Enhancing Food Safety Management by Understanding the Role of Filtration

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Food Safety in a process managed under HACCP[1] principles is achieved by applying a proactive program to analyze, identify, control, monitor, correct, verify and document critical control points in the process. If a critical control point in the system fails to perform as required, this can result in adverse effects that can impact food safety.

Even in the absence of formal HACCP procedures, the production of a safe food product is contingent upon the proper functioning of carefully selected and maintained equipment to satisfy process requirements.

Filtration is a process step that can provide critical protection of food products during various manufacturing stages. While some filtration is geared solely to removing coarse or fine particles that only impact the sensory attributes of a product, other filtration steps influence physical, chemical and microbiological safety.

Physical Contaminant Removal

Physical safety refers to the absence of particles that could cause injury to the consumer. Examples are glass shards from damaged UV lights or glass packaging, or plastic and metal fragments from pumps or equipment with moving parts. These contaminants can be the cause of costly product recalls. Although proactive measures can identify and limit such occurrences, and while detection equipment can be implemented to find such contaminants as part of a quality assurance program, a final polishing filtration step as a last barrier can serve as an additional safety measure.

Another area of protection from physical contaminants involves culinary steam filtration. Many food processes utilize direct steam injection for flash heating and cooking, sanitizing or sterilizing product contact surfaces on equipment, steam peeling, hot water creation for CIP systems, etc. There are requirements for removing particles, such as rust and debris from steam lines, which are achieved by filtration[2].

Chemical Contaminant Removal

Chemical safety describes a situation wherein food products are free of unwanted chemical contaminants, such as cleaning agents, or uncontrolled amounts of other food plant chemicals inadvertently ending up in the product. Where such upsets may be caused by malfunctioning chemical handling devices, which require instrument quality air or “particle-free” water for their operation, proper utilities filtration plays an indirect but important role in safeguarding against such upsets.

Another very important and growing aspect of ensuring safety from undesirable chemical components relates to the verification of food contact compliance concerning plant equipment, which includes filtration devices. Existing and rapidly emerging global regulations ensure that unwanted extractables from filtration devices cannot contaminate foods and adversely affect consumer health. Meeting these regulations and documenting compliance on an ongoing basis is a key aspect of a filtration supplier’s role.

Microbiological Quality

Microbiological quality is by far the most common food safety aspect safeguarded by filtration. By applying properly selected filtration devices, bioburden reduction or commercial sterility of a product is achieved. Aseptic processes, for example, rely on sterile air filters on aseptic surge tanks and fillers to maintain sterility within the process and during the packaging step. Additionally, where ingredients are aseptically dosed into a sterile environment, sterile liquid filters are selected to provide microbiological removal where heating would otherwise destroy heat-sensitive ingredients. In various types of bottled water applications, where no heat treatment is involved, sterilizing filtration prior to the bottling step, used in conjunction with corresponding well-controlled downstream operations, assures the microbiological safety of the bottled beverage. In certain dry powdered products, proper filtration of the air that comes into contact with these powders during manufacturing can reduce or eliminate unwanted microbes, which could later thrive in reconstituted form.

Securing Water Quality

Water is often an important source of pathogens found in food products. With the increasing scarcity of water supplies and the growing need to reuse and recycle water, food plants must pay special attention to their plant water quality, depending on its source and its previous history of use.

Where production plant water comes into direct contact with food materials or could cause contamination due to equipment malfunctioning, careful consideration must be given to its treatment. Process water, depending on its particular use, should be adequately filtered to remove any microorganisms or parasites that could contaminate the end product. An example involving special safety challenges is in the production of raw or minimally processed fresh produce, where water used in post-harvest practices such as washing or cooling must be carefully monitored for quality and the avoidance of cross-contamination. Filtration can ensure microbial levels are controlled.

Understanding Filtration Performance

The absence of standards regarding removal ratings and removal performance in the filtration world often causes the improper selection of filters. Filter retention ratings are often stated to be “nominal”, “absolute”, or microbial (even viral).

Nominal and absolute retention ratings refer to the removal solely of particles and should not be used to describe critical microbiological removal requirements. Particle removal efficiencies stated by filter manufacturers are based on tests, which document the degree of removal of standardized particles such as fine or coarse test dust or latex beads, usually hard spherical particles which have little to do with the morphology of microorganisms. Whether nominal or absolute, particle filters state removal efficiencies as the relationship between an upstream and a downstream particle count, expressed as a Beta ratio at a given particle size. Even the methods used to generate this data, such as the use of single pass or multiple pass challenge tests, type of particles, and the amount of challenge material must be looked at carefully in order to understand the true performance of a particle-rated filter.

Food contact compliance of filtration equipment brings food manufacturers one step closer to consumer protection.

Nominal filters provide only partial removal of contaminants and should never be used when critically important removal requirements exist. They can at best, be good prefilters for downstream final filters. Even within the nominal filter realm, removal ratings can range anywhere from 99 % removal efficiency (Beta 100 ratio) on downwards. Very nominal filters might, for example, only remove in the 60 % removal efficiency range, meaning 60 % of all particles at a given micron size. Additionally, nominally rated filters sometimes consist of fibrous, non-fixed pore structure media, which tend to unload contaminants under rising or fluctuating pressures.

Absolute filters are often understood to remove 99.9 % or greater of particles, although the term “absolute” is often used loosely. It is more precise to refer to removal efficiencies and specific Beta removal ratios. A 99.9 % removal efficiency means, that for every 1000 particles which hit the filter, only 1 particle passes through (Beta 1000 ratio). High-end absolute filters for critical applications remove 99.98 % of particles at a given micron rating, which means that for every 5000 particles which hit the filter, only 1 particle passes through (Beta 5000 ratio). Table 1 illustrates these concepts.

Table 1 - Particle Removal Performance

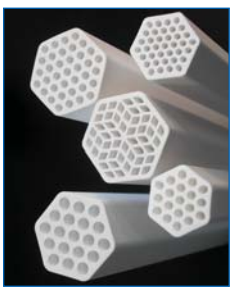
Beta Ratio[1]	Influent Particle Count	Particles Retained	Effluent Particle Count	Removal Efficiency[2]
Beta 10	5000	4500	500	90 %
Beta 20	5000	4750	250	95 %
Beta 100	5000	4950	50	99 %
Beta 1000	5000	4995	5	99.9 %
Beta 5000	5000	4999	1	99.98 %

[1] Beta Ratio = influent particle count/ effluent particle count

[2] Removal Efficiency = (influent particle count – effluent particle count) x 100 / influent particle count

Pall Aria™ FB Filtration System

Emflon® Filter Cartridges



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By contrast, microbiologically validated filters exhibit much higher removal ratings even than absolute rated particle filters. The removal efficiency of such filters is expressed as a titer reduction of model microbes, selected by virtue of their approximate size to express the performance of the filter. A validated microbial filter should be backed up by performance data showing the nature of the testing: the amount of microbes challenged to the filter (challenge level has an impact on performance!), the type of microorganisms, their size, the humidity and air flow rate of the test environment when validating sterile air filters, and so on. In addition, some filter manufacturers provide data on specific microorganism types and the filters' removal performance in specific liquids. It is only when carefully analyzing the nature of the testing done, that one can evaluate the true performance capability of the filter. In this respect, requesting a validation guide from a filter manufacturer will illuminate much information that would otherwise not be apparent from a simple data sheet.

Bioburden reduction filters provide a reduction in microbial levels. For example, a 0.45 micron rated membrane filter may claim a reduction of 10^6 when challenged with *Serratia marcescens* (a commonly used model organism for 0.45 micron rated membrane filters). It is important to pay special attention to the stated degree of removal, the challenge level, and the type of test microorganisms used. Obviously the resulting filtrate quality will be highly dependent on the incoming microbial load and on the application.

One example of a situation, in which bioburden reduction filters contribute indirectly to food safety is when their effective removal performance ensures that downstream heating equipment achieves the overall desired microbial kill effect. In the use of crossflow membrane filters in UHT milk processing, bacterial spore reduction upstream of the aseptic processing equipment is achieved.

By delivering lowered microbial loads to the UHT equipment, not only is quality degradation due to heating minimized but the target overall logarithmic reduction values are accomplished.

The 2004 FDA Guidance Document for Industry on Sterile Drug Products produced by Aseptic Processing[3], while referencing drug products and offering nonbinding recommendations, can be applied to critical food industry applications. It describes the use of hydrophobic, integrity-testable membrane filters for sterile compressed gas. Further, it describes sterilizing grade filters in general, to have a rated pore size of 0.2 micron or smaller. They should be validated for reproducible removal of viable microorganisms from a process stream, resulting in sterile effluent under worst-case production conditions when liquid challenged with 10^7 specific test organisms per cm^2 of effective filtration area. The common model microorganism used for this purpose is *Brevundimonas diminuta ATCC 19146*, with mean diameter of 0.3 micron, due to its small size. Based on the filtration area of a typical 10 inch filter cartridge, this equates to a titer reduction of $>10^{10}$ or a logarithmic reduction value (LRV) of >10. Conservative validation methodology provides a margin of safety beyond this requirement.

To contrast particle removal from microbial removal performance, while an "absolute-rated" Beta 5000 particle removal filter exhibits a removal efficiency of 99.98 % of *particles* challenging a filter, a sterilizing grade liquid filter exhibits a removal efficiency of >99.99999999 % of *microorganisms* challenged to the filter! Tables 2 and 3 compare filter microbial performance and its relation to downstream contamination.

Table 2 - Microbial Removal Performance

Titer Reduction[1] (Tr)	Log Reduction Value (LRV)	Challenge Level[2] (cfu/cm^2)	Filter Area (cm^2)	Influent Microbial Load (cfu)	Effluent Microbial Load (cfu)	Removal Efficiency[4]
10^6	6	125/cm^2	8000	10^6	1	99.9999 %
10^6	6	1.25 x 10^5/cm^2	8000	10^9	10^3	99.9999 %
10^6	6	1.25 x 10^7/cm^2	8000	10^{11}	10^5	99.9999 %
$>10^{11}$	>11	1.25 x 10^7/cm^2	8000	10^{11}	0 (sterile) [3]	>99.999999999 %

[1] Titer Reduction = influent microbial load / effluent microbial load

[2] Colony forming units (cfu) / cm^2

[3] In cases where the effluent contains 0 microorganisms (sterile effluent), a downstream load of 1 is used to calculate the titer reduction and resulting removal efficiency, as otherwise no division through 0 is possible

[4] Removal Efficiency = (influent microbial load – effluent microbial load) x 100 / influent microbial load

Table 3 - LRV Performance and Rate of Contamination

Log Reduction Value (LRV)	Influent Microbial Load (cfu/Liter)	Effluent Microbial Load (cfu/Liter)	Rate of Contamination
6	100000	0.1	1 cfu/10 Liters
11	100000	0.000001	1 cfu/ 1000000 Liters

The 2004 FDA Guidance Document also describes the use of membrane filters for air filtration on critical equipment such as tanks containing sterilized materials, and filters acting as sterile boundaries or supplying sterile gases. HEPA[4] filters are typically referenced mainly for aseptic processing room filtration, and exhibit at least a 99.97 % removal of particles in gas greater than 0.3 micron in diameter.

Critical applications are described in PDA Technical Report 40 for Sterilizing Filtration of Gases[5] as those applications in which “process fluids are in direct contact with sterile final product or critical surfaces of the associated equipment”.

For sterilizing gas filters on such critical applications, the removal performance should be exhibited not only in dry, but also in moist gas. Liquid bacterial challenge testing represents a worst case condition for these filters. Due to the way filtration mechanisms work, Brownian movement of gas molecules in gas streams (Figure 1) causes impingement of entrained particles on the filter media and their capture (Figures 2, 3), much more easily than when liquid streams pass through a filter (Figure 4). This is called diffusional interception. Filtration of gases is always easier to achieve than filtration of liquids, so that a given filtration removal rating in a gas is always tighter than the same filter’s performance in a liquid. As an example, a 0.2 micron microbially validated sterilizing grade filter removes bacteria in this size range in liquids but removes much smaller particles such as viruses (in the nanometer size range) in gas. In a related example, a 3 micron particle-rated liquid filter would perform as a much tighter filter on dry gas, generally removing particles in the approximate range of 1/5 to 1/10 of the particle size.

Sterile air filters that wet out due to moisture condensation in pipelines, fluctuating pressures, or malfunctioning of upstream air drying equipment, revert to their removal rating in liquids (Figure 4). Unless these filters are validated for sufficient bacteria removal in liquids, it is questionable whether sufficient protection is afforded in a critical air application. Use of hydrophobic filters prevents wetting out and the resulting blockage of air flow, however, as filters vary in their degree of hydrophobicity, depending on the specific type and treatment of the filter media, one cannot assume that all hydrophobic filters are equal, and further, that they will remain constantly hydrophobic even with multiple steaming cycles over time.

Hydrophobicity is expressed in terms of CWST (critical wetting surface tension), which is determined by a drop test and the measurement of the contact angle of a liquid with known surface tension on a solid surface. Measured in dynes/cm, with lower values indicating increased hydrophobicity, CWST of filter media is dependent on materials of construction and surface roughness of the media.

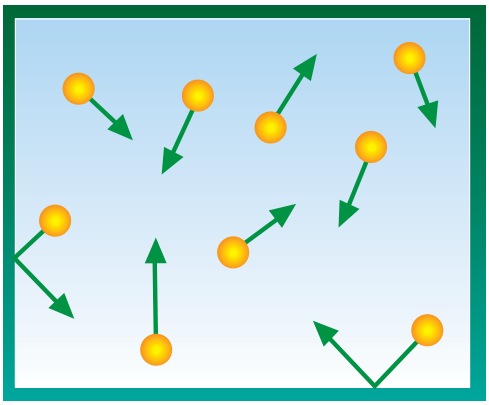

Figure 1 - Gas molecules are in a state of random motion, or Brownian movement.

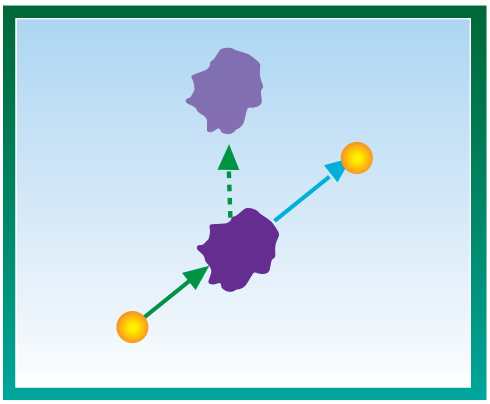

Figure 2 - Small particles or aerosol droplets in the gas are struck by the moving gas molecules and displaced.

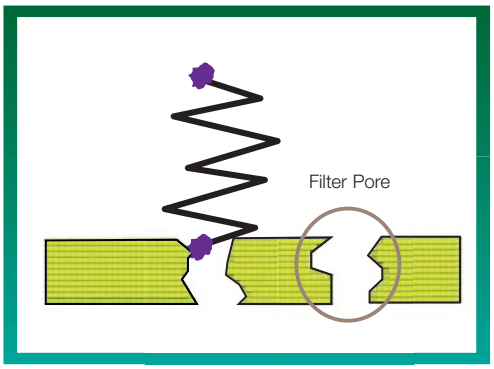

Figure 3 - Due to Brownian motion, diffusional interception is the key filtration mechanism occurring in dry gas. Particles many times smaller than the filter pore size are intercepted.

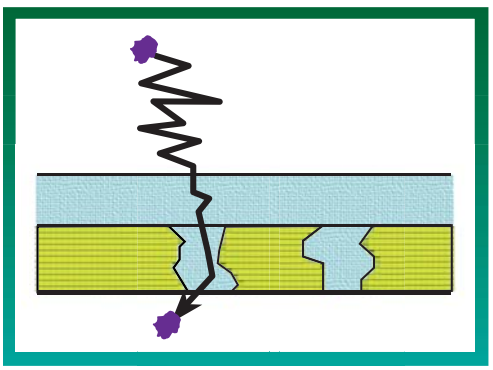

Figure 4 - Diffusional interception does not work under moist conditions.

Filter Integrity Monitoring

Finally, the proper monitoring of filter integrity is an important assurance that a filter is continuing to do what it is expected to do. Filter integrity test devices measure and document whether an integrity breach to the filter has occurred. Such integrity tests only make sense in sub-micron microbial filters.

Particle filter performance is monitored by virtue of differential pressure devices. Differential pressure should constantly and predictably rise across a particle removal filter, as it loads with contaminants. A sudden drop, or no pressure rise at all, would either indicate the filter is unloading contaminants or has actually been damaged.

In the pharmaceutical industry, microbial filters are often monitored for integrity both pre- and post-use. Food manufacturing plants often do not routinely integrity test before and after filtration but should consider the value of doing so. Pre-use monitoring documents any damage that may have occurred during shipment or installation. *In situ* monitoring can also document any potential bypass situations or system leaks once the filter is installed in its housing. Post-use monitoring provides a record of batch integrity. A special case is to monitor filter integrity after steaming a filter but before production. As steaming is the single most potentially damaging stress situation that a filter can undergo, a post-steaming integrity test makes good sense.

Figure 5 - Pall Flowstar: Sophisticated integrity test devices allow integrity testing of both liquid and gas filters.

Integrity test devices (Figure 5) are designed for use either on liquid or gas membrane filters. Depth filters cannot be integrity tested. There are many types of integrity tests, with those used on liquid membrane filters requiring the simplest handling, and those used on gas filters requiring more specialized procedures. Integrity test values are linked to microbial removal performance.

Conclusion

In summary, filtration is a key step in the manufacturing process, which impacts food safety. Users should be aware of the intricacies of filtration mechanisms and filtration terminology, critically evaluate the various filtration products they use and rely on the proven expertise of filtration manufacturers to assist with their proper selection.

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References and Footnotes

[1] Hazard Analysis Critical Control Points

[2] 3-A Accepted Practices for a Method of Producing Culinary Steam, Number 609-03

[3] Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice, Sept. 2004

[4] High Efficiency Particulate Air

[5] PDA Technical Report 40 (TR 40), Sterilizing Filtration of Gases

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