Microbiological testing strategies

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The use of testing and monitoring in the food industry has undergone many changes through the years. Initially, prior to HACCP based approaches, there was an over reliance on testing for ensuring food safety.

The food industry relied upon testing programmes to determine if the food manufactured was safe. This led to extensive testing programmes, positive release of materials and a great deal of rejected product as well as, undoubtedly, non-conforming material being accepted. The fate of products was very much in the hands of the testing laboratory.

Since the introduction of HACCP based approaches, the reliance for food safety is on determining appropriate and effective controls. Monitoring systems for these controls give real time evidence of compliance to food safety requirements and assurance of safe food, negating the need for high levels of positive release testing. Levels of testing have subsequently decreased to more appropriate amounts. But what is an appropriate amount in the wake of HACCP? What is the sensible application of microbiological testing? Is it even needed?

This article explains the rationale behind testing programmes and aims to assist in developing suitable testing programmes for the food industry. For the purposes of this article, testing refers to laboratory based microbiological analysis where post event data is generated, whereas monitoring activities are those where real time information is generated (pH measurements, temperature measurements).

The purpose of testing

The first question a food business needs to ask when setting up a surveillance programme is what is the purpose of the testing being considered?

Testing for micro-organisms is still a necessary and useful part of an effective food safety management system, but the programme to use is very dependant on why you need to do it.

The main reasons for testing fall into the following categories:

- **HACCP validation/verification.**

Within the principles underlying HACCP is a requirement to demonstrate the effectiveness and appropriateness of controls. This is known as validation.

For industry accepted controls this may not be necessary, being supported by the weight of evidence supporting their effectiveness and hence high levels of confidence, for example recipe modification to adjust pH to a level which prevents growth.

However, where a process specific control is required, for example a novel thermal process, such validation should be carried out. This may involve initial assessment of microbial levels pre and post control.

There is also a requirement for ongoing assessment that the HACCP is both being applied correctly (assessment of compliance) and that it is still valid (assessment of on going fitness for purpose). This is known as verification.

Testing can provide effective means of obtaining verification where controls are aimed at reducing, preventing or eliminating contamination or growth of micro-organisms.

Where such data is not generated, in the event of a food safety issue occurring there may be insufficient evidence to support a food business in defending against criminal prosecution where harm to the consumer has resulted.

- **Acceptance/rejection of raw material batches where little is known of its manufacturing control.**

As global sourcing increases, and commodity buying is included in the supply chain it may be more difficult to determine actual controls applied to material being purchased, due to the practicalities of assessment. In such cases, testing may be used to provide assurance of the required safety criteria for that material. This strategy is often applied to import of materials and will involve more stringent sampling plans than routine verification testing.

- **Investigation into issues.**

Despite the application of HACCP, food safety issues may still occur, as the system only serves to minimise risk, not eliminate it. Also, it is only as good as the knowledge base used to create it. Thus some evolution is inevitable, with issues potentially arising in the interim.

Testing can be a very useful tool for investigating potential causes of an issue or to determine the extent to which the issue has occurred.

Both routine verification testing and esca-

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lated focused testing regimes are used for this purpose

● **Risk assessment.**

Often, when performing a risk assessment on novel ingredients or processes, some of the information required on which to base an assessment may be provided via microbiological testing either over time or within a controlled experiment designed to provide that information.

Routine surveillance testing

The remainder of this article will focus on verification testing as this is the main consideration of routine surveillance testing programmes.

● **Legal context.**

Within UK food safety law, where a company can demonstrate a due diligence defence, they may avoid criminal prosecution. This is achieved through being able to demonstrate that the food business has taken all reasonable precautions to minimise the risk of a hazard occurring and, as such, it accepts that zero risk cannot be achieved.

Such a defence may be greatly supported by microbiological testing programmes, which can serve to provide evidence of fitness for purpose and compliance to food safety controls.

It is important, however, to note, that where such programmes highlight the potential for materials being placed on the market which may be injurious to health, there is a legal obligation to act on that information to an effect so as to minimise the risk to the consumer.

Such actions also require notification to

Table 1. The manufacturing process for a chilled ready meal.

Process step	Hazard	Control	Testing required
Raw materials intake	Salmonella presence	Heat processing	None required at site
Component cook	Survival of salmonella	Heat processing	Validation of heat process. Verification testing of finished product for salmonella
Cooling of meat component	Growth of Clostridium perfringens	Blast chill to achieve set time to cool below 5°C	Validated cooling curve. Meat component testing for Clostridium perfringens
Batter mixing for yorkshire pudding	Growth of B. cereus/ coagulase +ve staphylococci	Maximum holding time of batter and clean down of system	Validated holding time at maximum room/ plant temperature. Verification testing of batter component pre cook and plant swabs for Bacillus cereus and coagulase +ve staphylococci
Gravy cook	Outgrowth of non-proteolytic Clostridium botulinum in gravy component	Heat process of 90°C for 10 minutes	Validation of heat process. Verification testing n/a
High care assembly	Microbial contamination through plant, i.e. depositors of gravy	Plant hygiene	Verification testing of swabs from plant post clean
High care assembly	Post cook contamination with Listeria monocytogenes	Plant and environmental design and hygiene/ segregation	Verification testing of final product at end of life and plant swabs for L. monocytogenes

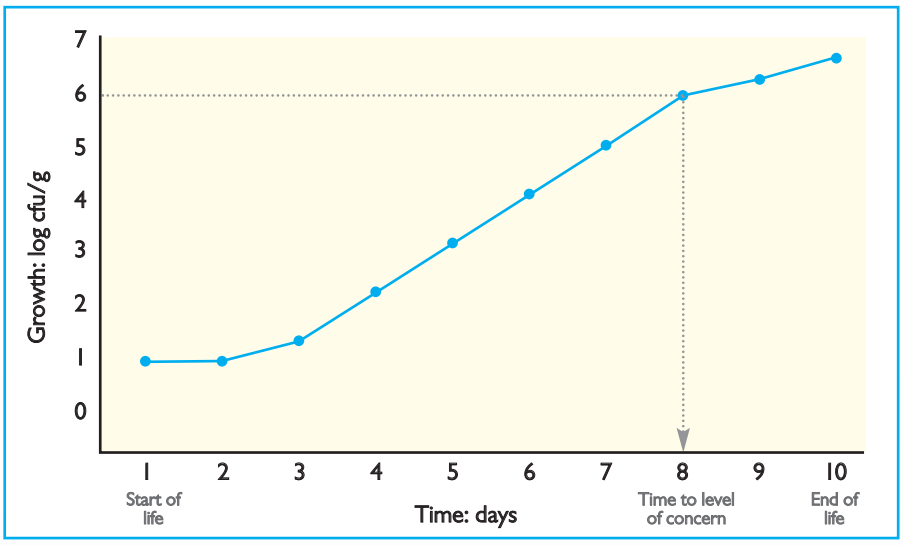

Fig. 1. Growth cycle consideration of a toxigenic organism for determining time point of testing.

the Food Standards Agency. Failure to do so is likely to lead to prosecution.

● Limitations of testing.

It is important to ensure that all parties to which a testing regime applies are aware that any testing regime does not infer any effective control over the materials/process to which it is applied.

Effective controls need to be applied 100% of the time and need to be proactive in reducing the risk of the hazard. Testing is applied to a very small percentage of the material being assessed and it is a measure only of acceptability for that sample. It does not control, it only measures. If a sample fails on test, the only level of control is to react, often too late.

Accuracy of information is subject to the suitability of the test, the laboratory performing it and the distribution of the organisms through the sample, all of which can vary. Thus 'normal' levels are difficult to predict and compare. This must be taken into account when setting up surveillance programmes.

● Which organisms to analyse for?

The specific organisms to test for are determined by hazard analysis. This considers the hazards that could reasonably be expected to occur in the material being assessed. If it is considered likely enough to warrant a control, then verification is required.

It is not always necessary to test for the specific organism of concern as indicator organisms can be used to verify process controls, for example total viable count, enumeration of enterobacteriaceae etc.

● What samples to test?

It is generally considered there is too much focus on finished product testing as this is seen as assessing all components and processes applied throughout manufacture.

However, this has drawbacks in that multi component final products will be a mixture of the micro flora from all sub components, such that setting a meaningful specification from such a mixture can be difficult. It can also lead to overburdening of 'capture all' testing regimes applied to all finished products, and can lead to dilution of otherwise problem levels which are therefore missed in the final product.

Furthermore, in the event of results indicating non-conforming product, the data may be limited in providing a guide to where a problem may have occurred. A good surveillance plan should not only provide data to demonstrate acceptability, but should also help guide you to the source of issues if they occur.

Lastly, some organisms can grow, release toxins and then be killed off by further processing into final product. Although the organism is killed, some toxins may remain and be undetectable in final product whilst still able to cause injury to the consumer. Testing of the intermediate material for the organism prior to destruction would thus be needed as opposed to final product analysis.

Thus, an effective surveillance programme should be considered throughout the manufacturing process, considering the points where control is needed, and should enable direction to subsequent investigations into out of specification results.

Typical effective systems may therefore encompass raw materials, process intermediates, environmental swabs/settle plates and finished product.

Table 1 considers the manufacture of a chilled ready meal consisting of meat, vegetable, gravy and Yorkshire pudding components. Note, this example is intended for illustration purposes only and is not intended for direct application. As such it may not be exhaustive in its assessment.

For finished product testing, consideration needs to be given to the timepoint at which samples are taken. Should you sample at the start of life, end of life or somewhere in between?

This decision will depend on the type of product and the hazard being considered. If the mere presence of a pathogen, such as salmonella, is of concern then start of life samples are required in order to minimise the delay in taking appropriate action.

However, for some pathogens, growth during the shelf life may be the issue, such as toxigenic organisms (for example clostridium, Bacillus cereus or coagulase + ve staphylococcus) or Listeria monocytogenes.

In such a case, end of life samples are of more use, unless the relationship with known levels at start of life and growth levels at end of life is known. For long life products, samples may be taken part way through the life provided the time point is likely to be representative of the final growth potential at end of life.

In the above scenario, where the hazard is toxin production through growth of a toxigenic organism to 10E6 cfu/g, clearly verification testing at start of life would be meaningless unless the growth relationship at start and end of life is known. Effective verification time point would thus be at eight days or end of life. Concerns over end of life testing include the inability to react but this infers reliance on testing for food safety – which is not the case. Testing of this type only enables verification of effective controls. Thus the above scenario is a valid approach.

● How often to test?

The frequency of testing will depend upon the risk of the hazard occurring, which in turn will be determined by the robustness of the control in place. Thus where controls are robust and even inherent (effective pasteurisation processes, preservative addition, pH effects of recipe) a much reduced frequency should be considered, typically monthly to annually.

However, where controls are unknown or are very manually dependant (geographically distant

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suppliers, hygiene practices), the risk may be considered to be higher, thus an increased frequency may be considered, typically from per batch to weekly.

● How many samples?

Sample number should be set according to the statistical probability of accepting/rejecting a problem batch.

However, in reality, such an approach is only practical where, because of lack of information on controls applied, there is a need to rely on the testing programme to differentiate acceptable and non conforming material (imported commodities).

Such an approach is not required and would be overburdening for routine verification programmes. The cost/benefit would not be justified, and reliance is correctly placed instead, on monitoring information supporting the application of known controls (pH measurements, temperature monitoring, etc).

In the latter case, often only single samples can be taken at each sample point for the purposes of routine verification.

● What to do with the result?

Any effective programme needs to set microbiological criteria, detailing what to test and what the limits are for determining acceptability.

However, often such criteria are deemed to require only one outcome in the event of non conforming results – rejection of material. This is not necessarily the action to take and infers that the testing programme only considers safe/unsafe criteria.

An effective programme will also consider levels at which an action must be taken prior to a reject level being reached. Thus the concept of action and reject levels is introduced.

The reject level infers unsafe material, whereas an action level suggests a move toward loss of control, allowing action to regain control before the problem escalates and lead to unsafe material. Thus surveillance programmes, normally being reactive, can, at least in part, become proactive.

For some tests, though, a reject level may not be appropriate at all, i.e. indicator tests such as TVC, where unless a relationship between high levels and pathogenicity is established, the higher levels should only ever require some action other than reject.

On the other extreme, where out of specification results require no action, including where their results demonstrate high peaks within a trending report, the question should be asked of the requirement for that particular test.

● Evolution of testing strategy.

Testing programmes should always be subject to review, in line with review requirements for HACCP systems.

There may be a need for more stringent programmes to be introduced where failures of current systems have been found, there may be modifications required as processes and materials change or there may be the potential to decrease testing requirements, particularly where trending of data demonstrates increased levels of confidence in the control applied – this therefore may demonstrate decreased risk and thus allow for reduced testing programmes.

A plan for escalation in the event of issue must also be developed as things may change with greater risk being inferred.

Conclusion

An effective testing plan should provide sufficient information to support a due diligence defence and enable a focused approach to problem solving in the event of an issue. It should align itself with the HACCP system, being supportive in terms of necessary validation, verification and out of specification actions.

Effective systems should not be overburdening and generate data for data's sake. If the data is not useful the plan should be modified.

RHM Technology's ethos is to work closely with their clients to help develop systems that work for their food business and not against them in order to demonstrate their effective manufacture of safe foods. ■

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