

US Food Safety Modernization Act (FSMA) and Pall's 'Seek and Destroy' Solutions

The **US 'Food Safety Modernization Act' (FSMA)** was signed into law by President Obama, changing the emphasis from a 'reactive' approach to food contamination events in the US, to one of 'prevention'. The FDA have made it clear that they intend to take a strong position on prosecutions where they find food producers/suppliers in breach of FSMA rules and have included this under their operational strategy.

On June 10th, 2015 the US FDA sent the first 3 rules, drawn up to implement the aims of the FSMA, to the US Office of Management and Budget (OMB) for approval. This is one of the final stages of the US legislative process. The 3 rules being :

- 'preventative control' rule related to CGMP for Human food — target for completion August 30th, 2015
- 'preventative control' rule related to CGMP for Animal food — target for completion August 30th, 2015
- the Foreign Supplier Verification Program rule — target date for completion Oct 31st, 2015

In each case the FDA appears to be advocating a '**seek and destroy**' policy towards food health risks.

Preventive Control Rules

The requirements under the preventative control rules may be summarised as making it the US human and animal food producer /supplier's responsibility to identify the risks to the safety of the foodstuff they provide, through risk assessment, and to take action to eliminate that risk through Current Good Manufacturing practices (CGMP) and control measures.

Whilst verifying the implementation and effectiveness of the preventative controls he has put in place.

US 'Foreign Supplier Verification Program' (FSVP)

The quality of foodstuff imported into the US from other countries is another important consideration, and the driver behind the Foreign Supplier Verification Program (FSVP) rules, proposed implement FSMA section 301.

It appears the proposal would mean food importers to the USA (other than of alcoholic beverages, juices, R&D /personal use or materials for further processing) should perform certain risk based activities to show the imported food 'provides the same level of public health protection as that required of domestic food producers'.

It is the food importers responsibility to meet the food quality requirements in the country he wishes to supply.

'Seek and Destroy'

A key driver in each of these FSMA rules is a concern over microbial contamination of food. Pall Corporation products offer producers, suppliers and importers the tools to detect the presence of certain key food contamination microorganisms, plus filtration and separation equipment to achieve the microbial control they desire.

'Seek' — Detection Solutions

This risk evaluation should include a hazard analysis for:

- nature of the hazard in the food and
- procedures / practices related to food safety

GeneDisc system is an ideal tool for also confirming the effectiveness of control measures against specific food contamination micro-organisms.

'Destroy' — Protection Solutions

Appropriate control measures should be used.

Pall filtration and separation products qualified microbial and particulate removal capability for food and its production environment.

Detection Solutions

Pall aims to provide an expanding portfolio of innovative solutions to simplify food producers' microbiological controls. **GeneDisc® solutions** provide the food industry with real time monitoring of variety of foodborne pathogens by PCR (Polymerase Chain Reaction) employing a range of organism specific consumables, the GeneDisc plates, with the GeneDisc Cyclor PCR system.

- **Accelerated batch release** — The high sensitivity of the GeneDisc method enables a short enrichment time, as only a few bacteria are required to generate a result. Combined with simplified sample preparation protocols and a reduced run time, the GeneDisc solution is an extremely fast method for foodborne pathogen detection.
- **Brand protection** — Using dedicated reagents, GeneDisc assays guarantee a high specificity of detection and a minimum rate of false results. Performances are AFNOR and AOAC tested.
- **Adaptive solution** — Users can make their own system corresponding to their throughput. Flexibility can be achieved thanks to the GeneDisc Cyclor subunits that can be connected to a single central base unit. Furthermore, multiplex applications provide multiple results for a same sample without additional hands-on time. With a full configuration system, up to 96 samples can be processed at once providing up to 576 results in an hour.
- **Cost effective** — All GeneDisc applications use one step enrichment protocols and minimal sample preparation procedures, drastically reducing operator time per sample. Ready-to-use reagents also minimize hands-on time and reduce your logistic workflow. Decisions are also simplified by an automated data interpretation by the GeneDisc Cyclor.



Figure 1: Hazard analysis and critical control points

One microorganism of concern is *Listeria monocytogenes*. This is an opportunistic foodborne pathogen that can affect a wide range of food products and can cause listeriosis with potentially high mortality rates in susceptible populations for example, the elderly, immunodepressed, pregnant women and newborns. *L. monocytogenes* can grow at refrigeration temperatures and has been found in a variety of foods particularly dairy products, ready-to-eat meats and fish products.

There is evidence suggesting the presence of other non-pathogenic *Listeria* spp. can be an early indication of *L. monocytogenes* contamination, highlighting the importance of its detection as well.

As part of the GeneDisc plate portfolio, Pall provides flexible solutions for food processors in need of rapid detection and quantification of *L. monocytogenes* and/or *Listeria* spp. risks, enabling detection of *L. monocytogenes* and *Listeria* spp. individually or simultaneously.

Another major concern for food processors is pathogenic *Escherichia coli* as it is mainly transmitted to humans through contaminated foods.

E. coli are common in human bacterial flora. Most *E. coli* are harmless, but Shiga Toxic *E. coli* or STEC can cause severe food borne illnesses. Among these STEC, several serogroups are more commonly

related to human diseases. The United States Department of Agriculture's Laboratory Guidebook defines the STEC Top 7 serogroups as *E. coli* O157, O26, O45, O103, O111, O121 and O145.

Pall GeneDisc technology provides a complete range of options for a reliable control of O157 and non-O157 STEC risk. These options include an enhanced solution for the detection of STEC Top 7 which provides a lower rate of presumptive positive results than any other available method and minimizes risk of false positive results. This is achieved thanks to a unique method principle, based on the detection of virulence factors, that allows discrimination of pathogenic strains from non-pathogenic ones.



Figure 2: GeneDisc unit and a detection plate

For further details on these and other GeneDisc plates, please visit <http://www.pall.com/main/food-and-beverage/product.page?id=20120614103141>.

Protection Solutions

Principal contributors of microbial hazards in food include water used in the product or for cleaning, air/gas, and organisms from ingredients, or introduced by plant personnel. Microfiltration removes or reduces microbial contamination (yeast, bacteria, protozoans, and viruses) rather than killing them within the product (e.g. by pasteurization, UV or ozone sanitization). This reduces the risk of bacterial spores germinating in the final product, removes the source of heat stable toxins (present in some pathogenic bacteria), and removes microbial contents (lipopolysaccharide/endotoxin, nucleic acids, and enzymes).

Regardless of the nature of the organism (pathogenic, opportunistic pathogen, economic risk, non-economic risk) or the method of introduction filtration can remove this type of contamination.

Filtration can be implemented at various stages during a production process and is applied to achieve a defined level of microbial removal using qualified procedures. The broad array of food products manufactured requires each manufacturer to determine the appropriate processing level to control microbial status.

<http://www.pall.com/main/food-and-beverage/enhancing-food-safety-management-by-unde-53722.page>

GeneDisc Option	Organism of Concern	Validation	Min. Total Time to PCR Result
GeneDisc Plate <i>Salmonella</i> spp.	Detection of <i>Salmonella</i> spp.	AOAC, NF Validation	10h
GeneDisc Plate Pathogenic <i>E. coli</i> O157	Detection of Pathogenic <i>E. coli</i> O157 with <i>stx</i> , <i>eae</i> genes	AOAC, NF Validation	
GeneDisc Plate STEC	Detection of STEC (<i>stx</i> , <i>eae</i> genes) including Pathogenic <i>E. coli</i> O157	AOAC, NF Validation (for <i>E. coli</i> O157)	
GeneDisc Plate STEC Top 7	Detection of virulence genes and <i>E. coli</i> O157, O26, O103, O111, O145, O45, O121 serogroups.	AOAC, NF Validation (for <i>E. coli</i> O157)	
GeneDisc Plate <i>Salmonella</i> spp. and Pathogenic <i>E. coli</i> O157 or GeneDisc Plate <i>Salmonella</i> spp. and STEC	Combined detection of Pathogenic <i>E. coli</i> O157 with <i>stx</i> , <i>eae</i> genes and <i>Salmonella</i> spp. or Combined detection of STEC (<i>stx</i> , <i>eae</i> genes) including Pathogenic <i>E. coli</i> O157 and <i>Salmonella</i> spp.	AOAC, NF Validation (for <i>E. coli</i> O157)	
GeneDisc Plate <i>Listeria</i> spp. or GeneDisc Plate <i>Listeria monocytogenes</i> or GeneDisc Plate <i>Listeria</i> DUO	Detection of <i>Listeria monocytogenes</i> and/or <i>Listeria</i> spp.	AOAC, NF Validation	20 h
GeneDisc Plate <i>Listeria</i> ID	Simultaneous identification of <i>Listeria</i> species (<i>L. monocytogenes</i> , <i>L. ivanovii</i> , <i>L. innocua</i> , <i>L. welshimeri</i> , <i>L. seeligeri</i> , <i>L. grayi</i> subsp. <i>grayi</i> and <i>L. grayi</i> subsp. <i>murrayi</i>)	AOAC	1 h

Microorganism Type	Removal Rating	Comments
Protozoan (e.g. <i>Giardia</i> and <i>Cryptosporidium</i>)	1 micron	Validation is sometimes performed with latex bead challenges due to safety risk of working with this class of organisms. Validation may also be performed with killed or live organisms.
Yeast and molds (e.g. <i>Saccharomyces</i>)	0.65 micron	Most vegetative yeast are removed efficiently with a 0.65 micron membrane filter. However, some yeast in stationary phase or early lag phase may penetrate 0.65 micron membrane filters. As these yeast do not pose health risks but only economic risk, we recommend reducing the filter rating to 0.45 micron if this condition exists.
Spore forming bacteria (e.g. <i>Bacillus</i> species)	0.45 micron	Bacterial spores have been shown to be removed by 0.45 micron membrane filters.
Coliform bacteria and bacteria with heat-stable toxin virulence factors (e.g. <i>Escherichia coli</i> , <i>Serratia</i> , <i>Shigella</i> , <i>Salmonella</i> , <i>Campylobacter</i>)	0.45 micron	Microbial challenge data is available for specific organisms, or model organisms, demonstrating complete removal or providing a titer reduction.
Bacteria used in or contaminating fermentation processes (e.g. <i>Oenococcus oeni</i> , <i>Pediococcus</i> , <i>Lactobacillus</i>)	0.45 micron	Microbial challenge data is available for validated filters demonstrating removal or reduction of common contaminants.
Waterborne bacteria (e.g. <i>Pseudomonas</i> species)	0.2 micron	Microbial challenge data is available for validated filters demonstrating removal or reduction of common contaminants.
Virus in liquid products or (e.g. <i>Caliciviridae</i> , Poliovirus, Adenovirus, Coxsackie virus, Echovirus)	Ultra or nano filtration	Specific microbial challenge tests are not yet available. This is partially due to virus detection problems including inability to culture and difficulties with laboratory contamination).
Virus in gas products or vents (e.g. bacteriophages, aerosolized viruses from plant personnel)	0.2 micron hydrophobic medium	Microbial challenge data is available for validated filters demonstrating removal or reduction of common contaminants.

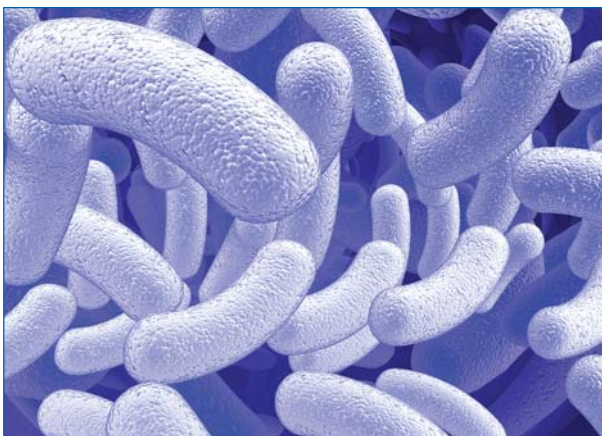


Figure 3: Microbes

Microbes may be introduced from the environment during process and storage steps. To prevent environmental contamination of storage tanks and fermentation vessels Pall recommends 'sterilizing' grade gas and vent filters. **Emflon® PTFE membrane filters** are made of fixed/stable membranes, with integrity testing that can be performed by the manufacturer and which is correlated with microbial removal capability data. Emflon filters have been proven cost-effective solution in numerous installations around the globe due to their reliability and efficiency in the protection of tanks and gas lines from bacteria and bacteriophage contamination.

- **Product protection** — 0.2 micron sterilizing grade membrane rating even in humid conditions.
 - Based on laboratory testing for liquid 0.2 micron bacteria removal and dry gas testing for sodium chloride aerosol particle removal to 0.003 micron.
 - Provides excellent product protection.
- **Reliable performance** — Hydrophobic PTFE membrane, resists wetting out in humid conditions, even after repeated use and steaming cycles, allowing for unimpeded gas throughput. Integrity testable by the user to demonstrate continued removal capability in use.
- **Cost effective** — Robust construction resistant to multi-cycle in situ steam challenged in forward and reverse direction, together with high area pleated, robust double-layer membranes — provides high throughputs and low pressure drops, with sizing resulting in compressor energy cost savings.

This is just one of the wide range of microbial and particulate removal filters which Pall F&B offers as part of its comprehensive filtration and separation 'FCC' product portfolio, made from food contact materials, specifically for food and beverage applications. The most up to date information on the US regulatory food contact compliance position of the materials of construction of Pall's FCC products is available on the Pall Corporation website at <http://www.pall.com/main/food-and-beverage/food-compliance-products-apps.page>.

There is on-going debate on the FSVP rules regarding food contact materials needs for 'production equipment' used in contact with US imported foodstuff. Pall's FCC products offer importers filtration and separation equipment which negate the outcome of this 'production equipment' materials debate. With GeneDisc products, Pall offers importers the tools to identify the presence of certain key food contamination microorganisms, plus filtration and separation equipment to achieve the microbial control they desire.

Pall's FCC products offer producers, suppliers and importers, filtration and separation equipment made with food contact grade materials. With GeneDisc products, Pall offers the tools to detect the presence of certain key food contamination microorganisms, plus filtration and separation equipment to achieve the microbial control they desire.

Should you have questions regarding microbial detection and protection please contact your local Pall representative or contact us at Julie_Tutton@europe.pall.com and Lisa_Madsen@pall.com.



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Please contact Pall Corporation to verify that the product conforms to your national legislation and/or regional regulatory requirements for water and food contact use.

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