# *Clostridium botulinum* in vacuum packed (VP) and modified atmosphere packed (MAP) chilled foods

## FINAL PROJECT REPORT JULY 2006 (Project B13006)

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## CONTENTS OF THE REPORT


### Part one – Executive Summary

1. Summary
2. Introduction
3. Production and sales of chilled VP/MAP foods
4. The position in the UK, other European countries and internationally with respect to guidance on control of non-proteolytic *C. botulinum* in chilled VP/MAP foods
    - THERMAL PROCESSING
    - HURDLES AND INTRINSIC FACTORS
    - CHILLED TEMPERATURE
    - SHELF LIFE
5. Chilled storage and handling of foods
6. Recent incidence of foodborne botulism
7. Summary of data on growth and toxin formation by non-proteolytic *C. botulinum* at ≤10°C
    - SUMMARY OF DATA
    - DISCUSSION OF THE DATA
8. Re-packing VP/MAP chilled foods during the 10 day shelf-life
9. Risk assessments
10. Conclusions

### Part two – Main text of the report

Chapter one - Introduction

Chapter two - Practice and Market: VP & MAP Equipment and Chilled Foods Sold in the UK and Overseas

2.1 Equipment for MAP and Vacuum Packaging
2.2 Overall chilled market structure
    - 2.2.1 UK
    - 2.2.2 Non-UK
2.3 Main chilled market segments using VP or MAP
2.4 Recommended generic shelf lives of chilled VP products
2.5 Recommended generic shelf lives and gas mixtures of chilled MAP products
2.6 UK sales of chilled MAP/VP/low oxygen foods
2.7 International sales of chilled MAP/VP/low oxygen foods
2.8 Details of sales and production of raw meat (to be cooked)
    - 2.8.1 Raw meat in the UK
    - 2.8.2 Raw meat outside the UK
2.9 Ready to eat/delicatessen meats
2.10 Fish and Seafood
    - 2.10.1 Smoked Fish - UK
    - 2.10.2 Smoked Fish - Non-UK
    - 2.10.3 Mussels
2.11 Bagged leafy salad and prepared produce
2.12 Fresh Pasta and Gnocchi
2.13 Dairy products
2.14 Retailed chilled ready meals
    - 2.14.1 Chilled ready meals in the UK
    - 2.14.2 Chilled ready meals in Belgium
    - 2.14.3 Chilled ready meals in Finland
    - 2.14.4 Chilled ready meals in France
    - 2.14.5 Chilled ready meals in Germany

2.14.6 Chilled ready meals in Hungary
2.14.7 Chilled ready meals in Netherlands
2.14.8 Chilled ready meals in Australia
2.14.9 Chilled ready meals in USA
2.15 Other chilled foods
2.15.1 Chilled Bread (packed in air)
2.15.2 Chilled Dough (packed in air)
2.15.3 Tofu
2.15.4 Herbs/Vegetables in Oil
2.16 Internet and Mail Order Foods
2.17 Farm Market Sales of VP/MAP foods
2.18 Domestic VP
2.19 Conclusions
2.20 References
2.21 Appendix 1 – Supplementary information for Chapter two (Practice and Market: VP & MAP Equipment and Chilled Foods Sold in the UK and Overseas)

Chapter three - The position in the UK, other European countries and internationally with respect to guidance on control of *C. botulinum* in chilled VP/MAP foods
3.1 Inventory of Guidance in Relation to Chilled Foods
3.2 Guidance at the European Level
3.2.1 EU Food Regulation
3.2.2 European Industry Guidance
3.3 Guidance in EU Member States
3.3.1 The position in the UK
3.3.1.1 ACMSF Guidance
3.3.1.2 Code of Practice for the Manufacture of VP/MAP Chilled Foods
3.3.1.3 Chilled Food Association guidance
3.3.1.4 Mail Order Foods
3.3.1.5 Sous Vide Advisory Committee
3.3.1.6 FSA Consumer Guidance on Homemade Flavoured Oils
3.3.2 The position in Finland
3.3.3 The position in France
3.3.4 The position in Italy
3.3.5 The position in the Netherlands
3.4 Guidance outside the EU
3.4.1 The position in Australia
3.4.2 The position in Canada
3.4.2.1 MAP Products
3.4.2.2 Chilled Foods with Extended Shelf life
3.4.2.3 Handling Practices for Chilled Food
3.4.2.4 Best Before/Durable Life
3.4.2.5 Garlic in Oil
3.4.3 The position in the USA
3.4.3.1 Reduced Oxygen Packaging
3.4.3.2 Cheese
3.4.3.3 Fish
3.4.3.4 Cook-Chill (US definition) or Sous Vide
3.4.3.5 Cooking
3.4.3.6 Cooling
3.4.3.7 Date Marking
3.4.3.8 Herbs/Vegetables in Oil
3.4.3.9 Fresh-Cut Produce
3.4.3.10 VP Sub-Primal Beef Cuts
3.4.3.11 Refrigerated Foods

3.5 International Trade - Codex Alimentarius Commission
3.5.1 Refrigerated Packaged Foods with Extended Shelf Life
3.5.2 Fish and Fishery Products
3.5.3 Smoked Fish
3.6 Summary of Key Stipulated Process Parameters for VP/MAP/ROP Chilled Foods
3.7 Conclusions
3.8 References

Chapter four - Storage and Handling of Chilled Food
4.1 Pre-distribution temperatures
4.2 Legislated commercial temperatures
4.3 Commercial Temperature Control in Practice
4.4 Temperatures from Shop to Home
4.5 Mail Order/Website Postal Sales
4.6 Farmers' Markets
4.7 Catering
4.8 Domestic Refrigerators
4.9 Domestic Food Refrigeration Temperatures in Practice
4.10 Domestic Chilled Food Storage Practices
4.11 Commercial Shelf Life Determination Protocols
4.12 Conclusions
4.13 References

Chapter five: Summary of recent outbreaks of foodborne botulism
5.1 Introduction to foodborne botulism
5.2 Method for collection of data on foodborne botulism
5.3 Recent outbreaks of foodborne botulism
5.3.1 Recent outbreaks of foodborne botulism involving proteolytic *C. botulinum*
5.3.2 Recent outbreaks of foodborne botulism involving non-proteolytic *C. botulinum*
5.4 Review of incidence of foodborne botulism in various countries
5.4.1 An overview of the position in different countries
5.4.2 Foodborne botulism in the UK
5.4.3 Foodborne botulism in France
5.4.4 Foodborne botulism in other European countries
5.4.5 Foodborne botulism outside Europe
5.5 Conclusions
5.6 References

Chapter six: Summary of data on growth and toxin formation by non-proteolytic *C. botulinum* at ≤10°C
6.1 Outputs from predictive models
6.2 Observations of time to toxin formation in chilled foods/food materials
6.2.1 Method for data collection
6.2.2 Summary of tests of toxin formation by non-proteolytic *C. botulinum* at 10°C
6.2.3 Summary of tests of toxin formation by non-proteolytic *C. botulinum* at 8°C
6.2.4 Evaluation of the significance of the positive results for toxin formation by non-proteolytic *C. botulinum* at 8°C by food type
6.2.5 Summary of tests of toxin formation by non-proteolytic *C. botulinum* at 4°C-7°C
6.2.6 Overall evaluation of tests of toxin formation by non-proteolytic *C. botulinum* in foods at ≤10°C and ≤10 days
6.3 Effect of other environmental factors on toxin formation by non-proteolytic *C. botulinum* in chilled foods
6.3.1 General comments
6.3.2 Combinations of storage temperature and shelf life

6.3.3 Predictive models of combinations of heat treatment, storage temperature, shelf-life and other preservative factors on time to toxin formation that prevent toxin formation by non-proteolytic *C. botulinum*
6.4 Effect of alternative and emerging processing technologies on toxin formation by non-proteolytic *C. botulinum* in chilled foods
6.4.1 High Hydrostatic Pressure (HPP)
6.4.2 Pulsed Electric Field (PEF)
6.4.3 Irradiation pasteurisation
6.4.4 Pulsed Light
6.4.5 Conclusions
6.5 Lag time of non-proteolytic *C. botulinum*
6.6 Conclusions
6.7 References

Chapter seven: Re-packing VP/MAP chilled foods during the 10 day shelf-life

Chapter eight: Risk assessments on the control of non-proteolytic *Clostridium botulinum* in VP/MAP chilled foods
8.1 ALOPs and FSOs
8.2 Microbiological Risk Assessment
8.3 Risk Assessments for *Clostridium botulinum*
8.4 Final Safety Assessment
8.5 Conclusions
8.6 References

Glossary

Appendix two – Data on growth and toxin formation by non-proteolytic *C. botulinum* in foods at 10°C and below

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## Chapter three - The position in the UK, other European countries and internationally with respect to guidance on control of *C. botulinum* in chilled VP/MAP foods

### 3.1 Inventory of Guidance in Relation to Chilled Foods

The guidance documents inventory produced by the European Union funded Harmony Project (Martens, 1997, 1999) in relation to codes of good hygienic practice for minimally processed foods was used as the base data set for this chapter, with those documents referring to VP/MAP foods being selected. Documents issued post-Harmony were also reviewed for relevance to VP/MAP foods.

Table 3.1 summarises the scope of 45 existing GMP codes, guidelines, safety reports etc relating to VP/MAP/ROP (reduced oxygen packaging) chilled foods. The last column indicates the sectoral focus of each document:
M: manufacturers of minimally processed foods
C: catering sector
R: retail/distribution of chilled foods
D: domestic

The key documents are reviewed in the following sections.

Table 3.1 An outline summary the scope of 45 existing GMP codes, guidelines, safety reports etc relating to VP/MAP/ROP (reduced oxygen packaged) chilled foods

| Organisation/Country | Year | Title of Document | Scope | Reference to VP/MAP/ ROP? | Sector |
|---|---|---|---|---|---|
| ACMSF 1992 | 1992 | Report on Vacuum Packaging and Associated processes | Production, handling and storage of VP and other low oxygen chilled foods | Yes | M, C, R |
| ACMSF 1995 | 1995 | Annual Report 1995, Annex III | Production, handling and storage of VP and other low oxygen chilled foods | Yes | M, C, R |
| AFIC, ASI, RWTAA (Australia) | 1999 | Australian Cold Chain Food Safety Programs | Handling, storage and transport of frozen foods, ice cream and chilled foods for retail sale and in food service outlets | Yes | M, C, R |
| Agriculture Canada | 1990 | Canadian Code of recommended practices for pasteurized/ MAP/ refrigerated food | Pasteurized products (before or after packaging) under vacuum or modified atmosphere | Yes | M |
| AIFST/Australian Cook Chill Council | 2000 | Guidelines for Chilled Food Production Systems including Food Safety Programs | Cook-chill systems – bulk foods, multi-portion packs, individual packs – catering and retail | Yes | M, C |
| AMI/NMA/SMA (USA) | 2003 | Best Practices for Handling Vacuum-Packed Sub-Primal Beef Cuts. | Safe handling of the primary and potential secondary end products from VP sub-primal beef cuts and clarification of testing of these products for pathogens. | Yes | M |
| ANZFA (applicable in Australia only) | 2001 | Standard 3.2.2 (Food Safety Practices and General Requirements) | Receipt, storage, processing, display, packaging, distribution, disposal and recall of food. | No | M, C, R |
| AFGC, AFIC, ASI, RWTAA (Australia) | 1999 | Australian Cold Chain Guidelines | Handling, storage and transport of frozen foods, ice cream and chilled foods for retail sale and in food service outlets | No | M, C, R |
| Australian Quarantine and Inspection Service (AQIS, Australia) | 1992 | Code of practice for heat-treated refrigerated foods packaged for extended shelf life. | Cook-chill products with extended shelf life (>5 days). Excluded: frozen meals, cured meat products, dairy products, fruit juices/purees | Yes | M, R |
| British Retail Consortium (UK) | 2005 | BRC Global Standard Food (Issue 4) | All retailer own label food products | No | M, R |
| Campden and Chorleywood Food Research Association (UK) | 1996 | Code of practice for the manufacture of vacuum and modified atmosphere packaged chilled foods with particular regard to the risks of botulism. Guideline No. 11 | VP or MAP products, but notes that VP or MAP are not the only circumstances which can give rise to *C. botulinum* risks | Yes | M |

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|---|---|---|---|---|---|
| Campden and Chorleywood Food Research Association (UK) | 1992a | Guidelines for the good manufacturing and handling of MAP food products. Technical Manual No. 34 | MAP foods, VP and air packed fresh fruit and vegetables. Excluded: other VP foods, such as cured, smoked and cook-chill products | Yes | M, R |
| Campden and Chorleywood Food Research Association (UK) | 1992b | The microbiological safety of sous vide processing. Technical manual No. 39 | Sous vide products | Yes | M |
| Canadian Food Inspection Agency | 1997 | Decisions: Best Before Date/Durable Life | MAP foods | Yes | M, R |
| CFSAN (USA) | 2005 | Food Code 2005 | Establishes definitions, sets standards for management and personnel, food operations, and equipment and facilities; and provides for food establishment plan review, permit issuance, inspection, employee restriction, and permit suspension. | Yes | M |
| Chilled Food Association (CFA - UK) | 2006 | Best Practice Guidelines for the Production of Chilled Foods. 4th edition | Pre-packaged chilled prepared foods for retail sale | Yes | M |
| Chilled Food Association (CFA - UK) | 1997 | Guidelines for Good Hygienic Practice in the Manufacture of Chilled Foods. 3rd edition | Pre-packaged chilled prepared foods for retail sale | Yes | M |
| Codex Alimentarius Commission | 1999 | Code of hygienic practice for refrigerated packaged foods with extended shelf life | chilled foods with shelf life >5 days<br>products with pH >4.6 and $a_w$ >0.85 | No | M |
| Codex Alimentarius Commission | 2005 (draft) | Draft Standard for Smoked Fish | Internationally traded cold smoked fish | Yes | M |
| Department of Health (UK) | 1989 | Chilled and Frozen Guidelines of Cook-Chill and Cook-Freeze Catering Systems. DoH Guidelines. | Pre-cooked chilled foods for institutional catering | No | C |
| European Chilled Food Federation (ECFF) | 1996 | Guidelines for the hygienic manufacture of chilled foods | Chilled retailed foods with pH > 4.5 or $a_w$ > 0.85 | Yes | M |
| European Chilled Food Federation (ECFF) | 1996 (pub 1999) | Sous vide: conclusions of an ECFF Botulinum working party | Chilled foods where there is no competition from other micro-organisms and/or where competitors are destroyed by a mild heat process | Yes | M |

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| Elintarvikevirasto (EVI) (Finland) | 2000 | Suositus tyhjiöpakattujen kylmäsavustettujen ja graavisuolattujen kalavalmisteiden enimmäissäilytysajaksi | VP cold smoked and gravad fish preparations maximum storage times and temperatures | Yes | M, C, R |
| FDA | 1993 | Unrefrigerated garlic-, spice-in-oil mixes potentially hazardous. | Domestic and commercially produced garlic/spice-in-oil mixes | Yes | M, C, R, D |
| Food Institute Canada | No date | Canadian Code of Recommended Handling Practices for Chilled Food | Processed foods which are stored and distributed at temperatures of between -1°C and +4°C, and are sold away from the point of manufacture | Yes | M |
| FSA | No date | Is it safe to make my own flavoured oils at home using herbs? | Domestically produced flavoured oils with herbs, spice, vegetables | Yes | D |
| FSAI (Ireland) | 2004 | Cook-chill systems in the Food Service Sector | Cook-chill catering | No | C |
| Food Standards Agency Scotland | 2005 | Food Safety Guide for Farmers Markets in Scotland | Handling and storage of food sold at farmers markets | No | M, R |
| Health Canada | 2002 | Guidelines for the Production, Distribution, Retailing and Use of Refrigerated Pre-packaged Foods with Extended Shelf Life | Low acid (pH 4.6), high moisture ($a_w$>0.85) chilled foods | Yes | M, C, R |
| Health Canada | No date | Garlic in oil | Domestic/non-industrial production of garlic in oil | Yes | M, C, R, D |
| International Fresh-Cut Produce Association (IFPA - USA) | 2001 | Food Safety Guidelines for the Fresh-Cut Produce Industry | Sanitary procedures for the fresh-cut industry | Yes | M |
| International Fresh-Cut Produce Association (IFPA - USA) | 2003 | Packaging Design for Fresh-cut Produce | Selection of packaging approaches for fresh-cut produce | Yes | M |
| Joint Hospitality Industry Congress (UK) | 1997 | Industry Guide to Good Hygienic Practice: Catering Guide | All catered foods | No | C |
| MOFFA (UK) | 2006 | Draft Industry Guide to Good Hygiene Practice: Mail Order Foods | Mail order foods | Yes | M, R |

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|---|---|---|---|---|---|
| NFPA (USA) | 1989 | Guidelines for the development, production, distribution and handling of refrigerated foods | Products that must be refrigerated to retard spoilage and to help prevent growth and toxin production by pathogenic microorganisms. | Yes | M, C, R |
| PTK/ETL/SKKL (Finland) | 2003a | Helposti Pilaantuvien Pakattujen Kalojen ja Kavalmisteiden Säilyvyysmerkinnät ja Säilyvyyden Varmistaminen | Highly perishable packed fish and fish preparations' storage instructions and the determination of shelf life | Yes | M, R |
| PTK/ETL/SKKL (Finland) | 2003b | Helposti Pilaantuvien Pakattujen Lihavalmisteiden ja Valmisruokien Säilyvyysmerkinnät ja Säilyvyyden Varmistaminen | Highly perishable packed meat products' and ready to eat foods' storage instructions and the determination of shelf life | No | M, R |
| PTK/ETL/SKKL (Finland) | 2003c | Tuoreen Lihan ja Raakalihavalmisteiden Säilyvyysmerkinnät ja Säilyvyyden Varmistaminen | Fresh meat and raw meat preparations' storage instructions and the determination of shelf life | No | M, R |
| Sous Vide Advisory Committee (UK) | 1991 | Code of practice for sous vide catering systems | Catered sous vide products with a shelf life ≤ 8 days | Yes | C |
| Syndicat National des Fabricants des Plats Préparés (SYNAFAP - France) | 1995 | Aide à la maîtrise de l'hygiène alimentaire | Implementation of GHP and HACCP in the production of refrigerated ready-to-eat meals | Yes | M |
| SYNAFAP (France) | Draft, 2006 | | GHP and HACCP in the production of refrigerated ready-to-eat meals | Yes | M |
| TNO<br>The Netherlands | 1994 | Code for production, distribution and retail of chilled pasteurized meals with extended shelf life | Cook-chill products with extended shelf life (11 to 42 days)<br>Excluded: products with pH < 4.6 or $a_w$ < 0.96 and VP sliced meats | Yes | M, R |
| Transport en Logistiek Nederland | 1996 | Transport, distribution and retail of food products. | All food products | No | R |
| University of California (UC Davis) (USA) | 2001 | Optimal Controlled Atmospheres for Horticultural Perishables | Choice of atmospheres for various produce (prepared and whole) | Yes | M |
| UNIPI (Italy) | 1999 | Guidelines for the application of general principles of food hygiene and the HACCP system in the pasta production industry | Fresh and dry pasta production | Yes | M |
| US Chilled Foods Association (USA) | 1990 | Technical Handbook for the Chilled Foods Industry | HACCP descriptions and flow diagrams common across chilled food product types. | Yes | M |

## 3.2 Guidance at the European Level

### 3.2.1 EU Food Regulation

From 1 January 2006, new food hygiene legislation has applied throughout the EU. In July 2000, the European Commission published a package of five measures to update and consolidate the 17 existing (vertical) hygiene directives. The texts were adopted on 29 April 2004 and published in the Official Journal (OJ) of the European Union on 30 April 2004. The EU food hygiene regulations package comprises:

- Regulation 852/2004 on the hygiene of foodstuffs
- Regulation 853/2004 laying down specific hygiene rules for food of animal origin
- Regulation 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
- Directive 2004/41 repealing the previous EU legislation or, in some cases, amending still existing legislation
- Directive 2002/99 laying down animal health rules on products of animal origin for human consumption.

The regulations have been amended since by the EU implementing measures and in the case of 854/2004 by Regulation (EC) 882/2004, the Official Feed and Food Controls Regulation.

On 22 December 2005 the Commission published the remaining implementing and transitional measures that support the application of the EU hygiene legislation in the EU Official Journal. These regulations are:

- Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs
- Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under 853/2004 and for the organisation of official controls under 854/2004 and 882/2004, derogating from 852/2004 and amending 853/2004 and 854/2004
- Regulation (EC) No 2075/2005 of 5 December 2005 laying down specific rules on official controls for trichinella in meat
- Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional arrangements for the implementation of 853/2004, 854/2004 and 882/2004 and amending 853/2004 and 854/2004

These now join Regulation (EC) No 1688/2005 of 14 October 2005 implementing 853/2004 as regards special guarantees concerning salmonella for consignments to Finland and Sweden of certain meat and eggs.

The new hygiene regulations build on the general principles of food law established by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

The General Food Law is supplemented by targeted legislation on a raft of food safety issues, such as use of pesticides, food supplements, colourings, antibiotics and hormones in food production.

In summary, the new EU hygiene legislation:

- Sets out the duty of food business operators to produce food safely.
- Requires food business operators (except primary producers) to implement a permanent procedure, or procedures, based on HACCP principles.

- Is structured so that it can be applied flexibly and proportionately according to the size and nature of the business.
- Requires registration or approval for certain food establishments.
- Allows for the development of guides to good practice for hygiene and for the application of HACCP principles by food business operators.
- Allows a special provision to ensure flexibility for food produced in remote areas and for traditional production and methods.

However, beyond there being a general product safety requirement there is no specific EU legislation relating to VP or MAP chilled prepared foods.

In practice, controls are stipulated in national rules or guidance (e.g. French legislation, CCFRA Industry Code, Chilled Food Association guidelines) in certain Member States, or, on a broader basis, through industry guidance (e.g. European Chilled Food Federation), compliance with which is voluntary.

### 3.2.2 European Industry Guidance

The European Chilled Food Federation in 1996 issued the first edition of its Guidelines for the Hygienic Manufacture of Chilled Foods (ECFF, 1996). With respect to the control of *C. botulinum* this built on the outputs of an international working party of researchers/academics and industry experts convened by ECFF, which published a report particularly of the safety of chilled products where there is no competition from other microorganisms and/or where competitors are destroyed by a mild heat process. The report was published as a review in Food Control (Gould, 1999).

The ECFF Botulinum Working Party concluded that controls for long shelf life hermetically sealed packs should be either:

- 6D process (non-proteolytic *C. botulinum* spores): 90°C/10 min and <10°C, or
- <6D process (non-proteolytic *C. botulinum* spores) and <3°C, or
- Demonstrably effective hurdles versus non-proteolytic *C. botulinum* spores

The 1996 ECFF Guidelines included the following example “if a chilled product is to be packed in a reduced oxygen atmosphere and has a shelf life of >10 days, one or more of the following hurdles should also be used to control non-proteolytic (psychrotrophic) *C. botulinum*:

- Heat to a temperature/time combination equivalent to 90°C for 10 min (or equivalent); or
- Adjust $a_W$ to < 0.97; or
- Increase acidity to < pH 5.0; or
- Use combinations of $a_W$, pH, atmosphere, temperature etc that demonstrably will inhibit the growth of non-proteolytic (psychrotrophic) *C. botulinum* within the shelf life and storage conditions”

Work is currently ongoing on the second edition of the ECFF guidance, with strong pressure being brought by some members for an approach reflecting actual loadings of non-proteolytic *C. botulinum* spores on raw materials rather than a blanket 6-log reduction approach.

See section 3.3.3 for the approach being sought by SYNAFAP, the French delegation to ECFF.

### 3.3 Guidance in EU Member States

EU Member States can introduce specific hygiene provisions provided they are not less stringent than the EU hygiene requirements and do not result in barriers of trade. In many Member States, more specific microbiological and temperature controls are laid down.

The publication of EC Regulation 2073/2005 on Microbiological Criteria for Foodstuffs in January 2006 harmonised many microbiological criteria applicable to foodstuffs, in particular regarding Salmonella and *Listeria monocytogenes*, the latter in relation to ready to eat products.

There remain many national criteria in EU Member States which have not been harmonised. However, none of these relate to non-proteolytic *C. botulinum* since it is not valid to set a criterion (and therefore a sampling plan) in relation to organisms which rarely occur.

There is no single EU legislated temperature for multi-component products. Differences in national temperature rules constitute a significant barrier to trade since they can affect the basis on which shelf life is determined.

Some examples of variations in national temperature rules are given in Chapter 4 where comment is also made regarding the conclusions of the 1996 SCOOP project (EC Scientific Cooperation) on temperature control.

Further differences in temperature requirements are evident in the different national GMP codes discussed below.

In practice, controls are stipulated in national rules or guidance in certain Member States (e.g. French legislation, CCFRA Code, Chilled Food Association Guidelines), or, on a broader basis, through industry guidance (e.g. European Chilled Food Federation), compliance with which is voluntary.

3.3.1 The position in the UK

National legislation in the form of Statutory Instruments (SIs) in England, and equivalent legislation in Scotland, Wales and Northern Ireland, is required to enforce EU regulations. In relation to EU hygiene legislation these cover:

- offences, penalties and powers of entry
- revocation of existing implementing legislation
- enacting the national measures required or provided for in the EU regulations
- any consequential amendments (where the revocation of existing legislation requires changed references in other pieces of legislation)

The Food Hygiene (England) Regulations 2006 (SI 2006/14) came into force on 11 January 2006 and also applied the provisions of the EU Microbiological Criteria Regulation 2073/2005.

The Official Feed and Food Controls (England) Regulations 2006 (SI 2006/15) also applied from 11 January 2006. These regulations apply the EU Official Feed and Food Controls Regulation (OFFC) in England.

There are no legislated UK requirements specific to VP/MAP chilled foods. However, ACMSF reports (1992 and 1995), and various industry guidance documents exist.

The voluntary ‘10 day rule’ (CCFRA, 1996) is generally applied in the UK for foods stored at chill (chill temperature is specified as a maximum of 8°C in England, Wales and Northern Ireland. In Scotland the requirement is to keep chilled food in “a refrigerator, or refrigerating chamber, or a cool ventilated place” (Food Law 2006)).

3.3.1.1 ACMSF Guidance

The 1992 ACMSF recommendations on the safe production of vacuum and MAP chilled foods with respect to non-proteolytic *C. botulinum* was published formally (ACMSF, 1992). It

recommended a maximum shelf life of 10 days at 10°C maximum unless appropriate controls (formulation and/or processing) were in place. The recommendations were taken up widely by professional food manufacturers and retailers in the UK and were taken forward into various other guidance including internationally.

Later, in response to questions raised by the team drawing up an industry code of practice (at CCFRA), the ACMSF recommendations were revised (ACMSF, 1995). These revisions were made on the basis of a review of 31 references from the literature on the production of toxin by non-proteolytic *C. botulinum* within 10 days at ≤10°C. Most of these were challenge tests carried out in food materials, not foods as purchased/eaten in the UK. A maximum shelf life of 5 days at 10°C maximum or 10 days at 5°C maximum was recommended unless appropriate controls (formulation and/or processing) were in place. The ACMSF 1995 approach was not taken up by industry or included in other guidance.

3.3.1.2 Code of Practice for the Manufacture of Vacuum and MAP Chilled Foods (CCFRA, 1996)

This was MAFF-funded work through a working group of manufacturers, retailers and MAFF and DH representatives. It aimed to crystallise various guidance into practical advice. One of the recommendations included was a maximum shelf life of 10 days at 8°C maximum unless appropriate controls (formulation and/or processing) were in place.

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| Based on previous evidence that growth and toxin production did not occur at <3°C, the guidance recognised that any period of storage at <3°C (e.g. during the manufacture stages before the product is distributed for retail display or other use) does not contribute to the designated shelf-life. |

3.3.1.3 Chilled Food Association guidance

The Chilled Food Association in its 2006 and 1997 guidance for prepared pre-packed foods sold at retail maintains the 10 day rule, based on storage at 8°C maximum (CFA, 1997; CFA, 2006). Beyond this shelf life demonstrably effective controls must be in place with respect to non-proteolytic *C. botulinum*. This is applicable to all chilled products, irrespective of whether or not they are VP, MAP or packed in air.

3.3.1.4 Mail Order Foods

The Mail Order Fine Foods Association (MOFFA) in February 2006 issued a draft Guide to GHP for Mail Order Foods for comment (MOFFA, 2006). The document is a Guide under EU hygiene legislation (852/2004) and makes the following points in relation to VP/MAP products:

- Technically it may be necessary to have a salt level of 3.5% (aqueous) throughout a VP food to control *C. botulinum*.
- For vacuum and MAP foods where chill temperatures (warmer than 3°C but cooler than 8°C) alone are used to control *C. botulinum*, a maximum total shelf life of 10 days should be assigned.
- For specific high risk products, e.g. VP foods, special precautions may be required to ensure a satisfactory product. Advice should be sought from your supplier, your local Environmental Health Service, Enforcement Officer or other expert. For vacuum or MAP foods the Industry Code (CCFRA, 1996) can be consulted.
- Whatever aspect of the product you are relying on, to ensure the product is safe to eat when it arrives with the consumer (e.g. temperature, and/or salt content and/or acidity and/or water activity), check it is in place, at least twice a year.

3.3.1.5 Sous Vide Advisory Committee

SVAC (1991) issued a code of practice for sous vide catering systems, applicable to products with a shelf life of no more than 8 days. Heat processes are specified (26 min at 80°C or 11 min at 85°C or 4.5 min at 90°C or 2 min at 95°C) in relation to non-proteolytic *C. botulinum* type E, followed by storage at 0-3°C.

3.3.1.6 FSA Consumer Guidance on Homemade Flavoured Oils

This guidance, which is not easy to locate within the FSA website (being found when searching for 'flavoured oil' but not 'herbs in oil') acknowledges that "even though recipes for flavoured oils can be found in cookery books, magazines and websites, these might not have considered the risk of botulism". The guidance states that "the safest option is to make a small quantity and use it on the day you have made it. If you have some left over, put it in the fridge straight away and use it within a week."

3.3.2 The position in Finland

The Finnish Food Authority (EVI) in 1991 recommended the storage of VP fish preparations at +3°C maximum and for no more than 3 weeks. This recommendation was revised in 2000 when EVI recommended the storage of VP fish preparations (cold smoked and gravad) at as low chill temperatures as possible, and at the most at +3°C for 10-14 days (EVI, 2000). This was based on mathematical modelling of *Listeria monocytogenes* growth potential. However, if documentary evidence is available that the temperature is no more than +3°C throughout the whole of the chill chain then the shelf life can be up to 3 weeks.

3.3.3 The position in France

The Arrêté of 26 June 1974 and related memoranda of 1988 and 1992 apply to the production of chilled prepared meals and their allowed shelf life. However their scope now only covers meals made from products from animal origin other than fish and meat products (i.e. milk, eggs).

The 1974 "Arrêté" limited shelf life of all pre-cooked chilled products to 6 days. The "Note de Service du 31 Mai 1988" (modified in 1992) established changes in manufacturing protocols to extend shelf life up to 42 days, according to the type of products (sous vide or not), the pasteurisation value (Pv) and the attained core temperature. The 1988 legislation enabled ready meals reaching a centre temperature of 65°C and a process equivalent of 70°C for 100 min (comparable to 90°C for 1 min, or 0.6 log inactivation of spores of non-proteolytic *C. botulinum*) to have a shelf life of up to 21 days, although the precise shelf life was to be determined by the manufacturer. Products reaching a centre temperature of 70°C and receiving equivalent lethality of 1,000 min (i.e. equivalent to 90°C for 10 min) could have a shelf life of 42 days.

Pasteurisation values are based on the heat resistance of the opportunistic pathogen *Enterococcus* (*Streptococcus) faecalis* with $D_{70}$ = 2.95 min and z = 10°C. The shelf life that can be safely achieved by minimally processed foods is therefore linked to the pasteurisation process given.

For ready-to-eat meals made from meat and fish products, the shelf life is set by the manufacturer using a protocol developed by industry with AFNOR (see Chapter 4).

French industry guidance is currently being finalised by SYNAFAP and proposed for inclusion in ECFF guidance, it provides a series of approaches:

The manufacturer shall implement measures such that the product remains safe until its usage (depackaging or pack opening), notably:

- The type of packaging used (taking account of the risk of cross contamination, MAP, etc);
- The labelling of products and the description of usage, storage, etc;

- Product shelf life: indication of a use by date.

Factors influencing shelf life are, notably:

- the type of microorganisms and the level of contamination at the end of production, which are related to:
  - the control of initial contamination of ingredients and growth during production (i.e. implementing GMP/GHP);
  - the application of a procedure aiming to reduce potential product contamination, e.g. thermal treatment, acidification;
- the potential for growth of microorganisms during distribution, which will depend on:
  - the physicochemical composition of the product;
  - the use of inhibitory factors or minimising the multiplication of microorganisms ('hurdles'), e.g. additives, MAP;
  - the storage temperature;
- the possibility of microbial destruction before product use (e.g. requirement to cook before use).

These elements are taken into account in the hazard analysis. For example, if a product is cooked in the final packaging, with a core temperature of 70°C for 10 minutes, and GMP/GHP are applied, the dangers in relation to vegetative pathogens are controlled, whatever the shelf life. Factors to take into account will therefore be sporeforming pathogens (and possibly sporeforming spoilage microorganisms). The shelf life will therefore take account of the initial potential level of contamination by sporeformers, the growth potential from spores and the possibility of toxigenesis. In relation to *C. botulinum*, two scientific studies are important:

- A study of the contamination of ingredients/raw materials used in France indicated that there was <10 viable *C. botulinum* organisms/kg. A number of samples were found to be contaminated with *C. botulinum* strains forming type A and/or B toxin, but not with *C. botulinum* strains forming type E toxin (Carlin *et al*., 2004). One limitation of this study, however, was that it did include positive controls to confirm the limit of the detection (i.e. it was not confirmed that low numbers of *C. botulinum* could be detected in all foods tested).
- A study was carried out with cod inoculated with two strains of non-proteolytic *C. botulinum* (at $10^4$-$10^6$ spores per 110g pack, a concentration approximately 20-100 times higher than natural contamination levels reported in the literature). Various heat treatments were applied in-pack, and then different storage regimes employed. The study was carried out at l'Institut Pasteur de Lille (1996) and is also discussed in Chapter 6. Briefly, this study showed that:
  - A core temperature of 90°C for 10 minutes or equivalent (e.g. 83°C for 100 minutes), destroyed the inoculated spores, while a core temperature of 75°C for 85 minutes, reduced the spore population by a factor of 10 (for the type E strain) or by 5 (for the type B strain).
  - Combinations of heat treatment and storage regime were identified that prevented toxin formation within 30-35 days (Table 3.2). These results are consistent with those obtained with sterile minced beef by Fernandez and Peck (1997, 1999). These and other studies with sterile minced beef provide details of combination of heat treatments less than 90°C for 10 min, that can be combined with pH, NaCl concentration, incubation temperature and shelf-life to prevent toxin formation from $10^6$ spores of non-proteolytic *C. botulinum* (Peck and Stringer, 2005). For example:
    - 90°C/ 10 min combined with storage at 8°C prevented toxin formation in 50 days
    - 80°C/ 98 min combined with storage at 8°C prevented toxin formation in 40 days
    - 75°C/284 min combined with storage at 8°C prevented toxin formation in 30 days
    - 80°C/ 11 min combined with storage at 8°C prevented toxin formation in 20 days

Table 3.2 Effect of specified heat treatments and storage temperature regimes on time to toxin formation by non-proteolytic *C. botulinum* in cod (data from l'Institut Pasteur de Lille, 1996)

| Storage temperature | Time (days) to toxin formation for specified heat treatment delivered | | | |
|---|---|---|---|---|
| | 75°C 85-90 min | 80°C 93 min | 83°C 100 min | 90°C 10 min |
| 4°C 30d | 30/NP* | nt** | nt | nt |
| 4°C 10d, then 8°C 25 d | 30/34 | 35/NP | 35/NP | 35/NP |
| 4°C 10d, then 22°C 4h, then 8°C 25 d | 21/30 | 30/35 | 35/NP | 35/NP |
| 8°C 20d | 20/NP | 30/35 | 35/NP | 35/NP |

Note: $10^5$-$10^6$ spores of non-proteolytic *C. botulinum* type B added per 110g pack prior to heat treatment

* First number = last day negative for toxin, second number = first day positive for toxin

NP = Not positive, nt = not tested

The SYNAFAP approach therefore aims to take account of natural levels of contamination and to tailor the heat process accordingly, not necessarily using a 6-log reduction process (i.e. equivalent to 90°C for 10 minutes). Account is also taken of the temperatures anticipated in the controlled chill chain. Sous vide product shelf lives up to 30 days are mooted by the guidance and have existed on the French market for two decades.

3.3.4 The position in Italy

UNIPI (1999) published guidelines in relation to pasta production, applicable to fresh and dry pasta. Process parameters are for the manufacturer to determine on the basis of HACCP, but lethal rate tables are included in relation to *Listeria monocytogenes* and non-proteolytic *C. botulinum*. Storage temperature and shelf life are not specified, this again being for the manufacturer to determine on the basis of HACCP.

3.3.5 The position in the Netherlands

TNO (1994) issued a code developed with industry in relation to cook-chill products (excluding VP sliced meats) with shelf life 11-42 days. The code requires a total 6D heat process of 90°C/10 mins (equivalent) including if the product is duo pasteurised (cooked, filled, sealed, cooked). Final product storage temperatures of 0-3°C are referred to for post-production storage on-site and a maximum of 6 weeks post-production is allowed, including a maximum of 3 weeks to consumption in the commercial and domestic chill chain (0-5°C) and 1 week maximum consumer storage (0-5°C).

3.4 Guidance outside the EU

3.4.1 The position in Australia

AQIS (1992) set a 10 day limit for MAP/VP foods held at $\leq$ 5°C (unless frozen), or >5 days if storage is at $\leq$ 3°C. For storage at >5°C to 10°C a 6D process for non-proteolytic *C. botulinum* is required: Extended shelf life is possible by storage at $\leq$ 3°C. If the product is at >10°C, it should be discarded. The Guidance is no longer in print however.

AFIC/ASI/RWTAA (1999) reiterates legal temperature requirements (0-4°C but never more than 5°C), including for MAP products.

AIFST/AFIC/ACCC (2000) guidelines are applicable to a variety of chilled food production systems including cook-chill, sous vide and MAP. The emphasis is on low temperature (0-3°C) storage and the selection of heat process "according to the recipe". Temperatures of 70°C/2 min or 90°C/11 min equivalent are referred to. The guidance does not give specific shelf life limitations but states 'long shelf life with correct practice can be achieved. It has been found that some products have a shelf life of up to 45 days.' The guidelines appear to be designed to apply to the catering sector rather than retail and are not believed to be complied with in the retail sector.

### 3.4.2 The position in Canada

#### 3.4.2.1 MAP Products

The Canadian Code of Recommended Manufacturing Practice for Pasteurized/Modified Atmosphere Packed/Refrigerated Food (Agriculture Canada, 1990) states that:

- Care should be taken to prevent the product temperature from rising above 10°C during cold filling
- Product should be maintained at temperatures of less than 4°C (or above 65°C).
- Refrigerated products to be used as ingredients or prepared foods should be held at temperatures below 4°C at all times
- The processed final product must be kept refrigerated (-1 to +4°C) at all times
- Whenever chilled food is received with the product temperature of +7°C or higher the manufacturer shall be notified immediately and 'special handling instructions requested'.
- Chilled food storage facilities/retail display cases must be capable of maintaining product temperature between -1 and +4°C.

The emphasis is therefore on low temperature storage.

#### 3.4.2.2 Chilled Foods with Extended Shelf life

Health Canada's 1992 Guidelines for the Production, Distribution, Retailing and Use of Refrigerated Pre-packaged Foods with Extended Shelf life note that 'under Division 27 of the Food and Drug Regulations, refrigeration is defined as 'exposure to a temperature of 4°C or less'. However, Provincial regulatory provisions for refrigeration range from no stipulated transportation temperature requirements (5 provinces) to <5°C (2 provinces), and regarding storage from voluntary 4°C (1 province) to up to 5°C in another.

With respect to shelf life, if this exceeds 10 days, 'the processor should on request, make available appropriate data to the agency bearing responsibility for food safety, showing that the food in question can safely be marketed for the intended shelf life. Such information should include results of microbiological challenge tests involving food poisoning or appropriate non-pathogenic organisms placed in the food and incubated under conditions of temperature abuse. Shelf life tests should also be performed to determine when spoilage occurs relative to the growth of potential pathogens.'

It is notable that the 10 day limit 'is based on considerations related to the time required for *Listeria monocytogenes* to reach levels of concern in a food readily supporting its growth under conditions of appropriate refrigeration, assuming an initial level of 1 cell/g'. i.e. *C. botulinum* is not highlighted as an organism of particular concern in relation to shelf life, but rather with respect to packaging technique.

The document states that Federal/Government agencies' microbiological surveillance programs 'should be instituted to determine the presence of foodborne pathogens in those products for which the shelf life has not been suitably validated by the processor. Priority for monitoring should be given to new extended shelf life foods (e.g. processed by sous vide technology) rather than products such as cured meats which generally have a long established record of safety.'

3.4.2.3 Handling Practices for Chilled Food

The Food Institute of Canada in its undated Canadian Code of Recommended Handling Practices for Chilled Food reiterates -1°C to +4°C as the storage temperature for chilled foods but also states that:

- 'Processed products intended for chilled distribution and sale should be designed with additional hurdles to inhibit food spoilage and poisoning, e.g. pH less than 4.5, reduced water activity, vacuum or modified atmosphere packaging.'

VP and MAP are therefore considered as hurdles to microbiological deterioration.

- Whenever chilled food is received with the products temperature of +7°C or warmer, the warehouse/receiver shall immediately notify the manufacturer and request instruction for special handling. These instructions may consist of any available method for effectively lowering the temperatures such as low temperature rooms with air circulation and proper use of dunnage or separators in stacking.'

The emphasis is therefore on low temperature storage.

3.4.2.4 Best Before/Durable Life

In its 12/1/91 Decision on the use of best before dates/durable life, the Canadian Food Inspection Agency provides the following information indicating no particular shelf life limitation for MAP meat:

*"Question:* When meat is pre-packed in individual portions at a manufacturing plant and shipped in retail stores in outer containers that have been flushed with a modified atmosphere (i.e. $CO_2$) designed to extend shelf-life, is the meat manufacturing plant required to label the individual portions of meat with a 'best before' date (durable life date)?

*Answer:* No, although section B.01.007 of the Food and Drug Regulations requires date marking on food products that have a durable life of less than 90 days, administratively, these products are not required to be so labelled by the manufacturer. The durable life of these products is largely dependent upon when the outer shipping container is opened and the pre-packaged product is exposed to air. Consequently, a best before date established by the manufacturer could be potentially misleading to the consumer. These products are date labelled by the retailer."

3.4.2.5 Garlic in Oil

Following an outbreak in Vancouver in 1985 in relation to a temperature abused garlic in oil product, Health Canada issued guidance targeting domestic/non-industrial production on the safe preparation of garlic in oil. This states "when you make it at home and use it right away it is a safe product. It's also safe if you keep it refrigerated on a continuous basis, and use it within a week. Never store garlic in oil at room temperature. Throw away any that has been in the refrigerator for more than a week."

3.4.3 The position in the USA

The 2005 US FDA CFSAN Food Code (CFSAN, 2005) stipulates the procedures for reduced oxygen packaged (ROP) products, and includes *Listeria monocytogenes* as a pathogen of concern that needs to be controlled in addition to *C. botulinum*.

The Code requires that bagged products must be cooled to 34°F (1°C) within 48 hours and held for no more than 30 days, unless a variance is obtained from the authorities. This appears to be based on *Listeria monocytogenes* growth potential rather than *C. botulinum*.

If foods are packaged using cook-chill (defined as being cooked then hot-filled under reduced oxygen) or sous vide, other food safety measures must be taken including establishment of a HACCP plan, records retention for 6 months, and no sale of the ROP bagged product to another business or consumer that may not have adequate temperature control. However, variances are again available on application to the authorities.

The 2005 Food Code also allows reduced oxygen packaging for hard cheeses, semi-soft cheeses, and pasteurised processed cheeses, but limits shelf life to 30 days. ROP of unfrozen fish is not permitted.

3.4.3.1 Reduced Oxygen Packaging

The 2005 Food Code requires that except for a food establishment that obtains a variance or is otherwise exempt, an establishment that packages potentially hazardous food using a reduced oxygen packaging method shall have a HACCP plan and addressing the need to:

- ensure that there are at least two barriers in place to control the growth and toxin formation of *C. botulinum* and the growth of *Listeria monocytogenes*. These are described as being chilled storage (at 5°C or less) and at least one of the following criteria:
    - an $a_W$ of 0.91 or less, or
    - a pH of 4.6 or less, or
    - a cured or irradiated meat or poultry product produced at a food processing plant regulated by the USDA, and is received in an intact package, or
    - a food with a high level of competing organisms such as raw meat or raw poultry;
- instructions are required on-pack to maintain the food at 5°C or below, and discard the food if within 14 calendar days of its packaging it is not served for on-premises consumption, or consumed if served or sold for off-premises consumption;
- the refrigerated shelf life is limited to no more than 14 calendar days from packaging to consumption, except the time the product is maintained frozen, or the original manufacturer's "sell by" or "use by" date, whichever occurs first;

However, a food establishment can obtain a variance from the regulatory authority before packaging food using a reduced oxygen packaging method where a barrier to *C. botulinum* does not exist in addition to refrigeration.

3.4.3.2 Cheese

The 2005 Food Code allows a food establishment may package cheese using a reduced oxygen packaging method without obtaining a variance if

- the cheese is commercially manufactured within a HACCP plan, and
- has no other ingredients added, and
- meets the Standards of Identity for hard cheeses, pasteurized processed cheese or semisoft cheeses, and
- it labels the package with a "use by" date that does not exceed 30 days or the original manufacturer's "sell by" or "use by" date, whichever occurs first; and
- discards the reduced oxygen packaged cheese if it is not sold for off-premises consumption or consumed within 30 calendar days of its packaging.

3.4.3.3 Fish

The 2005 Food Code states that except for fish that is frozen before, during, and after packaging, a food establishment may not package fish using a reduced oxygen packaging method.

3.4.3.4 Cook-Chill (US definition) or Sous Vide

The 2005 Food Code states that a food establishment may package food using a cook-chill or sous vide process without obtaining a variance if it implements a HACCP plan and the food is:

- Prepared and consumed on the premises, or prepared and consumed off the premises but within the same business entity with no distribution or sale of the bagged product to another business entity or the consumer,
- Cooked to heat all parts of the food to a specified temperature/time
- Protected from contamination after cooking
- Placed in a package or bag with an oxygen barrier before cooking, or placed in a package or bag immediately after cooking and before reaching a temperature below 57°C
- Cooled to 5°C in the package or bag and then cooled to 1°C or less within 48 hours of reaching 5°C, and:
    - Held at 1°C and consumed or discarded within 30 days after the date of preparation, or
    - If removed from a storage unit that maintains food at 1°C, held at 5°C or less for no more than 72 hours before consumption.

The emphasis is on low storage temperature and the control of *Listeria monocytogenes*.

3.4.3.5 Cooking

Heat processes stipulated by FDA are significantly milder than those used by UK industry. The 2005 Food Code requires, with exceptions, raw animal foods such as eggs, fish, meat, poultry, and foods containing these raw animal ingredients, to be cooked throughout to a temperature and one of the time/temperature combinations for ratites and injected meats if they are comminuted (Table 3.3).

Table 3.3 Heat treatments included in the 2005 Food Code for comminuted ratite and injected meats

| **Minimum** | |
|---|---|
| **Temperature (°C)** | **Time** |
| 63 | 3 minutes |
| 66 | 1 minute |
| 68 | 15 seconds |
| 70 | <1 second (instantaneous) |

A heat treatment of 74°C or above for 15 seconds is required for the cooking of poultry, baluts, wild game animals, stuffed fish, stuffed meat, stuffed pasta, stuffed poultry, stuffed ratites, or stuffing containing fish, meat, poultry, or ratites.

In the case of whole meat roasts including beef, corned beef, lamb, pork, and cured pork roasts such as ham, it is necessary to heat all parts of the food to one of the time-temperature combinations shown in Table 3.4

Table 3.4 Heat treatments included in the 2005 Food Code for whole meat roasts

| Temperature (°C) | Time in minutes[1] | Temperature (°C) | Time in seconds[1] |
|---|---|---|---|
| 54.4 | 112 | 63.9 | 134 |
| 55.0 | 89 | 65.0 | 85 |
| 56.1 | 56 | 66.1 | 54 |
| 57.2 | 36 | 67.2 | 34 |
| 57.8 | 28 | 68.3 | 22 |
| 58.9 | 18 | 69.4 | 14 |
| 60.0 | 12 | 70.0 | 0[2] |
| 61.1 | 8 | | |

[1] holding time may include post-oven heat rise
[2] to reach 70.0°C

3.4.3.6 Cooling

The 2005 Food Code requires cooked potentially hazardous food to be cooled:

- Within 2 hours from 57°C to 21°C; and
- Within a total of 6 hours from 57°C to 5°C or less, or to 7°C or less.

3.4.3.7 Date Marking

Except for infant formula and some baby food, product dating is not required by Federal regulations. There is no uniform or universally accepted system used for food dating in the United States. Although dating of some foods is required by more than 20 states, there are areas of the country where much of the food supply has some type of open date and other areas where almost no food is dated (USDA, 2001).

Based on the results of FDA's 2001 *Listeria* risk assessment and the recommendations from the 2004 Conference for Food Protection, FDA re-evaluated date marking provisions and focused its recommendations for date marking in the 2005 Food Code on high-risk foods with respect to *Listeria* contamination.

It is notable that the 2005 Food Code exempts 'deli salads' (e.g. ham, chicken, egg, seafood, pasta, potato, and macaroni) prepared and packaged in a food processing plant since 'Scientific data support the exemption of these products because deli salads prepared and packaged by a food processing plant contain sufficient acidity and preservatives to prevent the growth of *Listeria monocytogenes*.'

Whether this statement truly applies to all deli salads manufactured commercially in the USA is not known however.

3.4.3.8 Herbs/Vegetables in Oil

Guidance was developed by the FDA in 1993 targeting domestic and commercial industrial production. It:

- requires such mixes, especially those prepared fresh at home, to be kept refrigerated and states that people should dispose immediately of any products suspected to be spoiled or to have been stored unrefrigerated
- requires manufacturers to stop making garlic-in-oil mixes that rely solely upon refrigeration for safety. Commercial mixes are required to contain specific levels of microbial inhibitors, usually acidifying agents such a phosphoric or citric acid.

- Recommends that consumers do not prepare any homemade spice-in-oil, -margarine or –butter recipes for 'extended storage' because the protective additives used in commercial mixes are not generally available for homemade products

3.4.3.9 Fresh-Cut Produce

IFPA (2001) in its food safety guidelines for the fresh-cut produce industry states that:

- *"C. botulinum* associated with fresh produce will not grow or produce toxin at temperatures below about 10°C, in acid conditions (pH<4.6) or in the presence of a normal concentration of oxygen in the atmosphere". [It is noted that while the comment on oxygen may apply to some produce (although removal of oxygen through product respiration might be an issue), the presence of oxygen is unlikely to restrict toxin formation by non-proteolytic *C. botulinum* in many chilled foods].
- "Growth of spoilage microorganisms on fresh produce normally causes organoleptic deterioration before *C. botulinum* can produce toxin, and rapid growth of [non-pathogenic and facultative] microorganisms should contribute to spoilage before toxin production by proteolytic *C. botulinum* if temperature abuse (>10°C) occurs."

The guidelines appear to focus on the hazard presented by proteolytic *C. botulinum*.

Reference is made to the maximum recommended product temperature being 4.4°C (40°F).

The University of California (2001) issued a compendium of controlled (and modified) atmospheres for horticultural perishables, in which gas mixes and storage temperatures are recommended. For example, for cut or shredded lettuce 0-5°C is given as the recommended temperature and 0°C as optimum. No shelf lives are specified since 'in general, overt gross spoilage of fresh-cut produce occurs well before [*C. botulinum*] toxin is produced on shredded cabbage, shredded lettuce, broccoli florets, sliced carrots and rutabaga. Not only does the endemic microflora on fresh-cut produce play an important role in signalling end of shelf life but it is believed to suppress toxin production by *C. botulinum* (Larson and Johnson, 1999). However, some products such as butternut squash and onions have been demonstrated under temperature abuse conditions to have the potential of being acceptable after detection of botulinal toxin (Austin *et al.*, 1998).'

IFPA (2003) set out packaging approaches for fresh-cut produce, including MAP gas mixes and recommended temperatures (0-5°C). However, no shelf life limitation is given, but reference is made to produce spoiling prior to growth of *C. botulinum.*

Emphasis is on low temperature storage rather than shelf life limitation.

3.4.3.10 VP Sub-Primal Beef Cuts

Guidance regarding the vacuum packing of sub-primal beef cuts that are produced and sold as whole muscle cuts has been developed by the American Meat Institute, National Meat Association and Southwest Meat Association (AMI/NMA/SMA, 2003). However, it makes no mention of specific *C. botulinum* controls, noting that the temperature "at which foodborne pathogens do not grow is 7°C for *Salmonellae* and 7-8°C for pathogenic *E. coli"* and stating that "temperature control throughout the disassembly, storage distribution and further processing at all stages is extremely important. Under no circumstances should boxed sub-primal cuts be left in non-refrigerated cutting rooms, kitchens or unrefrigerated shipping or receiving docks for more than one hour".

3.4.3.11 Refrigerated Foods

NFPA (1989) states that "the establishment of an adequate thermal process to destroy vegetative cell pathogens should consider the number of organisms that are likely to be present in the unprocessed products and the greatest potential heat resistance of the target organism. In most cases, a process designed to destroy 2 log cycles above the maximum level likely to be found will be sufficient. When a product will tolerate a more severe heat process, the product should be processed to destroy the spores of non-proteolytic (psychrotrophic) *C. botulinum*. When a product will not tolerate a process severe enough to destroy these bacterial spores, the risk presented by non-proteolytic (psychrotrophic) and other Groups of *C. botulinum* must be considered and controlled to prevent outgrowth and toxin production".

Specific thermal processes are not given, and 4.4°C is referred to as the recommended storage temperature. No shelf life guidance is given.

## 3.5 International Trade - Codex Alimentarius Commission

### 3.5.1 Refrigerated Packaged Foods with Extended Shelf Life

CODEX standards and Codes relate to internationally-traded goods. The Codex Committee on Food Hygiene in 1999 produced a 'Code of Hygienic Practice for Refrigerated Packaged Foods with Extended Shelf Life' (CAC/RCP 46). Extended shelf life is defined in this case as being more than 5 days since the Codex mass catering code is applicable to products with shorter shelf lives. The code gives recommendations for processing, packaging, storage and distribution of refrigerated packaged foods, based on HACCP principles. This code must be used in addition to the Codex General Principles of Food Hygiene (Alinorm 97/13A).

The Code covers low-acid foodstuffs (whatever their packaging format) that are at risk from microbiological pathogens because of their extended shelf life. The Code excludes those food products for which there is already a specific Codex Alimentarius Code of Practice (see Codex website for examples (http://search.fao.org/opensearch, accessed 16/03/06)). The Code does not stipulate particular thermal treatments, shelf lives or storage regimes, but states that:

> "It is the responsibility of the manufacturer to ensure that the product is safe throughout its shelf-life, taking into consideration the potential for temperature abuse. This may warrant the use of hurdles to microbial growth in addition to refrigeration. When using the hurdle concept for product development, even where refrigeration is the sole hurdle, the effect of the hurdle(s) on product safety and shelf life should be considered thoroughly. Predictive microbiological models may be used to estimate both the effectiveness of preservation conditions and the effects of modifying product composition and varying handling/storage conditions on safety. Unless scientific evidence previously exists, challenge studies should be conducted to confirm the effectiveness of the chosen hurdle(s) against the pathogen(s) of concern."

Product shelf life is stated to depend on a number of factors, such as:

- product formulation (e.g. decreased pH, decreased $a_w$, other hurdles)
- scheduled heat or other preservation treatments
- cooling methods applied to product
- type of packaging (e.g. hermetically sealed or not, MAP)
- storage temperature
- other hurdles

3.5.2 Fish and Fishery Products

A Code of Practice for Fish and Fishery Products is currently being developed by CODEX, the latest publicly available draft of which is included in the report of the 2005 meeting of the CODEX Committee for Fish and Fishery Products (ALINORM 05/28/18 Appendix IX).

- The draft states in relation to VP and MAP products that: "The extent to which the shelf-life of the product can be extended by vacuum or MAP will depend on the species, fat content, initial bacterial load, gas mixture, type of packaging material and, especially important, the temperature of storage. Refer to Appendix 1 for process control issues in MAP".

- MAP should be strictly controlled by:
  - monitoring the gas to product ratio;
  - types and ratio of gas mixtures used;
  - type of film used;
  - type and integrity of the seal;
  - temperature control of product during storage;
- occurrence of adequate vacuum and package;
- fish flesh should be clear of the seam area;
- packaging material should be inspected prior to use to ensure that it is not damaged or contaminated;
- packaging integrity of the finished product should be inspected at regular intervals by an appropriately trained personnel to verify the effectiveness of the seal and the proper operation of the packaging machine;
- following sealing, MAP or vacuumed products should be transferred carefully and without undue delay to chilled storage;
- Ensure that adequate vacuum is attained, and the package seals are intact.

As mentioned above, Appendix 1 of this document relates to MAP, and is entitled "Good process controls are essential when packing fillets and similar products in a modified atmosphere" and follows below.

- Modified atmosphere packing (MAP), in which the composition of the atmosphere surrounding the fillet is different from the normal composition of air, can be an effective technique for delaying microbial spoilage and oxidative rancidity in fish.

- For white fish gas mixtures containing 35-45% $CO_2$, 25-35% $O_2$ and 25-35% $N_2$ are recommended. Gas mixtures containing up to 60% $CO_2$ in combination solely with $N_2$ are recommended for oily fish. The inclusion of $CO_2$ is necessary for inhibiting common aerobic spoilage bacteria such as *Pseudomonas* species and *Acinetobacter/Moraxella* species. However, for retail packs of fillets or similar products, too high a proportion of $CO_2$ in the gas mixture can induce pack collapse, excessive drip and may cause bleaching.

- Other gases, $N_2$ and $O_2$, are included as diluents to prevent these effects. $O_2$ is preferentially excluded from oily fish in MA packs so as to inhibit oxidative rancidity. A gas/product ratio of 3:1 is commonly recommended. Any reductions in this ratio can result in an impaired shelf-life extension.

- The extent to which the shelf-life of the product can be extended by MAP will depend on the species, fat content, initial bacterial load, gas mixture, type of packaging material and, especially important, the temperature of storage. Determination of the shelf life of a particular product should be by a suitably qualified person such as a food technologist or microbiologist. Since fish can be contaminated with non-proteolytic *C. botulinum* type E great care has to be exercised when determining the shelf life. Although it is generally accepted that non-proteolytic *C. botulinum* does not grow at temperatures below +3°C, other factors, e.g. salt content or pH etc., can also have an inhibitory effect. Thus when determining the

shelf life of MAP fresh fish it is advisable to do challenge tests on the product which accurately reflect the product conditions and storage and distribution environment. It is very important to note that the inclusion of $O_2$ does not preclude the growth of non-proteolytic *C. botulinum* type E and temperature control throughout the shelf-life of the product is very important. In many circumstances it is considered undesirable to use ice to cool these packs and therefore mechanical refrigeration methods are preferred.

- Seal integrity of MA packs is a critical control point since it determines whether a MA pack is susceptible to external microbial contamination and air dilution of the gas mixture. Essential checks on heat sealing should include proper alignment of the sealing heads or jaws, dwell time, temperature, pressure and machine speed.

- Great care should be taken to ensure that the seal area is not contaminated with product, product drip or moisture since seal integrity may be reduced. In addition, the quality of the film used is important, particularly with regard to gas permeability, and only film with a clearly defined specification from reputable manufacturers should be used.

- Maintenance of the correct gas mixture injected into MA packs is essential to ensure product quality, appearance and shelf life extension. For these reasons routine gas analysis of MA packs should be included as part of the process control. Analysis of the gases within MA packs can indicate faults with seal integrity, MA materials, MAP machinery or gas mixing prior to flushing. The use of continuous gas analysers is recommended. Immediate gas analysis following packing is necessary as $CO_2$ absorption takes place rapidly.

3.5.3 Smoked Fish

A Draft Standard for Smoked Fish is being developed within the CODEX Fish and Fishery Products Committee, although it is at an early stage at the time of writing (Step 3).

Para 5.6 of the current draft (ALINORM 05/28/18, Appendix V) states in relation to *C. botulinum* that: “Toxins of *C. botulinum* are not allowed in smoked fish products. The formation of *C. botulinum* toxin can be controlled through an application of science-based options involving packaging type, storage temperature, and the use of salt in the water phase. The table shown in Annex 1 addresses these control options”, and is reproduced as Table 3.5. Annex 1 on ”Control and prevention of *C. botulinum* toxin formation” states that:

- Countries where the products are to be consumed can be expected to make their science-based risk management choices within this framework, i.e. select some option and exclude others, based on conditions within the country (e.g. nature and enforcement of refrigeration and shelf life controls, transportation times and conditions, variability in amount of salt in the water phase that could occur despite best efforts to achieve a required percentage), and the level of protection that the country chooses for itself for this particular risk.

Table 3.5 Control and prevention of *C. botulinum* toxin formation in smoked fish (Draft CODEX)

| Storage temperature | Packaging | Water phase salt * | Comments |
|---|---|---|---|
| 0°C to 3°C | Any | No minimum water phase salt is needed. | Temperature monitoring required on each package |
| >3°C to 5°C | Aerobically Packaged | No minimum water phase salt is needed. Nonetheless, where there is a reasonable possibility of severe time/temperature abuse, the country where the product is being consumed might choose a water phase salt barrier of at least 3.0% to 3.5% as a precautionary measure. | Storage temperature is for the control of pathogens generally and for quality. In air-packaged products, aerobic spoilage organisms provide sensory signs of spoilage before the formation of toxin by *C. botulinum.* However, even in air packaging it is possible for anaerobic micro-environments to exist and toxin may form if the product is subject to severe time/temperature abuse. For that reason, the country where the product is consumed may still require water phase salt as a barrier to growth of non-proteolytic *C. botulinum* if there are concerns about the ability of transporters, retailers or consumers to maintain time/temperature control. |
| Frozen ≤ -18°C | Reduced Oxygen (inc. VP and MAP**) | No minimum water phase salt is needed for safety. | *C. botulinum* toxin cannot form when product is frozen. Because toxin production can occur after thawing, labelling information about the need to keep frozen, to thaw under refrigeration, and to use the product immediately after thawing is important. |
| >3°C to 5°C | Reduced Oxygen (inc. VP and MAP) | Water phase salt at minimum level of between 3.0- 3.5% may be selected by the country where the product is to be consumed. | Water phase salt at a minimum level of between 3.0-3.5% (water phase salt) in combination with chilling will significantly delay (or prevent) toxin formation. |
| >5°C to 10°C | Reduced Oxygen | 5% Water Phase Salt | Non-proteolytic *C. botulinum* is controlled under these conditions. |

* As an alternative to water phase salt, time/temperature controls alone may be used. *C botulinum* cannot grow and produce toxin at or below 3°C. Other time/temperature combinations exist that similarly control the formation of toxin (Skinner and Larkin, 1998) Where enforcement of shelf life as well as consumer acceptance of shelf life are norms, the country may select a system that relies on the combination of existing storage temperature conditions (i.e. during transport, retail storage, and consumer storage) and shelf life limitations. However, in countries where consumer acceptance and regulatory enforcement of shelf life are not norms, continuous monitoring, such as that provided by time/temperature integrators on consumer packages, may be selected as a control by the country where the product will be consumed. The necessity for time/temperature integrators exists because, unlike freezing, temperature control through refrigeration is not a visual condition and cannot be determined without an additional monitoring control.

** As new technologies are developed, e.g. modified atmosphere with high oxygen, new controls may be defined.

## 3.6 Summary of Key Stipulated Process Parameters for VP/MAP/ROP Chilled Foods in Different Documents

### Table 3.6 Summary of key stipulated process parameters for chilled foods in different documents

*The process parameters summarised below must only be applied within the context of the original document.*

| Reference | Pasteurisation | Other control parameters | Post process chilling | Pre-distribution storage temperature | Distribution/ retail storage | Shelf life | Basis |
|---|---|---|---|---|---|---|---|
| **ACMSF 1992** | If shelf life >10 days: 90°C/10 mins | If >10d under chill use at least one hurdle if not heated 90°C/10 mins equiv. i.e. pH<5, $a_w \leq 0.97$ throughout, NaCl 3.5% (aq) throughout or combination of heat and hurdles shown to prevent growth and toxin formation by non-proteolytic *C. botulinum* | Not specified | 10d max at 10°C unless non-proteolytic *C. botulinum* control in place in addition to chill | | | Predictive models, industry practice, product history, chill chain performance |
| **ACMSF 1995** | 90°C/10 mins unless stored at either 5-10°C for ≤5 days or 10 days maximum at <5°C | As ACMSF 1992 | Not specified | Where chilled storage is the sole controlling factor, chilled foods stored at 5-10°C should have an assigned shelf-life of ≤5 days. Where a shelf-life of up to 10 days is required, the Group recommended that the storage temperature should be at ≤5°C. | | | Growth in broth and fish/turkey homogenate challenge test data |
| **AFIC, ASI, RWTAA 1999** | Not applicable | Not specified | Not applicable | 0°-4°C, never warmer than 5°C | | Not specified | Australian law |
| **Ag Canada, 1990** | Determined by manufacturer. Reference is made to French legislation | Product ≤10°C before cold filling | to ≤ 4°C in 120 min | -1° to 4°C | | Not Determined by manufacturer. | French legislation? |

| Reference | Pasteurisation | Other control parameters | Post process chilling | Pre-distribution storage temperature | Distribution/ retail storage | Shelf life | Basis |
|---|---|---|---|---|---|---|---|
| **AIFST/ ACCC 2000** | Cook-chill cook tank: VP products placed in water tank or steam and slow cooked until the desired temperature is reached - either 70°C/2 mins or 90°C/11 mins equiv or 'according to recipe' | Determined by manufacturer (GMP) | Begin chilling within 30 mins of cooking. Chill to 3°C within 90 mins | -1° to 3°C | | 'Long shelf life with correct practice can be achieved.' 'It has been found that some products have a shelf life of up to 45 days.' Micro testing and quality evaluation must be carried out when setting up the process and on a regular basis. | Not stated/ HACCP |
| | Cook-chill sous vide: either 70°C/2 mins or 90°C/11 mins equiv or 'according to recipe' | Determined by manufacturer (GMP) | | -1° to 3°C | | 'It has been found that some products have a shelf life of up to 45 days.' 'Micro testing and quality evaluation must be carried out when setting up the process and on a regular basis, at least annually.' | Not stated/ HACCP |
| | Cook-chill VP & MAP/gas flushing: 70°C/2 mins at core. Extended shelf life: time-temperature control to eliminate *C. botulinum* | Determined by manufacturer (GMP) | Not specified | MAP meat <3°C | | Note shelf life tests need to recommence after repackaging as previous tests cannot be relied upon | Not stated |
| **AMI/NMA/SMA** | Not applicable | Chill, avoid cross-contamination | Not applicable | 7°C implied | | Not stated | Lower growth temperature of *Salmonella* |
| **AQIS 1992** | 6D reduction of target organism: Lm D70=0.34 min, z=7.5°C non-prot *C. bot* , D80=21.6 min, z=9°C | Determined by manufacturer (GMP) | Chilling to start within 30 min. To reach storage temperature in 4h. | Extended shelf life: ≤3°C or if 6D process for non-prot. *C. bot*: ≤ 5°C. If >5°C, shelf life max 5 days. If product >10°C, discard product | | >5 days if ≤ 3°C or if ≤ 5°C eat within 10 days of purchase unless frozen | Not stated |
| **CCFRA 1996** | Short shelf life: 70°C/2 min equiv<br><br>Long shelf life: 90°C/10 min equiv or <90°C/10 mins equiv + at least one hurdle<br><br>Note: shelf life is not impacted by storage at ≤3°C since there will be no growth of *C. botulinum*. | >10d under chill use at least one hurdle if not heated 90°C/10 mins equiv. i.e. pH<5, $a_w$ ≤0.97 throughout, NaCl 3.5% (aq) throughout or combination of heat and hurdles shown to prevent growth and toxin formation by *C. botulinum* | Chilling to start within 30 min. of cooking<br>As quick as possible<br>Portion size pack: to 5°C in 90 min.<br>Larger quantity: from 50°C to 10°C in 4 hours | If ≤3°C then no reduction of total shelf life.<br>If ≥3°C and ≤8°C then shelf life 'clock' to be started | ≤8°C | short shelf life: ≤10 days<br><br>long shelf life: >10 days | ACMSF 1992 + England, Wales & NI legal temperatures |

| Reference | Pasteurisation | Other control parameters | Post process chilling | Pre-distribution storage temperature | Distribution/ retail storage | Shelf life | Basis |
|---|---|---|---|---|---|---|---|
| **CCFRA 1992a** | Not specified - refers to CFA (1989) guidelines | Hygiene<br>Gas mixtures<br>Chill | Not specified | -1°C to +5°C, depending on product | | Various, depending on product | Various industry and other guidance |
| **CCFRA 1992b** | 90°C/10 mins (shelf life >10d)<br>70°C/100 mins (shelf life 1-10d) | Not specified | Chilling to start within 30 min. of end of cooking and reach 0-3°C in 90 min. | 0-3°C | 0-3°C<br>if product > 10°C, discard product | 1-10 days: short<br>10-42 days: long | Various published literature (90°C/10 mins), then current French legislation (70°C/100 mins) |
| **CFA 2006** | Shelf life 10 days max: equiv to 70°C/2 mins<br>Shelf life >10 days: equiv to 90°C/10 mins or other measures demonstrably controlling non-prot *C. botulinum* | If >10d (VP/MAP/air) under chill use at least one hurdle if not heated 90°C/10 mins equiv. i.e. pH<5, $a_w$ <0.97, or use demonstrably effective combination of hurdles.<br>GMP. | Chilling as soon as it is practicable after heating, assembly or air drying has been completed. The cooling rate must be such that significant growth of surviving microorganisms is prevented. | Determined by manufacturer but ≤8°C | ≤8°C | 1-10 days: short – limit *Listeria monocytogenes* survival/growth potential<br>>10 days: long – control measures to be determined by manufacturer to assure safety | ECFF Botulinum WP, CCFRA 1996 |
| **CFA 1997** | Shelf life 10 days max: equiv to 70°C/2 mins<br>Shelf life >10 days: equiv to 90°C/10 mins or other measures demonstrably controlling non-prot *C. botulinum* | Demonstrably effective combination of hurdles.<br>GMP | As quick as possible through temperature range 63°C to 8°C | ≤5°C | ≤8°C<br>preferable: ≤5°C | 10 days maximum for unless non-proteolytic *C. botulinum* controls in place | CCFRA, 1996 |
| **CFIA, 1997** | Not applicable | Not specified | Not specified | Not specified | | Not specified | Not stated |
| **CFSAN** | Various mild processes, e.g.<br>Raw animal foods:<br>• 63°C/3 mins or<br>• 66°C/1 min or<br>• 68°C/15 secs or<br>• 70°C/<1 sec<br>Poultry/stuffed products: 74°C/15 secs | Chill + aw≤0.91 or pH≤4.6 or is cured meat or has a high level of competing organisms e.g. raw meat/fish | Cooked potentially hazardous food is required to be cooled within 2h from 57°C to 21°C; and within a total of 6h from 57°C to 5°C or less, or to ≤7°C. | 5°C max | | 14 days: ROP products<br>30 days: ROP cheese | Various FDA documents. Control of *Lm* and *C. botulinum* (including proteolytic) |
| | • Whole meat roasts: range from 54.4°C/112 mins to 70°C/0 secs (instantaneous) | | Cook-chill and sous vide: cooled to 5°C in the package or bag then cooled to ≤1°C within 48h of reaching 5°C | Cook-chill and sous vide foods: 1°C max | | 30 days: cook-chill and sous vide foods | |

| Reference | Pasteurisation | Other control parameters | Post process chilling | Pre-distribution storage temperature | Distribution/ retail storage | Shelf life | Basis |
|---|---|---|---|---|---|---|---|
| **CODEX (draft)** | Not applicable | NaCl 3-3.5% (aq) at >3°C to 5°C, or NaCl 5% (aq) at >5 to 10°C | Not applicable | >3 NaCl to 5°C or >5 NaCl to 10°C (select NaCl accordingly) | | Not specified. Determined by manufacturer | Skinner/ Larkin |
| **ECFF 1996** | Up to 10d shelf life under chill: 70°C/2 mins equiv >10d shelf life under chill: 90°C/10 mins equiv or use combination of hurdles | Alternatively use combination of demonstrably effective hurdles | 'The cooling rate must be such that significant growth of surviving microorganisms is prevented, e.g. to 10°C within 2h' | ≤3°C predist. storage (sous vide products) | ≤4°C (sous vide products) | Determined by manufacturer on basis of demonstrable safety | ECFF Botulinum WP/ACMSF 1992 |
| **ECFF Botulinum WP 1999** | Long shelf life (>5 days): 90°C/10 mins equiv, or <90°C/10 mins equiv and 3°C, 'other preservative factors are present and operating' | Alternatively use combination of demonstrably effective hurdles | Not specified | Up to 5d shelf life without non-prot *C. botulinum* control or storage <3°C or combination of demonstrably effective hurdles | | Up to 5d or storage <3°C, or 6-log reduction process for non-prot *C. botulinum,* or intrinsic factors (hurdles) inc. lower heat process in-pack | Independent scientific review |
| **EVI 2000** | Not applicable | Not specified | Not specified | +3°C maximum | | 3 weeks at +3°C max | Predictive modelling (*Lm* growth) |
| **FDA, 1993** | Not applicable | Domestic: refrigerate Commercial: Add microbial inhibitors (e.g. citric or phosphoric acid) | Not specified | Refrigerate | | Not specified | Not specified |
| **Food Institute Canada** | Determined by manufacturer | Products should be designed with additional hurdles to inhibit food spoilage and poisoning, e.g. pH 4.5, reduced $a_w$, VP or MAP | Determined by manufacturer | -1°C to +4°C. If ≥7°C on receipt instruction for special handling shall be requested from the manufacturer. These instructions may consist of lowering the food temperature. | | Determined by manufacturer | Unknown |
| **FSA** | Not applicable | Chilled | Refrigerate | Refrigerate | | 1 week maximum | Not specified |

| Reference | Pasteurisation | Other control parameters | Post process chilling | Pre-distribution storage temperature | Distribution/ retail storage | Shelf life | Basis |
|---|---|---|---|---|---|---|---|
| **Health Canada** | Determined by manufacturer | Determined by manufacturer | Not specified | +4°C maximum | | Manufacturer to make available appropriate data showing safety for intended shelf life if >10 days | 10 day cut off based on *Listeria monocytogenes* growth potential |
| **Health Canada** | Not applicable | Chilled | Refrigerate | Refrigerate | | 1 week maximum | Not specified |
| **IFPA** | Not applicable | Chilled | Not specified | +4.4°C maximum | | Not specified | Various research |
| **IFPA** | Not applicable | Chilled | Not specified | 0-5°C | | Not specified | Various research |
| **MOFFA** | Not applicable | '3.5% NaCl (aq) may be necessary throughout a VP food' | Not applicable | 8°C max 'may be required by law' but note general exemption for mail order foods | | Limit shelf life for VP/MAP foods where temperature is the only control and is >3°C to no more than 8°C | CCFRA 1996 |
| **NFPA, US 1989** | 5D reduction of *E. coli* O157:H7 in ground beef<br>7D reduction of *Salmonella* in poultry | Determined by manufacturer (GMP) | Not specified for MAP/VP | < 4.4°C | < 5°C | Scientific evidence needed to support labelled shelf-life | Not specified |
| **PTK/ ETL/ SKKL** | Not applicable | Not specified | Not specified | 0-3°C | 0-3°C (max 6°C) | Not specified, but limited by document 16 | Predictive modelling of *Lm* growth potential |
| **SVAC 1991** | Targeting non-prot. *C. bot.* type E, $D_{80}$=4.3 min, z=13.2°C: 80°C/26 min, or 85°C/11 min, or 90°C/4.5 min, or at 95°C/2 min. | Not specified | Chilling to start within 30 min. of cooking. Reach 0-3°C in 90 min. | 0-3°C | | Max. 8 days | Not stated |
| **SYNAFAP 1995** | Determined by the manufacturer (after hazard analysis) | Determined by manufacturer (GMP) | Minimum time between 60°C and 10°C: gen. less than 2h | <4°C | | Determined by manufacturer using shelf life validation protocol | HACCP |
| **SYNAFAP (Draft, 2006)** | Determined by the manufacturer: for sous vide it is acceptable to take account of the natural level of contamination and adjust the process (log reduction) accordingly | Determined by manufacturer (GMP) | | <4°C | | For sous vide, a shelf life of 21 days, even 30 days, is acceptable, taking account of the natural level of contamination, respecting GHP and under controlled chill chain conditions. | Carlin *et al* spore loading study, Cemagref/ANIA chill chain study, Institut Pasteur Lille challenge test study |

| Reference | Pasteurisation | Other control parameters | Post process chilling | Pre-distribution storage temperature | Distribution/ retail storage | Shelf life | Basis |
|---|---|---|---|---|---|---|---|
| **TNO 1994** | 90°C/10 min total (including duo pasteurisation option) Reference org. non-prot. *C. bot.* type B. $D_{90}$=10 min. z=10°C if T>90°C or z=7°C if T<90°C | Determined by manufacturer (GMP) | to 10°C in 2h<br>to ≤ 3°C in 12 hours | 0-3°C | 0-5°C | Max. 42 days including max. 3 weeks outside manufacturers' facility max. 1 week in domestic fridge | CODEX HACCP, ACMSF 1992 |
| **UC 2001** | Not applicable | MAP gas mixtures | Not specified | Dependent on product, e.g. 0-5°C for MAP shredded lettuce | | Determined by manufacturer | Not specified |
| **UNIPI** | 70°C/2 mins or 90°C/10 mins Choice determined by manufacturer | Determined by manufacturer (GMP) | Determined by manufacturer | Not specified | | Determined by manufacturer | HACCP |
| **US CFA** | Determined by the manufacturer | Determined by manufacturer (GMP) | Determined by manufacturer | 1.7°C (35°F) | Not specified | Determined by manufacturer | HACCP |

## 3.7 Conclusions

***Overall approach***

- There are no legal requirements in the UK in relation to VP/MAP chilled foods, except that they should be stored at a temperature of 8°C or less (as defined in law in England, Wales and Northern Ireland. In Scotland the requirement is to keep chilled food in "a refrigerator, or refrigerating chamber, or a cool ventilated place") and produced using HACCP principles, as required under European hygiene law. Recommendations have been made by the ACMSF (1992 and 1995), and there is guidance in an industry code and other industry documents.
- The 1992 ACMSF recommendations on the safe production of VP/MAP chilled foods with respect to non-proteolytic *C. botulinum* were published formally (ACMSF, 1992). The report included the recommendation of a maximum shelf life of 10 days at 10°C maximum unless appropriate controls (formulation and/or processing) were in place. The recommendations were taken up widely by professional food manufacturers and retailers in the UK and were taken forward into various other guidance including internationally.
- In 1995, one of the key ACMSF recommendations was revised (ACMSF, 1995). In particular the recommendation of a maximum shelf life of 10 days at 10°C maximum unless appropriate controls were in place, was replaced with the recommendation of a maximum shelf life of 5 days at 10°C maximum or 10 days at 5°C maximum unless appropriate controls were in place. This change was made on the basis of a review of 31 references from the literature on toxin production by non-proteolytic *C. botulinum* within 10 days at $\leq$10°C (mostly challenge tests carried out in food materials). The ACMSF 1995 approach was not taken up by industry or included in other guidance.
- An Industry Code of Practice for the manufacture of VP/MAP chilled foods was written by a working group of manufacturers, retailers and MAFF and DH representatives (CCFRA, 1996). It aimed to crystallise various guidance into practical advice. One of the recommendations included was a maximum shelf life of 10 days at 8°C maximum unless appropriate controls (formulation and/or processing) were in place. The code recommendations were taken up widely by professional food manufacturers and retailers in the UK and were taken forward into various other guidance.
- Both in the UK and internationally, a variety of approaches are described, and most allow for flexibility of control measures on the basis of safety being demonstrable by the manufacturer on the basis of HACCP.

***Thermal Processes***

- Many documents refer to 6-log non-proteolytic *C. botulinum* processes for long shelf life products (90°C/10 min or equivalent), which are based on the ACMSF 1992 approach. However, different z values are referred to, resulting in a range of processes that are intended to be equivalent, but which are not in reality. The appropriate choice of z value is a matter that needs to be addressed by research.
- The use of heat treatments less than 90°C/10 min (or equivalents) can be effectively combined with storage temperature and shelf-life to prevent toxin formation from $10^6$ spores of non-proteolytic *C. botulinum* (i.e. provide a 6-log non-proteolytic *C. botulinum* process). For example, heating at 80°C for 11 min and for 98 min, prevented toxin formation at 8°C in 20 days and 40 days, respectively.
- In France, legislation has permitted the use of heat treatments that deliver less than a 6-log non-proteolytic *C. botulinum* process. For example, the 1988 legislation enabled ready meals receiving a process equivalent of 70°C for 100 min (core temperature of 65°C; and equivalent to only 90°C for 1 min) to have a shelf life of up to 21 days, although the precise shelf life was to be determined by the manufacturer.
- The French retail sous vide industry includes in its current approach the use of less than a 6-log non-proteolytic *C. botulinum* process. Heat treatments less than 90°C/10 min (or

equivalents), such as 80°C for 93 min, combined with chilled storage regimes have been shown to provide for shelf lives of up to 30 days.
- All approaches either leave the selection of thermal processes to the manufacturer to determine using HACCP, or provide example thermal equivalents, with flexibility for equivalents or otherwise demonstrably effective processes to be used.

***Post-Process Chilling***
- In all cases rapid chilling of cooked foods is recognised as being a key CCP. However, a range of time/temperature combinations are specified. CFA and ECFF guidance require chilling such that significant growth of surviving microorganisms is prevented.

***Hurdles/Intrinsic Factors***
- Examples of single hurdles targeted at control of non-proteolytic *C. botulinum* are included in many documents, such as those produced by the ACMSF (1992, 1995), and the Industry Code of Practice (CCFRA, 1996). Examples of the hurdles include, pH<5 throughout, $a_w \leq 0.97$ throughout, and NaCl 3.5% (aq) throughout.
- Some documents appear to be targeted at control of other pathogens such as *Listeria monocytogenes* and proteolytic *C. botulinum* (e.g. CFSAN, 2005), rather than non-proteolytic *C. botulinum*.
- The importance of HACCP is stressed, and allow for the manufacturer to select appropriate hurdles (e.g. CFA, ECFF and SYNAFAP guidelines).

***Chilled Temperatures***
- Storage at temperatures up to 3°C are generally recognised as being a means of preventing the growth and toxin formation by non-proteolytic *C. botulinum*.
- In all approaches the main emphasis is on low temperature storage (not necessarily with specific limitation of shelf life). However, the specified temperatures vary. For example the Canadian and French approaches refer to 4°C as the national legal maximum, while in England, Wales and Northern Ireland this is 8°C. In Scotland the requirement is to keep chilled food in “a refrigerator, or refrigerating chamber, or a cool ventilated place”.
- Cross-reference needs to be made to the actual performance of the chill chain, including in the home.

***Shelf life***
- A wide range of approaches exist, but the emphasis is on demonstrable safety and HACCP.
- In many cases the shelf-life relies on a controlling factor in addition to storage at chill temperature alone. For example, draft French industry guidance reflecting longstanding practice for sous vide foods allows for a shelf life of 21 days and potentially up to 30 days for products subjected to less than 6-log thermal reduction of non-proteolytic *C. botulinum*, provided that GHP is respected, and the product is distributed under controlled chill chain conditions.
- Other advice relies on storage at 3°C or below. For example, Finnish Government advice in relation to cold smoked and gravad fish is for shelf life to be a maximum of 3 weeks at 3°C, being based on the potential for *Listeria monocytogenes* growth rather than non-proteolytic *C. botulinum*.
- A general feature of many guidance documents is that a shelf life of 10 days is permitted under chilled storage conditions, and that if a shelf life of greater than 10 days is required then the manufacturer is required to make available appropriate data demonstrating safety. The importance of HACCP is stressed.

## 3.8 References

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