Thermal sterilization is aimed at eliminating the risk of food poisoning, and may be used to extend product shelf life. Here the guidelines for the microbiologically safe thermal sterilization of liquid food products recommended by the Continuous Heat Treatments subgroup of the European Hygienic Equipment Design Group (EHEDG) are summarized. This paper is the sixth in a series of articles featuring the EHEDG to be published in *Trends in Food Science & Technology*. The EHEDG is an independent consortium formed to develop guidelines and test methods for the safe and hygienic processing of food. The group includes representatives from research institutes, the food industry, equipment manufacturers and government organizations in Europe.*

Thermal sterilization of food products is aimed at eliminating the risk of food poisoning and, when used in conjunction with aseptic filling, at achieving extended product storage life under ambient conditions. Whereas pasteurization destroys vegetative microorganisms, sterilization destroys both vegetative microorganisms and relevant bacterial spores (see Definitions). The Continuous Heat Treatments Subgroup of the European Hygienic Equipment Design Group (EHEDG) has already published guidelines on the microbiologically safe continuous pasteurization of liquid foods; here they present guidelines on microbiologically safe continuous sterilization. Only liquid products and well-known, widely used technologies form the scope of this paper; more recent techniques such as Ohmic heating may form the basis of a future publication. The guidelines summarized here have been approved by the EHEDG.

The sterilization process

The main difference between sterilization and pasteurization is that temperatures required for sterilization are significantly higher than for pasteurization ($\geq 120^{\circ}C$ compared with 70–90°C).

As most bacterial spores will survive pasteurization, the process is used with products in which sporeforming bacteria do not grow (e.g. high-acid products) or product shelf life is too short for spore germination and growth to reach unacceptable levels. Sterilization is typically applied to low-acid products requiring extended shelf life at ambient temperature. Continuous-flow sterilization plants are therefore typically operated in conjunction with an aseptic filler or further aseptic processing.

For microbiologically safe sterilization, it is essential to maintain the correct sterilization conditions during the entire period of operation, and to prevent reinfection of sterilized product. Maintenance of the correct sterilization conditions requires that the product is held at the desired sterilizing temperature for a fixed time and that

*Readers requiring further information on the EHEDG are referred to Ref. 1. Details of previously published EHEDG articles are given in Refs 2–6.

The microbiologically safe continuous-flow thermal sterilization of liquid foods

the plant design, operation and control enable this to be achieved; prevention of reinfection requires that equipment in contact with sterile product can itself be sterilized and is impervious to bacteria.

Sterilization systems for liquid products

There are many types of continuous sterilization systems available, but all come into one of two categories: direct or indirect. The choice of system depends on

Definitions*

Aseptic equipment: Hygienic equipment that is, in addition, impermeable to microorganisms.

Cleaning: The removal of soil (any undesired matter, including product residues, whether or not containing microorganisms).

Destruction of microorganisms: Irreversible physical or chemical damage to microorganisms to prevent them from surviving and multiplying. Thermal destruction employs heat, possibly in combination with water or steam; chemical destruction employs biocidal chemical(s).

Hygienic equipment Class 1: Equipment that can be cleaned in-place and freed from relevant microorganisms without dismantling.

Hygienic equipment Class 2: Equipment that is cleanable after dismantling and that can be freed from relevant microorganisms by steam sterilization or pasteurization after reassembly.

Microbial impermeability: The ability of equipment to prevent the ingress of bacteria, yeasts and moulds from the environment to the product area.

Pasteurization: Thermal destruction of vegetative microorganisms excluding thermoresistant bacterial spores. Clean equipment is pasteurizable if it can be freed from such microorganisms by treatment with hot potable water of up to 95°C for 20 minutes; alternative conditions can be used depending on local circumstances. (In the dairy industry, usual!y refers to the destruction of pathogenic and some spoilage microorganisms.)

Relevant microorganisms: Bacteria, yeasts and moulds able to contaminate, multiply or survive in the product and harmful to the consumer or to product quality.

Sterilization: Removal or destruction of microorganisms, including all relevant bacterial spores. Clean equipment is steam/hot-water sterilizable if it can be freed from relevant microorganisms by treatment with saturated steam/water at 120°C for 30 minutes (alternative conditions can be used depending on local circumstances).

*These definitions have been drawn up by the EHEDG in an attempt to prevent confusion regarding standard terminology relevant to hygienic processing.

many factors related to product characteristics (e.g. viscosity and susceptibility to fouling), production requirements (e.g. capacity and run length) and economics (e.g. capital and running costs).

Direct heating

In a direct system the product is heated by condensation of steam brought into direct contact with the product. There are two types of direct heating: steam injection and steam infusion. In steam injection, steam is injected directly into the product, whereas in an infusion process the product is sprayed into a steam atmosphere.

A typical steam injection system is shown in Fig. 1 (inset). Product is pre-heated in a heat exchanger then heated to sterilizing temperature in the steam injector. The product at sterilizing temperature first passes into the holding tube, which is maintained under pressure to prevent boiling. Then it passes into a vessel operated



Fig. 1

Direct heating systems. Main view: steam infusion process. Replacement of the section within the dashed box by the section shown in the insert (below right) gives the circuit for the steam injection process. Red, steam or hot water; yellow, product; blue, coolant.

under vacuum, resulting in boiling of the product, and thus removal of steam added during injection and evaporative cooling of the product. By controlling the difference between the pre-heating and vacuum-cooling temperatures, all the steam condensed is removed and dilution or concentration of the product avoided. The cooled, sterile product is extracted from the vessel and further cooled prior to filling, buffer storage or further processing.

The steam must condense immediately on contact with the product. Otherwise, uncondensed steam will enter the holding tube, resulting in variable holding times. The temperature probes T_1 and T_2 are unlikely to be able to differentiate between alternate slugs of steam and cold product. Ineffective condensation in the injector may result in noise and vibration in the holding tube.

A typical steam infusion system is shown in Fig. 1 (main diagram). The product is heated as it falls through the steam to the bottom of the vessel, from where it is pumped to a holding tube and subsequent evaporative cooling vessel if required. In the example shown, preheated product is pumped into the infuser vessel by a positive displacement pump. A product distributor within the vessel provides a fine sheet or spray of product, generating a large surface area for steam-product contact. The infuser vessel is maintained at controlled pressure to give the desired temperature; this is important for non-deaerated products as otherwise non-condensible vapours can accumulate in the vessel and must be continually removed.

Product is extracted from the vessel base by a positive displacement pump operated at a constant rate and fed into the holding section, while the infuser vessel level is controlled by the feed pump. Level control could also be achieved by altering the outlet flow rate, but the recommended arrangement is level control via the feed pump and a constant extraction rate and hence holding time.

Control of liquid level in the infuser is key to product quality, since even small variations will result in substantial changes in the holding time at elevated temperature. Adequate holding time for microbiological safety must be controlled in the holding tube; no allowance should be made for the residence time in the infuser vessel or its outlet pipework due to the potential for variations in these residence times.

Indirect heating

In an indirect system the heating medium (steam or hot water) is separated from the product by a physical barrier; heat is transferred across the barrier to heat the product. Indirect heating systems are probably the most widely used for sterilizing liquid foods, and are generally much less complex than direct systems. The simplest sterilizer configuration comprises a heating section, holding section and product-cooling section. A backpressure device prevents the product from boiling. Steam or hot water can be used; hot water is favoured as it minimizes fouling.

Figure 2 shows an indirect heating system that includes a heat-recovery section; this increases the complexity of plant design but greatly reduces energy requirements.

System components

For all systems, construction materials must be corrosion resistant under normal use, taking into account the properties of the product at the sterilization temperature and of the cleaning solution at the cleaning temperature. All materials should be acceptable for food contact and therefore comply with US Food and Drug



Fig. 2

Indirect heating system with a heat-recovery section. Valve symbols and key to shading as in Fig. 1.



Fig. 3

Types of tubular heat exchanger. Grey, heating or cooling media; yellow, product. (a) Jacketed pipe or mono-tube: among the least efficient and most hygienic. (b) Concentric multitube with single product channel: care should be taken to ensure the absence of dead legs. (c) Example of a coiled tube: similar to (a) but unsuitable for products requiring regular inspection of heat-transfer surfaces, as difficult to inspect for corrosion or cleanliness other than by X-radiography. (d) Concentric multitube with more than one product channel: not recommended, as it is difficult to meet hygienic requirements and prevent pressure build-up between gaskets. (e) Shell-and-tube: can be of acceptable design, if aseptic couplings are used and welds are of good quality.

Administration (FDA) or German Bundesgesundheitsamt (BGA) guidelines.

Steam injector and steam supply

A key requirement for direct heating is dry, saturated, food-quality steam produced by the evaporation of potable water. As the steam condenses into the product, it must be considered part of the product formulation. There may be legislative restrictions on the use of boiler water treatment chemicals.

Injector design, steam pressure (and hence the amount of steam), the number of nozzles and product characteristics such as viscosity all influence steam condensation and product heating. The suitability of a chosen configuration should be checked experimentally with the product to be sterilized.

The steam supply line and injection unit should be of hygienic design, inside and outside. During shutdown, product may enter the steam supply line through the injection unit, so the nozzle must be cleanable both inside and outside. The injection unit must also be cleanable. No cleaning chemical residues should remain in the steam supply line or injection unit.

Process vessels for direct heating

Process vessels specific to direct heating systems are the steam infuser vessel and vacuum cooling vessels. They should be cleanable and fully drainable, and all internals and connections should meet the same standards as the vessel itself – they should be cleanable, sterilizable, and hygienic (e.g. infuser vessel) or aseptic (e.g. vacuum vessel).

In steam infusion systems, cleanability of the product flow distributor may require special attention. All vacuum vessel connections are critical as vacuum conditions increase the risk of bacterial ingress. Double seals increase assurance, with the gap between the seals flushed with steam or antimicrobial fluid or operated under vacuum.

Heat exchangers

A heat exchanger in a sterilization plant is not necessarily designed for maximum heat-transfer efficiency, as other factors such as fouling and the balance between capital and running costs are also considered. A wide variety of heat exchangers are used for heating and cooling in both direct and indirect heating systems. The requirements listed in Box 1 are common to all types.

The three main types of heat exchanger are tubular heat exchangers (Fig. 3), plate heat exchangers and scrapedsurface heat exchangers. Each type is suitable for particular applications and has particular requirements.

All tubular heat exchangers share the following important requirements in addition to the general requirements listed in Box 1.

- The manufacturer must ensure that welds are of sufficient quality, taking into account process and cleaning conditions.
- · Spacers must be easy to clean.

suitable for aseptic operation.

- The design should prevent 'channelling' of highly viscous products. If sufficient turbulence cannot be achieved, hygienic mixing elements may be necessary to ensure a homogeneous temperature at the end of the heating section.
- The design must prevent vibrations or resonance that loosen screwed connections such as pipe couplings; if they are unavoidable, product safety must be ensured (e.g. by installing aseptic dampeners).

Plate heat exchangers are widely used. In addition to the general requirements listed in Box 1, the following points should be taken into account.

- It is the plate manufacturer's responsibility to inspect the steel sheet for absence of flaws.
- · Stress corrosion of plates caused by mechanical damage by pulsations and vibrations should therefore be minimized by use of dampeners.
- · Plates in contact with sterile product should be regularly checked for mechanical damage. If information on plate life is available, plates should be replaced regularly.
- · Plates should have a surface roughness not exceeding an average R_A value of 1.0 μ m as determined by ISO 468:1982 (Ref. 7).

Scraped-surface heat exchangers are particularly suited to the heat treatment of viscous products. They should satisfy the following in addition to the general requirements listed in Box 1.

- Any internal bearings must be hygienic and cleanable.
- Single seals are satisfactory for static applications; dynamic seals should be double with steam or other antimicrobial fluid flushing.
- The design should ensure that air pockets cannot be trapped in the barrel; hence, the outlet should be at the highest point.
- The design should ensure adequate cleaning in-place of the annular space, through which flow velocity may be lower than in the rest of the line.

Holding tube

The holding tube is crucial as it ensures that each element of fluid receives the desired heat treatment. Sections of plate heat exchangers can also be used for holding, but tubes are almost exclusively used.

The main requirements are listed below.

• They should be fully cleanable and drainable.

Box 1. Requirements common to all types of heat exchanger

- They should be fully cleanable, and preferably drainable and accessible for inspection.
- · Any fluids used for cleaning-in-place must be compatible with the construction materials under in-use conditions.
- Service fluids should not be corrosive.
- If the service side of the heat exchanger is to be drained, complete removal of all service liquid must be assured.
- Pockets (dead legs) or crevices should not be present at the product side, as they are difficult to clean, and product will reside in them for much longer than the mean residence time.
- All connections in the sterile area of the plant must be aseptic.
- There must always be two gaskets between the product flow and the heat-• ing or cooling medium, and it must be impossible to build up pressure between these two gaskets. Hence, the space between them must have vent-and-drain grooves and be large enough to ensure that they cannot be blocked by leaking product, heating medium or coolant.
- · Replacement gaskets must fulfil the requirements specified by the manufacturer of the heat exchanger.
- In the case of high-fouling products, the flow passage should not be too narrow, to prevent blockage. For some products, increased velocity helps control fouling and product blockage.
- To prevent stress corrosion, the design should prevent differences in expansion and contraction leading to unacceptable stress at times of maximum differences in temperature, such as start-up, shutdown and cleaning.
- Product flows should be designed to avoid air entrapment within the system.
- · Fluid velocity and the slope of the tube should avoid air pocket formation.
- · Product entering the tube must not contain uncondensed bubbles of air or steam, to prevent variable holding times.
- It should be possible to determine the minimum holding tube residence time for any product to be processed commercially.
- Constant product flow rate is required.
- The flow rate should not be increased above the design value, or the required minimum residence time may not be achieved.
- If fouling is likely, its influence on the minimum residence time should be taken into account.
- Any sensors should be designed and installed for aseptic operation.
- · With direct heating, allowance must be made for the quantity of steam condensed in the product when determining the holding tube length.
- A minimum of fittings should be used, and should be Any insulation should not be corrosive towards the material of the holding section.

The residence time should not decrease below a certain minimum value; this may depend on legal requirements and should be discussed with health authorities. The distribution in residence times must be carefully assessed during system design. As the ratio of average to maximum velocity in a holding tube varies from 0.5 in laminar flow to 0.82 in fully turbulent flow, the holding tube may need to be up to twice the length calculated on the basis of the average holding time to achieve the minimum residence time. The food manufacturer is responsible for specifying the correct residence time. Measurement of the residence time in pasteurization plants is generally carried out by standard conductivity methods⁸. Similar approaches could in theory be used for sterilization plants, although the elevated temperatures and pressures may create some practical problems.

Buffer tanks

Buffer tanks (or 'aseptic tanks') can improve plant utilization and flexibility. They are pressure vessels and need to be designed to high standards. The basic design elements for the tank, all internals and connections are those for any hygienic tank: no dead spaces, sharp corners or narrow recesses; materials compatible with product and cleaning chemicals under conditions of use; and accessibility after installation. The tank should be fully drainable, cleanable in-place and steam sterilizable independently of the associated process plant and filler. If a cooling water jacket is needed it should be fully drained before sterilization. A combined inlet/outlet line is preferred.

It should be possible for product in the tank to remain sterile even if the process plant and/or filler become nonsterile (e.g. during cleaning of an ultrahigh-temperature plant). This can be achieved using an aseptic barrier.

Sterile air filters are necessary to provide sterile headspace for the fluid. These may be steam sterilized via the tank; thus, they must be able to handle vapour flow in both directions. Care must be taken to avoid mechanical damage to the filter by excessive air velocities. It may be necessary to use two filters in series if one is inadequate to prevent bacterial ingress. It is essential that filter installation and operation ensure no contact with the condensate.

Process operation

Pre-sterilization of equipment

Full pre-sterilization is necessary for all product contact surfaces in the sterile area of the plant, which includes everything downstream of the holding tube and thus can incorporate a wide variety of equipment including tanks, pumps, pipework, heat exchangers and fillers. Tanks are sterilized with steam, while other equipment is generally sterilized with pressurized hot water. All product contact surfaces must maintain a minimum sterilization temperature and time and have adequate venting and drainage; dead legs must be avoided. The sterilization time and temperature will depend on plant layout. Long uninsulated pipes may result in a lower achievable sterilizing temperature than short or insulated ones.

Production

After pre-sterilization, the plant is brought to production conditions while water is circulated through the system. This generally incorporates cooling areas of the plant downstream of the holding tube. When suitable conditions are achieved, product is allowed into the plant, displacing the water. The sterilizing temperature in the holding tube and the feed flow rate must be above the minimum level throughout cooling after presterilization and during changeover from water to product. It is the equipment supplier's responsibility to ensure that the heat exchanger can achieve the desired temperature at all times. A level control system should ensure that there is always a minimum level of liquid in the balance tank so the feed pump does not suck in air.

Flow diversion

Temporary diversion of product flow while restoring adequate conditions is not generally used in sterilization processes in the same way as with lower-temperature heat-treatment plants, as recirculation poses a risk to process integrity and often seriously affects both physical and flavour characteristics. However, it is used if immediate sealing of the route to tanks and fillers is necessary. Diversion valves must be of aseptic design and will often also be used to recirculate pressurized hot water during plant pre-sterilization. To avoid contamination of the aseptic tank and/or filler an aseptic barrier must be installed downstream of the diversion valve.

Cleaning

Cleaning normally takes place at the end of production. All product-contact surfaces must be cleaned. The chemicals must be compatible with the construction materials at the in-use temperatures and concentrations; and must be removed after cleaning by adequate water rinses.

Process control

The sterilizing plant is controlled by a combination of digital (for valve sequences) and analogue (for control at the major process variables) signals. The major process variables controlled are temperature, pressure, flow and level. For each control variable it is necessary to assess the required quality of control, speed of response, action to be taken if the variable is outside the set range, and the likelihood of control problems arising from interaction with other control loops.

Temperature

Temperature is controlled almost exclusively by the valve that allows heating or cooling medium into the heat exchanger or directly into contact with the product. Sensors for such critical variables as sterilization, presterilization, sterile barriers and seals must be accurate, reliable and have a sufficiently rapid response time to ensure the safety of the process. The sterilization temperature and lower temperature limits that define when to terminate sterilization must be based on legal requirements or discussed with health authorities. Specification of the correct temperatures is fully the food manufacturer's responsibility.

Pressure

It is important to control the pressure closely, to suppress boiling. If the pressure is insufficient, product will vaporize, reducing its temperature, the effective volume of the holding section and hence the holding time. Furthermore, fouling will be enhanced. As products usually contain dissolved air, whose solubility rapidly decreases with increases in temperature, it is recommended that the pressure is maintained at 0.7–1 bar above the saturated vapour pressure of the liquid.

Pressure may be controlled by: controlling the pressure of the gas above the product in a pressurized storage vessel; using a constant back-pressure valve (it may be necessary to install a sterile barrier); using a positive displacement pump with speed variation to control back pressure; using an orifice; or a combination of these.

The pressure must be high enough to maintain sterilization conditions and the plant should shut down automatically in the event of loss of pressure. A pressure alarm system is essential in some cases and desirable for early warning in all plants.

Flow rate and level

Flow rate may be controlled by the opening of a valve or the speed of a pump. Level control is achieved by controlling the flow rate to the unit. The control system must be designed to ensure that the minimum residence time is not compromised by increasing the flow rate above the allowable maximum.

Monitoring and recording

It is essential to record critical process parameters from the plant on a continuous basis. Legal requirements may also necessitate the continuous recording of certain data. Critical parameters include the sterilizing temperature, filling temperature, pre-sterilization temperature, level, flow rate, aseptic barrier temperatures and back pressure.

It is recommended that modern data logging facilities are used, as they enable a considerable number of variables to be monitored, allowing performance of the process to be closely monitored during routine operation. It is particularly important to monitor the process-equipment interactions that can result in adverse effects, such as fouling.

Inspection and maintenance

Regular inspection and maintenance should be considered an integral part of plant operation. Without it, faults will develop and safety may be severely compromised.

Critical sensing elements such as the sterilizing temperature should be checked regularly against a known standard, and plant records should be monitored continuously to provide the earliest possible warning of problems. For example, a higher than normal heatingmedium temperature at start-up may indicate poor cleaning after the previous production run. Any modifications or changes to the plant should be implemented only if the implications have been thoroughly evaluated. For example, if pipework is to be altered, extreme care should be taken to ensure that this will not increase the risk of recontaminating the sterile product or adversely affect the cleaning process.

Conclusions

In conclusion, in order to ensure the microbiological safety of a sterilization process the following must be achieved.

- The measuring and control equipment must ensure that temperature, flow and back pressure are maintained.
- Unacceptable deviations in key process variables must result in automatic shutdown of the plant.
- The process must be stopped when fouling becomes so severe as to compromise product safety.
- Process equipment downstream of the holding tube must be aseptic and hence cleanable, sterilizable and bacteria tight.

This paper summarizes the guidelines and methods recommended by the European Hygienic Equipment Design Group (EHEDG) subgroup on Continuous Heat Treatments. The full report, by A.P.M. Hasting, P.C. Jepson, M. Lalande, H.L.M. Lelieveld, M.A. Mostert, J. Nassauer, R. Ringström and S.A. Davies, is available from: D.A. Timperley, Campden Food and Drink Research Association (CFDRA), Chipping Campden, UK GL55 6LD (tel. +44-386-840319; fax: +44-386-841306).

The EHEDG will certify laboratories that intend to apply the EHEDG test methods. For details, please contact D.A. Timperley at the above address.

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