ACM /714

DISCUSSION PAPER

ADVISORY COMMITTEE ON THE MICROBIOLOGICAL SAFETY OF FOOD (ACMSF)

GUIDANCE ON THE SAFETY AND SHELF-LIFE OF VACUUM AND MODIFIED ATMOSPHERE PACKED CHILLED FOODS WITH RESPECT TO PSYCHROTROPHIC *C.BOTULINUM*

The attached paper relates to issues raised in response to our consultation of the attached guidance document covering the food safety aspects of the manufacture of vacuum and modified atmosphere packaged (VP/MAP) chilled foods.

The ACMSF is invited to:

1. Consider the comments received in response to the consultation, summarised in Annex 2, with key concerns relating to a shelf-life limitation of 5 days discussed in the attached paper

2. Consider the publication of the FSA document "Guidance on the safety and shelf-life of vacuum and modified atmosphere packed chilled foods", in the light of these key comments received through the consultation process.

Secretariat
November 2004

GUIDANCE ON THE SAFETY AND SHELF-LIFE OF VACUUM AND MODIFIED ATMOSPHERE PACKED CHILLED FOODS WITH RESPECT TO PSYCHROTROPHIC *C.BOTULINUM*

Issue

1. The ACMSF is invited to consider the publication of the FSA document "Guidance on the safety and shelf-life of vacuum and modified atmosphere packed chilled foods", in the light of the comments received through the consultation process.

Background

2. The attached document (Annex 3) relates to the food safety aspects of the manufacture of vacuum and modified atmosphere packaged (VP/MAP) chilled foods.

3. The document is a concise summary of the information contained in the industry Code of Practice for the Manufacture of Vacuum and Modified Atmosphere Packaged Chilled Foods (1996) and advice from the Advisory Committee on the Microbiological Safety of Food (ACMSF) in its Report on Vacuum Packaging and Associated Processes (1992) and subsequently (1995). The document was drafted in response to a request made by the ACMSF to make the guidance more accessible and relevant to manufacturers and retailers of chilled VP/MAP foods, and Local Authorities carrying out their enforcement duties. At its meeting held on 18 September 2003, the Committee agreed that the document should go out to a full public consultation. The consultation period ended on 27 August 2004.

Consultation comments

4. The comments received in response to the consultation are summarised in Annex 2.

5. There was broad support for the document, especially from Environmental Health Officers. There were also major concerns, particularly from the manufacturing and retail sector, if the document was to be published in its current form. These concerns relate to a perceived change in the "10-day rule" and the introduction of a 5-day shelf-life for foods stored at 5 - 8 ^{o}C. The "5-day rule" is based on ACMSF advice that chilled foods stored between 5^{o}C and 10^{o}C should have an assigned shelf-life of 5 days or less, and the concern is that this advice is slightly at odds with the industry Code of Practice which recommends a shelf-life of 10 days or less for chilled foods where the specific controlling factors are not demonstrated. The attached Background Note (Annex 1) provides further detail on the 5-day shelf-life issue..

Industry concerns with a shelf-life limitation of 5 days

6. The chilled food industry has the following concerns with the introduction of a 5-day shelf-life limitation:

- It would have a very serious impact on the shelf-life of chilled foods since it would be unlikely that a temperature of less than 5^{o}C could be maintained throughout the shelf-life, particularly when considering the period after customer purchase. This would give rise to a greatly increased amount of waste food

- It would have a significant effect on manufacturing and transport costs. It would become financially impossible to continue to produce many products, and the UK produced chilled market would reduce

- There is no evidence that the “10-day rule” has not been fully effective in food safety protection

- It lacks a transparent scientific basis. The 5-day recommendation of the ACMSF (1995) is not supported by referenced studies. This contrasts with the wealth of data and refereed publications considered during production of both the original ACMSF Report and the Industry Code

- Imposing such a restriction could be a barrier to trade and could put the UK chilled food industry at a distinct disadvantage against mainland Europe

- The new guidance would have a significant commercial impact and would require a Regulatory Impact Assessment to be carried out.

Action required by ACMSF

7. In the light of these serious concerns raised by the food industry, the ACMSF is invited to consider options for publishing the FSA guidance document. The options include:

1. Publishing the document in its current format thereby including the shelf-life limitation of 5 days

2. Revising the document so that it takes account of only the original ACMSF Report and the Industry Code (i.e. no reference is made to the additional ACMSF advice relating to the shelf-life limitation of 5 days)

3. Defer publication of the document and consider establishing a Working Group to revise advice in relation to the control of *C.botulinum* in VP/MAP chilled foods, taking account of previous advice and all subsequent evidence.

Microbiological Safety Division
November 2004

Background Note **Annex 1**

Why the guidance document includes a shelf-life limitation of 5 days at 5 – 8°C

1. One of the aims of the document was to bring together the 3 published pieces of advice in relation to the control of *C.botulinum* in VP/MAP foods; the industry Code of Practice (1996), the ACMSF Report (1992), and the ACMSF Annex to its 1995 Annual Report.

2. The industry Code and the ACMSF Report are consistent in terms of advising a shelf-life of 10 days or less for chilled foods where the specific controlling factors are not demonstrated or where the food has not been challenge tested to demonstrate a shelf-life longer than 10 days. However, they differ in that the ACMSF specifies a chill temperature of ≤10°C and the industry Code is more stringent in reducing the temperature to ≤8°C, in compliance to temperature control regulations. The ACMSF made its recommendation for the adoption of 10°C on the basis of proteolytic strains of *C.botulinum* (i.e. those that do not grow at chill temperatures) not being reported to grow below this temperature. But, **in order to consolidate the advice, the current guidance document refers throughout to a chill temperature of £8°C**.

3. The Annex to the ACMSF Annual Report (1995) recommended that, *"where chilled storage is the sole controlling factor, chilled foods stored between 5°C and 10°C should have an assigned shelf-life of 5 days or less*". As the current guidance document refers throughout to a chill temperature of ≤8°C, this recommendation is interpreted as foods stored between 5°C and 8°C should have an assigned shelf-life of 5 days or less. **This interpretation does not change the ACMSF recommendation that *"If a shelf-life of up to 10 days is required, the chilled storage temperature should be 5°C or less***."

4. The Annex to the ACMSF Annual Report was a written response by the ACMSF to questions raised by the Technical Secretary to the Vacuum Packaging Code of Practice Working Party. The recommendation relating to the "shelf-life of 5 days or less" was in response to a question seeking the ACMSF's opinion on whether 10 days at 8°C is still adequate as a controlling factor in the light of recent data, or whether the current recommendation should be reviewed. The ACMSF's view was that there was no evidence to suggest that an assigned shelf-life of less than 10 days has not proven to be effective. However, since publication of the Report "*additional information from laboratory based studies has been published. Data available from Food MicroModel support the leading edge of this recently published information*." It was in the light of this additional information that the ACMSF recommended that , *"where chilled storage is the sole controlling factor, chilled foods stored between 5°C and 10°C should have an assigned shelf-life of 5 days or less*".

ANNEX 2

RESULTS OF THE PUBLIC CONSULTATION ON THE FSA'S DRAFT GUIDANCE ON THE SAFETY AND SHELF-LIFE OF VACUM AND MODIFIED ATMOSPHERE PACKED CHILLED FOODS WITH RESPECT TO PYSCHROTROPHIC *C.BOTULINUM*

COMMENT	ORGANISATION
Overall Support for the document	
Respondents indicating broad support for the guidance document	Sainsbury's Wakefield Council Alan Speight, Consultant MLC CCFRA BMPA LACORS Rhondda Cynon Taf Council South Hams Council Weymouth & Portland Borough Council
Cannot support current content or format	CFA/BRC Uniq Prepared Foods NIMEA/Dungannon Meats FDF
Key Comments: Introduces a shelf-life limitation of 5 days	
Would have a very serious impact on the shelf life of chilled foods since it would be unlikely that a temperature of less than 5^{o}C could be maintained throughout the shelf life, particularly when considering the period after customer purchase	BRC & CFA
In order to maintain a 10-day shelf life they would need to ensure a temp of 5^{o}C or less throughout life. This can be achieved during manufacture, distribution and retail sale but they would have to assume temperatures in the home by customers would exceed 5^{o}C so they may be obliged to reduce all shelf lives to 5 days.	Sainsbury's MLC CCFRA
Has a significant effect on manufacturing and transport costs	BRC & CFA
A reduction in shelf life would cause severe distribution and stock management problems and potential losses through "waste" throughout the supply chain. This could result in removal of product ranges from the market to the detriment of consumer choice and business viability.	BMPA British Poultry Council Katsouris Fresh Foods
Maintaining a temperature of 5^{o}C or less will be technically difficult and may not be practicable when the Food Safety (Temperature Control) Regulations 1995 do not require it.	Seafish
Due to the significant commercial impact, calls for a Regulatory Impact Assessment	BRC & CFA, FDF
Key Comments: Where is the scientific evidence to support a change to the CoP?	
No evidence that the existing 10 day shelf life rule under the industry code is failing to keep food safe for consumers	Sainsbury's Northern Foods British Poultry Council FDF Seafish

Current guidance given in Industry CoP including a shelf life of ≤10 days at a temp of ≤8°C is still fully valid without amendment. This view is given with the understanding that all of the existing literature was reviewed and taken into consideration during the production of the Industry Code, that there has been no comprehensive review of any research done since the Code was published, but the with knowledge that we have seen no evidence that implementation of the control factors in the Industry CoP has resulted in food safety issues with respect to *C. botulinum.*	CCFRA
Express concern about experimental data used as a basis for the FSA guidance. Challenge tests on real products and under realistic storage conditions have not shown unsafe levels in the time periods set.	Sainsbury's Marks & Spencer FDF CFA/BRC
Suggest that the FSA request a further review of the risk presented using the most recent data and a more thorough assessment of scientific basis underpinning the guidance.	Sainsbury's
Need to show that guidance is based on scientific knowledge and facts.	Rose County Foods Ltd CFA/BRC SFAM NIMEA/Dungannon Meats Marks & Spencer Katsouris Fresh Foods NI Food Liaison Group
Key Comments: Barrier to trade	
Shelf lives differ across the EU. To impose restrictions could be a barrier to trade, unless they are to be applied equally throughout the EU	BRC & CFA Sainsbury's Uniq CCFRA CFA/BRC BMPA NIMEA/Dungannon Meats Seafish LACORS British Poultry Council Farne Salmon and Trout Ltd Northern Foods
Guidance should cover all products sold in UK not simply those manufactured in UK	Rose County Foods Ltd CFA/BRC NIMEA/Dungannon Meats
Enforcement issues	
As the FSA document is clearly for guidance and not a Statutory Instrument does the FSA see its use as one of "enforcement"?	CCFRA (p4) BMPA
Would welcome specific guidance on enforcement	Milton Keynes Council
Will be of limited use to enforcers due to lack of included legislation and thus could be misinterpreted.	NIMEA
Suggest change to title to add the words "with respect to *Clostridium botulinum*". Also suggestion of secondary title: "Guidance for Food Business Managers and Enforcement Officers"	IFR
Some smoked seafood and meat processors are unaware of the risk of *C. botulinum.* Believe the only way to change this is through enforcement of industry code of practice by EHO's	Inverawe Smokehouses

Where cooked meats are packed in bulk and supplied to a re-wrapper do both companies have to do challenge testing or predictive testing? Or is it just the re-wrapper who handles the food last before it is sent for retail sale? Local authorities have to consider who has responsibilities before taking any sort of enforcement action. The guidance must clearly describe the biochemical effects on control factors of different foods.	Wakefield Council
The need to challenge test even when there is a good safety record for the product is noted and the clarity welcomed, however it seems likely that the application of the advice would be challenged in court and in weighing up the chances of success authorities may conclude that pursuing the matter is not a sensible course of action. There is therefore the risk that the guidance would then gradually be discredited.	LACORS
Emphasis should be on policing the existing Industry Code so that manufacturers and packers work to that standard which is widely accepted by the industry and enforcement authorities as representing a safe standard.	British Poultry Council
The guidance does not deal with the issue of failures in the cold chain. It may be appropriate to advise on CCPs and documentation of specified temperatures.	Herefordshire and Worcestershire Food Group
The guidance could mention the need to register changes in food business registration such as the introduction of vac-packing. Should the postal exemption in General Regulations be reviewed?	Herefordshire and Worcestershire Food Group
The guidance seems to assume the existence of a chill chain beyond that specified in the Food Safety (Temperature Control) Regulations 1995 or the design criteria for a standard retail display or domestic fridge.	Northern Foods
Further shelf life comments	
Recommendations citing 3-8^{o}C could lead less enlightened processors to believe that food should be held only between 3-8^{o}C whereas storage closer to 0^{o}C would enhance the shelf life and safety of products; particularly with reference to *L. monocytogenes.* Guidelines from SFIA recommend storage at 0-2^{o}C for fish.	Donald C Cann
Some manufacturers put long shelf life on products with the proviso that they are kept at or below 3^{o}C. This is impractical.	Milton Keynes Council
The proposed change could unfairly discriminate against meat processors in Northern Scotland and Northern Ireland where long transport distances are an issue.	NIMEA/Dungannon Meats

COMMENT	ORGANISATION
Suggestions for widening the scope of the guidance	
The USA Federal Drugs Administration Food code criteria for food businesses that use reduced oxygen packing are more stringent than the FSA draft. Suggests the FSA draft should be more prescriptive and make detailed reference to HACCP, in particular the need to challenge test or carry out predictive modelling in the context of HACCP.	Wakefield Council
Suggestion that vacuum packing is included in the HACCP training given to butchers.	Calderdale Council
The FSA guidance should give more emphasis to the fact that the safe use of these packaging methods is dependent on those who use them understanding and constantly maintaining the correct procedure. Users should be referred to the key issues as given in the Industry Code of Practice:- training of food handlers, risk assessment, monitoring of control points, product formulation, temperature control, definition of product life, hygiene and the prevention of cross-contamination.	Tom Miller, Food Regulatory Affairs Consultant
The guidance should emphasise that if intending to use >10 day rule, special training and advice will almost certainly be required. Ideally the proprietor should be required/advised to notify the Local Authority.	Herefordshire and Worcestershire Food Group
Advice on whether the risk is great enough to require thermographic cooking records to verify 90^{o}C would be valuable.	Herefordshire and Worcestershire Food Group
The guidance needs to include advice on small businesses repackaging previously vacuum packed items into smaller units and assigning the same or possibly different date marking advice. The acceptability or otherwise of this practice needs to be covered and reference made to the need to recognise additional CCPs.	LACORS Herefordshire and Worcestershire Food Group Rhondda Cynon Taf Council
It would be very helpful if the guidance could include generic HACCP plans for VP products, eg a suggested plan for VP raw meat and VP cooked meat.	Dick Dailley, EHO, Carmarthenshire
Asks for more “pre-worked examples” such as for vegetables and raw meat.	David Bardwell, EHO, West Wiltshire.
Format	
Prefer the existing Industry Guide because the FSA guidance has over-simplified the issues. They would suggest as an alternative, producing a summarised/simplified Industry Code instead.	British Poultry Council SFAM
In favour of leaflet or laminated card	Inverawe Smokehouses Donald C Cann MLC Nottingham University Rhondda Cynon Taf Council Herefordshire and Worcestershire Food Group Scottish Association of Meat Wholesalers

Any leaflet/laminated card would need to contain a clear definition of scope of guidelines otherwise could lead to confusion	CCFRA
Dissemination	
Makes suggestions for disseminating the guidance. This could be through local authorities to help raise awareness and to target particular known premises, through trade associations, through publicly accessible website(s), and to those selling new or dealing in second hand vacuum packing equipment.	LACORS
Challenge testing	
The FSA should make a clear statement if they believe that predictive tools alone can be used to determine product safety for MAP/VP products that do not meet specific controlling factors, or if they believe that a challenge test must also be done.	CCFRA BMPA
A new final para should be added to read: "If a shelf-life of >5-10 days at >5-8^{o}C is desired (for example 10 days at 8^{o}C), then the specific controlling factors will need to be demonstrated, and challenge test studies should be carried out."	IFR Society for General Microbiology
Small manufacturers could find the cost of challenge testing prohibitive.	BMPA Milton Keynes Council SFAM NIMEA/Dungannon Meats British Poultry Council Farne Salmon and Trout Ltd
Could CCFRA share information they have on challenge testing?	Milton Keynes Council
Could info be given on accredited labs able to carry out challenge testing?	Milton Keynes Council Society for General Microbiology
Comments on which predictive systems should be included in guidance, eg include Growth Predictor system	CCFRA IFR Society for General Microbiology
Guidance about where to obtain specialist advice and where to pursue queries regarding challenge testing and the accurate measurement of controlling factors would be helpful. They suggest that many common scenarios will be very similar and it might be possible to give some standard advice linked to particular proven "worked examples" for different common food scenarios to avoid the need for similar/identical challenge tests needing to be repeated throughout the UK. Such advice might be developed with industry and enforcers as part of the Safer Food Better Business project being lead by the Agency's HACCP team.	LACORS

COMMENT	ORGANISATION
What is *Clostridium botulinum*?	
Suggest a redraft of this para to be more specific about anaerobic conditions in food, for example that botulism outbreaks have been associated with baked potatoes in aluminium foil.	IFR
Psychrotrophic *C. botulinum* is more commonly found in fresh water than in marine sediments.	Donald C Cann
Queries whether smoked fish should be specifically cited as incidences of botulism where VP/MAP smoked fish have been incriminated are very rare if not unknown in UK.	Donald C Cann
Which foods are covered?	
Document does not differentiate foods that may be high in oxygen MAP from those that may be under true anaerobic conditions.	Sainsbury's
High oxygen MAP not a risk But, some products which may not be conventional MAP packs may present a risk.	MLC CCFRA BMPA Sainsburys Katsouris Fresh Foods
Cooking of fish products before eating makes them safe. **(**Also encloses their own advisory note on botulism and fishery products.)	Nor Sea Foods Seafish
Need to clarify which products are covered by the guidance. Need to include raw meat and meat products	Rose County Foods Ltd Calderdale Council SFAM
Need to clarify if guidance includes raw products. CCFRA guideline 11 covers all raw products and specifically mentions raw/cooked vegetables, raw cured meats and raw uncured meats.	NI Food Liaison Group Hereford & Worcestershire Food Group
Suggest revision of line 3 to read: "Mesophilic *C. botulinum* does not grow below 10^{o}C, and is therefore not considered a risk in VP/MAP chilled foods properly stored at $\leq 8^{o}$C. However, both . . . "	IFR
Mesophilic *C. botulinum* has led to outbreaks of foodborne botulism following temperature abuse of products intended for chill storage in other countries. Revise lines 3-4 of the first paragraph to "Mesophilic *C. botulinum* is considered a low risk with respect to".	Society for General Microbiology
Separate guidance would be helpful for other risk foods not always kept chilled such as spices in oil and on the life of catering products such as sauces, spiced oils and dressings.	Herefordshire and Worcestershire Food Group
Target audience	
Further work is needed to be carried out to help local food businesses and local authorities	Wakefield Council
Need for guidance to be more easily available , simplified and published for small businesses in addition to information being provided for local authorities	Arun District Council, West Sussex
Have already devised their own checklist/guidance for their EHO's	Angus Council, Ireland Arun District Council
Vacuum packing seems very popular amongst small businesses, but awareness of food safety issues is extremely poor.	Arun District Council, West Sussex
Need to target manufacturers and retailers Retailers should include those who merely store VP/MAP foods	MLC Calderdale Council Milton Keynes Council

Suggests the guidance should include reference to the catering industry who use vacuum packing equipment.	Tom Miller, Food Regulatory Affairs Consultant Herefordshire and Worcestershire Food Group
Some of the language still too complicated for small retail and caterers. Perhaps the wall chart or leaflet version mentioned could stick to the basic "rules of thumb" outlined in Figs 1 & 2.	LACORS Rhondda Cynon Taf Council David Bardwell, EHO, West Wiltshire
The guidance would be of greatest value to small businesses, butchers and caterers who have limited access to technical expertise, but the CCFRA Guideline 11 and ACMSF reports are more appropriate as primary reference documents for larger manufacturers with technical manufacturers. This could be made clear in the "who should use" paragraph. If aimed at smaller businesses it could include guidance on controlling other pathogens, for example preventing cross contamination between packing raw and ready to eat foods.	NI Food Liaison Group
The guidance should consider advice to the final user. All VP/MAP foods should be labelled with recommended storage temperatures and use by dates. This is particularly relevant in the case of products which are not required to have such information under the current Food Labelling Regulations, eg products pre-packed for direct sale.	NI Food Liaison Group CCFRA
Comments on Fig 1 and Fig 2	
Suggests the key points in Fig 1 should be presented in reverse sequence. This would more logically follow the decision making process for manufacturers and retailers.	MLC CCFRA
It would be helpful if the figure and text referred to storage life below <3^{o}C as having no specific requirements for control of psychrotrophic *C. botulinum.*	MLC CCFRA
Fig 1 fails to specifiy a quantitative reduction in risk and should be rephrased to read "a combination of heat and preservative factors that provides a protection factor of 6 (6 log reduction) against the risk of survival and growth from spores of psychrotrophic *C. botulinum* throughout the shelf-life of the product". This change should be applied throughout the document.	Society for General Microbiology IFR
Asks for clarification of what is meant by "predistribution storage life" and how is shelf life defined in Fig 2.	BMPA Society for General Microbiology
Consideration should be given to omitting Fig 2 because it is mainly a duplication of information in Fig 1 and thus may confuse the issue. If retained then "storage at ≤8^{o}C" should be added to the "long shelf-life" section.	Society for General Microbiology
Suggests using words rather than symbols for less than/more than etc to make it more user friendly for small catering premises proprietors	LACORS

"Minimum heat treatment" should clarify that it is the slowest heating part of the food which must reach this temperature. Suggests "core temperature" or "centre temperature" should be used to describe the time/temp combination throughout the document.	Rhondda Cynon Taf Council
In Fig 1, more explanation of Step 3 is needed. Also suggests in both Fig 1 as a first alternative and Fig 2 as a third column, including wording to encourage seeking further professional advice.	David Bardwell, EHO, West Wiltshire
Minimum salt 3.5% etc, could be challenged by the current drive to reduce levels.	Alan Speight

COMMENT	**ORGANISATION**
Table 1 and 2	
References in Table 1 to organisms other than C. botulinum could be confusing.	CCFRA BMPA NIMEA
As the guidance document is to provide simply and easy to use guidance on the control of *C. botulinum*, the inclusion of this table is surprising since the code/ACMSF recommendations do not deal with most of the organisms in the table. In order to promote ease of use, deletion of Table 1 should be strongly considered.	Society for General Microbiology IFR
Table 2 – extend to include temperatures above 90^{o}C	CCFRA
Annex	
Annex – Background info. Remove reference to L. monocytogenes.	CCFRA
It is not clear why Lm is mentioned in background information. Also difficult to understand what specific steps could be used to remove spores of *C. botulinum*. Suggested revision: "In an unpreserved VP/MAP food stored at chill temperature, growth of *C. botulinum* will be slow. Since spores of *C. botulinum* are ubiquitous in the environment, it is assumed that the food is contaminated. It is on this basis . . . "	Society for General Microbiology IFR
Annex – Heat treatment. Queries the use of the term "protection factor"	CCFRA
The explanation of "protection factor of 6" (as given in brackets) in heat treatment section is incorrect and should read: "The protection factor is the number of decimal reductions in the probability of survival and growth of the organism in the product. It combines the effect of heat treatment and of inhibitory factors. A heat treatment at 90^{o}C for 10 minutes combined with subsequent maintenance at ≤8^{o}C for 40 days provides a protection factor of 6, ie this combination reduces the probability of survival and growth from spores of *C. botulinum* by a factor of 10^{6}, a 6-log reduction. The same heat treatment combined with maintenance at higher temperatures gives a lower protection factor."	Society for General Microbiology IFR
Nitrate/nitrite are important control factors particularly for cured meats eg hams (cooked) and bacon (raw) and should be mentioned in the combination of control factors. Suggested redraft of this para.	Alan Speight IFR
Clarification needed of recommendation on process temperature (90^{o}C/10min). Is this "in final pack"?	CCFRA
The wording of footnote 5 is important and should also appear in Figures 1 and 2.	Society for General Microbiology
The water activity of 0.97 mentioned throughout the document relates to when sodium chloride is the controlling factor. Lower	Society for General Microbiology

water activities may be required if other factors are controlling water activity (for example in chilled pasta). This should be revised to "an a_w of 0.97 (controlled by sodium chloride) or lower throughout the food". (There are other references to a_w in Fig 1, Fig 2 and Table 1.)	
AFDOS in the US have suggested another controlling factor: the introduction of non-competing (harmless to humans) organisms to compete against the growth of pathogenic organisms which do harm.	British Poultry Council

FOOD STANDARDS AGENCY

Annex 3

Guidance on the safety and shelf-life of vacuum and modified atmosphere packed chilled foods

January 2004 (DRAFT)

Introduction

This document provides advice on vacuum and modified atmosphere packaged (VP/MAP) chilled foods in relation to microbiological safety and shelf-life limitations and *Clostridium botulinum*.

The process of vacuum packaging removes air and prevents its return by an airtight seal of the food within the packaging material. With modified atmosphere or "gas" packaging, air is again removed and is replaced by a strictly controlled mixture of gases chosen from carbon dioxide, oxygen and nitrogen. There are various methods available to replace air in VP or MAP foods which are described in detail in the Industry Code of Practice for the Manufacture of Vacuum and Modified Atmosphere Packaged Chilled Foods[1].

Although VP/MAP techniques can protect food products from external contamination and increase the shelf-life, under certain circumstances a bacterium called *Clostridium botulinum* may grow. As this bacterium prefers to grow without air, **VP/MAP products are more at risk**. Some strains of *C.botulinum* are able to grow and produce toxin at low temperatures and therefore it is very important that these products are kept under controlled refrigeration.

Although this type of food poisoning is very rare in the UK, its serious nature means that VP/MAP should be carefully controlled. It is very important that all critical control points are identified and controlled at all times.

What is *Clostridium botulinum*?

Clostridium botulinum is a spore-forming, anaerobic bacterium – meaning it only grows in the absence of oxygen. This bacterium can produce a very powerful toxin in the food which causes botulism – a frequently fatal form of food poisoning. Botulinum toxin is one of the most potent substances known, causing the serious paralytic illness botulism, which can result in death if not treated promptly. The spores are widely distributed in the environment, are found world-wide in soil, dust and marine sediments and are generally considered to survive indefinitely. The toxin is produced when the spores are able to germinate in favourable oxygen-free environments that allow the bacteria to grow and release toxin.

As the organism can only grow in the absence of oxygen, foodborne botulism is usually associated with airtight foods such as canned or bottled foods which have not been processed sufficiently to either remove the spores or prevent bacterial growth. Home canned foods in particular, and foods preserved in oil

[1] 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.

(e.g. garlic in oil), have been associated with outbreaks. Outbreaks of botulism have also been associated with VP/MAP foods, the most commonly implicated food being smoked fish.

What does this guide cover?

The microbiological safety concerns summarised here will be restricted to the control of *C.botulinum* strains which are able to grow and produce toxin at chill temperatures (psychrotrophic). Mesophilic *C.botulinum* is not considered a risk with respect to VP/MAP chilled foods as it does not grow below 10°C. However, both organisms may cause safety problems if the foods are stored above 10°C, as the controlling factors may not be adequate. In general, ambient stable heat processed foods rely on a different set of controlling factors than VP/MAP chilled foods and take into account the potential for growth and toxin production by psychrotrophic and mesophilic *C. botulinum.* Recommendations covering these products are contained in the Department of Health Guidelines on Heat Preserved Foods[2].

Although this document is restricted to the safety concerns with respect to *C.botulinum*, Table 1 summarises the conditions permitting growth of other food poisoning bacteria of potential concern with chilled VP/MAP foods.

This document summarises the advice of the Advisory Committee on the Microbiological Safety of Food's (ACMSF) Report on Vacuum Packaging and Associated Processes[3], ACMSF advice annexed in its annual report[4] and the Industry Code of Practice for the Manufacture of Vacuum and Modified Atmosphere Packaged Chilled Foods[5]. The ACMSF advice and Code of Practice remain valid; this guidance document supplements that advice.

Who should use this guidance document?

The guidance is recommended for use by manufacturers and retailers of chilled VP/MAP foods. It is designed to meet the needs of all levels of expertise, from technical managers in large enterprises to individuals vacuum packing products for market stall trade. The guidance is also designed to help Local Authorities carrying out their enforcement duties. The aim is to help Environmental Health Officers and businesses become more aware of the steps they need to take to control *C. botulinum* in VP/MAP foods.

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[2] Department of Health. Guidelines for the safe production of heat preserved foods; 1994. HMSO, London.

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

[4] Advisory Committee on the Microbiological Safety of Food. Annual Report; 1995, Annex III. HMSO, London.

[5] 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.

Determination of the Safety of Chilled VP/MAP Foods

The shelf-life of a chilled VP/MAP food (i.e. one held at 3-8°C) should never exceed 10 days unless its safety under expected storage conditions can be demonstrated. In order to determine whether a chilled VP/MAP food is safe and to determine when challenge testing is appropriate, the 3-Step Principle in Figure 1 should be followed. These principles are also outlined in the flow chart in Figure 2.

Figure 1. Determination of the safety of chilled VP/MAP foods: The 3-Step Principle

Step 1: Determine whether the shelf-life of the chilled food is:

Short, i.e. £ 10 days ➪ Go to Step 2
or **Long, i.e. > 10 days** ➪ Go to Step 3

Step 2: Determine whether the product is chilled at:

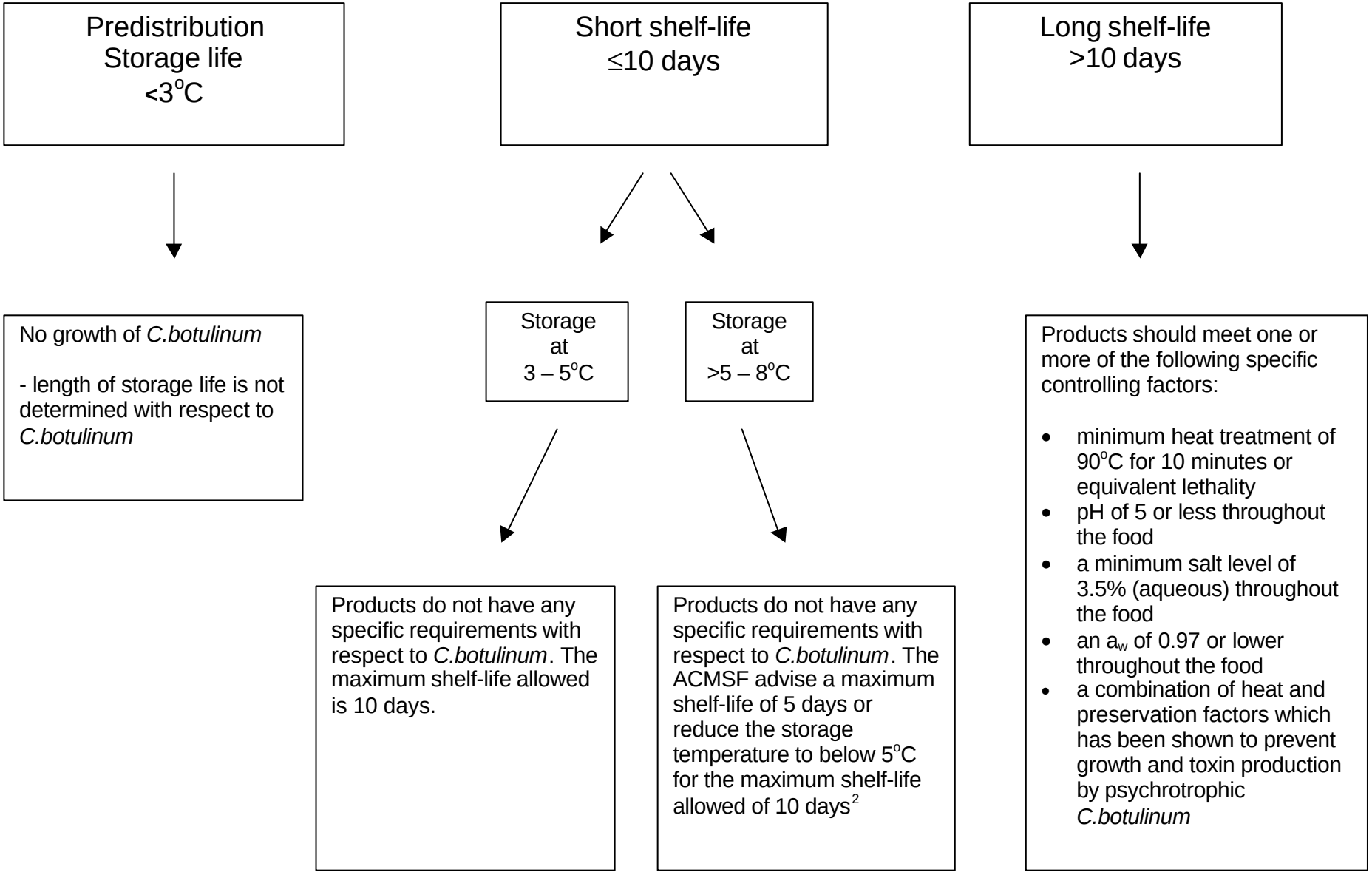
3 – 5°C ➪ Products do not have any specific requirements with respect to *C.botulinum*. The maximum shelf-life allowed is 10 days.

or >**5 – 8°C** ➪ Products do not have any specific requirements with respect to *C.botulinum*. The ACMSF advise a maximum shelf-life of 5 days or reduce the storage temperature to below 5°C for a maximum shelf-life of 10 days[2].

Step 3: Determine whether, in combination with storage at £8°C, one or more of the following specific controlling factors are demonstrated; **if not, the product should be challenge tested**:

- minimum heat treatment of 90°C for 10 minutes or equivalent lethality
- pH of 5 or less throughout the food
- a minimum salt level of 3.5% (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 psychrotrophic *C.botulinum*

Figure 2. Flow chart to determine the safety of chilled VP/MAP foods



When to Challenge Test

To establish the potential risk from growth and toxin production by *C.botulinum* in chilled VP/MAP foods with a long shelf-life (>10 days) which do not meet the specific controlling factors, challenge test studies should be carried out; direct microbiological testing for the organism in a product is inappropriate.

- **Where the specific controlling factors have not been demonstrated, a good safety record for the product cannot be relied upon; challenge testing must be carried out**.

- **Where the specific controlling factors (see Figure 1, Step 3) have not been demonstrated and where there is no challenge test data to show that psychrotrophic *C.botulinum* will not grow in the food within the specified shelf-life, then the shelf-life of the food should be reduced to £10 days (or the specific control factors detailed in Figure 1 implemented)**.

Due to the nature of the hazard, challenge testing must be conducted in research facilities with the necessary expertise to safely handle the organism. The procedure involves inoculation of the product with, in this case, *C.botulinum* spores which are able to germinate and grow at chill temperatures, and incubation of the product under controlled environmental conditions in order to assess the risk of food poisoning or to establish product stability. The risks associated with the product can be determined using predictive microbiological models, e.g. Food MicroModel, ComBase (http://wyndmoor.arserrc.gov/combase/). Modelling can be used as a tool to guide the need for challenge testing.

Troubleshooting

The industry Code of Practice[3] outlines types of problems that may occur during manufacture, storage, distribution and handling of VP/MAP foods and provides advice on possible scenarios which may be encountered. If you are a manufacturer, retailer or Environmental Health Officer and you are in any doubt about the safety of a VP/MAP food, you should contact the Food Standards Agency. The Agency will put you in contact with expert advisors as necessary.

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Food Standards Agency
Room 816C, Aviation House
125 Kingsway
London WC2B 6NH

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Table 1. Extremes of temperature, aw, pH and salt concentration permitting growth of food poisoning bacteria of potential concern to chilled VP/MAP foods

Organism	Minimum Temp (°C) for growth	Minimum a_w for growth	Minimum pH for growth	Maximum NaCl (%) for growth	Time/Temp to achieve 6 log reduction
C.botulinum - psychrotrophic	3.0	0.97[a]	5.0[a]	5.0	90°C/10 min (spores)
C.botulinum – mesophilic	10.0	0.94	4.6	10.0	121°C/1.2 min (spores)[b]
Bacillus cereus	4.0	0.91	4.3	-	100°C/30 min (spores)
Salmonella spp.	4.0[c]	0.94	4.0	6.0	70°C/2 min[d]
Listeria monocytogenes	-0.4	0.92	4.3	12.0	70°C/2 min
Aeromonas hydrophila	-0.1	-[e]	4.0	4.0	70°C/2 min
Yersinia enterocolitica	-1.0	0.96	4.2	7.0	70°C/2 min
Staphylococcus aureus	6[f]	0.83[f]	4.0	12.5	70°C/2 min
Vibrio parahaemolyticus	5.0	0.94	4.8	8.0	70°C/2 min
E.coli O157:H7 and other VTEC[g]	7.0	0.95	4.0+	-	70°C/2 min

Table modified from the Industry Code of Practice[3], and revised to reflect more recent studies[6]

[a]Inhibitory level
[b]Ambient foods are processed to achieve a 12 log reduction, 121°C/2.52min
[c]Most stains do not grow below 7°C
[d]This time/temperature combination is recommended as the min requirement for cooking of chilled foods
[e]Data not available
[f]No evidence of toxin production at this temperature
[g]The most important consideration here is to prevent contamination or eliminate the pathogens during processing

The above data represent approximate values for these growth limits under otherwise optimal conditions. Exact values will vary depending on the strain of microorganism and food composition.
Interactions between factors are likely to considerably alter these values.

Table 2. Alternative time/temperature combinations to achieve the equivalent of 90°C for 10 minutes

Process Temp (°C)	Time (mins)	Process Temp (°C)	Time (mins)	Process Temp (°C)	Time (mins)
90	10	85	36	80	129
89	13	84	46	79	167
88	17	83	60	78	215
87	22	82	77	77	278
86	28	81	100	76	359
				75	464

Table modified from the Industry Code of Practice[3]

[6] CCFRA Technical Manual on the evaluation of shelf life for chilled foods. No. 28 July 1991, Appendix 1 revised April 1997

ANNEX

Background Information on the Specific Controlling Factors

In an unpreserved VP/MAP food stored at chill temperature, growth of *C.botulinum* or *Listeria monocytogenes* will be slow. Under normal conditions it is assumed that the food is contaminated unless there is a specific step (e.g. pasteurisation for *L.monocytogenes*) which removes this possibility. It is on this basis that specific requirements for shelf-life are proposed to assure the safety of food, even though some limited growth of the food poisoning organism may be possible. Table 1 gives some data on the minimum growth requirements and suitable heat treatments for food poisoning organisms of potential concern to chilled VP/MAP foods.

Heat Treatment

For VP/MAP with a shelf-life of greater than 10 days at chill temperatures £8°C, where there are no other controlling factors, the minimum heat treatment required is that the slowest heating part of the food should be held at 90°C for 10 minutes or equivalent; equivalent temperatures are shown in Table 2.

NB: A heat treatment of 90°C for 10 minutes (or equivalent) in combination with storage at ≤8°C will give a protection factor of 6 with respect to spores of psychrotrophic C.botulinum[7]*. (This is a 6 log reduction, which will reduce the numbers of microorganisms present by a factor of 10^6. This is traditionally expressed as a "6D" value where D is the time required at a given temperature to reduce the number of viable cells or spores of a given microorganism to 10% of the initial number.)*

Acidity of the Food

The level of acid in a food is a controlling factor in the growth of microorganisms and a pH of 5.0 or below throughout a food stored at chill temperatures £8°C is sufficient to inhibit the growth of psychrotrophic *C.botulinum*.

NB: 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 met ***throughout*** *the food. This should be monitored for every production batch. Acidified foods containing meat, fats or oils are notoriously difficult to acidify uniformly and extra care should be taken with these foods.*

[5] For long shelf-life foods (>40 days) stored at chill temperature ≤8°C, research published since publication of the ACMSF advice[1, 2] and Industry Code of Practice[3] suggests that in addition to a heat treatment of 90°C for 10 minutes (or equivalent, see Table 2), challenge testing may be needed to establish the maximum shelf-life.

Salt Content

A level of 3.5% salt throughout the aqueous phase of a food stored at chill temperatures £8°C is sufficient to inhibit the growth of psychrotrophic *C.botulinum*[8]. The percentage of salt in the aqueous phase of a product can be calculated from the salt content (grams of NaCl present in 100g product) and the moisture content (grams of water per 100g of product) using the following calculation:

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

NB: If salt content is the controlling factor for safety, a level of 3.5% or above should be met ***throughout*** *the aqueous phase of a food. This should be monitored for every production batch.*

Water Activity (a_w)

Using water binding chemicals such as salt or sugar it is possible to remove the available water from a food to a point at which the growth of microorganisms is inhibited. For foods with salt or other solutes as the main a_w depressant, an a_w of 0.97 should be achieved throughout the food stored at chill temperatures £8°C to inhibit the growth of psychrotrophic *C.botulinum*.

NB: 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 met ***throughout*** *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.*

Combination of Factors

Combinations of a lower level of the specific controlling factors described above may be able to prevent growth of psychrotrophic *C.botulinum*. 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.

NB: These specific combinations need to be established using sound scientific principles; this is a highly specialised field and expert advice is needed. Mathematical models (e.g. Food MicroModel) can be used to obtain relevant information on controlling factors such as salt and pH. It is necessary to illustrate that the preservation system chosen can consistently prevent growth and toxin production by psychrotrophic C.botulinum*: this may be done by challenge testing and possibly predictive models , providing that sufficient validation data are available to substantiate the reliability of predictions.*

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[8] For long shelf-life foods (>40 days) stored at chill temperature ≤8°C, higher salt levels may be required to inhibit psychrotrophic *C.botulinum* and challenge tests may need to be conducted.