**ACM / 500**

**INFORMATION PAPER**

**ADVISORY COMMITTEE ON THE MICROBIOLOGICAL SAFETY OF FOOD (ACMSF)**

# *CLOSTRIDIUM BOTULINUM* AND THE ACMSF ADVICE AND INDUSTRY CODE OF PRACTICE ON VACUUM AND MODIFIED ATMOSPHERE PACKAGED PRODUCTS

## Purpose

1. To inform ACMSF of the outcome of discussions:

- with the Institute of Food Research (IFR) and Campden and Chorleywood Food Research Association (CCFRA) regarding the adequacy of the current ACMSF advice and industry Code on vacuum and modified atmosphere packaged products currently on the market. Secondly, whether IFR and CCFRA were aware of any other products of concern not covered by the advice and industry Code,

- with LACOTS regarding areas of difficulty for enforcement staff and

- about the role of challenge testing.

2. To ask the Committee whether, in the light of these discussions, any further advice from the ACMSF is required on this subject.

**Secretariat**
**November 2000**

**Summary**

At their meeting of 21 June 2000 the ACMSF requested information to enable them to form a view on whether their current advice (published in 1992) and the industry Code on VP and MAP products (published in 1996) were sufficient, or whether there was need for a review. Information was also requested on what the areas of difficulty for enforcement officers were and the case for challenge testing. In preparing this document, the IFR, CCFRA and LACOTS were consulted.

Although the retail market in VP and MAP products has expanded since publication of the ACMSF advice and industry Code, the advice contained within these documents was still considered valid with regard to risks associated with *Clostridium botulinum (C. botulinum)* in VP/MAP chilled products. However, the advice may need to be reiterated and simplified, in order to make it more accessible to a wider audience.

There has been expansion in a number of product ranges that are not specifically addressed in the ACMSF advice or the industry Code, for example VP/MAP baked products with extended shelf-life, and vegetable/spices/herbs in oil. There may be a need to consider these products further with regard to compliance with key controlling factors.

With regard to enforcement, LACOTS have identified difficulties that Local Authorities face relating to products with a long shelf-life, where few, if any of the key controlling factors are being applied. In such cases the recommendation is to carry out predictive modelling and/or challenge testing in order to demonstrate safety of the product. However, the decision to do this would need to be considered carefully, not only because of cost implications, but because it may become a test case with implications for local authorities and the whole food industry.

The view of the ACMSF is requested on the issues raised in this paper.

**Background**

1. The rapid growth in the chilled food market prompted the ACMSF at its June meeting in 1991 to review microbiological aspects of the safety of vacuum packing and associated processes such as “Sous Vide”, with particular reference to *C. botulinum.*

2. As a result the Committee set up a Working Group to produce a report on chilled foods and the hazards associated with psychrotrophic *C. botulinum* in chilled products. The Group looked closely at the preservation systems used, while taking into account a number of controlling factors. One of the recommendations of the report, which was published in 1992[11] was that there should be a comprehensive and authoritative Code of Practice for the manufacture of vacuum packaged (VP) and modified atmosphere packaged (MAP) chilled foods with particular regard to the risks of botulism (a summary of the recommendations from the report is provided at Annex A). In 1995, revised recommendations were made by the ACMSF[13] (see Annex A). The subsequent Code of Practice was published by Campden and Chorleywood Research Association (CCFRA), in May 1996[14] (a summary of the main points highlighted in the Code is provided at Annex B).

4. Since the publication of the ACMSF advice and the industry Code, there has been further growth in both the diversity and volume of the retail market in chilled foods and other ready-to-eat products which are designated for extended storage at ambient temperature. Following concerns about the potential for growth and toxin production by *C. botulinum* in some of these products, the DH commissioned the Institute of Food Research (IFR) to carry out a review of selected potential problem areas (ACM/479)[20]. This was discussed at the meeting of the ACMSF on June 21 2000. A summary of the main issues relating to the potential for growth and toxin production by *C. botulinum* (psychrotrophic and mesophilic) in these products is presented in Annex C.

5. The Committee invited the Food Standards Agency (FSA) in consultation with IFR and CCFRA to consider whether the products covered in ACM/479 and any others that might be on the horizon, necessitated a review by the ACMSF of its 1992 report, and whether there was a need to amend the industry Code. The Committee also suggested that the Local Authority Co-ordinating Body on Food and Trading Standards (LACOTS) be consulted for their views on areas of difficulty for enforcement staff and that the case for challenge testing should be discussed with

Campden and IFR. Based on information provided in this paper, the Committee would take a view on the need to offer advice to the FSA on the aspects covered.

**CCFRA View**

6. With regard to the current ACMSF advice and industry Code, CCFRA considered that there was no need to amend the advice contained within these documents concerning risks associated with VP and MAP chilled products, although it would be useful to reinforce the advice they contained. The essential message remains that adherence to the five controlling factors is required to prevent growth and toxin production by *C. botulinum* in chilled products, and that anyone making or developing new products should adhere to these factors.

7. Regarding specific products considered in the IFR report the following points were noted:

- ambient stable VP beetroot is a product that is not covered by the ACMSF advice and industry Code, and should be given an $F_0$3 thermal process. If the product is for chilled storage, it should adhere to ACMSF advice and the industry Code.

- there may be an issue with regard to the great expansion in the area of baked goods, such as part-baked breads. Although most of these products are designated for ambient temperature storage, they have long shelf lives and are not specifically addressed in the industry Code or ACMSF advice. In some cases, a small number of products had been challenge tested, and shown not to support growth and toxin production by *C. botulinum*.

- there may also be an issue for vegetable/spices/herbs in oil, particularly imported products where information on product composition and manufacturing process would be limited. These may need to be examined with regard to compliance with key controlling factors

- in general, ambient stable heat processed foods rely on a different set of controlling factors than VP/MAP products and take into account the potential for growth and toxin production by psychrotrophic and

mesophilic *C. botulinum.* Recommendations covering these products are contained in the DH Guidelines on Heat Preserved Foods (1994)[1].

- CCFRA were not aware of emerging products that might give rise to concern with regard to the potential risk of botulism. They have developed 'New Foods' software published as a CD-ROM by Blackwell Science that provides detailed product information and which is updated regularly. This can facilitate the gathering of information on what types of retail products there are and the rate at which the market is changing

8. CCFRA informed the FSA that a project was underway to examine the issue of spoilage and pathogenic organisms (including *C. botulinum*) in acid preserved foods. The preliminary findings will be available early next year.

9. CCFRA considered that a revision of the DH advice for cook-chill catering[2] was required for a number of reasons. The document was published in 1989 and the information and guidance in the document are now dated. Supply chains and technology in catering practice has changed, with the advent of new processing technologies such as microwaves and vacuum and modified atmosphere packing of raw materials and food products. There has also been developments in legislation (food hygiene and temperature control) and advice (codes of practice, guidelines).

10. Since the meeting, CCFRA have indicated that while they believe the current ACMSF advice and industry Code remain valid, the information is not readily accessible and is overly complicated for much of the target audience (i.e. SMEs, independent butchers, delicatessens etc). They consider that there is need for a more succinct and simplified guidance than that contained within the Code, especially with regard to safety and shelf-life limitations. Consideration could also be given to incorporating an extended table of product types. New guidance could be used to help non-scientists understand the safety criteria and by enforcement officers to advise manufacturers in their districts.

**IFR View**

11. Some of the main points made in the IFR report (ACM/479)[20] were reiterated.

- shelf-stable (ambient) VP beetroot was an area for concern, as the product is intended for long shelf-life storage at ambient temperature and is low acid (pH 5.2-5.3), with a water activity ($a_w$) of 0.98-0.99. There was a need to identify how the required protection factor is achieved and to confirm that it is applied. For refrigerated products, there is a need to ensure that the appropriate protection factor is applied with respect to spores of non-proteolytic *C. botulinum*.

- VP paneer cheese intended for refrigerated storage was a possible area of concern since Food MicroModel predicted that conditions within the product would support growth and toxin production by non-proteolytic *C. botulinum* in 20 days at 8°C, and in at least one case the assigned shelf-life was 42 days. Unless other controlling factors are contributing in a significant way, this product would not appear to meet the recommendations of the ACMSF on chilled foods.

- part-baked breads stored at ambient and refrigerated temperatures were evaluated. While part-baked breads had a low $a_w$ (0.94-0.95), their pH (5.3-6.8) was a in range that could support growth and toxin production by *C. botulinum*. Furthermore, addition of spices to some of these products could potentially contaminate the product with spores as well as leading to localised areas of higher $a_w$ and/or pH. Whilst these products may be a low risk, confirmation of achieving required protection factors is required.

- with regard to shelf-stable vegetable/spices/herbs in oil, it was not clear what combination of processing and formulation is used to provide protection against *C. botulinum* in these products. There is a need establish what the controlling factors are, that they provide the required protection factor, and to confirm that they are appropriately applied.

- with regard to shelf-stable canned fruits, producers need to understand whether their products are low-acid, high-acid or acidified foods, and to process so as to achieve the required protection factor with regard to *C. botulinum*. The resulting information should be made available to enforcement agencies.

12. IFR noted that the issue of concern is that for many of the products, the basis for safety is not clear, and needs to be established. For shelf-stable products, that is either an $F_0$3 treatment or a combination of heat treatment and preservation factors that would give equivalent protection ($F_0$3 is the minimum heat treatment (equivalent to 3 min at 121.1°C) required to destroy *C. botulinum* spores assuming a z value of 10°C). For refrigerated products, the basis of safety should be a protection factor of 6 with regard to spores of non-proteolytic *C. botulinum* as described in the 1992 ACMSF report[11]. For products intended for refrigerated storage, the margin of safety could be improved by reducing the pH to ≤ 5.0 or limiting product shelf-life".

13. IFR drew attention to the fact that that the 1995 ACMSF recommendation was not explicitly incorporated in the industry Code. This stated that "where chilled storage is the sole controlling factor, products stored between 5 and 10°C should have an assigned shelf-life of 5 days or less. If a shelf-life of up to 10 days is required, the chilled storage temperature should be 5°C or below. The Code states that "for products with a shelf-life of 10 days or less at >3 to ≤8°C, there are no specific requirements in terms of heat treatment or preservation system with respect to control for *C. botulinum,* unless risk assessment shows otherwise".

14. IFR also drew attention to recent published work[3, 4, 24] suggesting that the heat treatment (90°C for 10 min or equivalent) recommended by ACMSF[11] as that required to deliver a protection factor of 6 with regard to spores of non-proteolytic *C. botulinum* might not be adequate. Two studies[3, 4] have reported growth and toxin production at 35-63 days during storage at 8°C, and at 14-37 days during storage at 12°C following application of the recommended heat treatment.

15. IFR noted that they had been approached by LACOTS and individual Environmental Health Officers (EHOs) with regard to the safety of many refrigerated products that do not seem to comply with the ACSMF recommendations or the industry Code. An example is vacuum-packed cooked meat prepared by some butchers. IFR emphasised a need to establish what the extent of these problems were (probably with LACOTS), and then identify what the critical control points and the basis of safety were.

**LACOTS concerns regarding safety of products and enforcement**

15. EHOs working for Local Authorities (LAs) enforce the relevant food hygiene legislation, including the requirement that business operators have a hazard analysis system or, in the case of licensed butcher's shops, the full HACCP system[5, 6].

16. In order to ensure food safety and correct enforcement with respect to VP or MAP operations taking place in food businesses, LAs refer to the ACMSF advice and industry Code. LAs have looked to LACOTS for more practical guidance and to give advice when difficulties arise, such as those outlined in the following paragraphs.

17. Some LAs have raised concerns about safety of products with long shelf lives, typically 21-42 days, where manufacturers have not demonstrated that at least one of the Code's recommended five controls is being applied. The LAs and LACOTS view has been that the Code is the most current scientific assessment on how the hazard presented by *C. botulinum* should be controlled, and it must be followed. This appeared to be particularly true for small (and some medium sized) businesses.

18 VP and MAP products do, so far, have a very good safety record with regard to botulism, which may be due to application of key controlling factors or a combination of factors that have not been demonstrated scientifically to control *C. botulinum*. However, in the latter case the level of protection may be less than that advocated by the ACMSF and the Code. The concern is that safety here may be reliant on there being a low likelihood of spores being present, which would not be a satisfactory basis for safety.

19. The problem for LACOTS is how to determine whether a combination of factors providing protection against *C. botulinum* is in operation, so that the decision on whether or not to require challenge testing may be taken with confidence. LACOTS' view is that not enough is known about the combination of factors that might be in operation in a large proportion of cases. They therefore feel that if the controls specified in the Code are not being applied, the product should be challenge tested to show that *C. botulinum* will not grow during its specified shelf-life.

20. LAs are finding themselves faced with businesses that are not complying with the Code's requirements. These businesses fall back on their safety track record as a reason for challenging attempts by LAs to get businesses to either introduce relevant controls or undertake predictive modelling and/or challenge testing.

**LACOTS concern regarding how to get expert advice**

21. The industry Code to which LAs refer in carrying out their enforcement duties is quite technical. It is not written specifically for enforcers or typical small businesses and is therefore perceived as inaccessible.

22. This raises the issue of where LAs get their advice. The concern would be for accurate and appropriate expert advice to be available at an economically viable rate. This would also be an issue for small businesses.

23. LACOTS are supportive of a succinct and practical document addressing these issues, and which would bridge the gap between ACMSF advice and the industry Code on the one hand, and the needs of food businesses and enforcers on the other.

**The Case for Challenge Testing**

24. The ACMSF report and industry Code recommend that the safety of VP and MAP products not having the recommended controlling factors should be demonstrated either by predictive modelling and/or challenge testing. In general, the approach taken in assessing the potential for hazards from *C. botulinum* would use a combination of predictive modelling and challenge tests.

25. Predictive modelling (eg. Food MicroModel) offers a means of describing the growth and survival of bacterial pathogens with respect to the main controlling factors such as storage temperature, pH, and salt/water activity. Some models are available for other factors (eg. nitrite). Major stakeholders (CCFRA and IFR) recommend that modelling should not be used in isolation, but as a tool to guide the need for challenge testing.

26. Microbiological challenge testing simulates what can happen to a food product during distribution and subsequent handling. In the case of *C. botulinum,* this involves inoculation of the food with spores from a number of different strains, holding the food under a range of environmental conditions, and testing for growth and production of (functionally active) toxin.

27. For *C. botulinum* the mouse bioassay[7] is used, as it is the only test that measures *in vivo* activity of the toxin. However, attempts have been made to develop alternatives, including ELISAs[8], PCR based methods[9] and activity assays[10].

28. It should be noted that challenge testing can only be carried out at a limited number of centres and is a very costly procedure (with costs varying from about c. £1500 to c. £50,000, depending on the required experimental design and the number of food types being tested). Hence the use of challenge testing would be an issue for most companies, but particularly for small businesses.

29. With regard to the role for challenge testing, the major stakeholders (Campden, IFR and LACOTS) are in agreement that VP chilled foods that do not have the appropriate controlling factors should have a shelf life of <10 days or have suitable predictive modelling/challenge test data to show that psychrotrophic *C. botulinum* would be unable to grow in the product. Shelf-stable foods whose production and composition do not include appropriate controlling factors should be modified to include these, or have suitable predictive modelling/challenge test data to show that mesophilic *C. botulinum* would be unable to grow in the product.

30. LACOTS wants advice for situations where the recommendations in the Code have not been adhered to, and whether it is reasonable and necessary to require that the product should be challenge tested to show that *C. botulinum* will not grow during its specified shelf-life.

31. Small businesses have argued that their “good record” with respect to incidents of food-borne botulism could be taken as an indication that there are combinations of protective factors present. LACOTS and LAs do not believe a ‘good record’ is enough, but are concerned regarding what should be seen as the minimum businesses should do to assure food safety. Some businesses and representative associations have stated that requiring compliance with the code would be excessive and would result in businesses closing down.

## Conclusions

32. With regard to the 1992 ACMSF Report and the industry Code, the general view is that the advice contained within these remains valid and does not require

amendment. However, there is need to consider ways of making this advice more accessible, for example by simplifying it and placing it on websites. Any simplified advice could take into account the 1995 ACMSF advice[13].

33. It is apparent that for LAs and businesses, particularly SMEs, there can be difficulty in identifying sources of expert advice on the food safety issues relating to C. botulinum and VP/MAP. Whilst this could be at least partly rectified by the production of the simplified guidance suggested above, there may be a need for LAs and businesses to discuss problems directly with an expert. As such, the provision of a list of organisations/experts to which they could refer may be useful.

34. Whilst it is recognised that there would be difficulties for many businesses if they had to challenge test their products, this should still be the required option if they are unable to demonstrate that their product does not meet the recommendations outlined in the ACMSF Report and industry Code. Predictive modelling, whilst helpful in identifying the likelihood of growth of *C. botulinum* in a product, is not an alternative to challenge testing.

35. Although this paper has primarily focused on VP and MAP products, consideration may need to be given to the development of simple guidance for businesses, and consumers contemplating home bottling, in relation to safety issues associated with vegetable in oil products.

**Issues for the ACMSF to Consider**

i. ACMSF to summarise (via a small working group or the Secretariat) its 1992/1995 advice, and to consider ways of making it more accessible, for example by publication on the Committee's website. The emphasis would be that the advice was still valid, but communication was being improved.

ii. The industry Code to be simplified to make it more accessible and relevant for the target audience. Interest has been expressed by CCFRA and LACOTS on this option which the FSA could take forward through a small working party.

iii. In view of recently published work (see paragraph 14), does the heat treatment recommended by the ACMSF to control for *C. botulinum* need to be reconsidered?

iv. A list of organisations/experts to be identified to which small businesses trade associations and LAs can refer for expert advice across the range of products considered in this paper.

v. Guidance to be developed to address the dilemma for SMEs and LAs on challenge testing/predictive modelling in cases where recommendations of the Code are not being adhered to.

vi. On the issue of products in oil, consideration to be given to developing advice for businesses, and consumers contemplating home bottling.

**ANNEX A**

## ACMSF 1992 Advice[11]

1. The Committee made a number of recommendations in their report for the control of *C. botulinum* in VP and MAP chilled foods. These included:

- food manufacturers should assess all new food processing procedures to ensure elimination of the risk of botulism (R1)

- in addition to chill temperatures of less than 10°C, the following 5 controlling factors should be used singly or in combination to prevent growth and toxin production by psychrotrophic *C. botulinum* in chilled foods with an assigned shelf-life of more than 10 days (R4 and R7):

  - a heat treatment of 90°C for 10 min or equivalent lethality
  - a pH of 5 or less throughout the food matrix
  - a minimum salt level of 3.5% in the aqueous phase throughout the food matrix
  - a maximum $a_w$ of 0.97 throughout the food matrix
  - a combination of heat and preservative factors which can be consistently shown to prevent growth and toxin production by psychrotrophic *C. botulinum*

- food manufacturers, caterers and retailers should provide evidence to demonstrate to enforcement authorities that an assigned shelf-life is appropriate to ensure microbiological safety of food (R5)

- surveillance of vacuum packaged (VP) and modified atmosphere packaging (MAP) foods should be carried out, focusing on those areas designated as high priority for growth and toxin production by psychrotrophic *C. botulinum* (R13). The Government reported at the meeting of the ACMSF in January 1998[12] that considerable surveillance of VP and MAP products had been done. Preliminary investigations indicated that the market for “Sous Vide” products in the UK was small.

- There should be a comprehensive code of practice for the manufacture of VP and MAP chilled foods, with particular reference to the risks of botulism (R18)

2. In their report, the ACMSF grouped chilled foods of concern into three categories (low, medium and high priority for attention) reflecting the level of risk considered to be present for growth and toxin production by psychrotrophic *C. botulinum*. Categorisation was based on the composition and processing of the product, the form of packaging and controlling factors present. Controlling factors used in assessment included the water activity, pH, chill temperatures, nitrite and shelf-life.

3. Products of low priority for concern included yoghurt, fresh meat and fish, while products of medium priority for concern included meats, vegetable pates and filled pasta products. Products of high priority for attention are those where abuse of shelf-life or chill temperature conditions could result in growth and toxin production by psychrotrophic *C. botulinum,* and included smoked fish and cuisine Sous Vide products.

**Revisit of ACMSF Advice, 1995[13]**

4. In the light of additional information, the ACMSF recommended in 1995[13] that where chilled storage is the sole controlling factor, chilled foods stored between 5 and 10°C should have an assigned shelf-life of 5 days or less. Where a shelf-life of up to 10 days is required, the Group recommended that the storage temperature should be below 5°C.

5. The ACMSF considered that there was no additional information available at that time to necessitate amendment of any of the other recommendations[13].

**ANNEX B**

## Industry Code of Practice, 1996[14]

1. The Code makes the following essential points for the manufacture of VP and MAP chilled foods:

- there should be evidence to show that all Critical Control Points are under control
- all starting materials should be delivered under appropriate conditions, (eg chilled temperatures), otherwise they should not be used for the intended purpose
- chilled materials should be maintained at chill temperatures throughout storage
- during preparation the product temperature should ideally be maintained below 5°C
- cooked ingredients must be adequately segregated from raw ingredients
- it is critical that all preservation factors are controlled and meet specified requirement for every batch of product produced
- after cooking, products must be cooled as rapidly as possible and should be transferred to chilled storage as soon as possible
- it should be ensured that correct vacuum or modified atmosphere has been applied and that all seals are intact
- it is critical that the temperature during storage and distribution is controlled and meets the specified requirements
- it is critical that the shelf-life of a product is defined and based on the preservation factors used and that the product is used within the shelf life
- there should be an effective withdrawal procedure to ensure that any product which does not conform to the process requirements can be effectively traced and returned if necessary

2. When the Code was published, the Department of Health wrote to all Local Authorities drawing attention to the document with a view to its purchase. In addition, CCFRA advertised it widely in the relevant press.

3. CCFRA have previously published a number of other guidelines in this area, including: Guidelines for Modified Atmosphere Packaging (Technical Manual No 34, 1992)[15] and Sous Vide Processing (Technical Manual No 39, 1992)[16]. The EU published a booklet on 'Harmonisation of Safety Criteria for Minimally Processed Foods' in 1999[17]. The US Government has published the following guidelines in this area: the 1997 US Food Code (revised in 1999), Annex 6, dealing with reduced atmosphere and vacuum packaging[18], and Thermally processed low-acid foods packaged in hermetically sealed containers[19].

## ANNEX C

## IFR Review[20]

1. The Department of Health commissioned IFR to review review (ACM/479)[20] of a selection of products where there were perceived risks with regard to *C. botulinum*.

- vacuum packed beetroot (stored at ambient temperature)
- vacuum packed paneer (stored at refrigerated temperature)
- part-baked bread (stored at ambient and refrigerated temperature)
- vegetables/spices/herbs in oil (stored at ambient temperature)
- canned fruit with high pH (stored at ambient temperature)

2. Two types of problem were identified: either that there was no evidence that a) the recommended controlling factors were being applied, or b) that safety appeared to rely on combinations of controlling factors. In the latter case, it was not clear that the combination of factors a) deliver the required protection factor and b) were being appropriately applied and recorded. Both (a) and (b) need to be satisfied. The report came to the following conclusions:

- for some products, particularly those for extended shelf-life storage at ambient temperature (such as vacuum packed beetroot), information is needed to show that this product provides the same protection factor against survival and growth of *C. botulinum* as do other low-acid, heat processed foods in hermetically sealed containers

- for vegetables/spices/herbs in oil on retail sale in the UK, more information is needed about the composition and methods of processing, as is an understanding of the basis for safety in relation to *C. botulinum*. Manufacturers need to demonstrate that low-acid products provide the same protection against *C. botulinum* as do other similar low-acid, heat-processed foods

- there is need to ensure that production and/or formulation of paneer cheese (a refrigerated product with an intended shelf-life of at least 42 days) provides the required protection factor for *C. botulinum*

- for canned fruit products, there is need to ensure accurate classification of acid level, and that the required protection factor is applied

- for part-baked breads stored at ambient or refrigeration temperature, the required protection factor against *C. botulinum* needs to be ensured, for example by controlling water activity and pH

- emphasis on the use of HACCP by the food industry to identify, analyse and control risks due to *C. botulinum*

**ANNEX D**

## *Clostridium botulinum*

### Nature of organism and pathogenesis

1. Botulism is a rare but severe paralytic disease caused by an extremely potent neurotoxin produced by the spore-forming anaerobic bacterium *C. botulinum.* There are three main types of botulism: foodborne, wound and infant botulism. While the former is an intoxication caused by ingestion of pre-formed toxin in food, the latter two are due to infection of wound or infant gut respectively with the organism which can then grow and produce toxin *in situ*. The toxin causes a progressive flaccid paralysis, which affects respiratory muscles and may result in death if not treated. Other symptoms of the disease include nausea, dry mouth, double vision, muscle weakness and constipation.

### Physiology and Ecology

2. Six physiologically distinct organisms are capable of producing the botulinum neurotoxin. These include *C. botulinum* groups I, II, III and IV, and some strains of *C. butyricum* and *C. baratii*. *C. botulinum* group I and *C. botulinum* group II are most commonly associated with foodborne botulism. There are seven serotypes of botulinum toxin (A to G), four of which (A, B, E and F) are associated with human illness.

3. *C. botulinum* Group I is proteolytic and mesophilic and produces types A, B and F toxins. They have a minimum growth temperature of 10°C (optimum range 35-40°C), pH of 4.6 and water activity of 0.93. Their spores are more heat-resistant than those of Group I, although they are of little concern in adequately refrigerated products.

4. *C. botulinum* Group II is non-proteolytic and psychrotrophic and produces types B, E and F toxins. They have a minimum growth temperature of 3°C (optimum range 18–25°C), pH of 5.0 and water activity of 0.97. Psychrotrophic *C. botulinum* can grow and produce toxin down to 3°C, although the rate at which this will occur at low temperatures will be slow. Their spores are more sensitive to heat than those of Group I, and can be adequately destroyed by appropriate heat treatment.

5. The organism and its spores are widely distributed in nature, being found in the soil, salt and fresh water, as well as in the gut of animals and fish. They may be introduced into processed foods through raw materials or by contamination post processing.

6. As *C. botulinum* is strictly anaerobic, botulism is only associated with foods that can provide suitable anaerobic conditions. Spores allow the organism to survive in a dormant state until exposed to conditions that can support growth and toxin production. They are also heat-resistant and can survive for 2 hours in boiling water. They are only killed under stringent food processing conditions, and can survive in foods that are minimally processed or incorrectly cooked.

7. Traditionally botulism has been associated with home-prepared foods, although outbreaks do involve commercial foods and foods prepared in restaurants.

**Epidemiology**

8. Foodborne botulism is a disease of humans and animals. It has been reported from many countries around the world, including Poland, China, Iran, USA, Germany, Japan, Norway, France and Italy. In recent years, about 450 outbreaks of foodborne botulism with about 1000 cases are reported worldwide annually[21]. In one report, 70% of the outbreaks and 50% of the cases were reported from Poland[22]. Actual incidence may be higher due to under-reporting. Although foodborne botulism is rare compared to many other forms of foodborne illness, it has a high fatality rate and prolonged recovery period with associated high health costs.

9. Food types implicated in outbreaks include vegetables, fish and meat, the majority of which have been home prepared or home preserved. Two large outbreaks of type E botulism in the early 1960s in North America and one in 1970 in Germany were associated with vacuum-packed hot-smoked fish. Investigation of these outbreaks showed that the salting and smoking treatments had not been sufficient to eliminate *C. botulinum* or inhibit its growth during storage of the products. Three outbreaks of type A botulism in the United States were associated with potato salad where cooked or partly cooked potato had been stored at ambient temperatures under anaerobic conditions before processing. In 1988, an airline passenger in Europe contracted type A botulism from a pre-packed vegetable salad. Other foods implicated in recent years include baked potato which was wrapped in aluminium foil at ambient temperature, conditions that subsequently became

anaerobic and permitted growth and toxin production. Cheese sauce and garlic in oil have also been implicated.

11. Botulism is very rare in the UK, and since the first reported outbreak in 1922, there have only been 11 other outbreaks, involving a total of 58 cases with 19 fatalities. The range of foods involved includes meat pie, macaroni cheese, canned and pickled fish and hazelnut yoghurt. The hazelnut yoghurt incident was the largest outbreak of foodborne botulism reported in the UK to date, when 27 people fell ill and one person died[23]. Although the pH of most yoghurt is too low for toxin production *in situ*, the toxin (type B) had been produced in the hazelnut puree which was inadequately heat-processed.

12. Important features in these outbreaks were temperature abuse and anaerobiosis created by vacuum packing or wrapping in aluminium foil.

**Control**

13. The control of this organism in foods relies on achieving defined protection factors, through heating and/or combinations of other controlling factors (e.g. temperature, pH, $a_w$ and salt content). Although preserved foods may be potentially hazardous, growth and toxin production by *C. botulinum* usually occurs as a result of faulty manufacturing conditions and abuse of storage temperature.

## References


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