Food Standards Agency guidance on the safety and shelf-life of vacuum and modified atmosphere packed chilled foods with respect to non-proteolytic *Clostridium botulinum*

June 2016

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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 carrying 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 *C. 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. 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	June 2016	Clarification and updated legal references	Nick Laverty, Chris Rowswell, Kirsten Stone, Jo Edge & Antonis Ampatzoglou

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 in carrying 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 *C. 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 therefore should be included 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. Compliance with this advice is **not** required by law.

6. Businesses with specific queries may wish to seek the advice of their local enforcement agency, which will usually be the trading standards or environmental health department of the local authority.

Introduction

7. 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 *C. botulinum*. The guidance is applicable to both ready-to-eat and raw foods, including raw meat.

8. 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.

9. 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.

10. Although non-proteolytic *C. botulinum* food poisoning is very rare in the UK, it's 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

11. 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 are also liable to be present in food. In a favourable environment spores may germinate leading to toxin formation.

12. 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 as the sole control 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.

13. Examples of foods that have led to foodborne botulism outbreaks, without obviously being depleted of oxygen, include baked potatoes wrapped in aluminium foil, organic hummus, black bean dip, and carrot juice. The scientific literature also describes several challenge test studies where toxin formation by non-proteolytic *C. botulinum* was as rapid (or in some circumstances more rapid) in foods packed in air as under VP or low-oxygen MAP. Oxygen presence or air packing should not therefore be considered in itself, an adequate control measure to prevent the growth of non-proteolytic *C. botulinum* and other control measures should be present in such foods.

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 greater than 10 days are specific for this organism. However, FBOs must still take into account other 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. 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 Food Business Operators 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

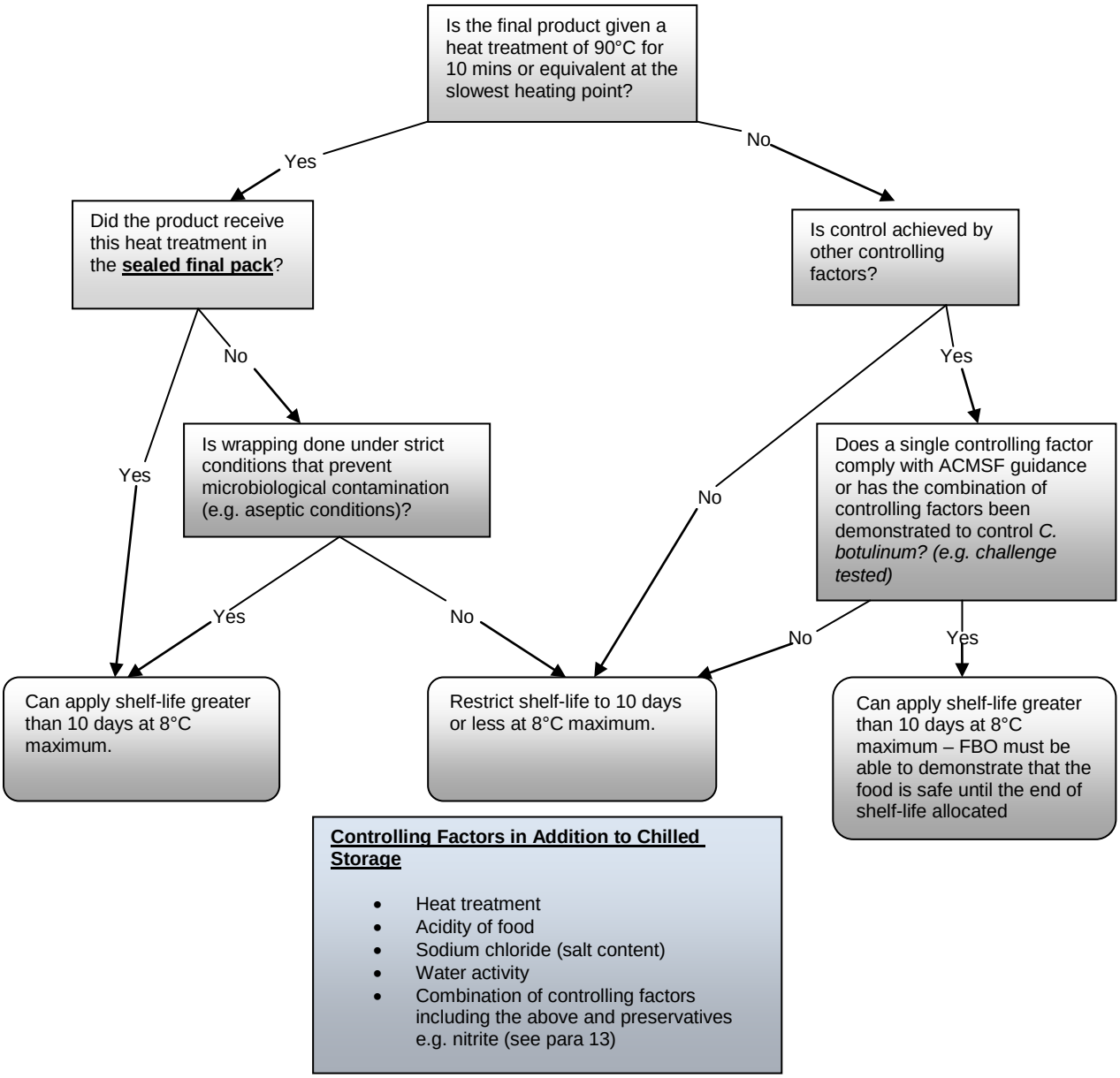
14. It is the FBO's responsibility to ensure that the shelf-life they set is appropriate and that the safety of the food at the end of shelf-life can be demonstrated. FBOs may wish to consult experts (e.g. research associations) on how to establish and validate the shelf-life and demonstrate the safety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

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
- 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 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 food business operator 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:

Determining the shelf-life of VP/MAP products stored above 3°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 para 13)

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.*

VP/MAP Ingredients

Where VP/MAP 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 product 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 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 greater than 10 days. The shelf-life will begin as soon as the controlling factor(s) have been first applied:

- a heat treatment of 90°C for 10 minutes or equivalent lethality (see Table 1)
- 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 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*

Table 1: Equivalent time/temperature combinations for spores of non-proteolytic *C. botulinum* [5, 6]

Temperature (°C)	Time (mins)
80	129
81	100
82	77
83	60
84	46
85	36
86	28
87	22
88	17
89	13
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. For foods stored at less than 3°C the shelf-life starts once the temperature of 3°C is exceeded and the controlling factors for chilled VP/MAP foods should be identified. Therefore, once the VP/MAP product reaches 3°C or above, a maximum 10 day shelf-life should be applied when stored between 3 and 8°C unless adequate controlling factors are applied.

[5] 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

[6] 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

20. Ideally heat treatment should be carried out in the final sealed pack as this is the safest method to destroy spores of non-proteolytic *C. botulinum* and there is no opportunity for re-contamination with non-proteolytic *C. botulinum* or other pathogens[7] 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 conditions that prevent microbiological contamination. As spores of *C. botulinum* are ubiquitous in the environment, this would involve a strict level of control to ensure that re-contamination is prevented post-heat treatment, for example using aseptic conditions. 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.

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 lower than or equal to 8°C 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 production batch. The food business operator must define the batch[8]. 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.

[7] http://www.food.gov.uk/business-industry/guidancenotes/hygguid/ecoliguide

[8] 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.

Sodium chloride (NaCl) content

22. A concentration of 3.5% sodium chloride in the aqueous phase of a food stored at temperatures less than or equal to 8°C 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:

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

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 less than or equal to 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, a a_w of 0.97 or below should be achieved throughout all components of the food. This should be monitored for every production batch. Due to the nature of the test it may be necessary to approach a specialised laboratory to do a_w measurements and to interpret the data.

Other controlling factors

25. Combinations of a lower level of the specific controlling factors described above may be able to prevent growth and toxin production of non-proteolytic *C. botulinum*. Other combinations, e.g. addition of nitrite, may also be used to prevent growth of non-proteolytic *C. botulinum*. 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 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 expert advice is needed. Mathematical models e.g. ComBase Predictor or Pathogen Modelling Program 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 HACCPbased 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 (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 specified controlling factors (either singly or in combination), 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 of batches of product. Without evidence to show that non-proteolytic *C. botulinum* won't grow in a product, a maximum shelf-life of 10 days should be applied. An appropriate centre of expertise should be consulted both to carry out challenge testing and interpret the results.

28. Interpretation of the results of challenge testing needs to be carried out by someone with the appropriate level of scientific expertise. If *C. botulinum* shows any evidence of growth in the product during the challenge test, the

maximum shelf-life applied should be 10 days.

29. 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

30. Where no other controlling factor can be identified, the maximum shelf-life should be 10 days from when the product is first vacuum packed (VP) or modified atmosphere packed (MAP). 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.

31. 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 to be greater than 10 days then this ought to be justified with respect to controlling factors to prevent the growth of non-proteolytic *C. botulinum*. The FBO may need to contact the manufacturer to determine what controlling factors are in place. 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.

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	water activity, 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 Advisory Committee for the Microbiological Safety of Food (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 micro-organisms, 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. 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. FBOs should assess and validate each individual product against the risk from *C. botulinum* and provide evidence of the controls in place (e.g. via challenge testing or predictive modelling, where the specified controlling factors in the guidance cannot be met), where the shelf-life is greater than 10 days, to show that non-proteolytic *C. botulinum* will not grow throughout the entire

shelf-life of the product.

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

A: The FSA guidance recommends that the shelf-life applied to VP and MAP products be restricted to a short shelf-life i.e. 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 or inhibit the growth of non-proteolytic *C. botulinum*. These are explained in the section 'Background information on the specific controlling factors'.

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

A: The FBO should look at the decision tree in this document. If the shelf-life is beyond 10 days the HACCP based procedures ought to specify the relevant control measures to ensure safety within the allocated shelf-life. Article 3.2, Annex II of Regulation (EC) 2073/2005: microbiological criteria for foodstuffs[9], describes the necessary practices and procedures to be considered for establishing shelf-life. It is noted that this is set out specifically for *Listeria 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 a VP/MAP product is to be stored at <3°C, this is outside the scope of the guidance with regards to the control of non-proteolytic *C. botulinum*, and therefore there is no maximum recommended shelf-life. It is still up to the FBO to decide on an appropriate shelf-life for their products, but other hazards must be taken into account that may be associated with their products, in particular *Listeria monocytogenes*, which is capable of growing at temperatures below 0°C and therefore must be taken into consideration when setting shelf-life. The FBO should be able to provide sufficient evidence (e.g. through shelf-life analysis, or demonstration that there are controlling factors to restrict growth of harmful organisms such as a low pH or water activity) to show that their products are safe for consumption throughout the shelf-life.

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

If a FBO labels their product to be stored at <3ºC, it is important that they consider the intended use of their products. If the product is likely to be stored at between 3°C and 8°C after it leaves the FBO's control (e.g. at retail or during storage in commercial or domestic kitchens) then the controlling factors of the product would need to be taken into account, if a shelf-life of more than 10 days at between 3°C and 8°C is to be applied.

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 Clostridia 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. In addition, Campden BRI's guidance states that "to establish the potential risk from growth and toxin production by *C. botulinum* in foods which do not meet the required controlling factors, direct microbiological testing for the organism in a product is inappropriate. Challenge test studies should therefore be carried out or the risks associated with the product determined using predictive microbiological models".

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 either alone, or in combination, are 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 to be carried out to determine whether a particular product is capable of preventing growth and toxin production of non-proteolytic *C. botulinum*. 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 or batches of product. Challenge testing 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 water activity) in a food to achieve a combined preservation effect or use additional preservatives such as nitrite. Where a lower level of factors is used, each factor is not able to inhibit the growth of *C. botulinum* on its own but is reliant 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 and toxin production of non-proteolytic *C. botulinum*; this may be done by predictive models and challenge testing.

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* are salt, pH and water activity 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 and toxin production of *C. botulinum* needs to be evaluated for each specific product, for example by challenge testing. A FBO's HACCP based food safety management procedures should have some ongoing monitoring to ensure that the products are of the right specification which can control growth.

9 Q: How are the results of challenge testing assessed to determine a safe shelf-life for extended life chilled VP/MAP products, with regards to growth and toxin production of non-proteolytic *C. botulinum*?

A: Currently, testing for evidence of growth by *C. botulinum* is the preferred approach rather than testing for toxin production. Whilst testing for toxin production is sometimes undertaken there are significant constraints on using this approach and growth is seen as providing a more reliable indicator or metabolic activity by *C. botulinum* and hence the potential for toxin to be produced. It is difficult to accurately determine the link between the levels of *C. botulinum* present and the presence of toxin. However, once there is evidence of metabolic activity then there is an increased likelihood that toxin could be formed. Because of the severity of the hazard, growth would be deemed unacceptable irrespective of any variation in the ability of strains to produce toxin. The FSA's view is that at present, growth (i.e. any demonstrable increase in viable count) of *C. botulinum* rather than time to toxin production during challenge testing would be considered an appropriate parameter when conducting challenge testing for determining shelf-life in relation to this hazard.

10 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, and is safe to place on the market. 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. If consistent results are achieved and documented and 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.

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

A: A food business operator must be compliant with the general principles and requirements of food law in Regulation (EC) 178/2002. It 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 permanent a procedure based on HACCP principles. A food business operator 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.

12 *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 a HACCP Plan will depend on the shelf-life the business applies to their products. If the shelf-life is up to and including 10 days, the controls are simple and straightforward with use of a clear 'use by' date within 10 days of packing, together with the storage of the product, which should be equal to or lower than 8°C throughout the shelf-life of the product. The product should display the 'use by' date and the required storage conditions clearly printed on the pack.[10]

13 *Is the FSA's Safer Food, Better Business pack suitable for manufacturers of VP/MAP products?*

A: A HACCP procedure based on the principles of the *Sfbb* pack is 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 control measures critical limits and monitoring procedures in more detail than is generally used in *Sfbb* and will need to keep appropriate records.

14 *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

[10] 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

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 (e.g. heat treatment of 90°C for 10 minutes, pH of 5.0 or less, minimum salt concentration of 3.5%, water activity of 0.97 or less) 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). However, when this is not the case (e.g. when using different time temperature combinations), validation should be undertaken.

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

A: Validation is a process that should be undertaken by the food business operator 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.

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

A: The local authority should ensure 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, when it was undertaken and who was involved, including their level of expertise.

17 *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 food business operator to put in place, implement and maintain permanent procedures based on HACCP principles. Under Article 5(4) (a), a food business operator 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.

Failure to meet 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. The use of a hygiene improvement notice (HIN) may be appropriate to require either (i) that validation is

carried out or (ii) that evidence is provided of the result of the validation process. 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.

18 *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[11]. General advice on enforcement is contained within the Food Law Code of Practice and associated Practice Guidance.

19 *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.

20 *Q: How concerned should the local authority be if a food business operator 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 Advisory Committee for the Microbiological Safety of Food (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. Local 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.

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

A: Powers exist in the Food Safety and Hygiene (England) Regulations 2013 and

[11] See Regulation (EU) No 1169/2011 Article 7 on the provision of food information to consumers http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX%3A32011R1169&from=en

equivalent legislation in Scotland, 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 local 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 Advisory Committee for the Microbiological Safety of Food (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.

22 *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 food business operator, followed by an application to a Magistrates' 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 7(2) or Regulation 8(4) of the Food Safety and Hygiene (England) Regulations 2013 and the other devolved UK equivalent regulations are likely to be satisfied. That is, there is a risk of injury to health under Regulation 7(2) or 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.[12] A food business operator 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 food business operator 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.

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

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

the local authority take?

A: The FBO should be provided with a copy of this FSA guidance. Officers should consider whether the food business operator'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.

24 *Q: If a food business operator (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.

25 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?

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.

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 factors used in addition to chilled storage was a heat treatment of 90°C for 10 minutes or equivalent, there is the potential for re-contamination with non-proteolytic *C. botulinum* spores once opened and therefore the shelf-life applied when re-wrapping the product should not be greater than 10 days unless other controlling factors are identified by the FBO re-wrapping the product. If there are less than 10 days remaining on the original shelf-life when the products are re-wrapped, then the shelf-life should not exceed this date.

If the controlling factors used in addition to chilled storage are factors other than heat treatment such as pH, salt or water activity; 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 these controlling factors have not changed and remain sufficient to control non-proteolytic *C. botulinum* and any

other relevant micro-organisms, 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 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 additional controlling factors (e.g. by carrying out their own testing). Again, the shelf-life should not exceed the shelf-life given to the original product.

Further advice

26 *Q: If an environmental health officer or a food business operator 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 organism 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
- a pH of 5.0 or less throughout the food
- a salt level of 3.5% or more (aqueous) throughout the food
- a 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 grows and produces botulinum neurotoxin at chill temperatures.

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 prevents its return by an airtight seal of the food within the packaging material.

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