VDMA Document
Food Processing Machinery and Packaging Machinery

General Requirements on Packaging for Filling Machines of VDMA Hygiene Classes IV and V

Nr. 16 / 2nd revised edition 2018

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Contents

This publication was drawn up by the Working Party for "Interface Problems in Aseptic Plants" of the VDMA technical department for packaging machines. This and other documents published by the same working party are available as free downloads from WWW.VDMA.ORG/NUV ’Publications’ database. An overview of all papers published by the working party is available as a download under the heading Aseptic Technology. Suggestions and proposals for additions may be sent to the following address:
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Preliminary remarks on the 2nd edition

The following changes have been made since the first edition in 2010:

- Adjustment of the pH value delimitation of acidic (pH value ≤4,6) and weakly acidic (pH value > 4,6) products to the delimitation of the FDA.
- Adaptation of the calculation example in Annex III to the state of the art
- New Annex IV with literature sources on requirements for the initial contamination of packaging materials (packaging manufacturing plant)
- Updating the bibliography
- Editorial changes

1 Introduction

Filling machines of VDMA Hygiene Classes IV and V are designed to fill commercially sterile products free of recontamination. This places high requirements not only on the filling ma¬chines themselves, their surroundings and the organisational procedures, but also on the packaging to be filled and on packaging aids which could come into contact with the product or could infiltrate the sterile region in the interior of these filling machines. This VDMA document formulates general guidelines for specifying quality requirements for such packaging and packaging aids. This document is thereby restricted to aspects concerning microbiological process reliability and the stability of the filling process. It should be noted that the quality requirements refer to the point in time at which the packaging is provided ready to feed into the filling machine. Thus, it does not suffice to solely define criteria for monitoring incoming goods, aspects of the in-plant packaging logistics system and influences from process stages upstream from filling (forming, cleaning, sterilization) also need to be considered.

Due to the long shelf life promised for filling commercially sterile products, there are special demands beyond the requirements depicted here which relate to the migration properties and barrier characteristics of the packaging used. No consideration is given to these here, nor to requirements concerned with marketing (package design) and quality assurance.

2 Terms and definitions

Terms and definitions	Definition	Explanation
Packaging	The main components forming the packaging intended to take up the filled product.	Packaging in the sense of this definition also includes foil packaging and flat packaging blanks, as processed in thermoforming, filling and closing machines. Packaging which could come into contact with the filled product or infiltrate the sterile region in the interior of these filling machines are of significance for this document.
Packaging aids	Components, which together with the packaging, fulfil the totality of functions required from the packaging.	Packaging aids which come into contact with the product or intended to infiltrate the sterile zone in the interior of filling machines are of significance for this document. These are closures, lids, sealing foils and possibly applications such as pouring aids.

Hygienic filling machines of Class V as per VDMA (aseptic filling machines)	Filling machines that fill a commercially sterile product with a pH of > 4.6 with recontamination prevention into packaging that has been sterilized, usually on the machine.	This is achieved by making high demands in terms of the efficiency of the systems used to sterilize the packaging, the machine interior and the components conveying product, (see VDMA document NuV No.11, formerly VDMA 8742). When sterilizing the packaging, microorganism reduction of at least four times the power of 10 is deemed necessary in the respective sterilization method with suitable test microorganisms. Aseptic filling machines are typically used for filling weakly acidic and neutral products (pH > 4.6) with a long shelf life without refrigeration.
Hygienic filling machines of Class IV as per VDMA	Filling machines that fill a commercially sterile product with a pH of ≤ 4.6 with recontamination prevention into packaging that has been sterilized, usually on the machine.	This is achieved by making high demands in terms of the efficiency of the systems used to sterilize the packaging, the machine interior and the components conveying product, although these are below the requirements made of Class V machines (see VDMA document NuV No. 10).
Commercially sterile product	Product free of viable microorganisms and free of organisms that can multiply in the product under normal, nonrefrigerated storage and distribution conditions.	
Commercially sterile packaging and equipment	Packaging or equipment free of viable microorganisms and free of organisms that can multiply in the product under normal, nonrefrigerated storage and distribution conditions.	Defined with reference to the FDA definition in 21 CFR 1131
Filling machine	In the context of this VDMA document: Hygienic filling machines of VDMA Classes IV and V	
Sterilizable packaging	In the context of this VDMA document: Packaging suitable for the respective method of sterilizing the packaging.	After the sterilizing agent has been applied under the foreseen process conditions, sterilizable packaging does not impair the specified packaging properties, such as dimensional tolerances, sealability, surface properties, thermo-formability, migration properties and stability of form.

[1] "Commercial sterility" of equipment and containers used for aseptic processing and packaging of food means the condition achieved by application of heat, chemical sterilant(s), or other appropriate treatment that renders the equipment and containers free of viable microorganisms having public health significance, as well as microorganisms of nonhealth significance, capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution.

Sterilisierbare Packmittel	Im Kontext dieser Fachverbandsschrift: Für das jeweilige Packmittelentkeimungsverfahren geeignete Packmittel.	Sterilisierbare Packmittel weisen nach der Beaufschlagung mit dem Entkeimungsmittel unter den vorgesehenen Prozessbedingungen keine negative Beeinträchtigung der spezifizierten Packmitteleigenschaften, wie z.B. Maßtoleranzen, Siegelbarkeit, Oberflächeneigenschaften, Thermoformbarkeit, Migrationseigenschaften, Formstabilität.

3 General notes on specifying quality requirements for packaging intended for filling on filling machines of VDMA Hygiene Classes IV and V

3.1 Fundamental requirements – checking suitability before start up

The fundamental suitability (process capability) of the packaging to be filled should be examined before a filling system is started up. The tests and action associated with sterilizing the packaging which are of particular significance for the microbiological safety of the filling process are listed below. [2] In this context, it should be noted that the examination of sterilizability can have repercussions on the design of the filling machine and should therefore be performed as early as possible in the planning process.

1. Investigate sterilizability (for preformed containers and closures delivered non-sterile)
2. Determine the maximum admissible initial germ count (if appropriate, differentiated by types of microorganisms)
3. If appropriate, investigate the effects of the forming processes upstream from filling on the material properties (including organoleptic stability) and dimensional tolerances of the packaging
4. Investigate the effects of the sterilization agent on the material properties and dimensional tolerances of the packaging
5. Investigate the effects of dimensional and recipe tolerances on the tightness of packages (closures, lids)
6. Determine material properties, dimensions and dimensional tolerances (technical specification of the packaging)[3]
7. Determine the requirements on the packing, storage and provision of the packaging
8. Verify the suitability of the packaging by means of a sterile test[4]. Release the technical packaging specification.
9. Document changes in the technical packaging specification after the sterile test has been performed

The technical specification should enable the purchasing and quality departments to reliably identify non-conformities in the processing properties of the packaging compared to the original samples tested in the qualification phase.[5] The change documentation should firstly serve to raise awareness that amendments to the technical specification can have knock-on effects on

[2] In addition, due to the long shelf life promised for filling commercially sterile products, special requirements need to be taken into account which relate to the migration properties and barrier characteristics of the packaging.
[3] The technical specification also takes account of legislation and requirements from the spheres of quality assurance and marketing (package design). The specification of the resulting packaging requirements should be concluded before the sterile test is performed. The sterile test aims to uncover negative effects of these requirements on the sterilizing functions and to enable the process of packaging sterilization to be adapted to these requirements.
[4] The sterile test is a microbiological examination of a sufficient number of packages filled under production conditions to uncover systematic errors before commercial production starts. This test is performed on the ready-for-production machine and usually with the original product to be filled. A successful sterile test is generally regarded as being a prerequisite for starting commercial production. (see VDMA 2007, FS No. 12)
[5] A prerequisite for this is that quality tests are available which enable conclusions to be drawn about the processing properties of the filling machine. This, for example, is not the case with deep-drawn foils and the sealing properties of foil caps and lids. Compliance with the technical specification alone does not suffice to fulfill the desired processing properties in these cases. In particular, processing problems can arise in practice if the supplier changes the recipe or if the supplier itself is changed, even though the technical specification has been observed.

microbiological process reliability. The documentation secondly helps to clarify causes in case microbiological problems occur.

3.2 Prevention of mechanical problems caused by the packaging

The productivity of the filling line is lowered considerably if packaging causes disturbances which need to be rectified by intervening in the sterile area of the filling machine because intermediate cleaning and subsequent intermediate sterilisation must be undertaken to restore microbiological process reliability. The packaging specification should therefore aim to achieve a high degree of process stability.

3.3 Notification of changes in recipes and suppliers

Technical tests on packaging, e.g. on deep-drawn and sealing foils, only allow certain conclusions to be drawn about the processing behaviour on filling machines. A change of recipe or a change of supplier for deep-drawn foils can lead to packaging-induced disturbances in practice, even if the supplier complies with the technical specification. It is therefore recommendable to have the supplier notify changes in recipe and to inform the production department of this, and likewise any change of supplier. This department can then be on the lookout for any problems that might arise and take precautionary action, perhaps by adapting the sampling schedule.

3.4 High demands on dimensional accuracy

The high requirements for sealing packages properly not only mean that the dimensional tolerances in the areas critical for the closure need to be specified more stringently. The tolerance to outliers should also be looked at critically because, in case of doubt, outlier can mean a leaky package or could even lead to disturbances in the sterile region inside the filling machine. The sensitivity of the statistical quality controls in the incoming goods department should take this into account.

3.5 Quality controls for packaging properties relevant to aseptic filling

The quality system should check the packaging properties critical for aseptic filling on a regular basis. These include the wettability of the packaging with the chemical sterilization agent used, the sealability of foils and the deep-drawn properties of the foils or films in question (thickness of the cup wall – no holes!).

3.6 Low initial germ count of the packaging and packaging aids

A low initial germ count of the packaging to be filled and packaging aids is essential for filling commercially sterile products free of recontamination. The correlation between the initial germ count and the risk of non-sterility in filling machines of Hygiene Classes IV and V is shown in tabular form in Appendix III. Annex IV contains a compilation of requirements for the initial germ count of packaging material contained in literature references.[6]

Empirical investigations have shown that it is not so much the manufacturing process itself that can cause a high germ count on the inner and outer surfaces of the packaging, but rather how the packaging is handled in the packaging production plant and in the filling plant.[7] The aim should therefore be to preserve the generally low germ count following on directly from manufacture by means of hygiene measures and suitable packing. Examples of possible sources of contamination are the ambient air (ambient air drawn in when cooling containers; contamination from the electro-static adherence of particles of dust) and manual handling of packaging (e.g. manual stacking of cups in cartons).

3.7 Packing, storage and provision of packaging in the filling plant

Investigations undertaken by the Fraunhofer Institute for Process Engineering and Packaging have found that a high germ count in packaging is primarily attributable to contamination **in the filling plant** (see Section 3.6). It is therefore recommendable to include the in-plant packing logistics in

[6] The Fraunhofer Institute for Process Engineering and Packaging in Freising has published guidelines for germ carriage in packaging and packing substances made of non-absorbent materials (see Hennlich (2004)). Requirements on germ carriage in milk packaging can furthermore be found at IDF (Bulletin 300/1995 - Technical guide for the packaging of milk and milk products – Third edition) and FDA (PMO 2007: Appendix J - Standards:Fabrication of Single-Service Containers & Closures for Milk and Milk Products Grade "A" Pasteurized Milk Ordinance (2007 Revision)). ABMI has published guidelines for drinks packaging (https://www.abm-industry.org/documents/dynamiccontent/abmi_tciii1.pdf - appendix 2).

[7] See, inter alia, Hennlich/Duong (2007)

the hygiene management system. This applies not only to packaging and packaging aids which come into direct contact with the product, but also to such applications as pouring aids, which could infiltrate the sterile zone inside filling machines and possibly need to be sterilized. The following action, among other things, is recommendable:

- Store the packaging in its original packing
- Cover the packaging provided near the filling machine
- Hygiene training for personnel entrusted with handling the packaging
- Cover/stow away unused packaging at the end of the shift
- Compile process instructions for handling the empty containers left in the machine at the end of a shift, with reference to the machine manufacturer's operating instructions

The storage conditions, the temperature and the moisture content of the packaging provided ready for filling can influence the processing properties of the packaging. In the case of deep-draw machines, for instance, a low temperature in the core of rolls of film or foil in winter can lead to problems during forming in the FFS machine. Manufacturers of machinery therefore formulate storage suggestions and recommendations for "acclimatising" the packaging before filling.

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General requirements on packaging for filling machines of VDMA Hygiene Classes IV and V

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Appendix I (informative)
Notes on quality criteria for specific packaging with particular relevance for filling machines of VDMA Hygiene Classes IV and V

1. Preformed cups
- Packing of the cups and lids (not touching the cardboard carton!)
- Wettability of surfaces with sterilization agents
- Special forms (sterilizability)
- Sealability
- Ease of de-stacking the cups

2. Bottles/preforms
- Ratio of recycled granulate
- Special forms (sterilizability)
- Wettability of surfaces with sterilization agents (effects of waxing preforms)
- Ambient air drawn in during cooling after forming (test for germs carried upstream from the filler)
- Handling of packaging by operatives (do not feed in preforms which have fallen onto the floor)

3. Containers on cardboard and paper basis
- Wettability of surfaces with sterilization agents
- Storage conditions (air humidity, temperature)

4. Closures
- Wettability of the surfaces with the sterilization agent (slip agent residues![8])
- Closures not sterilizable by chemical agents (supply of pre-sterilized closures)
- Special closures (sterilizability, tightness)
- Handling of packaging by operatives (do not feed in closures which have fallen onto the floor)

5. Thermoformable films and lid films
- Effects of a recipe change (film, sealing lacquer, etc.)on the wetting and sealing properties
- Wettability of surfaces with sterilization agents
- Expansion/shrinkage in length and breadth (deep-drawn film)
- Where multi-layered films are concerned, the barrier layer may not rip or thin out too much (ensure the barrier characteristic for products with a long shelf life)
- Core temperature of the roll of film

[8] Slip agents, such as erucic acid, used on closures can reduce the level of sterilization. It is therefore not recommended to use such substances in aseptic applications. If such agents must nevertheless be deployed for technical reasons, prior sterilization tests should examine whether the required level of sterilization is achieved.

Appendix II (informative)
Check list - Preformed cups and lids[9]

General details of the packaging	Material/container: Filling volume: Supplier: Date of manufacture:	**Remarks:**
Delivery	• Packed in plastic film or plastic containers (lids) (no direct contact with the cardboard carton!) • Open containers not able to be stacked: packed standing on their heads • No damage • No electrostatic charging • Recipe change notified? • Geometry change notified?	
Dimensions and tolerances:	• **Cup edge:** Diameter: Plus tolerance: Minus tolerance: • **Cup shoulder:** Diameter: Plus tolerance: Minus tolerance: • **Thickness of cup edge:** Plus tolerance: Minus tolerance: • **Cup ovality:** • **Lid diameter:** Plus tolerance: Minus tolerance:	
Requirements on sterilizability	• **Form/geometry** examined for sterilizability? (sterilization test) If a change in geometry has been notified, check whether a renewed sterilization test is necessary; if appropriate, adapt microbiological quality controls. • **Cup/lid material** examined for suitability of the sterilization method used? (effects of the sterilization method on dimensional accuracy, migration properties, sealability) If a change of recipe has been notified, check whether a renewed sterilization test	

[9] The following check list makes no claim to completeness. Using preformed cups and lids as an example, it summarises matters which have proven to be relevant in aseptic filling practice. The dimensions and tolerances of the packaging are usually determined in dependence on the application. The check list therefore solely states key points for which values should be determined in agreement with the manufacturer of the machinery and the packaging supplier. The structure of this check list can serve as an example for structuring check lists for other packaging.

	is necessary; if appropriate, adapt microbiological quality controls. • **Lids** examined for suitability of the sterilization method used? (no deformation, no misting, no impairment of the sealing properties) If a change of recipe has been notified, check whether a renewed sterilization test is necessary; if appropriate, adapt microbiological quality controls. • **Initial germ count (surfaces to be sterilized)[10]:** o Agreed target value (at least 70% of the delivery quantity): o Increased germ count (not more than 20% of the delivery quantity): o Maximum admissible initial germ count (number of KBE per packaging unit; not more than 10% of the delivery quantity): o If appropriate, requirements on the composition of the germ flora (e.g. ratio of spore formers): o Agreed method of determining the initial germ count:	
Packaging properties	• Wettability of the surfaces to be sterilized with the foreseen sterilization media • Test on practical sealability with a trial sealing device • Ease with which the cups can be lifted out	

[10] The initial germ count of cups and lids directly before filling is decisive. Suitable action should therefore be taken to ensure that the microbiological quality upon delivery is retained during storage and provision for filling.

Appendix III (informative)
Number of non-sterile packages in dependence on the initial germ count of the package and the germ reduction rate

Surface germ count	Number of spores*)		Failure rate**)		
per 100 cm^2	per 100 cm^2	per litre package 800 cm^2 (Tetra Brik)	given a mean logarithmic germ reduction rate of		
			4	5	6
0,1	0,03	0,24	$2{:}10^6$	$2{:}10^7$	$2{:}10^8$
0,5	0,15	1,2	$1{:}10^5$	$1{:}10^6$	$1{:}10^7$
1,0	0,3	2,4	$2{:}10^5$	$2{:}10^6$	$2{:}10^7$
5,0	1,5	12,0	$1{:}10^4$	$1{:}10^5$	$1{:}10^6$
10,0	3,0	24,0	$2{:}10^4$	$2{:}10^5$	$2{:}10^6$

Source: Tetra Pak Holdings GmbH Research, Stuttgart 2018

*) Based on the assumption: 30 % of germs are spores
**) Calculated for a package containing 1000 cm^3

Example: correlation between failure rate und initial germ count of the packaging: on the assumption that 30 % of the germs are spores*) and are distributed evenly over the package

Failure rate = (total germ count***/package) x spore ratio x germ reduction rate

0,5 germs per 100 cm^2 are measured as the surface germ count of the packaging. For packaging 800 cm^2 in size, the following results for a machine with a mean logarithmic germ reduction rate of 5 (=10^{-5}):

Total germ count/package = 0,5 germs/100cm^2 x 800 cm^2/package = 4 germs/package

Failure rate = (4 germs / package) x 0,3 x 10^{-5} = 1,2x 10^{-5} spores/package

or 1.2 surviving spores per 10^5 of packaging, thus under the aforesaid framework conditions, one non-sterile package per 100,000 filled units is to be expected.

*** germ count: mesophilic aerobic germ count

Appendix IV (informative) Requirements on the initial germ count of packaging and packaging means

The following table contains a compilation of literature findings on requirements for initial contamination of the surfaces of packaging materials that come into contact with the product. Hennlich (2004) and ABMI (2010) contain information on determining the surface microbial count.

Packaging type / source	Total surface bacterial count	Moulds and yeasts	Enterobacteriacae
Standard values for **packaging materials made of non-absorbent material** ex works **(foils, lid membranes/plates, punched)** **Hennlich (2004)**	≤ 2 cfu per 100 ml	≤ 1 cfu per 100 ml	undetectable
Standard values for **packaging materials made of non-absorbent material ex works (container ≤ 500ml, no bottles)** **Hennlich (2004)**	≤ 10 cfu per 500 ml	≤ 1 cfu per 500 ml	undetectable
Standard values for **packaging materials made of non-absorbent material ex works (containers > 500ml, no bottles)** **Hennlich (2004)**	≤ 5 cfu per 500 ml	≤ 1 cfu per 500 ml	undetectable
Bottles, Preforms, Closures Average values per packaging unit from 10 examined packaging units **ABMI (2010), Appendix 2**	**Preforms (outside + inside)** average: < 10 cfu maximum t: 50 kBE **Closures (outside + inside)** average: < 10 cfu maximum: 50 cfu **Bottles (inside)** average: < 10 cfu E maximum: 50 cfu **Bottles (outside + inside)** average: < 20 cfu maximum: 100 cfu	n.a.	n.a.
FDA (PMO 2007: Appendix J - Standards:Fabrication of **Single-Service Containers & Closures for Milk and Milk Products Grade "A"** Pasteurized Milk Ordinance (2007 2015 Revision)	75% of samples: **Ausspülverfahren Behälter < 100ml:** ≤ 10 cfu **Ausspülverfahren Behälter ≥ 100ml:** ≤ 50 cfu **Swab-Test:** ≤ 50 cfu / 50 cm²		**All samples: free of coliform organisms**
Cups, lids Bosch Packaging Technology Packaging material specification (bioburden)	70% of cups and lids: < 2 cfu 20% of cups and lids: ≥ 2 cfu and ≤ 5 cfu 10% of cups and lids: > 5 cfu and ≤ 10 cfu	n.a.	n.a.