



Guidance on the safety and shelf-life of vacuum and modified atmosphere packed chilled food with respect to non-proteolytic *Clostridium botulinum* – chilled fresh beef, lamb and pork

Launch date: 1 October 2020

Respond by: 11 November 2020

This consultation will be of most interest to

Local authorities, meat trade associations, meat manufacturers and food businesses with an interest in vacuum and modified atmosphere packed chilled fresh meat.

Consultation subject

Food Standards Agency (FSA) and Food Standards Scotland (FSS) review of 'guidance on the safety and shelf-life of vacuum and modified atmosphere packed chilled foods with respect to non-proteolytic *Clostridium botulinum*' in relation to the shelf-life of chilled fresh beef, lamb and pork.

Purpose of the consultation

To seek stakeholder views on how the FSA and FSS 'guidance on the safety and shelf-life of vacuum and modified atmosphere packed chilled foods with respect to non-proteolytic *Clostridium botulinum*' should apply to the shelf-life of chilled fresh beef, lamb and pork.

How to respond

Responses to this consultation should be sent to:

Email: meathygiene@food.gov.uk

Name: Mary McGlinchey

Division/Branch: Meat Hygiene Policy

Details of consultation

Acronyms

ACMSF - Advisory Committee on the Microbiological Safety of Food

C. botulinum – non-proteolytic *Clostridium botulinum*

EU – European Union

FSA – Food Standards Agency

FSS – Food Standards Scotland

VP/MAP – vacuum packed and modified atmosphere packed

Introduction

1. The FSA/FSS best practice '[guidance on the safety and shelf-life of vacuum and modified atmosphere packed chilled foods with respect to non-proteolytic *Clostridium botulinum*](#)' was issued in 2008 and was last updated in 2017. The update of the guidance in 2017 made explicit that the guidance applies to VP/MAP chilled fresh meat. The guidance recommends that a maximum shelf-life of 10 days is applied for VP/MAP chilled fresh foods in the temperature range from 3°C to 8°C, where other controls are not applied in relation to the risk of *C. botulinum*.
2. The FSA is undertaking a review of the best practice guidance in relation to the shelf-life for VP/MAP chilled fresh beef, lamb and pork.
3. The FSA is also reviewing the guidance in line with accessibility requirements, and in relation to Brexit to ensure that the guidance is fit for when the UK exits the Transition Period on 31 December 2020.

Main proposals:

4. Comments are requested from stakeholders to inform a review of the FSA/FSS '[guidance on the safety and shelf-life of vacuum and modified atmosphere packed chilled foods with respect to non-proteolytic *Clostridium botulinum*](#)' in relation to:
 - Consultation point A – To review the recommended 10-day shelf-life in relation to VP/MAP chilled fresh beef, lamb and pork in the temperature range from 3°C to 8°C as provided for in this guidance.
 - Consultation point B – To make certain amendments to the guidance as recommended in January 2020 by the ACMSF subgroup on *C. botulinum*.
 - Consultation point C - To remove any references in the guidance related to the European Union which will no longer be relevant at the end of the Transition Period.

- Consultation point D – To improve the accessibility of the guidance for users in line with accessibility requirements for public bodies.

Detailed Proposals

Consultation Point A: The shelf-life of Vacuum and Modified Atmosphere Packed chilled fresh beef, lamb and pork in respect of *C. botulinum*

5. The main purpose of this consultation is to seek comments to inform a review of the guidance in relation to the shelf-life of VP/MAP chilled fresh beef, lamb and pork in the temperature range from 3°C to 8°C where other controls are not applied in respect of the risk of *C. botulinum*.
6. This review applies only to fresh lamb, beef and pork without added ingredients or further processing beyond cutting, packing, chilling, freezing and quick-freezing. It does not apply to any beef, lamb or pork that is subject to further processing such as mincing, cooking or mixing with any other ingredients such as herbs, spices or curing salts.

Background

7. The non-proteolytic *C. botulinum* bacterium produces a very powerful toxin in food that causes the serious illness botulism, a potentially fatal form of food poisoning. In 1992 the Advisory Committee on the Microbiological Safety of Food (ACMSF) issued a [Report on Vacuum Packaging and Associated Processes](#) which considered the risk from *C. botulinum*.
8. In 2008 the FSA issued the best practice 'Guidance on the safety and shelf-life of vacuum and modified atmosphere packed chilled foods with respect to non-proteolytic *Clostridium botulinum*', which was underpinned by the ACMSF's 1992 Report. The best practice guidance included the ACMSF advice that the shelf-life of VP/MAP foods in the temperature range 3°C to 8°C should be a maximum of 10 days, when other specified controlling factors for *C. botulinum* cannot be identified.
9. The guidance provides best practice advice on how to produce VP/MAP chilled foods safely.
10. The guidance was updated in 2017 and made explicit that the guidance applies to both ready-to-eat and raw foods, including fresh meat.

Review of the guidance

11. Following representations from the fresh meat industry, the FSA is further reviewing the guidance in relation to the shelf-life of VP/MAP chilled fresh beef, lamb and pork. The meat industry has advised that no EU Member State applies, and no other country is known to apply, a shelf-life of 10 days to VP/MAP chilled fresh beef, lamb or pork in relation to the risk of *C. botulinum*. The meat industry has similar concerns about the 13-day shelf-life which it considers are based on

current shelf-life patterns which may themselves have been influenced by the 10-day shelf-life recommended in the FSA/FSS guidance.

12. The ACMSF recommendation of 13 days is based upon the findings of ACMSF subgroup who reviewed the evidence provided by industry and other scientific evidence underpinning FSA/FSS guidance.
13. Reviews carried out have found no evidence of outbreaks of botulism internationally linked to the shelf-life of such meat in other countries in the absence of temperature abuse from 1985 to July 2020.
14. The aim of the guidance review on shelf-life of VP/MAP chilled fresh beef, lamb and pork is to assess the appropriateness of the best practice guidance to assist with the application of appropriately validated shelf-life, i.e. use by dates, for VP/MAP chilled fresh beef, lamb and pork in respect of *C. botulinum*.
15. A risk management dossier will be prepared to inform the review which will include evidence provided by:
 - [The report of an ACMSF subgroup on *C. botulinum*](#) published in February 2020. The ACMSF review of recent scientific evidence on *C. botulinum* was commissioned by the FSA as part of this review. The subgroup concluded that based on current industry practice the recommended maximum shelf-life could be raised from 10 days to 13 days for VP/MAP chilled fresh beef, lamb and pork.
 - A review of whether there have been any outbreaks of botulism in the UK or internationally linked to VP/MAP chilled fresh beef, lamb and pork where there is not temperature abuse.
 - A review of the international standards and third country national standards applied for the shelf-life of VP/MAP fresh beef, lamb and pork including:
 - Details of the standards, legislation and guidance applied by other countries concerning the shelf-life of VP/MAP chilled fresh beef, lamb and pork.
 - Details of how other countries view the risk of *C. botulinum* and the need for controls to address that risk in relation to VP/MAP chilled fresh beef, lamb and pork.
 - Input from this consultation.
16. The following risk management options have been identified for consideration and we are seeking your feedback on the practical implications of these options to inform the development of the risk management dossier:
 - **Option 1:** Do nothing. Leave the guidance unchanged and continue to recommend a 10-day maximum shelf-life in the guidance to VP/MAP chilled fresh meat.

- **Option 2:** Amend the guidance to recommend a 13-day maximum shelf-life (in place of 10-days) for VP/MAP chilled fresh beef, lamb and pork as recommended by the ACMSF.
- **Option 3:** The FSA/FSS guidance is amended to no longer apply to VP/MAP chilled fresh meat beef, lamb and pork, enabling an outcome based approach to regulation. Food businesses are responsible for ensuring that food placed on the market is safe and industry led guidance would support food businesses in demonstrating the safety of the shelf-life applied for VP/MAP chilled fresh beef, lamb and pork.

Consultation Point B: Amendments to the guidance recommended by the ACMSF subgroup

17. The ACMSF subgroup on *C. botulinum* recommended in its [report](#) certain amendments to the guidance in January 2020. The recommendations were accepted by the full ACMSF at its meeting in January 2020 and were published in the subgroup's report in February 2020.
18. It is proposed that the following amendments to the FSA/FSS guidance recommended by the ACMSF subgroup should be made to the guidance under consultation point B:
 - **Challenge testing** - The subgroup recommended that detection of toxin is a minimum requirement for challenge testing, and that measuring viable counts is of merit in ensuring safety with appropriate expert advice. The subgroup recognises that current predictive models do not model toxin production and therefore recommends that all predictive modelling should be conducted following expert advice. The subgroup agreed that the mouse bioassay remains the 'gold standard' for BoNT (botulinum neurotoxin) detection and other detection methods should demonstrate at least equivalent specificity and sensitivity.
 - **Upper shelf-life limit for foods with controlling factors in place** - The FSA/FSS guidance does not currently provide any guidance on a maximum shelf life for foods that satisfy the grounds for a longer shelf life. In view of the evidence regarding lysozyme, the subgroup recommended that the maximum shelf-life of foods given a heat process of 90°C for ten minutes (or equivalent) should be limited to 42 days, unless it can be shown that lysozyme is absent from the food. The subgroup also recommended that expert advice should be sought if a shelf-life in excess of 42 days is desired.
 - **Controlling factors** – The five bullet points in paragraph 15, page 9 in the current FSA/FSS guidance detailing the suitable grounds for a longer shelf life were discussed by the subgroup. The subgroup recommended that the final bullet point be revised to appreciate that heat is not a necessary controlling factor in all cases. The bullet point currently is: "*a combination of heat and preservative factors which can be shown consistently to prevent growth and toxin production by non-proteolytic C. botulinum*". The subgroup recommended that the wording "*heat and preservative factors*" be amended to "controlling factors".

Consultation Point C: Review of references in the guidance related to the European Union as a result of the UK leaving the EU

19. As a consequence of the UK leaving the European Union, government guidance documents must be reviewed to remove references related to the European Union (EU) which will be no longer relevant to the UK after the Transition Period expires at the end of 2020.
20. There are only a few references related to the EU in the FSA/FSS guidance on the safety and shelf-life of vacuum and modified atmosphere packed chilled foods with respect to non-proteolytic *Clostridium botulinum*. The FSA does not consider that removal of these references will have a detrimental impact on the content of the guidance.

Consultation Point D: The accessibility of the guidance for users

21. The guidance will be reviewed to improve the accessibility of the guidance for users in line with accessibility requirements for public bodies

Impacts

Consultation Point A: The shelf-life of Vacuum and Modified Atmosphere Packed chilled fresh beef, lamb and pork in respect of *C. botulinum*

22. The FSA/FSS best practice guidance currently recommends that a 10-day shelf-life be applied to VP/MAP chilled fresh beef, lamb and pork in relation to the risk of *C. botulinum*.
23. It is assumed that food businesses manufacturing and packing VP/MAP chilled food will need to familiarise themselves with any revised guidance and therefore there will be a minimal one-off familiarisation cost associated with the final published revised guidance. We estimate that any familiarisation cost will be routine and therefore will assess the final impact in line with the standard FSA assessment model for reviewing the impact of FSA/FSS guidance.
24. As the guidance is best practice only this is not a requirement that businesses must follow, but they must ensure that food they place on the market is safe and therefore are required to demonstrate sufficient scientific evidence and testing to support their food safety management systems for any shelf life they apply to VP/MAP chilled fresh beef, lamb and pork beyond the limits given in the best practice guidance.
25. We do not foresee any costs on businesses and local authorities other than a one-off familiarisation cost, but would appreciate stakeholders' views on this assumption.
26. We assume that there would be benefits for businesses if the recommended shelf-life were to be extended under option 2. We would appreciate stakeholders' views

on the expected benefits associated with an extension of the recommended shelf-life for VP/MAP chilled fresh beef, lamb and pork.

27. If the FSA/FSS guidance is amended to no longer apply to VP/MAP chilled fresh meat beef, lamb and pork under option 3 and industry-led guidance was introduced, there could be costs to businesses in developing the guidance on how food businesses should demonstrate the safety of the shelf-life applied for VP/MAP chilled fresh beef, lamb and pork and to ensure that it provides a sufficient level of assurance for the safety of the shelf-life applied. We would appreciate stakeholder views on the expected costs and benefits associated with developing and applying industry guidance.

Q. Evidence is requested from stakeholders on whether there would be costs or benefits from:

- An extension of the current recommended 10-day shelf-life up to the 13-day shelf-life as recommended by the ACMSF for VP/MAP chilled fresh beef, lamb and pork. (Option 2)
- The introduction of industry led guidance on how food businesses should demonstrate the safety of the shelf-life applied for VP/MAP chilled fresh beef, lamb and pork, instead of the current guidance applying. (Option 3)

Consultation Point B: Amendments to the guidance recommended by the ACMSF subgroup

28. It is not expected that the amendments to the FSA/FSS guidance outlined at paragraph 18 above and recommended by the ACMSF subgroup on *C. botulinum* in its [report](#) will place additional costs on businesses, but would appreciate stakeholders' views on this assumption. We would appreciate views on any expected benefits.

Q. Evidence is requested from stakeholders on whether there would be costs or benefits from the amendments to the FSA/FSS guidance outlined at paragraph 18 above.

Consultation Point C: Review of references in the guidance related to the European Union as a result of the UK leaving the EU

29. We do not expect any impact on businesses associated with the removal of references in the guidance related to the European Union which will no longer be relevant to the UK after the end of the Transition Period on 31 December 2020 as this is only a technical amendmend to the guidance.

Consultation Point D: The accessibility of the guidance for users

30. Changes to the guidance in line with official accessibility requirements will enable more stakeholders to access and understand the guidance, which assures that all food business operators are treated fairly and have the relevant information to fully

meet their responsibilities to ensure food safety. The changes are therefore expected to have a positive impact on public health.

31. **One-off Familiarisation Cost:** It is assumed that food businesses manufacturing and packing VP and MAP chilled food will wish to familiarise themselves with any revised guidance and therefore there will be a familiarisation cost associated with the final published revised guidance. We estimate that any familiarisation cost will be routine and therefore will assess the final impact in line with the standard FSA assessment model for reviewing the impact of FSA/FSS guidance.

Engagement and Consultation Process

32. The FSA is working with industry to better understand the issues surrounding the shelf-life of VP/MAP chilled fresh beef, lamb and pork, in particular as regards the 10 shelf-life recommended by the guidance. The Working Group on the *C. botulinum* guidance includes representatives of the FSA, FSS, and trade associations and will include a representative from the local authorities.
33. Following the consultation stakeholders on the Working Group will continue to engage in relation to any proposed changes to the guidance. Comments made during the consultation will be taken into account during the review of the guidance in relation to VP/MAP chilled fresh beef, lamb and pork.

Questions asked in this consultation:

Consultation point A: The shelf-life of VP/MAP chilled fresh beef, lamb and pork

Q1: Do you have any comments on the review of the *C. botulinum* guidance in respect of the shelf-life of VP/MAP chilled fresh beef, lamb and pork, and on the following suggested options for amending this guidance? -

- **Option 1:** Do nothing. Leave the guidance unchanged and continue to recommend a 10-day maximum shelf-life in the guidance to VP/MAP chilled fresh meat.
- **Option 2:** Amend the guidance to recommend a 13-day maximum shelf-life (in place of 10-days) for VP/MAP chilled fresh beef, lamb and pork as recommended by the ACMSF.
- **Option 3:** The FSA/FSS guidance is amended to no longer apply to VP/MAP chilled fresh meat beef, lamb and pork, enabling an outcome based approach to regulation. Food businesses are responsible for ensuring that food placed on the market is safe and industry led guidance would support food businesses in demonstrating the safety of the shelf-life applied for VP/MAP chilled fresh beef, lamb and pork.

Q2: Please provide evidence as to whether there would be costs or benefits from an extension of the current recommended 10-day shelf-life up to the maximum 13-day shelf-life as recommended by the ACMSF for VP/MAP chilled fresh beef, lamb and pork.

Consultation point B: Amendments to the guidance recommended by the ACMSF subgroup on *C. botulinum*

Q3: Do you have any comments on making the following proposed amendments to the guidance as recommended by the ACMSF subgroup on *C. botulinum*? -

- **Challenge testing** - that detection of toxin is a minimum requirement for challenge testing, and that measuring viable counts is of merit in ensuring safety with appropriate expert advice.
- **Upper shelf-life limit for foods with controlling factors in place** - that the maximum shelf-life of foods given a heat process of 90°C for ten minutes (or equivalent) should be limited to 42 days, unless it can be shown that lysozyme is absent from the food. To recommend that expert advice should be sought if a shelf-life in excess of 42 days is desired.
- **Controlling factors** – the amend the wording of the final bullet point of the five bullet points on page 9, paragraph 15 in the current FSA/FSS guidance, detailing the suitable grounds for a longer shelf life. The final bullet point is currently: “a

combination of heat and preservative factors which can be shown consistently to prevent growth and toxin production by non-proteolytic C. botulinum". To amend the wording "heat and preservative factors" to read "controlling factors", as heat is not a necessary controlling factor in all cases.

Consultation point C: Update of EU related references

Q4: Do you have any comments on the proposal to review references in the guidance related to the European Union as a result of the UK leaving the EU?

Consultation point D: Accessibility of the guidance for users.

Q5: Do you have any comments on the intention to improve accessibility for users of the guidance?

Impact

Q6: We would welcome your views on our assessment of the impacts of the proposed consultation points A, B, C and D identified in this consultation. Please provide evidence, where possible, to support your views.

In particular:

Q6(a): For consultation point A evidence is requested from stakeholders on whether there would be costs or benefits from:

- An extension of the current recommended 10-day shelf-life up to the 13-day shelf-life as recommended by the ACMSF for VP/MAP chilled fresh beef, lamb and pork. (Option 2)
- If the FSA/FSS guidance is amended to no longer apply to VP/MAP chilled fresh meat beef, lamb and pork and industry led guidance is developed on how food businesses should demonstrate the safety of the shelf-life applied for VP/MAP chilled fresh beef, lamb and pork. (Option 3)

Q6(b): For consultation point B evidence is requested from stakeholders on whether there would be costs or benefits from the amendments to the FSA/FSS guidance outlined at paragraph 18 above as recommended by the ACMSF subgroup on *C. botulinum*.

Responses

34. Responses are required by close on **11 November 2020**. 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).

35. Responses should be sent to Mary McGlinchey, Email: meathygiene@food.gov.uk

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

Yours,

Mary McGlinchey
Food Policy Directorate

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 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 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:
informationmanagement@food.gov.uk

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](#).