



Microbial measurement – the inconvenient truth

This series of articles is intended to take a fresh look at microbiological testing in an attempt to broaden the understanding and accept the limitations and impact on quality and safety assessments.

Microbiological tests are performed on raw materials, finished products and environmental samples to assess risks and monitor manufacturing procedures and control. Raw material and finished product testing are accepted to be of limited value because it is impractical and too expensive to do enough testing to give statistical confidence for the batch. The test results apply only to the samples examined which are random snapshots but it is assumed to be indicative of the whole consignment. More effective control is obtained by the implementation of the principles of quality assurance and preventative systems (e.g. GMP, HACCP) that are now widely adopted and included in food safety regulations. Under these systems there is a greater emphasis and reliance on environmental and in-process samples to manage and minimise cross contamination. Environmental samples give more relevant information about risks to the product. Faster results would also permit timely intervention and corrective action.

The concept of zoning is used to identify, differentiate and segregate processing areas within the facility where potential sources of pathogen and non-pathogen contamination exist (e.g. air, traffic, people, equipment and materials). Controls are identified and implemented appropriate to the business, risk of cross-contamination and proximity to the product.

The gold standard for microbiological testing is the cultural method, the principles of which have remained largely unchanged since the pioneering day of Pasteur and Koch (mid 1800s). However the results are highly variable due to many different factors some of which will be addressed in future articles.

The unit of measurement is the colony forming unit (CFU) which is fundamentally flawed by the incorrect assumption that a single colony is derived from a single bacterium. Each replicate sub-sample

will yield a result with a different colony count. It is claimed that Einstein said the definition of insanity is doing something over and over again and expecting a different result. Several replicates for different dilutions of each sample are required to obtain a reasonable approximation but this is seldom done in routine testing.

Even in the best run laboratories the uncertainty of measurement is +/- 40%. This means that the actual value is not known for certain, and for a sample expected to contain 10,000 cfu the value lies somewhere within the range 6000 to 14000 cfu on 95% of occasions but can also be outside this range 5% of the time.

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 the above, 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. Several alternative and rapid methods exist yet their adoption has been limited by the requirement to validate their performance against the highly variable culture plate count methods in processes that are not making like-for-like comparisons. Tony Sharpe (1980) stated: "The plate count from its very nature provides data so unique that they can be related to no other analytical data than those from other plate counts" Some microbiological methods can be specific and very sensitive but enumeration is very imprecise.

The challenge is to break away from the reliance and vagaries of the CFU and find a better way to assess and express microbial contamination.

We cannot solve our problems with the same thinking we used when we created them.

Albert Einstein