Aseptic Packaging Machines for the Food Industry:
Minimum Requirements and Basic Conditions for the Intended Operation

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This publication has been drawn up by the Working Party for “Interface Problems in Aseptic Plants” in the VDMA Technical Department for Packaging Machines. It is available for downloading from WWW.VDMA.ORG/PACKTECH. Suggestions for improvements and additions may be sent to the following address: Fachverband Nahrungsmittelmaschinen und Verpackungsmaschinen im VDMA, Lyoner Straße 18, D-60528 Frankfurt/M., Fax: +49 69/6603-1211, nuv@vdma.org.
Preliminary Remark

This VDMA Document is the revised version of the VDMA Sheet 8742 published in 1996. Since the first edition of this working paper a series of documents have been edited by the VDMA Working Party "Interface Problems in Aseptic Plants". All papers were released as VDMA Documents 'Food Processing and Packaging Machinery'. The working Party decided to also publish the revision of VDMA 8742 under the roof of this working paper series. Thus enabling the download of the document from the internet free of charge. The revision of VDMA 8742 in a large extent is restricted to editorial modifications. E.g., references to VDMA Documents published later then 1996 are included now. The definition of aseptic packaging machines and the minimum requirements with respect to microbiological demands remained unchanged. The former Appendix C 'Dependence of the number of Unsterile Packages on the Initial Microbial Count of the Packaging Material and on the Count Reduction Rate - Example' was cancelled as is intended to include this issue in a new document on the topic 'Aseptic Performance Test' which is going to be published in the VDMA Documents 'Food Processing Machinery and Packaging Machinery' working paper series.

3. Scope and Purpose

This VDMA Document is aimed at providing a definition for aseptic packaging machines - i.e. hygienic filling machines of class V according to VDMA classification1 - for practical requirements. The reason for this is two-fold. On the one hand, microbiological performance commitments for the aseptic part of aseptic packaging machines have to be coupled to verifiable criteria. On the other hand, it appears desirable to explicitly represent the implicit microbiological minimum requirements concerning the aseptic part of such a machine to achieve an unequivocal delimitation between aseptically operating and other packaging machines.

Further, it is a concern of this VDMA Document to show that proper functioning of aseptic packaging machines - contingent on the system - necessitates various requirements to be satisfied by the operator of the machine unit.

This VDMA Document covers aseptic packaging machines in the sense of the definition detailed in Section 2, such as are used in the food industry. Aseptic packaging machines employed in the pharmaceutical industry are not being considered, since the conceptual terms and requirements in some parts deviate considerably from those in the food industry. The micro-biological comments refer to the aseptic part of aseptic packaging machines which, as a rule, comprises four functional modules:

- Active sterilization of the packaging material, e.g. by means of hydrogen peroxide or steam
- Sterilization and maintaining of sterile conditions of a defined machine section
- Metering and filling
- Sealing

3. Definition "Aseptic Packaging Machine"2

Aseptic packaging machines are packaging machines in which a sterile product is packaged free from recontamination in a package which has been presterilized - usually within the packaging machine - or which has been formed and sterilized in the packaging machine.

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1 VDMA Document "Hygienic Filling Machines for Liquid and Viscous Foods - Classification and Typical Fields of Application" defines five different classes of hygienic filling machines for the food industry wherein aseptic filling machines (Class V-Machines) are marking the upper range of hygienic demands for filling machines. Minimum requirements for Class IV-Machines are defined in VDMA Document "Hygienic Filling Machines of VDMA Class IV for Liquid and Viscous Foods - Minimum Requirements and Basic Conditions for Operation in Accordance with Specification"

2 This definition was phrased by reference to a definition edited by the work team "Prüfmethoden zur Packstoffsterilisation in Aseptikanlagen" of the work group "Mikrobiologie der Packstoffe" of the "Industrievereinigung für Lebensmitteltechnologie und Verpackung e.V. am Fraunhofer-Institut für Lebensmitteltechnologie und Verpackung", Institute at the Munich Technical University. For references see section "Further documents".
3. Minimum Requirements and Basic Conditions for the Intended Operation

In order to ensure aseptic operational reliability of aseptic packaging machines, several intercomplementary preconditions must be satisfied:

- The packaging machine must be technically suited to reliably kill microorganisms including bacterial spores (see Annex A, Section A.1).
- By means of appropriate control techniques, the machine manufacturer must ensure that the product to be packaged cannot be contaminated as a result of technical faults in the aseptic part of the packaging machine. If, nevertheless, such faults occur, it must be ensured that contaminated packages are either avoided or detected and discarded (see Annex A, Section A.2).
- The initial microbial count of the packaging material and of the aseptic part of the packaging machine must be minimized to the unavoidable limit by suitable technical and organizational measures (see Annex B, Section B.1 to B.7).
- Observance of the preventive organizational measures must be ensured by way of a suitable Quality System of the operator of the machine unit (see Annex B, Section B.8).

3. Performance commitments

If a contract makes reference to the present industry association publication the requirements enumerated herein provide no guarantee of quality as defined in §444 BGB (German Civil Code). This is merely a description limited to content and performance with respect to the due deliverable. This applies equally to the minimum requirements on machine technology set out in appendix A. Other requirements need to be explicitly regulated by contract in which the operational basic conditions are taken into account.

3. Further Documents


Checkliste "Qualitätssicherung und Wartung" für aseptische Verpackungsmaschinen für die Nahrungsmittelindustrie ['Checklist "Quality Assurance and Maintenance" for aseptic filling machines for the food industry']
German and English
VDMA Food Machinery and Packaging Machinery Documents No. 3 (English)
German version available from VDMA, Food and Packaging Industry Association Frankfurt, 1997.

Zwei Methoden zur Restperoxyd-Bestimmung in Leerbechern an der Abfüllmaschine - Prüfprozeduren [Two Methods for the Determination of Peroxide - residues in Empty Cups at the filling Machine]
VDMA Food Machinery and Packaging Machinery Documents No. 1
German and English

Hygienische Abfüllmaschinen für flüssige und pastöse Nahrungsmittel - Kategorisierung und typische Anwendungsfelder [Hygienic Filling Machines for Liquid and Viscous Foods - Classification and Typical Fields of Application]
VDMA Food Machinery and Packaging Machinery Documents No. 2
German and English
Aseptic Packaging Machines for the Food Industry: Minimum Requirements and Basic Conditions for the Intended Operation

Aseptische Produktionslinien: Unsterilitätsrisiken bei Produkt- und Versorgungsleitungen - Planungs- und Installationsfehler
[Aseptic Production Lines: Unsterility Risks in Product and Feed Lines - Planning and Installation Faults]
VDMA Food Machinery and Packaging Machinery Documents No. 4
German and English
Frankfurt, 2002.

Signaltausch für aseptische Abfüllmaschinen
- Mindestanforderungen für einen sicheren Betrieb [Signal exchange for aseptic filling machines - Minimum requirements for safe operation]
VDMA Food Machinery and Packaging Machinery Documents No. 5
German and English
Frankfurt, 2002.

Work team “Prüfmethoden zur Packstoffsterilisation in Aseptikanlagen” of the work group
“Mikrobiologie der Packstoffe” of the “Industrievereinigung für Lebensmitteltechnologie und
Verpackung e.V. am Fraunhofer-Institut für Lebensmitteltechnologie und Verpackung”, Institute at
the Munich Technical University (editor): Merkblatt - Prüfung von Aseptikanlagen mit H2O2-
Packstoffsterilisationsvorrichtungen auf deren Wirkungsgrad Verpackungsrundschau, Jahrgang 38
(1987) Nr. 6, Technisch - wissenschaftliche Beilage, pages 45 - 47
Document superseded by VDMA Document Food Processing Machinery and Packaging Machinery
No. 6/2002

Merkblatt
Prüfung von Aseptikanlagen mit Packmittelentkeimungsvorrichtungen auf deren Wirkungsgrad
[Code of Practice: Testing the Effectiveness of Aseptic Plants Fitted with Packaging Sterilization
Devices]
VDMA Food Machinery and Packaging Machinery Documents No. 6
German and English, Frankfurt
Frankfurt, 2002.

Was ist HACCP? [What is HACCP?]
VDMA Food Machinery and Packaging Machinery Documents No. 7
German and English
Frankfurt, 2002.

Merkblatt
Prüfung von Aseptikanlagen: Entkeimung des Sterilbereichs des Maschineninnenraums [Code of
Practice: Testing Aseptic Plants: Sterilizing the Sterile Zone in a Machine Interior]
VDMA Food Machinery and Packaging Machinery Documents No. 8
German and English

Hygienische Abfüllmaschinen der Klasse IV nach VDMA für flüssige und pastöse Nahrungsmittel -
Mindestanforderungen und Rahmenbedingungen für einen bestimmungsgemäßen Betrieb
['Hygienic Filling Machines of VDMA Class IV for Liquid and Viscous Foods - Minimum
Requirements and Basic Conditions for Operation in Accordance with Specification']
VDMA Food Machinery and Packaging Machinery Documents No. 10
German and English
Frankfurt, 2005.
Annex A: Minimum Requirements for Aseptic Packaging Machines

A.1 Microbiological Requirements
Aseptic packaging machines must reliably kill microorganisms including bacterial spores. Proof of this capability is considered as having been furnished if the following count reduction rates can be documented for certain test germs which are suitable for the respective sterilization procedure concerned (e.g. Bacillus subtilis SA 22 for packaging sterilization with H₂O₂). Test procedures for determination of the count reduction rates are listed in annex C.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Packaging material:</td>
<td>≥ 4</td>
</tr>
<tr>
<td>Packaging machine interior:</td>
<td>≥ 4</td>
</tr>
<tr>
<td>Filler:</td>
<td>Temperature/time-combination for sterilization steam: 121°C; 30 min. for product handling parts of the filler (or equivalent conditions)</td>
</tr>
<tr>
<td></td>
<td>With other sterilization media: logarithmic count reduction: ≥ 5</td>
</tr>
</tbody>
</table>

A.2 Measuring, control, monitoring and safety equipment

Aseptic packaging machines must be equipped

- with measuring devices to such an extent that all physical variables - concerning the packaging machine - which are important for safe operation can be measured and checked with adequate accuracy;
- with control devices for the packaging machine functions to such an extent that proper operation is ensured independent of fault factors (e.g. control of package material sealing);
- with monitoring and safety devices to such an extent that operational faults of the packaging machine which might affect product quality are indicated or cause measures for fault removal to be initiated.

Faults and malfunctions which are due to the product to be packaged or its supply or to the supply and service media system on the operator side, have to be precluded by the user of the machine unit through suitable measuring, control, monitoring and safety equipment.

The measuring, control, monitoring and safety equipment must be protected to prevent unauthorized intervention.

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3) This section was phrased with reference to section 2.3 of the Prüfrichtlinie Nr. 3 (1982) of the Erhitzerausschuss at the Bundesanstalt für Milchforschung Kiel.
Aseptic Packaging Machines for the Food Industry: Minimum Requirements and Basic Conditions for the Intended Operation

Annex B: Basic Conditions for the Intended Operation of Aseptically Operating Packaging Machines

B.1 Machine cleaning
Aseptic packaging machines are as a rule equipped with CIP (cleaning in place) systems for automatic machine cleaning. Continually perfect cleaning results necessitate the use of detergents recommended by the machine manufacturer and adherence to the cleaning times and cycles specified by the manufacturer. The detergents used must be agreed between the machine manufacturer and the final user, and depend on the product to be packaged. Use of unsuitable detergents may markedly reduce the aseptic performance of the machine through damage to materials.

B.2 Sterilization of the machine
Aseptic packaging machines are as a rule equipped with SIP (sterilization in place) systems for automatic sterilization of the aseptic machine section. Perfect sterilization requires that the sterilization cycles and sterilization parameters specified by the manufacturer are adhered to.

B.3 Machine maintenance
Strict adherence to the maintenance operations and maintenance cycles defined by the manufacturer is a prerequisite for perfect cleanability and sterilization of the aseptic packaging machine. This applies especially to the use of original equipment manufacturer spare parts as well as observance of the storage conditions recommended for elastomers. Maintenance and repair work shall be performed by appropriately qualified and trained personnel.

In view of the importance proper performance of maintenance work has with regard to faultless operation of an aseptic packaging machine, signing of a maintenance contract with the manufacturer is recommended.

B.4 Storage of packaging material
Packaging material intended for processing in an aseptic packaging machine must be stored and handled under conditions suitable to prevent high microbial load of the packaging material. Any possibility of exceeding the shelf life of the packaging material must be excluded. As a rule manufacturers of packaging material and manufacturers of packaging machines give recommendations for suitable storage conditions for the respective packaging material. Annex D shows storage conditions recommended by the company TetraPak by way of example.

B.5 Requirements concerning the operating personnel - training and hygiene
Within the scope of the GMP rules of the user of the machine unit, microbial contamination of the packaging material through the operating personnel and operating error shall be precluded by suitable measures in particular by training of the personnel.

B.6 Requirements concerning the product to be packaged
With the packaging machine in aseptic operation, the user of the machine unit must ensure that during the production run only sterile product enters the packaging machine for packaging.

B.7 General requirements concerning the environment of an aseptic packaging machine
The user of the machine unit must provide an environment suitable for the envisaged operation of the machine (machine room, utilities, qualified and trained operating and maintenance personnel, etc.).

4 Further information may be obtained from Checklist 'Quality Assurance and Maintenance for Aseptic Packaging Machines for the Food Industry', Frankfurt 1997.
B.8 Requirements concerning the quality system of the operator of the machine unit
The user of the machine unit shall maintain a suitable quality system which delineates suitable measures for satisfying the requirements specified under B.1 to B.7, and which ensures and documents their implementation.
Annex C: Test procedure for ascertaining the germ reduction rates in aseptic packaging machines

The following technical bulletins describe test procedures for ascertaining the microbiological efficiency of aseptic machines with packaging sterilisation devices. These are so-called challenge tests using artificial packaging contamination and controlled marginal conditions in order to obtain statistically meaningful and objectively comparable test results. The choice of the test germ suitable for the specific sterilisation process is of special significance. The choice is based on resistance of the germs and their spores to the sterilisation medium.

These tests differ fundamentally from so-called "Aseptic Performance Tests", which are carried out before releasing an aseptic filling machine for commercial production. These tests are used for verifying the microbiological reliability of the filling machine under practical production conditions and therefore do not include any artificial contamination with test germs.

The listed technical bulletins are available for downloading at www.vdma.org/packtech (publications database).

Merkblatt
Prüfung von Aseptikanlagen mit Packmittelentkeimungsvorrichtungen auf deren Wirkungsgrad
[Code of Practice: Testing the Effectiveness of Aseptic Plants Fitted with Packaging Sterilization Devices]
VDMA Food Machinery and Packaging Machinery Documents No. 6
German and English, Frankfurt
Frankfurt, 2002.

Merkblatt
Prüfung von Aseptikanlagen: Entkeimung des Sterilbereichs des Maschineninnenraums [Code of Practice: Testing Aseptic Plants: Sterilizing the Sterile Zone in a Machine Interior]
VDMA Food Machinery and Packaging Machinery Documents No. 8
German and English

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5 A further publication is planned about the "Aseptic Perfomance Test" in the series "VDMA Documents: Food Processing Machinery and Packaging Machinery".
Annex D: Storage Instructions of Tetra Pak for Packaging Material Intended for Processing in Aseptic Packaging Machines

Introduction
To ensure that the quality of the material is not changed it is vital to follow the storage and handling recommendations of packaging material and additional material.

Delivery
The packaging material will be delivered in "small" or "jumbo" reels on one way pallets. Normally the packaging material is wrapped in protective shrink film. The individually wrapped reels are stacked on pallets. A hood of shrink film or a stretch film is protecting the reel stack on a pallet. In this way the reels are secured to the pallet. This gives also protection against moist and dirt at the same time. With customer agreements the reels can be delivered without the protective films.

Pallets can be stacked three in height provided a rigid divider board is placed on top of the lower pallets. Pallets with packaging material with “fixed strips” is not allowed to be stacked.

The additional material is delivered in boxes/bags.

Wooden pallets
Regarding off-flavour from wooden pallets and container flooring treated with fungicides agents.

Reel wrapping
To keep the original properties of the packaging material the following specifications of shrink film are recommended:
1. 50 micron tight PE film* for condition < 25°C and 35-75% RH
2. 100 micron right PE film** for condition < 35°C and 35-90% RH
3. Special barrier is required for condition > 35°C
WVT: 1* 2,5g water/24 h/m²/ (0-50% RH)
    1** 1,5g water/24h/m²/ (0-50% RH)

Storage of material
Recommendations
- use the material on a first in – first out basis.
- the storage premises must be kept clean.
- the material must be stored completely separated from other goods, such as milk powder, essences, animal food, chemicals, detergents etc. There is a great risk that the packaging material is absorbing vapours which could result in taste problems
- store the material on pallets only! The space to nearest wall should be kept min. 100mm.
- the material must not be exposed to direct moisture, such as condensation dripping from pipe etc. neither exposed to direct sunlight.
- if the material is stored longer then recommended, see specification, reliable production check should be initiated.

Storage conditions
Packaging material
Temperature: storage temperature between 10°C and +40°C
Humidity: relative humidity (RH) of between 40% and 65%

Additional material
LS-strips, IS-strips, OS-strips, Tab-strips, FlexiCap, Lid material:
Temperature: storage temperature between 10°C and +40°C
Humidity: relative humidity (RH) of between 40% and 65%.

Caps
Temperature: storage temperature between 10°C and +30°C
Humidity: relative humidity (RH) of < 80%
Variation from recommended humidity during short period (4 to 5 days) have no noteworthy effect on the humidity of the materials.
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Storage time
Storage time limit which guarantees the function of the material is specified for each material and additional material types. The storage time is counted from the manufacturing date of the material.

Storage conditions prior to packing
The packaging material must be allowed time to reach the same temperature as the temperature prevailing in the packing premises. If the packaging material is protected with protective plastic film, this should be kept on until the reel will be used.

Handling
Packaging material
Use a special lifting/turning truck to handle the reel

Openings & Closures
See the instruction on how to handle closures in the most correct way during the storage, packing and loading phases.

Quelle: Tetra Pak Hochheim, Qualitätsmanagement 05.2005