

# WHITE PAPER ON ENVIRONMENTAL MONITORING

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February 2024 version



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**CHRISTEYNS**

FOOD HYGIENE



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# 1. Introduction

Contaminants in the food, dairy, beverage and brewing industries originate from a number of sources These include the production environment, the personnel and even traces and residues left over from previous production runs. These issues can cause issues with spoilage or shelf-life reduction. Or, in extreme cases present a risk to the health of the end consumer. In the case of the latter, these can be microbiological, chemical, physical or allergenic, with each of these requiring specialist verification techniques to ensure their control and to prevent them reaching the consumer.

In this document we will review the currently available validation and verification techniques for each of these potentially damaging contaminants, as these are of primary significance to the day to day activities of the hygiene professional. Of course, any cleaning validation exercise will also need to include these techniques to ensure a clear and seamless link between the two aspects of hygiene assessment.

Both validation and verification are a fundamental requirement in all 3<sup>rd</sup> party assessment schemes and Codes of Practice (such as BRC Global Standard for Food Safety Issue 9 and retailer CoP's). These methods are essential for ensuring the standard of hygiene achieved and hence the conditions of the contact surfaces. Thereby, enabling the safe production of food.

# 2. Definitions In This Sphere

Some confusion and merging of terms in this sphere can occur. For ease of understanding in this document we will be using: -

Validation	The process of checking that something satisfies a certain set of criterion	Will a cleaning regime “work”
Verification	The act of reviewing, inspecting, testing, etc. to establish and document that a regime meets the requirements	Has a cleaning regime “worked”
Monitoring	Visual inspection, hand-over sheets	Did it happen



## 3. Validation Methods

Validation of the hygiene regime is a critical first step in determining that practices, equipment and chemicals in use are fit for purpose in delivering a safe food production environment.

### 3.1. Microbiological.

The validation of cleaning via microbiological analysis can consist of both product and environmental/food contact surfaces sampling and requires the submission of those samples or swabs to specialist laboratories with the subsequent interpretation of the ensuing results.

In this section we'll consider both general microbiological flora analysis as well as the identification of specific species of bacteria.

#### 3.1.1. General Microbiological Flora.

This is often the first step in analysis. Whereby, an overall picture of the aerobic bacterial population on a surface, or sample, is assessed and quantified. Typically called a TVC (Total Viable Count) and taken to be indicative of the standard of hygiene achieved. In this analysis a “cotton bud” swab is used to sample an area typically of 25 cm<sup>2</sup> (5 x 5 cm) which is then placed into a transport tube containing a diluent to preserve bacteria present and neutralise any disinfectant remaining on the surface. The swab (s) will then be transported to a specialist laboratory.



Once at the lab, the sample is extracted, diluted using sterile water and plated out into a general growth media which sets when cooled. This plate is then stored, inverted and incubated at a specified temperature, for a defined period of time (typically 37°C and 22°C for 48 hours) before being removed and the colonies counted. The report then lists AA.A x 10<sup>-2</sup>, or similar depending on the dilutions used and the numbers of bacterial colonies identified.

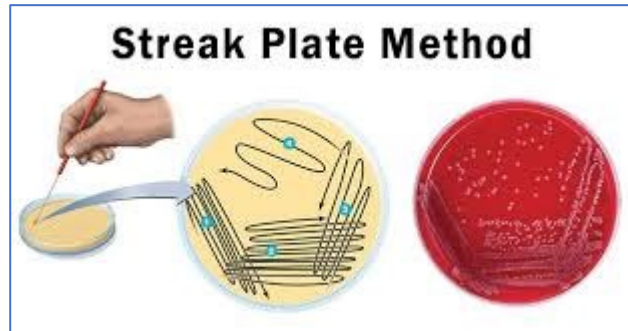


Alternative methods can utilise dip-slides which contain media designed to promote the growth of any aerobic organisms on one side and Coliform bacteria on the other.

### 3.1.2. Specific Species Identification.

If specific species identification is of concern, for example *Listeria* species or another specific pathogen, then further identification using specific growth media and conditions will be applied at the laboratory to “drill down” to determine if those species are present. Further analysis may be necessary to identify sub-species such as *Listeria monocytogenes*.

This sub-culturing may be undertaken using sterile loops which are then transferred onto different plates containing media even more specific for the micro-organism of concern.



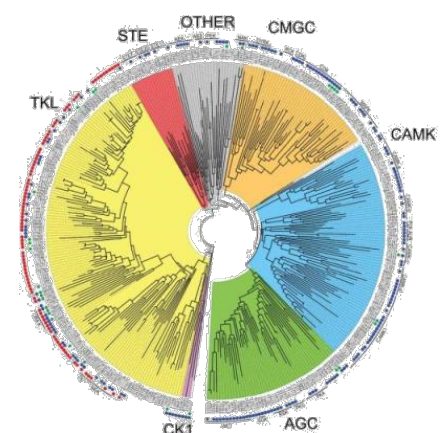
As an alternative, many laboratories are now equipped with genetic analysis technology where the DNA specific to the sub-species of

the bacteria can be easily identified. Caution must be exercised when employing DNA analysis as presence of the bacterial genetic material does not necessarily correlate with the presence of the viable bacterial cells. Linking of disparate testing technologies can however, overcome this limitation, moving genetic methods into a more productive space whereby the screening of surfaces can be quickly and readily achieved.

### 3.1.3. Genetic Methods of Analysis.

Advances in the speed, capabilities and cost per analysis of the DNA sequences has brought this form of microbiological assessment very much into the mainstream. The rapid, highly specific and targeted nature of genetic analysis has greatly increased both the accuracy and the reliability of bacterial species. Indeed, the science of Metagenomics has now made it possible to assess a bacterial population with only minimal pre-preparation.

The routine output of a Metagenomic assessment is represented as a “pin wheel” within which are contained all of the genetic profiles identified on a surface with none of the biases that can be introduced in traditional microbiological assessment. By this we mean that when selecting a media on which to grow a sample, a range of bias is introduced. For example, certain nutrients or atmospheric conditions. To expand on the food contact surface swab described in section 3.1.1, we assess the sample **only** for the presence of aerobic bacteria.



That is, those bacteria that could grow in an oxygen containing environment. However, consider that our sample surface also contained

anaerobic bacterial species that would not be able to grow in our artificially created environment. This

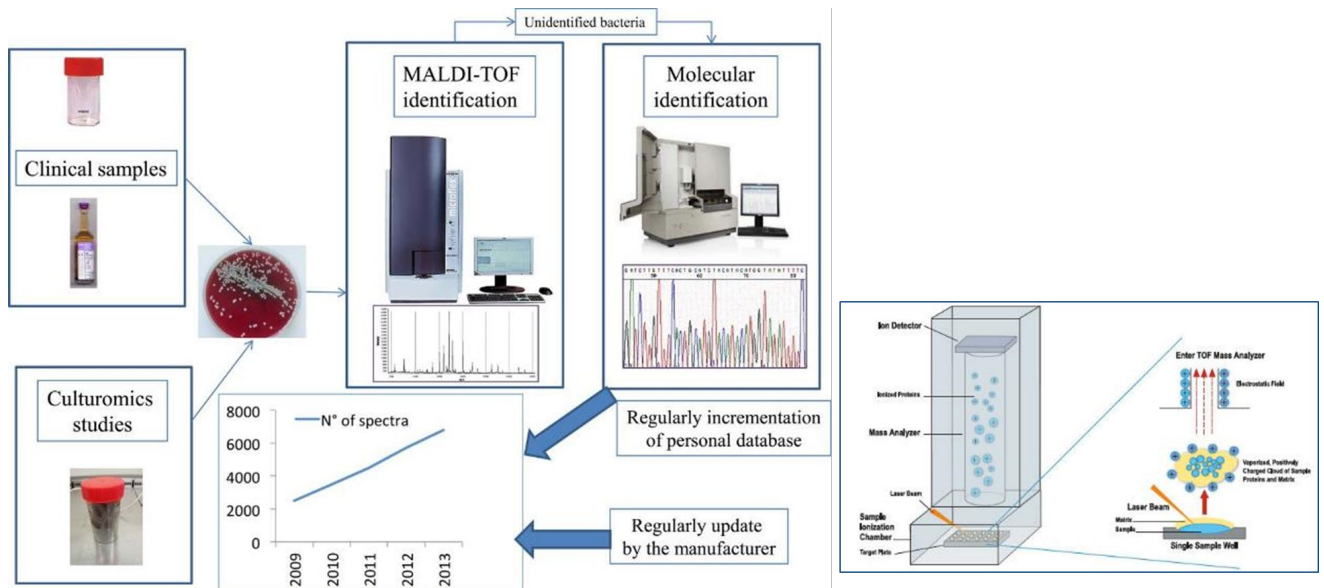
potentially useful information would not be collated and we could miss both spoilage and pathogenic bacteria.

In metagenomics, this information and speciation would be undertaken, without bias and the relative proportions of the pin-wheel would lead us to conclusions of the relative abundance of each class of bacteria. The only downside to this technology, as explained earlier, is that the viability of the bacteria isn't considered, as the technology is unable to determine "live" bacterial DNA from "dead" and in this respect the system requires some pre-work before being utilised in hygiene assessment. However, recent developments in the identification of viable bacterial populations can overcome this limitation enabling rapid, genetic based screening for specific micro-organisms to be undertaken at a site level..

### 3.1.4.MALDI-TOF

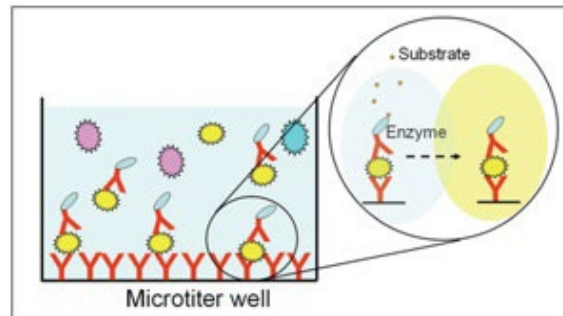
Matrix Assisted Laser Desorption Ionisation, Time of Flight (MALDI-TOF) analysis of bacterial populations combines the sciences of microbiological growth with mass spectrometry. In this technique, a sample (swab or product) is subject to growth in a standard microbiology laboratory and the resultant cultures transferred to a chamber where they are bombarded with laser energy. This leads to their proteins being liberated into flight and passed through a time of flight mass spectrometer. The time of flight of the proteins can then be determined allowing them to be accurately identified by the computing system. Re-assembly of the proteins detected can then be used to put an identify to the original bacterial species.

This graphic shows a typical MALDI-TOF setup which is becoming increasingly common in some laboratories.



## 3.2. Allergen.

Allergen validation is undertaken using ELISA (Enzyme Linked Immunosorbent Assay) which can provide incredibly specific analysis of the allergenic protein present, as well as giving information on quantification of the protein present.



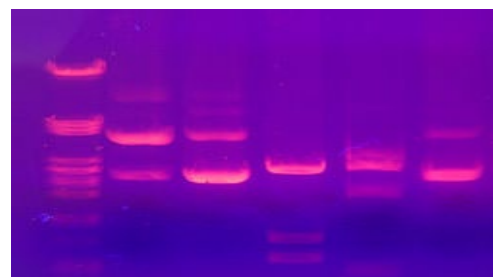
As these graphics show, this analysis is undertaken in dedicated equipment, often against standards which contain known levels of the allergenic protein of concern. Thereby, providing quantification of the level of allergenic protein present in the sample.

DNA analysis can also be utilised for the identification of allergens. However, in this instance, care must be taken, as the regime assesses the presence of DNA and **not** allergenic protein presence. As an example, DNA analysis cannot distinguish between milk proteins and the presence of beef or egg protein and the inclusion of chicken meat in a food stuff.

## 3.3. Species.

Species control hit the national headlines in 2013 in the now infamous “Horsegate” incident. This involved widescale food fraud and substitution of one meat species for another with DNA analysis being utilised to assess both product samples as well as food contact surfaces.

This analysis provides detailed, part per billion level assessment and quantification of the presence of meat species DNA. However, as described in section 3.2, the presence of DNA does not necessarily indicate the presence of the meat proteins. For example, in a ready meal that contains milk, this form of assessment will not discriminate between the milk and the presence of beef. However, where no meat species should be present, for example in a vegetarian product or a product that is believed to not contain a specific meat species, then the technology is highly advantageous.





## 3.4. Biofilm.

Microorganisms can colonise by adhering to living or inert surfaces and can become large enough to entrap organic and inorganic debris. Nutrients and other microorganisms are then captured, leading to the formation of a microbial biofilm. Due to their complex structure, biofilms provide a protective function to the microorganisms that they host, decreasing the efficacy of disinfection treatments. The presence of biofilms in food processing installations therefore represents a great risk for food safety and may also cause operational problems in equipment.

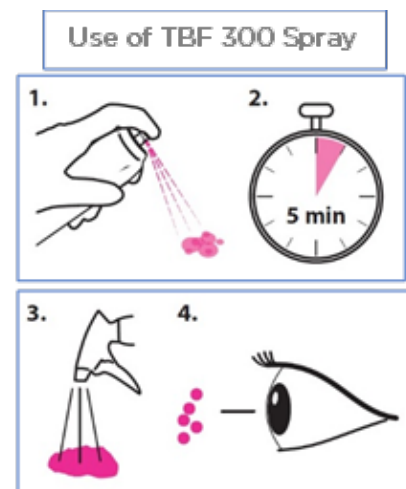
Biofilm development can occur on almost any surface and in any environment where there are viable microorganisms. This includes surfaces made of plastic, glass, metal, wood, or food products themselves. The sticky, viscous matrix develops on surfaces that favour its adhesion. Porous, scratched, rough and other surfaces that have been subjected to a poor cleaning and disinfection program are particularly susceptible. Ironically, more aggressive cleaning to remove the biofilm leads to further deterioration of the surface area and thus can aid biofilm growth in the longer term.

Detection and identification of biofilms can take two forms. The first is to rely on the production of the enzyme *catalase* when bacteria are exposed to hydrogen peroxide. This is employed in a detection matrix which is gelatinous and sprayed onto a surface. In the presence of catalase, the  $H_2O_2$  is degraded into hydrogen and water resulting in the visualisation of bubbles in the gelatinous substance on the surface.

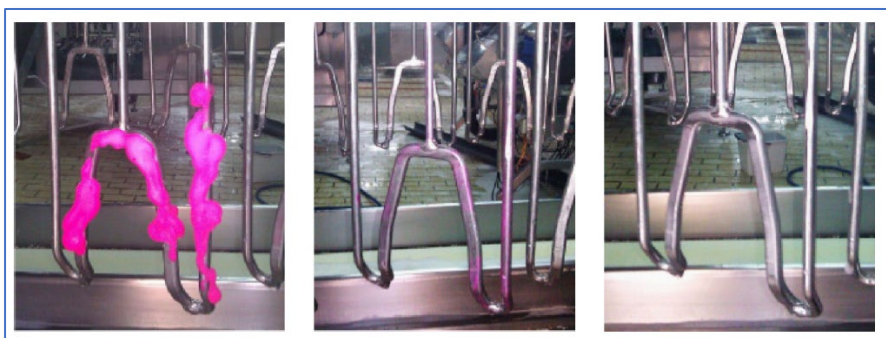
The downside with this system is that bacteria within a biofilm often have low metabolic processes and may be shielded from the  $H_2O_2$  by the presence of the extracellulose layer and any physical, inorganic components of the biofilm (mineral scale and the like). This can lead to false negatives whilst over-enthusiastic application of the spray can lead to false positives as a result of trapped air.

A far more robust mechanism is to employ a specialist dye which stains the extracellulose layer, thereby not relying on metabolic processes, and reducing the likelihood of both false negatives and positives. Christeysn Food Hygiene in Spain has developed such a system. This product is called TBF 300 and was developed in conjunction with Valencia University.

TBF 300 foam is applied to the area under test and is then left for 5 minutes before being rinsed free from the surface. Any remaining pink colouration is a positive indication of the presence of a biofilm which can then be removed using a specialist disinfectant inserted into the middle of the routine cleaning regime (typically based on a dual-active of QAC and Hydrogen Peroxide)



The images below show the application, identification and subsequent removal of a biofilm on shackles in a chicken processing operation: -



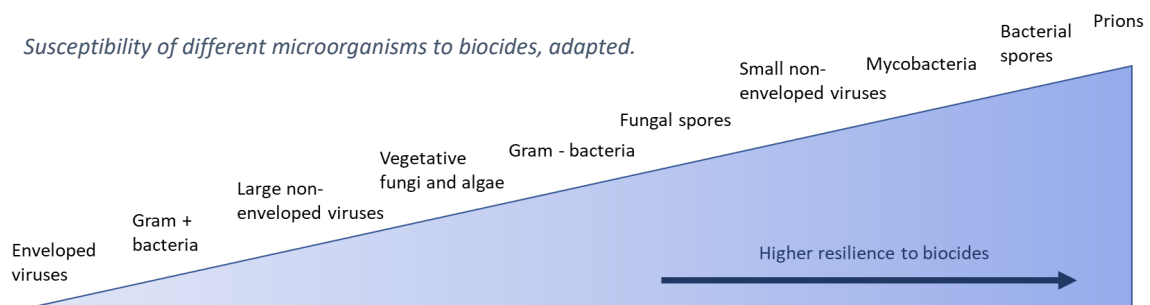




### 3.5. Viruses.

Unlike bacteria, viruses present a difficult challenge to the validation of a cleaning regime as they will not grow in a laboratory culture, do not have metabolic processes that can be tested for and will not be revealed through the application of chemicals or dyes. This is of particular concern at this present time with the SARS-CoV-2 viral pandemic in full swing globally and showing little signs of slowing. Cleaning and disinfection has been shown to be a major control measure in the management of fomite transmission of this virus via inanimate objects such as handles, screens, hand-rails and the like where an infected individual can place, inadvertently, infectious respiratory droplets which can be harvested and infect another individual.

Much of the control of viruses, including SARS-CoV-2, and the validation of cleaning regimes is based on the relative ease with which enveloped viruses can be inactivated. The logic is that if the regime is demonstrated to be capable of killing bacterial species then enveloped viruses will have been inactivated (as demonstrated in the below graphic).



Campden BRI are now offering a service employing the  $\phi 6$  bacteriophage which has been found to be a suitable, non-pathogenic, surrogate for the SARS-CoV-2 virus which can be safely inoculated onto surfaces before being subjected to the cleaning and disinfection regime. The surface is then sampled to assess if any of the bacteriophage has survived. If no activity is detected then the regime is deemed to have been validated to be capable of inactivating SARS-CoV-2. Alternative methods utilise the identification of the genetic RNA associated with this virus, however as documented earlier, genetic material such as RNA may remain on surfaces even though the viable bacteria has been destroyed via the disruption of the viral envelope.

Further information specifically related to concerns relating to cleaning and disinfection regimes when dealing with viruses can be found in the Christeys Food Hygiene technical briefing on our [web-site](#).



## 4. Verification

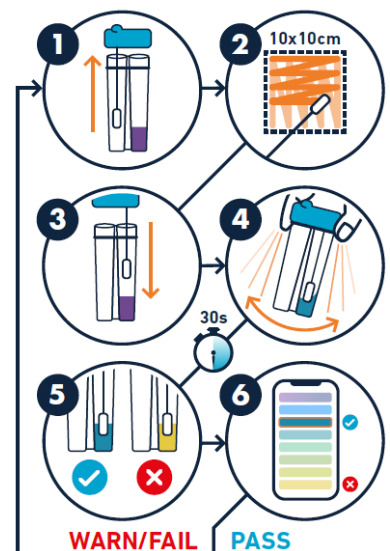
### 4.1. Microbiological.

Previously, direct identification of microbiological contaminants required the expertise and facilities of a fully equipped testing laboratory and can take a number of days to achieve results. This meant that action was always being taken retrospectively. Recent advancements in genetic profiling and analysis is developing in the science of Advanced Microbial Profiling (sometimes known as Metagenomics) to the point whereby the micro flora in a product can be accurately and quickly identified and the changes over time tracked. Currently, the technology isn't practical for hygiene assessment due the fact that the system cannot determine if the bacteria present are alive or dead. Recent advances such as FreshCheck™ are now enabling the rapid identification of viable population centers of bacterial species. Thereby enabling the application of genetic identification methods for specific pathogens.

A new technology launched to the market goes under the tradename of FreshCheck™ and utilises a patented chromatographic colour change to reveal the presence of viable bacterial populations on a surface.



This new and exciting development places a rapid, bacteria specific (present / not present), non-instrument method at the hands of hygiene professionals. Therefore, providing a verification technique designed to reveal the presence of micro-flora in a time frame which enables immediate remedial action to be taken.



As the graphic shows the surface under assessment is simply swabbed with FreshCheck™, you wait for 30 seconds and then examine the colour change using the above chart.

If the solution indicates a change to colours 3 or 4, then simply continue production. However, any other colour is indicative of contamination (chemical or bacterial) and a re-clean should be undertaken prior to re-test and release.

Testing time is only 30 seconds following the recommended contact time for the disinfectant product and the product has been tested and validated by Campden BRI.

## 4.2. LoopiX

This genetic based technology is ideally suited to the rapid identification of specific bacterial species through the analysis of swabbed surfaces within a 60 – 90 minute time-frame without the need for pre-enrichment or growth of potential pathogens on site.

The compact unit is a self-contained module to lyse bacterial cells. This releases the genetic material which is then amplified and replicated before being treated with a unique marker sequence which is identified through fluorescence if the target bacterial species is present. At the time of writing *Listeria monocytogenes* and all *Salmonella* species can be quickly and inexpensively identified using this technology.



The portability and ease of use are key advantages of this screening tool as is the lack of enrichment of the potential target pathogen.

Other rapid identification regimes currently available utilise a pre-enrichment stage which seeks to increase the number of micro-organisms present prior to detection.

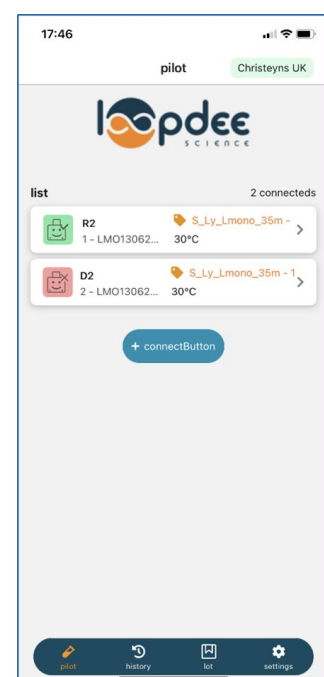
This introduces both a time of assessment delay of between 24 – 36 hours, as well as exposing the testing site to an increased risk of bacterial contamination due to the possible growth of pathogenic bacteria in a non-controlled environment. Not all production facilities have suitable containment facilities for pathogenic bacteria.

This introduces both a time of assessment delay of between 24 – 36

LoopiX removes this potential for contamination by **not** replicating the bacteria present. In fact, the first stage of testing is to kill any bacteria through thermal lysis, which then releases the genetic material which poses no risk to operators or product safety. This released genetic material is then replicated and analysed through the mobile phone app.

By combining technologies such as FreshCheck with LoopiX sites are, for the first time able to: -

1. Swab a test-point, or known hot-spot, using FreshCheck to ascertain if a viable bacterial population is present at that location.
2. Take a LoopiX swab sample and analyse for the presence of specific pathogenic bacteria.
3. If present, undertake remedial decontamination action.
4. Re-test sample point using FreshCheck to determine if viable bacteria remain on the surface.





In this way hygiene professionals now have the ability to react in real-time to potential bacterial contamination points and to screen those hot-spots for the presence of pathogens. Remedial action can then be taken within the space of a couple of hours. Of course, these activities are continued to be supported by the use of traditional swabbing techniques as a validation of the results.

### 4.3. Organic Material.

Non-specific organic material determination has been available for many years and utilises the ready availability of the energy storage chemical present in all living organisms – Adenosine Triphosphate (ATP).

The widespread prevalence of this energy source in organic material works to promote and fuel bioluminescence in the same way that a fire-fly produces its characteristic glow. Following swabbing of a surface the reaction commences and the result is then displayed on the screen of the bioluminometer in terms of Relative Light Units (RLU's). In essence, the more organic material present the more light is produced and the higher the reading.

As a non-discriminatory hygiene monitoring/screening device this technology is excellent for providing an overall assessment of any organic material (whether microbiological or product residue) present on the surface. However, caution should be taken, as bacteria killed during the cleaning & disinfection process will still contain ATP which is slow to degrade,



An ATP regime has no place in allergen monitoring.

When comparing rapid hygiene assessment technologies such as FreshCheck and ATP systems, the user should bear in mind that the technologies are approaching the detection of contaminants from different aspects. One is measuring the level of cellular energy present on a food contact surface (ATP) the other is measuring organic presence, however a crucial difference is the ability of FreshCheck to more readily identify the presence of stressed micro-organisms.

Stress is applied to a microbial population on a food contact surface during a cleaning & disinfection exercise where the application of both detergents and disinfectants will affect the underlying flora resulting in a dramatically lower level of ATP in any surviving organisms. This can be best explained via a comparison table evaluating the different results that Users may have encountered in “real life” scenarios when attempting to correlate different hygiene assessment results: -

ATP Failure	TVC Pass	ATP is from environmental and product residue not bacteria.	← This is where FreshCheck scores over ATP
ATP Pass	TVC Failure	Organisms are stressed (so little ATP) but recover and grow during incubation.	
ATP Pass	TVC Pass	Hygiene standards in control	
ATP Failure	TVC Failure	Problem in the plant	

The evaluation of FreshCheck by Campden BRI clearly identifies that the technology correctly detected the presence of bacterial species including Listeria and Salmonella following the application of stress scenarios. Whereas, comparative ATP swabs taken from the same bacterial populations on surfaces recorded levels as

low as 7 – 20 RLU's. This, in most cases, would constitute acceptable in many operations (a full copy of the FreshCheck™ report from Campden BRI is available from Christeys Food Hygiene).

## 4.4. Biofilm.

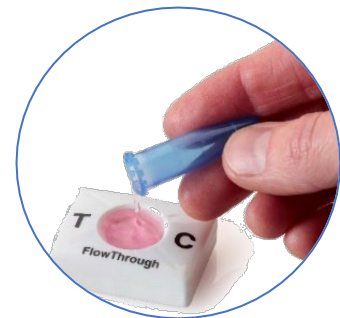
As outlined in section 3.4, sprays which stain the extracellular layer can be used as both a validation and a verification regime for the presence of biofilms.

## 4.5. Allergen.

Since the introduction of allergen labelling legislation in 2004, the pre-packed food industry has become experienced in managing allergen cross-contact. This includes the verification of cleaning activities. Whilst allergen recalls continue, the majority of those involve incorrect packaging or labeling errors rather than hygiene controls.

To undertake verification testing for allergen presence or absence, the only available technology is that based on antibody assessment using either lateral flow or flow-through tests specific to the allergenic protein of concern.

These tests are currently the best available technology for real-time rapid testing and whilst they have their limitations, their use is highly recommended where surety is needed that allergen cross-contact is suitably controlled. Therefore ensuring consumer safety and product integrity. Results are typically delivered in under 10 minutes with limits of quantification around the low PPM level, these results can be documented via photography and recording on monitoring reports.



## 4.6. Physical.

Physical contaminant identification can be as simple as visual inspection, but increasingly also utilises technology to minimise the risks to the consumer. For many decades, metal detectors have scanned packed product to ensure that any fragments or strands are identified and automatically rejected. To this technology the use of X-ray inspection has been added with computer processing becoming more advanced in determining the presence of extraneous foreign bodies in product.

## 4.7. Species.

Species control is of equal concern as the issue of cross-species contamination following the use of shared equipment in meat processing plants, for example bowl choppers, extruders, etc. is of equal importance.



This micro level of contamination is difficult to prevent in a busy processing environment and DNA analysis has been utilised to assess products to minimise the risks of this issue. The recent development of antibody based species testing by BioCheck has provided a rapid, on-site analysis tool sensitive to a 1% presence level. This can be used to assess food contact surfaces handling raw meat products.

Each test takes less than 10 minutes. Providing results in a control timeframe enabling remedial action to be taken should an issue be detected with the verification of a cleaning regime.



## 4.8. Chemical Residues.

Chemical residue testing has become of particular concern following the introduction of MRL's for the QAC based disinfectants. Of course, all detergent residues must always be thoroughly rinsed but in the case of disinfectants it is common custom and practice to apply these products and leave them in contact with food production surfaces to provide on-going microbiological control. This practice is particularly observed in high risk environments. Many of the verification tests for chemical residue are based on test strips. In their simplest form this may be pH paper through to PPM indication of specific chemical compounds and formulations.

Use of these test strips is simple, quick and provides an indication of the presence, absence or approximate level of the chemical of concern. For more detailed, accurate analysis then laboratory equipment is needed to undertake titration, chromatography or mass-spectrometry techniques along with the specialist knowledge to interpret the results.

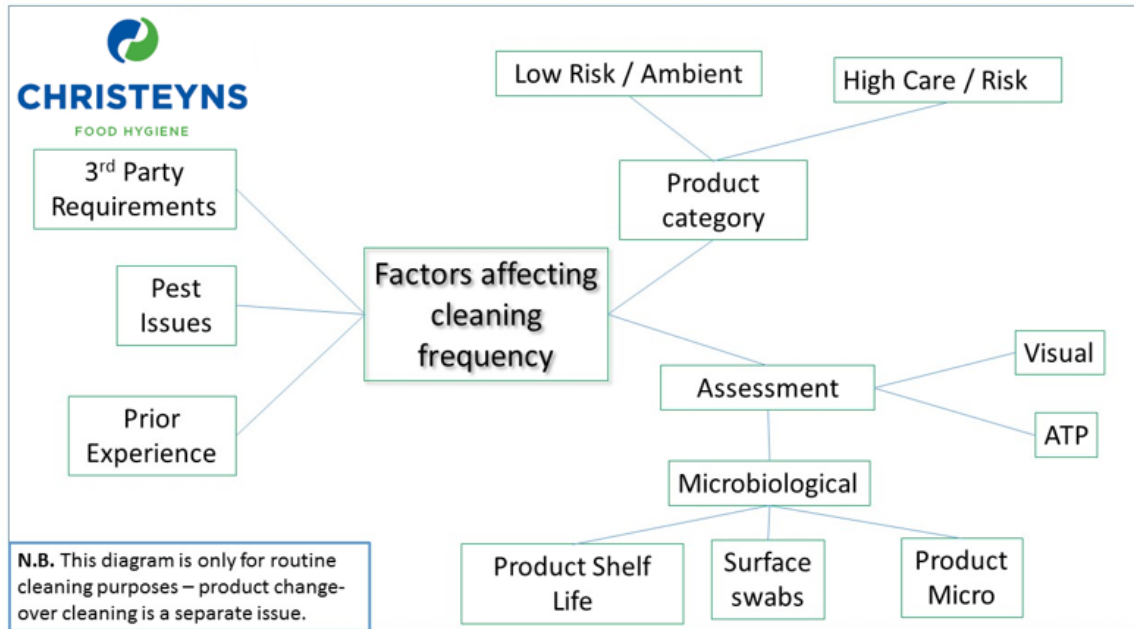
## 4.9. Viruses.

Use of non-specific hygiene assessment is currently the only viable technique for verifying that a cleaning regime has been effective at removing viral contamination. In particular, ATP is wholly ineffective at determining the efficacy of the cleaning regime due to the simple fact that viruses do not contain ATP as they possess no metabolic processes of their own. Applicable technologies such as FreshCheck may be appropriate at verifying that a surface had been rendered free from contaminants.



## 5. Monitoring Regimes

When building a site specific hygiene monitoring and documentation system, several key considerations should be taken into account: -



This determination of the frequency of cleaning will then feed into your documentation and control regime thereby enabling the hygiene professional to adequately manage, operate and control the delivery of food contact surfaces and environments which are in a suitable hygienic condition for the safe production of food.

Hygiene documentation should be suitably designed to enable properly trained individuals to effectively carry out the required tasks to a high standard. The system should be designed to utilise some of the following table. This is intended to provide guidance to determining cleaning frequencies in low and high risk areas of sites. This is however only a guide as determining cleaning frequencies. Replicating or comparing directly from site to site can be very difficult at times due to the different nature of each food manufacturing operation.

Surface / Equipment Type	Low Risk Area						High Risk Areas					
	D	W	M	3M	6M	A	D	W	M	3M	6M	
Food Contact Surfaces	✓						✓					
Operator Contact Surfaces	✓						✓					
Framework, underside etc.	✓						✓					
Cookers, Grills	✓	✓					✓	✓				
Tray / Rack Washers	✓						✓					
Knives, Scoops, Buckets, Tote Bins, Dolavs, Ingredient Bins, Trays, etc.	✓						✓					
Cleaning Equipment, Vacuum Cleaners, Floor Scrubbers etc.	✓						✓					
Low Level Fabrication – Up to 2 metres	✓	✓					✓					
High Level Fabrication – Above 2 metres			✓	✓	✓	✓			✓	✓	✓	
Evaporators – Process Areas (Raw, Cooked & Finished Product)			✓	✓					✓	✓		
Evaporators – Storage / Despatch Areas					✓						✓	
Air Socks / Air Conditioning Units										✓	✓	
Spiral Chillers							✓	✓				
Chillers							✓	✓				



## Key

D	=	Daily or after each use
W	=	Weekly
M	=	Monthly
3M	=	3 Monthly
6M	=	6 Monthly
A	=	Annually

Please bear in mind that there will always be variables across all sectors and sites within those sectors. Please also note that the below table is not an exhaustive list of equipment that may be present in any given food plant.

## 5.1. Create cleaning instruction card (CIC) system

Once the cleaning and disinfection methodology has been documented and agreed, the information needs to be combined into the cleaning documentation system. Most often called the Cleaning Instruction Card (CIC) system. This will document how the food processing environment and ancillary areas will be cleaned and how often. The CIC documentation may be created by the chemical supplier, however without the input from the food processing site management team the system will rarely be fit for purpose. The creation of these vital food safety management systems must be approached as a partnership exercise to ensure that the methods, frequencies and chemicals are fit for purpose.

The choice of methodology, and the Cleaning Instruction Cards, are therefore site specific and are developed from the experiences and requirements of the individual food manufacturing operation in conjunction with the skills and advice of the chemical supplier. All of the 3rd Party Standards and retailer codes of practice and manufacturing standards require that the site supplying them ensures that all items, areas and equipment have a cleaning method statement available. These should be appropriate to the product being handled and produced.

Training of hygiene personnel is critical to the CIC system effectiveness. After completion of the CIC System, the food processor will then need to put in place a training program so that all personnel involved in the cleaning and disinfection process can be trained against each CIC and any other aspects of cleaning and disinfection. Aspects that personnel will need to be trained in will include:

- Methodology
- Level of equipment strip down
- Frequencies
- Safety
- Key inspection points
- Standards required.



## 5.2. Validation of the cleaning regime

The next step is to validate the actual cleaning methodology against the standards required to confirm it works. Visual, microbiological, ATP, allergen, speciation and chemical assessments will need to be undertaken as required. This should ideally be repeated three times and all validation exercises recorded. Analysis from results of the validation exercises will help to determine if cleaning and disinfection methodology needs to be modified and training or retraining undertaken.

## 5.3. Verification & monitoring of the cleaning regime

On-going verification of the cleaning methodology will involve measurement of actual results against the standards required. Monitoring will ensure that the cleaning process is working within the set parameters required to deliver a factory environment suitable for the safe production of food. Analysis from results of verification and monitoring activities will also help if the methodology requires modification and training or retraining to be carried out.





## 6. Conclusion

A properly considered, designed and executed hygiene validation, verification and monitoring regime will afford the food/dairy/beverage manufacturing business a high degree of control over the safe, hygienic production of their products which will not present a risk to the end-consumer.

The documentation of this system will enable the business operator to assure both themselves and their customer base that the products produced will have been handled in a clean, hygienic environment as well as allowing for a thorough investigation and due diligence process should an issue occur. With any system, it is essential that the hygiene professional fully understands both the techniques used as well as the implications of the information delivered by the analysis methods enabling them to implement corrective action should it be needed.