify that all measurements throughout the day have been accurate. Some RTDs and their connection cables should be considered a matched pair. Replacing the connecting cable requires recalibration just as if the RTD itself had been changed.

For operations where maximum fill weight is a critical process parameter, food processors may want to install a checkweigher prior to the retort. The checkweigher would reject all containers over a certain maximum process weight. If checkweighers are employed, like all critical process machinery, they should be checked and calibrated at an interval frequent enough to ensure they are functioning correctly. All monitoring and maintenance activities should be documented.

For further information on retort maintenance and operation see Appendix A, “Twenty Important Considerations for the Proper Operation in the Retort Room of Retorts Using Steam as the Heating Medium.” For further information on temperature sensing and recording devices see Appendix B, “Temperature Indicators and Temperature Recorders.”

Leaker spoilage

Leaker spoilage, also known as post-process contamination, frequently occurs from seam/seal defects and mechanical damage to containers. It may occur in warehouses or retail stores if seams or seals are stressed or damaged, or if containers are punctured or otherwise compromised. Post-process contamination most often occurs during water cooling of the container.

During the cooling process, in the case of cans or glass containers, containers transition from being pressurized units with the ends/lids extended, to having an internal vacuum. Pouches and flexible packaging are extended during processing, but draw little, if any,

vacuum. While these changes in container configuration are occurring, or if the seam/seal were to receive a blow, the container may allow entry of trace amounts of cooling water. Vacuum by definition exerts less pressure than the surrounding atmosphere and consequently can serve to draw in water or air from the environment if the container seal is compromised. Even high quality seam/seals can draw in small amounts of water before the sealing compounds have set. If the water contains bacteria and product and environmental conditions are favorable, the bacteria will grow, thus resulting in possible spoilage of product. Such spoilage may or may not result in gas production that distends the container.

Less than optimum seam/seals or poor operation of processing systems only compounds the situation, as poor quality seams or seals are more prone to leakage. Improper pressure control during retorting and cooling operations may also stress the seam, resulting in poor seam/seal integrity and subsequent leaker spoilage.

For these reasons, the bacterial condition of cooling water is very important. The higher the number of microbes in cooling water, the smaller the amount of water that needs to leak into the container to create spoilage. Even the ingress of a single droplet of water containing a single bacterium capable of growing in the product could cause leaker spoilage to occur. Consequently, even low numbers of microbes may tax the ability of even the best closures to keep out microbial contamination. For example, a can immersed in cooling water containing 100 bacteria/ml of water would only have to draw in $1/100^{th}$ of a milliliter (0.01 ml) of water to allow entry of a single bacterium and cause spoilage. If the cooling water disinfection is not properly managed, and the microbial population of the water is allowed to reach 10,000 bacteria/ml, then only $1/10{,}000^{th}$ of a milliliter (0.0001 ml) would have to be drawn into the can to create a potential spoilage situation (Weddig, 2007)

Cooling water disinfection

Processors should manage cooling water so that it contains as low a microbial population as practical. All cooling water should be chlorinated or otherwise adequately treated to kill microorganisms that may be found in the water to minimize the potential that water that leaks through the seam/seal will carry organisms into the container. The regulations (21 CFR 113.60 (b), 9 CFR 381.305 (h) (2 and 3), 9 CFR 318 (h) (2 and 3)) only require chlorination, or other methods of sanitation, for cooling canals and recirculated cooling water. Nevertheless, disinfection of all cooling water, properly carried out, is a dependable means of maintaining microbial counts of cooling water at a low level.

Although municipal water is chlorinated, this may not be adequate for container cooling water disinfection. Also, many factories today recirculate their water for conservation of resources, both ecological and financial. Without a disinfection program, recycling of water raises the level of contaminants (Suslow, 2000). Disinfection of recycled water can be critical to minimizing the potential amplification of microbial contamination.

Processors may use compounds such as iodine, bromine, ozone and peracetic acid to treat cooling water. All these compounds are chemically described as oxidizers. The most common oxidizer used in the food industry is chlorine. Chlorine disinfection of cooling water can be accomplished by using chlorine gas, chlorine dioxide and hypochlorite to name a few. Hypochlorite is a common compound used in the treatment of container cooling water, however its efficacy as a disinfectant, like other chlorine compounds, is dependent on other factors. These details are addressed below.

Proper disinfection of container cooling water requires an active management process. Continuing changes in product volume, quality of incoming water or temperature of the water can require adjustments of the disinfection system. Iodine, bromine, chlorine and ozone can react with organic matter (dirt, dust, debris) in the water to create compounds that are not antimicrobially active. Disinfection using chlorine and bromine also requires control of the water pH in addition to controlling the concentration of the active compound in the disinfectant solution. This is typically accomplished by the addition of acids to the cooling water as well. Often times there is a sensitive balance between maintaining adequate microbial disinfection without producing disinfectant levels that could be corrosive (excess chlorine, bromine and ozone, low pH) or developing conditions that could be detrimental to the health and welfare of the employees (excessive levels of ozone or chlorine dioxide, creation of uncontrolled chlorine gas.)

If systems using hypochlorite and chlorine gas injection do not maintain the proper pH, the chlorine may not be in the chemical form of hypochlorous acid, which is the active disinfectant. Elevated pH values will yield hypochlorite, a poor sanitizer, and there will be little disinfectant activity. Unfortunately, conventional colorimetric test kits do not distinguish between concentrations of hypochlorous acid, a powerful disinfectant, and hypochlorite, a poor one. Historically, processors using hypochlorite and chlorine gas for disinfection have had to monitor multiple values: chlorine concentration in parts-per-million (ppm) and the pH of the cooling water. Similar situations exist for systems using bromine, though hypobromous acid is present at a higher pH than hypochlorous acid.

Recently, computer controlled systems have emerged that can control water disinfection automatically. Chlorine, ozone, bromine, iodine and peracetic acid are all oxidizers and oxidation involves the transfer of electrons. This flow of electrons creates an electrical potential or current, and this current can be measured as the oxidation-reduction potential (ORP) of the water. ORP monitoring provides a rapid and single value assessment of the disinfection potential of water. In tandem with pH sensors, ORP sensors can create an automated management system to provide demand-based injection of oxidizer and/or acid (Suslow, 2000.) Computerized systems can also provide real-time web access to data and enhance recordkeeping.

Water supplies vary from place to place; some supplies are more corrosive than others, pH values vary, and some have different mineral content (soft vs. hard water) than others. Therefore, the disinfectant level necessary to achieve and maintain recommended minimum residual concentration and the maximum level that can be tolerated (e.g., to maximize employee safety and minimize corrosivity) must be determined for each individual system.

Containers may be only sufficiently protected against leaker spoilage if the bacterial count, expressed as total aerobic plate count (APC), of the cooling water is <100 CFU/ml. (FAO, 1988; Graves et al., 1977; Put et al., 1972.) Containers must be maintained in as bacterial free an environment as possible during cooling if the risks of leaker spoilage are to be minimized. Disinfectant levels do not necessarily correlate with APC levels due to the difference in incoming water quality, cleanliness of cooling systems and many other factors. The presence of residual disinfectant at the container discharge area of a cooling water system may not be an accurate indicator of cooling water adequacy by itself. Consequently, it is a good practice to monitor the bacterial level of cooling water on a periodic basis. If APC levels in excess of 100 CFU/ml are obtained even though the cooling water system has residual disinfectant levels, further investigation of the cooling and disinfection systems could be warranted.

Other cooling water concerns:

Cooling water temperature should be controlled to prevent cans from being cooled to too low a temperature, which would prevent proper drying and possibly result in can rusting. For further information see GMA's *Container Corrosion: Shelf Life Guide for Metal Cans* available for purchase at:
http://www.fpa-food.org/store_category_browse.asp?ic_id=1

Cooling water that is too warm or premature removal of cans from the cooling water may result in containers not being cooled to a low enough temperature. This could result in thermophilic spoilage by allowing storage of cans in the temperature range for growth of thermophiles, which most processes are not designed to inactivate.

Air cooling:

Contamination of air-cooled cans is more likely to occur if the cans are wet. Because air-cooled cans are normally removed from a steam process without any exposure to water, this is generally not likely to occur. However, if wet items such as gloves, rags or slipsheets are laid upon the cooling cans, contamination may occur from these items (FDA, 1998). In addition to supplying the contaminating organisms the water on these items could give the microbes the means to move into the can or jar through the seams/seals. Typically, the seam compound or plastisol would not be set during the beginning of this period, just as it would be with water cooling, and at the same time the container is forming a vacuum while cooling. Plant personnel should be instructed not to lay foreign objects on cans stacked for air cooling. If air cooling is employed, containers should be air cooled in areas protected from condensation, birds, rainfall etc.

Container closure evaluations

Container closure evaluations (can seam teardowns, pouch burst strength, glass pack vacuum checks, pouch seal tensile strength and others) should be conducted before and

during processing to ensure the integrity of seams and seals. Such evaluations are important to maintain the continual integrity of container hermetic seals

Regardless of which type of container is utilized, container closure evaluations should be performed often enough to ensure the adequacy of the closure. Minimum frequencies for container closure evaluation may be specified in various federal and state regulations. These evaluations should be performed by competent, well-trained personnel. Training requirements as well may be designated in the regulations. Finally, records of container closure evaluations should not only be reviewed for compliance to specifications, but also viewed for trends that may indicate that a problem could be developing.

Metal containers

Metal can seaming requirements for container closure are addressed in federal regulations 21 CFR 113.60 (a) (1), 9 CFR 318.301 (b) and 9 CFR 381.301 (b). Processors operating under these regulations must conduct visual examinations every 30 minutes, immediately following a jam in a closing machine, after closing machine adjustment, or after startup of a machine following a prolonged shut-down. Teardown evaluations (one unit per seaming station) are to be done at intervals not to exceed four hours. Similar procedures can be applied for acid foods. Processors should have programs in place to properly maintain closing equipment. The same can be said for training programs designed to ensure that closing equipment is operated correctly and safely and that seam/seal evaluations are done properly.

A conventional method of double seam analysis is the manual seam teardown method. This method is inexpensive but very time consuming. The average inspection time for 12 cans could be one hour or more. The data generated from this test, which may also be used for plastic cans with metal lids, is typically not in an electronic format.

The use of digital technology for digital seam image measurement software (DSIMS) allows automatic measurement of seam dimensions, increases accuracy and reduces the time required for double seam analysis. This technology allows real time trend analysis, digital sending of seam images and data storage. Software with statistical process control analysis can also be a component of these systems. The technology is in use at hundreds of food plants world wide. The time to inspect 12 cans with a semi-automatic system is about 35 – 45 minutes. Other fully automatic DSIMS systems are also available. Such systems, in addition to automatic measurement of seam dimensions, include sample draining, can rinsing, drying, cutting and cleaning done automatically. The time to inspect 12 cans with a fully automated system is approximately 12 minutes (Charbonneau, 2008)

Certain on-line testers, sometimes known as dud-detectors, are available that can measure, indirectly, container vacuum of an entire production lot as it is being produced. Acoustic and proximity technologies can be employed. Acoustic technology is more often used for containers that do not have a measurable lid deflection. Proximity technology works by measuring lid deflection (Charbonneau, 2008). Containers with lid

deflections outside certain limits are rejected. While they offer another level of control, on-line testers do not satisfy the requirements mandated in the above mentioned regulations.

When using on-line detectors, processors should have monitoring and calibration procedures for these machines. Additionally, it may be useful to establish maximum reject rates that when exceeded will lead to a second level of testing to assess why the detectors are rejecting an atypical number of containers.

For further information on examination of metal container integrity, both for routine testing and evaluation of abnormal containers see the *Bacteriological Analytical Manual Online* at http://www.cfsan.fda.gov/~ebam/bam-22a.html.

Glass containers

Almost all low-acid and acidified shelf stable foods packaged in glass containers are sealed with vacuum-type closures. The vacuum within the package and the overpressure in the retort on the outside of the cap play an important role in forming and maintaining a good seal. The four primary factors affecting vacuum formation are headspace, product filling/sealing temperature, residual gas (air) in the product, and capper efficiency. The first two attributes may be stated as critical parameters in a packer's scheduled process.

One convenient, routine check for glass closures is the "cold water vacuum test." This test is required by regulation 21 CFR 113.60 (a) (2) for glass packaging of LACF. The regulation specifies that it shall be performed "before actual filling operations." Other observations for proper closure application and defects can include those for cocked or tilted caps, crushed finish lugs, stripped caps or low container vacuum. Visual observations of glass container closure may also be required. Frequency for visual examinations is required in 21 CFR 113 every 30 minutes or after similar situations as those described for metal containers. USDA regulations require four hour physical evaluations, similar to metal can analysis, for glass containers. These regulations, 9 CFR 318.301 (c) and 9 CFR 381.301 (c), do not specify the method to be used.

For further details see *Examination of Glass Containers for Integrity* from the *Bacteriological Analytical Manual Online* at http://www.cfsan.fda.gov/~ebam/bam-22b.html, or *Guide to Inspection of Low-acid Canned Food Manufacturers* at http://www.fda.gov/ora/inspect_ref/igs/lacfpt3/content.html#ccg or *Method for Evaluation and Examination of Hermetically Sealed Metal and Glass Containers* http://www.hc-sc.gc.ca/fn-an/res-rech/analy-meth/microbio/volume2/mfhpb06-01_e.html

Flexible Pouches

FDA specifies in 21 CFR 113.60(a)(3), with respect to flexible pouches, "For closures other than double seams and glass containers, appropriate detailed inspections and tests shall be conducted by qualified personnel at intervals of sufficient frequency to ensure

proper closing machine performance and consistently reliable hermetic seal production. Records of such tests shall be maintained." USDA requirements in 9 CFR 318.301 (c) (1 - 2) and 9 CFR 391.301 (c) (1 - 2) designate that visual examinations and appropriate physical tests shall be performed.

During evaluations, technicians should determine that heat sealing equipment is being used correctly to assure that the seal bar temperature, pressure and dwell time are adequate to create a well-fused seal. In addition to visual inspections, flexible pouches can be examined by squeeze testing, burst testing, or creep testing. (None of these should be used on swollen pouches, since they are likely to burst and may release harmful microorganisms or toxins.) The squeeze test encompasses applying manual kneading action that forces product against interior seal surfaces, then examining seal areas for evidence of product leakage or delamination. The repeatability of the squeeze test is often variable since different analysts will exert different levels of pressure on the package. Therefore any single failure should be further investigated, even when repeated squeeze tests do not yield an additional package failure. The further investigation should employ evaluations that are more controlled and yield repeatable results. Burst testing and creep testing are more controlled and therefore often more repeatable than squeeze testing. The burst test determines package strength by pressurizing a package until it bursts, and recording the pressure required to do this. The creep test determines package strength by pressurizing a package at 80% of its burst strength for a set amount of time. Tensile strength testing, where the force required to tear apart pouch seams is measured, may also be used.

Ultrasound technology may be used to detect flexible packaging defects (Charbonneau, 2008). These systems utilize non-contact airborne ultrasound technology to detect various types of defects, visible and invisible, such as channel leaks or incomplete seals in flexible packaging. Real time inspection data are available in numerical, statistical and seal image formats These machines take a "digital footprint" of the entire seal area, non-destructively, that allows detection of weak seals before problems happen. They can be used for on-line or off-line inspection

For further information on examination of flexible packaging see *Examination of Flexible and Semirigid Food Containers for Integrity* at http://www.cfsan.fda.gov/~ebam/bam-22c.html or *Guide to Inspections of Low-acid Canned Food Manufacturers* at http://www.fda.gov/ora/inspect_ref/igs/lacfpt3/content.html#ccg

Paperboard shelf stable packaging

Regulatory requirements for paperboard packaging are also covered in 21 CFR 113.60 (a) (3), which is quoted above. USDA requirements are specified in 9 CFR 318.301 (d) and 9 CFR 381.301 (d). Container closure evaluations may be facilitated by teardown procedures, compression testing, conductivity evaluation and dye penetration testing.

Paperboard typically consists of a food contact layer, followed by layers of aluminum foil, lamination, paperboard and the external layer. The dye penetration test tells very

quickly whether there is a defect that penetrates through the food contact layer, through the aluminum layer and into the paperboard layer. However, if the defect doesn't penetrate into the paperboard layer, a negative dye penetration test will result. Conductivity testing, on the other hand, measures the flow of current between the food contact surface and the aluminum layer. If there is a break in the food contact surface exposing aluminum, a positive conductivity test results (container failure). In this same situation, a negative dye penetration test would ensue (container would pass) (Charbonneau, 2008). For further information see *Examination of Flexible and Semirigid Food Containers for Integrity* at http://www.cfsan.fda.gov/~ebam/bam-22c.html

Design of container handling equipment and practices

Container performance can be maximized by the proper design and maintenance of container handling hardware responsible for transporting containers to and from filling, closing, processing and packaging operations, where applicable. Processors should observe the handling of filled and retorted containers and evaluate the likelihood of damage from rough handling. One approach would be to check retort crates and/or baskets and other container handling equipment (conveyors, channels, etc.) for sharp edges or protrusions that could damage container seams/seals or puncture containers. If containers are roughly handled after processing, the seams or seals may be damaged, or, in the case of rigid metal container bodies, dented under the seam. Rough handling or denting could cause a momentary break at the seal point. Leaks caused by dents or by damaged or defective seams and seals can result in the contamination of the commercially sterile product. Flexible and semirigid containers also should be handled carefully to prevent containers from being slit, punctured or damaged.

Empty can handling equipment should be designed to avoid damage to empty cans that could affect double seaming. Properly designed equipment will not squeeze cans into an out-of-round shape. This same equipment should not damage can flanges or impart dents to can bodies, especially on the can manufacturer's double seam or the side seam of the can.

Post retort can tracks should be designed so that cans do not ride on their double seams. Even after cooling, seaming compounds may not be fully set and the double seam area could be vulnerable to leakage. Excessive bacterial contamination may develop on wet and soiled post-cooling equipment and can be transferred to the seam/seal areas as containers pass through the handling systems. All worn belting, can retarders, cushions, etc. should be constructed of non-porous material. Can tracks should be routinely cleaned and sanitized. Processors may employ environmental monitoring of can tracks using microbial analyses for indicator organisms such as APC or ATP bioluminescence testing. Can conveyor systems should also have an automatic shut-off so that when there is a can jam the conveyor stops, which prevents the conveyor from abrading the can seams.

Warehousing and personnel practices should also treat lids with care. Lids that incur dents or coating scratches will not perform optimally in processing or over the expected shelf life of the container.

To further prevent the production of abnormal containers, roll stock packaging should be stored and handled properly. Storing roll stock flat on the floor can damage the ends of rolls and create leaks in the material or distort the shape of the roll stock material, making it difficult to form and seal properly. Rolls are especially vulnerable on their edges and care should be taken during handling by both fork lifts and operating personnel to protect these edges as much as possible. .

Roll stock is often delivered with protective wraps around the rolls. These wraps should remain in place until the roll is ready to be placed into production. When removing the wraps personnel should exercise caution so that edges and outside layers of the roll are not damaged due to inappropriate use of box cutters, knives or other tools. Partial rolls returned to storage should be protected from dust and other damage and not stored unwrapped. Rolls stored open (unwrapped) in a warehouse may attract dust due to electrostatic attraction. While it is recommended that rolls stored unwrapped not be used, if they are, the outer few layers of packaging material should be removed and discarded before these rolls are placed into production.

Warehousing, Labeling and Packaging

Storage conditions should be assessed to ensure they are compatible with the product's storage requirements. Prolonged storage of metal containers at elevated temperatures promotes corrosion and may result in perforation. Proper warehouse and material handling practices should include the observation of container condition. Warehouse and operations personnel should be on the lookout for wet cases, leaks on the floor, forklift damage or swollen and leaking containers. Swollen and leaking containers may also be detected during labeling of "brights," dud detection, and loading of cases for shipment. They should be removed from the warehouse to avoid the attraction of insects or rodents and to prevent the loss of sound product due to the presence of bursting or leaking containers (secondary damage) (Scott, 2008).

It is not a good practice to assume that abnormal containers, especially swollen or leaking ones, are single, isolated events. When abnormal containers are discovered, factory and/or warehouse personnel should look for additional abnormal containers in the same vicinity or same production lot (Scott, 2008). Management should develop policies where any discovered abnormal containers, even a single unit, are turned over to management, and the source lots of these containers are isolated and held until the cause of the abnormality can be determined. Employees should be encouraged to not simply discard even a single abnormal container into the garbage, but to turn it over to a designated individual. Finally, proper inventory control practices will include accounting for all containers removed from inventory.

Dealing with Abnormal Containers

Abnormal containers show evidence that the contents of an unopened container may be compromised, e.g., containers that are swollen and/or leaking. Sometimes these containers may result from underprocessing, and sometimes they may have been adequately processed but have been exposed to post-process conditions that have caused them to leak. Procedures and practices that could be used to avoid abnormal containers have been addressed in previous sections.

Abnormal containers are a warning sign that something could be wrong. As mentioned above, the discovery of even a single abnormal container, especially a swollen or leaking one, should not be treated arbitrarily. Each single incident should be investigated to determine the appropriate actions to take. The problem may be limited to a few containers (and sometime is), but abnormal containers may be a symptom of a larger problem.

There are several approaches that could be taken to determine the cause of an abnormal container. Visual examination of the container is often a good place to start. Many obvious structural problems can be seen with the naked eye, indicating that container abuse has occurred that, most likely, caused leakage. But when visual examinations do not reveal a plausible cause, more evaluation is necessary. At this point, it may be time to send the container to a laboratory.

An abnormal container with no obvious visual defects should be evaluated by a laboratory knowledgeable in the evaluation of spoiled shelf stable foods (Scott, 2008). This type of analysis may also be deployed when multiple abnormalities, such as swollen cans, are found from the same lot or when low levels of abnormal containers are found across multiple lots over time. Depending on the capabilities of an individual processor, this analysis could take place in-house, at a corporate facility or by an independent laboratory.

A detailed laboratory evaluation should include a determination of the probable cause of spoilage. Container examinations associated with food spoilage are usually accompanied by pH determination of the product, gas analysis of can headspace, a microscopic smear of product and microbiological testing of the product. A microbiological examination can determine if organisms of public health significance are present and may offer clues as to the nature of the spoilage (e.g., post-process contamination or underprocessing). The container integrity evaluation may include double seam evaluations for cans; dye leak tests for cans, aseptic packages and pouches; and tensile strength tests for pouches. Burst testing is not appropriate for swollen pouches, as noted previously. Analytical results that reveal differences from normal patterns may indicate changes within the container and help to pinpoint the cause of spoilage. Food spoilage experts may determine that other types of testing are warranted.

Other evaluations that are valuable whenever a potentially spoiled container is discovered include evaluation of process records, cooling water treatment records and container closure evaluation records, where applicable. These reviews, coupled with the results of the aforementioned tests, may lead to plausible explanations for the spoilage. All this has considerable importance, since a proper lot disposition and/or a corrective action is dependent on the outcome of the spoilage analysis.

Sorting and reconditioning lots

In addition to the results of the spoilage analysis, the decision to sort lots with abnormal containers is a company-by-company decision, based on compliance with appropriate regulatory requirements and the company's tolerance for risk. FSIS regulations 9 CFR 318.309 (d) (2) (ii) and 381.309 (d) (2) (ii) state that "When abnormal containers are detected by any means other than incubation, the establishment shall inform the inspector, and the affected code lot(s) shall not be shipped until the Program has determined that the product is safe and stable. Such a determination will take into account the cause and level of abnormals in the affected lot(s) as well as any product disposition actions either taken or proposed by the establishment."

In evaluating tolerance for risk, processors should also remember that section 301 (a) of the Federal Food Drug and Cosmetic Act (21 USC §331) (FFDCA) prohibits introduction or delivery into interstate commerce of any food that is adulterated. The FFDCA goes on, in section 402 (a) (1), to define a food as adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health. Toxins generated by organisms capable of growing in shelf stable low-acid foods due to underprocessing could fit this definition.

Generally, lots with swells where competent laboratory analysis indicate no public health concerns are present may be sorted. Conversely, sorting is not recommended for under-processed product. Delayed microbial growth can occur from injured microorganisms and have a potential public health impact (Scott, 2008).

Sorting of cans also benefits from following prescribed procedures. One common procedure is to hold the lot and allow it to incubate (75°F or higher) for 30 days. After the incubation is complete, the lot should receive a 100% visual inspection for abnormal containers. This lot is then re-incubated and re-sorted. This procedure is continued until no abnormal containers are found. This should be followed by additional evaluation to determine suitability for release, such as described in the next paragraph

It is not a good practice to sort out abnormal containers and assume that flat containers are commercially sterile (Scott, 2008). To complete the final disposition of sorted lots, a reasonably large number, e.g., 200, "normal" containers should be randomly selected from the incubated lot and evaluated for odor, appearance and pH. Results of these analyses, along with the sorting results and evaluation of process, container closure and cooling water records, should be considered when making final disposition of the lot.

Finally, corrective actions based on the outcome of the complete abnormal container assessment should be taken if necessary. All inventory records should be adjusted for product removed from inventory. Detailed records should also be made of each abnormal container found, analyzed, and the results of the analysis.

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Appendix A:

Twenty Important Considerations for the Proper Operation in the Retort Room of Retorts Using Steam as the Heating Medium

1. Make sure all cans are properly coded, and that the code is clearly readable.

2. Do not hold cans too long after closing and before retorting, or incipient spoilage may occur.

3. Use heat sensitive ink for coding containers, so that individual unretorted containers can be identified.

4. Verify ink jet coding equipment's clock agrees with the clock used to time retort processes.

5. Develop procedures to ensure there is no possibility of unprocessed cans bypassing the retort. Heat sensitive container coding inks typically aid in prevention of retort bypass, provided that color change checks are routinely performed downstream of the retorts.

6. Destroy all cans picked up from the floor or removed from the bottom of retorts.

7. Never operate a retort with a leaking steam, water or air valve. Replace such valves immediately, making sure that appropriate information is retained in a maintenance file.

8. Install double-block-and-bleed (3-way valve) piping on all air and water lines on retorts processing with steam.

9. Check the steam spreader regularly to make sure that all of the holes are open, of the proper diameter, and able to emit steam freely. If some of the holes are plugged or overly eroded, uneven heat distribution could result. Also make sure that steam spreaders are attached and that end caps have not deteriorated.

10. Before turning on the steam to a retort, make sure the vent and drain valves are wide open.

11. When venting retorts, make sure that the requirements for both minimum temperature and time are satisfied.

12. After the vent valves are closed, bring the retort to processing temperature as quickly as possible.

13. Always process by the official temperature-indicating device (MIG thermometer, RTD, etc.) and not by the temperature-recording device.

14. Make sure that the temperature-recording device agrees with the temperature-indicating device. Notify the area supervisor prior to making an adjustment. Use all temperature and pressure information from the retort to be certain that there is not a malfunction of the temperature-indicating or temperature-recording device. Once malfunction is ruled out, adjust the temperature-recording device to agree with, but not be higher than, the temperature-indicating device. If the adjustment is made during the process cycle, note it on the recording chart AFTER THE CYCLE is completed. Also make a notation of the adjustment on the operator's written record form.

15. Do not rely on memory for process time. Refer to the list of processes posted near the retort.

16. Time the process by the clock, digital or analog, in the retort room. Do not time the process using a wrist or pocket watch.

17. To prevent buckling the cans, do not drop the pressure too fast during the cool.

18. To prevent paneling, do not maintain the pressure too long during the cool.

19. Cool cans to an average temperature of 100° to 120°F at retort exit. If the cans are cooled to below 100°F, rusting of the tinplate may occur. If the temperature is above 120°F, stack burning or thermophilic spoilage may result. For some products cooling to 110° or below may be necessary.

20. Always notify supervisors and QC staff of any anomaly that occurs during a thermal process cycle. Document the observations on the retort operator form or in a separate incident report. Remember, you can never document a situation too much. Clear, concise documentation of incidents aid in the analysis of process deviations and provide important details for the troubleshooting of mechanical problems.

Appendix B:

Temperature Indicators and Temperature Recorders

The most common type of temperature indicator is the hand-held thermometer. These devices come in many forms, from simple to complex, from cheap to expensive. One of the most widespread types of thermometer is the bi-metallic coil thermometer. These units are available only with an analog readout. They are relatively inexpensive, readily available and easy to calibrate. Bi-metallic coil thermometers contain a coil made of two different metals with different rates of expansion that are bonded together. The bimetal element is coiled, fixed at one end, and attached to the pointer stem at the other end. As the temperature increases, the pointer will be rotated by the coiled bimetal element to indicate the temperature. The disadvantage of bi-metallic coil thermometers is that they lose calibration easily when dropped, bumped or otherwise shocked. Bi-metallic coil thermometers average temperature readings over a sensitive area of the thermometer stem, usually 2 inches. Consequently, temperature variation in this area can affect the thermometer readings (Anonymous, 2008).

Thermocouple thermometers function by measuring the voltage difference generated by two dissimilar metals having different thermal conductivity, joined at one junction. When heated, each metal generates a voltage different from the other. A meter measures the difference in voltage and translates this to a temperature reading. The temperature is sensed at the tip of a wide variety of available probes covering a wide range of temperatures. These types of thermometers are also relatively inexpensive. Thermocouples have a faster response time than other temperature indicating devices. Calibration can be difficult since there are electrical components in the digital display and the probe must be in good mechanical condition (Flores, 2000). Consider using a commercial calibration service provided by the thermocouple manufacturer or from a National Institute of Standards and Technology calibration laboratory (http://ts.nist.gov/MeasurementServices/Calibrations/Thermo-link.cfm)

Infrared (IR) thermometers collect radiant infrared energy emitted from an object. The detector converts the energy signal to a temperature reading. Most IR thermometers respond within 0.5 second and have 100 feet (30.5 m) maximum measuring distance, depending on the target size and environmental conditions. They provide non-destructive, non-contact, surface measurements. IR thermometers give rapid readings and are accurate under the right conditions. The accuracy of IR readings can be adversely affected by shiny surfaces, target size and environmental humidity. Consequently, their use for

measuring initial temperatures of thermally processed products may not be appropriate (Flores, 2000).

Thermistor thermometers are one of the most sensitive temperature measuring devices, able to detect small changes in temperature. Thermistors can be manufactured to fit any need and can be very tiny and very inexpensive. Thermistor thermometers generally operate over a relatively small temperature range, but are usable in the food storage range. They respond quickly and like thermocouples measure temperature at the tip of their probe. Their fragility often limits their applicability. Thermistors are highly accurate, but have a slower response compared to thermocouples (Anonymous, 2008).

A resistance temperature detector (RTD) comes in two methods of construction. One is a thin platinum wire wrapped around a glass or ceramic rod, known as wire-wound, and the second is a thin film of platinum deposited on a ceramic substrate, known as thin-film RTDs. A protective coating of glass or ceramic completely houses the wire-wound detector. Wire-wound RTDs are more expensive and fragile than thin-film RTDs. RTDs can be used in 2, 3 or 4-wire configuration. Two-wire RTDs and their connection cables should be considered a matched pair. Replacing the connecting cable requires recalibration just as if the RTD itself had been changed. Three- or four-wire RTDs are used to eliminate this problem and are the recommended choice. Once an RTD fails, it is best to replace it. RTDs are often linked with temperature recorders and are the most often used sensor in high-accuracy temperature controllers.

The use of glass thermometers, except for calibration purposes and where mandated by regulations, must be avoided because they are easily broken and some may contain mercury.

Temperature measuring devices must be calibrated against a known standard at appropriate regular intervals. Since simple hand held units are easily calibrated, daily standardization is recommended. For more complex RTD-based systems, annual calibration might be adequate.

Mechanical temperature recorders can be used whenever it is necessary to document critical temperatures. Temperature recorders should also be used to monitor any situation where it is important to document temperature consistency. Temperature recorders register data on a paper document, often a circular chart or strip chart. They yield a continuous confirmation of temperature activity over a given time period as opposed to hand-generated records that offer only a snapshot of data at a particular moment.