

Shelf life of Modified Atmosphere Packed (MAP) & Vacuum Packed (VP) 'Raw Meat Products' with respect to non-proteolytic *Clostridium botulinum*.

Note: This document is only intended as an aid to businesses in conducting their own risk assessments with regard to C. botulinum, it does not relieve a Food Business Operator of their responsibility to comply with Regulation on Foodstuffs. If in doubt you should consult your Competent Authority.

*This document should be read in conjunction with the [FSA 2017 guidance](#) 'The safety and shelf-life of vacuum and modified atmosphere packed chilled foods with respect to non-proteolytic *Clostridium botulinum*'.*

1. Background:

Regulation (EC) No. 178/2002 provides a framework for food and feed law within the EU and imposes obligations both on Member States (MS) and on food and feed business operators.

The Regulation also lays down other common principles and definitions for National and Community food law. It places primary responsibility to produce safe food on the food business operator (FBO). In addition, Article 14 of the Regulation states that "Food shall not be placed on the market if it is unsafe. Food shall be deemed to be unsafe if it is injurious to health or unfit for consumption".

Regulation (EC) No. 853/2004 Article 5 requires that all FBOs have food safety management procedures based on HACCP principles. This means that they must be able to demonstrate that all relevant hazards have been considered and the risks from them mitigated. It also requires them to provide evidence of the control procedures to the Competent Authority.

2. Summary of the elements that should be considered when assessing adequacy of risk mitigation for *C. botulinum* in chilled vacuum packed/ MAP foods:

An FBO must demonstrate that the risk has been considered: e.g. internal documents and HACCP (referencing the hazard), the [FSA 2017 guidance](#) (specifically the use of the four controlling factors listed in section 15, used singly or in combination and other controlling factors including low temperature) and other existing scientific data on the presence, survival and growth of non-proteolytic *C. botulinum*, some of which is included in the Annex to this document.

Product Characteristics & Scientific Literature review

It must be considered whether the food is likely to be contaminated with non-proteolytic *C. botulinum* spores and if so, whether the food is capable of supporting the growth of non-proteolytic *C. botulinum*. The ability to support growth will depend on the intrinsic characteristics of the food, such as the 'water activity' and extrinsic conditions¹ under which that food is produced, packaged and stored, including temperature control:

- The management of temperatures and time in VP / MAP should be assessed throughout the entire supply chain i.e. manufacture, storage, distribution, retail and customer. Where there is demonstrable evidence that the product temperature maintained during manufacture, storage and distribution is controlled below 3°C, this time can be excluded from the time that applies between 3 and 8°C with regard to non-proteolytic *C. botulinum*.

¹ Spores are potentially ubiquitous in the environment so consideration must be given to specific controlling factors. Each FBO must include this in their risk assessment – the *Hygiene data in Annex may also be a useful reference.

Where such a food is held at 3°C or above, '**Other controlling factors**' may legitimately be considered (FSA 2017: Section 25, page 14) including controlling factors (which may not have been characterised) demonstrated to be present by quantification of safety as part of a risk assessment. This should not be relied upon to allocate excessively long shelf lives.

Each product Risk Assessment should be based on a combination of direct and supporting evidence.

Direct evidence may include:

- The product meets one or more of the controlling factors in the FSA guidance
- **Predictive microbiology** (modelling)
- Historical data
- Specific laboratory shelf life studies
 - Durability Studies
 - Shelf Life Evaluation
 - **Challenge Tests**

Supporting evidence, e.g.:

- a. Spore loadings of raw materials used by the company.
- b. Number of packs sold over how many years with the same/similar packaging format (VP/MAP), for the company and for the sector (if applicable).
- c. Other scientific data on the survival and growth of non-proteolytic *C. botulinum*, some of which is included in the attached Annex.

If the results of these studies give sufficient confidence that non-proteolytic *C. botulinum* will not be present or will not grow during shelf life, the results should be integrated and monitored as part of the FBO's HACCP plan.

Other Controlling Factors:

Section 25 of the FSA Guidance on other controlling factors provides that combinations of the four controlling factors at lower levels may be used and other combinations such as the addition of nitrite may be effective in preventing growth of *C. botulinum*. This is a highly specialised field which should be supported by expert advice to produce the necessary data.

Predictive Modelling

Predictive modelling e.g. Combase (<https://www.combase.cc/index.php/en/>) can be used to support the safety assessment of the product. Note: Predictive microbiological models must only be used by trained, experienced personnel with an understanding of the limitations of use.

Challenge testing²

It is not necessarily a requirement that challenge testing be carried out, however, challenge testing can be used to determine whether *C. botulinum* will grow in specific conditions.

Use of 'worst case' representative products.

FBOs should assess and validate each individual product against the risk from *C. botulinum*. Where there are multiple, similarly formulated products, an approach that may be taken is to correctly

² Note: Guidance on challenge testing for non-proteolytic *Clostridium botulinum* has recently been developed, coordinated by the Chilled Food Association and the Quadram Institute in collaboration with other experts and stakeholders. This helps to further define when challenge testing for food products may be required and provides guidance on protocol considerations.

determine the worst-case products in each grouping for validation activities such as challenge testing. It is essential that all relevant factors for each individual product in the grouping are taken into account when selecting worst case representative products. The safe life limit demonstrated can be applied to other similar products in the grouping provided that it can also be demonstrated that a valid 'worst case product' has been used, and no relevant factors have been overlooked.

High Oxygen Modified Atmosphere Packaging and *C. botulinum*

Note: packing in high oxygen MAP carries no greater risk than packing in air, though of course the safety of any food should be assessed with regards to setting appropriate shelf life'

It is important to remember that FBOs must keep documentation on shelf life studies and verification as part of GMP and HACCP controls.

Annex:

Topic		Further Detail	References
Prevalence / Historical Occurrence of <i>C.botulinum</i> in Meat Products	Published review, shows that there is no evidence of botulism having occurred except very rarely when product is temperature abused.	<p>The UK's chilled food industry has produced an estimated 2×10^{10} chilled ready meals and a similar number of other chilled prepared food packs over the past 30 years without any issues associated with the shelf life of finished chill-stored products.</p> <p>Similar numbers of VP/MAP raw and cooked protein have also been produced in the UK over that time period, again without <i>Clostridium botulinum</i> issues arising. Issues have only arisen internationally when foods have not been stored chilled either during sale or in the home, which is not a production issue.</p> <p>An extensive review was commissioned by FSA (B13006). The report, the findings of which were endorsed by ACMSF, importantly states (see p23):</p> <p><i>“One issue noted while considering the risks presented by non-proteolytic C. botulinum in chilled MAP/VP products, is that while challenge test data may indicate the potential for growth and toxin formation, it is known that many thousands of millions of packs of product of this type have been sold around the world, with no evidence of botulism having occurred (except very rarely, when a product has been temperature abused). The use of data from this large commercial production enables an assessment of the risks arising from these products. This has been done previously for Proteolytic C. botulinum in canned meats, and this type of approach adds value to an assessment of non-proteolytic C. botulinum in chilled MAP/VP products. Some very preliminary data assessment indicates that the safety units for cooked chilled foods, sliced cooked meats and raw red meats are all >9.8 (i.e. 1 in $>10^{9.8}$ packs are associated with botulism).”</i></p> <p>These numbers are of the same order as for canned meats – in essence the risk of botulism occurring from raw meat is the same as in properly processed canned meats</p>	(B13006): <i>Clostridium botulinum</i> in vacuum packed (VP) and modified atmosphere packed (MAP) chilled foods. Final Project Report July 2006 (Project B13006) M.W.Peck, K.E.Goodburn, R.P.Betts & S.C.Stringer
	FBO data.	FBOs should also collate their own data showing number of packs of <i>X</i> that have been produced over a 5-year period (or more) with more than 10 days shelf life, e.g. skin packed, MAP or Vac packed chilled joint, chop etc.	

Spore Loading Data for Raw Materials used to prepare meat products	Published spore loading data shows that fresh meat had the lowest spore loading of material categories tested	<p>The LINK-funded SUSSLE (Sustainable Shelf Life Extension) project AFM266 quantified spores in a wide range of foodstuffs. This work resulted in the most comprehensive dataset in existence of non-proteolytic <i>Clostridium botulinum</i> spore loadings anywhere in the world. See Barker <i>et al</i> "Quantification of non-proteolytic <i>Clostridium botulinum</i> spore loads in food materials".</p> <p>Those data were published (free access) following peer review in AEM in Jan 2016. It is notable that one of the major findings was that fresh meat had the <u>lowest spore loadings of the food material categories tested</u>. The limit of detection was 5-10 spores/kg in meat. No sample had detectable spores. For meat, the probability of large loads was smaller than corresponding probabilities for other materials tested.</p> <p>Using data published primarily from outbreak investigations and combining it with test results from sampling during the project, it was calculated that the probability of there being more than the specified number of spores/kg in fresh meat were:</p> <p>> 1/kg probability 0.17 > 10/kg probability 2.1×10^{-7} > 30/kg probability 3.8×10^{-20}</p> <p>The spore load of fresh meat was therefore concluded to be below 10 spores/kg with a probability $1-2.1 \times 10^{-7}$ i.e. about 0.9999998</p>	<p>AEM Accepted Manuscript Posted Online 4 January 2016 Appl. Environ. Microbiol. doi:10.1128/AEM.03630-15. http://aem.asm.org/content/82/6/1675.full</p> <p>This is an open-access article distributed under the terms of the Creative Commons Attribution 4.0 International license.</p>
* Hygiene Controls	Assurance of control is a combination of very low likelihood of presence of spores coupled with existing long standing accepted	<p>Assurance of control is by application of standard longstanding chilled food production area hygiene practices coupled with the very low likelihood of presence of spores in chilled food ingredients. Spores may survive, but are unlikely to germinate and multiply or to accumulate, as some other pathogens do. Reasons for this are the need for an anaerobic microenvironment for growth and toxin production and destruction by chlorine.</p>	<p>Effects of germicides on microorganisms in can cooling waters, Ito, K.A., Seeger, M.L., J Fd Prot, 1980, 43 (6), p. 484-7</p> <p>Hypochlorite Injury of <i>C. botulinum</i> Spores Alters Germination Responses, Foedeging, P.M., Busta, F.F., Appl. Env. Micro., Apr. 1983, p. 1360-1368. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC242463/pdf/aem00173-0204.pdf</p>

	hygiene practices		<p>Effects of germicides on microorganisms in can cooling waters, Ito, K.A., Seeger, M.L., J Fd Prot, 1980, 43 (6), p. 484-7</p> <p>The Thermal and chlorine resistance of <i>Cl. botulinum</i> types A, B and E spores, in Botulism (Eds Ingram, M., Roberts, T.A.), London, UK: Chapman and Hall, p.108-22.</p> <p>CFA Best Practice Guidelines for the Production of Chilled Foods - Fourth Edition. ISBN-13 978-1-901798-11-1.</p>
	Other government assessments eg; Ireland FSAI	<p><u>FSAI shelf Life Validation doc issued 2017 (pp37-8):</u></p> <p>The FSAI recommends the following in relation to the safety and shelf-life of foods with respect to <i>Clostridium botulinum</i>^{14, 45}:</p> <ul style="list-style-type: none"> • The UK FSA/ACMSF approach for products with a shelf-life of greater than ten days is followed. However, in the case of chilled VP/MAP raw meats sold as whole joints or cuts, current industrial practice is acceptable • All food business operators opening and repacking VP or MAP products should establish a new product shelf-life⁴⁴ • Caution is always exercised by food business operators when modifying current industrial practices such as extending shelf-life beyond those currently used and in the research and development of new products 	<p><u>FSAI Shelf Life Validation GN 18, 2017</u></p> <p>Refs:</p> <p>14. Food Standards Agency (2017) Guidance on the Safety and Shelf-life of Vacuum and Modified Atmosphere Packaged Chilled Foods with Respect to Non-Proteolytic <i>Clostridium botulinum</i>. https://www.food.gov.uk/sites/default/files/multi-media/pdfs/publication/vacpacguide.pdf</p> <p>44. Food Safety Authority of Ireland (2009) Retail Display of Poultry from Opened Gas Flushed Packs. www.fsai.ie/WorkArea/DownloadAsset.aspx?id=9280</p> <p>45. Peck, M. W. Goodburn K. E. Betts R. P. & Stringer S. C. (2006) <i>Clostridium botulinum</i> in Vacuum Packed and Modified Atmosphere Packed Chilled Foods – Final Project Report (B13006). https://quadram.ac.uk/final_project_report0707</p>