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When should you challenge test your products?

A guide to modelling and risk assessment protocols

Peter Wareing

A Leatherhead Food Research white paper

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Challenge testing – should we or shouldn't we?

In this white paper, Dr Peter Wareing provides a technical overview recommending when a challenge test should be conducted, and looks at some of the test parameters.

Around one million cases of food poisoning are reported in the UK every year. Each case carries the potential for serious repercussions, including short term illness, hospitalisation (with associated costs to the health service), loss of productivity, legal costs, brand reputation damage, closure of the company, loss of earnings, permanent side effects, and in some cases death.

Challenge testing is a vital tool in the prevention of food poisoning – it involves deliberately contaminating food products with relevant microorganisms to understand issues that may arise during processing, distribution and storage. In this white paper, Dr Peter Wareing sets out an approach to help you identify when your products require challenge testing.

Product reformulation

When producing a completely new product, you can be fairly certain that various food safety procedures will be required to ensure its safety.

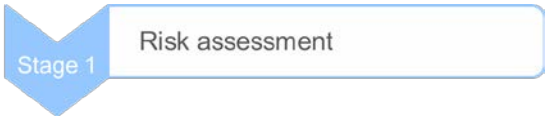
In contrast, however, small, often incremental changes to existing products/ingredients/ process parameters may make it difficult to establish when to carry out a challenge test. For example, current drivers for healthy, clean label products are leading product developers to tweak and subtly reformulate existing products. Each of these changes may be only subtly different to its predecessor, none of which are significant enough to cause any changes to the shelf life, but taken together, they represent a real shift in the overall safety of the product.

How can we make sure that the effects of these changes are effectively captured? In theory, all of these should initiate a review of the HACCP plan, but this may not happen if the changes are carried out by the NPD team without involving the HACCP team.

Food safety toolbox

Below are a set of procedures to follow to make sure that each product is treated consistently and that a logical process is followed.

But how does the process work in practice? Do we need to carry out all of the stages and in the order outlined above?



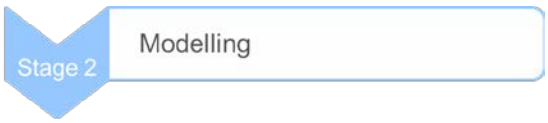
Key parameters to consider during an initial risk assessment include:

Recipe control factors – pH, water activity (a_w), salt, preservatives.

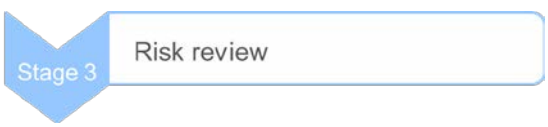
Shelf life – for example, the duration and conditions of storage (e.g. ambient vs chilled) and how these will affect the types of pathogens that could grow, and the speed of growth.

Ingredients – has there been a change to product format (e.g. ground vs dried), or the sourcing location? Or has any new information on ingredients been published?

Processing – what is the type of process (e.g. thermal, high pressure processing, ohmic heating, etc.)? What is the process duration, and is it aseptic or clean fill, open or closed?



Using the risk assessment data, modelling can be undertaken using free software such as Combase, Pathogen Modelling Program, Perfringens Predictor, Risk Ranger, Salmonella Predictions, MLA Refrigeration Index Calculator, to name a few. This approach can then inform a study on the likelihood of microbial growth or toxin production.

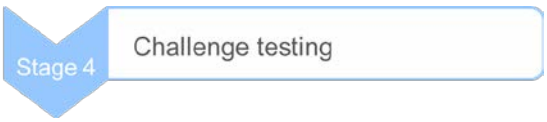


During this stage, the information gathered thus far is reviewed to determine whether the selected pathogens could grow, or produce toxins, over the intended shelf life of the product, either from contaminated ingredients or post process cross contamination. A synthesis of the available data is then undertaken, which is described as a risk review. In many cases, modelling programmes cover some, but not all, of the parameters that affect microbial growth.

One of the key microorganisms that can affect chilled products is psychrotrophic *Clostridium botulinum*. A chilled product is particularly at risk if it does not receive an in pack cook of 90°C for 10 minutes, and has an intended shelf life of greater than 10 days at greater than 3.3°C. In cases like these, if the risk assessment shows that the product does not contain one of the following control factors, then a challenge test should be undertaken:

- pH 5.0 or less
- A_w 0.97 or less
- Salt 5% or greater

In this particular instance, if a product is robust and passes the control factors, a challenge test should not be required. However, to be absolutely certain of a product's safety, it is always best to complete the full set of procedures.



If in any doubt, it is recommended to undertake challenge testing and the risk review will inform the way it should be carried out – by indicating the areas where information is in doubt. The risk review will outline the process of the pathogens and/or environmental organisms and their strains to be used in the challenge test. Similarly, the

length of the study should be based around the intended shelf life and beyond. In general, this is about 30% longer to allow for variation in the chill chain, domestic fridges and the consumer not adhering to the use by date. The modelling exercise will show the potential shelf life.

It should be noted, however, that in some cases products do not deteriorate as predicted by the modelling exercise (microbial growth could be faster or slower) due to unknown intrinsic factors within the product. For that reason, it is always advisable to challenge test the product, to be more certain of any potential issues.

Stage 5 Shelf life studies

Once products have been in production for some time, changes to the length of production runs, cleaning protocols or a build-up of resistant strains can alter the shelf life and leave it shorter than at inception. It is therefore important that correctly designed shelf life trials are conducted to determine if any potential issues could occur.

In addition, shelf life studies are recommended if a preserved product is intended to have a significant open shelf life.

Always be on the safe side

Do not underestimate the potential issues that may arise from subtle changes to product ingredients (source, format), recipe and processing parameters or seasonal climatic changes. Always review/risk assess the process if you are unsure and seek external advice where necessary.

Case study 1 – fruit bakery product

A fruit muffin became mouldy within its intended shelf life and our client was keen to understand why. Leatherhead conducted analysis of the mould, followed by a risk assessment of the whole process. This revealed that a change in supplier (and subsequently in the type of fruit) meant that the cooking process was not killing any mould spores that might be present.

Modelling of the cooking process, combined with the contamination level of the fruit effectively determined the thermal process required to kill the mould.

This was followed up with a laboratory based thermal kill challenge test to corroborate the revised process.

Case study 2 – cream filled confectionery

In a move towards clean label, several control factors were removed from the cream within our client's filled confectionery product. The modelling exercise indicated that this could allow outgrowth of *Bacillus cereus* spores. The product now required a more rigorous thermal process for the cream. After conducting thorough modelling, the optimal thermal kill parameters were determined. This was followed up by challenge testing the revised product in order to validate the new process.

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How Leatherhead can help

Contact safety@leatherheadfood.com to discuss any of your food and beverage safety needs. We can help you with desk-based as well as on-site risk assessments on any safety related issue. Challenge testing can be used to predict the shelf life of a product, validate the efficiency of a heat treatment or process or understand the behaviour of bacteria in the food. Leatherhead can also conduct challenge testing to support the expert testimonies required in legal disputes.

About the author

Dr Peter Wareing is a Food Safety and Manufacturing Consultant at Leatherhead Food Research. He obtained his B.Sc. in Agricultural Science from the University of Leeds, and a Ph.D. in Plant Pathology from the University of Hull. Before he joined Leatherhead Food Research in 2001, he worked for the Natural Resources Institute undertaking development work on food processing and food security projects in Central and South America, Africa and South East Asia. Peter has many years' experience working in microbiological research, development and training. His specialist areas are food safety systems including HACCP, microbiology and mycology. He is particularly interested in confectionery and snack foods, sauces and dressings, soft drinks and dried foods. At Leatherhead, Peter undertakes troubleshooting audits and investigations for clients, is an expert witness and delivers food safety-related sessions on training courses.

About Leatherhead Food Research

Leatherhead Food Research provides expertise and support to the global food and drinks sector with practical solutions that cover all stages of a product's life cycle from consumer insight, ingredient innovation and sensory testing to food safety consultancy and global regulatory advice. Leatherhead operates a membership programme which represents a who's who of the global food and drinks industry. Supporting all members and clients, large or small, Leatherhead provides consultancy and advice, as well as training, market news, published reports and bespoke projects. Alongside member support and project work, our world-renowned experts deliver cutting-edge research in areas that drive long-term commercial benefit for the food and drinks industry. Leatherhead Food Research is a trading name of Leatherhead Research Ltd, a Science Group (AIM:SAG) company.

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