



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

Summary of stakeholder responses

12th February 2021

Introduction

This consultation was issued on 1st October 2020 and closed on 11th November 2020.

This consultation concerned a review of best practice guidance on the safety and shelf-life of vacuum packed (VP) and modified atmosphere packed (MAP) chilled beef, lamb and pork with respect to non-proteolytic *Clostridium botulinum*. A wider review of the guidance with regards to safety and shelf-life may be considered for other foods with respect to non-proteolytic *Clostridium botulinum*.

The FSA is grateful to those stakeholders who responded and sets out in the table below responses in order of the issues considered/group responding.

The key proposals on which the consultation sought views were:

- **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 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.

The Food Standards Agency's considered responses to stakeholders' comments are given in the last column of the table. A summary of changes to the original proposal(s) resulting from stakeholder comments is set out in the final table.

A list of stakeholders who responded can be found at the end of the document.

Summary of substantive comments (in order received)

Respondent	Comment	Response
Food Business	<p>Consultation Point A, Q1 – Would opt for option 3.</p>	<p>Comment noted. The guidance has been amended.</p>
Local Authority	<p>Consultation Point A, Q1 – Option 2. The option of allowing the FBOs to set their own dates is unrealistic in the small retail butchers who lack the resources or knowledge to be able to conduct scientific trials. It would lead to confrontation with enforcement officers, who will have to decide what is too long a life without scientific trials.</p> <p>Would support longer dates in the guidance if the industry as a whole could produce evidence (perhaps different shelf lives for different meats) to support their safety. In this case the guidance that would need updating.</p> <p>Consultation Point A, Q2 – a longer date would support the industry as it could reduce wastage.</p> <p>Consultation Point B, Q3 – Agree with all</p>	<p>Comments noted. The guidance has been amended. Food businesses may choose to continue to follow the guidance and apply 13 days for VP/MAP chilled fresh beef, lamb and pork.</p> <p>Comments noted and will be considered as part of the</p>

Respondent	Comment	Response
	<p>Impact, Q6 – Any mirroring of EU standards may help future trade. As for A, B and D my only comment is that when I an enforcement officer refer a business to the guidance to demonstrate my point, it is the measurable specifics that matter, for example the number of days life, the limits of controlling factors, pH, Aw, and NaCl. I cannot give them a SMART target to achieve based on more vague descriptions which a much less educated FBO understands differently.</p> <p>Impact, Q6a – Leaving interpretation to small sole trader businesses could significantly increase intervention time by Local Authority Enforcement Officers.</p> <p>Impact, Q6b – Allowing 42 days would give some more confidence to producers to extend shelf life which usually is less than 28 days. There is risk if their heat treatment validation is less thorough that it might be. In terms of benefits, the businesses might be able to sell over a longer or slower supply chain and reduce wastage.</p>	<p>wider review of the guidance.</p> <p>Comment noted. Food businesses may choose to continue to follow the guidance.</p> <p>Comment noted and will be considered as part of the wider review of the guidance.</p>

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Food Business	<p>I am no expert so I asked those who are. C. Botulinum is present on all food but for some reason that is not yet understood there does not seem to have been any cases at all attributed to foodborne Botulism on VP red meat. It seems that there is very little risk of contracting botulism from red meat. It looks like there is no reason for shortened shelf life dates on vacuum packed meat or the store less than <3°C.</p>	<p>Comment noted. The guidance has been amended.</p>
Food Business	<p>A few comments in relation to our thoughts on the overall paper and current stance taken within UK are as follows:</p> <ul style="list-style-type: none"> • We feel that the UK market is currently at a commercial disadvantage given the short shelf life for VP / MAP foods stipulated in relation to the FSA guidance of 2017, which also creates specific and additional technical hurdles in an already complex market. Of course with Brexit coming, to have a further control in place that isn't in place in international markets would again just add another unfair advantage and complexities to a market that will be more difficult after 31st dec. Control of non-proteolytic C. Bot is internationally recognised as being controlled as part of our standard hygiene legislation and day to day production processes and not by reducing shelf life to 10 or 13 days, this almost implies that there is limited appreciation for the current controls in place during production process. 	<p>Comments noted. The guidance has been amended.</p>

Respondent	Comment	Response
	<ul style="list-style-type: none"> • The fact that the ACMSF report is now 28 years old, some may argue that this information is out dated, specifically given the advances in technology coupled with advances in day to day production techniques and dressing controls adopted at site level not to mention the pre requisites program and on site controls required in line with HACCP and food safety legislation, so we would welcome a complete review of the scientific evidence available to ensure the use of the most up to date data and information is included in any further trials and subsequent recommendations. • The ACMSF report seems to identify max shelf life for fresh meat (10 & 13 days) with no clear scientific basis or a risk based approach being adopted, particularly relating to the extremely important fact that the shelf life for fresh meat prior to this guidance was indeed longer than 10 or 13 days this was seen as custom and practise within the industry • In fact more up to date quantitative data is available in a project undertaken by UK government / industry funded research, this project included a quantitative microbiological risk assessment for non proteolytic C. Bot the findings of which showed that fresh meat has the lowest spore loading of all food materials, so this begs the question why has it been included in guidelines using 28 year old research when this more up to date research is available (findings of this report were published in 2016) 	

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	<ul style="list-style-type: none"> • Also important facts to note is the safety protection levels for chilled foods including fresh meat as detailed in the FSA project if 2005 – 2006 where it established a safety protection level of 10 (9.8), the BMPA project of 2019 found that the figure for fresh red meat in the UK was set at 10 (10.8) and internationally this level was 10 (11.87) in 2017. Specifically important to note here is that the time temperature combination for the current heat process (i.e. 90oC for 10 mins) deliver a protection level of 10 (6). • The fact that these guidelines have been released would surely undermine the main ethos within hygiene and food safety legislation, CODEX, retailer and industry standards not to mention our legal obligation to produce safe food, for these reasons would suggest that no further guidance around fresh beef is required in relation to controlling C.Bot. The heavy reliance on challenge testing within the consultation paper would also not provide the reassurances it would suggest in that it is only a one off piece of work and shouldn't be used as the main basis for risk assessment. It is also important to note the expense that would be required to conduct high challenge innoculua for our business, given we have multiple sites within the group would be substantial for us. • Whilst the use of ComBase and a risk based approach be required should inclusion of fresh meat continue to be within the regulation at FFG we would suggest that again fresh meat be removed from the scope given the 	

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	<p>evidence and points raised above. We believe that there is sufficient relevant and up to date research done which reiterates that in relation to non proteolytic C.Bot chilled foods have been established to be equivalent to that of canned foods, with the main controlling factors being the production processes adopted as a result of our legal obligation to produce safe food.</p> <ul style="list-style-type: none"> The document produced in 2017 is 'Guidance' and should be used as guidance only subject to each FBO being able to produce adequate risk assessments to further substantiate their obligation to product safe food, an example of this risk assessment could and should include the importance of pH and how this can be used as a part of your risk assessment to control non proteolytic C. Bot. 	
Food Business	<p>Any questions I have highlighted in blue and any responses I have highlighted in green.</p> <p>Firstly, in the Introduction of the Information provided it indicates: '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.'</p>	<p>Comments noted. The guidance has been amended. Food businesses, including businesses in Northern Ireland, may choose to continue to follow the guidance and apply 13 days</p>

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	<p>Are the Below Proposals and Potential Consultation Points also aiming to Bring and Keep Northern Ireland in line with Both UK and EU requirements for C. Botulinum Controls- if Proposed Changes are Passed? Or Will Northern Ireland be required to remain with existing Guidelines?</p> <p>Consultation point A, Q1: 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.</p> <p>Consultation Point A, Q2: There would Naturally be a benefit from extension of shelf-life to 13 Days: for Finished Products in MAP and Vacuum Packs- Based on Stock Management for the Site and for Retailers. For Us this would Drive down Food Wastage, and also means that large quantities purchased so price/kg conversations with Suppliers.</p> <p>Consultation point B, Q3: Upper shelf-life limit for foods with controlling factors in place - No I do not believe this needs to be a requirement, if products are validated for a shelf-life, and are using cooking as part of there preservative method, This should not be a requirement.</p> <p>Consultation point B, Q3: Controlling factors – Yes</p>	<p>for VP/MAP chilled fresh beef, lamb and pork.</p> <p>Comments noted and will be considered as part of the wider review of the guidance.</p>

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	<p>Consultation point C, Q4: Yes, Northern Ireland is still required to follow requirements laid out by the EU as it will not be recognised as a 3rd Country- Northern Ireland is still within the UK- Will there be different legislation provided for Northern Ireland and UK?</p> <p>Consultation point D, Q5: There is no real information on how this is proposed to be changed. Familiarisation costs; is this training with the FSA? – Or what does this Look Like?</p> <p>Impact Q6(a), (Option 2): Yes: Following FSA Industry Standard in addition to increasing holding time on packed finished goods.</p> <p>Impact Q6(a), (Option 3): No. As a Smaller Business the Costs associated with Validation of C Bot. through an Organisation such as Campden- for Challenge testing etc, is too expensive also for Companies such as this- also For NI Based Businesses having samples Couriered to Mainland UK under the Strict Chill Controls- is not something that can be relied upon.</p>	<p>This is UK guidance and will apply in Northern Ireland.</p> <p>A food business would familiarise itself with the content of the guidance.</p> <p>Comments noted. Food businesses may choose to continue to follow the guidance.</p>
Dairy UK	<p>In respect of the 2017 FSA guidance “The safety and shelf-life of vacuum and modified atmosphere packed chilled foods with respect to nonproteolytic Clostridium botulinum”, we believe that reference to hard cheese on page 17 is unnecessary and potentially confusing. The vast majority of these products are</p>	<p>Comment noted and will be considered as part of the wider review of the guidance.</p>

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	<p>stored at temperatures between 3°C and 8°C and exhibit one or more of the following absolute protective hurdles:</p> <ul style="list-style-type: none"> • A minimum salt in moisture content of 3.5; • A maximum water activity of 0.97; • A pH of 5 or less. <p>These are often coupled with additional factors which can play a role in the control of C. Botulinum growth, namely competition from other microorganisms. Due to the presence of one or more of these absolute hurdles, these products are not considered a risk for C. Botulinum growth and toxin production.</p> <p>The reference to hard cheese in the guidance has caused unnecessary concerns on the part of enforcement authorities and industry stakeholders. We therefore propose that this reference be removed or the wording be amended to reflect that hard cheese is not considered a risk for C. Botulinum growth.</p>	
<p>British Meat Processors Association (BMPA)</p>	<p>Consultation point A, Option 1 - No, the current 10 day maximum shelf-life is completely restrictive and a barrier to export trade due to the short prescriptive shelf-life rules. This 10 shelf-life also creates significant food waste - see WRAP report already submitted. No other country anywhere in the world limits shelf life of VP/MAP foods with respect to non-proteolytic Clostridium botulinum for chilled foods including fresh meat as the safety of these foods is recognised</p>	<p>Comments noted. The guidance has been amended.</p>

Respondent	Comment	Response
	<p>to be addressed by standard hygiene legislation and production practices that have vastly improved over the last 30 years needs to be taken into account. WRAP estimates a food waste reduction potential of a 1 day increase in fresh meat/poultry shelf life being c.10k te/year, and a 1 day increase across the board resulting in reduction of ca.250k te/year.</p> <p>Consultation point A, Option 2 - Firstly, it was not the role of the ACMSF mandate to suggest or recommend a shelf-life of 13 days. Neither of the shelf lives referred to in the consultation regarding fresh meat (10, 13 days) have a clear scientific nor risk basis, both reflecting the 2017 FSA guidance, and not previously long-established shelf lives either in the UK or internationally. It was also suggested at a recent ACMSF that if the risk assessment had been completed to the required standard the recommended 10 days would never have been included as there was no risk or history of Botulism.</p> <p>Consultation point A, Option 3 - Option 3 is the correct outcome that should be considered as the right approach going forward. The legislation already exist and sets out very clearly the responsibility that FBO's have when producing safe food.</p>	

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	<p>Consultation point A, Option 3 - of Consultation Point A would therefore be most appropriate, but there is no need for additional guidance for fresh meat. All the work (e.g. FSA chilled VP/MAP food project B13006 (2005-6), MLA/BMPA (2019)) has shown that no particular additional guidance is required on safe production as it is covered in, for example:</p> <ul style="list-style-type: none"> • CODEX, hygiene legislation, basic hygiene requirements, and industry and retailer standards • CFA/QIB/LFR/MLA/BRC 2018 International “Guidelines for Setting Shelf life of Chilled Foods in relation to non-proteolytic <i>Clostridium botulinum</i>”. This also covers the role and approach to use of challenge testing, if used, and alternative approaches, particularly exposure/risk assessment and the role of predictive modelling • BRC Global Standards 2018 guidance on “Shelf Life of MAP and VP Raw Meat Products in Relation to non-proteolytic. <p>Consultation point B - In the <u>guidance in general</u> emphasis on challenge testing should be reduced. Challenge testing is not proportionate to risk particularly where products with a long-established safety record are concerned. Using high challenge test inoculua are neither representative of reality⁸, and not cost-effective given the need to test each food formulation at significant expense (£10k+ per food), which is unlikely to be affordable by</p>	<p>Comment noted and will be considered as part of the wider review of the guidance.</p>

Respondent	Comment	Response
	<p>smaller businesses in particular, and which may lack internal technical resource. More appropriate alternative approaches than challenge testing should be included in the Guidance, such as exposure/risk assessment (e.g. number of packs or portions sold safely), which is an approach already used by ACMSF, process risk modelling, QMRA (e.g. as carried out in the SUSSLE projects) and predictive modelling. It should be noted that ComBase does not use heated spores, so is failsafe. The Guidance must state that if challenge testing is done it must be designed appropriately and include toxin testing as that is the hazard and toxin can be produced prior to growth being detectable by plating out methods, and give clarity on what is considered a representative sample, e.g. a test of a product with worst case parameters being able to be used to provide a safe shelf life for other equivalent foods. See 2018 CFA/QIB/LFR/MLA/BRC guidance.</p>	
Institute	<p>Consultation Point A:</p> <ul style="list-style-type: none"> • No other country limits the shelf life of fresh chilled meat or VP/MAP chilled foods with respect to nonproteolytic <i>C. botulinum</i>, as the safety of these foods is recognised to be addressed by standard hygiene legislation and production practices. • The 2017 FSA Guidance, and specifically the first explicit inclusion of a 10-day shelf life for VP/MAP fresh meat, puts the UK at a competitive 	Comments noted. The guidance has been amended.

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	<p>disadvantage, creates technical trade barriers, creates unnecessary waste and raises moral issues regarding assigning this shelf-life for sentient beings' meat.</p> <ul style="list-style-type: none"> • A referred scientific article from QIB Extra published in 2020 did not identify any foodborne botulism outbreaks in the UK or globally associated with correctly stored commercial chilled foods, including chilled VP/MAP fresh meat. It was established that by 2005, ca. 1010 person servings of chilled food (including fresh meat) had been marketed without association with foodborne botulism, and that from 1999 to 2017 more than 1010 person servings of fresh red meat had been sold in the UK without association with foodborne botulism. • Analysis of the loading of raw food materials with spores of non-proteolytic <i>C. botulinum</i> established that fresh meat had the lowest spore loading of all raw food materials examined. • A refereed scientific article from QIB Extra published in 2020 concluded that an exposure assessment and challenge test demonstrate the safety of current UK industry practices for the shelf-life of fresh, vacuum-packed beef, lamb and pork held at 3°C–8°C with respect to <i>C. botulinum</i>, and that botulinum neurotoxin was not detected within their organoleptic shelf-life. 	

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	<p>Option 3 of Consultation Point A is therefore the most appropriate way forward (The FSA/FSS guidance is amended to no longer apply to VP/MAP chilled fresh meat beef, lamb and pork, enabling an outcomebased approach to regulation etc.).</p> <p>Consultation Point B:</p> <ul style="list-style-type: none"> • While challenge testing can be very valuable, the Guidance fails to acknowledge developments in quantitative food microbiology. Further appropriate alternative approaches to challenge testing should also be included in the Guidance, such as exposure/risk assessment (e.g. the number of packs or portions sold safely - an approach already used by ACMSF), process risk modelling and QMRA (e.g. as carried out in the SUSSLE projects) and predictive modelling. The Guidance must state that if challenge testing is done it must be designed appropriately, and must include toxin testing as that is the hazard and toxin can be produced prior to growth being detectable by plating out methods. There should also be clarity on what is considered a representative sample, e.g. a test of a product with worstcase parameters being able to be used to provide a safe shelf-life for other equivalent foods. Further information on setting product shelf-life is available. 	<p>Comments noted and will be considered as part of the wider review of the guidance.</p>

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	<ul style="list-style-type: none"> • Numerous authors have reported that 90°C/10mins (and equivalents) will not deliver a 6D process if lysozyme is present in the food. However, relating this information to food safety guidance is not straightforward. One potential way of addressing this issue is to limit maximum product shelf-life. It is noted that the proposed maximum shelf-life of 42 days is based on tests with a larger concentration of spores than would be used today and higher than that in real foods. Additional work is required to establish the potential effect of lysozyme on product shelf-life and the merit of the recommendation “expert advice should be sought if a shelf-life in excess of 42 days is desired”. • The subgroup recommendation on controlling factors is supported (the wording “heat and preservative factors” be amended to “controlling factors”). Additional points relevant to the Guidance review • The original ACMSF report was published in 1992. In the last 28 years, the UK chilled food market has developed significantly, as has quantitative microbiological food safety. While some changes to the ACMSF guidance have been made since 1992, there is now a need for a comprehensive review of the risk of botulism in chilled foods. • The ACMSF sub-group report of January 2020 considered the issue of different lethal rate tables, but for an unknown reason, this important issue was not included in the consultation. This is a serious oversight. It has been 	

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	<p>previously pointed out that the lethal rate table in the 2017 Guidance and previous version of the Guidance is unsafe below 90°C. Furthermore, it is not in line with longestablished industry requirements (e.g. Chilled Food Association, European Chilled Food Federation), as evidence by the FSA-funded PhD by Wachnicka and CFA's first SUSSLE project AFM266. The z value of 7°C below 90°C, as has been referred to in industry technical documentation for some 25 years should be used in the Guidance.</p> <ul style="list-style-type: none"> • The Guidance should make clear that VP/MAP products for consumer sale cannot be re-packed to extend the shelf life beyond that of the raw material without a kill step being used. • A further important issue not presently covered is guidance on the need to control pH to assure safe production of herbs and other produce in oil with respect to <i>C. botulinum</i>. 	
Sainsbury's plc	<p>Consultation Point A, Q1: The favoured option is Option 3. Raw meat has been sold safely with lives up to and beyond 13 days globally without any incidents relating to non proteolytic <i>Clostridium botulinum</i>, where meat is stored correctly. It would be proportionate to allow this hazard to be managed by the industry.</p>	<p>Comment noted. The guidance has been amended.</p>

Respondent	Comment	Response
	<p>Consultation point A, Q2: There would be benefits of any increase in shelf life beyond 10 days for raw meat (as any chilled products) due to increased availability, less production runs resulting in increased efficiencies and costs and reduced food waste.</p> <p>Consultation point B:</p> <ul style="list-style-type: none"> As toxin is the recognised hazard, we remain supportive of the inclusion of toxin in challenge tests. This does however have a significant cost impact on the food industry with a challenge test including toxin typically costing around £10,000 per product. This places a significant burden on the UK industry. To allow the UK industry to remain competitive (no other country in the world restricts life with regards NP <i>C.botulinum</i>), the guidance needs to provide a broader range of risk assessment tools beyond challenge testing alone and clearer advice on what constitutes effective due diligence. This will help facilitate a consistent approach, and prevent the disagreements that have ensued between industry, accreditation bodies and enforcement authorities. We would make the following suggestions: <ol style="list-style-type: none"> ACMSF used exposure assessment (the number of packs of a given product sold safely) to make their recommendation to increase the shelf life of raw meat. This risk assessment approach has also been used previously for canned cured meats and should be recognised in the 	<p>Comments noted and will be considered as part of the wider review of the guidance.</p>

Respondent	Comment	Response
	<p>guidance as a means of demonstrating due diligence. The minimum number of packs sold safely should also be specified (e.g. equivalence to the safety factor achieved by a 90C/10 minute cook).</p> <p>2. Stating that “viable counts are of merit in ensuring safety with appropriate expert advice” and also the comment under 18. on page 5 of the consultation that “recommends that all predictive modelling should be conducted following expert advice” does not articulate the circumstances when these approaches can be used, nor the limits to be followed. Given that predictive modelling is freely available and accessible to industry, is designed to be failsafe and provides an alternative to costly challenge testing, it would be helpful to give clear guidance on when models can be used and what limits should be applied (e.g. how much growth/no growth etc?).</p> <p>3. The ACMSF review of the BMPA led challenge work on raw meat concluded that the challenge work was not representative of all fresh meat and it was dismissed on this basis. Given the current guidance largely restricts industry to conducting challenge testing, it is important that clearer guidance is provided on what is considered representative. Is it necessary to have a challenge test for every product with >10 days life that doesn't meet the current parameters in the guidelines (at huge cost), or is it possible to model a “worst case”</p>	

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	<p>product in a range to be representative of the rest? If so the guidance should clearly state what is/isn't representative with examples?</p> <p>The UK industry has a very long history of safety with regards non-proteolytic <i>C.botulinum</i>, and it is questionable whether the guidance in its current form is proportionate. We would encourage that there be a much broader review of its content beyond the ask in the consultation, to address the points raised.</p>	
Local Authority	<p>Consultation point A, Option 2: Preferred option "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.</p> <p><u>Rationale</u> The increase in the recommended maximum shelf life for these products is welcomed. However, looking at the ACMSF report, it would appear that the chosen maximum shelf life of 13 days is still a little over cautious and that it could be increased further. With regard to Option C - to adopt this approach could lead to significant enforcement issues as it would be difficult for an FBO to validate that a given shelf life will guarantee safety other than by using historical evidence and internationally recognised safe shelf lives for similar products. This approach would rely very heavily on utilising the laws of probability rather than science.</p>	Comments noted. The guidance has been amended. Food businesses may choose to continue to follow the guidance and apply 13 days for VP/MAP chilled fresh beef, lamb and pork.

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	<p>Consultation point B, Comments:</p> <p>Upper shelf-life limit for foods with controlling factors in place - The setting of a maximum shelf life of 42 days for VP/MAP products that have received an in-pack 6-log reduction heat treatment, unless it can be shown that lysozyme is absent from the food, is welcomed. The absence of an upper shelf-life limit in previous issues of the guidance had been identified as a significant omission.</p> <p>Controlling factors – Amending the wording of “heat and preservative factors” to read “controlling factors” within the guidance is welcomed as it recognises that not every “safe” VP/MAP product has been subject to a controlling heat treatment.</p>	<p>Comments noted and will be considered as part of the wider review of the guidance.</p>
<p>Chilled Food Association (CFA)</p>	<p>Consultation Point A, Q1:</p> <ol style="list-style-type: none"> 1. No other country anywhere in the world limits shelf life of VP/MAP foods with respect to non-proteolytic <i>Clostridium botulinum</i> for chilled foods including fresh meat as the safety of these foods is recognised to be addressed by standard hygiene legislation and production practices. 2. Neither of the shelf lives referred to in the consultation regarding fresh meat (10, 13 days) have a clear scientific nor risk basis, both reflecting the 2017 	<p>Comments noted. The guidance has been amended.</p>

Respondent	Comment	Response
	<p>FSA guidance, and not previously long-established shelf lives either in the UK or internationally.</p> <p>3. The 2017 FSA Guidance, and specifically the first explicit inclusion of a 10-day shelf life for VP/MAP fresh meat, puts the UK at competitive disadvantage, creates technical barriers to trade, creates unnecessary waste and raises moral issues regarding assigning arbitrary rules for the usage of sentient beings' meat. WRAP estimates a food waste reduction potential of a 1 day increase in fresh meat/poultry shelf life being c.10k te/year, and a 1 day increase across the board resulting in reduction of ca.250k te/year.</p> <p>4. FSA project B13006 (2005-6) established the level of safety protection as $10^{9.8}$ across all chilled foods including fresh meat, and the MLA/BMPA 2019 study determined the figure to be $10^{10.8}$ for fresh red meat in the UK over the period 1999-2005 and 2007-2017, and internationally in 2017 it was $10^{11.81}$. Note that the currently specified heat process to achieve a long shelf life (90°C/10 minutes) delivers a protection level of 10^6.</p>	

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	<p>5. Peer-reviewed UK Government/industry-funded research (the CFA's first SUSE (Sustainable Shelf Life Extension) project AFM266) included a full Quantitative Microbiological Risk Assessment (QMRA) for non-proteolytic <i>Clostridium botulinum</i>, results of which were published after peer review in January 2016 and notified to FSA at the time. It showed that fresh meat has the lowest spore loading of any food material, and quantified loadings for all food components.</p> <p>6. Option 3 of Consultation Point A would therefore be most appropriate, but there is no need for additional guidance for fresh meat. All the work (e.g. FSA chilled VP/MAP food project B13006 (2005-6), MLA/BMPA (2019)) has shown this to be the case since it is covered in, for example:</p> <ul style="list-style-type: none"> a. CODEX, hygiene legislation, basic hygiene requirements, and industry and retailer standards b. CFA/QIB/LFR/MLA/BRC 2018 International "Guidelines for Setting Shelf life of Chilled Foods in relation to non-proteolytic <i>Clostridium botulinum</i>". This also covers the role and approach to use of challenge testing, if used, and alternative approaches, particularly exposure/risk assessment and the role of predictive modelling c. BRC Global Standards 2018 guidance on "Shelf Life of MAP and VP Raw Meat Products in Relation to non-proteolytic <i>Clostridium botulinum</i>" 	

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	<p>Consultation point B:</p> <ul style="list-style-type: none"> • Challenge testing Research shows that toxin can be produced before detection of growth. It is therefore vital that detection of toxin is a minimum requirement for challenge testing as the presence of toxin, and not simply detectable growth, is the actual hazard. <p>However, in the <u>guidance in general</u> emphasis on challenge testing should be reduced. Challenge testing is not proportionate to risk particularly where products with a long-established safety record are concerned. Using high challenge test inoculua are neither representative of reality and not cost-effective given the need to test each food formulation at significant expense (£10k+ per food), which is unlikely to be affordable by smaller businesses in particular, and which may lack internal technical resource. More appropriate alternative approaches than challenge testing should be included in the Guidance, such as exposure/risk assessment (e.g. number of packs or portions sold safely), which is an approach already used by ACMSF, process risk modelling, QMRA (e.g. as carried out in the SUSSLE projects) and predictive modelling. It should be noted that ComBase does not use heated</p>	<p>Comments noted and will be considered as part of the wider review of the guidance.</p>

Respondent	Comment	Response
	<p>spores, so is failsafe. The Guidance must state that if challenge testing is done it must be designed appropriately¹⁰ and include toxin testing as that is the hazard and toxin can be produced prior to growth being detectable by plating out methods, and give clarity on what is considered a representative sample, e.g. a test of a product with worst case parameters being able to be used to provide a safe shelf life for other equivalent foods. See 2018 CFA/QIB/LFR/MLA/BRC guidance.</p> <ul style="list-style-type: none"> Upper shelf-life limit for foods with controlling factors in place Work carried out on lysozyme in relation to thermal processes to control non-proteolytic <i>C. botulinum</i> has only used high inoculua (e.g. $\sim 10^6$ spores/food sample, and 5×10^4 spores/g in the case of the single research paper referring to 42 days). This does not reflect the concentrations of spores found in real foods. See Barker <i>et al</i>, reference 9, for actual spore levels. We would reiterate that the safety of chilled prepared foods with respect to non-proteolytic <i>Clostridium botulinum</i> has been established to be of an order equivalent to canned foods, this being achieved by production according to standard GMP/GHP/HACCP requirements, and that internationally there are no stipulated limits to shelf life, instead the FBO being required to assure safety. 	

Respondent	Comment	Response
	<p>• Controlling factors wording</p> <p>We concur with the proposed change of the wording to read “<i>a combination of controlling factors which can be shown consistently to prevent growth and toxin production by non-proteolytic C. botulinum</i>” as heat is not a necessary controlling factor in all cases e.g. fresh meat.</p> <p>Consultation point C: References should be updated to transposed EU law coming directly into effect in the UK at the end of the Transition Period. We are not yet aware of the details of such legislation however.</p> <p><u>Consultation point D: Accessibility of the guidance for users:</u> This is welcomed.</p> <p><u>Additional points relevant to the Guidance review</u></p> <p>1. We have previously highlighted that the lethal rate table in the 2017 and previous version of the guidance is unsafe below 90°C. Not only is it unsafe but it is not in line with long-established industry requirements (e.g. CFA, European Chilled Food Federation), as borne out by the FSA-funded PhD</p>	

Respondent	Comment	Response
	<p>by Wachnicka² and CFA's first SUSSE project AFM266. This was recognised by the ACMSF sub-group's January 2020 report, but not mentioned in the consultation. The z value of 7 below 90°C, as has been referred to in industry technical documentation for some 25 years should be used in the guidance.</p> <p>2. The Guidance should make clear that raw VP/MAP chilled products for consumer sale cannot be re-packed to extend the shelf life beyond that of the raw material without a kill step being used.</p> <p>3. The Guidance document should be general guidance on the control of non-proteolytic <i>Clostridium botulinum</i>. However, separate clear guidance is needed on the requirement to control pH to assure safe production of herbs and other produce in oil stored at ambient.</p> <p>We look forward to continuing to work with FSA and ACMSF to arrive at scientifically sound yet straightforward information necessary to assist FBOs to carry out HACCP-based controls to assure food safety.</p>	

Respondent	Comment	Response
Local Authority	<p>Consultation point A, Q1: have considered the existing FSA guidance document in relation to C. botulinum in respect of the shelf life of VP/MAP of chilled foods and noted the studies referenced within the ACMSF report of February 2020, including that by FS Scotland and that of the BMPA/MLA 2019. They have also considered the FSAI guidance note 18 – validation of product shelf life, version 4.</p> <p>While the FSAI guidance note includes the FSA guidance in an appendix it recommends in the case of chilled VP/MAP raw meats sold as whole joints or cuts, current industrial practice is acceptable and does not recommend a limit on shelf life to 10 days. Acknowledges the close trading relationships between businesses and customers across the north/south border and can appreciate the benefit of equivalent guidance.</p> <p>Has noted the findings of the studies that indicate that there have been no clostridium botulinum outbreaks as a result of correctly stored chilled meats, rather incidents came from food subject to time/temperature abuse or where pre-formed botulinum toxin was inadvertently added. They also note that toxin formation takes considerable time to occur in fresh, chilled meat.</p>	<p>Comments noted. The guidance has been amended. Food businesses may choose to continue to follow the guidance and apply 13 days for VP/MAP chilled fresh beef, lamb and pork.</p>

Respondent	Comment	Response
	<p>The ACMSF acknowledges that the studies referenced above and indeed current industry practice indicates it is possible to achieve safe shelf lives in excess of ten days for chilled, fresh meats. However they note that it remains unclear as to what the controlling factors are that prevent growth and toxin formation. As such, they advise it is not possible to provide a measurement and therefore critical limit for shelf life.</p> <p>The ACMSF suggests the 13 day shelf life as this in line with the typical shelf life historically and currently applied to these fresh chilled beef, pork and lamb by industry. While some products may have shelf lives greater than 13 days this appears to be industry average.</p> <p>Are aware that small to medium sized businesses may use the existing FSA document as a means to validate their current use of vacuum packing or modified atmosphere packing for fresh chilled beef, pork and lamb. As such an extension from the current guideline of 10 days to 13 days would be of benefit to any business that follows the guidance.</p> <p><i>With this in mind agree with option 2. The current and historical shelf life and storage practices in industry appear to provide evidence that a 13 day shelf life</i></p>	

Respondent	Comment	Response
	<p><i>is suitable for beef, pork and lamb. The limitations of the studies are noted and without further evidence it is not recommended the 13 day shelf life be extended without the food business operator able to demonstrate the safety of doing so.</i></p> <p>Consultation point A, Q2: No evidence to provide</p> <p>Consultation point B: agree to the proposed amendments and have no comments to make in this respect.</p> <p>Consultation point C, Q4: agree with the proposal to review references in the guidance related to the EU as a result of the UK leaving the EU.</p> <p>Consultation point D, Q5: welcome any improvements to accessibility for users.</p> <p>Impact, Q6: recognise the use of this guidance document by food business operators as a means of validating their shelf life practices. They also acknowledge and agree that without this document the food business operator would be required to implement other validation methods that may require financial input in terms of both money and their time. Many small to medium sized businesses would not have the finances to provide validation beyond that of</p>	<p>Comments noted and will be considered as part of the wider review of the guidance.</p> <p>Comments noted. Food businesses may choose to continue to follow the guidance and apply 13 days</p>

Respondent	Comment	Response
	<p>recognised guidance documents such as this one. However, do not have evidence to present in this regard.</p> <p>Impact, 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 <i>C. botulinum</i>.</p> <p>No evidence in respect of either costs or benefits</p>	<p>for VP/MAP chilled fresh beef, lamb and pork.</p>
Local Authority	<p>Consultation point A, Q1: have considered the existing FSA guidance document in relation to <i>C. botulinum</i> in respect of the shelf life of VP/MAP of chilled foods and noted the studies referenced within the ACMSF report of February 2020, including that by FS Scotland and that of the BMPA/MLA 2019. They have also considered the FSAI guidance note 18 – validation of product shelf life, version 4.</p> <p>While the FSAI guidance note includes the FSA guidance in an appendix it recommends in the case of chilled VP/MAP raw meats sold as whole joints or cuts, current industrial practice is acceptable and does not recommend a limit on shelf life to 10 days. Acknowledges the close trading relationships between</p>	<p>Comments noted. The guidance has been amended. Food businesses may choose to continue to follow the guidance and apply 13 days for VP/MAP chilled fresh beef, lamb and pork.</p>

Respondent	Comment	Response
	<p>businesses and customers across the north/south border and can appreciate the benefit of equivalent guidance.</p> <p>Has noted the findings of the studies that indicate that there have been no clostridium botulinum outbreaks as a result of correctly stored chilled meats, rather incidents came from food subject to time/temperature abuse or where pre-formed botulinum toxin was inadvertently added. They also note that toxin formation takes considerable time to occur in fresh, chilled meat.</p> <p>The ACMSF acknowledges that the studies referenced above and indeed current industry practice indicates it is possible to achieve safe shelf lives in excess of ten days for chilled, fresh meats. However they note that it remains unclear as to what the controlling factors are that prevent growth and toxin formation. As such, they advise it is not possible to provide a measurement and therefore critical limit for shelf life.</p> <p>The ACMSF suggests the 13 day shelf life as this in line with the typical shelf life historically and currently applied to these fresh chilled beef, pork and lamb by industry. Whiles some products may have shelf lives greater than 13 days this appears to be industry average.</p>	

Respondent	Comment	Response
	<p>Are aware that small to medium sized businesses may use the existing FSA document as a means to validate their current use of vacuum packing or modified atmosphere packing for fresh chilled beef, pork and lamb. As such an extension from the current guideline of 10 days to 13 days would be of benefit to any business that follows the guidance.</p> <p><i>With this in mind agree with option 2. The current and historical shelf life and storage practices in industry appear to provide evidence that a 13 day shelf life is suitable for beef, pork and lamb. The limitations of the studies are noted and without further evidence it is not recommended the 13 day shelf life be extended without the food business operator able to demonstrate the safety of doing so.</i></p> <p>Consultation point A, Q2: No evidence to provide</p> <p>Consultation point B, Q3: agree to the proposed amendments and have no comments to make in this respect.</p> <p>Consultation point C, Q4: agree with the proposal to review references in the guidance related to the EU as a result of the UK leaving the EU.</p> <p>Consultation point D, Q5: welcome any improvements to accessibility for users.</p>	<p>Comments noted and will be considered as part of the wider review of the guidance.</p>

Respondent	Comment	Response
	<p>Impact, Q6(a): recognise the use of this guidance document by food business operators as a means of validating their shelf life practices. They also acknowledge and agree that without this document the food business operator would be required to implement other validation methods that may require financial input in terms of both money and their time. Many small to medium sized businesses would not have the finances to provide validation beyond that of recognised guidance documents such as this one. However do not have evidence to present in this regard.</p> <p>Impact, Q6(b): No evidence in respect of either costs or benefits</p>	<p>Comments noted. Food businesses may choose to continue to follow the guidance and apply 13 days for VP/MAP chilled fresh beef, lamb and pork.</p>
Food business	<p>Consultation point A, Q1: Response: Option 3 is the preferred and obvious option.</p> <p>The change in the 2017 FSA guidance was not based on clear scientific or risk evidence.</p> <p>There is no need for additional guidance on safe production of fresh meat (VP/MAP chilled fresh beef, lamb and pork) with respect to non-proteolytic <i>Clostridium botulinum</i> beyond what is already in place, food hygiene regulations, other government guidance on validating shelf-life, Codex, etc..</p>	<p>Comments noted. The guidance has been amended.</p>

Respondent	Comment	Response
	<p>There is ample of evidence to demonstrate that botulism is not a risk in VP/MAP chilled fresh beef, lamb and pork.</p> <p>The Chilled Food Association SUSSLE Quantitative Microbiological Risk Assessment demonstrated that fresh meat has the lowest spore loading of any food material of all food components.</p> <p>There has not been a record of an incident or occurrence of botulism in all the retail VP/MAP chilled fresh beef, lamb and pork sold in the UK and the EU. A 2006 FSA project established the level of safety protection as $10^{9.8}$ across all chilled foods including fresh meat.</p> <p>The more recently published 2019 MLA/BMPA study determined the figure to be $10^{10.8}$ for fresh red meat in the UK over the period 1999-2005 and 2007-2017, and internationally in 2017 it was $10^{11.87}$.</p> <p>The UK is the only country in the world that limits VP/MAP chilled fresh beef, lamb and pork shelf life with respect to <i>C. botulinum</i>.</p> <p>This demonstrates that other countries do not consider <i>C. botulinum</i> to be a risk in VP/MAP chilled fresh beef, lamb and pork.</p>	

Respondent	Comment	Response
	<p>This requirement also puts UK producers at a competitive disadvantage, with additional costs, including increased waste.</p> <p>Consultation point A, Q2: Response: With Option 3:</p> <ul style="list-style-type: none"> - Longer validated shelf lives will leave a longer period for the consumer to use the retail VP/MAP chilled fresh beef, lamb and pork, not throwing out at 10 days. - The product will remain on the retail shelf for longer, not pulled off at 10 days. - Longer retail shelf lives will give obvious efficiencies in production and supply chain. - WRAP has estimated a food waste reduction potential of a 1 day increase in VP/MAP chilled fresh beef, lamb and pork shelf life being around 10k tonne/year, and that a 1 day increase across the board would result in reduction in the region of 250k tonne/year. <p>Consultation point B, Q3, Challenge testing - Response:</p> <p>The general emphasis on challenge testing in the guidance should be reduced as challenge testing is not proportionate to risk particularly where products have long-established safety records.</p> <p>The high level of inoculation in challenge testing is not representative of reality.</p>	<p>Comments noted and will be considered as part of the wider review of the guidance.</p>

Respondent	Comment	Response
	<p>Challenge testing is not cost-effective given the need to test each food formulation at significant expense, we have spent over £20,000 on some individual challenge tests, and so is unlikely to be affordable by smaller businesses.</p> <p>Other alternative, more appropriate approaches or methods should be included in the Guidance, such as exposure/risk assessment considering for example the number of packs or portions sold safely, an approach already used by the ACMSF, process risk modelling, Quantitative Microbiological Risk Assessment as carried out in the SUSSLE projects and predictive modelling.</p> <p>Modelling should continue to be an accepted alternative approach and it should be noted that ComBase does not use heated spores, so should be considered failsafe.</p> <p>The Guidance must give more instruction on what is required where challenge testing is being carried out:</p> <ul style="list-style-type: none"> - Challenge testing, where used, must be designed appropriately, and include toxin testing. - Challenge testing must include toxin testing, as toxin, not growth, is the hazard, as toxin can be produced prior to growth, being detectable by plating out methods - Guidance should give clarity on what is considered a representative sample. 	

Respondent	Comment	Response
	<p>As stated above, the actual concentration of spores in food is not reflective of the levels of inoculation in the work carried out on lysozyme in relation to thermal processes to control non-proteolytic <i>C. botulinum</i>, $\sim 10^6$ spores/food sample and 5×10^4 spores/g in the case of the single research paper referring to 42 days.</p> <p>Internationally there are no stipulated limits to shelf life, the food business is responsible and required to assure safety.</p> <p>The safety of chilled prepared foods with respect to non-proteolytic <i>Clostridium botulinum</i> has been established to be of an order equivalent to canned foods, this being achieved by production according to standard HACCP/GMP/GHP requirements.</p> <p>The lethal rate table in the 2017 and previous version of the guidance is unsafe below 90°C.</p> <p>It is not in line with long-established industry requirements (e.g. Chilled Food Association¹², European Chilled Food Federation¹³), as borne out by the FSA-funded PhD by Wachnicka¹⁴ and CFA's first SUSE project AFM266.</p> <p>This was recognised by the ACMSF sub-group's January 2020 report, but not mentioned in the consultation.</p>	

Respondent	Comment	Response
	<p>The z value of 7 below 90°C, as has been referred to in industry technical documentation for some 25 years should be used in the guidance.</p> <p>Consultation point C, Q4: Response: We do not expect any impact on our business on reviewing EU references.</p> <p>Consultation point D, Q5: Response: We support improved accessibility. No additional comments.</p> <p>Impact, Q6(a): Response: Option 3 is the preferred and justified option. There would be little or no cost savings or benefits from moving shelf life to 13 days.</p> <p>Impact, Q6(a): Response: As stated above, there is no need for additional guidance on safe production of fresh meat (VP/MAP chilled fresh beef, lamb and pork) with respect to non-proteolytic <i>Clostridium botulinum</i> beyond what is already in place, food hygiene regulations, other government guidance on validating shelf-life, Codex, etc..</p> <p>Impact, Q6(b): Response: No additional comments.</p>	<p>Comments noted. The guidance has been amended.</p>

Respondent	Comment	Response
Private individual	<p>Consultation point A, Q1:</p> <ul style="list-style-type: none"> • Option 1: Not the best option in my opinion. Doing nothing and maintaining the 10 day rule would be a simple and safe solution but it is inflexible and will tend to lead to greater food waste and is potentially a competitive disadvantage for UK manufactures. • Option 2: Increasing the prescribed upper limit to 13 days would be better than leaving it at 10 days – but it is also inflexible and will also tend to lead to higher levels of food waste. • Option 3: Food businesses <i>are</i> responsible for ensuring that food placed on the market is safe. Therefore they should be free to determine safe shelf lives backed up with appropriate verifications. • Compromise Option: the legislation could prescribe a 10 or 13 day shelf life unless the FBO can demonstrate the safety of longer lives with appropriate verifications. That might tend to give a competitive advantage to bigger companies which have the wherewithal to conduct verification trials but would provide a safe and simple rule of thumb for smaller businesses. <p>Consultation point A, Q2: Fluctuations in the rate of sale can lead to over (or under) stocking. If you stock the shelves for a big BBQ weekend and then the weather turns bad, meat gets left on the shelf. In the worst case, product goes</p>	<p>Comments noted. The guidance has been amended.</p> <p>Comment noted. Food businesses may choose to continue to follow the guidance and apply 13 days for VP/MAP chilled fresh beef, lamb and pork.</p>

Respondent	Comment	Response
	<p>out of date and has to be disposed of before it can be sold and consumed. The longer the shelf life the greater the level of variability in the rate of sale that can be accommodated - and so there tends to be a reduction in food waste.</p> <p>Consultation point B, Q3:</p> <ul style="list-style-type: none"> • Challenge testing: is the detection of toxin a disproportionately strong requirement? Detection of toxin was not common practice in the verification of canning heat processes - and yet the development of heat processes for new canned products has proved to be safe over a long period of time. Whilst the proposed requirement to test for toxin is indubitably a gold standard, it may be a disproportionately robust requirement given the lack of recorded botulism outbreaks which can be related to VAC/MAP packed foods which have been stored at the correct temperature. However, I recognise that verification of shelf life, where the only controlling factor is refrigeration, presents a different set of variables and dynamics to the verification of canning heat processes. • Upper shelf-life limit for foods with controlling factors in place: not qualified to comment. Therefore accept ACMSF recommendation. • Controlling factors: accept proposed amendment to the wording. 	<p>Comments noted and will be considered as part of a wider review of the guidance.</p>

Respondent	Comment	Response
	<p>Consultation point C, Q4: No comments on review of references to EU.</p> <p>Consultation point D, Q5: A good idea to improve accessibility of the guidance</p> <p>Impact, Q6(a): extending the prescribed shelf life to 13 days will reduce food waste by introducing a longer buffer into the supply chain – which absorbs fluctuations in demand/rate of sale. Retailers and processors will still aim to keep product on the shelf or in the supply chain for as short a time as possible (for reasons of cost, safety and organoleptic quality) but extra time gives more opportunity to trade out stock where sales forecasts have proved to be higher than actual sales.</p> <p>Impact, Q6(b): the ACMSF recommendations on challenge testing and lysozyme testing would require most businesses to employ the services of technical specialists such as Campden BRI. The costs might be prohibitive for smaller businesses.</p>	<p>Comment noted. Food businesses may choose to continue to follow the guidance and apply 13 days for VP/MAP chilled fresh beef, lamb and pork.</p> <p>Comment noted and will be considered as part of a wider review of the guidance.</p>
Food Business	<p>Consultation point A, Q1:</p> <p>Option 1 should be amended and option 2 is equally as restrictive and I believe that option 3 should be chosen. My basis for this recommendation is based on the evidence collated in the paper “Assessment of the risk of botulism from</p>	<p>Comments noted. The guidance has been amended.</p>

Respondent	Comment	Response
	<p>chilled, vacuum/modified atmosphere packed fresh beef, lamb and pork held at 3 °C–8 °C” - <i>Michael Peck et al, Food Microbiology 91 (2020)</i></p> <p>Commonly produced foods intended to be stored and distributed within the UK chilled food distribution chain are not implicated in outbreaks of botulism. In fact there is no evidence globally of fresh chilled meat products in similar chilled chains being implicated. On the limit of shelf life research has established that it takes time for the pathogen to grow out and produce toxins and by that time food spoilage flora in the meat will have rendered the food unpalatable. This latter point is a key difference between heat processed foods and fresh foods as there is competition and grow out of natural micro flora in the meat. Exposure assessments and challenge studies validate this approach.</p> <p>The shelf life of fresh meat is established by meat processors who should conduct shelf life trials to validate the shelf life that they apply to products. Guidance on the protocols for these shelf life trials would be welcomed.</p> <p>The only negative would be if there was a requirement to conduct challenge tests as these can be prohibitively expensive due to the classification of the pathogen under investigation.</p>	

Respondent	Comment	Response
	<p>We should also fall in line with other countries, as we will face a commercial disadvantage in the post Brexit world</p> <p>Consultation point A, Q2:</p> <p>There would be benefits to the consumer in increasing availability on the supermarket shelves. There would be a reduced wastage bill to retailers and less food to landfill if the shelf life was extended. There would be efficiencies driven at meat processors with increased shelf life resulting in fewer production runs with larger volumes.</p> <p>Extra shelf life on pack would give cost benefit to our current range running to tens of thousands of pounds annualized.</p> <p>Consultation point B, Q3:</p> <p>Challenge Testing - We will be led by the expert advice in this area.</p> <p>Upper shelf life limit for foods with controlling factors in place - Again we would go with the advice of the expert microbiologists. 42 days life on 90 for 10 mins seems reasonable and would be in line with the expectations of our customer. This shelf life should be sufficient for the type of product that we sell.</p>	<p>Comments noted and will be considered as part of a wider review of the guidance.</p>

Respondent	Comment	Response
	<p>However as the CFA points out in their response; if we can prove the safety of the product with additional life then we should take advantage of this.</p> <p>Controlling factors - Agree with proposal. In relation to this pathogen the pH is an excellent controlling factor and it's application in combination of 90 for 10 will help give an extended life more than 42 days.</p> <p>Consultation point C - No comments.</p> <p>Impact, Q6: We do not anticipate any additional costs with assessing the impact of renewed guidance. We would conduct additional shelf life trials. These are routine and undertaken on a minimum annual basis.</p> <p>Impact, Q6(a): 13 day extension would have minimal impact. The removal of chilled fresh meat from the 10 day limit would be welcome. Future detailed guidance on measures to prove product safety would be welcomed. It is not anticipated that there would be any major additional costs. The only concern would be if we had to undertake our own challenge tests for shelf life of vacuum and modified atmosphere packed chilled food with respect to non proteolytic Clostridium botulinum.</p> <p>Question 6(b): We have outlined the benefits above:</p> <p>1) Increased product life increases consumer availability.</p>	<p>Comments noted. The guidance has been amended.</p> <p>Comments noted and will be considered as part of a</p>

Respondent	Comment	Response
	<p>2) Reduces retail food waste.</p> <p>3) Helps production efficiencies in food manufacturing factories, longer runs and perhaps limit the need for weekend working.</p>	<p>wider review of the guidance.</p>
<p>Local Authority</p>	<p>Consultation point A:</p> <ul style="list-style-type: none"> o Option 1: Given there is evidence from ACMSF which supports extending the shelf-life for these specific products we think it is reasonable to take this on board. We would, therefore, support option 2 below. If option 1 or 2 is agreed, we would recommend that this be stated in the form (Day of Production + X days) for clarity. o Option 2: We would agree that this is the preferred option, taking into account the evidence in the ACMSF report. o Option 3: While some businesses may have the expertise to determine an applicable shelf-life, SMEs may struggle to do so, even with industry advice. Experience is that a significant amount of officer time may be dedicated to reviewing data which businesses believe supports the application of an extended shelf-life. Often the level of evidence is insufficient. Determination of shelf-life may become overly complicated. 	<p>Comments noted. The guidance has been amended. Food businesses may choose to continue to follow the guidance and apply 13 days for VP/MAP chilled fresh beef, lamb and pork.</p>

Respondent	Comment	Response
	<p>If, however, the industry led guidance is sufficiently detailed and clear then it may be an appropriate going forward. Is it reasonable to ask industry to progress this for consideration at a later date?</p> <p>Consultation point, Q2: While there may be costs associated with amending procedures/labelling equipment, we would expect most businesses would be happy to accept this in return for the benefit of additional shelf-life. In the unlikely situation businesses didn't consider the costs reasonable, there would be no requirement for them to extend the shelf-life beyond the existing 10 days.</p> <p>Consultation point B: Agree with these proposals</p> <p>Consultation point C: Agree with this proposal.</p> <p>Consultation point D, Q5: Agree with this proposal.</p> <p>Impact, Q6(a), (Option 2): Unable to provide specific evidence as likely costs/benefits would be at business rather than within Local Authority.</p> <p>Impact, Q6(a), (Option 2): Unable to provide evidence beyond experience referred to at Option 3 above in relation to officer time dedicated to liaising with businesses where there is a desire to extend shelf-life.</p>	<p>Comments noted and will be considered as part of a wider review of the guidance.</p>

Respondent	Comment	Response
	<p>Impact, Q6(b): The introduction of a maximum 42 day shelf-life may require some businesses to reduce their shelf-life. Unable to indicate specific costs but believe this would impact at least one food business in our Local Authority.</p>	<p>Comment noted and will be considered as part of a wider review of the guidance.</p>
<p>Provision Trade Federation (PTF)</p>	<p>Consultation point A, option 3: PTF supports Option 3 that the FSA/FSS guidance is amended to no longer apply to VP/MAP chilled fresh beef, lamb and pork, enabling an outcome based approach to regulation. Neither of the shelf lives referred to in the consultation regarding fresh meat (10 and 13 days) have a clear scientific nor risk basis, both reflecting the 2017 FSA guidance, and not previously long-established shelf lives either in the UK or internationally.</p> <p>We are not aware of any similar guidance internationally which limits shelf life of VP/MAP foods with respect to non-proteolytic <i>Clostridium botulinum</i> for chilled foods including fresh meat as the safety of these foods is recognised as being addressed by standard hygiene legislation and production practices. The 2017 FSA Guidance, and specifically the first explicit inclusion of a 10-day shelf life for VP/MAP fresh meat, therefore puts the UK at competitive disadvantage and creates technical barriers to trade. In addition, it creates unnecessary</p>	<p>Comments noted. The guidance has been amended.</p>

Respondent	Comment	Response
	<p>waste, with WRAP estimating that just a small increase in product life of one day can lead to significant reductions in food waste.</p> <p>A number of research projects provide evidence of the safety of fresh meat and the level of protection of current industry practice regarding VP and MAP fresh meat. FSA project B13006 (2005-6) established the level of safety protection as 109.8 across all chilled foods including fresh meat, and the MLA/BMPA 2019 study determined the figure to be 1010.8 for fresh red meat in the UK over the period 1999-2005 and 2007-2017, and internationally in 2017 it was 1011. Peer-reviewed UK Government/industry-funded research (the Chilled Food Association's first SUSSE (Sustainable Shelf Life Extension) project AFM266) included a full Quantitative Microbiological Risk Assessment (QMRA) for non-proteolytic <i>Clostridium botulinum</i>, results of which were published in Applied Environmental Microbiology in Jan 2016 (Barker <i>et al</i>, enc). It showed that fresh meat has the lowest spore loading of any food material, and quantified this for all food components.</p> <p>With respect to the proposal for industry guidance to support food businesses in demonstrating the safety of the shelf-life applied for VP/MAP chilled fresh beef, lamb and pork, we do not feel that any additional guidance is required as this is already adequately covered by CODEX, hygiene legislation, basic</p>	

Respondent	Comment	Response
	<p>hygiene requirements, and industry and retailer standards including, for example, industry “Guidelines for Setting Shelf life of Chilled Foods in relation to non-proteolytic <i>Clostridium botulinum</i>”. This also covers the role and approach to use of challenge testing, if used, and alternative approaches, particularly exposure/risk assessment and the role of predictive modelling.</p> <p>Consultation point B, Q3:</p> <p>3.1 Challenge testing</p> <p>We welcome that the ACMSF subgroup recommended that detection of toxin is a minimum requirement for challenge testing. As outlined in the joint industry submission in 2016, botulinum toxin is the identified hazard, not the presence or quantity of the bacterium per se. Research shows that toxin can be produced before detection of growth. It is therefore vital that detection of toxin is a minimum requirement for challenge testing, as the presence of toxin, and not simply detectable growth, is the actual hazard. PTF, 17 Clerkenwell Green, London EC1R 0DP</p> <p>Overall, however, we are concerned that the current guidance, in general, places too much emphasis on challenge testing. It is neither representative of reality, owing to use of high inoculum levels, nor proportionate to risk where</p>	<p>Comments noted and will be considered as part of a wider review of the guidance.</p>

Respondent	Comment	Response
	<p>products with a long-established safety record are concerned, nor cost-effective given the need to test each food formulation at significant expense. This is unlikely to be affordable by smaller businesses, in particular. There are more appropriate alternative approaches than challenge testing, which should be included in the Guidance. PTF helped to develop the Industry “Guidelines for Setting Shelf life of Chilled Foods in relation to non-proteolytic <i>Clostridium botulinum</i> (2018) ” which covers the role and approach to use of challenge testing, if used, and alternative approaches, particularly exposure/risk assessment and the role of predictive modelling.</p> <p>3.2 Upper shelf-life limit for foods with controlling factors in place We do not support the proposal 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. More research is needed before considering whether the guidance should be amended to this effect.</p> <p>3.3 Controlling factors We support the sub-group recommendation that the final bullet point on controlling factors should 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</p>	

Respondent	Comment	Response
	<p>growth and toxin production by non-proteolytic <i>C. botulinum</i>". We agree that the wording "heat and preservative factors" should be amended to "controlling factors".</p>	
<p>WRAP (Waste & Resources Action Programme)</p>	<p>Response to the consultation questions:</p> <p>I would like to preface the points below by emphasizing that WRAP fully recognises the vital importance of food safety, and would not want anything we say below to suggest that we do not see food safety as an overarching priority. We support giving the food industry the increased flexibility proposed in this consultation, in order to reduce the proportion of meat that gets wasted, but it is vital that they do this while keeping food safe to eat.</p> <p>Consultation Point A, Q1: We would support both options 2 or 3, and are opposed to option 1. Option 3 gives the potential to increase product shelf life beyond 13 days, where it is safe to do so, and so might give greater opportunity for the sector to reduce food waste, and the associated negative environmental impacts, as long as this is done in such a way that food safety is not compromised.</p> <p>Consultation Point A, Q2: Increasing product life (where it is safe and appropriate to do so) gives significant potential to reduce food waste, both in</p>	<p>Comments noted. The guidance has been amended.</p>

Respondent	Comment	Response
	<p>the supply chain, and, most importantly, in our homes. We published evidence on this in March 2015 – see here. Reducing meat waste will also have a positive carbon impact.</p> <p>Our June 2020 report ‘Meat in a Net Zero World’ - see the report here provides a cross-industry vision. Within this document, a priority action, identified for each of the retail, hospitality & food service, and domestic sectors, is increasing product life. The current rule is identified as a significant challenge in both retail and hospitality & food service supply chains (but particularly the latter, as vacuum-packed supply is common in the industry) and in reducing food waste in our homes.</p> <p>Data on meat waste</p> <p>Point of sale:</p> <ul style="list-style-type: none"> - Around 10,000 tonnes of meat were estimated to have been discarded at retail outlets in 2015. This represented 0.3% of reported meat purchases. <i>(Latest dataset available: Quantification of food surplus, waste and related materials in the supply chain, WRAP 2016. Adjusted to meat vs fish based on relative purchase data from Defra’s Family Foods Survey.)</i> 	

Respondent	Comment	Response
	<p>- Around 50,000 tonnes of meat were estimated to have been discarded at hospitality & food service (HaFS) outlets/sites in 2012. (<i>Overview of Waste in the UK Hospitality and Food Service Sector, WRAP 2013. Latest dataset available. 'Avoidable' meat waste only (not including bones, skin). Adjusted to meat vs fish based on relative purchase data from Defra's Family Foods Survey.</i>)</p> <p>In our homes:</p> <p>- WRAP's evidence suggests that – once purchased and at home – more than 200,000 tonnes of meat that could have been eaten (>10% of purchases) are discarded every year (latest dataset: 2012. See the report here)</p> <p>Consultation Point B, Q3: We have no comments on this issue.</p> <p>Consultation Point C, Q4: We have no comments on this issue.</p> <p>Impact, Q6(a): Our response to Q2 above is also relevant to Q6(a).</p>	

Respondent	Comment	Response
<p>Australian Department of Agriculture, Water and the Environment (DAWE)</p>	<p>Consultation Point A, Q1: Australia would appreciate the FSA’s consideration of the following specific comments:</p> <p><u><i>Specification of shelf-life for vacuum and modified atmosphere packed chilled raw meat</i></u></p> <p>Australia considers that the shelf-life of meat, including vacuum and modified atmosphere packed (VP/MAP) chilled meat raw meat, is best assured by adequate hygiene practices during processing, storage and transport. In Australia, these requirements are specified for exported meat in the <u><i>Australian Standard for the Hygienic Production and Transportation of Meat and Meat Products for Human Consumption, AS 4969:2007</i></u> and relevant export legislation.</p> <p>Guidance information on meat shelf-life, including the results of numerous shelf-life trials, has been published by Meat & Livestock Australia (MLA, 2016). This guidance allows Australian processors to calculate shelf-life for their individual products, based on their own processing, storage and transport conditions. The guidance also demonstrates that Australian VP/MAP chilled meat routinely achieves long organoleptic and food-safety derived shelf-lives (e.g. greater than 180 for beef primals and greater than 90 days for lamb primals).</p>	<p>Comments noted. The guidance has been amended.</p>

Respondent	Comment	Response
	<p>In Australia, shelf-life limits for meat are not prescribed in legislation. Australia recommends that a similar approach is adopted by the FSA.</p> <p><i>Foodborne illness caused by C. botulinum in raw meats</i></p> <p>A recent literature search conducted by Peck et al. (2020) identified 26 botulism outbreaks worldwide associated with commercial foods from 1985 onwards. Of these, only four outbreaks were associated with non-proteolytic <i>C. botulinum</i> (all in vacuum-packed fish). None of the 26 botulism outbreaks implicated correctly stored commercially-prepared chilled foods. Kobayashi et al. (2003) reported a single cases of intestinal toxæmia botulism linked with the consumption of VP hashed beef, however, reported cases of botulism linked with the consumption of correctly stored, chilled VP/MAP meats are difficult to find elsewhere in the literature.</p> <p>OzFoodNet, Australia’s government network responsible for estimating the incidence of foodborne illness, did not identify any individual cases or outbreaks linking <i>C. botulinum</i> with foodborne illness in Australia between 2001 and 2015, see here for more information.</p> <p><i>Control of non-proteolytic Cl. botulinum in raw meats</i></p>	

Respondent	Comment	Response
	<p>There is published evidence to suggest that VP/MAP chilled meats do not pose a significant risk with respect to <i>C. botulinum</i>-mediated illness in consumers. Peck et al. (2020) demonstrated that VP/MAP chilled beef, lamb and pork visually spoiled many days before detectable neurotoxin was detected in samples artificially challenged with <i>C. botulinum</i> spores. These authors also noted that current production standards and shelf-lives provide a high level of protection with respect to <i>C. botulinum</i>, with an estimated 6.2×10¹⁰ portions safely sold in the UK between 1999 and 2017. Further, Barker et al. (2016) demonstrated that fresh meat had the lowest <i>C. botulinum</i> spore loadings of the food categories tested.</p> <p><i>Australia's trade in exported chilled meats</i></p> <p>Australia exports significant volumes of chilled meat to overseas markets, including to the UK (Appendix 1). There is no evidence linking these exports to reported cases or outbreaks of <i>C. botulinum</i>-mediated illness prior to, or during the reporting period.</p> <p>Conclusion</p> <p>Australia has shown a long history of safely exporting VP/MAP chilled meats to overseas markets, including the UK. There is no evidence of association between these products and foodborne illness caused by <i>C. botulinum</i>. Furthermore, Australian notes evidence to show that chilled meats are likely to</p>	

Respondent	Comment	Response
	<p>spoil prior to the development of <i>C. botulinum</i> neurotoxin which would reduce the risk due to consumption of meat containing toxin, were it to be formed.</p> <p>Australia strongly suggests specification of shelf-life limits for VP/MAP chilled meats at retail based on the perceived potential for <i>C. botulinum</i> neurotoxin presence in chilled meats is not supported by a review of the scientific literature and not warranted. As a result, Australia's strong view is that shelf-life limits based on perceived risk of <i>C. botulinum</i> should be removed.</p>	
Local Authority	<p>Consultation Point A, Q1:</p> <p>Option 1: Agree with this one as surely an increase of 3 days is a minimal gain to shelf life to warrant a change and add confusion for other products which have to remain at 10 days. If the big players in the meat industry can show the cool chain is maintained i.e. < 2°C in the vacuum pack whilst under their control eg storage before distribution and distribution itself they could extend the shelf life under the current guidance for VP/MAP as the stricter temperature control at the beginning of shelf life would be a controlling factor. They can add this shelf life to the maximum 10 days life in the 3-8°C temperature range which might be out with their control. Could be 13 days anyway?</p> <p>Option 2: Think the gain in life needs to be greater than 3 days to warrant change.</p>	<p>Comments noted. The guidance has been amended. Food businesses may choose to continue to follow the guidance and apply 13 days, or 10 days, for VP/MAP chilled fresh beef, lamb and pork.</p>

Respondent	Comment	Response
	<p>Option 3: Agree as this would bring UK in line with other countries, Ireland specifically mentioned in the study. The study showed that shelf life applied varied at retail ranging sometimes from 13 to 24 days life so retail not sticking to 10 day life anyway. Misunderstanding that Vac pack guidance doesn't apply to fresh meat. Since 1985 there have been 26 botulinum incidents and none in relation to fresh meat. Processing has moved on since the first guidance was publicised in 2008 and given the historical evidence strongly agree guidance shouldn't apply to fresh meat. Could be important if exporting where longer shelf life is needed. Only down side is by so extending the shelf life is it not getting away from the term "fresh"?</p> <p>Consultation Point A, Q2: See comments above 3 day life is minimal, option 3 better.</p> <p>Consultation Point C, Q4: Agree</p> <p>Consultation Point D, Q5: Agree</p>	<p>Comments noted. The guidance has been amended</p>

Respondent	Comment	Response
Food Business	<p>Consultation Point A, Q1: We stick rigidly to the 10 day maximum life on vacpac product and have never had any problem. For that reason we would not be in favour of changing the regulation.</p>	<p>Comment noted. The guidance has been amended. Food businesses may choose to continue to follow the guidance and apply up to 13 days, including 10 days, for VP/MAP chilled fresh beef, lamb and pork.</p>
Food Business	<p>Consultation point A, Q1, (Option 3):</p> <p>We believe that the FSA / FSS guidance should be amended to no longer apply to VP / MAP chilled fresh meat, beef, lamb and pork enabling an outcome-based approach to regulation. Following scientific evidence specifically relating to fresh meat including FSA Project B13006 (2005-6). See this report here which established a level of safety protection as $10^{9.8}$ across all chilled foods including fresh meat and the most recent MLA/BMPA 2019 study by Prof. Michael W. Peck at QIB Extra Limited, which determined the food safety protection factor to be $10^{10.8}$ for fresh red meat in the UK and internationally as $10^{11.87}$ (in 2017).</p>	<p>Comments noted. The guidance has been amended.</p>

Respondent	Comment	Response
	<p>In comparison it must be remembered that the current heat treatment in guidance to achieve a long shelf life (90 °C / 10 minutes) delivers a protection level of 10⁶. The food safety protection factor for fresh red meat hugely exceeds the prescribed thermal treatment.</p> <p>Knowing the established and accepted safety protection factor for fresh red meat together with the understanding that no other countries anywhere in the world restrict the shelf-life of VP / MAP chilled fresh meat with respect to non-proteolytic <i>Clostridium botulinum</i> for chilled fresh meat, we consider that there are clear substantiated scientific grounds to amend the FSA /FSS guidance as per Option 3.</p> <p>The safety of these foods is understood across the world to be addressed by standard hygiene legislation and production practices.</p> <p>Consultation point A, Q2: We believe that the current recommendation by the ACMSF to extend the shelf-life of VP/ MAP chilled fresh beef, lamb and pork from 10 days to 13 days is erroneous as it is not scientifically grounded and we contend is only an average of current industry practice that is restricted by an unnecessary and non-scientific ruling on <i>Clostridium botulinum</i> that should be removed for fresh meat.</p>	

Respondent	Comment	Response
	<p>Consultation point B, Q3: We find this section confusing as none of the ‘options’ suggested in Q3, namely ‘Challenge testing, Upper shelf-life for foods with controlling factors in place and Controlling factors’, are applicable specifically to fresh beef, lamb or pork meat to which this consultation relates. These ‘options’ <i>may</i> be relevant to non-fresh meat foods and should be considered by the Partnership Working Group once the fresh meat guidance is amended to no longer apply to fresh beef, lamb and pork meat.</p> <p>Consultation point C, Q4: We would like to make the point in relation to the question of removing EU references that no EU countries with whom we hope to continue to trade, and not be disadvantaged in the process, have any limits placed on fresh beef, lamb or pork meat with respect to non-proteolytic <i>Clostridium botulinum</i>.</p> <p>Consultation point D, Q5: We are unsure as to what ‘changes to the guidance in line with official accessibility requirements’ ‘to fully meet their responsibilities to ensure food safety’ actually means in practice. We consider that this consultation specifically relates to VP / MAP fresh beef, lamb and pork and that the scientific evidence moves this review to amend the FSA /FSS guidance as per Option 3 such that non-proteolytic <i>Clostridium botulinum</i> guidance no</p>	<p>Comments noted and will be considered as part of a wider review of the guidance.</p>

Respondent	Comment	Response
	<p>longer applies. If Question 5 relates to this position being very clearly and simply set out, then we would support that.</p> <p>We additionally strongly believe that it is very important that communication of the reviewed and amended position in relation to fresh meat clearly and specifically clarifies that challenge testing is not required for fresh beef, lamb and pork in relation to non-proteolytic <i>Clostridium botulinum</i>. Challenge testing has been an area of some confusion and it must be clear to enforcement bodies that it is not required for fresh beef, lamb and pork.</p> <p>Impact, Q6: The business produces up to approximately 2500 metric tonnes of retail packs every week of which a very large proportion is fresh beef and lamb which if the current FSA / FSS guidance is amended so that it no longer specifically applies then potentially significant volumes of goods could have extended shelf-lives across retail sales and customer fridges with out having any other detrimental affect on quality or safety. Goods sold to customers already have extensive microbiological food safety criteria which would still be applicable to each and every pack over and above removing any non-scientifically justified <i>Clostridium botulinum</i> restrictions to product life.</p>	<p>Comments noted. The guidance has been amended.</p>

Respondent	Comment	Response
	<p>Unnecessary restriction of shelf-life of fresh meat creates unnecessary barriers to trading for GB post transition and puts GB at a competitive disadvantage in EU and world markets.</p> <p>Unnecessary restriction of shelf-life of fresh meat creates unnecessary waste where consumers throw away packaged fresh meat that is absolutely food safe. The Waste and Resources Action Plan (WRAP) estimates that even a food waste reduction potential of just a 1 day increase in fresh meat life has a huge equivalence in avoided Green House Gas (GHG) emissions (c. half a million cars on the road), WRAP (2015)</p> <p>A key aspect of our business is ensuring animal welfare and we believe that there is additionally a significant moral issue in the UK wasting animal meat as a consequence of an unnecessary restriction in shelf life of fresh meat created by the current <i>Clostridium botulinum</i> guidance.</p>	
Food Business	<p>Consultation Point A, Q1: (Option 3):</p> <p>1. No other country anywhere in the world limits shelf life of VP/MAP foods with respect to non-proteolytic <i>Clostridium botulinum</i> for chilled foods including fresh meat as the safety of these foods is recognised to be addressed by standard hygiene legislation and production practices.</p>	Comments noted. The guidance has been amended.

Respondent	Comment	Response
	<p>2. Neither of the shelf lives referred to in the consultation regarding fresh meat (10, 13 days) have a clear scientific non risk basis, both reflecting the 2017 FSA guidance, and not previously long-established shelf lives either in the UK.</p> <p>3. As a small processor we are increasingly under cost pressures and the 10 day shelf life has heavy cost implications in relation to packaging, refrigeration costs and ability to compete especially with imported products.</p> <p>4. Industry and government research have been carried out over the last few years into the case for extending shelf life on a science-based route, involving experts from all areas of the sector.</p> <p>5. Option 3 of Consultation Point A would therefore be most appropriate, but there is no need for additional guidance for fresh meat. All the work (e.g. FSA chilled VP/MAP food project B13006 (2005-6), MLA/BMPA (2019)) has shown this to be the case since it is covered in, for example:</p> <ul style="list-style-type: none"> a. CODEX, hygiene legislation, basic hygiene requirements, and industry and retailer standards b. Discussions were held with Campden BRI in relation to using their predictive modelling system, we have used it for challenge testing and shelf life predictions. 	

Respondent	Comment	Response
	<p>c. BRC Global Standards 2018 guidance on “Shelf Life of MAP and VP Raw Meat Products.</p> <p>Consultation point B, Q3:</p> <ul style="list-style-type: none"> • Challenge testing - <p>It is vital that detection of toxin is a minimum requirement for challenge testing as the presence of toxin, and not simply detectable growth, is the actual hazard.</p> <p>As a small business with limited technical resources we rely on science-based approach such as Campden Bri, CODEX, and historical records. Risk assessments and a risk-based approach should be a suitable for of challenge testing along with predictive modelling. We have used the ComBase system, but it does not use heated spores, so is failsafe. Any guidance should state that if challenge testing is done it should be designed appropriately and include toxin testing as that is the hazard and toxin can be produced prior to growth being detectable.</p> <p>The testing of a product with worst case parameters being able to be used to provide a safe shelf life for other equivalent foods.</p> <ul style="list-style-type: none"> • Upper shelf-life limit for foods with controlling factors in place - 	<p>Comments noted and will be considered as part of a wider review of the guidance.</p>

Respondent	Comment	Response
	<p>The use of predictive modelling allows for variations of Water content, PH levels, sodium. To gain a worst- and best-case scenario what determining shelf life both upper and lower.</p> <p>The safety of chilled prepared foods with respect to non-proteolytic <i>Clostridium botulinum</i> has been established to be of an order equivalent to canned foods, this being achieved by production according to standard GMP/GHP/HACCP requirements, and that internationally there are no stipulated limits to shelf life, instead the FBO being required to assure safety.</p> <p>• Controlling factors wording - We concur with the proposed change of the wording to read “<i>a combination of controlling factors which can be shown consistently to prevent growth and toxin production by non-proteolytic C. botulinum</i>” as heat is not a necessary controlling factor in all cases e.g. fresh meat.</p> <p>Consultation point C, Q4: References should be updated to transposed EU law coming directly into effect in the UK at the end of the Transition Period.</p>	

Respondent	Comment	Response
Food Business	<p>Consultation Point A, Q1: (Option 3):</p> <p>1.Understandably the FSA seeks to ensure high standards of food safety and the protection of all of us as consumers. However the current FSA position of selective enforcement on C.Botulinum with a maximum 10 day life on raw meat above 3c is based on laboratory and theoretical exercises without taking into account the reality that in 40+years of vacuum packing across the world with various standards of hygiene and temperature control there has never been any food safety incident associated with C.Botulinum in raw meats.</p> <p>2.No other country in the EU or across the world considers there is a need to limit shelf life on raw meat with respect to non-proteolytic Clostridium botulinum and within the EU, red meat upto 7c continues to be considered food safe acceptable.</p> <p>3. The current shelf life of 10 days or the proposed life of 13 days has little if any practical scientific or risk basis especially when the FSA has approved a number of UK abattoirs to supply >20days and where its stated the abattoir's customers have the meat stored for 16 days above 3c .</p> <p>I was surprised the FSA has stated that one piece of beef or one processing site is a different unknown C.Botulinum risk to another piece of beef or another</p>	<p>Comments noted. The guidance has been amended.</p>

Respondent	Comment	Response
	<p>processing site. Surely the science on the specific raw meat species should either allow all of industry or none to give greater than 10 days.</p> <p>4. The 2017 FSA Guidance with the inclusion of a 10-day shelf life for VP/MAP fresh meat, puts the UK at competitive disadvantage, creates technical barriers to trade, creates unnecessary waste and raises issues regarding what appear to be arbitrary rules eg It is perplexing that where an abattoir is supplying eg beef that is stored >10days above 3c in the supply chain that even if Im using the same abattoir beef, Im not allowed to give >10days. If the science is valid then it shouldn't require each processing site to have to initiate challenge testing or extensive documentation methodology as we should all be able to use the same science/ justification information that's already known to the FSA.</p> <p>5. The level of food safety protection given by the FSA project B13006 (2005-6) stated safety protection as 109.8 across all chilled foods including fresh meat5.</p> <p>The MLA/BMPA 2019 study determined the figure to be 1010.8 for fresh red meat in the UK over the period 1999-2005 and 2007-2017, and internationally in 2017 it was 1011.8</p> <p>I understand the currently specified heat process to achieve a long shelf life (90°C/10 minutes) only delivers a protection level of 106.</p>	

Respondent	Comment	Response
	<p>6. The Chilled Food Association's project AFM266 January 2016 for non-proteolytic Clostridium botulinum results and notified to the FSA showed that fresh meat has the lowest spore loading of any food material, and quantified this for all food components.</p> <p>7. Therefore I recommend Option 3 of Consultation Point A allowing the processing site to determine its own life /temperature protocols in line with current EU requirements to be the most relevant and appropriate as the FSA chilled VP/MAP food project B13006 (2005-6) and MLA/BMPA (2019) project, CODEX, hygiene legislation, basic hygiene requirements, and industry and retailer standards has shown that no additional guidance is required.</p> <p>8. In the FSA Guidance, challenge testing should be removed as there has been sufficient testing within the industry which can be assumed to be relevant for any other meat of the same species and challenge testing is not proportionate to risk particularly where products with a long-established safety record are concerned and meat used could be from multiple country of origins and different abattoirs. Using high challenge test inoculua are neither representative of reality, and not cost-effective given the FSA stated to us the</p>	<p>Comments noted and will be considered as part of a wider review of the guidance.</p>

Respondent	Comment	Response
	<p>requirement to test each origin/abattoir and cut of meat at significant expense (£10k+ per product), which is unaffordable.</p>	
<p>International Meat Trade Association (IMTA)</p>	<p>Consultation Point A, Q1: (Option 3):</p> <p>1.0 IMTA supports option 3 of consultation point A, asserting that food business operators in the fresh meat sector are best placed to understand and assess microbiological and environmental risks within their process AND have the Regulatory obligation to do so.</p> <p>1.1 Regulation (EC) 178/2002 provides that the responsibility for placing safe food on the market is with the Food Business Operator (FBO). Furthermore Regulation (EC) 852/2004, article 5, obliges the FBO to put in place procedures based on HACCP principles. A risk assessment approach based on the food businesses process and backed by science and technical competence. Such prescriptive guidance is contrary to the obligations these regulations place on FBO's.</p> <p>1.2 Whilst IMTA completely respects the FSA mandate to put the consumer interest first, we must highlight that the FSA is the ONLY National Competent Authority to intervenewith a prescriptive standard in this way; In doing so the FSA contradicts the principles of FBO accountability laid in the</p>	<p>Comments noted. The guidance has been amended.</p>

Respondent	Comment	Response
	<p data-bbox="533 228 1581 316">Food Regulations it upholds - principles it reinforces in its note to OV's on 5th July 2017 concerning the 2017 Guidance.</p> <p data-bbox="483 411 1581 555">1.3 In order to support the FBO's regulatory obligation to assess process risk and enable safe and suitable shelf life to be applied to products there already exists significant guidance, rendering the FSA guidance unnecessary:</p> <ul style="list-style-type: none"> <li data-bbox="533 579 1581 667">a. CODEX, hygiene legislation, basic hygiene requirements, and industry and retailer standards <li data-bbox="533 691 1603 778">b. CFA/QIB/LFR/MLA/BRC 2018 International "Guidelines for Setting Shelf life of Chilled Foods in relation to non-proteolytic Clostridium botulinum": This also covers the role and approach to use of challenge testing, if used, and alternative approaches, particularly exposure/risk assessment and the role of predictive modelling <li data-bbox="533 962 1615 1050">c. BRC Global Standards 2018 guidance on "Shelf Life of MAP and VP Raw Meat Products in Relation to non-proteolytic Clostridium botulinum" <p data-bbox="483 1137 1615 1329">2.0 That the UK is the sole Country to limit the shelf life of VP/MAP foods with respect to non-proteolytic Clostridium botulinum is a form of gold plating, places some businesses at a competitive disadvantage and will present a technical barrier to trade.</p>	

Respondent	Comment	Response
	<p>2.1 Whilst the FSA Guidance is not statutory; within the enforcement community it carries significant weight and the obligations inevitably pass to the FBO. That the Competent Authorities in 3rd countries and influential global organisations concerned with food safety have not considered there to be sufficient risk to impose similar standards in well over a decade (since 2008) demonstrates that they do not believe specific interventions are needed.</p> <p>2.2 Indeed in the FSA's own 'Burden of Foodborne Disease in the UK' Report last published in 2018, used to inform FSA performance and priorities; Non Proteolytic Clostridium botulinum (NPCB) is not even listed in the 13 food borne illness organisms of interest. Based on this there is no evidence of an issue. Why therefore is there the need for such prescriptive limitation on shelf life?</p> <p>2.3 The point is further supported by lack of published botulinum cases since 1985, other than those where there is known temperature abuse or direct evidence of cross contamination. This demonstrates that typical hygiene controls in abattoirs and cutting plants are sufficient to control the issue.</p> <p>2.4 In trade negotiations the lack of scientific justification for a 10 or 13 day limitation for VP/MAP fresh chilled meat will not demonstrate the high standards of operation in our slaughter and cutting plants but could be seen as a</p>	

Respondent	Comment	Response
	<p>restrictive practice and reflect poorly on UK standards. For UK business looking to export into the EU and other third countries the short shelf life will be commercially disadvantageous and restrict value and volume of trade.</p> <p>2.5 FSA should consider the impacts of the cost of 'mandated' and expensive challenge testing to justify a life beyond either 10 or 13 days and what the impact on competitiveness of UK companies of all sizes would be. There is also the further additional cost to cover for Elisa testing for Toxin. Additional costs would need to be absorbed into already slim margins of 3-5% net, so it would inevitably be added onto the selling price of the commodities. A more proportionate approach that allows risk and exposure assessment, predictive modelling and the support of trade bodies and food industry guidance provides a more level playing field for all. Especially since this guidance already exists.</p> <p>Chilled, fresh meat including beef lamb and pork has been shown have one of the lowest levels of contamination with <i>C. botulinum</i> spores¹. relative to other foods and consequentially a reduced risk of growth and neurotoxin production under standard conditions of hygienic production. Moreover, supply chains vary, therefore the prescription of shelf life is unduly restrictive and unjustified.</p> <p>3.1 There will be several factors that contribute to this reduced spore loading associated with the common standards used in the rearing, slaughter and</p>	

Respondent	Comment	Response
	<p>cutting of beef, lamb and pork. These include elevated standards due to close OVS supervision in abattoirs and cutting plants, environmentally chilled conditions throughout the supply chain of <4°C and enhanced sanitation standards during processing. All of which would contribute to and inform an individual FBO risk assessment.</p> <p>3.2 The FSA guidance fails to recognise that hygiene and safe food concerns the whole supply chain, from Farm to Sale to the ultimate consumer; choosing to focus on product only once it is packed and going into a retail supply chain. Slaughterhouse, cutting and meat wrapping operators are both obligated and best placed to understand and manage the microbiological risks within their own process: We provide here just 2 examples to demonstrate this, which are unique to the meat supply chain:</p> <ul style="list-style-type: none"> • OVS and Suppliers are obligated to send animals into the lairages in a clean fashion thereby reducing the levels of soil contamination on the hide and fleece. Animals can and are rejected on arrival for slaughter if the OVS deems them unduly soiled. • The method by which the hides of cattle and sheep are removed - generally from the hind quarter down over the fore-quarter. The knowledge and a contributory factors are that the majority of primal cuts placed fresh chilled onto the market comes from the hind, mid quarters 	

Respondent	Comment	Response
	<p>and the loin which experience reduced exposure to potential microbiological cross contamination through the skinning process.</p> <p>4.0 As already stated we do not support either the 10 or 13 days given as options in the consultation.</p> <p>4.1 In 2019 the British Meat Processors Association and Meat Livestock Australia 2. published a study on three work streams demonstrating that current practices are safe.</p> <p>The study:</p> <ul style="list-style-type: none"> • gathered data on current practice with regards to maximum shelf life of VP / MAP fresh, chilled beef, pork and lamb. Demonstrating that it is current practice to give up to 23 days on beef, 27 days on lamb and 18 days for pork and that current production hygiene practices have not given rise to food safety incidents with respect to non-proteolytic Clostridium botulinum (NPCB). • gathered data on the number of units which have been sold without known incidence of botulinum. Using a risk assessment approach, it was established that the current industry practice provides a high level of protection with respect to NPCB, estimated as >10.8 safety units ie more 	

Respondent	Comment	Response
	<p>than 1010.8 units marketed per each causing botulism. Which is comparable to the level of safety of canned foods.</p> <ul style="list-style-type: none"> • commissioned challenge testing at 8°C where VP / MAP fresh chilled beef, pork and lamb were inoculated with NPCB spores. The testing demonstrated that the meat did not produce potentially fatal neurotoxin until day 50 for beef, day 35 for lamb, or day 25 for pork using current production standards when stored at 8°C. (NB. We are mindful that some products currently have a longer VP/MAP shelf life than this at <3°C, which is outside growth and toxin forming limits of CI botulinum. IMTA are NOT supporting or advocating any change to this current practice). <p>4.2 Whilst this new research is welcomed and is far more representative than previous challenge testing, it still represents worse than worst case conditions. Inoculum levels were still significantly higher than typically found and no-one stores or transports meat at 8°C, throughout its life. FBO's are better placed to know their supply chain characteristics and carry out a HACCP based risk assessment using actual knowledge and expertise on raw material, process and analytical results as well as sound science and research results.</p>	

Respondent	Comment	Response
	<p>4.3 One of the principles, as reinforced by the current Chief Executive Emily Miles is that the work of the FSA will be based on sound science.</p> <p>4.4 During the aging process (wet / dry) of red meat carcasses, conditions of competitive exclusion develop with respect to microflora. Wet aged meat is subject to post rigor autolysis altering the pH and presenting a more acidic environment; in dry aging the cut surface desiccates, resulting in reduced water activity. The consequential microflora reduces the opportunity for C. botulinum to develop.</p> <p>5.0 IMTA members believe that the guidance places too much emphasis on the need for challenge testing and that other methods are available to assess risk that are more proportionate and should be recognised.</p> <p>5.1 The guidance is unduly focussed and weighted towards a) the need for challenge testing and b) the maintenance of such testing to the 'Gold Standard'; or c) the use of testing that is demonstrably at least equivalent to the gold standard and d) the use of experts to set shelf life. There should be the flexibility for companies to use risk assessment and other methodologies to set shelf-life that is appropriate and proportionate to their particular product,</p>	

Respondent	Comment	Response
	<p>process and business. Availability of labs able to carry out toxin testing in addition to CI botulinum assay is a further restriction.</p> <p>5.2 Challenge test studies do not represent realistic situations, having excessively high inoculum levels. The 2019 study although more representative was still inoculated at a considerably higher that the level of spores found in the real world.</p> <p>5.3 The 2019 BMPA and MLA study showed that deterioration through enzymic and microbiological spoilage activity of the samples rendered the meat totally organoleptically and olfactorily inedible a considerable amount of time before they became toxic. Spoilage being an effective mechanism in this case to protect the consumer.</p> <p>5.4 There are several other approaches that can be used in combination to provide a more appropriate and proportionate and no less safe outcome. These include HACCP, risk and exposure assessment; predictive modelling tools; microbiological shelf life testing including indicator organisms, historic performance and scientific study review. The guidance should recognise these alternative approaches.</p>	

Respondent	Comment	Response
	<p data-bbox="483 228 1615 371">6.0 It is the neurotoxin produced by NPCB which is the food safety risk not the growth of the bacterium, therefore IMTA support amendment of the guidance to focus on toxin production when challenge testing is carried out.</p> <p data-bbox="483 451 1615 818">6.1 Whilst recognising that this in turn makes challenge testing even more expensive. However, IMTA believe that if challenge testing is done it must be sufficient to identify the food safety risk; otherwise it is an expensive exercise that may give a false sense of security. The risk of false positives and negatives as a result of the sampling location would need to be taken into consideration as part of (and may add to) a statistically valid sampling plan, potentially adding yet further to the excessive costs of challenge testing.</p> <p data-bbox="483 898 1615 1042">7.0 Artificially limiting the shelf fresh of chilled beef, lamb and pork without a sound scientific basis creates unnecessary food and packaging waste and is poor practice from a sustainability perspective.</p> <p data-bbox="483 1121 1615 1377">7.1 WRAP 3. reveal that 99,000 mt/yr (12%) of pork; and, 34,000 mt/yr (8%) of beef is wasted in the home. The reason given for one third to half of which is that it was not used in time. WRAP estimate that a 10,000 mt/yr reduction in wasted meat could be achieved for each additional day of shelf life that is given.</p>	

Respondent	Comment	Response
	<p>8.0 The guidance represents fresh chilled beef, pork and lamb. Whilst the obligation remains with the FBO to provide safe food for consumers, current custom and practice in the preparation, storage and consumption of meat in the UK is not taken into consideration.</p> <p>8.1 IMTA Members are surprised that whilst the control measure of 90°C for 10 minutes or equivalent lethality is detailed in the guidance as a suitable control mechanism to prevent growth and neurotoxin production. The control measure of temperatures greater than 85 °C for 5 minutes or more which is sufficient to break down the toxin is not.</p>	
Institute	<p>Consultation Point A, Q1: (Options 2 and 3):</p> <p>Welcome and support the active use of technically expert advisory committees to critically review the latest scientific evidence, interpret the impact and implications for food safety and make recommendations as to its application.</p> <p>With respect to specific 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</p>	Comments noted. The guidance has been amended.

Respondent	Comment	Response
	<p>risk of <i>C. botulinum</i>, proposes the following points and suggestions be considered:</p> <ul style="list-style-type: none"> • In complex areas relating to food safety, technical guidance from FSA/FSS provides useful expert advice for the food sector, in particular for SME food business operators. • The application of a combination of option 2 and option 3 for risk management would give more security to the industry rather than reliance on option 3 alone. A precautionary maximum shelf-life of 13 days for non-proteolytic <i>C. botulinum</i> could be considered as a default option to protect public health, as recommended by the ACMSF. Expert advice should be sought if a shelf life in excess of 13 days is desired. Shelf-life proposed should be justified and supported by scientific evidence per each specific food product as sold to end of shelf life pertinent to the food businesses specific operations, the inherent risks for the foodstuffs concerned, the proposed packaging format, and the intended and foreseeable use of the food by the consumer. • Should option 3 be considered, recommend that efforts be made to pursue and apply alternatives to requiring use of the <i>in vivo</i> mouse bioassay. 	

Respondent	Comment	Response
	<p>Botulinum toxin detection using this <i>in vivo</i> method is widely recognised as a reliable method. It is however not easy to perform, has ethical issues and not easily available in UK testing laboratories. Evidence of a lack of growth for <i>C. botulinum</i> would offer an alternative and precautionary endpoint as a lack of growth would be concomitant with a lack of biotoxin formation.</p> <ul style="list-style-type: none"> • FSA/FSS should review the lethal rate table below 90°C, taking into account established industry requirements, and providing further guidance on its application to support food safety. • Heat is not a necessary controlling factor in all cases, as identified by the ACMSF subgroup. The proposed amendments to guidance would address this point. It could be emphasised that the presence of controlling factors would not obviate the need for challenge testing to evidence shelf life. • Consumers may notice VP/MAP products placed on the market with significantly different shelf-life, some at 10-13 days and some longer. Recommends FSA provides clarity for consumers why this situation arises. 	

Respondent	Comment	Response
<p>Food and Drink Federation (FDF)</p>	<p>Consultation point A, Q1:</p> <p>FDF response: Option 3 is the preferred option since the addition of fresh meat to the guidance did not appear to be based on any new evidence or to have a clear scientific basis in the first place.</p> <p>Consultation point B, Q3:</p> <ul style="list-style-type: none"> • Challenge testing - FDF response: Where challenge testing is done it must be designed appropriately and include detection of toxin as the minimum requirement • Upper shelf-life limit for foods with controlling factors in place - FDF response: The proposal to limit shelf-life to 42 days for foods heated to 90°C for 10 mins, unless it can be shown that lysozyme is absent from the food, is not justified. There is no direct evidence that foods containing lysozyme that have been heated to 90°C for 10 mins will lead to growth of <i>C. botulinum</i> at spore levels normally found in foods. • Controlling factors – FDF response: The proposed change to the wording looks appropriate. 	<p>Comment noted. The guidance has been amended.</p> <p>Comments noted and will be considered as part of a wider review of the guidance.</p>

Respondent	Comment	Response
	<p>Consultation point C, Q4: FDF response: No comments</p> <p>Consultation point D5: FDF response: We support the principle of improved accessibility for users</p> <p>Impact, Q6(b): FDF response: There would be significant costs to the restriction of shelf-life for fresh meat in the way outlined in paragraph 18 of the consultation document. These would relate to the viability of supply chains to accommodate products with the short shelf-life proposed. There is no direct evidence that foods containing lysozyme that have been heated to 90°C for 10 mins will lead to growth of <i>C. botulinum</i> at spore levels normally found in foods. The recommendation that expert advice should be sought if a shelflife in excess of 42 days is desired could result in additional challenge testing being carried out which is not risk-based.</p>	
National Craft Butchers	<p>Consultation point A, Q1: We very strongly support Option 3 to amend the guidance to no longer apply to VP/MAP chilled fresh beef, lamb and pork.</p>	Comments noted. The guidance has been amended.

Respondent	Comment	Response
	<p data-bbox="483 228 1603 371">There is no scientific justification to back Options 1 and 2 and there is no room for extreme precautionary measures which are unnecessary and disproportionate.</p> <p data-bbox="483 427 1603 515">We urge the Food Standards Agency to adopt Option 3 with all possible haste and request that the following points are taken into account:</p> <ul data-bbox="483 571 1603 1281" style="list-style-type: none"><li data-bbox="483 571 1603 659">• Option 3 will bring the UK back into line with the rest of the World. No other country has anything similar.<li data-bbox="483 738 1603 882">• Impositions such as the 10 day rule tend to confuse and contradict requirements in other hygiene legislation which is therefore undermined and makes straightforward interpretation of legislation unnecessarily complex.<li data-bbox="483 962 1603 1050">• All food business operators are aware of the above two points and this tends to feed a dangerous culture of disrespect for regulators or enforcers.<li data-bbox="483 1129 1603 1281">• The current rule also creates confusion amongst EHO's. The author of this response has dealt with many examples of this over the last few years including cases where perfectly good meat has been destroyed.	

Respondent	Comment	Response
	<ul style="list-style-type: none"> • The risks, if they exist, are already very adequately controlled by general food hygiene legislation. There is no need for additional guidance for fresh meat. • 99.9% of fresh meat, or more, is cooked prior to consumption. There are other controls covering meat that is less than thoroughly cooked. This fact is usually considered sufficient in other legislation such as temperature control and microbiological criteria for example. • There is no scientific or risk based evidence to support strict shelf lives of 10 or 14 days. • The latest BMPA/MLA research justifies far longer time periods in line with established traditional custom and practice. • There has never been a known case of Clostridium Botulinum associated with fresh meat in a very long history. • Fresh meat has the lowest spore loading of any food material as established by previous government funded and peer reviewed research 	

Respondent	Comment	Response
	<ul style="list-style-type: none"> • The current guidance creates extensive food waste which causes unjustified environmental and sustainability problems. (WRAP estimates a massive potential reduction in food waste if the guidance was amended. Currently households throw away 240,000 tonnes of meat every year.) • The guidance also raises moral issues of imposing unnecessary restrictions on meat derived from sentient beings. • The UK is placed at a competitive disadvantage because the guidance directly causes an unnecessary barrier to trade. • The guidelines are discriminatory against small businesses: <ul style="list-style-type: none"> • They have less defence against aggressive enforcement • Cost of micro-testing is disproportionate and unaffordable • Testing is unnecessary and disproportionate to the risk, if there is any, with food that has a long established safety record • A loss of stock due to incorrect enforcement could represent a whole months profit for small traders. This would threaten their viability whereas a large multi-site operation will hardly notice. 	

Respondent	Comment	Response
	<ul style="list-style-type: none"> Not all traders belong to a trade association and can call on the necessary expertise to resist incorrect enforcement. 	
Food Business	<p>Consultation Point A, Q1: Our preference is Option 3</p> <p>We believe that there is a compelling case to remove restrictions on shelf life of VP/MAP chilled fresh pork, lamb and beef as set out by Peck, M.W., 2019. <i>Risk Assessment of Botulism from Chilled, VP/MAP (Vacuum 701 Packed/Modified Atmosphere Packed) Fresh Meat held at 3°C to 8°C</i>. This report was reviewed within the scope the ACMSF subgroup on non-proteolytic <i>Clostridium botulinum</i> and vacuum and modified atmosphere packaged foods final report published in January 2020 (ACM/1322). Both reports highlight the absence of cases of botulism globally caused by consumption of VP/MAP fresh meat whether shelf life limits are applied or not.</p> <p>Such a change would bring the UK in line with the global market place where no such restrictions apply.</p> <p>Consultation point A, Q2: The ability to extend shelf life would also support our initiative to reduce food waste as well as allowing for longer, more efficient</p>	Comments noted. The guidance has been amended.

Respondent	Comment	Response
	<p>production runs. We have not quantified these benefits as we would need to conduct extensive trials to establish the appropriate additional shelf life on a product by product basis. The benefits could be in the range of £Ms per annum across our group.</p> <p>Consultation Point B, Q3:</p> <p>Challenge testing – the above referenced reports summarise a wealth of data which shows the absence of risk from non-proteolytic Clostridium botulinum in VP/MAP fresh meat and therefore challenge testing as a routine activity is of little or no value. We believe this should be left to the discretion of producers in consultation with their customers and within reference to their own risk assessments.</p> <p>Upper shelf life limits – we do not support prescriptive limits being defined for any specific VP/MAP fresh meat category.</p> <p>Controlling factors – we have no objection to the proposed wording change.</p> <p>Consultation Point C, Q4: we have no adverse comments on this proposal.</p> <p>Consultation Point D, Q5: we have no adverse comments on this proposal.</p>	<p>Comments noted and will be considered as part of a wider review of the guidance.</p>

Respondent	Comment	Response
	<p>Impact, Q6: We have not quantified the impact of the proposals within Points A – D.</p>	
<p>Scottish Craft Butchers</p>	<p>Consultation Point A, Q1:</p> <ol style="list-style-type: none"> 1. No other country anywhere in the world limits shelf life of VP/MAP foods with respect to non-proteolytic <i>Clostridium botulinum</i> for chilled foods including fresh meat as the safety of these foods is recognised to be addressed by standard hygiene legislation and production practices. 2. Neither of the shelf lives referred to in the consultation regarding fresh meat (10, 13 days) have a clear scientific nor risk basis, both reflecting the 2017 FSA guidance, and not previously long-established shelf lives either in the UK or internationally. 3. The 2017 FSA Guidance, and specifically the first explicit inclusion of a 10-day shelf life for VP/MAP fresh meat, puts the UK at competitive disadvantage, creates technical barriers to trade, creates unnecessary waste and raises moral issues regarding assigning arbitrary rules for the usage of sentient beings' meat. 	<p>Comments noted. The guidance has been amended.</p>

Respondent	Comment	Response
	<ul style="list-style-type: none"> • WRAP estimates a food waste reduction potential of a 1 day increase in fresh meat/poultry shelf life being c.10k te/year, and a 1 day increase across the board resulting in reduction of ca.250k te/year. 4. FSA project B13006 (2005-6) established the level of safety protection as $10^{9.8}$ across all chilled foods including fresh meat, and the MLA/BMPA 2019 study determined the figure to be $10^{10.8}$ for fresh red meat in the UK over the period 1999-2005 and 2007-2017, and internationally in 2017 it was $10^{11.8}$. Note that the currently specified heat process to achieve a long shelf life (90°C/10 minutes) delivers a protection level of 10^6. 5. Peer-reviewed UK Government/industry-funded research (the CFA's first Sussle (Sustainable Shelf Life Extension) project AFM266) included a full Quantitative Microbiological Risk Assessment (QMRA) for non-proteolytic <i>Clostridium botulinum</i>, results of which were published after peer review in January 2016 and notified to FSA at the time. It showed that fresh meat has the lowest spore loading of any food material, and quantified loadings for all food components. 6. Option 3 of Consultation Point A would therefore be most appropriate, but there is no need for additional guidance for fresh meat. All the work (e.g. 	

Respondent	Comment	Response
	<p>FSA chilled VP/MAP food project B13006 (2005-6), MLA/BMPA (2019)) has shown this to be the case since it is covered in, for example:</p> <ol style="list-style-type: none"> a. CODEX, hygiene legislation, basic hygiene requirements, and industry and retailer standards b. CFA/QIB/LFR/MLA/BRC 2018 International “Guidelines for Setting Shelf life of Chilled Foods in relation to non-proteolytic <i>Clostridium botulinum</i>”. This also covers the role and approach to use of challenge testing, if used, and alternative approaches, particularly exposure/risk assessment and the role of predictive modelling c. BRC Global Standards 2018 guidance on “Shelf Life of MAP and VP Raw Meat Products in Relation to non-proteolytic <i>Clostridium botulinum</i>”. <p>Consultation point B, Q3:</p> <ul style="list-style-type: none"> • Challenge testing - Research shows that toxin can be produced before detection of growth. It is therefore vital that detection of toxin is a minimum requirement for challenge testing as the presence of toxin, and not simply detectable growth, is the actual hazard. <p>However, in the <u>guidance in general</u> emphasis on challenge testing should be reduced. Challenge testing is not proportionate to risk particularly where</p>	<p>Comments noted and will be considered as part of a wider review of the guidance.</p>

Respondent	Comment	Response
	<p>products with a long-established safety record are concerned. Using high challenge test inoculua are neither representative of reality, and not cost-effective given the need to test each food formulation at significant expense (£10k+ per food), which is unlikely to be affordable by smaller businesses in particular, and which may lack internal technical resource. More appropriate alternative approaches than challenge testing should be included in the Guidance, such as exposure/risk assessment (e.g. number of packs or portions sold safely), which is an approach already used by ACMSF, process risk modelling, QMRA (e.g. as carried out in the SUSSLE projects) and predictive modelling. It should be noted that ComBase does not use heated spores, so is failsafe. The Guidance must state that if challenge testing is done it must be designed appropriately and include toxin testing as that is the hazard and toxin can be produced prior to growth being detectable by plating out methods, and give clarity on what is considered a representative sample, e.g. a test of a product with worst case parameters being able to be used to provide a safe shelf life for other equivalent foods. See 2018 CFA/QIB/LFR/MLA/BRC guidance.</p> <p>• Upper shelf-life limit for foods with controlling factors in place -</p> <p>Work carried out on lysozyme in relation to thermal processes to control non-proteolytic <i>C. botulinum</i> has only used high inoculua (e.g. ~10⁶ spores/food</p>	

Respondent	Comment	Response
	<p>sample, and 5×10^4 spores/g in the case of the single research paper referring to 42 days). This does not reflect the concentrations of spores found in real foods. See Barker <i>et al</i>, reference 9, for actual spore levels.</p> <p>Reiterate that the safety of chilled prepared foods with respect to non-proteolytic <i>Clostridium botulinum</i> has been established to be of an order equivalent to canned foods, this being achieved by production according to standard GMP/GHP/HACCP requirements, and that internationally there are no stipulated limits to shelf life, instead the FBO being required to assure safety.</p> <p>• Controlling factors wording -</p> <p>We concur with the proposed change of the wording to read “<i>a combination of controlling factors which can be shown consistently to prevent growth and toxin production by non-proteolytic C. botulinum</i>” as heat is not a necessary controlling factor in all cases e.g. fresh meat.</p> <p>Consultation point C, Q4: References should be updated to transposed EU law coming directly into effect in the UK at the end of the Transition Period. We are not yet aware of the details of such legislation however.</p>	

Respondent	Comment	Response
Private individual	<p>Consultation Point A, Q1:</p> <p>These guidance notes are costing the industry a lot of aggravation and hard work , unnecessarily so . Micro modelling can prove the same function. Can you revert to how life was before these guidance notes please? After all how many people have died of Botulinum recently ? from VP prod >10d shelf life?</p>	Comments noted. The guidance has been amended.
Tesco	<p>Consultation Point A, Q1:</p> <p>We believe that Option 3 of Consultation Point A is the most appropriate option without the need for additional guidance specific to fresh meat. The reasons as follows;</p> <ul style="list-style-type: none"> • The UK is unique in its approach to significantly restrict the shelf life of chilled VP/MAP foods with respect to non-proteolytic <i>Clostridium botulinum</i>. Elsewhere, the safety of these foods is recognised to be controlled by standard hygiene legislation and production practices. • The 2017 FSA Guidance, where the first explicit inclusion of a 10-day shelf life for VP/MAP fresh meat is included, puts the UK at competitive disadvantage, creates technical barriers to trade and creates unnecessary waste. 	Comments noted. The guidance has been amended.

Respondent	Comment	Response
	<ul style="list-style-type: none"> • Neither the 10 or 13 day shelf life options regarding fresh meat have a clear scientific nor risk basis, and do not consider previously long-established shelf lives either in the UK or internationally. • Peer-reviewed UK Government/industry-funded research, Sussle (Sustainable Shelf Life Extension), included a full Quantitative Microbiological Risk Assessment for non-proteolytic <i>Clostridium botulinum</i>, and concluded that fresh meat has the lowest spore loading of any food material. We do not feel that this has been sufficiently considered. • Appropriate, alternative approaches to challenge testing should be given to support FBO's in setting product shelf life. Challenge testing is complex, expensive and not proportionate to risk particularly for products with a long-established safety record. Exposure/risk assessment (e.g. number of units sold safely), is a suitable alternative approach that has already been used by ACMSF. • The scope of the document requires absolute clarity. Whilst the title of the document relates only to vacuum packaged and modified atmosphere packaged products, page 7 point 13 states that 'It is important to note that the presence of air, or a similar oxygen-containing atmosphere, cannot be 	<p>Comments noted and will be considered as part of a wider review of the guidance.</p>

Respondent	Comment	Response
	<p>relied upon to prevent growth and toxin formation by non-proteolytic C. botulinum.’ This statement therefore extends the document scope to all products regardless of packaging format.</p>	
<p>Morrisons</p>	<p>Consultation point A, Q1: (Option 3)</p> <p>The guidance has to be reviewed. It was published almost 30 years ago and in that time we have seen huge changes in the way food production and consequently food safety is managed. I believe we are the only country to set shelf life limitations on fresh meat products in respect of non-proteolytic C.botulinum.</p> <p>Option 1 and 2 really have no clear water between them. A 10 or 13 day life creates waste, fails to allow us to trade competitively and seems to have been plucked from the air with little thought as to true food safety risks.</p> <p>Option 3 is the only sensible option as evidenced by the 2019 BMPA/joint industry challenge testing project. No further guidance would be required as we already have sufficient in the form of CFA Guidelines for Setting the Shelf Life of Chilled products, BRC Global Standards 2018 Shelf Life of MAP and VP</p>	<p>Comments noted. The guidance has been amended.</p>

Respondent	Comment	Response
	<p>Raw Meat products and the usual HACCP, legislation and retailer/industry requirements.</p> <p>Consultation Point A, Q2: There is no benefit associated with a 10 or 13 day option. Both would be detrimental to our business and would increase waste. Production, transport into depot and then into store knock several days off the product life leaving a short life product which is unappealing to customers. The joint industry / BMPA challenge testing clearly showed that a much longer shelf life would not be a food safety concern.</p> <p>Consultation point B, Q3:</p> <ul style="list-style-type: none"> • Challenge testing - Challenge testing has its place in food safety provided it is designed appropriately. However when considering the risk posed by raw chilled meat the value of this type of testing is low due to the unrealistic levels of inoculum required and the cost of the testing is incredibly prohibitive especially for smaller businesses. Alternative methods need to be promoted as viable alternatives, they include predictive modelling, historical evidence e.g x years sales = x number of packs sold without complaint. • Upper shelf-life limit for foods with controlling factors in place - My understanding is that there is very little evidence to suggest that 42 days is accurate. More work is required to ensure that the 42 days is science based. 	<p>Comments noted and will be considered as part of a wider review of the guidance.</p>

Respondent	Comment	Response
	<p>The work completed to date has involved high levels of spore inoculum which is much higher than we would expect to see in real life.</p> <ul style="list-style-type: none"> • Controlling factors – Agreed, it needs to be broader. <p>Consultation point C, Q4: No comments</p> <p>Consultation point D, Q5: The revised guidance only needs to be published on the FSA website to make it accessible.</p> <p>Impact, Q6: I am unable to provide details of any financial benefit but the ability for the company to demonstrate a self shelf-life would drastically reduce food waste and increase sales potential.</p>	<p>Comment noted.</p>
<p>Quality Meat Scotland</p>	<p>Consultation Point A, Q1: (Option 3)</p> <p>1. No other country anywhere in the world limits shelf life of VP/MAP foods with respect to non-proteolytic <i>Clostridium botulinum</i> for chilled foods including fresh meat as the safety of these foods is recognised to be addressed by standard hygiene legislation and production practices.</p>	<p>Comments noted. The guidance has been amended.</p>

Respondent	Comment	Response
	<p>2. Neither of the shelf lives referred to in the consultation regarding fresh meat (10, 13 days) have a clear scientific nor risk basis, both reflecting the 2017 FSA guidance, and not previously long-established shelf lives either in the UK or internationally.</p> <p>3. The 2017 FSA Guidance, and specifically the first explicit inclusion of a 10-day shelf life for VP/MAP fresh meat, puts the UK at competitive disadvantage, creates technical barriers to trade, creates unnecessary waste and raises moral issues regarding assigning arbitrary rules for the usage of sentient beings' meat.</p> <p>WRAP estimates a food waste reduction potential of a 1 day increase in fresh meat/poultry shelf life being c.10k te/year¹, and a 1 day increase across the board resulting in reduction of ca.250k te/year².</p> <p>4. FSA project B13006 (2005-6) established the level of safety protection as 109.8 across all chilled foods including fresh meat⁴, and the MLA/BMPA 2019 study⁵ determined the figure to be 1010.8 for fresh red meat in the UK over the period 1999-2005 and 2007-2017, and internationally in 2017 it was 1011.86. Note that the currently specified heat process to achieve a long shelf life (90°C/10 minutes) delivers a protection level of 106.</p>	

Respondent	Comment	Response
	<p>5. Peer-reviewed UK Government/industry-funded research (the CFA's first Sussle (Sustainable Shelf Life Extension) project AFM2667) included a full Quantitative Microbiological Risk Assessment (QMRA) for non-proteolytic <i>Clostridium botulinum</i>, results of which were published after peer review in January 2016 and notified to FSA at the time. It showed that fresh meat has the lowest spore loading of any food material, and quantified loadings for all food components.</p> <p>6. Option 3 of Consultation Point A would therefore be most appropriate, but there is no need for additional guidance for fresh meat. All the work (e.g. FSA chilled VP/MAP food project B13006 (2005-6), MLA/BMPA (2019)) has shown this to be the case since it is covered in, for example:</p> <p>a. CODEX, hygiene legislation, basic hygiene requirements, and industry and retailer standards.</p> <p>b. CFA/QIB/LFR/MLA/BRC 2018 International "Guidelines for Setting Shelf life of Chilled Foods in relation to non-proteolytic <i>Clostridium botulinum</i>". This also covers the role and approach to use of challenge testing, if used, and</p>	

Respondent	Comment	Response
	<p>alternative approaches, particularly exposure/risk assessment and the role of predictive modelling.</p> <p>c. BRC Global Standards 2018 guidance on “Shelf Life of MAP and VP Raw Meat Products in Relation to non-proteolytic <i>Clostridium botulinum</i>10”</p> <p>Consultation point B, Q3:</p> <ul style="list-style-type: none"> • Challenge testing - <p>Research shows that toxin can be produced before detection of growth. It is therefore vital that detection of toxin is a minimum requirement for challenge testing as the presence of toxin, and not simply detectable growth, is the actual hazard.</p> <p>However, in the guidance in general emphasis on challenge testing should be reduced. Challenge testing is not proportionate to risk particularly where products with a long-established safety record are concerned. Using high challenge test inocula are neither representative of reality, and not cost-effective given the need to test each food formulation at significant expense (£10k+ per food), which is unlikely to be affordable by smaller businesses in particular, and which may lack internal technical resource. More appropriate alternative approaches than challenge testing should be included in the</p>	<p>Comments noted and will be considered as part of a wider review of the guidance.</p>

Respondent	Comment	Response
	<p>Guidance, such as exposure/risk assessment (e.g. number of packs or portions sold safely), which is an approach already used by ACMSF, process risk modelling, QMRA (e.g. as carried out in the Sussle projects) and predictive modelling. It should be noted that ComBase does not use heated spores, so is failsafe. The Guidance must state that if challenge testing is done it must be designed appropriately and include toxin testing as that is the hazard and toxin can be produced prior to growth being detectable by plating out methods, and give clarity on what is considered a representative sample, e.g. a test of a product with worst case parameters being able to be used to provide a safe shelf life for other equivalent foods. See 2018 CFA/QIB/LFR/MLA/BRC guidance.</p> <ul style="list-style-type: none"> • Upper shelf-life limit for foods with controlling factors in place - Work carried out on lysozyme in relation to thermal processes to control non-proteolytic <i>C. botulinum</i> has only used high inocula (e.g. ~10⁶ spores/food sample, and 5x10⁴ spores/g in the case of the single research paper referring to 42 days). This does not reflect the concentrations of spores found in real foods. See Barker <i>et al</i>, reference 9, for actual spore levels. <p>Reiterate that the safety of chilled prepared foods with respect to non-proteolytic <i>Clostridium botulinum</i> has been established to be of an order equivalent to canned foods, this being achieved by production according to</p>	

Respondent	Comment	Response
	<p>standard GMP/GHP/HACCP requirements, and that internationally there are no stipulated limits to shelf life, instead the FBO being required to assure safety.</p> <ul style="list-style-type: none"> • Controlling factors wording - We concur with the proposed change of the wording to read “<i>a combination of controlling factors which can be shown consistently to prevent growth and toxin production by non-proteolytic C. botulinum</i>” as heat is not a necessary controlling factor in all cases e.g. fresh meat. <p>Consultation point C, Q4: References should be updated to transposed EU law coming directly into effect in the UK at the end of the Transition Period. We are not yet aware of the details of such legislation however.</p>	
Food Business	<p>Consultation point A, Q1: We urge you to opt for Option 3. From what we see and hear, The UK's short shelf life at 3-8 Ddeg C is not seen as a food safety strength in the way the tracability system now is, rather it is a negative illustration of a lack of confidence authorities have in both British and Scotch Beef. In our experience, the top-end market (e.g. for the super yachts) now expects a minimum 30 day shelf life, consequently Scotland is definitely losing</p>	Comments noted. The guidance has been amended.

Respondent	Comment	Response
	<p>out on this market. USDA and Argentinian Aberdeen Angus are seen as superior.</p> <p>Consultation point A, Q2: We estimate we would have a one-off cost of altering the shelf life to 13 days of approx £150, with a benefit of approx £200 p.a.. Unfortunately in our experience, the top-end market (e.g. for the super yachts) now expects a minimum 30 day shelf life, and local shops will still require weekly restocking as they cannot afford to have empty shelves.</p> <p>If we need to do challenge testing for a 13 day shelf life, the impact will move to negative.</p> <p>Consultation point B, Q3:</p> <p>Challenge testing - Challenge testing would make sense for an increase to 30+ days as long as <u>proportional to output</u>.</p> <p>Upper shelf-life limit for foods with controlling factors in place - Whilst the question is clear that this refers to heat treatment only, the title of this question suggest interpretation could easily slip, whether intentionally or unintentionally, to other controls such as pH, Aqueous salt etc.. The current chemical and microbiological tests are already expensive and if further restrictions and/or tests, which aren't required on imported goods, are demanded, the effect would</p>	<p>Comments noted and will be considered as part of a wider review of the guidance.</p>

Respondent	Comment	Response
	<p>be devastating on producers of smoked and cured foods, particularly the artisans.</p> <p>Consultation point C, Q4: In the building of our on-farm micro-abattoir for cattle (the first in the UK in 25 years?), we found multiple cases where "gold plated" UK regulation accidentally obstructed, even prevented the building of micro-abattoirs whilst EC regulation actively promoted it (E.g. "Adverse Weather Conditions requiring indoor lairage" under EC regs means heavy snow or extreme heat. In UK it's interpreted as light rain. This means a micro-abattoir owner in the south of England will need to build an enclosed lairage even if only operating 1-2 days a fortnight, whilst potentially one of the same size in the lowlands of Germany can build an outdoor cattle handling facility, saving tens of thousands of pounds). Whilst the UK's welfare needs to be up with the best, great care will need to be taken to keep the rules realistic for artisan as well as industrial if we are to thrive as a food industry.</p> <p>Consultation Point D, Q5: No comments.</p> <p>Impact, Q6:</p> <p>Q6, points (a) & (b): See answers to Q1-4</p>	

Respondent	Comment	Response
	<p>Point (c): Based on our experience, the cost of UK gold plating vs EC Regulation is approx £100,000-£150,000 per micro-abattoir.</p>	<p>Comments noted. The guidance has been amended.</p>
<p>British Retail Consortium (BRC)</p>	<p>Consultation Point A, Q1: (Option 3)</p> <p>This is a significant point of interest for the retail sector and its suppliers and we fully support a review of this area. After reviewing the options presented for this part of the consultation, we support option 3 ie. amendment of the document so that it no longer applies to VP and MAP pork, beef and lamb. We do not believe there is a need for additional guidance for industry and instead feel this is already covered by the FBOs responsibility to produce safe food. Our reasons in support of this option are below:</p> <ol style="list-style-type: none"> 1. No other country limits shelf life of VP/MAP foods with respect to non-proteolytic <i>Clostridium botulinum</i> for chilled foods including fresh meat as the safety of these foods is recognised to be addressed by standard hygiene legislation and production practices. The current inclusion of meat could be interpreted as a barrier to trade, anti-competitive and puts UK FBOs at a disadvantage. 	<p>Comments noted. The guidance has been amended.</p>

Respondent	Comment	Response
	<p>2. Neither of the shelf lives referred to in the consultation regarding fresh meat (10, 13 days) have a clear scientific nor risk basis.</p> <p>3. Retailers take their commitments to food safety and reduction of food waste very seriously. Safe, validated shelf life extensions by suppliers are part of the drive to tackle food waste and it is important that these are not arbitrarily penalised.</p> <p>Consultation point B, 3:</p> <ul style="list-style-type: none"> • Challenge testing - <p>Research shows that toxin can be produced before detection of growth. It is therefore vital that detection of toxin is a minimum requirement for challenge testing as the presence of toxin, and not simply detectable growth, is the actual hazard.</p> <p>However, in the guidance in general emphasis on challenge testing should be reduced. Challenge testing is not proportionate to risk particularly where products with a long-established safety records are concerned. Using high</p>	<p>Comments noted and will be considered as part of a wider review of the guidance.</p>

Respondent	Comment	Response
	<p>challenge test inoculua are neither representative of reality, and not cost-effective given the need to test each food formulation at significant expense (£10k+ per food), which is unlikely to be affordable by smaller businesses in particular, and which may lack internal technical resource. More appropriate alternative approaches than challenge testing should be included in the Guidance, such as exposure/risk assessment (e.g. number of packs or portions sold safely), which is an approach already used by ACMSF, process risk modelling, QMRA (e.g. as carried out in the CFA SUSSLE projects) and predictive modelling. It should be noted that ComBase does not use heated spores, so is failsafe.</p> <p>The Guidance must state that if challenge testing is done; it must be designed appropriately and include toxin testing as that is the hazard and toxin can be produced prior to growth being detectable by plating out methods and give clarity on what is considered a representative sample, e.g. a test of a product with worst case parameters being able to be used to provide a safe shelf life for other equivalent foods.</p> <ul style="list-style-type: none"> • Controlling factors wording - We agree with the proposed change of the wording to read “<i>a combination of controlling factors which can be shown consistently to prevent growth and toxin production by non-proteolytic C.</i>” 	

Respondent	Comment	Response
	<p><i>botulinum</i>" as heat is not a necessary controlling factor in all cases e.g. fresh meat.</p> <p>Consultation Point C, Q4: We have no objections to the amendment of EU references and</p> <p>Consultation Point D, Q5: support the intention to improve accessibility of the document.</p>	
<p>Scottish Association of Meat Wholesalers (SAMW) (1)</p>	<p>Consultation Point A, Q1: (Option 3)</p> <p>As all the current scientific evidence now clearly demonstrates that there are no public health intervention benefits from maintaining the current restrictive and costly guidance, we strongly support the option of removing all references to fresh and chilled beef, lamb and pork at the earliest possible opportunity to deliver both economics within the supply chain. The immediate benefits would include the customer having access to products that with extended shelf lives and reducing the volume of food currently consigned as waste.</p> <p>The industry led-approach, where the shelf life must be validated is the correct one. It allows processors to respond to commercial opportunities for long shelf</p>	<p>Comments noted. The guidance has been amended.</p>

Respondent	Comment	Response
	<p>life VP product without unduly incurring risk. It is also in line with general FBO-led approach to ensuring safety of food on the market</p> <p>Consultation Point A, Q2: No specific examples - an additional 3 days is not significant enough.</p> <p>Consultation Point B, Q3: We would be content to accept all the recommended changes suggested by the ACMSF subgroup.</p> <p>Agree broadly with proposed changes, however the maximum shelf life should be for guidance only too, subject to validation. Full restriction on maximum shelf life could inhibit commercial opportunities on the international market, particularly for lamb when antipodean producers are able to achieve >50days and continue to extend. This is somewhat nullified if option 3 for point A is taken.</p> <p>Consulation Point C, Q4: Agree this will be of little practical difference, but must make sure we remain aligned in a regulatory sense to EU approach.</p> <p>Consulation Point D, Q5: Agree - guidance is not so well known or practiced outside of FSA supervised plants. Smaller businesses must also be equally accountable. This should be done through LA registrations.</p>	<p>Comments noted and will be considered as part of a wider review of the guidance.</p>

Respondent	Comment	Response
	<p>Impact, Q6:</p> <p>Q6(a): see comments about competing on international market with long life products from other countries, also retailer needs for increasingly aged products entering supply.</p> <p>Q6(b): Commercial opportunities would be greater if more flexibility was incorporated.</p>	<p>Comment noted. The guidance has been amended.</p> <p>Comment noted and will be considered as part of a wider review of the guidance.</p>
<p>Scottish Association of Meat Wholesalers (SAMW) (2)</p>	<p>Q1 Point A - Option 3</p> <p>The industry led-approach, where the shelf life must be validated is the correct one. It allows processors to respond to commercial opportunities for long shelf life VP product without unduly incurring risk. It is also in line with general FBO-led approach to ensuring safety of food on the market.</p> <p>Q2 - No specific examples - an additional 3 days is not significant enough.</p> <p>Q3 Point B - Agree broadly with proposed changes, however the maximum shelf life should be for guidance only too, subject to validation. Full restriction on maximum shelf life could inhibit commercial opportunities on the international market, particularly for lamb when antipodean producers are able</p>	<p>Comment noted. The guidance has been amended.</p> <p>Comments noted and will be considered as part of a wider review of the guidance.</p>

Respondent	Comment	Response
	<p>to achieve >50days and continue to extend. This is somewhat nullified if option 3 for point A is taken.</p> <p>Q4 - Point C - Agree this will be of little practical difference, but must make sure we remain aligned in a regulatory sense to EU approach.</p> <p>Q5 - Point D - Agree - guidance is not so well known or practiced outside of FSA supervised plants. Smaller businesses must also be equally accountable. This should be done through LA registrations.</p> <p>Q6 a) see comments about competing on international market with long life products from other countries, also retailer needs for increasingly aged products entering supply.</p> <p>b) Commercial opportunities would be greater if more flexibility was incorporated.</p>	<p>Comments noted. The guidance has been amended.</p>
<p>Association of Independent Meat Suppliers (AIMS)</p>	<p>Consultation Point A, Q1:</p> <p>1. No other country anywhere in the world limits shelf life of VP/MAP foods with respect to non-proteolytic <i>Clostridium botulinum</i> for chilled foods including fresh meat as the safety of these foods is recognised to be addressed by standard hygiene legislation and production practices.</p> <p>2. Neither of the shelf lives referred to in the consultation regarding fresh meat (10, 13 days) have a clear scientific nor risk basis, both reflecting the 2017 FSA</p>	<p>Comments noted. The guidance has been amended.</p>

Respondent	Comment	Response
	<p>guidance, and not previously long-established shelf lives either in the UK or internationally.</p> <p>3. The 2017 FSA Guidance, and specifically the first explicit inclusion of a 10-day shelf life for VP/MAP fresh meat, puts the UK at competitive disadvantage, creates technical barriers to trade, creates unnecessary waste and raises moral issues regarding assigning arbitrary rules for the usage of sentient beings' meat.</p> <p>WRAP estimates a food waste reduction potential of a 1 day increase in fresh meat/poultry shelf life being c.10k te/year, and a 1 day increase across the board resulting in reduction of ca.250k te/year³.</p> <p>4. FSA project B13006 (2005-6) established the level of safety protection as 109.8 across all chilled foods including fresh meat, and the MLA/BMPA 2019 study determined the figure to be 1010.8 for fresh red meat in the UK over the period 1999-2005 and 2007-2017, and internationally in 2017 it was 1011.8. Note that the currently specified heat process to achieve a long shelf life (90°C/10 minutes) delivers a protection level of 106.</p>	

Respondent	Comment	Response
	<p>5. Peer-reviewed UK Government/industry-funded research (the CFA's first Sussle (Sustainable Shelf Life Extension) project AFM266) included a full Quantitative Microbiological Risk Assessment (QMRA) for non-proteolytic <i>Clostridium botulinum</i>, results of which were published after peer review in January 2016 and notified to FSA at the time. It showed that fresh meat has the lowest spore loading of any food material, and quantified loadings for all food components.</p> <p>6. Option 3 of Consultation Point A would therefore be most appropriate, but there is no need for additional guidance for fresh meat. All the work (e.g. FSA chilled VP/MAP food project B13006 (2005-6), MLA/BMPA (2019)) has shown this to be the case since it is covered in, for example:</p> <ul style="list-style-type: none"> a. CODEX, hygiene legislation, basic hygiene requirements, and industry and retailer standards b. CFA/QIB/LFR/MLA/BRC 2018 International "Guidelines for Setting Shelf life of Chilled Foods in relation to non-proteolytic <i>Clostridium botulinum</i>". This also covers the role and approach to use of challenge testing, if used, and alternative approaches, particularly exposure/risk assessment and the role of predictive modelling c. BRC Global Standards 2018 guidance on "Shelf Life of MAP and VP Raw Meat Products in Relation to non-proteolytic <i>Clostridium botulinum</i>". 	

Respondent	Comment	Response
	<p>Consultation point B, Q3:</p> <ul style="list-style-type: none"> • Challenge testing <p>Research shows that toxin can be produced before detection of growth. It is therefore vital that detection of toxin is a minimum requirement for challenge testing as the presence of toxin, and not simply detectable growth, is the actual hazard.</p> <p>However, in the guidance in general emphasis on challenge testing should be reduced. Challenge testing is not proportionate to risk particularly where products with a long-established safety record are concerned. Using high challenge test inocula are neither representative of reality⁹, and not cost-effective given the need to test each food formulation at significant expense (£10k+ per food), which is unlikely to be affordable by smaller businesses in particular, and which may lack internal technical resource. More appropriate alternative approaches than challenge testing should be included in the Guidance, such as exposure/risk assessment (e.g. number of packs or portions sold safely), which is an approach already used by ACMSF, process risk modelling, QMRA (e.g. as carried out in the SUSSLE projects) and predictive modelling. It should be noted that ComBase does not use heated spores, so is</p>	<p>Comments noted and will be considered as part of the wider review of the guidance.</p>

Respondent	Comment	Response
	<p>failsafe. The Guidance must state that if challenge testing is done it must be designed appropriately¹⁰ and include toxin testing as that is the hazard and toxin can be produced prior to growth being detectable by plating out methods, and give clarity on what is considered a representative sample, e.g. a test of a product with worst case parameters being able to be used to provide a safe shelf life for other equivalent foods. See 2018 CFA/QIB/LFR/MLA/BRC guidance.</p> <p>• Upper shelf-life limit for foods with controlling factors in place Work carried out on lysozyme in relation to thermal processes to control non-proteolytic <i>C. botulinum</i> has only used high inoculua (e.g. $\sim 10^6$ spores/food sample, and 5×10^4 spores/g in the case of the single research paper referring to 42 days). This does not reflect the concentrations of spores found in real foods. See Barker <i>et al</i>, reference 9, for actual spore levels.</p> <p>We would reiterate that the safety of chilled prepared foods with respect to non-proteolytic <i>Clostridium botulinum</i> has been established to be of an order equivalent to canned foods, this being achieved by production according to standard GMP/GHP/HACCP requirements, and that internationally there are no stipulated limits to shelf life, instead the FBO being required to assure safety.</p> <p>• Controlling factors wording</p>	

Respondent	Comment	Response
	<p>We concur with the proposed change of the wording to read “<i>a combination of controlling factors which can be shown consistently to prevent growth and toxin production by non-proteolytic C. botulinum</i>” as heat is not a necessary controlling factor in all cases e.g. fresh meat.</p> <p>Consultation point C, Q4: References should be updated to transposed EU law coming directly into effect in the UK at the end of the Transition Period. We are not yet aware of the details of such legislation however.</p> <p>Consultation point D, Q5: This is welcomed.</p> <p>Additional points relevant to the Guidance review</p> <p>1. We have previously highlighted that the lethal rate table in the 2017 and previous version of the guidance is unsafe below 90°C. Not only is it unsafe but it is not in line with long-established industry requirements (e.g. CFA, European Chilled Food Federation), as borne out by the FSA-funded PhD by Wachnicka and CFA’s first SUSSLE project AFM266. This was recognised by the ACMSF sub-group’s January 2020 report, but not mentioned in the consultation. The z value of 7 below 90°C, as has been referred to in industry technical documentation for some 25 years should be used in the guidance.</p>	

Respondent	Comment	Response
	<p>2. The Guidance should make clear that raw VP/MAP chilled products for consumer sale cannot be re-packed to extend the shelf life beyond that of the raw material without a kill step being used.</p> <p>3. The Guidance document should be general guidance on the control of non-proteolytic <i>Clostridium botulinum</i>. However, separate clear guidance is needed on the requirement to control pH to assure safe production of herbs and other produce in oil stored at ambient.</p>	

Summary of changes made

Issue	Response
<p>Consultation Point A: The shelf-life of Vacuum and Modified Atmosphere Packed chilled fresh beef, lamb and pork in respect of <i>C. botulinum</i> (Q1, Q2, Q6(a))</p>	<p>Following a review, the FSA's best practice guidance on the safety and shelf-life of vacuum and modified atmosphere packed (VP/MAP) chilled foods in relation to the bacterium <i>Clostridium botulinum</i>, has been revised so that it no longer applies to fresh beef, lamb and pork. Food businesses will be responsible for identifying and applying a safe shelf-life for VP/MAP chilled fresh beef, lamb and pork in relation to <i>C. botulinum</i> in line with their existing food safety management systems, in the same way they do for other types of food.</p>

Issue	Response
	<p>Those food businesses, including small and medium sized food businesses, that may lack technical expertise or resources to validate the shelf-life of their meat, and which are maintaining good hygiene practice, may choose to apply a maximum 13-day shelf-life for VP/MAP chilled fresh beef, lamb and pork in relation to <i>C. botulinum</i>.</p> <p>This decision has been taken after stakeholder engagement and evidence gathering and will support both consumer and industry interests in relation to food safety and reducing food waste.</p>
<p>Consultation Point C: Review of references in the guidance related to the European Union as a result of the UK leaving the EU. (Q4, Q6)</p>	<p>Advice on retained EU legislation has been included in the guidance.</p>
<p>Consultation Point D: The accessibility of the guidance for users. (Q5, Q6)</p>	<p>The guidance has been amended to improve accessibility.</p>

Actions to be implemented

Issue	Response
Consultation Point B: Amendments to the guidance recommended by the ACMSF subgroup (Q4, Q6(b))	Comments received to be considered as part of a wider review of the guidance with respect to non-proteolytic <i>Clostridium botulinum</i> .

List of respondents (in alphabetical order)

1. ABP Food Group
2. Association of Independent Meat Suppliers (AIMS)
3. Australian Department of Agriculture, Water and Environment (DAWE)
4. British Meat Processors Association (BMPA)
5. British Retail Consortium (BRC)
6. Chilled Food Association (CFA)
7. Cornwall Council
8. Dairy UK
9. Dubia UK
10. Environmental Health Northern Ireland
11. Fairfax Meadow

12. F C Robinsons
13. Food and Drink Federation (FDF)
14. Foyle Food Group
15. Glasgow City Council
16. Hannan Meats Ltd
17. Hardiesmill Ethical Scotch Beef
18. Institute of Food Science and Technology (IFST)
19. International Meat Trade Association IMTA
20. John Scott Meat PMP
21. Karro Food Group
22. Morrisons
23. National Craft Butchers
24. Newry, Mourne and Down District Council
25. Perth and Kincross Council
26. Pilgrim's Pride Ltd
27. Private Individual
28. Private Individual
29. Provision Trade Federation (PTF)
30. Quadram Institute
31. Quality Meat Scotland
32. Sainsbury's plc

33. Scotbeef
34. Scottish Craft Butchers
35. South Hams District Council / West Devon Borough Council
36. Scottish Association of Meat Wholesalers (SAMW)
37. Supreme Foods
38. Tesco
39. Waste and Resources Action Programme (WRAP)