Hygienic Filling Machines of VDMA Class IV for Liquid and Viscous Foods
Minimum requirements and basic conditions for operation in accordance with specification

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Contents

1. Field of application and purpose ................................................................. 3
2. Definition of "Hygienic Filling Machines of Class IV" .................................. 3
3. Minimum requirements and basic conditions for operation in accordance with specification .... 4
4. Performance commitments ........................................................................... 4
5. Other documents .......................................................................................... 5

Appendix A Minimum microbiological requirements for hygienic filling machines of Class IV ........ 7
Appendix B Basic conditions for operation in accordance with specification of hygienic filling machines of Class IV................................................................. 9
  B.1 Machine cleaning ..................................................................................... 9
  B.2 Disinfection or sterilization of the machine .............................................. 9
  B.3 Machine maintenance .............................................................................. 9
  B.4 Storage of packaging materials ............................................................... 9
  B.5 Hygiene of operating staff ...................................................................... 9
  B.6 Requirements on the product to be filled ............................................... 9
  B.7 General requirements on the local environment of an aseptic packaging machine .......... 9
  B.8 Requirements on the quality assurance system of the user of the machine unit ............ 10

Appendix C Dependence of the number of unsterile packages on the initial microorganism count for the packaging material and the microorganism reduction rate ................................................................. 11
Appendix D Test methods for determining microorganism reduction rates in hygienic filling machines of Class IV........................................................................... 12
Appendix E Tetra Pak storage and handling recommendation for packaging materials to be processed on aseptic filling machines................................................................. 12

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.
1. Field of application and purpose

In this industry association publication "Hygienic Filling Machines for Liquid and Viscous Foods - Classification and Typical Fields of Application" the VDMA Working Party for "Interface Problems in Aseptic Plants" has defined 5 categories of hygienic filling machines, whereby the highest requirements are imposed on Class V machines (aseptic filling machines in accordance with VDMA 8742). Class IV machines according to this industry association publication are filling machines for liquid and viscous foods which exhibit the key technical characteristics of a Class V machine but without fulfilling the high demands of aseptic filling machines for packaging material sterilization, sterilization of the filler and sterilization of the interior areas of the machine. Typical applications of Class IV machines are for

- acidic products (pH ≤ 4.5) which are distributed with a long minimum shelf life outside the cold chain (e.g. cold-filled strained tomatoes, cold-filled fruit juices, thermized fruit yogurt)
- pasteurized products in the pH range > 4.5 distributed in the cold chain (e.g. ESL milk, pudding)
- prevention of product contamination by decay-causing microorganisms, such as mold spores, to prolong minimum shelf life (e.g. natural yogurt, quark).

In the present industry association publication minimum requirements based on VDMA 8742 for the sterilization performance of Class IV machines are laid down. The basic conditions for operation in accordance with specification are described.

2. Definition of "Hygienic Filling Machines of Class IV"

In the aforesaid industry association publication hygienic filling machines for foods are divided into 5 classes. Class IV machines exhibit the following technical characteristics:

- construction in accordance with DIN EN 1672-2;
- cleaning in place (CIP) for systems conveying product;
- disinfection or sterilization of the filler¹;
- recontamination prevention for systems conveying product;
- packaging materials sterilization and recontamination prevention of the disinfected packaging material until the pack is sealed²; and
- cleaning and disinfection together with recontamination prevention of the areas exposed to product³.

Moreover, they fulfill the minimum requirements set out in Appendix A for the sterilization of the packaging material and the interior of the machine.

Depending on the specific application, the requirements on Class IV machines may differ considerably from those on Class V machines with regard to the required microbiological security, the required safeguards against operating errors, and the level of in-process control implemented. Table 1 shows an example of some of the technical differences between Class IV and Class V machines produced by a manufacturer of filling machines. It is generally the case that depending on the planned field of use the Class V machines are designed to provide the maximum technically possible and reasonable protection for the aseptic filling operation. In the case of Class IV machines, not least on grounds of cost, the restriction to the measures necessary in the context of the application in question for preserving the microbiological quality of the filled product together with the technical measures to be taken for this purpose to prevent operating faults and to monitor the filling process largely determines the technical specification of the filling machine. There are often possibilities of reducing the degree of automation, particularly in the area of in-process control and its documentation. In doing this, however, it has to borne in mind that reducing the degree of automation always imposes higher demands on the operating staff if a comparable level of process security is to be attained. It is the responsibility of the operating company to take the organizational measures, including staff qualifications, needed for this purpose.

¹ Insofar as sterilization of the filler is necessary, the requirements set out in VDMA 8742, Appendix A.1., should be fulfilled.
² Alternatively, packaging materials disinfected outside the packaging machine can also be fed free of contamination into the filling machine. In this case the requirements on packaging sterilization are the same as those for packaging sterilization inside the packaging machine.
³ Including parts in contact with the product.
3. Minimum requirements and basic conditions for operation in accordance with specification

In order to ensure the microbiological operating safety of hygienic filling machines of Class IV a series of mutually complementary preconditions must be met. These are listed below.

- The filling machine must be technically capable of reliably reducing the microbial load in accordance with the requirements in Appendix A and of maintaining the attained microbiological state during operation.
- The process parameters of the filling machine relating to microbiological operating safety must be measured and checked with adequate reliability.
- The prior exposure of packaging materials and of the aseptic region of the packaging machine to microorganisms has to be limited to the unavoidable minimum by suitable technical and organizational measures (Appendix B, Sections B1 to B7; Appendix C explains the relationship between prior microbial load and the failure rate of the packaged goods with reference to the example of the initial surface microorganism count of packaging materials).
- The maintenance of the level of microbiological operating safety has to be ensured by suitable measures in the quality assurance system of the company operating the machine.

4. 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.

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4 Notes on factors related to quality may be found in the publication: "Checkliste 'Qualitätssicherung und Wartung ' für aseptische Abfüllmaschinen in der Nahrungsmittelindustrie" which appeared in Verpackungsrundschau, issues 7 and 9, 1997. Reprints of this publication can be obtained from VDMA.[English version is available as VDMA Document Food Processing and Packing Machinery No. 3 'Checklist "Quality Assurance and Maintenance" for aseptic filling machines for the food industry']
5. Other documents

- Reuter, H.; Biewendt, H.-G.; Klobes, R.H. (eds.):

- VDMA 8742
  Aseptische Verpackungsmaschinen für die Nahrungsmittelindustrie - Mindestanforderungen und Rahmenbedingungen für den bestimmungsgemäßen Betrieb [Aseptic packaging machines for the food industry - Minimum requirements and basic conditions for intended operation], Beuth-Verlag Berlin, 1996; Revision planned for 2005.

- VDMA Food Machinery and Packaging Machinery Documents No. 3 (English)
  German version available from VDMA, Food and Packaging Industry Association Frankfurt, 1997.

- VDMA Food Machinery and Packaging Machinery Documents No. 1
  German and English

- VDMA Food Machinery and Packaging Machinery Documents No. 2
  German and English

- VDMA Food Machinery and Packaging Machinery Documents No. 4
  German and English
  Frankfurt, 2002.

- VDMA Food Machinery and Packaging Machinery Documents No. 5
  German and English
  Frankfurt, 2002.

- VDMA Food Machinery and Packaging Machinery Documents No. 6

The industry association publications cited are available for downloading at no cost from www.vdma.org/packtech under the heading Technik/Aseptik [Technology/Aseptic]. [English website: vdma.org VDMA sector 'packaging machinery' or 'food-processing machinery', heading 'technology']
Hygienic Filling Machines of VDMA Class IV for Liquid and Viscous Foods

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
Appendix A
Minimum microbiological requirements for hygienic filling machines of Class IV

Packaging sterilization (surfaces in contact with product)

<table>
<thead>
<tr>
<th>Sterilization method</th>
<th>Test microorganisms, required microorganism count reduction rate</th>
</tr>
</thead>
</table>
| \( \text{H}_2\text{O}_2 \) | Bac. subtilis SA 22  
Microorganism count reduction \( \geq \log 3 \)  
Aspergillus niger (DSM 1957/ATCC 6275 or DSM 1988/ATCC 16404)  
Microorganism count reduction \( \geq \log 4 \) |
| Steam and hot water | Aspergillus niger (DSM 1957/ATCC 6275 or DSM 1988/ATCC 16404)  
Microorganism count reduction \( \geq \log 4 \) |
| Peracetic acid products | Bac. subtilis SA 22  
Microorganism count reduction \( \geq \log 3 \)  
Aspergillus niger (DSM 1957/ATCC 6275 or DSM 1988/ATCC 16404)  
Microorganism count reduction \( \geq \log 4 \) |
| UV | Aspergillus niger (DSM 1957/ATCC 6275 or DSM 1988/ATCC 16404)  
Microorganism count reduction \( \geq \log 3 \) |
| Infrared and dry heat | Aspergillus niger (DSM 1957/ATCC 6275 or DSM 1988/ATCC 16404)  
Microorganism count reduction \( \geq \log 4 \) |

Note: Hygienic filling machines of Class IV are frequently employed in order reliably to kill off certain microorganisms harmful to products. In these cases it is recommended that the sterilization method, the test microorganism and the microorganism killing rate to be achieved be matched to the decay-causing microorganism.

Sterilization of the machine interior

<table>
<thead>
<tr>
<th>Sterilization method</th>
<th>Test microorganisms, required microorganism count reduction rate</th>
</tr>
</thead>
</table>
| \( \text{H}_2\text{O}_2 \) | Bac. subtilis SA 22  
Microorganism count reduction \( \geq \log 3 \)  
Aspergillus niger (DSM 1957/ATCC 6275 or DSM 1988/ATCC 16404)  
Microorganism count reduction \( \geq \log 4 \) |
| Steam | Aspergillus niger (DSM 1957/ATCC 6275 or DSM 1988/ATCC 16404)  
Microorganism count reduction \( \geq \log 4 \) |
| Peracetic acid products | Bac. subtilis SA 22  
Microorganism count reduction \( \geq \log 3 \)  
Aspergillus niger (DSM 1957/ATCC 6275 or DSM 1988/ATCC 16404)  
Microorganism count reduction \( \geq \log 4 \) |
| Dry heat | Aspergillus niger (DSM 1957/ATCC 6275 or DSM 1988/ATCC 16404)  
Microorganism count reduction \( \geq \log 4 \) |

Sterilization of systems conveying product
To the extent that sterilization is required:
Temperature-time combination for sterilization of a cleaned machine with saturated steam: 121 °C; 30 min. for the product-conveying systems in the filler (or equivalent conditions).

---

6 The choice of test microorganisms and the establishment of the microorganism reduction rate to be demonstrated for the selected test microorganism are done as a function of the sterilization method in question. The differing sensitivity of a test microorganism to the different sterilization methods results in different requirements for the microorganism reduction rate. Thus, Aspergillus niger of strains DSM 1957 and DSM 1988 is employed for verifying all commonly used packaging sterilization methods. The required minimum sterilization level, however, is set at different values depending on the method.
In the case of other sterilization media

<table>
<thead>
<tr>
<th>Sterilization method</th>
<th>Test microorganisms, required microorganism count reduction rate</th>
</tr>
</thead>
</table>
| Peracetic acid products    | Bac. subtilis SA 22  
                            | Microorganism count reduction ≥ log 4  
                            | Aspergillus niger (DSM 1957/ATCC 6275 or DSM 1988/ATCC 16404)  
                            | Microorganism count reduction ≥ log 5 |
| Steam and hot water        | Aspergillus niger (DSM 1957/ATCC 6275 or DSM 1988/ATCC 16404)  
                            | Microorganism count reduction ≥ log 5 |
Appendix B
Basic conditions for operation in accordance with specification of hygienic filling machines of Class IV

B.1 Machine cleaning
A consistently acceptable cleaning result is conditional upon the use of the cleaning agents recommended by the manufacturer of the machine and the adherence to the cleaning times and cycles prescribed by the manufacturer. The cleaning agents used, which depend on the nature of the product to be packaged, have to be agreed by the user with the machine manufacturer.

The use of unsuitable cleaning agents can damage materials and hence markedly reduce the sterilization performance of the machine.

B.2 Disinfection or sterilization of the machine
Effective disinfection or sterilization requires that the intervals specified by the manufacturer be adhered to.

B.3 Machine maintenance
A condition for ensuring the continuing process reliability of hygienic filling machines of Class IV is the strict observance of the maintenance tasks and cycles laid down by the manufacturer. This also applies in particular to the use of original spare parts and to compliance with the storage conditions recommended for elastomers. Maintenance and servicing tasks have to be carried out exclusively by appropriately qualified and trained personnel.

Due to the importance of the orderly conduct of maintenance tasks for troublefree operation of hygienic filling machines of Class IV it is recommended that a maintenance contract be concluded with the manufacturer.

B.4 Storage of packaging materials
Packaging materials to be processed on hygienic filling machines of Class IV should be stored and transported under conditions which prevent contamination of the packaging materials by microorganisms. Storage of the packaging materials for excessively long periods has to be ruled out. Appendix E sets out an example of suitable storage conditions.

B.5 Hygiene of operating staff
As part of the GMP (good manufacturing practice) rules of the operating company contamination of packaging materials by operating staff should be prevented by suitable measures.

B.6 Requirements on the product to be filled
The user of the machine unit must ensure that during the production run exclusively product of the microbiological quality underlying the design of the filling machine is delivered for filling in the packaging machine.

B.7 General requirements on the local environment of an aseptic packaging machine
The user of the machine unit should provide a suitable local environment (factory area, operating resources, qualified and trained operating and maintenance staff, etc.).
B.8 Requirements on the quality assurance system of the user of the machine unit
The user of the machine unit should maintain a quality assurance system which describes suitable measures for meeting the requirements set out under B.1 to B.7 and ensure and document its application.
Appendix C

Dependence of the number of unsterile packages on the initial microorganism count for the packaging material and the microorganism reduction rate

<table>
<thead>
<tr>
<th>Surface microorganism count per 100 cm²</th>
<th>Number of spores*) per 100 cm²</th>
<th>Number of spores per liter package 800 cm³ (Tetra Brik)</th>
<th>Failure rate**) for a mean logarithmic microorganism reduction rate of 4, 5, and 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.1</td>
<td>0.003</td>
<td>0.024</td>
<td>2:10⁶, 2:10⁷, 2:10⁸</td>
</tr>
<tr>
<td>0.5</td>
<td>0.015</td>
<td>0.12</td>
<td>1:10⁵, 1:10⁶, 1:10⁷</td>
</tr>
<tr>
<td>1.0</td>
<td>0.03</td>
<td>0.24</td>
<td>2:10⁵, 2:10⁶, 2:10⁷</td>
</tr>
<tr>
<td>5.0</td>
<td>0.15</td>
<td>1.20</td>
<td>1:10⁴, 1:10⁵, 1:10⁶</td>
</tr>
<tr>
<td>10.0</td>
<td>0.30</td>
<td>2.40</td>
<td>2:10⁴, 2:10⁵, 2:10⁶</td>
</tr>
<tr>
<td>100.0</td>
<td>3.0</td>
<td>24.00</td>
<td>2:10³, 2:10⁴, 2:10⁵</td>
</tr>
</tbody>
</table>

Source: Tetra Pak GmbH Research, Stuttgart 1994

*) Basic assumption: 3% of the microorganisms are spores
**) Calculated for a package having contents of 1000 cm³

Example: Relationship between failure rate and initial microorganism count for the packaging material

on the assumption that 3% of the microorganisms are spores*) which are uniformly distributed over the packaging material

\[
\text{Failure rate} = \left( \frac{\text{Total microorg. count}}{\text{Package}} \right) \times \text{Spores fraction} \times \text{Microorg. redn. rate}
\]

The surface microorganism count for the packaging material is measured as 5 microorganisms per 100 cm². For a package measuring 800 cm² this then yields for a machine having a mean logarithmic microorganism reduction rate of 5 (\(10^{-5}\)):

Total microorg. count/pack = 5 microorgs./100 cm² x 800 cm²/pack = 40 microorgs./pack

\[
\text{Failure rate} = \left( \frac{40 \text{ microorgs./pack}}{100000} \right) \times 0.03 \left( \frac{\text{spores}}{\text{microorgs.}} \right) = 1.2 \times 10^{-5} \text{ spores / pack}
\]

or 1.2 surviving spores per 10⁶ packages, i.e. given the basic conditions specified above one unsterile package per 100,000 filled units would be expected.
Appendix D

Test methods for determining microorganism reduction rates in hygienic filling machines of Class IV

The codes of practice specified below can be adapted for the examination of hygienic filling machines of Class IV. The precondition for doing so is that the filler is sterilizable. The codes of practice are available for downloading from www.vdma.org VDMA sector ‘packaging machinery’ or ‘food processing machinery’ (Heading: Technology).

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.

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.

Appendix E

Tetra Pak storage and handling recommendation for packaging materials to be processed on aseptic filling machines

Introduction
To ensure that the quality of the material is not changed it is vital to follow the storage and handling recommendation 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 moister 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/2hh/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.

**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.
Hygienic Filling Machines of VDMA Class IV for Liquid and Viscous Foods

Storage - Handling

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