The safety and shelf-life of vacuum and modified atmosphere packed chilled foods with respect to non-proteolytic *Clostridium botulinum*

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Summary

Introduction:	This guidance is applicable to all raw and ready-to-eat vacuum packed (VP) or modified atmosphere packed (MAP) chilled foods, and provides advice on how to produce these foods safely. The bacterium *Clostridium botulinum* is able to grow and produce a harmful toxin in the absence of oxygen. It is important that vacuum-packed chilled foods have the necessary controlling factors or hurdles in place to minimise the risk of growth and toxin production by this organism, throughout the shelf-life of the product. The guidance explains the 10 day shelf-life rule and the requirement for additional controlling factors, where the shelf-life is greater than 10 days.
Intended audience:	This guidance is recommended for use by manufacturers and retailers of chilled vacuum and modified atmosphere packed (VP/MAP) foods and to assist in the practical development of HACCP (Hazard Analysis Critical Control Point) procedures for these foods. It is designed to meet the needs of all levels of expertise, from technical managers in large enterprises to small businesses and individuals. The guidance is also designed to help Food Law Enforcement Officers carry out their enforcement duties.
Regional coverage:	United Kingdom
Legal status:	This guidance gives best practice information, summarising some advice of the Advisory Committee on the Microbiological Safety of Food (ACMSF).

Purpose:	The guidance summarises the ACMSF Report on Vacuum Packaging and Associated Processes, the Industry Code of Practice for the Manufacture of Vacuum and Modified Atmosphere Packaged Chilled Foods and the recommendations found in the ACMSF 2006 Report available at: http://acmsf.food.gov.uk/acmsfreps/acmsfannualreports. The ACMSF recommended a maximum 10 day shelf-life for vacuum and modified atmosphere packed foods stored at temperatures between 3°C and 8°C when other specified controlling factors could not be identified. The microbiological safety concerns summarised here will be restricted to the control of non-proteolytic (psychrotrophic) C. botulinum, which is able to grow and produce toxin at 3°C and above. Below 3°C, non-proteolytic C. botulinum will not grow and produce toxin so foods stored at less than 3°C are outside the scope of this guidance. The food business operator (FBO) 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.

Revision history

Revision No.	Revision date	Purpose of revision	Revised by
1	July 2008	Guidance	Kathryn Callaghan
2	January 2017	Clarification and updated legal references	Nick Laverty, Chris Rowswell, Kirsten Stone, Jo Edge & Antonis Ampatzoglou
3	June 2017	Update to Q and A	Chris Rowswell

Contents

Intended audience

1. The guidance is recommended for use by manufacturers and retailers of chilled vacuum and modified atmosphere packed (VP/MAP) foods (raw & ready-to-eat), and to assist in the practical development of HACCP (hazard analysis and critical control points) for these foods[1]. It is designed to meet the needs of all levels of expertise, from technical managers in large enterprises to small businesses and individuals. The guidance is also designed to help Food Law Enforcement Officers carry out their enforcement duties.

2. The guidance summarises the advice of the Advisory Committee on the Microbiological Safety of Food (ACMSF) Report on Vacuum Packaging and Associated Processes[2], the Industry Code of Practice for the Manufacture of Vacuum and Modified Atmosphere Packaged Chilled Foods[3] and the recommendations found in the ACMSF 2006 Report, available at: http://acmsf.food.gov.uk/acmsfreps/acmsfannualreports[4]. The ACMSF recommended a maximum 10-day shelf-life for vacuum and modified atmosphere packed foods stored at temperatures between 3°C and 8°C when other specified controlling factors could not be identified.

3. The microbiological safety concerns summarised here are focussed on the control of non-proteolytic *Clostridium botulinum*, which is able to grow and produce toxin at 3°C and above. Foods stored at less than 3°C are outside the scope of this guidance.

4. However, the food business operator (FBO) must still take into account other hazards that may be associated with their products, in particular *Listeria monocytogenes*, which is capable of growing at temperatures below 0°C and controls for which should be included in HACCP based procedures, as well as taken into consideration when setting shelf-life.

[1] Article 5 of Regulation EC 852/2004 on the hygiene of foodstuffs

[2] Advisory Committee on the Microbiological Safety of Food. Report on Vacuum Packaging and Associated Processes; 1992. HMSO, London

[3] Campden and Chorleywood Food Research Association. Guideline No 11: A Code of Practice for the Manufacture of Vacuum and Modified Atmosphere Packaged Chilled Foods; May 1996

[4] ACMSF Annual Report 2006 published by FSA August 2007, FSA/1191/0807

Purpose and legal status

5. These guidance notes have been produced to provide informal, non-binding advice on how to produce vacuum and modified atmosphere packaged chilled foods safely to achieve compliance with Article 5 of Regulation (EC) No 852/2004.

6. Note: where FBOs use additives as controlling factors to limit the growth of pathogens, they must comply with Regulation EC No 1333/2008.

7. Businesses with specific queries may wish to seek the advice of their local enforcement agency, which will usually be the environmental health department of the local authority or the Food Standards Agency if the establishment is approved by the FSA.

Introduction

8. This document provides advice on VP/MAP chilled foods irrespective of the distribution channel, in relation to microbiological safety and shelf-life limitations associated with control of non-proteolytic (psychrotrophic) *C. botulinum*. The guidance is applicable to both ready-to-eat and raw foods, including raw meat.

9. The process of vacuum packaging removes air and prevents its return by an airtight seal surrounding the food within the packaging material. With modified atmosphere or "gas" packaging, air is replaced by a strictly controlled mixture of gases usually chosen from carbon dioxide, oxygen and nitrogen. There are various methods available which are described in detail in the Industry Code of Practice for the Manufacture of Vacuum and Modified Atmosphere Packaged Chilled Foods.

10. Although VP/MAP techniques can increase the shelf-life of chilled foods by limiting the growth of microorganisms causing food spoilage, under certain circumstances a bacterium called non-proteolytic *C. botulinum* may grow in the absence of oxygen. Non-proteolytic *C. botulinum* is able to grow and produce a harmful toxin at temperatures of 3°C and above. It is important that VP/MAP chilled foods have appropriate controls in place to minimise the risk of this organism growing and producing harmful levels of toxin, throughout the shelf-life of the product.

11. Although non-proteolytic *C. botulinum* food poisoning is very rare in the UK, its very serious nature (see below) means that any business engaged in

producing VP/MAP foods must understand the risks associated with it and take steps to appropriately manage it. It is essential that all critical control points are identified and controlled at all times.

Non-proteolytic *C. botulinum* and foodborne botulism

12. Non-proteolytic *C. botulinum* is a spore-forming anaerobic bacterium. This bacterium produces a very powerful toxin in food that causes the serious illness botulism, a potentially fatal form of food poisoning. Botulinum toxin is the most potent biological toxin known. The spores are widely distributed in the environment, and may also be present in food. In a favourable environment spores may germinate leading to toxin formation.

13. Outbreaks of foodborne botulism have been associated with foods sealed in air-tight containers including VP/MAP foods (e.g. smoked fish). It is important to note that the presence of air, or a similar oxygen-containing atmosphere, cannot be relied upon to prevent growth and toxin formation by non-proteolytic *C. botulinum*. Such foods can contain oxygen free areas that will allow *C. botulinum* to grow and form toxin.

Risks from other Pathogens

This guidance is focussed on the risk from non-proteolytic *C. botulinum* and the additional controlling factors that can be used to extend the shelf-life to greater than 10 days are specific for this organism. However, FBOs must still take into account **all** other relevant hazards that may be associated with their products. This is particularly important for *Listeria monocytogenes*, which is also capable of growing under VP/MAP conditions and at refrigeration temperatures, whilst other hazards might not be able grow but may survive in the food. Therefore, other hazards, such as *L. monocytogenes*, should be included in the HACCP based procedures, as well as taken into consideration when setting shelf-life.

Links to shelf-life guidance that is available specifically for *L. monocytogenes* in ready-to-eat foods can be found below:

- EU Guidance document on *L. monocytogenes* shelf-life studies for ready-to-eat foods: http://ec.europa.eu/food/safety/docs/biosafety_food-hygiene_microbio_criteria-translation_guidance_lm_en.pdf

- FSA's 'General guidance for FBOs on Regulation 2073/2005': http://www.food.gov.uk/multimedia/pdfs/ecregguidmicrobiolcriteria.pdf

- CFA and BRC guidance on 'Shelf-life of ready-to-eat food in relation to *L. monocytogenes* – guidance for food business operators (2010)': http://food.gov.uk/business-industry/guidancenotes/hygguid/readytoeat

For advice on avoiding cross contamination when using vacuum packing machinery:

- FSA's Guidance for food businesses to clarify the steps that they need to take to control the risk of food becoming contaminated by *E. coli* O157 - *E. coli* O157: control of cross-contamination guidance

Factors controlling growth and toxin production by non-proteolytic *C. botulinum* in chilled foods

14. It is the FBO's responsibility to ensure that the shelf-life they set is appropriate and that the safety of the food at the end of shelf-life can be demonstrated. FBOs may wish to consult experts (e.g. research organisations) on how to establish and validate the shelf-life and demonstrate the safety of their products with regards to non-proteolytic *C. botulinum*, using appropriate methodology (e.g. modelling, challenge testing and other appropriate means of validation).

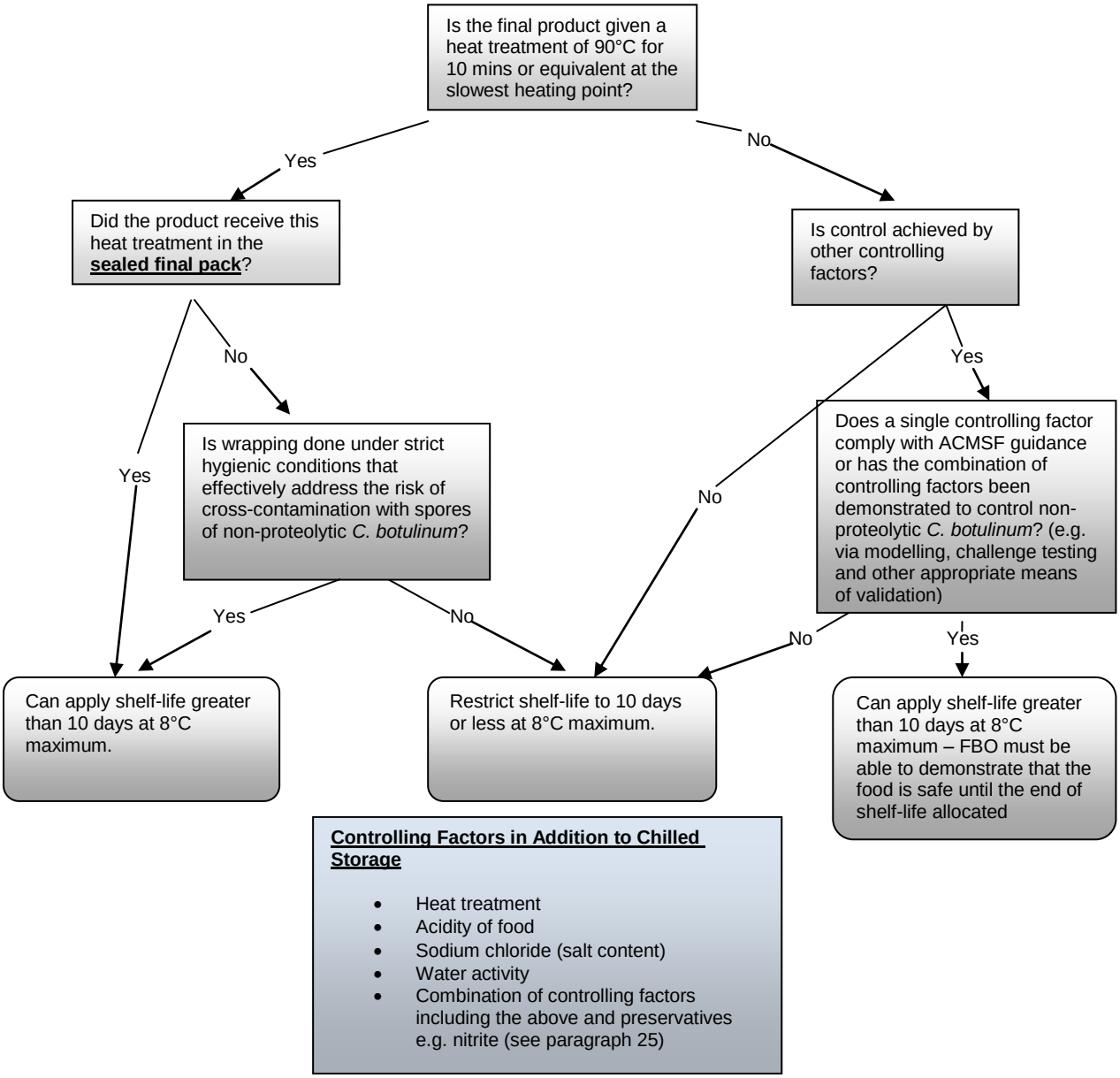
15. The ACMSF recommended that in addition to chill temperatures (3-8°C) which should be maintained throughout the food chain, the following controlling factors should be used singly or in combination to prevent growth and toxin production by non-proteolytic *C. botulinum* in chilled foods with a shelf-life of more than 10 days:

    - a heat treatment of 90°C for 10 minutes or equivalent lethality at the slowest heating point in the food[5]
    - a pH of 5.0 or less throughout the food and throughout all components of complex foods
    - a minimum salt level of 3.5% in the aqueous phase throughout the food and throughout all components of complex foods
    - a water activity ($a_{w)}$ of 0.97 or less throughout the food and throughout all components of complex foods
    - a combination of heat and preservative factors which can be shown consistently to prevent growth and toxin production by non-proteolytic *C. botulinum*

16. The following decision tree should be used by the FBO to determine if the risk of *C. botulinum* in the product they produce is effectively controlled where the shelf-life is greater than 10 days:

[5] shortened at points in this guidance to heat treatment of 90°C for 10 minutes, but this should always be I the slowest heating point of the food

Determining the shelf-life of VP/MAP products stored at 3-8°C



Controlling Factors in Addition to Chilled Storage

- Heat treatment
- Acidity of food
- Sodium chloride (salt content)
- Water activity
- Combination of controlling factors including the above and preservatives e.g. nitrite (see paragraph 25)

Re-Wrapping

If a VP/MAP product is unwrapped e.g. for slicing or portioning, and then re-wrapped (in VP/MAP), the shelf-life given to the re-wrapped product must not exceed the shelf-life given to the original product. Where the (VP/MAP) re-wrapped shelf-life is to be greater than 10 days then this must be justified with respect to controlling factors to prevent growth of non-proteolytic *C. botulinum* and toxin production. (see paragraphs 29 and 30)

VP/MAP Ingredients

Where VP/MAP food or ingredients are used in another product the life of the final product shall not exceed that of the original lives given to the ingredients. However, if the VP/MAP food or ingredient is given a further processing treatment to destroy vegetative cells, e.g. heating 70°C for 2 minutes or equivalent effect, the shelf-lives do not need to be incorporated into that of the final product providing the HACCP plan demonstrates that it remains safe for human consumption.

Background information on the specific controlling factors

for chilled VP/MAP foods in which a shelf-life of longer than 10 days is indicated

17. Since spores of non-proteolytic *C. botulinum* are widely distributed in the environment, it should be assumed that any ingredient/food might be contaminated. It is on this basis that specific recommendations for shelf-life of VP/MAP foods are made.

18. The controlling factors indicated in paragraph 15, should be used singly or in combination to prevent growth and toxin production by non-proteolytic *C. botulinum* in chilled foods with a shelf-life of greater than 10 days. The shelf-life will begin as soon as the controlling factor(s) have been first applied.

Table 1: Equivalent time/temperature combinations for spores of non-proteolytic *C. botulinum*[6, 7]

Temperature (°C)	Time (mins)
80	129.0
81	100.0
82	77.0
83	60.0
84	46.0
85	36.0
86	28.0
87	22.0
88	17.0
89	13.0
90	10.0
91	7.9
92	6.3
93	5.0
94	4.0
95	3.2
96	2.5
97	2.0
98	1.6
99	1.3
100	1.0

Heat treatment

19. If heat treatment is to be used as the single controlling factor, the minimum heat treatment that should be used to manufacture a chilled VP/MAP product is 90°C for 10 minutes or equivalent achieved at the slowest heating point in the product. Equivalent times and temperatures are given in Table 1. In most cases the shelf-life will apply from the time of cooking.

20. Ideally heat treatment should be carried out in the final sealed pack as this minimizes the opportunity for re-contamination with non-proteolytic *C. botulinum*

[6] Data from ACMSF Report of Vacuum Packaging and Associated Processes, 1992, ISBN 0-11-321558-4, and Best Practice Guidelines for the Production of Chilled Foods, Chilled Food Association, 2006, 4th edition, The Stationary Office, ISBN13 978-1- 901798-11-1

[7] Z values used for the calculation of the figures in Table 1 are based on ACMSF and CFA data. ACMSF Z values limited to 80°C to 90°C range. CFA Z values limited to 90°C to 100°C

or other pathogens[8] of the final product. However, if this is not possible, packing may be carried out post-heat treatment as long as it is done under strict hygienic conditions that prevent microbiological cross-contamination. As spores of *C. botulinum* are ubiquitous in the environment, this would involve a strict level of control to ensure that conditions are such that effectively address the risk of cross-contamination following the heat treatment. If this level of control cannot be applied, then one or more of the other controlling factors identified in this guidance should be used, if a shelf-life of greater than 10 days is to be applied. FBOs must be able to demonstrate to the satisfaction of the Competent Authority how the risk of cross-contamination with spores of non-proteolytic *C botulinum* is controlled in products packed post-heat treatment, as they must verify that the HACCP-based procedures in place are appropriate[9].

Acidity of the food

21. The level of acid in a food can be a controlling factor in the growth of microorganisms. A pH of 5.0 or less throughout a food and all of its components, stored at chill temperatures of 8°C or lower is sufficient to inhibit the growth of non-proteolytic *C. botulinum*. The pH of some multicomponent foods may vary within the product due to diffusion and mixing limitations and if pH is the controlling factor for safety, a pH of 5.0 or below should be achieved throughout all parts and components of the final product. This should be monitored for every batch of product. The FBO must define the batch[10]. Batch size is a key point to consider in any risk management action. Acidified foods containing meat, fats or oils are notoriously difficult to acidify uniformly and extra care should be taken with these foods.

Sodium chloride (NaCl) content

22. A concentration of 3.5% sodium chloride in the aqueous phase of a food stored at temperatures 8°C or lower is sufficient to inhibit the growth of non-proteolytic *C. botulinum.* The percentage of sodium chloride (NaCl, salt) in the aqueous phase of a product can be calculated from the grams of sodium chloride present in 100g product and the moisture content (grams of water per 100g of product) using the following calculation:

[8] http://www.food.gov.uk/business-industry/guidancenotes/hygguid/ecoliguide
[9] Article 4 of Regulation (EC) No 854/2004
[10] Batch is defined in Article 2 (e) of the Regulation for the microbiological criteria for foodstuffs (2073/2005/EC) as a group or set of identifiable products obtained from a given process under practically identical circumstances and produced in a given place within one defined production period.

$$\frac{(\text{NaCl content} \times 100)}{(\text{NaCl content} + \text{moisture content})}$$

Key

NaCl content = g NaCl / 100g product

Moisture content = g H_2O / 100g product

23. If salt content is the controlling factor for safety, a concentration of 3.5% or above should be achieved throughout the aqueous phase of a food. This should be monitored for every production batch.

Water activity (a_w)

24. By using water-binding chemicals such as sodium chloride or sugars, it is possible to remove the available water from a food, to a point at which the growth of microorganisms is inhibited. A water activity (a_w) of 0.97 or lower should be achieved throughout the food stored at temperatures between 3 and 8°C to inhibit the growth of non-proteolytic *C. botulinum*. The a_w of some multicomponent foods may vary within the product and if a_w is the controlling factor for safety, an a_w of 0.97 or below should be achieved throughout all components of the food. This should be monitored for every batch of product. However, there could be circumstances where reduced monitoring might be appropriate (see question 8). Due to the nature of the test it may be necessary to approach a specialised laboratory to take a_w measurements and to interpret and provide the results.

Other controlling factors

25. Combinations of a lower level of the specific controlling factors described above may be able to prevent growth of non-proteolytic *C. botulinum* and toxin production. Other combinations, e.g. addition of nitrite, may also be used to prevent growth of non-proteolytic *C. botulinum,* provided that it complies with the additive legislation Regulation (EC) No 1333/2008. Where a lower level of factors is used, each factor is not able to inhibit the growth of non-proteolytic *C. botulinum* on its own but inhibition of growth and toxin production is reliant on the combined effect of all factors (hurdle technology). These specific combinations need to be validated for each product using sound scientific principles; this is a highly specialised field and there is an expectation that expert advice is needed to produce the necessary data. Mathematical models such as ComBase Predictor and Pathogen Modelling Program and challenge testing are examples

of approaches that can be used to obtain relevant information on combinations of controlling factors.

The uses and limitations of predictive growth models

26. Predictive microbiology models are important tools for food safety management as they provide a scientific basis to underpin key aspects of HACCP-based food safety management procedures. Predictive models available include those that describe growth limits, growth and thermal inactivation. Predictive models for non-proteolytic *C. botulinum* are freely available in ComBase Predictor (www.combase.cc) and the Pathogen Modelling Program (http://pmp.errc.ars.usda.gov/PMPOnline.aspx). These models can be used to predict the effect of conditions in the food (e.g. pH, temperature) on the growth of non-proteolytic *C. botulinum*. It is important to recognise that models can only provide accurate information when interpreted by microbiologists with appropriate skills and experience. Where a business does not have such skill and expertise it should consult an expert in food microbiology (see the frequently asked questions section below). The models are of particular benefit in providing a guide for the need for challenge testing or to enable the effective targeting of a challenge test study.

Challenge Testing

27. To establish 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, challenge testing may be considered. If this is to be carried out, it is important to ensure that the analysis takes into account any variability that may occur within a batch and between batches of product. An appropriate centre of expertise should be consulted both to carry out challenge testing and interpret the results.

28. Where results from predictive models and challenge testing may 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 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.

Practice of re-wrapping VP/MAP foods

29. Where no other controlling factor can be identified, the maximum shelf-life should be 10 days from when the product is first vacuum packed or modified atmosphere packed. The shelf-life should not be restarted if the product is subject to a further re-wrapping under vacuum or modified atmosphere, unless other controlling factors are first applied.

30. The practice of giving a "rolling 10 day shelf-life" is of great concern. If a VP/MAP product is unwrapped, e.g. for slicing or portioning, and then re-wrapped (into VP or MAP), the shelf-life given to the re-wrapped product should not exceed the shelf-life given to the original product. Where the re-wrapped shelf-life is intended to be greater than 10 days then the FBO carrying out the re-wrapping must be able to demonstrate to their competent authority that it is safe to do so with respect to controlling factors to prevent the growth of non-proteolytic *C. botulinum* in the re-wrapped product.

31. In these cases, consideration should be given to the controlling factors used by the original manufacturer, as well as any other additional controlling factors the FBO may introduce to the re-wrapped (VP/MAP) product (see question 24).

Frequently asked questions

1 *Q: Do some foods have a greater risk of C. botulinum than others?*

A: Table 2 gives examples of foods that differ in their inherent risk with respect to *C. botulinum* e.g. hot smoked fish would have a greater inherent risk relative to a hard cheese like Cheddar. However, non-proteolytic *C. botulinum* must still be considered a potential risk for all raw and ready to eat VP/MAP chilled foods, and incorporated into HACCP based procedures.

Table 2: Risk assessment of non-proteolytic *C. botulinum* in chilled foods adapted from Table 12, page 29, Report on vacuum packaging and associated processes, ACMSF, London: HMSO 1992

Food category	**Examples**	**Usual controlling factors (in addition to chill temperature)**	**Priority for attention**
Hot smoked	mackerel, trout, shellfish	salt, shelf-life	High
Fresh chilled pasta (MAP)	cannelloni, ravioli	shelf-life	Medium
Hard Cheese	Cheddar	a_w, pH, salt	Low

2 *Q: Is raw meat included in the scope of this guidance with respect to the control of non-proteolytic C. botulinum?*

A: Yes, this guidance applies to all VP/MAP chilled raw and ready-to-eat food, including raw meat. During a review by the ACMSF on vacuum packaging and the associated risks, consideration was given to whether all VP/MAP chilled foods, whether raw or ready-to-eat, could present a food safety risk from anaerobic microorganisms, such as non-proteolytic *C. botulinum*. This is because spores of *C. botulinum* are ubiquitous in the environment, which includes soil, salt and fresh water sediments and in the gastrointestinal tracts of animals and fish, and are therefore

likely to be present on food. It is not possible to be certain that an unprocessed food will not contain spores of *C. botulinum*. In addition, although VP and MAP techniques are designed to increase the shelf-life of products, the removal of oxygen creates the right conditions for anaerobic organisms such as *C. botulinum* to grow and produce toxin. With this in mind, all VP/MAP chilled foods must therefore have controls in place, throughout the shelf-life of the product, to minimise the risk of this bacterium growing and producing toxin or the FBO must provide evidence that growth of pathogens is not supported. This should be included as part of HACCP-based procedures in identifying the relevant hazards associated with products, which includes non-proteolytic *C. botulinum* for VP/MAP chilled foods.

If controlling factors are not already validated, FBOs should assess and validate each individual product against the risk from *C. botulinum* and, where the shelf-life is greater than 10 days without a sufficient single controlling factor, provide evidence of the safety of the product throughout its entire shelf-life in respect to non-proteolytic *C. botulinum* (e.g. via modelling, challenge testing or other appropriate means of validation)

3 *Q: What are the key aspects of the guidance?*

A: The FSA/FSS guidance recommends that the shelf-life applied to VP and MAP products be restricted to no greater than 10 days unless the FBO is able to demonstrate that appropriate key control measures are in place. There are two recommended ways to ensure the safety of VP and MAP products. They should either be heated to a sufficient temperature to inactivate the spores of non-proteolytic *C. botulinum* (ideally in the final sealed pack) or subject to a single or a combination of preservative control factors to prevent the growth of non-proteolytic *C. botulinum* and production of toxin. These are explained in the section "Background information on the specific controlling factors".

4 *Q: How should FBOs establish the appropriate shelf-life with respect to C. botulinum for their products?*

A: FBOs should look at the decision tree in this document. If the shelf-life is beyond 10 days the FBO must be able to demonstrate how their HACCP-based procedures and control measures ensure that the food remains safe within the allocated shelf-life. Article 3.2, Annex II of Regulation (EC) 2073/2005: microbiological criteria for foodstuffs[11], describes the necessary practices and procedures to be considered for establishing shelf-life. It is noted that this is set out

[11] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02005R2073-20140601&from=EN

specifically for *L. monocytogenes* and is not a general legal requirement for *C. botulinum*; however, this information may assist in determining an appropriate approach.

5 *Q: How should a FBO establish the appropriate shelf-life for VP/MAP products stored* below 3°C?

A: If an FBO labels their product to be stored at <3°C, it is important that they have an appropriate understanding of the temperatures at which the product will be held during all stages after it leaves their control. If the product is likely to be stored at between 3°C and 8°C after it leaves the FBO's control (e.g. during transit or at retail or during storage in commercial or domestic kitchens), then if no other adequate controlling factors for C. botulinum exist, the maximum 10 day shelf-life for the VP/MAP product should be applied from the point the VP/MAP product reaches or is likely to reach a temperature of 3°C or above. If the FBO does not know the refrigeration temperatures at which their product will be held after it leaves their control, then they should consider that it may be held at temperatures above 3°C and that the label's instructions to ensure that the product will be kept <3°C may not ensure the product's safety if the shelf life is longer than 10 days.

Establishments not subject to approval under Regulation (EC) 853/2004 (such as catering businesses and retailers) may lawfully store food at temperatures up to 8°C. An in-home temperature survey published in 2010 by Waste and Resources Action Programme (WRAP) found that the majority of domestic refrigerators operate at a mean air temperature of around 7°C, with only 29 % of the sample operating at mean air temperatures of 5°C or less. It is therefore likely that food supplied directly to caterers, retailers and/or final consumers will not be stored at temperatures below 3°C.

6 *Q: If the FBO wishes to test their VP/MAP chilled product for the presence of non-proteolytic C. botulinum spores, will negative results be considered sufficient evidence to exempt them from applying the controls specified in this guidance?*

A: Spores of non-proteolytic *C. botulinum* are ubiquitous in the environment and may be present on food. Testing for the presence of non-proteolytic *C. botulinum* spores is unlikely to provide 100% reassurance that spores of *C. botulinum* are not present,

and should therefore not be relied upon as the only way of verifying the FBO's methods. In addition, testing for spores of other *Clostridium* species, such as *Clostridium perfringens*, is not considered a reliable indicator for *C. botulinum*. The best way to prevent the risk from growth and toxin production is by ensuring that sufficient controls are in place.

7 *Q: What can a FBO do if they wish to have a shelf-life of greater than 10 days for their VP/MAP chilled product, but is unable to heat treat in the final sealed pack and the product does not meet any of the specified controlling factors?*

A: For some products and production practices the product is not able to meet the controlling factors that would be sufficient to control non-proteolytic *C. botulinum* and the product cannot be heat treated in the final sealed pack. In this case, it would be acceptable for challenge testing or an appropriate alternative approach to be carried out to determine whether a particular product is unable to support growth of non-proteolytic *C. botulinum* and toxin production. If this is to be carried out, it is important to ensure that the analysis takes into account any variability that may occur within a batch and between batches of product. As this is a highly specialised area, challenge testing or any alternative approaches should be carried out by an appropriate centre of expertise.

8 *Q: Can nitrites be used as a controlling factor to prevent growth and toxin production of non-proteolytic C. botulinum, where a shelf-life greater than 10 days is to be applied?*

A: The guidance covers the main controlling factors that a FBO can apply in addition to chill temperatures to enable a shelf-life of greater than 10 days. In addition to these, it is also possible to use a lower level of factors (i.e. heat treatment, pH, salt concentration and a_w) in a food to achieve a combined preservation effect or use additional preservatives such as nitrite to comply with additive legislation Regulation EC No 1333/2008. Where a lower level of factors is used, each factor is not able to inhibit the growth of *C. botulinum* and production of toxin on its own but the safety of the food with respect to non-proteolytic *C. botulinum* relies on the combined effect of all factors. Where a combination of factors is used, it is necessary to illustrate that the preservation system chosen can consistently prevent growth of non-proteolytic *C. botulinum* and toxin production; this may be done by predictive modelling, challenge testing or other appropriate means of validation.

In relation to other preservatives, the only controlling factors in addition to heating at 90°C for 10 minutes, which are currently recommended to inhibit the growth of *C. botulinum* and production of toxin are salt, pH and a_w and these are explained in more detail in the FSA guidance. There are other preservatives which will have an

impact on the growth of *C. botulinum*, such as nitrite, sorbic acid, benzoate and lactate. Whilst there may not be sufficient data to allow a recommendation for any of these preservatives to be a controlling factor in their own right, they may contribute to the overall product safety.

The ACMSF report on vacuum and modified atmosphere packaging and associated processes states specifically for nitrite that "inhibition of *C. botulinum* by nitrite in foods depends heavily upon a number of factors such as acidity and salt content. In addition, there are pressures to reduce nitrite levels in some foods because of the risk of formation of carcinogenic N-nitroso compounds in some situations. Taken together these two limitations mean that the scope for the use of nitrite on its own to control *C. botulinum* is limited". Another issue surrounding the use of nitrite as a controlling factor is that nitrite depletes readily from the product during storage, thereby reducing the antimicrobial affect. The aforementioned ACMSF report is available at the following link:

https://www.food.gov.uk/sites/default/files/mnt/drupal_data/sources/files/multimedia/pdfs/acmsfvacpackreport.pdf

In summary, nitrite and other preservatives may have antibotulinal properties in a number of different food stuffs. However, as the efficacy of these preservatives seems to be dependent on the heat treatment given, the pH of the product and other constituents of the food, their use as controlling factors to prevent growth of non-proteolytic *C. botulinum* and toxin production needs to be evaluated for each specific product, for example by challenge testing or other appropriate means of validation. An FBO's HACCP-based food safety management procedures should have ongoing monitoring to ensure that the products are of the right specification, which can control growth of non-proteolytic *C. botulinum* and production of toxin. The FBO must be able to demonstrate to the satisfaction of the Competent Authority both that the controlling factors are effective and also that the level of monitoring to ensure consistent adherence to specification is appropriate.

9 *Q: Once the appropriate controlling factors for a specific product have been identified by the FBO, should every production batch be monitored for these controls?*

A: It is important that the controlling factors for chilled VP/MAP products are controlled for every production batch and achieved consistently and uniformly throughout the product, to ensure that the required level for safety is maintained. However, sampling every production batch may be impractical due to the cost and size of the FBO's operation. It is therefore the responsibility of the FBO to demonstrate to the Competent Authority that the monitoring of the controlling factors is adequate to guarantee that the specified level is being met for each production

batch. Ideally, monitoring of each production batch initially should be in place to verify that the recipe and production method used can consistently achieve the levels required throughout the product to prevent growth of non-proteolytic *C. botulinum* and production of toxin. If consistent results are achieved and the FBO can demonstrate to the satisfaction of the Competent Authority (e.g. through historical data) that there is confidence that the recipe and the production method (taking into account potential for human error if appropriate) can reliably produce a safe product, there may be circumstances where reduced monitoring could then be introduced, if the competent authority is satisfied that it is justified.

10 *Q: What specific food legislation is applicable to a business using VP/MAP technology?*

A: A FBO must be compliant with the general principles and requirements of food law in Regulation (EC) 178/2002. They must be able to identify the hazards associated with their operation and the methods to control those hazards. Article 5 of Regulation (EC) 852/2004 requires FBOs to have in place permanently a procedure based on HACCP principles. A FBO should be able to provide the local authority with evidence to demonstrate the way they control the hazards, including that of non-proteolytic *C. botulinum* in relation to their VP/MAP products. See Article 5(4) (a) of Regulation (EC) No 852/2004 on the hygiene of foodstuffs.

11 *Q: How much information should be contained in HACCP based food safety management procedures covering VP/MAP technology?*

A: The extent and detail of the information in an FBO's HACCP documentation will depend on the shelf- life the FBO applies to their products and the controls required. The HACCP-based controls must be proportionate to the risk. The product should display the "use by" date and the required storage conditions clearly printed on the pack.[12]

12 *Is the FSA's Safer Food, Better Business (SFBB) pack, or FSS's Cooksafe suitable for manufacturers of VP/MAP products?*

A: HACCP procedures as set out in the *SFBB* pack for caterers are unlikely to be suitable, especially when the business wishes to apply a shelf-life greater than 10 days. In such circumstances the business will need to set out their critical control points (CCPs) and monitoring procedures in more detail than is generally

[12] See Regulation (EU) No 1169/2011 – Article 9 - on the provision of food information to consumers http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX%3A32011R1169&from=en

used in *SFBB* and will need to keep appropriate records.

13 *Q: What level of process validation might be appropriate for a HACCP plan?*

A: Validation involves confirmation that, if followed, the HACCP plan will result in the production of safe food. This is to ensure that the control measures and their associated limits are appropriate and can be applied in practice. The level and nature of validation required will depend on the products and processes involved. The most important things to validate are that the control measures at the critical control points are sufficient to achieve the objectives. The performance of some control measures will have already been validated by others or be so well established in practice that validation can be considered to be achieved (some examples are provided in this document e.g. heat treatment of 90°C for 10 minutes, pH of 5.0 or less, minimum salt concentration of 3.5%, a_w of 0.97 or less). However, when this is not the case (e.g. when using different time temperature combinations or a combination of controlling factors that if used singly, would not control growth of non-proteolytic *C. botulinum*), validation should be undertaken.

14 *Q: Who is responsible for undertaking the validation process?*

A: The onus is on the FBO to demonstrate that their food products are safe. Validation can be undertaken by the FBO themselves, if they have the expertise, or by another organisation on their behalf. If the business is not using already validated procedures they should be able to demonstrate how they have validated their HACCP plan, in particular the critical control measures.

15 *Q: What steps should the competent authority take to ensure that validation is undertaken correctly?*

A: The competent authority should ensure, as part of their role in verifying that the controls in place are appropriate, that validation is undertaken by the business in meeting their obligation of complying with Article 5 of Regulation (EC) No 852/2004. If control measures are being used that have not already been validated or are not accepted practice, then the authority should request evidence of the validation process, including when it was undertaken and who was undertook it as well as their level of expertise.

16 *Q: What action can the local authority take if evidence of the validation process is not provided?*

A: Article 5(1) of Regulation (EC) No 852/2004 requires a FBO to put in place, implement and maintain permanent procedures based on HACCP principles. Under Article 5(4) (a), a FBO is also required to provide the Competent Authority with evidence of their compliance with Article 5(1) in the manner that the Competent Authority requires. This is monitored by on-going verification checks.

Failure to meet the requirements in the EU Regulations may mean that an offence under the Food Safety and Hygiene (England) Regulations 2013 (and equivalent 2006 Regulations in Wales, Northern Ireland and Scotland) has been committed.

A range of enforcement powers are available to competent authorities across the UK and these include:

The use of a hygiene improvement notice (HIN) to require either (i) that validation is carried out or (ii) that evidence is provided of the result of the validation process. Remedial Action or detention notices can also be applied in certain establishments to prohibit the use of any equipment or any part of the establishment specified in the notice; or to impose conditions or prohibit the carrying out of any process.

In some cases it may be appropriate to consider detention and/or seizure of non-compliant product/withdrawal or recall from your customers (see Q. 20).

The use of enforcement powers is subject to the guidance in the Food Law Code of Practice and to the local food law enforcement policy, as well as guidance set out in the Manual of Official Controls for approved meat establishments.

17 *Q: A business is applying a shelf-life of greater than 10 days to their VP/MAP products. How should the local authority satisfy itself that this is an appropriate shelf-life?*

A: Food businesses should be able to provide scientific evidence that supports the shelf-life determination applied to their products. If a business is unable to provide this evidence further investigation and action may be required to protect consumer safety. General advice on enforcement is contained within the Food Law Code of Practice and associated Practice Guidance, as well as the Manual of Official Controls.

18 *Q: What further investigation or action might be necessary?*

A: The first stage is to consider whether the FSA guidance in respect of VP and MAP products is being followed. The decision tree summarises the key questions that need to be considered.

19 *Q: How concerned should the competent authority be if a FBO continues to apply a shelf-life of greater than 10 days without the scientific evidence to support the shelf-life?*

A: The view taken by the ACMSF is that businesses producing VP and MAP should base their controls on the assumption that spores of non-proteolytic *C. botulinum* may be present in ingredients/foods. Competent authorities should ensure that such controls are in place in order to protect consumer safety. Local authorities should take a risk-based approach when prioritising enforcement activities e.g. focus on businesses using VP/MAP in respect of food categories falling within the "high priority for attention" category, examples of which are shown in Table 2 of this document.

20 *Q: What further action can be considered if a FBO continues to produce VP/MAP products and applies a shelf-life greater than 10 days contrary to the guidance and the advice of the competent authority?*

A: Powers exist in the Food Safety and Hygiene (England) Regulations 2013 and equivalent legislation in Scotland[13], Wales and Northern Ireland, to issue a hygiene emergency prohibition notice where there is evidence that there is an imminent risk to consumers. Before considering such action, the competent authority should consider the advice contained in this document and other references therein and seek advice of an appropriate expert who may be able to provide evidence in court on behalf of the authority if their action is challenged. The seizure of food and the possibility of product recall would also need to be considered. In considering whether enforcement action is appropriate or necessary it should be recognised that the advice of the ACMSF is based on best scientific advice and industry practice. There is no specific law across the EU, in the UK or other Member States that covers the use of VP/MAP technology.

21 *Q: Under what circumstances might a local authority consider the use of a hygiene emergency prohibition notice?*

A: If appropriate evidence is found, a hygiene emergency prohibition notice may be served on the FBO, followed by an application to a Magistrates' or Sheriff Court for a hygiene emergency prohibition order. The following provides an example of circumstances where an authorised officer may consider the use of these prohibition powers because the health risk condition in Regulation 8(4) of the Food Safety and Hygiene (England) Regulations 2013 and the other devolved UK

[13] Food Hygiene (Scotland) Regulation 2006 (as amended)

equivalent regulations is likely to be satisfied. That is, there is an imminent risk of injury to health under Regulation 8(4). This example is in no way prescriptive or exhaustive and is for illustrative purposes only.[14] A FBO producing a vacuum packed product which falls within the category requiring ”high” priority for attention (see paragraph 25 and Table 2), with a product shelf-life significantly in excess of 10 days and a complete failure to demonstrate effective control of non-proteolytic *C. botulinum*. The FBO is likely to have a general failure to satisfy relevant statutory obligations and a poor track record of compliance (i.e. a score of 15/20 in Part 2 of the Food Hygiene Scoring System and a confidence in management score of 20/30 in Chapter 5 of the Food Law Code of Practice).

Before considering such action the local authority should consider the information provided in the answer to question 13 particularly the need for expert evidence.

22 *Q: A business has been identified using VP and/or MAP technology for chilled foods. The FBO does not appear to understand the inherent hazards associated with this form of food packaging. What action should the local authority take?*

A: The FBO should be provided with a copy of this guidance. Officers should consider whether the FBO’s knowledge gap has resulted, or might result, in the production of food which is unsafe or otherwise non-compliant with food law. Help and guidance should be provided to the business using a risk-based and proportionate enforcement approach in accordance with the advice contained in the Food Law Code of Practice - http://www.food.gov.uk/enforcement/codes-of-practice/food-law-code-of-practice-2015 and equivalent codes elsewhere in the UK.[15]

23 *Q: If a FBO is repacking VP/MAP products what action should the local authority take to satisfy itself that the activity is safe and appropriate?*

A: An FBO must be able to identify the hazards associated with their business and the methods to control those hazards and reflect these in the business’s HACCP based food safety management procedures. Reference to the decision tree will identify those factors that need to be taken into account when a VP/MAP product is repacked.

24 *Q: If a FBO is opening VP/MAP products with a shelf-life of greater than 10 days and re-wrapping and wishes to continue applying a shelf-life of greater than 10 days, how can the FBO ensure that this process is safe?*

[14] Text taken from the Food Law Code of Practice

[15] http://www.foodstandards.gov.scot/food-law-code-practice-2015

A: For products that were originally given a shelf-life of 10 days by the manufacturer, the FBO who is re-wrapping the product needs to ensure adequate controlling factors are in place before applying a re-wrapped shelf-life of greater than 10 days. The FBO may need to contact the manufacturer to determine what controlling factors they put in place for their product. Importantly, the shelf-life of the re-wrapped product should not exceed the shelf-life given to the original product unless additional controls are applied before it is re-wrapped. All FBOs extending the shelf- life of the product will need to be able to demonstrate that it is safe.

The shelf-life given to the re-wrapped VP/MAP product will depend on the controlling factors used by the manufacturer when applying the original shelf-life of greater than 10 days. For instance, if the controlling factor used in addition to chilled storage was a heat treatment of 90°C for 10 minutes or equivalent, due to the potential for re-contamination with non-proteolytic *C. botulinum* spores between opening and re-wrapping, the shelf-life applied to the re-wrapped product should not be greater than 10 days, unless other controlling factors are introduced .

If the controlling factors used in addition to chilled storage are factors other than heat treatment such as pH, salt or a_w; these are unlikely to have changed following opening and re-wrapping, unless for example other ingredients are added to the product. If the Competent Authority is satisfied that there is evidence that these controlling factors have not changed and remain sufficient to control non-proteolytic *C. botulinum* and any other relevant microorganisms, then the shelf-life applied to the re-wrapped product may be greater than 10 days, but cannot exceed the shelf-life given to the original product. If information on the controlling factors used by the original manufacturer to apply a shelf-life of greater than 10 days cannot be obtained, the FBO would be best placed to apply a maximum 10 days shelf-life to the re-wrapped product unless the FBO can identify or introduce additional controlling factors. Again, the shelf-life of the re-wrapped product should not exceed the shelf-life given to the original product.

Further advice

25 *Q: If an environmental health officer, Official Veterinarian or a FBO is concerned about the safety of a process where can they go to seek technical advice and opinion?*

A: There are a number of food research organisations able to provide advice including:

- Campden BRI +44(0)1386 842 000
- Institute of Food Research +44(0)1603 255 000
- Leatherhead Food Research +44(0)1372 376 761

Trade associations may also be able to provide an opinion e.g. Chilled Food Association +44(0)1536 514 365.

Glossary

Batch: a group or set of identifiable products obtained from a given process under practically identical circumstances and produced in a given place within one defined production period.

Challenge testing: deliberate inoculation of relevant microorganisms into a food product to determine the product's ability to support survival, growth or inactivation of the organisms during storage at defined temperature(s).

Controlling factor: factors that can be used to prevent the growth and toxin production by non-proteolytic *C. botulinum*. In addition to chill temperatures (less than or equal to 8°C), the following factors should be used singly or in combination to prevent growth and toxin production by non-proteolytic *C. botulinum* in prepared chilled foods with an assigned shelf-life of more than 10 days:

- a heat treatment of 90°C for 10 minutes or equivalent lethality in the slowest heating point in the food
- a pH of 5.0 or less throughout the food
- a salt level of 3.5% or more (aqueous) throughout the food
- an a_w of 0.97 or lower throughout the food
- a combination of heat and preservation factors which has been shown to consistently prevent growth and toxin production by *C. botulinum*

Hazard Analysis Critical Control Point (HACCP): procedures applied by food businesses that identify, monitor, evaluate and control hazards which are significant for food safety.

Modified atmosphere packaging (MAP): atmosphere in a packaged product (gas) that differs from the ambient atmosphere.

Non-proteolytic *C. botulinum*: psychrotrophic clostridia that can grow and produce botulinum neurotoxin at chill temperatures. The terms "non-proteolytic *C. botulinum*" and "psychrotrophic *C. botulinum*" are equivalent and interchangeable.

Psychrotrophic *C. botulinum*: see Non-proteolytic *C. botulinum*.

Shelf-life: the period during which the product maintains its microbiological safety and organoleptic qualities at a specific storage temperature. It is based on identified hazards for the product, heat or other preservation treatments, packaging method and other hurdles or inhibiting factors that may be used.

Vacuum packaging (VP): the removal of all or most of the air within a package, without deliberate replacement with another gas mixture, and prevention of its return by an airtight seal around the food within the packaging material.

Validation: obtaining evidence that the elements of the HACCP plan are effective.