Hygienic packing of food products

Products with a short shelf life, or whose shelf life is extended by cold storage or in-pack heat treatments, do not have to conform to such strict microbiological requirements as aseptically packaged foods. Nonetheless, it is important to ensure that they are protected from unacceptable microbial contamination. This paper summarizes guidelines prepared by the Packing Machines subgroup of the European Hygienic Equipment Design Group (EHEDG) for the hygienic (but non-aseptic) packing of food products. This is the 12th 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.*

The Packing Machines subgroup of the European Hygienic Equipment Design Group (EHEDG) has previously produced guidelines on the microbiologically safe aseptic packing of food products[1]. This paper discusses the packing of food products that do not need aseptic packing, but which nevertheless need to be protected against unacceptable microbial contamination. Guidelines are provided for the hygienic design of packing machines, the handling of packing materials and the environment of the packing machines.

Difference between hygienic packing and aseptic packing

Aseptic packing is aimed at products with a long shelf life at ambient temperature. The acceptable presence of relevant microorganisms in such products is very low (e.g. less than one per 10 000 packs). If the shelf life is short or if the desired shelf life is obtained by cold storage, freezing, or in-pack heat treatments, the product usually contains higher numbers of microorganisms when ready to pack. Such products must be packed hygienically. Thus, a hygienic packing machine should be used. Such a machine must not allow an unacceptable increase in the number of microorganisms present in the product.

Microbially stable and microbially unstable products

Products may be divided into microbially stable and microbially unstable products. In microbially stable products, microorganisms, although viable, are unable to grow. Nevertheless, the concentration of microorganisms present in the product must not exceed legal limits or impair product quality in any way. For such products, at the time of filling, the packing machine must not contain any water (including any condensate) left after cleaning and decontamination of the machine. Even if the water is sterile when it comes in contact with the product, it will cause dilution, which might impair microbial stability.

In microbially unstable products, the required shelf life is obtained either by heat treatment after packing or by appropriate storage conditions. Any relevant microorganisms present will grow in any microbially unstable product. For this group of products, it is essential that the residence time of the product in the packing machine is controlled well. The lower the temperature, the longer the time packing can be continued between cleaning operations. If chilled products are packed, care must be taken that the product is not excessively heated anywhere in the machine, in particular during production stops. If the length of the stoppages exceeds a certain limit (depending on the product), the packing machine may have to be cleaned and decontaminated before restarting.

Responsibility

Food processors are responsible for the packed product and hence must define the acceptable risk. They must therefore not only specify the limits for the presence of microorganisms in the product delivered to the packing machine, but also specify the duty of the packing machine with respect to any acceptable increase in microbial concentration in the product during packing. Producers may do so – self-evidently – in consultation with interested parties, such as public health authorities and customers. Based on the results, processors must specify the requirements for the packing machine.

As requirements may differ between products, it is essential that requirements are redefined if other products are to be packed using a hygienic packing machine. If necessary, packing machine settings must be changed.

The design of hygienic packing machines

The main purpose of packing foods is to preserve quality, from processing to consumption. The physical integrity of the package is important in order to prevent product from leaking out, as well as to prevent contaminants, including microorganisms, from entering the package. Oxygen-sensitive products need a barrier to prevent spoilage due to oxidation.

A hygienic packing machine should comply with the definitions of hygienic equipment (see Definitions). Thus, the product-contact surface of the machine must be cleanable and it must be possible to free the product-contact surface from relevant microorganisms.

General requirements

All product-contact surfaces must be resistant to the product and the cleaning agents at the temperatures used

*Readers requiring further information on the EHEDG are referred to *Trends in Food Science & Technology* (1992) Vol. 3(11), p. 277.

and must be acceptable for contact with food. The supplier should list any materials used that are not resistant to commonly used cleaning and decontamination chemicals or conditions. The design of the machine must comply with the hygienic design criteria specified in Ref. 2.

Particular attention must be given to draining of the surfaces of packing machines, and to the control of condensate that may be formed during the packing of product. Condensation may occur due to differences in temperature between product and product-contact surfaces, or due to too high a humidity in the environment.

To limit difficulties with cleaning of the product-contact area, moving parts of the machine should as much as possible be situated outside the product area.

It must be demonstrated that all product-contact surfaces can be cleaned.

Equipment for filling and dosing of product

Hygienic packing machines must be equipped with hygienic fillers. This means that the filler must be cleanable (preferably in-place) and suitable for decontamination (if applicable, after reassembly).

To ensure that the equipment is easily cleanable in-place, it should have no dead spaces, crevices or areas of low velocity of the cleaning liquid. Ways of meeting these hygienic design criteria are given in Ref. 3.

Particular attention should be given to both static and dynamic seals (see Ref. 3), as the temperature variations that the equipment is subjected to may cause microbiological problems due to the differences in thermal expansion between materials of construction.

To allow adequate decontamination, all product-contact surfaces must reach the conditions specified by the producer (temperature; time; humidity; concentration).

Exposure of product

The risk of contamination of product with relevant microorganisms increases with their concentration in the environment. Further, the risk of recontamination depends on the length of time the product and the internal surfaces of the container are exposed to the environment.

To control the risk of contamination by microorganisms, several measures can be taken.

Firstly, the environment of the packing machine and the product must be kept clean and tidy. This puts requirements on the design of the surroundings of the packing machine, which are discussed under 'Environment of packing machines', below.

Secondly, the length of time that the product and the product side of the packaging materials are exposed to the environment may be reduced to the minimum required for filling and closing of the product container.

Thirdly, the area where the product or the product-contact surface of the packing materials is exposed may be covered by an overhead construction, such as a tunnel or a cover.

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 sterilization, pasteurization or chemical treatment 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.

Pasteurization: Thermal destruction of vegetative microorganisms (i.e. excluding thermoresistant bacterial spores).

Product-contact surfaces: 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.

Finally, the quality of air over the exposed surfaces and product can be controlled. The air may be decontaminated and the ingress of untreated air may be restricted by applying an overpressure. Decontamination of air may be achieved by filtration or by incineration (see Ref. 1).

Microbial quality of packing material

The material in which the product is packed must meet microbiological requirements. The food processor should agree the quality of the material with the packing material supplier.

It may be necessary to reduce the number of microorganisms on the packing material before use. This may be achieved using hydrogen peroxide, heat, ultraviolet light, or other treatments, either individually or in combination.

The effect of such a treatment on the relevant microorganisms must be known. Ideally, microbial reduction factors should be determined using standard test methods. It is strongly recommended to develop such methods.

Storage, handling and transport

Packing material must be handled with care before use to avoid too high a microbiological load at the time of use.

Often, packing material is almost free from microorganisms at the time of manufacture as a result of the heat applied during the extrusion of plastic materials, for drying varnishes, or for the melting of glass. Contamination takes place after manufacture. Examples of sources of contamination are:

- dust or other foreign matter (the outer casings used to pack the packing material can be an important source of dust; in particular, cardboard may contain high numbers of microorganisms, particularly moulds and bacterial spores);
- humidity (moisture, in the presence of even trace amounts of nutrients, will enable the multiplication of microorganisms);
- wooden pallets;
- people;
- insects or other pests.

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

- protection (by the packing material manufacturer) of the packing material (e.g. plastic bottles, trays, lids) by wrapping in foil, within a box, and with minimum use of cardboard or other materials that give off fibres or particles (dust) – it may be necessary to clean the outside of the casing before opening;
- removal of dust from the air brought into the packing area (e.g. by ionized air or filters in the ventilation system; see also 'Ventilation and air conditioning', below);
- minimizing touching the product-contact surface of the packing material by hand – if unavoidable, the material should be touched by clean (and possibly protected) hands only;
- ensuring that areas where packing material is stored are kept dry;
- removal of static charges.

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

Stocks of packing material must not be kept in the environment of the packing machine. Only a minimum amount of packing material may be suitably stored near its point of use.

The tightness, and therefore the microbiological safety, of the filled containers can be affected by mechanical damage or deformation during the transport and handling of packing material. Precautions must be taken to prevent faults, which may be caused by:

- mechanical damage (e.g. by forklifts, palletizers, or from stacking pallets too high);
- changes of the material properties due to inadequate storage conditions, such as excessive temperature, humidity or light;
- deformation in the filling machine (e.g. due to excessive heat, mechanical stress or chemical stress).

Often, mechanical damage can be detected visually and by applying adequate controls on packing material (see also DIN 16901; Ref. 4).

Environment of packing machines

As discussed under 'Exposure of product', above, it is important to control the concentration of microorganisms in the environment of the packing machine.

To reduce the risk of contamination by microorganisms from the immediate environment of the packing machine, attention should be paid to the design and maintenance of the packing machine area.

A series of measures that may contribute to minimizing the number of microorganisms threatening the product to be packed are discussed below.

Installation of the packing machine

The packing machine should be placed such that it is uncluttered and free access is available around the machine. Unless mounted such that dust and other foreign matter cannot accumulate, overhead services (lighting, piping and ducts) should be avoided. Clearance under the machine must allow for adequate cleaning and inspection to be carried out effectively. Machines should not be positioned over drains if, in doing so, access for inspection and cleaning of the drains is restricted. Equipment should be adequately located in position and mounting pads or feet suitably sealed to the floor.

Product lines

Product lines to the packing machine should be by the shortest route possible and must be suitably supported and designed so as to allow for easy inspection and cleaning.

Draining

Floor drains must be provided in all areas where water or any other liquid is spilled on the floor during normal operations or where floors are cleaned by hosing. Local regulations may apply regarding drainage systems. Drains must be kept in good operating condition with unrestricted access for inspection and cleaning.

Conveyors

Conveyors must be constructed in such a way as to prevent harbouring of soil and should allow easy access for inspection and cleaning, including the underside of belts, tracks and rollers.

Where lubricants are used on conveyor surfaces, they should be of a composition acceptable for food-contact application. The lubrication system should be correctly installed and maintained. Drip trays and tanks should be designed to prevent lubricants from dripping onto product-contact surfaces or the floor, and should be readily accessible for inspection and cleaning.

Floors

Floors must be smooth, tough, durable and washable, and any joint must be impermeable. They must be resistant to the cleaning materials and methods used and should be easily cleaned. They must be compatible with the type of product being processed and the temperature within the processing area. Falls to drains should prevent ponding, and drainage systems must be adequately gullied and trapped.

Walls and windows

Walls must be smooth, tough, durable, washable and of a light colour. Any joint must be impermeable. Wall panels must be sealed at their joints using an impermeable sealant, flush-finished with the wall surface. They must be resistant to microbial growth, and to cleaning materials and methods used. Wall fixtures should be kept to a minimum and must either be sealed to the wall or spaced off so as to allow access for easy inspection and cleaning. Windows should be avoided if at all possible; otherwise they must be non-opening and made of a suitable shatterproof polymer. If – by exception – opening is possible, screens should be placed to avoid birds and insects entering the product area. Window to frame to wall joints must be continuously sealed and finished flush. Wall to floor joints must be suitably curved to allow for easy inspection and cleaning. Window sills should be at an angle of 45°.

Ceilings

Ceilings may be of the fixed or suspended type and must be smooth, durable and of a light colour. They should be washable and easily cleaned. They should be resistant to microbial growth and to cleaning materials and methods used. If suspended panel systems are used they must be sealed at their joints using a continuous, flush seal. Adequate access to the void above the ceiling should be provided externally to the processing area for inspection, cleaning and services access. Ceiling fixtures (such as lighting) should be kept to a minimum and should be suitably sealed to the ceiling or spaced off to give easy access for inspection and cleaning.

Services

Services should be restricted in the process area as far as possible, and limited to those essential to the process. Service drops will usually be from the ceiling and should be totally sealed at their point of entry to the processing area. Service drops should comply with hygienic design criteria (see Ref. 2) and be rigidly supported at the packing machine. Service junction and control boxes should be of stainless steel and hygienically sealed. Lighting within the processing area should give good and even levels of illumination. Enclosures should be totally enclosed and of a shatterproof polymer. Compressed air must be dry and free from off-odours and may have to be sterile. The air should exhaust clear of product, preferably at ground level through a suitable filter.

Ventilation and air conditioning

Depending on the air quality and other local conditions, assisted ventilation may be needed. If, because of the vulnerability of the product, the quality of the air is not good enough, the packing operation may be located in a clean room. Alternatively, the air supplied might be filtered. The control of air flows and quality are the responsibility of the food processor.

It is recommended that the air coming out of the air-conditioning system has a relative humidity of below 55% to restrict the growth of microorganisms, in particular moulds, as much as possible.

Air-handling units must be designed so as to allow easy access for inspection and cleaning, and should as far as possible be kept out of the process area.

Packaging materials

Care should be taken that outer casings do not cause microbial contamination (see 'Storage, handling and transport', above).

Foreign bodies

Care must be taken that the machine itself does not form foreign bodies such as slivers of plastic or paper that may enter the product.

Cleaning

Compressed air should not be used for cleaning purposes. To avoid excessive aerosol formation, high-pressure cleaning should be avoided. Cleaning utensils should be clearly marked and stored away from the processing and packing areas on racks, tables or shelves (not on the floor). Disposable cloths too should be clearly marked and suitably stored (e.g. in a chlorinated bath). Washbasins and wash areas should be clearly marked as to their purpose.

Packing machine options

The basic hygienic packing machine consists of a means for the transport of packing material, a filling or dosing system, and a mechanism to close the pack.

Because of the potential sources of microorganisms that may contaminate the product during packing, hygienic packing machines may be equipped with a number of additional features.

The food processor must decide which of the features are needed (see 'Responsibility', above).

Features that may be needed include:

- an overhead constuction, from a simple cover to a sealed tunnel, with or without a sterile air system;
- an air decontamination system, which may consist of a compressor and a filter system or incineration module – the air may be used to flush a tunnel construction or to provide a (more-or-less) laminar air flow over the area of the packing machine to be protected;
- packing material decontamination (see Ref. 1).

Self-evidently, the design of any of the options must comply with hygienic design criteria (see Ref. 2).

Cleaning and decontamination of packing machines

The inside of the filling or dosing unit should preferably be cleaned in-place. Depending on local circumstances, this may be done simultaneously with the process line to which the machine is connected.

The immediate environment of the filler may cause contamination of the product if not adequately cleaned and decontaminated. Special attention may have to be paid to the means for transport of the filled packs (such as conveyor belts or chains) to prevent them from conveying spilled product through the machine.

The choice of cleaning method depends on which type of product is to be packed. Wheat flour and milk, for example, will require two completely different methods. The choice of cleaning agents also depends on the quality of the water (in particular the water hardness). The water quality must comply with legal requirements (see Ref. 5). Preferably, the design should allow in-place cleaning of the product-contact surface, without any dismantling. If this is not possible, each part of the machine must be accessible for cleaning manually, with or without dismantling. Decontamination must take place after reassembly. If dismantling and reassembly are needed, this should preferably be so easy that it can be done without tools. It is recommended that the machine is designed such that cleaning of the surrounding area does not significantly contaminate the machine (e.g. by using screens).

If an automatic cleaning in-place is applied, moving parts must be activated during cleaning or be placed in a cleaning position.

Table 1. Parameters that should be monitored during the cleaning, decontamination and operation of hygienic packing machines

Process	Parameters
Cleaning	Concentration of chemicals; temperature; flow rate; cleanliness
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 material (optional):	
Chemical	Temperature; time; quantity applied; concentration; residual amount
Ultraviolet radiation	Energy; time
Decontamination of air:	
Incineration	Temperature; flow rate
Filtration	Pressure drop; retention
Air system	Air velocities and direction
Packing	Sealing time; temperature; pressure; positioning; pack (seal) integrity

External cleaning with high-pressure nozzles will displace dirt from one place to another, in particular in the form of aerosols. The use of high-pressure systems is therefore not recommended. Foam or gel cleaning at low pressures are to be preferred.

The operation manual provided by the packaging machine manufacturer must recommend effective cleaning and decontamination procedures and suitable cleaning and decontamination chemicals.

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. The water present may cause two major problems. Firstly, it may cause dilution of the chemical used for decontamination. Secondly, when the machine is standing idle (e.g. overnight or over the weekend) with water residues, microorganisms are likely to multiply. The decontamination treatment might be insufficient for inactivation of the large number of microorganisms that results. Therefore, no significant amounts of water should remain anywhere in the product-contact area of the machine at the end of the cleaning procedure. Hence, the equipment must drain well.

Maintenance

Self-evidently, adequate maintenance should ensure that the packing machine continues to function reliably. It may be necessary for maintenance to be carried out during production. It must be ensured that such activities do not in any way compromise the microbiological safety of the product. If maintenance during production will result in unacceptable (microbial) contamination of the product or any product-contact surface, the packing operation must be discontinued and the packing machine must be cleaned and freed from relevant microorganisms before restarting.

Monitoring and control

Essential parameters must 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 packing machine. Examples are given in Table 1. Several of the parameters may be used to control processes such that the correct conditions are obtained and maintained automatically.

Operation manual

The operation or instruction manual, to be provided by the packing machine manufacturer, must give recommendations on effective cleaning and decontamination procedures, taking into account the resistance of all construction materials used. Further, the manual must give clear instructions on preventive maintenance.

Commissioning and validation

During commissioning it should be demonstrated that

the packing machine functions adequately, based on physical measurements (see 'Monitoring and control', above). In addition, if applicable, microbiological experiments should be carried out to demonstrate the hygienic performance of the machine. The experimental programme of validation should cover all issues that may influence the microbiological performance of the machine, such as:

- cleanliness of product-contact surfaces;
- microbial load of these surfaces;
- temperatures;
- pressures;
- differences between the concentration of relevant microorganisms in the product supplied to the packing machine and the concentration in the product immediately after packing;
- if applicable, efficiency of packing material decontamination, filter efficiency, incineration efficiency and air velocities.

Ordering

The purchasing contract must specify all essential requirements agreed between supplier and purchaser. The contract must also specify which requirements will be tested as well as where, when and by whom (supplier, purchaser or third party). It must be clear who (purchaser or supplier) is responsible for which tests.

Conclusions

The food processor must define which microorganisms are relevant to the product to be packed, as well as their concentration limits. Further, it is essential to agree and check the microbiological quality of the packing material and the likely concentration of microorganisms in the environment, in particular the air, of the packing machine. Based on such information it can be decided whether a hygienic packing machine must have any extra features to ensure that the packed product meets the microbiological standards.

All packing machine components that may come in contact with the product should be of hygienic design, allowing adequate cleaning and decontamination. During commissioning, all critical parameters must be monitored. When all parameters are set, the machine should be tested with product. Microbiological investigation of that product (making sure it is correct when entering the packing machine) should show that the machine operates correctly.

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This paper summarizes guidelines recommended by the European Hygienic Equipment Design Group (EHEDG) subgroup on Packing Machines, and has been approved by the EHEDG. The full report, by M.A. Mostert, S. Shießl, G. Rysstad, W. Weber, B. Wilke, L.S. Larsen, P.C. Harvey, G. Reinecke and Y. Delaunay, 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).

References

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3 *Hygienic Design of Closed Equipment for the Processing of Liquid Food* (1993) in *Trends Food Sci. Technol.* 4, 375–379

4 *Kunststoff-Formteile – Toleranzen und Abnahme bedingungen für Längenmaße (DIN 16901)* (1982) Beuth Verlag GmbH, Berlin, Germany

5 EC Council Directive 80/778/EEC (1980) [amended by Directive 91/692/EEC (1991)] Commission of the European Communities, Brussels, Belgium

EHEDG Updates in 1994

During 1994, the EHEDG plans to prepare further guidelines and test methods for the hygienically safe processing of food products, including papers on:

- The hygienic design of open plants
- The microbiologically safe continuous and semicontinuous thermal decontamination of liquids with particulates
- Plant monitoring and maintenance
- The hygienic design of pumps, valves, piping and couplings
- The hygienic design of blanching equipment
- Testing the performance of bacteria filters
- The hygienic design of refrigeration equipment
- Construction materials suitable for food-contact applications
- The hygienic design of robots for the food industry