Controlling *Clostridium botulinum*

Using challenge testing to create safe chilled foods

Dr Peter Wareing
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Botulism is a rare but serious paralytic illness caused by a toxin produced by the bacterium *Clostridium botulinum* (*C. botulinum*). This toxin is the most potent toxin known to mankind. In this white paper, Peter Wareing discusses the need for food business operators to understand the microbiological safety concerns relating to *C. botulinum*, and in particular, the need to control non-proteolytic *C. botulinum* which can grow in chilled vacuum and modified atmosphere packed foods.

**Understanding the problem**

Foodborne botulism is caused by eating foods containing preformed toxin. The bacterial spores that cause botulism are widespread in nature, commonly found in soil and dust, but rarely cause problems because they cannot grow and produce toxin if they are exposed to oxygen. However, where oxygen levels are restricted, adequate control during processing and formulation of foods is required. As well as being able to grow and produce harmful toxin in the absence of oxygen, non-proteolytic (psychrotrophic) *C. botulinum* are able to grow and produce toxin at refrigeration temperatures of 3°C and above. Although this type of foodborne botulism is rare in the UK, its serious nature means that manufacturers and retailers of chilled vacuum packed and modified atmosphere packed (VP/MAP) foods, including raw and ready to eat products, need to understand the risks and develop appropriate HACCP\(^1\) for these foods. Spores of *C. botulinum* are widely distributed in the environment, so it should be assumed that any ingredient/food might be contaminated.

**Gaining control**

The Advisory Committee on the Microbiological Safety of Food (ACMSF)\(^2,3\) recommends a maximum 10 day shelf-life for VP/MAP foods stored at temperatures between 3°C and 8°C if certain controlling factors (specified below) cannot be applied to the product. For a shelf life of more than 10 days, in addition to chilled storage (3-8°C)

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\(^1\) Hazard Analysis and Critical Control Point (HACCP) is an internationally-recognised food safety management system that is an essential tool for ensuring that commercial food processors make a safe final product.


\(^3\) ACMSF Annual Report (2007) published by FSA, FSA/1191/0807
throughout the food chain, the following controlling factors should be used singly or in combination to control growth and toxin production:

- Heat treatment (90°C for 10 min or equivalent)
- Acidity of food (pH ≤5)
- Salt (sodium chloride ≥3.5%)
- Water activity (Aw ≤0.97)
- Combination of the above controlling factors and preservatives (e.g. nisin)

**How to measure safe shelf life**

Predictive models are extremely useful for understanding safety and can be used to underpin key aspects of HACCP based management systems. Models for non-proteolytic *C. botulinum* are freely available (e.g. Combase Predictor) and are used to predict growth under clearly defined conditions (e.g. pH, temperature). The use of predictive models is limited to the range of experimental parameters used to construct them. The use of appropriate worst case scenarios can help to manage some known variation, but where the product falls outside the scope of the model, or the combined effect of several factors is unknown, or the variation in production batches is unknown, or the predicted result is marginal in terms of safety, the interpretation of the result may be difficult without access to appropriate food microbiology expertise.

Indeed, one important benefit of predictive models is to indicate the need for challenge testing. Challenge testing may be used to assess whether a shelf-life of greater than 10 days is safe when VP/MAP chilled foods do not have any of the single specified controlling factors (discussed above). Challenge testing involves deliberately contaminating food products with relevant microorganisms, in this case non-proteolytic *C. botulinum*, to understand issues that may arise during processing, distribution and storage. It is a well-established food safety and quality validation step and provides the most direct evidence of product safety and stability over shelf life.

The data you obtain from challenge testing is only as good as the methodology used, so rigorous testing is required using the most appropriate selection of test microorganisms, the correct inoculation procedure to maintain product and package integrity, the correct storage conditions and duration, and expert analysis of the results. Without this understanding, you might be basing your food safety decisions on unreliable data.

Where results from predictive models and challenge testing conflict, the results of challenge testing should always take precedence. Predictive models are useful as a general guide, however there are limitations that must be taken into account (as previously described) and challenge testing can therefore be used to back up these predictions and provide the evidence to show whether *C. botulinum* is capable of growing and producing toxin within a product.

**Other considerations**

Food business operators must still take into account other hazards that may be associated with their products, in particular *Listeria monocytogenes*, which is also capable of growing at refrigeration temperatures, and
therefore should be included in HACCP based procedures as well as taken into consideration when setting shelf-life.

In ambient long shelf life foods, proteolytic *C. botulinum* may be a concern, particularly considering the required heat processing to ensure safety. Spores of Group I (proteolytic) strains have the greatest heat resistance, and therefore require more stringent processing conditions. Spores of Group II (non-proteolytic/psychrotrophic) are less heat resistant than Group I. A ‘Botulinum Cook’ gives a 12 log kill, equivalent to at least 3 min at 121 °C, to allow the safe storage of foods at ambient temperatures. To control psychrotrophic *C. botulinum* in refrigerated processed foods of extended durability (REPFEDS), it is recommended to heat for 90 °C for 10 min to achieve a 6 log kill.

Full guidance on “the safety and shelf-life of vacuum and modified atmosphere packed chilled foods with respect to non-proteolytic *Clostridium botulinum*; January 2017” is provided by the Food Standards Agency\(^4\).

**Leatherhead’s *Clostridium botulinum* laboratory**

Leatherhead’s new *Clostridium botulinum* laboratory at our Great Burgh site is now open for business. This brand new facility allows us to continue to provide our members with a full testing service for *C. botulinum*, as previously provided over many years at the old Leatherhead site. This includes challenge testing of proteolytic and non-proteolytic *C. botulinum* to assess the safe shelf life of ambient and chilled products. We can also carry out heat inactivation studies to evaluate defined processing conditions in terms of reduction in botulinum spore numbers.

Botulism is a serious illness but control of *Clostridium botulinum* can be achieved with strict HACCP control methods and an ongoing programme of challenge testing. If you have any concerns or questions about *Clostridium botulinum*, contact Leatherhead – our Food Safety experts are on hand to recommend the most appropriate course of action.

\(^4\) Food Standards Agency (2017), The safety and shelf-life of vacuum and modified atmosphere packed chilled foods with respect to non-proteolytic *Clostridium botulinum*; Vacuum Packaging Technical Guidance
How Leatherhead can help

Contact Leatherhead Food Research for help with any of your food safety needs. Leatherhead has a Clostridium botulinum laboratory at its Great Burgh site, providing our members with a full testing service for C. botulinum. Challenge testing can be used to predict the shelf life of a product, validate efficiency of heat treatment or process, or understand 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. 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, and 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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