

Challenge tests for the evaluation of hygienic characteristics of packing machines for liquid and semi-liquid products

This article is adapted from the report prepared by the packing machines subgroup of the European Hygienic Equipment Design Group (EHEDG). It is the 21st in the series published in *TIFS*. The report outlines standard tests for validating the cleanability of packaging machines. All aspects of the process are considered, from simple commissioning tests, through to the detailed procedures required before using a packaging machine with product. 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. EHEDG (1991) definitions are used throughout this report. © 2001 Published by Elsevier Science Ltd.

Introduction

The guidelines set out in this paper explain the tests needed to determine whether packing machines comply with hygienic design criteria as outlined in Annex 1 of the Machinery Directive.

Once a food processor has clearly specified the requirements for a packing machine, it must be possible

to demonstrate whether the machine meets those requirements. This requires validation of the design. Often non-standard methods have been used, making evaluation of the data and therefore validation difficult. To improve this situation, standardization of challenge test methods is recommended. This paper outlines proven methods for testing the performance of the various functions of packing machines. These tests may also be useful if a manufacturer wants to optimize or redesign a packing machine (Box).

Cleanability of equipment and effectiveness of cleaning procedures

Cleaning tests may be done:

- during prototype testing, before a packing machine design has been finalized
- during commissioning, using relatively simple tests
- before a packing machine will be used with product to adjust the cleaning procedure for the product to be packed.

An effective procedure (detergent, concentration, time, temperature, flow rate, cleaning volumes, etc.) should be recommended by the equipment manufacturer for the specific equipment provided he has been informed about the product to be filled. This cleaning procedure must also be tested.

Testing the cleanability of the filler

The task of the filler is to fill product into the container without unacceptable changes to the quality. Cleaning of the filler is an important step for all filling machines (hygienic or aseptic) and all food products. To ensure cleaning is effective, it is necessary that the equipment is easy to clean. This should be verified using the following test procedures.

A microbiological method for relatively small equipment is given in EHEDG (2000a). In this method, a detergent resistant strain of *Bacillus stearothermophilus* var. *calidolactis* (NIZO C953) is used as a very sensitive indicator of soil residues. For larger equipment, the test procedure as described in EHEDG (1997) can be used. Here, an emulsion enriched with β -carotene as an indicator is used as soil. Finally, a test procedure using

fluorescent dye as an indicator can be used; details are described in Elopak (1995).

In all methods, if CIP is applied, the movable parts must be activated during cleaning. These test procedures will show which areas are relatively difficult to clean. More non-microbiological test procedures are under development.

Testing the cleanability of the filling zone

The filling zone is the area where the filler outlet is situated up to where the pack is closed, including the sterile air cabinet, if present. Although not intended to be in direct contact with the product, it is essential to have a clean filling zone. This will reduce the chance that soil residues contaminate the product during or after filling.

Cleanability of this area depends largely on the design. Special attention should be paid to fixings of filters, electric cabling protection and the avoidance of condensate. If, despite the use of jacketed pipes and other practical methods, condensation cannot be (completely) avoided, it should be drained away from the open product container.

Elopak's (1995) 'Assessment of filter cleanability by CIP', describes a test procedure that can be used to test the cleanability of this area. This method is suitable only if the equipment has a CIP system. If not equipped with a CIP system, the best way is to check the cleanliness visually. This can be combined with the use of an ATP method. Organic soil residues usually contain ATP, which can be determined using a mixture of Luciferin and Luciferase.

Testing the decontamination of the filler

Depending on the product to be packed, it may be necessary to decontaminate the filler after cleaning. Decontamination can be done in various ways, using chemicals and/or heat.

For testing the sterilizability of the filler by heat, the EHEDG developed a test method (EHEDG, 1993a) using spores of a heat-resistant strain of *Bacillus subtilis*. The spores have a relatively high D-value (0.9 min at 120 °C). A similar method can be used to test the pasteurizability of the filler, using heat-resistant ascospores of the fungus *Neosartorya fischeri* var. *glabra* (EHEDG, 1993b).

To determine the coldest spot in the filler, irreversible temperature indicators, as shown in Cole-Parmer may be used. When identified, preferably a temperature probe should be mounted at that spot to record the temperature during decontamination. If in practice this is not possible at the cold spot, the relation between the temperature at the cold spot and another measurable place in the equipment must be determined. When a chemical solution is used to sterilize the equipment, *B. subtilis* var. *globigii* may be used (see Elopak, 1995).

Testing the decontamination of the filling zone

When microbiologically vulnerable products are packed, it may be necessary to decontaminate the filling zone.

A general method is given in Bosch 'Testing of pre-sterilisation of aseptic zone', using aluminium strips which are inoculated with different loads of bacterial spores. These strips are fixed in positions within the filling zone, suspected to be difficult to decontaminate. After decontamination, the strips are removed and incubated in nutrient broth. After incubation the broth is checked for microbial growth. Using the 'most probable number' (MPN) method (Oblinger & Koburger, 1975), the reduction factor obtained can be determined.

The packing material

The packing material used for filling perishable food products is normally produced under hygienic, but not sterile conditions. Total counts from 0.2 to 34 microorganisms/100 cm² have been reported in the literature for PE/paperboard, plastic films, aluminium foil and preformed plastic cups (Cousins, 1993). Air-borne microflora are normally dominated by micrococci, yeast & moulds and aerobic spore formers (bacilli).

The main objective of a packing machine for food products is to fill the product without recontamination with microorganisms that could adversely affect safety and quality up to the end of shelf life through recommended storage and transport until consumption. This means that for some foods, decontamination of the packing material is not necessary (e.g. short shelf life at low temperature). However, there is a trend in the food industry to increase the level of safety, and also to withstand abuses in the cold chain. Consequently, some

This paper provides an extended summary of the guidelines recommended by The Subgroup on Packing Machines of the European Hygienic Equipment Design Group (EHEDG). Copies of the full report (EHEDG Doc. 21, July 2000) by M.A. Mostert (Chairman), E. Arthaud J. M. Boisson E. H. G. Bovee, E. Damagnez, P. Golz, P. R. Kamstra, D. Raynaud F. Bourion, G. Reinecke, G. Rysstad, U. Steinhäuser, H. O. Vongheur and B. Wilke are available from CCFRA at: pubs@campden.co.uk and information about EHEDG can be found on the website at: www.ehedg.org

kind of decontamination is often applied, together with filtered air systems in the filling area.

For products intended for increased shelf life under cold distribution, there is a need for decontamination of the packing material in order to prevent spoilage caused by microorganisms found on the packing material. High acid products like fruit juices and fermented milks are often subject to spoilage by yeast and moulds, and hence destruction of such microorganisms is necessary. The effectiveness of the method and the challenge organism(s) used for testing the system is not always documented. Risk analysis (EHEDG, 1993c) will show what reduction factor is needed. This may be less, or sometimes more, than required by legislation in some countries. It is always important to document the procedure, the challenge organism and the reduction obtained through testing and verification of the system.

Aseptic filling machines are packing machines that fill foods *without* recontamination into a package that has been sterilized on the machine or elsewhere prior to filling. Provided that the product was commercially sterile before filling, the filled product will be commercially sterile in the package, and hence microbiologically stable in ambient distribution. The requirements of the sterilization of the packing material in aseptic filling machines are obviously very strict in relation to microbial destruction and reliability required.

There are several chemical and physical methods that can be used to sterilize packing material used in aseptic filling of sterile products. The sterilant to be used must destroy relevant microorganisms to the required level, be compatible with the packing material, be easy to apply in the aseptic system, be easy to remove from the treated surface and, if residues are left, they must be within the accepted tolerance level (Toledo, 1975). The most common sterilants used for aseptic packing applications worldwide are hydrogen peroxide, gamma irradiation, hot air/ steam, UV light, halogens or combinations of these methods (EHEDG, 1993c) as well as a combination of peroxy acetic acid and hydrogen peroxide. The choice may be influenced by limitations, for reasons of occupational safety, corrosivity and the requirement of additional labelling and local legislation.

Test methods for the evaluation of packing materials

For decontamination by H₂O₂, the method described by Cerny (1992) is recommended. In principle, this method is also applicable for other decontamination methods. In those cases, other microorganisms and media may be used; e.g. *Aspergillus niger* for the effect of UV, and *Clostridium sporogenes*-spores (PA3679) or *B. stearothermophilus* spores (ATCC7953) for steam sterilization.

Decontamination of packing materials is also carried out using gamma irradiation. This is done off the plant at a radiation source. For a large number of micro-

organisms their sensitivity to gamma radiation has been established. This is the so called D₁₀-value. This is the dose required to kill 90% of the number of microorganisms (1 decimal reduction). For gamma treatment of packing material, the target has been set to a maximum residual contamination of one in a million. Normally, no microbiological tests are done to validate the gamma-irradiation system. Instead, dosimeters are used to ensure that the required treatment has been received and consequently, the destruction of the relevant microorganism is ascertained.

Testing of the bacteria tightness of the filler

For aseptic packing machines, it is very important that the equipment is bacteria tight. This is to avoid re-infection of the product with microorganisms. For testing the bacteria tightness, the EHEDG developed a test method (Robinson, Batt, & Patel, 2000b), using *Serratia marcescens* (CBS 291.93). This indicator organism is a small, strongly motile, rod-shaped bacterium that is able to penetrate through small holes and crevices, which is very difficult to detect by physical methods.

Testing systems supplying air to the packing machine

Normally, air contains microscopic dust particles and microorganisms such as bacteria, moulds and yeasts. Bacteria and yeasts are usually associated with dust or carried by aerosols. Mould spores are not usually attached to dust.

Airborne microorganisms do not multiply in the air due to the lack of free water, but they have the inconvenience of being around everywhere and move about with air disturbance. To determine the concentration of microorganisms in the environment, various methods can be used (Curiel, van Eijk, & Lelieveld, 2000) which includes the following: slit sampler, Andersen perforated disk sampler, impinger, filtration and centrifugation.

The only way to control air contamination is to confine the process step within an enclosed area and to treat the enclosed volume. The air system must be able to maintain the enclosed volume sterile through a constant and sufficient flow/pressure of filtered air. This over-pressure in the enclosed area will prevent airborne microorganisms from entering and re-contaminating the product. To be able to check the over-pressure, pressure sensors should be placed, both inside and outside of the enclosed area. Pressure-difference measurement with an appropriate control system and alarm settings must ensure that the over-pressure is maintained.

A relatively simple method to test the flow pattern of air in the enclosed area is the use of smoke tubes available from different suppliers, e.g. Dräger or Cole-Parmer. A smoke tube produces white, visible smoke. This smoke will be carried by the airflow, giving a good view

of the air direction (e.g. going in or out of the machine). To measure the air velocity, an anemometer may be used.

For testing sterile filters, different methods are used. The efficiency of depth filters is commonly specified according to the dioctyl phthalate (DOP) test. (DOP-Smoke penetration and air resistance of filters, MIL-STD 283 (1956), US Atomic Energy Commission, US National Bureau of Standards.)

Membrane filters can be checked by the water intrusion test. For this test, the filter is completely wetted and a fixed pressure is applied which allows air to diffuse through the liquid, which can be quantified with a flow meter. This value is a measure for the effective pore size. Alternatively, dust particle counters may be used. Test methods are discussed in Curiel *et al.* (2000) and in EHEDG (2000c); these methods require skilled staff and specialized equipment. It may be advisable to consult a specialist laboratory.

Commissioning testing

Whatever the equipment and the food product, when a machine is brought into the processing area, the cleaning procedure should be checked by simple commissioning tests.

Physical commissioning tests

After dismantling, the equipment could be checked by visual inspection. The use of swabs could be helpful for suspected places of poor cleaning. The tests done during commissioning are not meant to replace tests to determine the cleanability of the equipment. Their only purpose is to identify areas where cleaning is clearly inadequate, e.g. as a result of incorrect installation.

A method, using buttermilk with a fluorescent dye (Elopak, 1995) can be used. The fluorescent dye is easily detectable on places where cleaning was not optimal. The use of an ATP test is also often applied. These tests are based on the presence of ATP whether or not in microorganisms and hence give an indication of cleanliness, not of numbers of residual micro-organism.

Microbiological commissioning tests

During the validation testing of a packing system, data have to be collected which demonstrate separately the efficiency of the decontamination of the package material (if applicable) and the machine. These data should be gained during intensive test series of the machine, at least of prototypes of packing machines. Due to the fact that an artificial inoculation of packing material and packing machine is necessary, these data can rarely be gained in the plant of a food producing company. Therefore, these tests should be carried out at the site of the machine manufacturer or, if more convenient, at a test institute.

The commissioning testing of a packing system only demonstrates the functionality of the total system. The separate effects of machine sterilization, etc., are not measured; only a total failure/success rate is determined.

Commissioning tests for aseptic packing machines

There are various possibilities for commissioning testing. Two examples are mentioned:

1. Tests in accordance to the German 'type-testing' of UHT-plants. Here 3×312 samples are taken and incubated. As a difference to a 'normal' quality control, the number of cfus (colony forming units) is determined. After incubation a concentration of >100 cfu/ml shows that the pack after filling was not sterile. The machine passes if a maximum of one sample per trial is unsterile.
2. A similar test as the first example, however the number of samples is increased to 2–3×3000 samples. To determine a failure rate of 0.1% with a probability of 95%, a maximum of one out of 3000 samples may be unsterile. Incubation depends on the characteristics of the product, such as pH and water activity and the expected ambient temperatures. For low-acid products an incubation period of 5 days at 30 °C is recommended. In areas where the ambient temperature may exceed 30 °C, incubation at 55 °C may be required additionally. Acid products may have to be incubated for as long as 21 days at 32 °C, e.g.; the food processor microbiologist will have to provide the protocol needed. An important difference to procedure 1 is that the incubated samples are only checked for pH value and/or smeared on nutrient agar.

Both procedures have to be regarded as proposals. The statistical aspects have to be taken into careful consideration. The choice of method to be used has to be discussed in detail and agreed between the machine supplier and the operating company.

A method to test microbial growth in the samples taken can be found in Baggerman *et al.* (1996), 'Operating procedure for the detection of microbial contamination in UHT sterilized, aseptically packed products with the modified 3-drops method with TTC.'

Packing equipment and HACCP

HACCP is now well established in the food manufacturing industry. It is a well-defined process of identifying significant hazards associated with manufacturing process steps. Packing of the final product is an essential process part in food manufacturing and HACCP teams will need to assess whether significant hazards are in any

way associated with the different filling and packing process steps during their study. The equipment itself is at the heart of this process.

Areas of particular interest for a hazard analysis during the filling and packing process are:

- The microbiological vulnerability of the product. All kinds of variations on product types are possible and should be taken into account as part of the HACCP study.
- The filling step where the product is in contact with primary packing for the first time, providing an environmental barrier for the product.
- The integrity of the pack, e.g. whether the equipment provides the required seal width/strength.
- The primary packing material itself: deviation from the specification could result in filling and/or sealing problems; therefore it must be checked, carefully and regularly, whether the material does comply with the specification.
- Maintenance of the equipment: preventive rather than break down maintenance to ensure continuous good filling and packing performance.
- Areas identified by the team that relate to the specific type of equipment, type of packing material, type of product, etc.

It is important that after the HACCP study, the monitoring system devised is implemented and the plan for controlling the identified critical control points is verified. Reviewing the plant's functionality at regular intervals and/or when there are significant changes to the process should further ensure a safe filling and packing operation.

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