

Report

# **Consultation Details - Report on Report on Botulinum Neurotoxin-Producing Clostridia**

## **Consultation**

### **Report on Botulinum Neurotoxin-Producing Clostridia**

**Launch date: 9 June 2023**

**Respond by: 31 August 2023**

This consultation will be of most interest to

The food industry, health care practitioners, consumer bodies and government departments with an interest on the issue of foodborne botulism in humans.

## **Purpose of the consultation**

The ACMSF is inviting stakeholders views on their draft report. In particular, they would welcome comments on the report's conclusions and recommendations. Comments specifically on risk management are not within the remit of the Committee and are therefore not within the scope of this consultation.

The Committee returned to review foodborne botulism after its 1992 Report on this issue because of the high severity of the disease and to consider new information on *C. botulinum*, botulinum neurotoxin-producing clostridia and on food processing and packaging technologies. ACMSF would welcome comments, information or observations on the review, particularly material on the latest science and any observation on the conclusions and recommendations made in the report. In producing its report, the ACMSF has focussed on the UK situation and have drawn on the international scientific literature where appropriate.

# How to respond

Responses to this consultation should be sent to:

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## Introduction and background

The Advisory Committee on the Microbiological Safety of Food (ACMSF) is a scientific advisory committee that provides the Food Standards Agency (FSA) with independent expert advice. This helps the Agency ensure that policy development and consumer advice in relation to the microbiological safety of food are based upon sound science and relevant practical experience and expertise.

In 1992, the ACMSF published a report on “Vacuum Packaging and Associated Processes”, which forms the main evidence base for FSA guidance on vacuum packaged and modified atmosphere packaged chilled foods.

In the UK the frequency of occurrence of foodborne botulism is very low (very rare but cannot be excluded). However, the severity of botulism is classified as high (severe illness: causing life threatening or substantial sequelae or long-term illness). High severity demands that risk assessments for foodborne botulism should be regularly updated to keep in step with the changing practice of food production and with improved understanding of the biology of *C. botulinum* and

other neurotoxigenic clostridia.

Therefore, in April 2021, a proposal was put forward to the ACMSF to form an *ad hoc* subgroup to update the risk assessment of non-proteolytic *Clostridium botulinum* in chilled foods based on current industry practices. In addition, FSA risk management requested advice on the safety and shelf-life of VP/MAP and low oxygen ambient-stable foods with respect to botulinum-toxin producing clostridia.

## The report

The *Ad Hoc* Group's draft report was presented to the full ACMSF Committee in February 2023 where it was approved by the Committee to be published for a twelve week public consultation. The structure of the report is as follows:

- The Executive Summary provides the overall risk assessment and key recommendations.
- Chapter 1 provides the background to the review, and a summary of FSA current guidance, an introduction to the *Clostridium* genus, the botulinum neurotoxin-forming clostridia and non-clostridia, the botulism neurotoxins and the botulism illness. It also introduces the food processing relevant to this hazard.
- Chapter 2 discusses the taxonomy, or naming conventions, of botulinum neurotoxin-forming clostridia and non-clostridia, and their toxins.
- Chapter 3 provides a summary of the current detection methods for botulinum neurotoxin-forming clostridial cells, spores and botulinum neurotoxins.
- Chapter 4 discusses the UK and global epidemiology of botulism, with a focus on foodborne botulism trends.
- Chapter 5 summarises the occurrence in foods and the physiological responses in food environments for botulinum neurotoxin-forming clostridia, focusing on the effects of temperature, pH, water activity, nitrite, gaseous environment, novel processing and packaging technologies and other factors.
- Chapter 6 forms the risk assessment based on the information in preceding chapters.
- Chapter 7 provides the *Ad Hoc* Group's recommendations.

## Key findings and recommendations

- The frequency of occurrence of foodborne botulism remains very low (very rare but cannot be excluded) with high severity (severe illness: causing life threatening or substantial sequelae or long-term illness).
- In comparison with proteolytic *C. botulinum* and non-proteolytic *C. botulinum*, other clostridia such as neurotoxigenic *C. butyricum*, *C. baratii*, and *C. sporogenes* have only very rarely been associated with foodborne botulism. Data suggest that their growth and survival characteristics (including thermal and acid resistance) are comparable to proteolytic *C. botulinum*.
- Evidence continues to show that traditional low acid foods that experience a valid botulinum cook or other valid preservation step are exceptionally safe with respect to botulism. Since the 1992 ACMSF report, there have been very few reports of incidents in which UK consumers were exposed to botulinum neurotoxin in food, with only 10 reported outbreaks involving 13 cases. Eight of the ten most recent outbreaks involved foods produced or acquired abroad. For chilled foods, the reported incidents of botulism are dominated by incorrect home storage of food at temperatures exceeding 8°C.
- Existing controls act to maintain safety with respect to botulism in chilled and ambient manufactured foods. It is recommended that FSA guidelines should be slightly modified to include in the control actions “a combination of controlling factors which can be shown consistently to prevent growth and toxin production by non-proteolytic *C. botulinum*”. This can provide flexibility to support innovation by food business operators that can lead to reduced energy usage, waste reduction and safe shelf-life extensions.
- It is emphasised that nitrites exert an important anti-*C. botulinum* effect and other preservation factors should be adjusted if nitrite concentration is to be reduced in, or removed from, foods traditionally containing it.
- An appropriate level of preparedness in the detection and investigation of foodborne botulism incidents is essential and should include consideration of risks associated with small scale production or online distribution of food. Early detection of cases and rapid, effective coordinated responses to very rare incidents are identified as crucial elements for reducing risks from foodborne botulism.
- An update to the z-value indicated by the guidelines is necessary, with  $z = 7$  and  $z = 10$  centigrade degrees to be used to evaluate equivalent thermal processes for operating temperatures below and above the reference temperature respectively.
- The evidence does not facilitate revision of the current reference process, heating at 90°C for 10 minutes or an equivalent, but this may provide a lethality that exceeds 6 order of magnitude reduction in population size, and

thus could be subject to further investigation.

- Temperature abuse has been highlighted as the cause of the majority of incidents relating to botulism in chilled foods. It is recommended that the FSA highlight the importance of temperature control in consumer food hygiene campaigns, together with adherence to recommended Use By dates, to reinforce these critical consumer food safety controls.
- It is recommended that the FSA use academic partnerships to continue developing knowledge on botulism risks associated with non-vacuum or modified atmosphere packaged foods; molecular information relating to *C. botulinum* taxonomy; information on toxin production for neurotoxicogenic *C. sporogenes*, *C. butyricum* and *C. baratii* under otherwise optimal conditions in foods.

## Consultation process

This consultation is being held for 12 weeks. **Comments are invited on the draft report and its recommendations.** Consultation is not accompanied by an impact assessment because ACMSF has no regulatory status. The finalised report will be submitted by ACMSF to the FSA and it is for the FSA to decide whether to accept the recommendations outlined in the report and whether to produce an impact assessment should the recommendations be accepted.

We aim to publish a summary of responses received within three months of the consultation ending. The ACMSF will review its draft report in the light of any comments received before agreeing a final version for publication.

## Responses

**Responses are required by 5pm 31 August 2023.** Please state, in your response, whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents).

**Please send responses to [acmsf@food.gov.uk](mailto:acmsf@food.gov.uk)**

For information on how the FSA handles your personal data, please refer to the Consultation privacy notice at <https://www.food.gov.uk/about-us/privacy-notice-consultations>'.

## Further information

If you require a more accessible format of this document please send details to the named contact for responses to this consultation and your request will be considered.

This consultation has been prepared in accordance with [HM Government consultation principles](#).

Thank you on behalf of the Food Standards Agency for participating in this public consultation.

Yours,

Iulia Gherman

ACMSF Secretariat,

Science, Evidence and Research Division

Food Standards Agency

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## **Annex A: Standard Consultation Information**

### **Disclosure of the information you provide**

Information provided in response to this consultation may be subject to publication or release to other parties or to disclosure in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 2018 (DPA) and the Environmental Information Regulations 2004).

If you want information you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence.

In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances.

Any automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding. The Food Standards Agency will be what is known as the 'Controller' of the personal data provided to us.

## **Why we are collecting your personal data**

Your personal data is being collected as an essential part of the consultation process, so that we can contact you regarding your response and for statistical purposes. We may also use it to contact you about related matters.

The Data Protection Act 2018 states that, as a government department, the Food Standards Agency/ACMSF Secretariat may process personal data as necessary for the effective performance of a task carried out in the public interest. i.e. a consultation.

## **What we do with it**

All the personal data we process is located on servers within the European Union. Our cloud based services have been procured through the government framework agreements and these services have been assessed against the national cyber security centre cloud security principles.

No third parties have access to your personal data unless the law allows them to do so. The Food Standards Agency/ACMSF Secretariat will sometimes share data with other government departments, public bodies, and organisations which perform public functions to assist them in the performance of their statutory duties or when it is in the public interest.

## **What are your rights?**

You have a right to see the information we hold on you by making a request in writing to the email address below. If at any point you believe the information we process on you is incorrect you can request to have it corrected. If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter.

If you are not satisfied with our response or believe we are processing your personal data not in accordance with the law you can complain to the Information Commissioner's Office (ICO) at <https://ico.org.uk/>, or telephone 0303 123 1113.

Our Data Protection Officer in the FSA is the Information Management and Security Team Leader who can be contacted at the following email address: [kims@food.gov.uk](mailto:kims@food.gov.uk).