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*

July 2008

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Summary

Introduction:	This guidance is applicable to raw and ready-to-eat vacuum packed or modified atmosphere packed 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) 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:	The UK
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 3 ≤ 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 above 3°C. At less than 3°C growth of non-proteolytic *C. botulinum* does not occur. Foods stored at less than 3°C are outside the scope of this guidance.

Revision history

Revision No.	Revision date	Purpose of revision	Revised by
1	July 2008	Guidance	Kathryn Callaghan

Contents

Intended audience

1. The 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 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 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 3 ≤ 8°C when other specified controlling factors could not be identified.

3. 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 above 3°C. At less than 3°C growth of non-proteolytic *C. botulinum* does not occur. Foods stored at less than 3°C are outside the scope of this guidance.

Purpose and legal status

4. 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.

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[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

5. 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

6. 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.

7. 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.

8. 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 above 3°C. 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.

9. Although non-proteolytic *C. botulinum* food poisoning is very rare in the UK, its serious nature 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

10. 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.

11. 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.

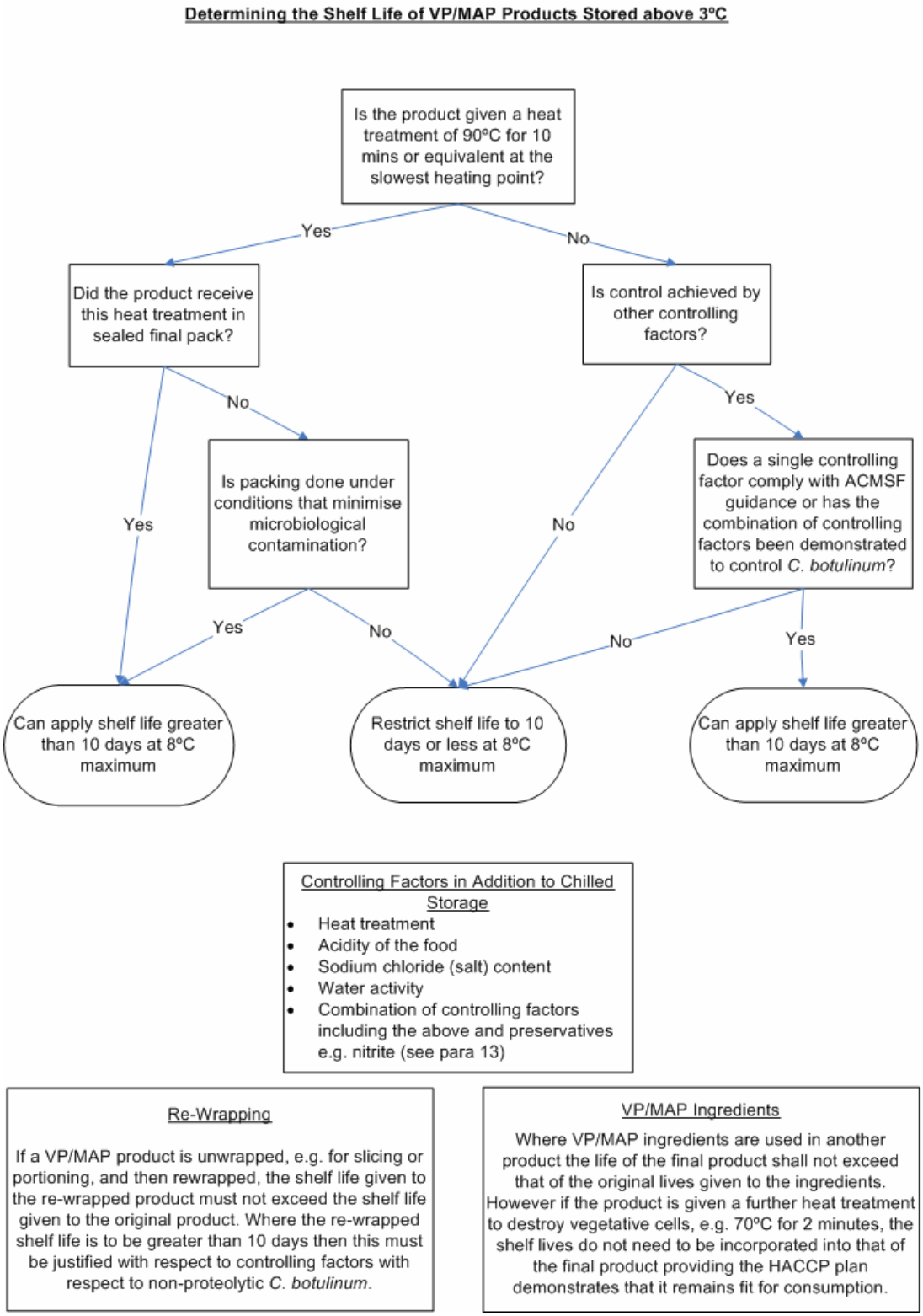
12. Examples of foods that have led to foodborne botulism outbreaks, without obviously being depleted of oxygen, include baked potatoes wrapped in aluminium foil, organic hummus, black bean dip, and carrot juice. The literature also describes several challenge test studies where toxin formation by non-proteolytic *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.

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

13. The ACMSF recommended that, in addition to chill temperatures 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 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*

14. The following decision tree should be used by the food business operator to determine if a shelf-life of greater than 10 days is appropriate:



Background information on the specific controlling factors for chilled VP/MAP foods in which a shelf-life of longer than 10 days is indicated

15. 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.

16. 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 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

[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] Table 1 includes Z values 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

Heat treatment

17. If heat treatment is to be used as the single control 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.

Acidity of the food

18. 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 less 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 food. This should be monitored for every production batch. The food business operator must define the batch[7]. Batch size is a key point to consider in any risk management action.

19. 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

20. 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:

[7] 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

21. 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)

22. 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

23. Combinations of a lower level of the specific controlling factors described above may be able to prevent growth of non-proteolytic *C. botulinum*. Other combinations, e.g. addition of nitrite, may also be used to prevent growth of non-proteolytic *C. botulinum*. These specific combinations need to be validated using sound scientific principles; this is a highly specialised field and expert advice is needed. Mathematical models e.g. Combase Predictor or Pathogen Modeling Program can be used to obtain relevant information on combinations of controlling factors.

The uses and limitations of predictive growth models

24. Predictive microbiology models are important tools for food safety management as they provide a scientific basis to underpin key aspects of HACCP. 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 Modeling Program (www.arserrc.gov/mfs/PMP6_CurMod.htm). 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.

Practice of repackaging VP/MAP foods

25. 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 packing under vacuum or modified atmosphere, unless other controlling factors are first applied.

26. 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 rewrapped, 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*.

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.

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: 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 food business operator (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* 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'.

3 Q: How should a food business operator (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 plan ought to specify the relevant control measures to ensure safety within the allocated shelf-life. Article 3.2, Annex II of EC Regulation 2073/2005: Microbiological Criteria for Foodstuffs, 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.

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

A: A business must be able to identify the hazards associated with their operation and the methods to control those hazards. Article 5 of Regulation (EC) No 852/2004 requires a permanent 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.

5 Q: How much information should be contained in a HACCP Plan 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 i.e. 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 below 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.[8]

6 Q: Would an approach to HACCP based on Safer food, better business principles be appropriate?

A: A HACCP procedure based on these principles 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 and will need to keep appropriate records.

7 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.

[8] See Regulation 5(c) of the Food Labelling Regulations 1996 (SI No 1499: 1996) as amended

The most important things to validate are that the control measures (e.g. heat treatment of 90°C for 10 minutes, pH of 5 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.

8 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.

9 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.

10 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. Failing to meet those community provisions may mean that an offence under the Food Hygiene (England) Regulations 2006 (as amended) 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.

11 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: 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[9]. General advice on enforcement is contained within the Food Law Code of Practice and associated Practice Guidance.

12 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.

13 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.

14 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 Hygiene (England) Regulations 2006 (as amended) and 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

[9] Includes consideration of Regulation 5 (c) of the Food Labelling Regulations 1996 (SI No 1499: 1996) as amended

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.

15 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 Hygiene (England) Regulations 2006 (as amended) is 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.[10]

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 Annex 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.

16 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 the local authority take?

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[10] Text taken from the draft Food Law Code of Practice

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.

17 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 system. Reference to the decision tree will identify those factors that need to be taken into account when a VP/MAP product is repacked.

Further advice

18 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 & Chorleywood Food Research Association +44(0)1386 842 000
- Institute of Food Research +44(0)1603 255 000
- Leatherhead Food International +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 chill foods with an assigned shelf-life of more than 10 days:

- a heat treatment of 90^{o}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): a system that identifies, evaluates and controls 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 forms 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.