Aseptic Production Lines:
Unsterility Risks in Product and Feed Lines
- Planning and Installation Faults
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This publication was drawn up by the Working Party for Interface Problems in Aseptic Plants in the Packaging Machines Division of the VDMA and was published originally in 2002 in German under the title "Aseptische Produktionslinien: Unsterilitätsrisiken bei Produkt- und Versorgungsleitungen - Planungs- und Installationsfehler". In 2012 this document was reviewed and updated. It is available as a downloadable file 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, 60528 Frankfurt am Main; Fax: +49 69 6603-1211.

1 Introduction

The need to run aseptic production lines at high levels of availability also increases the risks attributable to faults in the installation of product and feed lines. Incidences of partial unsterility and cleaning errors are of little significance in production units having a daily cleaning and sterilization routine. In the case of relatively long production cycles, however, this may give rise to incidences of unsterility some of which may have catastrophic financial consequences.

Typical of this group of causes are cases of unsterility which set in after a few hours of production and then exhibit a rising trend. In general, such occurrences are attributable to quite small infections which were able to develop on account of the time factor. A further phenomenon associated with this are cases of what are known as "Monday-morning unsterility". This involves the empirical finding that incidences of unsterility occur more frequently after weekends and public holidays. These are also attributable as a rule to cases of partial unsterility which can grow in the cleaned and sterilized plant in the days when no production takes place.

The following compilation of risk factors in product and feed lines is based on the experience of members of the Working Party for Interface Problems in Aseptic Plants in the Industry Association for Food Processing Machines and Packaging Machines Division of the VDMA. It is intended as an aid for production engineers in filling plants in the course of their duties in preventing cases of unsterility in mature plants and does not claim to be exhaustive. When eliminating any defects found, collaboration with an experienced plant constructor is recommended.1

The compilation concentrates on risks based on planning and installation faults. The weak points enumerated are found in practice in products deposits of which, in particular, are difficult to remove, thereby further increasing the magnitude of the cleaning problem.

Hygiene risks in individual components such as pumps and valves are not considered here. In general, in aseptic plants only components suitable for applications of this kind should be employed. Problems arising in the field of maintenance of aseptic plants are likewise not addressed here. Readers interested in such matters are referred to the Check List "Quality Assurance and Maintenance" drawn up by the same working party.2

1 Suggestions for improvements and additions may be sent to the following address: Fachverband Nahrungsmittelmaschinen und Verpackungsmaschinen im VDMA, Lyoner Straße 18, 60528 Frankfurt am Main; Fax: +49 69 6603-1211.
2 Check List "Quality Assurance and Maintenance", VDMA-Documents Food Processing Machinery ans Packaging Machinery, No. 3.2nd edition 2008. This check list is downloadable from the internet (www.vdma.org/nuv). A list with all VDMA-Documents on the topic "aseptic and hygienic filling of foods" is also available at the internet (www.vdma.org/nuv , section "Technology").
2 Construction guidelines for product lines and lines for feed media to prevent incidences of unsterility

The most important requirement on an aseptic production line is the guaranteed certainty of the aseptic condition of all the individual elements acting in conjunction, including their connecting and feed elements. This can only be guaranteed when as early as the planning and construction stage the general design principles for hygiene-compatible construction (e.g. EN 1672-2) and the preconditions and technical rules described below for the construction of product lines and lines for feed media are taken into account. Of course all of the components used must be suitable for the intended purpose and for aseptic operation.

Experience shows that the demands of theory and their implementation in practice often pull in opposite directions. Infringements of the guidelines set out below are frequently encountered in practice. These do not necessarily have to result in incidences of unsterility but have been repeatedly identified as causes thereof.

2.1 Product lines

The design of product lines commences with the assessment of the limits on the space available. The height of the room, existing ceiling joists, any differences in height between the processing and filling rooms together with their position must be assessed before technical planning begins and, if necessary, be adapted by means of building work.

**Cross-sectional areas** have to be determined with respect to both the capacity of the filling machines and the cleaning systems.

**The overall gradient** of the product line must be designed in such a way that complete discharge and filling of the line are guaranteed.

**Cleaning silhouettes** may be produced, for example, by abrupt changes in piping, changes in cross section, in the area of air pockets, elbow fittings and overdimensioned valves, etc. These are to be avoided.

It must be possible to **clean the product lines** separately from any sterile tank present in the system.

**Cleaning capacities** have to be of such a volume or regulated in such a way that the flow rates necessary for thorough cleaning can be achieved. 2 m/s in the major line is recommended.

“**Dead lengths of pipe**” in which product may reside for relatively long periods without being displaced are to be avoided.
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End nodes should be installed in each product line coming from the sterile tank. These are to be constructed in such a way that either there is permanent flow through the line leading to the end node or the product located therein is replaced at regular intervals.

Pivot bend panels are to be integrated into the piping network in such a way that no twisting effects on the screwed connections can arise.

Pipe fastenings have to be fitted in such a way that thermal stresses cannot act on pipe connections.

Screwed pipe connections without lateral guides are not suitable for aseptic product lines. For pipe connections reference should, moreover, be made to DIN 11864-1 (Fittings of stainless steel for the aseptic, chemical and pharmaceutical industry - Part 1: Aseptic screwed pipe connection, standard type), DIN 11864-2 (Stainless steel fittings for the aseptic, chemical and pharmaceutical industries - Part 2: Aseptic flanged pipe connection, standard type), and DIN 11864-3 (Stainless steel fittings for the aseptic, chemical and pharmaceutical industries - Part 3: Aseptic clamp pipe connection, standard type).

Valves are to be installed in such a way that dead spaces are avoided as far as possible. Furthermore, care has to be taken that sealing membranes and expansion joints are not subjected to stress due to excessively powerful surges.

Measuring instruments and sensors must be installed in such a way that dead spaces and cleaning silhouettes are avoided.

Welded joints must be produced in professional manner under an atmosphere of inert gas. This applies in particular to subsequent modifications of the piping system. Nondestructive testing of weld points is recommended.

Pumps must be installed in such a way that they can be completely emptied.

2.2 Pipes for feed media

Compressed air lines are to be laid in such a way that no condensed water can seep into the aseptic systems and valves. They are, in addition, to be of such a size that pressure fluctuations are reduced to a minimum.

Cooling water lines are to be safeguarded against penetration of other media such as steam and compressed air. In particular, any hot water injectors installed are to be monitored with regard to this.

Steam feed lines are to be sufficiently well drained that no condensed water can penetrate into the systems. Any water condensing in the systems must be reliably drained away.

Exhaust and incoming air lines are to be designed in such a way that condensed water is reliably prevented or drained away.
2.3 Exhaust process air

Exhaust air systems are to be designed in such a way that any recontamination of sterile regions of filling units is precluded. It is recommended that the manufacturer of the filling machine be involved in the design of the exhaust air system.

3 Installation faults – Case studies

A compilation of installation faults which occur in practice is presented below.

3.1 Case study: “Liquid and air pockets”

Further examples of air and water pockets including possible solutions are shown below.
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Problem 3:
In the event of relatively long production stoppages, e.g. at the weekend or over public holidays, the liquid together with any cleaning residues present in it may dry out onto pipes. The deposited layer grows over time with the consequence that microorganisms survive the sterilization of the product line and can multiply under the protection of the film. Infection ensues when parts of the deposit are detached from the pipe wall during production.

Prevention:
1. Planned avoidance of water pockets. This is usually possible in practice and, from experience, also easier to implement than aseptic drainage of the length of pipe. Subsequent modification of a faulty installation is usually associated with high costs.
2. If water pockets are unavoidable blowing the pipe out with sterile air after cleaning or prior to sterilization is a possible solution. If this is not possible it is absolutely essential to provide a method of drainage. (However, the drainage valve itself presents a risk of unsterility.)
3. Higher sterilization temperature (Improved microbicidal action. Does not eliminate the source of risk. If the deposited layer is sufficiently thick, microorganisms can survive even elevated sterilization temperatures.)
4. Ensure sufficiently high flow rate during production and cleaning. (Counteracts build-up of deposit. Does not eliminate the source of risk.)

3.2 Case study: “Sagging lines”

Water pockets form in pipes laid horizontally or with a small gradient. These “sag points” are often scarcely discernible with the naked eye.

Problem:
See “Water pocket” case study

Prevention:
Ensure adequate number of support points and gradient.
3.3 Case study: “Cleaning silhouette”

In a length of pipe of relatively large cross section which is filled at the start of production an air pocket forms during production due to outgassing from the product. This can give rise to “cleaning silhouettes” during cleaning.

![Diagram](image)

Problem:
A “cleaning silhouette” favors the build-up of a deposit in the length of pipe concerned whose thickness grows with the passage of time. Under this deposit microorganisms can survive the sterilization of the product line. This results in infection of the product when parts of the deposit are detached from the pipe wall during production.

Prevention:
Planned avoidance of air pockets.
Provision of means for venting is absolutely essential if air pockets cannot be avoided.
Furthermore, attention should be paid to an adequate flow rate for the cleaning media.
3.4 Case study: “Change in pipe cross section”

When narrowing or widening of a pipe is incorrectly carried out water pockets or air bubbles may form. There is the risk of cleaning silhouettes in zones of low turbulence.

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| Problem: see “Liquid and air pockets” and “Cleaning silhouette” examples. |
| Prevention |
| Replacement of defective tapered lengths of pipe by hygienically safe ones (see figure) and ensure adequate flow rate during cleaning. |
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| Transitions of inherently correct shape form an undrainable water pocket due to incorrect installation position. |
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| “Pipe widening” |
| eccentric reducing pipe |
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3.5 Case study: “Dead lengths of pipe”

Lengths of product line which, for example, are brought into operation only during a cleaning phase fill up with product on starting up again under sterile conditions and this remains enclosed there for relatively long periods of time.

Problem
If when filling the “dead” length of pipe some partial unsterility has occurred, this can grow and infect the downstream section of the plant at the next switching operation.

Prevention
Regular emptying (product line protected by steam barrier).

The steam barrier allows drainage while maintaining sterile conditions.
3.6 Case study: “End nodes”

Sometimes there are several meters of product line installed between the final machine take-off valve and the end node of a plant.

Problem:
If a partial infection occurs during production this is normally flushed out again with little damage. If at the same time, however, the length of pipe is infected up to the end node the microorganisms can grow and have a rising tendency to contaminate in particular the last machine in the line.

Prevention:
Product in the line up to the end node should be periodically replaced.
3.7 Case study: “Pivot bend panels”

Pivot bend panels are often constructed in such a way that they cannot compensate for the thermal stresses in the pipes.

Problem:
Thermal stresses give rise to twisting of the base plates and hence to leaky screwed connections. Since these processes usually give rise to only temporary leaks, product bridges form with the known consequences.

Prevention:
- Introduction of expansion regions
- Avoid fixed clamping points between walls, etc.
3.8 Case study: “Dead spaces”

Problem:
In the dead spaces the exchange of liquid with the main stream is inadequate.
The consequences are:
• long residence time for the product
• cleaning silhouettes
• risk of accumulation of product residues.
All of this favors microorganisms being left behind which may grow later.

Prevention:
If in planning or installation, sections of pipe through which there is no direct flow of liquid cannot be avoided (such as at connection points for valves, measuring instruments and sensors), these have to be designed in such a way that they are rendered sufficiently turbulent by the main stream so that no dead spaces can arise.
3.9 Case study: “Turbulent regions”

Problem:
Valve rods, valve diaphragms and sensors projecting into the stream of product result in stalling of flow with the risk of turbulent regions and the accumulation of product residues.

Prevention:
These danger points can often be minimized by suitable positioning of valves and sensors.
3.10 Case study: “Incorrect installation of valves”

Turbulent regions and cavitation

Aseptic valves are frequently installed with connecting flanges which are too long relative to the main stream and frequently with valve rods, bellows and rolling diaphragms which project too far into the main stream.

Problems:
All components projecting out into the main stream result in turbulent regions with the known consequences of product deposits and reduced cleaning effectiveness. Pressure surges in the main stream give rise to high mechanical stresses in diaphragms and bellows which may result in fissuring and cavitation right up to fracture. In these cases cavitation has to be regarded as a particular problem because cases of unsterility caused by this are difficult to identify.

Prevention
As far as possible aseptic valves should be fitted in such a way that the internal actuator elements do not project into the main stream in order to reduce the mechanical loads on the bellows and diaphragms.
Valves and tanks that cannot be drained

Due to factors in design or assembly valves are sometimes integrated into a unit in such a way that they cannot be drained.

This arrangement cannot be completely drained.

Tank cannot be drained with certainty. Cleaning of tank and pipe up to valve rendered difficult. Large dead space behind the valve.

Prevention:
Through the right choice of design, suitable installation position and appropriate positioning of pipes drainage can be ensured.

Solution
This installation position permits troublefree drainage.

Solution
Tank and valve nozzle design favoring flow aid cleaning and drainage. Minimum dead space at lower valve nozzle.
3.11 Case study: “Incorrect installation of measuring instruments”

Measuring instruments and sensors are often fitted transverse to the main stream. This usually results in turbulent regions with the known consequences.

Prevention:
Fit measuring instruments and sensors as far as possible longitudinally relative to the direction of flow. Avoid excessively long connecting flanges.
3.12 Case study: “Welded joints”

Weld points on product pipes are sometimes executed less than perfectly, that is to say they are encumbered with cavities, plugs and stepped transitions.

Problem:
Any cavities present are not cleaned and sterilized only to a certain extent.

If pressure fluctuations occur these result in alternate filling and drainage of the cavities. In doing so microorganisms are transferred into the aseptic product.
Plugs and stepped transitions give rise to turbulent regions with the known consequences.

Prevention:
Welded joints have to be made by trained, competent staff using suitable equipment and an appropriate welding method. A purely external inspection is not enough. It is recommended that the quality of the pipe-welding work be inspected during production of the piping at least on a spot check basis. A welding mirror or endoscope is suitable for this purpose. In this inspection particular attention should be paid to the following faults:

- rough, puffy welded joints due to inadequate formation;
- open butt ends of pipes are not welded through;
- welding wire or cinders in the interior of the pipe;
- raised seams;
- sunken seams.

Due to their manual construction not all joints will be completely flat. Convexity in the construction of the seam of between 0.0 and 0.5 mm is tolerable. Concave seams are to be avoided.
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3.13 Case study: “Incorrect installation of pumps”

Aseptic pumps are sometimes installed in such a way that they cannot be drained.

Problem:
Infected product residues may give rise to high levels of microbial contamination in the downstream elements to be sterilized.

Prevention:
Drainage of the pump sump is ensured by appropriate installation.
3.14 Case study: “Compressed air lines” and “Steam lines”

Main lines for steam or compressed air are often installed without gradients or means of drainage.

**Problems**

- Downstream pneumatic elements may be flooded. At the same time pressure losses due to cross sections which are too narrow may cause partial freezing of the system.
- A high moisture content in the compressed air may reduce the effectiveness of sterile filters (shorter service lives).
- A high moisture content in steam brings about a lowering of the temperature. As a consequence of this steam barriers may be rendered ineffective. In this case the sterility of the system is no longer guaranteed.

**Prevention**

- Replacement of connection points. It is essential that compressed air and steam be tapped off from above.
- Lay lines so that they have a gradient and provide means of drainage.
- Reduce the amount of condensate by adequate insulation of steam pipes.
3.15 Case study: “Hot water injectors”

Problem
When there is a closed valve in the outlet this results in back pressure for both media. In this case water can get into the steam line and cause partial flooding of downstream sterile nodes with unsterile water. This is very difficult to detect afterwards.

Prevention
Remove valve in the outlet and protect the steam and water lines with nonreturn valves.