# Useful tools to assess the microbiological safety and quality of foods

Within the food industry there is a requirement to ensure the safety, quality and legality of foods and this starts from the initial design of process and product, with validation being carried out to assess if the applied controls are fit for purpose or not.

At PAS we specialise in designing such validation studies and importantly in addressing what needs to be changed in the event that the work does not support what is required. It is therefore important to design the work such that it will give valuable information to guide next steps in the event of adverse results and not just to do the minimum to give a pass or fail output.

This gives real value to our clients and supports our approach of finding a way to market with the correct and valid control strategy as opposed to stopping at the first hurdle.

This ensures useful outputs from the study even if the control strategy is shown to fail and helps to consider alternative ways to safely deliver the concept to market, thus maximising the cost to benefit of each piece of work.

There are a variety of tools we use for validation and the most suitable approach is always defined through a detailed risk assessment of the product and process under consideration.

In some cases, there is a need to validate the elimination of various microorganisms and such control strategies are termed Elimination Strategies. In other cases, there is a need to consider approaches to prevent outgrowth of organisms which are termed Inhibition Strategies and in other cases we need to consider prevention of contamination which are called Exclusion Strategies.

Each type of strategy will have its own tools for validation and often more than one type of strategy is used as part of an overall control plan.

If you wish to know more about these strategies and the types of tools used at PAS, please contact Paslabs@premierfoods.co.uk or refer to the PAS Microbiological Validation Service link

**PAS Microbiological Validation Service**

In order to validate our client's control strategy, it is essential to fully understand the product concept and to perform a risk assessment on the controls in place.

Often this may lead to discussions to advise on amendments to the strategy in order to provide the most robust controls and hence maximise the chance of a successful validation.

It is important to not undertake a study where there is little chance of success and this would always be communicated to the client. However, in some instances it is simply not known on the whether the strategy will work or not, particularly where a number of controls are combined, which undertaken alone would not work but in conjunction with other points may be robust enough. Such hurdle technology is often used to deliver the desired product profile without the extreme measures needed if only a single control were to be used. Examples include the use of both water activity and pH where the use of only one of these controls would not give the desired flavour or mouthfeel required.

When risk assessing, consideration must be given to the fact that foods do not remain consistent through life and are subject to inherent changes as well as changes that might be imposed on them through distribution and consumer abuse. All such likely 'dynamic' parameters must be included within the study to consider worst case scenarios.

All control strategies can be classified into 3 categories, used alone or together in some way. These are:

Elimination Strategies – where the control is aimed to removing the microbe or microbes of concern as any presence is a problem. Examples of such strategies include Commercial Sterilisation or targeted at all microbes with the exception of Thermophiles, or Pasteurisation designed to eliminate vegetative pathogens such as Salmonella or Listeria.

Inhibition Strategies – where the control is aimed to preventing the outgrowth of microbes of concern. Here the type of microbe can still be present but would need to grow in the product to cause an issue. Examples include pH control of products to prevent outgrowth of toxin forming microbes such as *Bacillus cereus.*

Exclusion Strategies – where the control is aimed at preventing contamination of the foodstuff as it would subsequently then cause an issue. Such controls include specialist aseptic filling system as well as more simple barriers to protect the foodstuff through a high risk/high care area.

It is clear then that each part and each type of strategy is significantly different and requires a tailor made approach to the validation work required.

The tools used, similarly vary, depending on what it is we need to assess.

For elimination strategies it may be that the thermal process used requires validation. Whilst often this can be done by direct physical measurement, where this is not possible, the use of a biological

validation may be used. In such a study, non-pathogenic surrogate organisms are used which are pre-treated to represent the potential worst case condition of the microbes when in the foodstuff, then inoculated into the appropriate part/s of the foodstuff and process. This then follows the thermal process under the least possible parameters and assesses the level of kill achieved. In some instances, the process will also be turned down to the point of failure to assess the inbuilt robustness.

This approach is very useful, particularly to address the growing concerns around the lethality of 'dry heat' for dry or semi moist foods. Traditionally, this has been addressed through the use of calculating the required lethality by measuring indicators known as D and Z values. However, these values can be misleading, giving rise to over safe or unsafe processes. As such, a direct assessment via biological validation is by far the best approach to take and can also be used to optimise thermal processes, historically set by inaccurate D value calculations

Other elimination strategies include novel processes such as High Pressure Processing, Ozone treatments, etc all of which can be evaluated using biological validations.

In some instances, there is an inherent impact of the foodstuff on the microbes of concern, achieving their destruction through a combination of factors including such parameters as pH, acid type, humectants etc. Whilst this is a complex set of interactions it is possible to validate a robust control strategy but compliance to recipe control and the time required to eliminate the microbes must be taken into account.

For Inhibition strategies, there are various micromodels available which can provide a steer in terms of risk but should never be solely relied upon as they are too generic and can give over confidence as well as be too failsafe and result in inferior product profiles to market.

By far the most useful approach is to challenge test the product with appropriate microbes which are again pre conditioned and inoculated into the appropriate part of the product. Number of samples required is drastically reduced as each will contain the organisms of concern and is therefore representative of worst case.

This is the most accurate means of evaluating inhibition strategies.

In some cases, a durability study will be used in place of a challenge test whereby samples are not inoculated but are incubated and tested at appropriate times, but this must only be used where the organism/s of concern are known to be present as supported by testing at start of life. Often such studies are undertaken without such evidence and are therefore not a valid approach to assess the product. Such 'natural challenge tests' are of use though but often require higher numbers of samples due to the sporadic contamination present through a batch of product.

For both types of study, a risk based assessment will define how long into life the validation needs to be applied. This is most often not for the full shelf life required for long life ambient products and typically would be up to 3 to 4 months into life.

For Exclusion strategies, biological validations can be used for complex aseptic fillers but are also supported by incubating of a statistically defined number of samples which are then tested to ensure their sterility has been maintained.

Similarly, for samples processed under high care/high risk environmental controls or even where ambient products are processed within GMP facilities, validation of environmental control to achieve exclusion, is best assessed through high level sampling and testing for the presence of the organism/s of concern.

To conclude, there are many tools available, some of which are given here, but they must be aligned to the type of control strategy and embedded in a well-designed test protocol which covers all reasonable variables. Failure to consider this in terms of risk and validity of approach can result in failure to launch an acceptable product or worst case to launch an unsafe product.

At PAS our team of experts and facilities are dedicated to our clients to ensure a robust, valid and cost effective approach is achieved which will provide the necessary validation documents as part of a due diligence defence.

In the event of a study demonstrating concern with your strategy we then work closely to use the data obtained to find what modification is required to get your desired product to market.