FOOD STANDARDS AGENCY

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

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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:

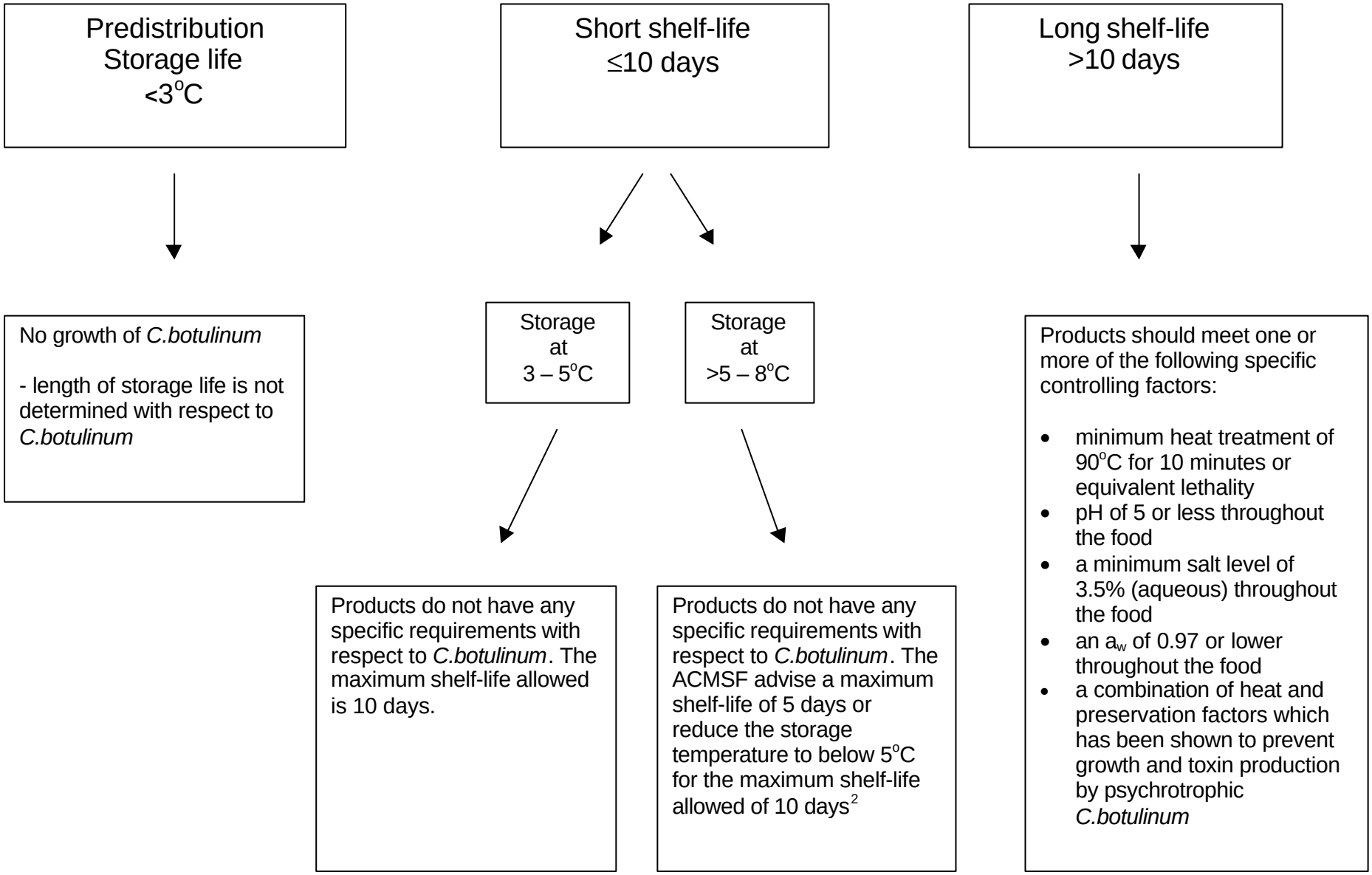
3 – 5°C ➪ Products do not have any specific requirements with respect to *C.botulinum*. The maximum shelf-life allowed is 10 days.

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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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 10⁶. 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.