Organisation	Comments on guidance	FSA reply
Local Authority	Greater clarity needed for micro businesses regarding *Listeria monocytogenes*	We have reviewed the guidance with the aim of bringing greater clarity to all types of food businesses on a number of issues, including the need to consider other pathogens such as *L. monocytogenes*. Links to industry guidance on shelf life with regard to *L. monocytogenes* are included.
Industry stakeholder	I was sent the link after an audit to help me with my HACCP plan and I found it very informative.	Noted the positive feedback.
Research organisation	Good to see an increased clarification that the Guidance Document only covers risks associated with psychrotrophic C. botulinum and that FBOs have to look at other hazards that may occur in their foods. Useful to have clarification from FSA that raw meat is specifically included within the guidance. Useful to have detail about the potential for growth of C. botulinum within non-low oxygen packed foods, and the need to consider C. botulinum risks and the need for control measures in such foods. Decision tree (Does a single controlling factor comply.) could be misinterpreted to mean that scientific data (e.g. challenge test) is required even in cases where ACMSF controls are correctly used. Heat treatment - 4th sentence (For Foods stored at----) begins to consider foods stored at less than 3°C. This	We noted the positive feedback and have taken on board the majority of recommendations made, incorporating them into the final guidance document. Use of the phrase aseptic conditions has been revised based on feedback received. Noted that the text regarding the heat

	has nothing to do with heat treated foods (and indeed is well covered in FAQ5). Consideration should be made to modifying this section through removal of the mention of storage temperatures below 3°C. Three new sections on challenge testing are useful additions to the guidance.	treatment of foods was not in the most appropriate section of the Guidance. This has been reordered. Although clarity on the use of challenge testing was welcomed by this stakeholder, the FSA has taken account of all views and will examine the strengths and weaknesses of different approaches as part of a more detailed scientific review. Challenge testing remains an appropriate means of validating the HACCP-based approach, in particular where the controlling factors used are not already validated, such as those included in the guidance which ACMSF have already recommended.
NGO	Concerned the document is not legally binding so will detract from enforcement officers ability to make FBOs compliant. Greater clarity required on some wording within the document. Also do not feel the need for a Q&A if the technical advice is thorough.	Noted the comments that were made and changes have been made where appropriate. Although the Guidance is not a legal requirement in itself it provides advice for businesses to help them to meet the requirements of Article 5 of Regulation (EC) No 852/2004 which they are obliged to demonstrate compliance

		with. The FSA feels that examples in the Q&A are relevant and will help LAs and FBOs share a common understanding of how the requirements apply.
Government department	Purpose and legal status – states that guidance should be followed yet the officer may have no legal power to take action. Is there evidence to support C. Botulinum being a hazard in vacuum packed fresh meat? FSA guidance refers to greater risk of C. botulinum in some foods compared with others it does not appear to fully take on board its own source material.	The guidance is provided to help food businesses comply with Article 5 of Regulation (EC) 852/2004. Where enforcement officers have evidence that a business is not able to demonstrate that they have understood the relevant hazards and have HACCP-based procedures in place that mitigate them, they can consider enforcement action as required. Advice already exists in the FSA Food Law Code of Practice on the appropriate approach to enforcement action. Botulism (caused by C. botulinum) is very rare, but it can have extremely serious consequences so it is important that FBOs take this into account. Furthermore Article 5 of Regulation (EC) 852/2004 requires FBOs to consider any relevant hazards that must be prevented,

	The source material risk rates various food types with regard to priority for attention. The FSA guidance takes an excessively risk averse approach as it takes no account of food type and historical data with regards to food associated with previous food poisoning outbreaks and recommends the same controls regardless of risk and the historical evidence available. Feels there are other food poisoning bacteria that are responsible for greater impact and fatality rate. The controls in the guidance are disproportional for raw meat and, depending on the nature of their business, can be onerous on FBOs.	eliminated or reduced to an acceptable level. It is known that spores of C. botulinum can be found in the environment, and so the onus must be on the FBO to demonstrate how the risks of C. botulinum are controlled. If FBOs are able to demonstrate that their specific products do not support growth and toxin production of C. botulinum, they can establish an appropriate shelf life, taking into account other pathogens and factors that are relevant. The FSA's priority is on ensuring food safety and protecting public health and has issued this advice to help FBOs put appropriate controls in place.
Trade Association	In the light of the significant changes to the document, we believe that it would be preferable for a full technical review to be initiated at this stage (including full impact assessment) to ensure that consumer protection is maintained. Believe the document as it stands should not be published.	Comments noted. The guidance has been updated for greater clarification on certain specific issues. A further scientific review is proposed as data become available. In the meantime more technical issues will not be updated. A full scientific review will be considered in the future and as data become

		available for consideration in certain areas. The FSA involve ACMSF in this, subject to a suitable slot being available in their work programme.
Industry stakeholder	There are several helpful clarifications in the update which are worthwhile and much appreciated, e.g. Pg. 5, Intended audience point 4, and in the box on pg. 8, noting that this document only covers shelf life with respect to psychrotrophic C. botulinum, and that other hazards need to be included in any product risk assessment. The term 'aseptic conditions' appears several times in the document, but is not commonly used in the food industry, and is liable to be interpreted in various different ways. On pg. 21, in the answer to FAQ 8 - It would be preferable to expand the statement to allow evaluation of a product representing the worst case with regard to control within a group of closely similar products.	Comments noted. The guidance has been updated for greater clarification and on certain specific issues. A further scientific review is proposed as data become available. In the meantime more technical issues will not be updated. See above regarding aseptic conditions.
Industry stakeholder	Could Decision tree be renamed ‘VP/MAP Foods or Ingredients’? Could this part of the guidance state ‘foods or ingredients that are further processed to destroy vegetative cells’ rather than ‘ingredients used in other products’, as the food industry routinely uses	Comment noted and title changed to add the 3-8°C temperature range.

	'rework' in this way?	
Trade Association	Do not have any concerns about ability to comply with what is being asked in guidance. Would have liked specific advice on salamis and continental meats with 8 week shelf life. Level of product information and specification supplied particularly in the case of products supplied by distributors and what is expected from EHOs. Suppliers' audits by small operators are not financially viable and requirements may cause some to cease trading.	Comments noted. The guidance gives broad advice covering many products and is not intended to go into detail for specific product categories. However, it is the responsibility of the FBO to ensure that that they have HACCP based procedures in place to meet the requirements relating to products with a longer shelf life.
Industry stakeholder	Would be a good idea to incorporate the <3°C storage in the decision tree as <3°C is mentioned a couple of times in the advice document. May help clarify where <3°C fits in.	Products being stored <3C are outside the scope of this guidance.
Trade Association	Would prefer delay of publication to allow full scientific review. Time to toxin rather than growth is the preferred method for assessment of risk, in this organisation's view. However, there are different views within the industry. This is an important technical point that requires further discussion before inclusion in the document. Use of challenge testing and aseptic techniques could be unduly burdensome to industry and we believe require a full impact assessment before final	Comments noted. The guidance has been updated for greater clarification and on certain specific issues. A further scientific review is proposed as data become available. In the meantime more technical issues will not be updated. The FSA does not agree that the guidance should be withdrawn since this would leave businesses and LAs without any advice on how to ensure VP and MAP foods are safe. Given the serious nature of C. botulinum infections, this

	publication. This is an important point to reiterate that the risk applies to product packed in air as well as VP and MAP. The references to risks from other pathogens in this section and in the “purpose” section at the start of the document are useful additions. The explanation on re-wrapping would benefit from editing to simplify the explanation. This has been interpreted in differing ways in industry. The main intention should be that product life should not be restarted or extended when product is rewrapped. The reference to VP/MAP ingredients is commonly misinterpreted and would benefit from provision of examples. The wording around 3°C after heat treatment has the potential to cause confusion. The temperature guidance should apply where a controlling factor is not in place. If the product has been subjected to a 90°C/10min treatment or equivalent then subsequent storage temperature should not be limited to 10 days. The reference to use of “aseptic conditions” is not routinely used in the food industry. This should also be addressed in the flow diagram where “aseptic	would be an unacceptable approach. See above regarding aseptic conditions. Text referred to has been moved to the relevant section of the guidance.

	conditions" is given as an example.	
Trade Association	Suggest using 'psychrotrophic' as it has more relevance to FBOs instead of 'non-proteolytic' The expectation that every batch should be tested for salt and moisture (and pH value) is likely to be unachievable and impractical for small businesses. Although C. botulinum is ubiquitous, it is a soil organism and is not widespread in the general environment. The concern about packing after a heat process, and re-wrapping, therefore seems to be overstated. Vacuum bags might be expected to be sterile internally after the heat treatment they receive in their manufacture.	Comments noted. In the glossary, there is reference to the term 'psychrotrophic' in the explanation for non-proteolytic *C. botulinum*. Circumstances where reduced monitoring appropriate are covered in the Q&A. Refer to earlier response with regard to aseptic conditions
Trade Association	For shelf life of more than 10 days other controls are suggested. These additional controls are largely impractical for companies marketing raw red meat. For shelf life of more than 10 days other controls are suggested. It is important that there is a level playing field across the UK (and for the time being across the EU) as failure to achieve this would financially disadvantage our members.	The controls described in the guidance are intended to ensure food safety and compliance with food hygiene legislation. Food safety and public health must always be given priority. FBOs can extend the shelf life of their products if they are able to provide sufficient evidence that demonstrates through other methods they can control growth of any relevant pathogens.
Local Authority	Welcomed clarification on scope of guidance (including Risk from other pathogens and advice on heat treatment) It is strongly recommended that this guidance or the guidance relating to *Listeria* makes to very	Comments noted. The guidance has been clarified and updated where appropriate. The validation process is addressed in the Q&A and gives greater clarity.

	clear that validation of shelf life is undertaken by references both to anaerobic and aerobic microbiological hazards. Frequently FBO only consider one or the other and not both. Strongly recommended that the guidance makes clear requirements that industry standard operating procedures are the subject of scientifically robust validation studies.	