Module 14. Aseptic Processing and Packaging Systems

Thermal Processing for Meat and Poultry Products Training

Aseptic Processing Inspection

Different from Traditional Canning

PA must ensure commercial sterility not only for product but also:

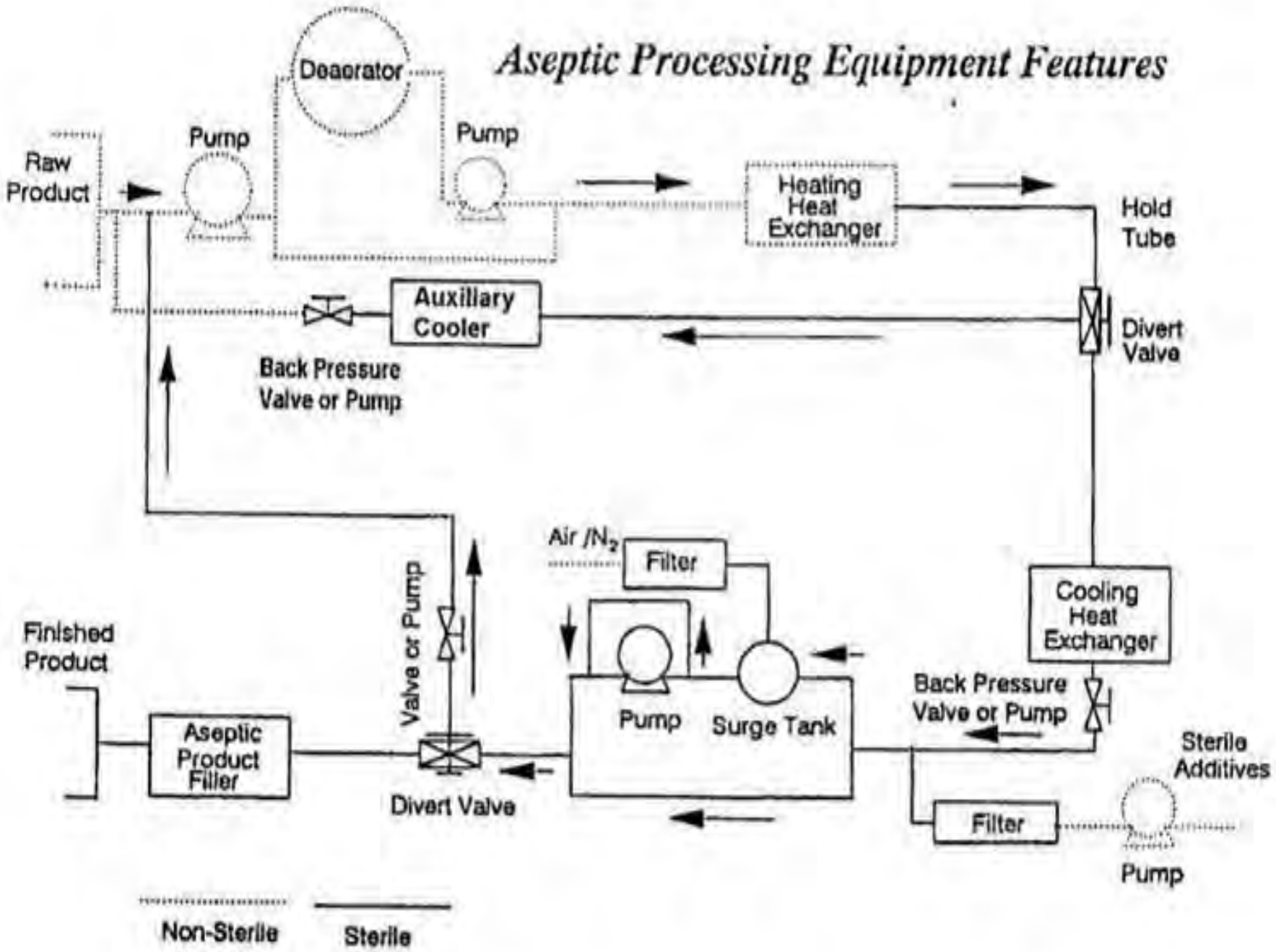
- Product sterilization system (hold tube) and all downstream equipment including the filler
- Packaging equipment; and
- Packaging materials

System Pre-Sterilization

- Processing Equipment
  - Steam or hot water under pressure
- Packaging Equipment and Materials
  - Saturated Steam
  - Superheated Steam
  - Hydrogen peroxide and heat
  - Other treatments
- Validated by placing resistant microbial spores on adhesive strips

Scheduled Processes

- Product
- Product “sterile zones”
  - hold tube downstream
- Packaging system
- Packaging materials


Aseptic Processing Equipment Features
Deaerator
Pump
Pump
Raw Product
Heating Heat Exchanger
Hold Tube
Auxiliary Cooler
Divert Valve
Back Pressure Valve or Pump
Air /N2
Filter
Cooling Heat Exchanger
Finished Product
Valve or Pump
Pump
Surge Tank
Back Pressure Valve or Pump
Sterile Additives
Aseptic Product Filler
Divert Valve
Filter
Pump
Non-Sterile
Sterile

Equipment and Controls

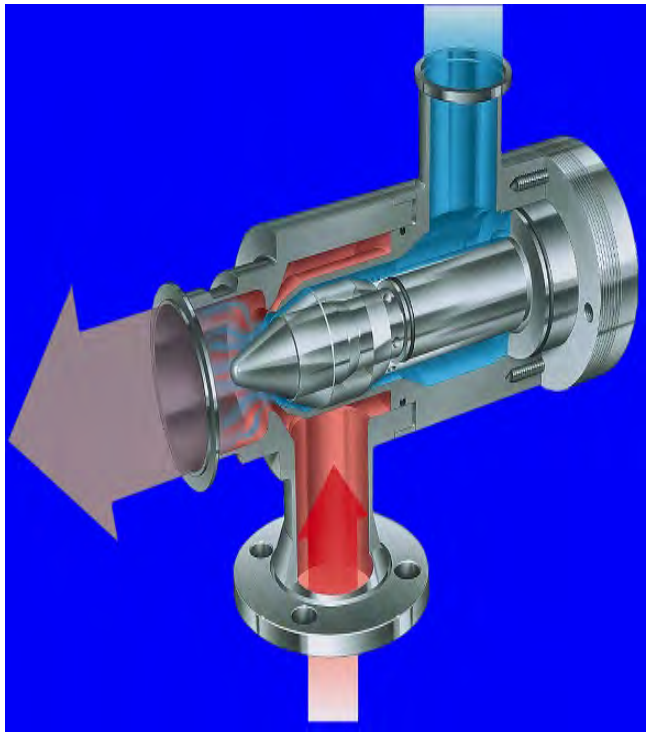
- Formulation controls
  - Starches, particle size, rehydration
- Metering (timing) pump
  - Fixed or variable speed
  - Flow meter (flow control must be validated)
  - Flow rate affects residence time in hold tube
  - System design, pumping rates, and product characteristics (formulation) affect flow rate

Equipment and Controls

- Process Authority determines and calculates residence time of the fastest moving particle
- Processor monitors specified flow rate
- Pump speed correlated to flow rate (indirect)
  - Count pump strokes per time period
  - Tachometer
- Flow meters (direct)
  - Gallons per minute
  - Containers per set time interval

Direct Product Heating Systems

- Steam Injection



- Steam Infusion

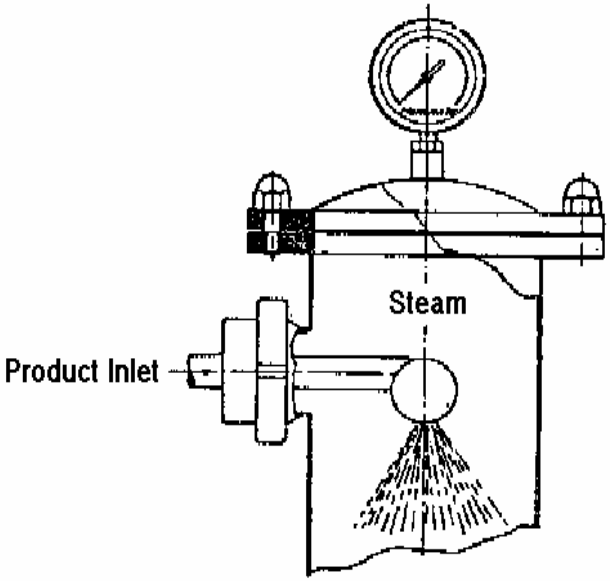
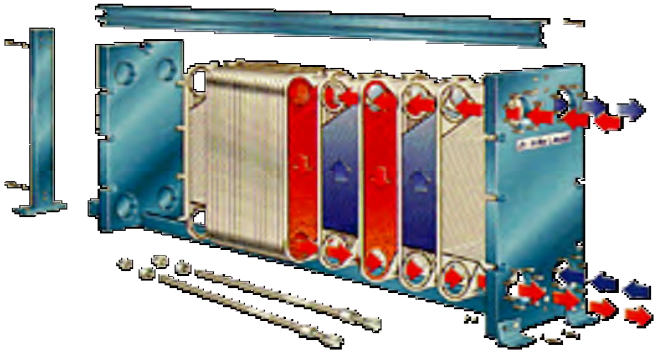


Figure 2 - Steam Infusion

Indirect Product Heating Systems

- Plate Heat Exchanger



- Tubular Heat Exchanger

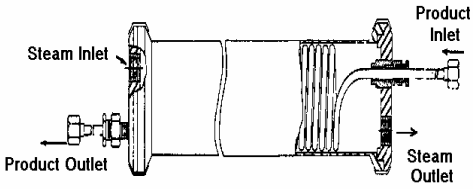
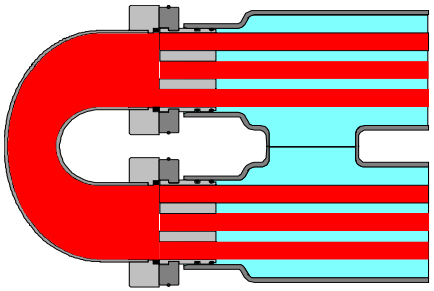


Figure 4 - Tubular Heat Exchanger



- Scraped Surface Heat Exchanger

Equipment and Controls

- Hold tube
  - Sloped upward at least 0.25”/foot
  - Diameter, length, and slope conform to tested
  - No portion of the tube is heated (can be insulated)

Equipment and Controls

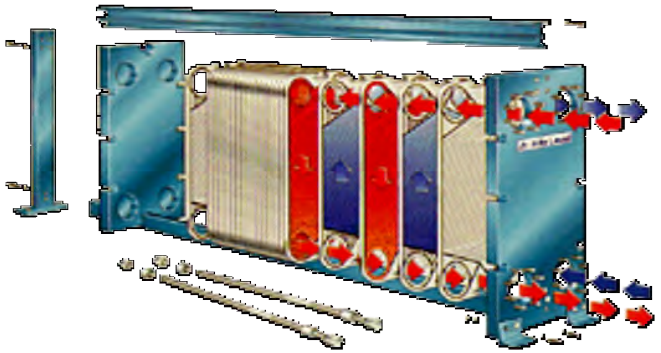
- Temperature Indicating Device
  - Must meet requirements
  - Checked for accuracy
    - upon installation and at least once per year
  - Calibration records
  - Bulb in vicinity of recorder
- Recorder
  - Accurate
  - If air actuated, clean air supply (filter maintenance)
  - Bulb located at the exit end of the hold tube

Equipment and Controls

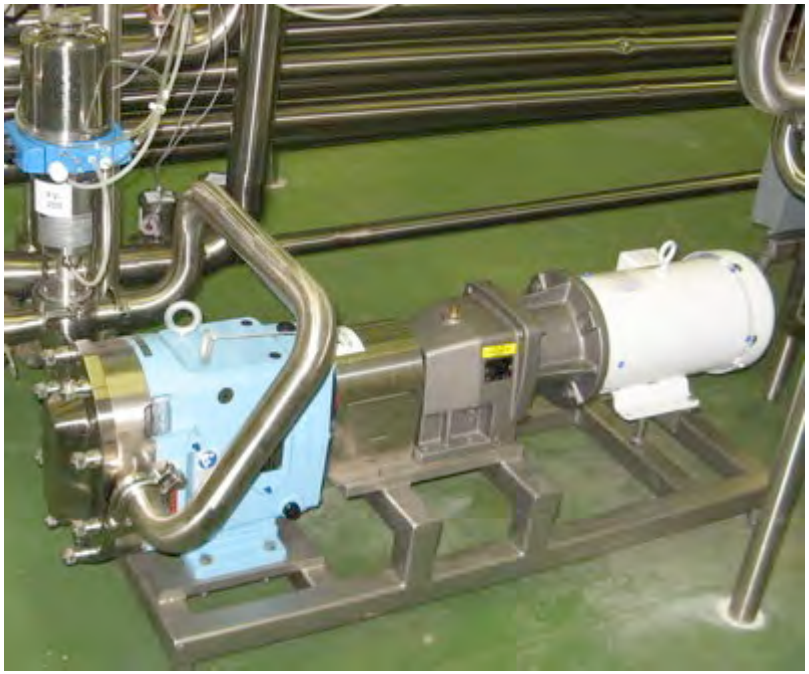
- Flow diversion system
  - Location
  - Automatic flow diversion parameters
    - Temperature drop
    - Pressure drop in product to product regenerator
  - Manual flow diversion notification system

Equipment and Controls

- Product to product regenerators
  - Pressure of sterilized product greater than the pressure on any unsterilized product
  - Differential Pressure Recorder-Controller Sensors
    - Sterilized product outlet (highest pressure)
    - Unsterilized product inlet (lowest pressure)
    - Tested for accuracy



Backpressure Device



- Valves, orifices, or pumps may be used to assure that pressure prevents flashing of product in hold tube.

Product Heating Control Systems

- Manually operated systems rely on review of production logs and recording charts to verify process schedule was delivered
- Automated systems prevent packaging non-sterile product
  - Routinely challenge system to verify function
  - Review recent challenge and calibration records including testing method, frequency of testing, and who performs the test

Verifying Operations

- Start-Up Verification
  - Follow scheduled process
  - Monitor temperature at coldest point downstream of the hold tube
  - Determine how the establishment prevents deviations during switch-over from water to product

Verifying Operations

- Operating Records
  - Temperature Indicating Device at end of hold tube
  - Temperature Recording Device at end of hold tube
  - Temperature Recorder-Controller at final heater outlet
  - Regenerator differential pressure record
  - Product flow rate
  - Surge tank sterile air overpressure
  - Performance of steam seals
  - Pre-sterilization records

Possible Process Deviations

- Temperature drop in hold tube
- Loss of differential pressure in regenerator
- Loss of sterile air pressure or other protection in the surge tank
- Loss of sterile air/gas to sterile zones
- Critical factors in PS outside specification
- Speed of variable speed pump too high

Cleaning and Reprocessing Following a Deviation

- Written procedures for cleaning and re-sterilizing the system
- If re-sterilization procedure differs from startup, verify the procedure is from a PA
- Verify
  - Establishment documents clean-up
  - System is returned to commercial sterility
  - Disposition of suspect product already filled into containers.

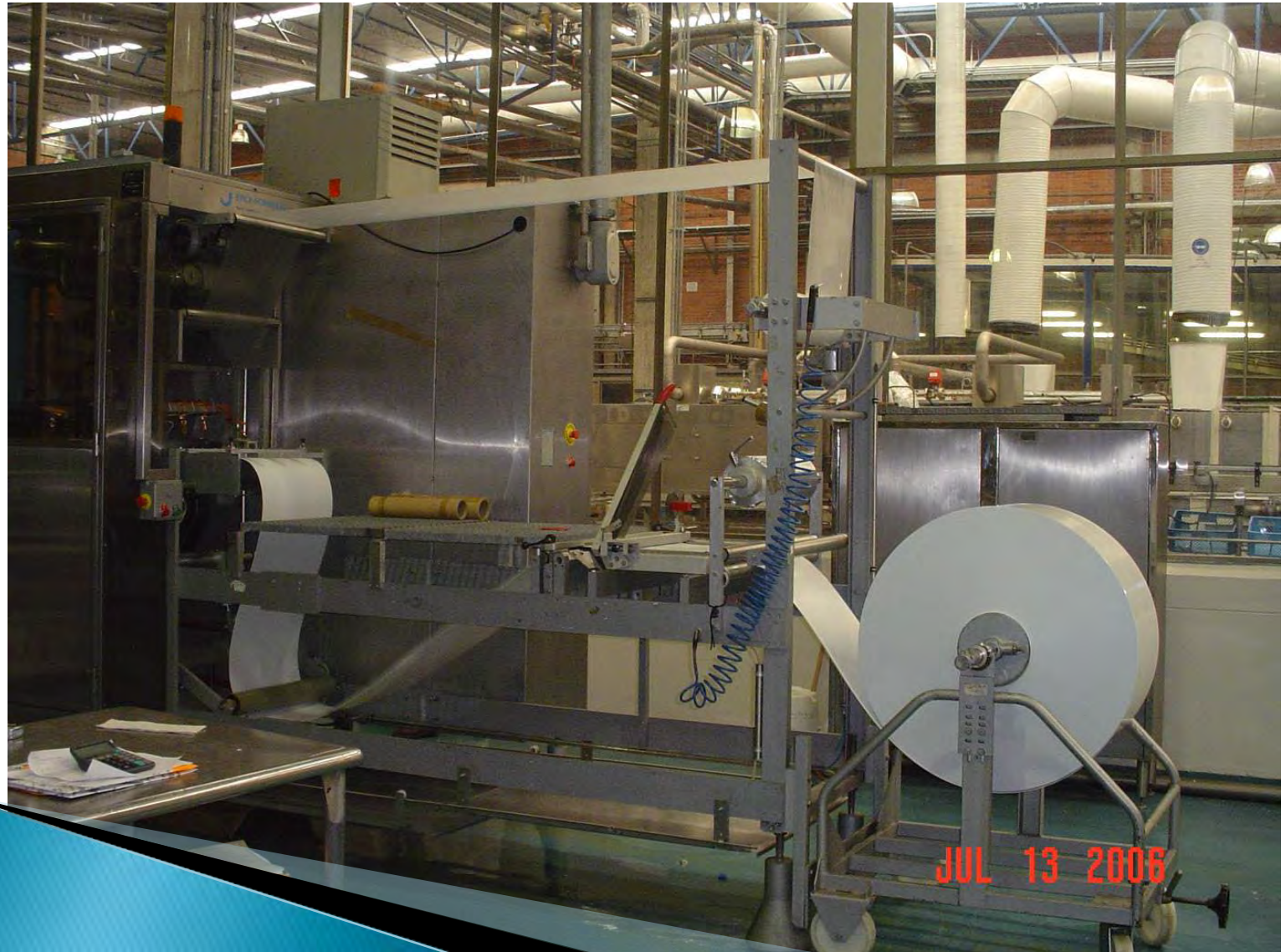
Reprocessing

- Previously processed product may exhibit different flow characteristics (starch/binders)
- Verify whether affected lots are to be reprocessed separately, together, or blended with new product

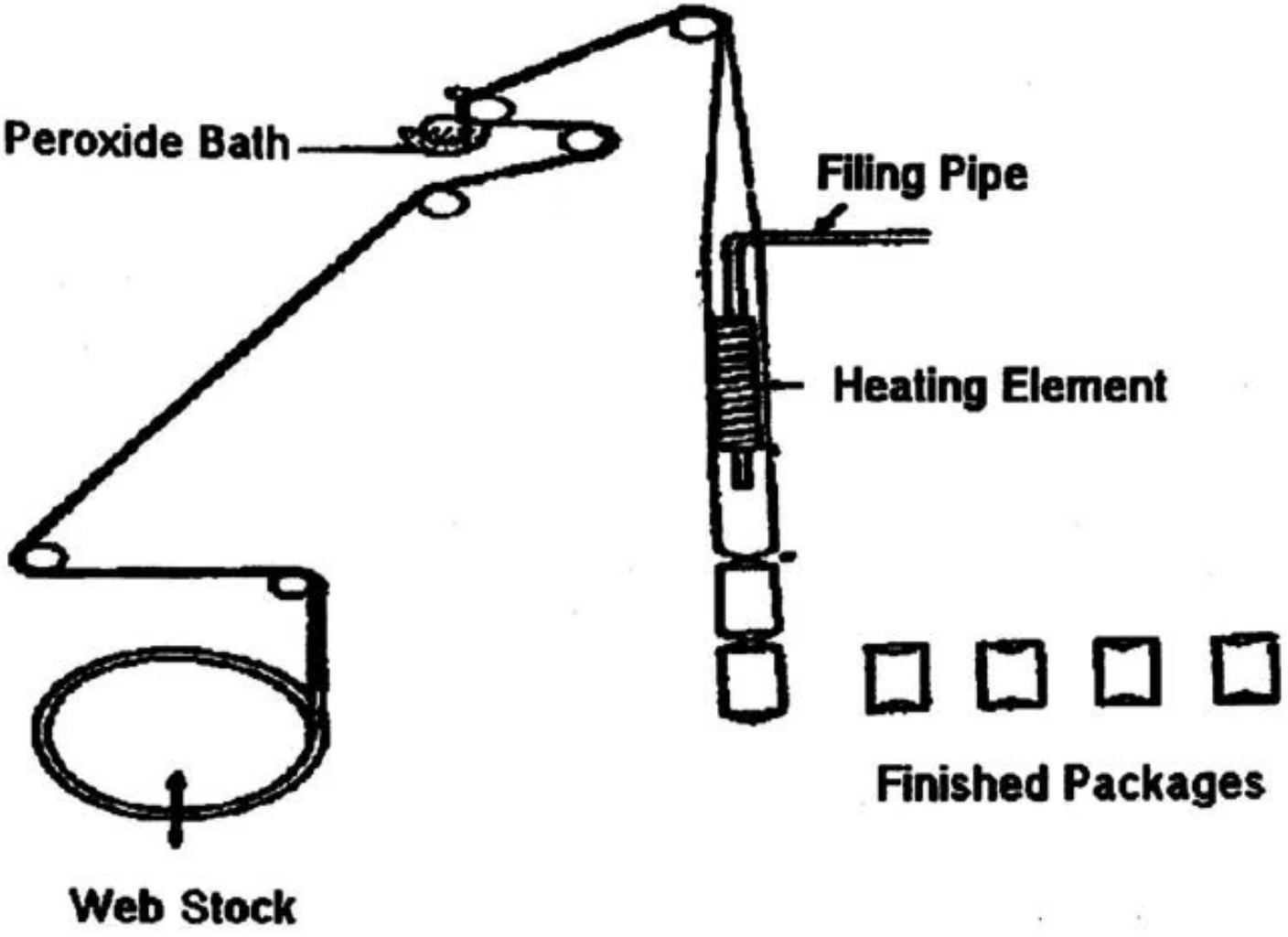
Package Sterilization Systems

- Cans and lids: super heated steam
- Webfed paperboard: H_2O_2 and heat
- Preformed or partially formed paperboard: H_2O_2 and heat
- Preformed plastic cups: H_2O_2 and heat
- Thermoform-fill-seal: H_2O_2 and heat or heat of co-extrusion
- Bag-in-box: gamma irradiated bags

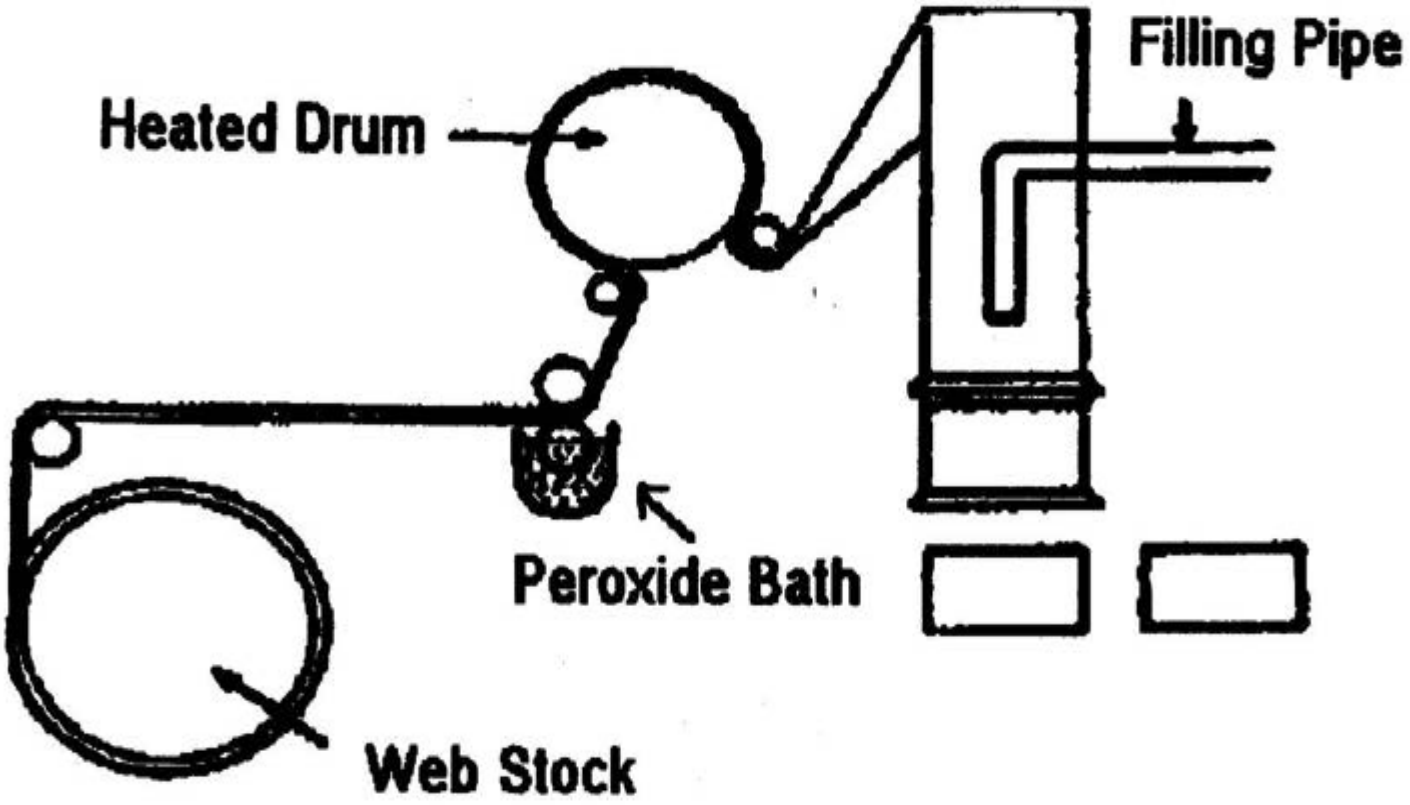
Webfed Paperboard System



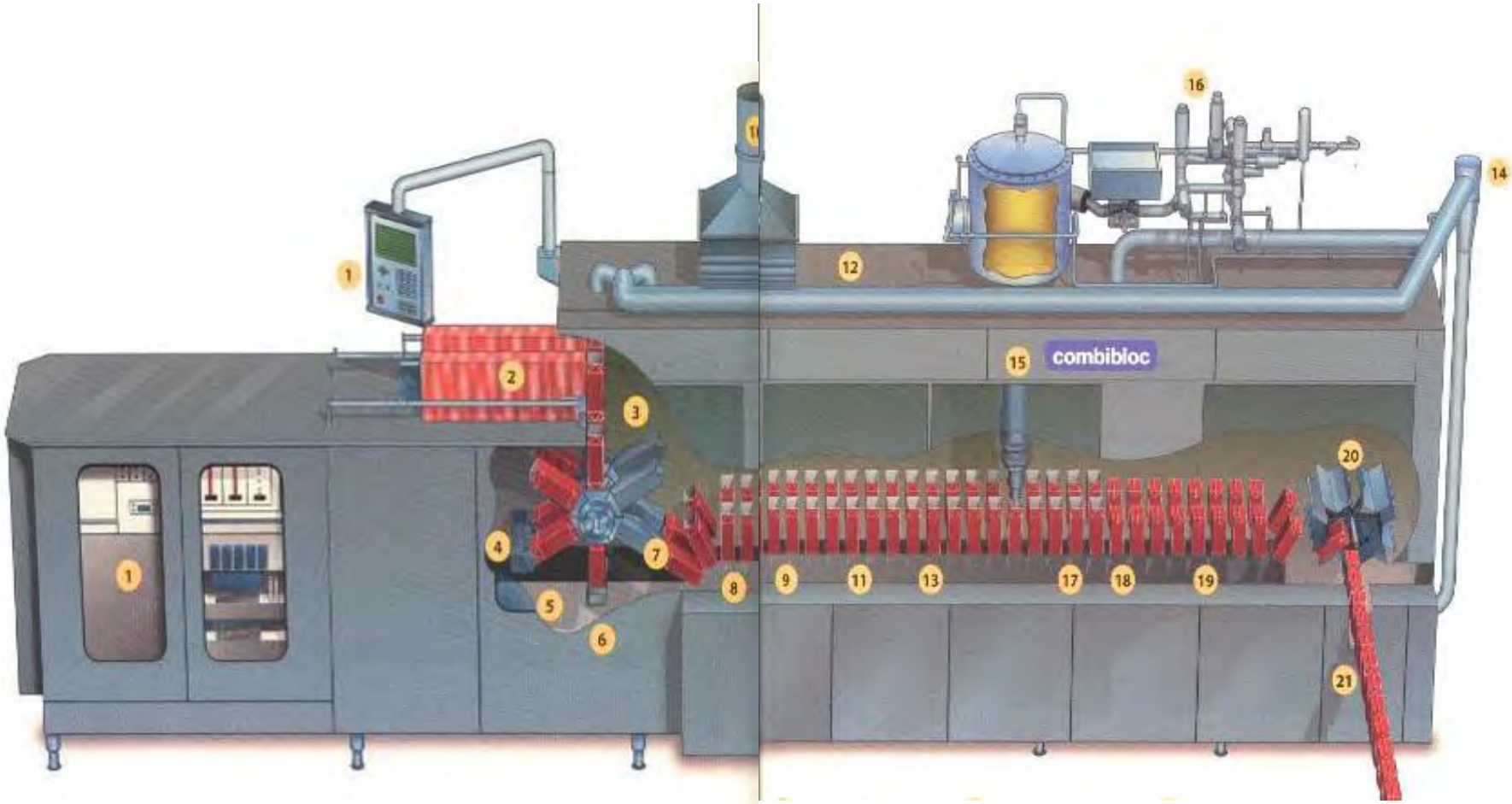
Webfed Paperboard System 1



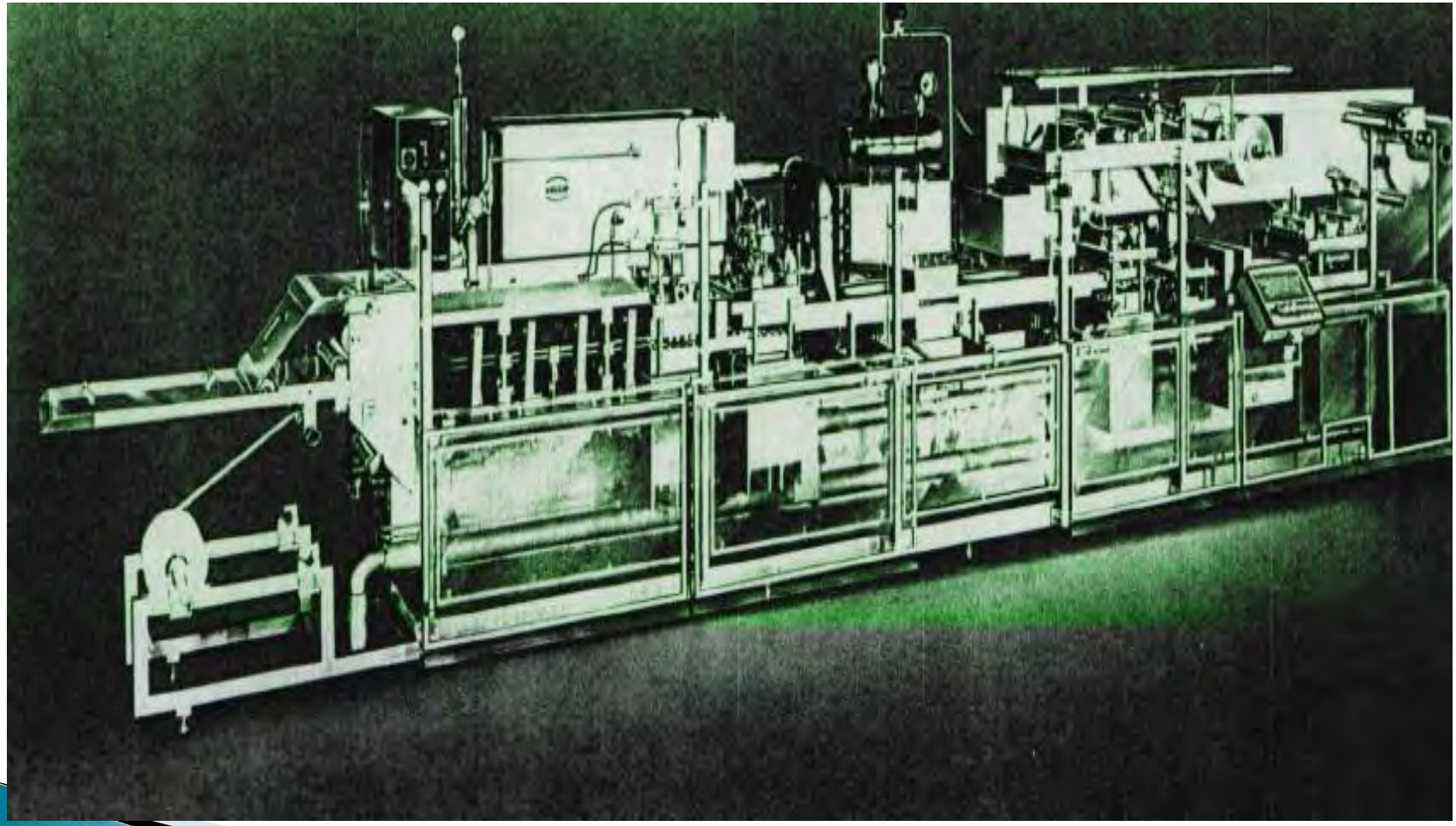
Webfed Paperboard System 2



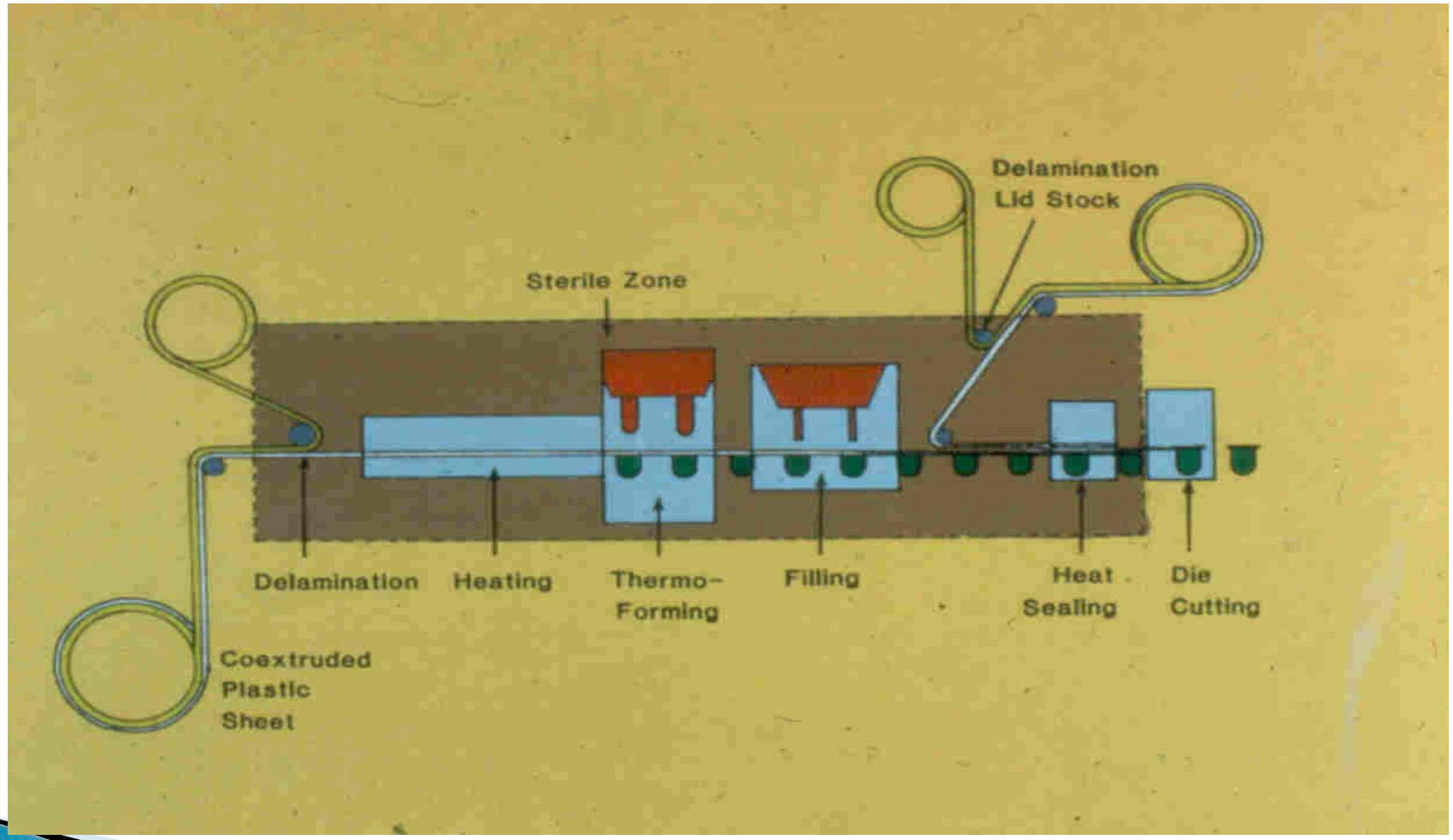
Preformed Container System



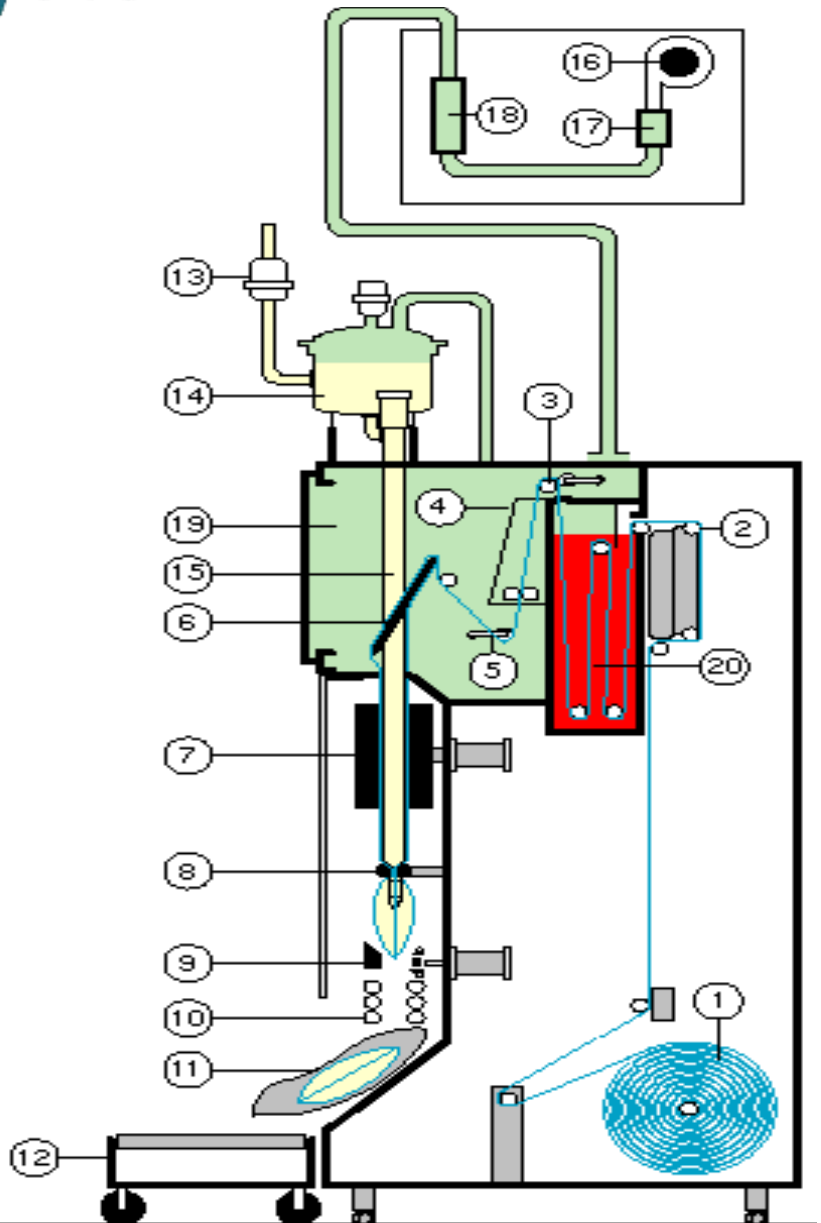
Thermoform Filler



Erca Filler



Pouch Filling System



Pouches

Pouch and Bag Materials

Bag Filler

Bulk Filler

Bulk Filler

Possible Packaging Critical Factors

- Sterile air temperature (or incinerated air, subsequently cooled and used to provide over-pressure in a sterile zone)
- Sterile air filters
- Sterile air over-pressure in sterile zone
- Gas flush - nitrogen or other sterile gases used to flush equipment or container headspace must be sterilized and maintained in a sterile condition
- Hold time after temperatures have reached that specified for thermoform, fill, and seal containers

Paperboard and Plastic Container Critical Factors

- Peroxide consumption rate
- Peroxide concentration
- Peroxide level (immersion) or deposition (roller or fog)
- Temperature of warming air to transport chemical sterilants
- Air or heating element temperature (to remove H_2O_2 and complete sterilization)

Packaging Process Deviations

- Many systems automatically stop the machine and preclude packaging into non-sterile containers
- Determine who calibrates and checks controls
  - Review calibration methods and recent results
- Determine how system is challenged
  - Review procedure and recent results
- Can manual override be initiated, by whom, and how is it recorded
- How is residual H_2O_2 on packaging tested for compliance with 21 CFR 178.1005(d)

Packaging System Records

- Observations/measurements must be made at frequency to ensure the product is commercially sterile
- Recommended frequency for critical factors and operating conditions should not exceed one hour

Key Points

- Aseptic systems target the same microorganisms as a typical commercial sterile low acid canned product.
- Aseptic systems consist of a means to heat the food, a timing pump, a hold tube, and a cooling system.
- Downstream from the hold tube must be brought to commercial sterility before filling.
- The thermal process of the food is performed in the hold tube by controlling flow rate, residence time, and temperatures.
- Aseptic zones of machines create and maintain a sterile zone for filling and sealing.
- Sterilizing agents such as heat, chemicals, irradiation, or a combination of treatments are used to treat packing materials or machine surfaces.