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Food Processing Machinery
and Packaging Machinery

Hygienic Filling Machines for Liquid and Viscous Foods – Classification and Typical Fields of Application

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Preliminary remark on the second edition

This VDMA document was revised six years after the first edition had been published. In doing so experiences with the classification of hygienic filling machines were considered as well as feed back to the stated shelf life for typical products

Preliminary remark on the third edition

The following changes have been made since the second edition:

- Harmonization of definitions with other documents of the same documents series (section 2)
- Supplementing the classification scheme of hygienic filling machines with additional classification criteria (section 3)
- Introducing a decision tree for the appropriate selection of VDMA Class of Hygienic Filling Machines (Appendix I)
- Update of examples for typical fields of applications (section 5)
- Update of references

1 Introduction

It has always been the aim of food manufacturers to prevent premature spoilage of their products. In the field of filling technology, it is important to ensure that the used machine technology is appropriate to the filled product. When selecting the machines, first of all the consistent implementation of hygienic design criteria has to be followed. Furthermore, depending on the application, the machines may be equipped with additional functions for improving product protection. At the upper end of the scale are the aseptic machines whose requirement profile are e.g. described in VDMA Documents Food Processing Machinery and Packaging Machinery No.11. Below this level of performance there has so far been no uniform terminology for machine concepts defined. Various terms such as “semiaseptic”, “clean or ultraclean designs” are used by machine manufacturers for comparable machine concepts. Sometimes, however, the same term means different machine concepts for different manufacturers. This was the starting point for a working group within the Packaging Machinery Division of VDMA to develop a classification of hygienic filling machines on the basis of the features with which the machines are equipped. The aim is to provide the user with a reference base for comparing the machine concepts of different manufacturers. A list with typical fields of application from each machine category should help the user to select the machine category suitable for a particular product to be packaged. However, it has to be pointed out that a clear allocation of products to machine categories is often difficult due to the diversity and variability of product characteristics. Accordingly, the hygiene configuration required for the filling machine should always be adapted based on the specific application.

2 Definitions and abbreviations

Terms and definitions	Definition	Explanation
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 sterilised, 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).

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.
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 113[1]
Sterile zone of the machine interior	Zone of the machine interior in an aseptic filling machine that must be kept commercially sterile after sterilisation has taken place to prevent recontamination of the commercially sterile product during the filling process.	
Test microorganism	Microorganisms used to test the sterilization equipment of a filling machine.	Test microorganisms should have high, defined resistance to the sterilization method being tested; they should be easy to detect and have no public health significance. The description of a test microorganism should include the following characteristics: name, precise strain description (ATTC no. or DSM no.), batch no. (for ready spore suspensions), D-value, possibly Z-value.

[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.

Inoculation	Artificial contamination of a microorganism carrier with test microorganisms.	

3 Categories of hygienic filling machines for liquid and viscous foods

			Hygienic filling machine of hygiene class ...				
			I (basic)	II	III	IV	V (aseptic)
Design principles	1	Designed according to EN 1672-2	Yes	Yes	Yes	Yes	Yes
	2	Cleaning of product contact surfaces (internal parts of product line incl. dosing)	Preferably CIP	CIP	CIP	CIP	CIP
	3	Cleaning of indirect product contact surfaces (e.g. splash zone)	Manual	Manual	Preferably automatic cleaning	Preferably automatic cleaning; complementary manual cleaning if appropriate	Preferably automatic cleaning; complementary manual cleaning if appropriate
	4	Cleaning of non product surfaces (e.g. rest of machine, packaging decontamination area)	Manual	Manual	Manual	Preferably automatic cleaning	Preferably automatic cleaning
	5	Disinfection/sterilisation of product contact surfaces (internal parts of product line incl. dosing)	Optional	Disinfection using heat or chemical disinfectants Target: killing of vegetative germs	Disinfection using heat or chemical disinfectants Target: killing of vegetative germs	According to VDMA Doc. 10	According to VDMA Doc. 11
	6	Disinfection/sterilization of machine cabinet (enclosed areas)	No	No	Optional Target: killing vegetative germs	Acoording to VDMA Doc. 10	Acoording to VDMA Doc. 11
	7	Disinfection of packing material	No	No	Yes	Acoording to VDMA Doc. 10	Acoording to VDMA Doc. 11
	8	Prevention of recontamination of product line (valve cluster to filler hopper till filling nozzle) using aseptic barrier	No	No	Optional	Yes	Yes
	9	Prevention of recontamination during packaging decontamination – transport – filling – closing, air treatment	No	No	Optional	Yes	Yes
	10	Automatic feedback control of parameters substantial for hygienic processing, e.g.: - Temperature of saturized steam - Sterile air consumption - H2O2 consumption - Temperature of sealing tools - Temperature and concentration of CIP media - Valve positions	No requirements	Monitoring Paramters relevant to CIP	Monitoring Parameters relevant to CIP and	Monitoring parameters relevant for CIP and sterilissation of product route Other parameters: According to requirements of applications and specified by machine user	Maximum technical safeguarding according VDMA Doc. 11
	11	Any ingress by operator into the sterile zone of the machine interior will trigger to change machine status in "unsterile".	-	-	-	No	Yes
	12	Protection against faulty operation by means of control and feedback control systems	No	No	No	According to user requirement specification	Maximum technical safeguarding

4 Criteria for selection of VDMA Hygiene Class

Appendix 1 provides an overview of essential criteria for the selection of the appropriate hygiene class of filling machines by means of a decision tree. The following criteria are considered:

- Microbiological stability of product at ambient temperature
- pH-value (above or below and equal 4.6)
- intended distribution chain and storage (refrigerated or at ambient temperature)
- product stabilization measures prior or after filling (e.g. hot filling, pasteurization after filling, autoclavation, carbonating)
- intended shelf life
- special cleaning requirements

5 Typical fields of application of hygienic filling machines

Typical products which are filled on hygienic filling machines are listed below. These products are characterized with regard to the criteria of "microbiological state", "pH", "distribution channel" and "minimum shelf life data (examples from practice)". In this way the reader is given some assistance with classifying products which are not listed. It has to be pointed out with regard to the criterion "minimum shelf life data (examples from practice)" that these are values taken from packaging practice. Microbiological reasons are not always the limiting factors determining minimum shelf life. Organoleptic reasons, for example, may also be decisive in establishing the minimum shelf life data. No precise shelf life predictions can be made for individual products with regard to the microbiological deterioration of the product. Due to the multiplicity of factors in production, filling, distribution and storage affecting deterioration of the product it is in the final analysis left to the business policy of the filling company to establish which shelf life data are justifiable. This explains why only time periods can be specified in the "minimum shelf life" column.

5.1 VDMA Class I - Machines

Machine class	Product examples	Microbiological state of product	pH	Distribution channel	Minimum shelf life (examples from practice)[2]
I	Edible Oil	Nearly germ-free (no growth at water content < 0.5 %)	-	ambient temperature	several months
	Margarine (80% fat) In tub	Nearly germ-free	≤ 4.6	temperature-controlled to 15-18 °C	up to 3 months
	Jam, hot filled or pasteurized after filling	Free of viable microorganisms (after filling or pasteurization)	≤ 4.6	ambient temperature	> 12 months
	Fruit juice, hot filling	Free of viable microorganisms	≤ 4.6	ambient temperature	> 6 months
	Crushed tomatoes in tins (with post-pasteurization)	Free of viable microorganisms (after postpasteurization)	≤ 4,6	ambient temperature	> 1 year
	Condensed milk (with post-sterilization)	Germ-free (after poststerilization)	approx.. 6.2	ambient temperature	> 1 year
	Spirits, alcohol content > 32 %	Free of viable microorganisms	-	ambient temperature	> 1 year
	White wine, < 4g sugar/l, glass bottle	Largely germ-free	< 3.4	ambient temperature	> 1 year
	Creamery butter		> 6.4	refrigerated to ≤ 7 °C	< 50 days (tub or 250g portion) < 90 day (butter in small portions)
	Meat pies (with post-sterilization)			ambient temperature	> 1 year
	Petfood (with post-sterilization)			ambient temperature	> 1 year

[2] Data on minimum shelf life of products drawn from practice. For many products microbiological reasons are not limiting for determining minimum shelf life.

5.2 VDMA Class II - Machines

Hot filled products and products thermally stabilized after filling by means of pasteurization or autoclaving

Machine class	Product examples	Microbiological state of product	pH	Distribution channel	Minimum shelf life (examples from practice)[3]
II	Low-acidity apple juice spritzer, CO2 content < 4g/l, in glass bottles and then pasteurized	Nearly germ-free	≤ 4.6	ambient temperature	> 6 months
	Cider, alcohol content 2% by vol., CO2 content < 4g/l, in glass bottles then pasteurized	Nearly germ-free	≤ 4.6	ambient temperature	> 6 months
	Nonalcoholic beer CO2 content > 5g/l in glass bottles then pasteurized	Nearly germ free	≤ 4.6	ambient temperature	> 6 months
	Fruit juice, hot filling	Free of viable microorganisms	≤ 4.6	ambient temperature	> 6 months
	Jam, hot filled or pasteurized after filling	Free of viable microorganisms (after hot-filling or pasteurization)	≤ 4.6	ambient temperature	> 12 months
	Ketchup, savoury sauces, hot filled	Free of viable microorganisms (after hot-filling	≤ 4.6	ambient temperature	> 6 months
	Ready to cook soups, filled cold and then sterilized		> 4.6	ambient temperature	> 6 months

Other products

Machine class	Product examples	Microbiological state of product	pH	Distribution channel	Minimum shelf life (examples from practice)[4]
II	Natural yogurt	Desired acid-forming cultures	≤ 4.6	Refrigerated	12-15 days
	Curd cheese	Desired acid-forming cultures	≤ 4.6	refrigerated	12-15 days
	Certified milk, pasteurized	Nearly germ-free	approx. 6.6	refrigerated	8 days
	Fresh cream, pasteurized	Nearly germ-free	Up to 6.6	refrigerated	2-3 weeks
	Red wine filled in disinfected glass bottles	Nearly germ free	> 3.4	ambient temperature	> 1 year
	Beer, alc. content appr. 5% by volume CO2 content > 5g/l	Nearly germ free	≤ 4.6	ambient temperature	> 6 months

[3] Data on minimum shelf life of products drawn from practice. For many products microbiological reasons are not limiting for determining minimum shelf life.
[4] Data on minimum shelf life of products drawn from practice. For many products microbiological reasons are not limiting for determining minimum shelf life.

Machine class	Product examples	Microbiological state of product	pH	Distribution channel	Minimum shelf life (examples from practice)[4]
	Delicatessen salads with preservatives	Free of spoiling microorganisms	≤ 4.6	refrigerated	< 40 days
	Delicatessen salads without preservatives	Free of spoiling microorganisms	≤ 4.6	refrigerated	< 25 days
	Sparkling water	Free of viable microorganisms	≤ 4.6	ambient temperature	> 6 months
	Softdrinks, carbonated		≤ 4.6	ambient temperature	> 6 months
	Mayonnaise with preservatives	Nearly germ-free	≤ 4.6	ambient temperature	appr. 6 months

5.3 VDMA Class III - Machines

Machine class	Product examples	Microbiological state of product	pH	Distribution channel	Minimum shelf life (examples from practice)[5]
III	Natural yogurt	Desired acid-forming cultures	≤ 4.6	refrigerated	2-4 weeks
	Carbonated drinking yogurt, CO_2 content < 4g/l, in aluminum can	Pasteurized	≤ 4.6	refrigerated	> 6 months
	Curd cheese	Desired acid-forming cultures	≤ 4.6	refrigerated	2-4 weeks
	Fresh cream, pasteurized	Nearly germ-free	6.6	refrigerated	up to 3 weeks
	Fruit yogurt	Desired acid-forming cultures	≤ 4.6	refrigerated	2-4 weeks
	Jam, cold filled	Nearly germ-free	≤ 4.6	ambient temperature	12 months
	Apple juice spritzer CO_2 content < 4g/l with preser-vatives or cold sterilized , not pasteurized after filling	Nearly germ-free	≤ 4.6	ambient temperature	> 6 months
	Smoothy refrigerated, not pasteurized	Nearly germ free	≤ 4.6	refrigerated	Few days
	White wine > 4g sugar/l, filled in disinfected glass bottles, not pasteurized after filling	Nearly germ free	≤ 4.6	ambient temperature	> 12 months
	Wine, nonalcoholic in disinfected glass bottle	Nearly germ-free	≤ 4.6	ambient temperature	> 12 months
	Beer, nonalcoholic in disinfected glass bottle	Nearly germ-free	≤ 4.6	ambient temperature	> 12 months
	Cider alcohol-content 2% by volume CO_2 content < 4g/l not pasteurized after filling	Nearly germ-free	≤ 4.6	ambient temperature	> 6 months
	Margarine (<60% fat) in tub[6]	Nearly germ-free	≤ 4.6	refrigerated	up to 3 months
	Mayonnaise without preservatives cold fiilling	Free of viable microorganisms	≤ 4.6	ambient temperature	< 6 months

[5] Data on minimum shelf life of products drawn from practice. For many products microbiological reasons are not limiting for determining minimum shelf life.
[6] If the microbial load of the tub is high it may be necessary to use machines of VDMA class V.

5.4 VDMA Class IV - Machines

Machine class	Product examples	Microbiological state of product	pH	Distribution channel	Minimum shelf life (examples from practice)[7]
IV	Natural yogurt	Desired acid-forming cultures	≤ 4.6	refrigerated	Appr. 30 days
	Stirred fruit yoghurt	Free of spoiling microorganisms	≤ 4.6	refrigerated	Appr. 4 weeks
	Curd cheese	Desired acid-forming cultures	≤ 4.6	refrigerated	appr. 30 days
	ESL milk[8]	Subjected to ultrapasteurisation, Free of vegetative microorganisms	6.6 – 6.8	refrigerated	> 3 weeks
	ESL-Milch[9]	Subject to microfiltration	6.6 – 6.8	refrigerated	2-3 weeks
	Rice pudding	Free of vegetative microorganisms	> 6.5	refrigerated	4-6 weeks
	Pudding Refrigerated (with and without cream)	Free of vegetative microorganisms	> 6.5	refrigerated	4-6 weeks
	Mixed milk drinks	Nearly germ--free	> 4.6	refrigerated	ca. 4 Wochen
	Fruit yogurt, heat-treated[10]	Free of viable microorganisms	≤ 4.6	not refrigerated	ca. 8 Wochen
	Crushed tomatoes, cold-filled	Free of viable microorganisms	≤ 4.6	not refrigerated	> 6 Monate
	Smoothy,sterilized cold filling	Germ-free	≤ 4.6	refrigerated (for quality reasons)	9 Monate
	Ice tea, CO_2-free	Free of viable microorganisms	≤ 4.6	not refrigerated	> 6 Monate
	Wine (in cup or carton)	Nearly germ-free	≤ 4.6	not refrigerated	ca. 1 Jahr
	Fruit juice, Cold-filled[11]	Germ-free	≤ 4.6	not refrigerated	mehrere Monate
	Non carbonated soft drinks cold filled	germ free	≤ 4.6	not refrigerated	< 6 Monate
	Low-acidity apple juice spritzer, without pre-servatives, not cold sterilized, not pasteurized after filling	Free of viable microorganisms	≤ 4.6	ambient temperature	> 6 months
	Dressings fat content < 50%	Free of viable microorganisms	≤ 4.6	ambient temperature	> 6 months
	Ketchup, cold filled (oxygen-proof package)	Free of viable microorganisms	≤ 4.6	ambient temperature	> 6 months
	Savoury sauces, cold filled	Free of viable microorganisms	≤ 4.6	ambient temperature	> 6 months
	Delicatessen salads, without preservatives	Free of viable microorganisms	< 5	refrigerated	< 40 days
	Liquid dough	Free of viable microorganisms	< 6	refrigerated	< 3 months

[7] Data on minimum shelf life of products drawn from practice. For many products microbiological reasons are not limiting for determining minimum shelf life.
[8] ESL: Extended Shelf Life. ESL milk can, for example, be subjected to ultrapasteurization or microfiltration
[9] ESL: Extended Shelf Life. ESL milk can, for example, be subjected to ultrapasteurization or microfiltration
[10] Sour milk product according to the German Labeling Directive.
[11] In the case of critical products it may be necessary to use machines of class V.

5.5 VDMA Class V - Machines (aseptic packaging machines according to VDMA Doc. No. 11)

Machine class	Product examples	Microbiological state of product	pH	Distribution channel	Minimum shelf life (examples from practice)[12]
V	UHT cream	Germ-free	6.6	ambient temperature	>. 3 months
	UHT milk	Germ-free	6.6	ambient temperature	> 3 months
	Condensed milk	Germ-free	6.5	ambient temperature	up to 9 months
	Mineral water, not carbonated	Nearly germ-free as per the German Mineral Water Ordinance	> 6	ambient temperature	12 to 18 months
	Ice tea, not carbonated	Germ-free	> 4.6	ambient temperature	approx. 12 months
	Café au lait, not refrigerated after filling	Germ-free	approx.. 6.7	ambient temperature	several months
	Pudding, UHT-heated not refrigerated after filling	Germ-free	> 6.5	ambient temperature	up to 12 months
	Sauces, soups	Germ-free	6 - 7	ambient temperature	several months
	Mixed milk drinks	Germ-free	> 4.6	ambient temperature	> 3 months
	Soya milk	Germ-free	> 4.6	ambient temperature	> 3 months
	Vegetable juice	Germ-free	> 4.6	ambient temperature	> 3 months
	Non carbonated soft drinks Cold filling	Germ-free	> 4.6	ambient temperature	Several months
	Fruit yogurt	Germ-free	> 4.6	ambient temperature	> 3 months
	Smoothy, sterilized cold filling	Germ-free	> 4.6	refrigerated (for quality reasons)	9 months

[12] Data on minimum shelf life of products drawn from practice. For many products microbiological reasons are not limiting for determining minimum shelf life.

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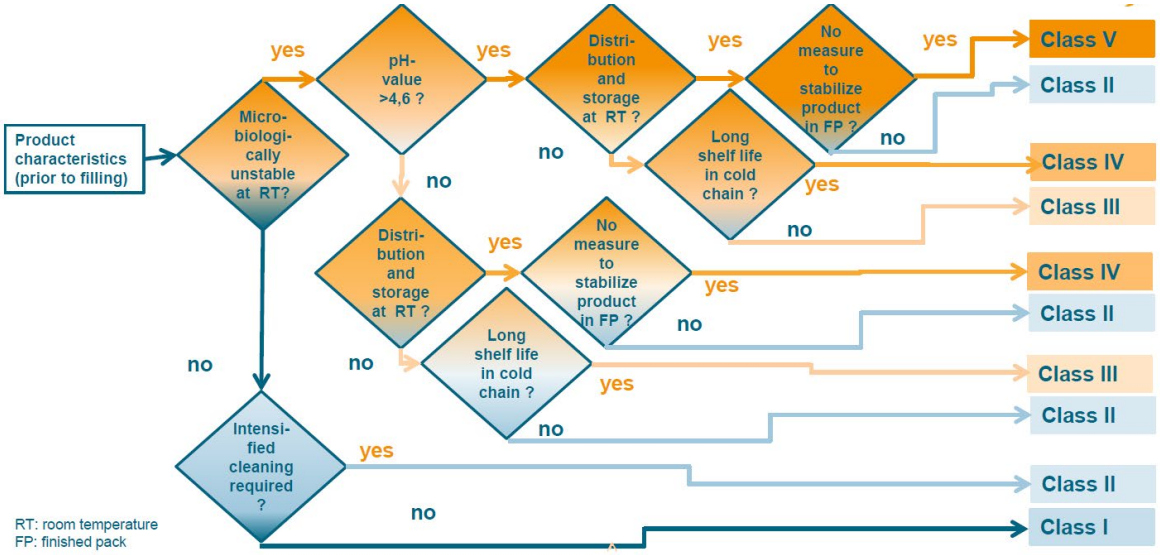
Appendix 1 – Criteria for appropriate selection of VDMA Class of Hygiene Filling Machines (decision tree)



Explanations on decision tree

Requirements concerning microbiological status of product prior to filling

- Requirements for filling microbiologically unstable products with filling machines of Hygiene Class IV or V intended for distribution and storage at room temperature: Product free of both, 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 (commercially sterile product).
- Requirements for ESL-products: pasteurized product with extended shelf-Life, (to the most possible extend) free of microorganisms capable of reproducing under refrigerated conditions in the cold chain.
  Note: Reproduction of spoiling microorganisms is dependent on the permitted maximum temperature in the cold chain. Therefore the selection of the appropriate Hygiene Class is sensitive to the maximum temperature applied for the specific cold chain under consideration.
- Requirements microbiologically unstable products intended for distribution and storage of microbiologically unstable products in cold chain: low germ load

Criteria for characterizing the microbiological stability of products:

- Water activity (a_W-value), sugar concentration, salt concentration, pH-value, …

Examples for required intensified cleaning

- Avoidance of cross-contamination (coloring, flavors, foodallergens, critical food-ingrendients…)

Product stabilization in the finished pack

- E.g. by means of carbonating, hot filling, addition of preservatives, pasteurization after filling, autoclaving