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EHEDG Update

Microbiologically safe aseptic packing of food products

This paper summarizes guidelines for the microbiologically safe aseptic packing of sterilized food products, as recommended by the European Hygienic Equipment Design Group (EHEDG). The value of a quantitative approach to identifying, avoiding and monitoring the risks of contamination with undesirable microorganisms is emphasized. This is the third 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 *

In theory, aseptic packing is extremely simple: a product, free from undesired microorganisms, is packed in packing material that is also free from undesired microorganisms; during this operation, microorganisms are denied access to the product or packing material. However, in practice, aseptic packing is usually a rather demanding process.

Methods of freeing the product from microorganisms, decontaminating the packing material, and sterilizing air in contact with the product and packaging are well understood. Other potential sources of microbial contamination, however, are often not recognized.

Firstly, it is essential to decide which microorganisms are relevant (see Definitions). It is also important, yet relatively unusual, to quantify the risks of contamination with microorganisms from the various sources. It is even more uncommon to quantify the target – to determine the maximum level of relevant microorganisms acceptable in the packed product, or, in other words, the maximum number of packs contaminated with potentially harmful microorganisms – yet this is necessary, as it is not realistically possible to reduce the risk to zero.

This paper discusses a quantitative approach to the aseptic packing of food products to achieve an acceptably low risk of contamination. It also summarizes the EHEDG's guidelines on the design, operation and maintenance of aseptic packing machines. The EHEDG intends to prepare separate guidelines on the non-aseptic packing of food.

*Readers requiring further information on the EHEDG are referred to *Trends in Food Science & Technology*, Vol. 3(11), p. 277.

Definitions*

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

Cleanability: The suitability to be freed from **soil.**

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 I: Equipment that can be **cleaned** in-place and freed from **relevant microorganisms** without dismantling.

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

In-place cleanability: Suitability to be cleaned without dismantling.

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

Product contact surface: All surfaces of the machine that intentionally or unintentionally come in contact with the product, or from which product or condensate may drain, drop, or be drawn into the product or container, including surfaces (e.g. unsterilized packs) that may indirectly cross-contaminate product contact surfaces or containers.

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

Soil: Any undesired matter, including product residues, whether or not containing microorganisms.

Sterilization: Removal or destruction of microorganisms, including all relevant bacterial spores.

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

Responsibility

The producer is always responsible for the product packed and, hence, the producer must define the acceptable risk, possibly in consultation with interested parties, such as public health authorities and customers. The minimum requirements for the packing machine depend on this target level.

As requirements may differ between products, it is essential that requirements are re-specified if other products are to be packed on an aseptic packing machine. If needed, packing machine settings must be changed.

Microbial contamination rates from various sources

The microbial contamination rate (CR) is defined as the number of contaminated packs divided by the total number of packs filled. The total CR of the packed product (provided that the individual rates are much smaller than 1) is the sum of the individual CRs contributed by a number of sources: packing material (CR_{pack}); air (CR_{air}); product adhering to the filling nozzle (CR_{nozzle}); product ($CR_{product}$); pack integrity ($CR_{integrity}$); and other sources, such as the product contact surfaces in the open-pack area (CR_{other}). The measured total value of CR should be less than or equal to the acceptable contamination rate for the packed product. Hence, if the acceptable contamination rate is x,

$$CR_{pack} + CR_{air} + CR_{nozzle} + CR_{product} + CR_{integrity} + CR_{other} \leq x$$

Thus, for example, if all contributions except packing material together contribute a contamination rate of $0.9x$, then the packing material should contribute $CR_{pack} \leq 0.1x$. If, without decontamination treatment, it would contribute, say, $1000x$, then to ensure that its contribution is acceptable, the decontamination treatment must result in a reduction factor (R) of at least $(1000x/0.1x)$; thus, $R \geq 10^4$.

A comprehensive review of this approach is provided in Ref. 1.

Differences in the risks of infection in aseptic processing and aseptic packing

In process lines, with or without a buffer tank, there is usually a continuous flow of product, so that a single microorganism able to grow in the product may affect the entire batch. On the other hand, after the product has been divided into individual, physically separated portions, a microbiological hazard caused by a single microorganism will be confined.

For example, if a pasteurized product in a stirred, 1000-litre buffer tank is contaminated with a single microorganism, which is allowed to multiply (at a suitable temperature and storage time), the number may easily increase to 10^6 – an average concentration of 1 microorganism/g. Consequently, depending on the intensity of mixing, this may result in every pack filled being infected and spoiled.

However, if the same microorganism infects the product during packing, even if it multiplies to a level of 10^9 microorganisms/g, it cannot infect any other pack; only one pack will be spoiled.

Requirements for equipment used in aseptic packing

Materials and surface finish

All product contact surfaces must be resistant to the cleaning agents and temperatures used. The supplier should list any materials used that are not resistant to commonly used cleaning and decontamination chemicals or conditions.

The surface roughness, R_A, (Ref. 2) of the product contact side must be less than 0.8 μm.

Equipment for filling and dosing of product

Aseptic packing machines must be equipped with aseptic fillers. To ensure that the equipment is easily cleanable in-place, it should have no 'dead' spaces or crevices, and no areas of low velocity of the cleaning liquid. During decontamination, all of the product contact surfaces should reach the specified conditions.

The equipment must be bacteria-tight to prevent the penetration of microorganisms from the non-product side to the product side. To this end, moving-shaft passages between the sterile and unsterile areas must be avoided, unless they are sealed against the ingress of microorganisms. This may be achieved by using diaphragms, bellows and double seals with a flush in between. The flush should remove or destroy microorganisms so that they do not enter the product side. The fluid used in the flush should be nontoxic.

All product contact surfaces must be resistant to the product under the process conditions. In principle, stainless steel [AISI (American Iron and Steel Institute) series 304 to 316 or better] should be used. Non-metallic materials should comply with the US Food and Drug Administration (FDA)[3] regulations. Some materials have so little resilience that they may creep under process or cleaning conditions; these should be avoided or used with great care, as their shape may deform permanently under load. More detailed guidelines on the selection of materials for food contact applications will appear in a forthcoming EHEDG publication.

The interior of the packing machine

To reduce the risk of contamination with microorganisms from the immediate environment of the exposed product, the interior of the machine, including all parts that may come into direct or indirect contact with product, air or condensate, should be cleaned sufficiently.

Preferably, the design should allow cleaning in-place (CIP) of the interior. If this is not possible, each part must be accessible for cleaning by hand, with or without dismantling. Decontamination must take place after reassembly.

Exposure of product

The risk of infection can be minimized by minimizing the time the product is exposed to air in an open container; thus, the container should be sealed as soon as possible after filling. During transfer from the filling station to the sealing station, the product must be protected against recontamination through the air. The air may have to be decontaminated, and the air pressure should be highest in the exposed product area.

Cleaning

To limit difficulties with cleaning the product contact area, any moving parts of the machine should, as far as possible, be situated outside the product contact area. If CIP is applied, the moving parts must be activated during cleaning.

The cleaning procedure selected should take into account the type of product packed and, hence, the type of soil in the machine. The development of methods to test the cleanability of the interior of the packing machines is strongly recommended.

Decontamination

Decontamination may be achieved by hot water, steam, chemical solutions or gaseous antimicrobial agents.

Decontamination may fail to be effective due to excess water residues, which may cause two major problems: dilution of the chemical used for decontamination; and multiplication of microorganisms when the machine is standing idle (e.g. overnight or over the weekend), leading to insufficient inactivation of the large numbers of microorganisms produced. Therefore, the equipment should be drainable, so that no water (or other liquid) remains anywhere in the interior of the aseptic area of the machine at the end of the cleaning procedure.

Storage, handling and transport of packing materials

Generally, the microbial load of packing materials for aseptic filling is low immediately after manufacture. This is partly due to the heat applied during the extrusion of plastic materials, for drying varnishes, or to melt glass.

Contamination takes place after manufacture, and should be controlled by adequate measures. Possible sources of infection are dust or other matter, humidity (moisture in the presence of even traces of nutrients will allow the multiplication of microorganisms), people, and insects or other pests.

To limit reinfection, special precautions may be needed, such as:

- protection (by the packing material manufacturer) of all packing material by wrapping in foil, within a box, and with minimum use of cardboard;
- removal of dust (e.g. by ionized air or filters in the ventilation system);
- ensuring that the product contact surface is touched by clean (and possibly protected) hands only, and not by contaminated equipment or materials, after removal of the protective wrapping;
- ensuring that areas where packing material is handled are always kept dry.

Suppliers of the packing material must provide instructions for storage and handling of the packing material.

The tightness, and therefore the sterility, of the filled containers can be influenced by mechanical damage or deformation during the transport and handling of packing material. Precautions must be taken to prevent such faults, which may be caused by mechanical damage (e.g. by fork-lifts, or from stacking pallets too high), changes in the material properties due to inadequate storage conditions (excessive temperature, humidity, light, etc.), or deformation in the filling machine (e.g. due to excessive heat, mechanical or chemical stress). Mechanical damage can be detected visually and by applying adequate controls on packing material (see also DIN 16901)[4].

Decontamination of packing material

The microbiological load of the packing material (tubs, lids, bottles, etc.) must be monitored, and has to

Table 1. Parameters that need to be monitored in aseptic packing processes

Process	Parameters to be monitored
Decontamination of machine (general)	
All methods	Temperature; time
Dry heat, hot water or steam	Humidity
Chemicals in liquid form	Concentration
Gaseous chemicals	Concentration; humidity
Decontamination of process line, dosing pump and filling nozzle	Temperature; time; pressure
Decontamination of packing materials	
Chemicals	Temperature; time; quantity dosed; concentration; residual amount
Ultraviolet radiation	Energy; time
Decontamination of air	
Incineration	Temperature; flow rate
Filtration	Pressure drop
Packing	Sealing time; temperature; pressure; positioning, pack seal integrity

be low enough to prevent exceeding the acceptable rate of contamination. Usually, the packing material must be decontaminated to achieve this, for example using hydrogen peroxide, heat, ultraviolet light, other chemical methods, or combinations of the above.

The manufacturer of the packing machine should specify conditions for obtaining specified decontamination rates (reduction factors), and provide evidence that they are effective.

Sterile air systems

The microbiological quality of the air supplied must be tested and made to comply with the minimum requirements to prevent CR_{air} from being too high; this is the responsibility of the user of the equipment. The concentration of microorganisms in the air may be reduced by incineration or by filtration.

Incineration

Air is sucked from outside or from the superstructure of the machine into the superheater, where it is heated (typically to 400°C), then cooled down to a temperature suitable to the individual packing system and fed back to the packing machine.

Filtration

Filters must be sterilizable (once-only or repeatably). Where once-only sterilizable filters are used, care must be taken that the flow of air through the filters is continuous, even when the packing machine is not in use. Sterilization of air filters may be achieved by means of chemicals (low-pressure filters and filter cartridges) or steam (filter cartridges only).

Preventive maintenance of the filter system is very important. Filters should be replaced before their performance becomes inadequate. The performance of the filters during use may be checked by measuring the pressure drop across the filter, by measuring the flow rate at constant pressure, or by measuring the level of particles in the air.

Pack integrity

Most aseptic packages are closed by heat-sealing, ultrasonic sealing or glue. Some containers are also closed by conventional methods (e.g. folded seams, snap-on lids, twist-off caps or screw caps).

High reliability of the closures is an essential precondition for a low contamination rate. Sealing defects may arise from many factors, not only as a result of the sealing operation itself. For this reason the following recommendations are given:

- the construction of the closure of container and lid should be such that the required seal can easily be obtained;
- temperature and pressure should be properly distributed over the sealing surfaces;
- all parameters for the sealing process, such as sealing time, pressure and temperature, have to be set with a safety margin and must be adequately controlled (monitored and alarmed for out-of-control situations);
- if several packages are sealed in the same operation, the packages must be uniformly sealed;
- contamination of the sealing surfaces by product or other material (e.g. from splashing, dripping or foaming) should be avoided;
- the seal must be accurately located, especially in the case of thermoform/fill/seal machines, where local deviations may occur between the forming station and the sealing station.

Integrity testing (e.g. biotesting) of filled packages is highly desirable. The further development of on-line monitoring of seals and closures is strongly recommended.

Monitoring

Essential parameters should be monitored and properly controlled. If safety limits are exceeded, the packing process must be stopped. Various parameters may have

to be monitored, depending on the type of aseptic packing machine used (Table 1). Depending on the machine design, additional critical parameters may need to be monitored and controlled.

Operation manual

The operation or instruction manual, to be provided by the packing machine manufacturer, must include information on the resistance of the materials used against cleaning and decontamination chemicals and conditions. It must also give recommendations of effective cleaning and decontamination procedures, and clear instructions on preventive maintenance.

Validation

It is essential that critical parameters are carefully controlled and cannot be changed accidentally in any way without being noticed. Particularly in the case of products in which pathogenic or toxigenic microorganisms are able to grow, it is essential that the complete process is carefully validated before commercial production is started, to minimize the chance of errors in design or procedures not being promptly recognized. Detailed procedures to achieve hygienic food manufacturing systems will be published in a separate forthcoming EHEDG publication; see also Ref. 5.

Conclusions

It is of prime importance for those involved with aseptic food packing to decide which microorganisms are relevant to the microbiological safety of the particular food product concerned. Acceptably low contamination rates must be determined for each relevant microorganism, and sources of contamination must be identified and quantified. Based on the results, measures to reduce the contamination rate to below the maximum acceptable level must be devised.

All packing machine components that may come in contact with the product should be of hygienic design, allowing adequate cleaning and decontamination. The construction should prevent unacceptable recontamination of decontaminated packing material or product. The efficiency of the aseptic packing operation should be validated during the commissioning of new equipment, and critical parameters (including seal integrity) must be monitored during use. Finally, if existing equipment is to be used for the packing of a new food product, the procedure to achieve an acceptably low rate of contamination must be repeated in its entirety.

This paper summarizes the guidelines and methods recommended by the European Hygienic Equipment Design Group (EHEDG) subgroup on Packing Machines. The full report, by M.A. Mostert, G. Buteux, P.C. Harvey, W. Hugelshofer, P. Mellbin, J. Nassauer, G. Reinecke, W. Weber and B. Wilke, is available from: D.A. Timperley, Secretary of the EHEDG, Campden Food and Drink Research Association (CFDRA), Chipping Campden, UK GL55 6LD (tel. +44-386-840319; fax: +44-386-841306).

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