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What is hygiene?

Hygiene comes from the name of the Greek goddess of health (Hygieia). Hygiene practices are employed as preventative measures to reduce the incidence and spreading of disease for the preservation of health. In the manufacture of food, good hygiene is a key part of quality assurance i.e. ensuring that the product complies with microbial specifications appropriate to its use. Standards can vary different in different facilities, processes and cultures and the terms cleanliness, hygiene and sanitation are often used interchangeably which can cause confusion .

Good hygiene can be described as deploying the highest standards of cleanliness together with the deployment of proactive preventative measures, regular monitoring and continuous improvement programs. Many of these systems are required by regulators across the entire food chain, for example Good Agricultural Practices (GAP), Good Manufacturing Practices (GMPs), Good Hygienic Practices (GHPs), Hazard Analysis and Critical Control Point (HACCP) systems. These are often supplemented by industry Codes of Practice. Within HACCP, many GMP's are described as Pre-requisite Programs (PRP) that form a solid foundation of the food safety pyramid. These systems and procedures are formalised into a management system which can be independently verified and certified to international standards such ISO.

Engineers and suppliers of processing equipment also have their part to play by incorporating Good Hygienic Design to ensure that equipment and processes are easily cleaned thus maximising efficiency and productivity, whilst preventing contamination hot spots and minimising design failure, wear and tear and maintenance costs.

Measurement enables the control of processes and monitoring hygiene is no different. The primary purpose of cleaning is the removal of residues from product contact surfaces and its environs. Residues may cause direct or indirect harm and are often considered as chemical, physical or biological hazards. Visual assessment of cleanliness is very subjective and can only detect macroscopic defects and gross lapses in practice. Their application is limited to pest control and foreign bodies detection that are often supplemented by other measurements such as on-line optical inspection and metal detection. Measurement of microbes as a hygiene monitor is well established including specific groups of indicator, index or pathogenic organisms. However microbiological methods are often complex, expensive and time consuming giving results in several days, which is too late for the production of many foods with short shelf lives.

Microbiological tests tell us nothing about the residues remaining on surfaces after cleaning. Over the past 40 years, rapid methods that give a direct objective measurement of product residues (for example ATP, protein and simple sugars) have been widely accepted in their own right as providing an assurance of cleanliness and good hygiene. They are not intended to be used as an alternative to microbiological testing because they are measuring different aspects of hygiene that are more relevant to the cleaning process (the removal of residues). Cleaning should not be confused with disinfection, which is the reduction of residual microbial contamination to an acceptable level. Trying to disinfect a dirty surface is a waste of time and money.

There are many benefits of deploying good hygienic practices that reduce the risks from foreign body hazards and cross contamination whilst ensuring the reliable consistent manufacture of products to specification. Safety and quality are assured whilst improving shelf life, and product recall and food poisoning incidents are prevented. Consequently customer satisfaction and brand loyalty are protected. Cost savings in manufacturing are obtained from a reduction in wastage and maintenance costs, and the optimisation of cleaning processes reduces chemical, water, energy and effluent costs, whilst minimising the environmental impact.

Conversely the cost of failure can be devastating in terms of money and health. Damage to a brand can cost millions and be very difficult to recover from, and directors of food businesses can be imprisoned. In 2011 the Food Standards Agency UK reported that one million people suffer from food borne illness every year, resulting in 19 million sick days, and 20,000 people are treated in hospital with 500 deaths.

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Hygiene monitoring

Good hygiene is the control of undesirable materials within the production process and its environment. Hygiene monitoring is the process of regular measurements to assess that the controls are operating within acceptable limits.

Many process controls are considered critical to food safety and the maintenance of high standards of quality. Cleaning is an essential component of good manufacturing practice and is often a pre-requisite of HACCP because history has shown that inadequate cleaning results in down-grades, spoilage, product recalls and food poisoning. Hygiene monitoring is frequently understood to mean the measurement of cleaning processes of production equipment or food contact surfaces and its immediate environment (non-food contact surfaces).

Cleaning and sanitation are often used interchangeably to describe cleaning processes but can mean different things and can have different requirements. The generally accepted order of events is rinse, clean, rinse and sanitise however dry cleaning can only be used for certain foodstuffs although these processes do not involve sanitation.

Cleaning is defined as the complete removal of food soil using appropriate detergent chemicals under recommended conditions. Different types of food soil require different chemistry of its removal. For example, alkaline detergents more efficiently remove fat- and protein-based soils, while mineral-based soils require acid cleaners. Accordingly the ideal test of cleaning efficiency is a direct objective test for food residue.

It is important to differentiate and define certain terminology:

- Sterilise refers to the statistical destruction and removal of all living organisms.
- Disinfect refers to inanimate objects and the destruction of all vegetative cells (not spores).
- Sanitise refers to the reduction of micro-organisms to levels considered safe from a public health viewpoint.

Chemical sanitisation involves the use of an approved chemical sanitiser at a specified concentration and contact time which for product contact surfaces are designed to reduce the contamination level by 99.999% (5 logs) in 30 seconds. Thermal sanitisation involves the use of hot water or steam for a specified temperature and contact time.

Accordingly the monitoring of these hygienic processes would require the measurement of time, temperature, chemical concentration and residual microbes.

Clearly sanitising an unclean surface would compromise the anti-microbial effect of the active agent and would be a waste of time and money, so a combination of appropriate tests need to be implemented to monitor the efficacy of each stage of the process.

Validation is intended to demonstrate that the process meets the operational needs and design specification. It measures the efficacy of the cleaning process and demonstrates its fitness for purpose and such studies are conducted when establishing cleaning for the first time, or when there is a change of chemical product/supplier or changes in food type or formulation. It establishes that the critical limits can be achieved.

Verification is intended to check that the process meets a set of design specifications. It is the regular measurement for compliance against the standards determined by the validation study and/or against an agreed standard. Tests are applied to critical control points which are influenced by the nature of the product and its manufacturing process. Clean-in-place systems are easier to control and deliver a higher standard compared to manual cleaning methods. Greater care and assessment is required for equipment that is complex and/or hard to clean.

The results of routine hygiene monitoring are assessed by trend analysis to aid interpretation and give an early warning of a drift out of control. Hygiene monitoring methods are also applied to identify and locate hotspots during trouble shooting or as part of a continuous improvement program.

For certain products and target consumers, cross contamination from the wider production environment may also require the monitoring of specific pathogens such as salmonella, listeria and cronobacter. But what methods and standards are applied to hygiene monitoring?

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Measuring hygienic status

"Measurement is the first step that leads to control and eventually to improvement. If you can't measure something, you can't understand it. If you can't understand it, you can't control it. If you can't control it, you can't improve it." (H. James Harrington)

Historically hygiene was primarily concerned with microbial contaminants and their associated risks. Modern food safety management systems are also concerned with chemical and physical hazards and incorporate the principle of prevention and quality assurance because quality cannot be tested into products. Process control and verification of cleaning rely on a variety of monitoring methods (chemical, physical and biological) such as chemical concentration, conductivity, time and temperature, and product residue tests. All give results in seconds at the point of use and are ideally suited for immediate corrective action.

By contrast the measurement of micro-organisms typically require specific controlled conditions isolated from production environments, skilled analysts and give results in days which is too late for the interim product manufacturing. Hygiene monitoring is usually applied after cleaning to product contact surfaces at critical control points, as well as hand contact points and in the immediate manufacturing environment that may represent a potential source of cross contamination.

The primary purpose of cleaning is to remove products, so the ideal test of cleaning efficiency is a direct objective test for food residue. Common food components such as ATP (adenosine triphosphate), protein and simple sugars have been used for decades and are well accepted. ATP detection systems are particularly well suited because they give instant quantitative results in electronic format linked to data analysis software to make interpretation, reporting and trending simple and easy. ATP detection is recommended by global food safety standards systems (e.g. BRC) and is also used by government food inspectors. Other specific tests for potentially hazardous residues such as allergens are also available, and the acceptable residue levels on surfaces are considered to be at their limit of detection i.e. 1–10ppm. However there are no agreed standards for any surface test method or product residue. Each food processing facility and its management is unique such that setting a common standard is difficult and unreasonable. Manufacturers are required to do the best that they can and to justify and prove that appropriate standards are achieved.

The primary purpose of sanitation/disinfection is the removal/reduction of residual micro-organisms to safe acceptable levels, so the ideal test is a test for micro-organisms. The number of total aerobic bacteria on surfaces indicates gross contamination and numbers can vary greatly from <10 to 100 million. Specific bacteria or family groups such as coliform and Enterobacteriaceae are used as indicators of process failure and/or potential faecal contamination and should be present in low numbers. Presence/absence tests for specific pathogen on surfaces are conducted in certain industries where the manufacturing environment can harbour these bacteria.

Microbiological tests are unique and also have severe limitations particularly when used to count bacteria on surfaces. This is due to the heterogeneous distribution of micro-organism such that sampling errors are very large but there are also inherent false assumptions and several sources of variation within plate counting methods themselves. Professional opinion acknowledges that the colony forming unit (CFU) is defined as "at best, an estimate and should not be reported as absolute." (Compendium of Methods for the Microbiological Examination of Foods (APHA 1992)). The working group of the International Laboratory Accreditation Cooperation states "it is virtually impossible to know the exact microbial concentration in any sample, natural or artificial." Despite this there is often an ignorance and blind belief in the CFU that leads to unreasonable expectations and demands for accuracy and precision in plate count results that cannot be delivered. It is not surprising that there are no standards for bacterial contamination on surfaces although there are some generally accepted broad guidelines. A pragmatic assessment of surface hygiene should include several different methods that give complementary information about the removal of food residues as well as microbes themselves.

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Hygiene results, data and information

Hygiena monitoring (HM) is intended to verify the efficiency of cleaning, identify environmental hazards and assess the residual risks. The results from HM are used for management purposes to measure the control of manufacturing processes, identify and prevent emerging hazards thus protecting quality, safety and brand value. The information generated provides positive reinforcement of best practice whilst identifying vulnerable areas and opportunities for continuous improvement. Rapid results identify hot spots and enable problems to be traced back to source quickly thus minimising the potential exposure and damage and offering cost effective solutions. Random single point determinations give only a brief snapshot in time, whereas regular routine HM and trend analysis is recognised as providing the most meaningful information.

The target analyte and methods used for HM will determine the type of results obtained and quality of information. Specific methods for environmental pathogens or specific allergens give presence / absence results so that the test location and number of samples examined are very important. A proportional change in the ratio of pass/fail results and their specific test location are used to assess the severity of the risk and remedial action.

The measurement of bacterial content has been used historically to assess hygiene, however microbial methods are known to be very variable typically 2-3 fold (or Log 0.3-0.5). When testing foodstuffs bacteria numbers can range from 1000 to 1 million per gram, but the significance between results is usually considered within an order of magnitude (10 fold or Log 1.0). The variation of results for environmental surface testing is far greater because very low numbers are expected (possibly stressed) that are unevenly distributed and the sample collection is highly operator dependent. Sample collection by swabbing relies on many factors including the removal of contamination by the swab/swab action and the subsequent recovery from the swab before applying the detection method. Consequently, there are no standards for bacterial surface contamination, and enumeration is imprecise and inaccurate. Significant control points for total aerobic bacteria on surfaces are considered to be Pass <10 and Fail >1000 by professional bodies whereas indicator organisms are considered to be <10 or absent. Using a statistical 'binning' technique is a better way to analyse data from surface contamination and to compare methods. This smooths the variation due to sample distribution and within the method itself to improve the correlation from <60 to >90% and give greater confidence in the result (see table below).

The primary purpose of cleaning is to remove product residues so the ideal test of cleaning efficiency is a direct objective test for food residue. ATP detection systems are well established over >30 years and widely accepted by retailers and regulators. This technology is particularly well suited because it gives instant quantitative results that enables immediate corrective action. The data generated is in an electronic format linked to bespoke data analysis software to make interpretation, reporting and trending simple and easy. The software can be used to create test plans for high and low risk areas and interrogating the database provides an early warning of emerging issues, customised reports and evidence of due diligence.

"You can have data without information, but you cannot have information without data"
(Daniel Keys Moran).

Contamination Level (CFU)	Interpretation	Plate count Bin avg. (CFU)	Rapid bacteria test (MicroSnap) Bin avg. (RLU)
<10	Good/Acceptable/ Pass/Low risk	9	2
10-100	Satisfactory/ Pass/ Low risk	82	56
100-1000	Adequate/Caution/ Moderate risk	137	245
>1000	Unsatisfactory/ Fail/High risk	787	2820

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"An ounce of prevention is worth a pound of cure." Benjamin Franklin

Prevention is better than cure

Regulators around the world require food producers to adopt preventative systems to manage hazards and risks to ensure public health. Formal food safety and quality systems benefit food suppliers and processors by protecting their business and consumers. Implementation also leads to improvements in productivity, quality, consistency and shelf life, generating significant financial savings. The cost of failure is high, from product downgrade/rework ($), product recall/restocking penalties/ brand devaluation ($$), sickness or even death, and litigation and imprisonment ($$$).

Underpinning these management systems are good manufacturing practices and pre-requisite programs such as sanitation and hygiene procedures that are considered fundamental frontline defences. Industrial food processing is mechanised and very efficient running >14 hours per day with between-shift cleaning and intensive overnight sanitation.

Verification of hygienic status after cleaning is essential for quality and safety but also to maximise efficiency, reduce wear and tear and maintenance. This requires rapid measurement systems such as ATP bioluminescence which is widely accepted, and recommended, and is the method of choice for many food manufacturers. The technology is cost effective, simple and easy to use at the point of use and has a wide range of applications. Its benefits include:

- Direct measurement of product residue giving objective meaningful data that improves communication, understanding and engagement of sanitation teams.
- Results in 15 seconds permitting immediate corrective action such as re-cleaning. Rapid results also enable fast trace-back and troubleshooting to quickly identify and prevent problems from escalating out of control.
- Improved cleaning efficiency and optimisation of resources, time and chemicals giving savings of 25-50%.
- Reduced risk of cross contamination, downgrades or rejected product.
- Generation of data that provides evidence of due diligence for auditors and trend analysis for continuous improvement.

Microbiology tests are used to measure surface hygiene (disinfection) but they only measure bacteria and provide an indirect assessment of cleaning. Bacteria tests are expensive giving results in days, which can be prolonged further if testing is contracted out to an external laboratory. Consequently, using the ATP technology gives additional complementary information about hygiene and risk enabling rapid response, better control and by bringing testing in-house also reduces costs.

The rapid ATP hygiene test measures ATP from all sources which is mostly derived from food residues. This application is not a replacement bacteria test, however there is a correlation between the two methods primarily because both product residues and microbes are simultaneously removed by the cleaning processes.

A study of the cleaning of 465 milk haulage tankers was conducted and six internal sampling areas were compared using both the traditional microbiological methods and the rapid ATP test. The following conclusions were drawn:

- The microbiological method produced a false view of the hygienic status of surfaces.
- The ATP test method gave a good indication of cleanliness.
- Implementation of the routine ATP test improved tanker cleaning by 77% as shown by a reduction in failure rates from 30 to 7% (see Fig. 1).

For the assurance of quality and safety, it is essential to deploy preventative measures and reap the benefits with timely effective monitoring systems.

Fig. 1. Rapid ATP hygiene monitoring of milk tanker cleanliness.