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t would be unusual to find anyone producing foods today, that does not undertake some form of microbiological analysis. The testing done may cover incoming raw materials and ingredients, environmental testing of the production environment and end product testing.

Some companies also continue their test regime by keeping 'library' samples of different batches of product under controlled conditions that they test at the end of the allocated shelf life.

The types of test that food producers use may vary considerably, and will include tests for specific pathogens (for example salmonella, listeria), tests for so called 'indicator groups' (enterobacteriaceae, faecal enterococci, coliforms), tests for potential spoilage micro-organisms (yeast and mould, Pseudomonas spp., lactic acid bacteria), and tests for general microbial level (Total Viable Count).

It is important that anyone dong microbiological testing defines suitable microbiological criteria against which to work.

Criteria come in three recognised forms: • Standards: these are criteria that are set in legislation.

• **Specifications:** these are criteria agreed between a supplier and a customer as part of a purchasing agreement.

• **Guidelines:** these are most often criteria defined by the producing company to give confidence that production is under control.





Microbiological criteria

Whichever the form of the criteria, they should contain several important parts in order to make them useful:

• A sampling plan. This should define when the sampling is to be done, and any requirement for replication of samples.

• The analyte. Which organism or range of organisms are to be tested.

• The method. It is well known that different methods can give slightly different results, so a specific criterion should define, in detail, which method should be used for the organism(s) noted.

• The 'action' values. It is of no value testing for a particular organism, if acceptable and unacceptable values are not specified, so criteria should contain a statement of what levels are considered acceptable in the samples tested, and why those levels were chosen. The reasons why may be varied, but could include: a level noted in legislation, a level at which the food may spoil before the end of its shelf life, a level denoting poor hygiene during production, a level at which there is an unacceptable risk that the safety of that food is compromised, a level in excess of a customer specification.

• Action to be taken if the acceptable levels are exceeded. These should be clear, and contain all the information required to take the appropriate action. The clear nature of these instructions is very important. On many occasions microbiological data become known at times when the full technical team from a company are unavailable; most people will have experienced the 'Bank Holiday Weekend' scenario when adverse results become known late on a Friday evening, to a depleted technical team. Clearly presented, well reasoned 'action' instructions will help ensure that the appropriate action is taken at all times.

Microbiological data

Of course, technical teams and microbiologists within food companies tend to firstly consider what happens when the results are poor and what actions are to be taken when criteria are breached.

However, every day an enormous number of microbiological tests are done on ingredients, environmental samples and food products and a vast majority are fully acceptable, and well within predefined criteria. So what do we do with this data?

The answer, in many cases, is unfortunately nothing. The microbiological test results will be quickly assessed, a judgement will be made as to whether they are 'acceptable' by comparison with pre-set criteria, and then the results will be consigned to a computer memory file or a filing cabinet for a prescribed number of years, after which they will be destroyed. Now let's just reassess those events. The testing itself will have consumed raw material or product that cannot then be sold to a customer, it will require a trained person to take a sample that will be delivered to a laboratory. The laboratory will use up microbiological media and reagents, and technical staff will spend time doing a test.

The laboratory itself may be accredited, and spend considerable time and money maintaining correct quality systems to ensure that its work is done correctly. This means that each test has a cost to the food producer, and each result is valuable – too valuable to be rapidly confined to a filing system.

The added value use of data

Microbiological data is often considered to be a single datum point at a single fixed point in time, but by extending this and viewing the data over a time period, we can start to use this data in another way, to see how the individual points are moving over a given time period.

Statistical process control

Industry is increasingly adopting automated monitoring and control of manufacturing processes, this tends to imply a 'real-time' feedback between monitoring and production control. Microbiological analysis times are generally too long to allow this form of 'control' so the term Statistical Quality Assurance (SQA) is often used.

In order to use a SQA approach, microbiological data needs to be viewed over time, we also need to use data that gives 'real values' i.e. counts, most of the time.

The results of presence/absence tests (as done for pathogens such as salmonella and



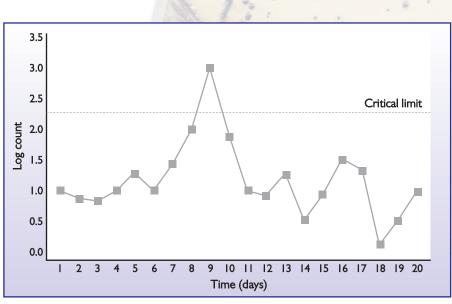


Fig. 1. The power of data trending in monitoring change over time.

listeria) is of little value as on most occasions the results will be negative, and when they move to being positive, the microbiological criteria are breached.

So SQA requires numerical results that can be plotted against time, producing a 'trend' of data of data for a particular test over the chosen time period. Such trending graphs are often known as Shewhart control charts after their inventor Walter Shewhart.

Shewhart worked for Bell Laboratories in the 1920s at a time when telephone transmission was unreliable. The company had realised the importance of reducing variation in the manufacturing process, and that a constant process adjustment in reaction to non-conformance increased variation and degraded quality.

Shewhart introduced the idea of using control charts to monitor trends against predetermined limits.

The purpose of control charts is to allow detection of events that are indicative of actual process change, once this is identified, action can be taken to find the cause and bring the process back under control.

In microbiological terms numerical data for a test, should be plotted over time. The graph should indicate critical limits, above which the 'process' is considered as moving out of control, in well set up systems such limits will be lower than the reject levels set in the criterion. As data continue to be plotted on the chart, the trend will be noted.

There will be a natural variation in results (Shewhard would note this as common variation), and this is fully acceptable. However, if the 'process' moves out of control, the results will cross the critical limits (special causes variation) and this would indicate that the time has come to investigate the cause, identify it, correct it and bring the 'process' back under control.

The example chart (Fig. 1) shows the power of data trending in monitoring change over time. The critical limit shown is not the reject criterion, which is a higher value. The trending does show that natural variation in results occurs, but also that on one occasion a value outside of the natural variation has been found.

This required action to be taken to establish a possible cause and to bring the situation under control, before the reject level has been reached.

This type of trending can be used to look for a variety of 'problems' that might occur during production and give rise to elevated microbial counts, for example higher counts in raw materials, poor cleaning in the production environment, variation in an antimicrobial process, upward variation in chiller temperature etc.

The key is that the problem will be noticed, before a major issue of product rejection occurs, saving time and money, this being achieved with no additional requirement for microbiological testing, but simply by using the data that is already available in a slightly different way.

Trending of microbiological data is a very under used tool within the food industry, but a tool that, with minimal cost, could help identify key problems at an early stage and allow corrective actions to be taken before major product loss has occurred. FaxNOW +44 1256 329728 Val.kane@thermofisher.com

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