



***Clostridium botulinum* in vacuum and modified
atmosphere packed (MAP) chilled foods**
(Project B13006)

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1. Summary

1. A substantial quantity of chilled foods has been sold in the UK and overseas in the last two decades, and when correctly stored has not been associated with foodborne botulism. Current practice would therefore appear to have a high degree of safety.

2. The majority of commercially produced pre-packaged chilled foods have a shelf life greater than 5 days, and some have a shelf life greater than 10 days without receiving any of the control measured specified by the ACMSF (1992). The ACMSF (1995) recommendation of 10 days at 5°C/5 days at 10°C is not adhered to any significant extent in the UK or elsewhere. The 10 day rule at 8°C specified in the 1996 industry code of practice is only adhered to by major producers in the UK and Benelux market. In some countries (e.g. France, Finland), chilled products have been safely produced, over several decades, with shelf lives greater than 10 days. Many of these products will not have received a 6 log non-proteolytic *C. botulinum* process or any of the other control measured specified by the ACMSF (1992) and their shelf lives take account of lower temperature storage than 8°C.

3. It is not easy to determine the maximum shelf-life of chilled foods at 8°C (where other controlling factors are not known) on only the data from 1307 independent challenge tests of toxin formation by inoculated non-proteolytic *C. botulinum*. It is clear that, given the correct circumstances, if present, non-proteolytic *C. botulinum* is able to form toxin in 10 days or less at 8°C. Also, predictive models indicate that toxin formation can occur in 10 days or less at 8°C (the model in ComBase Predictor estimates toxin formation in 6 days at 8°C). That toxin formation has not occurred in correctly stored short shelf-life chilled foods sold in the UK (and internationally) must be due to presence of one or more “unknown controlling factors”. The difficulty is that the magnitude, variability, and nature of these “unknown controlling factors” is not known, and it is suspected that the magnitude, variability, and nature are not the same for all chilled foods. The position is therefore that while short shelf-life foods have been produced safely in the UK (and internationally) for more than two decades, it is not known why they are safe with respect to foodborne botulism, or what the safety margins are.

4. Based on the extensive sales of chilled foods without any incidence of foodborne botulinum (when correctly stored), it is recommended that current industrial practice (application of GMP, GHP and HACCP principles) continue, and that the FSA include a recommendation of “storage at $\leq 8^{\circ}\text{C}$ and a shelf-life of ≤ 10 days” in their document, rather than “storage at $\leq 5^{\circ}\text{C}$ and a shelf-life of ≤ 10 days or storage at $5^{\circ}\text{-}8^{\circ}\text{C}$ and a shelf-life of ≤ 5 days”. It is cautioned, however, that if present, non-proteolytic *C. botulinum* can form toxin in 10 days and less at 8°C, and there is insufficient clear information as to what the safety margins are in foods as sold, particularly when attempting to take into account the temperature performance of the complete chill chain throughout foods’ shelf lives. It is therefore strongly recommended that extreme caution be used when modifying current industrial practice (e.g. extending the shelf-life of chilled foods over that currently used), and in the development of new products. Since, although current industrial practice appears safe, it is possible that chilled foods could be produced for which a 10 day shelf life at 8°C would not be suitable. It would seem logical to apply this approach to all chilled food sold in the UK.

5. It was noted in several studies that toxin formation by non-proteolytic *C. botulinum* was as rapid (or in some circumstances more rapid) in foods packed in air as under VP or low-oxygen MAP. This is presumably because there is no oxygen in the food, i.e. the food is reduced. Packaging under air or a similar oxygen-containing atmosphere is therefore not a guarantee that toxin formation by non-proteolytic *C. botulinum* will be prevented.

6. It has been brought to our attention that some chilled VP/MAP foods such as meat may be given a “rolling 10 day shelf-life”. That is, the product is opened during the initial 10 day shelf-life, some is used, and then the remainder is repacked and given a further 10 day shelf-life. Thus, the shelf-life is extended beyond 10 days without the identification of other factors that control

toxin formation by non-proteolytic *C. botulinum*. While we are not aware of this practice leading to outbreaks of botulism, this represents a significant divergence from the guidance and would appear to be a high risk practice. It is therefore proposed that for foods where no other controlling factor can be identified, the maximum shelf-life is 10 days, and that this commences once the product is first vacuum or modified atmosphere packed. The shelf-life must not be restarted if the product is subject to a further packing under vacuum or modified atmosphere, unless other controlling factors (as described by the ACMSF) are applied.

7. Improvements in temperature control throughout the chill chain could make a significant contribution to microbiological food safety with respect to foodborne pathogens that are able to grow at chilled temperatures, such as non-proteolytic *C. botulinum* and *Listeria monocytogenes*. It is noted that maintenance at a temperature of 5°C was recommended by Richmond in 1991. The chill chain of major UK multiples is targeted at 5°C or below throughout distribution and retail display. In practice, available surveys of all types of UK chilled food outlets (including major multiples, farmers markets, small stores and other outlets) indicated that the average temperature at retail was 4°C-6°C, with 6% of samples at >8°C. In the UK, domestic refrigerators are replaced on average every 8 years, thus the last domestic refrigerator survey that was carried out in 1990 is of date, and needs to be re-run in order to ensure the UK has up to date information on domestic refrigerator temperature performance. The 1990 UK survey found that there was variation in performance between domestic fridges and within each refrigerator over time. Also, different temperatures were recorded in different parts of single refrigerators. The overall mean temperature was 6.6°C, with approximately 9% of the time spent at >9°C. Temperature control in the chill chain appears to be similar in other developed countries.

2. Introduction

Foodborne botulism is a severe disease. It is an intoxication resulting from consumption of pre-formed botulinum neurotoxin in food, with as little as 30 ng of neurotoxin sufficient to cause illness and even death. The consumption of as little as 0.1g of food in which *Clostridium botulinum* has grown can result in botulism. Foodborne botulism is primarily associated with two physiologically and genetically distinct clostridia, proteolytic *C. botulinum* and non-proteolytic *C. botulinum*. Proteolytic *C. botulinum* is a mesophile, with a minimum growth temperature of 10°C-12°C, while non-proteolytic *C. botulinum* is a psychrotroph that grows and forms toxin at 3.0°C (Table 1).

Table 1 Characteristics of the two physiologically and genetically distinct clostridia most frequently associated with foodborne botulism

| | Proteolytic <i>C. botulinum</i> (mesophile) | Non-proteolytic <i>C. botulinum</i> (psychrotroph) |
|---|--|---|
| neurotoxins formed | A, B, F | B, E, F |
| minimum growth pH | 4.6 | 5.0 |
| minimum growth temperature | 10-12°C | 3.0°C |
| maximum growth NaCl | 10% | 5% |
| spore heat resistance (D _{100°C}) | >15 min | <0.1 min |

In view of the severity of botulism, regulators and industry work hard to ensure that the risk of it occurring is very low. This has led to the production of various guidelines, recommendations and codes of practice with respect to the control of *C. botulinum* in foods, including VP (vacuum packed) and MAP (modified atmosphere packed) chilled foods. There has been a substantial increase in sales of VP/MAP chilled foods over the last two decades. These foods address consumer demand in being of high quality and requiring little preparation time. The principal microbiological safety hazard is foodborne botulism, as presented by non-proteolytic *C. botulinum*.

In 1992, the ACMSF published a report that made recommendations on the safe production of VP/MAP chilled foods with respect to *C. botulinum* and the associated foodborne botulism hazard. These were:

- (1) storage at <3.0°C*
- (2) storage at ≤10°C and a shelf-life of ≤10 days (the “10 day rule”)
- (3) A heat treatment of 90°C for 10 min or equivalent lethality (e.g. 80°C for 129 min, 85°C for 36 min) combined with storage at chill temperature (designed to give a 6D process for non-proteolytic *C. botulinum*)** .
- (4) A ≤pH 5.0 throughout the food, combined with storage at chilled temperature
- (5) A salt concentration ≥3.5% throughout the food, combined with storage at chilled temperature
- (6) An ≤a_w 0.97 throughout the food, combined with storage at chilled temperature
- (7) Combinations of heat treatment and other preservative factors which can be shown consistently to prevent growth and toxin production by *C. botulinum*, combined with storage at chilled temperature

Notes:

* originally 3.3°C, but growth has now been demonstrated at 3.0°C

** chill temperature is specified as 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”.

All of these recommendations are still in place, except for the second one. The second recommendation deals with the maximum shelf-life/storage temperature for chilled foods for which no other controlling factors could be demonstrated, and is known as the “10 day rule”.

In response to questions raised by a team drawing up an industry code of practice (at CCFRA), in 1995 the ACMSF revised this recommendation 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 $\leq 10^{\circ}\text{C}$ in foods or food materials. The ACMSF also took account of predictions from a PC based version of Food MicroModel and unpublished data on *C. botulinum* (both provided by Dr. Baird-Parker, Unilever Research). In 1995, the ACMSF revised the second recommendation (10 day rule) to “storage at $\leq 5^{\circ}\text{C}$ and a shelf-life of ≤ 10 days, or storage at $5^{\circ}-10^{\circ}\text{C}$ and a shelf-life of ≤ 5 days”.

The group involved in drawing up an industry code of practice at CCFRA, considered the recommendations of the ACMSF (made in 1992 and in 1995), and replaced the second recommendation (10 day rule) with “storage at $\leq 8^{\circ}\text{C}$ and a shelf-life of ≤ 10 days”. The temperature of 8°C was selected as it is the legal upper limit for chilled food storage in England, Wales and Northern Ireland, rather than there being any scientific evidence regarding unsuitability of storage at 10°C . This code of practice was developed in conjunction with representatives of MAFF/Department of Health, and probably reflects much current industrial practice as it stands today, where specific controlling factors (e.g. 6 log reduction process, Aw, pH controls, other specific controls) are not present.

In response to a request from the ACMSF, in 2003 the FSA produced a draft small concise guidance document on the safe production of VP/MAP chilled foods with respect to *C. botulinum*. The recommendations included in this document are similar to those made by the ACMSF in 1995, and the industry code of practice in 1996, with an important difference for foods with a short shelf-life where other specific controlling factors cannot be demonstrated (10 day rule) (Table 2). At the ACMSF meeting held on 18th September 2003, the ACMSF agreed that the FSA concise document should go out to full public consultation. The consultation period ended in August 2004. The most significant issue raised by the consultation surrounded a perceived change in the “10 day rule”, and highlighted differences between the ACMSF recommendations and the industry code of practice. The different recommendations are summarised in Table 2.

Table 2 Recommendations on ensuring the safety of short shelf life chilled foods when other specific controlling factors cannot be demonstrated

| Recommendation from | Maximum storage temperature and shelf life recommended |
|---|--|
| ACMSF (1992) | storage at $\leq 10^{\circ}\text{C}$ and a shelf-life of ≤ 10 days |
| ACMSF (1995) | storage at $\leq 5^{\circ}\text{C}$ and a shelf-life of ≤ 10 days, or storage at $5^{\circ}-10^{\circ}\text{C}$ and a shelf-life of ≤ 5 days |
| Industry Code of Practice (CCFRA, 1996) | storage at $\leq 8^{\circ}\text{C}$ and a shelf-life of ≤ 10 days |
| FSA draft concise guidance document (FSA, 2003) | storage at $\leq 5^{\circ}\text{C}$ and a shelf-life of ≤ 10 days, or storage at $5^{\circ}-8^{\circ}\text{C}$ and a shelf-life of ≤ 5 days |

At its meeting in December 2004, the ACMSF concluded that in the light of the concerns that were raised in response to the consultation, it needed to examine recent scientific evidence before advising on the FSA concise guidance document with respect to recommendations for foods with a short shelf-life where other specific controlling factors cannot be demonstrated (10 day rule). The ACMSF proposed that the FSA commission an independent review of the current scientific evidence, with the findings to be presented at a future ACMSF meeting. The purpose of this document is to provide the ACMSF with all the necessary up to date information to enable them to judge recommendations included in the FSA document on “foods with a short shelf-life where other specific controlling factors cannot be demonstrated”.

3. Production and sales of chilled VP/MAP foods

The range of chilled foods sold in the UK and internationally is extremely varied, and the market is large. It is estimated that approximately 6×10^9 packs of chilled food are sold in the UK each year, and it is likely that more than 10^{11} packs have been sold during the two decades (Table 3). These chilled foods are packed under MAP, VP, air and other atmospheres containing oxygen. Even when air/oxygen is present above the food, there may be little oxygen within the food (i.e. the food is reduced), and these foods should be considered to present a similar botulism risk as MAP or VP foods.

Table 3 Details of chilled foods sold in the UK

| Product | Packing (VP/MAP/Air) | Mean number of packs sold per annum (million)* | Shelf life | UK legal storage temperature (°C)** | Notes |
|--|----------------------------------|--|---|-------------------------------------|---|
| Raw red meat | VP (primals, retail) | 1,153 | ≤ 6m (primals) 13d (retail) | 7 | High O ₂ (70%) |
| | MAP (retail) | | ≤10d | | |
| Meat preparations | MAP | 912 | minced meat: 8d major multiple, 14-21d butcher | 4 | |
| Poultry preparations | MAP | 327 | 10d | 4 | Low O ₂ |
| Poultry/products | MAP | 256 | 10d (uncured) 28-35d (cured) | 4 (whole) 8(products) | Low O ₂ |
| Sliced cooked meat and alternatives | MAP | 1,128 | 10-15d (uncured) 15 to >30d (cured) | 8 | Nitrite (cured) |
| Fish and seafood | MAP | 700 | 5-7d (MAP fresh fish) 8-9d (MAP cooked prawns) 21-28d (VP seafood sticks) | On melting ice (unpacked) 8 | High O ₂ (30%) (fresh fish/seafood and smoked trout) |
| Smoked fish | VP | 15 | 6-16d | 8 | Smoked trout not generally VP in UK, NaCl is a key CCP |
| Mussels | VP (cooked) MAP (live) | 2 | 10d to >21d (VP, cooked, not retorted) 6-9d (MAP, live) | On melting ice (unpacked) 8 | |
| Bagged salads | MAP | 71 | 4-7d | 8 | Iceberg lettuce |
| Bagged salads | Air | 286 | 4-7d | 8 | Excl. iceberg. Film permeability regulates pack atmosphere |
| Fresh pasta and gnocchi | MAP | 86 | ≤35d (longer for imports) | 8 | Low a _w (not NaCl), chill |
| Cooked chilled ready meals | Air – low O ₂ in meal | 1,185 | ≤10d, longer for imports | 8 | 10 day rule applied (voluntary) |
| Total mean number of packs sold per annum (million) | | 6,121 | | | |

* Typically based on sales over the last five years

** chill temperature is specified as 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”.

While the chilled food market in the UK is one of the largest in the world, other countries also have significant chilled food markets. It may be that global sales are an order of magnitude higher than those in the UK. It is estimated that more than 1.5×10^{10} pre-packed chilled ready meals have been consumed in the EU in the last 20 years. In 2004, 1.0×10^9 pre-packed chilled ready meals were consumed in the UK, 4.5×10^8 meals in France, 1.8×10^8 meals in Germany, 1.2×10^8 meals in Finland, and 7.5×10^7 meals in Italy. All of these products had a shelf life greater than 5 days, and many had a shelf life greater than 10 days without receiving a 6 log non-proteolytic *C. botulinum* process or any of the other control measures specified by the ACMSF (1992). The ACMSF (1995) rule of 10 day at 5°C/5 day at 10°C is not adhered to any significant extent in the UK or elsewhere. The 10 day rule at 8°C (CCFRA, 1996) is only adhered to by major producers in the UK and Benelux market. In some other countries (e.g. France, Finland), chilled products have been produced, over several decades, with shelf lives greater than 10 days. Many of these products will not have received a 6 log non-proteolytic *C. botulinum* process or any of the other control measures specified by the ACMSF (1992).

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

The only legal requirements in the UK in relation to VP/MAP chilled foods are that they should be produced using HACCP principles, as required under European hygiene law, and that they should be stored at a maximum of 8°C (as defined in law in England, Wales and Northern Ireland), or a refrigerator, refrigerating chamber, or a cool ventilated place (as specified in regulations in Scotland). As discussed above, recommendations have been made by the ACMSF (1992 and 1995), and there is guidance in an industry code (CCFRA, 1996). The code recommendations were taken up widely by professional food manufacturers and retailers in the UK and were taken forward into various other guidance documents. 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 PROCESSING

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 prevented toxin formation at 8°C in 20 days, while heating at 80°C for 98 min prevented toxin formation at 8°C in 40 days.

In France, legislation has permitted the use of heat treatments that deliver less than a 6-log non-proteolytic *C. botulinum* process. For example, 1988 French 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.

HURDLES AND 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 product and its components, $a_w \leq 0.97$ throughout a product and its components, and NaCl 3.5% (aq) throughout a product and its components.

Some other documents appear to be targeted at control of other pathogens such as *Listeria monocytogenes* and proteolytic *C. botulinum* (e.g. CFSA, 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 TEMPERATURE

Storage at temperatures of less than 3°C are generally recognised as being a means of preventing 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. Further details are also given below.

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 (note that this is based on control of *Listeria monocytogenes*).

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.

5. Chilled storage and handling of foods

The maximum temperature specified in legislation for retail of chilled food is 8°C in England, Wales and Northern Ireland. The Food Hygiene (Scotland) Regulations specify chilled food to be stored in a refrigerator, refrigerating chamber, or a cool ventilated place. Neither is there a harmonised approach to legislated temperature rules within the EU, with temperatures of 0°C to 8°C specified in different countries. There are also different requirements for different food groups.

Within the UK, when held and distributed by the manufacturer, it is likely that chilled food is maintained at no more 5°C, and probably lower. Indeed, agreed retailer own label chilled prepared food temperature on delivery to retailers' Regional Distribution Centres is commonly set at 5°C maximum, through commercial agreements.

In practice, surveys of all chilled food outlets (including major multiples, farmers markets, small stores and other outlets) indicated that in the UK, the average temperature at retail was 4°C-6°C, with 6% of samples at >8°C. The position appears similar in many other European countries.

In the UK, a 1990 study showed that transportation of food from the point of purchase to the domestic refrigerator took an average of 43 min, with most achieved in 60 min. The majority of people (87%) did not chill food during transport, and in some cases the food reached temperatures in excess of 20°C, albeit for a short period of time. It took several hours for the food to cool to below 7°C. The increased use of insulation bags or boxes would help consumers maintain the chill chain.

Chilled food purchased through mail order is exempt from legislation in England, Wales and Northern Ireland, although the temperature should be maintained at a "safe level". A MAFF study in 1991 reported that mail order chilled foods spent 70% of their time at 8°C or higher, and that the average temperature on receipt was 15°C. Since 15 years have elapsed, there would be merit in repeating the survey of the temperature control of chilled mail order foods. MOFFA (Mail Order Fine Foods Association) state that "if the temperature is likely to rise in transit above 8°C, the main order operator should be confident that it is safe by reference to supporting technical or other data".

Domestic refrigerators are present in >99% of households in the UK, and on average are replaced every 8 years. Refrigerators provide a key food safety device within the domestic kitchen, their correct operation will reduce the risks of the growth of food poisoning organisms in foods stored within them. Unfortunately there is a lack of recent published data on the temperatures of domestic refrigerators and the last UK domestic refrigerator survey was carried out in 1990. In order to ensure the UK has up to date information on domestic refrigerator temperatures, a new survey is required.

The 1990 UK survey found that the mean domestic fridge temperature ranged from -1°C to 11°C over a 7 day period, and that the overall mean temperature was 6.6°C, with 65-70% of fridges at more than 5°C. There was variation in performance between fridges, and within each fridge over time. Different temperatures were also recorded in different parts of single fridges. Overall, for all domestic fridges the time spent at various temperatures were as follows; 28% of the time at <5.0°C, 35% of the time at 5.0-6.9°C, 28% of the time at 7.0-8.9°C, and 9% of the time at >9°C. The position appears similar in other countries, and an average temperature of 6.64°C has been reported for European fridges. It was recommended in 1991 that the maximum temperature of domestic fridges in the UK should not exceed 5°C.

A survey of consumer behaviour in France established that for short shelf life chilled products, approximately 60% of the shelf life was spent in commercial refrigeration, and 40% in domestic refrigeration. The general applicability of this to other countries is not known, given different practices in various countries.

UK consumer understanding of the "use by date" or "best before date" is poor, and UK consumer handling of chilled foods in practice needs to be more widely studied. Recent FSA data indicate that 27-34% of consumers believe that food past the "use by date" or "best before date" should be thrown away, 24-31% of consumers believe that such food might be past its best but not necessarily unsafe to eat, and 36-37% believe that the action would depend on the food. An earlier survey found that 26% of consumers would eat products after the expiry of their use by date.

It is suggested that the UK continues to strive for better temperature control throughout the chill chain (including domestic storage), and that 5°C is adopted as a target for best practice. This could be aided by new domestic refrigerators including chill compartments and a temperature measuring device to assist consumers in assuring the appropriate chilled storage of foods. This proposal is made in order to further extend the margins of safety of chilled foods with respect to psychrotrophic foodborne pathogens, rather than on the basis of any specific problems.

6. Recent incidents of foodborne botulism

Foodborne botulism is a severe and deadly disease, with most outbreaks associated with home-made foods where known control measures have not been implemented. More rarely, outbreaks of foodborne botulism have been associated with commercial foods and with restaurants. Very large costs are associated with botulism outbreaks involving commercial foods, and are orders of magnitude greater than those associated with other foodborne pathogens (e.g. *Salmonella*, *Listeria*).

Foodborne botulism is most frequently associated with proteolytic *C. botulinum* or with non-proteolytic *C. botulinum*, than with other neurotoxin-forming clostridia. Proteolytic *C. botulinum* is a mesophile, has a minimum growth temperature of 10°C-12°C, and forms toxins of types A, B and F. Non-proteolytic *C. botulinum* is a psychrotroph that is able to grow and form toxin at 3.0°C, and forms toxins of types B, E and F. In view of its ability to grow and form toxin at 3.0°C, non-proteolytic *C. botulinum* is a larger concern in chilled foods.

In order to collect literature data on toxin formation in chilled foods/food materials, an extensive literature search was carried out. In Europe, more than 2,500 cases of foodborne botulism were reported in 1999/2000. In the UK, 62 cases of foodborne botulism were reported between 1922 and 2005 (Table 4). Twenty of these cases were fatal. In the last twenty years there have been 34 cases of foodborne botulism in the UK, three of which have been fatal. Non-proteolytic *C. botulinum* has been associated with one outbreak of botulism in the UK (four cases and two deaths) that involved post-process contamination of ambient stable canned salmon in 1978. Non-proteolytic *C. botulinum* has not been associated with foodborne botulism in correctly stored chilled foods in the UK.

Table 4 Foodborne botulism incidents reported in the UK

| Year | Food vehicle | Home prepared food | Number of cases (deaths) | Toxin type |
|------|--|--------------------|--------------------------|----------------|
| 1922 | Duck paste | No | 8 (8) | A ^p |
| 1932 | Rabbit and pigeon broth | Yes | 2 (1) | ? |
| 1934 | Jugged hare | Yes | 1 (0) | ? |
| 1935 | Vegetarian nut brawn | Yes | 5 (4)? | A ^p |
| 1935 | Minced meat pie | Yes | 1 (1) | B |
| 1949 | Macaroni cheese | Yes | 5 (1) | ? |
| 1955 | Pickled fish (from Mauritius) | ? | 2 (0) | A ^p |
| 1978 | Canned salmon (from USA) | No | 4 (2) | E ⁿ |
| 1987 | Rice and vegetables (Kosher airline meal) | No | 1 (0) | A ^p |
| 1989 | Commercial hazelnut yoghurt | No | 27 (1) | B ^p |
| 1998 | Home bottled mushrooms in oil (from Italy) | Yes | 2 (1) | B ^p |
| 2002 | Homemade sausage (from Poland) | Yes | 1 (1) | B |
| 2004 | Commercial chilled organic hummus | No | 1 (0) | * |
| 2005 | Travel from Georgia | ? | 1 (0) | A ^p |
| 2005 | Home preserved pork (from Czech Republic) | Yes | 1 (0) | B |

^p = proteolytic *C. botulinum*, ⁿ = non-proteolytic *C. botulinum*

* Case is suspected and not confirmed

Outbreaks of foodborne botulism have only been associated with commercially produced chilled foods when they have been time/temperature abused, and also when botulinum toxin has been inadvertently added (with a food component) to a correctly chilled food product. There have been outbreaks associated with each of these scenarios in the UK, and in other countries. Twelve examples are given in Table 5.

Table 5 Examples of foodborne botulism involving commercial chilled foods

| Country (year) | Product | Organism and toxin type | Cases (deaths) | Factors contributing to outbreak |
|----------------|---|---------------------------------------|----------------|---|
| Canada (1985) | Commercial garlic-in-oil | Proteolytic <i>C. botulinum</i> B | 36 | temperature abuse |
| UK (1989) | Commercial hazelnut yoghurt | Proteolytic <i>C. botulinum</i> B | 27(1) | Toxin added with hazelnut conserve to correctly chilled yoghurt |
| USA (1990) | Barbequed [fresh] surgeon fish (palani) | <i>C. botulinum</i> B* | 3 | temperature abuse |
| USA (1993) | Restaurant, commercial cheese sauce | Proteolytic <i>C. botulinum</i> A | 8 (1) | Recontamination and temperature abuse |
| USA (1994) | Restaurant; potato dip ("skordalia") and aubergine dip ("meligianoslata") | Proteolytic <i>C. botulinum</i> A | 30 | Toxin added with potatoes to correctly chilled yoghurt |
| USA (1994) | Commercial clam chowder | Proteolytic <i>C. botulinum</i> A | 2 | temperature abuse |
| USA (1994) | Commercial black bean dip | Proteolytic <i>C. botulinum</i> A | 1 | temperature abuse |
| Italy (1996) | Commercial mascarpone cheese | Proteolytic <i>C. botulinum</i> A | 8(1) | temperature abuse |
| Germany (1997) | Commercial hot-smoked vacuum-packed fish ("Raucherfisch") | Non-proteolytic <i>C. botulinum</i> E | 2 | Suspected temperature abuse |
| France (1999) | Commercial chilled fish soup | Proteolytic <i>C. botulinum</i> A | 1 | temperature abuse |
| Germany (2004) | Commercial vacuum-packed smoked salmon | Non-proteolytic <i>C. botulinum</i> E | 1 | Consumed after "use-by date" |
| UK (2004) | Commercial chilled organic hummus | Not known | 1 | Time/temperature abuse |

* Not clear whether proteolytic *C. botulinum* or non-proteolytic *C. botulinum*

No cases of foodborne botulism can be attributed to non-proteolytic *C. botulinum* and correctly stored commercial chilled foods in the UK or overseas. There is, however, speculation that a recent change in aetiology of foodborne botulism in France may be associated with refrigerated vacuum-packed foods, although a link with commercial chill foods has not been established.

7. Summary and discussion of data on growth and toxin formation by non-proteolytic *C. botulinum* at $\leq 10^{\circ}\text{C}$

SUMMARY OF DATA

Several predictive models have been developed for growth of non-proteolytic *C. botulinum*. Each model is based on a different dataset and gives a slightly different prediction but, in general, the models are constructed to deliver a fail-safe prediction of time to toxin formation when other factors are not limiting. Four predictive models have been considered:

1. Combase Predictor. This model was developed and validated by Graham *et al.* (1996), and is based on growth curves done in a microbiological broth medium. Most of the growth curves were at $\leq 10^{\circ}\text{C}$, and the model is most robust in this region. This model is freely available in ComBase Predictor (www.combase.cc). In this report, predicted time to a 1000-fold increase in viable count is taken to be time to toxin formation.
2. PMP (Pathogen Modeling Program). A probability model developed by Whiting and Oriente (1997) is freely available in PMP (www.arserrc.gov/mfs/PMP6_CurMod.htm). This probability model is also based on tests done in a microbiological broth medium, but time to turbidity is used as the measure of toxin formation. In this report, time to toxin formation is taken as the time to turbidity from a starting concentration of 10^4 spores/ml.
3. Baker/Genigeorgis model. This model is based on tests carried out in more than 17,000 raw fish homogenates (Baker and Genigeorgis, 1992). It is a lag time model, where lag time is taken as the last time that all replicate samples were negative for toxin. This model is freely available in the PMP website (www.arserrc.gov/mfs/PMP6_CurMod.htm).
4. Skinner/Larkin. The Skinner/Larkin model is a more conservative version of the Baker/Genigeorgis model, modified to take account of observations of growth in other experiments (Skinner and Larkin, 1998).

All four models predict that toxin formation will occur in less than 10 days at 8°C (Fig. 1, Table 6). The different predictions of time to toxin formation reflect the different datasets on which the models were based. The model in ComBase Predictor is designed to be most robust at $\leq 10^{\circ}\text{C}$, and may give more reliable predictions in this region than the other two original models. The Skinner/Larkin model is designed to be an ultimate failsafe model. It may be that the prediction of toxin formation in 5-6 days at 8°C is the most reasonable fail-safe prediction from the models, and the prediction of toxin formation in 4 days at 8°C is the most conservative failsafe prediction. It is important to recognise, however, that these models are designed to represent various worst-case scenarios, and the issue that must be addressed is how closely predictions from these models relate to toxin production in actual chilled foods sold in the UK and elsewhere.

Just as models developed using microbiological broth media predict toxin formation in less than 10 days at 8°C (Table 6), tests in microbiological broth media have also reported growth/toxin formation in 10 days or less at 8°C . In this report it is accepted that in microbiological broth media, growth and toxin formation can occur in 10 days or less at 8°C , and no further data have been collected on tests carried out in microbiological broth media.

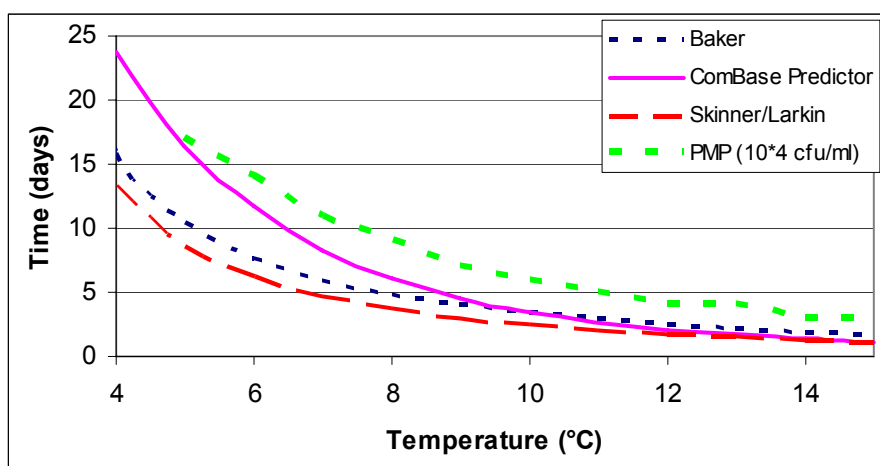


Fig. 1 Effect of incubation temperature on the time to toxin formation by non-proteolytic *Clostridium botulinum*, as predicted by four mathematical models

Table 6 Example predictions of time to toxin formation by non-proteolytic *Clostridium botulinum* at 4°C-12°C from four predictive models

| Model | Predicted time to toxin formation (d) at specified temperature | | | | | | | | |
|-------------------|--|-----|-----|-----|-----|-----|------|------|------|
| | 4°C | 5°C | 6°C | 7°C | 8°C | 9°C | 10°C | 11°C | 12°C |
| ComBase Predictor | 24 | 16 | 12 | 8 | 6 | 5 | 3 | 3 | 2 |
| PMP | -- | 17 | 14 | 11 | 9 | 7 | 6 | 5 | 4 |
| Baker/Genigeorgis | 16 | 10 | 8 | 6 | 5 | 4 | 3 | 3 | 3 |
| Skinner/Larkin | 13 | 9 | 6 | 5 | 4 | 3 | 3 | 2 | 2 |

In order to collect literature data on toxin formation in chilled foods/food materials, an extensive literature search was carried out in January 2006, and combined with articles held in the personal libraries of the authors of this report. Data extracted from 61 literature publications yielded 887 independent tests of time to toxin formation. Additionally, 27 confidential datasets that contained 420 independent tests of time to toxin formation were kindly donated by members of the food industry. This gave a total of 1307 independent tests. One independent test would typically be one product, inoculated with a defined number of spores of non-proteolytic *C. botulinum* (a mixture of strains), incubated at one temperature, and sampled a number of times. Replicate samples would be removed and tested for toxin at various time points (often in duplicate or triplicate), and the last time when all the replicate samples were negative, and the first time that one of the replicate samples was positive noted. Toxin would typically be detected using a mouse test, although some data were based on growth tests. All the data are therefore from “challenge tests”, where spores of non-proteolytic *C. botulinum* have been added to foods/food materials.

It should be noted that most of the data included in this assessment had not been generated for the purpose of evaluating the potential for growth and toxin production by non-proteolytic *C. botulinum* in chilled foods sold in the UK within 10 days or less at 10°C or below. The relevance of these data to short shelf-life chilled foods sold in the UK is in some cases, therefore, limited. Also, the number and proportion of positive tests is to some extent a reflection of the experimental design in the tests that have been carried out. For example, some tests have been carried out in sterile raw materials where conditions are very favourable for growth and toxin formation, while other tests have been carried in conditions not at all conducive to growth and toxin formation (e.g. preservatives added). The proportion of positive tests is a reflection of the balance between these extremes (and all intermediate positions). It is not easy to relate the number and proportion of positive tests to the safety of short shelf life chilled foods sold in the UK.

The results from 1307 independent challenge tests do, however, demonstrate that non-proteolytic *C. botulinum*, if present, is in some circumstances able to form toxin in foods and food materials at ≤10°C within 10 days. In total, 237 individual tests were positive for toxin formation by day 10 (19%). At 10°C, 132 of the tests were positive at day 10 (36%); at 8°C, 100 of the tests were positive at day 10 (19%); and at 4°C-7°C, five of the tests were positive (1%) (Table 7).

Since the current recommended storage temperature for chilled foods in England, Wales and Northern Ireland is ≤8°C, much effort has been dedicated to analysing data at 8°C. A total of 527 independent challenge test datasets with storage at 8°C were considered, and 100 of these were positive for toxin at day 10. Of the 100 positive tests, 56 were with raw or smoked fish, 41 were with sterile or pre-cooked food, two with sous-vide foods, and one with salted ham (Table 8). Based on these data there is a possibility that if contaminated with spores of non-proteolytic *C. botulinum*, raw or smoked fish could become toxic within 10 days at 8°C. Many of these positive tests provide a fail safe indication of the time to toxin formation in chilled foods, however in view of the large variety of chilled foods sold in the UK, it is possible that these observations of

toxin formation within 10 days at 8°C may be relevant to some chilled foods. The difficult issue is to identify which chilled foods. It should be noted that two sous-vide foods that were inoculated with spores prior to the heat treatment became toxic in nine days at 8°C, with eleven other sous-vide foods becoming toxic at day 11/12.

Table 7 Effect of storage conditions on toxin formation by non-proteolytic *C. botulinum* in challenge test experiments

| Storage conditions | | Number of samples (percentage) negative/positive for toxin under specified storage conditions | |
|--------------------|----------|---|--------------------|
| Temperature | time | Negative for toxin | Positive for toxin |
| 10°C | ≤5 days | 319 (93%) | 24 (7%) |
| | ≤10 days | 238 (64%) | 132 (36%) |
| | ≤15 days | 166 (50%) | 166 (50%) |
| 8°C | ≤5 days | 500 (98%) | 12 (2%) |
| | ≤10 days | 414 (81%) | 100 (19%) |
| | ≤15 days | 360 (72%) | 142 (28%) |
| 4-7°C | ≤5 days | 389 (100%) | 0 (0%) |
| | ≤10 days | 382 (99%) | 5 (1%) |
| | ≤15 days | 360 (94%) | 22 (6%) |
| TOTAL (4-10°C) | ≤5 days | 1208 (97%) | 36 (3%) |
| | ≤10 days | 1034 (81%) | 237 (19%) |
| | ≤15 days | 886 (73%) | 330 (27%) |

Table 8 Summary of different food types in which toxin formation has been reported by non-proteolytic *C. botulinum* in 10 days at 8°C in challenge test experiments

| Food type | Total number of positive tests (total number of all tests) | Number of positive tests at each indicated day | | | | | | | |
|----------------------------|--|--|----|----|----|----|----|----|-----|
| | | 3d | 4d | 5d | 6d | 7d | 8d | 9d | 10d |
| Raw/smoked fish | 56 (169) | - | 5 | - | 1 | 24 | 2 | 0 | 24 |
| Sterile minced beef | 25 (97) | - | 2 | 5 | 3 | 5 | 2 | 7 | 1 |
| Cooked turkey breast | 13 (75) | - | - | - | - | - | 7 | 6 | - |
| Pre-cooked sous-vide foods | 2 (15) | - | - | - | - | - | 2 | - | - |
| Sous-vide foods | 2 (110) | - | - | - | - | - | - | 2 | - |
| Other foods | 2 (61) | - | - | - | - | - | - | - | 2 |
| Total | 100 (527) | - | 7 | 5 | 4 | 29 | 13 | 15 | 27 |

All the data for toxin production within 25 days or less are summarised in Fig. 2, along with the prediction of time to toxin formation from ComBase Predictor. In 38 independent tests, time to toxin formation was more rapid than predicted by this model. These tests were from ten different publications, and the foods/food materials involved were raw fish (in 21 tests), cooked turkey breast (1 test), pre-cooked sous-vide beef with gravy (2 tests), cooked minced beef (12 tests), and sterile chicken skin and exudate (2 tests).

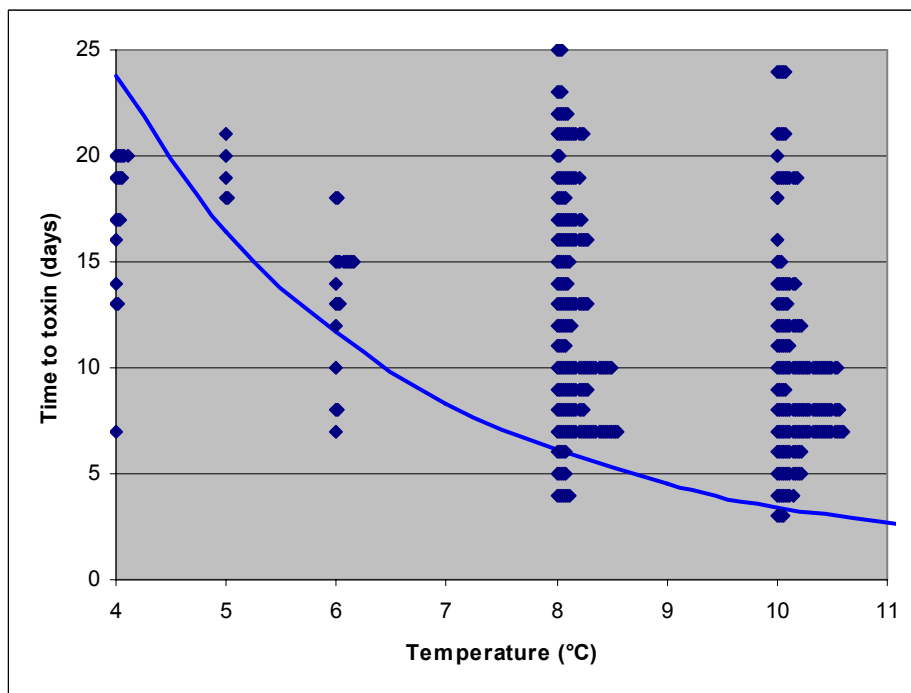


Fig. 2 Effect of incubation temperature on time to toxin formation by non-proteolytic *C. botulinum*. The curve is predicted time to toxin from ComBase Predictor. Observations of time to toxin formation in foods and food materials at 4°, 5°, 6°, 8° and 10°C are shown. Where there is more than one observation at each temperature/time, successive observations are plotted to the right (and give the “bars”). Many tests were negative for toxin formation at 25 days (especially at 4°C-7°C) and are not shown.

It was noted in several studies that toxin formation can be as rapid (or in some circumstances more rapid) in foods packed in air as under VP or low-oxygen MAP (presumably because there is no oxygen in the food, i.e. the food is reduced [in some cases possibly by aerobic organisms]). For example, in one study at 12°C flounder became toxic in 11 days in air, in 10-14 days in various anaerobic modified atmospheres, and in 15 days in VP. Packaging under air or a similar oxygen-containing atmosphere is therefore not a guarantee that toxin formation by non-proteolytic *C. botulinum* will be prevented.

In considering the effect of new processing technologies, it is apparent that there is very little information on the effect of these technologies compared to the wealth of data on the effect of heat. This results in a major issue when it comes to using a new process, while some of its effects may be predictable, the confidence in the prediction will be low, and the need for extensive validation is high. The effects of four “new” processes (high hydrostatic pressure (HPP), pulsed electric field, irradiation pasteurisation and pulsed light) on non-proteolytic *C. botulinum* have been considered, and the effectiveness is dependent on the type of process applied, some do have a killing effect if properly applied, whilst others have a very limited effect. Thus, any use of new process technology to inactivate non-proteolytic *C. botulinum* will have to be extensively validated. The validation would need to take into account strain variation, the effects of the food type, composition and storage regime, and any effects on other food microflora. In establishing safe processes, it is important that at the very least, ‘equivalence’ with established safe technologies must be assured.

DISCUSSION OF THE DATA

At a first glance, the reported ability of non-proteolytic *C. botulinum* to form toxin at 8°C and below within 10 days would appear to be in conflict with the observation of safe production and

sale of large quantities of correctly stored commercial chilled food in the UK and overseas without incidence of botulism. For example, approximately 4×10^9 commercial chilled prepared meals have been produced following 8°C/10 days (shelf-life often 7-8d) since 1990 in the UK. That there have been no botulism outbreaks associated with correctly stored chilled foods is presumably a reflection that one or both of the following controls has ensured safety;

- (i) the foods contain no spores or only a low number of spores of non-proteolytic *C. botulinum*,
- (ii) the foods do not support growth and toxin formation by non-proteolytic *C. botulinum* within the time and temperature of storage.

Short shelf-life chilled foods that have been sold in the UK would therefore appear to have “unknown controlling factors (unknown hurdles)” that have prevented growth and toxin formation by non-proteolytic *C. botulinum*. These “unknown controlling factors” might include:

- a. low spore contamination
- b. a heat process that damages or decreases the number of spores
- c. an inhibitory background microflora
- d. a reduced pH, low water activity, high NaCl concentration, preservatives, inhibitory modified atmosphere, an effect of food structure, or a combination of these
- e. storage at less than 8°C through part or all of the chill chain
- f. consumption of the food before the end of shelf-life
- g. the food is heated before consumption to inactivate any toxin formed

It is important to note however, that:

- (i) different “unknown controlling factors” are likely to be important in different chilled foods
- (ii) the magnitude and variability of these “unknown controlling factors” is not known and is likely to be different for different foods, consequently the safety margin is not known and will vary from chilled food to chilled food, and may also vary from pack to pack for each food.

Considering the large range of short shelf life chilled foods sold in the UK, and the above comments, it is likely that some chilled foods are a bigger risk than others. It may be possible to categorise the foods as a high, medium or low risk, and for these different risk categories to have a different maximum shelf-life at 8°C. For example, raw fish is a high risk product, with numerous challenge tests indicating the possibility of toxin formation in 10 days at 8°C. A difficult matter is to decide which foods fit into which category, and from the unpublished work of Baker on sous-vide foods, it is clear that this will not be straightforward. The designation of low, medium or high risk should be made only on the basis of sound scientific evidence.

In conclusion, it is not easy to base a determination of the maximum shelf-life of chilled foods at 8°C (where other controlling factors are not known) on only the data from 1307 independent tests of toxin formation by non-proteolytic *C. botulinum*. It is clear that, given the correct circumstances, if present, non-proteolytic *C. botulinum* can form toxin in 10 days or less at 8°C. That this has not happened with short shelf-life chilled foods sold in the UK (or internationally) must be due to presence of one or more “unknown controlling factors”. The difficulty is that the magnitude, variability and nature of these “unknown controlling factors” is not known, and it is suspected that they are not the same for all chilled foods. The position is therefore that although short shelf-life foods have been produced safely in the UK and internationally for more than two decades, it is not known precisely what the safety margins are with respect to foodborne botulism. Research is needed to identify the magnitude, variability and nature of these “unknown controlling factors”. This will aid the continued safe development of chilled foods in the UK and internationally.

This study noted a dramatic effect of storage temperature on toxin formation by non-proteolytic *C. botulinum*. For example from the model in ComBase Predictor, time to toxin is predicted as 3 days at 10°C, 6 days at 8°C, 12 days at 6°C, 16 days at 5°C, and 24 days at 4°C. Thus, if all chilled food could be maintained at 4°C/5°C (for example) throughout the chill chain (including in

the home), the safety margin would be extended further. It is likely that there will also be a benefit with other psychrotrophic pathogens and shelf-life extension may also be possible. In order to further extend the margins of safety of chilled foods with respect to psychrotrophic foodborne pathogens, it is suggested the UK continues to strive for better temperature control throughout the chill chain (including domestic storage), and that 5°C is adopted as a target for best practice. It should be noted that this comment is not based on any particular outbreak of food poisoning. This suggestion re-iterates various recommendations made by Richmond in 1991.

8. Re-packing VP/MAP chilled foods during the 10 day shelf-life

It has been brought to our attention that some chilled VP/MAP foods such as meat may be given a “rolling 10 day shelf-life”. That is, the product is opened during the initial 10 day shelf-life, some is used, and then the remainder is repacked and given a further 10 day shelf-life. Thus, the shelf-life is extended beyond 10 days without the identification of other factors that control toxin formation by non-proteolytic *C. botulinum*. While we are not aware of this practice leading to outbreaks of botulism, this represents a significant divergence from the guidance and would appear to be a high risk practice.

For foods where no other controlling factor can be identified, the maximum shelf-life is 10 days, and this should commence once the product is first vacuum or modified atmosphere packed. The shelf-life must not be restarted if the product is subject to a further packing under vacuum or modified atmosphere, unless other controlling factors (as described by the ACMSF) are applied.

9. Risk assessments

Risk assessment is a frequently used term that can have many definitions. Formal Codex type risk assessments are well defined, require considerable data and are formally recorded, in order to provide a transparent assessment of the risks associated with the production of particular products. In this review, formal risk assessments of growth and toxin formation by non-proteolytic *C. botulinum* in a cooked sliced meat and in gnocchi, have been considered. Both assessments used slightly different approaches, but came to the conclusion that the products (which were not given a 90°C/10 min process and did not have pH or Aw controls), could be stored for longer than 10 days at 8°C, and remain safe with respect to the risks from non-proteolytic *C. botulinum*. In the case of the gnocchi the results from the risk assessment were confirmed in a challenge test.

The term risk assessment is also often used to describe less formal determinations of product risk, however these less formal and structured assessments provide useful information in specific product categories. Work done on fresh produce packed in MAP, suggests that whilst there may be risks of growth from *C. botulinum*, this may only occur in temperature abused product (>12°C) and will usually be preceded by gross product spoilage that would render that product organoleptically unacceptable to the consumer. Assessment of various fish products has considered that unless a sporicidal heat process is given, the presence of non-proteolytic *C. botulinum* spores should be assumed, and suitable controls (pH or Aw) put in place. These assessments have not however indicated any shelf life requirements (times or temperatures) if the controls are not in place. In these situations where no specific controls are recognised, recommendations to employ predictive microbiology or challenge testing are often given.

One issue noted while considering the risks presented by non-proteolytic *C. botulinum* in chilled MAP/VP products, is that while challenge test data may indicate the potential for growth and toxin formation, it is known that many thousands of millions of packs of product of this type have been sold around the world, with no evidence of botulism having occurred (except very rarely, when a product has been temperature abused). The use of data from this large commercial production enables an assessment of the risks arising from these products. This has been done

previously for proteolytic *C. botulinum* in canned meats, and this type of approach adds value to an assessment of non-proteolytic *C. botulinum* in chilled MAP/VP products. Some very preliminary data assessment indicates that the safety units for cooked chilled foods, sliced cooked meats and raw red meats are all >9.8 (i.e. 1 in >10^{9.8} packs are associated with botulism) while for smoked fish it is estimated that the safety unit is >8.0 (i.e. 1 in >10^{8.0} packs are associated with botulism). These of the same order as for canned meats.

10. Conclusions

1. It is concluded that for short shelf life foods where other controlling factors are not identified, the FSA should include in their document, “storage at ≤8°C and a shelf-life of ≤10 days”, rather than “storage at ≤5°C and a shelf-life of ≤10 days or storage at 5°-8°C and a shelf-life of ≤5 days”. This conclusion is based on the extensive sales of chilled foods without any incidence of foodborne botulinum (when correctly stored). It is cautioned, however, that if present, non-proteolytic *C. botulinum* can form toxin in 10 days and less at 8°C, and there is insufficient clear information as to what the safety margins are in foods as sold, particularly when attempting to take into account the temperature performance of the complete chill chain throughout foods’ shelf lives. Great care must be used when modifying current industrial practice (e.g. extending the shelf-life of chilled foods over that currently used), and in the development of new products. Since, although current industrial practice appears safe, it is possible that chilled foods could be produced for which a 10 day shelf life at 8°C would not be suitable. It would seem logical to apply this approach to all chilled food sold in the UK.

2. The safety of short shelf life commercial chilled foods in the UK (and internationally) relies on the presence of one or more “unknown controlling factors”, the magnitudes, variabilities or natures of which are not known. Research is needed to improve understanding of these “unknown controlling factors”, in order to aid the continued safe development of chilled foods in the UK (and internationally).

3. It is concluded that for foods where no specific controlling factor can be identified, the maximum shelf-life is 10 days, and that this commences once the product is first vacuum or modified atmosphere packed. The shelf-life should not be restarted if the product is subject to a further packing under vacuum or modified atmosphere, unless other controlling factors (as described by the ACMSF (1992)) are applied.

4. Software tools and predictive models should be developed to contribute to the continued safe development of chilled foods. Software tools could be built using existing data and models, for example to describe the effect of time/storage temperature during manufacture, distribution, retail storage and domestic storage on time to toxin formation by non-proteolytic *C. botulinum*. There would be merit in including distributions of time and temperature. Software packages could also be developed, using existing data, to describe the effect of heating time and temperature and incubation temperature (and also mild preservative factors) on time to toxin formation from 10⁶ spores of non-proteolytic *C. botulinum*. Predictive models are not available that describe the effect of nitrite on growth of non-proteolytic *C. botulinum* and further work is needed in this area (e.g. the current model in ComBase Predictor could be extended to a four factor model, with nitrite added).

5. 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.

6. The last surveys of UK domestic refrigerator temperatures and the temperature of UK mail order chilled food during distribution were carried out in the early 1990s. In view of the elapsed

time, there would be merit in repeating these surveys. This would provide up to date information on current practice.

7. It is proposed the UK continues to strive for better temperature control throughout the chill chain (including domestic storage), and that 5°C is adopted as a target for best practice. This could be aided by new domestic refrigerators that include chill compartments and a temperature measuring device to assist consumers in assuring the appropriate chilled storage of foods. This proposal is made in order to further extend the margins of safety of chilled foods with respect to psychrotrophic foodborne pathogens (since their growth is slower at 5°C than 8°C), rather than on the basis of any specific problems.

11. References

A full list of references is included in the main report.