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*

Background

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

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 at its meeting held on 5 December 2000.

Purpose

1. To invite comments from the Committee on the content of the paper and to ask the Committee whether:

- the document encompasses the key elements contained in the Industry Code of Practice and the ACMSF advice
- the document would benefit from any additional guidance e.g. a risk assessment for *C.botulinum* in VP/MAP foods as an annex
- the information is in a format suitable for target audiences

2. To ask the Committee whether it is content for the document to go forward for public consultation.

Secretariat
November 2001

FOOD STANDARDS AGENCY

Guidance on the safety and shelf-life of vacuum and modified atmosphere packed chilled foods with respect to psychrotrophic *C.botulinum*

November 2001 (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 document summarises the advice of the Advisory Committee on the Microbiological Safety of Food's (ACMSF) Report on Vacuum Packaging and Associated Processes[1], ACMSF advice annexed in its annual report[2] and the Industry Code of Practice for the Manufacture of Vacuum and Modified Atmosphere Packaged Chilled Foods[3]. The ACMSF advice and Code of Practice remain valid; this guidance document supplements that advice. The guidance is recommended for use by manufacturers and retailers of chilled VP/MAP foods, and Local Authorities carrying out their enforcement duties.

VP/MAP techniques have the potential to increase the shelf-life of many chilled foods without adversely affecting the quality. Whilst changing the atmosphere may prevent the growth of spoilage organisms, it may allow the growth of pathogens such as *C.botulinum*; it is therefore important that all critical control points are identified and controlled at all times.

The microbiological safety concerns summarised here will be restricted to the control of psychrotrophic (non-proteolytic) *C.botulinum* which is able to grow and produce toxin at chill temperatures. Mesophilic (proteolytic) *C.botulinum* is not considered a risk with respect to VP/MAP chilled foods as it does not grow below 10^{o}C. However, both organisms may cause safety problems if the foods are stored above 10^{o}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[4].

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

Determination of the Safety of Chilled VP/MAP Foods

These guidelines do not cover products held continuously at <3.0^{o}C. The shelf-life of a chilled VP/MAP food (i.e. one held at 3-8^{o}C) should never exceed 10 days unless their 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.

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

[2] Advisory Committee on the Microbiological Safety of Food. Annual Report; 1995, Annex III. 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] Department of Health. Guidelines for the safe production of heat preserved foods; 1994. HMSO, London.

When to Challenge Test

To establish the potential risk from growth and toxin production by psychrotrophic *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)**.

Challenge testing must be conducted in a suitable laboratory with the necessary expertise and facilities to safely handle the organism. The procedure involves inoculation of the product with, in this case, psychrotrophic *C.botulinum* spores, and incubation of the product under controlled environmental conditions in order to assess the risk of food poisoning or to establish product stability. **Expert advice should be taken when considering the requirement for challenge testing** and the Food Standards Agency may be contacted in the first instance. The risks associated with the product can be determined using predictive microbiological models, e.g. Food MicroModel (Food MicroModel can be obtained from Food MicroModel Ltd., Randalls Road, Leatherhead, Surrey). 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. Local authority EHOs may also be able to obtain further advice from Campden and Chorleywood Food Research Association as part of the package of technical support for authorities funded by the FSA [DN: The details of the scheme are currently under discussion and will be announced shortly].

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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[5]*. (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*.

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*[6]. 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:

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

[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.

[6] 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.

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.*

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	3.3	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 [7]

[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]

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

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