Food Packaging (FS 522 / FS 495)
Aseptic Processing and Packaging

Components of an aseptic processing system

Aseptic processing is a thermal process in which the product and container are sterilized separately and brought together in a sterile environment. It involves pumping, deaeration, and sterilization of a food product, followed by holding it for a specified period of time (in a holding tube -- required to have a 1/4" rise per foot length of tube), cooling it, and finally packaging it in a sterile container. The use of high temperature for a short period of time (in comparison with conventional canning) in aseptic processing yields a high quality product. Care should be taken to ensure that all process calculations are performed after the deaeration stage and not based on the initial raw product. Deaeration is accomplished in a vessel maintained at a certain degree of vacuum by means of a vacuum pump. The product is fed into the vessel at 55 - 70 ˚C through a nozzle at the center of the vessel. Vacuum is controlled to obtain a product flash of about 5 ˚C. An internal spiral condenser condenses vapors and other condensable gases. The deaerated product is discharged through the bottom and pumped to the heating section. Another important part of an aseptic processing system is the back pressure valve which provides sufficient pressure to prevent boiling of the product at processing temperatures which can be as high as 125-130 ˚C. An aseptic surge tank provides the means for product to be continuously processed even if the packaging system is not operational due to any malfunction. It can also be used to package the sterilized product while the processing section is being resterilized.

History

1913:	Nielsen of Denmark — first aseptic packaging of food (milk in metal cans)
1917:	Dunkley of U.S. — sterilization of cans and lids by saturated steam; fill pre-sterilized product
1923:	Aseptically packaged milk from S. Africa reached a trade fair in London in perfect condition
1927:	Work of Olin Ball and American Can Research Development laid the foundation of aseptic processing in the U.S. – heat, cool, fill (HCF) process developed
1933:	American Can Company developed a filling machine called the heat-cool-fill (HCF) system which used saturated steam to sterilize the cans and lids; sealing was done in a closed chamber which was kept pressurized with steam.
1942:	Avoset process – steam injection of the product coupled with retort or hot air sterilization of packages such as cans and bottles
1948:	Dole-Martin aseptic process – product sterilization in a tubular heat exchanger, metal container sterilization using superheated steam at temperatures as high as 450 ˚F since dry heat requires higher temperature than wet heat, followed by aseptic filling and sealing of cooled product in a superheated steam environment
1950:	Dole Company bought the first commercial aseptic filling plant on the market
1953:	Alpura (a dairy enterprise in Switzerland) and Sulzer (a machinery manufacturer) marketed aseptic milk in Switzerland; not economical due to cost of cans
Early 60s:	Form-fill-seal package -- tetrahedron package
1961:	Alpura and Tetra Pak (Sweden) developed an aseptic carton system for milk
Late 60s:	Tetra Brick aseptic processing machine

Late 70s: Combibloc (blank carton) aseptic system; aseptic filling in drums and bag-in-box fillers
1981: Hydrogen peroxide was permitted for sterilization of food packaging surfaces
1997: Tetra Pak received a no-objection letter from FDA for aseptic processing of a low-acid product containing large particulates

Advantages and disadvantages

Better product quality (nutrients, flavor, color, and texture), less energy consumption, fewer operators, less space requirements, eliminating the need for refrigeration, easy adaptability to automation, use of flexible and any size package, and cheaper packaging costs are some of the advantages of aseptic processing over the conventional canning process. It also does not have the problem of texture changes associated with frozen products and increased permeability of EVOH (to oxygen) due to the high temperature as in retortable pouches. Some of the reasons for the relatively low number of aseptically processed products include slower filler speeds and higher overall cost. Aseptic processing also requires better quality control of raw products, better trained personnel, and better control of process variables & equipment. It is also subjected to stringent and extensive validation procedures. Some of the disadvantages of aseptic processing include increased shear rates, degradation of some vitamins (some vitamins are stable at pasteurization temperatures but not at sterilization temperatures), separation of solids & fats, precipitation of salts, and change in flavor of the product (steam injection followed by flash cooling may eliminate off-flavors) relative to what consumers are accustomed to.

Extended shelf life (ESL) versus aseptics

Due to some of the stringent regulatory requirements of aseptic processing, many processors adopt an aseptic process, but package it in non-aseptic containers. This results in products that are called “extended shelf life products”. Such processes are easier to adopt, require less monitoring (since the resulting product-package combination does not need to be sterile), and are easier to file with regulatory agencies. One such process involves ultra-pasteurization of milk wherein extended shelf-life can be obtained.

Companies and products

Notwithstanding the problems associated in producing aseptically processed foods, several companies have adopted this technology. Some of the products that are aseptically processed include fruit juices, milk, condensed milk, coffee creamers, puddings, soups, butter, gravies, and jelly. Some of the companies that deal with aseptic processing and packaging equipment are International Paper, Tetra Pak, Combibloc, Elopak, Cherry Burrell (tubular: Unitherm; plate: Thermaflex; SSHE: Thermutator; steam injection: Aseptic direct steam incorporation), Alfa Laval (Plate: Steritherm; SSHE: Contherm; steam followed by SSHE: Viscotherm; steam injection: VTIS – Vacu-therm instant sterilizer; corrugated tube: Spiraflo), Connofast, Dole, ASTEC, VRC, APV (Plate: Juicematic; Plate for low-acid: Super ultramatic; steam injection: Uperizer), FranRica, Benco, Scholle, Bosch, and Metal Box.

Regulatory aspects

During aseptic processing, the FDA does not credit lethality accumulation (accumulation of F-value) within a product in the cooling section. This is because particulates could possibly

break up in the cooling section and thus, due to its smaller size cool rapidly, thereby not accumulating significant amount of F-value. Also, due to the uncertainties in the temperature distribution within the product in the heat exchanger, lethality credit is not given in this section.

Unlike in European countries, where regulations are based on spoilage tests, the FDA requires microbiological tests to prove the safety of a process with sufficient latitude for variability in process conditions. In the U.S., different regulatory agencies and rules apply to different products. For example, UHT milk processing is covered under title 21 (parts 108, 113, 114) of the code of federal regulations (CFR). The process should also adhere to the pasteurized milk ordinance (PMO). When meat is involved, the regulations are imposed by the USDA. In addition to these regulations, certain states have state regulations imposed on certain processes. During the past few years, HACCP has gained tremendous importance and its implementation has been extended by the FDA to various products after its initial application to certain acidified and low-acid canned foods.

Critical point

In aseptic processing, if we ensure that the slowest heating point (critical point) within the product is sufficiently processed, the entire product will be sufficiently processed. The critical point within a particulate product is usually the center of the particle that receives the least heat treatment (critical particle). The critical particle in a system containing only one type and size of particle is the fastest particle in the holding tube. In a multi-particle product, the critical particle is the slowest heating particle, which is not necessarily the fastest particle since slower particles may potentially have a lower thermal diffusivity than the fastest particle.

Sterilization of processing, packaging, and air flow system

Sterilization of the processing, packaging, and the air flow system prior to processing is of utmost importance. This is what is referred to as presterilization. Pre-sterilization of the air system is done by HEPA filtering or incinerated air. For equipment, it is accomplished by steam, hydrogen peroxide, or other disinfectant solutions. For filling lines, pre-sterilization is done with steam or water at high pressure. The recommended heating effect for presterilization (using hot water) of the processing equipment for low-acid foods is the equivalent of 250 ˚F for 30 minutes. The corresponding combination for acid or acidified products is 220 ˚F for 30 minutes. This often involves acidification of the water (to below a pH of 3.5 for acid products) used for sterilization. Presterilization of an aseptic surge tank is usually done by saturated steam and not hot water due to the large volume associated with the surge tank.

CIP cycle for low-acid foods: Hot water, alkali, hot water, acid, hot water
CIP cycle for high-acid foods: Hot water, alkali, hot water

Sterilization of food contact surface of packaging material

For non-sterile acidic products (pH < 4.5), a 4D process is required. For sterile, neutral, low acid products (pH > 4.5), a 6D process is required. However, if there is possibility that *C. botulinum* is able to grow in the product, then a full 12D process is required.

It has been suggested that only 3% of the total number of microorganisms on the package surface are spores. An upper value of 1,000 microorganisms per m^2 (30 spores per m^2) has been

assumed for plastic films and paperboard laminates on reels, and 3,000 microorganisms per m^2 (90 spores per m^2) for prefabricated cups.

Radiation

- UV-C radiation (250-280 nm); optimum effectiveness at 253.7 nm; applicable only to smooth, even surfaces
- Infrared radiation: Applicable only to smooth, even surfaces (Aluminum lids coated with plastic laquer)
- Ionizing radiation: Co-60 or Cs-139; 25 kGy (2.5 Mrad); 100 keV of electron beam (empty sealed containers such as bag-in-box)

Heat

- Saturated steam: 165 ˚C and 600 kPa for 1.4 s (cups) and 1.8 s (lids); disadvantages include need for high pressure, removal of air (to promote heat transfer), and possible dilution of product as steam condenses
- Superheated steam: 220-226 ˚C for 36-45 s
- Hot air: 315 ˚C (surface temperature reaches 145 ˚C for ~ 3 min.); suitable only for acidic products
- Hot air & steam: Hot air is blown through a nozzle in such a way that the base and walls are uniformly heated; used for cups and lids made of polypropylene which is thermally stable up to 160 ˚C.
- Extrusion: During extrusion of plastic granules prior to blow molding of plastic containers, temperatures of 180 - 230 ˚C are reached for up to 3 min. However, because the temperature distribution inside the extruder is not uniform and the residence time of the plastic granules varies considerably, it is not possible to guarantee that all particles will achieve the minimum sterility. It has been suggested that extrusion results in a 3-4 D process. Thus, aseptic filling into extruded containers should be used only for acidic products. For low-acid products, a hydrogen peroxide treatment is usually done.

Chemical treatment

- Hydrogen peroxide: Dipping, spraying, rinsing processes, or combined with UV-C or heat; At least 80 ˚C and 30% concentration is required; residual peroxide should be less than 100 ppb at time of filling and must decrease to 1 ppb within 24 hrs. Since it is hard to detect peroxide in foods, containers filled with water are run through the machine, initially.
- Peracetic acid: Produced by oxidation of acetic acid by hydrogen peroxide; effective even at 20 ˚C (1% solution will eliminate 7-8 logs of the most resistant spores in 5 min at 20 ˚C; maximum usable temperature is 40 ˚C)
- Ethylene oxide: It is a toxic gas and can penetrate porous materials; thus used for pre-sterilization of paperboard-based packaging materials (particularly preformed carton blanks which are to be assembled in an aseptic filler)

<u>Verification of sterilization</u>

This is done by inoculation of the surface of the web, cup, or lid stock with the proper concentration of the test organism and allowing it to dry. The system is then run as in a commercial run and the finished containers are filled with an appropriate growth medium and observed for growth. Two of the most important factors affecting the success of the tests are the

choice of the indicator organism and the physical state of the microorganisms used. The indicator organisms used are: *B. stearothermophillus* — strain 1518 (Superheated steam, peroxide + steam, extrusion), *B. polymyxa* — PSO (dry heat), *B. subtilis* strain A (peroxide + UV), *C. sporogenes* — PA 3679 (ethylene oxide), and *B. pumilus* (gamma radiation).

Types of packaging systems

1. Can systems: Pioneered by Martin in the late 1940s; first system commissioned by Dole Corp. (CA) in 1950 for soups; uses superheated steam at 225 ˚C for up to 40 s to sterilize can and ends; temperature should not exceed 232 ˚C since tin flow underneath the enamel can occur, resulting in blister formation. During seaming of lid (the lining compound is still at ~ 220 ˚C and is plastic; thus seamed can should be transported in vertical position for at least 15 s after seaming to allow compound to settle and hermetically seal the can). For composite cans consisting of spirally wound body made from laminations of foil, plastics, and paper with metal ends, hot air at 143 ˚C for 3 min. is used to sterilize packaging materials. Steam would cause swelling of the paper layers.

2. Bottle systems

Glass: Saturated steam or dry heat (when dry heat is used, extended cooling by sterile air is required to minimize thermal shock when cool product is filled in it; no commercial unit, yet)

Plastic

Non-sterile bottles: After blowing, the plastic bottles are conveyed into a sterile chamber which is kept at a slight over-pressure of sterile air. The bottles are inverted and sprayed inside with hydrogen peroxide and passed through a hot air tunnel to evaporate the residual peroxide. The bottles are rinsed with sterile water and then filled. A chemically sterilized, heat sealable closure, such as a plastic film or cap is then applied.

Sterile blown bottles: Bottles are extruded, blown with sterile air, and sealed under conditions that ensure internal sterility of the container. The sealed bottles are introduced into a sterile chamber (maintained at a slight positive pressure) where the outside surfaces are sterilized by hydrogen peroxide sprays. The closed top of the bottle is cut away, the neck trimmed, the bottle filled, and a foil cap or heat sealable sterile closure applied.

Single station blowing, filling, and sealing: This is a complex system. The separate operations of parison extrusion, blow molding, bottle filling, and sealing all take place in sequence in a single mold. Sterility of the inside surface of the container is ensured by the high temperature (164 to 234 ˚C) of the plastic material during extrusion of the parison, and the use of sterile air for blowing. After filling, the tube projecting from the bottle mold is vacuum-formed or sealed with jaws into a cap which closes the bottle. No special arrangements to ensure sterility are required since filling and sealing are carried out within the closed mold.

3. Sachet and pouch systems

Form-fill-seal systems: A vertical form-fill-seal machine operates in a sterile chamber. The packaging material is passed through hydrogen peroxide and then drained and dried.

Layflat tubing: This system uses a blown film polymer in the form of a layflat tubing so that only a transverse seal is required to form the bag. It is assumed that the inside of the tubing is sterile due to the temperature achieved during the extrusion process. The tubing is fed from the reel into a sterile chamber in which an over-pressure of air is maintained. The sachets are sealed at the bottom, cut, and moved into a filling station. After filling, they are sealed at the top and leave the chamber through a water seal.

4. Cup systems

Preformed plastic cups: The cups are fed onto a conveyor which is inside a sterile tunnel supplied with sterile air. The cups are sprayed with hydrogen peroxide and after about 3 s, the solution is removed with compressed hot air at ~ 400 ˚C with the inside surface of the cups reaching ~ 70 ˚C which completes the surface sterilization and reduces the peroxide residue to acceptable levels. The cups are then filled and sealed with an aluminum foil (sterilized by peroxide with residue removed by heat) with a thin coating of a thermoplastic to provide heat sealability.

Form-fill-seal cups: The plastic material (usually polystyrene) in the form of a web is fed from a roll into a thermoformer. Sterilization of the web is done prior to forming using a hydrogen peroxide bath. It then passes through a tunnel where it is heated to 130-150 ˚C to prepare it for thermoforming. Mechanical force and compressed air are used to form the container in a water-cooled mold below the web.

5. Carton systems

Form-fill-seal cartons: The packaging material is supplied in rolls which have been printed and creased (for ease in the forming process). A polyethylene strip is sealed to one edge and the packaging material sterilized using a wetting system or a deep bath system. The sterilized packaging material is fed into a machine where it is formed into a tube and closed at the longitudinal seal by a heat sealing element. In this process, the polyethylene which was added prior to sterilization is heat sealed across the inner surface of the longitudinal seal to provide protection of the aluminum and paperboard layers from the product which could corrode or swell the layers if such a strip were absent. Product is then filled into the tube and a transverse seal made below the level of product, thus ensuring that the package is completely filled.

Prefabricated cartons: In this method, prefabricated carton blanks are used, the cartons being die-cut, creased, and the longitudinal seam completed at the factory of origin. The cartons are delivered to the processors in lay-flat form, ready to be finally shaped in the filler and the top and bottom seams formed and bonded. Stacks of blanks are loaded into a magazine from which they are individually removed by suction pads, opened up into a rectangle, and placed on a mandrel. Polyethylene at the bottom of the carton is softened by hot air. The bottom is then folded by transverse and longitudinal folders and sealed. The top is then pre-folded. All of this takes place in a non-sterile zone. The inside surface is then sterilized by peroxide in a sterile zone (over-pressure of sterile air). The carton is then filled, closed, and heat sealed.

6. Bulk packaging systems

Metal drum: Two major systems are in use and both use a 55 gallon metal drum constructed from steel with an electrolytically coated tin lining outside. The ends are double-seamed onto the body of the drum during manufacture and filling takes place through a threaded hole in which a cap is swaged after filling.

Bag-in-box: In this system, the product is filled into a plastic bag which when full is put into an outer container such as a drum or a paperboard box. For large containers, filling occurs after the bag is placed in the box.

Integrity testing of aseptic packages

Destructive methods

Teardown: The flaps of the package are unfolded and pressure applied to the package to check the tightness of the transverse seals. The quality of the transverse and longitudinal seals is determined by carefully pulling apart the seals — if the seal is good, the polyethylene layers will be removed and the aluminum foil laid bare in the sealing zone.

Electrolytic test: This test is based on the principle that a tight plastic container is an electrical insulator. By introducing an electric potential across a brine-filled package which is partially immersed in a brine solution, the existence of holes in the package can be determined. Positive tests are generally followed by a dye test for confirmation.

Dye test: After rinsing with water and drying, a solution of 0.5% Rhodamine B in isopropanol is applied to the critical areas of the package including the longitudinal and transverse seals. The carton is then allowed to develop for 5 minutes and dried in a warm cabinet overnight. The flaps of the package are unfolded and the dye coated paper removed and examined for ink penetration. Any sign of the pink ink indicates the presence of holes in the polyethylene layers.

Nondestructive methods: These include visual inspection, computer-aided video inspection, and automatic profile scanning.

Biotest methods: The package is filled with a nutrient broth, sealed, and placed in contact with a medium infected with a test organism. After contact for a certain period of time, the package is placed in an incubator and microbial growth assessed after an appropriate time.

7-layer aseptic package

Paper -- 70% by weight
Polyethylene (PE) -- 24% by weight
Aluminum -- 6% by weight

Layers from inside to outside: PE, ionomer, Aluminum foil, PE, paperboard, printed PE, PE